

A Critical Analysis of Recent Research on Resilon™ Obturation Material

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Introduction

Resilon Research, LLC introduced the resin-based Resilon™ Obturation System in 2003. This innovative root canal treatment is rooted in adhesive dentistry and has had many studies conducted on it over the past two years. Fundamental to the credibility of these studies, whether they are in vitro or in vivo, is sound scientific practice to ensure objective and repeatable results providing clinically relevant and reliable findings.

Five articles published on Resilon™ in Fall issues of the Journal of Endodontics appear to have bypassed standard scientific practices and their results are therefore called into question. This paper seeks to compare generally accepted scientific principles for the objective evaluation of dental materials to the studies in question which are individually listed and critiqued accordingly in Section 2.

Section 1: What constitutes the standard for the scientific evaluation of materials?

The scientific quality of a clinical or in vitro study depends upon the adherence of the investigator to a number of conditions including the criteria listed below:

1. Stated Objective(s)

Clearly define the specific purpose for which the study is to be carried out.

2. Experimental design

Select more than one material or system for investigation and include a control. Without a control serving as a baseline, any flaws inherent in the scientific method employed for the study will not be identified and the results obtained may be biased, either favorably or unfavorably, toward the one material or system selected for testing.

3. Number of specimens

The number of specimens, or sample size, for each variable to be examined is determined by conducting a “pilot study.” The pilot study provides an indication of the range of values to be anticipated in the final investigation and ensures that

the results obtained are sufficient for relevant statistical analysis. In addition, it is important to refer to other studies in which similar parameters were investigated so scientific design can be compared and contrasted. Lastly, a properly designed study should include both a positive and a negative control to ensure reliable and repeatable results.

4. Preparation of specimens

It is important to disclose information about the specimens used in scientific evaluation as they constitute a variable that can affect the outcome. Information on specimens should include:

- A. Identification of the details of preparation including disclosure of any relevant information associated with the preparation of individual specimens.
- B. Conditions of storage including medium, time, temperature, etc. Conditions during the actual testing procedures such as wet, dry, temperature, etc. should also be disclosed.

5. Results

The results section of a reliable study should provide statistical information regarding the specific number of specimens for each parameter investigated and for each variable tested. The information necessary includes:

- Values for each specimen
- Mean values for each variable tested
- Standard deviations for each mean
- Level of significance
- Analysis of variance
- Type of statistical test employed to determine differences and level of confidence
- Selection of test to be dependent upon metric or parametric values

6. Discussion

This section should contain a discussion of the following conditions:

- The test employed

- Clinical relevance of data
- Clinical significance: Results may be statistically significant but not clinically significant.
- Treatment of zero values: Zero values need to be defined as part of the testing procedure or as part of the specimen preparation phase. If the specimen is separated during the preparation stage, the values should not be included as part of the testing results. If zero values are included, then the reported mean values and the related standard deviations, should reflect both processes. If the zero values are reported as part of the testing values and fall considerably apart from the general group of data, they are called “outliers” and a reason should be given as to why they occurred and why they are relevant if included in the statistical analysis. Outliers, in general, are discarded when statistical analysis is conducted as they run contrary to the scientific design and can skew the results.

7. Significance

In addition to presenting the clinical significance of the completed study, the author(s) should also define any deficiencies associated with or discovered during the course of the study. In addition, suggestions should be made for future investigations as each study conducted collects information that can potentially improve the scientific design and reliability of subsequent studies.

Using the criteria defined above, an analysis of the five publications in question is presented in Table 1.1. This analysis demonstrates whether these studies comply with generally accepted scientific principles for good research and clinical relevance.

Section 2: Critique of Individual Articles

Tay FR, Loushine RJ, Weller RN, Kimbrough WF, Pashley DH, Mak Y-F, Lai CN, Raina R, Williams MC. Ultrastructural Evaluation of the Apical Seal in Roots Filled with a Polycaprolactone-based Root Canal Filling Material. JOE 2005; 31(7):514-519.

Much of the study deals with the presence of gaps between the obturating material and the sealer, as well as between the sealer and the chamber wall. Both SEM and silver nitrate tracers were used to determine these apparent defects. It is important to note that the dye leakage tests were conducted on non-continuous sections. There is an inherent flaw in this type of testing since leakage is a three-dimensional phenomenon. The cross section technique measures only two dimensions. The use of only one or two selected specimens for scanning electron microscopy is also insufficient and statistically irrelevant. Because of the small sample size and lack of complete data, there is no quantification of the data and therefore no statistical analysis that would serve to validate the scientific design. All of the data presented is qualitative in nature and is therefore subjective. As a result, the apparent defects detected by the authors at the various interfacial regions are clinically insignificant.

Table 1.1

Study Title	Stated Objective(s)	Experimental Design & Controls	Number of Specimens	Specimen Preparation & Storage	Results & Statistical Analysis	Discussion of Relevance	Clinical Significance
Ultrastructural Evaluation of the Apical Seal in Roots Filled with a Polycaprolactone-based Root Canal Filling Material	✓			✓			✓
Susceptibility of a Polycaprolactone-based Root Canal Filling Material to Degradation. I. Alkaline Hydrolysis	✓		✓	✓			
Geometric Factors Affecting Dentin Bonding in Root Canals: A Theoretical Modeling Approach				✓			✓
Susceptibility of a Polycaprolactone-based Root Canal Filling Material to Degradation: II. Gravimetric Evaluation of Enzymatic Hydrolysis	✓	✓		✓			✓
Interfacial Strength of Resilon™ and Gutta Percha to Intraradicular Dentin	✓		✓			✓	✓

With regard to sample preparation, this study does not disclose the history of the teeth used to conduct the investigation. It is important to consider the age and condition of the teeth, particularly as it relates to calcification of the canals. It would have been appropriate to present information on the presence or absence of any auxiliary canals which theoretically could influence leakage of the dye penetrating agent.

Other problems in the experimental design of this study also exist. Examples include the fact that the concentration of NaOCl was half of the concentration used clinically. No information was provided about the application of the primer or the sealer, there was a lack of comparison of the results to other published studies and, finally, the clinical experience of those conducting the testing was not disclosed.

Tay FR, Pashley DH, Williams MC, Raina R, Loushine RJ, Weller RN, Kimbrough WF, King NM. Susceptibility of a Polycaprolactone-Based Root Canal Filling Material to Degradation. 1. Alkaline Hydrolysis. JOE. 2005; 31(8):593-598.

In this study, highly caustic sodium ethoxide (20%) was used to demonstrate that the plasticizer (polycaprolactone) in Resilon™ is degradable. It was hypothesized that the plasticizer in Resilon™ is degradable in the presence of lipases and enzymes. Sodium ethoxide is neither an enzyme nor a lipase. Commercially, it is a highly caustic material which undergoes spontaneous combustion when mixed with water and is typically used as a deplasticizer for polycaprolactone agents. The selection of this material to test the solubility or biodegradation of any Resilon™ components is not only clinically insignificant, but specifically demonstrates a known mode of failure for a *single component* of Resilon™ and not the Resilon™ material itself.

It has been documented that polycaprolactone is biodegradable in vivo and that it is also highly biocompatible. Due to the potential for biodegradation, polycaprolactone is compounded with a bioactive glass during Resilon™ synthesis for the purpose of generating mineralization should degradation occur.

The authors speculate that biodegradation of Resilon™ may occur in the event of apical or coronal leakage and may therefore further compromise the seal achieved after endodontic therapy. Should leakage occur, whether at the corona or the apical aspect, the first and foremost problem is the deteriorating effect created by the microorganisms that will infiltrate the canal and inflame periapical tissues, not the potential for the dissolution or degradation of the obturating material.

Finally, this article does not cite or discuss any of the recent publications that demonstrate the reduction of microbial

activity at the obturation/sealer interface when obturations completed with Resilon™ materials are compared with gutta-percha. *Tay FR, Loushine RJ, Lambrechts P, Weller RN, Pashley DH. Geometric Factors Affecting Dentin Bonding in Root Canals: a Theoretical Modeling Approach. JOE 2005; 31(8):584-9.*

In this theoretical and limited laboratory study, the authors use the C-factor concept to propose that bonding to the walls of the prepared chamber with the methacrylate-based sealer indicated for use with Resilon™ is problematic. Cavity configuration factor (C-factor) is the ratio of the bonded surface area in a cavity to the unbonded surface area. This concept relates to the published data that suggests that the greater the number of walls associated with a cavity preparation, the greater the stresses at the interfacial bond. By proposing that a sealed root canal is similar to a Class I resin restoration, it was suggested in this study that the interfacial stresses of a bonded obturation would be very high.

This highly theoretical study employed only a limited number of specimens. Assuming that the basic theoretical calculations are reliable, the assumptions associated with the application of the sealer were incorrect. The authors made their calculations based, in part, upon a system that uses a rapid setting-bonding agent. The methacrylate-based sealer cures over a 40 to 45 minute period in the canal. This means that when compared to conventional light-cure or rapid-setting bonding agents, the sealer takes up to 200 times longer to set. An immediate coronal seal can be achieved with the sealer by light curing the coronal aspect, however the depth of light cure is only 0.5 – 1.00mm. Because of the dual cure formulation of the sealer, the longer intra-canal set time results in a considerable reduction in interfacial stress.

The methacrylate-based sealer possesses a curing shrinkage of 2.2% compared to the 4 – 5% shrinkage associated with conventional dentinal adhesives. And due to a definable level of water sorption, Resilon™ sealer actually undergoes an expansion of 0.2%.

Tay FR, Pashley DH, Yiu CK, Yau JY, Yiu-Fai M, Loushine RJ, Weller RN, Kimbrough WF, King NM. Susceptibility of a Polycaprolactone-Based Root Canal Filling Material to Degradation. II. Gravimetric Evaluation of Enzymatic Hydrolysis. JOE. 2005; 31(10):737-741.

This study deals with the degradation of polycaprolactone with and without the glass fillers in the presence of lipases and esterases of enzymes. During this study, these agents were used in concentrations twenty times greater than their clinical occurrence. While using high concentrations of lipases and esterases produce fast results, they may not produce clinically relevant results.

It should also be pointed out that the polycaprolactone used in this study was not encased in the resin sealer as it would be in

clinical application. The methacrylate-based sealer indicated for use with Resilon material contains calcium hydroxide filler particles and is bacteriostatic in the presence of fluids. If the polycaprolactone samples had been treated with sealer, the microbes could not have remained vital to release their associated esterases.

It is one thing to measure the degradation of the plasticizer in a bath of highly concentrated lipases and esterases but a completely different matter to expose the obturation material when sealed in an endodontically treated tooth. To this end, it would have been far more clinically relevant to subject a series of extracted endodontically treated teeth to an oral environment. While this experiment was well conducted, it is not clinically relevant.

Gesi A, Raffaelli O, Goracci C, Pashley DH, Tay FR and Ferrari, M. Interfacial Strength of Resilon and Gutta Percha to Intraradicular Dentin. JOE. 2005; 31(11):809-813.

This investigation was an attempt to measure the comparative interfacial strength of gutta percha and Resilon™ materials. The authors used a conventional push-through test consisting of thin slices of sectioned roots perpendicular to the long axis of the tooth. While this type of test may be appropriate for porcelain fused to metal restorations, it may not necessarily be relevant to the evaluation of obturated canals. gutta percha and Resilon™ materials are considerably less rigid and possess significantly less hardness when compared to ceramic materials; consequently, the control of the debonding process is difficult to standardize.

Furthermore, due to variations in specimen thickness and the configuration and size of the instrumented canal, the relationship between the stylus producing the force and the surface area of the gutta percha or Resilon™ materials would vary considerably and uncontrollably. The variables inherent in this experimental design could easily influence the results obtained for each specimen.

Another serious problem with this study is that the authors do not present any of the experimental data thereby preventing any quantitative review of their results. While statistical analysis was apparently employed through their reporting of mean values, no other statistical results were presented, including such basic data as standard deviation or tests for statistical relevance.

Furthermore, since the orifice dimensions on the surface of the root sections exhibit different values due to the size of the chamber and the irregularities of the area associated with these walls, it is not possible to generate accurate values for stress. The values reported for bond strengths are essentially without merit since no practicable, routine test exists for accurately measuring all interfacial surface areas.

Conclusion

The introduction of an entirely new material to replace an existing treatment standard will and should provoke thorough and extensive scientific study. While clinical experience is by far the best measure of success for a product, manufacturers and dentists alike rely heavily on research and scientific exploration to provide the industry with much needed information on the materials and products that are used in dentistry every day. Studies that seek to objectively predict the long term clinical efficacy of dental materials must be structured to accomplish this through the generally accepted principles of scientific research. Failure to do so can result in incomplete and biased results that do not serve the practice of dentistry or the betterment of patient care.