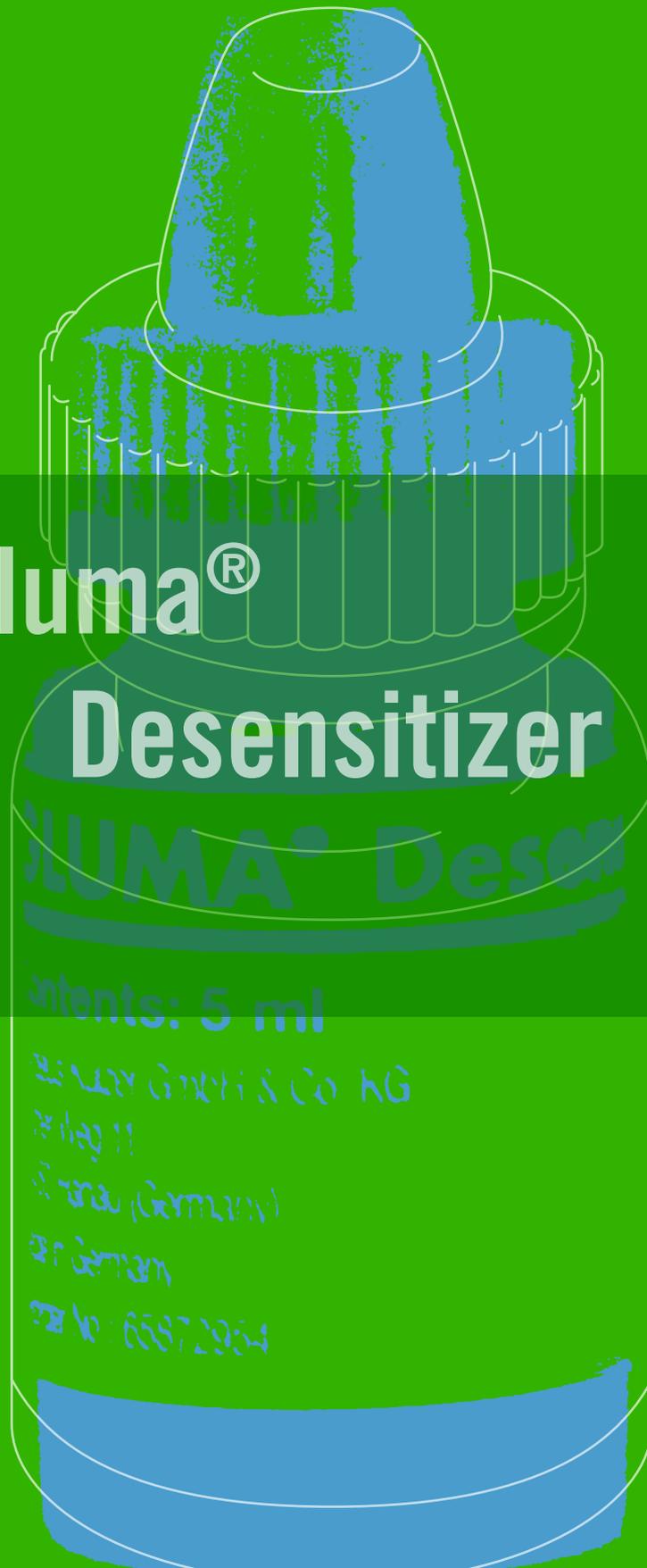


Gluma®

Desensitizer



Contents: 5 ml

DENTSPLY GINCH & CO. KG

Postfach 11

D-74700 (Germany)

Made in Germany

Order No.: 65872954

Gluma® Desensitizer

Description of the product

Gluma Desensitizer has been in the market for over 10 years and has been used in over 45 million restorations worldwide to reduce hypersensitivity. Gluma Desensitizer penetrates up to 200µm into the exposed dentin tubuli where it forms multiple layers of protein septa thereby preventing intratubular movement following osmotic changes and preventing hypersensibilities.

Composition:

- (-hydroxyethyl-)methacrylate
- Glutaraldehyde
- Purified water

Indications:

- Reduction of sensitivity of exposed cervical areas which do not require restoration
- Reduction or prevention of postoperative sensitivity following preparation of teeth for direct or indirect restorations

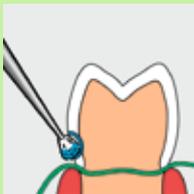
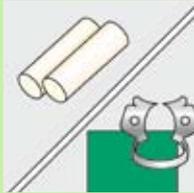
Advantages:

- Highly effective yet easily handled
- No mixing, at a reaction time of only 30–60 secs., no light-curing required
- Initial efficacy
- Immediate pain reduction
- More effective than pure fluoridation
- Intradentinal effect, no surface film
- Clinically proven to be effective for at least 12 months
- Also used to good effect in combination with bonding agents

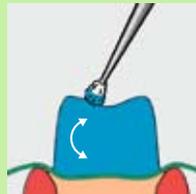
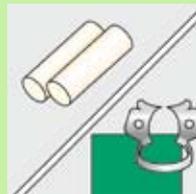
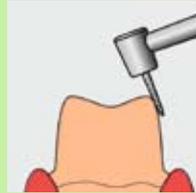
Clinical application

Awards

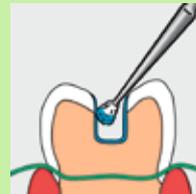
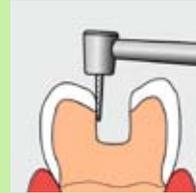
Hypersensitivity



Crown preparation



Inlay



Received a 4.5 @ 91 % rating in Vol. 18, No. 10
Received a 4.0 @ 88 % rating in Vol. 7, No. 1



Desensitizing effect of Gluma[®] Desensitizer on prepared teeth

Evaluation of the Desensitizing Effect of Gluma Dentin Bond* on Teeth Prepared for Complete-Coverage Restorations

Authors: Felton, D.A., Bergenholtz, G., Kanoy, B.

Publication: Int J Prosthodont 1991; 4:292–298

Abridged version

Objective

The clinical trial assessed the ability of Gluma Dentin Bond* (= Gluma Desensitizer) to inhibit dentinal sensitivity in teeth prepared to receive complete cast restorations.

Materials und Methods

20 patients provided 76 teeth for the study. Following tooth preparation, dentinal surfaces were coated with either sterile water (control) or two 30-second applications of Gluma Dentin Bond* (test) on either intact or removed smear layers. Patients were recalled after 14 days for a test of sensitivity of the prepared dentin to compressed air, osmotic stimulus (saturated CaCl₂ solution), and tactile stimulation via a scratch test under controlled loads.

Conclusion

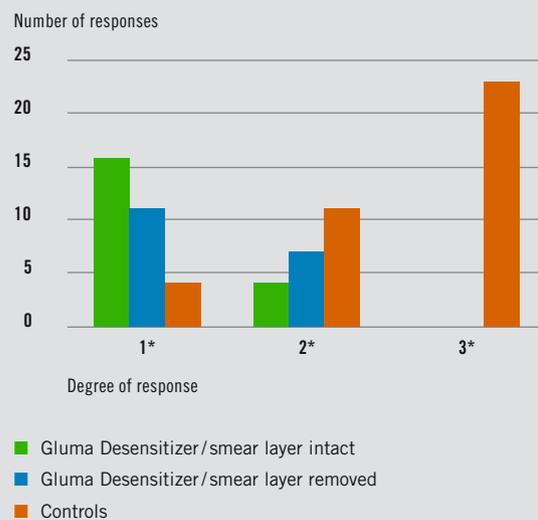
Within the experimental limitations of this investigation, the following conclusions can be drawn: 1. Compared to sterile water, Gluma Dentin Bond provided a significant reduction in dentin sensitivity when placed on exposed dentin of complete veneer crown preparations. 2. The presence of a dentinal smear layer had no appreciable effect on dentin sensitivity responses for either Gluma treatment group.

* Gluma Dentin Bond was the former name of Gluma Desensitizer

Results

A significantly lower number of teeth responded to the test stimuli for both Gluma groups when compared to the controls ($p < 0.01$). No difference was noted between teeth with smear layers intact or removed prior to treatment with Gluma Dentin Bond*.

Response to air stimulus



1*: No sensation to stimulation

2*: Mild to moderate sensation, but little discomfort (nonlingering)

3*: Severe sensation or discomfort (lingering)

The desensitizing effect of Gluma® Desensitizer on hypersensitive dentin

Desensitizing Effects of Gluma Primer and Gluma 2000 on
Hypersensitive Dentin

Authors: Dondi dall'Orologio, G., Malferrari, S.

Publication: Am J Dent 1993; 6: 283–286

Abridged version

Objective

The aim of this clinical trial was to investigate the effects of topical applications of Gluma 3 Primer* (= Gluma Desensitizer) or Gluma 2000 conditioning solutions on hypersensitive erosion/abrasion lesions.

Materials und Methods

Thirty-four patients were included in the trial with at least two teeth each presenting severe sensitivity. From a total of 116 teeth, 40 were treated with Gluma 3 Primer* (Heraeus Kulzer), 42 with Gluma 2000 Conditioner and 34 served as the control. Sensitivity was recorded as response to tactile and cold air stimuli prior to treatment as baseline, immediately after the topical application of the agents, after 1 week, 1 month and 6 months.

Conclusion

Single topical treatments of hypersensitive erosion/abrasion lesions with Gluma 3 Primer* and Gluma 2000 conditioning solutions, respectively, eliminated or at least significantly reduced dentin sensitivity throughout the 6 month observation time.

* identical to Gluma Desensitizer

Results

Both Gluma groups showed a highly significant reduction in sensitivity between baseline and postoperative pain scores ($p < 0.05$) and between the postoperative and the 1-week responses ($p < 0.05$). The sensitivity scores were not different between 1 week and 6 months. In the control group, no pain reduction was registered between baseline and up to 1-month recall. After 6 months, however, the sensitivity was spontaneously slightly reduced. At the end of the 6-month observation time, 29 Gluma 3 Primer* and 31 Gluma 2000 treated teeth no longer showed dentin sensitivity.

Sensitivity score	Baseline			Post-treatment			1 week			1 month			6 months		
	GL	GT	CO	GL	GT	CO	GL	GT	CO	GL	GT	CO	GL	GT	CO
0	–	–	–	10	19	–	28	31	–	29	31	–	29	31	–
1	–	–	–	16	13	–	8	9	–	7	9	–	7	9	2
2	18	18	24	14	10	24	4	2	26	4	2	27	4	2	30
3	22	24	10	–	–	10	–	–	8	–	–	7	–	–	2

GL: Gluma 3 Primer*

GT: Gluma 2000 Conditioner

CO: Control Group

Efficiency of desensitizing treatments with Gluma® Desensitizer

Efficiency of Desensitizing Treatments of Hypersensitive Dentin with Gluma and Gluma 2000

Authors: Blunck, U., Roulet, J.-F.

Publication: internal report to Heraeus Kulzer, data on file
Abridged version

Objective

The purpose of this clinical investigation was to evaluate the effectiveness of four different treatments for teeth with severe sensitivity.

Materials und Methods

30 patients who already suffered from hypersensitive dentin for at least two months with unsuccessful treatments before that time were included in the study. 58 severe sensitive teeth were randomly assigned to four different treatment groups. A: 60s application of Gluma Primer* (= Gluma Desensitizer), B: 60s application of Gluma Primer* after using Gluma Cleanser, C: 60s application of Gluma 2000 Conditioner and D: application of the entire Gluma bonding system (Cleanser, Primer and Adhesive).

The treatment as described under D was used as a control since it was unethical to observe untreated hypersensitive dentin for one year. The sensitivity was recorded as a response to tactile and cold air stimuli before treatment, after the different topical applications, after one week, one month, six and twelve months.

Conclusion

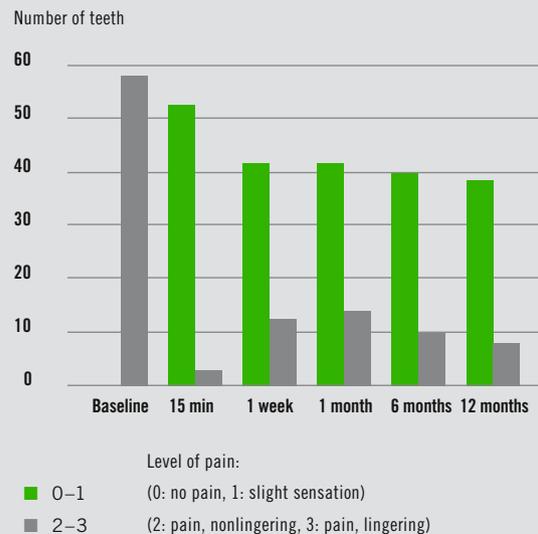
Even a single topical application of Gluma Primer* without prior cleansing significantly reduced the severe hypersensitivity of exposed cervical dentin and was as effective as the more time consuming application of a total dentin adhesive system.

* identical to Gluma Desensitizer

Results

All treatments showed a significant reduction of hypersensitivity between baseline and directly after application. No statistically significant difference could be calculated by Chi-square-tests between the four different groups up to the reevaluation after three months. The recording of the sensitivity after 6 and 12 months showed significantly more severely sensitive teeth in the group tested with Gluma 2000 Conditioner (group C). After one year for the group A (Gluma Primer*) 39 out of 48 teeth (81%), for group B (Gluma Cleaner + Gluma Primer*) 36 out of 44 (82%) and for group D (Gluma Bonding System) 37 out of 48 teeth (77%) were still recorded without severe sensitivity but only 6 out of 49 teeth (11%) in group C (Gluma 2000 Conditioner). In this group the number of reapplications also was highest.

Efficiency of Gluma Primer*



Clinical evaluation to dentin hypersensitivity

Clinical Evaluation of Gluma 3 Primer to Dentin Hypersensitivity

Autoren: Inoue, M., Yoshikawa, K., Okamoto, A., Kota, K., Fujii, B., Iwaku, M.

Publication: Japanese Journal of Conservative Dentistry 1996; 39: 768–776

Abridged version

Objective

The objective of this study was to evaluate pain reduction in hypersensitive cervical regions immediately after applying Gluma 3 Primer* (= Gluma Desensitizer) and during the following 8 weeks.

Materials und Methods

This study was carried out at the conservative dentistry departments of the Universities of Osaka and Niigata, using the same protocol. A total of 82 teeth (60 patients) with severe dentine hypersensitivity symptoms were involved in this study. The pain causing stimulants were an air blast, cold water or scratching with a dental probe. Gluma 3 Primer* was applied for 60 seconds. The effectiveness was evaluated after intervals of 15 minutes, 1, 4 and 8 weeks.

Conclusion

The authors confirmed that Gluma 3 Primer* is an effective and reliable topical desensitiser for treating dentin hypersensitivity. No side-effects were recorded in cases where the site was kept completely dry with a rubber dam or where it was kept relatively dry with cotton rolls.

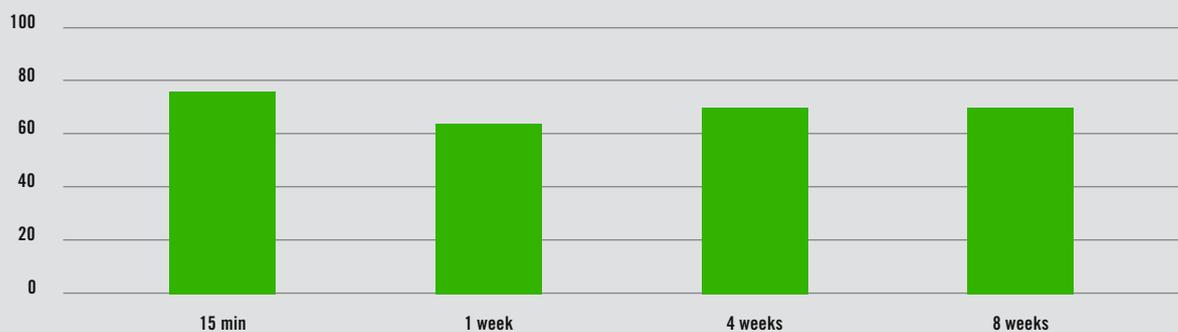
* identical to Gluma Desensitizer

Results

15 minutes after topical application, the dentin hypersensitivity had already been reduced considerably or eliminated in 79 % of the teeth. This high initial effectiveness remained unchanged throughout the ensuing 8 week observation period.

Pain reduction (stimulant air blast)

Pain reduction in %



Clinical effectiveness of Gluma® Desensitizer on tooth cervical hypersensitivity

Clinical Effectiveness of Two Agents on the Treatment of Tooth Cervical Hypersensitivity

Authors: Kakaboura, A., Rahiotis, CH., Thomaidis, S., Doukoudakis, S.

Publication: Am J Dent 2005; 18: 291–295

Abridged version

Objective

To investigate the desensitising ability of a one-bottle agent and a glutaraldehyde-based HEMA formulation on sensitive tooth cervical areas for a period up to 9 months.

Materials und Methods

The sample consisted of 40 patients with cervical hypersensitivity. Three sensitive teeth per patient were treated; one received One-Step (one-bottle bonding agent, Bisco), the other Gluma Desensitizer (glutaraldehyde-based agent, Heraeus Kulzer) and the third distilled water (control group). The hypersensitivity level was determined before, immediately after the desensitising session, at 8 weeks, and 9 months post-treatment. Measurements of sensitivity were determined by the patient’s response to tactile and air-blast

stimuli. A verbal rating scale was used and scored as follows: 0, no discomfort; 1, discomfort but no severe pain; 2, severe pain during stimulation; 3, severe pain after stimulation. The results were subjected to statistical analysis by Kruskal-Wallis test ($\alpha=0.05$).

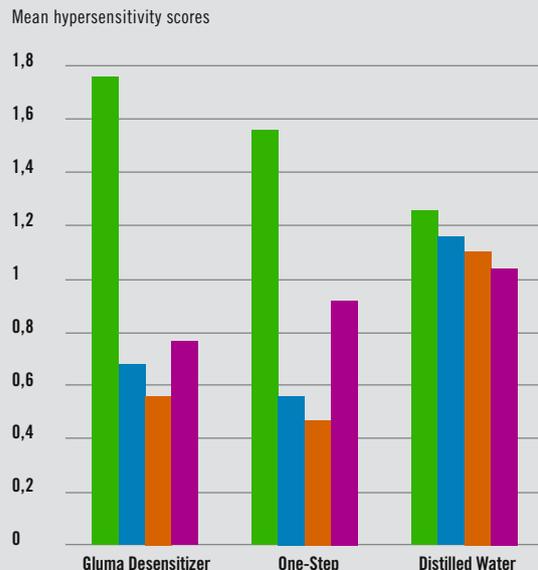
Conclusion

Even though the one-bottle agent tested may offer a short-term, adequate reduction of hypersensitivity, a significant reversal of the sensitivity may occur long-term, particularly for air-blast stimulation. The glutaraldehyde-based agent was proven more efficient in treating cervical sensitivity up to the 9-month follow-up.

Results

Both treatment procedures resulted in reduction of hypersensitivity to both stimuli, for up to 9 months. No significant differences were recorded between One-Step and Gluma Desensitizer at immediate and 8-week examinations, whereas Gluma Desensitizer produced lower hypersensitivity than One-Step at the 9-month assessment. In general, a lower level of reduction was found for the 9-month interval compared to the 8-week hypersensitivity score for both agents tested. A placebo effect was effected with water treatment, ranging from 4.7 to 27.5% reduction of hypersensitivity.

Mean hypersensitivity scores for air-blast stimulus



The references to the manufacturer’s name have been expanded by Heraeus Kulzer.

Effectiveness after periodontal therapy

Effectiveness of Desensitizing Agents for Dentin Hypersensitivity after Periodontal Therapy

Authors: Tenorio, S. B., Santos, R. L., Gusmão, E. S.

Publication: J Dent Res (Spec Iss B) 2002, 48: 54

Abridged version

Objective

The effectiveness of two desensitising agents were analyzed on 48 teeth of male and female patients who had presented with hypersensitive dentin after periodontal therapy.

Materials und Methods

Teeth were selected and divided into two groups of twenty-four according to the substance applied: group I (Oxagel, Art Dent) and group II (Gluma Desensitizer, Heraeus Kulzer). For the first section, all patients were instructed in oral hygiene, prophylaxis and their sensibility was evaluated using criteria proposed by Uchida et al. (J. Periodontol., 51: 10, p. 578–81, 1980). For evaluation tactile stimulus (pathfinder), air jet and thermic stimulus (cold) were employed. Solutions were applied and after seven days

the patients returned for measuring the degree of sensitivity again and re-applying the desensitizing agents. This was continued for a period of four weeks and after this period a new evaluation was carried out after 60 days.

Conclusion

These data indicate that desensitising agents were efficient to decrease hypersensitive dentin after periodontal therapy.

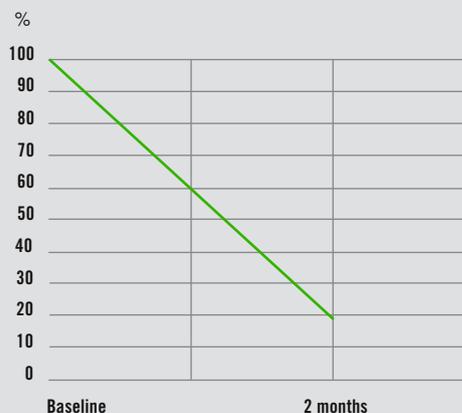
Comment of Heraeus Kulzer:

Gluma Desensitizer effectively reduces hypersensitivity of dentin after periodental therapy.

Results

Results of the present study corroborate that both groups underwent a medium percentual decrease exceeding 81% between initial and final analysis (two months).

Reduction in sensitivity



The references to the manufacturer's name have been expanded by Heraeus Kulzer.

Influence of retention of cemented castings

Crown Retention with use of a 5% Glutaraldehyde Sealer on Prepared Dentin

Authors: Johnson, G. H., Lepe, L., Bales, D. J.

Publication: J Prosthet Dent 1998; 79: 671–6

Abridged version

Objective

This study determined whether a non-resin sealer applied to prepared dentin affected the retention of cemented castings.

Materials und Methods

Extracted molars were prepared with a flat occlusal, 20-degree taper and 4 mm axial length. The axial surface area of each preparation was determined and samples were distributed to achieve equivalent groups. Gluma Desensitizer (Heraeus Kulzer) sealer was used to seal the dentin before provisionalization and again before crown cementation. An Olympia alloy casting was produced for each preparation and cemented with a seating force of 20 KG with either Mizzy's zinc phosphate (Mizzy Inc.),

Ketac Cem glass ionomer (3M ESPE) or Resinomer material (Bisco) in combination with One Step adhesive (Bisco). Castings were thermocycled, then removed along the path of insertion with an Instron testing machine. A two-factor analysis of variance was used with $\alpha=0.05$ and $n=9-10$.

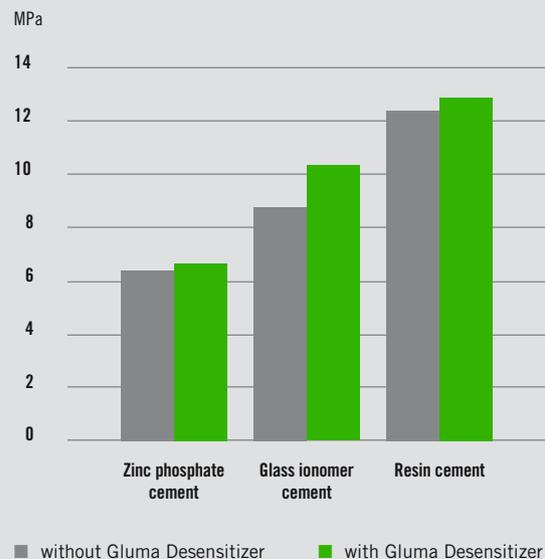
Conclusion

The use of the glutaraldehyde-based system as a desensitizing treatment for prepared teeth had no effect on crown retention for any of the three cements evaluated and the modified resin cement produced the highest mean dislodgement stress that exceeded the strength of the tooth.

Results

Mean dislodgement stresses for unsealed and sealed conditions were 6.3 and 6.4 MPa for zinc phosphate, 9.1 and 10.1 MPa for glass ionomer, and 12.1 and 12.6 MPa for the resin cement. The means for the three cements were statistically different ($p<0.001$). The effect of sealer ($p=0.369$) and cross product interactions ($p=0.820$) were not significant.

Crown retention with and without Gluma Desensitizer



The references to the manufacturer's name have been expanded by Heraeus Kulzer.

Influence of Gluma[®] Desensitizer on bond strength

Influence of Desensitizers on Bond Strength of 2 Adhesive Systems at Dentin

Authors: Bedran de Casgro, A.K.B.; Aramal, C.M.; Shinohara, M.S.; Ambrosano, G.M.B.; Pimenta, L.A.F.

Publication: J Dent Res 2002 ; 81: B-176

Abridged version

Objective

The aim of this study was to evaluate the influence of desensitizer agent treatment on the bond strength of two adhesive systems.

Materials und Methods

One hundred and fifty bovine incisors were mounted, their dentin polished, and divided into 10 groups (n=15): G1 – Singlebond/3M (SB); G2 – Excite/Vivadent (EX); G3 – Oxagel (OXA)+ SB; G4 – OXA + EX; G5 – Gluma Desensitizer/Heraeus Kulzer (GLU) + SB; G6 – GLU + EX; G7 – Desensibilizer/FGM (DES) + SB; G8 – DES + EX; G9 – Experimental/FGM (EXP) + SB; G10 – EXP + EX. In all groups, the dentin was etched with 37 % phosphoric acid. Soon after, the desensitiser, respectively the adhesive, was applied according to manufacturers’ instructions. Then a resin (Z100, 3M ESPE) was inserted in a teflon matrix

and cured. The specimens were stored under humidity for 7 days at 37 °C. The SBS tests were performed in an EMIC universal test machine with a crosshead speed at 0.5 mm/min. The mean values were analyzed with two-way ANOVA and Tukes Test (p<0.05) and the differences were expressed by different letters (p<0.05).

Conclusion

No significant difference was observed between the adhesive, the use of Gluma Desensitizer presented the higher values and OXA presented the lower values. It could be concluded that the use of desensitizer agents does not interfere with the bond strength of two adhesives.

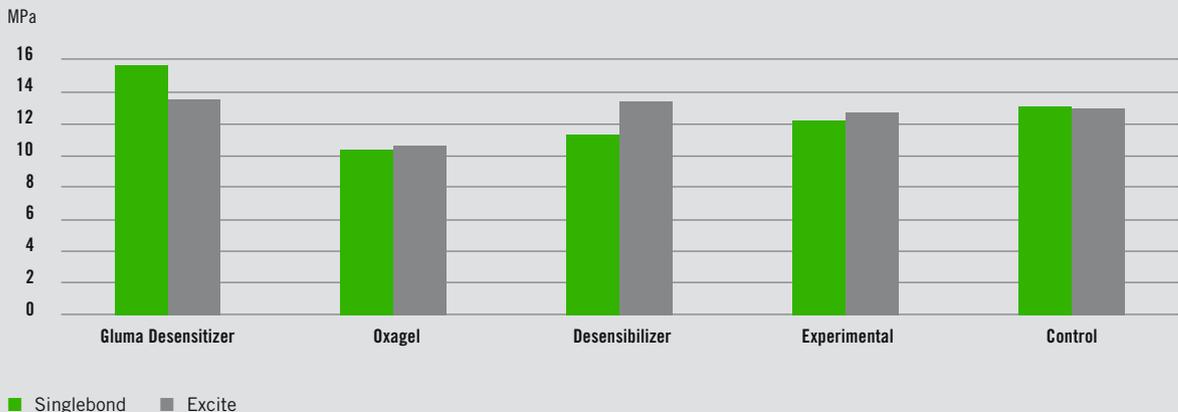
Comment of Heraeus Kulzer:

The adhesives showed the highest bond strength in combination with Gluma Desensitizer.

Results

The values in MPa (SD) were: G1 = 13.07 (5.82); G2 = 13.00 (4.83); G3 = 10.21 (5.01); G4 = 10.57 (3.94); G5 = 15.77 (4.09); G6 = 13.55 (4.19); G 7 = 11.17 (4.17); G 8 = 13.31 (3.11); G 9 = 12.18 (5.22); G10 = 12.57 (4.43).

Bond strength in MPa



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Notes

All graphs and page titles were provided by Heraeus Kulzer.

The studies were chosen with the objective of resuming bond strength results and desensitising effects of the Heraeus Kulzer products iBond, Gluma Comfort Bond + Desensitizer, Gluma Solid Bond and Gluma Desensitizer.

The studies on page 16, 40, 41 were translated into English.

Contact in Germany

Heraeus Kulzer GmbH

Grüner Weg 11
63450 Hanau
Phone +49 (0) 6181 355 444
Fax: +49 (0) 6181 353 461
info.dent@heraeus.com
www.heraeus-kulzer.de

Contact in the United Kingdom

Heraeus Kulzer Ltd.

Heraeus House, Albert Road
Northbrook Street, Newbury
Berkshire, RG 14 1 DL
Phone +44 1 635 30500
Fax +44 1 635 30606
Mail: sales@kulzer.co.uk
Website: www.heraeus-kulzer.com

Contact in Australia

Heraeus Kulzer Australia Pty. Ltd.

Locked Bag 750
Roseville NSW 2069
Phone +61 29 417 8411
Fax +61 29 417 5093
Mail: sales@kulzer.com.au
Website: www.kulzer.com.au