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FDA investigates handheld dental X-ray devices

Daniel Zimmermann
DTI

SILVERSPRING, Md., USA: The Food and Drug Administration is advising dental professionals and veterinarians in the US to stay away from handheld X-ray devices that are being offered by online sellers and shipped from abroad. At least one of these devices was recently found not to comply with safety standards and therefore to be potentially hazardous for dentists and patients, the organisation said.

FDA officials told *Dental Tribune Asia Pacific* that they are currently monitoring handheld dental X-ray units throughout the United States. Information about the device in question were recently sent to the organisation by the Washington State Department of Health in Tumwater, Washington, which found during an inspection that a device purchased from a seller outside the country did not fulfil the FDA's X-ray performance standards.

The organisation said to have notified state regulators as well as dental and other health organisations about the potential



The FDA is warning of handheld dental X-ray devices offered by online sellers outside the United States. (DTI/Photo sevenke)

health risks. Dentists will be also advised to verify whether the devices they are using have the required labelling and to contact state officials in case they are unsure if their device is safe.

The organisation refused to disclose further information

about the extend of the problem or when and where these devices could have entered the country. However, this newspaper found that several devices produced in Asia are directly offered via internet to customers in the West including those in North America.

FDA-approved devices are currently available from a dozen manufacturers including Sigma, Digimed or Aribex. It's president and CFO Ken Kaufman welcomed the investigation while emphasising that these systems

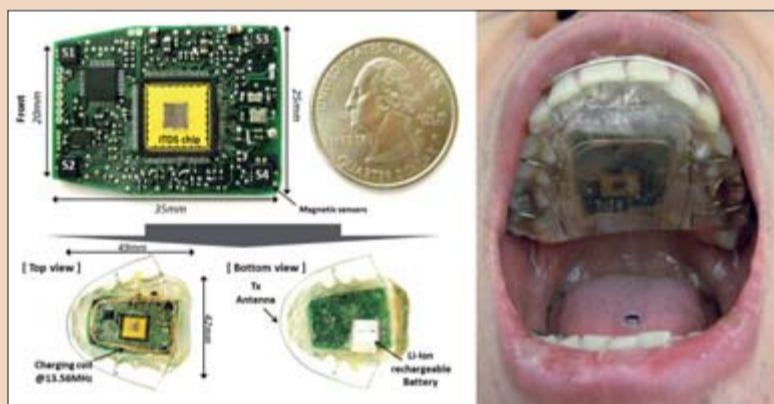
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Waiting times accumulate

People living in Morley, Western Australia, should better take their dental hygiene seriously. Latest statistics by the Government of Western Australia Department of Health have revealed that getting an appointment for a non-emergency dental procedure in the small suburb near the city of Perth can toll up to three years.

According to figures of the latest Western Australia Health Performance report, similiar waiting times have recently been observed throughout the state ranging between one and a half and two years on average. Besides Morley, patients from Amadale and Fremantle also had to wait 18 months for a dental appointment. Overall, more than 24,000 patients are waiting for treatment in public dental clinics.

Health officials said that the latest increase in dental appointments was due to rising awareness of people that are eligible for subsidised dental treatment including low-income families and pensioners. More than 400,000 people or one fifth of the population are currently estimated to fall into that category. DTI



This wireless intraoral device developed by scientists in the US is supposed to enable people with high-level spinal cord injuries to control an electric wheelchair by simply moving their tongue. (DTI/Photo courtesy of Georgia Institute of Technology, USA) ▶ WORLD NEWS, page 5

Rapist gets 40 years in prison

A judge in the Philippines has sentenced a 52-year old man to a maximum of 40 years in prison and a P180,000 (US\$4,200) fine for raping and robbing two female dentists in the capital Manila last May. The man is also facing charges for having committed sexual crimes against 23 other dentists. DTI

Morita receives design awards

Morita has been awarded the renowned iF Design Gold Award for Product Design for its Soaric dental treatment unit. The Japan-based provider of dental equipment also received two Communication Design Awards for Soaric's user interface and for the Soaric catalogue, advertising and printed media design. DTI

Poor oral health among trekkers

German researchers have evaluated the mouth and tooth hygiene of trekkers in the Himalaya and discovered that their oral flora changes significantly while travelling. Among others, they found elevated levels of the bacteria typically responsible for dental infections, such as periodontitis and gingivitis.

Their study also found that trekkers who had had a dental check-up within the previous six months were less likely to have dental problems and bleeding gums in particular. In addition, they determined that 16.5 per cent of the trekkers reported problems that could have been treated with a dental emergency kit. Although thousands of tourists go on trekking vacations every year, there is no information regarding the procedure to follow in case of dental emergencies or no systematic guidelines for prevention. DTI



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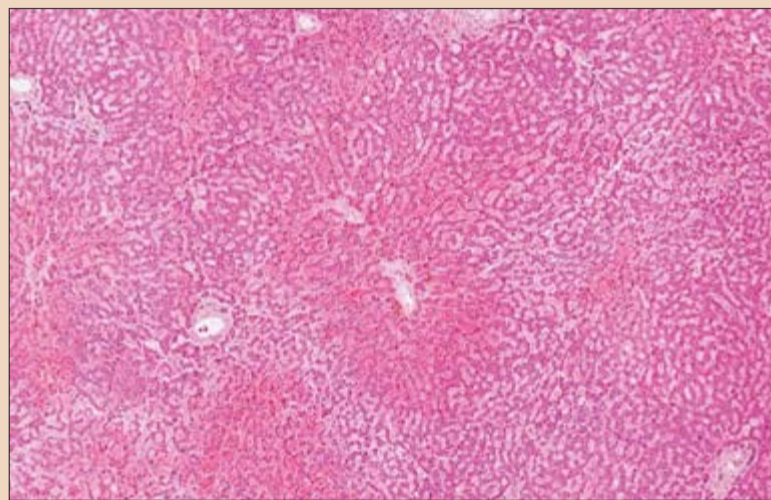
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AD

Bad breath gas used to make liver cells from teeth

DTI

TOKYO, Japan: A team of Japanese researchers has demonstrated that hydrogen sulphide, one of the main causes of bad breath, could be a key component in developing future medical therapies. In a recent study conducted at the Nippon Dental University in Tokyo, they reported that stem cells isolated from dental pulp transformed into liver cells after being incubated with the characteristically foul smelling gas for at least three days.



Microscope picture of normal human liver. (DTI/Photo Convit)

While dental pulp stem cells have been found to have the ability to transform into a number of different cells, including muscle and blood cells, this is the first time that researchers have claimed to have produced a huge number of cells that were able to store glycogen and collect urea—the two main functions of the liver. They said that although more research might be needed on the possible carcinogenic effects of the method, results indicate that it produced cells with little potential to differentiate, hence limiting the risk of developing tumours after transplantation.

“Hydrogen sulphide did not cause apoptotic changes in the cells,” they stated in the report.

Common methods of producing hepatic cells for human transplantation include the use of foetal bovine serum, which is heavily regulated worldwide. The researchers however extracted stem cells for their study from patients undergoing regular tooth extractions. These were then divided into two groups, of which one was incubated with hydrogen sulphide and the other with a different medium.

Commonly associated with the smell of rotten eggs, hydrogen sulphide is produced in small amounts by the human body for signalling and other biological functions. In the oral cavity, where it is considered highly toxic to tissue, it is produced by forms of bacteria that do not require oxygen to grow.

It is estimated that between 20 and 50 per cent of people in developed countries suffer from halitosis, the main side-effect of this process. [DTI](#)

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including the company’s NOMAD unit have generally proven safe and effective.

“Clinician and patients safety have always been our number-one priority in developing and

distributing our handheld X-ray device,” he said. “We are disappointed to learn that other manufacturers may not share a similar perspective.”

Aribex received FDA clearance for NOMAD in 2005. Since then, the company has been able

to sell 8,000 pieces of its handheld system worldwide.

Research has found that radiation from handheld dental X-ray devices is below recommended levels and pose no greater risk than standard dental radiography like CT’s. [DTI](#)

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Indian dental clinic chain aims for expansion

DTI

HYDERABAD, India: India's rising dental health-care sector is expected to receive another significant investment, as Alliance Dental Care has announced that it will triple its number of dental clinics

by mid-2015. The expansion is intended to serve different market segments, including dental spas, regular dental clinics, as well as express cleaning and whitening spots located in public places like airports and shopping malls.

Alliance Dental Care was founded in 2002 as a subsidiary of Alliance Medicorp, a joint venture between Apollo Hospitals and medical equipment provider

Trivitron. Both companies have been reported to seek private investors in order to raise Rs 0.5 trillion (US\$10 million) for the first phase of the expansion in 2012. The new clinics, as well as the existing ones, have been re-branded as White Dental Clinics, they said.

Alliance Dental Care currently maintains over 20 dental clinics in major Indian cities like Chennai, Bangalore and Hyderabad. In ad-

dition to its Indian business, the joint venture is also eyeing potential markets overseas, including South-East and West Asia, Africa and Eastern Europe.

According to the latest financial reports, Apollo boasted revenues of Rs 25 trillion (US\$460.4 million) in 2010/2011. Once the expansion has been completed, the company will hold a 70 per cent share in Alliance Dental Care. **DTI**



Dutch supplier acquired by SomnoMed

Daniel Zimmermann
DTI

SYDNEY, Australia/ZURICH, Switzerland: SomnoMed has expanded its own distribution network in Europe through a new acquisition. According to the terms of an agreement closed between the Australian-based company and Goedegebuure Slaaptechniek B.V. (GS) in Loenen aan de Vecht near Amsterdam, GS will market and distribute SomnoMed's range of dental solutions for the treatment of sleep breathing disorders exclusively in the Netherlands.



The SomnoDent MSA device has seen increasing sales in the Netherlands. (DTI/Photo SomnoMed, Switzerland)


Currently, GS is one of the leading Dutch suppliers of mandibular repositioning appliances. With the take-over, SomnoMed intends to boost its presence and business development in Europe, particularly in important Central European markets, CEO Ralf Barschow said. He told *Dental Tribune Asia Pacific* that sales have jump-started in the Netherlands because devices for the treatment of conditions like obstructive sleep apnoea syndrome have been reimbursed by the country's health insurance companies since 2010.

The acquisition will be paid half in cash and half in shares and is expected to be completed by 2019. SomnoMed stocks listed on the Australian Securities Exchange reacted positively to the announcement.

According to Barschow, sales in Europe contribute approximately 25 per cent to SomnoMed's global business results. Last year, revenues in the region grew by over 50 per cent.

He confirmed that the company is also in talks with other suppliers in Europe. Since 2008, the company has been operating actively in Europe through its subsidiary in Zurich in Switzerland. **DTI**

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Dear reader,



Daniel Zimmermann
DTI

When I got the chance to interview Dr Melvin Cheatham for this edition's article on dentistry in North Korea (page 9), I was impressed with the voluntary work his charity organisation, Samaritan's Purse, has done and is currently doing in many underprivileged parts of the world.

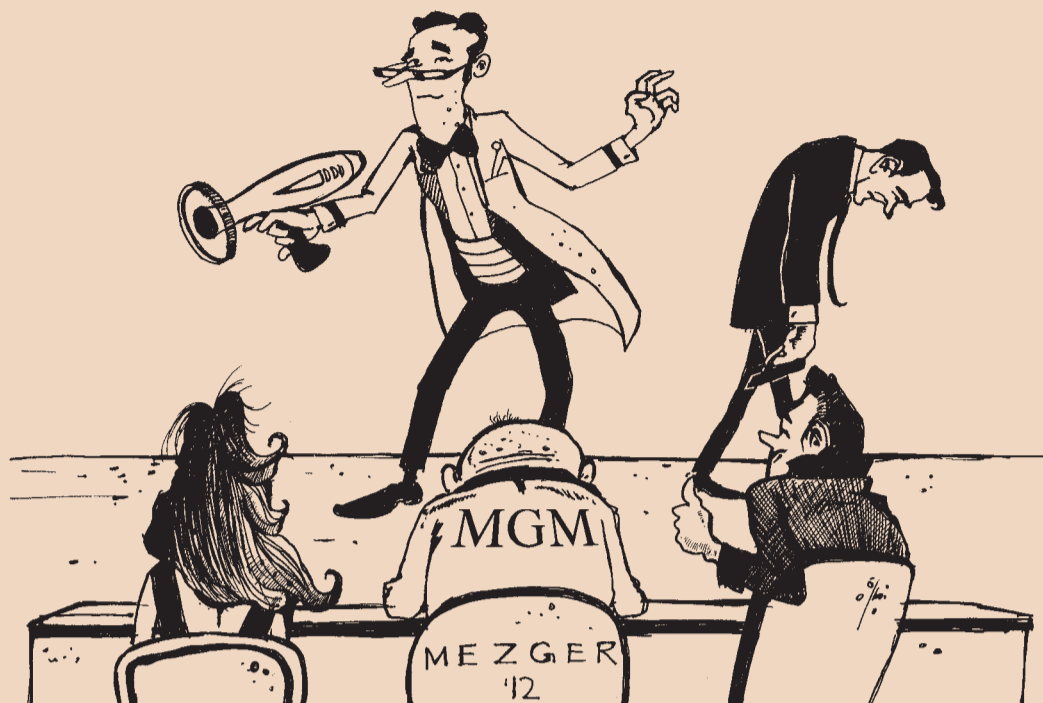
It remains a sad and not widely known fact that in the DPRK and many other countries in Asia, public health-care systems are heavily dependent on help from outside organisations in order to provide even the most basic level of medical or dental care. Moreover, their assistance has become increasingly essential during widespread emergency situations like natural disasters, which most of these systems, I think we can agree, are not able to handle adequately.

During my work for this newspaper, I have found that dentists are generally very open to using their professional skills for the greater good, for example, by forming part of a temporary dental relief workforce. Without their enthusiasm and willingness to spend a significant amount of their time in far-off places, there would be fewer smiles in the world today. [DTI](#)

Yours sincerely,

Daniel Zimmermann
Group Editor
Dental Tribune International

"Looks like we have our new Bond."



Not all hand-helds are created equal



Dr Joel Gray
USA

There are two sources of radiation from an X-ray system—leakage radiation from the X-ray tube and scattered radiation from the patient. The leakage radiation is minimised by placing highly absorbing material, such as lead, around the X-ray tube. The major issue with the hand-held X-ray units is the scattered radiation, that is X-rays that are scattered from the patient towards the operator. In fact, about 20 to 30 % of the X-rays are scattered from the patient towards the person holding the device.

The X-ray units from outside the USA, which are under FDA scrutiny, do not provide any protection from X-rays scattered from the patient.

These systems look like a large camera that you hold with both hands. There is no shielding provided by these hand-held systems, that is the user's hands are exposed to all of the X-rays scattered from the patient. Consequently, the user's hands are going to receive a radiation dose that will probably exceed the radiation-protection limits for skin and extremities. Therefore, these units should not be hand-held.

We evaluated one hand-held X-ray unit manufactured in the USA (Nomad, Aribex Inc.) and compared staff doses with those for the same staff using conventional wall-mounted systems prior to acquiring the hand-held systems (Gray et al. 2012). This hand-held system uses a proprietary shielding material around the X-ray tube, resulting in leakage radiation levels that are virtually immeasurable. In addition, it has an integral leaded-acrylic shield that protects the user

from radiation scattered from the patient. The results of our study indicated that the users of the hand-held X-ray system received lower radiation doses than they did when they were using conventional wall-mounted systems.

Buyers should be beware that not all hand-held X-ray systems are created equal and not all of those being sold on the web have been reviewed by the FDA. Hand-held X-ray units should have sufficient shielding to minimise leakage radiation and an integral shield to protect from radiation scattered from the patient. [DTI](#)

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Rajiv Narayan is a researcher for Amnesty International in London.

Decaying health care



Rajiv Narayan
UK

Relief efforts are laudable as it goes some way towards helping the North Korean government ensure that it meets its obligations to respect, protect and fulfil the right to health of its citizens.

In its report, "The Crumbling State of Health Care in North Korea", (ASA 24/001/2010), Amnesty International documented the devastating impact of long-term food insecurity on the population's health and concluded that the North Korean state bears the responsibility for the country's decaying health care infrastructure, failure to provide basic health care, and a lack of public health education and information. Food shortages and a more general economic crisis persist to this day. Health facilities are rundown and operate with frequent power cuts and no heat. Medical personnel often do not receive salaries, and many hospitals function without medicines and other essentials.

To this end, Amnesty International has urged the North Korean authorities and its new leader Kim Jong-un to address severe shortages in the healthcare system including through accepting international humanitarian assistance and for providing full cooperation and access (to efforts by organizations like Samaritan Purse) to ensure that care reaches those most in need. [DTI](#)

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Dentists patent novel soft-tissue augmentation technique

Daniel Zimmermann
DTI

ALEXANDRIA, Va., USA: An invention from Saudi Arabia that could help more patients to get dental implants is reported to have been granted patent status by the US Patent and Trademark Office. The new method, called

the tunnelling technique, is claimed to increase the thickness of soft tissue prior to block grafting procedures using an acellular dermal matrix.

Developed by implant specialist Dr Ali Thafeed AlGhamdi, who is also head of the Periodontic Division at King Abdulaziz University's Faculty of Dentistry in Jeddah in Saudi Arabia, the technique was first filed for

patent application in February last year by a Virginia law firm.

In the application, the researchers explain how to position an acellular dermal matrix over the recipient site and fix it coronally via a tunnel that is formed by making two incisions through the mucosa. Using this method, the researchers detected an increase of 1 to 2 mm in soft-tissue thickness following allografts.

The acellular dermal matrix has been successfully applied in many surgical fields, including cosmetic procedures and regenerative medicine. It has been on the market since the early 1990s.

Al-Ghamdi told the Saudi Press Agency in Riyadh that he started looking into the technique when he noticed rapid healing in dental implant patients who had been treated with

allografts for soft-tissue augmentation prior to symphyseal block grafts. He said that his invention could contribute significantly to the improvement of block graft surgery in diseased jaws.

According to the latest research, thin soft-tissue biotypes affect implant success significantly by failing to maintain the required crestal bone level. [DTI](#)

AD

Intraoral device manœuvres wheelchair

DTI

ATLANTA, Ga., USA: Researchers at the Georgia Institute of Technology have developed the latest version of the intraoral Tongue Drive System, which is embedded into a dental retainer and is worn inside the mouth. The system, which only requires free movement of the tongue, allows people with high-level spinal cord injury to control a powered wheelchair.

The user receives a clinical tongue piercing, with which he can control the magnetic field sensors mounted on the device's four corners. The sensors track the relative location of the magnetic piercing and transmit the data wirelessly to an iPod or iPhone. Software installed on this computer device interprets the user's tongue position and moves the wheelchair accordingly.

In earlier versions, the sensors were attached to an externally worn headset. "One of the problems we encountered with this earlier version was that it could shift on a user's head and would need to be recalibrated," said Maysam Ghovanloo, associate professor at the institute. The new device sits tightly against the roof of the mouth because it is moulded from dental impressions. As it is worn inside the mouth, it is protected against such disturbances and is less conspicuous.

The new device includes a lithium-ion battery and an induction coil to charge the battery. It is covered with an insulating, water-resistant material and vacuum moulded inside standard dental acrylic.

The researchers also created a multifunctional interface, which holds the iPod, receives and delivers the sensor data, charges the iPod and is fitted with a holder for charging the dental retainer at night. The system can be hooked up to any standard electric wheelchair.

Ghovanloo and his team plan to begin testing the usability of the system by able-bodied individuals soon and then move onto clinical trials. [DTI](#)

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3Shape releases Dental System 2012

DTI

COPENHAGEN, Denmark: 3Shape, a Danish company specialising in 3-D scanners and CAD/CAM software solutions, has released its next-generation Dental System 2012 to the market. For the first time,



it offers different scanner models and Stan-

dard or Premium software versions in order to provide a flexible and scalable solution that can be matched to labs of any size or business model with upgrade possibilities for future requirements. 3Shape offers a

wide range of new digital workflows and communication tools designed to help labs expand their range of services to dentists. 3Shape's Dental System 2012 introduces a variety of scanner/software combinations so that labs, regardless of their size or business model, can find suitable CAD/CAM tools to match their business needs and ambitions. 3Shape recently declared its new mission, "Helping labs to help their dentists".

"In today's competitive climate, labs that shift from production-only to service-provider profiles are winning market share. With Dental System 2012, 3Shape is bringing labs solutions designed to help them build new services and stronger business relationships with their dentists," stated Tais Clausen, CTO of 3Shape.

The new Dental System 2012 features 3Shape Communicate, which enables labs to send their dentist clients 3-D design visualisations for use in their discussions with the lab and with their patients; ModelBuilder, which allows technicians to design lab models, including implant models, for an extensive range of indications directly from intra-oral scans and conventional impression scans; TRIOS integration, which enables labs to receive TRIOS digital impression scans from the clinic directly to their Dental System inbox; Texture Scanning, which enhances visualisation of surface details and allows technicians to incorporate hand-drawn design guidance markings into the digital design (texture scanning is available on D800/810 scanners); and Dynamic Virtual Articulator, which offers support for the market's most widely recognised articulators, providing the optimal user experience. In addition, with Occlusion Compass functionality, the colours of contact points are mapped to specific occlusal movements.

Furthermore, the Dental System 2012 features Temporaries and Diagnostic Wax-ups, a revolutionary workflow solution for producing temporary crowns and diagnostic wax-ups (including Virtual Prep, Virtual Gingiva, CAD Temporaries and Virtual Diagnostic Wax-up design); Multilayer Design, which enables highly productive bridge design for pressing or combinations of milled glass-ceramics and zirconia, and automatically splits full anatomy designs into two true and entire parts, without undercuts or lost areas; the Improved SmileComposer, which enables optimised auto-placement of crowns and morphing to preparation; as well as Advanced Telescope design, new software for optimised creation of telescopic crowns, including sophisticated primary telescope modelling and improved edge design.

3Shape has also introduced a new scanner: the new D500 model and impression scanner, which was developed based on 3Shape's advanced scanning technologies for full and accurate capture. The D500 was designed specifically to fulfil the needs of labs seeking to enter CAD/CAM manufacturing equipped with the latest and best technologies. Additionally, 3Shape offers 5.0 MP D700 and D800 scanners with extensive indications and texture-scanning capabilities for medium to large labs.

According to 3Shape, its solutions are timeless because the company ever strives for innovation and continues to provide major feature-packed upgrades for its users every year. 3Shape backs its Dental System users with an extensive support network and comprehensive training package. [D](#)

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“Units are considered a national treasure by the North Koreans”

An interview with Samaritan's Purse's Dr Melvin Cheatham, USA

Through its World Medical Mission programme, the US-based Christian charity Samaritan's Purse provides health care by means of medical and dental volunteers in developing countries around the world. It is also one of few organisations that maintain relations with the Democratic People's Republic of Korea, also known as North Korea. DTT's Group Editor Daniel Zimmermann spoke with Dr Melvin Cheatham, member of the advisory board, about the organisation's projects there and the state of dental care in the communist state.

Daniel Zimmermann: Dr Cheatham, like many things that concern the Democratic People's Republic of Korea, very little is officially known about the dental infrastructure there. How would you describe the level of dentistry in the country?

Dr Cheatham: Although I have been to the DPRK more than 20 times and met with people at the highest level, it is very difficult to identify the current depth and availability of dental care and education. Obviously, dentistry there is performed on a much lower level than in Germany, the US or in any other country in the developed world. If you also look to another developing country as an example, there is reason to believe that dental care is being provided by people who do not have the level of education which is normally required to perform dentistry.

Your organisation, led by Reverend Franklin Graham, is supporting the country through a number of dental care-related projects. When did these start?

The relationship between the Graham family and the DPRK dates back to the 1950s when Franklin Graham's mother Ruth Belle Graham, who was born in China, attended a missionary school in Pyongyang, which was then under Japanese occupation. Wanting to go there himself, her husband Billy Graham, a world renowned religious leader and founder of the Billy Graham Evangelistic Association, first met with the DPRK's leader Kim Il-sung before his passing in 1994.

During this visit, the organisation equipped the first mobile dental vehicle, which was intended to provide dental care to those people who weren't able to get it, for example, in North Korea's countryside. A second mobile dental unit was equipped years later by Samaritan's Purse, led by Billy Gra-



Dr Melvin Cheatham unpacking dental supplies during a visit to the DPRK. (DTI/Photo courtesy of Samaritan's Purse, USA)

ham's son Franklin at the request of the DPRK. Both units are considered a national treasure by the North Koreans, as they were given to them with the blessings of their beloved leader.

Are these units still operational today?

Although these services are still operational, the focus has lately shifted towards developing permanent dental care in the capital. A few years ago, the DPRK's Ministry of Public Health asked Samaritan's Purse for assistance in equipping a dental centre in Pyongyang that would not only serve as a place where dental care was given but also where dentists could obtain continuing education on the newest dental procedures and techniques with the goal of improving oral health care throughout the country.

This centre is now well equipped with six complete operatories, teaching facilities and materials as well as laboratory equipment to manufacture dentures and crowns.

What is the relationship with your Korean partners like?

I think they appreciate both the supplies and teaching opportunities very much. The needs for dental care are substantial in that country, which is supported by the fact that the Ministry of Public Health asked for assistance in that area. Similar to dental communities in most countries around the world, there is obviously great interest in learning, for example, on how to perform more sophisticated procedures like dental implants. From my point of view, it has always been a warm and friendly relationship.

Samaritan's Purse works closely with officials and with dentists and other professionals in the DPRK in order to be able to identify and understand the

opportunities for development in that country and to be able to

appropriately respond through providing training, supplies and equipment. All work in the DPRK is done in a spirit of friendship, and aimed toward building further upon the special relationship that has been established through Samaritan's Purse with government and with medical and dental care officials.

You are also conducting projects in other developing countries. How is working in the DPRK different from those?

Owing to the fact that the DPRK is almost a closed country, one always has to gain permission for a delegation to visit far ahead of time. The visits themselves are also limited to several days or just one or two weeks, so

staying for a longer period of time is not possible.

Have you noticed any change in light of the recent death of Kim Jong-il and the passing of power to his son Kim Jong-un?

With the 100th birthday of Kim Il-sung coming up in April, this is a very important time for the country. A lot is going on and whether there will be political changes owing to the recent passing of Kim Jong-il has to be seen. From the standpoint of communication that we have on behalf of our president with the DPRK's leadership and those involved in the work that is being done, I expect it to remain very productive.

Dr Cheatham, thank you for this interview. □

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