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A Comparison of Flexural Strength and Diametral Tensile Strength of a Ceramic-based ORMOCER® and a Conventional Resin-based Composite

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Submitted in partial fulfillment of the requirements for the degree of Master of Science in the Department of Oral Biology in the Uniformed Services University of Health Science
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Abstract

Purpose: The purpose of this bench-top study was to compare the flexural strength and diametral tensile strength of a ceramic based ORMOCER® restorative material to a resin-based composite restorative material.
Materials and Methods: Forty samples of commercially available composite resin restorative materials were assessed for diametral tensile strength (DTS) in accordance with ADA Specification No. 27 and maximum flexural strength (FS) in accordance with ISO 4049. The samples were evenly divided between two different composites including 3M™ ESPE™ Filtek™ Supreme Ultra and Admira® Fusion. All testing was completed on an Instron® 5943: three-point flexural strength test, compression platens and a load cell of 1 kN. Exploratory data analyses were conducted on continuous data (DST, FS). Analyses of variance (ANOVA) was conducted to assess differences in DTS and FS between the two composites. Statistical significance for all statistical tests was declared at $P < 0.05$.
Results: Differences were found between the composites in FS and DTS, both $P<0.001$. The Filtek samples had higher FS ($M = 146.11$ MPa, $SD = 18.69$) as well as higher DTS ($M = 33.57$ MPa, $SD = 2.60$) compared to the Admira samples. The calculated FS for Admira was 99.04 MPa ($SD = 14.21$) and the DTS was 26.91 MPa ($SD = 6.90$). The effect sizes for the differences in FS and DTS were $\eta^2 = 0.68$ and $\eta^2 = 0.30$ respectively, indicating statistically large differences in both FS and DTS between the groups.
Conclusions: The flexural strength and diametral tensile strength of the ceramic-based ORMOCER restorative material was less than the conventional resin-based composite restorative material.

Background

Global health and environmental agencies are working together to eliminate all mercury containing products and processes, including dental amalgam (DA) and as such, comparable mercury-free alternatives will be required.[1,2] However, DA has proven a greater challenge to replace; its long history of clinical success, patient safety record, ease of use and low cost make it a reliable and affordable choice for many patients and supports its continued use in many dental offices[3], including the US military.

Resin-based composites (RBC) are the most popular alternative to DA, with more than 800 million restorations placed annually.[4] However they are not without inherent challenges. Posterior RBC restorations have reported higher failure rates due to restoration fractures, polymerization shrinkage, decrease wear resistance, marginal leakage and secondary caries.[4,5,6,7] There is evidence supporting adverse biologic responses and cytotoxicity associated with RBCs and the commonly utilized organic monomers such as bisphenol-A glycidyl dimethacrylate (BisGMA), triethylene glycol dimethacrylate (TEGDMA), and 2-hydroxy-ethyl methacrylate (HEMA)[8,9,10]. Moreover, RBCs require strict adherence to technique and can take as much as two and half times longer to place than a comparable amalgam restoration.[6] In preparation for a global ban of mercury-containing materials, extensive research and development in RBCs has been directed at overcoming these challenges.

Approximately 50 million mercury containing DA restorations are placed annually in the US[11] and DA remains the restorative material of choice for many providers and patients as an inexpensive, reliable, long term posterior restoration. For the US Army, when deploying soldiers present with an endodontic emergency, time constraints and mission requirements may prevent the fabrication of a definitive final crown restoration. In such an event, military providers often choose DA for its predictability as a core build-up material and posterior cuspal coverage restoration. In the realization of a DA ban,[1,2,3] military providers will have to rely on a mercury-free alternative for a long term, direct restorative material.

In 2015, the dental company VOCO GmbH launched Admira® Fusion (VOCO GmbH, Cuxhaven, Germany), an organically modified, pure ceramic-based nanohybrid ORMOCER® (Fraunhofer Gesellschaft zur Förderung der angewandten Forschung e.V., München, Germany).[12] The filler and resin matrix chemistry for the ORMOCER® Admira® Fusion (Admira) is a silicon oxide-based glass-ceramic with alternative aromatic and aliphatic matrix monomers free of the traditional monomers such as BisGMA, TEDGMA, or HEMA.[8,9,12] Addressing some of the greater challenges faced by RBCs, VOCO GmbH claims that Admira has the lowest polymerization shrinkage, has high biocompatibility and can meet the highest demands in the posterior region[12]. The significance within this study are the indications of use of Admira as a direct posterior restoration.

The primary objective of this study was to compare the flexural strength (FS) and diametral tensile strength (DTS) of two products indicated for use as a posterior restorative material: the ceramic based ORMOCER® restorative material, Admira® Fusion (VOCO GmbH, Cuxhaven, Germany) and a conventional RBC restorative material 3M™ ESPE™ Filtek™ Supreme Ultra (3M™ Oral Care Solutions Division; St. Paul, MN, USA).

Hypotheses

HYPOTHESIS #1: Admira® Fusion has a higher diametral tensile strength than 3M™ ESPE™ Filtek™ Supreme Ultra.
HYPOTHESIS #2: Admira® Fusion has a higher flexural strength than 3M™ ESPE™ Filtek™ Supreme Ultra.

Materials and methods

Flexural strength

In accordance with International Standard for polymer-based filling, restorative and luting materials ISO 4049[13], twenty specimens of each core restorative material were subjected to a three-point flexural strength test using the Instron® 5943 machine; 20 specimen of the purely ceramic-based nanohybrid ORMOCER®, Admira and 20 specimen of the RBC 3M™ ESPE™ Filtek™ Supreme Ultra (Filtek). Both Admira and Filtek were used in compule form and all specimens were light cured as per manufacturer's instruction. Specimens were prepared using a stainless steel mould measuring 25 mm x 2 mm x 2 mm and a mould-release agent. Three glass microscope slides and a polyester film were used to create a stable base. The material was expressed into the mould and was covered with another polyester film and glass slide; firm

digital pressure was applied to extrude the excess material. The specimens were light cured on both sides of the mould according to the manufacturer's instructions using the 3M ESPE Elipar™ DeepCure-S curing light (3M™ Oral Care Solutions Division, St. Paul, MN, USA) with the tip directly on the glass slide, beginning in the center of the sample and progressively overlapping either side of center until the entire length had been exposed for the recommended time. The specimen was separated from the mould and excess material was removed by abrasion with 320 grit abrasive paper. The specimens were stored in distilled water at 37°C in a Whip Mix Digital Water Bath (Whip Mix; Louisville, KY; USA) until time of testing (approximately 1 hour). Prior to testing, the specimen dimensions were measured using a digital micrometer to 0.001 mm accuracy. Three-point loading FS testing was conducted using the Instron® 5943, with 20 mm between the supports and at a crosshead speed of 0.75 +/- 0.25 mm/min until fracture. Specimens that did not fracture were estimated to achieve a maximum load of 1000 N, the limit of the Instron® 5943 machine used. Testing parameters were set using BlueHill® 3 software (Instron®; Norwood, MA; USA).

Diametral tensile strength

Twenty specimens of each core restorative material were subjected to a DTS test using the Instron® 5943 machine; 20 specimen of the purely ceramic-based nanohybrid ORMOCER®, Admira and 20 specimen of the RBC Filtek. Admira and Filtek were used in compule form and all specimens were light cured as per manufacturer's instructions.

DTS testing was conducted following ADA Specification No. 27[14]. As conducted by Dr. Caroline Mikaloff (2019)[15], a mould was created by making an EXAFLEX® Vinyl Polysiloxane (GC America, Inc.; Alsip, IL) putty impression of a BIC® (BIC, France) mechanical pencil eraser, which has dimensions approximately the size of the recommended mould (3 mm height and 6 mm diameter). After insertion of the material into the mould, the mould was covered with a polyester film and glass slide, and firm digital pressure was applied to extrude the excess material. Light-cured specimens were cured using the 3M ESPE Elipar™ DeepCure-S (3M™ Oral Care Solutions Division, St. Paul, MN, USA) curing light, with the tip directly on the glass slide. Excess material was removed by abrasion with 320 grit abrasive paper. The specimens were stored in distilled water at 37°C in a Whip Mix Digital Water Bath (Whip Mix; Louisville, KY; USA) until time of testing, approximately one hour. Prior to testing, the specimen dimensions were measured using a digital micrometer to 0.001 mm accuracy. Diametral tensile strength testing was conducted using the Instron® 5943 with compressive strength platens at a crosshead speed of 1.0 mm/min. For DTS, each specimen was placed on its side between the platens with a small piece of filter paper wet with distilled water on each platen. The vertical force produced by the platens resulted in lateral tensile stress, perpendicular to the vertical plane in which fractures would result. Thus, the tensile stress applied was directly proportional to the compressive load. Specimens that did not fracture were estimated to achieve a maximum load of 1000 N, the limit of the Instron® 5943 machine used. Testing parameters were set using BlueHill® 3 software (Instron®; Norwood, MA; USA).

Exploratory data analyses were conducted on continuous data (DST, FS). The Shapiro-Wilk test was used to assess the normality of the data distributions. Consequently, measures of central tendency are presented as means with associated standard deviations. An analyses of variance

(ANOVA) was conducted to assess differences in DTS and FS between the two composites. The DTS was calculated using the formula: DST = (2 × maximum tensile strength) / (π × diameter × height). The FS was calculated using the formula: FS = (3x the maximum load) x (the distance between the supports) / (2 x the width x the height)^2. All forces are measured in newtons (N) and distances are measured in millimeters (mm). Summary data are therefore reported in megapascals (MPa). Eta squared (η^2) statistics are presented as measures of effect size for significant ANOVA.[16] Statistical significance for all statistical tests was declared at $P < 0.05$. Data were analyzed using SPSS 25.0 (IBM, Armonk, NY, USA).

Results

Sample characteristics are summarized in Table 1. Differences were found between the composites in FS and DTS, both $P<0.001$. The Filtek samples had higher FS (M = 146.11 MPa, SD = 18.69) as well as higher DTS (M = 33.57 MPa, SD = 2.60) compared to the Admira samples. The calculated FS for Admira was 99.04 MPa (SD = 14.21) and the DTS was 26.91 MPa (SD = 6.90). The effect sizes for the differences in FS and DTS were $\eta^2 = 0.68$ and $\eta^2 = 0.30$ respectively, indicating statistically large differences in both FS and DTS between the groups.

Table 1. Material Characteristics, M(SD)

Material	Filtek	Admira	P[1]	η^2
Flexural Strength (MPa)	146.11 (18.69)	99.04 (14.21)	<0.001	0.68
Diametral Tensile Strength (MPa)	33.57 (2.60)	26.91 (6.90)	<0.001	0.30

1. Significance based on ANOVA.

Discussion

In this experiment, both hypotheses were unfounded, indicating that under these parameters, the FS and DTS of the ORMOCER® Admira® Fusion were less than those of 3M™ ESPE™ Filtek™ Supreme Ultra.

In expanding on the research performed by Dr. Caroline Mikaloff[15] at the Fort Bragg Advanced Education in General Dentistry program, we compared the FS and DTS of a popular dimethacrylate-based composite resin restorative material, 3M™ ESPE™ Filtek™ Supreme Ultra[17] and a pure ceramic-based silicon oxide ORMOCER, Admira® Fusion, free of the traditional dimethacrylate monomers.[8,9,12] FS and DTS were evaluated due to the positive relation between the physical properties and these values are often an indication of the quality of a posterior composite resin and its ability to withstand occlusal forces.[18]

The FS test determines a material's strength and the expected amount of distortion by using a 3-point test where stress is loaded in the middle of a beam supported on either end.[19] All of the specimens tested in this experiment fractured.

The DTS test is a simple, reproducible test that examines brittle materials in which a tensile stress is introduced in the same plane that a force is applied.[18,19] Due to the physical limitations of the Instron machine available, all tests conducted in this study were at a maximum of 1000N. The reported immediate fracture of the Filtek specimens in Dr. Mikaloff's trial[15] was not observed in this trial, however 13 of the 20 Filtek specimens tested in this experiment did not fracture at the maximum load of 1000N. As the average human bite force is approximately 250-280 N,[15,20] it can be assumed that the clinical relevance of the performance of the unfractured materials within the DTS test exceeded the resistance required to withstand the average force produced in a human bite.[15] All of the Admira specimens fractured below 1000N.

The reported values in this study significantly underperformed with respect to the values posted in the manufactures technical data sheets for both FS and DTS with the exception of the DTS for Admira, which was not posted on the Scientific Compendium Technical Data Sheet[12]. The deviations in the values are most likely attributed to the limitations of the equipment and the imprecise uniformity in the measurements of the specimens themselves. A manufactured mould was used for the FS test, however in continuing with the study done by Mikaloff in 2019, the same PVS mould was used. This and the hand-sanding performed on all specimens would have contributed to the same sources of error in the size and surface irregularities of the specimens. General differences within the testing protocols and materials would also be sources of error. Information can be gathered from the non-uniformity though, as the clinical application of RBC material is rarely uniform or without surface irregularities.[15] It is recommended that precise testing on equipment with higher capacity limits and the use of manufactured moulds with precise specimen sizes be conducted in order to minimize errors and improve the internal validity of the experiment.

At the third meeting of the Conference of the Parties to the Minamata Convention on Mercury, the Executive Director of the United Nations Environment Programme, Inger Andersen stated that "the [convention] had immense potential […] in its campaign to make mercury history."[2] Not surprisingly, DA and the timeline for its phase out was still a cause of contention amongst the participants. One of the reasons cited was the potential negative implications the alternative materials could have on the standard of dental care, specifically their decreased physical properties required to withstand masticatory occlusal forces, their lack of versatility and cost effectiveness.[1,2,3] In addition to the environmental hazards, the initiative to ban DA is also recommended due to the risks on human health.[1,2,3,7] On 24 September 2020, the US Food and Drug Administration released their recommendation against the use of mercury dental restorations in certain high-risk populations, including children under the age of six years.[21] The health concerns highlight the fact that success in the elimination of DA will also hinge on the biocompatibility of the alternative restorative materials. The use of RBCs has increased as DA decreases[4,5] and there is evidence demonstrating cytotoxic effects and health concerns regarding the long term degradation of traditional RBCs. [8,9,10,22,23]

For this study, the Admira restorative material was specifically chosen to be compared to the traditional RBC Filtek based on the assumption that if all things being equal- time, cost effectiveness and physical properties- the most significant advantage the ORMOCER® has over the RBC is its biocompatibility.[12]
Evidence supports that traditional dimethacrylate resins are cytotoxic and the high content of residual monomers present biocompatibility challenges during polymerization at placement and as a result of long term degradation. [8,9,10,22,23] More than 30 chemicals are released from dimethacrylate resin restorations into the oral cavity causing an array of biologic responses from irritation, allergies and cytotoxicicty.[10] The substances released after polymerization have also be identified as a concern regarding the neuropsychological development in children.[1,22] The silicon oxide resin matrix of Admira Fusion demonstrates an absence of residual monomers following polymerization.[12] As DA is phased out and more and more RBC restorations are placed, logically there is a concern for the potential increase in long term health effects from the alternative materials.

In further investigation regarding the concerns for banning DA, much of the evidence citing the inferior physical properties of RBCs is dated. The 2014 Cochrane Review comparing posterior direct RBC versus DA fillings acknowledges that that the quality of evidence included was low to moderate with high risk of bias and that the composite materials used have advanced significantly since the report in 2014.[7] This is even more so since this study in 2021. There are many clinical studies indicating that there are few to no clinically significant differences in long term success rates between posterior RBC restorations and DAs.[5,24,25] In 2019, Borgia published a 5- to 20-year retrospective longitudinal study on posterior composites that indicated a clinical success rate of 95.1% with a mean survival time of 11 years and 7 months.[25]

An interesting question arises when comparing the strength of materials versus required material strength; how strong does the material need to be? Resistance to bite forces vary greatly for teeth with respect to anterior or posterior dentition, endodontic treatment, restored vs unrestored, stability of the periodontium, degrees of edentulism, parafunction and so forth. In healthy occlusion, bite forces required for normal mastication are generally less than 207 MPa for less than 30 minutes per day,[26] with an average bite force between 250 and 280 MPa[20] and natural teeth have been reported to have a fracture strength of 305 MPa, the suggested standard of optimal strength for composite resins in posterior teeth.[15,27] The compressive strength of Admira® Fusion is 307 MPa[12] and 3M™ ESPE™ Filtek™ Supreme Ultra has 370.56 MPa.[17] Thus, when comparing results of physical property tests of restorative materials to the actual force required to resist average masticatory forces, Admira® Fusion may be an effective, more biocompatible alternative.

Moreover, in selecting a posterior restorative material for military soldiers, there are extra considerations, particularly the unpredictable external and emotional stressors that routinely fluctuate based on duties, remote deployments and austere environments. Relative to provisional restorations that may be expected to endure for an extended period of time, this is especially important when evaluating long term tooth survivability and overall patient health. Military command must balance budgetary considerations, product quality, soldier wellness and mission requirements when deciding which restorative products will be provided for the dental treatment of its members. As global environmental obligations continue to pressure governments to find

mercury-free alternatives, the military will need to choose replacements that are safe, effective, versatile, and inexpensive without compromising the structural integrity of treatment or the overall oral health of its soldiers. Research and development on mercury-free alternatives must include physical properties as well as biocompatibility.

Research and development in mercury-free alternative restorative materials is rapidly advancing. In addition to conducting this experiment with advanced equipment and manufactured specimen moulds, randomized, controlled clinical trials including split-mouth designs comparing direct posterior restorations of pure-ceramic based ORMOCER® and RBCs are required. Moreover, research using a chairside bite force device in order to individualize the selection of a posterior restorative material based on the required physical properties could be instrumental in meeting some of the proposed challenges to replacing DA.

Conclusion

Within the parameters of this study, the flexural strength and diametral tensile strength of the ceramic-based ORMOCER® material was less than the conventional resin-based composite, thus disproving the study hypotheses.

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