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Resin-based composite performance: Are there some things we can't predict?

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Abstract

Objective—The objective of this manuscript is to address the following questions: Why do direct dental composite restorative materials fail clinically? What tests may be appropriate for predicting clinical performance? Does in vitro testing correlate with clinical performance?

Materials and methods—The literature relating to the clinical and laboratory performance of dental composite restorative materials was reviewed. The main reasons for failure and replacement of dental composite restorations provided the guidance for identifying specific material's properties that were likely to have the greatest impact on clinical outcomes.

Results—There are few examples of studies showing correlation between laboratory tests of physical or mechanical properties and clinical performance of dental composites. Evidence does exist to relate clinical wear to flexure strength, fracture toughness and degree of conversion of the polymer matrix. There is evidence relating marginal breakdown to fracture toughness. Despite the fact that little confirmatory evidence exists, there is the expectation that clinical fracture and wear relates to resistance to fatigue. Only minimal evidence exists to correlate marginal quality and bond strength in the laboratory with clinical performance of bonded dental composites.

Conclusions—The use of clinical trials to evaluate new dental composite formulations for their performance is expensive and time consuming, and it would be ideal to be able to predict clinical outcomes based on a single or multiple laboratory tests. However, though certain correlations exist, the overall clinical success of dental composites is multi-factorial and therefore is unlikely to be predicted accurately by even a battery of in vitro test methods.

Keywords

dental materials; testing; physical properties; clinical performance; dental composites; direct restoratives

Introduction

The use of dental composite as a posterior restorative is increasing worldwide, though its use in relation to dental amalgam varies widely from country to country [1]. An extensive

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database from the Washington Dental Service in the U.S. reveals that composite use for posterior teeth surpassed that of amalgam in 1999 [2]. As until recently there were actually very few restrictions on the use of amalgam in countries around the world [1], it is likely that the main reasons for this change in usage is the desire for tooth-colored fillings and the increasing familiarity and comfort of the practitioner with the use of composites.

The title of this manuscript suggests that there some aspects to the clinical performance of dental composite that we can't predict. This implies that there are things that we can predict. This is a very optimistic outlook, as will become apparent through this manuscript. Despite substantial effort by the manufacturing and research communities, the ability to predict clinical performance of virtually all dental materials has not advanced significantly. Certain correlations between specific properties and clinical performance have been identified over the years and have been used to guide materials selection and placement, but the science remains largely empirical.

Current research and development efforts are aimed at modifications of the resin and/or filler component to produce formulations with reduced curing contraction, and more importantly, reduced curing contraction stress. This effort is a direct response to the sensitive and somewhat complex placement techniques required for these materials and the fact that recurrent decay has consistently been the primary reason given for replacement of dental composite restorations in private practice, with fracture being the second most important reason [3–10]. While some have suggested that replacement is primarily a response to fracture during the first five years of service, and for secondary caries after that [11], other data does not support this trend [12]. Little progress has been made on increasing the fracture resistance of dental composites. In fact, on the whole, the most popular current formulations are significantly weaker and less fracture resistant than those sold in the 1970's and 1980's, before the major push to minimize particle size occurred.

There are well over one hundred published studies evaluating the clinical performance of dental composites. Undoubtedly nearly as many more clinical studies have been conducted but have not been documented in the peer-reviewed literature. Despite this extensive investment in time, energy, and money to study these materials in the ultimate proving ground, it is still not possible to identify a precise level of required properties or characteristics that ensure the clinical success of a new formulation. Thus, new materials are subjected to a battery of test modalities in order to describe their physical characteristics, predominantly in comparison to other products already on the market for which some indication of clinical success exists. In this regard, the development of dental composites is only to a limited extent based on sound engineering design principles, and therefore many questions surround the release of a new product line. These questions must typically be answered through clinical evaluation, which either delays acceptance of the product, or allows immediate use with some substantial degree of discomfort and uncertainty. A rational approach to this dilemma would seem to be to analyze the primary reasons for the clinical failure or success of dental composite restorations, and then to identify testing methods that address these most important aspects of the material's performance. An excellent review article in this area has been published by Sarrett [13].

The objective of this manuscript is to address the following questions: Why do direct dental composite restorative materials fail clinically? What tests may be appropriate for predicting clinical performance? Does in vitro testing correlate with clinical performance? The discussion primarily concentrates on composite placement in stress bearing areas, as the use of composites in other sites is generally considered to be without serious problem or concern aside from esthetics and marginal sealing. While the bonding and sealing of composites remains a major issue, it is equally critical for anterior and posterior composites. Further, these aspects of the restoration relate largely to the adhesive material, and have been addressed by others [14,15].

Why do direct dental composite restorative materials fail clinically?

In order to address the issue of predicting clinical outcomes through laboratory tests, it is necessary to have a firm understanding of the actual clinical performance through controlled studies or evaluations [16]. This in itself is a significant problem. Clinical data, even from controlled studies, is typically plagued by high variability. A good example of this was pointed out years ago when trying to correlate data generated on the wear of dental composites using an in vitro testing device with clinical wear reported in the literature. In an attempt to calculate “average” wear results for developing a correlation, the wide range of results for similar materials from different studies precluded making a meaningful attempt [17]. Instead, developing a similar ranking of materials was considered to be a more reliable method for relating the laboratory to the clinical situation. Wear is a particularly difficult characteristic to assess clinically. It may be produced in a variety of ways, and is very dependent upon the oral conditions, but generally must be of significant amount to be recognizable. Studies have shown that relatively simple assessments of casts produced from impressions are not very accurate in most cases [18]. These methods cannot quantitate the wear of an entire surface, and are typically confined to semi-quantitate assessments at margins, when the bulk of wear may be occurring elsewhere on the restoration. More sophisticated techniques require more expensive equipment and time and are therefore less readily available [19,20].

This limitation is common for all types of clinical assessments, in part due to the difficulties in developing clear and specific diagnoses of “failures” as well as to differences in clinical opinion, [21,22]. Marginal staining around a dental composite may cause the restoration to be identified as a failure due to compromised esthetics, but the composite itself is largely unaffected and remains serviceable. How is it possible to predict this in anything other than a clinical situation? Likewise, marginal fracture of composite restorations on occlusal surfaces possibly may be related to inherent deficiencies in the properties of the composite that were revealed under the conditions of cyclic loading. However, this “failure” may also be due to deficiencies in the bonding, or placement procedure, either of which predisposed an otherwise acceptable material to premature degradation. In any case, the underlying assumption is that the clinical judgment that differentiates “failure” from “acceptable” is capable of being standardized across multiple evaluators and sites. This is likely incorrect. Despite the laudable past and more recent efforts of investigators to develop well-defined criteria for clinical assessment of dental restorations [23], clinical opinion is still left to interpretation and affects the accuracy, and precision, of the evaluation. Thus, we are left with an imperfect system and it is not surprising that there are so few instances in which a reasonable prediction of clinical performance is generated from laboratory testing. However, clinical studies do provide guidance on the primary reasons for failure, and therefore which properties may be most applicable for testing.

Clinical studies show increasing evidence for the successful long-term performance (10+ years) of dental composite in small to moderate-sized restorations [24–26]. A 17 year study of four UV-cured conventional composites [27] reported excellent outcomes, and a 17 year and 22 year study of two visible light-cured hybrid composites [12,28] placed in class I and II cavities under rubber dam showed overall success rates of 75% and 64%, respectively. The main reasons for failure in these studies were wear and secondary caries [27] and fracture [28]. An evaluation of clinical outcomes from an extensive insurance database for approximately 200,000 amalgams and 100,000 composites showed survival rates of 94% and 93%, respectively at 7 years [2]. While this difference seemed minimal, statistical evaluation for this large dataset showed about a 16% greater chance of failure for composite than amalgam. A nearly double rate of failure for composite compared to amalgam as a posterior restorative has been reported based on reviews of controlled clinical studies [29–31]. More recently however, Opdam et al. [32] have shown equivalent or even higher success rates for posterior composites vs. amalgam, except perhaps in situations where the patient had a high caries status.

Results from cross-sectional studies from private practices vary showing an equivalent failure rate for composite and amalgam over three years [31] to nearly twice the mean longevity for amalgam over 12–14 years [33]. A recent study reporting on the 5-year success of over 700 posterior composites placed by dental students showed a failure rate of 14%, with class II restorations failing at nearly three times the rate of class I restorations [34]. The predominant cause of failure was caries/marginal openings and restoration fracture. Further evidence for the performance of composites in larger cavities, with many restorations involving cusp replacement, has shown survival rates at 11 years of 73% [35] and 70% [36], with success being better in premolars than in molars. The predominant reason for failure in both studies was fracture of the restoration. Another study of the survival of extensive composite restorations (where a crown would have been the first choice), showed a median survival of 7.8 years for composite, which was less than that for amalgam (12.8 years) and metallic crowns (more than 14.6 years), with the primary reason for failure again being composite fracture followed by secondary caries [37].

The clinical studies cited suggest that dental composite can be expected to provide excellent service for small to moderate-sized restorations, and perhaps adequate service for large restorations. However, performance seems to be better in premolars than in molars, and the most common reasons for failure are fracture and secondary caries. Wear seems to continue to be a concern, but perhaps only for patients with heavy occlusal patterns, such as bruxing and clenching.

What tests may be appropriate for predicting performance?

An obvious question to be addressed is “What controls the clinical performance of dental composite restoratives?” Three separate factors may be considered to answer this question. First, the mechanical properties, as well as wear resistance, must play a significant role. These properties are highly dependent upon the material’s formulation as defined by the manufacturer, but are also heavily influenced by the extent of the curing reaction and the care in placement, both of which are controlled by the clinician. While it is true that specific design criteria have been elusive, few would deny that there is a threshold for every mechanical property below which premature failure would be very likely. The best evidence for this is the fact that certain materials, such as glass ionomer and zinc oxide eugenol, can typically only be used as temporary restoratives in stress bearing situations in permanent teeth due to a high propensity for fracture and wear under occlusal loads [31]. Further evidence is the fact that clinical studies have shown fracture of the restorative material to be either the primary or secondary reason for failure of dental composite restorations placed in stress bearing situations.

Second, the dimensional characteristics that determine marginal adaptation are of critical importance, as evidenced by the fact that secondary caries is a primary reason for composite restoration replacement. Included in this consideration is the volumetric shrinkage of the material during polymerization and the subsequent swelling that may occur due to solvent uptake in the oral environment. These properties are highly dependent upon the material’s formulation as defined by the manufacturer, but may also be affected by the extent of curing. The placement technique, entirely under the control of the clinician, is also critical to the overall adaptation, retention and sealing of the material within the preparation. Finally, the preparation design plays a key role in success, including its geometry (i.e. quantity and quality of the remaining tooth structure), location in the arch, and relation to opposing and adjacent teeth. These factors are for the most part under the control of the clinician, though they may often be steered from the ideal by the dictates of the particular case.

a. Mechanical Properties and Wear

The mechanical properties of consideration for use in evaluating composites and predicting clinical success are highlighted in Table 1. The table presents the property of interest, what physically it relates to or tests, and what in the author's opinion its possible relation may be to the clinical performance of dental composites.

Based on the main reasons for failure of composites, and the experience derived from the use of these materials, the most important mechanical properties to evaluate for dental composites are likely fracture toughness, fatigue resistance, and wear. Since all restorations are likely to contain flaws, fracture toughness may be the most critical factor in determining resistance to intraoral fracture. However, it seems essential to include some assessment of strength itself when evaluating these materials. Since composites have much lower tensile than compressive strength, and tensile strength is typically much more affected by internal flaws, this property is likely the most appropriate test of strength. However, it is more difficult to evaluate precisely. Therefore, flexure, a potentially simpler test method that relates well to tensile failure, is usually substituted in its place. Flexure testing is the standard means for strength testing of dental composites (ISO 4049), and has been shown to correlate with wear in some studies [38,39]. While compressive strength seems intuitively important, there has been no indication that it relates to clinical performance, especially in light of the fact that most failures are probably related to tensile stresses.

Hardness also intuitively seems an important property, especially for predicting wear, but in vitro studies have been equivocal in showing a correlation for dental composites. Elastic modulus would also seem to be important, but success of posterior restoratives with comparatively high and low elastic modulus have been shown to be equally good as posterior restoratives over five years [40]. A potential correlation between low elastic modulus and better retention of composites in class V cavities subjected to occlusal stresses has essentially been disproven [41,42]. Wear, though much less of a concern now for restorations of small to moderate size, may still be an important limiting property for dental composites for very large restorations with heavy occlusal contacts and especially for patients with heavy or abnormal occlusal function [35,43]. Therefore, wear should continue to be a screening tool for new composites prescribed for posterior teeth.

Finally, though it is not proven, it seems logical that the repetitive cyclic stressing of dental restorations may lead to the development of flaws that after several years of service may cause the catastrophic failures seen clinically. Therefore, it may be important to include an assessment of fatigue resistance when developing new formulations or attempting to predict clinical performance. This property has been tested for recent dental composites by several investigators [44,45]. There also is some in vitro indication that this property may relate to marginal deterioration in dental composites, as will be discussed later.

b. Physical Properties

The physical properties of consideration for use in evaluating composites and predicting clinical success are listed in Table 2, using the same format as presented in Table 1.

Based on the main reasons for failure of composites, and the experience derived from the use of these materials, the most important physical properties to evaluate for dental composites are likely polymerization shrinkage and shrinkage stress, and adhesion, though the latter is predominantly a function of the adhesive material used in conjunction with the composite. Because secondary caries has been identified as the primary reason for replacement of composite restorations, properties that influence the ability of the composite to adapt to and bond to the cavity wall are important to assess. The polymerization shrinkage of the material during setting is considered to be of primary concern, since a non-shrinking material would be well adapted after setting. There are numerous methods for analyzing shrinkage, including dilatometry, Archimedes method, the bonded disk, and other linear methods [46]. The advent of strong adhesives has provided the possibility for good adaptation and seal in spite of the curing contraction. Therefore, an evaluation of the internal stress generated during curing, which may manifest as forces countering the interfacial bonds, may be the most useful parameter to test. The issue of composite contraction stress generation and its many variables recently has been reviewed by several authors [47–49]. Generally, the contraction stress is enhanced for composites with high shrinkage, high elastic modulus, and low molecular flow and stress relaxation. The primary concern is the loss of marginal adaptation and the occurrence of leakage at the tooth/composite interface. Contraction stress has been correlated to marginal leakage in class V cavities by numerous investigators [50–52].

Other properties, such as thermal expansion coefficient, may also influence composite adaptation to cavity walls. Because there is a mismatch between the thermal expansion coefficient of composites and enamel and dentin, one would expect that stress will be applied to the interfacial bond during the exposure to hot and cold food and drink. While this is likely to be the case, and some have suggested that this is a concern, it seems unlikely to be as important as the volumetric changes occurring during composite curing for two reasons. First, the volumetric shrinkage during curing occurs when the bond is being established, not after the bond has matured. While thermal changes will affect this matured bond, stresses produced by the small dimensional changes associated with variations in oral temperature of 10–20°C should be minimal. Second, exposure to high or low temperatures is of short duration, thus minimizing thermal transfer due to the low thermal diffusivity and conductivity of composite. These thermal properties, while of interest, are unlikely to be correlated with clinical success, and in fact no evidence has been shown to the contrary.

Other properties such as color stability are of critical importance for anterior composites, but of much less concern for posterior restoratives. Viscosity is a critical property since it influences the handling and placement of the material. However, handling is a very subjective property and is unlikely to be of great importance in predicting clinical success, as long as the material can be at least adequately manipulated. The extent of cure and the solubility and sorption properties are important from the standpoint of biocompatibility concerns over residual monomer leaching, and in terms of the long-term stability of the composite due to degradation from the uptake of solvents and the wash-out of poorly cured material. Because many of the mechanical properties of dental composites are dependent upon the extent of cure, this characteristic is extremely important. The clinical wear of dental composite has been directly related to the degree of conversion in a series of experimental hybrid dental composites [53], emphasizing the importance of maximizing the cure of the occlusal surface of posterior restorations.

Does in vitro testing correlate with clinical performance?

There are a variety of tests of properties available for evaluating dental composites, and standardized test methods exist. Recent reviews of the tests and their correlation with clinical performance concluded that laboratory assessments alone cannot be used to predict the clinical success of a composite [22,54]. However, there are instances reported in the literature where the clinical performance of a dental restorative could be predicted by relatively simple and reproducible in vitro testing. A very common example is dental amalgam during the 1970's and 1980's. With the introduction of copper-enriched dental amalgam came the observation that these materials appeared to perform in a superior manner to the conventional, so called "low copper", formulations of the G.V. Black design [55–57]. The reason for the improved performance, most specifically the obvious improvement in marginal breakdown characteristics, was associated with the elimination or minimization of the gamma 2 (tin-mercury) phase in the material in favor of the enhanced formation of copper-tin compounds [58,59]. Through the examination of many physical properties, a predictive model was ultimately proposed whereby the clinical marginal fracture of 14 low-and high-copper amalgams was well correlated ($R^2 = 0.944$) to creep and zinc content [56]. Interestingly, the correlation between creep alone and marginal fracture was significant, but much poorer ($R^2 = 0.625$). A significant correlation between creep and marginal fracture was confirmed in other studies when both low- and high-copper alloys were evaluated [60,61]. However, they also showed that the correlation was not strong when only high-copper amalgams were included. Other studies also drew the conclusion that the in vitro creep evaluation could not be used to predict or distinguish the clinical performance of copper enriched amalgams [62,63]. Thus, it was concluded that an accurate assessment of the clinical performance of modern amalgams could only truly be realized through clinical trial. The same statement can be made for dental composite.

A previous study by Tyas [64] demonstrated a good correlation between fracture-related failures in class IV composites and fracture toughness for two hybrid and two microfill materials. A similar correlation was described between fracture toughness (K_{Ic}) and marginal breakdown in a clinical trial of composites in denture teeth at 2 years [53]. This study showed that microfill composites, with lower K_{Ic} than the hybrids (X=1.03 vs D, E = 1.9–2.2 MPa $m^{1/2}$) had more marginal chipping (% margins), as has been reported for composites in natural teeth (Figure 1). In addition, the microfill showed reduced marginal breakdown when heat treated (XH), due to an improvement in K_{Ic} of 1.03 to 1.39 MPa $m^{1/2}$. Using a wear simulator, a similar correlation between marginal breakdown and K_{Ic} has been shown for six commercial dental composites [65].

Several investigators have suggested that flexural strength, modulus of resilience, or fracture toughness may be predictors of clinical wear [38,66]. In the denture model study described above, the abrasion wear at 1 year of 13 experimental hybrid dental composite formulations was correlated to five properties. The best correlations were shown between wear and fracture toughness and wear and flexure strength, with poorer correlations between wear and hardness and no significant correlation between wear and elastic modulus [39] (Figure 2). It should be noted though that when the results for a microfilled composite tested in the study were included in the analysis, its low wear and relatively low mechanical properties reduced the overall correlation. There have been numerous wear testing devices that have been shown to have some correlation with clinical results. But due to the high variability reported in the in vivo wear data, perhaps it is only realistic to compare the in vitro and the in vivo data in terms of product rankings.

There have been many attempts to correlate in vitro leakage and clinical outcomes, such as staining and marginal gaps. Some of these have been reviewed previously [67,68]. Most in vitro studies of marginal leakage, as determined with dyes, or marginal adaptation, as determined with microscopic techniques, show that most materials or placement methods result in imperfect adaptation or seal [69]. It has further been concluded that there is not a good correlation between the results obtained from in vitro marginal leakage tests and clinical outcomes [67,70]. Similarly, a recent 10 year longitudinal study of composite/glass ionomer hybrid class I and II restorations showed nearly half of the restorations to contain marginal imperfections at baseline; and while these imperfections increased with time, this change did not correlate with the success of the restorations [71]. Thus, the predictive nature of microleakage tests in terms of clinical performance remains suspect. Therefore, despite the fact that studies have shown differences in contraction stress attributed to different light curing techniques, and that these differences have in some cases yielded poorer in vitro marginal quality, it is unlikely that a strong relationship between in vitro marginal analysis and clinical performance can be determined.

Summary

Clinically relevant testing for new direct restorative materials should include some assessment of strength, most likely the flexure test, and an evaluation of fracture toughness. The rationale for these choices is the fact that one of the main reasons for clinical failure of direct dental restorative materials is fracture. Fatigue resistance is an important property to assess because most materials likely fail due to accumulated damage from cyclic loading in the oral cavity rather than a single loading event. Wear should also be evaluated as a screening tool for materials that will replace occlusal surfaces. The dimensional change of the material during setting is important to evaluate as it will affect its marginal seal. The extent and depth of cure of the material is also important to evaluate as they likely influence the long term durability of the restoration. Handling and ease of use will always be important properties to assess for any new material. The biocompatibility of the material must be assessed to ensure safety. But the overall clinical success of dental composites is multi-factorial and therefore is unlikely to be predicted by even a battery of in vitro test methods.

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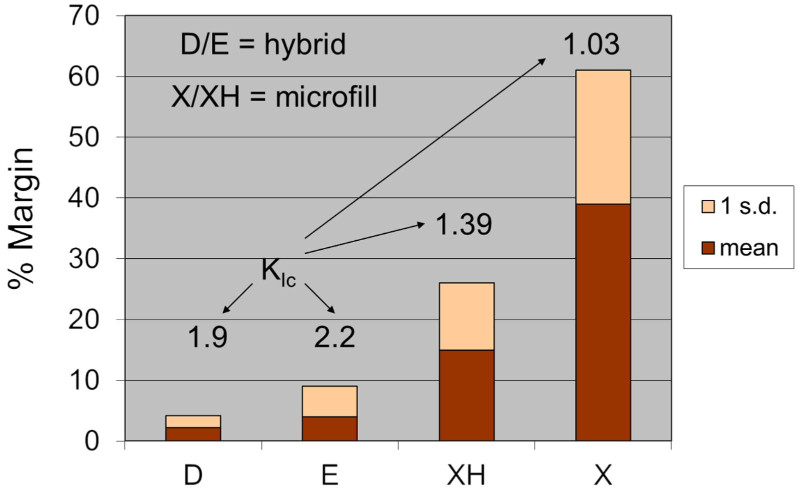
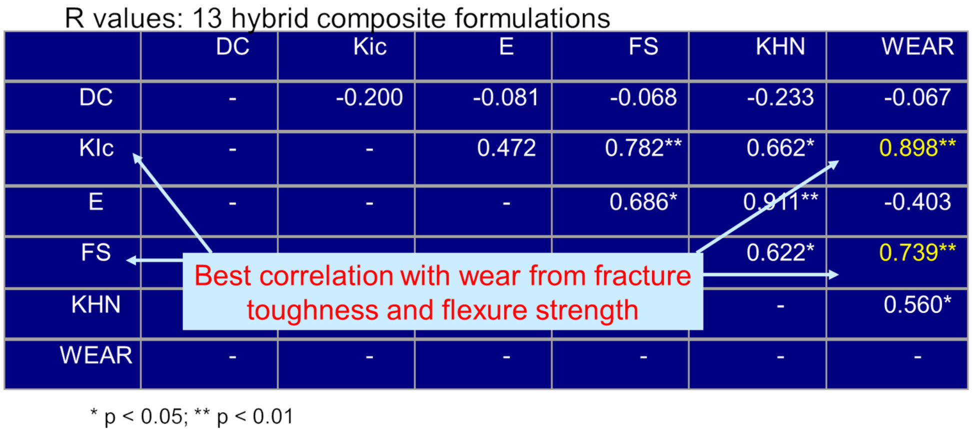


Figure 1.

Relationship between % Margin Showing Marginal Degradation and Fracture Toughness for Four Dental Composites.



R values: 13 hybrid composite formulations

	DC	Kic	E	FS	KHN	WEAR
DC	-	-0.200	-0.081	-0.068	-0.233	-0.067
KIc	-	-	0.472	0.782**	0.662*	0.898**
E	-	-	-	0.686*	0.911**	-0.403
FS					0.622*	0.739**
KHN					-	0.560*
WEAR	-	-	-	-	-	-

Best correlation with wear from fracture toughness and flexure strength

* $p < 0.05$; ** $p < 0.01$

Figure 2.
Correlation Matrix for Properties of Experimental Dental Composites vs. Clinical Wear At 1 Year in a Denture Model

Table 1

Potentially Important Mechanical Properties

Property	**What It Relates To**	**Possible Relation to Clinical Performance**
Compressive strength	Fracture in compression	Intuitively important, but most restorations likely fail in tension or shear (easy to test)
Elastic modulus	Elastic deformation under force	Intuitively important to maintain form, especially under high forces (easy to test)
Fatigue resistance	Repeated mechanical stressing	Important – likely many failures due to fatigue (difficult to test)
Flexure strength	Fracture – includes tensile and compressive components	Important – has tensile aspect and failures likely due to tensile stresses; some correlation with wear (easy to test)
Fracture toughness	Chipping and bulk fracture	Important – many failures due to fracture; not geometry dependent (more difficult to test)
Hardness	Resistance to indentation (and wear?)	Intuitively important, but only limited correlation with wear (easy to test)
Tensile strength	Fracture in tension	Important – failures likely due to tensile stresses (difficult to test)
Wear	Volume loss due to abrasion and opposing contact stresses	Important – abrasive and occlusal contact stresses (difficult to test)

Table 2

Potentially Important Physical Properties

Property	**What It Relates To**	**Possible Relation to Clinical Performance**
Adhesion	Mediated by adhesive	Important – dictated by shrinkage and quality of adhesive (easy to test)
Contraction/expansion stress	Affects integrity of bonded interfaces	Important – especially restorations with margins in dentin/ cementum (difficult to test)
Color stability	Esthetics	Important for anterior teeth mostly, though most materials good (more difficult to test)
Dimensional change during curing (shrinkage)	Affects adaptation and marginal integrity	Important – especially restorations with margins in dentin/ cementum (easy to test)
Extent and depth of cure	Affects biocompatibility and other properties	Important – affects wear and potentially support of restoration if undercured material is washed out (easy to test)
Solubility/Sorption	Affects biocompatibility and other properties	Important – affects biocompatibility, staining and possible reduction in properties with aging (easy to test)
Thermal conductivity	Affects pulpal health	Not important for resin-based materials (low conductors)
Thermal expansion	Affects marginal integrity	Questionable importance in terms of stresses at margins (easy to test)
Viscosity	Affects handling	Often personal preference, so only of marginal importance (easy to test)