RelyX™
Luting Cement

RelyX™
Luting Plus Cement

Technical Product Profile

3M ESPE

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Introduction

RelyX™ Luting Cement and RelyX™ Luting Plus Cement from 3M ESPE are self-curing, radiopaque, fluoride-releasing, resin-modified glass ionomer luting cements. They are indicated for the permanent cementation of metal-based and strengthened-core ceramic restorations, posts and orthodontic appliances.

The primary purpose of a luting cement is to aid in retaining and sealing fixed prosthetic devices to prepared teeth. The better the crown preparation on the tooth (long axial walls with an approximate 6° taper) and the better the crown fit at the margins, the less a clinician has to rely on the retentive properties of the cement. Glass ionomer-based cements provide excellent properties for the retention of these types of restorations.

The RelyX Luting cement and RelyX Luting Plus cement will provide for molecular bonding to the tooth surface without the use of a separate tooth conditioner, good strength properties, fluoride ion release, and low solubility or acid erosion of the margins in an easy to use, non-technique sensitive procedure.

History

Clinicians have many options for luting routine crown and bridge restorations. They range from zinc phosphates, polycarboxylates, conventional glass ionomers, resin-modified glass ionomers, compomers and resin cements. In the North American markets, the conventional and resin-modified glass ionomer luting cements have become the most frequently used for routine crown and bridge restorations. Resin cements have been used for special situations where added retention is required, however they traditionally required multiple steps and have been technique sensitive. However, with the introduction of the unique RelyX™ Unicem Self-Adhesive Universal Resin Cement from 3M ESPE, clinicians now have an easy to use resin cement that offers low potential for sensitivity and is gaining in popularity for these types of restorations.

A comparison of the various classes of luting cements is provided in Table 1.

Table 1. Luting Cement Comparison

Strengths	Areas of Application	Weaknesses
Zinc Phosphate Cement		
• Over 100 years of clinical experience	• Routine application in metal supported crowns and bridges	• Occasional postoperative sensitivity • Low hardness • High solubility
Polycarboxylate Cement		
• 25 years of clinical experience • Low fluoride ion release • Molecular bonding to the tooth surface • Low postoperative sensitivity	• Acceptable for retention of metal supported crowns and bridges • Long-term provisional	• High solubility • Low hardness
Conventional Glass Ionomer Cement		
• 20 years of clinical experience • Fluoride ion release • Molecular bonding to the tooth surface • Minimal dimensional change • Simplicity of use • Medium material strength • Good routine cement	• Routine application for metal supported crowns and bridges • Limited application with high strength ceramics	• Occasional postoperative sensitivity • Sensitive to water and mechanical loading • Solubility
Resin-Modified Glass Ionomer Cement		
• 10 years of clinical experience • Fluoride ion release • Molecular bonding to the tooth surface • Low solubility or erosion of cement margins • Simplicity of use • Medium material strength • Good routine cement • Low postoperative sensitivity	• Routine application for metal supported crowns and bridges • Limited application with high strength ceramics	• Moisture sensitive powder • Swelling/linear expansion

Strengths	Areas of Application	Weaknesses
Compomer Cements		
• Easy technique • Good adhesive qualities (with pretreatment: etching, priming, bonding) • Low solubility • Good mechanical properties	• Metal-supported restorations • Most all-ceramic systems • Indirect composite restoratives • Lining material • Emergency provisional restoration	• Little long-term experience • Moisture sensitive • Low or no fluoride release
Resin Cements (Composite)		
• 10-20 years of clinical experience • High adhesion with use of pretreatments (etching, priming, bonding) • High hardness • Low solubility • High mechanical properties • Good esthetics	• All metal-based, ceramic and indirect composite restorations	• Difficult to use • Requires use of separate primers or adhesives • Difficult clean up • Technique sensitive • Low or no fluoride release • Potential for postoperative sensitivity
Self-Adhesive Resin Cements (RelyX™ Unicem Self-Adhesive Resin Cement from 3M ESPE)		
• New self-adhesive technology • High adhesion without use of etchant, primer or adhesive • Ease of use • Capsule delivery system • Low potential for postoperative sensitivity • High hardness • Low solubility • High mechanical properties • Good esthetics • Easy clean up	• All metal-based, ceramic and indirect composite restorations with the exception of veneers	• Limited long-term clinical history • Available only in capsule delivery • Low fluoride release

Product Description

RelyX™ Luting Cement (formerly known as Vitremer™ Luting Cement when first launched) was first introduced into the market in 1994. The product consists of a powder and liquid, which are dispensed in a 1:1 scoop:drop ratio, and mixed by hand for 30 seconds. The working time of the mixed cement is 2.5 minutes. The resulting mix has a mousse-like consistency, which is easily loaded into the restoration and allows for easy seating of the restoration. The excess cement is then easily cleaned-up after 2-3 minutes in the mouth. The RelyX Luting cement quickly gained in popularity of use for its ease of use, handling and clean-up properties, and low incidence of post-operative sensitivity. It has been a market leader for many years.

As with any hand-mixed, powder/liquid system, there can occasionally be an issue with the ease of use and consistency in dispensing the proper powder/liquid ratios, which if not done properly, can result in variance of the setting properties of the cement. Additionally, some of the powders can be sensitive to moisture uptake or contamination, which can also result in a variance of the setting properties of the cement. Therefore, there has been a strong desire to develop an easier to use paste/paste system that would overcome these variables and provide a product that could deliver greater consistency of use.

RelyX™ Luting Plus Cement is a paste/paste, resin-modified glass ionomer luting cement dispensed in a larger Clicker™ Dispenser system from 3M ESPE. The Clicker dispenser is similar to the Clicker dispenser used with the RelyX™ ARC Resin Cement system also from 3M ESPE, but is 2.3 times larger. The RelyX Luting Plus cement pastes are easily dispensed out of the Clicker dispenser and hand-mixed for 20 seconds. The working time of the mixed cement is 2.5 minutes. As with the powder/liquid system, the mixed cement from the paste/paste has the same mousse-like consistency, which is easily loaded into the restoration, and allows for easy seating of the restoration. The excess cement can also be easily cleaned up after two minutes in the mouth with final set being achieved in five minutes. The paste/paste system will provide for an even easier to use system and provide for more consistent use when compared to the powder/liquid system.

For both RelyX Luting cement and RelyX Luting Plus cement, the setting reactions are very similar. Two setting reactions occur for each system, an acid-base reaction between the fluoroaluminosilicate glass and the methacrylate functionalized polycarboxylic acid (this is the true glass ionomer setting reaction) and a free radical polymerization of the pendant methacrylate groups of the polymer and HEMA (2-hydroxyetyhlmethacrylate). The free radical polymerization reaction takes place without the need for light activation, therefore it is self-curing. The additional methacrylate reactions provides for higher strengths and reduced marginal solubility without sacrificing adhesion or fluoride release. Because of this chemistry, the cements can be described as resin-modified glass ionomer cements.

Indications for Use

RelyX Luting cement and RelyX Luting Plus cement are indicated for luting the following types of restorations:

- Porcelain-fused-to-metal (PFM) crowns and bridges
- Metal crowns, inlays and onlays
- Prefabricated metal provisional crowns
- Strengthened core all-zirconia or all-alumina ceramic crowns and bridges (i.e. Lava™ Zirconia from 3M ESPE or Procera® AllCeram)
- Prefabricated or cast posts
- Orthodontic bands and appliances

Composition

RelyX™ Luting Cement

RelyX Luting cement is composed of a powder and a liquid. The powder and liquid are mixed in a 1.6:1 ratio by weight, which equates to one scoop of powder to one drop of liquid.

The RelyX Luting cement powder is composed of a radiopaque fluoroaluminosilicate glass (FAS glass). It contains a microencapsulated potassium persulfate and ascorbic acid catalyst system providing the methacrylate cure in the absence of light (self-cure). The powder also contains an opacifying agent for shading to allow differentiation from the tooth.

The RelyX Luting cement liquid is an aqueous solution of polycarboxylic acid modified with pendant methacrylate groups. It also contains HEMA, water and small amounts of tartaric acid.

Powder	Liquid
• Fluoroaluminosilicate (FAS) glass	• Methacrylated polycarboxylic acid
• Potassium persulfate	• Water
• Ascorbic acid	• HEMA
• Opacifying agent	• Tartaric acid

RelyX™ Luting Plus Cement

RelyX Luting Plus cement is composed of two separate pastes dispensed out of the Clicker™ Dispenser in a 1:1 volume ratio.

The RelyX Luting Plus cement Paste A is composed of a radiopaque fluoroaluminosilicate glass (FAS glass), opacifying agent, HEMA, water, a proprietary reducing agent that allows for the self-cure methacrylate setting, and a dispersion aid.

The RelyX Luting Plus cement Paste B is composed of a non-reactive zirconia silica filler, the methacrylated polycarboxylic acid, HEMA, BisGMA, water and potassium persulfate.

Paste A	Paste B
• Fluoroaluminosilicate (FAS) glass	• Methacrylated polycarboxylic acid
• Proprietary reducing agent	• BisGMA
• HEMA	• HEMA
• Water	• Water
• Opacifying agent	• Potassium persulfate
	• Zirconia silica filler

Properties

In order to achieve proper performance, the cements must provide for a variety of physical properties with respect to adhesion, strength, film thickness, work time, set time and radiopacity.

The glass ionomer based cements are regulated under the ISO 9917:2003 standard for Dental Water Based Cements and Self-curing Resin Modified Cements. The RelyX™ Luting Cement and RelyX™ Luting Plus Cement both pass the requirements for the ISO 9917 standard.

The physical properties of the RelyX Luting cement and RelyX Luting Plus cement are described and shown in this section. Additionally, results for the following cements are also provided for most tests:

GC's FujiCEM™ (paste/paste resin modified glass ionomer)

GC's Fuji Plus™ (powder/liquid resin modified glass ionomer)

GC's Fuji 1® (powder/liquid conventional glass ionomer)

Adhesion to Tooth Structure

An advantage of the glass ionomer cements is their inherent ability to provide a molecular bond to tooth structure without the use of separate etching and bonding techniques. Although, some products do recommend the use of a separate conditioner on the tooth surface to promote adhesion, RelyX Luting cement and RelyX Luting Plus cement do not need a separate conditioning step. While the adhesion is lower than that of properly placed composite resin systems, clinical experience has proven it to be adequate for most metal-based or strengthened-ceramic restorations.

Bovine dentin and enamel substrates were prepared by potting the teeth in acrylic, then grinding and polishing to expose the enamel or dentin surface. Sandblasted metal test buttons were used to simulate the restoration. Cements were mixed according to manufacturer's directions and placed onto the metal surface. The metal buttons were then seated onto the tooth surface under moderate pressure. The samples were placed into a heated humidity chamber (37°C/95%RH) for 20 minutes, and then placed into distilled water. The samples were stored at 37°C for 24 hours and the shear adhesion results were measured using an Instron test machine. Figures 1 and 2 show the adhesion results for both enamel and dentin. RelyX Luting cement and RelyX Luting Plus cement show similar results for adhesion.

Source: 3M ESPE laboratory test data

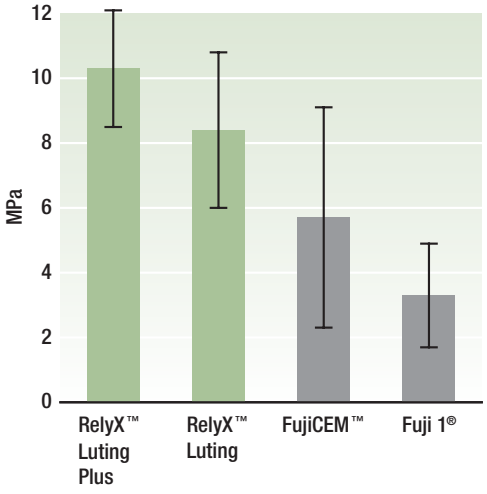


Figure 1. Shear Adhesion to Enamel

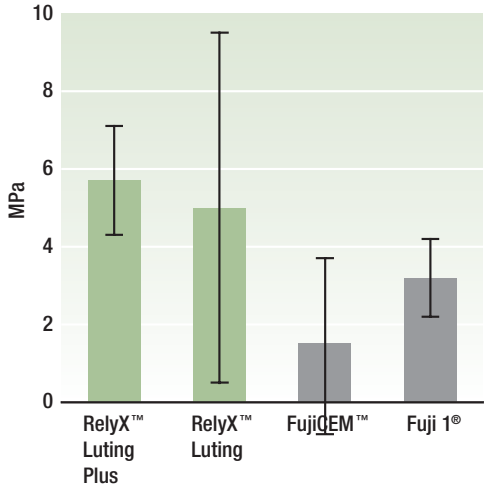
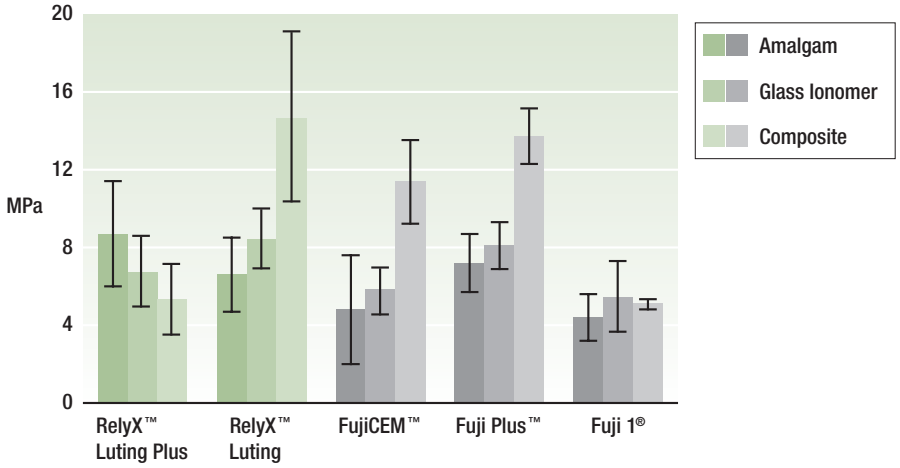


Figure 2. Shear Adhesion to Dentin

Adhesion to Core Build-Up Substrates

In addition to bonding to tooth structure, the cements must also be able to bond to various types of core build-up materials that may be used as a base under indirect restorations. The common types of build-up materials include amalgam, glass ionomer, and composite resins. In this test, the cements were tested for adhesion in a similar manner to that described above for the dentin and enamel.

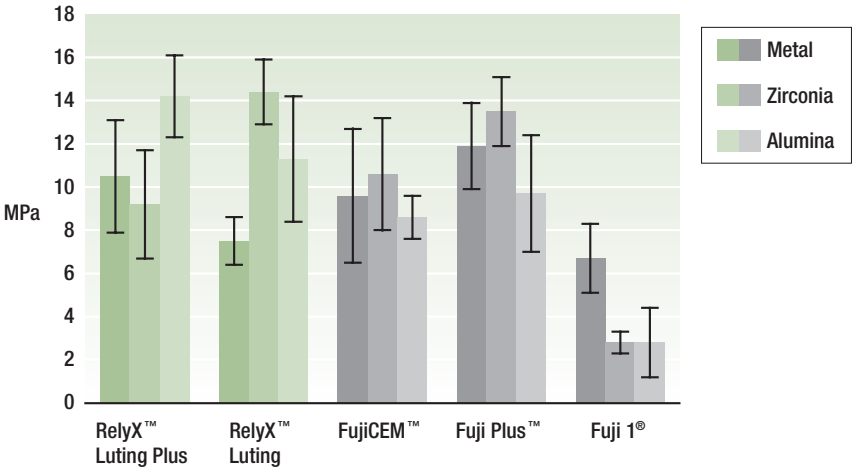


Source: 3M ESPE laboratory test data

Figure 3. Adhesion to Core Build-up Substrates

Adhesion to Restorative Substrates

In addition to bonding to the tooth structure and the core build-up substrates, the cements must also be able to bond to the various restorative substrates, for which they are indicated. The primary restorative substrates that are indicated for the resin-modified glass ionomers are metal, alumina and zirconia. In this test, the cements were tested sandblasted metal (Rexillium III), Lava™ Zirconia and Procera® AllCeram alumina buttons were bonded to enamel in a similar procedure as described above.



Source: 3M ESPE laboratory test data

Figure 4. Adhesion to Restorative Substrates

Mechanical Properties

A metal-based and strengthened-core ceramic restoration gains much of its supporting strength and stability from the coping and does not rely as heavily on the cement as is the case with weaker strength ceramics where composite resin cements are indicated and needed for support. The compressive and flexural strength of the cements were measured in accordance with the ISO 9917 test standard. Additionally, the diametral tensile strength of the cements was also measured. The cements tested provided for similar results for the three strength measurements with the exception of the Fuji 1® one conventional glass ionomer, which was significantly lower for flexural strength.

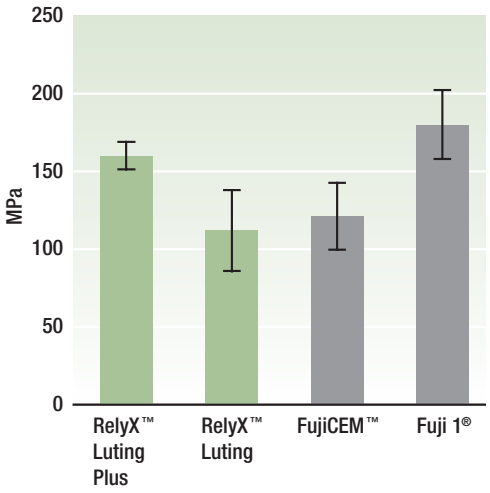


Figure 5. Compressive Strength

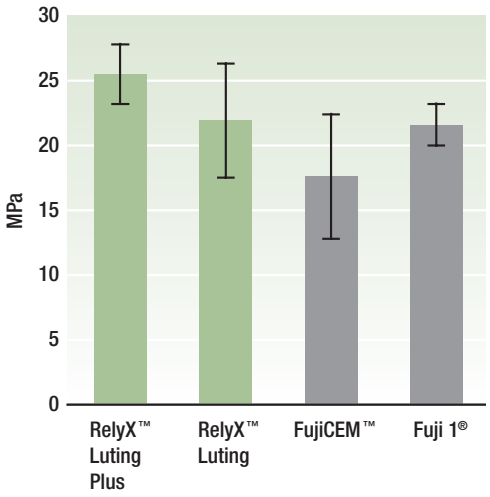


Figure 6. Diametral Tensile Strength

Source: 3M ESPE laboratory test data

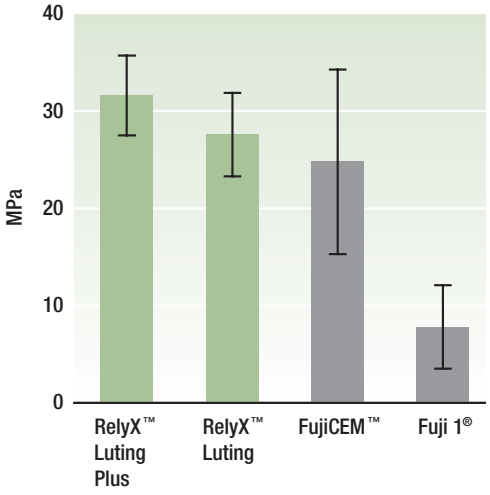
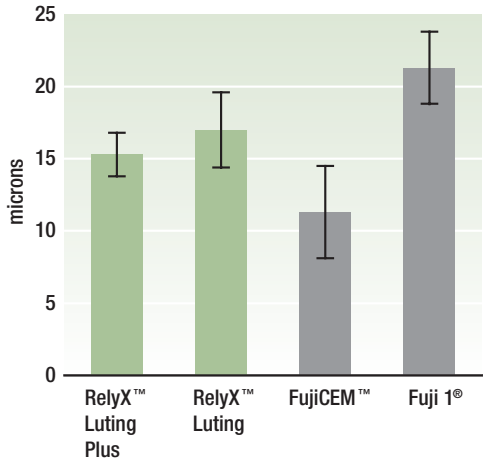


Figure 7. Flexural Strength

Film Thickness

The film thickness of the cement plays an important role in determining how well a precision indirect restoration will fit. Film thickness is determined by placing the mixed cement between two glass plates and placing a load on the top plate to see how thin the cement layer can get. A material with a low film thickness has the ability to allow a very tight fitting indirect restoration to seat completely. This test was conducted in accordance with ISO 9917 and requires the film thickness to be less than 25 microns. The results show that all of the cements were below the 25 micron limit.

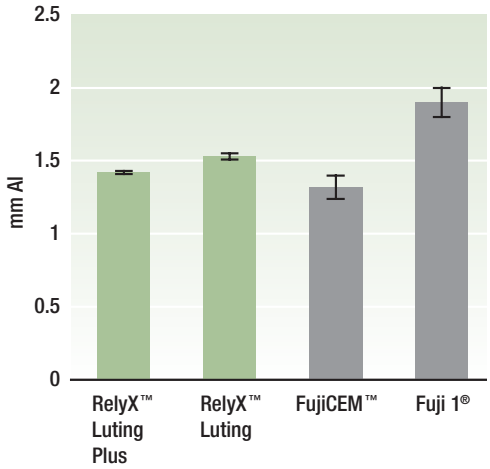


Source: 3M ESPE laboratory test data

Figure 8. Film Thickness

Radiopacity

Radiopacity is important during an indirect procedure for two reasons, it allows the doctor to discover any excess material subgingivally and allows the doctor to discover any large marginal discrepancies. Radiopacity allows the clinician to distinguish the cement from tooth structure on an x-ray. The radiopacity was measured in accordance with the ISO 9917 test standard. The test compares the radiographical density of the cement test sample to that of aluminum. A value of 1.0 or greater is considered to be radiopaque. The results show that all of the cements were in a similar range are considered to be radiopaque.



Source: 3M ESPE laboratory test data

Figure 9. Radiopacity

Fluoride Release

One of the key features of a glass ionomer-based cement is their sustained fluoride release. It is generally believed that the release of fluoride ions and uptake into the tooth structure aids in the reduction of secondary caries[1], which can be difficult to detect under a crown or bridge. Fluoride release was measured in-vitro in a buffer solution using a fluoride ion-specific electrode. The chart shows the sustained release of both RelyX™ Luting Cement and RelyX™ Luting Plus Cement in comparison to the other resin-modified glass ionomers and the conventional glass ionomer (Ketac™ Cem Glass Ionomer Luting Cement from 3M ESPE).

Source: 3M ESPE laboratory test data

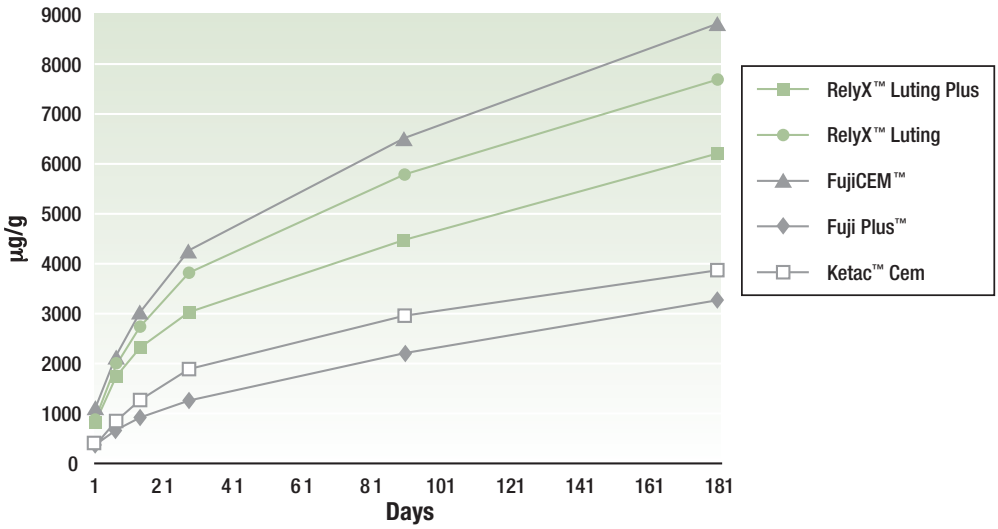


Figure 10. Cumulative Fluoride Release

Field Evaluation Results

With the introduction of the RelyX Luting Plus cement, a clinical use field evaluation was conducted. One hundred thirty seven dentists cemented a total of 1889 restorations with the RelyX Luting Plus cement. The observation period was approximately six weeks. The dentists completed a questionnaire regarding their experiences in use and application of the product.

The dentists that participated in the study used a variety of cement types for their routine cementation including resin cements, resin-modified glass ionomers, conventional glass ionomers, polycarboxylates, and zinc phosphate.

Figure 11 shows the range and numbers of types of restorations that were placed during the evaluation.

Source: 3M ESPE laboratory test data

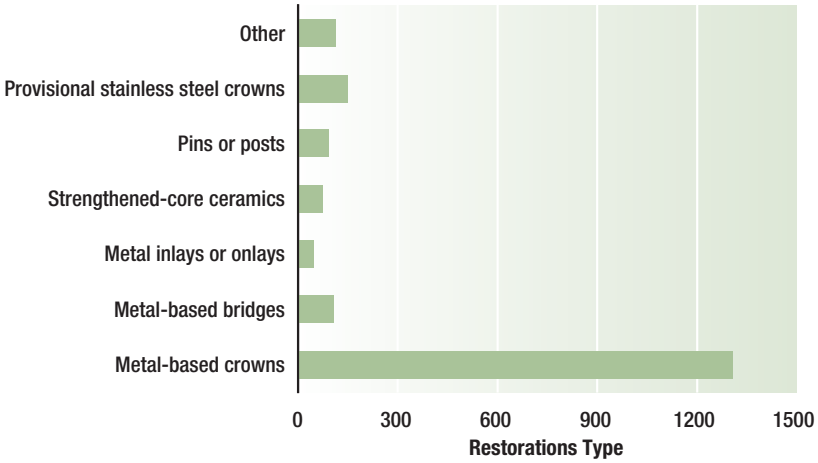
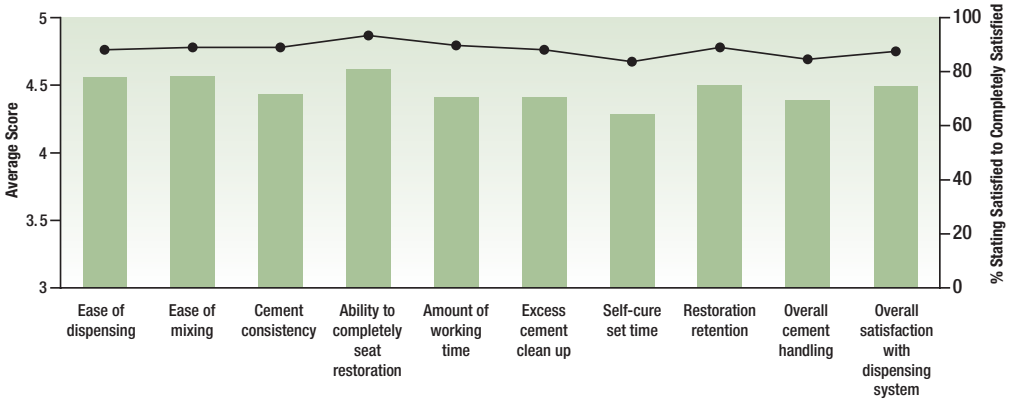


Figure 11. Types of Restorations

[1] *Hicks MJ, Flaitz CM, Quintessence Int. 2000 Sep;31(8): 570-8.*

Clinicians were asked to rate various handling properties of the RelyX™ Luting Plus Cement on a scale of 1 to 5 with a 1 being completely dissatisfied and a 5 being completely satisfied.

Figure 12 shows the average rating for the various properties and the percentage of clinicians that stated they were satisfied to completely satisfied. Overall, clinicians were very satisfied with all attributes and performance of the RelyX Luting Plus cement.

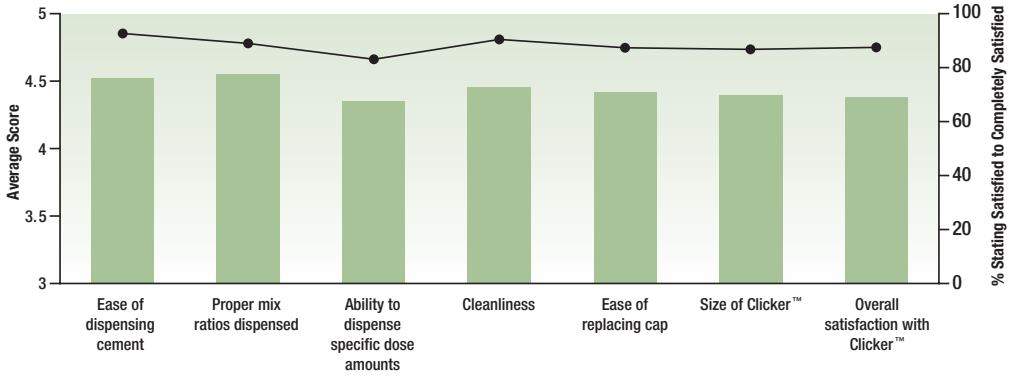


Source: 3M ESPE laboratory test data

Figure 12. Overall satisfaction with RelyX™ Luting Plus Cement

Clinicians were asked to rate various properties of the new larger Clicker™ Dispenser on a scale of 1 to 5 with a 1 being completely dissatisfied and a 5 being completely satisfied.

Figure 13 shows the average rating for the various properties and the percentage of clinicians that stated they were satisfied to completely satisfied. Overall, the clinicians were very satisfied with the new larger Clicker dispenser.



Source: 3M ESPE laboratory test data

Figure 13. Satisfaction with the Clicker™ Dispenser

Clinicians were also asked to rate how well the RelyX™ Luting Plus Cement met their overall expectations for a routine crown and bridge luting cement. They were asked to rate their satisfaction on a scale of one to five with one corresponding to not meeting expectations at all and a five corresponding to completely met expectations. Figure 14 shows the average rating for meeting expectations and the percentage of clinicians that stated that the product either generally met or completely met expectations. The results were determined for the various user groups. Overall, the cement met the clinician's expectations very well.

Source: 3M ESPE laboratory test data

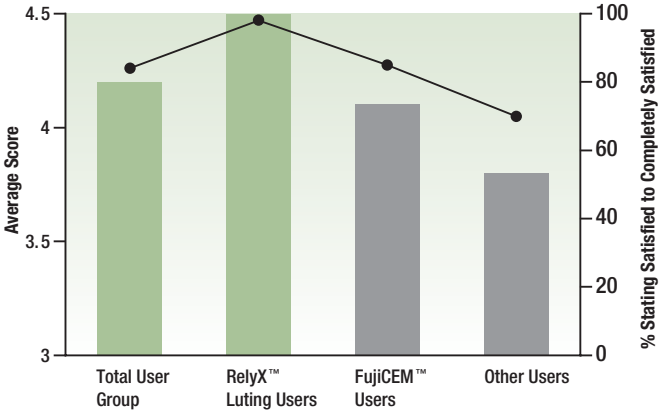


Figure 14. Overall Satisfaction with RelyX™ Luting Plus Cement

The clinicians that currently use the powder/liquid RelyX Luting cement were asked if they felt that the paste/paste RelyX Luting Plus cement would provide more consistent performance, by eliminating the variability with dispensing separate powders and liquids.

Source: 3M ESPE laboratory test data

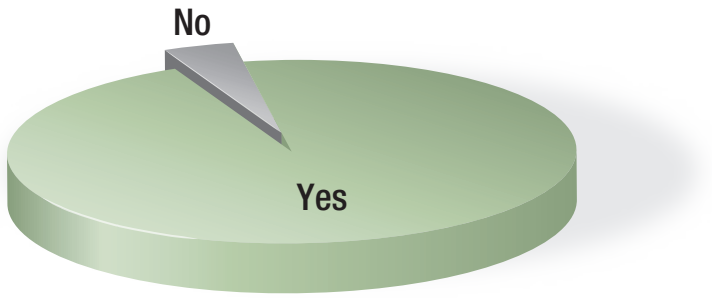


Figure 15. Consistency of RelyX™ Luting Plus Cement

Questions and Answers

How many applications can be done out of each system?

For the RelyX™ Luting Cement powder/liquid system it is recommended to use three scoops to three drops of liquid for a single crown. Based on these ratios, approximately 80 single units can be seated out of one set of powder and liquid.

For the RelyX™ Luting Plus Cement paste/paste system it is recommended to dispense two "clicks" of material out of the Clicker™ Dispenser for a single crown. Based on this amount, approximately 40 single units can be seated out of one Clicker dispenser. There are 80 total clicks of material out of a single Clicker dispenser. The back of the plunger has a scale that shows how many clicks are remaining in the Clicker dispenser.

What is the shelf life for the cements?

RelyX Luting cement powder/liquid system: This product is designed to be stored and used at room temperature. Shelf life at room temperature is 24 months. Ambient temperatures routinely higher than 27°C/80°F, or lower than 10°C/50°F may reduce shelf life. See outer package for expiration date. During use it is very important to make sure that powder vial is completely sealed after use to avoid moisture contamination of the powder, which can eventually cause slow setting.

RelyX Luting Plus cement paste/paste system: This product is designed to be used at room temperature. If stored in cooler, allow product to reach room temperature prior to use. Shelf life at room temperature is 24 months. Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life. See outer package for expiration date. It is important to make sure the Clicker dispenser cap is securely latched after use to avoid water loss and drying out of the pastes.

Are the RelyX Luting cement and RelyX Luting Plus cement indicated for use with ceramic restorations?

The only ceramic restorations indicated are the strengthened-core ceramic restorations fabricated out of alumina (i.e. Procera® AllCeram) or zirconia (i.e. Lava™ Zirconia).

Technical Data Summary

Source: 3M ESPE laboratory test data

	RelyX™ Luting Plus Cement	RelyX™ Luting Cement	FujiCEM™	Fuji 1®
Compressive Strength (MPa)	160.0 ± 8.8	111.7 ± 26.0	121.0 ± 21.4	180.7 ± 22.2
Diametral Tensile Strength (MPa)	25.5 ± 2.3	21.9 ± 4.4	17.6 ± 4.8	21.6 ± 1.6
Flexural Strength (MPa)	31.6 ± 4.1	27.6 ± 4.3	24.8 ± 9.5	7.8 ± 4.3
Shear Adhesion to Dentin (MPa)	5.7 + 1.8	5.0 + 4.5	1.5 + 2.2	3.2 + 1.0
Shear Adhesion to Enamel (MPa)	10.3 + 1.8	8.4 + 2.4	5.7 + 3.4	3.3 + 1.6
Shear Adhesion to Metal (Rexillium III) (MPa)	10.5 + 2.6	7.5 + 1.1	9.6 + 3.1	6.7 + 1.6
Shear Adhesion to Alumina (Procera® AllCeram) (MPa)	14.2 + 1.9	11.3 + 2.9	8.6 + 1.0	2.8 + 1.6
Shear Adhesion to Zirconia (Lava™ Zirconia) (MPa)	9.2 + 2.5	14.4 + 1.5	10.6 + 2.6	2.8 + 0.5
Shear Adhesion to Amalgam Core Build-up (MPa)	8.7 + 2.7	6.6 + 1.9	4.8 + 2.8	4.4 + 1.2
Shear Adhesion to Glass Ionomer Core Build-up (MPa)	6.7 + 1.9	8.4 + 1.6	5.8 + 1.2	5.4 + 1.9
Shear Adhesion to Composite Resin Core Build-up (MPa)	5.3 + 2.1	14.6 + 4.1	11.4 + 2.3	5.1 + 0.3
Film Thickness (microns)	15.3 ± 1.5	17.0 ± 2.6	11.3 ± 3.2	21.3 ± 2.5
Radiopacity (mm)	1.42 ± 0.01	1.53 ± 0.02	1.32 ± 0.08	1.90 ± 0.1

Customer Care Center: 1-800-634-2249 **www.3MESPE.com/relyx**

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