NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

TESTING OF DENTSTAT™ AND COMPETING DENTAL MATERIALS

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Declaration of Interest

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, nor the U.S. Government. *This work was funded by work unit number G1009/1111.* *CAPT Stahl is a military service member, and Dr. Yoon Hwang and Dr. Wayne Deutsch are, or were, employees of the U.S. Government during the drafting of this manuscript. This work was prepared as part of their official duties. Title 17 USC §105 provides that 'copyright protection under this title is not available for any work of the U.S. Government.' Title 17 USC §101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person's official duties.*

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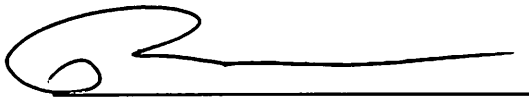

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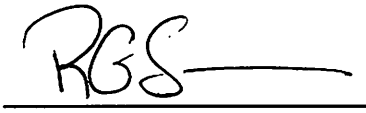

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Executive Summary

Background: Glass ionomers (GI) were developed for use as direct dental repair materials. They are made of calcium or strontium aluminofluoro-silicate glass powder (base) combined with a water-soluble polymer (acid). Glass ionomers were later modified with the addition of a light-polymerized liquid resin component that allows the provider to photocure the cement. Recently the US Navy developed a new resin modified glass ionomer (RMGI), DentStat™, to be utilized in emergency situations to temporarily replace lost restorations or repair fractured teeth. The purpose of this study was to determine if DentStat™ has physical properties comparable to three commercially available RMGIs and one commercially available GI.

Methods: DentStat™ was prepared according to the procedure of patent US 2010/0197825 A1 "Multifunctional Acrylates Used as Cross-Linkers in Dental and Biomedical Self-Etching Bonding Adhesives" with modification. The flexural strength, flexural modulus, and compressive strengths of DentStat™ were compared with three RMGIs (Fuji II™ LC, Vitremer™, and UltraCem™) and one GI (Fuji IX™ GP).

Results: DentStat™ showed significantly higher flexural strength compared with all tested materials except Fuji II™ LC. The flexural modulus of DentStat™ was significantly higher than Fuji II™ LC and UltraCem™, however, the flexural modulus of Fuji IX™ GP was higher than DentStat™. DentStat™ showed significantly higher compressive strength than all other material tested.

Conclusions: DentStat™ demonstrated physical properties in line with other commercially available RMGI and GI cements and could serve as an interim restorative material in remote military settings. Further studies with additional test conditions and methods are suggested.

Introduction

Dental emergencies are a common occurrence during military operations. Up to 10% of all emergency health visits during conflicts, deployments, and field training exercises were due to dental problems (1). Many dental emergencies are due to sensitive tooth surfaces being exposed when a tooth fractures or a restoration is lost. Although most tooth or restoration fractures cause only minor problems, these emergency situations can have a major impact on the unit effectiveness, fighting strength, and warfighter morale (2, 3). A number of dental products can be used to temporarily repair fractured restorations or teeth. Unfortunately, currently-available products are poor choices for field use because they are technique sensitive, difficult to mix, and adversely affected by temperature and humidity extremes.

The use of tooth colored dental restorative materials for direct dental repair has increased dramatically since their introduction in the 1970s. Glass ionomers (GI) are tooth colored dental restorative materials that consist of an acid-degradable glass made of calcium or strontium aluminofluoro-silicate glass powder (base) combined with a water-soluble polymer (acid) (4). The polymerization reaction takes place in three steps: (a) The acid soluble glass reacts with polyacids releasing aluminum, calcium, sodium, and fluoride ions; (b) Calcium and later aluminum poly salts are formed as the hydrogen on the carboxyl groups of the polyacids are replaced by calcium and aluminum; (c) The salts hydrate to form a gel matrix while the unreacted glass particles are surrounded by silica gel that arises from removal of the surface cations. Therefore, the set cement consists of unreacted glass surrounded by silica gel bound together by a matrix of hydrated calcium and aluminum polysalts (5). The significance of this chemistry is that the fluoride ions are not an integral part of the matrix formation and therefore are available for clinical release without compromising the structure of the cement. The fluoride released from GI has an anti-cariogenic effect and GI are capable of fluoride recharge and can serve as a long-term reservoir for fluoride release (6-8).

Additional advantages of GI include: chemical adherence to tooth structure through an ionic interaction with calcium and phosphate ions of the tooth to form a salt bridge, minimal shrinkage upon setting, low coefficient of thermal expansion, resistance to microleakage, good marginal integrity at the restoration tooth interface, and antibacterial properties associated with continuous fluoride release (9-13). Drawbacks to GI include moisture sensitivity, low physical

properties with regard to their mechanical strength limiting their use to non-stress bearing tooth surfaces, and low wear resistance (14-17).

Some of the less desirable characteristics of conventional GI have been negated with the introduction of resin-modified glass ionomers (RMGI) in which the acid-base setting reaction has been supplemented by a polymerization reaction of added resin methacrylate components (18). The polyacid component in the RMGI includes a photopolymerizable resin that hardens the material substantially with visible light exposure. Once the resin component cures, the GI hardening reaction continues, protected from moisture and over-drying by the hard resin framework. Addition of the resin component to the GI formula decreases initial hardening time and handling difficulties, as well as increases physical strength (19). In addition to fluoride ion hydrodynamics, biocompatibility, favorable thermal expansion and contraction properties, which were major advantages of traditional GI, fracture toughness, fracture resistance, and resistance to wear, were all improved in the RMGI (20, 21)

Resin modified glass ionomers are well-suited to serve as temporary dental restorations, as they are known for preventing postoperative tooth sensitivity when placed under direct application resin-based composite restorations (22, 23), protecting against bacterial access to dentinal tubules, internal fluoride ion release (24), and antimicrobial action (13, 25). The U.S. Navy took advantage of the properties of RMGI and developed DentStat™ (DS) to serve as a self-setting RMGI interim restorative material that could be placed not only by dentists, but also by corpsmen/medics in battlefield conditions with no special equipment required. The purpose of this study was to compare DS, against four commercially available materials to determine if DS has physical properties that would make it an appropriate material in the treatment of dental emergencies in military settings.

Materials and Methods

Materials

Preparation of DentStat™. Powder and liquid parts were mixed in a powder:liquid ratio of 3:1, by weight, to form the DS paste as follows. The liquid was placed on a room temperature glass slab and the powder was divided into two equal parts. The first part was mixed into the liquid over 10 seconds, and the remaining portion was added evenly over the total mixing time of 30 seconds. After mixing, the paste hardened by way of an acid/base reaction and a free-radical

polymerization reaction in 4 to 4.5 minutes. The formulations used are as listed in US patent 2010/0197825 A1 dated Aug 5, 2010 (26).

Preparation of Commercial Materials. DentStat™ was tested against three commercially available RMGIs (GC Fuji II™ LC, Vitremer™ and UltraCem™) and one GI (Fuji IX™ GP). GC Fuji II™ LC and GC Fuji IX™ GP were purchased from GC America, Inc. (Alsip, IL). Vitremer™ was purchased from 3M ESPE (St. Paul, MN). UltraCem™ was purchased from Ultradent Products, Inc. (South Jordan, UT). Each of the four materials were prepared by mixing powder and liquid according to manufacturer directions.

Preparation of Samples for Mechanical Testing

Flexural Strength and Flexural Modulus. To prepare each specimen for testing the flexural strength and flexural modulus, a (2 mm × 2 mm × 25 mm) stainless-steel mold (Sabri, Downers Grove, IL) was placed on a Mylar-strip-covered glass slide. Specimens were made by inserting the restorative material into the mold. The top surface of the mold was then covered with a second Mylar strip and glass slide to ensure that the specimen was flat and parallel to the opposite surface of the specimen. One side of the specimen was then exposed to a light polymerization unit for 40 seconds. Next, the mold was flipped over, and the opposite side of the specimen was exposed to the light in a similar manner. The specimens were then removed from the mold and stored in deionized water overnight at 37 °C. Fifteen specimens for each of the five restorative materials were prepared. Each specimen was visually inspected without magnification and any specimens having surface defects or air inclusions were rejected. The first 10 non-defective samples were tested for flexural strength and flexural modulus.

Compressive strength. To prepare each specimen for testing its compressive strength, a split mold with internal dimensions 6 mm high and 4 mm in diameter (Sabri, Downers Grove, IL) was placed on a Mylar-strip-covered glass slide. Cylindrical specimens per each of the restorative materials were made by inserting the restorative material to a slight excess in the split mold. The top surface of the mold was covered with a second Mylar strip and a glass slide to ensure that the top of the specimen was flat and parallel to the opposite surface of the specimen. One side of the specimen was then exposed to a light polymerization unit for 40 seconds. Next, the mold was

flipped over, and the opposite side of the specimen was exposed to the light in a similar manner. Then, the specimens were removed from the mold and their surfaces were checked visually for air-voids or chipped edges. Fifteen specimens for each of the five restorative materials were prepared. Each specimen was visually inspected without magnification and any specimens having surface defects or air inclusions were rejected. The first 10 non-defective samples were tested for compressive strength. Specimens were stored overnight in deionized water at 37 °C.

Mechanical Testing

1. Flexural strength was measured according to International Organization for Standardization (ISO) 9917-2 (27). Each polymerized specimen was placed on a three-point bending test device that is constructed with a 20 mm span length between the supporting rods. The central load was then applied with a head diameter of 2 mm using the universal strength testing machine (MTS Insight, Eden Prairie, MN) at a crosshead speed of 0.25 mm/min.

The flexural strength was calculated using the equation:

$$\sigma = 3FL/2bh^2$$

Flexural strength (σ) is measured in megapascal (MPa), where F is the loading force at the fracture point, L is the length of the support span (20 mm), b is the width, and h is the height (for or case, $b = h = 2$mm). Measurements of the width and height were made using an electronic digital caliper (733M, Starrett, Mount Airy, NC). The mean and standard deviation of the flexural strength were calculated for each of the five restorative materials.

2. Flexural modulus was measured according to ISO 9917-2 (27). Flexural modulus was determined from the slope of the linear region of the load-deflection curve using the following equation of analytical software (TestWorks 4, MTS). The mean and standard deviation of the flexural modulus were calculated for each of the five restorative materials using the following equation:

$$E = FL^3/4bh^3d$$

where F is the load at some point on the linear region of the stress-strain curve, d is the slack compensated deflection at load F. L, b, and h are as defined above.

3. Compressive strength tests were conducted according to ISO 9917-1 (27). Each specimen was placed between the platens of the universal strength testing machine and a compressive load along the long axis of the specimen was applied. The maximum force applied to fracture each specimen was recorded and the compressive strength (C) was calculated using the following equation:

$$C = (4p)/(\pi d^2)$$

Compressive strength (C) is measured in megapascal (MPa), where p is the maximum force applied, in newtons, and d is the average measured diameter of the specimen, in millimeters. The resultant number is the force/unit area (strength) required to break a standard specimen during compression. The mean and standard deviation of the compressive strength were calculated for each of the five restorative materials.

Statistics. A Levine test was first performed to determine if variances among the dental material groups for each test differed. If no difference was found, then a one-way analysis of variance (ANOVA) was performed to determine the significance of any difference of mechanical properties of each dental material. Tukey's multiple comparison test was used to compare the data at a p-value of 0.05. If variances between the groups differed, then multiple t-tests with Bonferroni corrections were used for statistical analysis. Data were presented as mean ± standard deviation. Statistical analysis was performed using SAS version 9.2.

Results

Flexural Strength

DentStat™ displayed a flexural strength of 42.8 (±4.6) MPa compared with 37.6 (±7.8) MPa for Fuji II™ LC, 14.0 (±8.7) MPa for Vitremer™, 12.1 (±4.7) MPa for Fuji IX™ GP, and 27.6 (±8.5) MPa for UltraCem™. A one-way ANOVA was used for statistical analysis. The flexural strength of DS was significantly greater for all groups ($p \leq 0.05$) except for Fuji II™ LC (Figure 1).

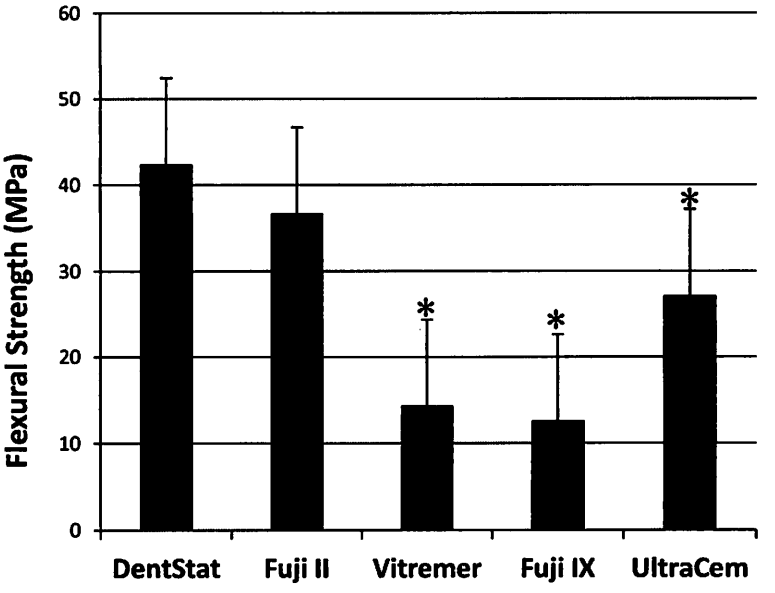

Figure 1. Comparison of Flexural Strength. Rectangular specimens of each restorative material were made by inserting the material into the 2 mm x 2 mm x 25 mm mold. Each specimen was placed on a three-point bending test device, and the central load was applied with a head diameter of 2 mm using a crosshead speed of 0.25 mm/min. The flexural strength of DentStat™ was significantly greater for all groups except for Fuji II (* = $p \leq 0.05$ for DentStat™ compared to other materials).

Flexural Modulus

This test determines stiffness of the dental restoratives or cements with higher values indicating increased stiffness to bending. The flexural modulus of DS was 4517.3 (±1035.5) MPa compared with 1725.6 (±469.6) MPa for Fuji II™ LC, 2925.9 (±758.5) MPa for Vitremer™, 8785.4 (±4362.0) MPa for Fuji IX™, and 1775.0 (±696.1) MPa for UltraCem™. Multiple t-tests with Bonferroni corrections were used for statistical analysis. The flexural strength of DS was significantly greater compared with Fuji II™ LC and UltraCem™ ($p \leq 0.05$). However, Fuji IX™ GP had a significantly higher flexural modulus value than DS ($p \leq 0.05$) (Figure 2).

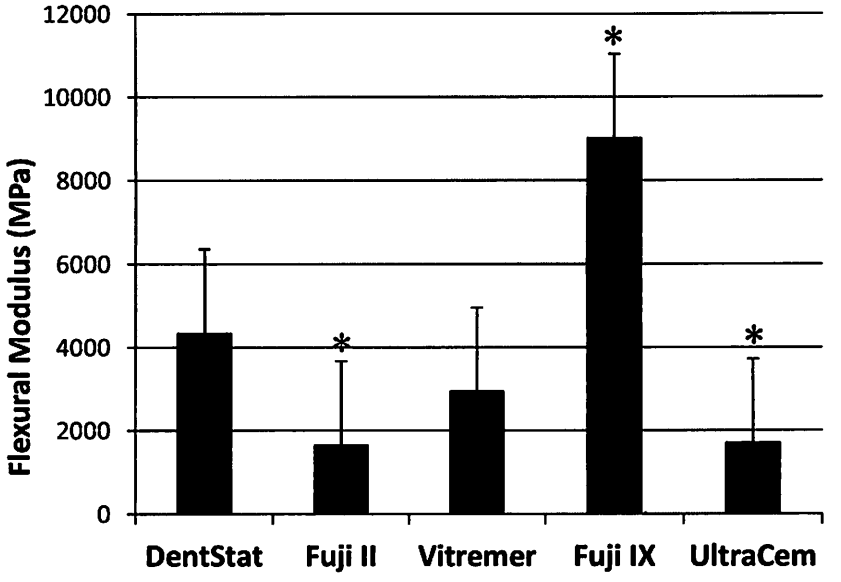

Figure 2. Comparison of Flexural Modulus. Rectangular specimens of each restorative material were made by inserting the material into the 2 mm x 2 mm x 25 mm mold. Each specimen was placed on a three-point bending test device, and the central load was applied with a head diameter of 2 mm using a crosshead speed of 0.25 mm/min. Flexural modulus was determined from the slope of the linear region of the load-deflection curve using the analytical software (TestWorks 4, MTS). The flexural modulus of DentStat™ was significantly greater compared with Fuji II and UltraCem. However, Fuji IX GP had a significantly greater flexural modulus value than DentStat™ (* = $p \leq 0.05$ for DentStat™ compared to other materials).

Compressive Strength

DentStat™ compressive strength was 154.4 (±7.5) MPa compared with 92.6 (±18.1) MPa for Fuji II™ LC, 73.5 (±21.9) MPa for Vitremer™, 105.5 (±45.4) MPa for Fuji IX™ GP and 80.8 (±7.5) UltraCem™ (Figure 3). A one-way ANOVA was used for statistical analysis. The compressive strength of DS was significantly greater for all groups ($p \leq 0.05$).

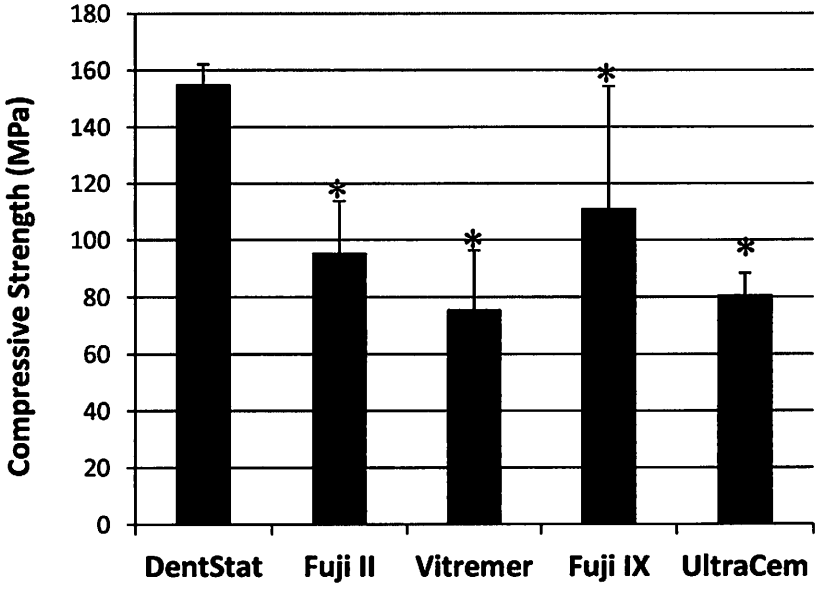

Figure 3. Comparison of Compressive Strength. Cylindrical specimens 4 mm diameter with a height of 6mm were made in a mold and a compressive load along the long axis of the specimen was applied. The maximum force applied when the specimen fractured was recorded and the compressive strength was determined. The compressive strength of DentStat™ was significantly greater than all materials tested (* = $p \leq 0.05$ for DentStat™ compared to other materials).

Discussion

The main goal in the development of DS was to make a material that possessed field-friendly handling characteristics. These characteristics include being easy to mix and clean-up, setting (hardening) quickly, insensitivity to temperature and humidity extremes, providing pain relief, visualization during placement, and compactness for easy portability. The results of this study demonstrated that the formulation of DS has resulted in a material that is on par with other GI and RMGI.

In a recent product review of GI containing restoratives, American Dental Association (ADA) stated that higher flexural strength and compressive strength were desirable properties of a restorative material (28). The flexural strength of DS (42.8 MPa) was higher than 25 MPa, which is the ISO 9917-2 minimum strength requirement for a restorative resin-modified glass ionomer. The minimum desired compressive strength is 100 MPa for glass ionomer cements as recommended by ISO 9917-1. DentStat™ demonstrated a compressive strength (154.4 MPa)

which exceeds 150% of the recommended strength. A higher flexural modulus provides better resistance to deformation under occlusal forces. However, an optimum range for flexural modulus tests has not been determined and would depend on the location and occlusal load of the restoration (28). The flexural modulus of DS was the second highest (4517.3 MPa) among 5 tested samples.

DentStat™ was tested against three commercially available RMGIs and one GI (Fuji IX™ GP). Overall, DS performed better in the comparison with other materials tested. The results of this study suggest that the novel methods used in the formulation of DS reduced the rigidity of the polymer structure while increasing its capacity to withstand loads making the material less brittle and less prone to bulk fracture. Improvements in these physical characteristics are critical factors in the success of dental materials. DentStat™ can be used in a multitude of dental applications, such as interim restorations, stabilizing agents for dislocated teeth, or as a liner and base under amalgam dental restorations.

DentStat™ has unique chemical properties compared with other RMGIs. The polyacylic acids in the liquid component were replaced with esters, which is a potential explanation for the improved physical properties of the material (Personal Communication with Dr. Amer Tiba). Additionally, the liquid component does not contain water, which makes DS more stable by avoiding a slow hydrolysis of the liquid component over time. Eliminating water in DS may lead to the material having an improved shelf life compared to other RMGIs. The mixed material is not moisture sensitive, and laboratory data demonstrated that when the liquid component was placed in a 37 °C oven for 36 months it was still very stable when mixed with powder and resulted in a material that set very well (unpublished data).

In general, GI or RMGI have less strength compared with traditional resin composite. However, in areas subject to light mechanical forces and where some therapeutic fluoride release is desired, GI or RMGI may be a better choice. DentStat™ may be ideal for use as a field-friendly, forward-deployable, temporary dental restorative material to serve as a dental dressing in remote military settings where definitive treatment of a dental emergency is unavailable.

Conclusion

DentStat™ was compared to commercially available alternatives. In flexural strength and compressive strength comparisons, DS showed the highest values, and in flexural modulus,

it was the second stiffest among the tested dental restoratives and cements. DentStat™ was found to have excellent physical and mechanical properties that could be used in a number of dental applications in addition to its current usage as a temporary restoration.

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14. ABSTRACT

Recently the US Navy developed a new resin modified glass ionomer (RMGI), DentStat™, to be utilized in emergency situations to temporarily replace lost restorations or repair fractured teeth. The purpose of this study was to determine if DentStat™ has physical properties comparable to three commercially available RMGIs and one commercially available glass ionomer (GI). DentStat™ showed significantly higher flexural strength compared with all tested materials except Fuji II™ LC. The flexural modulus of DentStat™ was significantly higher than Fuji II™ LC and UltraCem™, however, the flexural modulus of Fuji IX™ GP was higher than DentStat™. DentStat™ showed significantly higher compressive strength than all other material tested. DentStat™ demonstrated physical properties in line with other commercially available RMGIs and GI cements and could serve as an interim restorative material in remote military settings. Further studies with additional test conditions and methods are suggested.

15. SUBJECT TERMS
Glass ionomer, resin modified glass ionomer, flexural strength, flexural modulus, compressive strength

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