# REASONS OF REPLACEMENT AND REPAIR OF DIRECTLY PLACED DENTAL RESTORATIONS: A SYSTEMATIC REVIEW


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**A dissertation presented in fulfilment of the requirement for the degree of**
**Master of Philosophy**
**In**
**Applied Clinical Research and Public Health**
**Of**
**School of Dentistry**

**The College of Biomedical and Life Sciences**

**Cardiff University**

**October 2020**

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## ACKNOWLEDGEMENTS

I would like to acknowledge my sincere gratitude to my supervisors for their invaluable advice and assistance throughout this project - Professor Barbara Chadwick (BC), Professor of Paediatric Dentistry, Joint Acting Head of School, Director of Education and Students, School of Dentistry, College of Biomedical and Life Sciences, Cardiff University, and Professor Christopher Lynch, Professor and Consultant in Restorative Dentistry at University College Cork, Ireland, Honorary Visiting Professor at Cardiff University, and Vice Dean of the Faculty of Dentistry at the Royal College of Surgeons in Ireland.

I am also very grateful to the other people who kindly gave up their time and assistance at various stages of the project. My particular thanks go to Ms Mala Mann, Information Specialist/Systematic Reviewer at the Specialist Unit for Review Evidence, Cardiff University, for her assistance in deriving the search strategy; and Dr Damian Farnell, Senior Lecturer of Applied Mathematics in Dentistry, Cardiff University, for his help with the data synthesis phase of the review and the statistical advice.

## SUMMARY

**Introduction:** Replacement of defective restorations represents the major part of restorative dentistry, and repair is an important alternative to save tooth structure.

This project systematically reviewed the available evidence on the replacement and repair of restorations from three different study designs. It compared the rates and reasons of replacement and repair according to the restorative material used and cavity type. It also looked at the change, if any, in the patterns and reasons of replacement and repair over the years.

**Methods:** The NHS Centre for Reviews and Dissemination guidelines were used as a reference for conducting this review. A search of the electronic databases was performed looking for studies reporting on replacement or repair of amalgam or resin-based composite (RBC) restorations in permanent teeth in adults. Reference lists, hand and citation searching were also undertaken.

**Results:** 7,255 articles were identified through the searches, and 151 papers met the initial inclusion criteria. Forty-five clinical trials (CTs) and longitudinal cohort studies (LCSs) and 3 cross-sectional studies (CSSs) were included. The results of the studies were analysed separately then compared. Quality assessment of the studies was conducted using the “Newcastle-Ottawa Scale”.

**Conclusions:** Included studies mostly reported on RBC restorations.

Results from CTs and LCSs suggest that failure/replacement rate of anterior and posterior RBC restorations is declining. Secondary caries as a reason for failure/replacement is also declining, while tooth fracture in increasing.

None of the included amalgam studies were published after 1998, indicating the decline in amalgam use.

No accurate conclusions could be drawn on amalgam due to the small number of studies included.

Few studies reported on repair of posterior RBC restorations and the rate was lower than replacement (3% compared to 9%). No studies reported on repair of amalgam restorations.

Most published CSSs did not meet the inclusion criteria due to the lack of detailed reporting.

# 1. INTRODUCTION

## 1.1 DENTAL CARIES

Despite being a preventable disease, dental caries is the most prevalent chronic disease in both children and adults (NIH, 2018). According to the World Health Organisation (WHO), dental caries affects 60-90% of school children and the vast majority of adults. These figures vary in different countries and in different parts within the same country, socioeconomic and environmental factors playing an important role.

Since the 1980s, there has been a steady improvement in dental health in developed countries. This was mainly due to increased awareness of the importance of oral hygiene measures and diet control, increased access to oral care, and most of all, due to the benefits of fluoride. It is well known that the daily use of fluoride in toothpastes is the most cost-effective, evidence-based approach to reduce dental decay (Lancet, 2009), but its cost prohibits its widespread use in many low-income and middle-income countries leading to inequalities in dental health (SDCEP, 2018a). Caries rates are shown to be higher in children living in poor households or those from ethnic minorities (Pitts et al., 2017).

So, although there has been a decline in the prevalence of caries in many developed countries, this does not mean that this disease is being “eradicated”, but rather only controlled by an increased awareness towards prevention, and it remains a global health burden (WHO, 2003).

In the UK, almost a third of dentate adults have visible caries into dentine (White et al., 2012). Although there was a dramatic fall in the prevalence of caries from 54% to 31% between 1998 and 2009, the number of teeth in those people affected by caries is almost unchanged at around 2.7 affected teeth per person. Also, 84% of dentate adults have at least one filled tooth, and for those with a filling, the mean number of teeth affected was 7.2 with an average of 2.1 surfaces affected per restored tooth. Among these with at least one restoration, 26% have either secondary caries or a defect in the restoration that needs some sort of intervention (Steele and Sullivan, 2011). This intervention historically involves the replacement of the whole restoration, or a more recent trend of repair/refurbishment of the existing restoration.

## 1.2 TREATMENT OF DENTAL CARIES

The traditional treatment of most carious lesions reaching dentine involves the provision of dental restorations with a lifelong commitment to the maintenance of such restorations. It is well known that dental restorations are not permanent and have a limited life span. Once a tooth is restored, the filling is likely to be replaced many times in a patient's life time; the "restorative cycle" (Nuttall and Elderton, 1983). As a result, dental caries and its sequelae present a significant public health problem and a substantial financial burden on the dental healthcare system, which increases with recurrence of the disease process or failure of the existing restorations (Burke et al., 2001, Yee and Sheiham, 2002). It has been estimated that the total annual expenditure on dental restorations in the UK is around £300 million (Lynch and Wilson, 2013). In the US, the national dental expenditures were estimated to exceed $60 billion in 2000 (this represents the costs of all dental care provided by dentists in practice settings) (Rockville, 2000). Oral disease is considered the fourth most expensive disease to treat in most industrialized countries (WHO, 2003).

### 1.2.1 Type of restoration

Dental restorations can be classified as direct and indirect.

Direct restorations are restorations placed at chairside in one visit using a material that can be moulded into the prepared cavity in the tooth. The material sets hard and is retained in the tooth by mechanical and/or chemical bond. Materials used for direct restorations include amalgam, resin-based composite (RBC), glass ionomer cement (GIC), resin-modified glass ionomer (RMGIC), and compomers.

Indirect restorations are fabricated in a dental laboratory after taking an impression of the tooth and its cavity or preparation. Examples of materials used are porcelain, metal alloys, zirconia and RBC.

This review will only focus on dental amalgam and RBC as they are the two main direct dental restorative materials used in dental practice (Rasines Alcaraz et al., 2014).

#### 1.2.1.1 Amalgam

Amalgam is an alloy of silver, copper, tin and zinc combined with mercury. Its use has been recorded historically as far as the 16$^{th}$ century and has had many adjustments since to improve its physical and mechanical properties. Once placed in the tooth cavity while in a paste-like consistency, it hardens within a few minutes, through chemical reactions, and forms a stable alloy. It became the material of choice for the restorations of teeth due to its durability, ease of manipulation, tolerance in wet conditions, resistance to wear, and cost-effectiveness. It has been considered the direct restorative material with the longest duration and lowest cost (Chadwick et al., 1999). On the other hand, some of the major limitations of dental amalgam are its un-aesthetic appearance and its inability to bond to tooth structure, therefore relying on mechanical retention resulting in excessive loss of healthy tooth substance. Moreover, amalgam has always been subject to concerns about safety of use due to mercury exposure.

There is no valid scientific evidence that amalgam causes harm to patients according to many extensive studies and reviews (ADA, 2010, SCENIHR, 2015). Nevertheless, mercury is one of the most hazardous environmental toxins that can cause serious health adverse effects. With the increased awareness of the implications of mercury on the environment came a push from the United Nations Environment Programme leading to the international treaty of the Minamata Convention in 2013 aiming to reduce mercury pollution (www.mercuryconvention.org).

The treaty is signed by 128 countries and promotes a phase-down of dental amalgam with a long-term aim for a phase-out. From July 2018, the European Union mercury regulation programme prohibited the use of amalgam in children under the age of 15 and in pregnant or breastfeeding women. Norway and Sweden have banned the use of dental amalgam completely in 2008 and 2009 respectively (UNEP, 2016). Other countries including Denmark, Finland, and the Netherlands have phased down amalgam use to 1-5% of restorations (SDCEP, 2018b). The treaty also promotes further research and development of alternative restorative materials in addition to focusing on prevention of dental caries.

#### 1.2.1.2 Resin-based composite (RBC)

RBC is a tooth-coloured dental filling material composed of three components: polymeric matrix, filler particles, and coupling agents. It was originally developed in the 1950s to replace silicates and acrylics used mainly for anterior restorations. Early resin-based composites had many drawbacks and needed improvement. Initially, resin-based composites were self-cured and did not bond to tooth substance, which caused problems as short working time and marginal defects. The major advancement was in 1962 when Bowen developed the highly durable matrix, bis-GMA (bisphenol-A Glycidyl dimethacrylate), and the coupling agent to bond the filler particles to the matrix (Leinfelder, 1997), which is the same technology used today but with further innovations.

Buonocore introduced the acid-etching technique in the late 1950s to facilitate enamel bonding, which allowed minimal tooth preparation compared to amalgam, saving more tooth structure (Galan and Lynch, 1993).

Light-curing resin-based composites were also introduced in the late 1970s/early 1980s to control working time (Jandt and Mills, 2013).

The other critical advancement occurred in the filler particles. Early resin-based composites had very large filler particles (10µm) which adversely affected the mechanical properties. In today's resin-based composites, the largest particles are less than 1µm and can be as small as 0.04µm. This has significantly improved the handling properties and polishability, increased wear resistance, and lowered polymerization shrinkage. The current generations of RBC are proven to be strong enough to withstand occlusion forces in the posterior teeth (Lynch et al., 2014).

The superior aesthetic properties and the continuous improvements in the physical properties have made RBC a very popular and successful restorative material in the practice of dentistry today. There are however some disadvantages to resin-based composites.

Polymerization shrinkage, and associated sensitivity, microleakage, and secondary caries, has always been a problem, and although it has improved significantly over the years, it remains a concern. Moreover, resin-based composites need more skill and time to place and are relatively more expensive compared to amalgams. Additionally, they are less forgiving with regards to moisture control (Ritter, 2008).

There have been concerns regarding bisphenol A (BPA) in RBCs being an endocrine disrupter having estrogenic properties. But composite dental restorations and fissure sealants appear to be a minor source of BPA relative to other environmental exposures such as water bottles and plastic food storage containers, and are unlikely to contribute substantially to chronic exposure (Fleisch et al., 2010).

# 2. REVIEW OF THE LITERATURE

## 2.1 USE OF RESTORATIONS AND PATTERNS OF RESTORATIVE THERAPY

A wide search of the literature was conducted to identify relevant studies looking into replacement and repair of amalgam and resin-based restorations. An electronic databases search was carried out which included Medline, Embase, CENTRAL, and CINAHL. Citation searching was performed electronically using Web of Science and Scopus. The references of potentially relevant papers were examined to identify any further studies of interest. Only papers published in English were included. The findings of the identified papers are summarised below according to the geographical area where the studies were conducted.

In general, amalgam use is declining with concurrent increase in RBC use as shown in a recent literature review looking at placement and replacement of dental restorations (Eltahlah et al., 2018). According to this review, Amalgam placement reduced from 57% pre-1998 to 31% post-1998, while RBC use increased from 37% to 49%. The review included data from 13 countries, which varied widely with regards to the change of use of amalgam, with Scandinavia seeing the most reduction, while in the developing countries, for example Nigeria, amalgam still predominates.

The review also found that 57% of the 86,720 restorations placed across all 25 studies reviewed were replacements of failed restorations. The reasons for replacements were not recorded to the same level of details amongst the studies, but secondary caries was found to be the most common reason for replacement in both amalgam and resin-based composite. Other reasons varied according to the type of material. Early resin-based composites were commonly being replaced due to bulk/marginal discolouration and poor anatomic form. Later advancements in the material reduced those deficiencies, but other problems remain, such as restorations fracture and post-operative sensitivity. Fracture of amalgam has always been one of the major reasons for replacement too (Eltahlah et al., 2018, Rasines Alcaraz et al., 2014).

### 2.1.1 North America

A study based on the Washington Dental Service, **USA** (which has details of the dental services provided to 1.5 million patients) reported changes in dental care patterns between 1993 and 1999. The study reported a decline in the use of amalgam from 57% of the total direct restorations provided in 1993 to 36% in 1999. A proportionate increase in the use of resin-based composites was observed during the same period (del Aguila et al., 2002).

Data from insurance claims for care provided by dentists in Michigan found similar results. The number of claims assessed in the study ranged between 1.25 million in 1992 to 1.84 million in 2007, and it showed the use of amalgam had halved between 1992 and 2007 with an associated increase in resin-based composites (Eklund, 2010).

A retrospective analysis of 2,780 dental records of the U.S. Navy and Marine Corps personnel documented an increase in the use of RBC from 10% in 1997 to 25% in 2005 (Simecek et al., 2009). The same study found that more than 15% of existing posterior amalgam and RBC restorations needed replacement at the initial examination, and a further 15% required replacement during the observation period.

Two cross-sectional studies recorded the use of materials in general practice in the USA. In 1991, Pink et al. recorded amalgam use in 54% of all restorations placed and 54% replacement rates (Pink et al., 1994), while in 1998, Mjör and Moorhead reported a similar replacement rate (53%) but a reduced use of amalgam (38%) (Mjör and Moorhead, 1998).

Recent data published by the DPBRN (Dental Practice-Based Research Network) in 2010 showed that the use of materials for the restorations placed due to primary caries varied widely between the regions studied (Nascimento et al., 2010). DPBRN is a “consortium of dental practices that have affiliated to investigate research questions and share experiences to improve clinical practice through research and collegiality”. The study collected data from outpatient dental practices in five regions: Alabama/Mississippi (AL/MS), Florida/Georgia (FL/GA), Minnesota (MN), Portland, Oregon (PDA), and Denmark, Norway, and Sweden (SK). The use of amalgam was highest in Portland, Oregon (63%) followed by Minnesota (56%). In the other two areas studied (Alabama/Mississippi and Florida/Georgia), the use of RBC predominated (66% and 75%).

Few studies have investigated the use of restorations in **Canada**. One study reported that the replacement rate of amalgam restorations in general dental practice in Canada remained the same between the years 1972 and 1984, despite the significant reduction of the prevalence of caries, and

these replacements were estimated to cost over $150,000 a day (at a rate of 6.8 surface per dentist per day) (Boyd and Richardson, 1985).
A cross-sectional survey in 1991 investigated 2,280 restorations provided to military personnel in Canada and recorded the use of amalgam in 69% of restorations placed and replaced. The restoration replacement rate in this study was 46% (MacInnis et al., 1991).

### 2.1.2 Scandinavia

The decline in the use of amalgam was most predominantly seen in the Scandinavian countries as the health authorities in Scandinavia encourage the phase-down of amalgam and using alternatives whenever possible. Amalgam was completely banned in Norway and Sweden in 2008/2009 (UNEP, 2016). This has led to a considerable shift towards increased use of adhesive materials.
According to the DPBRN data in 2010, the use of amalgam was negligible (6%) in the Scandinavian countries (Denmark, Norway and Sweden) (Nascimento et al., 2010).

In **Norway**, a cross-sectional survey of 243 general dental practitioners in public and private practices in 1997 reported on 24,429 restorations in permanent teeth. This showed that RBC was used in 40% of all restorations, while amalgam was used in 32%. Glass ionomer and resin-modified glass ionomer were used in 25% and indirect restorations in the remaining 3%. The restoration replacement rate in this study was 15% in children and 68% in adults (Mjör et al., 1999).

A retrospective study collected data from dental records of 7,278 children in 1995 and compared it to findings from the reports of the public dental services on 9,224 children in 1978. They reported that the use of amalgam in children and adolescents (ages 5-18) on primary and permanent teeth had substantially reduced by 73% (in 18-year-old children) and 97% (in 5-year-old children) between 1978 and 1995 (Wang, 2000). The most widely used material in this study was glass ionomer.

A later survey in 2001-2004 carried out in the Public Dental Health Service (PDHS) on children and adolescents reported data from 4,030 occluso-proximal restorations placed in 1,912 patients. They found that RBC was the predominant material of choice in occluso-proximal restorations in permanent teeth (82%), followed by compomer (13%), while amalgam was only used in 4.6% (Vidnes-Kopperud et al., 2009).

In **Sweden,** Mjör studied the selection of restorative materials by 177 GDPs in private dental practices in Stockholm and compared it to a similar survey carried out 16 years earlier (Mjör, 1981, Mjör, 1997b). He found that in 1978/79, Swedish dentists used amalgam in 65% of restorations, while in 1993/95, amalgam was used in 21% of restorations. This was mirrored by a significant

increase in the use of resin-based composite. An interesting finding in this study was that the replacement of failed restorations remained high (around 80%) over both the surveys.
After 1999, the patients in Sweden were not getting reimbursement from the dental insurance for amalgam fillings (Kemi and Miljö Konsulterna, 2005), and after 2009, when amalgam use was banned completely, its use was negligible, whereas RBC use predominated. This was observed in a cross-sectional study at the public dental health clinics in north Sweden. This survey collected data on 2,449 restorations placed in permanent teeth in patients older than 15 years. RBC was used in 93% of new restorations and 89% of replaced restorations. The restoration replacement rate in this study was 69% (Sunnegårdh-Grönberg et al., 2009).

The use of amalgam is still allowed in **Denmark**, but the government has placed strong restrictions. There are no recent data available in the literature, but some surveys showed a reduction in the use of amalgam from 86% in 1980/1982 to 66% in 1987/1988, while RBC use increased respectively from 13% to 31% (Qvist et al., 1986a, Qvist et al., 1986b, Qvist et al., 1990b, Qvist et al., 1990a). Replacement of failed restorations increased slightly between the studied periods for amalgam (52% to 61%) but remained the same for RBC (61%).

The use of amalgam also saw a significant decrease in **Finland**. A series of three cross-sectional surveys analysed changes in restorative treatment over an 8-year period. The first survey in 1992 collected data on 9,886 restorations placed by 855 dental practitioners in private and public health centres. This showed that amalgam was used in 15% of restorations placed in children (0-16) and in 29% in adults. In adults, RBC was used in 52% of restorations placed by private practitioners and 43% in public health centres (Widstrom and Forss, 1994). In 1997, another survey collected data from 659 private and public practitioners and reported on 6,322 restorations placed in adults (>17 years). RBC use increased compared to the previous survey, 75% of restorations placed, while amalgam use dropped to 4.8% (Forss and Widström, 2001). The last survey in 2000 presented data from private practitioners only. It reported on 3,455 restorations placed in adults by 548 practitioners and found that RBC was used in 79% of restorations, while amalgam was used in 5% (Forss and Widström, 2004). Replaced restorations accounted for 65% of the total restorations throughout the three surveys.

In **Iceland,** a study in 2002 collected data from 91 general dental practitioners about 8,395 restorations placed in children and adults. RBC was placed in 68% of occlusal restorations and amalgam in 59% of occluso-proximal restorations in adults. Participating dentists were asked to estimate their current use of RBC and amalgam and compare it to their use 15 years previously. This showed a trend towards increased use of resin-based composite, that being more pronounced in occlusal restorations. The same study indicated that 52% of the restorations placed in permanent teeth were replacements of failed restorations (Mjör et al., 2002).

### 2.1.3 Rest of Europe

In the **UK**, the use of amalgam did not observe the same trend of decline as that in Scandinavia, but the attitudes of the General Dental Practitioners (GDPs) seem to be changing.

In a recent survey in 2009, over 95% of the dentists who responded to the questionnaire said they would consider placing posterior resin-based composites, although only 33% would “regularly” or “often” place RBC occlusally in molars (Gilmour et al., 2009). One of the main reasons for this is thought to be the lack of availability of RBC to patients treated under the National Health System (NHS) regulations. The placement of RBC is not encouraged in load-bearing surfaces in posterior teeth within the NHS general dental services, but GDPs can provide them privately (Burke et al., 2003a).

The research carried out by the British Dental Association (BDA) in 2002 by sending a postal survey to over 2,600 dentists, followed up by 80 telephone interviews, indicated that RBC restorations are the most commonly received treatment in private services (Ray Robinson and Pennycate, 2004).

Approximately half of the restorations provided in the UK are amalgam according to many cross-sectional surveys. In 1997, a study involved general dental practitioners working in mixed NHS and private practices presented data on 2,379 restorations. Amalgam was used in 45% of the restorations, and RBC in 37% (Wilson et al., 1997).

Another survey was carried out in 1996/1997 involving 56 vocational dental practitioners and their 17 trainers working purely in NHS practices provided data on 9,031 restorations. 54% of those were amalgams restorations and 30% were RBC (Burke et al., 1999).

Similar results were found in a survey on dental students at the university of Manchester in 1996/7 which collected data on 1,431 restorations (Deligeorgi et al., 2000). Burke et al study also reported similar finding in 2002 from 32 general dental practitioner who were interested in carrying out practice-based research. The majority worked under the NHS, but some worked privately or combined NHS/private practices. Few dentists from the Armed Forces participated. They collected data on 3,196 restorations, of these, 54% were amalgam and 32% were RBC (Burke et al., 2002).

Replacement of restorations rate was also similar across the studies at around 50-59%, but was recorded as high as 66% in one survey (Burke et al., 2002).

In the **Netherlands,** a retrospective study recorded data from patients' records on 2,867 posterior restorations placed by two operators between 1990 and 1997 in a general dental practice. This showed that after 1994, almost no amalgam was used anymore (Opdam et al., 2007b).

In **Italy**, a survey from 62 private dental practitioners who placed 2,960 restorations showed amalgam was used in 65% of restorations and RBC in the rest (35%). The replacement rate was 43% (Mjör and Toffenetti, 1992a, Mjör and Toffenetti, 1992b).

Similar results recorded in **Germany** in 1991 from 102 dentists in a rural area of Southern Germany (60% amalgam use, 38% resin-based composite, and 50% replacement rate) (Friedl et al., 1994, Friedl et al., 1995).

In **Greece,** a survey was carried out on dental students at the University Dental School of Athens during 1996-1997 academic year. Data collected on 1,189 restorations showed that amalgam was used in 44% of the restorations while RBC in 51%. The replacement rate was recorded to be 39% (Deligeorgi et al., 2000).

### 2.1.4 Australia

A questionnaire-based survey was conducted in 2002 to determine the attitudes of Australian dentists towards the use of direct restorative materials. A reply was received from 560 dentists and it showed RBC to be widely used in posterior teeth. Almost three-quarters of respondents would place large RBC restoration in molars. Around 59% of respondents recorded a decreased use of amalgam over the previous five years, and 74% said that their use of RBC has increased (Burke et al., 2004).

These findings are confirmed by a cross-sectional survey in 2005 which collected data from 28 GDPs on 2,716 restorations. RBC was used in 55% of restorations, while amalgam used in 28%. The replacement rate in this study resembled that of other studies around the world at 54% (Tyas, 2005).

### 2.1.5 Rest of the world

In **Nigeria**, a cross-sectional study surveyed 370 patients referred to the restorative clinic at the University of Nigeria Teaching Hospital (UNTH). The survey recorded data on 450 restorations. Amalgam was the most commonly used material, placed in over 70% of restorations, while RBC in 21% only. The reported replacement rate was lowest recorded amongst all other studies at 28% (Udoye and Okechi, 2009).
In a questionnaire done in 2008, 81% of the 70 participating dentists in South-eastern Nigeria did not support an amalgam ban (Udoye and Aguwa, 2008).

The use of amalgam is similarly high in **South Korea** according to a small survey in 1993. The survey recorded data from 9 clinicians in general practice, mostly staff in the dental school, who placed 1,175 restorations over a two weeks period. Amalgam was used in 65% of restorations, and RBC in the remaining 35%. The replacement rate was 40% (Mjör and Um, 1993).

In **Jordan,** a cross-sectional survey from 213 dentists who placed 5,405 restorations showed that amalgam was used in 59% or the restorations, and the restoration replacement rate was 42% (AlNegrish, 2001, Al-Negrish, 2002).

**Brazil,** on the other hand, reported a high use of RBC in a survey from 37 general dental practitioners working in private practice who placed 551 restorations during the study period. RBC was used in 89% of all restorations, while amalgam was used in 10%. The restoration replacement rate was 60% (Braga et al., 2007).

In **Saudi Arabia**, a survey undertaken in 2003 in 10 private polyclinics recorded information about 326 restorations. Of these, 53% were amalgam restorations and 31% resin-based composite. The replacement of restorations rate was around 30% (Mahmood et al., 2004).

A questionnaire survey conducted in 2015 in northern Saudi Arabia from 136 participating dentists revealed that 97% of them did not prefer to place RBC in a restoration with heavy occlusal contacts and 83% did not select RBC for occluso-proximal restoration (Akbar, 2015).

Another study conducted in Riyadh in 2016 showed a different picture. This study involved 336 dentists from both private and public sectors with different qualifications (interns, GDPs, Specialists, and Consultants). Most of the participants (81%) did not use amalgam frequently in their practice, aesthetics being the main reason for that. Also, dentists working in private practice used amalgam less frequently than those working in public sector (Alkhudhairy, 2016).

## 2.2 REPLACEMENT OF RESTORATIONS

### 2.2.1 Definition

Removal of an existing defective/failed restoration and any adjacent pathologically altered and discoloured tooth tissue that is aesthetically or functionally unacceptable, followed by the replacement of a new restoration of the same or different material (Gordan et al., 2012).

### 2.2.2 Studies investigating restoration failure/replacement/repair

Many studies are available in the literature investigating the rates, reasons, and patterns of "failure" of dental restorations. When a filling is considered to be "defective" or has "failed", practitioners intervene. This intervention was usually total replacement, but more recently, minimal intervention dentistry is considered more often. This includes restoration repair, refurbishment, finishing, or sealing. The decision falls on the clinician and it is highly subjective in most studies (Wilson et al., 2016).

Studies investigating the failure, replacement, or repair of restorations are mainly one of the following types:

#### 2.2.2.1 Retrospective surveys

These surveys are designed to analyse pre-existing data by searching patients' clinical records. They are quick, cheap, and easy to conduct, but they usually do not give reliable data and are subject to reporting and/or recall bias, i.e. might not provide enough information why the restoration was replaced or repaired, depending on the accuracy of reporting of the operating dentist (Jacob and Carr, 2000).

#### 2.2.2.2 Cross-Sectional observational Surveys (Case series)

These surveys are usually carried out using a self-reported questionnaire. A large number of clinicians and restorations can be examined in a short time during the study and it is believed that these represent "real-life" dentistry. Usually, there is no standardization among the practitioners or the examiners, but the clinicians are provided with a list of reasons for replacement/repair (according to the criteria used) to choose from. The decision to replace/repair a restoration in these studies is therefore subjective, that is why such studies do not rate highly in the hierarchy of evidence, but they provide valuable data with regards to the research question for this review that can be generalized to the whole population (Jokstad et al., 2001).

### 2.2.2.3 Longitudinal observational cohort studies

These studies are usually conducted in general practice or dental institutions. Like cross-sectional surveys, they may provide valuable data closer to real everyday dentistry. The clinicians/evaluators may or may not be calibrated and standardized. They involve following a cohort of patients for a period of time, usually in years, and record when the restoration failure has occurred and why it occurred. They are very useful for longevity studies and can give reliable data on how long the restoration has served. They are more difficult to conduct compared to cross-sectional surveys as they require the clinicians to invest much more of their time and effort and can take many years to yield results. Another problem is the dropouts, thus needing to recruit a large number of patients initially to overcome the dropout rate, which can make these studies very expensive to conduct (Mjör, 2001, Mjör et al., 1990).

### 2.2.2.4 Controlled clinical trials

These studies generally aim to investigate the performance of a specific material or technique and compare it to a control. They can be randomised or non-randomised. The operator and assistant are usually trained and standardized, and the examiners, who ideally should not be the operators, calibrated in using well-defined and standardized criteria for restoration assessment. Such studies are often conducted in dental institutions by experienced specialised dentists and there are strict criteria for patient selection and follow-up, so their results might be unrealistic and not generalisable to everyday general practice, but they still provide valuable data. It is important though that this data be interpreted differently to data from cross-sectional surveys (Mjör, 2001).

### 2.2.3 Criteria for replacement/repair

#### 2.2.3.1 The Mjör protocol

This protocol is mainly used in cross-sectional practice-based surveys. It is based on the original study by Mjör (Mjör, 1981) and has been modified over the years by other researchers (Mjör and Toffenetti, 1992a, Mjör and Toffenetti, 1992b, Mjör and Um, 1993, Pink et al., 1994, Wilson et al., 1997, Mjör and Moorhead, 1998, Burke et al., 1999, Deligeorgi et al., 2000).
The operating dentist is asked to assess each restoration requiring replacement, in his/her opinion, and record a reason for the replacement from a list of reasons provided in the survey form. The dentists receive no training or calibration; therefore, the results are highly subjective.

Many studies demonstrated the great variation between dentists when recording the reasons for restoration failure (Elderton, 1976, Drake et al., 1990) and there is a wide variability in the diagnosis of dental problems because of differences in perception and importance among clinicians (Bader et al., 2001). For example, there is poor agreement between dentists in diagnosing secondary caries clinically as a reason for replacement (this is discussed further in section 2.2.4.1). The dentists' decisions are likely to be varied depending on the education received at dental schools, clinical experience, and continuing dental education (Jokstad et al., 2001).

The Mjör protocol (Mjör, 1981) included the following reasons for restoration replacement:

**A.** Replacement of Amalgam restorations:

1. Secondary caries
2. Poor marginal adaptation (ditching/leakage)
3. Isthmus fracture
4. Fracture of tooth
5. Other reasons

**B.** Replacement of tooth-coloured restorations:

1. Discoloration – whole filling
2. Discolouration – margins
3. Secondary caries
4. Poor anatomical form (lack of contact/incomplete filling)
5. Other reasons

The above reasons were modified and expanded further in multiple studies. Below is an example of the modified criteria (Burke et al., 1999):

1. *Secondary/recurrent caries:* this means caries detected clearly at the margins of an existing restoration, directly related to that restoration
2. *Discolouration:* this is related to tooth-coloured restorations and can be further classified into:
   I. *Bulk discolouration:* a mismatch between the colour of the body of the restoration and the tooth
   II. *Marginal discolouration*: staining found at the tooth/restoration interface
3. *Fracture of the tooth:*
   I. *Bulk fracture:* a fracture of a whole cusp of the tooth
   II. *Marginal fracture:* a fracture of an enamel margin
4. *Fracture of the restoration:*
   I. *Bulk fracture:* a fracture through the main body of the restoration, including isthmus fracture
   II. *Marginal fracture/degradation:* a small fracture of the margin of the restoration without associated caries, sometimes referred to as ditching or defective margins
5. *Poor anatomic form:* this is related to the restoration material and means any loss of substance in the restoration due to material degradation, wear, lack of contact, or incomplete filling
6. *Pain/sensitivity*

7. *Change of material:* this refers to replacement of serviceable restoration where the change *per se* was the reason for replacement rather than the failure of the restoration

Other surveys added “other reasons” and used it where the reason does not fall under any of the previous categories and this can include patient request, prosthodontic reasons, extraction etc. Usually “other reasons” is used when the restoration is replaced for reasons not related to the quality of restoration but for another needed intervention to the tooth.

### 2.2.3.2 The US Public Health Service (USPHS) Guidelines or “Ryge” criteria

These criteria are most commonly used in clinical studies. It is a defined system developed for the evaluation of the performance of dental restorative materials by Cvar and Ryge in the early 1970s (Ryge and Snyder, 1973). It constitutes observation of specific restoration parameters and grading them in scores of Alpha (excellent or good), Bravo (sufficient), Charlie (insufficient), or Delta (poor) as a way of ranking the key clinical stages of change, “Charlie” and “Delta” indicating a need for replacement. The original parameters were caries, colour match, anatomic form, cavosurface marginal discoloration, and marginal adaptation. The criteria have been modified by several authors to include other categories such as surface texture, postoperative sensitivity, proximal contacts, occlusal contacts, fracture, and other reasons.

An essential step in using these criteria is the training and calibration of at least two examiners with a minimum of 85% of reproducibility (Bayne and Schmalz, 2005). Another important part of the original USPHS guidelines is the requirement of at least dual examination with an agreed process to resolve differences when they arise.

Table 1 shows an example of the modified criteria (Moncada et al., 2014).

**Table 1: USPHS (Ryge) criteria based on (Moncada et al., 2014)**

| Variable | Alpha (A) | Bravo (B) | Charlie (C) |
|---|---|---|---|
| Secondary Caries | No clinical diagnosis of caries | Not applicable | Clinical diagnosis of caries along the margin |
| Colour (For tooth-coloured restorations) | The restoration matches in colour and translucency the adjacent tooth structure | The mismatch in colour and translucency is within the acceptable range | The mismatch is outside the acceptable range |
| Anatomic form | The general contour of the restoration follows the contour of the tooth | The general contour of the restoration does not follow the contour of the tooth | The restoration has an overhang |
| Marginal staining | There is no discolouration between the restoration and the tooth | There is discolouration on less than half the circumferential margin | There is discolouration on more than half the circumferential margin |
| Marginal adaptation | Explorer does not catch or has one-way catch when drawn across the restoration/tooth interface | Explorer falls into crevice when drawn across the restoration/tooth interface | Dentin or base is exposed along the margin |
| Surface roughness | The restoration surface has no surface defects | The restoration surface has minimal surface defects | The restoration surface has severe surface defects |
| Lustre of restoration (For tooth-coloured restorations) | The restoration surface is shiny and has an enamel-like translucent surface | The restoration surface is dull and somewhat opaque | The restoration surface is distinctly dull and opaque and aesthetically displeasing |

### 2.2.3.3 FDI criteria

FDI (*Fédération Dentaire Internationale*) or the World Dental Federation, is an international member-based organisation that acts as the main representative body of more than 1 million dentists worldwide. They develop health policies and aim to advance the science and practice of dentistry.

In 2007, Hickel et al. introduced new clinical criteria for the evaluation of direct and indirect dental restorations (Hickel et al., 2007) and they were further developed in 2010 (Hickel et al., 2010). The criteria were approved by the science committee of the FDI world dental federation and considered the “standard” criteria to be used in clinical trials as well as in clinical practice. By April-2017, 30 clinical studies has utilized this criteria, with a further 27 ongoing studies also applying them (Marquillier et al., 2018).

The FDI criteria is designed to detect early deterioration and failures in dental restoration in a more sensitive and discriminative way compared to the modified Ryge criteria, having specific scores that indicate a need for restoration repair in addition to scores for replacement. As for the Ryge criteria, all examiners and evaluators should be trained and calibrated in the use of the FDI criteria. Alongside clinical calibration in clinical settings on patients, there is a web-based training and a calibration tool (e-calib).

When using the FDI criteria, the restorations are judged on three main categories, which are further divided into subcategories:

**1.** Aesthetic:
- **i.** Surface luster
- **ii.** Staining:
  - a) Surface
  - b) Margin
- **iii.** Colour match and translucency
- **iv.** Aesthetic anatomical form

**2.** Functional
- **v.** Fracture of material and retention
- **vi.** Marginal adaptation
- **vii.** Occlusal contour and wear
- **viii.** Proximal anatomical form
  - a) Contact point

b) Contour

**ix.** Radiographic examination (when applicable)

**x.** Patient’s view

**3.** Biological

**xi.** Post-operative (hyper-)sensitivity and tooth vitality

**xii.** Recurrence of caries, erosion, abfraction

**xiii.** Tooth integrity (enamel cracks, tooth fractures)

**xiv.** Periodontal response (always compared to a reference tooth)

**xv.** Adjacent mucosa

**xvi.** Oral and general health

Each subcategory is given a score from 1 to 5 as follows:

**1)** Excellent – fulfils all quality criteria

**2)** Highly acceptable – some deviation from ideal but no risk of damage

**3)** Sufficiently acceptable – minor shortcoming

**4)** Unacceptable – repairable

**5)** Poor – needs replacement

The final score in each category is the most severe score obtained among all subcategories. It not necessary to use all 16 criteria. Authors can select the most suitable criteria related to their study. Also, the five-step grading may also be reduced to four-steps (two acceptable and two unacceptable) or to two-steps by combining scores 1–3 and scores 4 and 5 into “acceptable restoration” and “unacceptable restoration” respectively (Marquillier et al., 2018).

Some recent studies used both FDI and modified USPHS criteria to allow the comparison between the two. The FDI evaluation criteria seems to be more sensitive to small variations in the clinical outcomes compared to the USPHS criteria, when evaluating restorations of non-carious cervical lesion, especially for the marginal staining and marginal adaptation criteria (Loguercio et al., 2015, Perdigão et al., 2014). However, the FDI criteria may be less reliable, encouraging some authors to reduce the number of scores used (Marquillier et al., 2018).

### 2.2.4 Reported reasons for failure/replacement of restorations

#### 2.2.4.1 Secondary Caries

Secondary caries is frequently reported as the most common cause of failure/replacement of restorations (Rasines Alcaraz et al., 2014, Moraschini et al., 2015, Eltahlah et al., 2018, Opdam et al., 2014).

The diagnosis of secondary caries is mostly made clinically, but there is a wide variation among clinicians, and an even wider variation in the methods used, which is therefore likely to result in many false diagnoses leading to unnecessary replacements (Kidd et al., 1995).

One of the major problems in diagnosing secondary caries is that it is often difficult to differentiate between marginal staining, crevices without caries, and secondary caries. So far, there are no standards or criteria to be followed for the detection of secondary caries, but many methods have been suggested.

Visual or visual-tactile examination combined with bitewing radiographs are the most common and reliable methods. Other suggested methods include laser fluorescence (e.g. DIAGNOdent and KaVo) and Quantitative Light-induced Fluorescence (QLF). A systematic review looking into the accuracy of these detection methods found the validity of tactile assessment and quantitative light-induced fluorescence to be unclear (Brouwer et al., 2016).

Other available methods for caries detection include FOTI (Fiber-Optic Trans-Illumination), ECM (Electrical Caries Monitor), NIDIT (Near-Infrared Digital Imaging Transillumination) (e.g DIAGNOcam), OCT (Optical Coherence Tomography), Ultrasound and LED fluorescence. These methods either use fluorescence, which permits the detection of some surface bacteria, or transillumination, which detects voids in the tooth.

These methods can be useful adjuncts to caries diagnosis with varying specificity and sensitivity, but many of them are not recommended to detect secondary caries as the restoration present in the tooth can disrupt the technology used (e.g. laser or LED) producing an artifact leading to false positive diagnosis (Amaechi, 2009).

CBCT (Cone Beam Computed Tomography) was proven to detect cavitated approximal caries at significantly higher sensitivity compared to conventional and digital radiography (Sansare et al., 2014), but the presence of a restoration produces beam hardening artifacts, which lowers the quality of the CBCT image considerably (Abogazalah and Ando, 2017), so it is not recommended for secondary caries detection.

Another emerging technology is the Canary Dental Caries Detection System®. The technology is based on the detection of optical and thermal changes in the tooth using a combined PTR-LUM response (Photothermal Radiometry and Modulated Luminescence). This new high-tech system is promising and claiming to allow examination of the margins of restoration to detect caries and cracks accurately, but most available studies are in-vitro (Abrams et al., 2012) and there is not any evidence to support its use in secondary caries detection.

A Cochrane review in 2014 compared the use of amalgam versus RBC in permanent posterior teeth (Rasines Alcaraz et al., 2014). It included 7 randomised-controlled trials with a minimum follow-up of 3 years. All the studies were considered to have a high risk of bias and only two of the studies were eligible for the meta-analysis. It was reported that the risk ratio (RR) of failure of RBC due to secondary caries compared to amalgam is 2.14 (95% CI: 1.67 to 2.74); meaning that resin-based composites failed due to secondary caries twice as often as amalgams. Corresponding figures for failure due to fracture were (RR = 0.87, 95% CI: 0.46 to 1.64); no statistical difference between both materials failing due to fracture.

Another systematic review (Moraschini et al., 2015) also found secondary caries to be the most common reason of failure of amalgam and RBC occlusal and occluso-proximal restorations in posterior teeth, and it was significantly lower in amalgam restorations (RR = 0.23, 95% CI: 0.18 to 0.30). This review included 8 studies (2 RCTs, 5 prospective cohort studies, and one retrospective cohort study) with a minimum follow-up period of 12 months. The 2 RCTs included in this review were different studies to the ones in the Cochrane review mentioned previously. Fracture of the restoration or the tooth was found to be the second most common reason with no difference between the two materials.

Similar findings were reported in Longitudinal (Opdam et al., 2014, Astvaldsdottir et al., 2015) and cross-sectional studies (Lavelle, 1976, Eltahlah et al., 2018).

Some authors attributed amalgam having less secondary caries than RBC to the fact that amalgam has antibacterial properties (Leinfelder, 2000), mercury rather than copper being the major contributor to the antimicrobial activity of dental amalgams according to many in-vitro studies (Morrier et al., 1998).
On the other hand, plaque studies showed higher levels of plaque accumulation on RBC restorations compared to amalgam (Zalkind et al., 1998), and higher amounts of lactic acid-producing bacteria (*Streptococcus Mutans*) in the plaque present on resin-based composites too (Svanberg et al., 1990).

Secondary caries has also been connected to the marginal seal of the restoration. RBC is more technique sensitive than amalgam and requires excellent conditions of moisture control to achieve good adhesion to tooth structure. The complete or partial lack of this adhesion is believed to cause microleakage or gaps at the interface between the restoration and the tooth, in addition to the problem of polymerization shrinkage.

However, many studies confirmed that secondary caries does not develop as a result of microleakage, except if the crevice is large enough to cause “macroleakage” (Mjör, 2005), but microleakage can cause unsightly marginal discolouration in RBC restorations.

It is also believed that microleakage under amalgam restoration is slowly sealed by corrosion products over time, and that high copper amalgams form corrosion product much slower than conventional amalgams.

There is some evidence that applying copalite varnish or dentinal adhesive under amalgam restorations can help seal the restoration until corrosion products are formed (Ben-Amar et al., 1995).

Most secondary caries lesions are seen predominantly on the gingival margins of all types of restorations irrespective of material used (Mjör, 1998, Mjör and Qvist, 1997). An explanation for this is the difficulty in controlling the gingival fluid and salivary contamination at the gingival margin and the lack of direct visualisation, which can lead to deficiencies in the adaptation of the restorative material causing voids. In addition, bonding of RBC to dentine or cementum at the gingival margin is less effective than bonding to enamel.

Another important factor is that the gingival margins are more difficult for the patients to keep plaque free (Mjör, 1998).

It is important to note that the occurrence of secondary caries, as primary caries, is highly influenced by the patients’ caries risk rate (van de Sande et al., 2013). In the study by (Jokstad and Mjör, 1991), 256 occluso-proximal amalgam restorations inserted by Scandinavian dentists in their practices were followed for 10 years. It was observed that the rate of secondary caries correlated with the total number of restorations placed (as an indication to caries activity) during the observation period, irrespective of the quality of the cavosurface margins or the size of the cavity.

A study by Köhler et al. followed 51 occluso-proximal RBC restorations placed by general practitioners over five years and found that the majority of the patients where the restorations had failed due to secondary caries had higher counts of *Streptococcus Mutans* at baseline (Kohler et al., 2000).

### 2.2.4.2 Fracture of restorations

Bulk/marginal fracture of the restoration is another commonly reported reason for replacement of amalgam restorations. For RBC restorations, fracture seems to occur more frequently after 1998 according to the recent review (Eltahlah et al., 2018).

The Florida dental care study (which is a longitudinal study of changes in oral health) recorded findings from 723 subjects who were followed for 24 months (1993-1995), and reported an incidence rate of bulk fracture of restorations to be 13 teeth per 100 adults every two years (Heft et al., 2000).

Few studies reported fracture of restoration as the main reason for replacement. Rytömaa et al. examined 767 amalgam restorations in first permanent molars in 20-year-old students at the Helsinki university during the academic year 1981-82. They reported that 10% of these restorations needed replacement, the most common reason was fractured filling (38%), followed by secondary caries or improper marginal adaptation (23%) (Rytomaa et al., 1984). These findings are difficult to generalize as the population studied is not representative of the general population and amalgam had many improvements in properties since the study was conducted.

Mjör and Jokstad reported in their cross-sectional survey that bulk fracture of the restoration was the main reason for replacement of both amalgam and glass ionomer occluso-proximal restorations. For resin RBC restorations, the main reasons were both secondary caries and bulk fracture (Mjör and Jokstad, 1993). But this study had a high dropout rate (113 restorations assessed at 5 years from the original 274 restorations) which can introduce bias when interpreting the results (attrition bias).

Letzel and co-workers analysed data from 14 independent controlled clinical trials carried out at Nijmegen Dental School, Netherlands, between 1974-1989 (Letzel et al., 1997). The restorations were placed by a group of 7 operators working mostly in the dental school and partly in general practice. They looked at all placed occlusal and occluso-proximal amalgam restorations with a follow-up between 5 and 15 years. Data was available from 3,119 restorations. 481 restorations (15%) failed, and of these failures, 297 (62%) were due to restoration fracture, while secondary caries was the reason of failure of 17 restorations only (4%).

This suggests that results from cross-sectional practice-based surveys differ widely from those of clinical trials. While secondary caries is the most common reason cited in general practice surveys for replacement of restorations, it is rarely noted in clinical trials as noted by Mjör (Mjör, 2001). This can be attributed to the fact that clinical trials are usually followed for a relatively short duration to allow secondary caries to develop. Also, the patients recruited for clinical trials are generally carefully selected to have good oral hygiene and regular attenders, which makes them at lower risk of developing caries.

Despite the major advances in RBC composition, (Ferracane, 2013) believes the current formulations are weaker and less fracture resistant than those sold in the 1970’s and 1980’s, before the major push to minimize particle size occurred.

(Letzel et al., 1997) also found a correlation between the composition of the amalgam alloy and the failure of amalgam restorations due to fracture. Early conventional zinc-free, low copper alloys had the shortest survival time as they rapidly corrode in the oral environment due to the gamma-two phase. This corrosion results in reduction of strength of amalgam leading to fracture when subject to mastication. The addition of zinc reduced this corrosion, as well as the inclusion of high copper content (Watkins et al., 1995). So high copper, zinc-containing amalgams lead to less marginal fracture (ditching) compared to conventional amalgams and they have the highest survival rate.
But despite this improvement in amalgam composition, the proportion of replacement of amalgam restorations due to bulk fracture remained more or less the same between 1978 and 1995 as found by Mjör’s cross-sectional survey (Mjör, 1997a).

### 2.2.4.3 Poor anatomic form

This reason for replacement of restorations was reported by many authors investigating resin-based composites in the earlier studies (pre-1990). One of the earliest surveys by Mjör (Mjör, 1981) reported poor anatomic form to be the major reason for replacing tooth-coloured restorations (40% of 1,544 replaced restorations). Tooth-coloured restorations in this study constituted 92% resin-based composites and 8% silicate cements. But when Mjör compared the reasons for replacement of RBC restorations between 1978 and 1995, there has been a considerable decrease of restoration degradation and wear and increase in bulk and marginal fracture (Mjör, 1997a). This change is attributed to the changes in the properties of the RBC material over the years, as early resin-based composites had low wear resistance leading to loss of anatomic form. Despite that, wear of RBC restorations seems to continue to be a concern, but perhaps only for patients with heavy occlusal patterns, such as bruxing and clenching (Ferracane, 2013).

For amalgam restorations, poor anatomic form as a reason for replacement has been reported in some studies too, but not as commonly as secondary caries and fracture (Qvist et al., 1986a, Qvist et al., 1990a, Deligeorgi et al., 2000).

### 2.2.4.4 Tooth fracture

Tooth fracture has been reported infrequently in most studies. It can occur as either fracture of the whole cusp of the tooth or just the enamel margin. Fracture of the enamel maybe be caused by insufficient elimination of unsupported enamel during cavity preparation.

A study recorded tooth fractures reported by 9 general dentists at 7 clinics in Oregon, USA, over a two-week period in 1994. They reported 174 fractures amongst 74,503 enrolled adults and calculated an incidence estimate of 5 fractures per 100 adults per year, 88% of these being in previously restored teeth (Bader et al., 1995).

Another study examined 1,902 consecutively seen adult patients by two general practitioners at a private practice in Delaware, USA, between September 2001 until February 2002. They obtained data on 10,869 restorations, of which 10,082 were amalgam and 787 RBC, and found the prevalence of cusp fracture to be 1.88% for amalgam and 2.29% for resin-based composite. They also found that the rate of cusp fracture increased with the patients age and the number of surfaces restored in the tooth, but there was no difference in fracture rates between amalgam and resin-based composite. But this study examined a relatively small number on teeth restored with RBC compared to amalgam, which makes this finding difficult to generalize (Wahl et al., 2004).

In the UK, a questionnaire study recruited three general dental practitioners to collect information on each patient attending for treatment of a fractured posterior tooth over four months. They recorded 129 cases of fracture and found that mesio-occluso-distal restorations are a major predisposing factor to tooth fracture (Patel and Burke, 1995).

Cusp fracture is believed to be more common in endodontically treated teeth compared to vital teeth (Tang et al., 2010). A retrospective study in Denmark in 1988 collected data from 91 dentists working as general practitioners on 1,639 endodontically treated and amalgam-restored posterior teeth without cuspal overlays, and found that 62% of teeth with mesio-occluso-distal (MOD) restorations and 26% of teeth with mesio-occlusal or disto-occlusal (MO/DO) restorations had fractured over 20 years (Hansen et al., 1990). In addition, they reported that the type of food and the patient's parafunctional habits (bruxism) can play a big role in causing tooth fracture.

A retrospective study reported on the influence of "high occlusal stress" as a risk factor for restoration failure. The authors investigated 306 posterior RBC restorations and found 39 (13%) had failed due to restoration and/or tooth fracture. They calculated the hazard ratio of failure in "high occlusal-stress" restorations to be 2.78. In addition, tooth type, arch, and tooth vitality significantly affected the survival of the restorations. The hazard ratio for endodontically treated teeth was 2.5 compared with that for vital teeth (van de Sande et al., 2013).

#### 2.2.4.5 Discolouration

This is a commonly reported reason for replacement of RBC restorations, more so in the earlier studies before 1990. Self-cured resin-based composites discoloured much more than light-cured resin-based composites (Tyas, 1992), and insufficient polymerization of the RBC results in reduced colour stability and increased water absorption (Martin, 1998).

The introduction of enamel etching and microfillers in the 1970s greatly improved the discolouration of RBC restorations, but it is still observed. It is suggested that there are complex events happening in the oral cavity which lead to this discolouration and increased opacity, largely through water absorption of the RBC material (Jokstad et al., 2001). Patient-related factors also have a large influence on discolouration, e.g. smoking habit, alcohol and hot beverages consumption, and poor oral hygiene, causing extrinsic staining (Qvist and Strom, 1993).

#### 2.2.4.6 Lost restoration

This problem mainly occurs with cervical restorations in carious and non-carious defects, especially if no tooth preparation was carried out (Lee and Eakle, 1996). It is also a complication in indirectly placed restorations as a result of poor bonding. Loss of amalgam and RBC restorations that are placed directly is rarely reported. If it occurs, it is a result of a major deficiency in the handling of the material or cavity preparation (Jokstad et al., 2001).

The reasons for failure of cervical restorations are different to other cavity types. In contrast to other cavity types, secondary caries is rarely a reason for failure of cervical restorations, loss of restoration being the most common reason (Stewardson et al., 2012). Factors such as tooth flexure due to occlusal forces (Heymann et al., 1991), lack of enamel for bonding, and bonding to sclerotic dentine in older patients (where these cavities are usually more common) (Van Meerbeek et al., 1994) all play a role in the failure of cervical restorations.

#### 2.2.4.7 Pain/sensitivity

Post-operative sensitivity (POS) is one of the common problems following the placement restorations. Several studies have reported an incidence as high as 30% in RBC (Stangel and Barolet, 1990, Briso et al., 2007) and in amalgam (Qazi FR, 2012), and it tends to fade over few weeks, but in rare occasions can lead to the need for replacement of the restoration to alleviate the symptoms.

There is also evidence that POS is correlated to the complexity of the cavity; sensitivity being more frequent in three-surface restorations followed by two-surface then one surface RBC restorations

(Briso et al., 2007). On the other hand, Gordan et al. found no influence of dentine depth on the POS in amalgam restorations (Gordan et al., 1999).

Many factors have been suggested to cause POS. In resin-based composite, polymerization shrinkage can induce stress at the adhesive interface resulting in cusp deflection leading to sensitivity. Excessive stress created during polymerization has been related to the formation of cracks in the dentine on the pulpal floor which can cause pain and sensitivity on chewing (Jokstad et al., 2001).

Many studies have attributed the sensitivity to the use of the total-etch adhesives (Perdigao et al., 2003, Opdam et al., 1998, Unemori et al., 2004). Over etching can lead to excessive demineralisation and incomplete monomer penetration leaving voids in the hybrid layer and denuded collagen fibres that can sensitise the nerve endings when the tooth is subject to extreme temperatures, sweet stimuli, or occlusal stress. Some authors suggested that the use of the self-etch systems can lower the risk of POS, as they incorporate rather than remove the smear layer in the hybrid system. However, a recent systematic review (Reis et al., 2015) looked at the influence of adhesive strategy on POS in adult patients with posterior RBC restorations. The review included 29 trials, with only 13 judged to have low risk of bias to be used in the meta-analysis. The 13 trials were mostly conducted at university hospitals, except one trial was community-based. The trials were conducted in Brazil (5 trials), Turkey (2 trials), USA (3 trials), Belgium, Thailand, and Germany. In total, 1,437 posterior RBC restorations were placed in 526 patients. The overall relative risk of the spontaneous POS was 0.63 (95% CI 0.35 to 1.15), while the stimuli-induced POS was 0.99 (95% CI 0.63 to 1.56). It was also found that the adhesive strategy for posterior RBC restorations does not influence the risk or the intensity of POS.

In amalgam, some authors have postulated that the microleakage on the restorations-tooth interface causes POS and suggested that using liners can reduce it. A review in 2011 investigated which dental liners (including glass-ionomer, fluoridated desensitising agent, calcium hydroxide, zinc phosphate, copal varnish, and dental adhesive) under amalgam restorations are more effective in reducing postoperative sensitivity (Nasser, 2011). The review found inadequate evidence to claim or refute the efficiency of dental liners in reducing post-operative sensitivity, but there was weak evidence that amalgam restoration with copal varnish have less postoperative sensitivity.

## 2.3 REPAIR OF RESTORATIONS

### 2.3.1 Definition

Removal of part of the existing restoration and any adjacent pathologically altered and/or discoloured tooth tissue that is aesthetically or functionally unacceptable, followed by placement of a new restorative material in the prepared site. The new restorative material can be of the same type or different to the original restoration.

Repair can also include light grinding and polishing, removal of overhangs, polishing discoloured tooth-coloured restorations, or sealing margins (Gordan et al., 2012).

### 2.3.2 Popularity

Repair of dental restorations was first discussed in the literature as early as the 1970s. The published literature was mainly focusing on in vitro studies and few expert opinions, and there was a paucity of evidence of its applicability in clinical settings until the early 2000s. The published clinical studies looking into repair of restorations have markedly increased over the last 15 years, as well as surveys investigating the teaching of repair in dental schools (mostly resin-based composite) (Hickel et al., 2013). Those surveys show that teaching of repair is now included in most dental schools in Europe and North America (Blum and Lynch, 2014).

A recent systematic review and meta-analysis looked into the teaching and management of dental restoration repair (Kanzow et al., 2018). The review included 29 studies with a total of 7,228 dentists and 276 dental schools had been surveyed and 30,172 restorations evaluated. The review analysed the studies in three parts:

**(1)** Studies regarding dentists' "theoretical" repair behaviour
**(2)** Studies about dental schools teaching repair
**(3)** Studies regarding dentists' repair behaviour by treatment data collection

The first two parts included studies from all around the world including USA, UK, Europe, Brazil, Oceania, Nigeria, and Saudi Arabia. For the third part, only 5 studies were available, 4 from the USA (which reported on amalgam, resin-based composite, indirect tooth-coloured and gold restorations), and a much smaller sample study from the UK (amalgam and RBC only). The lack of data from other countries poses a risk of publication bias.

The review reported that the mean (95% CI) proportion of dental schools teaching repair was 83.3%, the mean of dentists stating to perform repair was 71.5%, and the mean of restorations which had actually been repaired was 31.3% (Kanzow et al., 2018). These findings suggest that the actual implementation of repair in clinical practice is lagging behind the available evidence. The review also showed that amalgam restorations are being repaired less often than resin-based composite, and repair is performed more if the dentist worked in public health practice or he/she was the dentist who placed the original restoration.

### 2.3.3 Advantages of restoration repair

Repair of restorations is a more conservative treatment option for defective restorations, saving tooth structure when compared to total replacement, and can increase the restoration longevity by preventing or “delaying” many complications that can arise through the “restorative spiral”, such as loss of vitality, increasing cavity size, or tooth fracture, which can eventually lead to loss of the tooth. Another advantage is that repair is much easier to perform than replacement, takes less time, and can often be performed without local anaesthetic, therefore less distressing for the patients (Javidi et al., 2015).

Repair of restorations in general is less costly for the patients and the clinicians. It has been suggested that a major factor influencing the treatment decision is the system of remuneration. A system paying a fee per item may encourage replacement while capitation-based system prefers repair (Sharif et al., 2010). No studies so far have looked at the influence of the method of funding on treatment decisions to repair or replace a restoration, but one retrospective study investigated the association between the method of funding and the age of failed restorations in general dental practice in the UK (Burke et al., 2002). The study collected data on 3,196 restorations, of which 2,099 were replacements. Four methods of funding were investigated (NHS, armed forces, private, and insurance or private capitation scheme). They found that restorations placed under the NHS have a significantly lower age at failure than restorations placed under other arrangements. The authors explained that the reason for this is multifactorial but one possible explanation is that a person working in an item-of-service scheme (i.e. NHS or fully private) might be more inclined to replace a failed restoration than someone working in a capitation scheme.

### 2.3.4 Success of restoration repair

Many studies in the recent few years have been conducted to examine how the repair or “minimal” intervention treatment affects the longevity of defective dental restorations, and how it compares to total replacement. In general, repair is proven to be a safe, reliable, and effective treatment alternative to replacement in the long term, but correct clinical diagnosis and indications for repair is key to the success of treatment.

#### 2.3.4.1 Clinical studies

A randomised clinical trial comparing replacement versus repair of RBC (Fernandez et al., 2015) and amalgam (Moncada et al., 2015) posterior restorations with localized marginal or anatomical deficiencies (scored as Bravo according to the modified USPHS criteria), and/or secondary caries (scored as Charlie) followed 46 RBC and 30 amalgam restorations for ten years. The trial was carried out at the Operative Dentistry Clinic at the Dental School of the University of Chile. The quality of restorations was scored according to the modified USPHS criteria by two examiners who were calibrated each year throughout the ten years. The treatment was carried out by another two clinicians. The two groups (repair and replacement) behaved similarly with regards to the parameters measured (marginal adaptation, secondary caries, anatomic form, and colour for resin-based composite, and marginal adaptation, secondary caries, marginal stain, contact, roughness and luster for amalgam). One exception was the anatomic form parameter in amalgam where the replacement group performed better. The authors explained the reason for this is that repair included only a partial correction area of the restorations, and it is not possible to recover the total anatomy without replacement.

In a prospective cohort study carried out at the University of Florida College of Dentistry, 88 (81 anterior and 7 posterior) defective RBC restorations (scored as Bravo in any of these parameters: marginal adaptation, anatomical form, surface roughness, marginal staining and interfacial staining) (Gordan et al., 2009) and 113 posterior defective amalgam restorations (Gordan et al., 2011) (scored as Bravo in marginal adaptation or anatomic form) to one of five treatment groups (repair, replacement, sealing, refinishing, or no treatment). The “defective restorations were evaluated by two calibrated examiners according to the modified USPHS criteria and made the treatment assignments randomly for restorations in the repair, replacement and no-treatment groups. For the sealant and refinishing groups, the authors assigned the restorations according to their need. The actual treatment was carried out by third- and fourth-year students. The teeth were followed for seven years. Only 53 RBC and 54 amalgam restorations were available for review at seven years. Repaired restorations remained stable over the seven-year period with no recorded failures in either the repair or the sealing group. The replacement and no treatment groups had three failed restorations each in the RBC study and one each in amalgam. This study had a high risk of bias due to the high dropout rate and lack of randomisation, as the treatment was assigned according to clinical judgment of the examiners. They also did not include any restorations with secondary caries, despite it being a very common reason for restoration replacement.

A retrospective study from dataset of large occluso-proximal (3-5 surface) posterior restorations placed in a general practice in the Netherlands reported on 246 repaired restorations (133 amalgam and 113 RBC restorations), all repaired using RBC (Opdam et al., 2012). Overall, 61% of the repaired restorations were still in service after 4.8 years, repaired amalgam exhibiting higher annual failure rate compared to resin-based composite. They also found that the restorations repaired due to fracture had a lower survival than those repaired due to caries.

Another retrospective study collected data from three general practices in Adelaide, Australia (Smales and Hawthorne, 2004). They compared the survival of 24 repaired and 609 replaced amalgam restorations and found no significant survival difference between the two groups at 5 years, but repaired amalgam restorations showed higher failure rates at 10 years. Around 63% of the replaced amalgams were still present at 10 years and 50% at 15 years, while only 37% of the repaired amalgams were still present at 10 years. This study has many flaws due to the retrospective design and the relatively small number or repaired restorations compared to replaced restorations.

### 2.3.4.2 In Vitro studies

Many in vitro studies have been conducted to investigate the success of bonding of a new amalgam or RBC to the old one during a repair. In vitro studies are easy and inexpensive to perform, and provide a research experience for clinical dental faculty (Sarrett, 2007), but those studies are inconsistent, with no standardization on how to measure bond strength or how to age the restorations and for how long (Hickel et al., 2013), which makes in vitro studies unreliable and not valid predictors of the clinical outcome in real life.

In these studies, bond strength is usually measured by tensile (or micro-tensile) testing or shear testing. Few studies assessed the quality of repair using microleakage analysis. But so far, there does not seem to be a consensus on which protocol for restoration repair works best.

1. **RBC repaired with RBC**

The studies have shown widely variable repair bond strengths between old and new RBC ranging from 25% to 80% of the cohesive strength of the original material (Cavalcanti et al., 2007).

The conditioning method has been investigated widely as it has a major influence on the bond strength. Some studies found air abrasion followed by a self-etching system to be the best technique providing repair strengths comparable to the RBC ultimate tensile strength when compared to no surface treatment or diamond bur roughening (Cavalcanti et al., 2007), while others preferred diamond bur roughening (Bonstein et al., 2005). (Loomans et al., 2011) recommended using a type of RBC for repair with similar composition to the old RBC if known. If not, a repair technique with phosphoric acid and sandblasting is recommended.

### 2. Amalgam repaired with amalgam

Multiple studies have investigated the interfacial bond between new and existing amalgam by modes of measuring the tensile strength, shear strength, or flexure strength. Hadavi et al. reported tensile strengths ranging between 50% to 79% of the control group (intact amalgam). Using the same type of amalgam and having uncontaminated interface lead to higher strengths (Hadavi et al., 1992). In contrast, Shen et al. reported strengths of 26% to 54% and that repairing amalgam with a different composition amalgam achieves greater repair strengths (Shen et al., 2006). Fruits et al. also concluded that the strength of a repaired amalgam is only 40% of that of unrepaired amalgam (Fruits et al., 1998).

Old studies in the 1960s suggested wetting of amalgam surface with mercury to produce the maximum bond strengths. This is an unacceptable practice as to concerns regarding mercury poisoning and environmental pollution.

Surface roughening with a carbide bur seems to be sufficient, with no additional advantage in using microetching (abrasion) or adhesive bonding in improving bond strengths. In fact, the use of adhesive bonding can significantly reduce shear bond strength (Diefenderfer et al., 1997).

### 3. Amalgam repaired with RBC

This method is suggested to be more successful than repairing amalgam with amalgam. A microleakage study showed that repair with RBC has a significantly greater sealing ability compared to repair with bonded amalgam, but neither techniques was able to completely eliminate marginal microleakage (Popoff et al., 2011).

Conditioning method has a major influence on bond strengths between amalgam and resin-based composite. “No conditioning” showed the least favourable results, while surface conditioning by coating amalgam with silica (using a silicon carbide abrasive) followed by silane application then etch and bond yielded a high bond strength (Ozcan et al., 2010), and etch and rinse adhesives seem to be more successful than self-etch (Cehreli et al., 2010).

### 2.3.5 Indications for restoration repair

So far, there are no universally acceptable guidelines on when and how a repair should be carried out. The FDI clinical criteria has been developed to facilitate a more sensitive evaluation of direct and indirect dental restoration in clinical studies (Hickel et al., 2010). In these criteria, a restoration given a score of 4 is regarded as “relative failure” and consequently possible to repair depending on the location and size of the defect. These include:

- Large marginal opening/ditching (>250 μm)
- severe marginal staining which is aesthetically unacceptable
- secondary caries without deep undermining caries, if accessible
- Chipping/partial fracture or marginal fracture of restorative material
- Marginal breakdown of enamel or minor/localized cusp fracture
- Erosive/abrasive loss of tooth structure at restoration margin
- Wear of the restoration

Apart from the previous tooth-specific criteria, Blum and Lynch suggested having patient-centred criteria when deciding on repair (Blum and Lynch, 2014). They recommend a careful selection of patients who are dentally motivated and attend on regular basis. The patients should have good oral hygiene and low caries risk. Other suggested suitable candidates for repair are patients with complex medical history or limited cooperation where the treatment needs to be quick, simple, and without local anaesthetic if possible.

## 2.4 PUBLISHED LITERATURE AND RATIONALE FOR CONDUCTING THE SYSTEMATIC REVIEW

Few systematic reviews have been published, mainly interested in RBC behaviour and comparing it to amalgam as a control. An excellent systematic review by Cochrane looked at RBC versus amalgam for posterior teeth (Rasines Alcaraz et al., 2014). But as with all Cochrane reviews, they only included randomised controlled trials and were interested in restorations placed in permanent teeth in adults as well as children, and in fact, the two studies they included were conducted on children.

While well conducted randomised controlled trials (RCTs) are considered the “gold standard” in research evidence, they can be very difficult and expensive to conduct, and their follow-up period is not usually as long as other study designs. In addition, when considering dental restorations, the behaviour of a certain material under the strict conditions of a randomised trial might be very different to the behaviour of the same material in general practice or “real life”. This means that the results of RCTs, as important and useful as they can be, might be difficult to generalise to everyday practice.

Another systematic review by (Moraschini et al., 2015) compared RBC and amalgam in posterior teeth in adults or children, but they included RCTs as well as prospective and retrospective cohort studies in one analysis. While this review included a wide range of studies compared to the Cochrane review, it might not be very accurate to combine the results of the different study designs together. We know from previous published literature that the results of different studies vary considerably depending on the design and this has been highlighted many times (Jokstad et al., 2001, Mjör, 2001).

Other reviews looked at the performance of RBC or amalgam separately. The review by (Opdam et al., 2014) studies the behaviour of RBC in posterior teeth from longitudinal studies (both retrospective and prospective) and restricted to publications between 2001-2011. Another review by (el-Mowafy et al., 1994) was interested in RBC placed in posterior primary and permanent teeth and included prospective LCSs and CTs published between 1981-1991, while (Heintze and Rousson, 2012) only reviewed occluso-proximal RBC restorations placed in posterior teeth, but they excluded studies that repaired existing restoration.

Many other non-systematic reviews investigated the behaviour or longevity of posterior RBC and amalgam (Hickel and Manhart, 2001, Demarco et al., 2012, Downer et al., 1999).

(Heintze et al., 2015) conducted a systematic review looking at the clinical effectiveness of anterior RBC restorations only and included prospective trials.

As noticed, the available reviews in the literature can have strict criteria for inclusion of studies which makes their results less generalisable to everyday practice. Also, many of the reviews are only interested in studies of just one design, which can limit their applicability, or even combine multiple studies of different designs in one analysis which might impact the accuracy of their conclusions.

To our knowledge, this is the first systematic review that looks at the behaviour of both RBC and amalgam in anterior as well as posterior teeth, and including studies that were conducted prospectively as clinical trials or longitudinal cohort studies, as well as cross-sectional studies, with the view of comparing the results of different study types. The review also did not put any restrictions on the publication date, or the criteria used for the assessment of restorations as done previously in many reviews.

In addition, this review is unique in providing details about the reasons for restoration replacement/repair and comparing them according to different study designs as well as different year of conduction.

Only restorations placed in permanent teeth in adults (≥ 16 years) were included in this study. Primary teeth in children were not included due to the differences in the anatomy and the limited life span of the primary dentition.

Restorations in permanent teeth in children were also excluded because it is believed that restorations placed in children can be affected by many factors not usually present in adults. These factors can include the cooperation of the patient, which can highly influence the restoration performance, and the difference in caries risk in children when oral health habits and behaviours are being established (Chisini et al., 2018). In addition, restorations in permanent posterior teeth in children are almost always placed because of primary caries while in adults, most restorations are replacements of failed restorations.

This review was not interested in cervical non-carious restorations. The reasons of failure of non-carious cervical lesions are unique and very different to other cavity types, and the behaviour of restorative materials in cervical restorations should be judged separately and this was beyond the scope of this review. In addition, an extensive research has been done already looking at these lesions and including them in this review will lead an unmanageable number of publications, so they were excluded for practical reasons too.

## 2.5 REVIEW QUESTION, AIMS, AND OBJECTIVES

The review question to be answered is: “What are the reasons of replacement and repair of direct dental restorations in permanent teeth in adults?”

The review aims and objectives are subdivided into the following parts:

1. To find out the rate of replacement and repair of direct dental restorations
2. To compare the differences in the reasons of replacement and repair between dental restorative materials used and cavity type
3. To ascertain if the patterns and reasons of replacement and repair changed over the years
4. To determine if there is an increasing trend towards repair rather that complete replacement of restorations
5. To compare the reasons of replacement and repair between different study designs

# 3. MATERIALS AND METHODS

## 3.1 METHODS

This systematic review followed the guidance from the Centre for Reviews and Dissemination (CRD) at the University of York (Centre for Reviews and Dissemination, 2009). CRD is a research department that produces high quality world leading systematic reviews covering a wide range of healthcare topics, promoting and influencing evidence-based decision making. Their third edition guidelines for undertaking reviews in healthcare, published in 2009, offered a valuable reference during the conduction of this review.

### 3.1.1 The review team

The review team was responsible for conducting and managing the systematic review. Three researchers were involved in the review to minimise bias and error throughout the process. The researchers were:

1. Dr Dena Eltahlah (DE), Specialist in Paediatric Dentistry, conducting the review as a requirement for the degree of Master of Philosophy in Applied Clinical Research and Public Health, Cardiff University
2. Professor Barbara Chadwick (BC), Joint Acting Head of School, Director of Education and Students, Professor of Paediatric Dentistry at Cardiff University. Professor Chadwick has an extensive experience in conducting systematic reviews, epidemiological studies, qualitative studies, and clinical trials in primary care
3. Professor Christopher Lynch (CL), Professor and Consultant in Restorative Dentistry at University College Cork, Ireland. Professor Lynch was the head of Prosthodontic Teaching and Head of Learning and Scholarship at Cardiff University, and is currently an honorary visiting Professor there. He has a special interest in minimally invasive dentistry, in particular the use of posterior composites

### 3.1.2 The advisory group

These are experts who were consulted at various stages of the review for specialist advice. They are:

1. Ms Mala Mann (MM), an Information Specialist/Systematic Reviewer at the Specialist Unit for Review Evidence, Cardiff University. Ms Mann provided expert advice for advanced literature searching and formulating the search strategy for this review
2. Dr Damian Farnell (DF), a Senior Lecturer of Applied Mathematics in Dentistry, Cardiff University. Dr Farnell provided statistical advice and performed statistical analysis for this review

### 3.1.3 The review protocol

The review protocol sets out the methods to be used in the review. These methods are explained in more details in the following sections and were set at the beginning of the review to minimise the risk of introducing bias.

Few modifications to the protocol were needed and they are clearly documented and justified when so. The modifications were discussed and agreed on amongst the review team and they resulted from clearer understanding of the review question.

The review protocol was addressed using the PICOS process, which is a technique used to frame and answer a clinical or health care question and recommended by the CRD. PICOS is an acronym the stands for: Population, Intervention, Comparators, Outcome, and Study design. However, the Comparator component does not apply to this project and was omitted. The other components were employed as follows:

| | |
|---|---|
| **P**opulation | Adults ≥ 16 years |
| **I**ntervention | Direct restoration in permanent teeth using amalgam or RBC |
| **O**utcome | Replacement or repair of restoration |
| **S**tudy design | Cross-sectional surveys (case studies), prospective observational cohort studies or controlled trials (randomised and non-randomised) |

CRD recommends registration of systematic reviews using PROSPERO.
PROSPERO is an international database of prospectively registered systematic reviews in health and social care, welfare, public health, education, crime, justice, and international development, where there is a health related outcome (www.crd.york.ac.uk/prospero). It provides a comprehensive listing of systematic reviews registered at inception to help avoid duplication and reduce reporting bias. Registration involves the submission and publication of key information about the design and conduct of a systematic review, and it is then published on an open access electronic database. PROSPERO was launched in 2011 and its annual number of registered records has steadily increased.
This review was not registered in PROSPERO. This was mainly due to the lack of popularity of registration of systematic reviews in PROSPERO at the time this review started.
However, it is important to acknowledge the important benefits of registering systematic reviews in providing transparency in the review process and safeguarding against reporting biases.

### 3.1.4 Determining the Inclusion and Exclusion Criteria

A wide search of the literature was conducted to identify relevant studies looking into the research question. This search was also the basis for the published non-systematic literature review of the reasons of placement and replacement of dental restorations (Eltahlah et al., 2018) as an update to the previously published review (Deligeorgi et al., 2001). The search helped identify the types of studies investigating failure, replacement, or repair of restorations.

The types of studies to be included were carefully discussed amongst the review team.

Retrospective surveys were to be excluded from the review due to the potential of inaccuracy in reporting, or lack of/incomplete data on the reasons of replacement or repair of dental restorations.

Cross-sectional surveys provide valuable information in relation to the research question and their results can be generalized to the population, and so they were included in this review.

Clinical trials (randomised and non-randomised) and prospective cohort studies mostly look at the behaviour of different types of materials over a time period and report on failures in the restorations through that period. Failures were dealt with in many ways, including, but not restricted to, repair or replacement. Some failures were managed by other treatments as extraction or crown placement.

The review group was uncertain whether these studies would have valuable information related to the review question. So, the group decided to review a random sample of 20 studies to assess their usability. The 20 studies were reviewed separately by the three reviewers and they all agreed that 8 out of 20 (40%) had information on failures and how they were managed. Following this, a decision was made to include all clinical trials, but to exclude studies with less than 2 years follow-up time as it was unlikely that many restorations will fail or need replacement or repair before 2 years. If the study was not reporting on how the failure was dealt with, the outcome to be reported as “failure” only.

Many studies investigated non-carious cervical lesions. As discussed in section 2.2.4.6, the reasons of failure of non-carious cervical lesions are unique and very different to other cavity types. And for that reason, they were excluded from this review.

Only studies reporting in English language were selected due to the lack of resources and facilities for translation.

The following inclusion/exclusion criteria were agreed on by the review team to assure capturing all studies of interest, while keeping it practical to apply to avoid yielding an overwhelming amount of information that is hard to compare and analyse.

As discussed before in section 1.2.1, only amalgam and RBC material were considered as they are the most commonly used dental materials for directly placed permanent restorations. Only restorations placed in permanent teeth in adults (≥16 years) are considered. The reason was based on the clinical difference in reasons for restorative therapy in adults and children. Restorations in permanent posterior teeth in children are almost always placed because of primary caries while in adults, most restorations are replacements of failed restorations.

#### 3.1.4.1 Definitive Inclusion Criteria

1. Cross-sectional surveys (case studies), prospective longitudinal cohort studies, randomised-controlled or non-randomised trials followed for two or more years
2. Studies investigating replacement, repair, or failure of directly placed restorations
3. Restorations in permanent teeth in adults (≥16 years)
4. The use of amalgam and/or resin-based composite (RBC) dental materials only
5. Studies in English language only

#### 3.1.4.2 Exclusion Criteria

1. Non-human or laboratory-based studies
2. Retrospective studies, review papers or case reports
3. Restorations in primary teeth
4. Restorations in children (<16 years) or both adult and children but not possible to separate data for adults only
5. Indirect/lab made restorations
6. Tunnel or atraumatic restorative technique restorations
7. Non-carious cervical lesions

## 3.2 IDENTIFYING RESEARCH EVIDENCE

To minimize bias in the review process, a thorough search to identify relevant studies must be conducted. This search should be as transparent as possible and documented in a way that enables it to be evaluated and reproduced. Studies were located using the following approaches:

### 3.2.1 Searching Electronic Databases

For the research topic, the electronic databases considered most suitable to search were MEDLINE, EMBASE, CENTRAL, and CINAHL.

**MEDLINE** is the U.S. national library of medicine bibliographic database of life sciences and biomedical information, containing more than 25 million references to journal articles. Time coverage for the articles is 1946 to present.

**EMBASE** is Elsevier® produced biomedical and pharmacological bibliographic database of published literature containing more that 32 million records from 1947 to the present.

**CENTRAL** is The Cochrane Central Register of Controlled Trials, a highly concentrated source of reports of randomized and quasi-randomized controlled trials. CENTRAL records are taken from bibliographic databases and from other published and unpublished sources.

**CINAHL** (Cumulative Index to Nursing and Allied Health Literature) is an index of journal articles about nursing, allied health, biomedicine and healthcare dating back to 1982.

#### 3.2.1.1 The search strategy

Designing a careful and sensitive search strategy is key to ensure retrieval of all relevant studies without being overloaded with an unmanageable number of records. At this stage, Ms Mann was consulted for her extensive expertise and advice in that field.

The keywords of interest were chosen carefully to yield relevant articles. Free text or medical subject headings (MeSh) were used as appropriate for each database. Wildcards or truncations were used carefully where needed. Boolean operators and adjacency searching were applied when necessary.

An initial search strategy was designed by DE and MM. This strategy was piloted on MEDLINE and EMBASE and tested for sensitivity and specificity. Thirty Key papers related to this research question were identified, and these were looked for in the results of the search. Not all key papers were picked up by the initial search. Some adjustments were carried out by adding few MeSh headings and free texts, and the search was run again. The key articles were picked up following the adjustments, but the number of articles was very high. Scanning the results revealed many studies were related to implants or root canal therapy. The strategy was adjusted to exclude implant and endodontic-related articles, then tested again for sensitivity. The results still included all 30 key papers, while the number of records went down to a manageable number.

### 3.2.1.2 Definitive search strategy and results

The search strategy used for the four databases is provided in Appendix 1.
MEDLINE search yielded 3,715 papers, EMBASE 1,522, CINAHL 458, and CENTRAL 46 (5,741 in total).

### 3.2.2 Citation Searching

This was carried out electronically using Web of Science and Scopus.

**Web of Science** is an online citation indexing service. It gives access to multiple databases that reference cross-disciplinary research. It consists of ten indexes containing information gathered from thousands of scholarly journals, books, book series, reports, conferences, and more. For the purpose of this review, Science Citation Index Expanded (1900-present) was used as it is most relevant to the review topic.

**Scopus** is another citation database covering research topics across all scientific and technical disciplines, ranging from medicine and social sciences to arts and humanities.

Search details of both databases is provided in Appendix 2.
The search generated 747 papers from web of Science and 673 from Scopus (1,420 in total).

### 3.2.3 Reference List Searching

The reference list of the papers identified as relevant after the first phase of study selection (see section 3.4.1) were carefully examined to identify any further studies of interest. In addition, systematic reviews reporting on longevity, failure, replacement, or repair of RBC or amalgam were also screened. Ninety-four additional studies were found and added to the potentially included list of studies.

### 3.2.4 Searching Trials Registers

Ongoing or unpublished trials were searched for using two large online resources; www.ClinicalTrials.gov and www.who.int/trialsearch.
No trials were related to the review question.

## 3.3 MANAGING REFERENCES

The reference management software package EndNote X8$^{TM}$ was used to record and manage all references. All the identified studies from the previous searches were downloaded and dealt with in EndNote.

## 3.4 STUDY SELECTION

The literature search result in a large number or records, but only some are potentially eligible to be included. This is determined by assessing the records against the predetermined criteria. The process of selecting eligible records should be explicit and thorough to minimize error and risk of bias.

Prior to proceeding to the study selection phase, all duplicate publications were removed using the duplicate detection method in EndNote. Even after using this method, it is common to detect more duplicate publications mainly due to errors that occur during downloading the articles, discrepancies in publication year or volume or page numbers. These will be detected and accounted for during the next stage.

### 3.4.1 First Phase of Study Selection

This phase involved screening the titles and, where available, abstracts of identified studies. These should be assessed against the inclusion criteria to determine studies that do not meet these criteria and reject them. As advised by the CRD protocol, it is important to err on the side of over-inclusion during this phase.

An initial exercise to determine agreement across the three reviewers was carried out. A random selection of 100 titles (with or without abstracts) were screened by the three reviewers (BC, CL, DE). The reviewers agreed on 85% of the titles. A discussion session was carried out to determine the areas of disagreement and to revise the selection criteria. A consensus was reached, and it was decided to repeat the exercise for a different 100 random titles. The second exercise resulted in 95% agreement, and the areas of disagreement were discussed again. Following this, another 50 random titles were reviewed and resulted in 100% agreement amongst the three reviewers. The remainder of the screening was undertaken by DE only.

Rejected studies fell into two categories: those that are clearly not relevant to the topic of the review and were excluded straightaway without explanation of the reason, and those that address the topic of the review but fail to meet the inclusion criteria. For those that fall in the second category, the reasons of exclusion were recorded. Whenever a decision could not be made based on the title and abstract alone, or the abstract was not available, the studies were included to go onto the second phase.

### 3.4.2 Second Phase of Study Selection

For all the studies passing through the first phase, full papers were obtained. The full papers were collected through Cardiff University Libraries either electronically or paper copies. If the full paper was not available through that way, an inter-library loan was requested from the British library.

The selection process was piloted by applying the inclusion criteria to a sample of 20 studies. The full paper studies were screened by three reviewers (BC, CL, DE) and this showed complete agreement. DE screened all full papers independently, and if any doubt existed about any study, it was sent to both BC and CL to be screened and discussed.

A study selection proforma (Appendix 3) was used for each paper to collect information about the study in details, and reach a decision to include or exclude, and the reason for exclusion. A spread sheet was created to include all the details in the proforma to allow easier comparison and management of data.

### 3.4.3 Dealing with duplicate publications

It is important to identify duplicate publications for research results to ensure they are not treated as separate studies in the review. The same study can be published several times to report results at different follow-up times, to report different results, or even for translation purposes.
Every effort was made to identify these duplications. When multiple reports of one study are identified, they are treated as a single study, but reference made to all the publications and data extracted in one form.

### 3.4.4 Reporting Study Selection

The CRD guidance recommends presenting a flowchart showing the number of studies/papers remaining at each stage. Such a chart has been developed by the PRISMA group (Moher et al., 2009). PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) is a group that gives guidance for authors and researcher to improve the reporting of systematic reviews by providing an evidence-based minimum set of items as a checklist to follow. The flowchart has been adapted from the group with slight modifications. It depicts the flow of information through the different phases of the review, by mapping the number of records identified, included and excluded, and the reasons for exclusion. This flow chart is represented in the results section.

## 3.5 DATA EXTRACTION

This is the process of obtaining the necessary information about the characteristics and findings of the included studies. To assure consistency in the systematic review and to improve reliability and validity, a standardised data extraction form was used for all the included studies. The form was an extension of the proforma used in the second phase of study selection (Appendix 3). Additional sections were added to the previous proforma to collect all required data (Appendix 4).

The data required for later analysis were collected at this stage and were organised in a spreadsheet to allow easier management and avoid extracting unnecessary data which can be time wasting.
As this review is including different types of studies, two separate spreadsheets were created, one for cross-sectional studies, the other for clinical trials/prospective cohort studies. As discussed previously, the results from both types of studies vary and will be interpreted separately.

Data from each included study was recorded on a data extraction form, then transferred into the corresponding spreadsheet.

The extracted data included (when available and applicable): first author, study design, year of study, country, type of practice, length of follow-up, patient/tooth/study characteristics, number/age/gender of patients, number/type of restoration, dropouts (in patients and restorations), number/ training and calibration of operators/examiners, criteria used for restorations assessment, and the number of failures/replacements/repairs and their reasons according to material/tooth type/cavity type.
For cross-sectional studies, in addition to the above data, placement: replacement ratio was recorded if available.

If a study had any additional reporting, e.g. exclusion criteria for recruitment (high caries risk, smoking, or parafunctional habits) or use of rubber dam, it was noted under patient characteristics.

Quality assessment of each study (see section 3.6) was undertaken at the same time and the quality score was added in the spreadsheets.

### 3.5.1 Piloting data extraction

Following discussions between reviewers, it was decided to pilot data extraction and quality assessment forms on a random sample of 10% of the included studies (15 studies) to ensure that all relevant information is captured without wasting time and resources on extracting data that is not required. All three reviewers (BC, CL, and DE) extracted data from 7 studies and provided a score for quality. This was important to ensure consistency between the reviewers and that they are interpreting the forms correctly. All reviewers had complete agreement. Another sample of 8 studies was piloted by two reviewers (BC and DE) and again, they had complete agreement. As agreed previously, if disagreement arises, it is to be discussed with the third reviewer (CL) until a consensus is reached.

### 3.5.2 Process of data extraction

Data extraction should be as unbiased and reliable as possible. Ideally two researchers should independently perform the data extraction, but due to constraints on time and resources, and the large number of included studies, DE extracted the remainder of the studies alone, and any uncertainties arising throughout were shared with the other two reviewers (BC and CL) until a consensus was reached.

When data extraction commenced, it was found that not all papers reported their findings to the same level of detail. At this point, any paper with insufficient information necessary for the review was excluded. This missing information was mostly related to the age of patients, number of patients or restorations, dropouts, or details about the number and reasons of failures/replacements/repairs. Ideally, the authors of the papers should be contacted to request more details. Due to time constraints and the high number of studies, this was not possible.

## 3.6 QUALITY ASSESSMENT

### 3.6.1 Introduction

Research vary considerably in methodological rigour, and bias can result from flaws in the design or conduct of the study. Assessment of the study quality is a very important part of a systematic review. It involves recording the strengths and weaknesses of the study, thereby influencing the strength of evidence provided by the review and whether it is robust enough to guide treatment decisions.

As discussed in section 2.2.2, studies related to this review question are of multiple designs. The randomised controlled trial (RCT) is widely regarded as the design of choice and the highest in the hierarchy of study designs for assessing the effect of healthcare interventions, followed by quasi-experimental studies. Observational studies come last in this hierarchy grading.

When considering what this systematic review is looking for, data from observational studies were found to provide valuable information that cannot be dismissed because observational studies do not rank highly in the evidence hierarchy.
Simply grading studies using this hierarchy does not provide an adequate assessment of the study quality because it does not take into account variations in quality among studies of the same design (Centre for Reviews and Dissemination, 2009).

It is also important to note that the terminology used in the literature to describe study designs can be ambiguous and misleading, so it is imperative to have a clear understanding of each study design. Appendix 5 outlines in details the different types of study designs according to the CRD and it provided a valuable reference throughout the process of data extraction and quality assessment.

### 3.6.2 Defining quality

When undertaking quality assessment for any study, it is important to consider how appropriate the study design was to the research objective, any risk of bias, outcome measures, quality of reporting, and generalisability of the findings.

The Cochrane handbook for systematic reviews of interventions (Higgins JPT, 2011) has classified bias into selection bias, performance bias, detection bias, attrition bias, and reporting bias. Although this classification applies to randomised trials, they can also be used in non-randomised studies, with more attention to be paid to selection bias (Higgins JPT, 2011). Not all the previous bias types apply to observational studies and should be regarded as applicable.

Outcome measure is an important factor in this review. As discussed in section 2.2.3, the reporting studies use different criteria to measure why a restoration has failed and/or needs replacement or repair. Studies that undertake training and calibration of the examiners/evaluators are considered of higher quality compared to studies where no calibration took place.

Generalisability of the findings of a specific study outside the context of that study; to and across other situations, people, stimuli, and times, is referred to as external validity (Khorsan and Crawford, 2014). This is related to the presence of bias during selection of participants to be included in a study and therefore, how closely a study reflects routine practice where the intervention would be implemented.

### 3.6.3 Tools for assessing quality

There are two main approaches towards assessing quality: checklist tool or a numerical scale. In 2003, a systematic review was carried out to evaluate both tools in assessing the quality of non-randomised studies (Deeks et al., 2003). This systematic review provided valuable guidance in this review.

The review found 182 tools meeting their inclusion criteria. The tools were assessed against 12 quality domains covering the major aspects of study quality, six related to internal validity, five related to the quality of reporting, and one to external validity. At first, the tools were considered “top tools” if they included at least 5 of the 6 internal validity tools. Sixty of the 182 tools were selected as “top tools”. Two of the 6 internal validity domains were considered most important: the creation of the intervention groups and the comparability of the groups. These were called “core domains”. Within the core domains, 4 core items were identified. All the top tools that covered at least 3 of the 4 core items were then classified as “best tools”. Fourteen tools were selected as “best tools”, of which 8 were judged to be unsuitable for use in systematic reviews. Six tools were judged to be useful for systematic reviews.

All 6 tools were considered for use in this review. One tool was found most relevant and applicable to this review as it can be modified to accommodate all three included study designs. The tool is called “the Newcastle-Ottawa Scale (NOS)” (Wells GA).
NOS is an ongoing collaboration between the Universities of Newcastle, Australia and Ottawa, Canada. It was developed using a Delphi process to define variables for data extraction and then tested on systematic reviews and further refined. Two separate tools were developed, one for case-control studies and another for cohort studies. The tool evaluates a study on three broad perspectives: selection, comparability, and outcome. A star system is used for semi-quantitative assessment of study quality. NOS has been used widely in many systematic reviews of non-randomised studies and can be modified to adapt different study designs.

As discussed previously, this review did not have a “comparative” component, so this was removed from the tool. The tool was further adapted in relation to the three main study designs in this review. The assessment of the quality of clinical trials consisted of three major domains. The first one relates to sample selection. How the sample represents the community affects the generalisability of the results. For example, a study excluding patients with poor oral hygiene or high caries rate scores less than a study not implying such restrictions.
Randomisation is another important factor to consider, and whether the method of randomisation is adequate.
Sample size should ideally be justified in the paper and the method detailed.

The second domain considers attrition bias due to dropout in the sample. This is measured in relation to the follow-up time. A maximum of 5% dropout in number of restorations per year of follow-up is considered appropriate to clinical studies looking at dental restorations and seems to be an agreed standard amongst many studies (Astvaldsdottir et al., 2015).

The third domain is the outcome. Studies using the predetermined criteria discussed in section 2.2.3 along with the recommended training and calibration for the examiners score higher. In addition, detailed reporting of findings added to the score of the quality.

The assessment of longitudinal cohort studies was very similar to clinical trials, but the randomisation section of the first domain was omitted as not applicable.

For cross-sectional studies, another factor to consider was the response rate of the reporting dentists which can affect selection bias.

Each study was given a score between 0-10 indicating quality.

Appendix 6 shows the three forms used for each study design.

The three forms were agreed among the three reviewers and piloted along the data extraction piloting stage.

## 3.7 DATA SYNTHESIS

This is the process of collating and combining the findings of the included studies to produce a summary of their results, taking into consideration the strength of the evidence. This allows meaningful and reliable conclusions to be drawn across the studies.

Data synthesis can be done quantitatively using formal statistical technique, such as meta-analysis, but if formal pooling of results is inappropriate, a narrative approach can be used.

The main aim of meta-analysis is to combine the results of several independent studies addressing the same question to produce a pooled estimate of the overall or average effect of interest with an increased statistical power and precision as more data is used, producing a weighted average from the results of the individual studies (explained in the next section).

If the studies are too diverse (either clinically or methodologically) to combine in a meta-analysis, a narrative synthesis is required to fully interpret the collected data. Narrative synthesis is inherently a more subjective process than meta-analysis; therefore, the approach used should be rigorous and transparent to reduce the potential for bias (Centre for Reviews and Dissemination, 2009).

To allow data synthesis, a clear descriptive summary of the included studies should be constructed. This is done by tabulating details about each study along with an indication of study quality (in the form of score of 0-10 using NOS as described previously in section 3.6).

## 3.8 STATISTICAL METHODS

Specialist statistical advice was sought from DF, as part of the advisory group, in carrying out meta-analyses using the extracted data.

- **Meta-analysis**

Meta-analysis allows one to find a pooled estimate across a group of studies (subgroup analysis) or over all studies (overall analysis) for the point estimate and confidence interval of some measure, e.g., such as a single proportion, as used here.

- **Forest Plots**

Forest plots provide a method of visualising the results of specific studies included in the analysis and also pooled estimates from meta-analysis, which are commonly shown as a diamond. Here, the point estimate for each study is indicated by a small square and the confidence interval is indicated by the ends of a horizontal line. By contrast, the centre of the diamond indicates the pooled point estimate from meta-analysis and the edges of the diamond indicate the associated confidence interval.

- **Heterogeneity**

Statistical heterogeneity refers to amount of variation in the outcome across all studies used in the analysis. It is measured by using $I^2$, where $I^2$ a value of near to 100% indicates strong heterogeneity and where $I^2$ a value of near to 0% indicates weak (or no) heterogeneity.

- **Fixed effects meta-analysis**

Fixed effects meta-analysis assumes that variation is limited to that within the studies included in the analysis and not between the studies. It weighs the contribution of each study in inverse proportion to the standard error (squared). It is used when heterogeneity is low.

- **Random effects meta-analysis**

Random effects meta-analysis assumes that variation can occur both within the studies included in the analysis and also between the studies. Confidence intervals of pooled estimates for random effects meta-analyses are therefore larger than for fixed effects meta-analyses. It is used when heterogeneity is of moderate to large strength.

- **Sensitivity analysis or omission of analysis**

When heterogeneity is strong, sensitivity analysis is carried out, i.e., outlying studies (e.g., for small sample sizes or results outside the pooled effect) are removed and meta-analysis is repeated to determine the effects of omission of the study. When heterogeneity is extremely strong, meta-analysis may not provide reliable pooled results and so meta-analysis might even be omitted.

- **Subgroup analysis**

Subgroup analysis is carried out for a subset of the studies according to some criteria. Pooled estimates from meta-analysis are found for these subgroups in addition to any overall analysis.

- **Meta regression**

Meta regression allows an analysis of the results of different studies as a function of a continuous variable, e.g., such as follow-up time, as in this review. Results of meta regression are shown as a scatter plot with the regression line superimposed. The weight that each study is given is shown by the size of the "bubble".

- **Bias in the data**

Bias in the data might occur due to numerous reasons, including publication bias (e.g., due to statistically non-significant results being harder to publish than significant results). A common way to asses potential biases is the funnel plot, which (as is normal) was carried in this review when the number of studies was greater than or equal to ten. When asymmetry was seen in the funnel plots, "trim-and-fill" methods were used to address this source of bias and meta-analysis was carried out again for comparison.

The software package R V3.6.1® was used by the statistician (DF) to carry out the statistical analysis. The details of the meta analyses used in the review are:

- Meta-analysis of a single proportion (for amalgam or RBC separately) was carried out via the "metaprop" command. In order to ensure that a proportion lies in limits between 0 and 1, the logistic function (i.e., the default for the "metaprop" command in R) was used to transform the data. This is the standard approach for analysing a single proportion. Other functions (e.g., arcsine) were also used and they gave comparable results.

- Meta regression of the proportion for each study was carried out as a function of follow-up time using the "metareg" command in R. The data was plotted using the "ggplot" function in R, where the follow-up time was on the x-axis and the proportion was on the y-axis. Those studies with small standard errors had a higher "weight" on the meta regression, which is the normal approach for meta regression. Results of each study individually are shown by the filled circles on this figure, where the "weight" of a study is indicated by the circumference of the circle. The line of best fit (full blue line) from meta regression and associated 95% confidence interval of the estimate (dashed red lines) were also plotted on the "ggplot" figure.

- Bar charts listing reasons for failure/replacement/repair: a simple proportion $p$ (expressed as a percentage) of the numbers of failures/replacements/repairs was found either as a function of the total number of failures/replacements/repairs or of the total number of restorations placed. The data is shown as a bar chart (plotted via MS EXCEL) for each reason and standard errors are indicated by the error bars. (Standard errors, which are also expressed as a percentage, used the "usual" formula for a proportion, i.e., $se = \sqrt{p(100 - p)/n}$.).

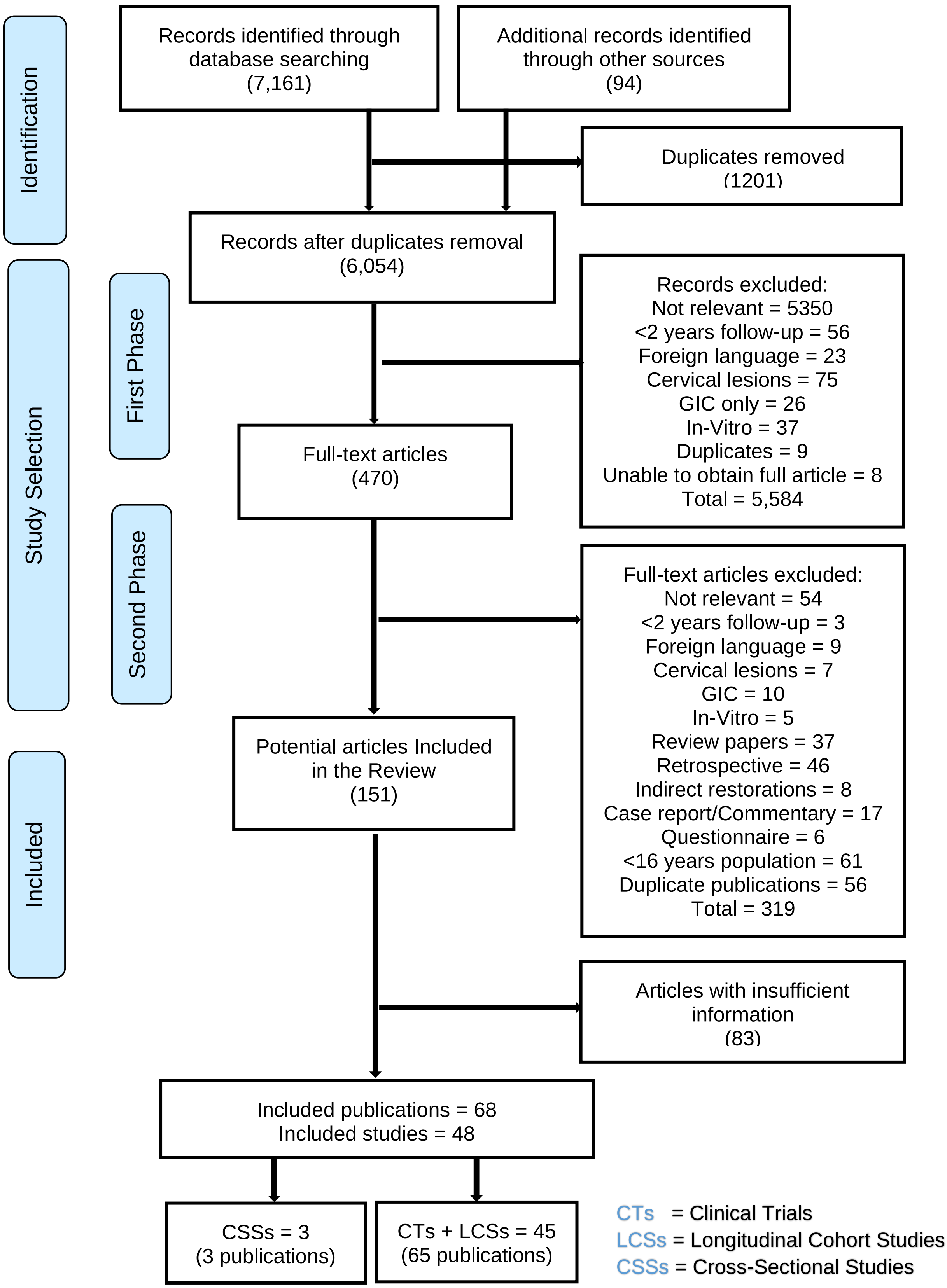
# 4. RESULTS

## 4.1 FLOW CHART OF THE SCREENING AND SELECTION PROCESS

As discussed in section 3.4.4, a flowchart adapted from the PRISMA group with slight modifications was used to depict the flow of information through the different phases of the review, by mapping the number of records identified, included and excluded, and the reasons for exclusion. Figure 1 shows detailed information about this selection process.

Please not the following abbreviations:
CTs = Clinical trials
LCSs = Longitudinal cohort studies
CSSs = Cross-sectional studies

**Figure 1. A summary flow diagram of the search results and studies excluded at each stage**



## 4.2 DETAILS OF THE INCLUDED AND EXCLUDED STUDIES

470 full-text articles were reviewed.

68 papers (48 studies) met the inclusion criteria and were included in the review (45 clinical trials/longitudinal cohort studies (65 publication) and 3 cross-sectional studies (3 publications)).

319 full-text papers did not meet the inclusion criteria and were excluded.

83 papers were excluded at this stage due to not having enough information. The details and reasons for exclusion are detailed in Appendix 7. The most common reasons for their exclusion were pooling data for different materials or teeth, and not being able to separate adult from children data.

Table 2 provides details of the specific characteristics of the 45 clinical trials (CTs) and longitudinal cohort studies (LCSs) included in the review.

Table 3 provides details about the 3 cross-sectional studies included in the review.

## Table 2: Clinical trials (CTs) and longitudinal cohort studies (LCSs)

| | Author, Year of publication | Year of start of study | Design Follow-up (in years) | Country (Setting) | # of patients (start-end) Age range | Tooth type Cavity type and size | Type of restoration | # of restorations (start-end) | Outcome | # of events | Quality score |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1.** | (Kramer et al., 2015), (Kramer et al., 2011), (Kramer et al., 2009a), (Kramer et al., 2009b) | 2004 | RCT<br>10 yrs | **Germany**<br>(University + Private practice) | 30-29 pts<br>24-59 yrs | Molar/Premolar<br>Cl 2 (2,3,4 surfaces) | **RBC**<br>Grandio (nano-filled) vs Tetric Ceram (conventional hybrid) | 68-66 | Failure | 3 | 8 |
| **2.** | (Fennis et al., 2014) | 2001 | RCT<br>5 yrs | **Netherlands**<br>(University) | 157-140 pts<br>35-81 yrs | Premolar<br>Cl 2 + cusp # | **RBC**<br>direct vs indirect<br>(Only direct RBC data is included)<br>AP-X, Kuraray (highly filled hybrid) | 92-80 | Failure | 8 | 6 |
| **3.** | (Celik et al., 2014), (Arhun et al., 2010) | 2013 | CT<br>3 yrs | **Turkey**<br>(University) | 31-23 pts<br>16-60 yrs | Molar/Premolar<br>Cl 1 or Cl 2 | **RBC**<br>Grandio (nano-hybrid) vs QuiXfil (micro hybrid) | 82-62 | Replacement | 4 | 5 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **4.** | (van Dijken and Pallesen, 2014a), (van Dijken and Pallesen, 2013) | 2003 | RCT<br>10 yrs | **Sweden**<br>(University) | 52-48 pts<br>29-82 yrs | Molar/Premolar<br>Cl 2 | **RBC**<br>Tetric Evo Ceram (nano-hybrid) vs Tetric Ceram (conventional hybrid) | 122-114 | Failure | 22 | 7 |
| 5. | (van Dijken and Pallesen, 2014b) | 2010 | RCT<br>3 yrs | **Sweden**<br>(University) | 38-37 pts<br>32-87 yrs | Molar/Premolar<br>Cl 1 or Cl 2 (2,3,4 surfaces) | **RBC**<br>Ceram X (nano-hybrid) With SDR flowable vs Ceram X only | 106-104 | Failure | 2 | 8 |
| 6. | (Laegreid et al., 2012) | 2005 | LCS<br>3 yrs | **Norway**<br>(University) | 74-73 pts<br>31-80 yrs | Molar<br>Extensive (≥3 surfaces + 1 cusp) | **RBC**<br>Filtek Supreme XT (Nano-filled) | 74-73 | Replacement<br>Repair | 2<br>7 | 5 |
| 7. | (Stefanski and van Dijken, 2012) | 2008 | CT<br>2 yrs | **Sweden**<br>(Public dental health clinic) | 48-40 pts<br>16-74 yrs | Molar/Premolar<br>Cl2 (2 surfaces) | **RBC**<br>Filtek Supreme XT (Nano-filled) with or without intermediate layer of Filtek Flow Supreme | 108-92 | Failure | 2 | 4 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 8. | (van Dijken and Pallesen, 2011b) | 2004 | RCT<br>4 yrs | **Sweden + Denmark**<br>(University + Private practice) | 78-76 pts<br>28-86 yrs | Molar/Premolar<br>Cl 2 (2,3,4 surfaces) | **RBC**<br>Ceram x (Nano-ceramic) with either Xeno (self-etch) or Excite (Etch and rinse) | 165-162 | Failure | 11 | 6 |
| 9. | (van Dijken and Pallesen, 2011a) | 2003 | CT<br>7 yrs | **Sweden**<br>(University) | 48-46 pts<br>21-85 yrs | Molar/Premolar<br>Cl 2 | **RBC**<br>Tetric Ceram (conventional hybrid) +/- Tetric Flow intermediate flowable in box | 118-114 | Failure | 17 | 6 |
| 10. | (van Dijken, 2010), (van Dijken, 2003) | 1996 | RCT<br>12 yrs | **Sweden**<br>(University) | 29-23 pts<br>26-72 yrs | Molar/Premolar<br>Extensive Cl 1 | **RBC**<br>Closed sandwich (PMRC Dyract + RBC Prisma TPH) vs Prisma TPH | 90-76 | Replacement<br>Repair | 5<br>1 | 5 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 11. | (Shi et al., 2010) | 2007 | RCT 3 yrs | **China** (University) | 32-24 pts Mean 20.5 yrs (Dental students) | Molar/Premolar Medium Cl 1 | **RBC** Synergy Compact (Packable Nano-Hybrid) vs TPH spectrum (conventional Hybrid) | 100-80 | Replacement | 6 | 6 |
| 12. | (Monteiro et al., 2010) | 2008 | RCT 2 yrs | **Portugal** (University) | 26-? pts 18-58 yrs | Premolar Cl 2 | **RBC** - 3 groups (A= CXM+OIT) (B=CXM+SF+MIT) (C=SF+OIT) SF= SureFil (Packable) CXM= CeramXMono (Nanohybrid) OIT=Oblique Incremental Technique MIT=Modified Incremental Technique | 105-92 | Failure | 3 | 5 |
| 13. | (Manhart et al., 2010), (Manhart et al., 2009) | 2005 | RCT 4 yrs | **Germany** (University) | 43-38 pts >18 yrs | Molar Cl 1 or Cl 2 | **RBC** QuiXfil (Micro hybrid) vs Tetric Ceram (Fine hybrid) | 96-83 | Replacement | 5 | 9 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 14. | (van Dijken and Lindberg, 2009) | 2003 | RCT<br>5 yrs | **Sweden**<br>(University + Public health clinic) | 50-46 pts<br>17-64 yrs | Molar/Premolar<br>Cl 2 | **RBC**<br>InTen-S (Low-shrinkage hybrid) vs Point 4 (Micro hybrid) | 106-97 | Failure | 12 | 7 |
| 15. | (Mahmoud et al., 2008) | 2006 | LCS<br>2 yrs | **Egypt**<br>(University) | 40-40 pts<br>(Dental students) | Molar/Premolar<br>Cl 1 (small) | **RBC**<br>4 types: Admira (ORMOCER), TetricEvoCeram (Nanohybrid), FiltekSupreme (Nanofill), Tetric Ceram (Micro hybrid) | 140-140 | Failure | 2 | 5 |
| 16. | (Lindberg et al., 2007), (Lindberg et al., 2003) | 1997 | RCT<br>9 yrs | **Sweden**<br>(Public dental health clinic) | 57-? pts<br>17-68 yrs | Molar/Premolar<br>Cl 2 | **RBC vs PMRC + RC (Sandwich)**<br>(Only RBC data included)<br>Prisma (Hybrid) | 75-69 | Failure | 8 | 8 |
| 17. | (Bekes et al., 2007) | 2005 | RCT<br>2 yrs | **Germany**<br>(University) | 50-34 pts<br>>18 yrs | Molar/Premolar<br>Cl 1 or Cl 2 | **RBC**<br>Tetric Ceram (Micro hybrid)<br>Two etching techniques: AdheSE (Self-etch) vs Excite (total-etch) | 100-67 | Failure | 4 | 5 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 18. | (van Dijken and Sunnegardh-Gronberg, 2006) | 1997 | LCS<br>6 yrs | **Sweden**<br>(University) | 63-55 pts<br>23-78 yrs | Molar/Premolar<br>Cl 2 (Large) | **RBC**<br>Nulite F vs Alert<br>Fiber reinforced Packable | 87-75 | Failure | 14 | 6 |
| 19. | (Sarrett et al., 2006) | 2003 | LCS<br>3 yrs | **USA**<br>(University) | 32-? pts<br>27-42 yrs | Molar/Premolar<br>Cl 1 or Cl 2 (2,3,4 surfaces) | **RBC**<br>Prodigy (Packable) | 57-25 | Failure | 11 | 5 |
| 20. | (Efes et al., 2006) | 2003 | RCT<br>2 yrs | **Turkey**<br>(University) | 54-50 pts<br>18-48 yrs | Molar<br>Cl 1 | **RBC**<br>Admira (Ormocer) (+/- Admira Flow base) vs Filtek Supreme (+/- Filtek Flow base) | 108-100 | Failure | 1 | 6 |
| 21. | (Ernst et al., 2006) | 2003 | RCT<br>2 yrs | **Germany**<br>(University) | 50-50 pts<br>Mean 35.7 yrs | Molar Cl 2 (2,3,4 surfaces)<br>Premolar Cl2 (2,3 surfaces) or | **RBC**<br>Filtek Supreme (Nano filled) vs Tetric Ceram (Hybrid) | 112-112 | Failure | 2 | 8 |
| 22. | (Turkun et al., 2005), (Türkün et al., 2003) | 2002 | LCS<br>3 yrs | **Turkey**<br>(University) | 36-? pts<br>Average 39.4 yrs | Molar/Premolar<br>Cl 1 or Cl 2 | **RBC**<br>SureFil (Packable Hybrid) | 55-47 | Failure | 3 | 4 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 23. | (Poon et al., 2005) | 2001 | LCS 3.5 yrs | **China** (University) | 65-37 pts 18-66 yrs | Molar/Premolar Cl 1 or Cl 2 | **RBC** SureFil {Packable Hybrid) vs TPH Spectrum Conventional (Hybrid) | 105-54 | Failure | 8 | 3 |
| 24. | (Burke et al., 2005), (Burke et al., 2003b) | 2001 | LCS 2 yrs | **UK** (General dental practice) | 61-49 pts >18 yrs | Molar/Premolar Cl 1 or Cl 2 | **RBC** Solitaire 2 (Packable) | 100-88 | Failure | 2 | 4 |
| 25. | (Kramer et al., 2005) | 2002 | LCS 2 yrs | **Germany** (University) | 31-29 pts 20-45 yrs | Molar/Premolar Cl 1 or Cl 2 | **RBC** Ariston PHc (Ion releasing) without etching vs Solitaire (Packable) with total etch + rubber dam | 99-89 | Replacement | 49 | 5 |
| 26. | (Van Dijken and Sunnegardh-Gronberg, 2005), (van Dijken and Sunnegardh-Gronberg, 2003) | 1999 | LCS 4 yrs | **Sweden** (University) | 63-60 pts 30-85 yrs | Molar/Premolar Cl 1 or Cl 2 | **RBC vs calcium aluminate** (only RBC data is included) TetricCeram (Highly filled fine hybrid) | 71-67 | Failure | 5 | 6 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 27. | (Mannocci et al., 2005) | 1996 | RCT<br>5 yrs | **Italy**<br>(Private practice) | 219-198 pts<br>32-63 yrs | Premolar<br>Cl 2 and endodontically treated | **Amalgam vs RBC with fiber post**<br>Amalgam (Valiant PhD)<br>Palladium Enriched phase-dispersed<br>RBC Z100 (Micro hybrid) with fiber post (Composipost RTD) | 219-198<br>Am 109-100<br>RBC 110-98 | Failure | Am 13<br>RBC 15<br>Total 28 | 6 |
| 28. | (Summitt et al., 2004), (Summitt et al., 2001) | 1997 | RCT<br>6 yrs | **USA**<br>(University) | 28-? pts<br>>18 yrs | Molar/Premolar<br>Cl 2 (extensive with at least one cuspal replacement | **Amalgam**<br>Tytin (Spherical)<br>Pin retained (Self-threading stainless-steel pins) vs Bonded (Amalgambond Plus with HPA powder) | 60-36 | Failure | 10 | 4 |
| 29. | (Pallesen and Qvist, 2003) | 1990 | RCT<br>11 yrs | **Denmark**<br>(University) | 28-27 pts<br>19-64 yrs | Molar/Premolar<br>Cl 2 | **RBC (two types) vs RBC inlays**<br>(Only RBC data is included)<br>Brilliant dentin vs Estilux Posterior | 56-54 | Replacement<br>Repair | 9<br>2 | 8 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 30. | (Lopes et al., 2003) | 1999 | RCT<br>2 yrs | **Brazil**<br>(University) | 36-34 pts<br>20-40 yrs | Molar/Premolar<br>Cl 1 or Cl 2 | **RBC**<br>Prodigy Condensable PC vs Definite Ormocer D<br>(Packable posterior) | 78-74 | Failure | 2 | 7 |
| 31. | (Van Dijken, 2001), (Van Dijken, 1999), (van Dijken, 1996) | 1993 | CT<br>6 yrs | **Sweden**<br>(University) | 50-46 pts<br>33-72 yrs | Anterior teeth<br>Large Cl 3<br>Cervical margins in dentine | **RBC vs PMRC vs RMGIC**<br>Only RBC data is included<br>Pekafill (Hybrid) | 52-51 | Failure | 3 | 4 |
| 32. | (Gaengler et al., 2004), (Gaengler et al., 2001) | 1987 | LCS<br>10 yrs | **Germany**<br>(University) | 73-? pts<br>18-52 yrs | Molar/Premolar<br>Cl 1 or Cl 2 (small) | **RBC**<br>(Visio-Molar radiopaque) with a base of GIC (Ketac-bond) | 194-86 | Failure | 40 | 2 |
| 33. | (Wilson et al., 2000) | 1996 | LCS<br>3 yrs | **UK**<br>(General dental practice) | 22-18 pts<br>17-59 yrs | Molar/Premolar<br>Cl 2 (2,3 surfaces) | **RBC**<br>Tetric (Fine Hybrid) using "Decoupling Technique" | 43-35 | Failure | 3 | 2 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 34. | (Wassell et al., 2000), (Wassell et al., 1995) | 1989 | RCT<br>5 yrs | **UK**<br>(University) | 73-? pts<br>Mean 29.6 yrs | Molar/Premolar<br>Cl 1 or Cl 2<br>(Large) | **RBC**<br>Inlay vs Conventional<br>Only RBC data is included<br>(Coltene Brilliant Dentine (Hybrid)) | 100-67 | Replacement | 5 | 6 |
| 35. | (van Dijken et al., 1999) | 1993 | RCT<br>5 yrs | **Sweden**<br>(University) | 52-? pts<br>33-76 yrs | Anterior teeth<br>Cl 3 or Cl4 | **RBC**<br>Pekafil (Hybrid)<br>3 groups of bonding systems<br>Gluma 2000 vs Gluma 3 step vs Gluma 1 (37% Phosphoric acid) | 163-149 | Failure | 15 | 5 |
| 36. | (Raskin et al., 1999), (Raskin et al., 2000) | 1987 | LCS<br>10 yrs | **Belgium**<br>(University) | 36-? pts<br>19-40 yrs | Molar/Premolar<br>Cl 1 or Cl 2 | **RBC**<br>Occlusin (Hybrid highly filled)<br>Two groups (With or without rubber dam) | 100-60 | Failure | 23 | 6 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 37. | (Qvist and Strom, 1993), (Qvist et al., 1985) | 1981 | RCT<br>11 yrs | **Denmark**<br>(University) | 35-30 pts<br>24-65 yrs | Anterior teeth<br>Cl 3 | **RBC**<br>Silar (Chemically cured micro filled)<br>Two groups: A: Bevelling<br>B: Dentine adhesive, re-etching and coating with low viscous resin | 104-90 | Replacement | 15 | 3 |
| 38. | (Roberts et al., 1992) | 1988 | RCT<br>3 yrs | **USA**<br>(University) | 34-34 pts<br>Mean 57.9 yrs | Molar/Premolar<br>Cl 2 | **Amalgam vs RBC**<br>Dispersalloy + Copalite Varnish vs Herculite Condensable (small particle) | 108-108<br>Am 55-55<br>RBC 53-53 | Replacement | Am 2<br>RBC 5 | 7 |
| 39. | (Knibbs and Smart, 1992) | 1986 | CT<br>3 yrs | **UK**<br>(University) | 31-30 pts<br>17-23 yrs | Molar/Premolar<br>Cl 1 or Cl 2 | **Amalgam vs RBC**<br>Dispersalloy vs Heliomolar (Micro filled) | 106-104<br>Am 53-52<br>RBC 53-52 | Replacement | Am 1<br>RBC 4 | 3 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 40. | (Van Dijken, 1991) | 1984 | CT<br>6 yrs | **Sweden**<br>(University) | 44-42 pts<br>25-65 yrs | Molar/Premolar<br>Cl 2 | **Amalgam**<br>3 types (Standalloy 68 (conventional low copper), Dispersalloy (high copper 12%), Epoque 80 (Single composite Lathe cut high copper 23%) | 132-126 | Replacement | 13 | 4 |
| 41. | (Barnes et al., 1991) | 1982 | LCS<br>8 yrs | **USA**<br>(University) | 12-? pts<br>Adults | Molar/Premolar<br>Cl 1 or Cl 2 | **RBC**<br>Ful-Fil (Posterior fine particle) | 33-30 | Replacement | 7 | 6 |
| 42. | (Norman et al., 1990) | 1984 | RCT<br>5 yrs | **USA**<br>(University) | 62-? pts<br>Adults | Molar/Premolar<br>Cl 1 or Cl 2 | **Amalgam vs RBC**<br>Dispersalloy vs Occlusin (Hybrid highly filled) | 160-123<br>Am 53-43<br>RBC 107-80 | Failure | Am 3<br>RBC 6 | 6 |
| 43. | (Wilson et al., 1988b), (Wilson et al., 1988a), (Wilson et al., 1985) | 1983 | LCS<br>5 yrs | **UK**<br>(University) | 41-? pts<br>16-66 yrs | Molar/Premolar<br>Cl 1 or Cl 2 | **RBC**<br>Occlusin (Hybrid highly filled) | 77-72 | Replacement | 12 | 4 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 44. | (Robinson et al., 1988) | 1984 | RCT<br>3 yrs | **UK**<br>(University) | 58-? pts<br>19-66 yrs | Molar/Premolar<br>Cl 1 or Cl 2 | **Amalgam vs RBC**<br>Aristaloy vs Occlusin (Hybrid highly filled) | 125-98<br>Am 27-20<br>RBC 98-78 | Replacement | Am 0<br>RBC 8 | 5 |
| 45. | (Hendriks et al., 1986) | 1982 | RCT<br>3 yrs | **Netherlands**<br>(University) | 49-47 pts<br>(University students) | Molar/Premolar<br>Cl 1 or Cl 2 | **Amalgam vs RBC (3 types)**<br>Dispersalloy vs Profile (Stronium glass filled) or Estic (Micro filled) or Adaptic Radiopaque (Conventional macrofilled) | 232-224<br>Am 58-56<br>RBC174-168 | Failure | Am 1<br>RBC 7 | 4 |

**Table 3: Cross-sectional studies (CSSs)**

| | Author, Year | Year of start of study | Observation period | Country | Number of patients | Age range | Tooth type Cavity type and size | Type of restoration | Outcome measured | # of events | Quality score |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1.** | (Oginni and Olusile, 2002) | 1998 | 2 months | Nigeria | 291 pts | 16-62 yrs | Posterior Cl 1 & 2 | Amalgam | Replacement | 121 | 2 |
| **2.** | (Asghar et al., 2010) | 2009 | 5 months | Pakistan | 413 pts | 17-63 yrs | Anterior and posterior Cl 1, 2, 3, 4 | RBC | Replacement | 413 | 2 |
| **3.** | (Allander et al., 1990) | 1980 | 20 restorations | Sweden | ? | Adults | Posterior Cl 2 | Amalgam | Replacement | 1,788 | 3 |

### 4.3 FINDINGS OF THE REVIEW

#### 4.3.1 Clinical trials (CTs) and Longitudinal cohort studies (LCSs)

Under this category, 45 studies with 65 publications were included. There are 25 randomised controlled trials (with 35 publications), 6 non-randomised clinical trials (with 9 publications), and 14 longitudinal cohort studies (with 21 publications).
In the following sections, results are reported per study (with referral to the publications when needed as appropriate).

The studies had been published between 1986 and 2015, and the follow-up times ranged between 2-12 years (9 studies were followed up for 2 years, 12 for 3 years, 3 for 4 years, 7 for 5 years, 4 for 6 years, 1 for 7 years, 1 for 8 years, 1 for 9 years, 4 for 10 years, 2 for 11 years, and 1 for 12 years).

Ten studies were judged to be of very good quality, 30 of acceptable quality, and 5 of poor quality.

The studies were undertaken in 14 different countries across 5 continents (12 in Sweden, 6 in Germany, 6 in the UK, 5 in the USA, 3 in Turkey, 2 in Denmark, 2 in China, 2 in the Netherlands, 1 in Norway, 1 in Portugal, 1 in Egypt, 1 in Italy, 1 in Brazil, 1 in Belgium, and 1 in Sweden and Denmark combined).

The studies included data about 4,013 restorations (3,525 RBC restorations and 488 Amalgam restorations). Of the 3,525 RBC restorations, 3,235 were placed in posterior teeth (molars and premolars) and 290 in anterior teeth (incisors and canines). All 488 amalgam restorations were placed in posterior teeth.

Thirty-four studies looked at 2,706 posteriorly placed RBC restorations, 2 studies at 162 posterior amalgam restorations, 6 studies compared 529 posterior RBC and 326 amalgam restorations, and 3 studies reported on 290 anterior RBC restorations.

As mentioned previously, when the data was collected from the studies, it was found that studies report the outcome of the restorations differently. Some studies record the outcome as “failure” without mentioning what the solution for that failure was. This means that “failed” restorations may have been replaced, repaired, or even the tooth was crowned or extracted. It was impossible to deduce this information from the publication and the data was classified under the category of

"failure". Other studies record the outcome clearly as replacement or repair and the data was clear and classified accordingly.
Of the 45 studies (65 publications), 30 studies (43 publications), 66.7%, reported on failures, 12 studies (18 publications), 26.7%, reported on replacement, and 3 studies (4 publications), 6.7%, reported on both replacement and repair.

In total, this review collected data about 4,013 restorations placed and followed across all studies, of which, 252 were RBC failures, 27 were amalgam failures, 136 were RBC replacements, 16 were amalgam replacements, and 10 were RBC repairs.

#### 4.3.1.1 Data analysis

Separate analysis was undertaken for amalgam and RBC, as well as anterior (incisors and canines) and posterior (molars and premolars) restorations.

Overall, 28 studies reported on posterior failures (27 RBC failure and 4 amalgam failure), 14 on posterior replacement/repair (13 RBC replacement, 3 RBC repair, and 4 amalgam replacement).

Only 3 studies reported on anterior teeth (RBC only), 2 as failures and 1 as replacement.

A second analysis was undertaken for the reasons of failure/replacement/repair for anterior and posterior teeth.

### 4.3.1.2 Failure/replacement/repair rates

#### 1) Posterior RBC failure

Twenty-seven studies reported on RBC failure. The studies followed 2,378 RBC restorations and reported on 236 failures.

Heterogeneity was assessed and $I^2$ was found to be 82%, so random-effects meta-analysis was carried out.

Figure 2 shows the forest plot of the results. Note that (a), (b), (c), (d) refer to the different types of RBC used in each study for differentiation purposes in the plot. To be clear, RBC (a) in one study is not the same in another study. It just means that there was one or more types of RBC in the study and these were given a letter (a) or (b) etc. to separate them in the plot. These types were detailed in Table 2 previously.

Also note that the year following the author in the plots refers to the year the study was conducted, not the year it was published.

The forest plot is presented with three columns. The left-hand column lists the names of the studies arranged according to the follow-up time ascending from the top downwards. The middle column is a plot of the failure rate of each type of RBC in each study (represented by the small square) incorporating confidence intervals (represented by horizontal lines on either side of the square). The right-hand column details the failure rate with confidence interval in numbers. The area of each square in the middle column is proportional to the study's weight in the meta-analysis. The overall meta-analysed failure rate is represented on the plot as a dashed vertical line and plotted as a diamond for all the studies of similar follow-up period, then as one diamond at the bottom of the dashed line as an overall estimate of failure rate over all the studies. The lateral points of the diamond indicate confidence intervals for this estimate.

The overall failure rate averaged over all the years of follow-up (2-10 years) is 6% (95%CI:4%-9%).

As there were enough studies to assess bias, this was carried out using funnel plot shown in Figure 3. A funnel plot is a scatterplot of the effect estimates from individual studies against a measure of study precision (measured as total sample size, standard error, weight of effect etc). Here, it is measured according to standard error. Each dot on the plot represents a separate study. Larger and most powerful studies are placed towards the top. In the absence of bias, the scatter will be due to sampling variation alone, and the plot will resemble a symmetrical inverted funnel (a triangle centred on a fixed effect summary estimate and extending 1.96 standard errors either side to include about 95% of studies)(Sterne et al., 2011).

The plot showed evidence of bias, so a “trim-and-fill” technique was applied. “Trim-and-fill” is a method used to estimate the number of studies missing from a meta-analysis that were suppressed by publication bias and provides bias-adjusted results. The idea of this method is to first *trim* the studies that cause a funnel plot's asymmetry so that the overall effect estimate produced by the remaining studies can be considered minimally impacted by publication bias, and then to *fill* imputed missing studies in the funnel plot based on the bias-corrected overall estimate. The closed dots on the plot indicate the observed studies, while the open dots indicate the imputed missing studies (Shi and Lin, 2019).
Figure 4 shows this plot and it suggests that the overall failure rate might be slightly higher at 15% (95%CI:11%-20%).

Meta regression of the proportion for each study was carried out as a function of follow-up time in Figure 5. Results of each study individually are shown by the filled circles on this figure, where the “weight” of a study is indicated by the circumference of the circle. The full blue line represents the line of best fit and the dashed red lines are the associated 95% confidence interval of the estimate.

Figure 5 indicates the percentage of failure goes up strongly with the length of follow-up in years.

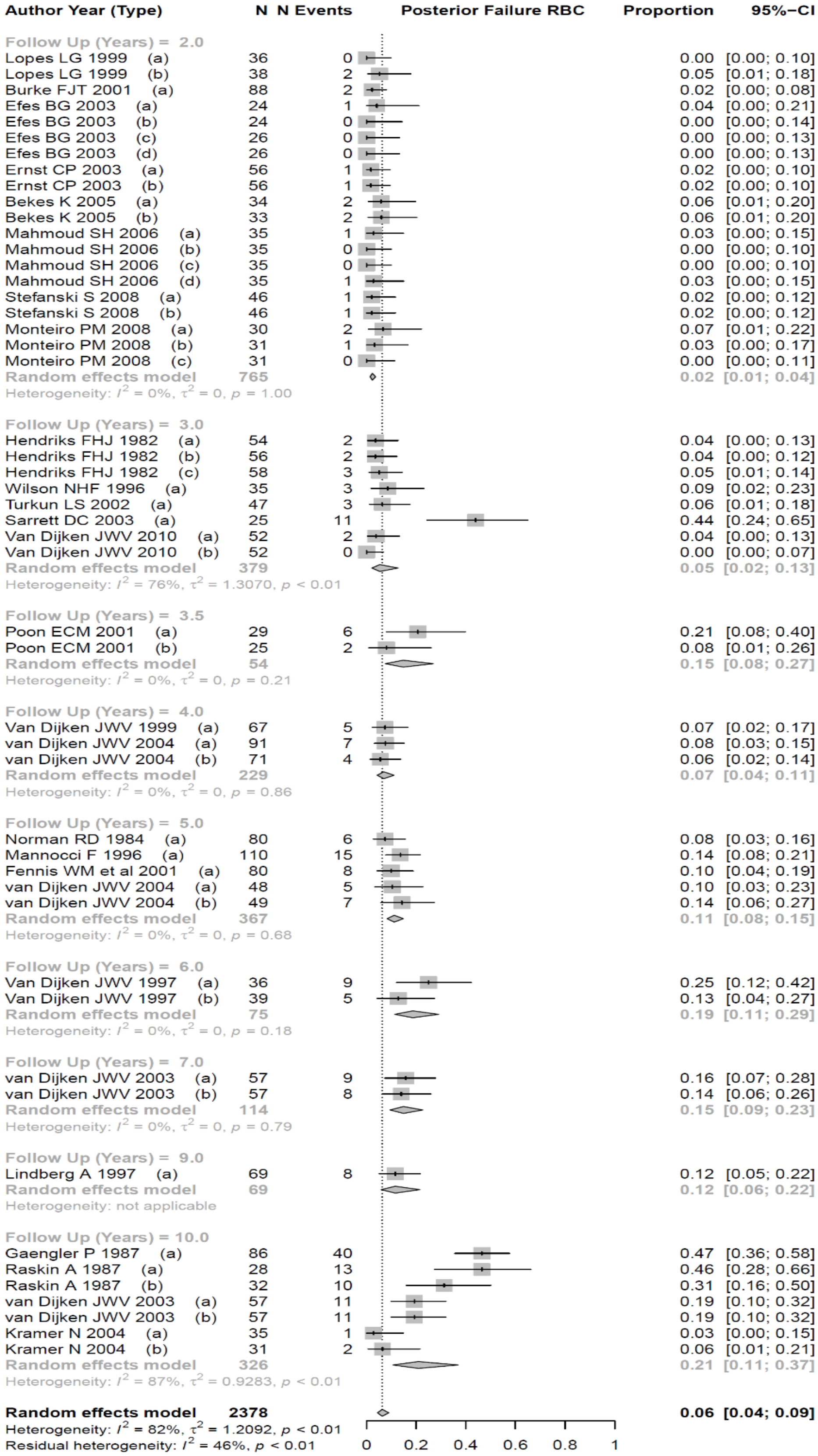


**Figure 2. Forest plot for posterior RBC failure in CTs and LCSs**

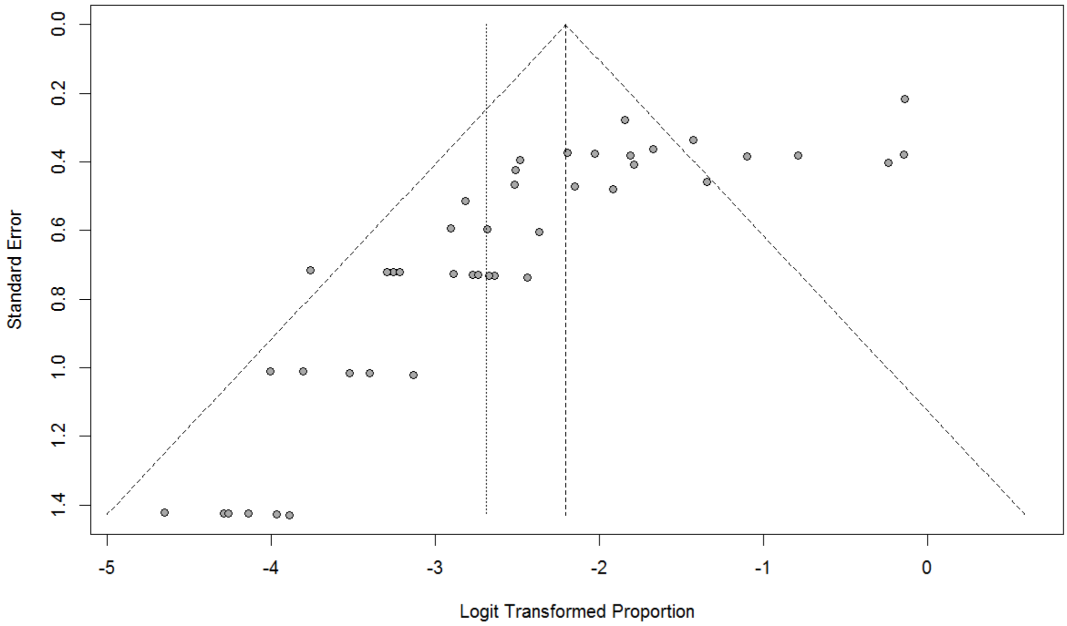


**Figure 3. Funnel plot assessing bias in posterior RBC failure in CTs and LCSs**

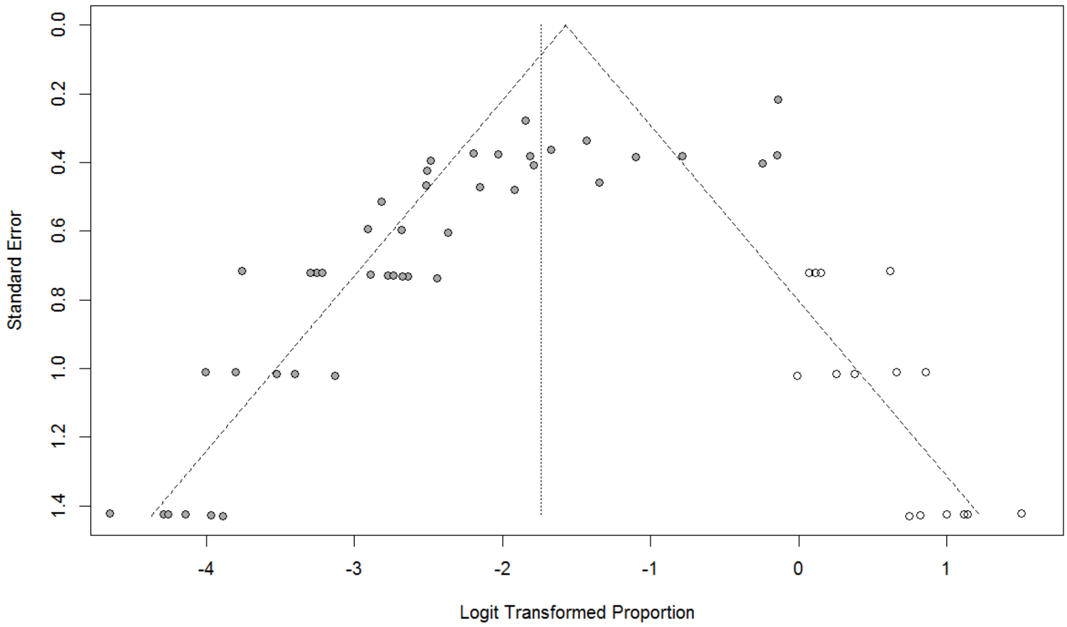


**Figure 4. “Trim-and-fill” funnel plot for posterior RBC failure in CTs and LCSs**

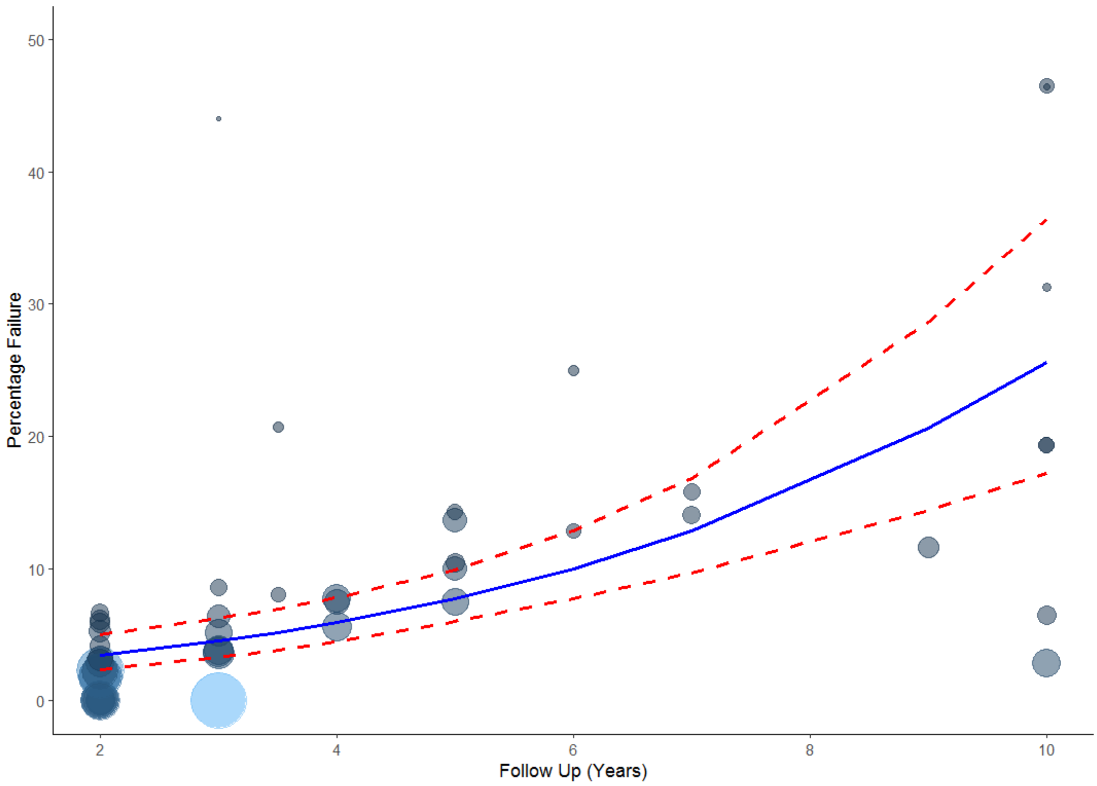


**Figure 5. Meta regression of posterior RBC failure in CTs and LCSs**

## 2) Posterior amalgam failure

Only 4 studies reported on posterior amalgam failure. The studies followed 235 posterior amalgam restorations and reported on 27 failures.

Heterogeneity was assessed and $I^2$ was found to be 78%, so random-effects meta-analysis was carried out.

Figure 6 shows the forest plot of the results. Note that (a) and (b) refer to the different types amalgam for each study. The types were detailed in Table 2 previously.

The overall failure rate averaged over all the years of follow-up (3-6 years) is 10% (95%CI:4%-24%).

There were not enough studies to assess bias.

Meta regression of the proportion for each study was carried out as a function of follow-up time. This is shown in Figure 7 and shows that the percentage of failure goes up with the length of follow-up in years.

The above results should be interpreted with caution due to the small number of studies analysed.

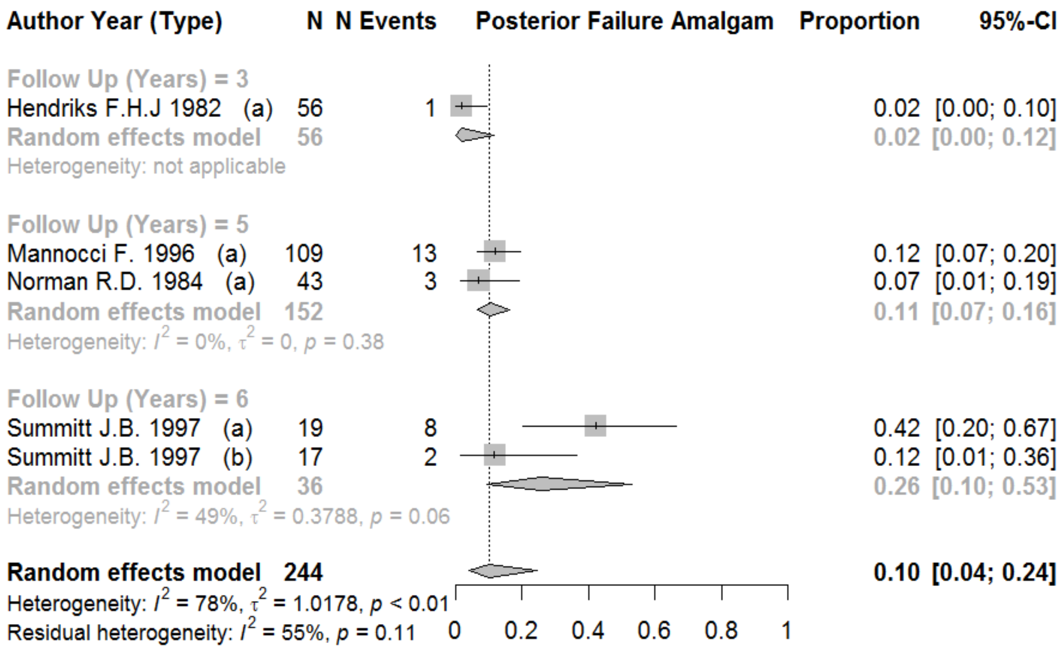


**Figure 6. Forest plot for posterior amalgam failure in CTs and LCSs**

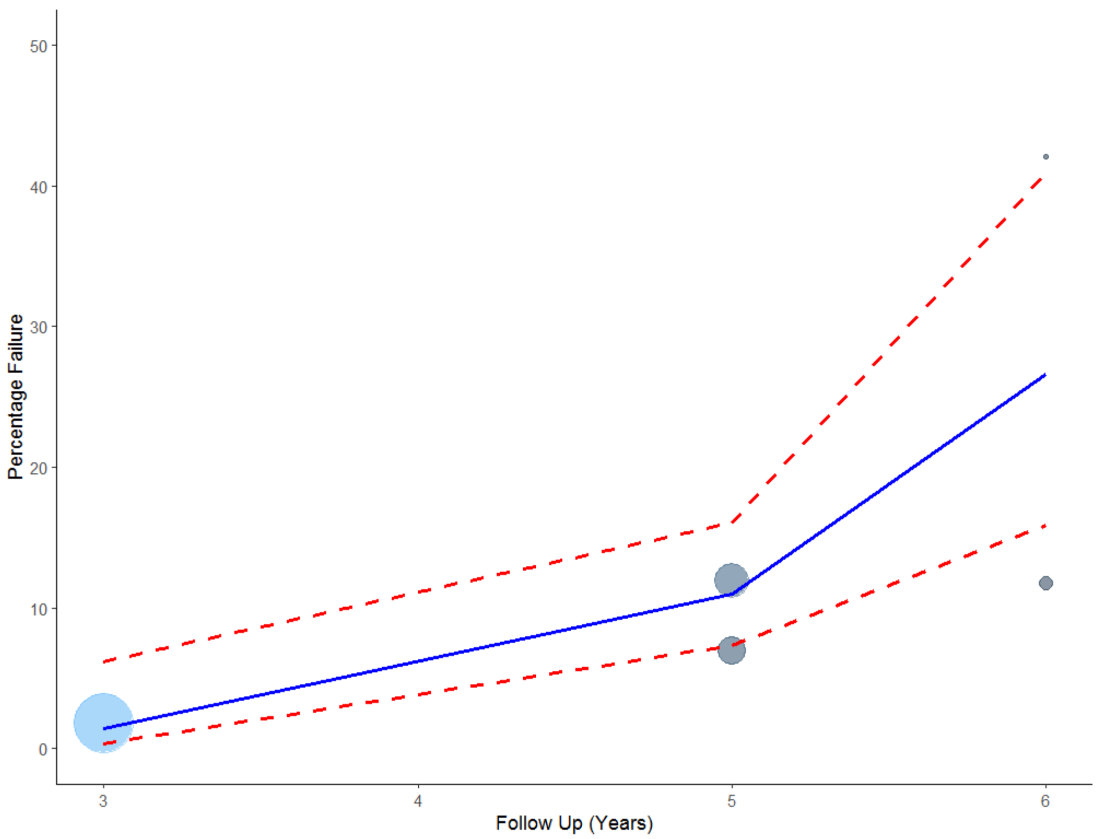


**Figure 7. Meta regression of posterior amalgam failure in CTs and LCSs**

### 3) Posterior RBC replacement

Overall, 13 studies reported on RBC replacement. The studies followed 869 posterior RBC restorations and reported on 121 replacements.

Heterogeneity was assessed and $I^2$ was found to be 83%, so random-effects meta-analysis was carried out.
Figure 8 shows the forest plot of the results. Note that (a) and (b) refer to the different types of RBC for each study. The types were detailed in Table 2 previously.

The overall replacement rate averaged over all the years of follow-up (2-12 years) is 14% (95%CI:12%-16%).

A major outlier was noticed on the plot from one study (Kramer et al., 2005). Please note that this study is referred to as Kramer 2002 in the plot. As mentioned before, the year following the author in the plots refers to the year the study started, not the year it was published.

This study is a longitudinal cohort study that compared two RBCs; (a); Ariston PHc (Ion releasing) without etching vs (b); Solitaire (Packable) with total etch + rubber dam. The Ariston group had a high failure rate (86%). This study was removed as a "sensitivity" analysis. Heterogeneity was assessed again and $I^2$=32%, so a fixed-effects model was used as the results were fairly homogeneous following removing the outlier as shown in the forest plot in Figure 9. The replacement rate went down to 9% (95%CI:7%-11%).

As there were enough studies to assess bias, this was carried out using the funnel plot shown in Figure 10. The plot showed evidence of bias, so a "trim-and-fill" technique was used to address this before undertaking the meta-analysis again (this was done without the outlier study).
Figure 11 shows this plot and it indicated the overall replacement rate might be slightly higher at 13% (95%CI:10%-16%).

Again, meta regression of the proportion for each study was carried out as a function of follow-up time and is shown in Figure 12. The percentage of replacement goes up strongly with the length of follow-up in years.

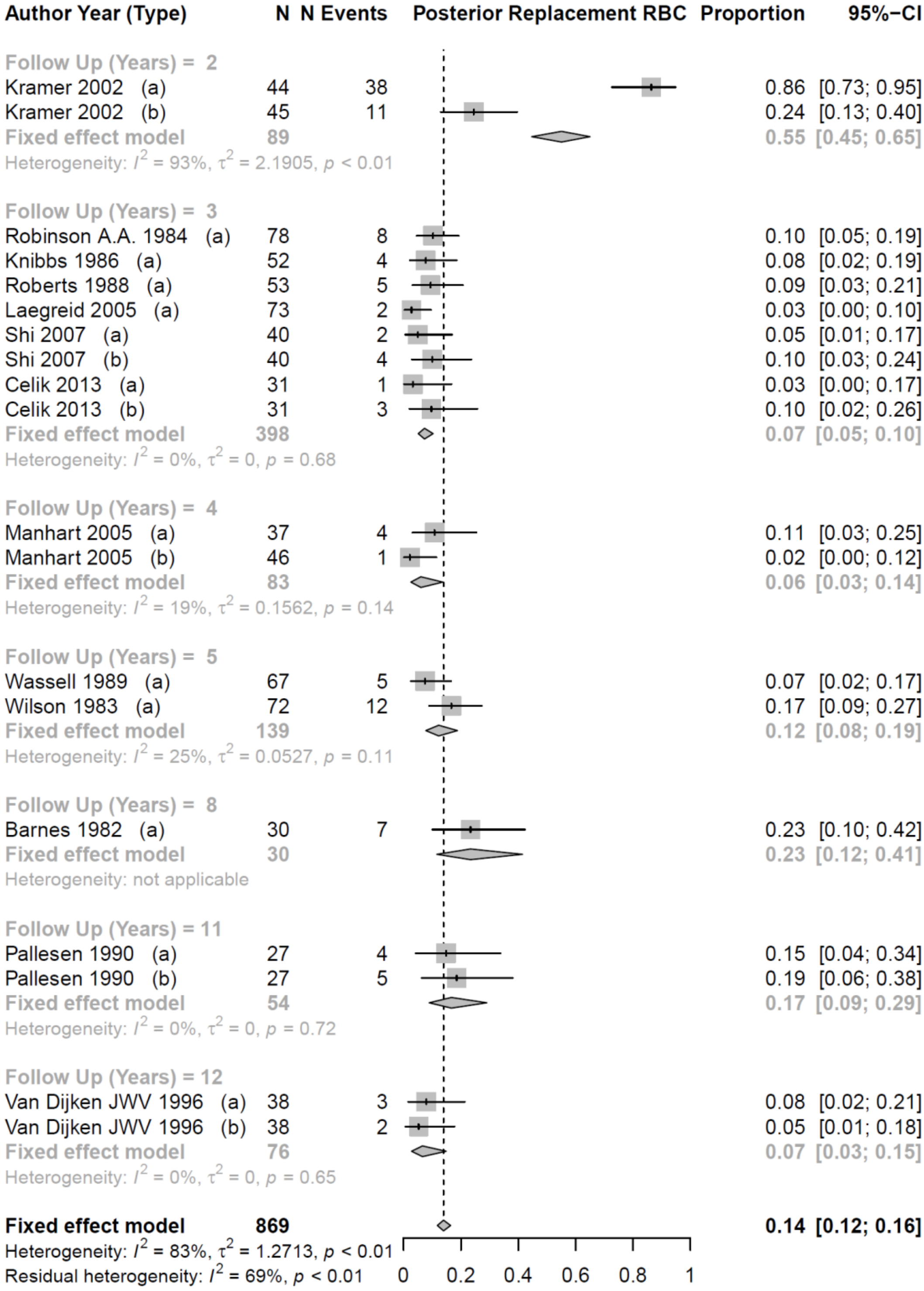


**Figure 8. Forest plot for posterior RBC replacement in CTs and LCSs**

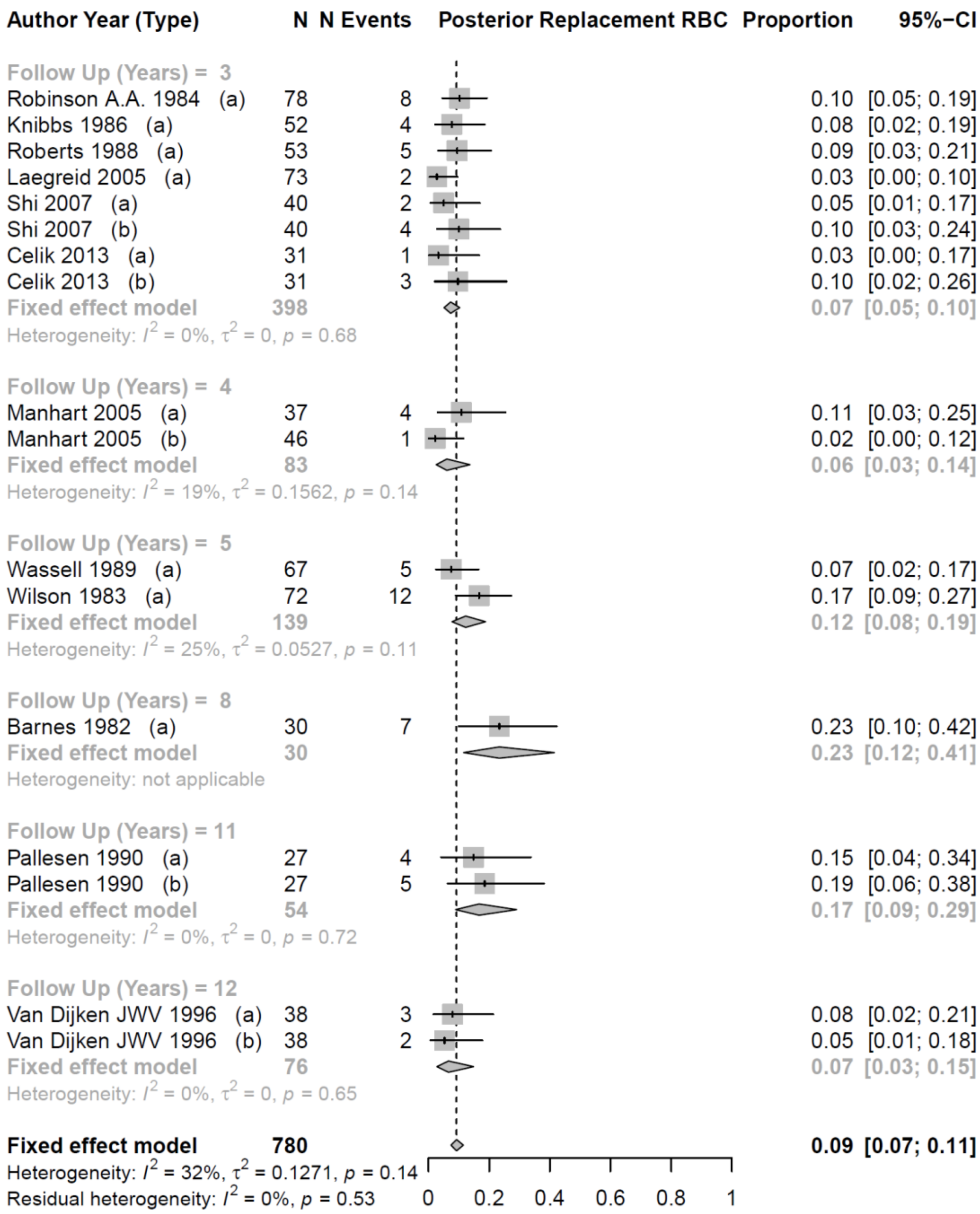


**Figure 9. Forest plot for posterior RBC replacement in CTs and LCSs following removal of outliers**

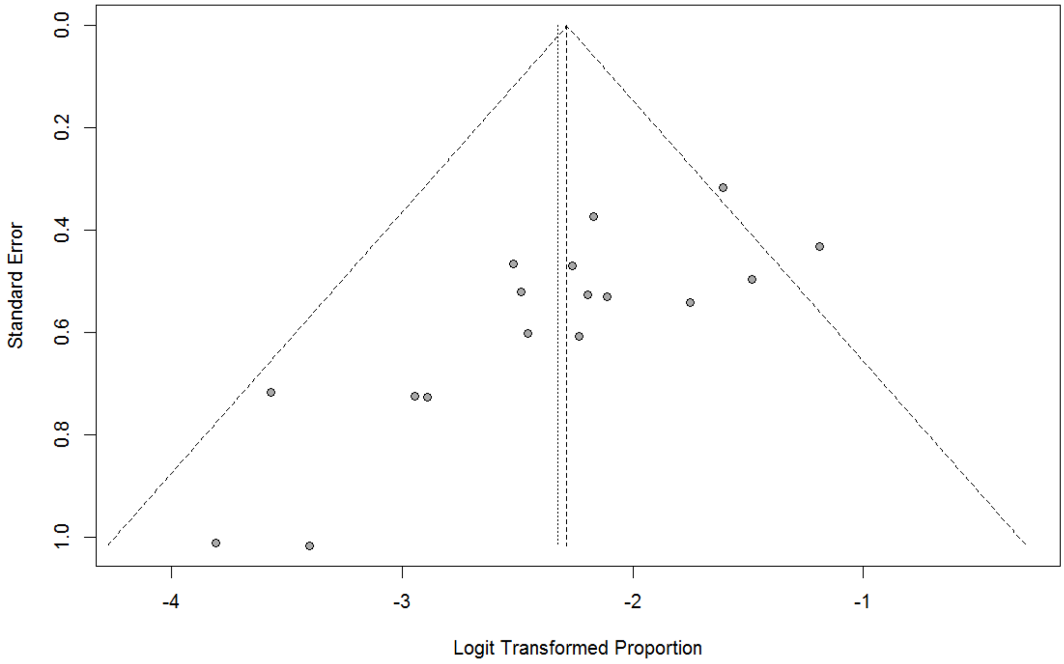


**Figure 10. Funnel plot assessing bias in posterior RBC replacement in CTs and LCSs**

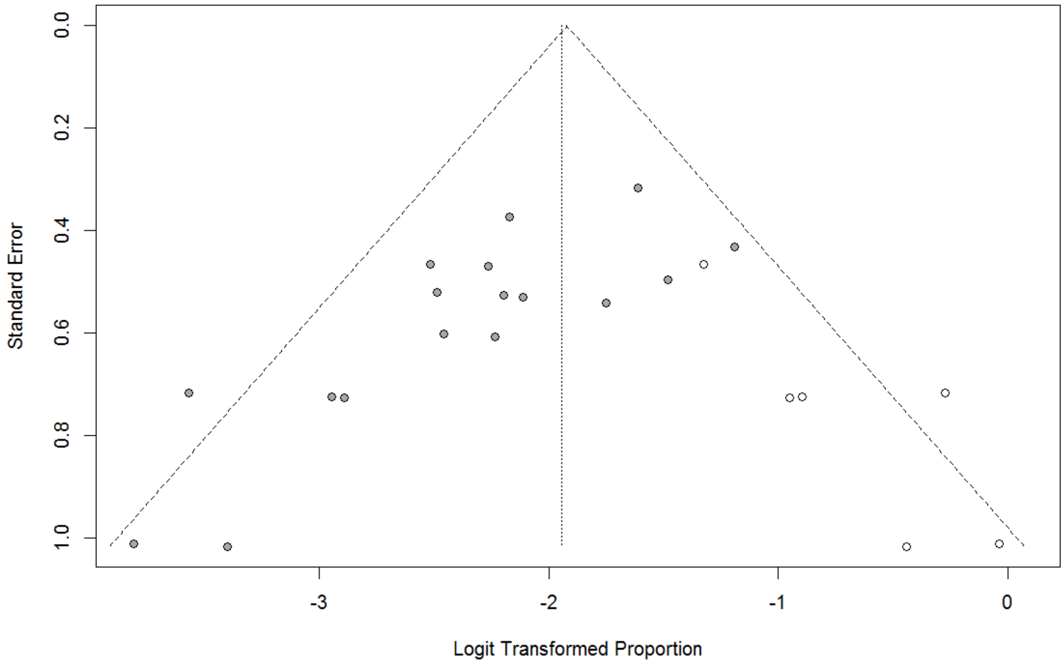


**Figure 11. “Trim-and-fill” funnel plot for posterior RBC replacement in CTs and LCSs**

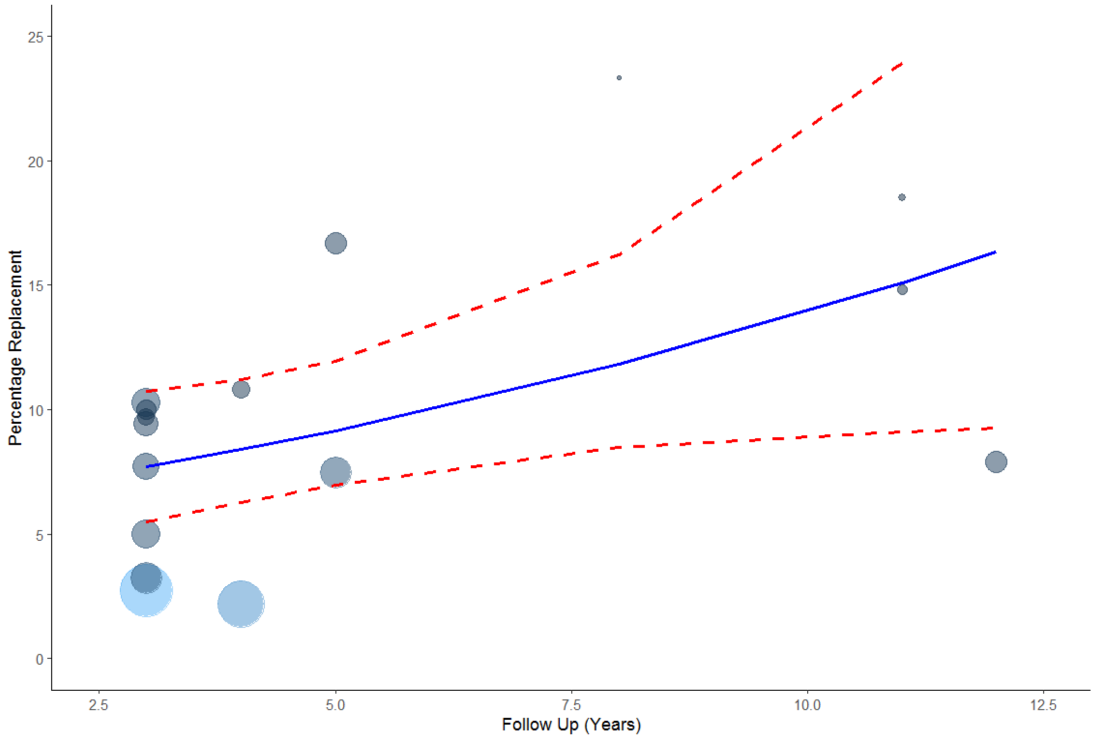


**Figure 12. Meta regression of posterior RBC replacement in CTs and LCSs**

### 4) Posterior amalgam replacement

Four studies reported on amalgam replacement. The studies followed 253 posterior amalgam restorations and reported on 16 replacements.

Heterogeneity was assessed and $I^2$ was found to be 53%, so random-effects meta-analysis was carried out.

Figure 13 shows the forest plot of the results. Note that (a), (b), (c) refer to the different types amalgam for each study. The types were detailed in Table 2 previously.

The overall replacement rate averaged over all the years of follow-up (3-6 years) is 5% (95%CI:2%-11%).

There were not enough studies to assess bias.

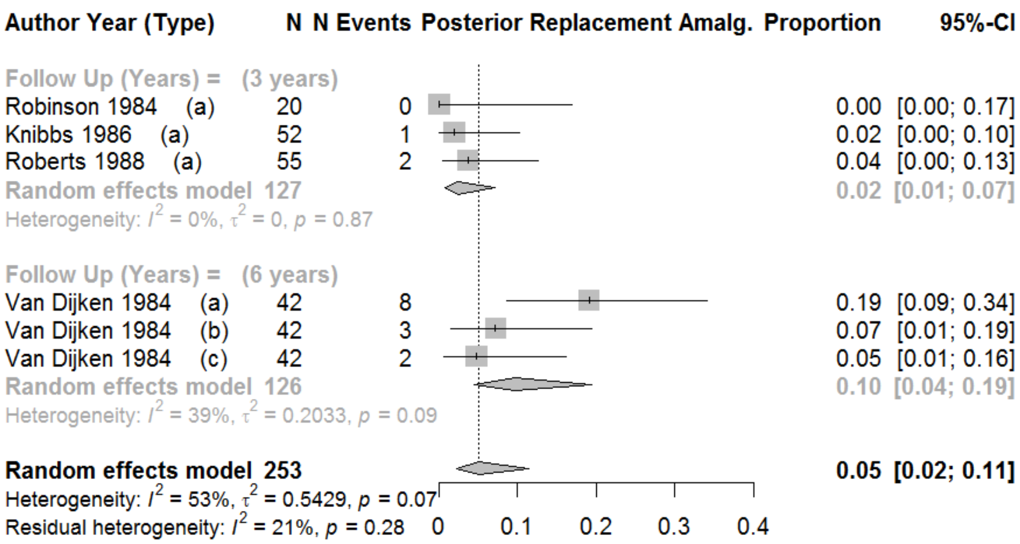


**Figure 13. Forest plot for posterior amalgam replacement in CTs and LCSs**

## 5) Posterior RBC repair

Three studies reported on RBC repair. The studies followed 203 posterior RBC restorations and reported on 10 repairs.

Heterogeneity was small and $I^2$ was found to be 43%, so both fixed-effect and random-effect meta-analysis were carried out with comparable results.

Figure 14 shows the forest plot of the results. Note that (a) and (b) refer to the different types of RBC for each study. The types were detailed in Table 2 previously.

The overall repair rate averaged over all the years of follow-up (3-12 years) is 3% (95%CI:1%-11%).

There were not enough studies to assess bias.

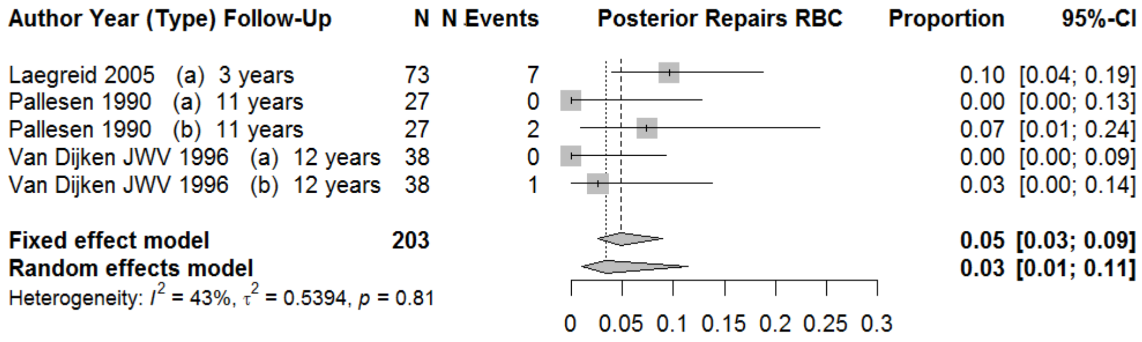


**Figure 14. Forest plot for posterior RBC repair in CTs and LCSs**

## 6) Posterior amalgam repair

No studies reported on amalgam repair.

## 7) Anterior RBC failure

Only 2 studies reported on anterior RBC failure. The studies followed 200 anterior RBC restorations and reported on 18 failures.

A fixed-effects meta-analysis was carried out as heterogeneity was $I^{2=}0$.

Figure 15 shows the forest plot of the results. Note that (a), (b), (c), (d) refer to the different types of RBC for each study. The types were detailed in Table 2 previously.

The overall failure rate averaged over all the years of follow-up (5-6 years) is 9% (95%CI:6%-14%).

Again, there were not enough studies to assess bias.

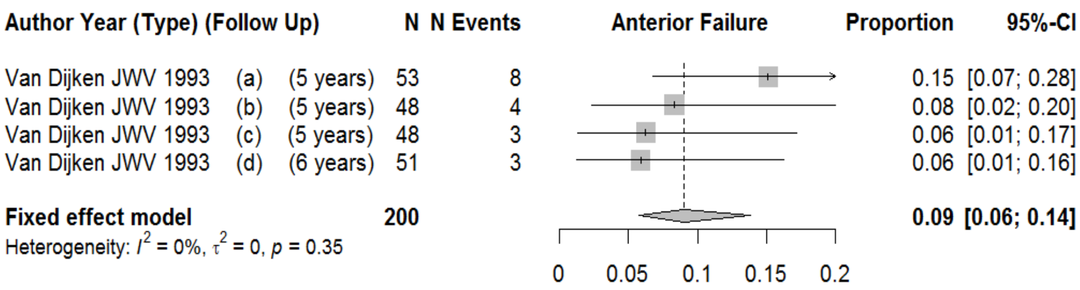


**Figure 15. Forest plot for anterior RBC failure in CTs and LCSs**

## 8) Anterior RBC replacement

Only 1 study reported on anterior RBC replacement. The study followed 90 anterior RBC restorations and reported on 15 replacements.

A fixed-effects meta-analysis was carried out.
Figure 16 shows the forest plot of the results. Note that (a) and (b) refer to the different types of RBC used in the study. The types were detailed in Table 2 previously.

The overall replacement rate over a follow-up period of 11 years is 17% (95%CI:10%-26%).

Again, there were not enough studies to assess bias.

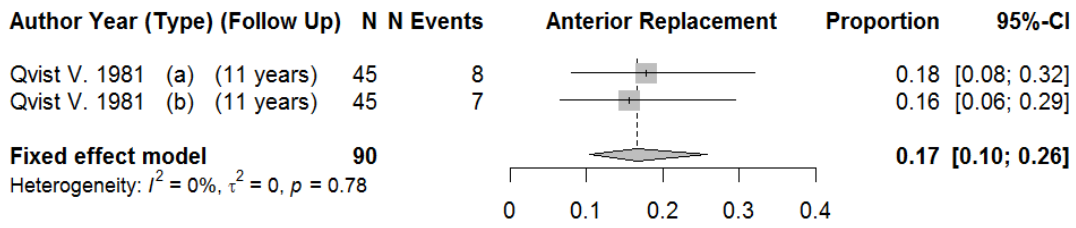


**Figure 16. Forest plot for anterior RBC replacement in CTs and LCSs**

### 4.3.1.3 Reasons for failure/replacement/repair

Out of the 45 included studies, 40 studies used Ryge/USPHS/modified USPHS criteria (see section 2.2.3). The other 5 studies used their own criteria. Information related to examiner/evaluator training and calibration when using the criteria were extracted and taken into consideration when giving the study a quality score.

In general, the reason for failure/replacement/repair was one or more of the reasons mentioned below:

- Secondary Caries **(SC)**
- Bulk Discolouration **(BD)**
- Marginal Discolouration **(MD)**
- Bulk Fracture **(BF)**
- Marginal Fracture **(MF)**
- Restoration fracture **(Rest #)**
- Poor Anatomic Form **(PA)** (includes marginal defect and abrasion/attrition of restoration)
- Tooth Fracture **(TF)**
- Lost Restoration (**LR)**
- Aesthetic Reasons **(AR)**
- Pain/Sensitivity **(P/S)**
- Endodontic reasons **(Endo)**
- Other Reason **(ORR)** (this mainly includes primary caries somewhere else on the tooth not related to the restoration, prosthodontic reasons; crown or tooth needed as a pontic for bridge placement, tooth extracted for reasons other than above, periodontitis, and patient request)

For each event (failure/replacement/repair) occurring, the reason was recorded, and data entered into an excel sheet.

The following sections show the bar charts of the reasons for the different categories.

The reasons were analysed using two bar charts. First chart as a percentage of the reason of the event as a function of the total number of restorations placed and followed. Second chart as a percentage of the reason of the event as a function of the total number of restorations that have failed/replaced/repaired.

### 1) Posterior RBC and amalgam failure

The reasons were combined in one chart for both RBC and amalgam for comparison.
As discussed previously, the reasons were analysed using two bar charts: chart in Figure 17 as a percentage of the reason of failure as a function of the total number of restorations placed and followed, and chart in Figure 18 as a percentage of the reason of failure as a function of the total number of restorations that have failed. This is detailed in the percentages given below; first as a function of total restorations, then, between brackets, as a percentage of failed restorations.

Please note that the results below are extracted from 27 RBC studies (reporting on 236 failures in 2,378 restorations) and 4 amalgam studies (reporting on 27 failures in 244 restorations). The 4 amalgam studies reported failures due to 4 reasons only, and they should be interpreted with caution.

For both RBC and amalgam restorations, secondary caries was found to be the most common reason for failure, accounting for 4.26%±1.3 (37.04%±9.29) for amalgam and 2.53%±0.32 (27.31%±2.96) for RBC.

The second most common reason for both amalgam and RBC was restoration fracture. This accounted for 3.83%±1.25 (33.33%±9.07) for amalgam and 1.14%±0.21 (12.33%±2.18) for RBC.

Some papers reported more details for RBC restoration fracture as either bulk fracture or marginal fracture, and these were recorded separately. If both bulk fracture and marginal fracture are combined with restoration fracture, the percentage of posterior RBC failure due to fracture goes up to 2.53%±0.32 (27.31%±2.96). This makes the percentage of restoration fracture in RBC equivalent to secondary caries.

Other reported reasons for posterior amalgam failure are tooth fracture at 2.13%±0.94 (18.52%±7.45) and endodontic reasons at 1.28%±0.73 (11.11%±6.05).

For posterior RBC, additional reasons for failure included “other reasons” at 1.1%±0.21 (11.89%±2.15), poor anatomic form at 0.9%±0.19 (9.69%±1.96), tooth fracture at 0.77%±0.18 (8.37%±1.84), pain/sensitivity at 0.57%±0.15 (6.17%±1.6), lost restoration at 0.33%±0.12 (3.52%±1.22), endodontic reasons at 0.2%±0.09 (2.2%±0.97), restoration fracture combined with secondary caries at 0.16%±0.08 (1.76%±0.87), tooth fracture combined with lost restoration at 0.08%±0.06 (0.88%±0.62), aesthetic reasons at 0.04%±0.04 (0.44%±0.44), and marginal discolouration at 0.04%±0.04 (0.44%±0.44).

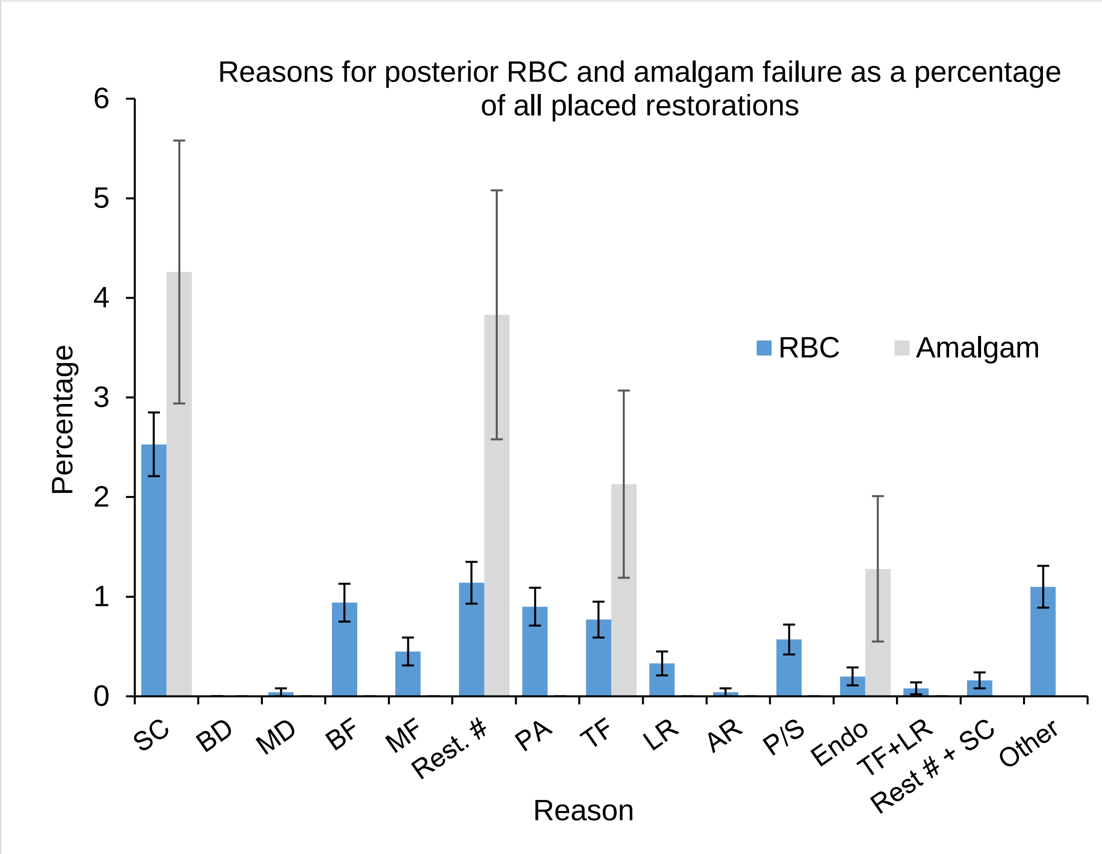


**Figure 17. Bar chart of the reasons of posterior RBC and amalgam failures in CTs and LCSs as a percentage of all restorations placed**

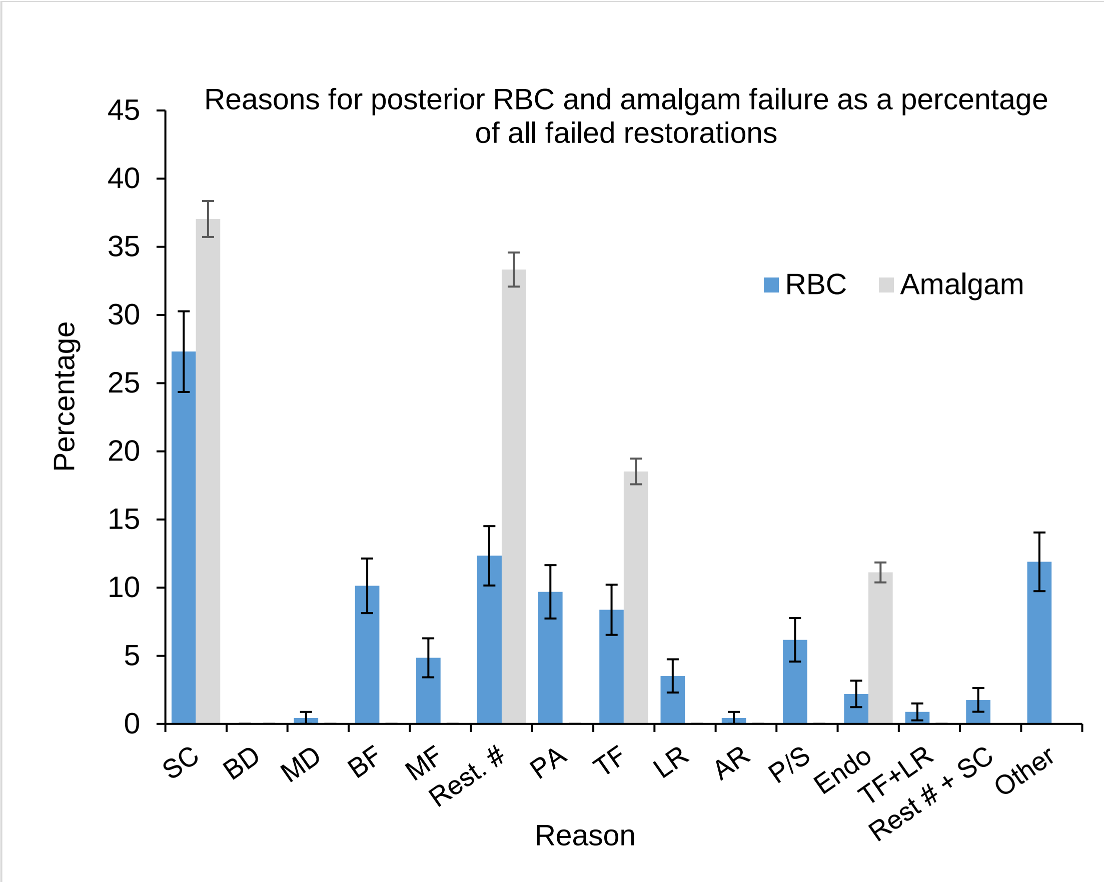


**Figure 18. Bar chart of the reasons of posterior RBC and amalgam failures in CTs and LCSs as a percentage of failed restorations**

## 2) Posterior RBC and amalgam replacement

The reasons were combined in one chart for both RBC and amalgam for comparison.
Again, the reasons were analysed using two bar charts; chart in Figure 19 as a percentage of the reason of replacement as a function of the total number of restorations placed and followed, and chart in Figure 20 as a percentage of the reason of replacement as a function of the total number of restorations that have been replaced. This again is reflected in the percentages given below; first as a function of total restorations, then, between brackets, as a percentage of replaced restorations.

Please note that the next results are extracted from 13 RBC studies (reporting on 121 replacements in 869 restorations) and 4 amalgam studies (reporting on 16 replacements in 253 restorations). The 4 amalgam studies reported replacements due to 5 reasons only, and they should be interpreted with caution.

For posterior amalgam, bulk fracture was found to be the most common reason for replacement at 3.16%±1.1 (50%±12.5). As discussed previously, when combining bulk fracture, marginal fracture, and restoration fracture together, this percentage goes up to 3.95%±1.22 (62.5%±12.1).
The second most common reason was both secondary caries at 1.19%±0.68 (18.75%±9.76) and tooth fracture at 1.19%±0.68 (18.75%±9.76).

For posterior RBC, the most common reason for replacement was tooth fracture at 3.68%±0.64 (26.45%±4.01). When combining bulk fracture, marginal fracture, and restoration fracture, this would be the second most common reason at 3.34%±0.61 (23.97%±3.88). Secondary caries comes third at 2.3%±0.51 (16.53%±3.38). Other reasons include poor anatomic form at 1.61%±0.43 (11.57±2.91), pain/sensitivity at 1.38%±0.4 (9.92%±2.72), "other reasons" at 1.04%±0.34 (7.44%±2.39), endodontic reasons at 0.35%±0.2 (2.48%±1.41), aesthetic reasons at 0.12%±0.12 (0.83%±0.82), and lost restoration at 0.12%±0.12 (0.83%±0.82).

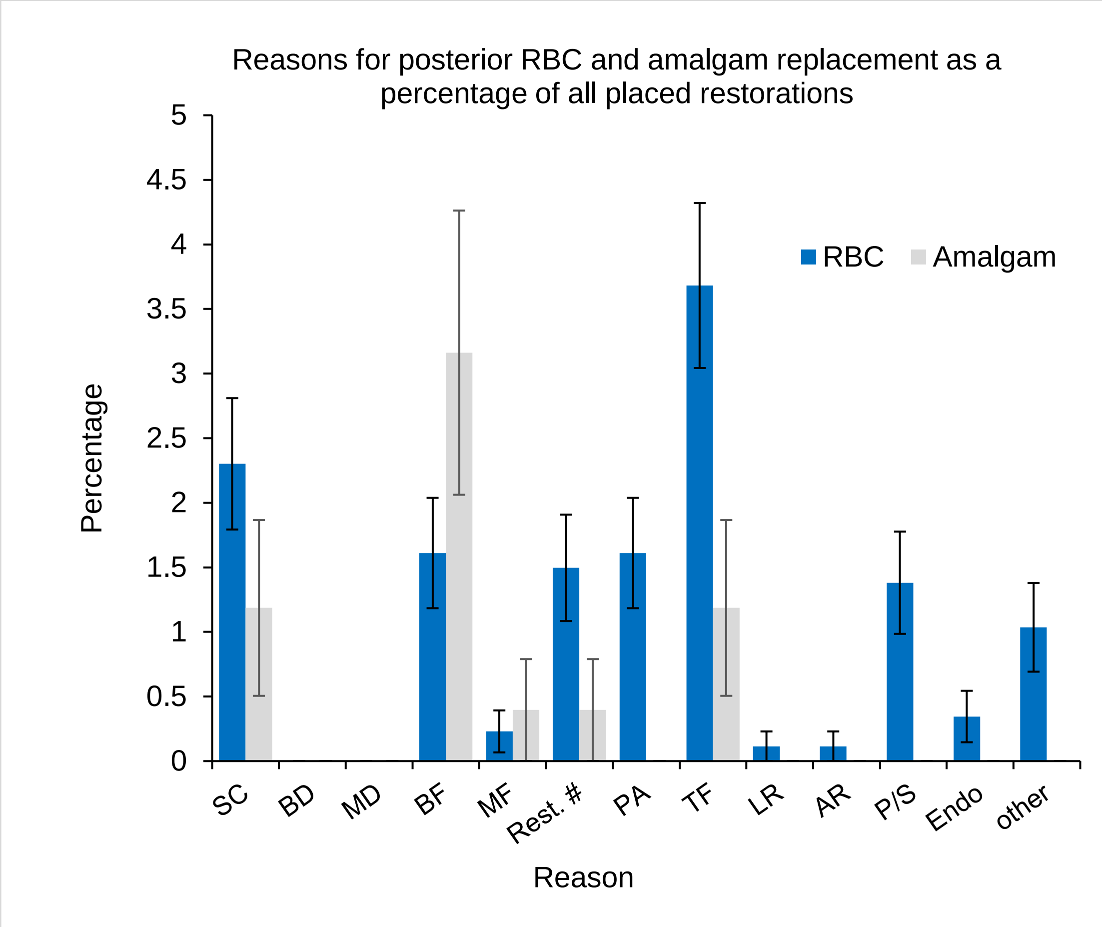


**Figure 19. Bar chart of the reasons of posterior RBC and amalgam replacement in CTs and LCSs as a percentage of all restorations placed**

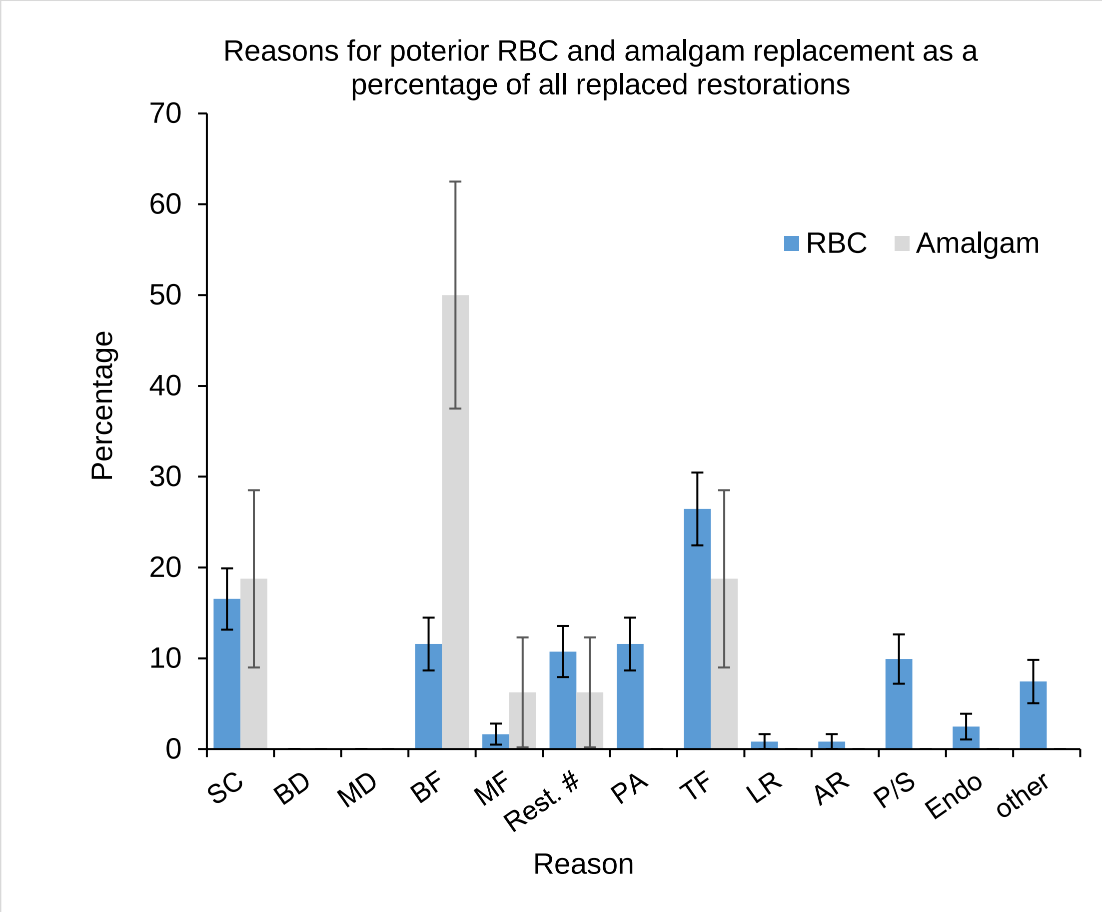


**Figure 20. Bar chart of the reasons of posterior RBC and amalgam replacement in CTs and LCSs as a percentage of replaced restorations**

### 3) Posterior RBC and amalgam repair

There were no data on amalgam repair from the included studies, so only RBC data is detailed below.

For RBC, data from only 3 studies was included (reporting on 10 repairs in 203 restorations), therefore, the results should be interpreted with caution.

As in the previous sections, the reasons were analysed using two bar charts: chart in Figure 21 as a percentage of the reason of repair as a function of the total number of restorations placed, and chart in Figure 22 as a percentage of the reason of repair as a function of the total number of restorations that have been repaired.

The most common reason for posterior RBC repair was restorations fracture at 1.97%±0.98 (40%±15.49). When adding bulk fracture and marginal fracture, the percentage goes up to 3.45%±1.28 (70%±14.49). This is followed by secondary caries at 0.99%±0.69 (20%±12.65) then endodontic reasons at 0.49%±0.49 (10%±9.49).

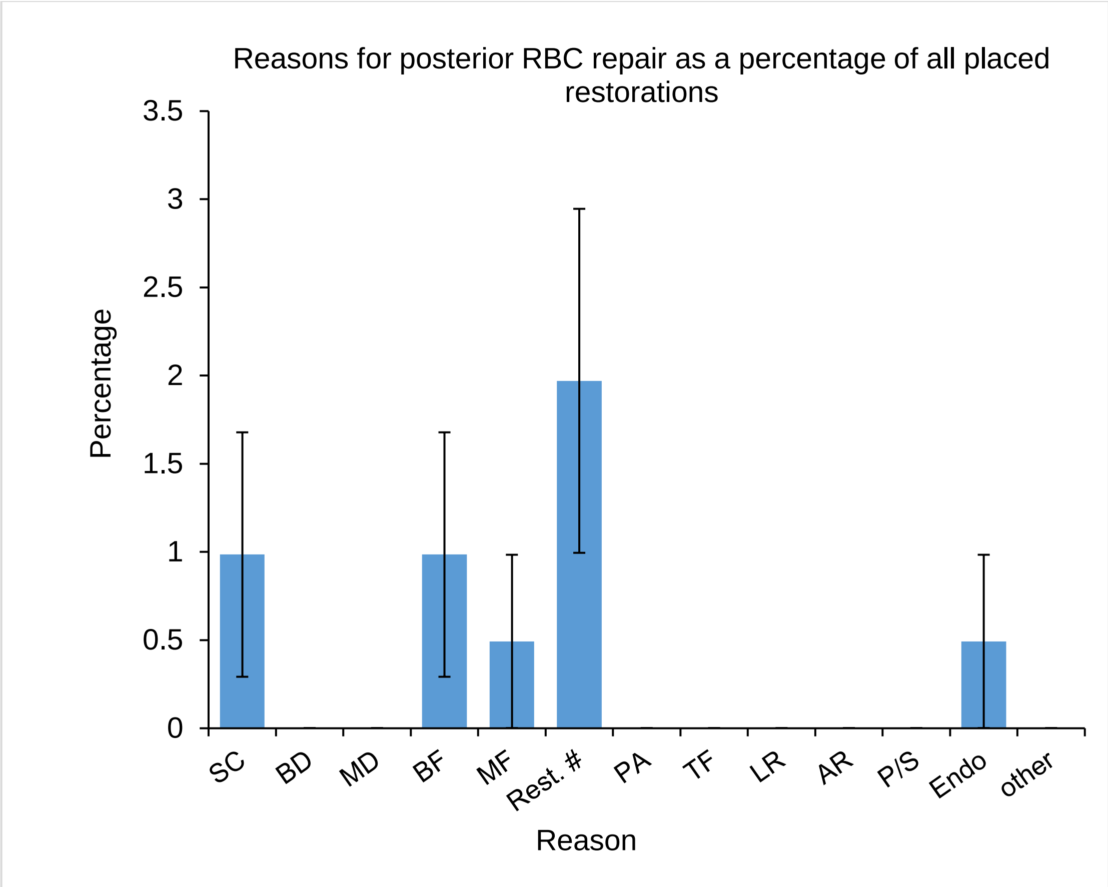


**Figure 21. Bar chart of the reasons of posterior RBC repair in CTs and LCSs as a percentage of all restorations placed**

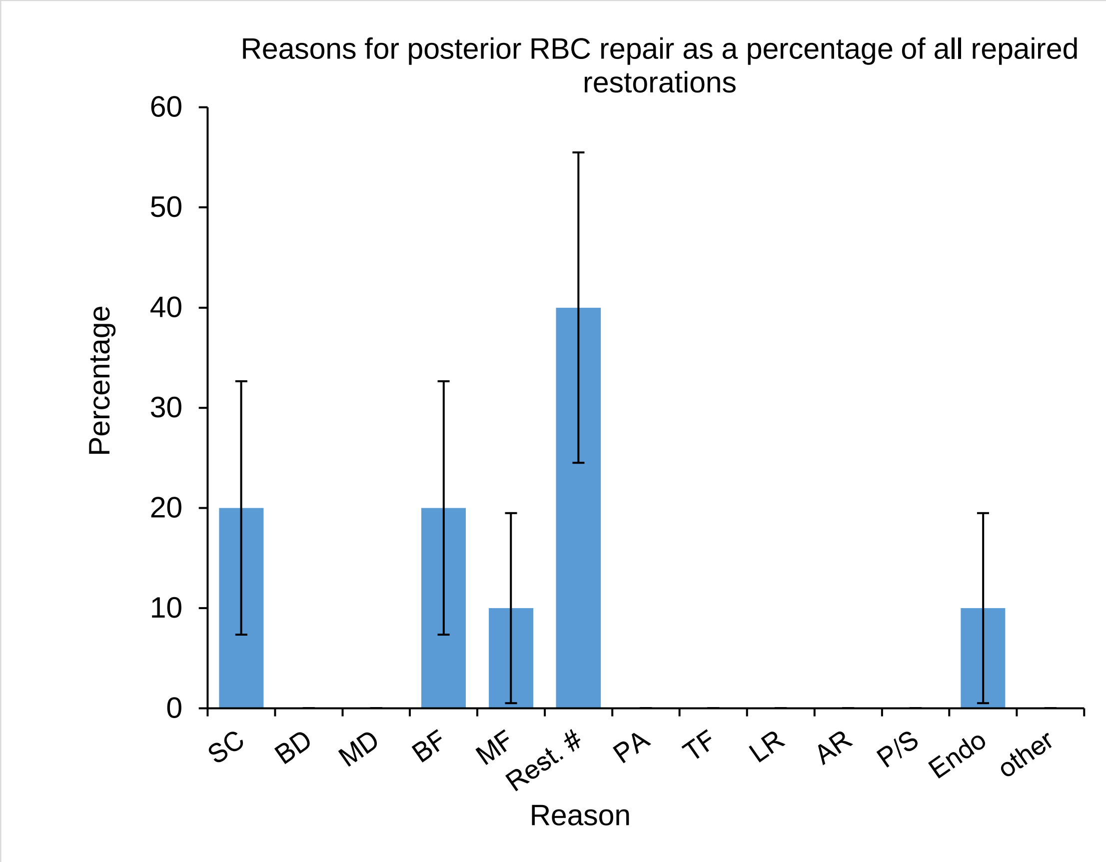


**Figure 22. Bar chart of the reasons of posterior RBC repair in CTs and LCSs as a percentage of repaired restorations**

### 4) Anterior RBC failure and replacement

As only 3 studies reported on anterior RBC replacement and failure (reporting on 18 failures in 200 restorations and 15 replacements in 90 restorations), the reported reasons of both were combined.

No studies reported on anterior RBC repair.

Figure 23 shows the reasons of failure/replacement as a percentage of all anterior restorations placed, and Figure 24 as a percentage of failed/replaced anterior restorations.

The most common reason for anterior RBC failure/replacement was tooth fracture at 4.48%±1.21 (39.39%±8.51).

The second most common reason was secondary caries at 2.67%±0.96 (24.24%±7.46), followed by restoration fracture at 1.38%±0.69 (12.12%±5.68) and “other reasons” at 1.38%±0.69 (12.12%±5.68).

Other reasons included bulk discolouration at 1.03%±0.59 (9.09%±5) and endodontic reasons at 0.34%±0.34 (3.03%±2.98).

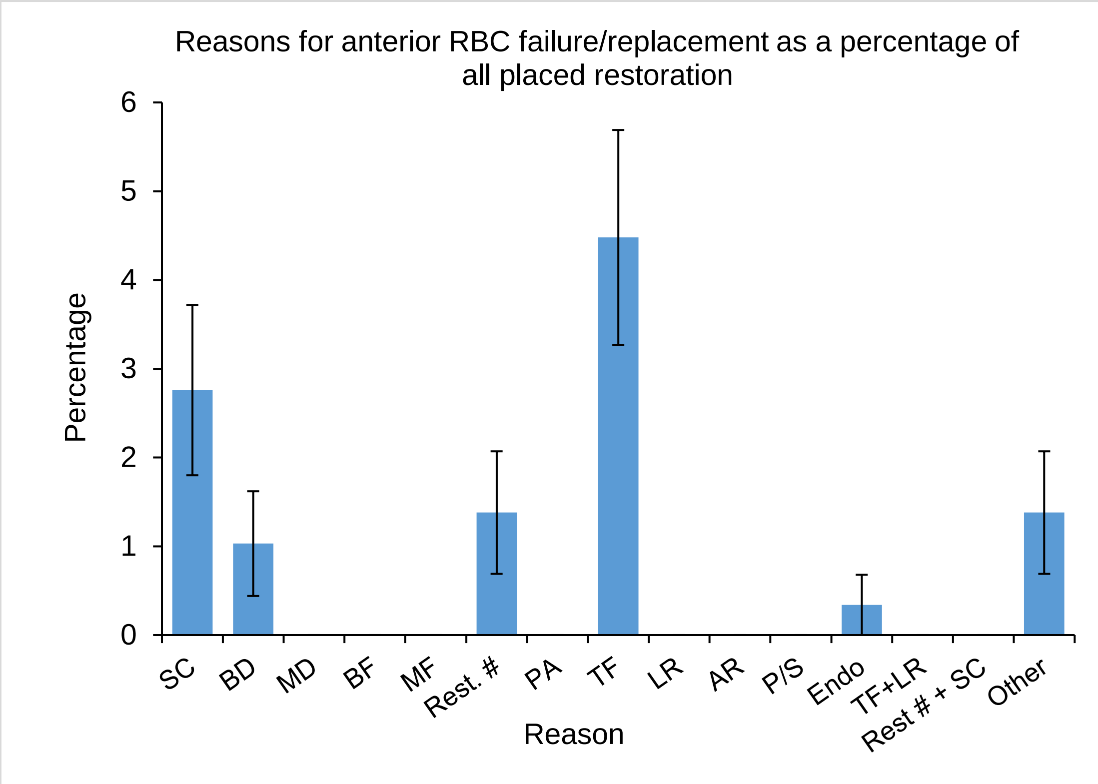


**Figure 23. Bar chart of the reasons of anterior RBC failure/replacement in CTs and LCSs as a percentage of all restorations placed**

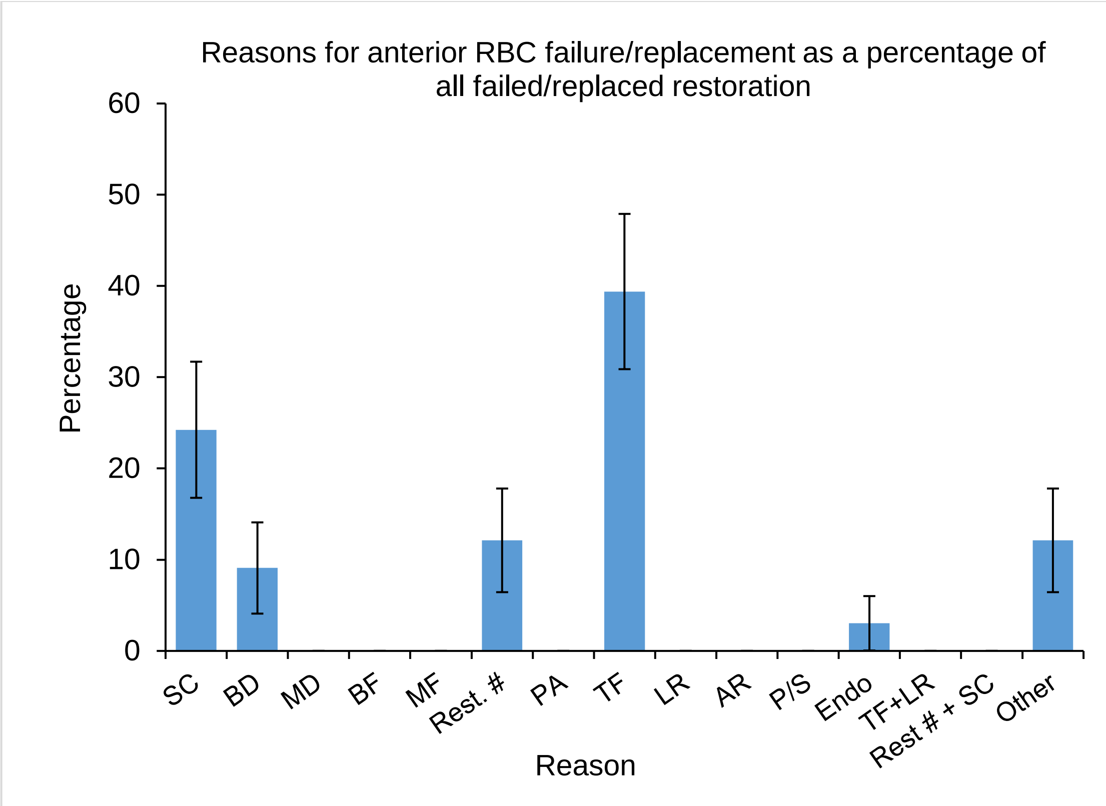


**Figure 24. Bar chart of the reasons of anterior RBC failure/replacement in CTs and LCSs as a percentage of failed/replaced restorations**

### 4.3.1.4 Comparing studies according to quality scores

Of the 45 included studies, 10 studies were judged to be of very good quality, 30 of acceptable quality, and 5 of poor quality.

The review team considered removing the 5 poor quality studies and repeating the meta-analysis. This was discussed with BC and DF. DF advised as the funnel plots did not have any outliers (except in Figure 8 (posterior RBC replacement) where one major outlier was found and removed, then the meta-analysis was done again), that removing the poor-quality studies was unlikely to impact the results.

### 4.3.1.5 Comparing studies according to the year it was conducted

For the purpose of this analysis, the studies were categorised into one of three periods, according to the year each study started rather than the publication date. The periods are 1981-1989, 1990-1999, and 2000-2010.

Here, all events (failure, replacement, or repair) are combined and considered as an event needing intervention to allow easier comparison between the three periods.

The analysis was undertaken for three categories, posterior RBC restorations, posterior amalgam restorations, and anterior RBC restorations.

#### 4.3.1.5.1 Failure/replacement/repair rate

Tables 4, 5, and 6 summarise the findings for each category in each period.

For posterior RBC, this review included 10 studies conducted between 1981-1989 with follow-up times between 3-10 years, 8 studies conducted between 1990-1999 with follow-up times between 2-12 years, and 22 studies between 2000-2010 with follow-up times between 2-10 years.

The percentage of events happening (failure or replacement or repair) during the follow-up periods appears to decline over the studied periods, 15.7% in 1981-1989 period, 11.7% in 1990-1999, and 9.5 % in 2000-2010. This might be related to improvements in RBC materials over the years, better training of dentists in RBC placement technique, or even better understanding and correct diagnosis of restorations failure. This will be discussed in detail in the discussion section.

For posterior Amalgam, this review included six studies conducted between 1981-1989 with follow-up times between 3-6 years, and only two studies conducted between 1990-1999 with follow-up times between 5-6 years. No studies looking at amalgam were found in the period 2000-2010.

In contrast to RBC, the percentage of events in amalgam is higher in the period 1990-1999 (16.9%) compared to the period 1981-1989 (5.7%), but the review had a small number of studies for amalgam so this comparison should be reviewed with caution. This will be discussed in more details in the next section, explaining the possible biases in the included studies that might have caused the conclusion of having more failures/replacements in amalgam occurring over the years despite improvements in the material itself.

For anterior RBC, only three studies were included. For the period 1981-1989, the review included one study with a follow-up of 11 years and had a replacement rate of 16.7%. Two studies were conducted in the period 1990-1999 with a follow-up of 5-6 years and reported a failure rate of 6%.

## Table 4: Posterior RBC failure/replacement/repair in CTs and LCSs according to the year it was conducted

| 1981-1989 | | | | 1990-1999 | | | | 2000-2010 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Publication** | **Year Follow-up** | **Country** | **# Events / # of rests (%)** | **Publication** | **Year Follow-up** | **Country** | **# Events / # of rests (%)** | **Publication** | **Year Follow-up** | **Country** | **# Events / # of rests (%)** |
| **(Hendriks et al., 1986)** | 1982<br>3 y | Netherlands | 7/168<br>(4.2%) | **(Wilson et al., 2000)** | 1996<br>3 y | UK | 3/35<br>(8.6%) | **(Kramer et al., 2005)** | 2002<br>2 y | Germany | 49/89<br>(55.1%) |
| **(Robinson et al., 1988)** | 1984<br>3 y | UK | 8/78<br>(10.3%) | **(Lopes et al., 2003)** | 1999<br>2 y | Brazil | 2/74<br>(2.7%) | **(Burke et al., 2005)** | 2001<br>2 y | UK | 2/88<br>(2.3%) |
| **(Wilson et al., 1988b)** | 1983<br>5 y | UK | 12/72<br>(16.7%) | **(Pallesen and Qvist, 2003)** | 1990<br>11 y | Denmark | 11/54<br>(20.4%) | **(Poon et al., 2005)** | 2001<br>3.5 y | China | 8/54<br>(14.8%) |
| **(Norman et al., 1990)** | 1984<br>5 y | USA | 6/80<br>(7.5%) | **(Mannocci et al., 2005)** | 1996<br>5 y | Italy | 15/98<br>(15.3%) | **(Turkun et al., 2005)** | 2002<br>3 y | Turkey | 3/47<br>(6.4%) |
| **(Barnes et al., 1991)** | 1982<br>8 y | USA | 7/30<br>(23.3%) | **(Van Dijken and Sunnegardh-Gronberg, 2005)** | 1999<br>4 y | Sweden | 5/67<br>(7.5%) | **(Ernst et al., 2006)** | 2003<br>2 y | Germany | 2/112<br>(1.8%) |
| **(Knibbs and Smart, 1992)** | 1986<br>3 y | UK | 4/52<br>(7.7%) | **(van Dijken and Sunnegardh-Gronberg, 2006)** | 1997<br>6 y | Sweden | 14/75<br>(18.7%) | **(Efes et al., 2006)** | 2003<br>2 y | Turkey | 1/100<br>(1%) |
| **(Roberts et al., 1992)** | 1988<br>3 y | USA | 5/53<br>(9.4%) | **(Lindberg et al., 2007)** | 1997<br>9 y | Sweden | 8/69<br>(11.6%) | **(Sarrett et al., 2006)** | 2003<br>3 y | USA | 11/25<br>(44%) |
| **(Raskin et al., 1999)** | 1987<br>10 y | Belgium | 23/60<br>(38.3%) | **(van Dijken, 2010)** | 1996<br>12 y | Sweden | 6/76<br>(7.9%) | **(Bekes et al., 2007)** | 2005<br>2 y | Germany | 4/67<br>(5.9%) |
| **(Wassell et al., 2000)** | 1989<br>5 y | UK | 5/67<br>(7.5%) | | | | | **(Mahmoud et al., 2008)** | 2006<br>2 y | Egypt | 2/140<br>(1.4%) |
| **(Gaengler et al., 2001)** | 1987<br>10 y | Germany | 40/86<br>(46.5%) | | | | | **(van Dijken and Lindberg, 2009)** | 2003<br>5 y | Sweden | 12/97<br>(12.4%) |
| | | | | | | | | **(Manhart et al., 2010)** | 2005<br>4 y | Germany | 5/83<br>(6%) |
| | | | | | | | | **(Monteiro et al., 2010)** | 2008<br>2 y | Portugal | 3/92<br>(3.3%) |
| | | | | | | | | **(Shi et al., 2010)** | 2007<br>3 y | China | 6/80<br>(7.5%) |
| | | | | | | | | **(van Dijken and Pallesen, 2011a)** | 2003<br>7 y | Sweden | 17/114<br>(15%) |
| | | | | | | | | **(van Dijken and Pallesen, 2011b)** | 2004<br>4 y | Sweden & Denmark | 11/162<br>(6.8%) |
| | | | | | | | | **(Stefanski and van Dijken, 2012)** | 2008<br>2 y | Sweden | 2/92<br>(2.2%) |
| | | | | | | | | (**Laegreid et al., 2012)** | **2005<br>3 y** | Norway | 9/73<br>(12.3%) |
| | | | | | | | | (**van Dijken and Pallesen, 2014b)** | 2010<br>3 y | Sweden | 2/104<br>(1,9%) |
| | | | | | | | | **(van Dijken and Pallesen, 2014a)** | 2003<br>10 y | Sweden | 22/114<br>(19.3%) |
| | | | | | | | | **(Celik et al., 2014)** | 2010<br>3 y | Turkey | 4/62<br>(6.5%) |
| | | | | | | | | **(Fennis et al., 2014)** | 2001<br>5 y | Netherlands | 8/80<br>(10%) |
| | | | | | | | | **(Kramer et al., 2015)** | 2004<br>10 y | Germany | 3/66<br>(4.5%) |
| **Total** | | 117/746<br>(15.7%) | | **Total** | | 64/548<br>(11.7%) | | **Total** | | 186/1941<br>(9.5%) | |

### Table 5: Posterior amalgam failure/replacement in CTs and LCSs according to the year it was conducted

| 1981-1989 | | | | 1990-1999 | | | |
|---|---|---|---|---|---|---|---|
| **Publication** | **Year<br>Follow-up** | **Country** | **# Events / # of rests (%)** | **Publication** | **Year<br>Follow-up** | **Country** | **# Events / # of rests (%)** |
| **(Hendriks et al., 1986)** | 1982<br>3 y | Netherlands | 1/56<br>(1.8%) | **(Summitt et al., 2004)** | 1997<br>6 y | USA | 10/36<br>(27.8%) |
| **(Robinson et al., 1988)** | 1984<br>3 y | UK | 0/20<br>(0%) | **(Mannocci et al., 2005)** | 1996<br>5 y | Italy | 13/100<br>(13%) |
| **(Norman et al., 1990)** | 1984<br>5 y | USA | 3/43<br>(7%) | | | | |
| **(Van Dijken, 1991)** | 1984<br>6 y | Sweden | 13/126<br>(10.3%) | | | | |
| **(Knibbs and Smart, 1992)** | 1986<br>3 y | UK | 1/52<br>(1.9%) | | | | |
| **(Roberts et al., 1992)** | 1988<br>3 y | USA | 2/55<br>(3.6%) | | | | |
| **Total** | | 20/352<br>(5.7%) | | **Total** | | 23/136<br>(16.9%) | |

### Table 6: Anterior RBC failure/replacement in CTs and LCSs according to the year it was conducted

| 1981-1989 | | | | 1990-1999 | | | |
|---|---|---|---|---|---|---|---|
| **Publication** | **Year<br>Follow-up** | **Country** | **# Events / # of rests (%)** | **Publication** | **Year<br>Follow-up** | **Country** | **# Events / # of rests (%)** |
| **(Qvist and Strom, 1993)** | 1981<br>11 y | Denmark | 15/90<br>(16.7%) | **(van Dijken et al., 1999)** | 1993<br>5 y | Sweden | 15/149<br>(10.1%) |
| | | | | **(Van Dijken, 2001)** | 1993<br>6 y | Sweden | 3/51<br>(5.8%) |
| **Total** | | 15/90<br>(16.7%) | | **Total** | | 18/200<br>(9%) | |

#### 4.3.1.5.2 Reasons for failure/replacement/repair

As previously, the analysis was undertaken for the reasons both as a percentage of all placed and followed restorations and, between brackets, as a percentage of failed/replaced/repaired restorations (the events). Please note that for easier comparison between periods, the reasons reported as bulk fracture, marginal fracture, and restoration fracture were all combined under the category “Restoration fracture #”.

### 1) Posterior RBC

Reasons for failure/replacement/repair from 40 studies (reporting on 236 failures in 2,378 restorations, and 121 replacements and 10 repairs in 869 restorations) are compared according to the year of the study as bar chart in Figure 25, as a percentage of the reason of failure/replacement/repair as a function of the total number of restorations placed, and chart in Figure 26, as a percentage of the reason of failure/replacement/repair as a function of the total number of restorations that have failed/replaced/repaired.

Secondary caries was high in the period 1981-1989 and 1990-1999 at 3.49%±0.67 and 4.74%±0.91 (22.22%±3.84 and 40.63%±6.14) respectively. Secondary caries as a reason for failure/replacement/repair was lowest in the period 2000-2010, and the corresponding figures were 1.75%±0.3 (18.28%±2.83).

For restoration fracture, the percentage was similar for the two periods 1981-1989 and 1990-1999 (3.62%±0.68 (23.08%±3.9) for 1981-1989 and 2.74%±0.7 (23.44%±5.3) for 1990-1999). The percentage was slightly higher for the period 2000-2010 at 3.19%±0.4 (33.33%±3.46).

The reported reason “other reasons” appeared much more in the first period 1981-1989 at 3.62%±0.68 (23.08%±3.9). These percentages were less in the following period 1990-1999 at 1.46%±0.51 (12.5%±4.13) and went even lower in the last period 2000-2010 at 0.05%±0.05 (0.54%±0.54).

Poor anatomic form (PA) and pain/sensitivity (P/S) were much higher in the period 1981-1989 (2.4%±0.56 (15.38%±3.34) for PA and 1.61%±0.46 (10.26%±2.81) for P/S). These figures were much lower in the other two periods. For the period 1990-1999, the percentage of PA was 0.73%±0.36 (6.25%±3.03) and P/S 0.36%±0.26 (3.13%±2.18). Similarly, for the period 2000-2010, PA appeared at 0.72%±0.19 (7.53%±1.93) and P/S at 0.52%±0.16 (5.38%±1.65).

In contrast to PA, P/S and “other” reasons, tooth fracture seems to be increasing over the years. In 1981-1989, it appeared in only 0.13%±0.13 (0.85%±0.85), going higher in 1990-1999 at 1.28%±0.48% (10.94%±3.9), then even higher in 2000-2010 at 2.37%±0.35 (24.73%±3.16).

Interestingly, discolouration almost never reported as a reason for failure/replacement/repair for posterior composite, appearing only in the period 2000-2010 at 0.05%±0.05 (0.54%±0.54).

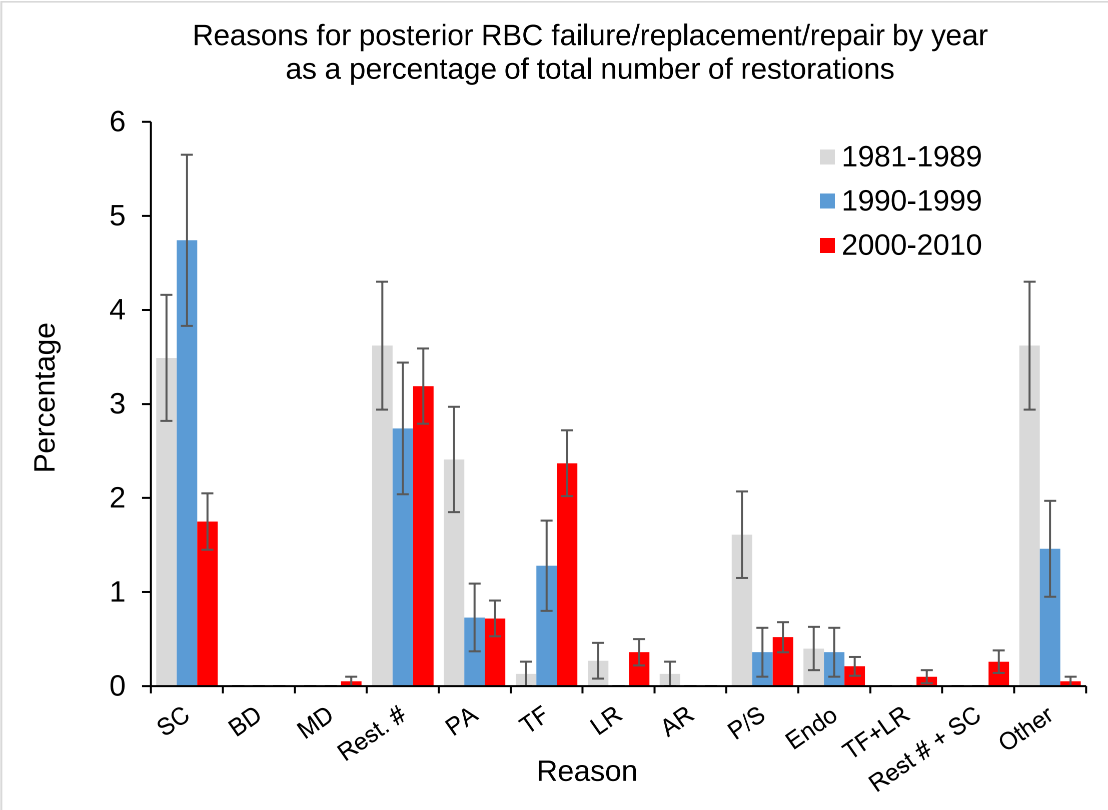


**Figure 25. Bar chart comparing the reasons for posterior RBC failure/replacement/repair in CTs and LCSs according to the year of the study as a percentage of all restorations placed**

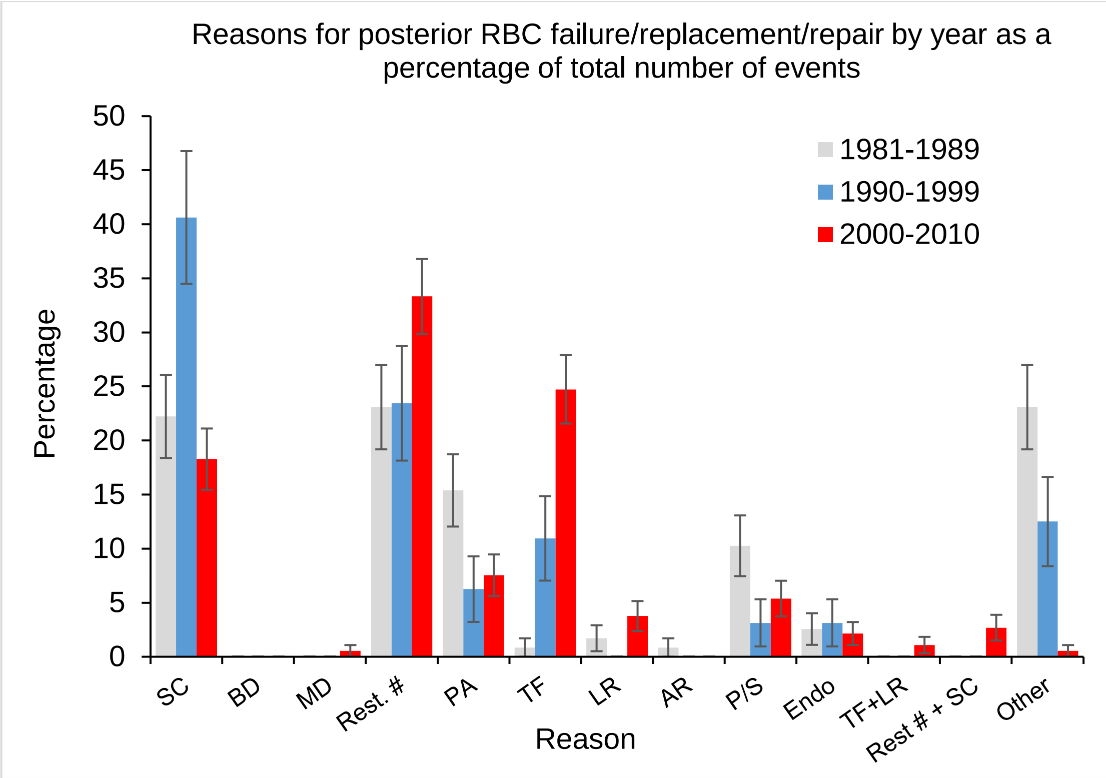


**Figure 26. Bar chart comparing the reasons for posterior RBC failure/replacement/repair in CTs and LCSs according to the year of the study as a percentage of all failed/replaced/repaired restorations**

## 2) Posterior amalgam

Reasons for failure/replacement from eight studies (reporting on 27 failures in 244 restorations and 16 replacements in 253 restorations) are compared according to the year of the study in Figures 27 and 28.

Please note there were no studies reporting on posterior amalgam repair, so an “event” here means failure or replacement only. Also, there were no studies on amalgam in the period 2000-2010, so only the reasons in the other two periods (1981-1989 and 1990-1999) are compared next.

From the eight included studies, posterior amalgam failure/replacement reasons fell into 4 categories only.

Restoration fracture was the most common reason for failure/replacement in both periods. In 1981-1989, the percentages were 2.84%±0.89 (41.67%±10.06) and going up in 1990-1999 at 6.62%±2.13 (39.13%±10.18).

Secondary caries appears to have increased too over the two periods. In 1981-1989, it appeared in 1.42%±0.63 (20.83%±8.29), going up in 1990-1999 at 5.88%±2.02 (34.78%±9.93).

In contrast, tooth fracture had reduced from 2.27%±0.79 (33.33%±9.62) in 1981-1989 to 2.94%±1.45 (17.39%±7.9).

Endodontics as a reason for failure/replacement appeared in 0.28%±0.28 (4.17%±4.08) in the 1981-1989 period, and slightly higher at 1.47%±1.03 (8.7%±5.88) in the 1990-1999 period.

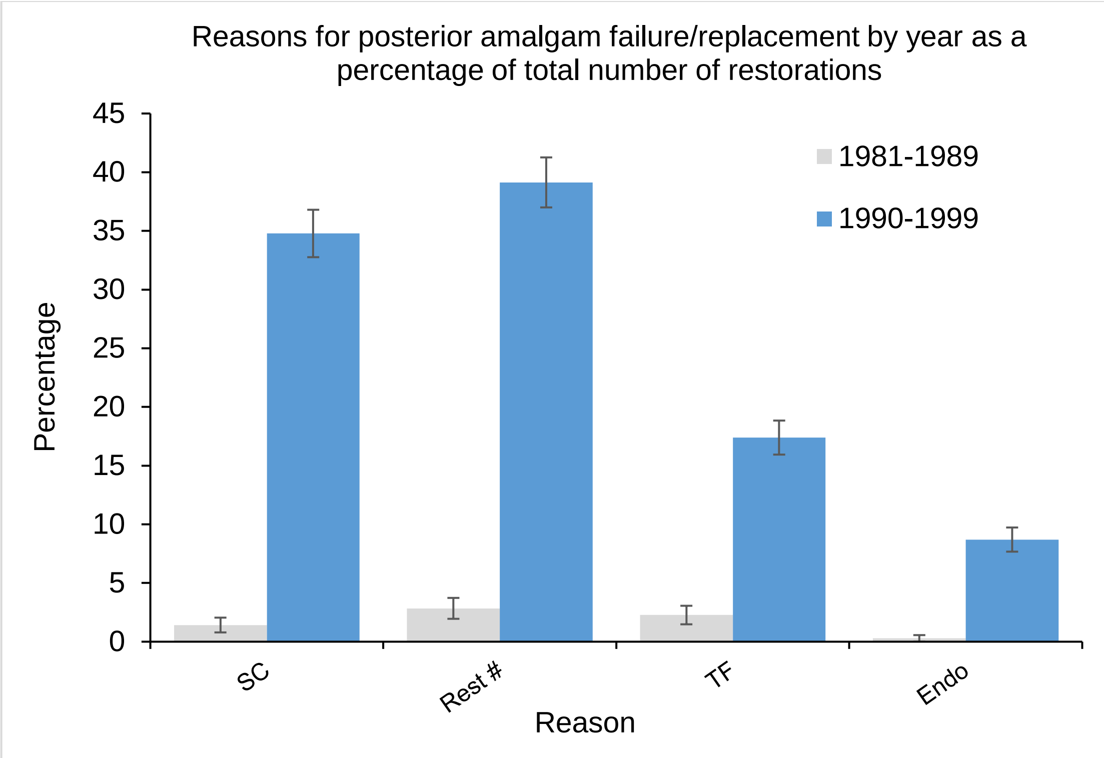


**Figure 27. Bar chart comparing the reasons for posterior amalgam failure/replacement in CTs and LCSs according to the year of the study as a percentage of all restorations placed**

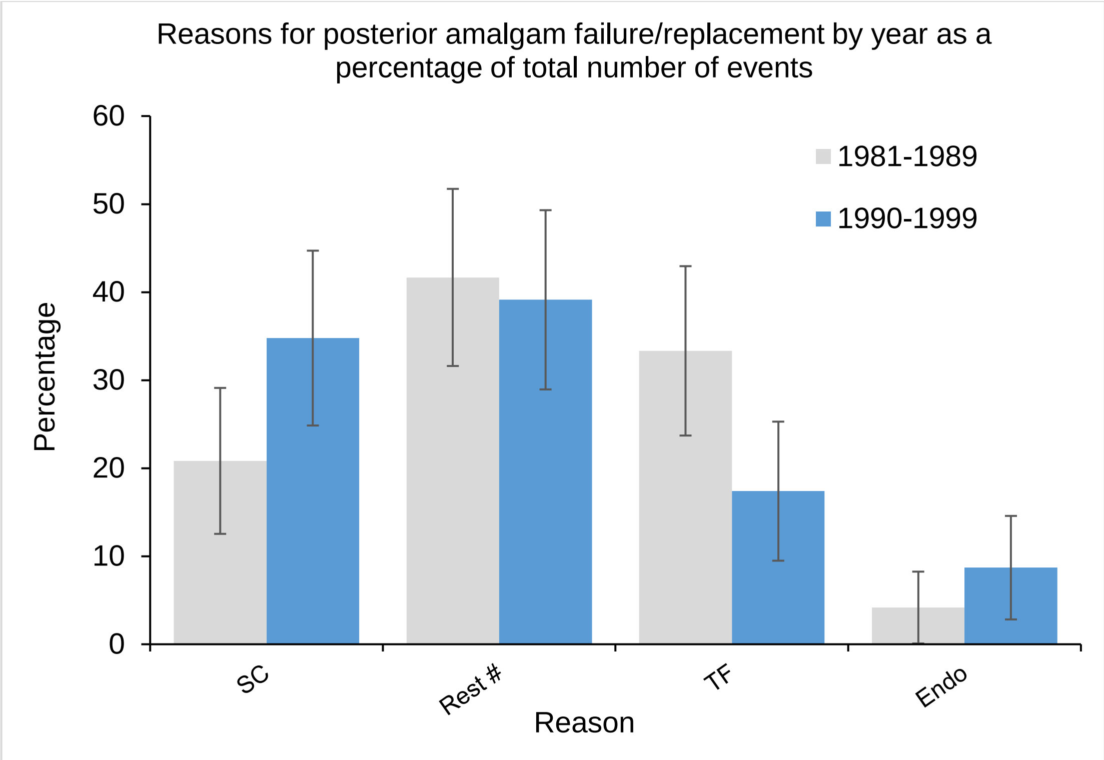


**Figure 28. Bar chart comparing the reasons for posterior amalgam failure/replacement in CTs and LCSs according to the year of the study as a percentage of all failed/replaced restorations**

### 3) Anterior RBC

Reasons for failure/replacement from three studies (reporting on 18 failures in 200 restorations and 15 replacements in 90 restorations) are compared according to the year of the study in Figures 29 and 30.

Please note that no studies reporting on anterior RBC repair were included in this review, so an "event" here means failure or replacement only. Also, no studies on anterior RBC were included in the period 2000-2010, so only the reasons in the other two periods (1981-1989 and 1990-1999) are compared below.

Secondary caries was the most common reason for failure/replacement in the period 1981-1989 at 5.56%±2.42 (33.33%±12.17), but this was less in 1990-1999 period at 1.5%±2.72 (16.67%±8.78).

"Other" reason was high in the 1981-1989 period at 4.44%±2.17 (26.67%±11.42), but during 1990-1999 period, this reason was not reported.

In contrast, restoration fracture was not reported in 1981-1989, but was slightly high in 1990-1999 at 4.44%±2.17 (22.22%±9.9).

Tooth fracture also increased from 3.33%±1.89 (20%±10.33) in 1981-1989 to 11.11%±3.31 (55.56%±11.71) in 1990-1999.

Bulk discolouration in 1981-1989 was reported at 2.22%±1.55 (13.33%±8.78). This decreased in 1990-1999 down to 1.11%±1.1 (5.56%±5.4).

Endodontic reason was reported in 1981-1989 at 1.11%±1.1 (6.67%±6.44) but was not reported in the next period.

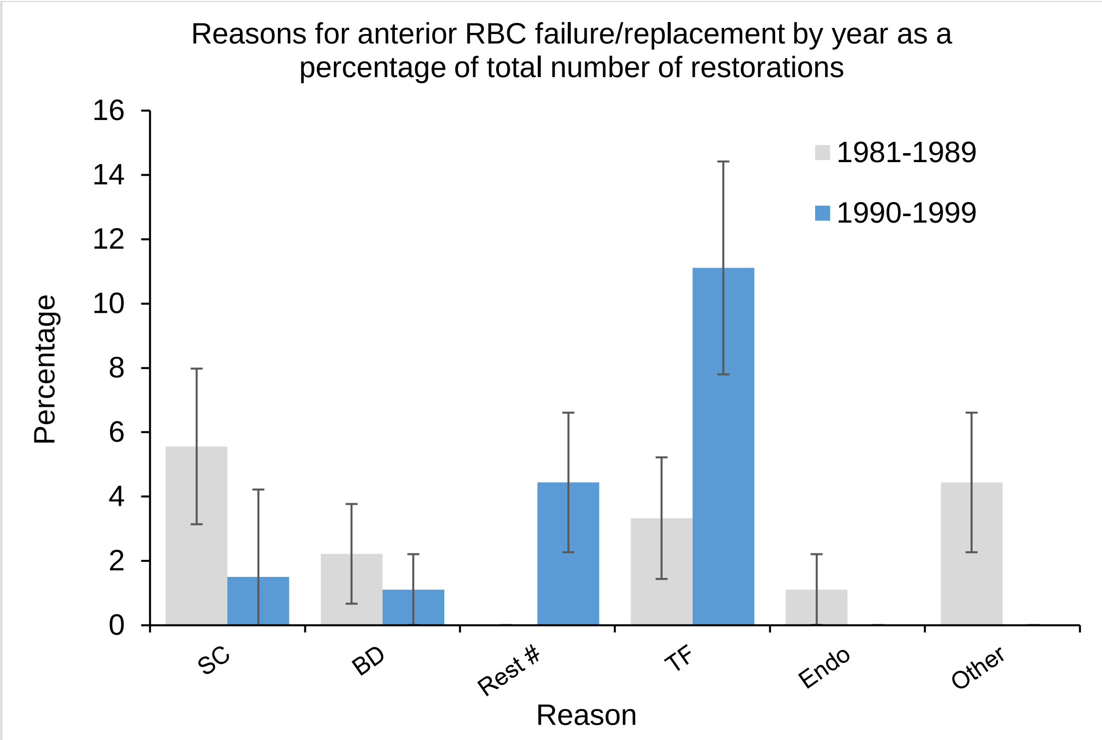


**Figure 29. Bar chart comparing the reasons for anterior RBC failure/replacement in CTs and LCSs according to the year of the study as a percentage of all restorations placed**

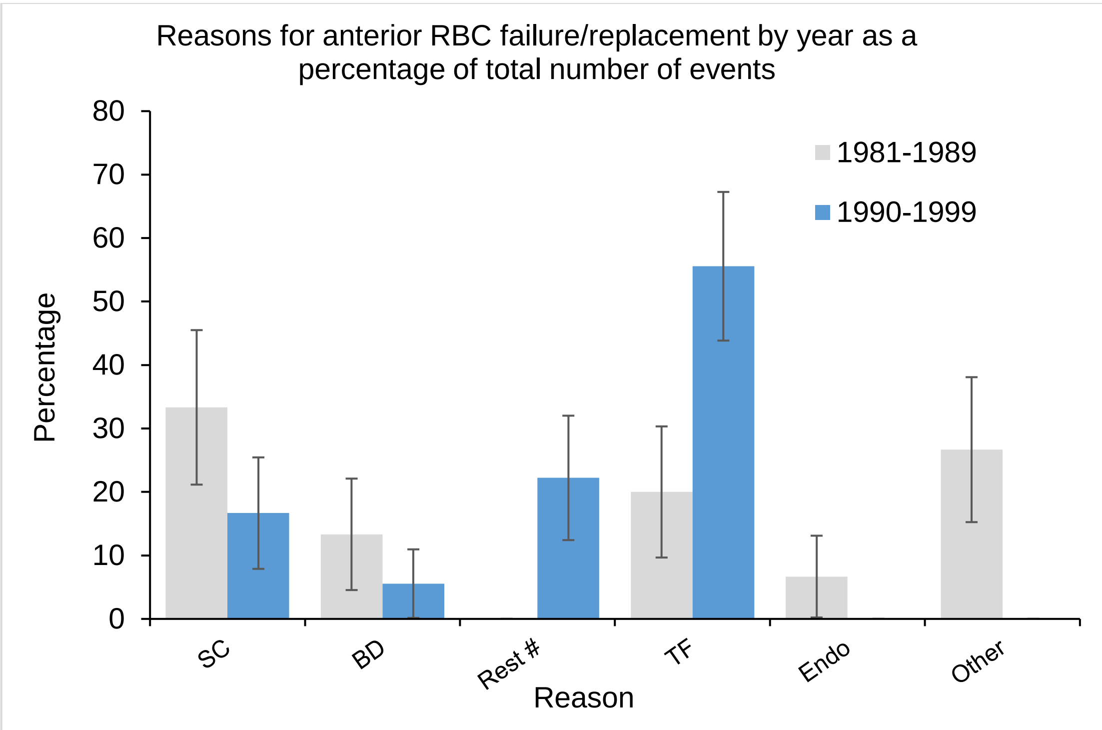


**Figure 30. Bar chart comparing the reasons for anterior RBC failure/replacement in CTs and LCSs according to the year of the study as a percentage of all failed/replaced restorations**

### 4.3.2 Cross-sectional studies (CSSs)

Only three cross-sectional studies met the inclusion criteria and were included in the review. Most published cross-sectional studies had to be excluded as they usually include all cavity types, thus it was not possible to differentiate between anterior and posterior restorations or exclude cervical lesions from the data provided.

Details of all the excluded studies with reasons are given in Appendix 7.

The three studies were published in 1990, 2002, and 2010. The studies reported on restorations replaced for all patients followed during the observation period.

Two studies had an observation period of 2 and 5 months respectively. The third study reported on the first 20 restorations the dentists decided to replace.

The studies were undertaken in Nigeria, Pakistan, and Sweden. Two studies were done in a University setting and the third study in a private dental practice.

All three studies were considered of poor quality (two studies were given a score of 2 and one a score of 3). This was mostly due to lack of details in reporting, using own or unspecified criteria, and lack of examiner training/calibration.

The studies included 2,322 replaced restorations, of which, 1,909 were amalgam and 413 were RBC. Two studies reported on 1,909 posterior replaced amalgam restorations and one study reported on RBC, both anterior (148 replacements) and posterior (265 replacements).

#### 4.3.2.1 Data Analysis

For the included cross-sectional studies, data reported is different to clinical trials and longitudinal cohort studies. The included cross-sectional studies reported only on replaced restoration over the observation period, while CTs and LCSs follow the same cohort of patients who had restorations placed over a certain period and report on outcome. So, failure/replacement/repair rate, as used in CTs and LCTs analysis, could not be used in the analysis of the cross-sectional studies included in this review.

An analysis was undertaken for the reasons of replacement for anterior (incisors and canines) and posterior (molars and premolars) teeth.

#### 4.3.2.2 Reasons for replacement

Two studies used their own criteria and one followed Mjör protocol (Mjör, 1981).

The reason for replacement was one or more of the reasons mentioned below:

- Secondary Caries **(SC)**
- Bulk Discolouration **(BD)**
- Marginal Discolouration **(MD)**
- Bulk Fracture **(BF)**
- Marginal Fracture **(MF)**
- Restoration fracture **(Rest #)**
- Poor Anatomic Form **(PA)** (includes marginal defect and abrasion/attrition of restoration)
- Tooth Fracture **(TF)**
- Lost Restoration (**LR)**
- Aesthetic Reasons **(AR)**
- Pain/Sensitivity **(P/S)**
- Endodontic reasons **(Endo)**
- Other Reason **(ORR)** (this mainly includes primary caries somewhere else on the tooth not related to the restoration, prosthodontic reasons; crown or tooth needed as a pontic for bridge placement, tooth extracted for reasons other than above, periodontitis, and patient request)

The reason for each replacement was recorded, and data entered into an excel sheet.

The following sections show the bar charts of the reasons for the different categories.

### 1) Posterior RBC and amalgam replacement

The reasons for replacement were combined in one chart for both RBC and amalgam for comparison. The reasons were analysed using a bar chart in Figure 31 as a percentage of the reason of replacement as a function of the total number of restorations replaced (1,909 amalgam restorations and 265 RBC restorations).

For both RBC and amalgam restorations, secondary caries was found to be the most common reason for replacement (38.29%±1.11 for amalgam and 70.19%±2.81 for RBC).

The second most common reason for amalgam was "other reasons", accounting for 17.29%±0.87. This was followed by restoration fracture (13.88%±0.79). One paper reported more details for amalgam fracture as being bulk fracture, and this was recorded separately. If restoration fracture and bulk fracture are combined for amalgam, the percentage goes up to 16.87%±0.86. Other reported reasons were tooth fracture (10.74%±0.71), poor anatomic form (9.43%±0.67), lost restoration (4.14%±0.46), and endodontic reasons (3.25%±0.41).

For posterior RBC, the second most common reason for replacement was poor anatomic form (28.3%±2.77). Other reported reasons for RBC replacement were discolouration (0.75%±0.53) and restoration fracture (0.75%±0.53).

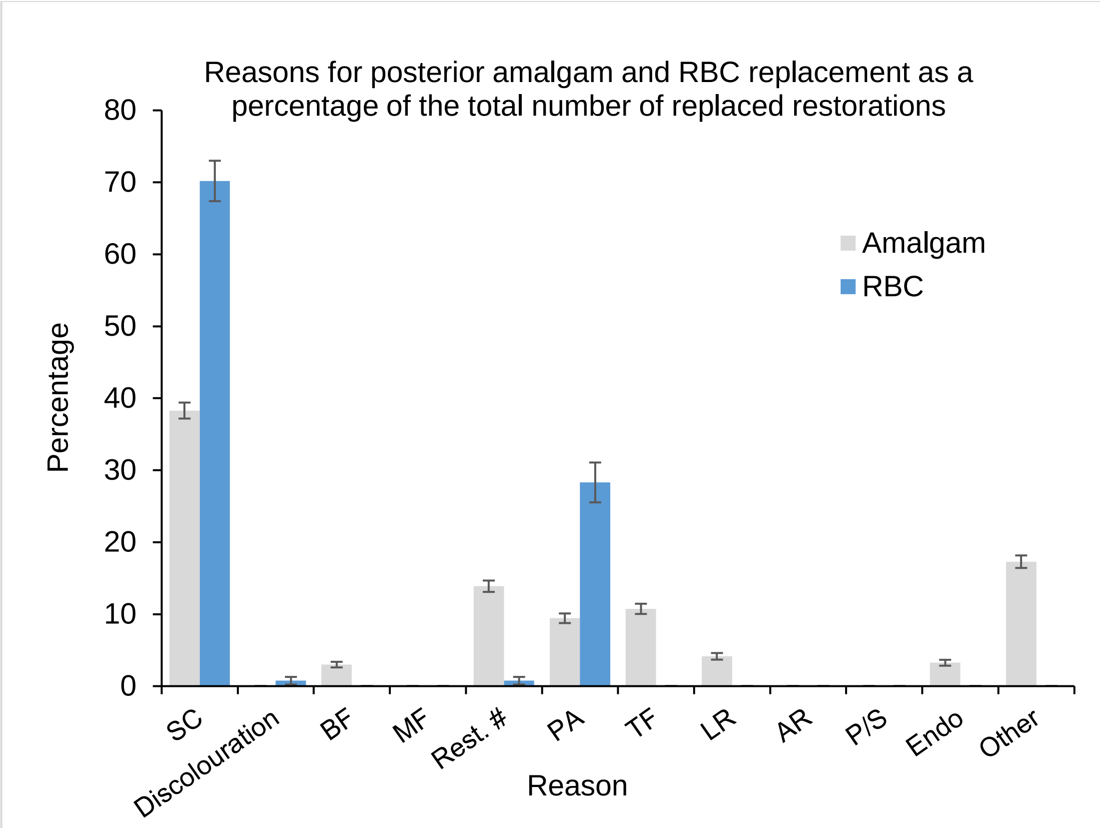


**Figure 31. Bar chart of the reasons of posterior RBC and amalgam replacement in CSSs as a percentage of all replaced restorations**

## 2) Anterior RBC replacement

Only a single study reported on 148 anterior RBC replacements. Figure 32 shows the reasons of replacement as a percentage of all replaced anterior RBC restorations.

The most common reason for anterior RBC replacement was found to be discolouration of restoration, accounting for 45.95%±4.1, followed by restoration fracture at 33.78%±3.89 then secondary caries at 20.27%±3.3.

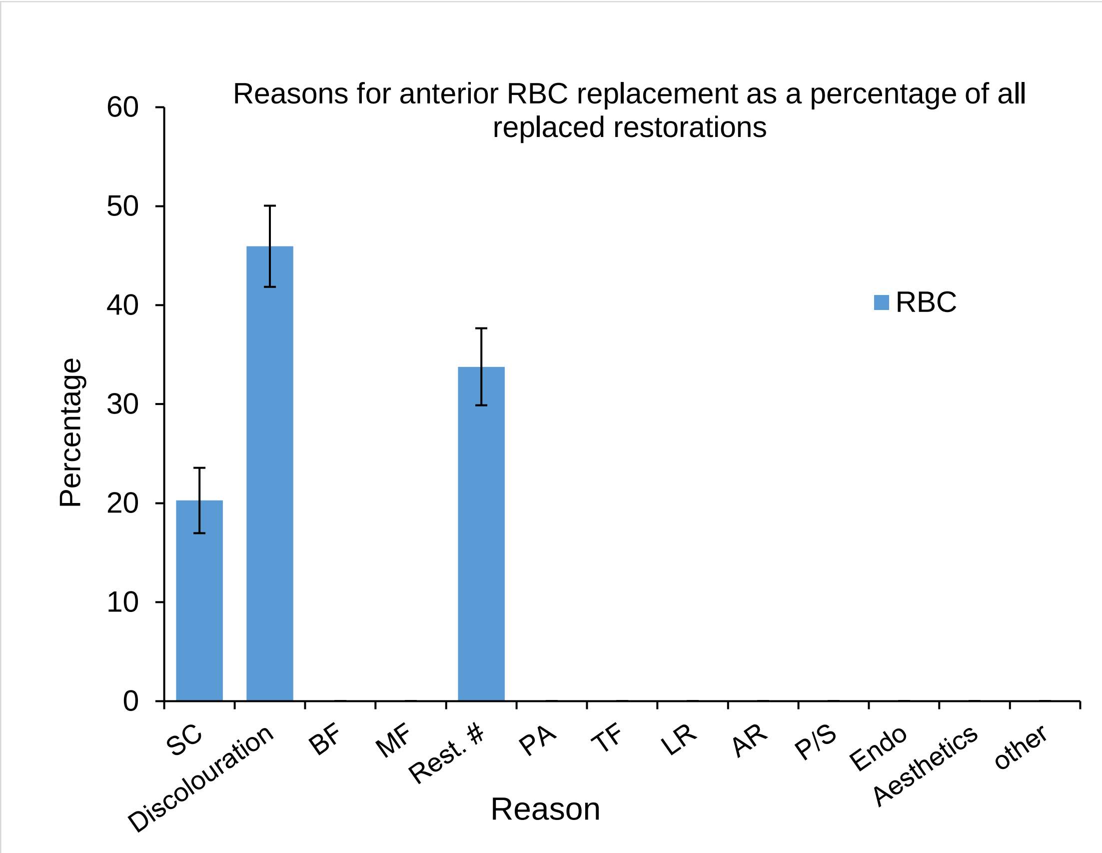


**Figure 32. Bar chart of the reasons of anterior RBC replacement in CSSs as a percentage of all replaced restorations**

### 4.3.2.3 Comparing studies according to quality scores

All three included studies were considered of poor quality (two studies were given a score of 2 and one a score of 3). Due to this, no comparison could be carried out.

### 4.3.2.4 Comparing studies according to the year it was conducted

#### 1) Posterior amalgam

The review included two studies reporting on the replacement of posterior amalgam, the first one was conducted in 1980 in Sweden and the second one in 1998 in Nigeria.

Figure 33 compares the reasons for replacement of posterior amalgam between the two time periods.

The small number of studies and the low-quality score mean that the results should be interpreted with caution. However, the percentage of secondary caries as a reason for replacement decreased from 38.8% in 1980 to 30.59% in 1998, while restoration fracture increased from 14.8% in 1980 to 47.1% (as bulk fracture) in 1998.

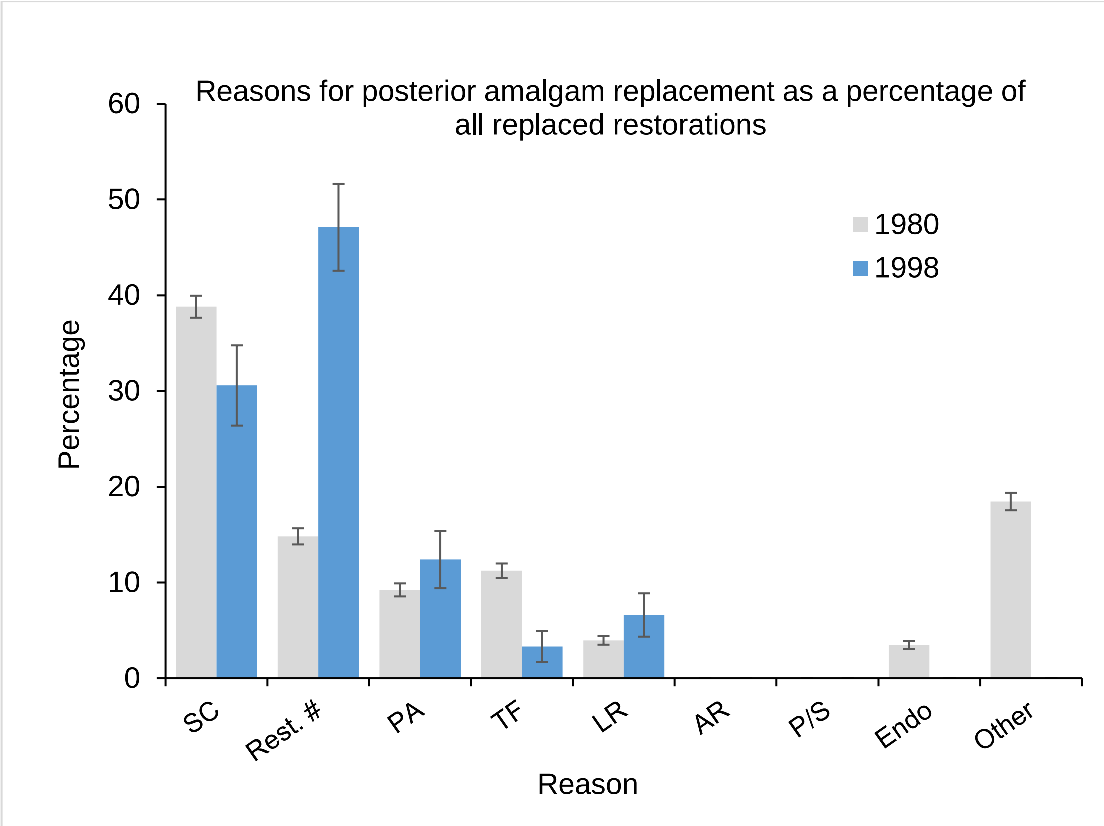


**Figure 33. Bar chart comparing the reasons for posterior amalgam replacement in CSSs according to the year of the study**

### 2) Posterior RBC

As only a single study reporting on posterior RBC was included, it was not possible to compare according to the year of the study.

### 3) Anterior RBC

Similarly, only a single study reporting on anterior RBC was included, so no comparison could be undertaken.

## 4.4 SUMMARY OF THE RESULTS

To make the comparison across the studies easier, the results are summarised in the following tables.

Table 7 summarises the results of the rates of failure/replacement/repair for anterior and posterior RBC and posterior amalgam in CTs and LCSs.

Table 8 details the reasons of failure/replacement/repair of anterior and posterior RBC and posterior amalgam in CTs and LCSs in descending order. Please note the percentages quoted in this table are calculated as a function of the total restorations placed, then, between brackets, as a function of the total failed/replaced/repaired restorations.

Tables 9, 10, and 11 compare the reasons of failure/replacement/repair of posterior RBC, posterior amalgam, and anterior RBC in CTs and LCSs according to the year of study.

Table 12 summarises the reasons of RBC and amalgam replacements as reported in CSSs. Please note the percentages quoted in the table are calculated as a function of the total replaced restorations.

Table 13 compares the reasons of posterior amalgam replacement in CSSs according to year of study.

**Table 7: Summary of the rates of RBC and amalgam failure/replacement/repair in CTs and LCSs**

| | # of studies | # of restorations | Years of follow-up | Rate of failure or replacement or repair | Rate after "trim-and-fill" |
|---|---|---|---|---|---|
| **Posterior RBC failure** | 27 | 2,378 | 2-10 yrs | 6% | 15% |
| **Posterior RBC replacement** | 13 | 869 | 2-12 yrs | 14% (9% after sensitivity analysis) | 13% |
| **Posterior RBC repair** | 3 | 203 | 3-12 yrs | 3% | - |
| **Posterior amalgam failure** | 4 | 235 | 3-6 yrs | 10% | - |
| **Posterior amalgam replacement** | 4 | 253 | 3-6 yrs | 5% | - |
| **Anterior RBC failure** | 2 | 200 | 5-6 yrs | 9% | - |
| **Anterior RBC replacement** | 1 | 90 | 11 yrs | 17% | - |

**Table 8: Summary of the reasons of RBC and amalgam failure/replacement/repair in CTs and LCSs**

| | Posterior RBC failure | Posterior RBC replacement | Posterior RBC repair | Posterior amalgam failure | Posterior amalgam replacement | Anterior RBC failure+ Replacement |
|---|---|---|---|---|---|---|
| 1 | **SC** 2.5%±0.32 (27.31%±2.96) | **TF** 3.68%±0.64 (26.45%±4.01) | **Rest #** 3.45%±1.28 (70%±14.49) | **SC** 4.26%±1.3 (37.04%±9.29) | **Rest #** 3.95%±1.22 (62.5%±12.1) | **TF** 4.48%±1.21 (39.39%±8.51) |
| 2 | **Rest #** 2.5%±0.32 (27.31%±2.96) | **Rest #** 3.34%±0.61 (23.97%±3.88) | **SC** 0.99%±0.69 (20%±12.65) | **Rest #** 3.83%±1.25 (33.33%±9.07) | **SC** 1.19%±0.68 (18.75%±9.76) | **SC** 2.67%±0.96 (24.24%±7.46) |
| 3 | **Other** 1.1%±0.21 (11.89%±2.15) | **SC** 2.3%±0.51 (16.53%±3.38) | **Endo** 0.49%±0.49 (10%±9.49) | **TF** 2.13%±0.94 (18.52%±7.45) | **TF** 1.19%±0.68 (18.75%±9.76) | **Rest #** 1.38%±0.69 (12.12%±5.68) |
| 4 | **PA** 0.9%±0.19 (9.69%±1.96) | **PA** 1.61%±0.43 (11.57%±2.91) | - | **Endo** 1.28%±0.73 (11.11%±6.05) | - | **Other** 1.38%±0.69 (12.12%±5.68) |
| 5 | **TF** 0.77%±0.18 (8.37%±1.84) | **P/S** 1.38%±0.4 (9.92%±2.72) | - | - | - | - |
| 6 | **P/S** 0.57%±0.15 (6.17%±1.6) | **Other** 1.04%±0.34 (7.44%±2.39) | - | - | - | - |

**Table 9: Summary of the reasons of posterior RBC failure/replacement/repair in CTs and LCSs according to year of study**

| Posterior RBC | 1981-1989 | 1990-1999 | 2000-2010 |
|---|---|---|---|
| SC | 3.49%±0.67 (22.22%±3.84) | 4.74%±0.91 (40.63%±6.14) | 1.75%±0.3 (18.28%±2.83) |
| Rest # | 3.62%±0.68 (23.08%±3.9) | 2.74%±0.7 (23.44%±5.3) | 3.19%±0.4 (33.33%±3.46) |
| PA | 2.41%±0.56 (15.38%±3.34) | 0.73%±0.36 (6.25%±3.03) | 0.72%±0.19 (7.53%±1.93) |
| TF | 0.13%±0.13 (0.85%±0.85) | 1.28%±0.48 (10.94%±3.9) | 2.37%±0.35 (24.73%±3.16) |
| LR | 0.27%±0.19 (1.71%±1.2) | - | 0.36%±0.14 (3.76%±1.39) |
| AR | 0.13%±0.13 (0.85%±0.85) | - | - |
| MD | - | - | 0.05%±0.05 (0.54%±0.54) |
| P/S | 1.61%±0.46 (10.26%±2.81) | 0.36%±0.26 (3.13%±2.18) | 0.52%±0.16 (5.38%±1.65) |
| Endo | 0.4%±0.23 (2.56%±1.46) | 0.36%±0.26 (3.13%±2.18) | 0.21%±0.1 (2.15%±1.06) |
| ORR | 3.62%±0.68 (23.08%±3.9) | 1.46%±0.51 (12.5%±4.13) | 0.05%±0.05 (0.54%±0.54) |

**Table 10: Summary of the reasons of posterior amalgam failure/replacement in CTs and LCSs according to year of study**

| Posterior amalgam | 1981-1989 | 1990-1999 |
|---|---|---|
| SC | 1.42%±0.63<br>(20.83%±8.29) | 5.88%±2.02<br>(34.78%9.93) |
| Rest # | 2.84%±0.89<br>(41.67%±10.06) | 6.62%±2.13<br>(39.13%±10.18) |
| TF | 2.27%±0.79<br>(33.33%±9.62) | 2.94%±1.45<br>(17.39%±7.9) |
| Endo | 0.28%±0.28<br>(4.17%±4.08) | 1.47%±1.03<br>(8.7%±5.88) |

**Table 11: Summary of the reasons of anterior RBC failure/replacement in CTs and LCSs according to year of study**

| Anterior RBC | 1981-1989 | 1990-1999 |
|---|---|---|
| SC | 5.56%±2.42<br>(33.33%±12.17) | 1.5%±2.72<br>(16.67%±8.78) |
| Rest # | - | 4.44%±2.17<br>(22.22%±9.8) |
| BD | 2.22%±1.55<br>(13.33%±8.78) | 1.11%±1.1<br>(5.56%±5.4) |
| Endo | 1.11%±1.1<br>(6.67%±6.44) | - |
| TF | 3.33%±1.89<br>(20%±10.33) | 11.11%±3.31<br>(55.56%±11.71) |
| ORR | 4.44%±2.17<br>(26.78%±11.42) | - |

**Table 12: Summary of the reasons of RBC and amalgam replacement in CSSs**

| | Posterior RBC replacement | Posterior amalgam replacement | Anterior RBC replacement |
|---|---|---|---|
| 1 | **SC**<br>70.19%±2.81 | **SC**<br>38.29%±1.11 | **Discolouration**<br>45.95%±4.1 |
| 2 | **PA**<br>28.3%±2.77 | **ORR**<br>17.29%±0.87 | **Rest #**<br>33.78%±3.89 |
| 3 | **Discolouration**<br>0.75%±0.53 | **Rest #**<br>16.87%±0.86 | **SC**<br>20.27%±3.3 |
| 4 | **Rest #**<br>0.75%±0.53 | **TF**<br>10.74%±0.71 | - |
| 5 | - | **PA**<br>9.43%±0.67 | - |
| 6 | - | **LR**<br>4.14%±0.46 | - |
| | - | **Endo**<br>3.25%±0.41 | - |

**Table 13: Summary of the reasons of posterior amalgam replacement in CSSs according to year of study**

| Posterior amalgam | 1980 | 1998 |
|---|---|---|
| SC | 38.81%±1.15 | 30.58%±4.19 |
| Rest # | 14.82%±0.84 | 47.11%±4.54 |
| PA | 9.23%±0.68 | 12.4%±3 |
| TF | 11.24%±0.75 | 3.31%±1.63 |
| LR | 3.97%±0.46 | 6.61%±2.26 |
| Endo | 3.47%±0.43 | 0 |
| ORR | 18.46%±0.92 | 0 |

# 5. DISCUSSION

The aim of this project was to evaluate by means of a systematic review and meta-analysis the rates of failure, replacement, and repair in dental restorations, mainly amalgam and resin-based composite (RBC).
It also aimed to explore the reasons for these failures, replacements, and repairs and compare them according to restorative material used and cavity type (anterior or posterior).
In addition, it intended to investigate the popularity of restoration repair, and to ascertain if there is an increasing trend towards the use of this conservative approach as an alternative to replacement.
The rates and reasons of failure/replacement/repair were compared between different study designs and according to the year the studies were conducted too.

This systematic review identified studies that investigated dental restorations and reported on failure, replacement, or repair. The study designs included were clinical trials (CTs), longitudinal cohort studies (LCSs), and cross-sectional studies (CSSs), with the aim to highlight the differences in the findings between different study designs.
Data from clinical trials and longitudinal cohort studies were combined as they were carried out prospectively and followed for a certain period. They also use pre-defined criteria for the assessment of restorations, along calibration and training of the examiners/operators.
Cross-sectional studies data were collected separately as these differ greatly from clinical trials and cohort studies. They provide a snapshot of how restorations behave in everyday practice under less strict conditions and by operators that are not usually trained or calibrated.

The results of the meta-analysis are provided as a single proportion of a point estimate along confidence intervals for amalgam or RBC separately and shown in forest plots. Heterogeneity was explored and fixed or random effects models for the meta-analyses were used accordingly. Sensitivity analyses were carried out, and if outliers were present, they were removed, and the analyses were repeated.
Bias was assessed statistically if sufficient studies were available and this was presented in funnel plots.
Meta regression of the proportion for each study was carried out as a function of follow-up time.
The reasons of failure/replacement/repair were analysed in bar charts as simple proportion expressed as a percentage along with standard errors.

This review is the first systematic review that looks at the behaviour of both RBC and amalgam in anterior as well as posterior teeth with no restrictions on the publication date or the criteria used for the assessment of restorations, while collating data from three different study designs but analysing them separately.

Below is a detailed discussion on the findings from CTs and LCSs then from CSSs, followed by a comparison with previous published reviews. A narrative analysis to compare the findings of CTs and LCSs with those of CSSs is carried out as well.

## 5.1 CLINICAL TRIALS (CTs) AND LONGITUDINAL COHORT STUDIES (LCSs)

### 5.1.1 Overview

This systematic review included 45 studies in this category, 31 CTs and 14 LCSs with details of 4,013 restorations (3,525 RBC restorations and 488 Amalgam restorations).

The included studies reported mainly on RBC restorations, either following a certain type of RBC, comparing two or more types of RBC, comparing RBC with GIC or indirect restorations, or comparing the same type of RBC with different placement or bonding/etching technique over the follow-up period.

Six studies compared RBC to amalgam, while only 2 studies reported on amalgam only.

Generally speaking, all the studies had similar effect sizes (meaning that the confidence intervals of the studies on the forest plot overlap with the confidence interval of the pooled effect), with the exception of a single outlier in posterior RBC replacement (Kramer et al., 2005).

This study compared Ariston PHc RBC (non-bonded resin composite material, promising the release of fluoride, calcium, and hydroxy ions) used without enamel etching or rubber dam versus Solitaire RBC (packable) used with total etching and bond and placed under rubber dam. Of the 44 Ariston PHc restorations that were placed and followed for 2 years, 38 failed and had to be replaced, while only 11 of 45 Solitaire restorations had to be replaced. Due to the very high failure rate of the Ariston PHc in this study, which is expected as no etching was used, the results were very different to the rest of the included studies as shown on the forest plot in Figure 8 where the confidence interval of the Kramer et al. study does not overlap with the confidence interval of the pooled effect.

Most of the studies reported on posterior RBC (40 studies reporting on 3,235 restorations), so the results of this analysis can be interpreted with confidence.

Twenty-seven studies reported on posterior RBC failure (reporting on 2,378 restorations placed and 236 failures), and the overall rate averaged over all the years of follow-up (2-10 years) was found to be 6% (95%CI:4%-9%), while thirteen studies reported on posterior RBC replacement (reporting on 780 restorations placed and 72 replacements), and the overall rate averaged over all the years of follow-up (2-12 years) after removing the one outlier was found to be 9% (95%CI:7%-11%).

For posterior amalgam, the review included data from eight studies involving 488 restorations. This is considerably fewer than for RBC and we cannot be as confident when reading the results on amalgam.

Four studies reported on failure (reporting on 244 restorations placed and 27 failures) and the rate was found to be 10% over 3-6 years, and 4 studies reported on replacement (reporting on 253 restorations placed and 16 replacements), where the rate was found to be 5% over 3-6 years.

Interestingly, after the year 1997, none of the studies reported on amalgam, and in the period 2000-2010, the studies were exclusively on RBC only, which agrees with most published literature that amalgam use is declining (Burke, 2004, Alexander et al., 2014).

It is worth mentioning that of the four studies reporting on amalgam failure, two studies had a slightly higher failure rate (Summitt et al., 2004, Mannocci et al., 2005) compared to the other two (Norman et al., 1990, Hendriks et al., 1986), but the difference wasn't large enough to be detected as outliers. The two studies with increased failures included more compromised teeth compared to the other studies. The study by (Summitt et al., 2004) placed one type of amalgam (Tytin, high silver content and spherical particle amalgam) in molars or premolars with at least one proximal surface and one or more missing cusps using two techniques; pin retention or amalgam bonding system. The study by (Mannocci et al., 2005) placed amalgam (Valiant PhD, palladium enriched high copper, phase-dispersed amalgam) in endodontically treated premolars with occluso-proximal cavities.
So, the differences between the failure and replacement rate in posterior amalgam reported in this review may therefore relate to the size of the restorations and the underlying pulpal status of the teeth investigated in the included studies rather than the amalgam specifically. Many studies confirmed that larger restorations have a higher risk of failure, which increases with the number of surfaces involved (Burke and Lucarotti, 2018a), with every extra surface included in a restoration increasing this risk by 30%-40% (Opdam et al., 2014). Tooth fracture is also believed to be more common in endodontically treated teeth compared to vital teeth (Tang et al., 2010, van de Sande et al., 2013).

For anterior RBC, only three studies met the inclusion criteria reporting on 290 restorations, again a small number for the results to be viewed with confidence.
Two studies reported on anterior RBC failure (reporting on 200 restorations placed and 18 failures), and the overall rate averaged over all the years of follow-up (5-6 years) was found to be 9% (95%CI:6%-14%), while one study reported on anterior RBC replacement (reporting on 90 restorations placed and 15 replacements), and the overall rate averaged over 11 years of follow-up was found to be 17% (95%CI:10%-26%).

In four of the meta-analysis carried out as part of this systematic review (posterior RBC failure, posterior RBC replacement, posterior amalgam failure, posterior amalgam replacement), heterogeneity was found, and random effects model was used.

For the other four categories (posterior RBC repair, anterior RBC failure, anterior RBC replacement), a fixed effect model was used as the studies were found to be homogenous.

The heterogeneity in the included studies can be related to variability of study designs, as this review combined both CTs and LCSs in the analysis. It can also be a result of bias, mainly publication bias here, so this was explored using the funnel plots when sufficient studies were included, and if present, a “trim-and-fill” method was applied.
Other reasons for heterogeneity can be related to clinical factors that can affect the longevity of a restorations, for example patient selection (e.g. gender, age, socio-economic status, caries rate, parafunctional habits, oral hygiene, smoking), tooth selection (e.g. type of tooth, type of occlusion), cavity selection (e.g. size, site), material selection (e.g. content of copper in amalgam, filler size in RBC, type of etch/bond used with RBC), or operator factors (use of rubber dam, setting of the study, experience of the operator, training/calibration). As known from previous research, all the previous factors can affect the failure/replacement/repair rate of the restorations placed and can be called “effect modifiers” (Chadwick et al., 2001, Downer et al., 1999). The majority of these effect modifiers were recorded during data extraction, but not all studies reported data to the same level of detail. Analyses for these modifiers were not undertaken as it was beyond the scope of this research and it was not reported to the same level of accuracy in the studies. So, it is difficult to confirm if these effect modifiers are responsible for the heterogeneity, but they are likely to be.

Meta regression analyses were carried out as a function of follow-up times when sufficient studies were available (posterior RBC failure and replacement, and posterior amalgam failure), and they all indicated that the percentage of failure/replacement goes up strongly with length of follow-up in years. This is expected and has been reported in previous studies. In the systematic review looking at posterior RBC longevity (Opdam et al., 2014), the mean annual failure rate at 5 years was reported to be 1.8%, increasing to 2.4% at 10 years. Other studies also confirmed the increase of failure/replacement in posterior RBC and amalgam over the years of follow-up (Soncini et al., 2007, Astvaldsdottir et al., 2015, Burke and Lucarotti, 2018a, Brunthaler et al., 2003).

The results from 40 studies included in this review suggest that failure/replacement rate of posterior RBC is declining over the years. This can be attributed to better handling and understanding of RBC materials by operators that received better training in placing RBC restorations due to the steady growth in evidence-based teaching of posterior resin-based composites in dental schools around the world over the last 20–25 years (Wilson and Lynch, 2014), as well as enhancements in the manufacturing of RBC material itself, especially in reduced polymerisation shrinkage and increased wear resistance (Ritter, 2008, Ferracane, 2011).

For anterior RBC restorations, this systematic review suggests some evidence, but from only 3 studies, that the failure/replacement rate is also decreasing at the same rate as that seen in posterior RBC.

For amalgam, comparing the 6 studies conducted in 1980-1989 with the 2 studies in the period 1990-1999 suggests the opposite. Failure/replacement rate increased by almost three folds over the two periods. These results should be interpreted with caution, as the two studies in the 1990-1999 period are the same two studies mentioned previously which had a higher failure rate due to including extensively compromised teeth (Summitt et al., 2004, Mannocci et al., 2005).

When looking at the reasons of failure/replacement/repair of RBC and amalgam, the three most occurring reasons seem to be secondary caries, restoration fracture, and tooth fracture.

For posterior RBC, this review found that secondary caries as a reason for failure/replacement/repair is declining over the years, similarly is poor anatomic form, pain/sensitivity, and "other reasons". On the other hand, restoration fracture stayed the same, while tooth fracture increased.

The decline is secondary caries can be related to the substantial decline in caries prevalence in the industrialized countries (Marthaler, 2004), mainly due to the increased availability and use of Fluoride (Petersen and Ogawa, 2016).

Poor anatomic form was reported more frequently in earlier studies due to excessive wear loss observed in the earlier RBC materials which led to problems such as open contacts and loss of contour occlusally, but this has improved greatly and no longer a major concern (Sarrett, 2005).

Restoration fracture as a reason for failure/replacement of posterior RBC has not changed over the years in the reports studied in this review. There have been claims that despite improvement in other physical properties of RBC, fracture resistance has stayed the same, and current formulations are significantly weaker and less fracture resistant than those sold in the 1970s and 1980s, before the major push to minimize particle size occurred (Ferracane, 2013).

Many studies suggested that failure/replacement of posterior RBC is primarily caused by fracture in the first five years of service, and by secondary caries after that (Ferracane, 2013, Brunthaler et al., 2003). In this systematic review, 30.6% of events in posterior RBC in studies with follow-up of 5 years or less (30 studies) were caused by restoration fracture compared to 23.6% caused by secondary caries. While in studies with follow-up of more than 5 years (10 studies), 23.13% of events were caused by secondary caries compared to 21.6% caused by restoration fracture.

For posterior amalgam, secondary caries, restoration fracture, tooth fracture, and endodontic reason have increased over the two periods 1980-1989 and 1990-1999, but again these finding might be biased due to the higher failure rate in the included studies in the second period as discussed previously.

From the three studies on anterior RBC failure/replacement, there is some evidence that secondary caries is decreasing, as well as discolouration. Similar to the posterior RBC findings, tooth fracture seems to be increasing. Restoration fracture in anterior RBC is also increasing.

When considering repair of restorations, none of the studies reported on repair of amalgam restoration. Only 3 studies reported on repair of posterior RBC restorations. The studies reported on 203 RBC restorations placed and 10 repairs, and the overall rate averaged over all the years of follow-up (3-12 years) was found to be 3% (95%CI:1%-11%). The studies were conducted in 1990, 1996, and 2005 in Norway, Denmark, and Sweden. Within the same studies, some restorations were replaced, and some were repaired, and they were both considered separately.

This suggests that repairing restorations is still not a very popular option amongst studies and hardly considered when undertaking clinical trials or cohort studies. This agrees with the findings of (Kanzow et al., 2018) that the actual implementation of repair in clinical practice is lagging behind the available evidence.

It might also suggest that Scandinavian countries are ahead of others in considering the repair option, but this is hard to ascertain as no studies were found to confirm this finding.

### 5.1.2 Comparison with previous published research

### 1) Posterior RBC and amalgam

This review showed a failure rate of 6% in posterior RBC (2-10 years of follow-up) and 10 % in posterior amalgam (3-6 years of follow-up). The replacement rates were 9% for posterior RBC (2-12 years of follow-up) and 5% for posterior amalgam (3-6 years of follow-up). It also concluded a repair rate of 3% in posterior RBC (3-12 years of follow-up). Below is a comparison of the findings of this review with previous published data.

A recent Cochrane review (Rasines Alcaraz et al., 2014) looked at amalgam versus RBC for permanent posterior teeth and included 7 RCTs (two parallel group design and five split-mouth) but the meta-analysis was carried out using only the two parallel group studies, which were considered of “low-quality”. The two studies analysed 1,365 amalgam and 1,645 RBC restorations with a follow-up period of 5-7 years. In this analysis, the failure rate of amalgam was 7.5% and for RBC 14.2%.

The pooled estimate showed that composite restorations had a significantly higher risk of failure than amalgam (risk ratio (RR) 1.89 (95%CI:1.52% to 2.35%). In the review, failure was defined as the rating of the clinical performance greater than bravo using the assessment criteria of the USPHS guidelines, but it did not specify how the failure was handled, but when looking at the two analysed studies, (Bernardo et al., 2007) replaced all failed restorations, while (Soncini et al., 2007) replaced and repaired restorations, but the Cochrane review only included the replaced restorations, so all comparisons below will be done with replaced restorations. The Cochrane review considered posterior restorations in the occlusal or occluso-proximal surface in molars and premolars in any dental institution or practice, but the two studies they included were carried on children aged 6-12 years, hence why the two studies were not included in the current review.

The replacement rates in this review for both RBC (9% over 2-12 years) and amalgam (5% over 3-6 years) were lower than the Cochrane review (14.2% and 7.5% over 5-7 years respectively), but both reviews agreed that RBC restorations were replaced more often compared to amalgam.

The Cochrane review also investigated the risk of secondary caries (which was the most common reason for failure in the included studies) in amalgam (5.7%) and RBC (12.2%). They also investigated the risk of restoration fracture in amalgam (1.4%) and RBC (1.2%). They concluded that RBC is twice at risk of secondary caries compared to amalgam, while the risk of restoration fracture is almost similar in the two types of restorations.

In comparison with this review, tooth fracture and restoration fracture were much higher that secondary caries as a reason to replace RBC restorations, and restorations fracture was higher than secondary caries for amalgam, but both reviews agreed that RBC restorations have a higher risk of secondary caries than amalgam, and restoration fracture occurred at a similar rate in both materials.

The higher replacement rate in the Cochrane review can be attributed to the fact that the studies were conducted in children where factors such as the cooperation of the patient and the difference in caries risk as oral health habits and behaviours are being established, can highly influence the restoration performance, leading to more replacements due to secondary caries in children compared to adults.

In contrast to what have been suggested previously that failure/replacement of posterior RBC is primarily caused by fracture in the first five years of service, and by secondary caries after that (Ferracane, 2013, Brunthaler et al., 2003), this review included studies with longer follow-up periods (2-12 years) for posterior RBC compared to the Cochrane review (5-7 years), but reported less secondary caries than restoration and tooth fracture as a reason for replacement.

It must be emphasised here that this review included fewer numbers of amalgam restorations (253) compared to RBC (869), and compared to the number of restorations in the Cochrane review (1,365 amalgam and 1,645 RBC restorations), which might contribute to the difference in results. In addition, the dissimilarities in the cohorts studied (children versus adults) and in the types of studies included (RCTs versus CTs (randomised or non-randomised) and LCSs) can have an influence on the findings.

The details of the data included in the reporting studies can also have a major influence on results. For example, if considering the studies that reported on “failure” of posterior RBC and amalgam, where they did not specify how the failed restoration was managed (replaced, repaired, or even the tooth extracted), then different results can be found.
Posterior RBC failure rate was lower than replacement rate (6% compared to 9%) over similar follow-up periods, while posterior amalgam failure rate was higher than replacement (10% compared to 5%) over the same follow-up period. Secondary caries was the most common reason for failure of posterior amalgam, while both secondary caries and restoration fracture occurred at a similar rate in posterior RBC failures.

Similar results of the Cochrane review were found in another systematic review (Moraschini et al., 2015). This review compared amalgam with RBC placed in occlusal or occlus-proximal molars or premolars. They included 8 studies (2 RCTs, 5 LCSs, and 1 retrospective cohort study). None of

their included studies were included in this review, because they studied children (3 studies), they had observation period of one year (2 studies), they provided no information regarding the age or number of patients (2 studies), or they had a retrospective design (one study).
The Moranschini et al. review had data on 1,844 amalgam and 1,642 RBC restorations with a follow-up range of 1-10 years. They reported a mean risk of failure of amalgam and RBC to be 7.2% and 13.8% respectively, and RBC had a significantly higher incident of secondary caries while the risk of restoration fracture was the same for both types.

Many other non-systematic reviews reported higher failure rates in posterior RBC compared to amalgam (Hickel and Manhart, 2001, Downer et al., 1999, Manhart et al., 2002, Soares and Cavalheiro, 2010).

No reviews were found looking at the repair of RBC, so no comparison could be done with other reviews. One of the two studies included in the Cochrane review (Soncini et al., 2007) is a randomised controlled trial in children comparing amalgam and compomer or RBC placed in primary and permanent posterior teeth. They reported on replacement of restorations as well as repair. The repair rate in RBC placed in permanent teeth over the 5-year follow-up period was 2.8% (21 repaired restorations of a total 753 RBC restorations placed in permanent teeth). This is very similar to the rate reported in this review (3%, 10 repairs in 203 restorations), with the difference that this review only included adults. The trial did not report the reasons of repair of restorations.

### 2) Anterior RBC

When looking at anterior RBC failure and replacement, only one systematic review (Heintze et al., 2015) looked at the clinical effectiveness of direct anterior restorations (class III and IV). They included 21 prospective trials that utilised the Ryge or modified Ryge criteria for assessment of restorations. They included RBC as well as resin modified glass ionomer and polyacid modified resin composite restorations, but they excluded the last two in the statistical calculations of success rate.

The estimated median overall success rate (without replacement) after 10 years for Class III RBC restorations was 95% and for Class IV restorations 90%.

The reasons for restoration replacement were predominantly bulk fractures of Class IV restorations. Secondary caries had a median prevalence of about 2.5% after 10 years in both class III and IV (similar to the findings of this review), but the main reason for failure/replacement in this review was tooth fracture.

The rates found in this review are slightly different at 9% failure rate over 5-6 years and 17% replacement rate at 11 years.

## 5.2 CROSS-SECTIONAL STUDIES (CSSs)

### 5.2.1 Overview

Only 3 studies met the inclusion criteria for this review, and they reported on 2,322 defective restorations, 1,909 were amalgam and 413 RBC restorations, and they were all replaced.

All three studies were considered of poor quality, so the results should be interpreted with caution because of the weaknesses in the study design.

For both posterior amalgam and RBC, secondary caries was the main reason for replacement, agreeing with most published cross-sectional studies. Secondary caries appeared almost twice as much in RBC compared to amalgam.

Poor anatomic form was the second most common reason for replacement of RBC. For amalgam, “other reasons” and restoration fracture come after secondary caries.

Secondary caries as a reason for replacement of posterior amalgam has decreased slightly when comparing the two included studies published in 1980 and 1998, while restoration fracture has largely increased.

### 5.2.2 Comparison with previous published research

In the literature review conducted recently (Eltahlah et al., 2018), 20 cross-sectional studies (25 publications) were included and reported on 86,720 restorations, of which, 49,704 (57.3%) were replacements. For both amalgam and RBC (without differentiating between posterior or anterior), the most common reason for replacement was secondary caries. For amalgam, the second most common reason was bulk/marginal fracture. For RBC, the second most common reason was bulk/marginal discolouration and poor anatomic form before 1998. This has changed after 1998 to bulk/marginal fracture and discolouration.

None of the studies included in the literature review were included in this review due to not being able to differentiate between anterior and posterior restorations.

This review also reported secondary caries as the most common reason for replacement of RBC and amalgam in posterior teeth, but this was different when looking at anterior teeth, as the most common reason was discolouration followed by restoration fracture. This shows how the results can change when differentiating between cavity types as done in this review.

A large cross-sectional study by (Gordan et al., 2012) reported on 9,484 defective restorations (both anterior and posterior) in permanent teeth that were either repaired or replaced by 197 practitioner-investigators participating in the DPBRN (The Dental Practice-Based Research Network). Most restorations (75%) were replaced, while 25% were repaired. Restorative materials were classified as amalgam, direct tooth coloured restorations (RBC, compomer, and glass ionomer), indirect restorations (indirect RBC, ceramic, and porcelain fused to metal), and gold or any other metal casting.

The most common reason for both replacement and repair was secondary caries again. It was not possible to separate data for RBC or amalgam in this study, hence in was not included in this review.

## 5.3 COMPARING THE FINDINGS OF CTs AND LCSs WITH CSSs

From the 45 CTs and LCSs included, this review included data on 4,013 restorations. In comparison, 3 CSSs provided data on 2,322 restorations. This shows that CSSs can provide information on a much higher number of restorations in shorter periods of time.

It was not possible to compare the rate of failure/replacement/repair between the two types of studies as the CSSs included reported on defective restorations only, rather than all restorations placed. Most CSSs in the literature do report on all restorations placed and failed (replaced mostly) and this gives information on replacement rate. Unfortunately, all these studies do not differentiate between cavity type, tooth type, or material used so they were not included.
While results from CTs and LCSs cannot be directly compared to CSSs, it is useful to consider similarities and emerging trends.

In the literature review (Eltahlah et al., 2018) data was collected from 20 CSSs, which provided information on 86,720 restorations. This review reported a replacement rate of 57%. Results from the CTs and LCSs included in this review suggest a failure/replacement rate of amalgam and RBC ranging between 5-10% over 2-12 years of follow-up.

Secondary caries is the most quoted reason for restoration replacement in published CSSs (Mjör, 2001), and even in the results of the 3 CSSs included in this review on posterior RBC and amalgam replacement. But from the included CTs and LCSs, that was not always the case. For example, for posterior RBC replacement, restoration fracture and tooth fracture appeared more commonly than secondary caries. Similarly, for posterior amalgam replacement, restoration fracture occurred twice as much as secondary caries. Even when the outcome was recorded as failure in posterior RBC, both secondary caries and restoration fracture appeared equally.
When looking at anterior RBC restorations, tooth fracture was the most common reason for failure and replacement, appearing almost as twice as secondary caries in CTs and LCSs. In the one included CSS on anterior RBC, discolouration followed by restoration fracture occurred more than secondary caries.

None of the included CSSs reported on repair of restoration, so no comparison could be undertaken for repair between the different types of studies.

Below is a comparison of the findings from the included CTs and LCSs on repair of restorations in this review with a large retrospective study conducted in a general practice in the Netherlands looking at the longevity of repaired occluso-proximal restorations (3-5 surfaces) and the reasons for the original repair (Opdam et al., 2012).

This study was excluded from this review due to the retrospective design. The basis of this study was the dataset of large occluso-proximal amalgam and RBC restorations placed at the practice and published in a previous paper (Opdam et al., 2010). The practitioners in the practice placed 1,947 restorations (1,202 amalgam and 747 RBC). With a follow-up period of up to 25 years, 407 (20.9%) restorations had failed; 161 (8.3%) replaced and 246 (12.6%) repaired. Of the repaired restorations, 133 (11% of total amalgam restorations) were amalgam and 113 (15%) were RBC, and they were all repaired with RBC. The findings from the retrospective study reported a much higher rate of repair (12.6%) compared to this review (3%), which shows that, as the case of replacement of restorations, repair rate is higher in CSSs in general practice compared to CTs and LCSs.

The main reason for amalgam repair in the retrospective study was tooth fracture (6.3% of all followed amalgam restorations), followed by secondary caries (2.6%). For RBC, the main reason for repair was secondary caries (9.4%) followed by endodontic reasons (3.2%). These reasons are different again from the findings in this review, where the main reason for posterior RBC repair was restoration fracture, which occurred more than 3 times than secondary caries.

This shows how the results of CSSs differ markedly from controlled studies conducted under more strict guidelines and criteria, where few experienced operators carefully select their patients and place the restorations under standardised conditions and follow them for a relatively short period. So, this might not reflect what would actually happen when the same material is placed in a busy general dental practice by less experienced operators. (Jacobsen, 1984) wrote ”it is quite possible for materials to perform well in a trial, but to appear less good when subjected to the vagaries of general practice and the patients at large”. In a busy dental practice, treatment times are constrained and the diagnostic thresholds for replacement may vary with the patient load, and can be influenced by cost (Drake et al., 1990).

Many of the CTs and LCSs have strict inclusion criteria for their patients. Almost half (20 of 45 studies) of the included CTs and LCSs in this review had restrictions on the patients recruited. Examples of these restrictions are exclusion of patients with poor oral hygiene, parafunctional habits, reduced salivary flow, systematic disease, pregnancy, deep caries, caries into pulp, caries extending beyond the cemento-enamel junction, periodontal disease, pain, endodontically treated teeth, mental or physical handicap, or even irregular dental attenders. These exclusions were considered when scoring the quality of restorations, but no analysis was done to consider how they affect the failure/replacement/repair of restorations as this was beyond the scope of this review. These exclusions are not usually found in CSSs. This can have a large attribution to the difference in failure/replacement rate of dental restorations between the different study designs.

The observation period or the time the restoration has been in service can also have a major impact on the failure/replacement rate. As expected, the longer the restoration is present, the higher the chances of failure become. This was shown in the results of CTs and LCSs included in this review where the percentage of failure/replacement goes up strongly with length of follow-up in years, as was also reported in many previous studies. For CSSs, the data collected is a “snapshot” of the behaviours of restorations in a normal day in practice, with no information given regarding the time these restorations have served. This can also attribute to the higher replacement rate reported in these studies compared to CTs and LCSs, where the restorations are followed for a relatively short period of time.

The judgment of failure of a restoration due to secondary caries is very subjective, especially if the examiner/evaluator has not been calibrated to a pre-defined strict criterion like USPHS or FDI criteria. This can lead to false reporting of secondary caries as the reason for “failure” while in fact the caries might have been located in a surface of the tooth away from the actual restoration (Opdam et al., 2014), or even marginal discolouration in RBC and ditching in amalgam being mistaken for secondary caries leading to unnecessary replacement (Kidd et al., 1995).
In most if not all CSSs, no calibration or training is carried out for the examiners/operators. Whilst this can give an indication to “real life” dentistry, it does not provide accurate data that can be trusted to be used as strong evidence. On the other hand, CTs and LCSs mostly train and calibrate the examiners/evaluators to the use of the criteria, although not always to the same level of adherence to the rules of using these criteria. In assessing the quality of the studies included in this review, considerable attention was given to the clinical examiners being trained and calibrated, and using well-defined and standardised criteria for failure, replacement, or repair. This was reported in CTs and LCSs but often not in accurate details.

Without proper and universally acceptable guidelines, assessment of the quality of restorations would remain very subjective (Elderton, 1977), and this highlights the importance of utilising the scoring criteria in studies assessing dental restorations, in addition to following the recommendations in the training and calibration of at least two examiners with a minimum of 85% of reproducibility and having at least dual examination with an agreed process to resolve differences when they arise as recommended by the USPSH criteria (Bayne and Schmalz, 2005).

The FDI criteria is very promising as it is designed to detect early deterioration and failures in dental restoration in a more sensitive and discriminative way compared to the USPSH criteria, having specific scores that indicate a need for restoration repair in addition to scores for replacement (Hickel et al., 2010). Unfortunately, none of the studies included in this review utilised the FDI criteria, as most of the studies that used the criteria so far are looking at cervical restorations, which they were excluded in this review. Using the FDI criteria in the future to look at anterior and posterior RBC replacement and repair can provide valuable information that can be considered more reliable. It can also encourage repair of dental restorations rather than replacement, which is very rarely seen in the studies included in this review.

## 5.4 REFLECTION AND CLINICAL IMPLICATIONS

Restoration longevity or survival is one of the most important and commonly studied topics in dentistry. Determining how a restorative material behaves inside the mouth and how long it survives before needing further intervention is often the way to measure its success. Dentists are obliged to inform their patients about the survival rates of different materials and restorative procedures. This will allow the patients to make informed decisions regarding their treatment options.

As shown in this review, the behaviour of restorations has been studied using clinical trials (randomised or non-randomised), longitudinal studies (prospective or retrospective), or cross-sectional trials (prospective or retrospective), and these are available in abundance in the published literature. But drawing accurate conclusions can be very difficult and confusing due to the differences in study designs. In addition, the lack of uniform criteria for decisions to replace or repair restorations (or lack of knowledge and training of dentists to use such criteria) complicates the studies even further.

Many factors can have an influence on restoration longevity. These factors can be impossible to standardize in one single study, let alone multiple ones. So, it is always important to consider these factors carefully when looking at studies of longevity/survival of restorations.

These factors can be classified as clinical, operator, patient, or material related factors.

Clinical related factors such as the position of the tooth in the mouth or the type of the tooth directly affects the longevity. For example, it has been reported that the risk of restoration failure in molars is higher than premolars (Da Rosa Rodolpho et al., 2011), and than anterior teeth (Fernandes et al., 2015). Similarly, cavity size, cavity type, and the number of restored surfaces are directly related to the failure risk (Soncini et al., 2007, Opdam et al., 2007b), as well as restorations placed in endodontically treated teeth (Van Nieuwenhuysen et al., 2003). Other clinical factors studied are the placement of a liner or base and its type or thickness, the etching technique (for RBC), and the use of bonding agent, with varying results. The use of rubber dam during placement of restoration may influence the longevity of the restoration with conflicting evidence (Wang et al., 2016, Cajazeira et al., 2014).

Operator related factors such as age, gender, years of experience, training, country of qualification, and employment status have all been looked at in relation to the restoration survival.

Some studies found that older dentists with longer experience had shorter restoration longevity, but increased crowns survival time (Burke and Lucarotti, 2018b), while others suggested the opposite; more experienced clinicians having higher restoration survival rates (Fernandes et al., 2015). The dentist’s gender doesn’t seem to influence restoration longevity. There is also evidence that patients who change dentists have reduced lifetime for composite and amalgam restorations (Bogacki et al., 2002).

Patient related factors are concerned with the type of patients and their oral environment. The caries risk of patients plays a very important role in restorations survival. The higher the caries risk, the higher the risk of restoration failure due to secondary caries (Opdam et al., 2010, Opdam et al., 2007a, Kohler et al., 2000). This can be measured or estimated from past dental history, using caries risk assessment methods, or using the DMFT (Decayed, Missing, and Filled Teeth) index, and is directly related to the oral hygiene and the consumption of cariogenic diet. In addition, patients with higher socioeconomic status are reported to have longer restoration survival (van de Sande et al., 2013). Bruxism and parafunctional habits are also risk factors that could affect restoration survival, with higher risk of restoration failure due to fracture (Hamburger et al., 2011).

Finally, when looking at material related factors, it means the properties related to the restoration material itself. When considering amalgam, the early conventional zinc-free, low copper alloys had the shortest survival time as they rapidly corrode in the oral environment due to the gamma-two phase, resulting in increased risk of fracture of amalgam. The addition of zinc and the inclusion of high copper content reduced this corrosion, increasing the survival rate compared to the old low copper, zinc-free amalgams (Watkins et al., 1995).

For RBC, the amount and size of the filler particles play an important role in the longevity. Early resin-based composites had very large filler particles (10µm) which adversely affected the mechanical properties and had high failure rates. This had drastically improved over the years and nowadays we have nanofilled, microfilled, or micro/nanohybrid materials with filler quantities varying from 42-55% and particle sizes less than 1µm and can be as small as 0.04µm. This has significantly improved the handling properties and polishability, increased wear resistance, and lowered polymerization shrinkage, hence increasing survival rates (Fernandes et al., 2015).

So, success of restorations (whether measured as longevity, survival, or success rate) is dependent upon all the previously discussed factors, and direct comparison of studies' findings can be very difficult and even misleading. The role of systematic reviews in this aspect is extremely helpful. Saying that, readers should not accept systematic reviews' results uncritically, and clinicians should be proficiently able to critically appraise studies and reviews, and know where and how their evidence can be applied.

Longevity of restorations has been reported by many studies differently. One study in Finland reported the median age of failed direct restorations to be 15 years for amalgam, 6 years for RBC, and 7 years for glass ionomer cements (Forss and Widström, 2004), while in the USA, a study estimated the median survival time for amalgam to be 22.5 years (Kolker et al., 2005). An older study found that 50% of all amalgams exceeded 8 to 10 years in lifespan, cast gold restorations may last longer, and multisurfaced composite restorations have a shorter lifespan (Mjör et al., 1990). Early posterior RBCs studies estimated up to 50% failure by 10 years (Raskin et al., 1999).

The survival rate was reported for posterior amalgam to be 90% at 5 years and 79% at 10 years, and for RBC to be 92% at 5 years and 82% at 10 years in the Netherlands (Opdam et al., 2007b), while (Brunthaler et al., 2003) reported the survival rate for posterior RBC to vary from 55% to 95% over 5 years. In the review by (Chadwick BL, 2001), they reported an average failure rate of amalgam to be less than 10% at 10 years (but this should be viewed in the context that 52% of restorations were lost to follow up), and they reported the survival of RBC to be 90% after 3 years and 59% after 8 years. In another review and meta-analysis of posterior RBCs, 86% of restorations were clinically acceptable after 5 years (el-Mowafy et al., 1994).

On the other hand, many studies reported on the performance of the restorations as annual failure rates. A comprehensive literature review by (Manhart et al., 2004) reported mean annual failure rates for posterior stress-bearing restorations to be 3% for amalgam, 2.2% for RBC, 3.6% for RBC with inserts, 1.1% for compomer restorations, 7.2% for glass ionomer restorations, 2.9% for composite inlays, 1.9% for ceramic restorations, 1.7% for CAD/CAM ceramic restorations, and 1.4% for cast gold inlays and onlays.

Previous evidence had consistently shown gold inlays, onlays, and crowns to perform very well and to be the "gold standard" against which the longevity of other types of restorations is measured. Ten-year survival rates for gold restorations placed at a German university were 76% for occlusal inlays, 88% for MO inlays, 83% for DO inlays, 88% for MOD inlays, and 86% for partial crowns (Stoll et al., 1999). Another Swiss study estimated 96% 10-year, 87% 20-year, and 74% 30-year survival rates for cast gold restorations (Studer et al., 2000). But despite the excellent performance of gold cast restorations, concerns about aesthetics limit their use.

Ceramic or porcelain inlays and onlays have been used as an aesthetic alternative with reasonable success. A literature review on IPS-Empress inlays and onlays reported 96% survival rate at 4.5 years, and 91% at 7 years (El-Mowafy and Brochu, 2002). Another review estimated the survival rates for glass-ceramics and feldspathic porcelain inlays and onlays to be between 92% and 95% at 5 years and 91% at 10 years (Morimoto et al., 2016). But one of the main limitations to their use is the need for two visits to complete the treatment, hence the CAD/CAM (Computer-Aided Design/ Computer-Aided Manufacturing) technology was developed to fabricate inlays, onlays, and crowns at chair-side allowing immediate cementation. The variety of CAD/CAM restorative systems is constantly evolving to meet the increased demands for highly aesthetic, biocompatible, and long-lasting restorations produced conveniently from blocks of different materials at chair-side in just one visit, and it is providing promising survival rates that can sometimes exceed that of directly-placed regular RBC restoration, and should be considered as a suitable alternative (Spitznagel et al., 2018). In comparison with hand-built materials, CAD/CAM blocks reveal a decreased presence of flaws and pores, resulting in increased reliability (Zhang and Kelly, 2017). The survival probability of CAD/CAM-generated restorations (CEREC) was reported to be approximately 97% for five years and 90% for 10 years (Fasbinder, 2006). A systematic review on CEREC ceramic inlays reported a mean survival rate of 97.4% over a period of 4.2 years (Martin and Jedynakiewicz, 1999).

So, given all the previously discussed evidence related to restoration longevity/success/survival, it is clear that there is no one single simple answer to predict how long a restoration will last before needing some sort of intervention. But it is important for the clinician to be familiar with the data available and to know how and where to apply it to be able to convey an evidence-based advice to guide the patients to make informed choices (Schwass et al., 2013).

As reported by many previous studies and confirmed by this systematic review, replacement of dental restorations still constitutes a large part of the work carried out by dentists, secondary caries and restoration fracture being the two main reasons for replacement/failure of directly placed dental restorations. This confirms that the dental profession is still faced with the enormous task of managing dental caries and its sequelae (restoration, replacement or repair of restoration, root canal treatment, extraction etc.), and the patient’s quality of life remains hugely affected by the consequences of the dental disease. Understanding this, dentists should move away from the “surgical” care approach and embrace the “MID (minimal intervention dentistry)” or “biological” approach. This has been highlighted and encouraged by the FDI since 2002 (www.fdiworlddental.org, 2002). The FDI’s policy aims to reduce the need for restorative therapy by placing greater emphasis on caries prevention by conserving remineralizable and intact tooth tissue, and using minimally invasive operative techniques to treat diseased tissue (Frencken et al., 2012).
The major MID principles are:

- Early detection of carious lesions and assessment of caries risk and activity
- Remineralisation of demineralised enamel and dentine
- Optimal measurements to keep sound teeth sound
- Tailor-made dental recalls
- Minimally invasive operative interventions to ensure tooth survival
- Repairing rather than replacing defective restorations

The first three MID aspects should be employed throughout a person’s life by implementing good oral hygiene measures, controlling the frequency and timing of consumption of fermentable carbohydrates, and continuous exposure to Fluoride. These measures, in particular the increased exposure to Fluoride, were the main attributors to the reduction in caries prevalence in most developed countries in recent decades shown by abundance of evidence (van Loveren and Duggal, 2001, Petersson and Bratthall, 1996, Walsh et al., 2010). Only when oral health maintenance has failed, and a cavity has developed should a minimally invasive operative intervention be undertaken using adhesive materials.

The implementation of the MID philosophy will vary in different countries for many reasons, which include professional dental training, availability of dental equipment and materials, and oral health remuneration systems. It is therefore important for the future of dentistry to incorporate MID in the dental curriculum and try to shift the dental professionals' mentality to be oral physicians and counsellors rather than only dental surgeons.

# 6. CONCLUSIONS

The results of this systematic review on the reasons of replacement and repair of directly placed dental restorations support the following conclusions:

- There is a wide variation in the type of studies that look at failure/replacement/repair of dental restorations and there is lack of standardisation amongst the studies when reporting outcomes
- Clinical studies that met the inclusion criteria mostly reported on RBC restorations. No studies looking at amalgam restorations were published after the year 1998, which indicates the decline in using amalgam in recent years
- There is evidence from clinical trials and longitudinal cohort studies that failure/replacement/repair rate of RBC restorations in both anterior and posterior teeth has declined between the years 1980-2010
- There is also evidence that secondary caries as a reason for failure/replacement/repair of RBC restorations is declining while tooth fracture in increasing
- No accurate conclusions on amalgam could be drawn due to the small number of studies meeting the inclusion criteria
- Repair of restorations was reported in 3 studies only (2 RCTs and 1 LCS), all reporting on posterior RBC restorations and the rate was much lower than replacement (3% compared to 9%)
- No studies reported on repair of amalgam restoration
- The most common reason for posterior RBC repair was restoration fracture, and for replacement was tooth fracture, while for failure it was secondary caries
- Most published cross-sectional studies did not meet the inclusion criteria, due to the lack of detailed reporting of findings
- There is weak, low quality evidence that secondary caries is still the major reason for replacement of posterior amalgam and RBC in cross-sectional studies

## 7. SUGGESTIONS FOR FURTHER STUDIES

- There is a need for better guided practice-based research that follow more strict criteria on when and how to treat defective restorations, with more emphasis on considering repair as a valid option that can be as successful as replacement
- There is also a need for considering repair in clinical trials more often as it is hardly reported as an outcome in the available literature
- Implementing the FDI criteria when conducting clinical trials or even practice-based cross-sectional studies can lead to better understanding of the reasons of deterioration or failure of dental restorations which can then guide the best way to deal with it
- There is a pressing need for better reporting of studies and considering variables that can influence their results which would allow better evidence-based decisions to be made
- Further research to compare replacement against repair of restoration, preferably using well-conducted randomised-controlled trials performed by trained and calibrated assessors using a well-defined standard criteria and providing appropriate detailed outcomes is highly encouraged to provide dentists with strong evidence that supports the benefits of repair rather than replacement which can lead to change in the current practice, supported by the increased teaching of repair at dental schools

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# APPENDICES

## APPENDIX 1: SEARCH STRATEGY FOR ELECTRONIC DATABASES

### OVID MEDLINE 1946-week 1 July 2015

1. exp Dental Amalgam/ or amalgam.mp.
2. composite resin.mp. or exp Composite Resins/
3. exp Dental Cements/ or exp Glass Ionomer Cements/ or glass ionomer.mp.
4. compomer.mp. or exp Compomers/
5. polyacid modified composite.mp. or exp Resin Cements/
6. exp Dental Restoration, Permanent/ or dental restoration.mp.
7. 1 or 2 or 3 or 4 or 5 or 6
8. dental restoration failure.mp. or exp Dental Restoration Failure/
9. (replac* adj3 restoration).mp.
10. dental restoration repair.mp. or exp Dental Restoration Repair/
11. (repair* adj3 restoration).mp.
12. (restoration adj3 refurbish*).mp.
13. (restoration adj3 defect).mp.
14. exp Dental Marginal Adaptation/
15. 8 or 9 or 10 or 11 or 12 or 13 or 14
16. 7 and 15
17. exp Dentistry/ or exp Public Health Dentistry/ or exp Dentistry, Operative/
18. (dental or dentistry).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
19. 17 or 18
20. 16 and 19
21. exp Dental Implants/ or implants.mp. or exp Dental Implants, Single-Tooth/
22. endodontic*.mp.
23. *"Root Canal Therapy"/
24. In Vitro/
25. 21 or 22 or 23 or 24
26. 20 not 25
27. limit 26 to humans

**EMBASE 1947-July 2015**

1. exp amalgam/ or amalgam.mp.
2. exp composite material/
3. composite resin.mp. or exp resin/
4. glass ionomer.mp. or exp glass ionomer/
5. resin modified glass ionomer.mp.
6. compomer.mp. or exp compomer/
7. (dental adj3 restoration).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. repair*.mp.
10. refurbish*.mp.
11. replac*.mp.
12. 9 or 10 or 11
13. exp dentistry/ or dentistry.mp.
14. (dental or dentistry).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
15. 13 or 14
16. 8 and 12
17. 15 and 16
18. implant.mp. or exp tooth implant/ or exp implant/
19. 17 not 18
20. limit 19 to human

## CINAHL

S1 (MH "Dental Amalgam")

S2 amalgam

S3 (MH 2Composite Resins")

S4 composite resin

S5 (MH "Glass Ionomer Cements")

S6 glass ionomer

S7 (MH "Dental Restorations, Permanent")

S8 dental restoration

S9 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8

S10 "repair"

S11 "replace*"

S12 "refurbish*"

S13 S10 or S11 or S12

S14 S9 and S13

S15 (MH "Dentistry") OR (MH "Dentistry, Operative") OR (MH "Public Health Dentistry") OR (MH "Evidence-based Dental Practice")

S16 dentistry OR dental

S17 S15 or s16

S18 S14 and S17

**CENTRAL**

1. MeSH descriptor: [Dental Amalgam] this term only
2. amalgam
3. MeSH descriptor: [Composite Resins] this term only
4. composite near resin
5. MeSH descriptor: [Glass Ionomer Cements] this term only
6. glass near ionomer
7. MeSH descriptor: [Compomers] this term only
8. compomer
9. resin modified glass ionomer
10. MeSH descriptor: [Dental Restoration, Permanent] this term only
11. dental near restoration
12. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #10 or #11
13. MeSH descriptor: [Dental Restoration Repair] this term only
14. repair
15. refurbish*
16. replace*
17. #13 or #14 or #15 or #16
18. #12 and #17
19. MeSH descriptor: [Dentistry] this term only
20. MeSH descriptor: [Dentistry, Operative] this term only
21. dental or dentistry
22. #19 or #20 or #21
23. #18 and #22

## APPENDIX 2: SEARCH STRATEGY FOR CITATION SEARCHING

### Web of Science

1. TS=(Amalgam)
2. Topic=(composite NEAR resin)
3. Topic=(glass NEAR ionomer)
4. Topic=(compomer)
5. Topic=(resin modified glass ionomer)
6. #5 OR #4 OR #3 OR #2 OR #1
7. TS=(replace*)
8. Topic=(repair)
9. Topic=(refurbish*)
10. #9 OR #8 OR #7
11. #10 AND #6
12. Topic=(dental OR dentistry)
13. #12 AND #11

### Scopus

TITLE-ABS-
KEY (dental AND amalgam OR composite AND resin OR glass AND ionomer OR compomer)

AND TITLE-ABS-KEY (replace OR repair OR refurbish OR failure)

AND TITLE-ABS-KEY (dental OR dentistry)

AND NOT TITLE-ABS-KEY (implant))

## APPENDIX 3: STUDY SELECTION PROFORMA

Reference ID: Reviewer Name:

**Accept study** Yes No

**Study Details**

- **Study Design**

○ Case Study/Cross-sectional survey
○ Prospective Case-Control Study
○ Prospective Longitudinal Cohort Study
○ Randomised Controlled Trial
○ Case report / Case Series
○ Retrospective Study
○ Other Clinical Trial

- **Study Details**

| | |
|---|---|
| Year of Study | |
| Country of Study | |
| Length of Study or follow-up time | |
| Number of Patients | |
| Type of patients | |
| Initial Number of Restorations | |
| Final number of restorations | |
| Dropout rate | |
| Age Range of Patients | |
| Gender | |
| Type of Practice | |
| Exclusions | |
| Number of Examiners Assessing Restorations | |
| Number of Operators | |
| Examiner Training | |
| Operator Training | |

| | |
|---|---|
| Please specify if the operator is the examiner as well | |
| Ethical Approval | |
| Response Rate | |
| Funding Details | |
| Clinical Evaluation Criteria<br><br>e.g. USPHS/Major/FDI | |
| Outcome measured | |

**Evaluation of the Paper**

State Main Findings and summary, Comment on Bias, Generalizability

**Decision**

Accept Paper? **YES** **NO**

If No, Why?

Additional Notes:

## APPENDIX 4: DATA EXTRACTION FORM

Reference ID: Reviewer Name:

**Accept study** Yes No

**Quality assessment score:**

**Study Details**

- **Study Design**

○ Case Study/Cross-sectional survey
○ Case report / Case Series
○ Prospective Case-Control Study
○ Prospective Longitudinal Cohort Study
○ Retrospective Study
○ Randomised Controlled Trial
○ Other Clinical Trial

- **Study Details**

| | |
|---|---|
| Year of Study | |
| Country of Study | |
| Length of Study or follow-up time | |
| Number of Patients | |
| Type of patients | |
| Initial Number of Restorations | |
| Final number of restorations | |
| Dropout rate | |
| Age Range of Patients | |
| Gender | |
| Type of Practice | |
| Exclusions | |
| Number of Examiners Assessing Restorations | |
| Number of Operators | |
| Examiner Training | |
| Operator Training | |

| | |
|---|---|
| Please specify if the operator is the examiner as well | |
| Ethical Approval | |
| Response Rate | |
| Funding Details | |
| Clinical Evaluation Criteria<br><br>e.g. USPHS/Major/FDI | |
| Outcome measured | |

**Evaluation of the Paper**

State Main Findings and summary, Comment on Bias, Generalizability

**Decision**

Accept Paper? **YES** **NO**

If No, Why?

Additional Notes:

- **Details of Restorations**

| | Placed | | Replaced | | Repaired | | Failed | |
|---|---|---|---|---|---|---|---|---|
| **Material used** | **Am** | **RBC** | **Am** | **RBC** | **Am** | **RBC** | **Am** | **RBC** |
| **Number** | | | | | | | | |
| **Percentages** | | | | | | | | |
| **Total** | | | | | | | | |

- **Failures**

| ***Failures*** | **Class I** | **Class II 2 Surfaces** | **Class II 3 surfaces** | **Class III** | **Class IV** | **U/S** |
|---|---|---|---|---|---|---|
| **Amalgam** | | | | | | |
| **RBC** | | | | | | |

***Please record both numbers and percentages if available**

| ***Failures*** | **Incisor** | **Canine** | **Premolar** | **Molar** | **U/S** |
|---|---|---|---|---|---|
| **Amalgam** | | | | | |
| **RBC** | | | | | |

*** U/S:** Unspecified

- **Replacements**

| ***Replacements*** | **Class I** | **Class II 2 Surfaces** | **Class II 3 surfaces** | **Class III** | **Class IV** | **U/S** |
|---|---|---|---|---|---|---|
| **Amalgam** | | | | | | |
| **RBC** | | | | | | |

***Please record both numbers and percentages if available**

| ***Replacements*** | **Incisor** | **Canine** | **Premolar** | **Molar** | **U/S** |
|---|---|---|---|---|---|
| **Amalgam** | | | | | |
| **RBC** | | | | | |

*** U/S:** Unspecified

- **Repairs**

| ***Repairs*** | **Class I** | **Class II 2 Surfaces** | **Class II 3 surfaces** | **Class III** | **Class IV** | **U/S** |
|---|---|---|---|---|---|---|
| **Amalgam** | | | | | | |
| **RBC** | | | | | | |

***Please record both numbers and percentages if available**

| ***Repairs*** | **Incisor** | **Canine** | **Premolar** | **Molar** | **U/S** |
|---|---|---|---|---|---|
| **Amalgam** | | | | | |
| **RBC** | | | | | |

*** U/S:** Unspecified

- **Reasons for Failure**

| | SC | BD | MD | BF | MF | PA | TF | LR | AR | P/S | Endo | ORR |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Amalgam #/%** | | | | | | | | | | | | |
| **RBC #/%** | | | | | | | | | | | | |

**SC,** Secondary Caries**; BD,** Bulk Discolouration**; MD,** Marginal Discolouration**; BF,** Bulk Fracture**; MF,** Marginal Fracture**; PA**, Poor Anatomic Form(includes marginal defect and abrasion/attrition of restoration)**; TF,** Tooth Fracture**; LR,** Lost Restoration; **AR,** Aesthetic Reasons; **P/S,** Pain/Sensitivity**; Endo,** Endodontic reasons**; ORR,** Other Reason

- **Reasons for Replacement**

| | SC | BD | MD | BF | MF | PA | TF | LR | AR | P/S | Endo | ORR |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Amalgam #/%** | | | | | | | | | | | | |
| **RBC #/%** | | | | | | | | | | | | |

- **Reasons for Repair**

| | SC | BD | MD | BF | MF | PA | TF | LR | AR | P/S | Endo | ORR |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Amalgam #/%** | | | | | | | | | | | | |
| **RBC #/%** | | | | | | | | | | | | |

## APPENDIX 5: CLASSIFICATION OF STUDY DESIGNS TO ASSESS THE EFFECTS OF INTERVENTIONS

**Randomised controlled trials**
The simplest form of RCT is known as the parallel group trial which randomises eligible participants to two or more groups, treats according to assignment, and compares the groups with respect to outcomes of interest. Participants are allocated to groups using both randomisation (allocation involves the play of chance) and concealment (ensures that the intervention that will be allocated cannot be known in advance). There are different types of randomised study designs, such as:

**Randomised cross-over trials**
Where all participants receive all the interventions; for example, in a two-arm cross-over trial, one group receives intervention A before intervention B, and the other group receive intervention B before intervention A. It is the sequence of interventions that is randomised.

**Cluster randomised trials**
A cluster randomised trial is a trial where clusters of people rather than single individuals are randomised to different interventions. For example, whole clinics or geographical locations may be randomised to receive particular interventions, rather than individuals.

**Quasi-experimental studies**
The main distinction between randomised and quasi-experimental studies is the way in which participants are allocated to the intervention and control groups; quasi-experimental studies do not use random assignment to create the comparison groups.

**Non-randomised controlled studies**
Individuals are allocated to a concurrent comparison group, using method other than randomisation. The lack of concealed randomised allocation increases the risk of selection bias.

**Before-and-after study**
Comparison of outcomes in study participants before and after the introduction of an intervention. The before-and-after comparisons may be in the same sample of participants or in different samples.

**Interrupted time series**
Interrupted time series designs are multiple observations over time that are ‘interrupted’, usually by an intervention or treatment.

**Observational studies**
A study in which natural variation in interventions or exposure among participants (i.e. not allocated by an investigator) is investigated to explore the effect of the interventions or exposure on health outcomes.
**Cohort study**
A defined group of participants is followed over time and comparison is made between those who did and did not receive an intervention.

**Case-control study**
Groups from the same population with (cases) and without (controls) a specific outcome of interest, are compared to evaluate the association between exposure to an intervention and the outcome.

**Case series**
Description of a number of cases of an intervention and the outcome (without comparison with a control group). These are not comparative studies.

## APPENDIX 6: QUALITY ASSESSMENT FORMS

**Quality assessment for Clinical trials (CTs)** Maximum 10 points

7-10 points: Very good study ☐

4-6 points: Acceptable ☐

0-3 points: Poor ☐

1. **Selection**
   1. **Representativeness of the sample:**
      a. Truly representative of the average in the target population ☐
      b. Somewhat representative of the average in the community ☐
      c. Selected group of users
      d. No description of the derivation of the cohort

   2. **Randomization:**
      a. Randomised and method of randomisation adequate ☐ ☐
      b. Randomised but method of randomisation not adequate ☐
      c. Non-randomised

   3. **Sample size:**
      a. Justified and satisfactory ☐
      b. Not justified and unsatisfactory
      c. No information provided

2. **Follow-up**
   1. **Drop-out rate**
      a. Drop-out rate appropriate in relation to the length of the study ☐ (<5% dropout in restorations per year)
      b. Drop-out rate is high and unacceptable

3. **Assessment of outcome**
   1. **Criteria used:**
      a. USPHS criteria (including modified) ☐
      b. FDI criteria ☐
      c. Not specified or using own criteria

   2. **Examiner training and calibration:**
      a. Two examiners independently trained and calibrated ☐ ☐
      b. One examiner trained and calibrated ☐
      c. No training or calibration
      d. No information provided

   3. **Details of the results:**
      a. Were the results clearly described with details about tooth type, extent of restoration etc. ☐ ☐
      b. Results given but not in details ☐
      c. Difficult to extract data

**Quality assessment for longitudinal Cohort studies (LCSs)** Maximum 8 points

7-8 points: Very good study ☐

3-6 points: Acceptable ☐

0-2 points: Poor ☐

1. **Selection**

   1. **Representativeness of the sample:**
      a. Truly representative of the average in the target population ☐
      b. Somewhat representative of the average in the community ☐
      c. Selected group of users
      d. No description of the derivation of the cohort

   2. **Sample size:**
      a. Justified and satisfactory ☐
      b. Not justified and unsatisfactory
      c. No information provided

2. **Follow-up**

   1. **Drop-out rate**

      a. Drop-out rate appropriate in relation to the length of the study ☐ (<5% dropout in restorations per year)
      b. Drop-out rate is high and unacceptable

3. **Assessment of outcome**

   1. **Criteria used:**
      a. USPHS criteria (including modified) ☐
      b. FDI criteria ☐
      c. Not specified or using own criteria

   2. **Examiner training and calibration:**
      a. Two examiners independently trained and calibrated ☐ ☐
      b. One examiner trained and calibrated ☐
      c. No training or calibration
      d. No information provided

   3. **Details of the results:**
      a. Were the results clearly described with details about tooth type, extent of restoration etc. ☐ ☐
      b. Results given but not in details ☐
      c. Difficult to extract data

**Quality assessment for cross-sectional studies (CSSs)** Maximum 9 points

7-9 points: Very good study ☐
3-6 points: Acceptable ☐
0-2 points: Poor ☐

1. **Selection**
    1. **Representativeness of the sample:**
        a. Truly representative of the average in the target population ☐
        b. Somewhat representative of the average in the community ☐
        c. Selected group of users
        d. No description of the derivation of the cohort

    2. **Sample size:**
        a. Justified and satisfactory ☐
        b. Not justified and unsatisfactory
        c. No information provided

    3. **Response rate:**
        a. Satisfactory (>60%) with established comparability between responders and non-responders ☐ ☐
        b. Satisfactory (>60%) with no comparability between responders and non-responders ☐
        c. Unsatisfactory
        d. No information provided

2. **Assessment of outcome**

    1. **Criteria used:**
        a. Major criteria (including modified) ☐
        b. USPHS criteria (including modified) ☐
        c. FDI criteria ☐
        d. Not specified or using own criteria

    2. **Examiner training and calibration:**
        a. Two examiners independently trained and calibrated ☐ ☐
        b. One examiner trained and calibrated ☐
        c. No training or calibration
        d. No information provided

    3. **Details of the results:**
        a. Were the results clearly described with details about tooth type, extent of restoration etc. ☐ ☐
        b. Results given but not in details ☐
        c. Difficult to extract data

# APPENDIX 7: TABLE OF EXCLUDED STUDIES WITH REASONS

| | Publication | Reason for exclusion |
|---|---|---|
| 1 | (Moncada et al., 2015) | No information about reasons for replacement/repair |
| 2 | (Fernandez et al., 2015) | No information about reasons for replacement/repair |
| 3 | (Ijaimi et al., 2015) | No details in numbers about reasons of failure/replacement |
| 4 | (Gordan et al., 2014) | No data on reasons of repair/replacement according to material or tooth type<br>Tooth coloured restorations included GIC |
| 5 | (Ajayi et al., 2013) | Cannot separate cervical restorations |
| 6 | (Chrysanthakopoulos, 2012) | Cannot separate cervical restorations |
| 7 | (Chrysanthakopoulos, 2011) | Cannot separate cervical restorations |
| 8 | (Sonbul and Birkhed, 2010) | No accurate details in numbers about failures<br>Only looked at recurrent caries |
| 9 | (Chrysanthakopoulos, 2010) | Cannot separate cervical restorations |
| 10 | (Udoye and Okechi, 2009) | Cannot separate cervical or anterior and posterior restorations |
| 11 | (Schirrmeister et al., 2009) | Insufficient information about age of patients |
| 12 | (Parpaiola et al., 2009) | Insufficient information about reasons of replacement |
| 13 | (Bottenberg et al., 2009) | No details in numbers about reasons of failure/replacement |
| 14 | (Rosin et al., 2007) | Insufficient information about dropouts<br>Cannot separate cervical or anterior and posterior restorations |
| 15 | (Loguercio et al., 2006) | No details in numbers about reasons of failure/replacement |
| 16 | (Gallo et al., 2005) | Insufficient information about reasons of failure |
| 17 | (Mahmood et al., 2004) | Insufficient information about reasons of replacement<br>Cannot separate cervical restorations |
| 18 | (Forss and Widström, 2004) | Cannot separate cervical or anterior and posterior restorations |

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|---|---|---|
| **19** | (Geitel et al., 2004) | Insufficient information about reasons of failure |
| **20** | (Van Nieuwenhuysen et al., 2003) | Insufficient information about dropouts Insufficient information about reasons of failure |
| **21** | (Turkun et al., 2003) | Insufficient information in numbers for each type of RBC or reasons of failure |
| **22** | (Palotie and Vehkalahti, 2003) | Cannot separate data for different restorative materials |
| **23** | (Brennan and Spencer, 2003 ) | Cannot get accurate data about restorations in numbers |
| **24** | (Ernst et al., 2003) | Insufficient information about reasons of failure |
| **25** | (Mach et al., 2002) | Insufficient information about age of patients |
| **26** | (Ernst et al., 2002) | Insufficient information about reasons of failure |
| **27** | (Forss and Widström, 2001) | Cannot separate cervical or anterior and posterior restorations |
| **28** | (Ernst et al., 2001) | Insufficient information about reasons of failure |
| **29** | (Busato et al., 2001) | Insufficient information about reasons of replacement |
| **30** | (Smales and Wetherell, 2000) | Insufficient information in numbers for each type of restoration or dropouts |
| **31** | (Mjör et al., 2000) | Cannot separate cervical or anterior and posterior restorations |
| **32** | (McDaniel et al., 2000) | Cannot get accurate data about restorations in numbers |
| **33** | (Manhart et al., 2000) | Insufficient information about age of patients |
| **34** | (Deligeorgi et al., 2000) | Cannot separate cervical or anterior and posterior restorations |
| **35** | (Davidson and Suzuki, 1999) | Cannot get accurate data about dropouts or restorations replaced in numbers |
| **36** | (Setcos et al., 1999) | Insufficient information about age of patients |
| **37** | (Wilder et al., 1999) | Insufficient information about reasons of failure |
| **38** | (Plasmans et al., 1998) | Insufficient information about numbers and reasons of failure/replacement |

| | | |
|---|---|---|
| **39** | (Mair, 1998) | Insufficient information about age or number of patients |
| **40** | (Tobi et al., 1998) | Cannot get accurate data about restorations or reasons for failure in numbers |
| **41** | (Wilson et al., 1997) | Cannot separate cervical or anterior and posterior restorations |
| **42** | (Mjör, 1997a) | Cannot separate cervical or anterior and posterior restorations |
| **43** | (Browning and Dennison, 1996) | Insufficient information about age of patients<br>Cannot separate cervical restoration |
| **44** | (Friedl et al., 1995) | Cannot get accurate data about restorations or reasons for failure in numbers<br>Cannot separate cervical restorations |
| **45** | (Cipriano and Santos, 1995) | No information about reasons for repair |
| **46** | (Widstrom and Forss, 1994) | Cannot separate cervical or anterior and posterior restorations |
| **47** | (Wendt and Leinfelder, 1994) | Insufficient information about age of patients or reasons for restorations failure/replacement |
| **48** | (Pink et al., 1994) | Cannot separate cervical restorations<br>Insufficient information about reasons for replacement in numbers |
| **49** | (Jokstad et al., 1994) | Cannot separate cervical or anterior and posterior restorations |
| **50** | (Foster, 1994) | Cannot separate cervical restorations |
| **51** | (York and Arthur, 1993) | Cannot separate cervical restorations |
| **52** | (van Noort and Davis, 1993) | Cannot separate cervical restorations |
| **53** | (van der Merwe, 1993) | Insufficient information about reasons of failure |
| **54** | (Mjör and Um, 1993) | Cannot separate cervical or anterior and posterior restorations |
| **55** | (Mjör and Toffenetti, 1992a) | Cannot separate cervical or anterior and posterior restorations |
| **56** | (Mjör and Toffenetti, 1992b) | Cannot separate cervical or anterior and posterior restorations |
| **57** | (Smales and Gerke, 1992) | Cannot separate cervical restorations |
| **58** | (Osborne et al., 1991) | Insufficient information about number or reasons of restorations failure |

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|---|---|---|
| **59** | (MacInnis et al., 1991) | Cannot separate cervical or anterior and posterior restorations |
| **60** | (Tyas and Wassenaar, 1991) | Insufficient information about number or reasons of restorations failure |
| **61** | (Qvist et al., 1990b) | Cannot separate cervical or anterior and posterior restorations |
| **62** | (Kroeze et al., 1990) | Cannot separate cervical or anterior and posterior restorations |
| **63** | (Drake et al., 1990) | Insufficient information about reasons of restorations replacement<br>Cannot separate cervical restorations |
| **64** | (Tyas, 1990) | Insufficient information about reasons of restorations failure |
| **65** | (Dietschi and Holz, 1990) | Insufficient information about reasons of restorations failure |
| **66** | (Qvist et al., 1990a) | Cannot separate cervical restorations |
| **67** | (Osborne and Norman, 1990) | Insufficient information about reasons of restorations failure |
| **68** | (Sturdevant et al., 1988) | Insufficient information about age of patients |
| **69** | (Lemmens et al., 1988) | Insufficient information about reasons of restorations failure |
| **70** | (Klausner et al., 1987) | Insufficient information about age of patients |
| **71** | (Qvist et al., 1986a) | Cannot separate cervical restorations |
| **72** | (Qvist et al., 1986b) | Cannot separate cervical or anterior and posterior restorations |
| **73** | (van Dijken, 1986) | Insufficient information about reasons of restorations replacement |
| **74** | (Doglia et al., 1986) | Insufficient information about age of patients |
| **75** | (Klausner and Charbeneau, 1985) | Insufficient information about age of patients |
| **76** | (Rytomaa et al., 1984) | Insufficient information about reasons of restorations replacement |
| **77** | (Osborne and Wolff, 1984) | Insufficient information about reasons of restorations failure |
| **78** | (Letzel and Vrijhoef, 1984 ) | Insufficient information about reasons of restorations failure |

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|---|---|---|
| **79** | (Kelsey et al., 1981) | Insufficient information about reasons of restorations failure |
| **80** | (Dahl and Eriksen, 1978) | Insufficient information about reasons of restorations replacement |
| **81** | (Lavelle, 1976) | Cannot separate cervical restorations |
| **82** | (Leinfelder et al., 1975) | Insufficient information about replacements or failures in restorations |
| **83** | (Allan, 1969) | Insufficient information about replacements or failures in restorations |