



FINAL REPORT

A Laboratory Evaluation of Localized Wear of Splint Materials

Principal Investigator: Mark A. Latta D.M.D., M.S.

Dean and Professor

**Creighton University School of Dentistry: Center for Oral Health Research
2500 California Plaza, Omaha, Nebraska 68178 | (402)-280-5061**



Sponsor: Keystone Industries

480 S. Democrat Road Gibbstown, NJ 08027

INTRODUCTION



Mark A. Latta

Dr. Latta is a dentist (DMD) and biomaterials scientist (MS) with 30+ years in both corporate research and development and academic dentistry. He has received dozens of research grants for both laboratory and clinical research on dental materials devices and techniques. He's published more than 200 abstracts and 100 manuscripts in the biomaterials field and is an inventor or co-inventor on more than a dozen patents.

A major concern in clinical practice is the wear resistance of resin materials used in dental materials.^{1,2} One clinical aspect of longevity for occlusal splint materials is the ability to resist masticatory forces and the resultant wear on the material. Two distinct kinds of wear have been described by Kawai & Leinfelder.³ One of these is wear initiated by generalized conditions (the type of wear generated by a food bolus during mastication) and the other is wear generated under localized conditions (represented by direct tooth to materials contact). Some authors^{4,5} have suggested that localized wear may be a more important contributor to the breakdown of a material and contact wear may be more than two times as great as that in non-contact areas. Clinical studies offer the most meaningful data on the performance of a given material. However, the time involvement and costs associated with clinical studies have driven dental manufacturers to have a strong interest in the use of wear simulation of prototype materials as a screening tool and predictor of clinical performance. Leinfelder et al^{6,7} developed a laboratory simulator capable of evaluating both generalized and localized wear. This system transfers masticatory stresses to a composite specimen by means of a flattened steel (generalized wear) or a stainless steel conical stylus (localized wear) in the presence of a slurry of polymethylmethacrylate beads (PMMA). This device has facilitated the development of in vitro studies capable of helping predict in vivo performance. Previous work⁶ showed a correlation between in vitro wear and in vivo generalized wear of dental restorative materials. The Leinfelder system has been used extensively for the wear evaluation of restorative materials and provisional crown and bridge resins.⁹⁻¹⁴ This wear model also compared favorably to other wear machine systems tested in a round robin project for restorative materials.¹¹ While this system can evaluate both contact and non-contact wear mechanisms, contact or localized wear is a more important property for high occlusal stress areas such as the kinds of forces in posterior teeth or on occlusal splints. The Leinfelder system is calibrated to use a contact force of 80N which is a relevant load based on clinical studies of mastication forces in molar teeth. In the original validation of the system, 400,000 cycles was able to generate in the laboratory about three years of clinical wear observed in

MATERIALS TESTED

clinical studies of the materials evaluated in the laboratory.⁶

It must be noted that in context, the biting force generated by the wear simulation is set to mimic point contact on a restorative material place intra coronally in a tooth. A properly adjusted occlusal splint however functions to distribute mastication forces over a larger area thus the conditions of any wear simulation device will likely overestimate the real mastication force that is likely to be observed in clinical service. Still, abrasion resistance is one aspect of the physical properties of splint materials that is important for longevity. The Leinfelder system described here can provide useful information when used to study similar materials whose clinical function will be similar. The purpose of this study was to evaluate the localized wear of selected splint materials.

-
1. **KeySplint Hard™**
 2. **KeySplint Soft®**
 3. **KeySplint Soft® Clear for Carbon®**
 4. **Dual laminate 2 mm thickness (sheet)**
 5. **2mm Splint (sheet)**
 6. **Standard Clear PMMA Disc**
 7. **Lucitone Clear Acrylic**
-

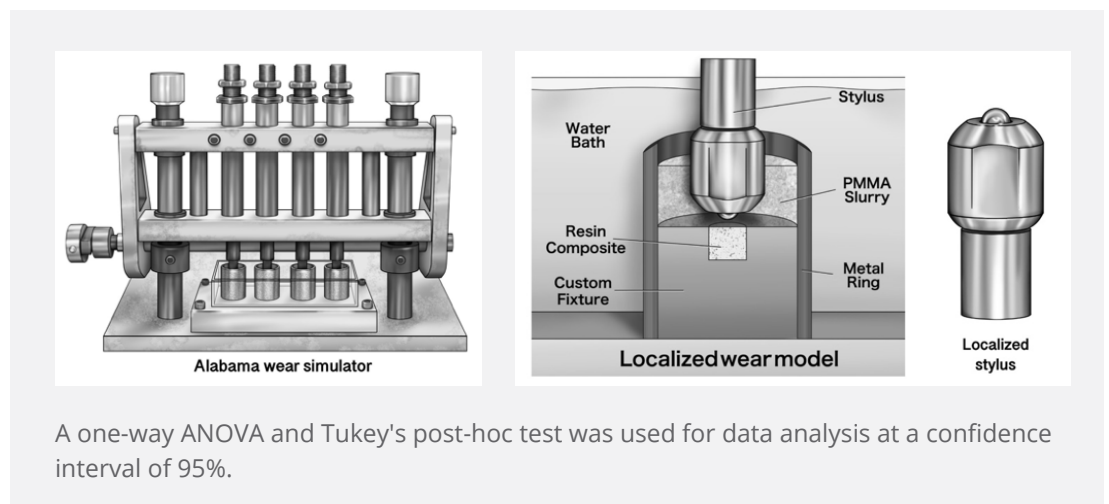
The test materials in this study represent a wide range of polymeric structures. The 2mm sheet material and the dual-laminate material are thermoformed materials. These are composed of thermoplastic sheets of high molecular weight, linear polymers. Characteristic of these polymers is a glass transition temperature much higher than body temperature. Thus the rigidity of these materials is similar whether at room temperature or mouth temperature. One important clinical aspect of occlusal appliances is that they are retained by slight flexing over the height of contour of the supporting teeth. These sheet materials exhibit less flexibility than other kinds of splint polymers reducing the ease of mouth insertion and removal.

On the other hand, acrylic splints like Lucitone have both very low molecular weight monomers and plasticizers. In an aqueous environment, unreacted monomers can leach out of the body of the material resulting in a change in the physical properties of the splint over time. Typically, high initial flexural strength degrades over time usually causing the splint to become more brittle and susceptible to fracture—reducing the service life of the device. KeySplint Soft represents a new approach in composition compared to traditional splint materials. This material has the unique ability to change flexural properties over the temperature range of the indicated uses. The glass transition temperature of the material is approximately 50°C. This means at room temperature conditions the material feels rigid with an average flexural modulus of 1,100 MPa (ASTM D790 method). At body temperature, the flexural modulus is approximately 120 MPa (ISO20795-2). This means that the

KeySplint Soft materials at body temperature are more pliable and becomes comfortable to wear and will yet maintain the shape outside of the mouth. These dynamic properties add a unique characteristic that should extend the life of the splint device by preventing the degradation due to brittle fracture.

METHODS AND MATERIALS

For localized wear, twelve specimens were prepared in a stainless steel custom fixture for testing in a Leinfelder wear simulator. Into cavities (5 mm in diameter x 3 mm deep) in the custom fixture the splint materials were placed and mounted with acrylic. For the Lucitone material the powder liquid mixture was placed directly into the cavity and heat processed. For the sheet materials, discs 4 mm in diameter were core drilled and then mounted in the holder. All other materials were printed as discs and mounted as noted. Each specimen was stored for at least 24 hours at 37° C prior to being polished flat using a sequence of 320 to 4000 grit silicon carbide papers. Prior to testing, the specimens were surface profiled with Proscan 2100 Scanner. The assembly was mounted into a water bath fixture in the wear simulator and a tight fitting cylinder used to create a reservoir for a slurry of PMMA beads (unplasticized) averaging 44 μm in diameter. Localized wear was produced using a stainless steel bearing mounted in custom fixture attached, to a spring-loaded piston. The stylus was vertically loaded (80 N) onto the specimen at a rate of approximately 1 Hz. During the loading process the stylus rotated 30° as the maximum load was achieved, and then counter-rotated as the piston moved to its original position. Each specimen was subjected to 400,000 cycles. Following the wear challenge, the specimens were surface profiled with Proscan 2100 Scanner and the before and after data sets were compared. Volume loss (mm^3) and maximum depth (μ) were calculated for each specimen. The test apparatus is illustrated in the schematic below:



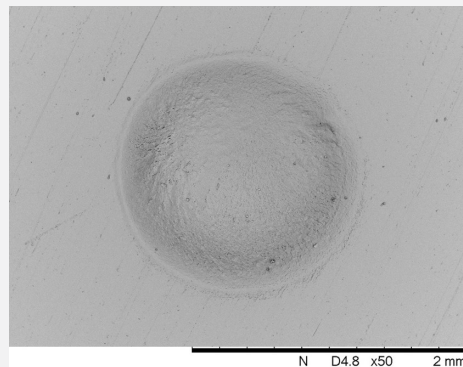
RESULTS- LOCALIZED WEAR

MATERIAL	LOCALIZED WEAR (VOLUME mm ³)	MAXIMUM DEPTH (μ)
KeySplint Hard™	0.322 ± 0.066 ^a	343.2 ± 54.7 ^a
Lucitone Clear Acrylic	0.347 ± 0.095 ^a	418.5 ± 143.6 ^a
2mm Splint (sheet)	0.430 ± 0.117 ^{a,b}	994.8 ± 336.1 ^c
Standard Clear PMMA Disc	0.720 ± 0.334 ^b	1468.9 ± 545.6 ^d
KeySplint Soft®	1.138 ± 0.168 ^c	646.6 ± 99.8 ^b
KeySplint Soft® Clear for Carbon®	1.238 ± 0.432 ^c	681.8 ± 129.1 ^b
Dual laminate 2mm thickness	3.643 ± 1.141 ^e	2844.1 ± 860.7 ^e

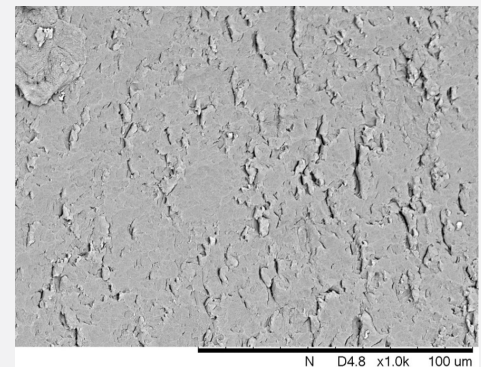
Groups with the same letter were statistically similar (p>0.05). There were statistical differences among the materials tested.

SCANNING ELECTRON MICROSCOPY IMAGES

KeySplint Hard™



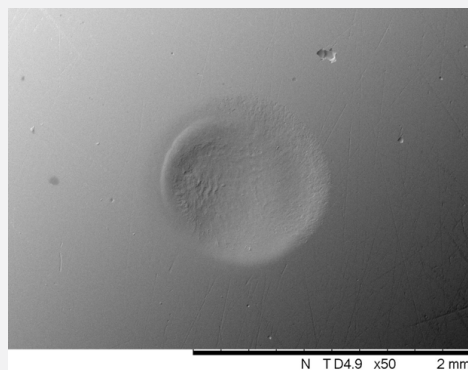
Creighton University



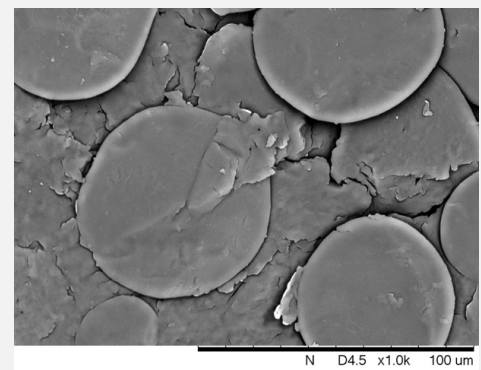
Creighton University

The KeySplint Hard surface is smooth without evidence of cracking or crazing. The pattern is suggestive of excellent abrasion resistance.

Lucitone Clear Acrylic



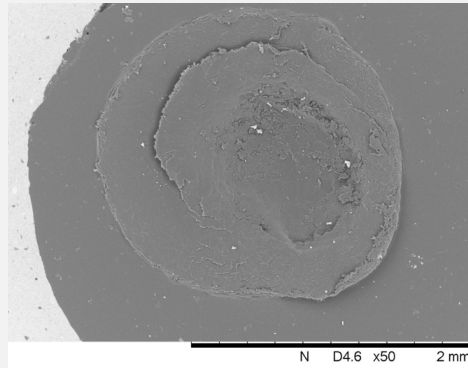
Creighton University



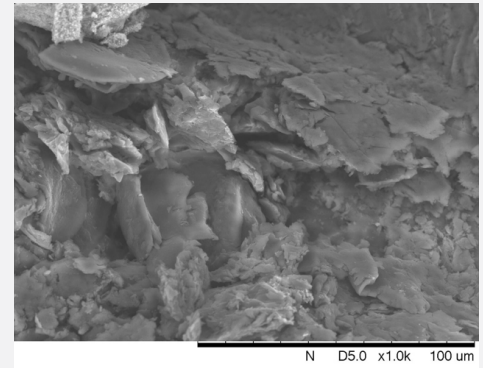
Creighton University

Lucitone wear facet above is uniform and smooth. Aged acrylics however, after monomer leaching would likely exhibit brittle fracture. The higher magnification shows the acrylic polymer bead surrounded by the continuous phase monomer gel.

2mm Splint Material



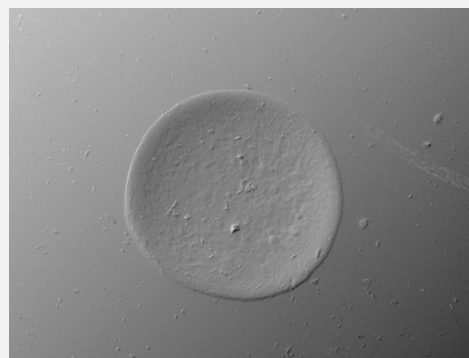
Creighton University



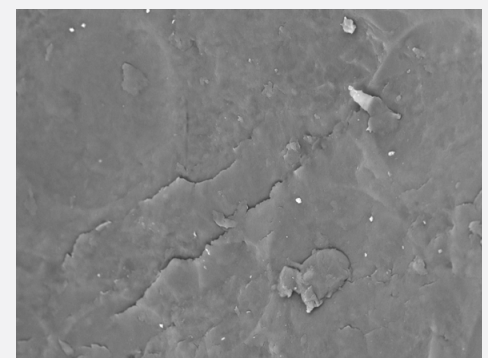
Creighton University

The wear facet above is distorted and in conjunction with the higher magnification image is suggestive of brittle fracture.

Standard Clear PMMA Disc



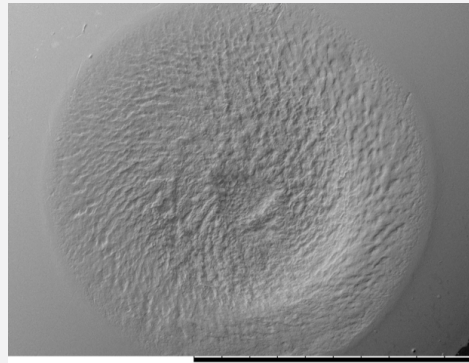
Creighton University



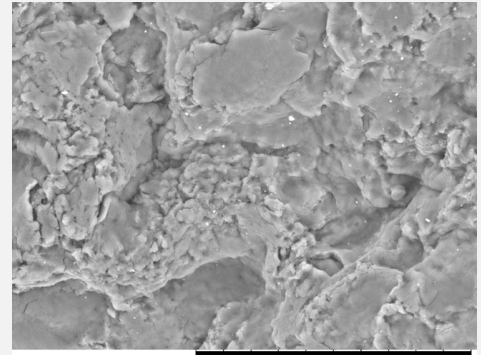
Creighton University

The morphology of the standard clear disc is similar to the Lucitone. The higher magnification image does suggest the beginning of some surface and sub-surface cracking.

KeySplint Soft®



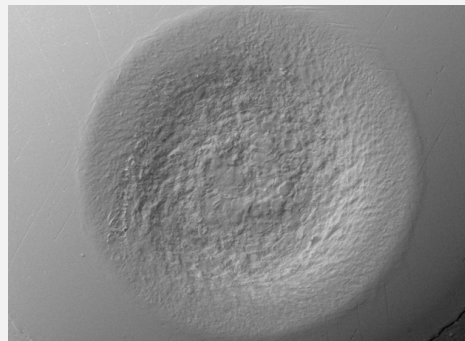
Creighton University



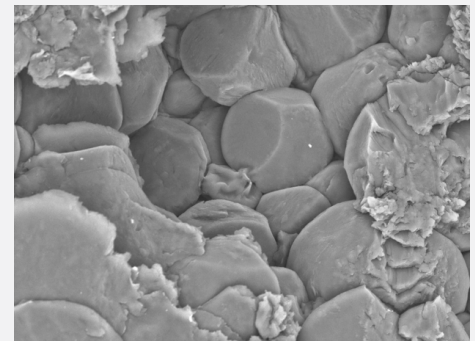
Creighton University

The KeySplint Soft wear facet appears slightly distorted and is suggestive of the occurrence of some plastic deformation initiated by the wear antagonist force or possibly temperature rise at the wear surface. No clear evidence of cracking is noted in the higher magnification image.

KeySplint Soft® Clear for Carbon®



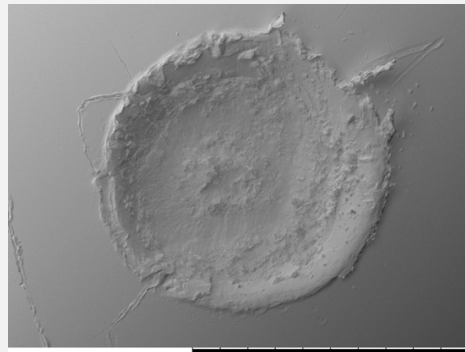
Creighton University



Creighton University

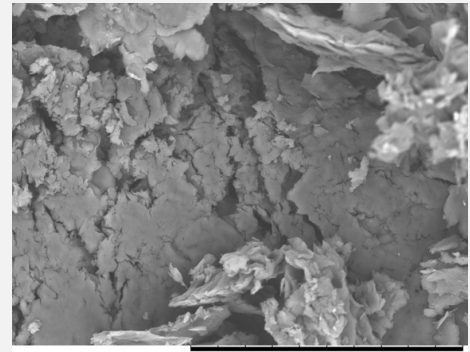
Resembling the force or temperature plastic deformation of the KeySplint Soft above material the KeySplint Soft Clear for Carbon material's wear facet shows some clear evidence of swirling consistent with the 30 degree rotation of the wear antagonist. Based on the dynamic modulus change with temperature this finding is likely due to an increase in temperature at the contact point. The higher magnification does not show any cracking.

2mm Dual Laminate



Creighton University

N T D4.8 x50 2 mm



Creighton University

N D4.8 x1.0k 100 um

The dual laminate facet and higher magnification image show evidence of surface and sub-surface cracking. The facet is highly irregular but does not exhibit the swirling deformation pattern seen with other materials. The ragged edge in the wear facet is suggestive of edge fracture of the material.

DISCUSSION

Qualitatively, the knowledge about the influence of temperature on the KeySplint Soft splint materials must be taken into consideration when interpreting the localized wear values in this study. The variety of surface deformations observed in the SEM images is consistent with materials whose flexural modulus changes with temperature and we believe that the force of the wear antagonist does increase the surface temperature of the material during the wear challenge. While the volume loss and maximum depth measurements are usually closely correlated in terms of ranking the materials, surface and sub-surface cracking can create small areas of deep depth while the overall volume loss of material is less extensive. This is likely the reason that the 2mm splint values and the Standard Clear Disc values are high for the maximum depth compared to the volume loss for these materials. The Standard Clear Disc and 2 mm sheet materials in particular exhibited micro cracks and the wear facet of the Dual Laminate material exhibited strong evidence of edge fracture. This finding would be consistent with the high volume loss. Notable for both KeySplint Soft specimens were signs of dynamic surface changes without cracking suggesting energy absorbing behavior.

The acrylic and sheet materials used in this study were tested under ideal conditions. That is they were not subjected to water storage or cyclic fatigue prior to wear testing as they would be in a clinical situation. It is highly likely that these specimens if aged, particularly the Lucitone specimens, would exhibit much higher wear values. This is due to the predicted increase in brittleness and decrease in fracture resistance as a result of the aging. On the other hand, the unique modulus change for the KeySplint Soft materials afford a favorable handling characteristic given the cycles of placing and removing from the oral environment on a continual basis. Room temperature stability combined with a lower modulus behavior intra-orally will likely result in enhanced longevity for the appliance. The brittle behavior of conventional splint materials is well known by both patients and dentists and the dynamic

behavior of the properties of this material offers the potential of a real clinical benefit compared to other materials. The KeySplint Hard Material exhibited excellent wear resistance- equal to the lab processed Luciton 199. Further the wear pattern suggests excellent wear resistance without tearing or cracking suggesting excellent resistance to fatigue failure.

The Leinfelder model used in this experiment has been correlated with clinical studies of direct composite resin restorative materials. 400,000 cycles has been associated with about three years of clinical service in posterior composite restorations. Occlusal splints are supra-supported by the dental arch and restorative materials are bonded to the intra-coronal tooth structure, thus correlation from restorative dental material trials is not likely applicable to occlusal splint materials. Further the unique modulus change with temperature adds a significant feature and benefit compared to heat processed acrylic as the latter material are known to become more brittle and prone to fracture over time. Thus the overall clinical longevity of these materials cannot be only characterized by wear resistance but also by overall function and utility.

There are few references to the wear resistance of splint materials in the literature. One, using the Leinfelder model but only a test with 200,000 wear cycles generated the following data:

MATERIAL	VOLUME LOSS (VOLUME mm³)
InTerra	1.17
Astron Clear Splint	24.3
Pro-form®	1.59
Eclipse	0.11
Eclipse Resilient	1.27

A direct comparison is not precise, however it is reasonable to judge that based on these data and the current study that with the exception of the dual laminate material, all other materials would be equal to or better than every material from the abstract except the Eclipse material. Eclipse is a highly cross-linked and stiff material that has many of the same drawbacks as a conventional acrylic. Therefore, while it's abrasion resistance is high, the overall utility of the material may not be as robust as a material like KeySplint Soft materials.

REFERENCES

1. Swift EJ Jr. Wear of composite resins in permanent posterior teeth. *J Am Dent Assoc* 1987; 115: 584-588.
2. Hu X, Marquis PM, Shorttall AC. Two-body wear study of some current dental composites and amalgams. *J Prosthet Dent* 1999; 82: 214-220.
3. Kawai K, Leinfelder KF. In vitro evaluation of OCA wear resistance of posterior composites. *Dent Mater* 1995; 11: 246-251.
4. Lutz F, Phillips RW, Roulet JF, et al. In vivo and in vitro wear of posterior composites. *J Dent Res* 1984; 63: 914-920.
5. Lambrechts P, Braem M, Vanherle G. Accomplishments and expectations with posterior composite resins. In: Vanherle G, Smith DC. *Posterior composite resin dental restorative materials*. Netherlands: Peter Szulc Publishing Co., 1995; 521-540.
6. Leinfelder K, Suzuki S. In vitro wear device for determining posterior composite wear. *J Am Dent Assoc* 1999;130: 1347-1353.
7. Leinfelder KF, Beaudreau RW, Mazer RB. An in vitro device for predicting clinical wear. *Quintessence Int* 1989; 20: 755-761.
8. Latta, M.A., Barkmeier, W.W. Wilwerding T.M, Blake S.M. Localized wear of compomer restorative materials. *Am J Dent* 2001 ; 14: 238-240.
9. Barkmeier WW, Erickson RL, Latta MA, & Wilwerding TM. Wear simulation of resin composites and the relationship to clinical wear. *Oper Dent* 2008; 33: 177-182.
10. Barkmeier WW, Latta MA, Erickson RL, & Lambrechts P. Comparison of laboratory and clinical wear rates of resin composites. *Quintessence Int* 2004;35: 269-274.
11. Heintze SD, Barkmeier WW, Latta MA, & Rousson V. Round robin test: wear of nine restorative materials in six different wear simulators—supplement to the round robin test of 2005. *Dent Mater* 2011;27:e1-e9.
12. Barkmeier WW, Takamizawa T, Erickson RL, Tsujimoto A, Latta M, & Miyazaki M. Localized and generalized simulated wear of resin composites. *Oper Dent* 2015; 40: 322-335.
13. Barkmeier WW, Erickson RL, Latta MA, & Wilwerding TM. (2013) Wear rates of resin composites. *Oper Dent* 2013; 38: 226-233.
14. https://www.researchgate.net/publication/266790473_Mechanical_Properties_of_a_Novel_Impression-less_Chairside_Nightguard_Material