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Learning to Care for Those in Harms' Way

Evaluation of ACTIVA BioACTIVE-RESTORATIVE flexural strength in comparison to traditional composite resin, glass ionomer, and resin modified glass ionomer.

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ABSTRACT

Objective: The objective of this project is to assess the relative flexural characteristics of four commercially available restoration composites.

Methods: Forty samples each of ACTIVA BioACTIVE-RESTORATIVE[®], GC Fuji II LC[®] resin modified glass ionomer, GC Fuji IX GP[®] EXTRA glass ionomer, and 3M[®] Filtek[®] Supreme Ultra restorative resin composite, were prepared for flexural testing according to ISO 4049:2000 (E) 7.11 Flexural Strength Class 2 Group 2 materials. Samples were subjected to a 3-point bending test using Instron[®] 5943. Flexural characteristic data for the samples were calculated and subject to analysis of variance followed by post hoc testing to elucidate pairwise differences.

Results: Of the four tested composites, 3M Filtek Supreme Ultra had the highest flexural modulus ($M=653.69 \text{ N/mm}^2$, $SD = 257.36$), indicating it to be the most rigid of the groups, $P<0.001$. In contrast, ACTIVA BioACTIVE-RESTORATIVE displayed significantly higher deformation tolerance with nearly twice the mean flexural strain at maximum load compared to the other groups, $P<0.001$.

Significance: Constant change and development of dental materials to reach restorative needs of the patient and dentist are necessary for accurate care. Continued studies on strengths and physical properties of materials should be continued to ensure the most appropriate materials are being utilized.

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INTRODUCTION

The introduction of resin-based materials as an alternative to amalgam has introduced the ability to select different restorative options based on the patient's esthetic, strength, and functional needs. Resin based materials on the market today have varying esthetics, physical properties, and now bioactive capabilities. The Bioactive portion of the name means the material is able to stimulate apatite formation and remineralization. This results in stronger enamel that is more difficult to demineralize by bacterial acids and can decrease tooth sensitivity.

This study examined the flexural strength of ACTIVA BioACTIVE-RESTORATIVE in comparison to traditional materials such as resin composite, resin modified glass ionomer (RMGI), and glass ionomer (GI). This test measures a material's resistance to deformation when a force is applied perpendicular to the long edge of a sample. In contrast to many other isotropic materials, dental resin composites do not demonstrate the same deformation characteristics for tension and compression. Consequently, the flexural modulus (also referred to as "modulus of elasticity" or "bending modulus") is required to describe the rigidity of a composite. Flexural strength will be evaluated by finding the force necessary to create a permanent change or break of the material. The comparison will determine if the new bioactive material can perform with the same flexural strength as traditionally used materials.

Significance

Composite resins have gone through multiple iterations and improvements since their first appearance as a dental restorative material. The ACTIVA BioACTIVE-RESTORATIVE iteration takes traditional composite resin and adds synthetic rubber and bioactive materials. The bioactive component of the material is Crysta^{23, 24, 25}; a Pulpdent patented molecule that releases calcium and phosphate minerals that stimulate the remineralization of enamel and formation of mineral apatite. Additionally, the material differs from traditional composite resins because it is moisture friendly. The layer of mineral apatite forms a chemical bond between the restorative material and dentin and a mechanical bond is also formed due to apatite formation into the dentinal tubules.^{1, 4, 16, 18, 23}

Pulpdent claims that this material is not brittle like traditional resins and can flex with the natural flex of the tooth.^{16,17} This means the material should deflect more before breaking under flexural stress. Should this material show strength properties and clinical outcomes equivalent or better than current composite resin products; the addition of bioactive and flexural features to traditional composite resin should allow for greater reported flexural strength than traditional composite resins.

This material is advertised to be esthetic, require less accompanying materials than other composites on the market, be moisture friendly, and the bioactive feature is thought to seal micro-gaps and margins and create longer lasting restorations.^{1,2,16,17} The preventive features are similar to resin-modified glass ionomer cements, compomers, and giomers in that they release fluoride ions, qualifying this material as a 'smart' material.^{3,12,21}

Dentists serving populations in remote areas or situations requiring the dentist travel to the patient away from a traditional clinic setting could benefit greatly from a product that performs well in structural and preventive capacities. Examples of the populations are people living in health care deserts (a populated region more than 60 minutes away from the nearest

acute-care hospital)²², persons of all age ranges living in assisted care facilities, persons that may not have physical or mental capabilities to perform adequate oral hygiene, and military units that are deployed for extended periods of time without the ability to maintain regular oral health maintenance. Using materials that are also preventative and last longer are ideal in treating these populations with limited access to care because they should survive longer time spans and provide some preventative features between clinical visits.

Purpose

This study is designed to test the flexural strength of ACTIVA BioACTIVE-RESTORATIVE in comparison to traditional materials such as composite resin, RMGI, and GI. The comparison will determine if the bioactive material, can perform with the same or better flexural strength as traditionally used materials.

HYPOTHESIS

ACTIVA BioACTIVE-RESTORATIVE will have comparable flexural strength to resin composite and higher flexural strength than glass ionomer and resin modified glass ionomer.

MATERIALS AND METHODS

Flexural strength of ACTIVA BioACTIVE-RESTORATIVE will be tested and compared to resin composite, resin modified glass ionomer, and glass ionomer. Specimens of all materials will be made according to ISO 4049:2000 (E) 7.11 Flexural Strength Class 2 Group 2 materials. Flexural strength of each specimen will be measured using a three-point bend test on the Instron® 5943.

Specimens will be made with ISO produced stainless steel mold (Image 1) to create 40 specimens of each material for a total of 160 specimens. Each material specimen will be made in the dimensions of (25 ± 2) mm x (2 ± 0.1) mm x (2 ± 0.1) mm. All samples, regardless of being light cure, dual cure, or self cure were light cured. The 3M™ Elipar™ DeepCure-S LED curing light was used holding the tip at a distance of 1mm from specimen and constantly moved along length of specimen for 40 seconds.

Image 1. ISO Procured Stainless Steel Mold



Detailed Methodology

In total, the flexural properties of one hundred sixty samples, evenly split between four different composites, were tested. The restorative materials tested are 3M Filtek Supreme Ultra, ACTIVA BioACTIVE-RESTORATIVE, GC Fuji II LC, and Fuji IX GP EXTRA. The Instron 5943 machine was used to perform a three-point flexural strength test. (Image 2 & 3) Flexural strength of a material is defined as its ability to resist deformation under load. For materials that deform significantly but do not break, the load at yield, typically measured at 5% deformation/strain of the outer surface, is reported as the flexural strength or flexural yield strength. The resulting force measurement will be in units of megapascals and used to calculate flexural strength using the equation.

$$\sigma = \frac{3FL}{2wh^2}$$

Units of the equation defined as follows:

σ = Flexural strength or modulus of rupture

F = maximum load in newtons (N)

L = distance between supports in millimeters (mm)

w = width of specimen in millimeters (mm)

h = height of specimen in millimeters (mm)

Data Analysis

Sample size of the five materials was determined by using a priori power analysis. This gave information on what sample size would be needed to detect some level of effect with inferential statistics. For one way ANOVA with power $(1 - \beta)$, the priori analysis was set at 0.80 and two-tailed $\alpha = 0.05$ was conducted. To resolve differences of a large effect size ($f=0.40$), the total sample required was $n=80$ or 16 per group. To resolve medium sized differences between the groups (effect size $f=0.25$), the total sample required was $n=200$ or 40 per group. Previous study analyzing diametral strength utilized $n=60$ or 12 per group. For this study, $n=160$ or 40 per group was chosen.

The Shapiro-Wilk test was used to assess the normality of the data distributions for continuous data. Accordingly, measures of central tendency are presented as means with associated standard deviations. Analyses of variance (ANOVAs) were conducted to check for differences in the maximum load at break (N/mm^2) as well as the flexural modulus (N/mm^2) between the different composites. Post-hoc testing was accomplished using Tukey's test. Eta squared (η^2) statistics are presented as measures of effect size for significant ANOVA results and Cohen's d is reported for significant t-test results. Statistical significance for all statistical tests was declared at $P < 0.05$. Data were analyzed using SPSS 25.0 (IBM, Armonk, NY, USA).

RESULTS

One sample from the 3M Filtek Supreme Ultra group was excluded as an outlier. This left 159 samples for testing (ACTIVA BioACTIVE-RESTORATIVE, $n = 40$; 3M Filtek Supreme Ultra, $n = 39$; GC Fuji II LC, $n = 40$; and GC Fuji IX GP EXTRA, $n = 40$). The flexural characteristics of the groups are summarized in Table 1.

A significant difference in flexural modulus was found among the four composites, $P < 0.001$. Post-hoc testing revealed that 3M Filtek Supreme Ultra had significantly higher flexural modulus ($M=653.69 \text{ N/mm}^2$, $SD = 257.36$) compared to all other composites (all $P < 0.001$). The effect size for the difference was $\eta^2 = 0.61$. This indicates that 61% of the variance in sample stiffness was accounted for by the type of composite. No difference in sample stiffness was noted between the GC Fuji II LC, GC Fuji IX GP EXTRA, and ACTIVA BioACTIVE-RESTORATIVE samples (all $P > 0.05$).

3M Filtek Supreme Ultra also sustained a significantly higher load prior to breaking compared with the other composite groups (all $P < 0.01$). The mean maximum load at break was 32.94 N ($SD=13.13$) for 3M Filtek Supreme Ultra, 26.81 N. Figure 1 shows the average maximum load of the various groups. While the GC Fuji IX GP EXTRA group had the lowest mean maximum loads from a numerical standpoint, it is worth noting that there was no statistical difference between the average maximum loads experienced by GC Fuji IX GP EXTRA and GC Fuji II LC, $P = 0.41$.

Figure 2 shows the mean flexure strain at maximum load experienced by each of the groups. As expected, the group with the highest stiffness score (3M Filtek Supreme Ultra) had the lowest mean flexure strain at maximum load / deformation ($M = 0.19$, $SD = 0.01$) before breaking, $P < 0.001$. Post-hoc analysis further revealed that despite a lack of difference in flexural modulus (stiffness) between the ACTIVA BioACTIVE-RESTORATIVE, GC Fuji II LC, and GC Fuji IX GP EXTRA groups, the ACTIVA BioACTIVE-RESTORATIVE group nonetheless displayed higher overall deformation tolerance. The mean flexure strain at maximum load of the ACTIVA BioACTIVE-RESTORATIVE group was 0.46 ($SD = 0.01$). In contrast, the mean flexure strain at maximum load for FujiII and GC Fuji IX GP EXTRA was 0.22 ($SD = 0.05$) and 0.23 ($SD = 0.04$) respectively.

Table 1. Flexural Characteristics, M (SD)

Composite	Load at Break (N)	Flexure Stress at Maximum Load (N/mm^2)	Flexure Strain (Extension) at Maximum Load	Flexural Modulus (N/mm^2)
Filtek Supreme	32.94 (13.13)	123.54 (49.23)	0.19 (0.01)	653.69 (257.36)
Fuji II	14.09 (5.03)	52.82 (18.88)	0.22 (0.05)	256.39 (116.57)
Activa Bioactive	26.81 (8.31)	100.54 (31.16)	0.46 (0.01)	221.68 (70.86)
Fuji IX	11.16 (4.18)	41.85 (15.69)	0.23 (0.04)	194.53 (89.74)

Image 2. Samples

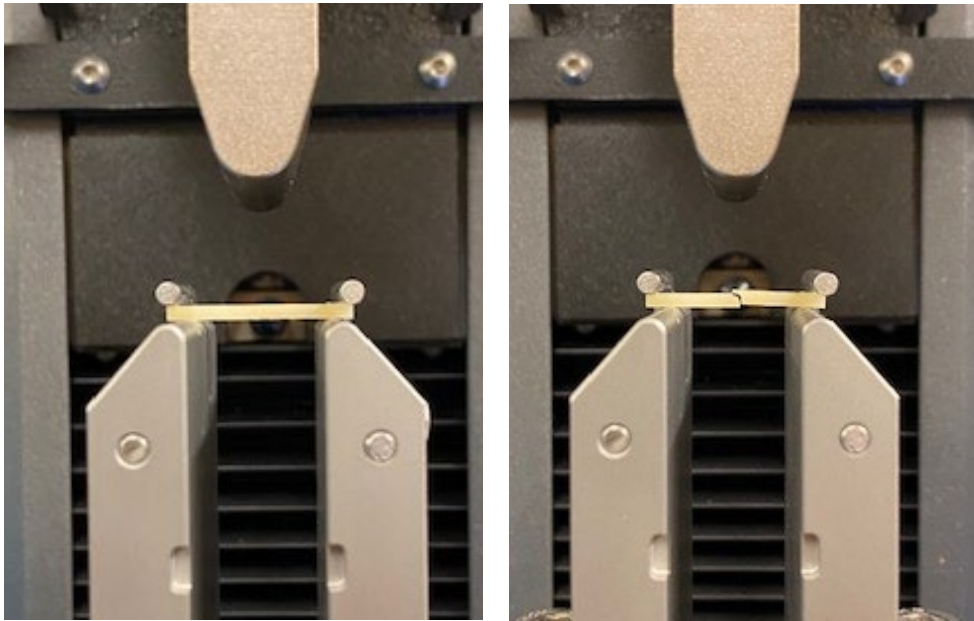


Image 3. Instron Testing

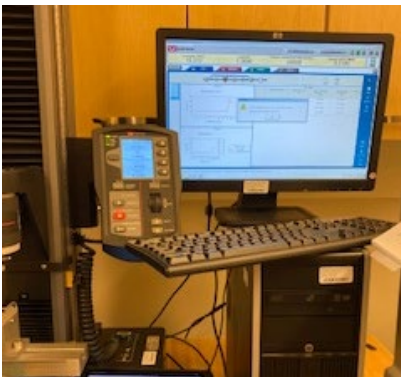


Figure 1. Maximum Load on Sample at Break

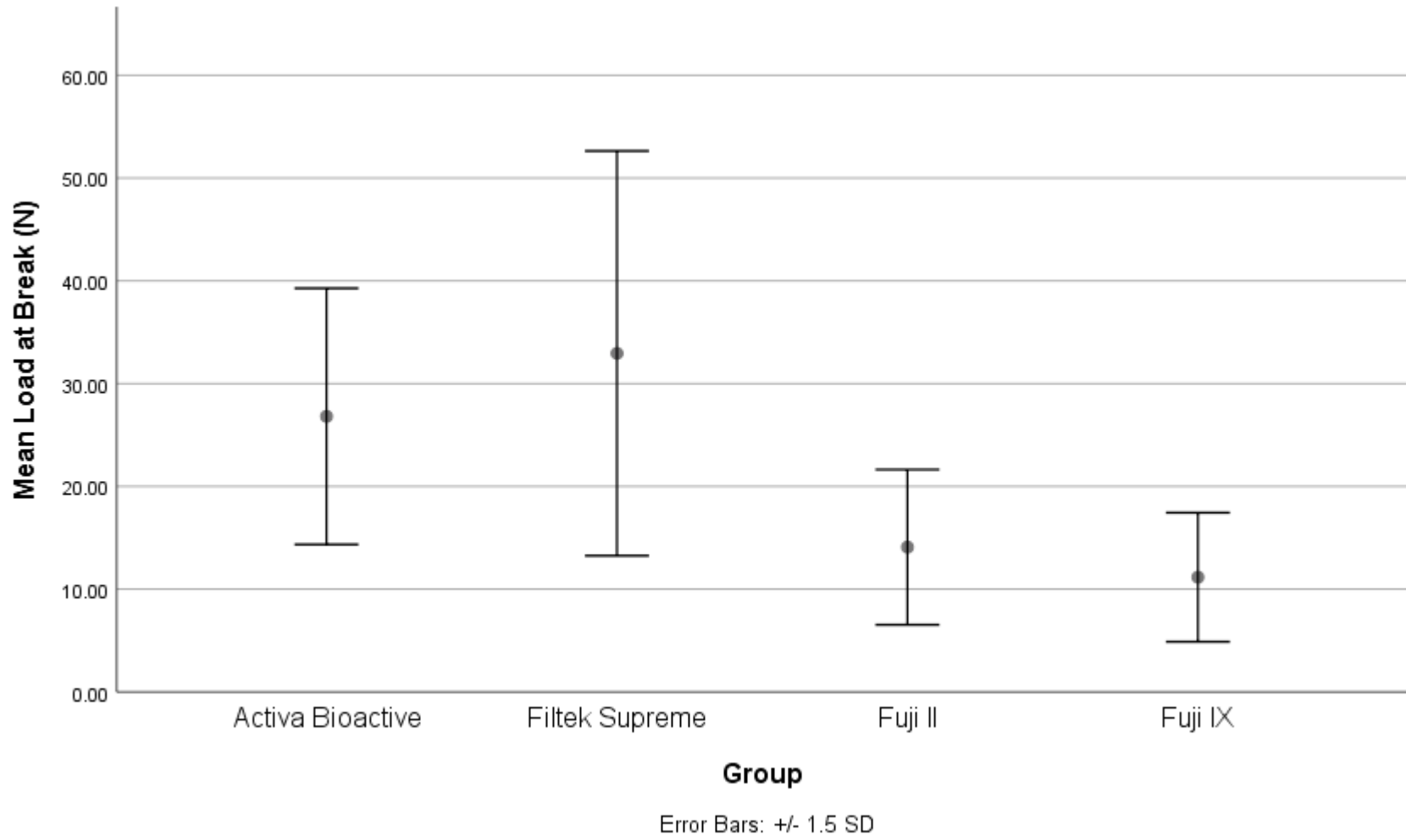
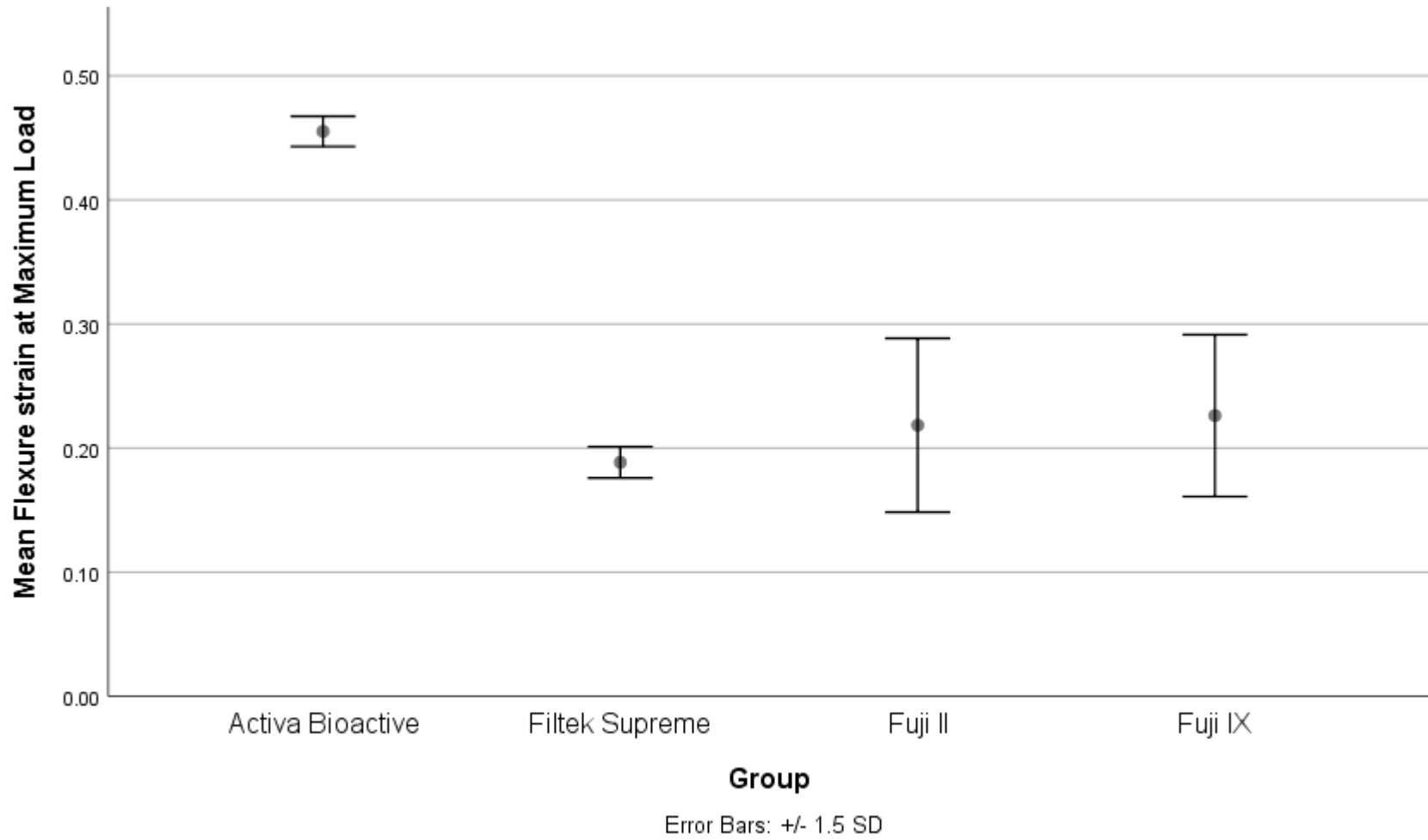


Figure 2. Flexural Strain at Maximum Load



DISCUSSION

ACTIVA BioACTIVE-RESTORATIVE's ability to release fluoride and have comparable esthetic properties of resin composite makes the material an appealing restorative material. The bioactive ability of the product is appealing, but insignificant if the physical properties of the material do not perform. Considering load applied at break of the materials, the Filtek Supreme Ultra was able to withstand the highest force of 32.94N. ACTIVA BioACTIVE-RESTORATIVE came in second with a slightly lower value of 26.81N. These two were closer in value than the glass ionomer products. The load at break drops when considering these. The values were 11.16 and 14.09 for Fuji IX and Fuji II, respectively. So, the ACTIVA BioACTIVE-RESTORATIVE, performs closer to a composite resin than a glass ionomer when evaluating the load at break.

When considering the flexure stress at maximum load, this is the stress caused by the bending movement at the point right before breaking. The flexure strength is the point of break, so is the point just after or equal to, the flexure stress. The values for this also show that Filtek Supreme Ultra showed ability to withstand the highest stress, followed by ACTIVA BioACTIVE-RESTORATIVE. Similar to the load at break values, the glass ionomer product values were closer in value and significantly lower than the resin base restorative products. This similar pattern would make sense because the flexure stress is calculated using the load value right before break.

Flexure strain was also evaluated. This is the value of the change in length along the outer surface of the test specimen at midspan, where the maximum strain occurs.^{26, 27} This will show the change at the point the flexure stress is measured. Again, the results mimic the pattern of the glass ionomers performing close to one another, but the ACTIVA BioACTIVE-RESTORATIVE and Filtek Supreme Ultra do not perform close in value. Here the ACTIVA BioACTIVE-RESTORATIVE has the greatest flexure strain. This product is deforming more under force. This is likely attributed to the addition of rubber particles to the material.

Flexural modulus is the inverse of the deflection and shows the difficulty of bending the material. The composite resin Filtek Supreme Ultra showed the highest modulus and least deflection; meaning this material is the hardest to bend of the four materials measured. The GC Fuji II LC, GC Fuji IX GP EXTRA and ACTIVA BioACTIVE-RESTORATIVE had comparable values, showing they are easier to bend and bend at about the same values, so it could be hypothesized that this material would be suitable for areas of high flex, specifically for class 5 restorations.

The tooth should be able to flex and the material will bend with movement of the tooth and not debond or fracture. And like RMGI, this material also has fluoride release resulting in remineralization of the tooth. The mineral apatite formation between the restorative material and dentin into the dentinal tubules works in addition to the bonding layer to maintain the marginal seal during function. Research suggests that the bioactive feature could seal microgaps^{6,8,9}

The ability to biologically integrate with the tooth should result in less need to replace failed restorations due to marginal leakage. The ability to seal microgaps initially led Pulpdent to advertise there is no need for bonding agent when utilizing this material. Commercial use and further research of the product led the company to change the manufacturer instructions to say that, without retentive prep, use of the product should include a bond application step.

In situations where the patient is not able to tolerate long procedures due to special health needs or physical limitations, elimination of a step in the treatment process would be advantageous to both the patient and provider. A possible next question to ask would be, if the dentinal integration strength was equal to or greater than bond strengths, does the bioactive feature not just seal microgaps, but also prevent microgaps from forming if the bond material breaks down? Further research investigating timelines for the volume, density, and rate of bioactive apatite formation is warranted.

ACTIVA BioACTIVE-RESTORATIVE is an outlier when considering the flexure strain. The material bends as easily as the GC Fuji II LC and GC Fuji IX GP EXTRA products but deforms more. The material deflects under stress at more than double the deflection of the composite resin Filtek Supreme Ultra. If the flexural modulus of the glass ionomer products and ACTIVA BioACTIVE-RESTORATIVE are similar, how is it that the strain of the ACTIVA BioACTIVE-RESTORATIVE is so much greater? It is possible that the bending of the GC Fuji II LC and GC Fuji IX GP EXTRA stopped when the material fractured at a lower load. And the ACTIVA BioACTIVE-RESTORATIVE was able to continue to bend and as a result deform more because it continued to bend until it reached maximum load.

Cost of the ACTIVA BioACTIVE-RESTORATIVE compared to cost of traditional resin composites and bonding materials would also be interesting to consider. If the use of this product is still more costly than the resin composite or glass ionomer products, does the time spent modifying or replacing unsealed margins on traditional materials outweigh the additional cost of this new material? If it is used as a base layer underneath traditional composite resin, this could allow the provider to keep the bioactive properties and form the mineral apatite dentin bond. And since both products have a resin component, they would be able to be layered and bond well to each other. A sandwich technique restoration using a bioactive material and traditional resin composite should result in a stronger, longer lasting, and less costly option than using just one of the materials alone.

CONCLUSION

ACTIVA BioACTIVE-RESTORATIVE is a product that should be considered when deciding on restorative materials. It has esthetic properties like resin composite and fluoride releasing properties like glass ionomer products, so can be viewed as a step between the two products. The material is flexible like a glass ionomer making it a good option for restorations in areas of high flex but stands apart from the GC Fuji II LC and GC Fuji IX GP EXTRA products because it has a higher flexural strength. The Crysta molecule component that creates a mineral apatite seal via chemical and mechanical bond is where this material is stands apart from the other materials tested. This combination of features with the addition of bioactive properties makes ACTIVA BioACTIVE-RESTORATIVE an appealing restorative product.

Selecting a restorative material is an important step in the function and lifespan of the restoration. Consideration for function of tooth, patient habits, and future restorative needs are important for selection of a restorative material. Regularly, new materials reach the market and it is important to research and consider these in order to maintain proper implementation of

materials. ACTIVA BioACTIVE-RESTORATIVE restorative is one of many types of dental products that should be utilized to provide a patient with the most effective dental solutions. As this product continues to be developed and researched, new and alternative uses for the product will likely arise as well as better formulations of the product. Maintaining a well versed knowledge of the restorative options available is advantageous to the dentist. In the long run, it is the patient that will benefit the most from ever evolving products.

DISCLAIMER

The views expressed herein are those of the author and do not necessarily reflect the official policy of the Department of the Army, Department of Defense, or the US Government

DISCLOSURE

The authors disclose that they have no financial gain or affiliations with any company or product used in this research.

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AUTHOR CONTRIBUTIONS

Kindel Kaelke conceived the study concept, collected the data and wrote the manuscript. Thomas Beltran analyzed the data.

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