Retention Of Long-Term Interim Restorations With Sodium Fluoride Enriched Interim Cement

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RETENTION OF LONG-TERM INTERIM RESTORATIONS WITH SODIUM FLUORIDE ENRICHED INTERIM CEMENT

by

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ABSTRACT
RETENTION OF LONG-TERM INTERIM RESTORATIONS WITH SODIUM FLUORIDE ENRICHED INTERIM CEMENT

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Purpose: Interim fixed dental prostheses, or "provisional restorations", are fabricated to restore teeth when definitive prostheses are made indirectly. Patients undergoing extensive prosthodontic treatment frequently require provisionalization for several months or years. The ideal interim cement would retain the restoration for as long as needed and still allow for ease of removal. It would also avoid recurrent caries by preventing demineralization of tooth structure. This study aims to determine if adding sodium fluoride varnish to interim cement may assist in the retention of interim restorations.

Materials and methods: stainless steel dies representing a crown preparation were fabricated. Provisional crowns were milled for the dies using CAD/CAM technology. Crowns were provisionally cemented onto the dies using TempBond NE and NexTemp provisional cements as well as a mixture of TempBond NE and Duraphat fluoride varnish. Samples were stored for 24h then tested or thermocycled for 2500 or 5000 cycles before being tested. Retentive strength of each cement was recorded using a universal testing machine.

Results: TempBond NE and NexTemp cements performed similarly when tested after 24h. The addition of Duraphat significantly decreased the retention when added to TempBond NE. NexTemp cement had high variability in retention over all tested time periods. Thermocycling for 2500 and 5000 cycles significantly decreased the retention of all cements.

Conclusions: The addition of Duraphat fluoride varnish significantly decreased the retention of TempBond NE and is therefore not recommended for clinical use. Thermocycling significantly reduced the retention of TempBond NE and NexTemp. This may suggest that use of these cements for three months, as simulated in this study, is not recommended.

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INTRODUCTION

Interim fixed dental prostheses, or "provisional restorations", are fabricated to restore teeth when definitive prostheses are made indirectly. Patients undergoing extensive prosthodontic treatment frequently require provisionalization for several months or years. This is especially true when evaluating changes in esthetics, function, or occlusal vertical dimension, or when periodontal crown lengthening has been performed.[1-4] For example, a waiting period of six months has been recommended following crown lengthening before final tooth preparation and definitive impressions.[5-8] During this time restorations may be dislodged and secondary caries can become a problem. In fact, research on definitive restorations, which provide better protection than provisional restorations, shows that the main cause of failure of crowned teeth is caries.[9, 10] One solution is to recall the patient approximately every four weeks to remove, clean, and recement the restorations; this is time consuming and inefficient for both the patient and the practitioner. The ideal interim cement would retain the restoration for as long as needed and still allow for ease of removal. It would also avoid recurrent caries by preventing demineralization of tooth structure. This study aims to determine if adding sodium fluoride varnish to interim cement may assist in the retention of interim restorations.

REVIEW OF LITERATURE

Long-term Interim Restorations

There are many clinical situations when a patient may wear a provisional restoration for an extended period of time. One such situation is the healing period following surgical crown lengthening procedures. Deas' clinical investigation found significant changes in soft tissue following surgery that were not fully stabilized by six months.[5] A review by Hempton and Dominici gave a similar conclusion recommending a waiting period of six months following crown lengthening before final prosthetic treatment.[6] A study of 25 patients by Brägger found no changes in the free gingival margin between six weeks and six months in 85% of sites. However, it was concluded that for esthetically important areas, a waiting period of six months was optimal.[7] Another similar recommendation comes from Lanning et al who followed 23 patients undergoing surgical crown lengthening over six months. At a three month follow up, the biologic width was found to be significantly different from the baseline whereas the six month follow up showed the biologic width reestablished to the baseline level. It was concluded that definitive restorations placed before a healing period of six months could result in incorrect margin placement.[8]

Another situation where patients may require provisional restorations for several months is during extensive prosthodontic rehabilitations. The provisional restorations can be used to evaluate phonetic function and changes in esthetics, and the practitioner may make changes to the restorations during this time.[11]

Moslehifard and Prasad both recommended an observation period of two to three months if a patient's occlusal vertical dimension will be altered.[3, 4] This can be done with a removable appliance, but the results of the observation will be more accurate if the provisional restoration is in the form of the final prosthesis, that is, fixed restorations. Cases where patients are undergoing implant therapy, serial extractions, or orthodontics are also situations where provisional restorations may be worn for an extended period of several months to years.[2, 12-14] Additionally, the provisional restoration will prevent tooth movement so the definitive restorations can be fabricated accurately and without problems in the occlusion or interproximal contacts at the time of insertion.[15]

When provisional restorations are fabricated with the intention to be used for several months, it is important that they are constructed well. Rieder lists qualities of a good provisional restoration: eliminate caries and mechanical defects, give prepared tooth protection, achieve maxillomandibular stabilization, allow for periodontal healing and adequate maintenance, evaluate tooth stability, create optimum crown and pontic form, and develop appropriate esthetics.[16] Fabrication of high quality restorations is time-consuming and requires a skillful practitioner. Even so, problems such as fracture, loss of retention, and recurrent caries are possible during the provisionalization period. In a technique article, Hazelton writes, "Failure of the provisional restoration, in any form, results in a major inconvenience to both patient and clinician."[12] Spear gives some suggestions for managing long-term provisional restorations.[1] They can be cemented with resin-reinforced glass ionomer cement, but the restorations need to be cut off requiring

fabrication of new provisional restorations following any additional procedures such as impression making. Another option is to use a zinc oxide eugenol cement, but the teeth need to be thoroughly cleaned with pumice when the provisionals are removed so the definitive restorations may be bonded to the tooth if desired. The patient also must be recalled every eight to twelve weeks to ensure the restorations have not come loose.[1] This is a major inconvenience and considered "unacceptable" to the patient and the practitioner.[17]

Interim Luting Agents

One of the most frequently encountered issues in long-term provisionalization is the loss of the marginal seal with the provisional cement. "Provisional crowns cemented with provisional luting agents are… susceptible to cement washout, margin leakage, bacterial infiltration, and caries, especially when placed for prolonged periods of time," writes Lewinstein.[18] If caries occurs under a provisional restoration, it can remain undiagnosed for the length of the provisionalization period.[19] Since the loss of the marginal seal over an extended time seems to be inevitable, it would be advantageous if the cement or the provisional restorative material could combat recurrent caries. Recently, improvements in the provisional cement itself have been suggested in order to reduce the caries risk.[18, 20]

Literature pertaining to provisional cements is much less common than permanent cements. Four articles by the same author were reviewed.[18, 21-23] Lewinstein studied retention and marginal leakage of provisional cements mixed with sodium fluoride varnish, stannous fluoride, and chlorhexidine diacetate. In the first two studies, TempBond and Freegenol provisional cements, Opotow zinc oxide eugenol, with and without Duraphat fluoride varnish additions to the cements were compared in cementation of a provisional crown. Duraphat alone was also evaluated. The provisional crowns were seated onto prepared extracted human molars and after storage at 100% humidity, they were thermocycled for 500 cycles in the 2003 study. The samples were assessed for marginal leakage by immersing in dye and then they were subjected to shear dislodgement forces. It was found that

the addition of Duraphat varnish to TempBond increased retention and decreased dye penetration better than any other combination of products or the provisional cements alone.[18]

Lewinstein's third study was similar in that 12 extracted human molars were prepared and provisional crowns were cemented with TempBond, TempBond NE, and Freegenol. Each cement was also tested when mixed with chlorhexidine diacetate salt. Samples were stored for 24 hours before being thermocycled for 100 cycles, then stored for 6 days. The samples were immersed in dye and then subjected to tensile dislodgement forces. It was found that the addition of chlorhexidine diacetate to Freegenol greatly enhanced the retention while the marginal leakage remained the same throughout all groups. [22]

Finally, the fourth study by Lewinstein was very similar to the previous one using chlorhexidine diacetate, but stannous fluoride was added to the cements in this case. The sample size and methods were the same, and it was found that the addition of stannous fluoride significantly increased the retention of both TempBond NE and Freegenol. The stannous fluoride additions did not significantly affect the dye penetration in this study.[18]

In Vitro Testing

Performing in vivo studies with standardized protocols and large sample sizes is exceedingly difficult. For this reason, in vitro tests are commonly used to assess experimental techniques. In a literature review of crown pull-off tests by Heintze, the advantages of this type of in vitro test are reproducibility, ease of conducting the test, and simulation of clinical procedure.[24] The recommendations given for a pull-off test set up include prepared extracted human molars grouped by similar size. The crowns should be luted with cement according to manufacturer's instructions under 100N seating force. They should be stored in water at 37°C for one week, then thermocycled 5°/55°C for 5000 cycles or stored in water for 6 months. Tensile force should be measured with a universal testing machine with a crosshead speed of 0.5mm/min.[24]

This thermocycling regimen was also suggested in a review by Gale and Darvell.[25] Thermocycling simulates thermal changes that occur in the oral cavity which induce mechanical stresses and cause volume changes allowing passage of fluid and bacteria. By thermocycling samples in a laboratory test, the data may be considered more applicable to clinical situations. After an analysis of 130 studies, the authors concluded that the standard cycling regimen should be 35°C, 15°C, 35°C, 45°C, for 28 seconds, 2s, 28s, and 2s, respectively. While this was given as their "standard," its use in literature is absent while the use of 5°/55° was very commonly found throughout the literature and in ISO 10477 for testing of Polymer-based crown and bridge materials.[26] It was suggested that 10,000 cycles should simulate one year of clinical use of a restoration. One limitation of this method of artificial

aging of a sample is that it is unknown whether the effects of thermocycling are truly equivalent to those seen clinically. However, the authors note that, "cycling has been adopted as a superficial 'simulation' of supposed surface conditions," and it has proven a useful tool in many studies throughout the dental literature.[25]

Caries Process

Dental caries remains a constant problem in clinical practice. It has been found that caries is the main cause of failure of crowned teeth with an 18% incidence in fixed partial denture abutment teeth and 8.5% incidence in removable partial denture abutments.[9, 10] One new coronal lesion per year is estimated in adults.[27] The rates of recurrent caries around long-term provisional restorations may be even higher due to poorer marginal adaptation and less stable materials. Patients requiring extensive prosthodontic therapy may have a higher caries risk prior to starting treatment and meticulous cleaning around extensive provisional restorations can be difficult and time consuming. Given these possible risks, secondary caries under long-term provisional restorations is a definite risk that needs to be managed during patient care.

The pathologic factors influencing the caries process include: acid-producing bacteria, ingestion of fermentable carbohydrates, and low saliva flow or function.[28] The caries process begins when a bacterial biofilm of mutans streptococci and lactobacilli develops. When fermentable carbohydrates are introduced, the bacteria produce lactic, acetic, formic, and propionic acids, all of which dissolve minerals of enamel and dentin. Calcium and phosphate ions from the tooth structure are dissolved into solution more and more rapidly as the pH decreases from the production of acids. The critical pH at which this occurs in enamel is 5.5 and 6.3 in dentin.[29] This process can be reversed when the pH is restored to a more neutral level. However, if this process leans toward the demineralization stage over remineralization, over time, a carious lesion will develop. This can take several

months to years, which makes patients with a long-term provisional restoration at risk for new lesions.

There are a few strategies for preventing demineralization and encouraging remineralization. Fluoride is one such strategy that is used prevalently among patients at any risk level. There are three mechanisms of action of fluoride in caries prevention. First, fluoride inhibits demineralization in an acid challenge on teeth. Fluoride can replace the extremely soluble carbonate ions in the hydroxyapatite crystalline structure making a surface veneer of fluorapatite with a new critical pH of 4.7.[29, 30] It also enhances remineralization by attracting calcium and phosphate ions to the tooth surface, speeding the growth of the new crystal structure. Finally, fluoride inhibits bacterial metabolism by diffusing into bacteria, acidifying the cytoplasm, and inhibiting glucose transport and enolase and adneosine triphosphatase enzymes.[29, 30]

With the three mechanisms of caries defense, fluoride can be a powerful tool in caries prevention. Of the materials used in conjunction with provisional cements, sodium fluoride varnish seems to be the most promising. One in vivo study by Castillo and Milgrom measured fluoride release from three applications of five percent sodium fluoride varnish over 21 weeks.[31] The Duraphat varnish released 23.7±1.6 μmol fluoride over the time period after one application and 34.9±0.3 μmol after three applications in the same time period. These findings show that the use of fluoride in a varnish carrier may be safe for use more frequently than previously recommended. This slow, low release of fluoride may be useful in caries prevention

as shown by Magalhães' study in which Duraphat varnish was able to significantly reduce dentin loss compared to an untreated group in vitro.[32]

Other materials that have been considered to augment provisional cements are chlorhexidine and casein phosphopeptides with amorphous calcium phosphate (CPP-ACP).[20, 22] Chlorhexidine is an antimicrobial agent used to reduce bacterial colonization.[33] While it has been well demonstrated that chlorhexidine can reduce levels of mutans streptococci, there is a lack of evidence showing a reduction in caries rate. A literature review of 16 systematic reviews and randomized controlled trials using chlorhexidine revealed no significant reduction in caries, although it was noted that there is a lack of long-term data.[33] A three-year study investigating the efficacy of chlorhexidine varnish on the incidence of occlusal caries found no caries-reducing effect.[34] A large multicenter, placebo-controlled, double blind, randomized clinical trial using chlorhexidine varnish also found it to be ineffective at caries prevention.[35] Similarly, a review of evidence-based clinical recommendations of caries-preventive agents did not recommend chlorhexidine as a means of caries prevention.[36] One proponent of the use of chlorhexidine is Featherstone who includes a 0.12% chlorhexidine gluconate rinse as a component of an overall caries-prevention protocol.[10, 30] Overall, the evidence for the use of chlorhexidine as a means of preventing caries is weak and additional studies are needed before it can be recommended for widespread use.

The other material considered was CPP-ACP. This product provides readily available calcium and phosphate ions increasing the efficacy of remineralization.[37] It also buffers acid in the oral environment reducing the rate of demineralization.[38]

The properties of this material may be beneficial in preventing caries, but little clinical research is available and there have not been any recommendations for its use at this time.

Given the positive results using a combination of TempBond and Duraphat in the previous in vitro studies, it may be beneficial to gather additional data with these materials. Larger sample sizes and increased artificial aging via thermocycling can assist in providing reliable data that may be more applicable to clinical situations.

The purpose of this study was to examine the influence of Duraphat 5% sodium fluoride varnish additions to TempBond NE provisional cement on the retention of acrylic provisional restorations with and without thermocycling. The tensile load necessary to dislodge the restorations was measured using a universal testing machine.

Two hypotheses were considered:

1. Duraphat additions will not affect the tensile strength of the cement.
2. Thermocycling will not affect the tensile strength of the cement.

MATERIALS AND METHODS

Study design: The study was designed to include two main factors, i.e., "cement types" and "exposure time". Each factor included three levels, for a total of nine cement-time combinations (groups). Each group included ten test units consisting of a die and an acrylic crown. To limit the study cost, each die was used three times, with a different cement type each time. Acrylic crowns were used once.

Fabrication of dies and crowns: Thirty stainless steel dies, representing a crown preparation, were milled (Myshock Tool & Die Corp, Milwaukee, Wisconsin). The dies were fabricated with a 6 mm flat surface diameter, 5 mm vertical height, a 1 mm rounded chamfer finish line on the right circular cone die, and a total convergence angle of 6 degrees.[24, 39, 40] The surface of the dies had 0.01 mm deep grooves spaced 0.25 mm apart as in a customized CAD/CAM abutment. The surface texture was incorporated to simulate the irregular surface of a prepared human tooth and may aid in retention of the interim cement to the die. Details of the die design are shown in Figure 1.

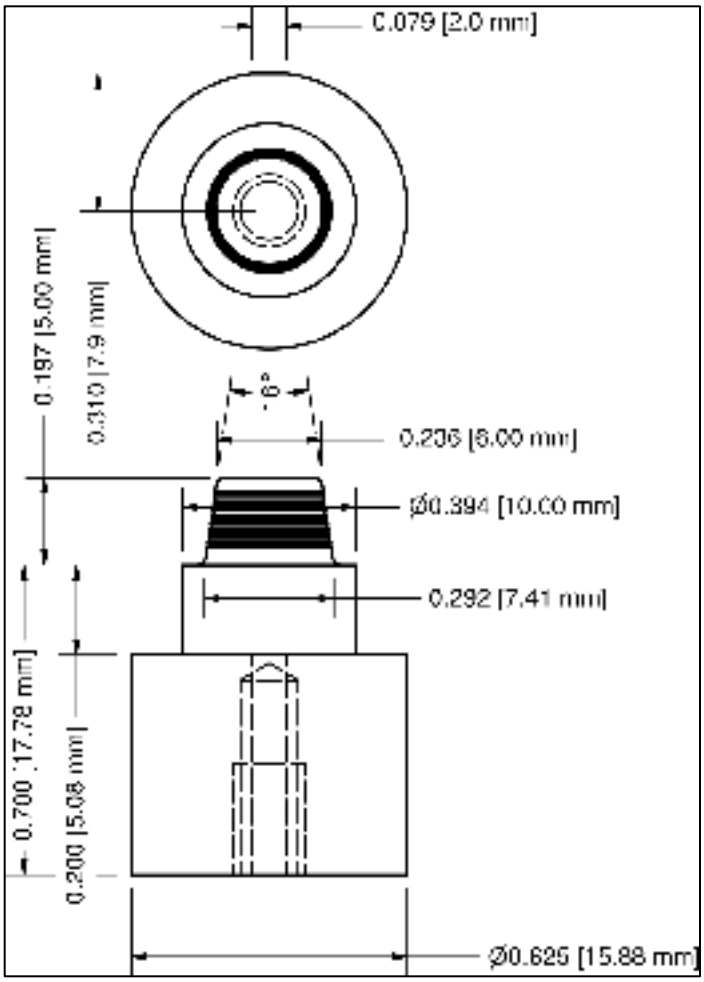

Figure 1 – Dimensions of dies

A randomly selected stainless steel die was scanned with the Nobel Procera scanner (serial no. 15610, Nobel Biocare AB, Stockholm, Sweden) with conoscopic holography technology (software version 4.6.3, Nobel Biocare AB, Stockholm, Sweden). Figures 2 and 3 show the scanning process and the resultant three-dimensional representation of the die, respectively.

Figure 2 – Procera scanning process

Ninety acrylic copings (Telio – polymethyl methacrylate, Nobel Biocare AB, Stockholm, Sweden) were milled to fit the dies. The copings were fabricated to simulate a provisional crown on a mandibular second molar, tooth #18. This was chosen to allow for a distinct central fossa in which to align a small hook for tensile testing (Screw eyes #216, zinc plated, Crown Bolt, Aliso Viejo, California). The internal surface of the die included 0.01 mm virtual die spacer beginning 2 mm from the margin as set by the manufacturer. Figure 4 shows a cross-section of the provisional crown and a 3-dimensional presentation of the die.

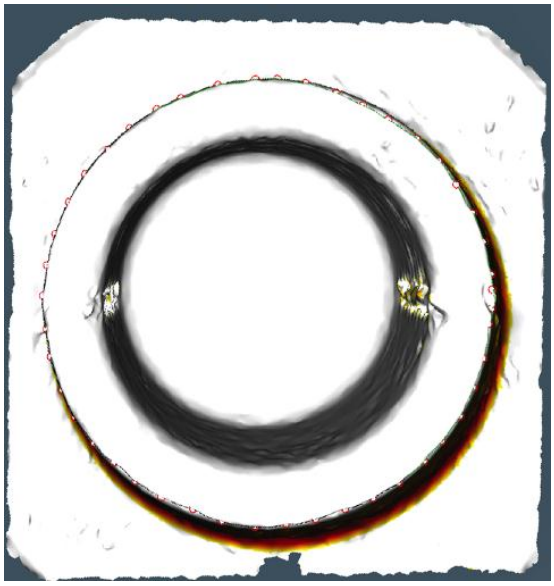

Figure 3 – Three-dimensional representation of scanned die in Nobel Procera design software

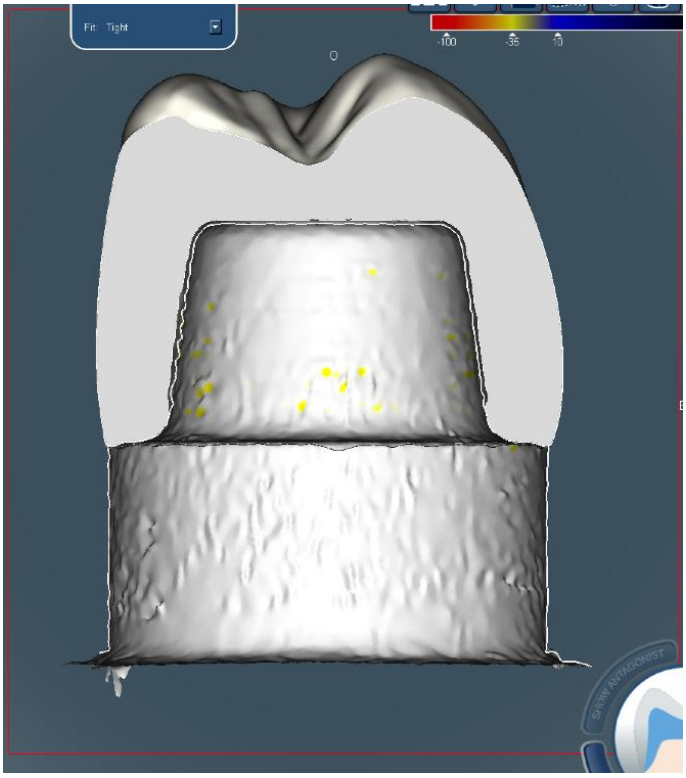

Figure 4 – Three-dimensional design of provisional crown on scanned die

The occlusal surfaces of the provisional crowns were airborne particle abraded with aluminum oxide particles (50 μm, Comco Inc, Burbank, California) at a

distance of 10 mm from the crown surface for 10s at 59 bar to facilitate bonding while attaching the hooks. After airborne particle abrasion, the crowns were steam-cleaned and dried with oil-free compressed air.

The thirty dies were used three times for three groups. Each group contained thirty provisional crowns cemented on the dies. Groups were separated by cement type and time before testing.

Cement types: In the control group, TB, (N=30) the copings were cemented onto the dies using TempBond NE (Kerr, Orange, California). The first experimental group, TBD, (N=30) Duraphat 5% sodium fluoride varnish (Colgate, New York, New York) was added to TempBond NE before the copings were cemented. The third group, NT, was another experimental group (N=30) where the copings were cemented with NexTemp (non-eugenol temporary resin cement with fluoride, potassium nitrate, and chlorhexidine, Premier, Plymouth Meeting, Pennsylvania). In all groups, 12 mm of TempBond NE or NexTemp were dispensed from the product syringe. In the TBD group, an 8 mm circle of varnish was dispensed as shown in Figure 5. This was chosen based on trials of mixtures to have little effect on cement setting time as described by Lewinstein.[21, 23] Ten samples of each group were prepared to be tested for each time period (Table 2).

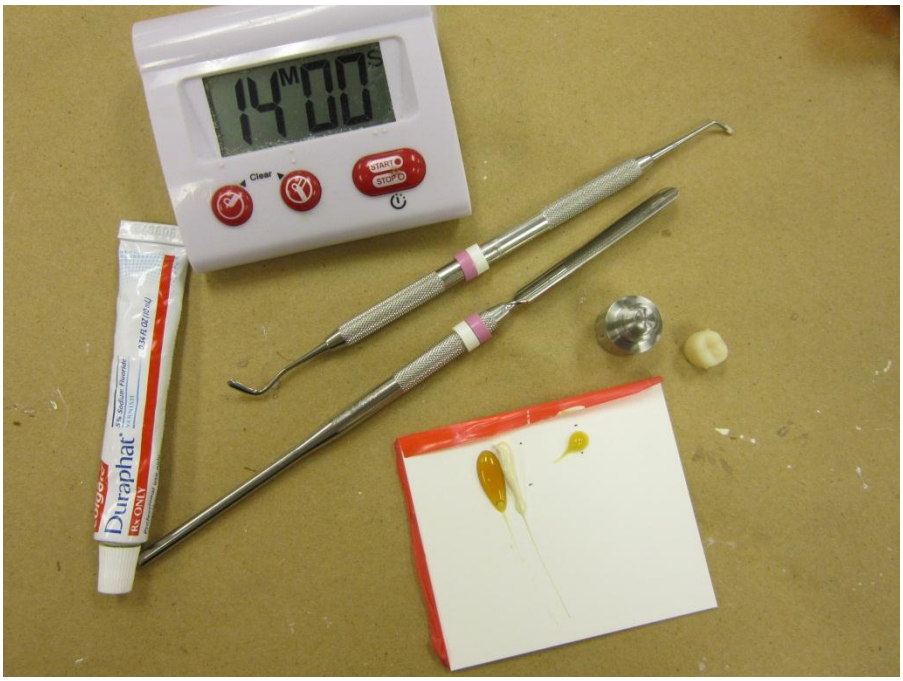

Figure 5 – Set up of TBD group prior to mixing

Preparation of test units: Provisional cements were mixed for 30s according to manufacturer specifications. A thin coating of cement was applied to the axial walls of each provisional crown before being seated on the stainless steel die with 49 N seating force.[18, 21-23, 39, 40] The cements were allowed to set for double the manufacturer's recommended time.[41] Following 14 minutes for TB and TBD and 10 minutes for NT, any excess cement was gently removed with a curette.

Once the provisional crowns were seated on the dies, they were placed on a survey table to allow placement of the hook perpendicular to the occlusal surface of the crown. A thin layer of Prime & Bond NT (Dentsply, Milford, Delaware) was applied, air dried for 10s, and light cured at ≥1500 mW/cm^2 (Smart Lite Max, Dentsply, Milford, Delaware) for 10s per manufacturer instructions. To attach the hook for tensile testing in an axial orientation, a hook was suspended from a dental surveyer (Dentsply Neytech, Yucaipa, California) and tacked to the occlusal surface

of the crown with a small amount of flowable composite (Revolution Formula 2, Kerr, Orange, California) as shown in Figure 6. Once the hook was stable, the test unit was removed from the survey table, additional flowable composite was added to secure the hook, and it was light cured for 20s according to the manufacturer instructions. Table 1 shows a list of all materials used.

Figure 6 – Attaching hook to provisional crown

Product and manufacturer	Type of material	Lot number
TempBond NE, Kerr	Zinc oxide non-eugenol cement	2-1139
Duraphat, Colgate	5% sodium fluoride varnish	909072
NexTemp, Premier	Non-eugenol, resin based temporary cement with fluoride, chlorhexidine and potassium nitrate	4148QTP
Prime & Bond NT, Dentsply	Bonding agent	120803
Revolution Formula 2, Kerr	Flowable composite resin	4759760

Table 1 – List of materials used

All prepared test units were stored for 24 hours in 100% humidity at 37°C. Following storage, ten specimens from each cement type were tested making up groups TB1, TBD1, and NT1. Artificial aging procedures were performed for groups TB2, TBD2, NT2, TB3, TBD3, and NT3. To simulate thermal stresses and aging of the crowns and cement, the 10 test units of each group were cycled 5/55°C for 2500 cycles to simulate 3 months of use and 5000 cycles to simulate 6 months of use (Sabri Enterprises, Buffalo Grove, Illinois).[25, 26] The dwell time was 30s with a transfer time of 15s. Table 2 shows the nine test groups by material and time.

	TB	**TBD**	**NT**
24h	TB1, n=10	TBD1, n=10	NT1, n=10
24h + 2500 cycles	TB2, n=10	TBD2, n=10	NT2, n=10
24h + 5000 cycles	TB3, n=10	TBD3, n=10	NT3, n=10

Table 2 – Test groups

After the conditioning of the test units was completed, they were subjected to crown pull off tensile testing using a universal testing machine (Model 5500R; Inston Corp, Canton, Massachusetts) with a 1000 kg load cell. Each die was threaded onto a screw which remained in the same location in the lower member of the Instron unit. The hook on the occlusal surface of the crown was attached to the upper member of the testing machine and the provisional crown was subjected to tensile stress at a constant speed of 5 mm/min until failure of the provisional cement.[21-23] Figure 7 shows the testing apparatus. The maximum force at dislodgment was recorded.

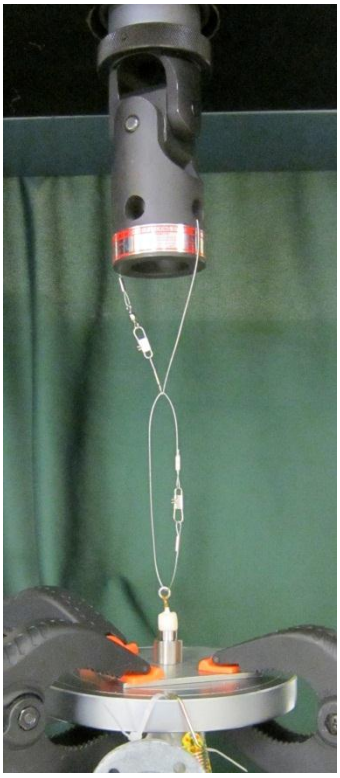

Figure 7 – Tensile test apparatus

Data management and statistical analysis: Maximum tensile loads were recorded for each test unit. Data were entered into an Excel spreadsheet (MS Office, Microsoft Corp. Redmond, Washington), and their distribution assessed using scatter plots. If indicated, transformations were used to stabilize variances. Descriptive data presentation included group means, minimum, maximum, and standard deviations. The statistical data analyses were executed in JMP 9 (SAS Institute Inc., Cary, North Carolina). A standard least squares model was constructed with main effects “cement” and “exposure time” and an interaction term “cement x exposure time”. Means were compared using the Tukey honestly significant difference test. Statistical significance was set at $\alpha = 0.05$.

RESULTS

The tensile load at the time of failure of the cement was measured for the three groups. The data are shown in Tables 3-5. Sample graphs of the tensile test of each group are shown in Figures 8-16.

Sample	Load at failure (N)	Sample	Load at failure (N)	Sample	Load at failure (N)
TB1-1	73.70	NT1-1	84.38	TBD1-1	20.19
TB1-2	110.35	NT1-2	81.05	TBD1-2	39.40
TB1-3	96.53	NT1-3	181.59	TBD1-3	68.01
TB1-4	82.81	NT1-4	31.75	TBD1-4	34.59
TB1-5	97.12	NT1-5	27.15	TBD1-5	41.16
TB1-6	119.27	NT1-6	34.59	TBD1-6	49.20
TB1-7	103.68	NT1-7	120.25	TBD1-7	45.96
TB1-8	122.40	NT1-8	47.43	TBD1-8	29.40
TB1-9	117.21	NT1-9	169.34	TBD1-9	46.06
TB1-10	86.14	NT1-10	42.43	TBD1-10	29.30
Mean ± SD	**100.92±16.60**	**Mean ± SD**	**82.00±57.31**	**Mean ± SD**	**40.33±13.29**

Table 3 – Results for groups TB1, NT1, TBD1

Sample	Load at failure (N)	Sample	Load at failure (N)	Sample	Load at failure (N)
TB2-1	Not recorded	NT2-1	Not tested	TBD2-1	14.11
TB2-2	20.87	NT2-2	65.37	TBD2-2	1.27
TB2-3	5.68	NT2-3	61.54	TBD2-3	8.04
TB2-4	9.11	NT2-4	14.99	TBD2-4	1.29
TB2-5	8.33	NT2-5	22.64	TBD2-5	22.93
TB2-6	37.83	NT2-6	5.49	TBD2-6	1.86
TB2-7	12.84	NT2-7	0.88	TBD2-7	17.93
TB2-8	4.21	NT2-8	1.76	TBD2-8	4.21
TB2-9	14.60	NT2-9	48.41	TBD2-9	5.98
TB2-10	22.54	NT2-10	1.27	TBD2-10	2.16
Mean ± SD	**15.11±10.59**	**Mean ± SD**	**24.71±26.65**	**Mean ± SD**	**7.98±7.74**

Table 4 – Results for groups TB2, NT2, TBD2

Sample	Load at failure (N)	Sample	Load at failure (N)	Sample	Load at failure (N)
TB3-1	11.07	NT3-1	22.54	TBD3-1	Not tested
TB3-2	2.65	NT3-2	2.06	TBD3-2	Not tested
TB3-3	8.43	NT3-3	1.27	TBD3-3	8.04
TB3-4	11.66	NT3-4	117.80	TBD3-4	3.63
TB3-5	10.58	NT3-5	36.46	TBD3-5	1.76
TB3-6	14.80	NT3-6	5.00	TBD3-6	10.88
TB3-7	16.27	NT3-7	51.65	TBD3-7	7.45
TB3-8	2.16	NT3-8	10.39	TBD3-8	1.76
TB3-9	7.45	NT3-9	11.96	TBD3-9	3.33
TB3-10	30.87	NT3-10	37.83	TBD3-10	15.88
Mean ± SD	**11.59±8.17**	**Mean ± SD**	**29.69±35.59**	**Mean ± SD**	**6.59±4.97**

Table 5 – Results for groups TB3, NT3, TB3

While preparing the universal testing machine for groups TB2, NT2, and TBD2, the equipment was mistakenly set for the incorrect platform. The first test unit from the TB2 group was removed without any data recorded. Three samples, one from the NT2 group and two from the TBD3 group, were dislodged from the dies during the thermocycling regimen and therefore were not tested. These test units were excluded from the statistical analysis, reducing the sample size to N = 86 evaluable test units.

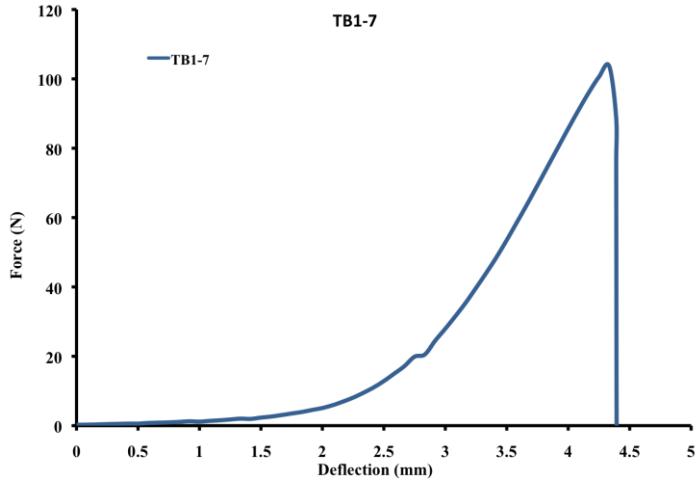

Figure 8 – TB1

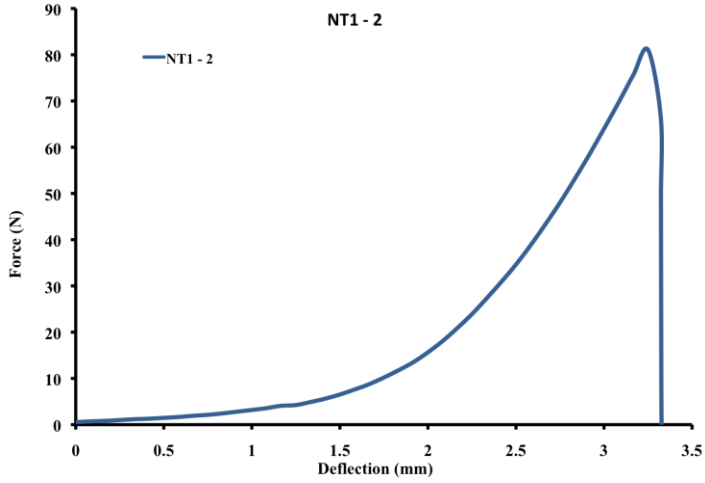

Figure 9 – NT1

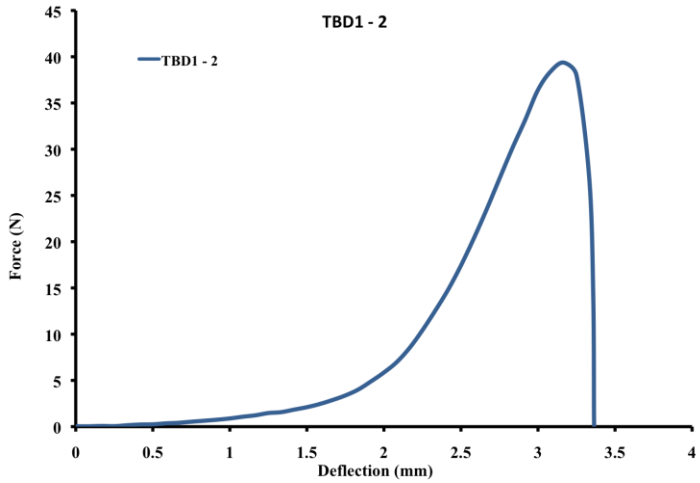

Figure 10 – TBD1

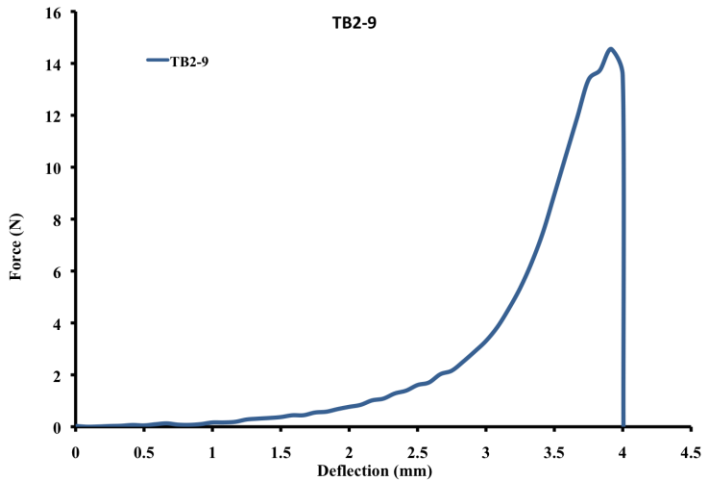

Figure 11 – TB2

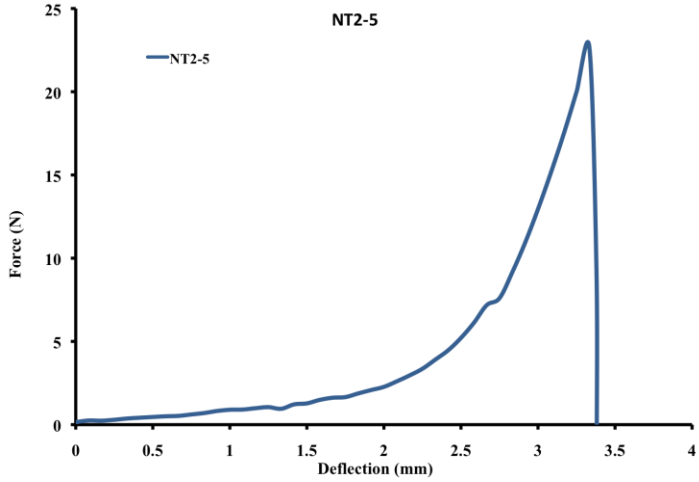

Figure 12 – NT2

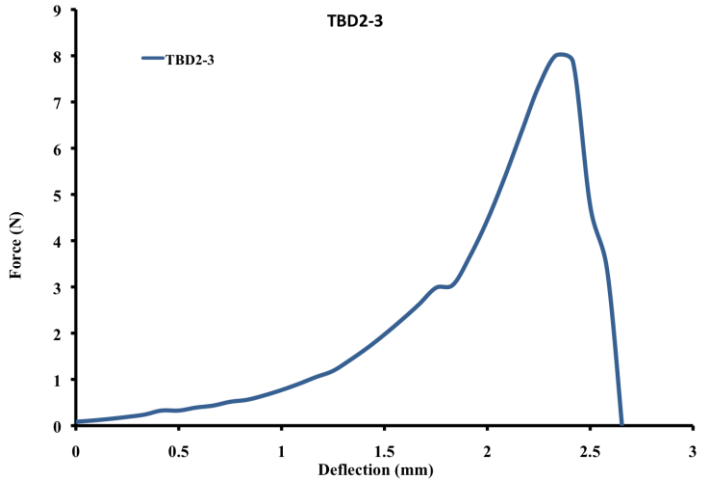

Figure 13 – TBD2

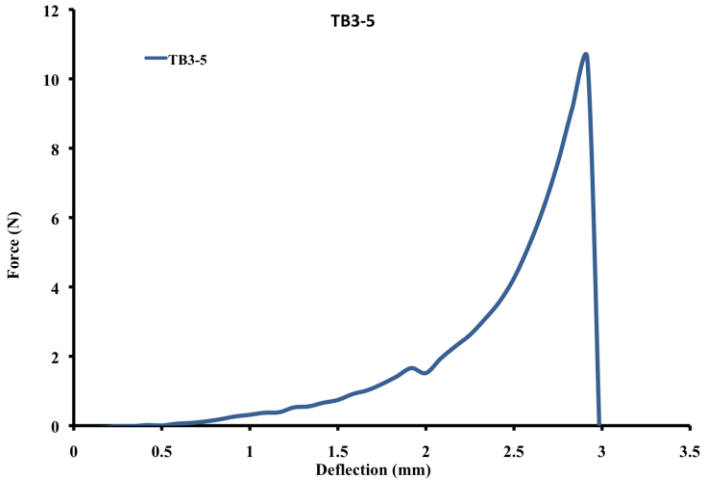

Figure 14 – TB3

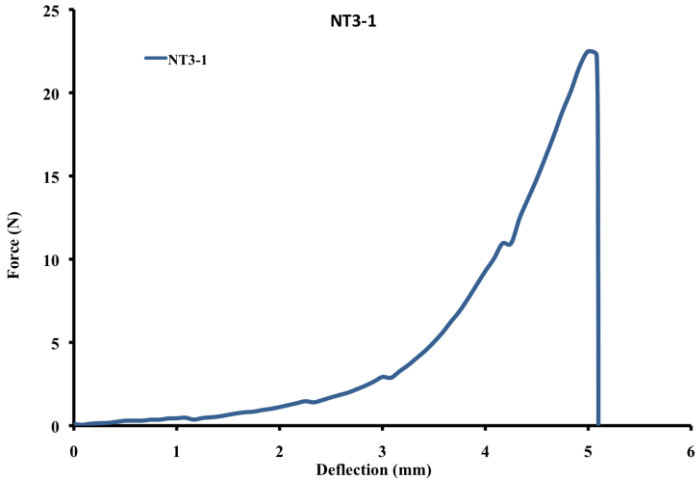

Figure 15 – NT3

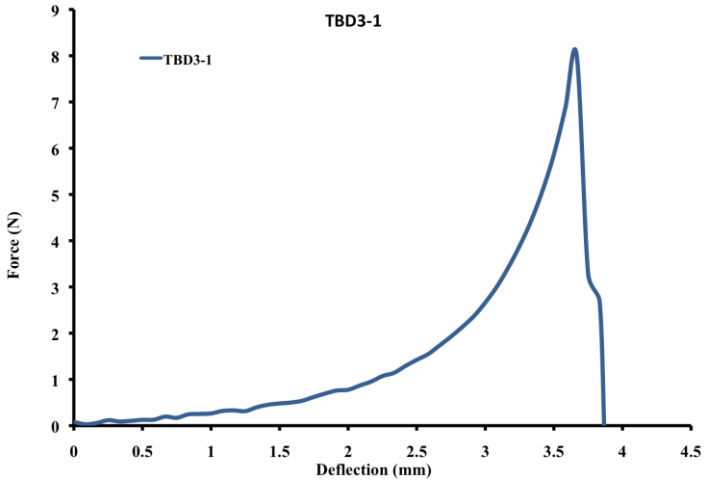

Figure 16 – TBD3

The variability of the measured tensile data was large, resulting in heteroscedasticity. Statistical analysis was carried out using transformed values to account for the high variability in the data. Tables 6-9 display important components of the 2-way analysis of variance model that was executed on square-root-transformed data.

Table 6 shows statistically significant effects for cement and exposure time. The interaction cement * exposure time did not reach statistical significance, thus permitting the careful, direct interpretation of the main effects.

Source	Nparm	DF	Sum of squares	F ratio	Prob > F
Cement type	2	2	73.82	9.53	0.0002
Cycles	2	2	458.81	59.21	< 0.0001
Cement type * cycles	4	4	31.80	2.05	0.09

Table 6 – Effect tests

The difference between cements NT and TB was statistically not significant (P>0.05) as shown in Table 7. However, both cements were statistically significantly different from cement TBD (P≤0.05).

Level			Least square mean
NT	A		5.79
TB	A		5.64
TBD		B	3.73

Table 7 – Comparison among the three levels of main effect "cement"

Test units tested 24h following preparation and with no exposure to thermocycling required statistically significantly higher forces than test units that underwent either 2500 cycles or 5000 cycles (P≤0.05). No difference was found between 2500 cycles and 5000 cycles (P>0.05).

Level			Least square mean
Group 1 (24h)	A		8.29
Group 2 (24h + 2500 cycles)		B	3.45
Group 3 (24h + 5000 cycles)		B	3.42

Table 8 – Comparison among the three levels of main effect "exposure time"

Level					Least square mean
TB1	A				10.01
NT1	A	B			8.58
TBD1		B	C		6.27
NT3			C	D	4.65
NT2			C	D	4.14
TB2			C	D	3.69
TB3				D	3.23
TBD2				D	2.52
TBD3				D	2.40

Table 9 – Multiple comparisons among various group combinations

The results shown in Table 9 and Figure 17 confirm the findings for main effects. In addition, the table allows making comparisons within each cement type as well as within each exposure time. The force needed to remove the crown when TBD was used as the temporary cement was lower than for TB, even when test units were not exposed to thermocycling. No difference was found among any group of test units that underwent thermocycling.

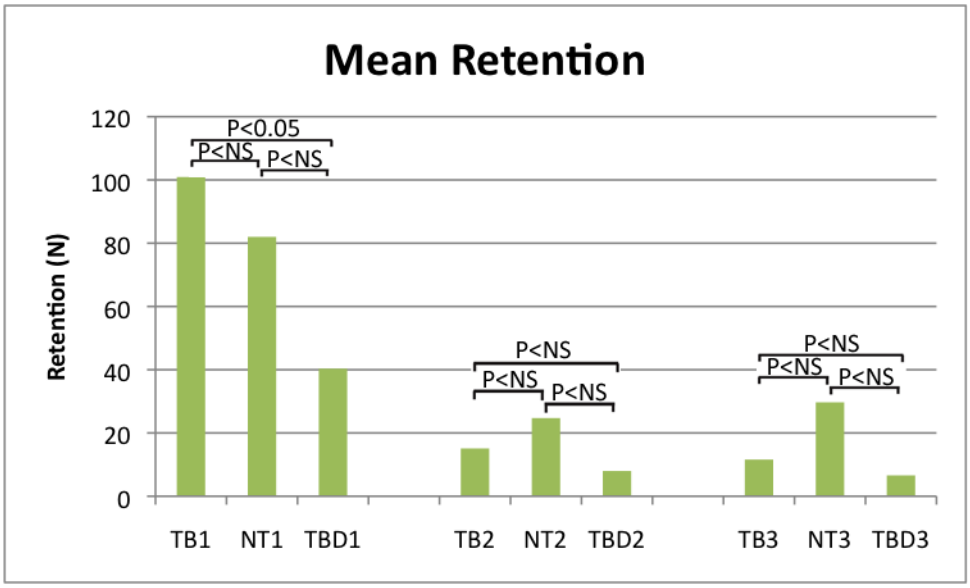

Figure 17 – Comparison of individual groups (NS = not significant)

DISCUSSION

The first null hypothesis that Duraphat will not affect the tensile strength of the cement should be discarded and the alternative accepted. The addition of Duraphat 5% sodium fluoride varnish significantly reduced the tensile strength of all test groups with the addition of Duraphat. The second null hypothesis that thermocycling will not affect the tensile strength of the cement was rejected and the alternative accepted. The results show a great reduction in tensile load after the treatment of 2500 cycles.

Duraphat and TempBond NE is a combination of materials that had not been previously studied, so direct comparisons are not possible. Lewinstein evaluated TempBond NE when combined with stannous fluoride and reported a mean retention of 12N following a regimen of 100 thermocycles and six days of storage.[18] The current study recorded mean values of 100.9N after 24 hours of storage and 15.1 N and 11.6 N following 2500 and 5000 cycles, respectively. Since the previous study did not test any specimens prior to artificial aging treatments, the 24 hour storage values of the current study cannot be compared. The values after thermocycling and storage are similar, suggesting that TempBond NE behaves similarly when thermocycled 100 times and stored for six days or stored for 24 hours and thermocycled for 2500 or 5000 cycles.

The addition of Duraphat fluoride varnish significantly reduced the retentive strength of TempBond NE provisional cement which is different from a previous study using traditional TempBond. In the prior study which compared traditional TempBond (zinc oxide eugenol) alone to a mixture of TempBond with Duraphat

varnish, a significant increase in retention was found with the addition of the varnish.[21] TempBond alone failed at a mean of 44.5 N and the mixture of TempBond and Duraphat failed at a mean of 109.0 N following 500 thermocycles and storage for 6 days. The improvement in retention found in this study was not observed when mixing TempBond NE with Duraphat varnish.

The current results suggest that even three months of clinical use of any of the tested cements may already be beyond the cements' capability for adequate retention. The retention observed after 5000 cycles was not statistically significantly different from the values at 2500 cycles. This shows that the loss of retention occurred in the cements between zero and 2500 cycles and little further change occurred during the cycles from 2500 to 5000. Further studies should be conducted to determine how long a provisional cement may be used before retention is lost.

Several authors have written of the need for long-term provisional restorations, but few have considered methods of retaining the restorations over time[1-8, 11-15, 18-23]. While these studies are very promising, there are a few limitations. Traditional TempBond and ZOE, as used in Lewinstein's experiments, are no longer frequently used due to the presence of eugenol and its implications for cementation of definitive restorations. In all of the similar previous studies extracted human teeth were used. Due to the variability in natural teeth, it cannot be ensured that the samples were uniform. Additionally, each tooth was cleaned and reused between samples and tests; it is possible that the various cements or

cleaning methods could have had an effect on the porous tooth structure. Ideally, samples would be prepared uniformly and remain unchanged between groups.

For the previously stated reasons the current study used machined stainless steel dies. By doing so, each die is similar to the others ensuring the same geometry, occlusal convergence angle, and surface area between samples. Selection of stainless steel allowed for cleaning and reuse of each sample presumably without any changes to the surface of the die. There are some limitations of such a design. Using a conical die with a machined surface gives a situation less realistic compared to a clinical setting. Natural teeth are not uniformly conical and would have an irregular surface and texture. However, the purpose of this study was to assess the provisional cement and not the effects of the natural tooth form. Since the provisional crowns were pulled axially, the conical nature of the dies should not affect the retention of the crowns. To account for the surface texture, small grooves were included on the walls of the preparation. This set up gave a close representation to a clinical situation while minimizing the variables present when using prepared human teeth.

The previous studies used chemically polymerized and hand-prepared temporary crowns that were relined between each use.[18, 21-23] This can also introduce variability into the experiment due to the inconsistencies of the materials. Each hand-made provisional crown will be slightly different according to the mixing and handling of the acrylic and the overall shrinkage of the material as it sets. Fit of the restoration and the available space for the provisional cement were not controllable. Moreover, the method for cleaning and reusing of the provisional

restorations is not clear. By using CAD/CAM Telio acrylic temporary crowns milled from solid blocks of material in the current study, such variables were minimized. Some of the advantages include: 1) polymerization shrinkage is eliminated, 2) the material is uniform throughout, 3) dimensions are standardized, and 4) cement spacing is uniform. Shrinkage is eliminated and the material is uniform throughout all specimens since they are milled from solid blocks of acrylic material. As mentioned previously, this design is not always applicable to clinical situations, but it does allow for more control over the experimental variables. The combination of uniform dies and milled acrylic provisional crowns permits an evaluation of the behavior of the cements as the only variable.

There are several possibilities for the outcomes of the current study. One major factor is that the properties of TempBond NE may be significantly different when compared to traditional TempBond. The differing formulations were compared in one study which demonstrated 25 N of retention for TempBond alone and 29 N when mixed with stannous fluoride.[18] The same study showed 12 N of retention in TempBond NE and 35 N with the addition of stannous fluoride. These differences are a good example of the variations in cement properties when each formulation is augmented with additional materials. It demonstrates a potential reason why the retention of TempBond NE was not increased with the addition of Duraphat varnish.

Another possible reason an increase in retention was not observed with the addition of Duraphat fluoride varnish is the ratio of materials in the mixture. The studies by Lewinstein where Duraphat was used are unclear as to how the ideal

mixture was determined. The current study could not use the previously determined mixture directly as the formulations and therefore the densities of TempBond versus the non-eugenol version are not equal. Lewinstein stated the base/catalyst/Duraphat ratio when using TempBond to be 6:2:1.[21, 23] This was chosen based on acceptable setting and working times. In the current study, various amounts of TempBond NE and Duraphat varnish were assessed to determine what ratio would provide setting and working times similar to those suggested by the manufacturer. A mixture made by dispensing a 12-millimeter strip through the syringe of the TempBond NE base and catalyst with an eight-millimeter diameter circle of Duraphat was found to be comparable to the times set by the manufacturer. Since the cements were dispensed using a syringe system, it was not possible to compare the base and catalyst by weight separately. It is possible that a different ratio of cement to varnish could have provided another outcome. Further studies should be performed to determine if there exists an ideal combination of TempBond NE and Duraphat fluoride varnish that provides mechanical properties more similar to the unaltered cement.

The evaluation of NexTemp cement was performed to determine whether a commercially available cement containing fluoride and other ingredients might perform better than altering a cement by adding fluoride varnish. After 24 hours, groups TB and NT were not significantly different, but the NT group had a high amount of variability in the data collected. Groups NT2 and NT3 also had a few outlying data points. All of the samples were prepared in the same method from one lot of cement, so the cause of the high degree of variability is unknown. It is possible

that with the additions of fluoride, chlorhexidine, and potassium nitrate, the cement properties are not uniform throughout one lot. Based on the results in this investigation, the clinical use of NexTemp cement should be cautioned due to the high variability in retention.

Of the studies by Lewinstein, one stored the samples for 24 hours before testing[23], two thermocycled for 100 cycles[18, 22], and one used 500 cycles[21]. For the purposes of long-term provisionalization, these regimens are inadequate to suggest use over an extended period. Thermocycling for 10,000 cycles has been suggested to correspond to a year of clinical use of a restoration[25]. In this investigation, treatments of 2500 and 5000 cycles were used to simulate three and six months of wear of the provisional crowns to observe how the cements would behave over such a time period.

There were several limitations to this study. As previously mentioned, the stainless steel, conical dies may behave differently than human teeth when subjected to various provisional cements. This material was used to control for the variability in natural teeth. Another limitation is the use of thermocycling to artificially age the specimens. While it has been suggested that this is an acceptable method[25], thermocycling does not account for the functional use of crowns or the effects of saliva or bacteria. Additional studies could be performed to evaluate the behavior of provisional crowns and cements in a clinical environment.

CONCLUSIONS

The use of Duraphat varnish as an addition to TempBond NE provisional cement to increase retention cannot be recommended. NexTemp provisional cement should be used with caution as the retention observed was highly variable. When evaluating the cements over a simulated period of three to six months, a large reduction of retention was observed. Based on these results, the use of any of the tested cements over such a time period should be cautioned.

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