

NEWS FLASH!

*Serendipitous medical outcome leads to NO SHOT DENTISTRY!
Coming Soon.*



Astounding, a simple nose spray could replace shots for the top front teeth.

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Penn Study Finds Nasal Spray Effective and Safe Anesthesia for Dental Work

How bout these apples?

A dentist gets 12 stitches and we get a possible quantum leap.

A fear of pain causes many people with dental phobias to avoid or delay needed treatment. In some cases, the injection of a numbing agent can be the most painful part of the visit. But with a new United States Food and Drug Administration-approved anesthetic that is administered with a brief nasal spray, that injection may not be necessary to achieve pain relief.

The spray, a drug called Kovanaze, was deemed safe and effective in a recent Phase 3 clinical trial led by University of Pennsylvania School of Dental Medicine researchers. The results of the study were published in the Journal of the American Dental Association.

“There is really nothing else like this out there,” said Elliot V. Hersh, the study’s lead author and a professor in the Department of Oral and Maxillofacial Surgery/Pharmacology at Penn Dental Medicine. “This is obviously a great thing for needle-phobic individuals, and it can reduce inadvertent needle-stick injuries in the clinic as well.”

The double-blind, randomized trial found that the compound, a combination of the local anesthetic tetracaine and the nasal decongestant oxymetazoline, was effective at preventing pain during a single restorative procedure in an upper bicuspid, canine or incisor in 88 percent of patients, a rate comparable to the

success of commonly used injectable numbing agents. The most common side effects were runny nose and nasal congestion; no serious side effects were reported.

Kovanaze was developed by St. Renatus and received FDA approval on June 29.

“St. Renatus would like to thank all of the dental professionals from the University of Pennsylvania, University of Maryland and Loma Linda University who conducted one of our Phase 3 clinical trials in support of our Investigational New Drug filing with the FDA,” said Steve Merrick, CEO of St. Renatus. “Their dedication to dental research has supported a number of new products being approved by the FDA. We look forward to working with Dr. Hersh and his team on future projects.”

Hersh collaborated on the work with Penn Dental Medicine’s Andres Pinto (now at Case Western Reserve University), Mana Saraghi (now an attending dentist anesthesiologist at St. Barnabas Hospital Health System), Najeed Saleh and Lisbeth Pulaski; the University of Maryland’s Sharon M. Gordon, Douglas Barnes, Gary Kaplowitz, Ira Bloom and Mohammad Sabti; Loma Linda University’s Sean Lee, Michael Meharry and Yiming Li; the University of Pittsburgh’s Paul A. Moore; and the Analytical Solution Group’s David Y. He.

The idea for Kovanaze, or K305, emerged when St. Renatus co-founder, Mark Kollar, was hit in the chin playing basketball, requiring 21 stitches. A fellow player happened to be an ear, nose and throat specialist, who placed the sutures and also diagnosed Kollar with a deviated nasal septum. The ENT performed the septum repair and, when Kollar returned to his office for a follow-up visit, gave him a nasal spray containing tetracaine to remove a nasal stent.

Once the stent was removed, Kollar noticed his teeth were numb. The ENT said a few other patients had reported the same sensation. Kollar, who happened to be a practicing dentist, went to his office to test his teeth with a dental electronic pulp stimulator and found that they were indeed numb.

The serendipitous discovery led Kollar to start a company with his business partner and co-founder, Jim Mulvahill. Shortly after the project was initiated, Kollar and Mulvahill became aware that Bryan Clay, an ENT from Jackson, Miss., had a patent issued on the idea of an intranasal dental anesthetic. Mulvahill, Kollar and Clay combined their resources, with Kollar taking the lead in formulation and scientific development. Kollar's research refined the anesthesia formula, leading to the invention of Kovanaze and additional patent protection.

To lead the Phase 3 trial, St. Renatus reached out to Penn Dental Medicine and Hershey, who had previously evaluated the safety and efficacy of a number of analgesic drugs including an early safety study on Kovanaze.

The trial recruited 150 adults who passed a health screening and were set to undergo a single dental filling in an upper bicuspid, canine or incisor. One hundred patients were assigned Kovanaze and 50 were assigned a placebo.

Patients received one spray, waited four minutes, received a second spray, waited 10 minutes and then a test drilling was performed. If the patients experienced pain at that point, they received a third spray. Patients who still experienced pain at that point received a rescue injection of local anesthetic to complete the procedure. Patients' heart rate and blood pressure were recorded at various times throughout the visit.

Eighty-eight percent of the people who received Kovanaze were able to have the dental restorative procedure completed without a rescue injection, compared to 28 percent for the placebo vehicle spray.

Before receiving the spray, all patients were given what's known as an alcohol sniff test to measure baseline sense of smell. Repeating the test just after the procedure and again a day later, the researchers found that the drug caused minimal changes in olfaction.

The K305 treatment had a small effect on blood pressure, causing it to rise slightly. Some patients reported nasal congestion, nasal discomfort, throat pain and irritation, headache and eye watering, but no serious adverse events were reported.

To follow up on the study, Hersh said the company will likely pursue additional investigations to see if more intensive dental procedures can be performed using this anesthetic, such as root canals or oral tissue biopsies. It's likely that further studies will also evaluate whether the drug can be safely administered to children. Currently the FDA has approved the drug for use only in individuals weighing at least 40 kilograms, roughly 88 pounds.

“It would certainly make for a more stress-free dental office visit for children as well as adults if we could replace some of these anesthetic injections with a simple spray,” Hersh said. “It may also keep some children out of the operating room, which would be a major cost savings to the child’s family and reduce potential morbidity associated with general anesthetic procedures.”

The research was supported by a grant from St. Renatus.

Dr. Madson has two doctorates a DMD in Medical Dentistry and an NMD in Naturopathic Medicine and he is adjunctive faculty at The Dental College of Georgia in the General Practice Residency where he teaches and lectures and has done so for over a decade. He is also certified in the ND YAG Laser, stem cells, biologic dentistry, and is also Board Certified in Botox and Facial Fillers. He is also Board Certified in Biologic Dentistry.

God Bless and have a brighter day,

Dale C. Madson, DMD, NMD, IBDM

PS. Should you have interest in stem cells, please come by and we can chat a bit.