Clinical Evaluation of Chlorhexidine Hydrochloride/Ketorolac Tromethamine Orobuccal Bilayered Device for Treatment of Periodontitis and Apthous Ulcer (Preliminary Study)

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Purpose
To evaluate the clinical effects of new orobuccal bilayered devices contain Chlorhexidine hydrochloride (Chx) and Ketorolac tromethamine (KT) in periodontitis and aphthous ulcer cases.

Methods
Seven devices (M1 to M7) contain Chx and KT were subjected to this study. Ethical approval for this clinical study was obtained from the Research Ethical Committee, Faculty of Pharmacy, Cairo University. Ten out patients Clinic of Oral Medicine, Periodontology and Oral Diagnosis Department, Faculty of Dentistry, Misr university for science and technology (MUST)for each device under a periodontal examination at baseline (week 0) and after two weeks. All patients showed at least two teeth with periodontal pockets of 5-8mm in depth without involving the apex of the tooth. Each patient was supplied with a new toothbrush and they asked to clean their mouth and teeth with a tooth paste and brush. Then the dentist cleaned each pocket by scaling. Scaling removed tartar and bacteria from tooth surface and beneath gum. Then root planning smoothes the root surfaces. One device was put at the base of the periodontal pocket. Treated sites were evaluated during two weeks. Clinical periodontal parameters were recorded, these are the Plaque Index, Bleeding on Probing, Pocket Probing Depths and Probing Attachment Levels at pocket site of tooth. The devices achieved the best improvement were subjected to evaluate their analgesic activity on six patient suffered from aphthous ulcer by using a special scoring system.

Results
The bilayered orobuccal device was expected to provide drug delivery of Chx towards buccal infection (periodontal pockets or aphthous ulcers) and the other layer provides KT to the site of injury to decrease pain sensation associated with the disease. The results of clinical parameters showed that there was a significant difference for M1 and M3 devices than the control group. M1 device was significantly different than M3 in term of decreasing of the pain sensation accompanied with aphthous ulcer cases.

Conclusion
This new device contains Chx and KT is useful for both periodontal and local analgesic application and showed good patient compliance with lower G.I.T side effects. The device showed immediate analgesic activity. The device is a safe, well tolerated and highly effective promising new treatment for healing common mouth ulcers.