

Gene therapy appears safe to regenerate gum tissue

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Scientists at the University of Michigan have developed a method of gene delivery that appears safe for regenerating tooth-supporting gum tissue -- a discovery that assuages one of the biggest safety concerns surrounding gene therapy research and tissue engineering.

Gene therapy is an accepted, viable therapeutic concept, but safety is a major hurdle, said William Giannobile, professor at the U-M School of Dentistry. The most notable incident highlighting the safety concerns of [gene therapy](#) research and treatment occurred several years ago when a teenager died when given the adenovirus during a gene therapy clinical trial at the University of Pennsylvania.

The U-M therapy also uses the adenovirus, Giannobile said, but the big difference in the U-M approach lies in the local application and much lower dose. Instead of injecting the genes into the blood vessels, where they can then travel through the [bloodstream](#) and result in unexpected and sometimes fatal reactions, U-M scientists put the genes on a localized area, directly on the tissue during surgery much like a paste.

"What the U-M study showed is (the topical method) is very well contained and doesn't distribute throughout the body," said Giannobile, who also directs the Michigan Center for Oral Health Research and has an appointment at the U-M College of Engineering's Department of Biomedical Engineering. "This approach alleviates the safety concern about negative reactions within the body.

"When the teenager died, it got into his bloodstream and he reacted to it. It was tragic. This is the first study of [periodontal disease](#) therapy that demonstrates the distribution of these genes is very safe, suggesting that it could be used in the clinic for clinical application.

"Our study doesn't look at all the safety concerns, but certainly this is very important to the field. The two clinical applications to date where it shows potential are periodontal disease and diabetic wounds. Maybe the reason for this is that both diseases result from a compromised or a defective healing environment."

The next step for the U-M team is to use the new gene delivery approach in human clinical trials, Giannobile said. The planning stages for these studies will commence in the next year.

The paper, called "Adenovirus Encoding Human Platelet-Derived Growth Factor-B Delivered to Alveolar Bone Defects Exhibits Safety and Biodistribution Profiles Favorable for Clinical Use," is partially available online. It's scheduled to appear in the May issue of the journal Human Gene Therapy. Co-authors include Po-Chun Chang, Joni Cirelli, Yang-Jo Seol, Qiming Jin, Jim Sugai, Nisha D'Silva and Theodora Danciu. The study was supported by the National Institutes of Health and the AO Foundation.

Source: University of Michigan ([news](#) : [web](#))

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