GC Tooth Mousse® & GC Tooth Mousse Plus®

A WORLD OF PROOF
RESEARCH STUDIES FROM AROUND THE GLOBE
As more and more dental professionals discover the benefits that GC Tooth Mousse® and GC Tooth Mousse Plus® deliver to their patients, researchers all around the world are investigating and documenting the clinical and laboratory evidence of their effectiveness.

The volume and extent of supportive independent research on GC Tooth Mousse® and GC Tooth Mousse Plus®, as summarised in this booklet, clearly emphasises the global significance of these remarkable products.
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RECALDENT™ (CPP-ACP)

GC Tooth Mousse® is a great tasting water-based crème that contains RECALDENT™ (CPP-ACP), casein phosphopeptide amorphous calcium phosphate, a milk-derived protein that provides high concentration bio-available calcium and phosphate. GC Tooth Mousse Plus® has the added benefit of 900 ppm fluoride, which approximates the level of fluoride present in adult strength toothpastes. GC Tooth Mousse Plus® is recommended for children at least 6 years old and older patients where additional fluoride exposure is desired. When GC Tooth Mousse® or GC Tooth Mousse Plus® are applied in the oral environment, RECALDENT™ (CPP-ACP) binds to biofilms, plaque, bacteria, hydroxyapatite and soft tissue localising calcium, phosphate (and fluoride).

Molecular model of CPP-ACP nano complex (RECALDENT™)
Key research-proven benefits

RECALDENT™ (CPP-ACP) is the end result of many years of research by the University of Melbourne into the anticariogenic properties of milk. Within the oral environment, RECALDENT™ (CPP-ACP) binds to biofilms, plaque, bacteria, hydroxyapatite and soft tissue, localising high levels of water soluble calcium, phosphate (and fluoride).

Synergises with fluoride

CPP-ACP promotes the incorporation of fluoride into plaque and sub-surface enamel, producing effects superior to those that can be achieved by using fluoride alone.

Buffers plaque acid

In a recent clinical study, application of GC Tooth Mousse® elevated plaque pH levels for 48 hours, while application of GC Tooth Mousse Plus® elevated plaque pH levels for 96 hours.

Inhibits demineralisation and promotes subsurface enamel remineralisation

CPP-ACP is the only proven technology that promotes sub-surface enamel remineralisation.

Acts as a prebiotic

CPP-ACP suppresses the growth of Streptococcus mutans and encourages the selection of commensal (good) bacteria.

Key


References:

Published results from key research fields

**HIGH CARIES RISK PATIENTS**

GC Tooth Mousse® suppresses the growth of Streptococcus mutans on desiccated glass-ionomer and resin-modified glass-ionomer materials. 
Connor et al.36

GC Tooth Mousse® and GC Tooth Mousse Plus® reduce caries lesion depth in enamel and dentine.  
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Katsura et al.77

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GC Tooth Mousse® and GC Tooth Mousse Plus® do not interfere with the action of bleaching agents.

Borges et al.20 Borges et al.21 Lago et al.86 Manton et al.94

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Mobarak, Ali, Daifalla121

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Connor et al.37

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Xiaojun et al.180

Key

Clinical trials and laboratory studies from around the world
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Europe/North Africa

Clinical Trials

BELGIUM
Author: Poitevin et al.114
Year: 2004
Location: Leuvin
Design: Cohort study, N=61 subjects, over 21 days.
Outcomes: TM reduced sensitivity to air and tactile stimuli.

DENMARK
Author: Bröchner et al.23
Year: 2011
Location: Copenhagen
Design: RCT, N=60 subjects, over 4 weeks.
Outcomes: The mean area of WSL decreased by 58% in the TM group and by 26% in the fluoride group.

HOLLAND
Author: van der Veen et al.158
Year: 2009
Location: Amsterdam
Design: RCT, N=34 subjects, over 12 weeks.
Outcomes: TMP induced a reduction in cariogenic bacteria, while the placebo paste did not.

ITALY
Author: Baroni et al.15
Year: 2010
Location: Bologna
Design: Cohort study, N=30 children, 3 years.
Outcomes: TM improved the morphology and microstructure of enamel in teeth affected by MIH.

Author: Baroni, Bazzocchi, Marchionni14
Year: 2012
Location: Bologna
Design: Enamel fragments from newly erupted MIH molar cusps were analysed after 6 months of TMP application.
Outcomes: TMP accelerated the maturation of MIH enamel, elevating the concentrations of calcium and phosphate, with ratios of calcium to carbon similar to normal enamel. The treated surface had mineral crystals with a regular shape that were better organised, with less porosity and fewer interprismatic spaces.

POLAND
Author: Kowalczyk et al.81
Year: 2006
Location: Poland
Design: Cohort study, N=13 subjects, over 4 weeks.
Outcomes: For treatment of dentine hypersensitivity, a single application of TM gave immediate relief on response to air stimulation. There was no further treatment so relapse occurred.

SERBIA
Author: Peric et al.110
Year: 2015
Location: Belgrade
Design: RCT to evaluate efficacy of TM and TMP among patients with Sjögren’s syndrome (SS).
Outcomes: The use of TM and TMP contributed to a significant rise in plaque pH. TM and TMP enhanced remineralisation potential compared with NaF mouthrinse in patients with SS.

SPAIN
Author: Llena, Leyda, Forner89
Year: 2015
Location: Valencia
Design: Double-blind RCT to evaluate the effects of TM, TMP and fluoride varnish on the remineralisation of 786 WSL over a 12-week follow-up period.
Outcomes: At 4 weeks, TMP was superior to fluoride varnish at remineralising smooth-surface WSL.
Author: Özdas et al.¹⁰⁷  
Year: 2015  
Location: Istanbul  
Design: Experimental prospective clinical controlled trial (cerebral palsy).  
Outcomes: Daily application of TM effectively changed saliva buffering capacity and plaque pH, thus promoting caries prevention in the primary and mixed dentition of cerebral palsy children.

Author: Ünlü et al.¹⁵⁶  
Year: 2013  
Location: Konya  
Design: RCT post-orthodontic WSL reversal, N=20, 36 months.  
Outcomes: TM prevented WSL development during orthodontics and remineralised post-orthodontic WSL.

Author: Akin, Basciftci⁵  
Year: 2011  
Location: Konya  
Design: Experimental prospective clinical controlled trial, N=80, 967 teeth with post-orthodontic WSL.  
Outcomes: TM was more effective than neutral NaF when applied twice daily over 6 months, with greater reduction in the area of WSL and in the frequency of persisting WSL.

Author: Aytepe et al.¹⁰  
Year: 2008  
Location: Istanbul  
Design: Cohort study, N=15 children, 56 days.  
Outcomes: TM elevated saliva buffering capacity and plaque pH over 8 weeks in children with cerebral palsy.

Author: Yazıcıoglu, Ulukapı¹⁷⁸  
Year: 2014  
Location: Istanbul  
Design: Experimental in-vivo controlled trial, WSL reversal, N=42.  
Outcomes: TM significantly slowed the progression of approximal lesions and promoted remineralisation.

Author: Aytepe et al.¹⁰  
Year: 2008  
Location: Istanbul  
Design: Cohort study, N=15 children, 56 days.  
Outcomes: TM elevated saliva buffering capacity and plaque pH over 8 weeks in children with cerebral palsy.

Author: Caruana et al.²⁷  
Year: 2009  
Location: London  
Design: RCT, N=15.  
Outcomes: TM applied immediately before a sucrose challenge reduced plaque acid production.

Author: Garry et al.⁴⁹  
Year: 2015  
Location: Liverpool  
Design: Randomised cross-over in situ study, N=12 orthodontic patients, 4 weeks.  
Outcomes: TM, combined with fluoride toothpaste, showed a significantly greater reduction in both WSL depth and width compared to fluoride toothpaste alone.

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Key  
AFM Atomic Force Microscopy  
RMGI Resin-modified Glass-ionomer  
MH Molar Incisor Hypomineralisation  
TM GC Tooth Mousse®  
NaF Sodium Fluoride  
APP Acidulated Phosphate Fluoride  
XRD X-ray Diffraction  
MSBS Microshear Bond Strength  
TMP GC Tooth Mousse Plus®
Egyption

Author: Elsayad, Sakr, Badr
Year: 2009
Location: Cairo
Design: Molar teeth with WSL.
Outcomes: TM remineralised WSL. The remineralisation was further enhanced when F was added simultaneously.

Author: Talaat, Mahmoud
Year: 2015
Location: Alexandria
Design: In vitro enamel caries model.
Outcomes: Enamel surfaces treated with TMP became more resistant to further acid attack.

Greece

Author: Rahiotis, Vougiouklakis
Year: 2007
Location: Athens
Design: Dentine slabs with WSL.
Outcomes: TM treatment reduced demineralisation and enhanced remineralisation of dentine.

Italy

Author: Ceci et al.
Year: 2015
Location: Pavia
Design: In vitro erosion study (AFM).
Outcomes: TM prevented enamel erosion produced by soft drinks.

Author: Giulio et al.
Year: 2009
Location: Bologna
Design: Stripped and unstripped enamel slabs with WSL.
Outcomes: TM reduced enamel demineralisation for both intact and abraded enamel surfaces.

Poland

Author: Mielczarek
Year: 2012
Location: Warsaw
Design: WSL reversal.
Outcomes: TMP applied twice daily increased surface microhardness and longitudinal microhardness, with mineral gain to the subsurface region of the lesion.

Author: Mielczarek, Michalik
Year: 2013
Location: Warsaw
Design: Enamel erosion challenge (7 day challenge using Coca-Cola*, pH 2.6; 4 cycles of 2 min. per day). TM and TMP were applied before erosive challenge.
Outcomes: TMP was effective in protecting teeth from erosion and provided an additive anti-erosion effect over a regular fluoride toothpaste.
TURKEY

Author: Bayrak et al.\textsuperscript{17}
Year: 2009
Location: Turkey
Design: TM applied to enamel slabs daily after bleaching, 15 days (enamel microhardness).
Outcomes: TM caused a significant increase in enamel microhardness when applied daily following bleaching.

Author: Baysal, Uysal\textsuperscript{18}
Year: 2012
Location: Kocaeli
Design: SBS of orthodontic brackets bonded to demineralised enamel surface, TM, micro abrasion.
Outcomes: TM pre-treatment, micro abrasion of the enamel and the combination of these two treatments improved the bonding to demineralised enamel.

Author: Kargul et al.\textsuperscript{74}
Year: 2012
Location: Istanbul
Design: Enamel slabs acid challenge.
Outcomes: A 5 minute application of TM protected enamel surfaces, made enamel resistant to subsequent acid challenge and caused recovery of surface microhardness.

Author: Kutuk, Firat, Gurgan\textsuperscript{85}
Year: 2012
Location: Ankara
Design: Experimental enamel WSL.
Outcomes: TM was more effective at treating experimental WSL than fluoride varnish, increasing the surface microhardness of artificial early enamel lesions.

Author: Kara, Ünlü\textsuperscript{73}
Year: 2013
Location: Konya
Design: In vitro study of the inhibition of demineralisation in enamel sections produced by Er:YAG laser and TM.
Outcomes: TM used alone or in combination with an Er:YAG laser increased the acid resistance of enamel.

Author: Tabrizi, Cakirer\textsuperscript{148}
Year: 2011
Location: Istanbul
Design: In vitro evaluation of SBS of orthodontic brackets.
Outcomes: TM pre-treatment prior to bonding orthodontic brackets is a safe option to reduce the risk of demineralisation during fixed orthodontic treatment.

Author: Uysal et al.\textsuperscript{157}
Year: 2011
Location: Kayseri
Design: In vitro evaluations of SBS and fracture mode of orthodontic brackets bonded to demineralised enamel.
Outcomes: TM pre-treatment was more efficient than fluoride pre-treatment for bonding orthodontic brackets.

UK

Author: Chapman, Jones, West\textsuperscript{31}
Year: 2011
Location: Bristol
Design: Laboratory model of dental erosion using citric acid.
Outcomes: TM and TMP reduced enamel surface loss in a laboratory model of dental erosion using citric acid.

Author: Chapman, Jones, West\textsuperscript{30}
Year: 2010
Location: Bristol
Design: Enamel slabs (profilometry).
Outcomes: TM and TMP reduced enamel surface loss from citric acid challenge.

Author: Duggal et al.\textsuperscript{40}
Year: 2009
Location: Leeds
Design: Dentine slabs eroded with citric acid and abraded with toothbrush.
Outcomes: TM significantly reduced dentine surface loss from erosion/abrasion.

Author: Lovel, Pender, Higham\textsuperscript{90}
Year: 2007
Location: Liverpool
Design: Enamel slabs with WSL (QLF).
Outcomes: TM was more effective than 1000 ppm F toothpaste in promoting remineralisation of WSL.

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Key
AFM Atomic Force Microscopy
RMGI Resin-modified Glass-ionomer
MIH Molar Incisor Hypomineralisation
TM GC Tooth Mousse®
NaF Sodium Fluoride
APP Acidulated Phosphate Fluoride
XRD X-ray Diffraction
MSBS Microshear Bond Strength
TMP GC Tooth Mousse Plus®
# Clinical Trials

**BRAZIL**  
**Author:** Groisman et al.\(^53\)  
**Year:** 2015  
**Location:** Rio de Janeiro  
**Design:** WSL reversal, \(N=12\) orthodontic patients, TMP applied for 4 weeks.  
**Outcomes:** TMP remineralised WSL in orthodontic patients. At a 12-month follow-up, TMP protective effect was noticed as WSL did not progress.

**MEXICO**  
**Author:** Juárez-López et al.\(^69\)  
**Year:** 2014  
**Location:** Zaragoza  
**Design:** Quasi-experimental study, \(N=104\) six year old children, TMP biweekly applications at school for 6 months (DIAGNOdent).  
**Outcomes:** TMP protected and remineralised incipient carious lesions, compared to sodium fluoride gel applications.

**USA**  
**Author:** Robertson et al.\(^128\)  
**Year:** 2011  
**Location:** Houston  
**Design:** RCT, \(N=50\), over 12 weeks.  
**Outcomes:** TMP prevented WSL development during orthodontics, and reduced the number of existing WSL. Patients using the placebo paste showed an increased number of WSL.

**ARGENTINA**  
**Author:** Rodríguez et al.\(^129\)  
**Year:** 2011  
**Location:** Córdoba  
**Design:** Enamel with post-orthodontic WSL.  
**Outcomes:** TM and TMP gave mineral gain in the subsurface region up to 230 microns, as well as surface mineral deposition.

**BRAZIL**  
**Author:** Aguiar et al.\(^4\)  
**Year:** 2011  
**Location:** São Paulo  
**Design:** TM effect when applied to enamel prior to adhesive procedures.  
**Outcomes:** Application of TM before adhesive systems increased bond strength to enamel.

**USA**  
**Author:** Sheharyar et al.\(^139\)  
**Year:** 2007  
**Location:** Iowa  
**Design:** RCT, \(N=45\), over 2 weeks.  
**Outcomes:** TM significantly reduced bleaching sensitivity and produced a greater, although not significant, shade change.

**ARGENTINA**  
**Author:** Borges et al.\(^20\)  
**Year:** 2011  
**Location:** Pernambuco  
**Design:** In vitro bleaching efficacy and TM (microhardness of bleached enamel), 14 days.  
**Outcomes:** The use of TM with 10% or 16% carbamide peroxide bleaching agents increased the bleached enamel microhardness and did not have an influence on whitening efficacy.
Author: Borges et al.  
**Year:** 2013  
**Location:** Campinas  
**Design:** In vitro bonding/sealant evaluation.  
**Outcomes:** Applying TM on enamel before adhesive systems increased bond durability of the tested sealant.

Author: Carvalho et al.  
**Year:** 2012  
**Location:** Paraiba  
**Design:** In vitro enamel erosion model.  
**Outcomes:** TMP prevented enamel erosion from repeated challenges using a cola soft drink over 7 days, when applied immediately following each erosive challenge.

Author: Gomes et al.  
**Year:** 2010  
**Location:** São Paulo  
**Design:** De-proteinated enamel.  
**Outcomes:** TM applied after in-office bleaching helped to restore the glossy nature of the enamel surface.

Author: Lago et al.  
**Year:** 2012b  
**Location:** São Paulo  
**Design:** TM application on enamel slabs prior to tooth whitening.  
**Outcomes:** TM prevented the reduction of enamel surface microhardness caused by exposure to 35% hydrogen peroxide during in-office bleaching, with full recovery of enamel microhardness after 7 days storage in artificial saliva.

Author: Publio et al.  
**Year:** 2012  
**Location:** São Paulo  
**Design:** TM application on enamel blocks after tooth whitening and prior to exposure to cigarette smoke.  
**Outcomes:** Treatment of bleached enamel with neutral fluoride increased staining of the enamel due to cigarette smoke, while treatment with TMP did not.

Author: Souza e Silva et al.  
**Year:** 2012  
**Location:** São Paulo  
**Design:** Dentine eroded with Coca-Cola® (pH 2.6) for 90 sec, 4 times a day. TM and TMP applied after erosive challenge.  
**Outcomes:** TM and TMP applied to dentine protected the surface when challenged with Coca Cola® (pH 2.6) four times per day. Both significantly reduced dentine surface loss compared with a placebo paste.

Author: Turssi et al.  
**Year:** 2008  
**Location:** São Paulo  
**Design:** Enamel slabs with erosion lesions (microhardness).  
**Outcomes:** Treatment of eroded enamel with TMP reduced progression of erosion compared with the untreated control.

**USA**

Author: Augustson, Tantbirojn, Versluis  
**Year:** 2010  
**Location:** Minneapolis  
**Design:** Enamel eroded with Hydrochloric acid (HCl) (microhardness).  
**Outcomes:** After HCI erosion, 60 minutes exposure to TMP or TM (but not 3000 ppm F rinse) increased the enamel hardness. Greater recovery was seen with TMP than with TM.

Author: Behnan et al.  
**Year:** 2009  
**Location:** Ann Arbor  
**Design:** Enamel slabs (QLF).  
**Outcomes:** TM prevented enamel demineralisation around orthodontic brackets during an in vitro acid challenge.

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USA (cont.)
Author: Connor, Banfield, Vandewalle
Year: 2014
Location: Lackland
Design: In vitro study to assess the effect of various surface treatments on the antimicrobial activity of desiccated glass-ionomer (GI) and resin-modified glass-ionomer (RMGI) materials.
Outcomes: TM suppressed the growth of Streptococcus mutans on desiccated GI and RMGI materials.

Author: Connor et al.
Year: 2014
Location: Indianapolis
Design: In vitro model testing the effect of various surface treatments on the mechanical properties of desiccated GI and RMGI materials.
Outcomes: Exposure for 1 week to TM did not adversely affect the physical properties of desiccated GI and RMGI materials.

Author: Dehghan et al.
Year: 2012
Location: Memphis
Design: In vitro enamel erosion model.
Outcomes: Both TM and TMP increased the hardness of enamel that had been softened by exposure to HCl for 10 minutes, which mimicked regurgitated stomach acid. TMP restored the enamel surface microhardness within one hour to the baseline value. Hardness recovery of enamel was minimal with saliva alone.

Author: Garcia-Godoy et al.
Year: 2009
Location: Fort Lauderdale
Design: Root segments were exposed to a demineralising solution (PLM).

Author: Hicks, Flaitz
Year: 2014
Location: Houston
Design: In vitro root surface caries model.
Outcomes: TMP significantly improved root surface caries resistance and provided a greater degree of caries prevention than 5000 ppm fluoride pastes (Colgate Prevident*, 3M Espe Clinpro 5000*).

Author: Hicks, Flaitz
Year: 2013
Location: Houston
Design: In vitro enamel caries model.
Outcomes: TMP significantly reduced caries lesion depths, compared with fluoride varnish containing tri-calcium phosphate.

Author: Hicks, Flaitz
Year: 2011
Location: Houston
Design: In vitro caries model.
Outcomes: TMP provided protection against root surface caries in an in vitro caries model, with lower mean lesion depths versus controls.
Author: Hicks, Flaitz⁶³
Year: 2010
Location: Houston
Design: In vitro, enamel slabs were exposed to a demineralising solution (PLM).
Outcomes: TMP reduced caries lesion depths as effectively as a 5000 ppm F toothpaste, despite having a fluoride content of only 900 ppm F.

Author: Hicks⁶²
Year: 2006
Location: Houston
Design: Enamel slabs were exposed to a demineralising solution.
Outcomes: TMP enhanced the resistance of enamel surfaces to in vitro caries formation compared with TM or fluoride alone.

Author: Hicks, Flaitz⁶¹
Year: 2005
Location: Houston
Design: Root segments were exposed to a demineralising solution (PLM).
Outcomes: TM enhanced the resistance of root surfaces to artificial caries formation, when compared with fluoride rinse (0.05% NaF).

Author: Huang, Tantbirojn⁶⁵
Year: 2008
Location: Minneapolis
Design: Enamel slabs eroded with Coke®*.
Outcomes: TM treatment improved enamel hardness more than artificial saliva.

Author: Kao et al.⁶²
Year: 2008
Location: West Virginia
Design: Enamel slabs were exposed to a demineralising solution.
Outcomes: TM treatment increases acid resistance of enamel when exposed to a demineralising solution.

Author: Setien et al.¹³⁸
Year: 2008
Location: Dallas
Design: Enamel slabs with WSL (microhardness).
Outcomes: TM treatment increased the microhardness of demineralised enamel.

Author: Tantbirojn et al.¹⁵¹
Year: 2008
Location: Minnesota
Design: In vitro erosion challenge (cola drink for 8 min).
Outcomes: TM increased hardness of enamel softened by a cola drink.

Author: Trajtenberg, Flaitz, Hicks¹³⁴
Year: 2007
Location: Houston
Design: Root segments were exposed to a demineralising solution (PLM).

Author: Westerman, Flaitz, Hicks¹⁶⁹
Year: 2014
Location: Omaha and Houston
Design: In vitro root surface caries challenge.
Outcomes: TMP significantly reduced the effects of an in vitro root surface caries challenge, and was more effective than fluoride rinses.

Author: Westerman et al.¹⁶⁸
Year: 2009
Location: Houston
Design: Root surfaces caries model.

Author: Xie, Wu, Bedran-Russo¹⁸¹
Year: 2007
Location: Chicago
Design: Root segments were exposed to a demineralising solution (microhardness).
Outcomes: TMP treatment significantly increased the hardness of root dentine.

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Key

Asia

Clinical Trials

CHINA
Author: Duan et al.39
Year: 2009
Location: Wuhan
Design: RCT, N=30 subjects, 14 days.
Outcomes: TM reduced sensitivity with equal effectiveness to potassium nitrate gel.

Author: Mahesuti et al.91
Year: 2014
Location: Wuhan
Design: Experimental controlled trial (treatment of dentine hypersensitivity), N=102, 2 months.
Outcomes: A sustained clinical reduction in dentine hypersensitivity was observed with TM.

Author: Zhou, Sun, Zhu184
Year: 2009
Location: Changchun
Design: Cohort study, N=10 subjects, 2 months.
Outcomes: TMP reduced visible enamel demineralisation and improved the appearance of long-standing post-orthodontic WSL.

Author: Wang, Yan, Wang166
Year: 2012
Location: Beijing
Design: Single-blind clinical study (N=20 orthodontic patients with WSL, TM applied every night after tooth-brushing; 6 months).
Outcomes: TMP remineralised existing WSL.

INDIA
Author: Grewal, Kudupudi, Grewal132
Year: 2013
Location: Amritsar
Design: In situ clinical trial.
Outcomes: TM promoted significant remineralisation of enamel eroded by cola drinks as revealed by significant morphological changes seen in SEM magnification and spectrophotometric analyses.

Author: Gugnani, Gupta, Pandit54
Year: 2008
Location: India
Design: RCT, N=48, 28 days.
Outcomes: A single application of TM provided short term reduction in dentine hypersensitivity.

Author: Krithikadatta et al.83
Year: 2013
Location: Chennai
Design: RCT, N=45, 30 days.
Outcomes: TM and TMP showed greater remineralising effect of WSL than NaF mouthrinse.

Author: Subramaniam, Naidu144
Year: 2009
Location: Bangalore
Design: RCT, N=30 subjects, 16 days.
Outcomes: TMP (79.5%) and Cervitec Gel® (51.6%) produced a significant reduction in levels of Streptococcus mutans.

Author: Srinivasan, Kavitha, Longanathan143
Year: 2010
Location: Chennai
Design: In situ study, N=5.
Outcomes: As measured by microhardness values, both TM (+46%) and TMP (+64%) substantially remineralised eroded enamel compared to a saliva control (+3%).

Author: Vashisht et al.159
Year: 2013
Location: Punjab
Design: Experimental ex-vivo controlled trial (early enamel lesions), N=10, TM was applied twice a day for 14 days.
Outcomes: TM remineralised early enamel lesions.

IRAN
Author: Banava, Houshyari, Safaei17
Year: 2015
Location: Tehran
Design: RCT, N=20, TM applied twice daily, 6 weeks.
Outcomes: Twice daily applications of TMP improved resting and stimulated salivary rates as well as saliva’s buffering capacity in patients undergoing chemotherapy.

Author: Heshmat, Abdian, Faraji57
Year: 2013
Location: Tehran
Design: In a clinical study with 40 subjects, plaque acidity (pH) at distal of first molar was evaluated before and 10 minutes after 10% sucrose consumption. In the next step, TM and TMP pastes were used as directed on tooth surface. Plaque pH was assessed 30 and 60 minutes, 24, 48, 72 and 96 hours after application.
Outcomes: TM and TMP both elevated plaque pH levels for the first 48 hours. The pattern differed after this period, with TMP giving elevated pH until 96 hours.

Author: Memarpour et al.98
Year: 2015
Location: Shiraz
Design: RCT, N=140 children aged 12-36 months, WSL reversal, 12 months.
Outcomes: Twice daily application of TM was effective in stopping and reversing WSL in young children.

JAPAN
Author: Katsura et al.77
Year: 2010
Location: Nigata
Design: RCT, N=19, 6 months.
Outcomes: TM recalcified root surfaces in patients with radiation induced xerostomia. TM combined with fluoride was superior to fluoride alone.

Author: Kitasako et al.80
Year: 2009
Location: Tokyo
Design: Cohort study, N=7 subjects, 6 months.
Outcomes: TM produced remineralisation of WSL over 6 months, and increased the surface pH of the lesions (using a micro sensor).

Author: Sakaguchi et al.134
Year: 2006
Location: Tokyo
Design: In situ study, N=5 subjects, 7 days.
Outcomes: TM gave greater remineralisation than 950 ppm fluoride toothpaste, and even greater remineralisation was achieved with TMP, indicating synergy of fluoride with CPP-ACP.

MALAYSIA
Author: Venkiteswaran, Awang, Rahim161
Year: 2009
Location: Kuala Lumpur
Design: Cross-over design with 3 groups, N=40, 5 days.
Outcomes: TM and TMP increased saliva buffering capacity and salivary concentration of calcium and phosphate ions.

THAILAND
Author: Amompipithkul, Sanguansin, Leelataweewud7
Year: 2009
Location: Bangkok
Design: Cohort study, N=21 children, 14 days.
Outcomes: Daily application of TM increased plaque calcium and inorganic phosphate levels in a time-dependent manner.

Author: Thepyou et al.153
Year: 2013
Location: Bangkok
Design: Randomised, cross-over, double blind in situ trial (N=6; TM applications twice a day, 4 weeks).
Outcomes: TM promoted sub-surface enamel remineralisation.

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Laboratory Studies

CHINA
Author: Cao et al.25
Year: 2013
Location: Hong Kong
Design: In vitro dentine slabs exposed to phosphoric acid and sodium trimetaphosphate. TM and a remineralising solution were used for 10 days.
Outcomes: TM induced the biomimetic mineralisation of dentine through apatite formation along and between the phosphorylated dentine collagen fibers.

Author: Kumar, Itthagarun, King84
Year: 2008
Location: Hong Kong
Design: Enamel slabs with WSL.
Outcomes: TM remineralised WSL and showed a higher remineralising potential when applied after application of a fluoride toothpaste.

Author: Wang et al.167
Year: 2014
Location: Chengdu
Design: In vitro erosion model using Coca Cola* (pH = 2.7) (AFM, XRD).
Outcomes: TM protected teeth against cola drink erosion.

Author: Wu, Liu, Hou173
Year: 2010
Location: China
Design: Enamel with WSL (polarised images).
Outcomes: TM remineralised WSL and was even more effective when used in conjunction with F toothpaste.

Author: Xiaojun et al.180
Year: 2009
Location: Shanghai
Design: In vitro orthodontic bracket bonding (SBS enamel).
Outcomes: Application of TM prior to orthodontic bracket bonding significantly increased SBS of orthodontic brackets and did not compromise brackets bond strength.

Author: Zhang et al.182
Year: 2011
Location: Chengdu
Design: In vitro caries model (enamel microhardness).
Outcomes: TM was effective in remineralising early enamel lesions of the primary teeth. Enamel treated with TM had mineral crystals with a more regular shape (crystals were better organised), with less porosity and fewer interprismatic spaces than enamel treated with 500 ppm NaF. TM increased the enamel surface microhardness near baseline levels.

Author: Zhao, Cai183
Year: 2001
Location: Guangdong
Design: In vitro caries model.
Outcomes: TMP remineralised WSL in vitro. The remineralising rates were increased with the experiment time (within 10 days).

Author: Zhou et al.185
Year: 2014
Location: Beijing
Design: In vitro caries model (AFM).
Outcomes: TM repaired the microstructure of enamel, including prism and interprismatic spaces, through significantly increased hydroxyapatite crystal size and Ca/P molar ratios compared to 500 ppm NaF.
**INDIA**

**Author:** Agrawal et al.3  
**Year:** 2014  
**Location:** Madhya Pradesh  
**Design:** In vitro artificial erosion model (primary and permanent teeth, surface microhardness).  
**Outcomes:** TM was more effective at preventing dental erosion than 1.23% APF gel and iron supplement.

**Author:** Duraisamy et al.4  
**Year:** 2015  
**Location:** Salem  
**Design:** In vitro evaluation of demineralisation (artificial caries challenge for 10 days).  
**Outcome:** TMP was superior in inhibiting enamel demineralisation compared to fluoride varnish or TM alone.

**Author:** Hegde, Moany5  
**Year:** 2012  
**Location:** Karnataka  
**Design:** Enamel slabs were exposed to a demineralising solution and treated with TM twice daily for 14, 21, 28 and 35 days.  
**Outcomes:** TM significantly remineralised the artificial enamel subsurface lesions. The remineralisation achieved was dose-dependent (increased number of days of TM treatment, increased remineralisation rate was observed).

**Author:** Jayarajan et al.6  
**Year:** 2011  
**Location:** Tamil Nadu  
**Design:** Tooth slabs were exposed to demineralisation solution.  
**Outcomes:** TMP showed marginally more amount of remineralisation than TM.

**IRAN**

**Author:** Banava et al.13  
**Year:** 2011  
**Location:** Tehran  
**Design:** In vitro caries model (microhardness).  
**Outcomes:** TM applications twice a day for 4 weeks resulted in higher resistance of enamel to demineralisation compared to a fluoride varnish application.

**Author:** Memarpour, Soltanimehr, Sattarhazad17  
**Year:** 2015  
**Location:** Shiraz  
**Design:** Enamel slabs (primary teeth) exposed to erosive challenge (enamel microhardness).  
**Outcomes:** The efficacy of TM for remineralising eroded enamel was greater than fluoride toothpaste, fluoride varnish or TCP varnish.

**Author:** Yassaei et al.177  
**Year:** 2014  
**Location:** Yazd  
**Design:** In vitro study of the inhibition of demineralisation in enamel sections produced by Er:YAG laser and TM.  
**Outcomes:** TM used alone or in combination with an Er:YAG laser increased the acid resistance of enamel.
India

**Author:** Hamba et al.55  
**Year:** 2011  
**Location:** Tokyo  
**Design:** In vitro artificial caries challenge for 24h, 72h and 120h (polychromatic micro-CT).

**Outcomes:** The application of TM or TMP to sound enamel surfaces resulted in inhibition of enamel demineralisation; a higher acid resistance effect was noted for TMP.

**Author:** Imamura et al.66  
**Year:** 2012  
**Location:** Tokyo  
**Design:** In vitro model of extrinsic tooth staining after in-office bleaching.

**Outcomes:** TM and TMP prevented staining of freshly bleached enamel by black tea.

**Author:** Ogata et al.104  
**Year:** 2010  
**Location:** Tokyo  
**Design:** Enamel slabs with WSL.

**Outcomes:** A combination of TM and NaF was superior to F alone for prevention of demineralisation and for remineralisation of WSL.

**Author:** Oshiro et al.106  
**Year:** 2007  
**Location:** Tokyo  
**Design:** Enamel and dentine slabs were exposed to 0.1M lactic acid buffer solution.

**Outcomes:** TM was effective in preventing demineralisation of enamel and dentine.

**Author:** Kariya et al.75  
**Year:** 2004  
**Location:** Tokyo  
**Design:** Enamel slabs were exposed to a demineralising solution.

**Outcomes:** TMP reduced enamel mineral loss compared with TM. Acid resistance of remineralised lesions was greater for TMP compared with TM.

**Author:** Sakaguchi et al.133  
**Year:** 2005  
**Location:** Tokyo  
**Design:** Enamel slabs were exposed to a demineralising solution (QLF).

**Outcomes:** TM preserved the inorganic component of enamel by preventing demineralisation.

**Author:** Sato et al.136  
**Year:** 2011  
**Location:** Tokyo  
**Design:** In vitro study of biofilm interaction with CPP-ACP.

**Outcomes:** Biofilms of Streptococcus mutans bind to CPP-ACP and serve as a reservoir for calcium and phosphate ions. Of the commercial products tested, only CPP-ACP based products gave high levels of water soluble calcium phosphate.

**Author:** Sato, Yamanaka, Yoshii135  
**Year:** 2003  
**Location:** Tokyo  
**Design:** Enamel slabs were exposed to a demineralising solution (microhardness).

**Outcomes:** TM buffered acids produced by Streptococcus mutans. TM reduced enamel demineralisation from acidic gel and Streptococcus mutans fermentation.

**Author:** Takamizawa et al.149  
**Year:** 2005  
**Location:** Tokyo  
**Design:** Enamel slabs were exposed to a demineralising solution (ultrasound).

**Outcomes:** TM preserved the inorganic component of enamel by preventing demineralisation.

**Author:** Yamaguchi et al.174  
**Year:** 2006  
**Location:** Tokyo  
**Design:** Enamel slabs were exposed to a demineralising solution (ultrasound).

**Outcomes:** TM preserved the inorganic component of enamel by preventing demineralisation.

**Author:** Yamaguchi et al.175  
**Year:** 2007  
**Location:** Tokyo  
**Design:** Dentine slabs were treated with TM and then exposed to demineralising solution.

**Outcomes:** TM prevented demineralisation of dentine.
Author: Yasuda et al.176
Year: 2010
Location: Tokyo
Design: In vitro caries model.
Outcomes: TMP prevented demineralisation and retained enamel surface layer. TMP contained significantly higher bio-available calcium and phosphate ions than Clinpro 5000* and Clinpro C950*.

THAILAND
Author: Juntavee et al.70
Year: 2011
Location: Khon-Kaen
Design: In vitro WSL reversal.
Outcomes: TM remineralised enamel white spot lesions.

South Korea
Author: Kim et al.78
Year: 2007
Location: South Korea
Design: In vitro, enamel slabs with WSL (microhardness).
Outcomes: TMP was more effective than TM alone or 3000 ppm F solution in preventing demineralisation.

Author: Oh et al.105
Year: 2014
Location: Anyang
Design: In vitro model assessing the colour and surface hardness of bovine teeth after bleaching treatments, subsequent to the application of TM or various fluoride varnishes.
Outcomes: Both TM and varnishes applied before bleaching did not reduce the effectiveness of bleaching, and led to increased surface hardness.

Author: Kallayathi, Panich, Poolthong71
Year: 2008
Location: Bangkok
Design: Enamel slabs (microhardness).
Outcomes: TM treatment protected enamel from softening from cola drink exposure.

Author: Panich, Thanyakoop109
Year: 2011
Location: Khon-Kaen
Design: Effect of TM treatment on the microtensile bond strength of 4 adhesive systems to enamel.
Outcomes: Application of TM to enamel improved the microtensile bond strength for Optibond all-in-one*. It did not affect the microtensile bond strength for Optibond FL*, Clearfil SE bond*, and Adper Single Bond 2*.

Author: Panich, Poolthong108
Year: 2009
Location: Bangkok
Design: Enamel slabs, eroded with cola.
Outcomes: TM significantly increased the hardness of eroded enamel.

Author: Sukasaem, Panich, Poolthong106
Year: 2006
Location: Bangkok
Design: In vitro erosion model (cola drink).
Outcomes: TM increased hardness of enamel eroded by cola-drink. The remineralisation effect of TM was significantly higher than that of artificial saliva.

Author: Theerapiboon, Puanaiyaka, Maneenut152
Year: 2008
Location: Bangkok
Design: Enamel slabs with WSL (PLM).
Outcomes: TM treatment remineralised and reduced the volume of WSL in both permanent and deciduous enamel.

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Clinical Trials

AUSTRALIA

Author: Bailey et al.¹¹
Year: 2009
Location: Melbourne
Design: RCT, N=45 subjects (post-orthodontic WSL reversal), 12 weeks.
Outcomes: TM, applied twice daily for 12 weeks, produced more regression of post-orthodontic WSL than the placebo crème.

Author: Manton et al.⁹²
Year: 2006
Location: Melbourne
Design: RCT, in situ model, N=6, over 10 days.
Outcomes: TM produced 551% more remineralisation of enamel WSL than the placebo crème.

Author: Pukallus et al.¹¹⁷
Year: 2013
Location: Brisbane
Design: RCT, N=345 infants, 2 years.
Outcomes: Daily application of TM, from the time of tooth eruption until approximately 24 months old, has the greater ability, compared to chlorhexidine, to reduce Streptococcus mutans presence in children who had these bacteria detected at early stages.

Author: Shen et al.¹⁴⁰
Year: 2011
Location: Melbourne
Design: RCT, in situ model, N=6, over 10 days.
Outcomes: Only TM and TMP significantly increased salivary calcium and phosphate levels. TM and TMP were superior to 5000 ppm F toothpaste. TMP produced the highest level of enamel lesion remineralisation. Clinpro® was not significantly different to 1000 ppm F toothpaste.

Author: Tabatabaee, Walsh¹⁴⁷
Year: 2015
Location: Brisbane
Design: RCT, N=60, 4 weeks.
Outcomes: TMP reduced plaque area, plaque maturity and plaque acid production on maxillary anterior teeth, compared to both a fluoride placebo paste which was identical but lacking CPP-ACP, and a no-treatment control.

Author: Vlacic¹⁶²
Year: 2007
Location: Brisbane
Design: RCT, N=12, over 12 months.
Outcomes: TM caused a progressive reduction in sensitivity to air stimulation, and also improved stimulated salivary flow and pH.

Author: Walsh et al.¹⁶⁵
Year: 2010
Location: Brisbane
Design: RCT, N=36 subjects, over 56 days, versus potassium nitrate toothpaste.
Outcomes: TM reduced sensitivity to air, osmotic, thermal and tactile stimuli, with equal effectiveness to potassium nitrate toothpaste.
Laboratory Studies

AUSTRALIA

Author: Adebayo, Burrow, Tyas
Year: 2008
Location: Melbourne
Design: Dentine slabs Microshear Bond Strength (MSBS), Clearfil SE Bond*, G-Bond.
Outcomes: TM treatment did not affect the MSBS of both the 2-step and the all-in-one adhesive to dentine, when the smear layer was retained before treatment. Removal of the smear layer before treatment resulted in higher MSBS on deep dentine for the 2-step self-etching adhesive, and a lower MSBS on superficial dentine for the all-in-one adhesive.

Author: Adebayo, Burrow, Tyas
Year: 2009
Location: Melbourne
Design: Enamel slabs.
Outcomes: Treatment with TM did not inhibit phosphoric acid etching of enamel. Resin infiltration into enamel was unaffected. Enamel etching/conditioning improved bonding efficiency of a self-etching primer adhesive, after TM application.

Author: Alkhtib et al.
Year: 2013
Location: Melbourne
Design: In vitro bleaching (enamel hardness).
Outcomes: Application of TM after bleaching was able to re-establish the baseline enamel hardness and reduced modulus, decreasing the adverse effects of bleaching enamel.

Author: Cai et al.
Year: 2009
Location: Melbourne
Design: Analysis of available Calcium, Phosphate and Fluoride ions.
Outcomes: Compared to other calcium/phosphate containing products, TMP has significantly more bio-available Calcium, Phosphate and Fluoride ions.

Author: Crombie et al.
Year: 2013
Location: Melbourne
Design: In vitro post-eruptive ‘maturation’ of MIH-affected enamel, TM, 14 days.
Outcomes: TM applications increased mineral content and reduced porosity of developmentally hypomineralised enamel.

Author: Manton et al.
Year: 2008
Location: Melbourne
Design: Enamel stained with tea.
Outcomes: TM used with carbamide peroxide did not affect bleaching effectiveness and enhanced aesthetics by increasing lustre and translucency.

Author: Manton et al.
Year: 2006
Location: Melbourne
Design: Enamel slabs with WSL.
Outcomes: TM caused more remineralisation of white spot lesions than human saliva.

Author: Mayne et al.
Year: 2011
Location: Melbourne
Design: Enamel slabs with WSL and orthodontic brackets.
Outcomes: TMP produced high percentages of remineralisation of WSL, which reduced the extent of enamel damage caused by bracket removal subsequently.

Author: Piekarz et al.
Year: 2008
Location: Adelaide
Design: In vitro demineralisation cycles (1500 one-minute exposure cycles) to white wine (pH = 3.5); TM was applied every 20 cycles.
Outcomes: TM reduced wine erosion in both enamel and dentine/cementum.

Key

AFM Atomic Force Microscopy
RMGI Resin-modified Glass-ionomer
MIH Molar Incisor Hypomineralisation
TM GC Tooth Mousse®
NaF Sodium Fluoride
APP Acidulated Phosphate Fluoride
XRD X-ray Diffraction
MSBS Microshear Bond Strength
TMP GC Tooth Mousse Plus®

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Laboratory Studies (cont.)

**Australia/New Zealand**

Author: Ranjitkar et al.\(^{122}\)
Year: 2009
Location: Adelaide
Design: Enamel and dentine, eroded with citric acid and abraded with toothbrush.
Outcomes: TM significantly reduced enamel and dentine wear compared to placebo paste and control.

Author: Ranjitkar et al.\(^{123}\)
Year: 2009
Location: Adelaide
Design: Enamel slabs, severe erosion under load.
Outcomes: TM wear reduction was significantly better than placebo paste (TM minus CPP-ACP), which was significantly better than the control.

Author: Ranjitkar et al.\(^{124}\)
Year: 2009
Location: Adelaide
Design: In vitro erosion model (dentine wear rate, HCl, pH 3.0, TM).
Outcomes: Dentine wear was reduced significantly with continuous application of TM.

Author: Sudjali et al.\(^{145}\)
Year: 2007
Location: Melbourne
Design: Extracted teeth were exposed to a demineralising solution (QLF).
Outcomes: TMP was better at reducing mineral loss around orthodontic brackets than TM or fluoride alone.

Author: Wong et al.\(^{171}\)
Year: 2010
Location: Melbourne
Design: Analyses of H\(_2\)O\(_2\) levels in the pulp chambers of teeth treated with and without TM prior to bleaching.
Outcomes: A 2 week application of TM, prior to the use of an in-office bleaching gel, did not adversely affect the bleaching effectiveness, but reduced the levels of hydrogen peroxide entering the pulp chamber.

**NEW ZEALAND**

Author: Batra et al.\(^{16}\)
Year: 2011
Location: Dunedin, New Zealand
Design: In vitro MIH enamel slabs treated with 1.5% sodium hypochlorite and TM.
Outcomes: Application of TM improved the mechanical properties of enamel affected by MIH.


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References (cont.)


References (cont.)


GC Tooth Mousse® and GC Tooth Mousse Plus®

GC Tooth Mousse® is a great tasting water-based crème that contains RECALDENT™ (CPP-ACP), a milk-derived protein that provides high concentration bio-available calcium and phosphate. GC Tooth Mousse Plus® has the added benefit of 900 ppm fluoride, which approximates the level of fluoride present in adult strength toothpastes. GC Tooth Mousse Plus® is recommended for children at least 6 years old and older patients where additional fluoride exposure is desired. When GC Tooth Mousse® or GC Tooth Mousse Plus® are applied in the oral environment, RECALDENT™ (CPP-ACP) binds to biofilms, plaque, bacteria, hydroxyapatite and soft tissue localising calcium, phosphate (and fluoride).

RECALDENT™ (CPP-ACP) is the end result of many years of research by the University of Melbourne into the anticariogenic properties of milk. Key applications supported by research include: high caries risk patients, salivary disfunction, reversing active white spot lesions, hypomineralised molars, root caries prevention, erosion, sensitivity, tooth whitening (lightening), orthodontics, radiation induced xerostomia and bonding strength enhancement.

GC Tooth Mousse Plus®
Topical crème with calcium, phosphate and fluoride
Assorted pack 10pcs contains:
4 x Mint, 4 x Strawberry, 2 x Vanilla, 40g tube (35ml)
Also available in single flavour 10 pack:
Mint only.

GC Tooth Mousse®
Topical crème with calcium and phosphate
Assorted pack 10pcs contains:
2 x Melon, 2 x Strawberry, 2 x Tutti-Frutti, 2 x Mint,
2 x Vanilla, 40g tube (35ml)
Also available in single flavour 10 pack:
Strawberry, Vanilla or Mint.