Poster # 1291

Tetrahydrocurcumin (Turmeric) *In-Vitro* and Clinical Validation for Oral Care Therapeutics Benefits

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Objective

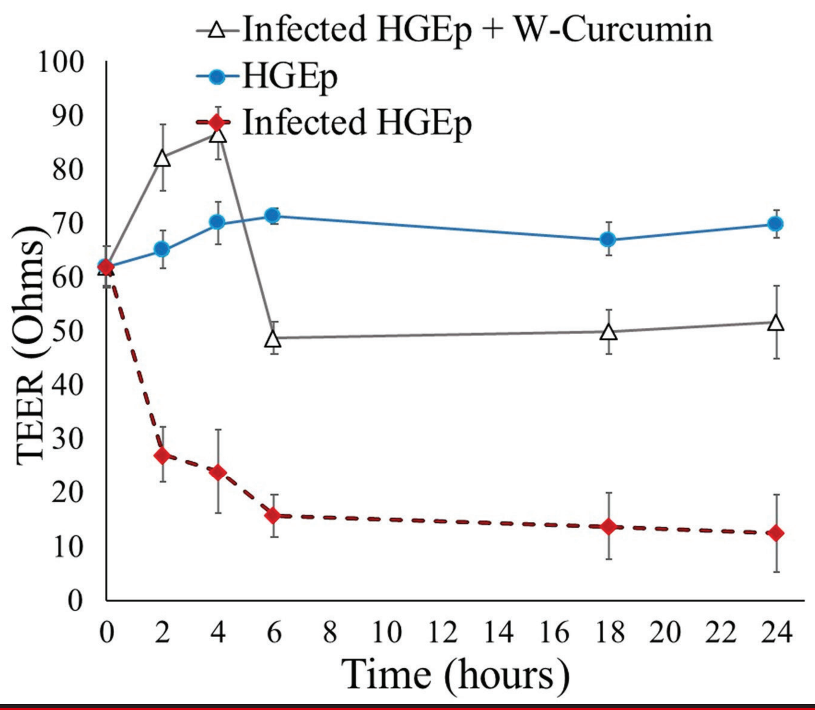
In-vitro and clinical validation of tetrahydrocurcumin toothpaste for maintaining epithelial barrier integrity, inflammation and gingivitis reduction.

Conclusions

The *in-vitro* data demonstrate that treatment of tetrahydrocurcumin maintains gingival barrier integrity measured as TEER response to *P.gingivalis* infection, reduces PGE2 inflammatory markers and delivers strong antioxidant potential. Finally, the human clinical study demonstrated that a toothpaste formulation with 0.3% tetrahydrocurcumin provided significantly greater reductions in plaque and gingivitis compared to a regular fluoride dentifrice and provides a therapeutic alternative for patients with gingivitis.

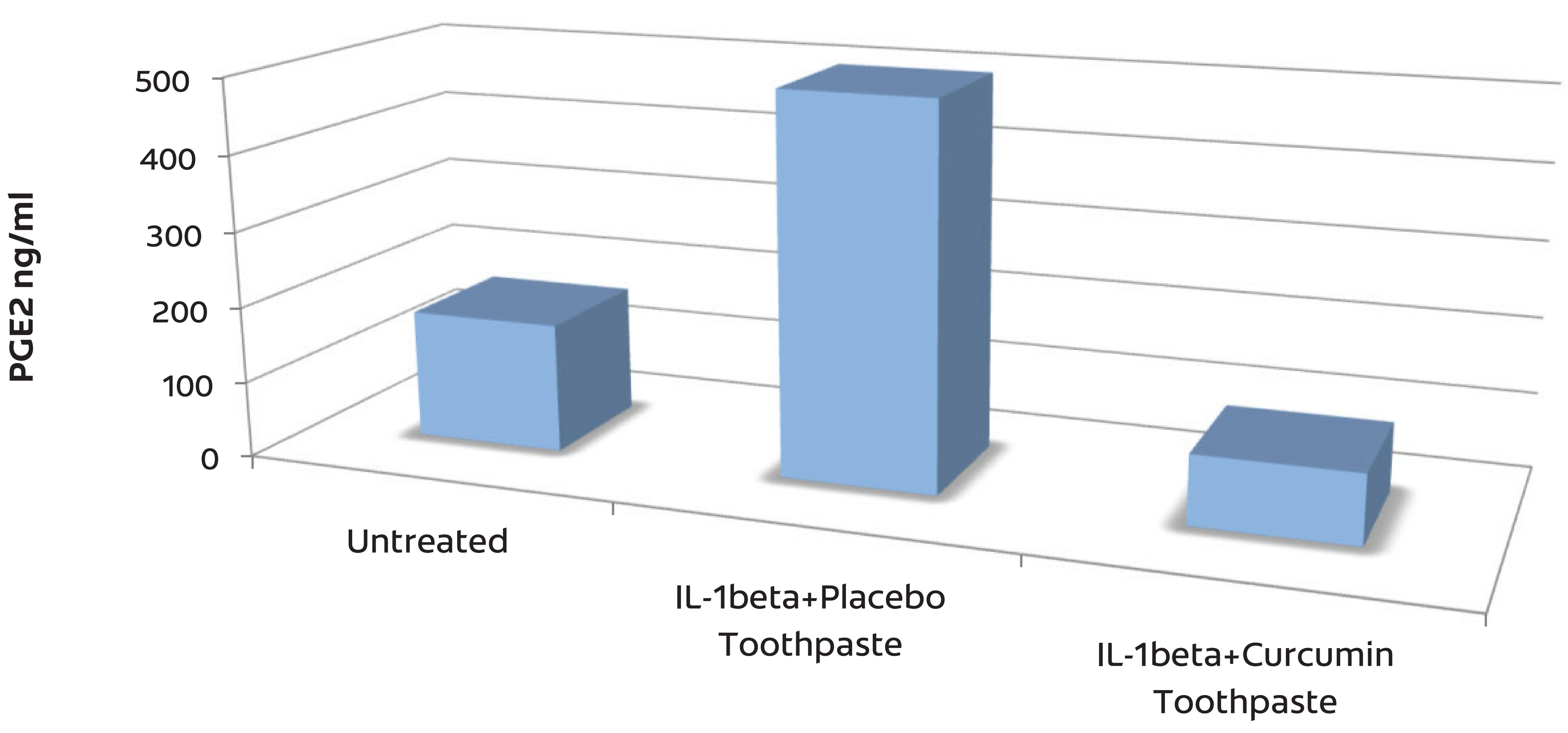
Results

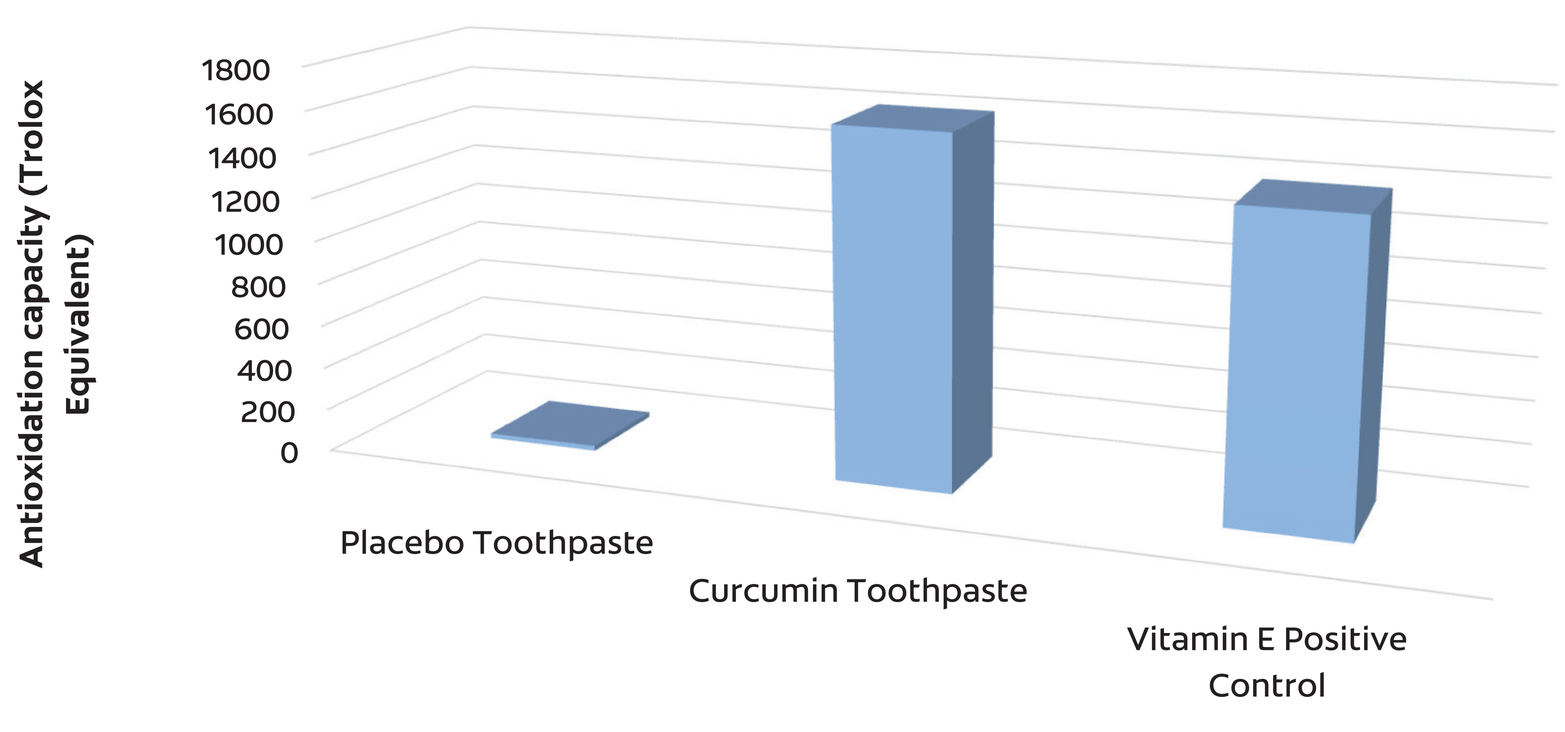
In vitro **validation - effect of *P. gingivalis* infection on the Transepithelial Electrical Resistance (TEER) values of gingival epithelial cells (HGEp) monolayers in comparison to curcumin pre-treated HGEp monolayers. The TEER values of HGEp subjected to pre-treatment with curcumin did not significantly decreased at the end of the challenge period as compared to non-infected HGEp; in contrast, the TEER significantly decreased during the bacterial infection period in comparison to curcumin pre-treated cells at the same time points. p < 0.001 (Figure-1)**



In-vitro **validation studies demonstrated that compared to placebo toothpaste curcumin toothpaste deliver strong antioxidant efficacy (Figure-2)**

In-vitro **studies demonstrate that when compared to placebo toothpaste treated gingival tissues, curcumin toothpaste treated tissues demonstrated significant reduction in IL-1beta mediated PGE2 inflammatory biomarker in culture supernatants (Figure-3)**





The results of single-center, double-blind, parallel-group and randomized human clinical study supports that (i) a fluoride toothpaste containing 0.3% tetrahydrocurcumin exhibited statistically significant reductions from baseline in dental plaque and gingivitis parameters after 6 months of product use and (ii) a fluoride toothpaste containing 0.3% tetrahydrocurcumin provided significantly greater reductions in dental plaque and gingivitis parameters as compared a commercially available fluoride toothpaste after 6 months of product use (Table-1)

Gingival Index
6 Month Results
Between Treatment Reductions

Index	Percent Reduction	Sig.
Gingival Index (Whole Mouth)	30.9%	p<0.001
Gingival Severity (Gum Bleeding)	50%	p<0.001
Gingival Interproximal (In-between teeth)	17.5%	p<0.001

Plaque Index
6 Month Results
Between Treatment Reductions

Index	Percent Reduction	Sig.
Plaque Index (Whole Mouth)	18.8%	p<0.001
Plaque Severity (High scores)	50%	p<0.001
Plaque Interproximal (In-between teeth)	28.8%	p<0.001

Methods and Materials

- *In-vitro* barrier Integrity efficacy
  - Primary gingival epithelial *in-vitro* tissue models (HGEp) were pretreated with Curcumin and infected with *P. gingivalis* bacteria
  - Barrier function was assessed via transepithelial electrical resistance (TEER) assay
- Curcumin stability in toothpaste
  - HPLC based analytical method was used to assess stability of tetrahydrocurcumin in toothpaste formulation. The initial assessment of tetrahydrocurcumin in the paste had 98% stability, and after 13 weeks of accelerated aging at 40 degree Celsius the stability of tetrahydrocurcumin was 99.99%
- Curcumin toothpaste *in-vitro* antioxidant efficacy
  - Curcumin toothpaste slurry was prepared in water
  - Antioxidation capacity of toothpaste was measured by a biochemical anti-oxidation *in-vitro* assay
- Curcumin toothpaste *in-vitro* anti-inflammatory efficacy
  - Curcumin slurry was prepared in water and applied topically on gingival Matek tissues for 2 minutes and rinsed off
  - Treated tissues were fed with tissue culture media, incubated overnight in the incubator and supernatants were collected and assessed by PGE2 ELISA assay
- Curcumin toothpaste Plaque/Gingivitis human clinical validation
  - Randomized, single-center, two-cell, double-blind and parallel-group clinical study was conducted in the San Luis Potosi, Mexico area to evaluate the effect on gingival inflammation of a fluoride toothpaste containing 0.3% tetrahydrocurcumin in patients with established dental plaque and gingivitis over a 6-month period of product use.

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