

**STATUS OF RESIN BASED COMPOSITE RESTORATIONS, REASON
FOR FAILURE AND ASSOCIATED FACTORS IN ADULT PATIENTS
WHO ATTENDED TERTIARY LEVEL DENTAL CLINICS IN DAR ES
SALAAM.**

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DEPARTMENT OF RESTORATIVE DENTISTRY



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SALAAM.**

By

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**A dissertation submitted in Partial Fulfilment of the Requirements for the Degree of
Masters of Dentistry (Restorative Dentistry) of the Muhimbili University of Health
and Allied Sciences.**

October, 2021

DECLARATION AND COPYRIGHT

I, **Grace Matasha**, declare that this **dissertation** is my own work and It has not been presented and will not be presented to any other University for similar or any degree award.

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CERTIFICATION:

The undersigned certify that they have read and hereby recommended for acceptance the dissertation entitled “**Status of Resin Based Composite restorations, reasons for failure and associated factors in adult patients who attended tertiary level dental clinics in Dar es salaam**” in fulfillment of the requirements for the degree of Masters of Dentistry (Restorative Dentistry) of Muhimbili University of Health and Allied Sciences.

Dr. Irene Kida Minja.

(Supervisor)

Date

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DEDICATION

I dedicate my dissertation to:

*GOD Almighty, my creator, my strong pillar, my source of inspiration, wisdom, knowledge
and understanding.*

My Parents:

My Father, **DR AVELIN T.J. MATASHA.**

My Mother, **THERESIA S. NYAKI.**

My Husband, **ADOLPH W. NDYEABURA.**

My son, **ARTHUR A. NDYEABURA.**

My daughter, **ABIGAIL GRACE (Precious daughter, An angel in Heaven.)**

ABSTRACT

Background: Resin-based composite material has been known as a suitable restorative material for lost hard tooth tissue due to its esthetic tooth-color and compressive strength allowing for posterior and anterior restorations, respectively. In Tanzania, RBC has gained popularity as a restorative material; especially in cosmetic dentistry. However, information about its clinical outcome performance is not retrievable.

Objective: Aim of this study was to assess the status, reasons for failure, and associated factors of resin based composite restorations in adult patients who attended tertiary dental clinics in Dar es Salaam.

Methodology: The study was an analytical cross-sectional study, which was conducted at Muhimbili University of Health and Allied Science and Muhimbili National Hospital (MNH). A systematic random sampling method was used to select the participants. A total of 426 patients participated in this study, conducted from January to May 2021. Information was obtained using a structured questionnaire and clinical examination. All information obtained were coded, entered to a computer, and analyzed using SPSS version 20.0 software. Frequency distribution was used to determine the distribution of different variables. Chi square test was used to test bivariate associations between variables. Multivariate analysis was done using multiple logistic regressions.

Results: A total of 426 adult patients treated from the year 2013 to 2018 participated in this study. More 237 (55.6%) than half of the participants were aged below 40 years, males were 243 (57.0%), and those with college education were 311 (73.0%). About 90.1% of the participants reported dental caries being the reason for RBC restoration, with 53.5% of the patients presenting with a failed RBC restoration. The mean age of the restoration was four years. Clinical elements assessed by the USPHS modified Ryge criteria, showed that majority (27.7%) of the failed restorations were due to marginal discoloration. Defective restorations were more common among those who were 60+ years (66.7%, $p=0.001$), widowers/ widows (64.7%, $p=0.032$), and retired from employment (94.1%, $p=0.003$). Those with a duration of restoration of more than 60 months (70.7%) had failed restorations compared to those with lesser duration, ($p=0.000$). On association between the patients' factors with the status of

RBC, patients with high caries risk and those with bruxism had a higher number of defective restorations, ($p=0.001$ and $p=0.001$, respectively).

Multivariate logistic regression on socio-demographics, showed that participants aged 60+ years and those who were retired had a higher chance of having a defective restoration, (OR=2.18, 95% CI: 1.02-4.66 and OR= 19.657, 95%CI: 2.48 - 155.6, respectively). Also those who had bruxism and those with high caries risk had a higher chance of having a defective restoration, (OR=1.96, 95%; CI: 1.255 - 3.054 and OR=3.06, 95%CI: 1.462 - 6.419, respectively).

Conclusion.

Failure of RBC restorations among examined was substantial. Age of the participants, duration of restorations, high caries risk and bruxism contributed largely on the status of RBC restorations. Routine dental checkups are key for the success of RBC restorations.

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ACRONYMS

| | |
|----------------|---|
| MDENT | Master of Dentistry. |
| MNH | Muhimbili National Hospital. |
| MOHCGEC | Ministry of Health, Community Development, Gender, Elderly, and Children. |
| MUHAS | Muhimbili University of Health and Allied Sciences. |
| ODRM | Oral Disease Risk Management. |
| PS | Polymerization shrinkage. |
| RBC | Resin Based Composite. |
| SPSS | Statistical Package for Social Sciences. |
| UNEP | United Nations Environmental Program. |
| USPHS | United States Public Health Service. |
| WHO | World Health Organization. |

DEFINITIONS OF TERMS.

| | |
|-------------------------------------|--|
| Class I: | Cavity in pits or fissures on the occlusal surfaces of molars and premolars; facial and lingual surfaces of molars; lingual surfaces of maxillary anteriors. |
| Class II: | Cavity on proximal surfaces of premolars and molars. |
| Class III: | Cavity on proximal surfaces of incisors and canines that do not involve the incisal angle. |
| Class IV: | Cavity on proximal surfaces of incisors or canines that involve the incisal angle. |
| Class V: | Cavity on the cervical third of the facial or lingual surfaces of any tooth. |
| Class VI: | Cavity on incisal edges of anterior teeth and cusp tips of posterior teeth (1). |
| Dentrix system software: | Dental practice management software for dental offices, for storage of patient's records, images, and clinical notes. |
| Direct resin based composite | Acrylic based material, to which a high percentage of ceramic reinforcing filler has been added, such as particles of glass or silica coated with a coupling agent to bind them to the matrix. |
| High caries-risk patient | Patient with at least two cavitated or active carious lesions. |
| Jeeva system software: | An information software system that keeps track of the patient's records, clinical notes information, and investigations. |

Low caries-risk patient

Patients with no cavitated or active carious lesions; no incipient occlusal or interproximal lesions; have fewer than four cervical decalcifications or white spot lesions.

Polymerization shrinkage

Phenomena which occurs during polymerization process were semi-solid resin based composite converts to solid, a change in density occurs which causes a reduction in volume. This phenomenon can lead to internal stresses and stresses at the margins of the restoration, over time can lead to marginal leakage and secondary caries.

Secondary caries

Caries is adjacent to an existing restoration.

Tertiary care

A specialized consultative health care, usually for Inpatients and on referral from a primary or secondary health professional, in a facility that has personnel and facilities for advanced medical investigation and treatment.

1.0 INTRODUCTION:

1.1 Background:

In permanent teeth, resin based composite restoration is known to be the most important tooth color filling material. They are complex mixed materials which consist of organic polymerizable matrix, inorganic mainly reinforcing fillers, and a silane coupling agent, which connects the inorganic fillers and the organic matrix. They are known worldwide for their provision of good quality restorations, optimal longevity, and aesthetic appearance, hence preferred by patients. However, in Tanzania the most commonly used and available direct permanent restorative material is dental amalgam, because it is cheap, has a long survival rate, and its long-term familiarity with dentists on its use. Unlike the resin based composite, dental amalgam has disadvantageous properties such as lack of aesthetic appearance and staining of teeth, and lack of chemical bonding with the tooth (2). It may have adverse biological effects, both locally (it can cause an erythematous lesion on the adjacent oral soft tissues) and systematically free mercury in the amalgam may give rise to the hypersensitivity reaction. (2). As per UNEP (United Nations Environmental Program) and WHO report of 2013 80% of restorative materials used in Tanzania is dental amalgam (3). Worldwide, mercury in the soil has been shown to cause environmental pollution; dental amalgam has been shown to contribute 0.2% of mercury emission from poor disposal of mercury and cremation of the dead who had amalgam restorations. The Minamata convention in 2013 resolved to phase down the use of dental amalgam as a restorative material. Further the cessation of use in pregnant women and children was a way of commencing reduction in the use of dental amalgam. This led to more research advocating the use of alternative mercury-free restorative materials.

Resin based composite (RBC) material is reported to be a suitable alternative to amalgam as they are characterized by a high compressive strength relative to most other restorative materials (4). When polymerized, the monomers convert from a liquid phase to a highly cross-linked solid polymer. Polymerization is initiated by chemical or visible light. Typically, the base monomer is a viscous dimethacrylate; bisphenol-a-glycidyl methacrylate (Bis-GMA), or urethane dimethacrylate (UDMA). Other less viscous dimethacrylates such as triethylene glycol

dimethacrylate (TEGDMA), ethyleneglycoldimethacrylate (EGDMA) hydroxyethyl methacrylate (HEMA), or bisphenol-a-dimethacrylate (Bis-DMA) are usually incorporated to reduce the high viscosity. RBC became available to dentistry in the 1960s following the development of the first methacrylate-based polymer system by Bowen in 1962 (5). Effective dentine bonding agents became available at the beginning of the 1990s, and since then, composites have found increasingly broad use as a universal restorative material (6). There have been many advances in RBCs development to improve their clinical success rate and overcome the many disadvantages of the first materials such as poor appearance and poor marginal adaptation. These materials which are cured by visible light, and light-curing units have also undergone considerable development. This, in turn, has resulted in the quest for composite materials that offer improved physical, aesthetic, and handling properties. The advent of tooth whitening or bleaching has also resulted in the need for whiter shades of RBCs (7).

Resin based composite materials have high tensile strength, and have improved characterized adhesive bonding materials allows for minimal invasive dentistry (8). Hence slight changes in the properties of the resin can provide a wider range of uses with the ability to sustain the forces of mastication in posterior restoration, and used multisurface restoration (9).

Paralleled with other posterior tooth-colored restorative materials, such as glass ionomer cement, resin composites are desired by patients as a result of their increased need for aesthetic restoration by the presence of different color shades similar to enamel. Its availability which is more esthetically pleasing has prompted many private practitioners to use them for posterior restorations.

However, resin based composite restorative materials are reported to be expensive and sensitive to dental tissues. If placed directly on open dentinal tubules, RBC can cause pulp hyperemia hence a source of discomfort and pain to patients. The major disadvantage of Resin based composite includes polymerization shrinkage and wear which results in marginal defects and formation of secondary caries on a restored tooth (10). The most common reasons for restoration failure are caries development and fracture of tooth with secondary caries as the main cause of composite restorations failures in high caries risk patients (1). Factors that affect clinical status

of RBCs can be grouped into four: firstly, the patient factors including high caries risk, poor oral hygiene, and oral parafunctional activities; secondly, tooth related factors in terms of the numbers of surfaces and the type of tooth restored (2,3). However, the third and fourth factors i.e. material factor and dental practitioner factors, were not assessed in the current study due to logistical reasons (2,3)

In Tanzania resin based composite has also gained popularity as restorative material particularly in cosmetic dentistry, yet evidence of its functional durability in the oral cavity, the reason for its failure, and the associated factors are not known. “Therefore, this study aimed to assess the clinical performance of resin based composite, the reasons for failure, and associated factors.”

1.2 Problem statement

Resin based composite restoration material being a tooth color restorative material is used for conservation of anterior and posterior teeth in classes I, II, III, IV, and V. It is also used in cosmetic dentistry for veneering, however, post-restoration, patients have reported back to the dental clinic seeking replacement of a previously sound restored resin based composite restoration due to pain, or the discomfort of a dislodged filling.

Clinical examination reveals blackish-grey discoloration of the tooth tissue adjacent to the resin based restored tooth, impaired marginal integrity, appears roughed with evidence of micro leakage of oral fluid. Also, the presence of loose restored filling compared to the cavity holding the restoration, with radiographic evidence of enlargement of the previously prepared cavity, and clinical evidence of presence of secondary caries adjacent to the restoration. Patients often report to the dental clinic with a dislodged filling. Patients have also presented with a yellowish discolored resin based composite restoration, which appears to be of a darker shade compared to the color of the restored tooth, impairing its esthetic property, particularly for anterior teeth.

Failure of restoration may lead to pain/discomfort, wastage of resources, and may ultimately lead to the need for replacement of a restoration, complex treatment e.g. endodontic treatment or loss of tooth through extraction.

Some studies conducted in Europe, compared the status of resin-based composite restorations and other permanent restorations such as amalgam and found that the risk of secondary caries was significantly higher for resin based composite (11). Levin and colleagues in Norway evaluated bitewing radiographs of interproximal restorations of resin based composite and found the failure rate as a result of secondary caries to be 43% (12).

In Tanzania, there are no studies that have assessed the status of RBC tooth filling material and the causes of failure. Furthermore, data on the number of years of a functional RBC restoration in the oral cavity **and what factors need to be rectified to increase its duration of function in the oral cavity** could not be retrieved.

1.3 Rationale of the study

The number of patients presenting in the restorative clinic for tooth restoration using Resin based composite materials as permanent restoration has increased in recent years, probably after the Minamata convention of phasing down of Dental Amalgam. Also, both dental practitioners and dental patients have shown more interest in using the RBC material due to its aesthetic property. This study will enlighten dental practitioners and patients on the status of RBC materials placed on a tooth after two years or more. The study will also provide information on the reason for RBC failure and factors that are associated with the failure of RBC. This information has not been reported before in the Tanzanian setting. Furthermore, information obtained will provide data that will lead to more research on RBC restorative materials in Tanzania.

1.4 Research questions

1. What proportion of provided composite restorations develops defects after two years?
2. What are the commonly observed defects on composite restoration which have been placed for more than two years?
3. What are patient factors and tooth related factors which are associated with the failure of direct resin-based composite filling material among adult patients who attended tertiary dental clinics in Dar es Salaam?

1.5 STUDY OBJECTIVES

Broad objectives:

To assess the status of resin based composite, reasons for failure, and associated factors in adult patients who attended tertiary dental clinics in Dar es Salaam

Specific objectives

1. To determine the status of direct resin-based composite filling material in adult patients who attended tertiary dental clinics.
2. To assess the reasons for the failure of direct resin-based composite filling material in adult patients who attended tertiary dental clinics.
3. To assess the influence of patient factors and tooth related factors in the failure of direct resin based composite filling material among adult patients who attended tertiary dental clinics.

1.6 Conceptual framework

This is a conceptual framework to assess the status of Resin based composite, where factors including patient's factors, material factors, tooth-related factors, and dental practitioner factor might bring about the success of RBC restorations. However, in this study we assessed patient factors and tooth related factors.

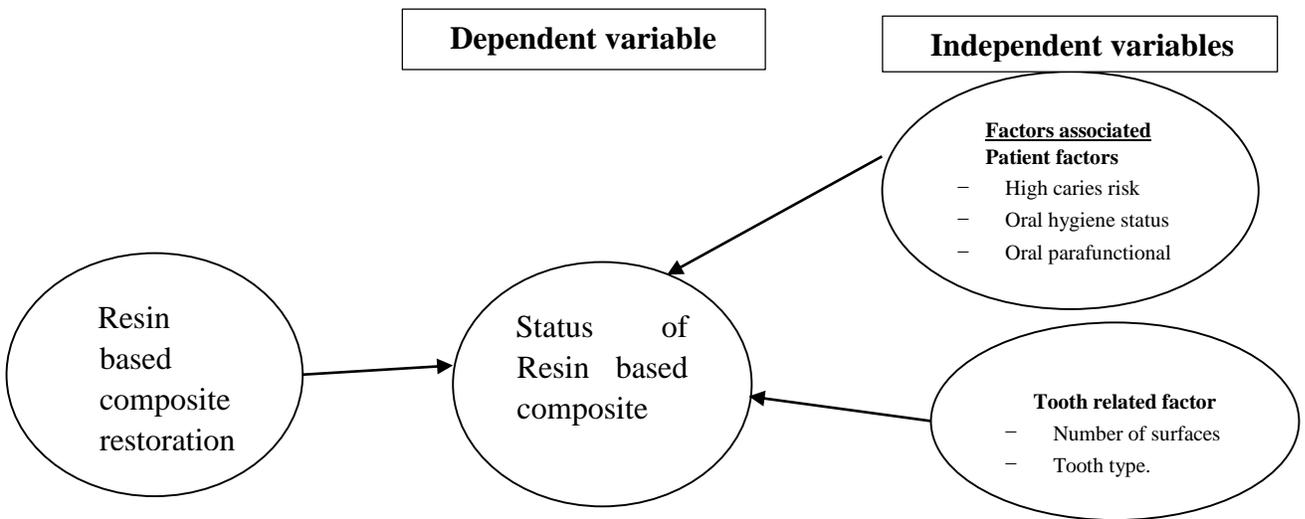


Figure 1:Conceptual framework, Source: Matasha, 2020.

The status of resin-based composite as a dependent variable can be affected by different factors (independent variables) that can be grouped into four: **firstly**, the status of a resin based composite can be influenced by **patient factors** including high caries risk patient, poor oral hygiene, and oral parafunctional activities. Secondly, **tooth-related factors** in terms of the numbers of surfaces restored, and the type of tooth.

2.0 LITERATURE REVIEW

The status of resin based composite, reasons for failure, and associated factors have been studied by many authors in the world where findings on

The status of direct resin-based composite filling material

Several studies that have been conducted including in the United Kingdom show that a good clinical success and longevity of the direct RBCs in posterior teeth have been reported to be above 90% for 2 to 5 years (13,14), and over 70% at 10 years (14,15). A study in the USA at the University of Manitoba clinic restorations on patients aged from 13 to 102 years, with a mean age of 52 years during the time of treatment had a failure of 7.9% for composite resin fillings, long-term failures (greater than 2 years) included 77 (4.5%) RBC restorations (9). The survival probability was 12 years with 86% for composite resin. Most research studies approach a zero failure rate in the first year of the study for direct RBC restorations (16–18), however, a study done by Manhart et al. reported a mean annual failure rate of 2.2% for direct posterior resin composites (19). Other clinical studies show increasing evidence for the successful long-term performance (10+ years) of dental composite small to moderate sized restorations (20–22). A 17-year study of four UV-cured conventional composites reported excellent outcomes, (23). Another 17 years, and a 22-year study of two visible light-cured hybrid composites placed in class I and II cavities under rubber dam showed overall success rates of 75% and 64%, respectively (24,25). In South Africa 90% of composite resins were found to have a survival rate of over 10 years (26).

There are no studies available in Tanzania assessing the status of resin based composite, the reason for failure, and associated factors.

Reasons for failure of direct resin-based composite filling material.

In a study conducted in USA, the integrity of posterior composite restorations has been reported to be compromised as a result of secondary caries and marginal leakage due to polymerization shrinkage (27). So it is important for the resin based composite fillings to have good mechanical and physical properties and improved handling to increase their success rate. A study of similar

design demonstrated a 2.9% annual failure for resin composite restorations, after 6 years' observation (28).

In the USA at the University of Manitoba student clinic, the main reasons for impaired integrity of composite resin restoration was recurrent caries accounting for 27.6% (29). The other leading reasons for RBC impaired integrity included tooth fracture (15.7%), missing/fallen out (14.2%), and pain/ sensitivity (9.7%). Other reasons included failed/defective (the reason for failure not specified by the student), fracture of restoration, void, open contact, leakage, loose, over contoured margin, and overhangs.

A study that was done in Tanzania reported 8.3% clinically and 10.5% radiographically diagnosed secondary caries was the reason for replacement of restorations (30). However, these findings are relatively lower compared to another study done by Wilson et al (2005) which showed that more than 50% of replacements of RBC are due to secondary caries.

Factors associated with the failure of direct resin-based composite filling material.

In a study conducted in USA large composite restorations showed annual failure rates of 1%. In high caries risk patients, there was a tendency for more failures of the posterior resin composites, significantly for smaller restorations, and annual failure increased to more than 3% (31). Similar findings were obtained in England, two clinical trials comparing restorations of dental resin composites placed in the management of primary caries in children (32).

A study conducted in the U.S navy determined that the need for RBC restorations replacement were the presence of acute or chronic symptoms and restoration defects (such as fractures, overhangs, open margins), fractures of remaining tooth structure and/or recurrent caries that, in the examiner's judgment, are likely to cause symptoms or tissue damage within 12 months (11). In Norway, secondary caries was the most common reason for replacement, it indicates that poor oral hygiene is a risk predictor for the development of secondary caries (28).

A study that was done in the USA revealed that within a group of more than 300,000 patients with restorations placed during 1993–1999, the probability of survival of posterior resin composites was 93% over five years if the patient was followed up by the same dentist (33).

When patients changed dentists, the probability of survival of resin composite over the five years dropped to 60%. One study found the same results in restorations placed by U.S. dental students where the greater failure rates of composite resin restorations were attributed to several factors involving the dental students' technique (34).

These include improper tooth preparation, saliva contamination, excessive etching of dentin, failure to adequately polymerize the bonding agent, improper positioning of polymerization light, and not properly sealing cavity margins.

Moisture control, poor moisture control in an oral environment makes the resin based composite prone to early failure. Good moisture control is essential during the placement of resin composites to avoid, in particular, failure of adhesive bonding. The use of an effective rubber dam is ideal.

The number of tooth surfaces restored at baseline helped predict subsequent restoration failure; a study done in the USA, showed that restorations with higher restored surfaces were more likely to fail compared to single surface restorations. Restorative material was not associated significantly with longevity; neither was tooth type, where older patient age was highly associated with failure ($P < 0.001$) (35). Another study done in the USA showed that regardless of the tooth type (pre-molar or molar), Class II RBC restorations most frequently fail by marginal leakage (36).

A study conducted in the USA to assess wear of RBC restoration in vitro found that wear is a particularly difficult characteristic to assess clinically. It may be produced in a variety of ways and is very dependent upon the oral conditions, but generally must be of a significant amount to be recognizable. The methods could not quantify the wear of an entire surface, and are typically confined to semi-quantitative assessments at the margins, when the bulk of wear may be occurring elsewhere on the restoration (37).

Hardness, depth of cure, and interfacial gap formation is a function of the energy dose of LED (light emitting diode). A study done in Brazil showed that higher energy dose produces a slight increase in hardness for the resin based composite, but it also increases the internal gap

formation due to polymerization shrinkage (38). Besides, gap formation seems to be a consequence of an underperformed bonding approach rather than the differences in the resin composite formulation. Another study conducted in South Africa showed that polymerization shrinkage of resin based composites generates a degree of stress at the tooth/restoration interface (39). The magnitude of the stresses so produced depends on resin composite composition and its ability to flow before solidification, concluding that PS has negative effects of post-operative sensitivity on the resin composite/tooth interface.

A study conducted in Nigeria showed a post-operative sensitivity right from the time of placement of restoration (40). Both were class II molar restorations, related to the dentine adhesives ability to seal up open dentinal tubules rather than to the effects of polymerization shrinkage. The study also found that reduction in marginal discoloration, recurrent caries, and post-operative sensitivity improves the longevity and success rate of RBC. This compared to other studies that had the lowest failure of RBC, whereby at the end of the one-year study there was neither radiographic nor clinical evidence of secondary caries. Failure was due to bulk fracture at 6month post-restoration, indicating clinical safety of the restorative material. One failed restoration due to secondary caries was detected after 24 months in this study.

There is no data found in Tanzania which is assessing the factors associated with RBC; hence this study was conducted to assess the status of RBC restoration, reasons for failure, and associated factors.

3.0 MATERIALS AND METHODS

3.1 Study design.

This was an analytical cross-sectional study.

3.2 Study area (setting).

This study was conducted at the Muhimbili University of Health and Allied Science (MUHAS) School of Dentistry-restorative department, and the Muhimbili National Hospital (MNH), restorative department, in Dar es Salaam.

These are a tertiary-level dental clinics in the hierarchy of health services. These dental clinics comprise of staff ranging from dental specialists, residents, registrars, intern dentists, to undergraduate students pursuing a doctor of dental surgery degree.

3.3 Study population and participants:

The study population included patients aged 18 years and above who had attended MUHAS and MNH restorative dental clinics and received a direct resin based composite (RBC) restoration materials which had a duration of two years and above. A minimum of two years' duration was given for appropriate assessment of the status of RBC in the oral environment since a short follow up could overestimate the clinical effectiveness/success of RBC restorations. This study was conducted for a period of five months, from January to May 2021.

3.4 Sample size and sampling method

The sample size was calculated using the formula; N

$$= \frac{z^2 p (100-p)}{e^2}$$

Whereby: n = sample size (n=n/1-0.1)

Z = standard normal deviation which is 1.96 at 95% confidence level

P = 50% (since there was no retrievable study like this in Tanzania)

E = maximum error accepted, set at 5%

Therefore, n = $\frac{1.96^2 \times 50 (100 - 50)}{5^2}$

52

N = 384 adding 10% of estimated sample size =426

The estimated sample size for this study was **426** patients.

3.5 Sampling technique.

MUHAS and MNH restorative clinics were purposely selected due to the high number of patients, of different social demographic characteristics representative sample. Taking into consideration the proportion to size, sample frame that was obtained from MNH JEEVA system was 6917 and MUHAS DENTRIX system was 2700 hence study participants from MNH and MUHAS were 69.1% and 30.9%. Systematic random sampling was used to select the participants from Dentrix at MUHAS restorative dental clinic and JEEVA database from MNH dental clinic who have had a resin based composite restorations done from the year 2013 to 2018.

These patients were listed from January 2013 to December 2018, the total numbers obtained was divided by the sample size of 426 to obtain the K value which was every 5th patient.

The first patient was randomly selected by writing down in a pieces of paper the first ten patients and random select the first participant.

3.6 Inclusion criteria

Patients aged 18 years and above.

Both single and multi surfaces direct resin based composite restorations on the anterior and posterior teeth.

3.7 Exclusion criteria

Patients with a mental disability.

Patients with fixed orthodontic appliances.

3.8 Data collection:

Secondary data on patient's name, contacts, date of restoration of RBC filling materials from the year 2013 to 2018 were retrieved from the procedure registration book, DENTRIX system, and at MUHAS and JEEVA system at MNH. The recalled patients were contacted via a telephone communication protocol (**Appendix 5**). Phone calls were conducted during the weekdays from 900 to 1300hrs, whereby the participants were explained on the purpose of the study and were given an appointment to attend the clinic for an interview and clinical examination. The participants who did not pick up the phone call for the first time were called back for the second time after two days. The participants who did not respond at the second and the third time were categorized as non-respondents. Both the investigator and the participant determined the date and time for the examination, considering some participants were at work during the weekdays, the weekends were allocated for their convenience. The recalled participants were interviewed and examined and given a feedback on their oral health status. Those who were found to have oral problems, were referred for treatment accordingly.

Tool for data collection.

Two data collection instruments were used.

The first instrument was a **detailed structured questionnaire**, on recalled selected participants at the dental clinic. It had closed-ended questions with few items left open to allow more elaboration. (**Appendix 5a**). The interview form was written in English, translated into Swahili, and back to English to check discrepancy in meaning when in Swahili.

The questionnaire consisted of questions on socio-demographic items including age, sex, level of education, employment status, and marital status.

The questionnaire also consisted of questions on the restoration including the reason for restoration were measured using dichotomized question whether its dental caries, dental trauma or other which required specification. If the participant experienced a post op sensitivity after RBC restoration with a yes and no response. The duration of RBC restoration was dichotomized in months from 25-36 months, 37-48 months, 49-60 months, and above 60 months. Whether the patient has ever replaced the RBC restoration with a yes or no response. For the participants who responded yes to replacement of the restoration, a reason was required which were dichotomized to secondary caries, change in color of the restoration, dislodging of the restoration, fracture of the tooth, other which needed a specification from the participant.

The parafunctional habit (bruxism) was questioned with a yes and no response.

Clinical examination to assess the success of resin based composite restoration:

Clinical examination was conducted by the principal investigator (Dr Grace Matasha) after being calibrated by more experienced clinician (Dr Godbless Mandari). A trained recorder entered information on clinical examination form. The examination was done with the subject seating on a dental chair, using both overhead light was used to assess the surface of both the surface/tooth and natural light as the source of illumination to assess the status of RBC restoration. A mouth mirror, an explorer, twizzer, and gauze (2X2 cm) was used to examine the oral cavity, teeth and restorations by visual, inspection, and probing.

The clinical examination form had two parts.

Part 1: The dentition status and oral hygiene assessment criteria (Mucosal plaque score)

Clinical examination records form (Appendix 6) recorded

Dentition status which assessed by (1=sound, 2=decayed, 3=missing, 4=filled) and surface restored.

Oral hygiene assessment criteria assessed Oral plaque score (PS) and Mucosa score (MS).

Oral plaque score was assessed by 1=No easily visible plaque, 2=Small amounts of hardly visible, 3=Moderate amounts of plaque, 4=Abundant amounts of confluent.

Mucosa score (MS) was assessed by 1=Normal appearance of gingiva, 2=Mild inflammation and oral mucosa, 3=Moderate inflammation marked redness and hypertrophy/hyperplasia of the gingiva, 4=Severe inflammation severe redness and hypertrophy.

The Mucosal Plaque Score (MPS) was the sum of Plaque score and Mucosal, whereby:

2 – 4 Denotes good oral hygiene.

5 – 6 Denotes fair oral hygiene.

7 – 8 Denotes poor oral hygiene.

Part II: Clinical examination to assess the status of resin based composite restoration

The United State Public Health Services (Appendix 2a) was a tool that used to assess the clinical status of restoration materials, A USPHS modified Ryge 1980 criteria (41) (Appendix 2b) was used to suit the objectives of this study to assess the status of resin based composite restorations and reasons for failure. It assessed eight clinical elements which were the investigator examined and score each resin based composite restorative assessing surface texture clinically ranking 1=acceptable (surface of restoration is smooth), 2= fair (slightly rough, pitted correctable), 3= unacceptable (deeply pitted, can't be corrected)), color mismatch ranking 1=excellent (no mismatch), 2= fair (minimal mismatch), 3= unacceptable (aesthetically unacceptable color/shade). Each of the element has a score ranking 1 to scores 3, 1 was categorized as

acceptable restoration, 2 and 3 as unacceptable i.e. (anatomical contours, contact points, gingival marginal contours, marginal discoloration, fracture restoration/teeth and secondary caries) (Appendix 2b) gives the summary of each element their clinical rankings.

Pre-testing of data collection tools

The questionnaire and clinical form tools were pre-tested among 20 patients who were included in a pilot study that was conducted at MUHAS restorative clinic. **The aim of pre-testing was to check validity of the tools (applicability of the tools with the study, and whether the questions in the tools are clear and understood by participants).** Test- retest for a questionnaire and clinical examination form could not be performed due to ethical issues, as all participants were provided with health education and those who were found with a defective Resin based restoration were immediately schedule for treatment.

3.9 Variables:

The dependent variable in this study was the status of the restored tooth, where a successful sound resin based composite restorations had a smooth surface, no mismatch, continuous with existing anatomical form, had functional contact point restored, no overhang, no marginal discoloration, no fracture of restoration/tooth, and no evidence of secondary caries.

A defective RBC restoration had a rough surface, or color mismatch, or did not have a continuity with the existing anatomical form, or did not have a functional contact point, or had an overhang, or had marginal discoloration, or had a fracture of either restoration or tooth/ both, or had evidence of secondary caries.

Independent variables included *patient factors* included high-risk caries patients (patients with more than two active dental caries), the oral hygiene status and oral parafunctional activities such as bruxism which can affect the status of RBC restorative material by causing surface roughness, crack wear, and fracture, or formation of secondary caries on the restored tooth.

Tooth related factors, included the number of surfaces restored on the tooth, and the tooth type, and the location of the restoration.

3.10 Data management and analysis.

Quality check was done at the end of every patient examination to ensure that the information obtained was properly recorded. All the gathered data were entered into a computer using Statistical Package for Social Sciences (SPSS, version 20.0). Before data analysis in line with each specific objective, some information was transformed by the use of “counts” and “recoding” to suit data handling. The characteristics of variables were described using frequency distribution for categorical variables and continuous variables; the mean and standard deviation were applied. Pearson Chi-square test was used to compare proportions, logistic regression was used to assess the strength of association between associated factors and status of Resin based composite.

The level of statistical significance was set at $p < 0.05$.

3.11 Ethical issues.

Ethical clearance for this study was obtained from the Muhimbili University of Health and Allied Science - research ethical committee (MUHAS-REC). Permission to collect data at MUHAS and MNH restorative clinics was obtained from relevant authorities. Participants were provided with information about the aims, possible risks, and benefits of the study. Participants were informed that they had a right to participate or refuse to participate in the study and that they could withdraw from participation at any stage of the study. Informed consent were signed by each participant before their participation into the study. The participants were ensured of confidentiality and strict usage of the results for the intended purpose only.

4.0 RESULTS:

A total of 426 adult patients, from MUHAS 209 (49%) and MNH 217 (51%) from year 2013 to 2018 participated in this study. Majority 237 (55.6%) of the participants were aged below 40 years. Distribution of the participants by sex showed a slight male dominance of 57.0%. Over two thirds (73.0%) of the participants had a college education and above. Those who were married were 64.3%, while widowers were only 4.0%. More than two thirds (68.3%) of the participants were employed.

Table 1: Social demographic characteristics of participants (n=426)

| Variable | Frequency | Percentage (%) |
|--------------------------|------------------|-----------------------|
| Age <40 | | |
| | 237 | 55.6 |
| 40-59 | 144 | 33.8 |
| 60+ | 45 | 10.6 |
| Department | | |
| MUHAS | 209 | 49.0 |
| MNH | 217 | 51.0 |
| Sex | | |
| Male | 243 | 57.0 |
| Female | 183 | 43.0 |
| Education | | |
| ≤Secondary education | 115 | 27.0 |
| ≥ Diploma education | 311 | 73.0 |
| Marital status | | |
| Not married | 135 | 31.7 |
| Married | 274 | 64.3 |
| Widower/widow | 17 | 4.0 |
| Employment status | | |
| Student | 78 | 18.3 |
| Unemployed | 40 | 9.4 |
| Retired | 17 | 4.0 |
| Employed | 291 | 68.3 |

Majority (90.1%) of the participants reported dental caries being the reason for restoration. Majority (43.2%) of participants had a restoration ranging from 25 to 36 months. Only 5.2% reported to have experienced sensitivity post restoration. 16.7% of the participants responded to dislodged filling being the reason for replacement of a previous restoration.

Table 2: Frequency distribution of different variables. (n=426)

| Variable | Frequency | Percentage (%) |
|---|------------------|-----------------------|
| Reason for restoration Dental | | |
| caries | 384 | 90.1 |
| Others | 42 | 9.9 |
| Duration of restoration 25- | | |
| 36 months | 184 | 43.2 |
| 37-48 months | 90 | 21.1 |
| 49-60 months | 70 | 16.4 |
| More than 60 months. | 82 | 19.2 |
| Post operation sensitivity after restoration | | |
| Yes | 22 | 5.2 |
| Replaced the previous RBC restoration | | |
| Yes | 93 | 21.8 |
| Reason for RBC restoration replacement | | |
| Dislodged filling | 71 | 16.7 |

SPECIFIC VARIABLES

Patient associated factors

Patients who had high caries risk were only 10.6%, and those who responded yes to bruxism were 28.6%. A mucosa plaque score assessed the oral hygiene status in this study. All (100%) of the participants in this study had a good acceptable mucosal plaque score, i.e. with none to small visible plaque and normal appearance of gingiva. Multisurface restorations were higher for both anterior and posterior restored teeth which were 75.3% and 61.8%. Majority of Resin based composite restorations were done on posterior teeth which was 76.8%.

Table 3: Frequency distribution associated factors associated with status of Resin Based

| Variable | Frequency | Percentage (%) |
|--|------------------|-----------------------|
| Caries risk patients | | |
| Low | 381 | 89.4 |
| High | 45 | 10.6 |
| Parafunctional habits (bruxism) | | |
| Yes | 122 | 28.6 |
| Number of surface restored | | |
| Anterior teeth | | |
| Single surface | 39 | 24.7 |
| Multi surfaces | 119 | 75.3 |
| Posterior teeth | | |
| Single surface | 123 | 38.2 |
| Multi surfaces | 199 | 61.8 |
| Type of tooth | | |
| Posterior teeth (filled) | 327 | 76.8 |
| Anterior teeth (filled) | 160 | 37.6 |

Restorative status:

All the RBC restorations were assessed using USPHS modified Ryge 1980 criteria those with code 1 in all the eight elements of clinical features were categorized as normal (not defective), those with code 2 and above in a single or all elements of clinical features were categorized as defective. The prevalence of failed RBC in this study is 53.5%. i.e. 53.5% of patients had a failed RBC restoration.

Table 4: frequency of distribution of status of Resin based composite restoration.

| Variable | Frequency | Percentage (%) |
|-----------------|------------------|-----------------------|
| Normal | 198 | 46.5 |
| Defective | 228 | 53.5 |

Reason for failure of RBC restoration.

Of the eight clinical elements assessed by the USPHS modified Ryge criteria, majority of the patients with defective restorations were found with marginal discoloration as a reason for failure which was 27.7%.

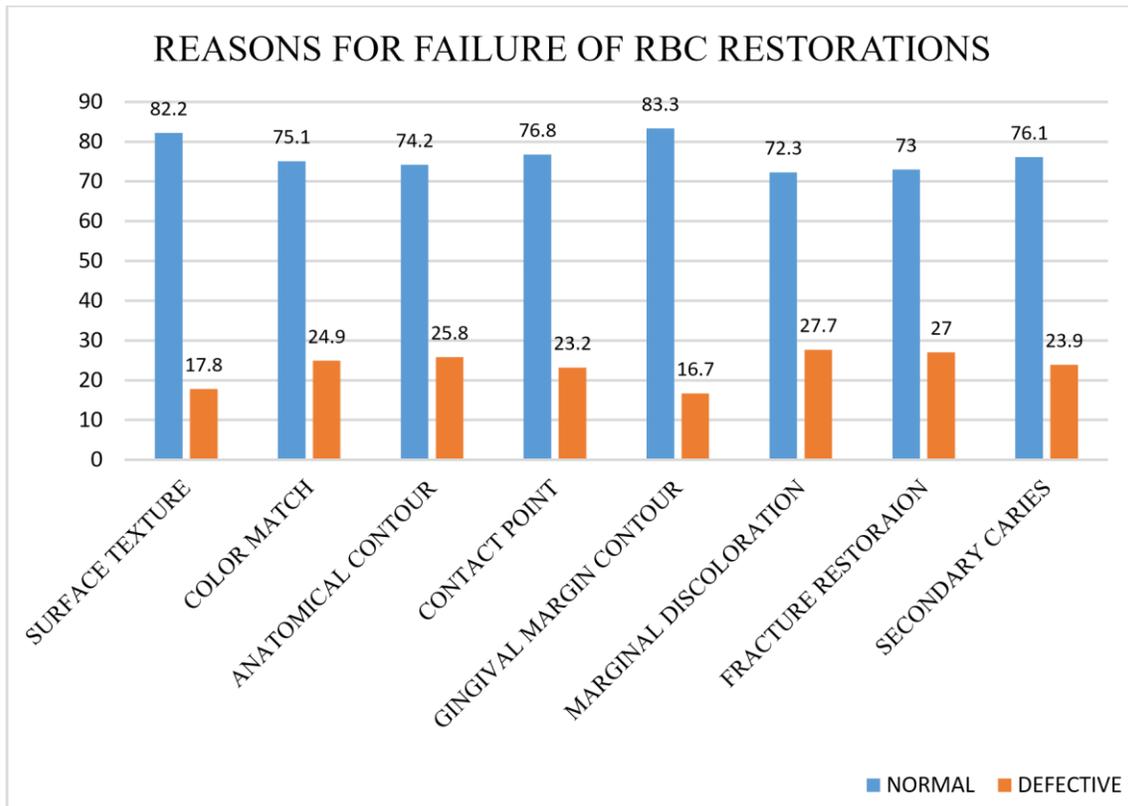


Figure 2: Bar chart showing reasons for failure of RBC based composite restoration in percentage.

Social demographic factors associated with Status of RBC

The number of defective restorations increased with the age of participant. Those whose age ranged from 40 to 59 had 62.5% defective restorations, those whose age was 60+ had 66.7% of defective restorations, (p value was 0.001). On marital status, widowers/ widows had a higher (64.7%), number of defective restoration followed by those who were married by 57.3%, (p value was 0.032). On employment status those who were retired had 94.1% of defective restorations, followed by those who were employed by 54.0%. (p value was 0.003). The longer the duration of restoration the higher the defective restoration. Those with a duration of restoration of more than 60 months had 70.7% defective restorations, those with restorations with a duration of 49 to 60 months had 68.6% defective restorations, and those whose restoration had a duration of 37 to 48 months had 50.0% defective restorations. (p value was 0.000).

Table 5: Chi square statistics of social demographic characteristics and Status of RBC

| Variable | Normal restoration (%) | Defective restoration (%) | X² | P-Value |
|-------------------------------|-------------------------------|----------------------------------|----------------------|----------------|
| Age | | | | |
| <40 | 129 (54.4%) | 108 (45.6%) | 13.9 | 0.001 |
| 40-59 | 54 (37.5%) | 90 (62.5%) | | |
| 60+ | 15 (33.3%) | 30 (66.7%) | | |
| Sex | | | | |
| Male | 107 (44.0%) | 136 (56.0%) | 1.36 | 0.243 |
| Female | 91 (49.7%) | 92 (50.3%) | | |
| Education | | | | |
| ≤Secondary education | 56 (48.7%) | 59 (51.3%) | 0.31 | 0.58 |
| ≥ Diploma education | 142 (45.7%) | 169 (54.3%) | | |
| Marital status | | | | |
| Not married | 75 (55.6%) | 60 (44.4%) | 6.89 | 0.032 |
| Married | 117 (42.7%) | 157 (57.3%) | | |
| Widower/widow | 6 (35.3%) | 11 (64.7%) | | |
| Employment status | | | | |
| Student | 43 (55.1%) | 35 (44.9%) | | |
| Unemployed | 20 (50.0%) | 20 (50.0%) | 13.8 | 0.003 |
| Retired | 1 (5.9%) | 16 (94.1%) | | |
| Employed | 134 (46.0%) | 157 (54.0%) | | |
| Reason for restoration | | | | |
| Dental caries | 176 (45.8%) | 208 (54.2%) | 0.67 | 0.716 |
| Dental trauma | 19 (52.8%) | 17 (47.2%) | | |
| Others | 3 (50.0%) | 3 (50.0%) | | |

| Duration of restoration | | | | |
|--------------------------------|-------------|------------|-------|-------|
| 25-36 months | 107 (58.2%) | 77 (41.8%) | 26.67 | 0.000 |
| 37-48 months | 45 (50.0%) | 45 (50.0%) | | |
| 49-60 months | 22 (31.4%) | 48 (68.6%) | | |
| More than 60 months. | 24 (29.3%) | 58 (70.7%) | | |

| Post-operative sensitivity | | | | |
|-----------------------------------|-----------|------------|------|------|
| yes | 9 (40.9%) | 13 (59.1%) | 0.59 | 0.66 |

* - Statistical Significant P-value <0.05

Clinical factors associated with status of RBC restoration.

On association between the patient's factors with the status of Resin based composite, patients with high caries risk had a higher (77.8%), number of defective restoration (p value 0.001). Patients who had responded yes to bruxism had a higher number of defective RBC restorations 66.4%, P value 0.001. Oral hygiene status had no impact on the status of RBC restoration since all participants were found to have a good acceptable oral hygiene. On tooth related factors, which are number of surfaces restored, and type of tooth restored, they had no influence on the status of RBC restoration in this study. All factors showed no statistically significant difference.

Table 6: Chi square statistics of factors associated with status of RBC restoration.

| Variable | Normal restoration (%) | Defective restoration (%) | X ² | P-Value |
|-----------------------------------|------------------------|---------------------------|----------------|---------|
| caries risk patients | | | | |
| Low | 188 (49.3%) | 193 (50.7%) | 11.901 | 0.001 |
| High | 10 (22.2%) | 35 (77.8%) | | |
| Parafunctional habits | | | | |
| (bruxism) | 157 (51.6%) | 147 (48.4%) | 11.387 | 0.001 |
| No | | | | |
| Yes | 41 (33.6%) | 81 (66.4%) | | |
| Number of surface restored | | | | |
| Anterior teeth | 18 (46.2%) | 21 (53.8%) | 0.205 | 0.651 |
| Single surface | | | | |
| Multi surfaces | 50 (42.0%) | 69 (58.0%) | | |
| Posterior teeth | | | | |
| Single surface | 64 (52.0%) | 59 (48.0%) | 3.595 | 0.058 |
| Multi surfaces | 82 (41.2%) | 117 (58.8%) | | |

* - Statistical Significant P-value <0.05

The relationship of social demographic characteristics that influence the status of Resin based composite is shown in Table 5. Logistic regression analysis sociographic factors on status of RBC showed that age, marital status, employment status, and duration of restoration had statistically significance with the status of RBC restoration $p < 0.05$. **Table 7:** Multivariate logistic regression showed that participants aged 40 to 59 years of age (OR=1.83, 95%CI: 1.12-2.98), and those aged above 60 years (OR=2.18, 95% CI: 1.02-4.66) had higher chance of having a defective restoration, than younger participants age less than 40 years. Multivariate logistic regression of employment status and status of restoration, showed that those who were retired had a higher chance of having a defective restoration (OR= 19.657, 95%CI: 2.48 - 155.6).

Table 7: Logistic regression on social demographic characteristics and status of RBC restoration (adjusted odds ratio and 95% confidence interval)

| Variable | Defective restoration (%) | OR | 95% CI | P value |
|--------------------------|----------------------------------|-----------|---------------|----------------|
| Age | | | | |
| <40 | 108 (45.6%) | 1 | | |
| 40-59 | 90 (62.5%) | 1.83 | 1.1-2.98 | 0.015 |
| 60+ | 30 (66.7%) | 2.181 | 1.02-4.66 | 0.044 |
| Marital status | | | | |
| Not married | 75 (55.6%) | 1 | | |
| Married | 117 (42.7%) | 1.18 | 0.73-1.92 | 0.496 |
| Widower/widow | 6 (35.3%) | 1.20 | 0.368-3.91 | 0.761 |
| Employment status | | | | |
| Student | 43 (55.1%) | 1 | | |
| Unemployed | 20 (50.0%) | 1.229 | 0.572- 2.637 | 0.597 |
| Retired | 1 (5.9%) | 19.657 | 2.483 - 155.6 | 0.005 |
| Employed | 134 (46.0%) | 1.439 | 0.871 - 2.379 | 0.155 |

The relationship of clinical factors and the status of Resin based composite is shown in Table 6. Multivariate logistic regression showed that a participant who had bruxism had a higher chance of having a defective restoration, (OR=1.96, 95% CI: 1.255 - 3.054) than those who did not report bruxism. Furthermore, those who had high caries risk had a higher chance of having a defective restoration, (OR=3.06, 95%CI: 1.462 - 6.419) than their counterparts with low caries risk.

Table 8: Logistic regression analysis on clinical factors and status of RBC restoration

| Variable | Defective restoration (%) | OR | 95% CI | P value |
|--|----------------------------------|-----------|---------------|----------------|
| Parafunctional habits (bruxism) | | | | |
| Yes | 81 (66.4%) | 1.957 | 1.255 - 3.054 | 0.003 |
| Caries risk patients High | | | | |
| High | 35 (77.8%) | 3.063 | 1.462 - 6.419 | 0.003 |

5.0 DISCUSSION:

Methodological issues

The study assessed "status of resin-based composite restorations, reasons for failure and associated factors in adult patients who attended the tertiary dental clinics in Dar es Salaam" in a period of 5 years from year 2013 to 2018.

This study was an analytical cross-sectional type of study, which included an interview using a structured questionnaire and clinical examination form assessing the tooth status, oral hygiene status and status of resin-based composite restorations using USPHS modified Ryge criteria (41). Nevertheless, it is a fact that cross-sectional studies fail to ascertain the cause and effect relationship, they are cost effective and moreover, interview questionnaire has been criticized as being liable to recall bias (42). Despite the latter, structured interviews are useful, as they allow data to be collected from large samples and at a short period of time. The status of resin based composite restorations can be affected by the patients' factors, tooth related factors, the dental material factors and practitioners' factors. This study will give an insight of the status of the RBC restorations which were done in a period of 5 years, and it's a doorway to other new studies on Resin-based composite restoration materials.

Social demographic data

This study had 426 participants, slightly more than half (55.6%) were aged below 40 years. These findings are similar to findings from study done in Norway which found younger aged client preferred tooth color materials, where majority had RBC restorations (46). Also studies done in Israel, Kuwait, United Kingdom and North America suggesting that there is a trend of majority of young dentist who are less than 40 years to prefer RBC restoration, as a result of teaching of posterior resin composites in dental schools hence likely practical application of newer schools of thought in the field of restorative dentistry (43–45). Distribution of the participants by sex showed a slight male dominance of (57.0%), similar to the findings reported by Malhotra N et al in Pretoria, (47). Two thirds of the participants in this study had a college education and above, were employed, with male dominance. This can be explained by the fact

that, current situation in Tanzania only 25 to 30 percent of females have participated in higher learning education (48).

Status of Resin based Composite restorations

All the RBC restorations were assessed using USPHS modified Ryge 1980 criteria. Those with code 0 in all the eight elements of clinical features were categorized as normal (not defective), those with code 1 and above in a single or all elements of clinical features were categorized as defective. In this study 53.5% of patients had failed restored RBC which had a duration 2 years to 5 years. Restoration success is established by the ability of a restoration to perform as expected, whereas the length of time that a restoration survives, is often used as a measure of clinical performance (47). The study found that as age increases, the percentages of defective resin based composites increases. Those who were aged 60 years and above had the highest number of defective restorations. These findings are similar to a study done in Pretoria, SA where restoration failures were highest among older patients and lowest in the 4-18-year age group (49). This may purely be due to older patients having older restorations, however, caries incidence is also higher in the elderly due to changes in their stomatognathic system, impaired motor function, and reduced salivary flow rates, amongst others (47).

Reasons for failure of direct resin based composite

Majority of RBC restorations in this study showed impairment of marginal integrity i.e. marginal discoloration which was 27.7%. Note that Marginal integrity is one of the most important criteria for the success of a restoration (49). These findings are similar to a studies done in Germany and USA which found that the main reason for failure was marginal discoloration associated with the formation of secondary caries (50,51). Reasons being the elastic behavior and fatigue of the composite and bonding agent, which has negative influences of occlusal stress factors on teeth. This is more crucial for large restorations, at the restoration-tooth interface. For direct composite restorations, the larger the volume of composite to be polymerized, the greater the residual internal stresses in the polymerized composite. Another study observed in a period of 0

to 5 years' failure was due to restoration fracture, followed by secondary caries contrary to this study findings (52).

In this study the modified USPHS criteria was used for clinical assessment status of RBC restoration which were performed from year 2013 to 2018, comparable assessments where 82.2% of restorations had acceptable surface texture, 74.2% of the restorations had optimal anatomic form, 83.3% for marginal integrity, 72.3% did not have marginal discoloration, and intact restoration had 73.0%. These results are in accord with a study by Burke *et al* in the United Kingdom where 97% of the restorations were rated optimal for anatomic form, 84% for marginal integrity, and 77% for marginal discoloration. Ninety-three percent (93%) of the restorations were rated optimal for surface quality (53). This finding was contradictory to a study done in Germany on direct composite restorations where clinical performance was better for color match, anatomic form at the marginal step, discoloration of the margin, and integrity of the restoration (50).

The major reason for replacement of a previous RBC restoration in this study was filling dislodgement. It was also found in the USA that replacing failed RBC restorations due to dislodgement, constituted about 60% of all operative procedures carried out by dentists (47).

However, different studies found that the need for replacing patients' RBC restorations was mainly due to secondary caries and discoloration (31,54). Replacing of existing restorations will result only in larger restorations, additional stress on the tooth with possible pulp and dentin reaction to thermal, chemical, bacterial or mechanical stimulus, (51). These are influenced by the size and depth of the existing restoration. This study found that there was no statistical significance between the existing restorations and the replaced RBC restoration on status of RBC restoration. Similar findings were found in a study done by Gordan *et al* in the USA (51). This puts an emphasis on minimal invasive procedure before surgical irreversible procedures, the use of adhesive fluoride release cements in large cavities as base, as a gold standard in RBC restorations.

In this study 22 participants responded yes to post- operative sensitivity similar to a study in

South Africa where participants reported post-operative sensitivity during the follow-up period (49). Other studies have indicated that up to 30% of the study populations reported postoperative sensitivity following the placement of a posterior resin composite restoration (55).

This can be due to the use of phosphoric acid etching and aggressive self-etch adhesives, polymerization shrinkage of resin, and micro leakage around the margins of restoration which can cause pulp irritation, even pulp death (56). Liners must be used in deep dental cavities, including the use of desensitizing agents.

Factors associated with failure of RBC composite filling materials.

In this study those who were found to be high caries risk, had the highest rate of failed RBC restorations. These findings were statistically significant. ($p=0.003$) Another study done in the Netherlands had similar findings, the patient who were high caries status had a higher number of failed RBC restorations (57). The caries risk of patients has been shown to significantly influence the longevity of restorations. Several studies investigated the caries risk and found increased risk of failure of restorations placed in patients with high caries risk (14,58). These patients may be considered to have a higher risk of caries which would explain the higher rates of restoration failures observed in these patients. In this study those who are high caries risk had a three times more chance of experiencing a defective restoration. Similar findings were observed in a study done by Opdam N et al which found that high-caries risk group had a failure rate more than twice as high compared to low-risk patients (58). Reasons for these findings being a decrease in pH and increase in acidity in the oral cavity, which affect roughness of RBC restorations, increase biofilm adhesion and formation of secondary caries. (59).

In this study those who reported to have parafunctional habits (bruxism) had higher number of defective restorations. These findings were statistically significant. ($p=0.003$). A clinical 3-year study on the longevity of composite restorations placed in patients with severe tooth wear showed unfavorable results compared to 'normal patients', indicating that the destructive mouth habits of these patients (probably with bruxism) resulted in more failures (60). Tooth and restoration fracture also are important reasons for restoration failure. It is, therefore, likely that bruxing habits such as grinding and clenching play an important role in fatigue development in

the tooth-restoration complex, resulting in fracture in the long term. In this study those who had responded yes to bruxism had a 1.9 higher chance of having a defective RBC restoration.

This is a study which was conducted in hospitals, and may not essentially represent community characteristics, so findings from this study cannot be generalized to the whole population. However, it gives an insight on the status of RBC restorations which were done from year 2013 to 2018, reasons for failure and the factors associated.

6.0 CONCLUSION:

More than half of the RBC restorations were defective. The major reason for defective RBC restorations was marginal discoloration followed by fracture of the restorations. Patient factors which are high caries risk and parafunctional habits had an influence on the status of RBC restorations. Tooth related factors did not have an influence on the status of RBC restorations.

7.0 RECOMMENDATION:

1. Dentists should be made aware of the factors that influence the status of Resin based composite restorations such as patients factors, tooth related factors, dental material factors, and practitioner factors.
2. High caries risk patients need to receive primary prevention, before conservation with RBC since high caries status has a negative influence on the status of RBC restoration.
3. Patients who have parafunctional habits may need preventive measures (e.g. mouth guard) and frequent recall visits to the dental clinic to assess the status of RBC restorations.
4. More longitudinal research is recommended to ascertain practitioner and material factors related to status of RBC.

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APPENDICES

Appendix 1a – INFORMED CONSENT FORM – English version.

(DIRECTORATE OF RESEARCH AND PUBLICATIONS, MUHAS).

STATUS OF RESIN BASED COMPOSITE RESTORATIONS, REASONS FOR FAILURE AND ASSOCIATED FACTORS IN PATIENTS WHO ATTENDED TERTIARY DENTAL CLINICS IN DAR ES SALAAM.

ID. No. [__|__|__]

Age (Yrs)

Sex: (M=1, F=2) [__]

Consent to participate in a study.

Greetings! My name is Dr. Grace Matasha; I am doing research on the status of resin based composite restorations, reasons for failure, and associated factors inpatient attending MUHAS and MNH dental clinic in Dar es Salaam purpose of the study.

The study is conducted in partial fulfillment of the requirements for the degree of Master of dentistry in restorative of MUHAS. This study is aiming to determine the status of Resin based composite restorations, reasons for failure, and associated factors inpatient attending MUHAS and MNH dental clinic in Dar es Salaam.

You are kindly requested to participate in this study as part of major stakeholders in the field and information will contribute value important information for improving services and science. Kindly please be honest and true for the betterment of the results that could lead to better intervention and recommendations for the future.

What participation involves

If you agree to join the study, you will first be given a questionnaire to answer some questions. Secondly, a dentist will perform a brief examination of your mouth. The examiner will provide you with a summary of the findings offer advice and refer for suitable treatment.

Confidentiality

All information collected on forms will be entered into computers with only the study identification number. Confidentiality will be observed and unauthorized persons will have no access to the data collected.

Risks: there is no any harm expected to happen to you because of participating in this study. Some questions could potentially make you feel uncomfortable or raise your consciousness about dental appearance. However, you are to answer or not to answer them.

Right to withdraw and alternatives

Taking part in this study is completely voluntary. You can stop participating in this study at any time, even if you have already given your consent. Refusal to participate or withdraw from the study will not involve penalty or affect your scheduled treatment.

Benefits

If you agree to participate in this study, you will be advised on what to do (management) by the examination findings to prevent further deterioration of the restoration. The information you provide will help to determine the status of resin based composite restorations, reasons for failure, and associated factors inpatient attending MUHAS and MNH dental clinic in Dar es Salaam.

The result of the study will give information that will enable create awareness on the status of resin based restoration, reasons affecting its success, and also will enable oral health stakeholders to plan for oral health services as per need and intervene on the reported problems.

Who to contact

If you ever have questions about this study, you should contact the principal investigator, Dr. Grace Matasha of Muhimbili University of Health and Allied Sciences, P. O. Box 65001, Dar es Salaam.

If you ever have questions about your rights as a participant, you may call:

Dr. Bruno Sunguya,

Director of Research and Publication,
The Muhimbili University of Health and Allied Sciences,
P.O. BOX 65001,
Dar es Salaam.

Office Tel: 022-2152489 or

Supervisors of this study Dr. Irene Kida Minja (Tel: 255763000333), Dr. Makoye
Ndalahwa (Tel: 255754756367), and Dr. Godbless Mandari (Tel: 25565817428)

Signature: Do you agree?

Participant agrees

Participant does NOT agree

I Have read the contents in this form. My questions have
been answered. I agree to participate in this study.

Signature of participant

Date of signed consent

Appendix Ib INFORMED CONSENT FORM - Swahili version.

(KURUGENZI YA TAFITI NA UCHAPISHAJI CHUO KIKUU CHASAYANSI ZA AFYA MUHIMBILI).

FOMU YA RIDHAA.

Namba ya utambulisho [__|__|__] Umri: (*miaka*); Jinsia: (*me=1, ke=2*) [__]

Ridhaa ya kushiriki kwenye utafiti

Hujambo! Ninaitwa Dr Grace Matasha; nashughulika kwenye utafiti huu wenye lengo la kutathmini ukubwa wa tatizo la kudorora kwa kizibio cha Composite na visababishi vya kudorora kwa kizibio na pamoja na viwango vya kufanikiwa kwa rbc katika wagonjwa waliokwisha tibiwa katika kitengo cha meno, MUHAS, na MNH, kitengo cha meno. Utafiti huu unafanyika katika kutimiza sehemu ya matakwa ya shahada ya uzamili ya matibabu ya kurekebisha na kuziba meno ya Chuo Kikuu cha Afya na Sayansi ya Tiba Muhimbili. Utafiti unalenga kutathmini ukubwa wa tatizo la kudorora kwa kizibio cha Composite na visababishi vya kudorora kwa kizibio na pamoja na viwango vya kufanikiwa kwa RBC katika wagonjwa waliokwisha tibiwa katika kitengo cha meno, MUHAS, na MNH, kitengo cha meno.

Unaombwa kushiriki katika utafiti huu kutokana na upeo na ufahamu ulio nao ambavyo ni muhimu kwa utafiti huu. Tafadhali kuwa mkweli na muwazi kwa vile matokeo ya utafiti huu yanaweza yakatoa maamuzi na mapendekezo ya baadaye.

Jinsi ya kushiriki

Ukikubali kushiriki katika utafiti huu, utasailiwa ili kuweza kujibu maswali toka kwenye dodoso lililoandaliwa kwa ajili ya utafiti huu.

Usiri

Taarifa zote zitakazokusanywa kupitia dodoso zitaingizwa kwenye ngamizi kwa kutumia namba za utambulisho.kutakuwa na usiri na hakuna mtu yeyote asiyehusika atakayepata taarifa zilizokusanywa.

Hatari

Hatutegemei madhara yoyote kukutokea kwa kushiriki kwako kwenye utafiti huu.

Faida

Kama utakubali kushiriki kwenye utafiti huu taarifa utakazotoa zitatuwezesha kutupa mwanga zaidi juu ukubwa wa tatizo la kudorora kwa kizibio charbc na visababishi vya kudorora kwa kizibio na pamoja na viwango vya kufanikiwa kwa rbc katika wagonjwa waliokwisha tibiwa katika kitengo cha meno, muhas, na mnh, kitengo cha meno.

Matokeo ya utafiti huu yanaweza kutoa taarifa ambazo zitaweza kusaidi katika kuonyesha na kuongeza uelewa kuhusu tatizo la ludorora kwa kizibio cha rbc, visababishi na kiwango gani zinafaikiwa. Pia, itasaidia wadau mbali mbali ikiwemo watunga sera kuchukua hatua.

Athari na kukitokea madhara

Hutegemewi kupata madhara yoyote kutokana na ushiriki wako katika utafiti huu. Baadhi ya maswali yanaweza yasikupendeze, unaweza kukataa kujibu swali lolote la aina hiyo.

Uhuru wa kushiriki na haki ya kujitoa

Kushiriki kwenye utafiti huu ni hiari. Unaweza kujitoa kwenye utafiti huu wakati wowote hata kama umeshajaza fomu ya ridhaa ya kushiriki utafiti huu. Kukataa kushiriki au kujitoa kwenye utafiti huu hakutaambatana na masharti yoyote.

Nani wa kuwasiliana naye

Kama una maswali kuhusiana na utafiti huu, wasiliana na mtafiti mkuu wa utafiti huu, Dr Grace Matasha wa chuo kikuu cha afya na sayansi ya tiba muhimbili, S. L. P. 65001, Dar es Salaam. Kama una swali kuhusu stahili zako kama mshiriki unaweza kumpigia simu:

Dr. Bruno Sunguya,

Mkurugenzi wa Tafiti na Machapisho,

Chuo kikuu cha Afya na Sayansi Shirikishi Muhimbili,

S. L. P 65001,

Simu: 022 -2152489

Dar es salaam au

Msimamizi wa utafiti huu study Dr. Irene Kida Minja (Simu: 255763000333), Dr. Makoye Ndalaha (Simu: 255754756367) and Dr Godbless Mandari (Simu: 25565817428)

Sahihi:.....

Je umekubali?

Mshiriki amekubali Mshiriki hajakubali

Mimi Nimesoma maelezo ya fomu hii.

Maswali yangu yamejibiwa.nakubali kushiriki katika utafiti huu.

Sahihi ya mshiriki..... Sahihi

ya mtafiti msaidizi.....

Tarehe ya kutia sahihi ya idhini ya kushiriki.....

Appendix 2a Ryge Criteria 1980

STATUS OF RESIN BASED COMPOSITE RESTORATIONS, REASONS FOR FAILURE AND ASSOCIATED FACTORS IN ADULT PATIENTS WHO ATTENDED TERTIARY DENTAL CLINICS IN DAR ES SALAAM.

| Clinical features | Test procedure | Ryge's criteria |
|----------------------------------|---|--|
| Color match | Visual Inspection with at 18 inches | <ol style="list-style-type: none"> 1. The restoration matches the adjacent tooth structure in color and translucency. 2. Light mismatch in color shade or translucency between the restoration and adjacent tooth. 3. The mismatch in color and translucency is outside the acceptable range of the tooth color and translucency. |
| Cavosurface margin discoloration | Visual inspection with a mirror at 18 inches | <ol style="list-style-type: none"> 1. No discoloration anywhere along the margin between the restoration and adjacent tooth. 2. Slightly discoloration along the margin between restoration and the adjacent tooth. 3. Discoloration penetrated along the margin of the restorative material in a pulpal direction. |

| | | |
|--|--|---|
| Marginal adaptation (occlusal and proximal) | Visual inspection with explorer and mirror if needed | <ol style="list-style-type: none"> 1. No visual evidence of a crevice along the margin. 2. No visual evidence of crevice along the margin into which the explorer will penetrate. 3. The dentin or the base is exposed 4. The restoration is fractured, mobile, or missing. |
| Anatomical form (occlusal and proximal) | Visual inspection with explorer and mirror if needed | <ol style="list-style-type: none"> 1. The restoration is continuous with the existing anatomical form 2. The restoration is discontinuous with the existing anatomical form. But the material is not sufficient to expose the dentin or base. 3. Sufficient material is lost to expose the dentin or base. |
| Surface texture | Visual inspection with explorer and mirror if needed | <ol style="list-style-type: none"> 1. The restoration surface is smooth as a surrounding enamel. 2. The restoration surface is rougher than the surrounding enamel. 3. There are a crevice and fracture on the surface of the restoration. |
| Secondary caries | Visual inspection with explorer and mirror if needed | <ol style="list-style-type: none"> 1. No evidence of caries. 2. Evidence of caries along the margin of the restoration. |

Appendix 2b USPHS Modified Ryge 1980 Criteria

STATUS OF RESIN BASED COMPOSITE RESTORATIONS, REASONS FOR FAILURE AND ASSOCIATED FACTORS IN PATIENTS WHO ATTENDED TERTIARY DENTAL CLINICS IN DAR ES SALAAM.

| Clinical features | Elements of clinical features | Ranking |
|--------------------------|--------------------------------------|--|
| Surface feature | Surface texture | <ol style="list-style-type: none"> 1. The surface of restoration smooth. 2. Slightly rough, pitted correctable. 3. Deeply pitted, can't be corrected. |
| | Color match | <ol style="list-style-type: none"> 1. No mismatch. 2. Mismatch within an acceptable range. 3. Mismatch outside the acceptable color/shade. |
| Anatomical form | Anatomical contours | <ol style="list-style-type: none"> 1. Restoration is continuous with existing anatomical form. 2. Restoration slightly under/over contoured correctable. 3. Under/over contoured: dentin/base exposed/lost. |
| | Contact point | <ol style="list-style-type: none"> 1. The functional contact point was restored. 2. Slightly open (maybe selfcorrecting). 3. Faulty (self-correction is unlikely). |

| | | |
|--------------------|--|--|
| | Gingival margin contour | <ol style="list-style-type: none"> 1. No overhang. 2. Small overhang- tears floss but pass through. 3. Large overhang- dental floss cannot pass. |
| Marginal integrity | Marginal discoloration | <ol style="list-style-type: none"> 1. No marginal discoloration. 2. Discolorations not penetrating in a pulpal direction. 3. Discoloration has penetrated in a pulpal direction. |
| | Fracture restoration both/filling mobile | <ol style="list-style-type: none"> 1. No fracture of restoration/tooth. 2. Restoration mobile/fractured or caries contiguous with a margin of restoration, or tooth structure fractured. 3. The restoration is fractured, mobile, or missing. |
| Secondary caries | Secondary caries | <ol style="list-style-type: none"> 1. No evidence of secondary caries. 2. Evidence of secondary caries. |

Appendix 3 Oral hygiene assessment criteria Mucosal-plaque index (MPS) (Henriksen, B et al 1999).

| Criteria for mucosal score (MS) | Criteria |
|---|-----------------|
| Normal appearance of the gingiva | 1 |
| Mild inflammation and oral mucosa | 2 |
| Moderate inflammation marked redness and hypertrophy/hyperplasia of the gingiva, which bleeds easily when the pressure is applied marked redness in large areas (2/3 or more) of the palate marked inflammatory redness of the oral mucosa in sites other than in the palate ulceration(s) caused by dentures | 3 |
| Severe inflammation severe redness and hypertrophy | 4 |
| Plaque Score (PS) on teeth and dentures | Criteria |
| No easily visible plaque | 1 |
| Small amounts of hardly visible | 2 |
| Moderate amounts of plaque | 3 |
| Abundant amounts of confluent | 4 |

Appendix 4 Oral Disease Risk Management (ODRM)

| Caries risk status | Criteria |
|--|---|
| LOW | <p>No cavitated or active carious lesions; no</p> <p>Incipient occlusal or interproximal lesions; fewer than four cervical decalcifications or white spot lesions.</p> |
| MODERATE | <p>One to three cavitated or active carious.</p> <p>Lesions; one or more incipient occlusal or</p> <p>Interproximal lesions; four or more cervical</p> <p>Decalcifications or white spot lesions.</p> |
| HIGH | <p>Four or more cavitated or active carious lesions.</p> |
| Caries risk status according to the ODRM protocol. | |

Appendix 5a : Standardized phone record schedule and protocol

ENGLISH VERSION

Greetings

I am Dr. Matasha from Muhimbili University of Health and Allied Science, School of Dentistry

Am I speaking to.....

According to our database, it shows that you came to the MUHAS or MNH dental clinic where restoration was done on your teeth, in the year..... is this correct?

Well we are conducting scientific research to evaluate the progress of this restoration, is it still intact, if there are any deformities on the restoration or the tooth, the entire oral status will also be assessed, and you will receive a summary and free oral health education and advice concern your oral health status.

May please narrate to you on the content of the research,

This research you will be interviewed, followed by a clinical examination of your oral cavity and the previously restored tooth. You will be given a free examination, and a summary of the status of your oral cavity.

Do you agree to participate?

No... thank the patient for his/ her time.

Yes. Continue with the dialogue

Which of these weekdays (Monday, Tuesday, Wednesday, Thursday, Friday, Saturday) are convenient for you to visit the MUHAS dental clinic for half an hour of your time to participate in this study?

For any question, concern please communicate with this number

Thank you very much, we look forward to seeing you on time

End of dialogue.

Appendix 5b: Standardized phone record schedule and protocol

SWAHILI VERSION

Habari

Unaongea na Dr Matasha kutoka chuo cha Muhimbili shule ya meno.

Naongea na

Kumbukumbu zetu zinaonyesha umewahi kuja Muhimbili kitengo cha meno kwa matibabu ya kuziba meno mwaka je hii ni sahihi?

Tunafanya utafiti wa kisayansi kuafwatilia maendeleo ya meno uliyoziba, tunaangalia uiamara wake, kama kuna hilitafu yeyote kwenye jino hili, au kizibio. Pia tutaangalia hali ya kinywa na meno yako yote, na majibu ya hali ya kinywa chako utapewa hapo hapo, pia ushauri kuhusu afya ya kinywa na meno. Haya yote yatafanyika bure.

Naomba nikupe ufafanuzi ya kitakachofanyika.

Utafiti huu una sehemu ya maswali ya kujibu kwa mdomo, kutakuwa na kukuangalia kinywa na meno yote na pia jino uliloliziba kuangalia hali yake. Baada yapo utapewa majibu ya hali ya kinywa na meno yako.

Je unaridhia kuhusika na utafiti huu?

Hapana... mshukuru kwa mda wake....

Ndiyo. Endelea na mdahalo:

Siku gani kati ya jumatatu mpaka jumamosi kuanzia saa 3 asubuhi hadi saa 8 mchana utakuwa ni muafaka kwako kufika MUHAS kitengo cha meno ili kufanikisha zoezi hili?

Kwa maswali, au maelezo zaidi tafadhali wasiliana na number za simu.....

Asante, tutaonana siku ya saa..... Mwisho
wa maongezi ya simu.

Appendix 6a: Questionnaire (English Version)

QUESTIONNAIRE ON STATUS OF RESIN BASED COMPOSITE RESTORATIONS,
REASONS FOR FAILURE AND ASSOCIATED FACTORS INPATIENT WHO
ATTENDED TERTIARY DENTAL CLINIC IN DAR ES SALAAM.

ID no. [__|__|__]

Date of interview (d,m,y)[__|__|__]

Name of dental clinic: _____

Social-Demographic Characteristics

1. Sex (1 female, 2 male)[__] 2. Age. (yrs)[_ | _] 3. Occupation _____
4. Education level: (1 none, 2 primary education, 3 secondary education, 4 college school, 5 universities) □__□
5. Marital status (1 not married, 2 married, 3 divorced, 4 widows/widower) (___)

Questions***Tick/place a correct number into the box provided for the correct answer***

6. What are the reasons for the RBC restoration?
6. 1= Dental caries. (___)
- 2= Dental trauma.
- 3= Others (specify: _____)
7. Did you experience tooth sensitivity post RBC placement restoration?
7. 1= No (___)
- 2= Yes

8. What is the duration of the RBC restoration:

8. 1=25-36 months ()

2=37-48 months

3= 49-60 months

4= more than 60 months.

9. Have you ever replaced the previous resin based composite restoration?

9. 1= Yes. ()

2=No

10. If yes what was the reason for the replacement of RBC restoration?

1= Recurent caries

2= Filling discoloration ()

3= Dislodged filling

4=Fractured tooth

5=Others (specify: _____)

11. Have you notice any abnormal grinding of your teeth particularly at night?

1= No ()

2= Yes

Appendix 6b Questionnaire (Swahili Version) (DODOSO)

MASWALI KUHUSU UBORA WA RESIN BASED COMPOSITE, SABABU ZA KUDHOOFIKA, NA VISABABISHI KATIKA WAGONJWA WALIOTIBIWA KATIKA CHUO CHA AFYA MUHIMBILI, SHULE YA MENO NA HOSPITALI YA TAIFA MUHIMBILI, KITENGO CHA MENO.

Kumbu Na: [__|__|__]

Tarehe: [__|__|__]

Jina la idara ya meno: _____

Taarifa za kijamii

1.Jinsia: (1 mke, 2 mume)[__] 2.Umri: (miaka)[_ | _] 3.Ajira: _____

4. Elimu: (1 sijasoma, 2 elimu ya msingi, 3 elimu ya sekondari, 4 diploma, 5 chuo)
□__□

5. Hali ya ndoa: (1 sijaoa/sijaolewa, 2 nimeoa/sijaolewa, 3 talaka, 4 mjane)
□__□

Maswali

Tiki/ au andika jibu sahihi kweye kiboxi pembeni

6. Sababu gani zilikusababisha kuziba jino kwa RBC:

1= Meno kutoboka ()

2=Kuvunjika jino

3= Mengineo (fafanua: _____)

7. Ulisikia ganzi baada ya matibabu ya kuziba jino na rbc?

1= Hapana ()

2= Ndiyo

8. Ni mda gani umepita tokea umeziba jino lako na rbc?

1= Miezi 25-36 ()

2= Miezi 37-48

3= Miezi 49-60

4= Zaidi ya miezi 60

9. Umeshawahi badilisha hiyo rbc material uliyozibia kwenye jino?:

1= Hapana. ()

2= Ndiyo

10. Kama jibu ni ndiyo, sababu zipi zilikupelekea kuibadilisha?:

1= Kutoboka kwa jino pembeni ya kizibio

2= Kubadilika rangi kwa kizibio ()

3= Kumomonyoka kwa kizibio.

4=Kuvunjika kwa jino

5=Mengineo (fafanua: _____)

11. Je una tabia ya kusigina meno haswa wakati wa usiku

1= ndiyo

2= hapana ()

Appendix 7 Clinical Examination Form (English Version)

STATUS OF RESIN BASED COMPOSITE RESTORATIONS, REASONS FOR FAILURE AND ASSOCIATED FACTORS IN PATIENT WHO ATTENDED TERTIARY DENTAL CLINIC IN DAR ES SALAAM.

ID no. [__|__|__]

Date: (d,m,y) [__|__|__]

Name of the dental clinic:

Social-demographic characteristics

1. Sex (1 female, 2 male) [__] 2. Age. (yrs)[_ | _] 3. Occupation _____
4. Education level: (1 none, 2 primary education, 3 secondary education, 4 college school, 5 universities) __
5. Marital status (1 not married, 2 married, 3 divorced, 4 widow/widower) __

Dentition status and oral plaque score

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

KEY:

T/N- Tooth number

ST- Surface texture

CM- Color match

AC- Anatomical contour

CP- Contact point

GMC- Gingival margin contours

MDC- Marginal discoloration

FR/T- Fracture of restoration or tooth

SC- Secondary caries

N.b: Score on Modified Ryge criteria (1980) Appendix 2b.