Title: Assessment of Pulpotomy Procedure Using NeoMTA Plus in Permanent Teeth with Carious Exposure

A-I: ABSTRACT

Vital pulp therapy is recommended for teeth diagnosed with reversible pulpitis or partially inflamed pulps in which the remaining healthy tissue can be conserved and protected by a biologically active material to generate a hard tissue barrier that seals and protects the pulp from future microbial insult. The aim of this in vivo study is to clinically and radiographically assess the outcome of full pulpotomy using a calcium silicate based material (NeoMTA Plus) in permanent teeth with carious exposure. Ethics approval will be obtained from the institutional ethics and research committee, and the patients will be informed for the possible complication and informed consent will be obtained. Seventy patients meeting the inclusion criteria will be selected for this study and they will be subsequently followed up clinically and radiographically after 3 months, 6 months, and 1 year.

A-II: PROJECT GOALS AND OBJECTIVES

The aim of this in vivo study is to clinically and radiographically assess the outcome of full pulpotomy in cariously exposed pulps using NeoMTA Plus in permanent teeth with carious exposure.
B-I: REVIEW AND ANALYSIS OF RELATED WORK

The invading microorganisms in carious lesions are the primary cause of pulpal inflammation. Clinical signs and symptoms such as the degree and characteristics of pain do not reflect the actual histological status and subsequently the healing potential of the inflamed pulp. Vital pulp therapy is recommended for teeth diagnosed with reversible pulpitis or partially inflamed pulps in which the remaining healthy tissue can be conserved to generate a hard tissue barrier that seals and protects the pulp from future microbial insult.¹

According to Seltzer and Bender,²,³ pulp capping should be discouraged for carious pulp exposures, since microorganisms and inflammation are invariably associated, and it was shown that it has lower success rate than in traumatic exposure.⁴ This perspective has encouraged clinicians to deliver alternative treatments, such as pulpotomy or pulpectomy, particularly in immature permanent teeth.⁵,⁶

Due to better understanding of pulp physiology, caries microbiology, and the inflammatory mechanisms responsible for irreversible changes in pulp tissue, teeth with the potential for repair and continued vitality can now be more readily identified and predictably treated.⁵ It is recognized that outcomes for vital pulp therapy can vary, depending on the age of the patient, extent of bacterial contamination, and degree of pulp inflammation. Perhaps of greater importance may be the choice of pulp capping material and the quality of the permanent restoration.⁸ Appropriate case selection, through a detailed differential diagnosis using multiple tests paired with a careful radiographic interpretation is required. A study done by Aguilar & Linsuwanont concluded that vital permanent teeth with cariously exposed pulp can be treated successfully with vital pulp therapy.⁹

The dental pulp is a highly vascular and innervated loose connective tissue that has the unusual distinction of being enclosed within a rigid envelope composed of enamel, dentin, and cementum.¹⁰,¹¹ These hard tissues impart mechanical support and offer protection from the oral microbiota.¹² A comparison analysis of gene expression levels reflecting the activity of biologic cell function, proliferation, differentiation, and development found them markedly higher in young pulps compared to older dental pulps. Analyses of young dental pulps indicated a greater expression level in cell and tissue differentiation, proliferation, and development of the lymphatic, hematologic, and immune systems compared to older dental pulps where the apoptosis pathway is highly expressed.¹³

Pulpotomy defined as “the removal of the coronal portion of the vital pulp as a mean of preserving the vitality of the remaining radicular portion: may be performed as emergency procedure for temporary relief of symptoms or as a therapeutic measure.”¹⁴ After complete amputation of the coronal pulp, a capping material is placed over the pulp. The introduction of new bioactive materials makes more teeth with carious exposures viable candidates for innovative pulp therapies designed to potentiate and maintain pulp survival.
Preliminary investigations with Calcium Silicate Cements have demonstrated physio-chemical and bio-inductive properties comparable to those of MTA, indicating the potential future application of these materials in vital pulp therapy. Some of these tricalcium-based materials include BioAggregate (Innovative Bioceramix, Vancouver, British Columbia), Biodentine (Septodont, Cambridge, Ontario, Canada), MTA-Angelus, MTA Bio, and MTA Branco (MTA-Angelus, Londrina PR, Brazil) and NeoMTA plus (Avalon Biomed, Bradenton USA). Other formulations include EndocemMTA (Maruchi, Wonju-si, Gangwon-do, South Korea) and Endosequence root repair material (Brasseler USA, Savannah, Georgia). Additional compounds are currently undergoing clinical investigations to establish their safety and efficacy.

NeoMTA Plus (Avalon Biomed Inc. Bradenton, USA), is noncytotoxic, inhibits bacterial growth, does not contain resin, washout resistant, no staining potential, and does not require special equipment for mixing or placement. Furthermore, the fine particle size powder with the special gel creates a material that has superior handling properties. The setting time is less than 10 minutes and the manufacturer recommends no waiting time before placement of the permanent filling, which is time saving and particularly important for the early achievement of coronal seal.

**B-II: SIGNIFICANCE OF WORK**

Until now there are no published data available on the outcome of pulpotomy procedures using NeoMTA Plus in human teeth with carious exposure, however animal studies have shown favourable response. Therefore; the aim of this study is to explore the clinical and radiographic outcome of pulpotomy procedures using NeoMTA plus in permanent teeth with carious exposure.
**C-I: METHODOLOGY**

Ethics approval will be obtained from the institutional ethics and research committee. One hundred and twenty patients meeting the inclusion criteria will be selected for the study.

**Inclusion Criteria:**

- Permanent teeth with mature or immature apices
- Have no significant medical problems
- The tooth should give positive response to cold test and Electric Pulp Test (EPT)
- Probing pocket depth and mobility within normal limits
- No Signs of pulp necrosis including sinus tract or swelling
- Radiographically; caries either exposing the pulps or reaching more than 2/3 the distance from the dentino-enamel junction (DEJ) to the pulp
- The tooth can be restored via direct restoration

**Exclusion criteria:**

- Medically compromised patients
- Negative response to cold test
- Mobility
- Sinus tract
- Swelling
- Non restorable teeth or badly broken teeth

All the patients will be informed for the possible complication and informed consent will be obtained. After Clinical and radiographic examination the tooth will be anaesthetised using Lidocaine 2% and adrenaline 1/80000 and subsequently isolated using rubber dam. Then the tooth will be wiped with a gauze soaked in 2.5% sodium hypochlorite to disinfect the surface.

Cavity will be prepared using high speed fissure bur and the caries will be excavated using large
round bur in the slow speed handpiece. The exposed pulpal tissue will be amputated using sterile round bur in the high speed hand piece to the level of canal orifices (full pulpotomy). A pellet soaked with sodium hypochlorite (2.5%) will be placed for 3-5 minutes over the pulpal wound to achieve hemostasis.

NeoMTA Plus (Avalon biomed Inc, USA) will be mixed according to manufacturer instructions, then it will be placed over the pulp wound. Then permanent restoration will be placed in the same visit. The patient will be reviewed after one week to evaluate symptoms. The patients will be asked to score the preoperative pain levels using visual analogue scale from 0-10, 0 equals no pain while 10 is maximum value. The patients will be contacted by phone 2-3 days after treatment to score pain levels again.

The patients will be followed up after 3 months, 6 months, and 1 year, all teeth will be examined both clinically and radiographically to see if there is any symptoms, tenderness to percussion, presence of calcifications, resorption or new apical pathosis.

The outcome will be considered as unfavorable if one or more of the following is present: pain, tenderness to percussion, sinus tract, swelling, evidence of new periapical lesion, or persistence of a preoperative lesion. In case of failure RCT will be initiated.

C-II: LOCATION AND SAFETY CONSIDERATIONS

The clinical procedures will be done at the postgraduate clinics at the faculty of dentistry (JUST), universal precautions regarding infection control and radiation safety will be followed and respected.

C-III: EXPECTED RESULTS/OUTPUTS

To maintain the vitality of the teeth and to preserve them in function without any signs and symptoms of apical periodontitis.

NeoMTA plus will be easy to use and manipulate with high clinical and radiographic success in patients due to its favourable biological properties.
REFERENCES

20. Mozayeni MA, Milan AS, Marvasti LA, et al: Cytotoxicity of calcium enriched mixture cement...
compared with mineral trioxide aggregate and intermediate restorative material, Aust Dent J 2012, 38:70.