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The Potential of Statins for Buccal Delivery

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Introduction:
Several drugs are currently available for the treatment of hyperlipidemia, but the most potent agents are known as 3-hydroxy- 3-methylglutaryl-coenzyme (HMG CoA reductase) inhibitors or statins. Statins like Atorvastatin, fluvastatin, lovastatin, Pravastatin, Simvastatin and Rosuvastatin are effective in modifying low-density lipoproteins (LDL), high-density lipoproteins (HDL), total cholesterol (TC) and triglycerides (TG) levels. All agents lower LDL in a dose dependent manner, approximately 20-38% with initial doses and 35- 61% with maximal doses. Statins act by competitively inhibiting HMG-CoA reductase. On a molecular level, statins are similar to HMGCoA occupying the place of HMG-CoA in the enzyme and thereby reduce the rate of mevalonate production which in turn reduces the cholesterol production, as well as a number of other compounds via several mechanisms.

Objectives:
Simvastatin appears to have the ability to reduce low-density lipoprotein cholesterol (LDC-C) and increase HDL cholesterol (HDL-C) to a greater degree than the other approved statins providing a 63% LDL-C reduction at a dose of 40 mg. Simvastatin is also considered as a stimulator for bone formation. Statins are widely prescribed as cholesterol-lowering therapy, and are considered firstline therapeutic agents for the prevention of coronary heart disease and atherosclerotic disorders related to hypercholesterolemia. Statins also have immunomodulatory, neuroprotective and antiinflammatory properties that are being explored for potential benefits in central nervous system disorders. Statins may also be used to reduce mortality and neurological disability from stroke and reduce the incidence of dementia, although the latter is controversial [7,8]. All statins, both fungal metabolites and synthetic compounds, reduce the coronary heart disease similarly when adjusted for differences in lipid changes. Statins are categorized based on their origin, hydrophilicity/hyrophobicity and specificity. Lovastatin, pravastatin and simvastatin are all obtained by fungal fermentation while atorvastatin, fluvastatin, rosuvastatin and cerivastatin (withdrawn from the market in 2001) are entirely synthetic.

Results:
Buccal mucoadhesive formulations may prove to be an alternative to the conventional oral medications as they can be readily attached to the buccal cavity which can be retained for a longer period and removed at any point of time. Buccal adhesive drug delivery systems using, films, layered systems, matrix tablets, discs, microspheres, ointments and hydrogel systems have been studied and reported by several research groups. There are numerous important considerations that include biocompatibility (both the drug/device and device/environment interfaces), permeability, reliability, durability; environmental stability, accuracy, delivery scalability and are to be considered while developing such formulations. Several buccal adhesive delivery devices were developed at the laboratory scale by many researchers either for local or systemic actions. Recent reports suggest that the market share of buccal adhesive drug delivery systems are increasing in the American and European market with the steady growth rate of above 10% with an increasing demand now in India. Some of the commercially available buccal adhesive formulations are seen.

Conclusions:
Stains have wide variety of advantages in the treatment using buccal delivery systems. Many steps have been taken in this direction, but research must continue to provide ever better controls, improved efficacy and targeting better drug loading and lowering of the drug dose to diminish side effects, toxicity and enhance bioavailability. The future research on buccal delivery of statins with ionic or nonionic polymers having excellent mucoadhesive properties, biocompatibility and stability is very important to meet the patient needs..