

## ~ Research Spotlight ~

### **Penn Dental Medicine Researchers Study Safety of Nasal Spray to Numb Teeth**

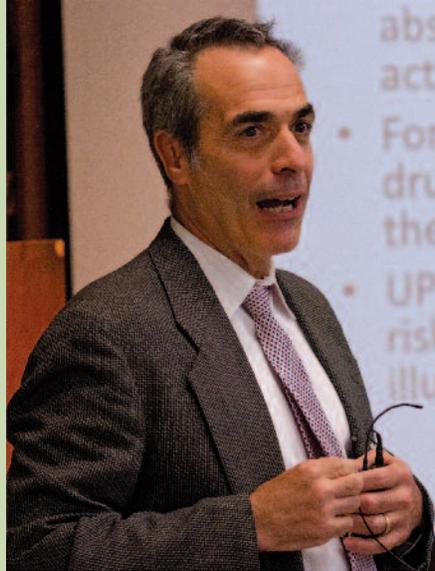
Surveys indicate that up to 40 million people in the U.S. may avoid going to the dentist because they fear needle injection pain, says Dr. Elliot Hersh, Professor, Department of Oral Surgery and Pharmacology. To counter that problem, Dr. Hersh and a Penn Dental Medicine research team recently published findings on the safety of promising technology to numb the top teeth using an intranasal spray.

In a second study that will be submitted for publication soon, Dr. Hersh and Penn Dental Medicine researchers tested an intranasal application of the pain reliever ketorolac to see how well it controlled pain following dental implant procedures, the first time it had been tested in this patient population.

While these two studies focus on the nose as a means to deliver pain relief and numb teeth, Dr. Hersh, who was principal investigator of both studies, says his more general research interest is to study novel formulations of local anesthetics and analgesics. He was an investigator in a number of studies that led to FDA approval for new formulations of delivering medication, including ibuprofen in liquigel form.

One advantage of intranasal delivery, as with the liquigel formulation, is that medication often can get into the bloodstream faster than something in tablet form, which must disintegrate and dissolve in the stomach, Dr. Hersh says. The intranasal ketorolac, he notes, appears as quick acting as an intramuscular injections.

In the study that was published in August in the *Journal of the American Dental Association*, Dr. Hersh and his colleagues tested a nasal spray that was



Dr. Elliot Hersh, Professor, Department of Oral Surgery and Pharmacology

3 percent tetracaine, a local anesthetic, and 0.05 percent oxymetazoline, a vasoconstrictor that helps the tetracaine stay in place. Spraying a plume to the back of the nose allowed the drugs to reach the three nerves in the maxillary sinus that give sensation to the upper teeth.

This phase II trial tested the medical tolerance of participants, measuring blood pressure, heart rate, and blood oxygen saturation. Even at double the maximum dose, the tetracaine/oxymetazoline combination “produced modest and generally clinically insignificant changes in cardiovascular parameters,” according to the study.

Based on these promising results, the FDA has approved Phase III efficacy trials to see how well the intranasal anesthetic works on patients undergoing restorative procedures. One of these trials, led by Dr. Hersh, is expected to get underway at Penn Dental Medicine by early November. “We’re hoping for an 85 to 95 percent success rate of procedures completed without the need for injections,” he says, which would

be close to the 92 – 97% percent success rate of a lidocaine plus epinephrine injections.

Although the nasal spray has its drawbacks—it only works on the upper teeth, and doesn’t reliably anesthetize the nerve that impacts the molars and wisdom teeth — Dr. Hersh says, “I think if you can get most of the maxillary teeth numb without the use of needles, a lot of clinicians and patients are going to jump on that.”

The second study involved intranasal ketorolac, a pain medication marketed as SPRIX, which was approved more than a year ago for moderate to moderately severe pain, but has not been studied in patients following routine dental implant surgery. The researchers found that the intranasal application of ketorolac produced meaningful pain relief in about five minutes and it lasted at least six hours for the majority of dental implant patients studied.

“I was pleasantly surprised at how quickly the pain relief came on — more rapidly than any tablet formulation I’ve studied,” Dr. Hersh says.

In addition, Dr. Hersh says the study is just one of a handful to look generally at pain levels in patients who receive implants. Although small, the study found that almost 90 percent of subjects experienced pain of at least moderate intensity within 4 hours of surgery, and more than half continued to use the intranasal ketorolac for pain control for three days following their implants. “We wanted to characterize dental implant pain, and it was more than expected considering these patients had only 1 – 3 implants placed with no significant bone regeneration procedures performed,” he notes.

— Debbie Goldberg