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RESEARCH ARTICLE

THERACAL LC: AN EXTENSIVE LITERATURE REVIEW

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ABSTRACT

This review was undertaken as preparatory work to provide the background and scientific rationale for a laboratory study on TheraCal. A review of the literature was performed by using electronic and hand-searching methods for the chemical and physical properties. More clinical studies will be necessary. Gaps in the research field for TheraCal include the topics solubility, setting mechanism, microhardness, and bond strength.

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INTRODUCTION

TheraCal LC, the focus of this literature review, is a light-curable resin-modified calcium silicate (RMCS) liner manufactured by BiscoCompany to perform as a barrier and protectant of the dental pulpal complex. TheraCal is first of a new class of internal pulpal protected materials known as RMCS (Comisi, 2012). TheraCal can be used as an alternative to calcium hydroxide, GIC, RMGI & IRM/ZOE. TheraCal is dentistry's first radiopaque, HEMA-free, a light-curable flowable resin containing "apatite stimulating" calcium silicates. Research supports that calcium silicates stimulate the formation of hydroxyapatite onto the surface of the supplying material and provides a biological seal (Brown, 2012). The primary objective of restorative dentistry is to preserve pulpal health (Savas *et al*., 2014). Pulp capping materials are applied on the floor of deep cavities as a protective liner (Gandolfi *et al*., 2015). Currently, there is no single protocol, with respect to the use of liners and bases, for clinicians to follow (Weiner, 2011). These materials should have specific features such as biocompatibility, bio-interactivity& bioactivity (Savas *et al*., 2014). Several properties are necessary for an ideal liner:

- The antibacterial activity of the material; bacteriocidal or bacteriostatic.
- Property of reparative dentine formation.
- Maintain pulp vitality.
- Establishing a tight bacterial seal.
- Resist forces during restoration placement and function.
- Adhering to dentine as well as the restoration.
- Sterile.
- Radiopacity (Rada, 2013; Qureshi *et al*., 2014).
- Prevent post-operative sensitivity by sealing the dentinal tubules (Weiner, 2008).
- Protect against marginal leakage; this is disputed point since one research reported that using a base increases microleakage whereas others state a liner is necessary to reduce microleakage (Weiner, 2011).

In deep cavities, calcium hydroxide cement has been commonly used due to its potential to stimulate dentine formation. However, the majority of these cases show pulpal infection and necrosis caused by microleakage of such capping materials and tunnel defects in the dentine bridges within only a few years. This cement typically display low strength properties with high solubility, both undesirable features. Over time, according to previous researches conducted, it is thought that due to the material's solubility or water sorption, bases and liners are incapable to remain stable under restorations, leaving the cavity without protection and the restoration without support. This may happen when the material interacts with either dentinal fluid, in freshly prepared cavities or saliva due to marginal infiltration or hydrolytic decomposition. This indicates the importance of liner or base durability between the tooth structure and the final restoration. Due to these

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disadvantages, there are several new products in the category of liners and bases recently. The new materials contain calcium in a resin-based apparatus having greater physical properties when compared to cement without resin components (Francisconi *et al*., 2009). TheraCal is the easiest of calcium silicate material to use due to its efficient syringe placement & its ability to be light cured (Burgess, 2013). Other calcium silicate cements include MTA & Biodentine. TheraCal's main indication is as a liner for indirect or direct pulp capping, so the comparison to calcium hydroxide is necessary, as calcium hydroxide is considered worldwide as the gold standard for direct pulp capping materials (Qureshi *et al*., 2014). TheraCal has been assessed by 20 specialists in 438 uses with a 96% clinical rating, according to the manufacturer Bisco.

Application Method

Due to TheraCal's syringe application, precise placement of the flowable material is easy and is an advantage noted by clinicians, along with the light cured ability (Burgess, 2013). According to the manufacturer Bisco, TheraCal is placed in 1mm increments and light cured for 20 seconds. Hand mixing, instrument placement or trituration is not required (Brown, 2012). According to research conducted by Gandolfi, TheraCal had a cure depth of 1.7mm (Gandolfi *et al*., 2012). This is a great advantage of easy usage as other calcium silicate cement for example MTA takes around 3 to 4 hours to set, and Biodentine has a liquid and powder component. The powder is in a capsule and liquid in a pipette which is mixed into the capsule and placed in a trituration similar to amalgam for 30 seconds; once the material is mixed, it sets between 12 and 15 minutes (Burgess, 2013).

Formulation

TheraCal consists of a single paste containing CaO, calcium silicate particles (type III Portland cement), Sr glass, fumed silica, barium sulphate, barium zirconate & resin containing Bis-GMA & polydimethacrylate (Griffin, 2012). The proprietary formulation of TheraCal consists of tricalcium silicate particles in a hydrophilic monomer that provides significant calcium release making it a uniquely stable & durable material as a liner or base. Calcium release stimulates hydroxyapatite & secondary bridge formation (Qureshi *et al*., 2014). Calcium ions are necessary for the differentiation and proliferation to odontoblast-like cells (Gandolfi *et al*., 2012). The rapid release of calcium makes it an excellent material to cause repairing & healing of dentine and studies have shown it to be more effective at stimulating pulpal healing than traditional liners (such as light-cured resin-modified CaOH) with less pulpal necrosis. The significant calcium release provides reparative ions, creates a sustaining alkaline environment required to promote wound healing, provides immediate bond and sealing properties, and stimulates hydroxyl-apatite & secondary dentine formation within affected tissues (Gandolfi *et al*., 2012). Calcium has shown to be crucial to the formation of apatite, dentine bridge formation & re-apatite potential of affected dentine. Additionally, alkalinity also seems to be the contributor toward this goal. This combination in the RMCS material appears to form good, hard & thick dentine bridges & stimulates dentine pulp cells to turn into odontoblastic dentine cells (Comisi, 2012).

Gandolfi *et al*. investigated the chemical-physical properties of TheraCal, a novel light-curable MTA-like material for pulp capping and concluded that TheraCal released significantly more calcium than MTA and Dycal. The amount of leached calcium decreased with time for all three materials. The release of calcium by ProRoot MTA, during the first three days of testing, is fluctuated. TheraCal resulted to be an ion-leaching material that is able to release calcium and hydroxyl ions for at least 28 days; furthermore, a concentration range of calcium ions was within potential stimulatory activity for bone forming cells, dental pulp cells and odontoblasts (Gandolfi *et al*., 2012). The findings of this research suggest that the resin portion of TheraCal (comprising hydrophobic and hydrophilic monomers) is able to promote/sustain Ca and OH ion release within the wet pulp and/or dentine and could favour the interaction of the formulation with the hydrophilic tooth dentine. The results of the water absorption test showed that the hydrophilic resin in TheraCal formulation allows some water absorption that is likely responsible for the initiation of the hydration reaction of the Portland cement particles with subsequent formation of calcium hydroxide. The amount of water absorbed by TheraCal was significantly higher than Dycal and significantly lower than MTA (Gandolfi *et al*., 2012). According to Camilleri, TheraCal releases significantly more calcium than MTA & Dycal and thus was able to alkalinize the surrounding fluid. Regardless the calcium ion release contact of TheraCal with pulp cells resulted in a reduction in cell metabolism & reduced protein expression (Camilleri, 2014). TheraCal was able to alkalinize the surrounding fluid initially to pH 10-11 (3 hrs-3 days) required for pulpal healing and subsequently to pH 8-8.5 (7-14 days) (Gandolfi *et al*., 2012).

TheraCal's hydrophilic resin formula is unique. It is permeable to the dentinal fluid but relatively insoluble to resist dissolution. TheraCal may act or resemble a scaffold for dentine formation. Dentinal fluids are readily absorbed within resulting in the release of calcium and hydroxide ions. Immediately one of the tooth's responses is to form hydroxyapatite to the undersurface of TheraCal potentiating the natural sealing ability to assist in the formation of apatite may play a critical role in pulpal protection (Brown, 2012). Gandolfi *et al*. evaluate the ability of TheraCal to form hydroxyapatite when immersed in a phosphate-containing solution. TheraCal demonstrated the capacity to form apatite on its surface after 24 hours immersion in Dulbecco's Phosphate Buffered Saline, as did MTA. Amorphous apatite was detected within the first 24 hours while a more crystalline apatite was noticed at seven days. The ability to form apatite may play a critical/positive role in the new dentine formation (Gandolfi *et al*., 2011).

Cytocompatibility & Antibacterial Properties

TheraCal is well tolerated by immortalized odontoblast cells. TheraCal showed a decreasing antibacterial effect on S. mutans and very little effect on S. salivarius & S. sanguis. At 24 hrs, TheraCal presented cytocompatibility values significantly lower than Biodentine & MTA, Dycal showed the lowest. At 48 & 72 hrs, the lowest cytocompatibility was shown by Dycal& TheraCal (Poggio *et al*., 2014).

Setting Reaction

The setting mechanism and characterization of set material are still not known. The presence of a resin matrix modifies the setting mechanism and calcium ion leaching of TheraCal (Camilleri, 2014).

Characterization of Materials

The setting mechanisms and characteristics of TheraCal compared to Biodentine were investigated by Camilleri (2014). The results showed that TheraCal exhibited a complex microstructure with the presence of various particles. The cement particles varied in size and some particles were larger than the cement particles present in Biodentine. The cement particles exhibited some reaction by-product. The cement matrix included shiny particles with barium, and zirconium peaks and other particles which exhibited peaks for silicon, strontium aluminum and calcium. The presence of aluminum in the cement analysis suggests that the main cementitious phase is a Portland cement which includes tricalcium aluminate together with tricalcium and dicalcium silicate phases. The XRD analysis exhibited peaks for tricalcium silicate, zirconium oxide and barium strontium zirconium oxide. No calcium hydroxide peak was evident for TheraCal.
The surface of Biodentine immersed in water was coated with very small particles, which exhibited peaks for calcium and silicon while the TheraCal surface was bare. Both materials exhibited the presence of globular deposits on their surfaces when immersed in HBSS (Hank's Balanced Salt Solution). The surface XRD scans of Biodentine exhibited peaks for calcium hydroxide and tricalcium silicate regardless the immersing solution. On the other hand TheraCal exhibited no crystalline deposits when immersed in water. Storage in HBSS resulted in the deposition of calcium phosphate on the material surface. Peaks for barium strontium zirconium oxide were also observed.

Biodentine leached more calcium in both solutions when compared to TheraCal. This contradicts a previous research in which it was reported that TheraCal has a higher calcium releasing ability than MTA and Dycal. The leaching was marginally higher in the physiological solution for both materials. To summarise, Calcium phosphate was deposited over the TheraCal surface. The calcium ions are not in hydroxide form as no Portlandite (calcium hydroxide peak) was exhibited in the XRD scans of the powdered TheraCal after 28 days immersion in HBSS (Camilleri, 2014). Camilleri *et al*. tested the hydration of Biodentine, Theracal LC, and a Prototype Tricalcium Silicate-based dentin replacement material after pulp capping in entire tooth cultures. Polished samples of all three materials were placed in Hank's balanced salt solution for 14 days and then assessed by electron microscopy and energy dispersive spectroscopy. Calcium hydroxide deposition was also measured by x-ray diffraction analysis and calcium ion leaching was assessed by ion chromatography. Biodentine and the prototype cement formed calcium hydroxide and leached calcium ions into the solution. However in the case of TheraCal, hydration was not completed due to limited moisture diffusion in the material, therefore minor calcium ion leaching was logged, no calcium hydroxide was formed, and the material displayed a heterogenous structure with large unhydrated particles (Camilleri *et al*., 2014).

Density & Porosity

The mechanical resistance of calcium silicate based materials is also dependant on their low level of porosity. Porosity and mechanical strength are inversely related: the lower the porosity, the higher the mechanical strength Calcium silicate containing cement showed the highest values of open pores; MTA being the highest followed by Biodentine and TheraCal (Gandolfi *et al*., 2015).

Solubility

Ideally, a liner or base material should be reasonably insoluble and have high strength. However, a base material must show a little amount of dissolution at the vital dentine base interface for the material to release its biological properties. If this material is relatively insoluble, ion exchange with the odontoblastic layer may be stalled, therefore secondary dentine formation is reduced, and its main function of the liner as pulp protection is debatable (Francisconi *et al*., 2009). Water sorption and solubility along with porosity (permeability of the material to water diffusion) is responsible for ion release of the liner or base (Gandolfi *et al*., 2015). In 2012, Gandolfi *et al*. concluded that TheraCal displayed lower solubility than ProRoot MTA and Dycal (Gandolfi *et al*., 2012). In 2014, Gandolfi *et al*. yet again concluded than TheraCal displays low solubility (2.75%) stating that the resin-containing materials yielded the lowest solubility values whereas the water-containing calcium-silicate based materials showed the highest solubility. It is thought that due to the presence of resin along with the ability to release a moderate but rather constant amount of Ca ions (Gandolfi *et al*., 2015). It must be noted that results obtained from laboratory studies with distilled water are significantly different from clinical situations where simulated dentinal fluid & saliva is present. The duration to test solubility should be three months, not the one week which is the ADA#8 specification, since the liners continue to dissolve in the next three months (Francisconi *et al*., 2009).

Bonding

TheraCal has the ability to bond to deep moist dentine, unlike Dycal which lacks adhesion. [Qureshi *et al*., 2014] TheraCal is self-sealing, which aids in antimicrobial activity with initial bonds to dentine to resist accidental air-drying removal (Griffin, 2012). Cantekin compared the bond strength of TheraCal with a methacrylate-based composite, a silorane based composite and GIC; the same tests were conducted with MTA as a comparison. Each block of material was secured in a shear bond strength testing machine and examined under a stereomicroscope at x25 magnification. The highest bond strength established was between methacrylate composite with TheraCal, whereas the lowest strength (3.4MPa) was found to be with GIC-TheraCal. In general, TheraCal showed higher shear bond strengths than MTA (Cantekin, 2015).

Effect of Temperature Changes in the Pulp during Polymerization of TheraCal with a Light Cure Device

TheraCal is a light cured material so the heat generated during the polymerization could lead to an irreversible pulpal damage. The type of light curing unit used also affects the amount of heat generated. Another factor affecting the temperature increase is the distance between the device and the material. However, increasing the distance between the device and the material might lead to incomplete polymerization due to insufficient power and may decrease the microhardness of the material. For this reason, clinicians increase the irradiation time and light intensity which in turn causes an increase in temperature. The rise in pulpal temperature could be due to two reasons: from the exothermic polymerization of the material and the energy absorbed from the light curing unit.

Savas *et al*. tested the temperature changes in the pulp chamber during polymerization of four different pulp capping materials using an LED-light-curing-unit in the contact and noncontact positions. Two different distances were used between the tip of the unit and the material surface during polymerization; 0 and 2 mm. The results stated that the contact groups produced significantly lower temperature rise compared with noncontact groups. TheraCal recorded the lowest average temperature increase independent of distance factor; in the two different positions of the light cure device, there was a difference of 2.43°C. A control group concluded when no liner was used, and the light curing unit was applied, excess heat was produced. TheraCal contains calcium silicate which has a low specific heat capacity; meaning has high thermal insulation properties. Due to these insulation qualities, calcium silicate has been used over the years as an insulation material in many industrial branches. For that research to mimic a clinical situation, pulpal microcirculation mechanism was used, fluid motions in dentinal tubules and the surrounding periodontal tissues of the teeth were not considered. For this reason, the study cannot be an accurate clinical representation. Furthermore, the research was conducted at room temperature which differs from intra-oral conditions (Savas *et al*., 2014).

Flexural Strength, Flexural Modulus & Compressive Strength

Strength is an important aspect of any liner as their function is to support an overlying restoration. Nielsen *et al*. investigated *Mechanical Properties of New Dental Pulp-Capping Materials over Time* and evaluated flexural strength /modulus & compressive strength of TheraCal, Biodentine, MTA and Dycal over 15 minutes, 3 hours and 24 hours. At all time periods, TheraCal had the greatest flexural & compressive strength. TheraCal had a greater early strength to potentially resist fracture during immediate placement of a final restorative material. MTA had not set at 15 minutes. After 3 and 24 hours, Biodentine has the greatest flexural and compressive strength; but had the least flexibility after 3 hours (Nielsen *et al*., 2016).

Effects of Adhesives on Calcium-Release, PH and Bonding of TheraCal

An article by Y. Wang *et al*. evaluated calcium-release, pH & bonding of TheraCal discs coated with various adhesives (control without adhesive). The bond strength of TheraCal was significantly increased by the adhesives tested. The pH of TheraCal was slightly decreased with adhesives. TheraCal coated with adhesives was still able to release calcium (Wang and Suh, 2012). Another experiment by Gandolfi *et al*. calculated calcium release and pH by immersing the material disks in deionized water and measured at six intervals (3 hours, 24 hours, 3 days, 7 days, 14 and 28 days) and totalled. The results stated that the Ca release of TheraCal decreased over time but was not marked i.e. no significant changes over time. TheraCal induced the lowest pH alkalization compared to the other liners; TheraCal alkalized the soaking water to pH 11-12 at 3 days, then decreased to pH 7-8 after 14 days. Dycal, Biodentine and MTA Angelus were able to keep the pH > 9 after 28 days of soaking. TheraCal's moderate alkalizing activity was the most constant among all of the materials (Gandolfi *et al*., 2015).

Radiopacity

TheraCal is a radiopaque material according to the manufacturer. Gandolfi *et al*. investigated the *Chemical-Physical Properties of TheraCal, a novel Light-Curable MTA-like Material for Pulp Capping* and stated that TheraCal as well as Dycal are weakly radiopaque whereas ProRoot MTA had a radiopacity in line with ISO 6878 (Gandolfi *et al*., 2012).

Cytotoxicity Tests

Hebling *et al*. tested the Cytotoxicity of Resin-based Light-Cured Liners; the aim of this research was to evaluate TheraCal, Vitrebond (RMGIC) & Ultrablend Plus on the culture of pulp cells. TheraCal decreased the cell metabolism by 31.5%. Less protein was expressed by the cells by TheraCal compared to the other two materials. TheraCal presented the lowest cytopathic effects. The experiment concluded that TheraCal could be used securely as a liner in order to protect the pulpal tissue from external noxious products. However, further in vivo studies are still necessary to evaluate the biocompatibility of TheraCal as all the resin-based liners were toxic to the cultured odontoblast cells. Light cured resin-based MTA cementpresented the lowest cytopathic effects (Hebling *et al*., 2009).

Effect of TheraCal on OD-21 Cells

Wang *et al*. researched the effect of 3 pulp capping materials on the growth of immortalized rodent pulp cells (OD-21). Light-cured discs of TheraCal LC, TheraCal DC and TheraBag65 LC were soaked in Dulbecco's Modified Eagle Medium (DMEM) for 4 days at 37^{0}C. At every time point, cell survival following the first treatment with all three materials tested were all similar and greater than 80%. The day 3 cell survival rate following the second treatments showed differences between materials, with TheraCal LC being the lowest, however by day 4, only TheraCal DC remained significantly different from the other two materials. All three materials tested were not detrimental to OD21 cells (Wang *et al*., 2013).

TheraCal™ LC is used as a Direct Pulp Capping Material

In this case, the clinician performed a direct-composite restoration for a patient presenting with an asymptomatic direct carious exposure. Light bleeding was controlled with sterile saline compression. TheraCal LC was placed directly over the exposure site, and then additional increments were added to seal and provide a barrier for healing (Brown, 2012). TheraCal has been tested clinically as a direct pulp capping agent in primates by Cannon *et al*. The aim of the research was to investigate the healing of bacterially contaminated primate pulps with TheraCal, a Portland cement, light cured Dycal and GIC. The pulps of 12 teeth for each group were exposed from the buccal surface, covered in cotton pellets soaked in bacteria found in human pulps, haemostasis obtained and the liner of choice is placed. The teeth were collected at 4 weeks and were demineralized, sectioned, stained and histologically rated. The results displayed no statistically significant differences between the materials related to pulpal inflammation. However, at 28 days TheraCal and the Portland cement showed a complete hard tissue dentine bridge and more frequent hard tissue bridge formation than the Dycal and GIC groups. Dycal and GIC showed an incomplete dentinal bridge. The experiment concluded that TheraCal created complete dentinal bridges and mild pulpal inflammation suitable for pulp capping (Cannon *et al*., 2014). It must be kept in mind that the consequences of pulp capping in animals may be different from what occurs in humans (Hilton, 2009).

TheraCal™ LC is used as an Indirect Pulp Capping Agent

Infected soft dentine is removed, leaving affected dentine. Radiograph shows a close approximation of an asymptomatic pulp. TheraCal LC was placed onto moist dentine. A base was placed over the TheraCal and the restoration completed. Since TheraCal LC has low temperature changes during light curing it is preferable to use in deep cavities as an indirect pulp capping agent (Savas *et al*., 2014).

TheraCal™ LC is used to Seal Root Canal Orifices

TheraCal LC also protects endodontically treated teeth. In a particular case, endodontic retreatment was completed. The chemically softened, disinfected furcation floor required sealing of root orifices and softened dentine at the furcation floor. TheraCal LC was added in 1mm increments to provide a visually discernible orifice and furcation floor seal (Brown, 2012).

Conclusion

TheraCal addresses the needs of healing & pulpal protection (dentine bridging & remineralisation), as well as sustained alkalinity, calcium stimulation, immediate sealing to assist against bacterial invasion and the physical strength to uphold under pressure. More clinical studies will be necessary. Gaps in the research field for TheraCal include the topics solubility, setting mechanism, microhardness, and bond strength.

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