ADA PREVIEW EDITION

DENTAL TRIBUNE

The World's Dental Newspaper · U.S. Edition

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An undetectable, single veneer
Learn one dentist's techniques for preparing and bonding veneers.
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HYGIENE TRIBUNE
The World's Dental Hygiene Newspaper · U.S. Edition

Handling pediatric patients
These patients require a unique approach, which may not be intuitive for some adults.
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LAB TRIBUNE
The World's Dental Lab Newspaper · U.S. Edition

How to choose a CAD/CAM
One key aspect is yhr time required to adapt and utilize system.
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Dental diplomat brings relief to Afghanistan

An interview with Dr. James Rolfe, founder of the Afghanistan Dental Relief Project

Dr. James Rolfe from Santa Barbara, Calif., works as a dentist in Afghanistan. (Photo/Provided by Dr. James Rolfe)

By Robin Goodman, Group Editor

Dr. Rolfe, please tell our readers about what led you to become involved with dentistry in Afghanistan?

I watched the people of Afghanistan as they were continually abandoned by the world; first when the Soviets invaded, later when they were defeated, and still later when the Taliban were ousted. Virtually no aid was getting to the people.

In 2003, I was told that we needed to forget about Afghanistan and support invading Iraq, as a matter of national security. I had to do something. In September 2003, I flew to Wardak Province in Central Afghanistan with portable equipment and worked in an orphanage at an elevation of 11,000 feet for three weeks.

I would treat an orphan, and he would become my assistant. Working through the 40 or so orphans, I found that about 85 percent had the ability to work in dentistry.

Then I started seeing people from the surrounding cities. I saw many people who were literally on the

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Orlando welcomes ADA

World-class dentistry, Disney World and Universal Studio is the impressive triumvirate that awaits you in Orlando during the annual ADA meeting.
→ See pages 16A, 17A

INDUSTRY NEWS

The compromised implant site solution

The use and acceptability of implants today is considered both routine and highly predictable. With that, people more than ever before are considering the replacement of missing teeth by this method. Unfortunately, until now, a segment of this population has not been viewed as a viable candidate, particularly patients with compromised situations having to do with limited interdental spaces, advanced bone loss, convergent roots, age and financial constraints.

Anew® Implants (Dentatus, USA, New York) are "ideally designed for the compromised implant site; these 1.8 mm, 2.2 mm and 2.4 mm diam-

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New test to detect oral cancer

A new test for oral cancer, which a dentist could perform by simply using a brush to collect cells from a patient's mouth, is set to be developed by researchers at the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust.

The international research team, involving scientists in Sheffield, has been awarded $2 million from the United States National Institutes of Health to develop the test, which could provide an accurate diagnosis in less than 20 minutes for lesions where there is a suspicion of oral cancer.

The current procedure used to detect oral cancer in a suspicious lesion involves using a scalpel to perform a biopsy and off-site laboratory tests, which can be time consuming. The new test will involve removing cells with a brush, placing them on a chip, and inserting the chip into the analyzer, leading to a result in eight to 10 minutes. This new procedure will have a number of benefits, including cutting waiting times and the number of visits, and also cost savings for the National Health Service.

Professor Martin Thornhill (above) of the department of oral medicine at the University of Sheffield, England. The battery-powered analyzer (left) reads disposable nano-biochips that are slotted like credit cards and hold brush biopsies from patients' mouths in order to detect if the cells are cancerous. (Photos/ Provided by the University of Sheffield)

The team in Sheffield, led by Prof. Martin Thornhill, in the department of oral medicine at the University of Sheffield and a consultant in oral medicine at Sheffield Teaching Hospitals, has begun carrying out clinical trials on patients at Charles Clifford Dental Hospital for two years to perfect the technology and make it as sensitive as possible. If the trials confirm that the new technology is as effective as carrying out a biopsy, then it could become a regular application at dental offices in the future.

If oral cancer is detected early, the prognosis for patients is excellent, with a five-year survival rate of more than 90 percent. Unfortunately, many oral cancers are not diagnosed early and the overall survival rate is only about 50 percent, among the lowest rates for all major cancers. The project is being led by Prof. John McDevitt from Rice University, who has developed the novel microchip.

This new technology uses the latest techniques in microchip design, nanotechnology, microfluids, image analysis, pattern recognition and biotechnology to shrink many of the main functions of a state-of-the-art clinical pathology laboratory onto a nano-biochip the size of a credit card.

The nano-biochips are disposable and slotted like a credit card into a battery-powered analyzer. A brush-biopsy sample is placed on the card and microfluidic circuits wash cells from the sample into the reaction chamber. The cells pass through mini-fluidic channels about the size of small veins and come in contact with "biomarkers" that react only with specific types of diseased cells. The machine uses two LEDs, or light-emitting diodes, to light up various regions of the cells and cell compartments. Healthy and diseased cells can be distinguished from one another by the way they glow in response to the LEDs.

The technology is also being considered for future research projects for diagnosis and management of heart attacks, diabetes and other diseases. Thornhill said: "This new affordable technology will significantly increase our ability to detect oral cancer in the future. Diagnosis currently involves removing a small piece of tissue from the mouth and sending it to a pathologist. This is typically done at a hospital, can take a week or more and involves extra visits for the patient.

"With the new technology, a brush would be used to painlessly remove a few cells from the lining of the mouth that would be analyzed within minutes in the presence of the patient, so that the patient would know the result before leaving the clinic.

"This technology will make it easier for us to screen suspicious lesions in the mouth and separate non-cancerous lesions from those where there is a risk of cancer and those where cancer has already developed. We have just started to recruit patients to a study that is designed to ensure that the new technology is at least as good as the old method at distinguishing these different types of lesion.

"Ultimately, dentists and doctors may be able to use this technology to check suspicious lesions in the mouth and reassure the vast majority of patients that they haven't got cancer without even having to send them to the hospital." DT

(Source: University of Sheffield)

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The World's Dental Newspaper · US Edition

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The formula for making teeth

Each cusp of our teeth is regulated by genes that carefully control its development. A similar genetic puzzle also regulates the differentiation of our other organs and of all living organisms.

A team of researchers at the Institute of Biotechnology of the University of Helsinki has developed a computer model reproducing population-level variation in complex structures such as teeth and organs.

The research takes a step toward the growing of correctly shaped teeth and other organs. The results were published this month in Nature, the science journal.

Academy Professor Jukka Jernvall and his team investigated the evolutionary development of mammal teeth. After more than 15 years of work, the team has compiled so much data that the main aspects of a formula for making teeth are beginning to be clear.

The model shows that regulation of tooth development is already well known. Teeth are a kind of "model species" for Jernvall's team, which means that the study results also tell about the development of other organs.

A mathematical model applied to the teeth of ringed seals

According to a mathematical computer model, a rather simple basic formula seems to be behind the complex gene puzzle resulting in tooth formations; the jungle of gene networks has a "patterning kernel" regulating the variation of teeth among individuals in the same population.

In addition, the variation of human teeth from the incisors to the molar teeth may result from a single factor regulating cell division.

The researchers tested their theoretical model, which is based on mouse tooth development, by investigating seal teeth. The Ladoga ringed seal collection of the Finnish Museum of Natural History at the University of Helsinki provided an ideal population sample for the research because dentitions are highly variable.

New teeth and organs?

The mathematical model proposed by the research team may provide a new kind of understanding on the formation of organisms' three-dimensional shapes: How do different levels of ontogeny function together? What factors guide the emergence of specific external features?

The new research results may promote medical research, such as growing new organs.

Jernvall is known as an international pioneer in cross-disciplinary evolutionary development biology. A few years ago, the science journal Nature chose a teeth evolution work conducted by Jernvall and two post-doc researchers as one of the 15 educational topics in the field of evolutionary biology.

The research published now was conducted with Jernvall's third post-doc researcher, Isaac Salazar-Ciudad. Salazar-Ciudad currently works at the Autonomous University of Barcelona in Spain. DT

(Source: www.Eurekalert.com*)*

Reference

- Isaac Salazar-Ciudad, Jukka Jernvall. A computational model of teeth and the developmental origins of morphological variation. Nature, 2010; DOI: 10.1038/nature08838.

Could modern day research mean that one day in the future those missing teeth can have new ones grown in a lab? (Photo/Michael Jung, www.dreamstime.com*)*

Dentists extract stem cells for future regenerative medicine

The recent discovery by the National Institutes of Health that stem cells exist in teeth has the potential to transform dentistry and the future of medical treatments.

Now, three dentists in Denver — Dr. James DeLapp, Dr. H. Candace DeLapp and Dr. Sarah Parsons — are offering their patients a chance to bank valuable stem cells for use in future regenerative medical therapies.

Stem cells found in teeth are extracted by Cottonwood Dental Group and are cryo-preserved, enabling patients to recover and save very powerful stem cells found in their teeth. The dental practice is partnering with a company called StemSave to preserve the stem cells.

Stem cells are the basis for the emerging field of regenerative medicine. There are more than 78 clinical trials involving stem cell treatments under way, and the U.S. military is developing stem cell therapies to treat soldiers wounded in action.

The current research being conducted suggests that stem cell therapies may, in the future, be able to treat many of today's most difficult diseases, such as diabetes, Parkinson's, Alzheimer's, muscular dystrophy, cancer and many more.

Living stem cells have been routinely found in teeth and for the most part have been discarded after extraction. Stem cells from teeth appear to replicate at a faster rate than stem cells from other tissues. Stem cells in the body age over time, and their ability to regenerate slows down and become less effective. The earlier in life that the stem cells are secured, the more valuable they are likely to be later in life.

Not all teeth are eligible for stem cell preservation. As an example, the tooth needs to have a healthy pulp. It needs to have an intact blood supply and be free from infection and deep cavities. Stem cells may be recovered from patients who are middle aged, but the younger they are the better.

Deciduous teeth or baby teeth may be the best source of stem cells. The incisors that have begun to loosen or the baby canine teeth appear to be the best candidates. The pulps of naturally loosened teeth may not have an adequate blood supply. Wisdom teeth between the ages of 16 and 20 years old may be a very good source. The pulp at this stage is large and the potential for viable stems cell is high. Obviously teeth that have root canals or extensive dental treatment are poor candidates.

StemSave is a collaborative effort between stem cell researchers and the dental community to provide families and individuals an affordable, non-invasive methodology for the recovery and cryopreservation of the powerful and valuable adult stem cells residing within baby teeth, wisdom teeth and permanent teeth for future use in personalized medicine and regenerative medical therapies.

According to StemSave, the patented technology has the potential to turn a patient visit into what may one day be a potentially life-saving experience. Patients should consider banking their stem cells while undergoing procedures such as the extraction of wisdom teeth or baby teeth, the dentists said. These planned dental procedures provide an ideal time to preserve one's stem cells.

Although there are no current medical treatments available using stem cells, much research for various diseases involve treatment that may involve stem cells in the future.

StemSave provides an affordable and non-invasive method for the recovery and cryo-preservation of the powerful children or adult stem cells found in teeth by teaming up with dentists to harvest stem cells during routine dental procedures. DT

(Source: PRWeb)

Hu-Friedy product donation benefits NCOHF affiliate

Hu-Friedy, a manufacturer of dental instruments, recently donated dental products valued at more than $11,000 to the National Children's Oral Health Foundation: America's Toothfairy (NCOHF) to enhance vital oral health services for children from vulnerable populations. Howard University, a member of the NCOHF affiliate network, is recipient of the contribution.

The Hu-Friedy dental supplies will aid in expansion of Howard University's pediatric oral health outreach programs in the Washington, D.C., metropolitan area.

As an NCOHF affiliate, Howard University is part of a national network of more than 60 nonprofit health-care programs with a shared mission to provide the best education, prevention and treatment programs for underserved children.

In less than five years, NCOHF has delivered more than $7 million in funding and donated products to affiliate partners across the country.

"Hu-Friedy is proud to be affiliated with National Children's Oral Health Foundation, and we are happy to make this donation, which will help children get access to care that will improve their overall oral health," said Ron Saslow, president and CEO of Hu-Friedy.

"At Hu-Friedy our mission is to improve lives through better dentistry — smile after smile — so our support of the NCOHF is a natural extension of this fundamental purpose."

"We are very grateful that Hu-Friedy supports our mission to eliminate children's suffering from preventable pediatric dental disease," said Fern Ingber, NCOHF president and CEO.

"Generous NCOHF partners such as Hu-Friedy make it possible for NCOHF affiliates to give underserved children the comprehensive care they deserve." DT

Hu-Friedy dental supplies will aid in the expansion of Howard University's pediatric oral health outreach programs in and around Washington, D.C. (Photo and text/NCOHF)

Diagnosis for Michael Douglas highlights oral cancer risk

The British Dental Health Foundation is calling for more attention to be paid to mouth cancers. Oral health experts and the foundation are advising the public to regularly check their mouths after news broke recently of actor Michael Douglas being diagnosed with oral cancer.

The Academy Award winner was diagnosed with a tumor in his throat, and he now faces an eight-week course of chemotherapy and radiotherapy. This high-profile case has brought oral cancers into the limelight, and oral health experts are keen to make the public more aware of the key risk factors and early warning signs.

Douglas quit smoking in 2006, after a long "half a pack a day" habit. Yet, the possibility of developing oral cancer remains higher for ex-smokers than non-smokers for 20 years after quitting.

Tobacco is considered to be the main cause of mouth cancer, with three in four cases being linked to smoking. Drinking in excess is also a known factor, with those who both smoke and drink in excess being up to 30 times more likely to be at risk.

"It is crucial the public know about the risk factors and early symptoms as early detection can save lives," said Dr. Nigel Carter, chief executive of the British Dental Health Foundation. "Survival rates can increase from just 50 percent to over 90 percent with early detection, yet over two-thirds of cases are diagnosed at a late stage."

"Many people have not heard of mouth cancer and do not realize how common it is," Carter said. "The latest figures show that men over the age of 40 are twice as likely to develop the condition as women." DT

(Source: British Dental Health Foundation)

Tell us what you think!

Do you have general comments or criticism you would like to share? Is there a particular topic you would like to see more articles about? Let us know by e-mailing us at *feedback@dental-tribune.com*. If you would like to make any change to your subscription (name, address or to opt out) please send us an e-mail at *database@dental-tribune.com* and be sure to include which publication you are referring to. Also, please note that subscription changes can take up to 6 weeks to process.

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verge of death from their dental problems.

I learned that no dental care was available in the entire province. Thus, I decided to start a dental clinic to provide basic dental treatment, and a training program to train the orphans and widows to be dental technicians.

What did you do then?

I purchased a 40-foot steel, shipping container and spent 18 months modifying it into a modern, three-chair dental office that was completely self-contained with its own water and power. Then I shipped it, along with 120,000 pounds of other equipment and supplies, to Afghanistan on a cargo ship.

When it arrived in Pakistan, I flew to Kabul to look at the site for the clinic that was donated by an Afghan cabinet minister. I went to the land site, but I had been deceived; I found that it was not available.

For the next six weeks, I searched for another site, but in the end, I had to return the shipment to America or lose it to the minister, who was sponsoring the shipment. It took almost a year to locate another site. I shipped it again, and this time the shipment became hung up on the Pakistan-Afghanistan border for almost four months. When it was released, it was the dead of winter.

I had to work outside setting up the clinic during the coldest part of the Afghan winter. The house on the property had no heat, water or electricity. My fingers were frostbitten and I lost about 15 pounds.

By the time I was finished in January, the cold winter had frozen all of the pipes in the clinic, and I had to leave everything and come back later. Returning in May, I hired an Afghan dentist and an assistant, and opened the clinic to the public.

How has this worked out?

Good. We operated the clinic with one dentist for about a year, then hired two more dentists and began training orphans and widows as dental technicians. In the first year of the school, we were able to train dental assistants, laboratory technicians and dental hygienists.

We recently opened three more operatories, and now the clinic is treating about 50 patients a day. Our commercial dental laboratory is now open as well, providing removable prosthetics for patients in our clinic.

Also, our guesthouse is now available to people who want to volunteer their services by teaching or providing treatment.

Most people would think that Afghanistan is a scary place to be right now. Is this true?

There is some element of risk there, but risk also exists in our own society. About 100 miles from where I live in the United States is the murder capital of America: Compton, Calif. I go there on a regular basis to pick up donated supplies from a dental supply company. There is an element of risk in every area.

Recently, an attempted car bombing occurred in New York City. I have never felt at risk in Afghanistan. We have never had a problem at our facility in Kabul. I have a motorcycle that I use daily, when I am there. The Afghan people are warm and friendly, and appreciate what I am doing there. They have nothing, but are very generous with what they have.

How would you characterize the life in Afghanistan today?

Life is very hard now in Afghanistan. The average life span is 42 years, due to the harsh conditions of life, lack of health care and a 70 percent level of malnutrition. Only 15 percent of the populace can read and write.

Afghanistan has the highest infant mortality rate in the world, and 20 percent of children die before age 5. So many adults have died that there are 3,000,000 orphans, with the average age of the population being 14 years.

Most children believe that life is not worth living. Ninety percent of Afghan citizens have no access to dental care, and most have never had a toothbrush. There is one dental X-ray machine in all of Afghanistan.

How can these conditions exist in our modern world?

When Afghanistan was attacked by the Soviet Union, anyone who could afford to leave the country did so with the entire family. These privileged people were also the elite of the country: the intellectuals, people with technical knowledge, all the elements making up the infrastructure.

When they left, they took the heart out of Afghanistan. What was left were the poor people, with no means to survive or maintain their lives. This is the way it is there now. The Afghan people feel that the world has forgotten them. They need to know that people care.

How can people help?

Donations can be mailed to ADRP, P.O. Box 734, Santa Barbara, Calif., 93102. Those who want to become supporting members can access our

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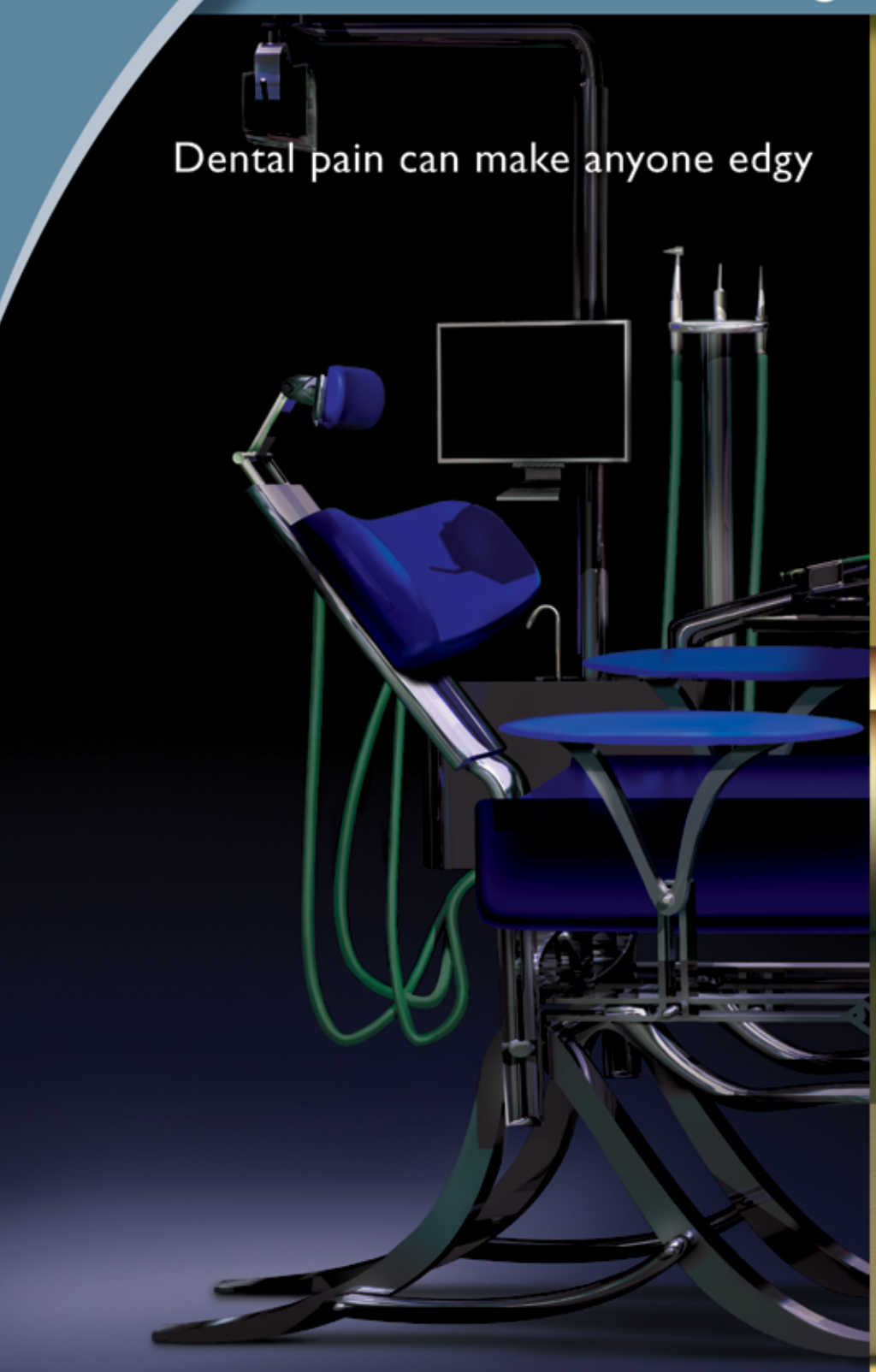

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Articadent® is indicated for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures. Articadent® with epinephrine 1:100,000 is preferred during operative or surgical procedures when improved visualization of the surgical field is desirable. Reactions to Articadent® (pain and headache, for example, or convulsions or respiratory arrest following accidental intravascular injection) are characteristic of those associated with other amide-type local anesthetics. Articadent® contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. **Accidental intravascular injection may be associated with convulsions, followed by central nervous system or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. Dental practitioners and/or clinicians who employ local anesthetic agents should be well versed in diagnosis and management of emergencies that may arise from their use. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use. Articadent®, along with other local anesthetics, is capable of producing methemoglobinemia. The clinical signs of methemoglobinemia are cyanosis of the nail beds and lips, fatigue and weakness. If methemoglobinemia does not respond to administration of oxygen, administration of methylene blue intravenously 1-2 mg/kg body weight over a 5-minute period is recommended.**

Please see Brief Summary of Prescribing Information on adjacent page.

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4% Articadent™ DENTAL with epinephrine 1:200,000
(articaine hydrochloride 4% (40 mg/ml) with epinephrine 1:200,000)

BRIEF SUMMARY. [See Package Insert For Full Prescribing Information]

USE
Articadent™ is indicated for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures. For most routine dental procedures, Articadent™ with epinephrine 1:200,000 is preferred. Articadent™ with epinephrine 1:100,000 is preferred during operative or surgical procedures when improved visualization of the surgical field is desirable.

CONTRAINDICATIONS
Articadent™ is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type, or in patients with known hypersensitivity to sodium metabisulfite.

WARNINGS
Accidental intravascular injection may be associated with convulsions, followed by central nervous system or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. Dental practitioners and/or clinicians who employ local anesthetic agents should be well versed in diagnosis and management of emergencies that may arise from their use. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use.

Intravascular injections should be avoided. To avoid intravascular injection, aspiration should be performed before Articadent™ is injected. The needle must be repositioned until no return of blood can be elicited by aspiration. Note, however, that the absence of blood in the syringe does not guarantee that intravascular injection has been avoided.

Articadent™ contains epinephrine that can cause local tissue necrosis or systemic toxicity. Usual precautions for epinephrine administration should be observed.

Articadent™ contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Articadent™, along with other local anesthetics, is capable of producing methemoglobinemia. The clinical signs of methemoglobinemia are cyanosis of the nail beds and lips, fatigue and weakness. If methemoglobinemia does not respond to administration of oxygen, administration of methylene blue intravenously 1-2 mg/kg body weight over a 5 minute period is recommended.

The American Heart Association has made the following recommendation regarding the use of local anesthetics with vasoconstrictors in patients with ischemic heart disease: "Vasoconstrictor agents should be used in local anesthesia solutions during dental practice only when it is clear that the procedure will be shortened or the analgesia rendered more profound. When a vasoconstrictor is indicated, extreme care should be taken to avoid intravascular injection. The minimum possible amount of vasoconstrictor should be used." (Kaplan, EL, editor: Cardiovascular disease in dental practice, Dallas 1986, American Heart Association.)

PRECAUTIONS
General: Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use (see **WARNINGS**). The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses of Articadent™ may cause significant increases in blood levels with each repeated dose because of possible accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient.

Debilitated patients, elderly patients, acutely ill patients and pediatric patients should be given reduced doses commensurate with their age and physical condition.

Articadent™ should be used with caution in patients with heart block.

Local anesthetic solutions, such as Articadent™, containing a vasoconstrictor should be used cautiously. Patients with peripheral vascular disease and those with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result. Articadent™ should be used with caution in patients during or following the administration of potent general anesthetic agents, since cardiac arrhythmias may occur under such conditions.

Systemic absorption of local anesthetics can produce effects on the central nervous and cardiovascular systems. At blood concentrations achieved with therapeutic doses, changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance are minimal. However, toxic blood concentrations depress cardiac conduction and excitability, which may lead to atrioventricular block, ventricular arrhythmias, and cardiac arrest, possibly resulting in fatalities. In addition, myocardial contractility is depressed and peripheral vasodilation occurs, leading to decreased cardiac output and arterial blood pressure.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be performed after each local anesthetic injection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression, or drowsiness may be early warning signs of central nervous system toxicity.

In vitro studies show that about 5% to 10% of articaine is metabolized by the human liver microsomal P450 isoenzyme system. However, because no studies have been performed in patients with liver dysfunction, caution should be used in patients with severe hepatic disease.

Articadent™ should also be used with caution in patients with impaired cardiovascular function since they may be less able to compensate for functional changes associated with the prolongation of A-V conduction produced by these drugs.

Small doses of local anesthetics injected in dental blocks may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Confusion, convulsions, respiratory depression and/or respiratory arrest, and cardiovascular stimulation or depression have been reported. These reactions may be due to intra-arterial injection of the local anesthetic with retrograde flow to the cerebral circulation. Patients receiving these blocks should be observed constantly. Resuscitative equipment and personnel for treating adverse reactions should be immediately available.

Dosage recommendations should not be exceeded (see **DOSAGE AND ADMINISTRATION** in package insert).

Information for Patients:
- The patient should be informed in advance of the possibility of temporary loss of sensation and muscle function following infiltration and nerve block injections.
- Patients should be instructed not to eat or drink until normal sensation returns.

Clinically Significant Drug Interactions: The administration of local anesthetic solutions containing epinephrine to patients receiving monoamine oxidase inhibitors, nonselective beta adrenergic antagonists or tricyclic antidepressants may produce severe, prolonged hypertension. Phenothiazines and butyrophenones may reduce or reverse the pressor effect of epinephrine. Concurrent use of these agents should generally be avoided. In situations when concurrent therapy is necessary, careful patient monitoring is essential.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies to evaluate the carcinogenic potential of articaine HCl in animals have not been conducted. Five standard mutagenicity tests, including three *in vitro* tests (the nonmammalian Ames test, the mammalian Chinese hamster ovary chromosomal aberration test and a mammalian gene mutation test with articaine HCl) and two in vivo mouse micronucleous tests (one with Articadent™ with epinephrine 1:100,000 and one with articaine HCl alone) showed no mutagenic effects. No effects on male or female fertility were observed in rats for Articadent™ with epinephrine 1:100,000 administered subcutaneously in doses up to 80 mg/kg/day (approximately two times the maximum male and female recommended human dose on a mg/m2 basis).

Pregnancy: Teratogenic Effects-Pregnancy Category C.

In developmental studies, no embryofetal toxicities were observed when Articadent™ with epinephrine 1:100,000 was administered subcutaneously throughout organogenesis at doses up to 40 mg/kg in rabbits and 80 mg/kg in rats (approximately 2 times the maximum recommended human dose on a mg/m2 basis). In rabbits, 80 mg/kg (approximately 4 times the maximum recommended human dose on a mg/m2 basis) did cause fetal death and increase fetal skeletal variations, but these effects may be attributable to the severe maternal toxicity, including seizures, observed at this dose.

When articaine hydrochloride was administered subcutaneously to rats throughout gestation and lactation, 80 mg/kg (approximately 2 times the maximum recommended human dose on a mg/m2 basis) increased the number of stillbirths and adversely affected passive avoidance, a measure of learning, in pups. This dose also produced severe maternal toxicity in some animals. A dose of 40 mg/kg (approximately equal to the maximum recommended human dose on a mg/m2 basis) did not produce these effects. A similar study using Articadent™ with epinephrine 1:100,000 rather than articaine hydrochloride alone produced maternal toxicity, but no effects on offspring.

There are no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. Articadent™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether articaine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Articadent™ is administered to a nursing woman.

Pediatric Use: In clinical trials, 61 pediatric patients between the ages of 4 and 16 years received Articadent™ with epinephrine 1:100,000. Among these pediatric patients, doses from 0.76 mg/kg to 5.65 mg/kg (0.9 to 5.1 mL) were administered safely to 51 patients for simple procedures and doses between 0.37 mg/kg and 7.48 mg/kg (0.7 to 3.9 mL) were administered safely to 10 patients for complex procedures. However, there was insufficient exposure to Articadent™ with epinephrine 1:100,000 at doses greater than 7.00 mg/kg in order to assess its safety in pediatric patients. No unusual adverse events were noted in these patients. Approximately 13% of these pediatric patients required additional injections of anesthetic for complete anesthesia. Safety and effectiveness in pediatric patients below the age of 4 years have not been established. Dosages in pediatric patients should be reduced, commensurate with age, body weight, and physical condition. See **DOSAGE AND ADMINISTRATION** in package insert.

Geriatric Use: In clinical trials, 54 patients between the ages of 65 and 75 years, and 11 patients 75 years and over received Articadent™ with epinephrine 1:100,000. Among all patients between 65 and 75 years, doses from 0.43 mg/kg to 4.76 mg/kg (0.9 to 11.9 mL) were administered safely to 35 patients for simple procedures and doses from 1.05 mg/kg to 4.27 mg/kg (1.3 to 6.8 mL) were administered safely to 19 patients for complex procedures. Among the 11 patients ≥ 75 years old, doses from 0.78 mg/kg to 4.76 mg/kg (1.3 to 11.9 mL) were administered safely to 7 patients for simple procedures and doses of 1.12 mg/kg to 2.17 mg/kg (1.3 to 5.1 mL) were safely administered to 4 patients for complex procedures.

No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
Approximately 6% of patients between the ages of 65 and 75 years and none of the 11 patients 75 years of age or older required additional injections of anesthetic for complete anesthesia compared with 11% of patients between 17 and 65 years old who required additional injections.

ADVERSE REACTIONS

Reactions to Articadent™ are characteristic of those associated with other amide-type local anesthetics. Adverse reactions to this group of drugs may also result from excessive plasma levels (which may be due to overdosage, unintentional intravascular injection, or slow metabolic degradation), injection technique, volume of injection, hypersensitivity, or may be idiosyncratic.

The reported adverse events are derived from clinical trials in the US and UK. Table 1 displays the adverse events reported in clinical trials where 882 individuals were exposed to Articadent™ with epinephrine 1:100,000 and Table 2 displays the adverse events reported in clinical trials where 182 individuals were exposed to Articadent™ with epinephrine 1:100,000 and 179 individuals were exposed to Articadent™ with epinephrine 1:200,000.

Table 1. Adverse Events in controlled trials with an incidence of 1% or greater in patients administered Articadent™ with epinephrine 1:100,000.

Body System	Articadent™ with epinephrine 1:100,000 N (%)
Number of patients	882 (100%)
Body as a whole	
Face Edema	13 (1%)
Headache	31 (4%)
Infection	10 (1%)
Pain	114 (13%)
Digestive system	
Gingivitis	13 (1%)
Nervous system	
Paresthesia	11 (1%)

Table 2. Adverse Events in controlled trials with an incidence of 1% or greater in patients administered Articadent™ with epinephrine 1:100,000 and Articadent™ with epinephrine 1:200,000.

Number of patients exposed to drug	Articadent™ with epinephrine 1:100,000 (N=182)	Articadent™ with epinephrine 1:200,000 (N=179)
Number of patients that reported any Adverse Event	35	33
Pain	14 (7.6%)	11 (6.1%)
Headache	6 (3.2%)	9 (5.0%)
Positive blood aspiration into syringe	6 (3.2%)	3 (1.6%)
Swelling	5 (2.7%)	3 (1.6%)
Trismus	3 (1.6%)	1 (0.5%)
Nausea and emesis	0 (0%)	3 (1.6%)
Sleepiness	1 (0.5%)	2 (1.1%)
Numbness and tingling	2 (1.0%)	1 (0.5%)
Palpitation	2 (1.0%)	0 (0%)
Ear symptoms (earache, otitis media)	2 (1.0%)	1 (0.5%)
Cough, persistent cough	2 (1.0%)	0 (0%)

The following list includes adverse and intercurrent events that were recorded in 1 or more patients, but occurred at an overall rate of less than one percent, and were considered clinically relevant.

Body as a Whole: abdominal pain, accidental injury, asthenia, back pain, injection site pain, burning sensation above injection site, malaise, neck pain.

Cardiovascular System: hemorrhage, migraine, syncope, tachycardia, elevated blood pressure.

Digestive System: constipation, diarrhea, dyspepsia, glossitis, gum hemorrhage, mouth ulceration, nausea, stomatitis, tongue edemas, tooth disorder, vomiting.

Hemic and Lymphatic System: ecchymosis, lymphadenopathy.

Metabolic and Nutritional System: edema, thirst.

Musculoskeletal System: arthralgia, myalgia, osteomyelitis.

Nervous System: dizziness, dry mouth, facial paralysis, hyperesthesia, increased salivation, nervousness, neuropathy, paresthesia, somnolence, exacerbation of Kearns-Sayre Syndrome.

Respiratory System: pharyngitis, rhinitis, sinus pain, sinus congestion.

Skin and Appendages: pruritus, skin disorder.

Special Senses: ear pain, taste perversion.

Urogenital System: dysmenorrhea.

Persistent paresthesias of the lips, tongue, and oral tissues have been reported with use of articaine hydrochloride, with slow, incomplete, or no recovery. These post-marketing events have been reported chiefly following nerve blocks in the mandible and have involved the trigeminal nerve and its branches.

OVERDOSAGE
Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics or to unintended subarachnoid injection of local anesthetic solution (see **WARNINGS, PRECAUTIONS;** ***General*** and **ADVERSE REACTIONS**).

Management of Local Anesthetic Emergencies: The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anesthetic injection. At the first sign of change, oxygen should be administered.

The first step in the management of convulsions, as well as hypoventilation, consists of immediate attention to the maintenance of a patient airway and assisted or controlled ventilation as needed. The adequacy of the circulation should be assessed. Should convulsions persist despite adequate respiratory support, treatment with appropriate anticonvulsant therapy is indicated. The practitioner should be familiar, prior to the use of local anesthetics, with the use of anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor.

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

HOW SUPPLIED
Articadent™ (articaine HCl 4% with epinephrine 1:100,000 or 1:200,000 injection) is available in 1.7 mL glass cartridges, in boxes of 50 cartridges. The product is formulated with a 15% overage of epinephrine.

NDC 66312-602-16 4% Articadent™ with epinephrine 1:200,000 Box of 50 cartridges
NDC 66312-601-16 4% Articadent™ with epinephrine 1:100,000 Box of 50 cartridges

Manufactured for:
DENTSPLY Pharmaceutical by
Novocol Pharmaceutical of Canada, Inc.
Cambridge, Ontario Canada N1R 6X3

Dr. Rolfe works in Afghanistan building the dental clinic he founded.

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website at *www.adrpinc.org* and pledge a monthly donation. We are a 501C3 non-profit charitable organization.

We are always loading a shipping container, so equipment donations and supplies are welcome; just call our headquarters at (805) 963-2329, or send an e-mail to *adrp@verizon.net.*

Volunteers who want to treat or teach at the Kabul Project Site should request information. All volunteers pay their own travel expenses and $15 a day board and room to stay in our modern guesthouse. The residential facility offers meals, laundry, Internet, hot showers and 24-hour security.

Is there anything else that people should know?

As the richest nation in the world, we have an obligation to help the poorest. We owe the Afghan people a debt of gratitude for dying to defeat the Soviet Union and for elevating the United States into the status of superpower of the world. We are overdue in paying this debt. All of our officers are volunteers.

Our organization has no overhead, so that means that 100 percent of each donation goes directly into the project. We are actually saving lives in Afghanistan. Orphans with no options are being educated so that they can have a normal life. Widows are being trained so that they can feed their children.

For the first time, Afghan dentists can access professionally trained dental assistants, laboratory technicians and hygienists. Vital elements are being created to improve the technical infrastructure. Women are being empowered to be authority figures in the male-dominated society there. Patients accessing our facility enjoy better health.

Anyone may volunteer and donate through our organization to bring benefits to the people of Afghanistan, which might not occur otherwise. Combined benefits improve social stability. Everyone benefits. DT

Congratulations to Dr. Rolfe!

Since this interview was conducted, Dr. Rolfe has been selected as an honoree for the 2010 National Awards for Citizen Diplomacy and will fly to Washington, D.C., in November to receive the award. Rolfe has also done interviews with NPR and People magazine. In addition, the LA Times published an article about Rolfe, which can be accessed at *www.latimes.com/health/la-me-afghan-dentist-20100908,0,164334.story.*

More information

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