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An Integrative Review on the Clinical Performance of ORMOCER-based Resin Composites used in Dentistry

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Ana Rita Queirós

Dissertação conducente ao Grau de Mestre em Medicina Dentária (Ciclo Integrado)

Gandra, 29 de setembro de 2021

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Trabalho realizado sob a Orientação de Mestre Lígia Rocha (MSc)

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RESUMO

Introdução: Com o objetivo de reduzir a contração de polimerização, aumentar a resistência ao desgaste e a biocompatibilidade das resinas convencionais baseadas em metacrilatos, os ORMOCERs ("Organically modified ceramics") foram introduzidos no mercado como materiais baseados em oligómeros orgânicos/inorgânicos.

Objetivo: Avaliar e comparar a performance clínica das resinas à base de ORMOCER com a das resinas convencionais.

Materiais e métodos: Foi feita uma revisão da literatura através da PUBMED (via National Library of Medicine), usando os seguintes termos: "ORMOCER"; "ORganically MOdified CERamics"; "Resin Composite"; "Clinical performance"; "Failure". Os critérios de inclusão envolveram ensaios clínicos que avaliassem a performance clínica de resinas ORMOCER, com períodos de follow-up de 1 ano no mínimo.

Resultados: Os estudos incluídos compararam parâmetros como taxa de falha, retenção, descoloração marginal e adaptação marginal, textura superficial e sensibilidade pós-operatória de resinas ORMOCER e resinas convencionais. A taxa de falha variou entre 0-17% para grupos controlo e entre 1.3-17% para ORMOCERs. Nenhum dos estudos identificou diferenças estatisticamente significativas entre as variáveis.

Conclusões: Este estudo não identifica vantagens claras na utilização das resinas ORMOCER em vez das resinas convencionais. Apesar de avaliadas em estudos laboratoriais, estas não puderam ser confirmadas clinicamente. No entanto, os resultados podem ser altamente influenciadas por limitações no desenho de estudo, relacionadas com a seleção de pacientes, procedimentos clínicos e processo de avaliação. Estudos clínicos adicionais de longo prazo serão necessários, a par de uma maior standardização dos mesmos, para demonstrar a performance clínica dos ORMOCERs e as suas vantagens.

PALAVRAS-CHAVE: "ORMOCER"; "ORganically MOdified CERamics"; "Resin Composite"; "Clinical performance"; "Clinical Failure"

ABSTRACT

Introduction: In order to lower polymerization shrinkage, improve wear resistance and biocompatibility of conventional methacrylate-based resin composites, ORMOCERs ("ORganically MOdified CERamics") were introduced in the market as organic/inorganic oligomer- based materials.

Objective: To assess and compare the clinical performance of ORMOCER-based composites to others conventionally used.

Materials and methods: A literature search was carried out on PUBMED (via National Library of Medicine), using the following search terms: "ORMOCER"; "Organically modified ceramics"; "Resin Composite"; "Clinical performance"; "Failure". Inclusion criteria involved controlled trials assessing the clinical performance of ORMOCER-based materials with follow-up periods of at least one year.

Results: Included studies compared parameters such as failure rate, retention, color match, marginal discoloration and adaptation, surface texture and postoperative sensitivity of ORMOCER and conventional composites. Failure rates ranged from 0-17% for control groups and 1.3 to 17% for ORMOCER restorations. None of the studies identified statistically significant differences between the studied variables.

Conclusions: This study does not identify any clear advantages in using ORMOCER-based materials rather than the conventional ones. Although assessed in laboratory studies, they could not be confirmed clinically. However these findings may be influenced by study-design limitations, related to patient selection, clinical procedures and scoring evaluations. Further long-term clinical studies are required along with standardization among them to demonstrate the clinical performance of current ORMOCERs and their promised advantages.

KEY TERMS: "ORMOCER"; "Organically modified ceramics"; "Resin Composite"; "Clinical performance"; "Clinical Failure"

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LIST OF ABBREVIATIONS

ORMOCER: ORganically MOdified CERamics

Bis-GMA: Bisphenol A-glycidyl methacrylate

TEGDMA: Triethylene glycol dimethacrylate

USPHS: United States Public Health Service

C-Factor: Cavity Configuration Factor

1. INTRODUCTION

Dental resin composites were introduced commercially for restoring teeth in the 1960s and remain widely used due to their esthetic properties and handling. The significant development of composites has allowed the growth of their indications to larger posterior restorations, which were classically only restored with amalgams (1). Nowadays, they provide a variety of clinical of applications, including but not limited to restorative materials, liners, sealants, inlays, onlays, crowns, and root canal posts (2). The composition of resin composites varies according to clinical applications and manufacturers, but the main components are an organic polymeric matrix, typically dimethacrylates, in which reinforcing inorganic fillers typically made from radiopaque glass are distributed, and a silane coupling agent that coats the filler particles for chemically binding the filler to the matrix (2,3).

Several approaches were suggested to modify these components to create materials with lower shrinkage/stress on polymerization, improved wear resistance and biocompatibility, problems that are known to be associated with conventional methacrylate-based composites. (4,5). These stresses may produce defects in the composite-tooth bond, leading to micro-leakage and bond failure and causing deformation of the surrounding tooth structure, predisposing the tooth to fracture and ultimately clinical failure.

Some years ago, in an attempt to overcome these drawbacks, a new type of inorganic-organic hybrid restorative material called ORMOCER was developed and introduced in the market (6).

ORMOCERs ("ORganically MOdified CERamics") are organic/inorganic oligomer-based materials that can still be considered as glass-filled composites. The main difference from conventional composition lies in the nature of the resin phase. Oligomers within ORMOCER materials consist of silane molecules similar to those used to functionalize the surface of fillers in conventional resin composites, which are hydrolyzed and condensed, forming a specific oligomer structure. The main purpose of introducing these new type of compounds is to increase the amount of silicium, a change marketed as an increase in filler content (7).

However, little is known about the actual design of the organic/inorganic molecules in commercial materials, thus characterization is required in order to correlate compositional changes to physio-mechanical properties and subsequent clinical performance. Although laboratory investigations are crucial for an early assessment of dental restorative materials, only clinical studies can take into account all of the potential variables influencing the overall performance of a restorative, including complex mastication forces and chemical and mechanical degradation (8). Clinical studies are, therefore, the ultimate test to evaluate the clinical effectiveness and durability of restorative materials (9).

Thus the main aim of this study is assess and compare the clinical performance of ORMOCER-based composites to other conventionally used resin composites.

2. MATERIALS AND METHODS

A literature search was carried out on PUBMED (via National Library of Medicine), using the following combination of search terms: "ORMOCER"; "ORganically MOdified CERamics"; "Resin Composite"; "Clinical performance"; "Failure"

The inclusion criteria involved articles published in the English language, up to June 2021, regarding controlled trials that aimed to assess or compare the clinical performance of ORMOCER-based materials to other conventional composites, with follow-up periods of at least one year. The exclusion criteria were the following: articles without abstract; clinical studies with follow-up periods shorter than one year.

The total of articles was compiled for each combination of key terms, then the duplicates were removed using Mendeley citation manager (Elsevier B.V.). The titles and abstracts of potentially pertinent articles were evaluated. Selected articles were then individually read and analyzed concerning the main aim of this study.

Finally, the eligible articles were organized and data was collected and catalogued by author name; publication year; study design and results.

Also, a hand-search was performed on the reference lists of all primary sources and eligible studies of this systematic search for additional relevant publications.

3. RESULTS

The literature search on PUBMED identified a total of 264 articles of which 129 duplicates were removed, as seen in Figure 1. After a preliminary evaluation of the titles and abstracts, 110 studies were excluded since they did not assemble the inclusion criteria. The remainder 11 potentially relevant studies were selected for full reading. However, 3 studies were excluded due to the lack of relevant information according to the purpose of this study. Finally, 8 studies were included in the present integrative review.

The major findings are shown in Table 1 and drawn as follow:

- 1 study out of the 8 included in Table 1 (12%) compared the clinical outcomes of ORMOCER restorations to one control group in anterior teeth for recontouring and diastema closure. No statistical difference was found in survival rates or color matching, marginal discoloration, wear, loss of anatomical form, caries formation, marginal adaptation, and surface texture (10).
- 1 study (12%) compared the clinical outcomes of ORMOCER restoration to one control group in class V restorations. No statistical difference was found in survival rates, retention, color match, marginal discoloration, anatomic form, marginal adaptation, surface texture, postoperative sensitivity (9).
- 1 study (12%) compared the clinical outcomes of one ORMOCER restoration placed with two different adhesive systems (one-step self-etch adhesive vs two-step etch-and-rinse adhesive) in class II restorations. No statistical difference was found in any of the studies on survival rates, anatomical form, marginal adaptation, colour match, marginal discolouration, surface roughness and caries (11).
- 5 studies (62%) compared the clinical outcomes of ORMOCER restorations to one or two control groups in classes I or II preparations in posterior teeth. No statistical difference was found in any of the studies on survival rates, retention, color match, marginal discoloration, anatomic form, marginal adaptation, surface texture and postoperative sensitivity (8,12–15).

- Failure rate results ranged from 0% to 17% for control groups and from 1.3% to 17% for ORMOCER restorations.
- 100% of the studies concluded that there was no significant differences between ORMOCER and control groups in class I, II, V, diastema closures and recontourings regarding failure rate, retention, color match, marginal discoloration, anatomic form, marginal adaptation, surface texture, postoperative sensitivity in a 1-8 follow-up period. (8,10,12–15)

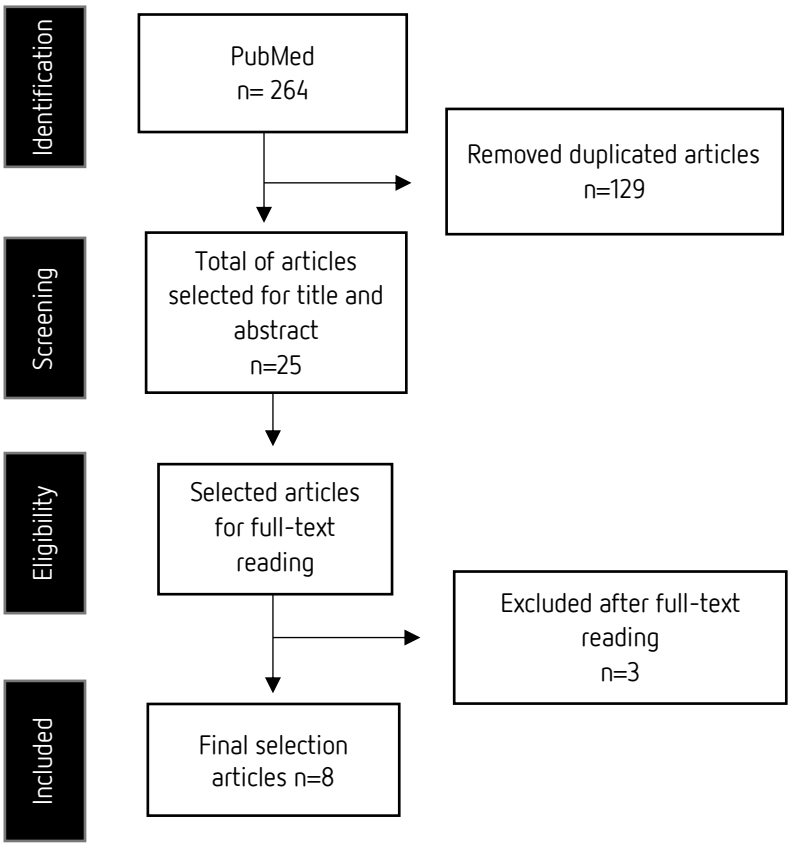

Figure 1: Flow diagram of the search strategy used in this study.

Table 1: Relevant data of the studies selected.

Author (year)	Purpose	Study design	Materials	Evaluation	Follow-up	Parameters	Results
Schirrmeister *et al.* (2006) (12)	To evaluate the clinical performance of ORMOCER compared to micro-hybrid	prospective clinical trial	43 patients 86 restorations class I or II -43 oroceram -43 microhybrid	Modified Ryge's criteria	2 years	Marginal integrity Color stability Recurrent caries Marginal discoloration Anatomic form Surface texture Postoperative sensitivity	• Failure rate: ○ ORMOCER: 2,3% ○ Microhybrid: 0% No statistical difference • Clinical parameters: all suffered statistically similar degradation of marginal integrity, surface roughness and contact point
Bottenberg *et al.* (2009) (13)	To evaluate the performance of ORMOCER composite and small-particle hybrid composite	prospective randomized clinical trial	32 patients 128 class II -87 ORMOCER -41 microhybrid	USPHS Bite-wing radiographs	4 and 5 years	Color Marginal stain Marginal gap Anatomy Contact point Sensitivity Surface roughness General failure	• Failure rate: ○ ORMOCER: 17% ○ Microhybrid: 17% No statistical difference • Clinical parameters: all suffered statistically similar degradation of marginal integrity, surface roughness and contact point
Mahmoud *et al* (2014) (8)	To evaluate and compare two ORMOCER with a nano- filled and a microhybrid composite	prospective long-term clinical trial	40 patients 160 class I and II under-occlusion -80 ORMOCER -40 nanofilled -40 microhybrid	USPHS	3 years	Retention Colour match Anatomical form Marginal discolouration Marginal adaptation Surface roughness Anatomical form Post-operative sensitivity Secondary caries	• Failure rate: ○ ORMOCER: 2,5% ○ Nanofilled: 2,5% ○ Microhybrid 2,5% No statistical difference • Clinical parameters: no statistically significant differences among the materials used

Beck *et al.* (2014) (14)	To assess the long-term performance of two direct composite resins in posterior teeth	prospective randomized-controlled clinical trial	279 patients 1180 class I and II (by undergradutate students) -528 ORMOCER -580 microhybrid	USPHS	1 year	Substance loss Contact point Color match Marginal staining Marginal adaptation, Secondary caries Radiographic examination	• Failure rate: ○ ORMOCER: 5.3% ○ Microhybrid: 6.1% No statistical difference • Clinical parameters: no statistically significant differences among the materials used
Yaman *et al.* (2014) (9)	To compare the clinical performances of low-shrinkage resin composite and ORMOCER composite mono in non-carious cervical lesions (NCCLs) over 36 months	double-blind randomized clinical trial	24 patients 144 class V -72 ORMOCER -72 microhybrid	USPHS	3 years	Retention Color match Marginal discoloration Anatomic form Marginal adaptation Surface texture Postoperative sensitivity	• Failure rate: ○ ORMOCER: 6,9% ○ Microhybrid: 1,3% No statistical difference • Clinical parameters: no statistically significant differences among the materials used
Schmidt *et al.* (2015) (15)	To investigate the clinical performance of a low-shrinkage silorane-based composite material to ORMOCER	randomized clinical trial	48patients 107 cass II -55 ORMOCER -52 microhybrid	USPHS	5 years	Marginal adaptation Marginal discoloration Approximal contact Anatomic form Fracture Secondary caries Hypersensitivity	• Failure rate: ○ ORMOCER: 7% ○ Microhybrid: 13% No statistical difference • Clinical parameters: no statistically significant differences among the materials used
Van Dijken *et al.* (2015) (11)	To evaluate the durability of Class II ORMOCER composite restorations, placed with two different adhesive systems	randomized clinical trial	78 patients 158 class II restorations -89 ORMOCER + one-step self-etch adhesive -69 ORMOCER + two-step etch-and-rinse adhesive	Modified Ryge's criteria	8 years	Anatomical form Marginal adaptation Colour match Marginal discolouration Surface roughness Caries	• Failure rate: ○ One step 13% ○ Two step 13% No statistical difference • Clinical parameters: there were no statistically significant differences among the two adhesives used
Demirci *et al.* (2015) (10)	To evaluate the medium-term clinical performance of direct composite build-ups for diastema closures and recontouring using a ORMOCER and a nanohybrid composite in combination with three- or two-step etch-and-rinse adhesives	prospective clinical trial	30 patients 147 diastema closures and recontours -73 ORMOCER -74 nanohybrid	Modified Ryge's criteria	4 years	Color match Wear or loss of anatomical form Marginal discoloration Marginal adaptation Surface texture Caries	• Failure rate: ○ ORMOCER 7% ○ Nanohybrid 7,2% No statistical difference • Clinical parameters: good clinical results and no statistically significant differences among the materials used

4. DISCUSSION

4.1. ORMOCER – Composition and physio-mechanical properties

4.1.1. Composition

Over the years, new types of promising composite resins with different formulations have been introduced to overcome disadvantages of traditional materials. The key improvements were made regarding the filler component. Filler content has increased and the size of filler particles has decreased. The majority of composites today belong to the nano- category, being either nanofilled or nanohybrids. The small particles are favorable to obtain good wear resistance, high fracture toughness, optimum polishability and good aesthetics (16,17).

On other developments, ORMOCERs ("ORganically MOdified CERamics") emerged in the late 1990s as new hybrid organic/inorganic oligomer- based material, in conjunction with nanoparticle fillers already in use in nanocomposite restorative systems (16). They are composed of inorganic-organic polymers with inorganic silanated filler particles. The solution and gelation (sol-gel) process induces polymerization of multi-functional urethane and thioetheroligo(meth)acrylate alkoxysilanes, producing a silica glass by hydrolysis of the alkoxy groups followed by polycondensation. The result is a matrix of inorganic silica chain backbones with organic lateral chains that are available to react during curing using conventional photoinitiators (4,18,19).

4.1.2. Physio-mechanical properties

When they were first introduced, the aim of ORMOCERs was to reduce polymerization shrinkage and to improve the marginal adaptation, abrasion stability and biocompatibility of composites. (4). In fact, the larger size of the monomer molecules may be responsible for reducing polymerization shrinkage, wear and leaching of monomers (20). Also, the monomers are better embedded in the matrix which reduces their release (11). ORMOCERs are therefore expected to combine the advantages of organic polymers, like flexibility, and of inorganic materials, like mechanical strength (16).

In vitro studies have been performed in order to investigate these promised advantages, however they have provided controversial results and are hard to correlate. While some show reduced volumetric shrinkage and shrinkage stress (21), other proved equal shrinkage to that of hybrid composites (18). Wear resistance could be lower (22,23), similar (24) or improved (25) according to different authors. ORMOCERs claim decreased surface roughness, which is supported by *in vitro* evidence involving a variety of polishing techniques (26). Their marginal adaptation is comparable to that of conventional composites (22). Studies show ORMOCERs have similar strength, fracture toughness and elastic modulus (22,27) when compared to conventional resin composites. Biocompatibility also seems to remain inconclusive, with authors stating ORMOCERs are more biocompatible (28) and other questioning these results (29,30).

Currently, the mostly available ORMOCER-based composites Admira (Voco GmbH, Germany), Definite (Degussa AG, Germany) and Ceram X (Dentsply DeTrey GmbH, Germany) are associated with conventional methacrylate monomers such as bisphenol A-glycidyl methacrylate (Bis-GMA) and triethylene glycol dimethacrylate (TEGDMA) to reduce the viscosity of the final composite, which may reduce their ability to fulfill their initial promises (4,31,32).

Recently there was a development of new ORMOCER matrices that can be described as pure ORMOCERs because they claim to be entirely free of any dimethacrylate monomers, thus potentially more stable, resistant and biocompatible (33). One example is Admira Fusion (Voco GmbH, Germany) (32,34). Given the very recent introduction in the market, few studies can be found on their physio-mechanical properties and very few regarding their long term clinical performance (35). Studies regarding this new family of pure ORMOCERs are required in the future in order to confirm their upgrade from conventional ORMOCERs that are still mainly used today.

4.2. ORMOCER - Clinical performance and outcomes

The most frequently reported reasons for replacement of composite restorations are secondary caries and fractures (22,36). Polymerization shrinkage could be the main cause, leading to gap formation, caries, wear with loss of anatomy, disturbance of occlusal relationships and degradation, ultimately leading to fracture. Therefore, to reduce the risk of failure, the development of new materials like ORMOCERs has mainly focused on reducing polymerization shrinkage, providing good marginal adaptation (13,15).

Regarding clinical failure rate, results among studies showed no significant differences between ORMOCER and non-ORMOCER composites, with ORMOCER performance being mainly as acceptable as other materials in various follow-up periods. Other clinical outcomes that were assessed (color matching, marginal discoloration, wear, loss of anatomical form, caries formation, marginal adaptation, and surface texture) also presented no significant differences.

However, several factors may have influenced the clinical performance of the restorations in these studies, mainly being associated to clinical and evaluation procedures, and to the patient.

4.2.1. Evaluation procedure

Regarding evaluation procedure, in the studies present in this review, composite restoration quality is evaluated using a system of clinical parameters developed by Gunnar Ryge and known as the United States Public Health Service (USPHS) Criteria or Ryge Criteria. These criteria were adapted by the California Dental Association for quality evaluation and referred to as Modified USPHS Criteria or USPHS/CAD Criteria (37). In none of the studies a statistically significant difference was found in the scorings of any group. This may be due to the fact that this evaluation technique was designed to reflect differences in acceptability rather than degree of success.

4.2.2. Patient-related factors

Bottenberg *et al.* (13) concluded that patient-related factors played a significant role in the success of the restorations. Different factors, like mastication force, parafunctional habits, food and drinking habits, saliva composition and oral environment factors, contribute to wear. Bottenberg *et al.* (13) also concluded that a higher failure rate was reported when compared to most other clinical evaluations, partly due to an elevated patient drop-out, because initially placed restorations were no longer available for inspection, although possibly still functional. van Dijken *et al.* (11) and Beck *et al.* (14) also state that another factor which influences the outcome of the results is the type of selected participants: if the sample represents a normal population, a higher frequency of failed restorations would be observed, due to the inclusion of in high-risk participants. In contrast, some studies included in this review excluded patients with parafunctional habits and high risk of caries, possibly resulting in lower failure rates (9).

4.2.3. Clinical procedure

Regarding clinical procedure, many factors may strongly influence the results: respectively the operator performance and the procedure protocol. In some studies, like Bottenberg *et al.* (13) and Beck *et al.*(14) , operators were undergraduate students from dental school clinics: this may explain the higher failure rates for both control and ORMOCER groups (17%).

Bottenberg *et al.* (13) referred the importance of preparation type and extension. In the study, the butt-joint occlusal outline, instead of a beveled preparation outline in combination with the extensive nature of the restorations, could be an explanation for the formation of marginal fractures.

Only one study (8) explicitly stated all the 160 class I and II restorations were intentionally executed in under-occlusion. This may explain the lowest failure rate in ORMOCER and control groups (2.5% in both).

Yaman *et al.* (9) studied ORMOCER performance in class V restorations, with results being as acceptable as shown in the other studies that assessed performance in class I and

II. Although class V cavities exhibit a similar Cavity Configuration Factor (C-Factor) to class I cavities, different results may be obtained because of the difference in stress (involving erosion, abrasion, and abfraction) in the cervical region, which vary among different patients (38).

Regarding marginal adaptation, in the studies by Yaman *et al.* (9) and Schmidt *et al* (15), no significant differences were found among the tested restorative systems. These findings, as stated by the authors, indicate that factors other than polymerization shrinkage (characteristic of the material) are important for marginal adaptation, mainly the use of different adhesive systems. Others, like Schmidt *et al.* (15) attribute the success of marginal adaptation solely to technique. Although better results would be expected for ORMOCERs, the similar findings suggest that incremental layering technique could mask polymerization shrinkage, decreasing its negative effects (39).

One study (11) assessed the efficacy of one-step self-etch adhesive vs two-step etch-and-rinse adhesive in class II ORMOCER restorations. No significant clinical differences were found in the 8-year follow-up, resulting in similarly low failure rates in both adhesive systems. Schirrmeister *et al.* (12) states that it is disputable whether simplifying an adhesive system leads to higher failure. In literature, significant higher bond strengths for multi-bottle adhesives than for primer-adhesives were determined (40). However as shown by Van Dijken *et al.* (11), one-bottle adhesives can have similar bond strengths like three-step-systems when used with ORMOCER composites.

Regarding post-operative sensitivity, no major findings were encountered in ORMOCER-based resins compared to others. Postoperative sensitivity has been attributed in literature to several factors, including dentin etching, shrinkage stress and deformation of composite by occlusal forces (41). Schirmmeister *et al.* (12) found that sensitivity assessments in his study may be explained by the large size of the cavity, resulting in higher polymerization stress and formation of gaps, rather than the composite's composition. Bottenberg *et al.* (13) references the importance of the use of rubber dam isolation to prevent post-operative sensitivity. However, contrary to what would have been expected, no major differences in success rate, performance or sensitivity were encountered among the studies in this review, three of which used rubber dam (12,13,15), the others using only cotton rolls (8–11,14).

At last, marginal discoloration is one of the first clinical signs of failure of a resin composite restoration, indicating a breakdown of the bond between the restorative material and tooth structure, and marginal leakage (8). Color alteration of a resin composite is a multifactorial phenomenon associated to intrinsic discoloration, involving alterations in chemical stability of the matrix; and extrinsic discoloration, closely dependent on patient factors, like hygiene, dietary, and smoking habits (42). Also, failing the adhesion step may result in marginal staining (43). Some studies studies found slight discolorations among the compared materials, although mostly superficial, being easily removed by finishing and polishing procedures. (9)

5. CONCLUSIONS

Within the limitations of the selected clinical studies, the following concluding remarks can be drawn as follow:

- This systematic review found that the clinical outcome of ORMOCER based materials is comparable to the clinical outcome of conventional composites over various follow-up periods. Therefore, this study does not identify any clear advantages in using ORMOCER-based materials rather than the conventional ones.
- The early promises that stated ORMOCER based composites provided several advantages from the conventional resin-composites, such as lower polymerization shrinkage, reduced surface roughness and better marginal adaptation, although verified in laboratory studies, could not be confirmed clinically.
- It must be stated that these findings may be highly influenced study-design limitations, related to patient selection, clinical procedures and scoring evaluations.

Finally, comparing clinical outcomes from various studies is a rather complex task. Further long-term clinical studies are required along with standardization among them to demonstrate the long-term performance of current ORMOCERs and their promised advantages.

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