DENTAL TRIBUNE

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Singapore eases registration of devices

Daniel Zimmermann
DTI

The restructured regulations will benefit dental manufacturers. (DTI/Photo courtesy Koelnmesse, Singapore)

SINGAPORE: Manufacturers of dental impression materials, surgical instruments or abutments breathed a sigh of relief when the Singapore Health Science Authority (HAS) recently announced that it would lower its regulatory requirements for low risk medical devices, *Dental Tribune Asia Pacific* has learned. Registration fees for Class B products like dental abutments and scaling systems will also be lowered soon, the government agency responsible for medical product regulation said.

Beginning in May, manufacturers of Class A devices will only be required to register their devices with HAS for the purposes of market monitoring. The registration fees for approximately 3,600 Class B products will be reduced from S$2,300 to S$1,400 from September.

According to the HSA, about 70 per cent of all medical devices registered in Singapore currently fall under Classes A and B.

The organisation said that it will look into revising fees for Special Authorisation Route registrations and regulations for higher risk Class C and D devices.

"These changes reflect a flexible and responsive regulator that is willing to listen to the teething issues faced by the industry with the introduction of medical device regulation in Singapore, without compromising patients' well-being," Dr Amy Khor Lean Suan, Minister of State at the Ministry of Health, said. "I am confident that these enhancements, for lower risk devices in particular, will address the concerns of the industry and that HAS will continue to enhance the framework to facilitate access to safe medical devices."

Since 2008, medical devices, including dental equipment, have had to be registered with the HSA. Prior to that, regulation was voluntary and followed international regulatory standards, like those of the US Food and Drug Administration. The guidelines have continuously sparked unrest among importers and doctors over the past few years who blamed the regulations for preventing medical and dental professionals from using state-of-the-art equipment and for increasing health-care costs. DT

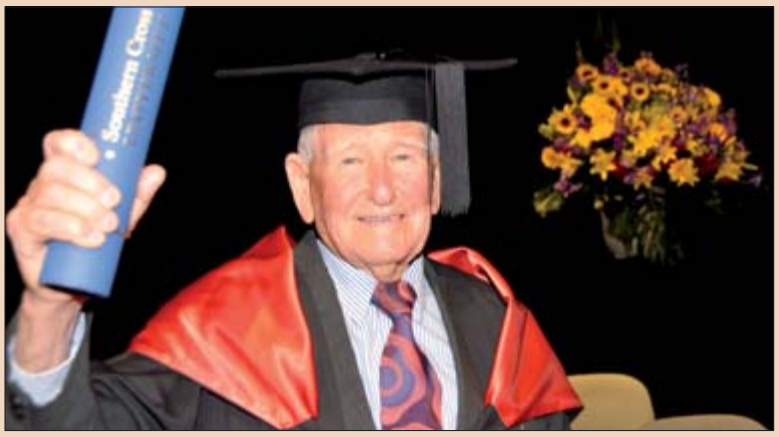
Shorter service period for Malay grads

Owing to the increasing number of dental professionals graduating from universities, the Malaysian Dental Council has recently approved a reduction in the period of the compulsory national service for dental graduates in the country.

Instead of three years, graduates will have to serve the government for only 24 months in the future, Ministry of Health officials said during the launch of Colgate Oral Health Month 2012 in Bandar Utama last month.

According to statistics released by the Ministry of Health earlier this year, the number of dental graduates has increased by 400 per cent in the last decade. In 2011, 415 graduates registered with the Malaysian Dental Council. With the shorter period, the government hopes to keep graduates enrolled in government service.

Of the more than 4,000 dentists currently practising in Malaysia, almost 60 per cent work in the public sector. DT



Former dentist Allan Stewart from Port Stephens in Australia has recently gained his fourth degree—with the age of 97. (DTI/Photo courtesy of Southern Cross University/Sharlene King)
ASIA NEWS, page 2

First vitamin B12 toothpaste

A German natural cosmetics manufacturer has launched a toothpaste that could benefit people unable to absorb vitamin B12 from food. Developed in partnership with the German Vegetarian Union, the toothpaste allows the absorption of the essential nutrient through the oral mucosa. DT

GC, Unison buys Showa Yakuhin

One of Japan's largest dental products manufacturers GC has acquired Showa Yakuhin Kako through private equity firm Unison capital. The Tokyo-based pharmaceutical company was put on sale by majority shareholder Tokyo Marine Capital last year and is currently estimated to be worth US$ 650 million. DT

High hopes for regulatory head

The Australian Dental Industry Association (ADIA) has called on the Therapeutic Goods Administration (TGA) in Canberra to free the industry from unnecessary regulatory burden with regard to dental goods. In view of the recent appointment of Dr John Skerritt as new head of the country's body for medical device regulation, ADIA emphasised that future regulatory reform should not be implemented at the cost of patients.

TGA is in charge of the regulation of most of the goods available on the country's AUS$4 billion (US$4.14 billion) dental market. Skerritt, who currently holds an administrative position in the Victorian government, was appointed new national manager by the organisation's board last month. He will assume duties at the end of May. DT

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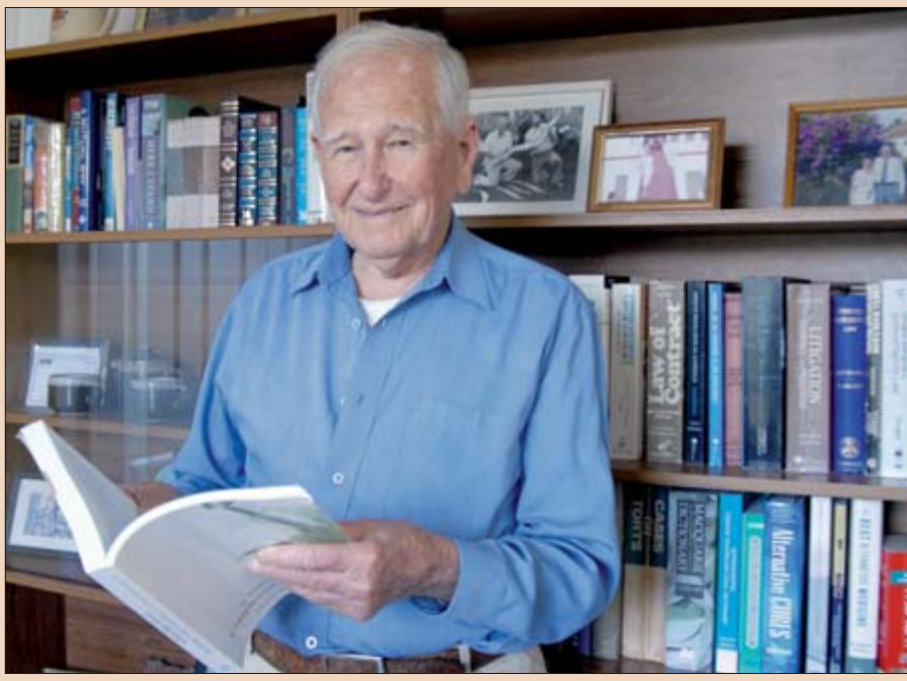
Australian dentist sets graduation record

Dental Tribune Asia Pacific

LISMORE, Australia: At the age of 97, most people probably consider learning to be the very least of their priorities. Not Dr Allan Stewart from Australia. The former dentist from Port Stephens just received his fourth degree —Master of Clinical Science (Complementary Medicine)— surpassing his own world record of being the World's Oldest Graduate set in 2006.



Dr Allan Stewart is the oldest living person to have ever graduated. (DTI/Photo courtesy of Southern Cross University, Australia)

A father of six children and with 12 grandchildren, Stewart gained his first academic title with a Bachelor of Dentistry from the University of Sydney during the 1930s. After completing postgraduate studies in dental surgery in the US, he practised dentistry in Australia and the UK for more than 40 years.

Things took an unusual turn in the late 1980s, when Stewart decided to study law at the University of New England in Armidale at an age when most of his dental colleagues were already enjoying their retirement. Not having completed the programme, he took it up again in 2001 and completed it in only four and a half years, making him then the oldest living person to have ever graduated from university.

According to Stewart, his latest academic endeavour, which ended successfully last Friday with a graduation ceremony in East Lismore near Brisbane, was sparked when one of his daughters began studying arts at Southern Cross University at the age of 70. He enrolled at the same institute in 2009 in spite of his original intention never to go to university again.

"I must say that although it's been a tremendous challenge, I have recently enjoyed it immensely," Stewart told reporters. "I would strongly encourage any older person to go back to studying."

University supervisors said that despite his advanced age, he used modern tools of communication, like Skype, during his studies and was actively involved in online discussions and forums.

Besides Stewart, so far only a handful of people worldwide have obtained academic qualifications so very late in life. In 2010, for example, Hazel Soares from the US earned her first college degree from Mills College in Oakland, California, at the age of 94. Three years before, 95-year-old fellow countrywoman Nola Ochs also graduated with a general studies degree with emphasis in history from Fort Hays State University in Hays, Kansas.

Stewart, who is said to like boating, fishing and playing bridge in his spare time, announced that he would finally hang up his academic robes after having graduated from Lismore. He remains a member and Fellow of the Royal Australasian College of Dental Surgeons. DT

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Market report forecasts extensive growth of Korean implants in AP

Daniel Zimmermann
DTI

TORONTO, Canada: Dental implants produced in the Republic of Korea have gained significant market shares in recent years. Now a report by the Millennium Research Group (MRG) in Canada has predicted that manufacturers from that country could dominate dental implant markets in the Asia Pacific region as early as 2016 owing to their price advantage.

Implants from Korea are also catching up in terms of clinical data, the report states, a fact that will make them increasingly adoptable for implant specialists in the region.

The total regional market for dental implants is expected to exceed US$800 million by 2016 with the key driving market being Australia, which was historically underdeveloped and is now expected to grow by 10 per cent annually, according to MRG.

Japan, the largest national market in the region, will experience slower revenues despite an overall rise in implant procedures.

Alongside Germany and Israel, South Korea currently has one of the highest rates of dental implants per capita worldwide. This market saturation has recently forced many manufacturers to pursue sales markets overseas. While exports to Western countries have remained relatively slow, Korean manufacturers like OSSTEM already rival established implant providers, such as Straumann or Zimmer Dental, in Asian countries like Pakistan, Malaysia or Hong Kong.

Other significant market players in the region include DIO Implants, a company partly owned by DENTSPLY, as well as MegaGen and Shinhung. DT

Research suggest old folks should clean teeth

Dental Tribune Asia Pacific

TAIPEI, Taiwan: Data analysis of patients with public health insurance in Taiwan has backed up the claim that oral health and heart disease might be associated later in life. People over the age of 50 who had received at least one tooth scaling showed slightly lower incidence of myocardial infarction, other cardiovascular events and strokes than those who had received none, according to a paper recently published in the *American Journal of Medicine*.

In the study, which took seven years to complete, the records of more than 22,000 patients selected from the country's National Health Insurance Research Database were analysed.

According to the researchers at the Taipei Veterans General Hospital and National Yang-Ming University's Cardiovascular Research Center, the results made public this month revealed less heart disease in those people who had had their teeth cleaned.

The incidence of stroke was 1.1 per cent higher among those whose teeth had not been cleaned, and acute myocardial infarction occurred in only 0.6 per cent more people who had not undergone tooth scaling.

Lead researcher Dr Zu-Yin Chen told *Reuters Health* in London that the results, although convincing, did not prove that better oral hygiene can lower the risk of heart disease but that dental problems like gum disease most likely increase the risk of these conditions.

Chen said that the new study followed research that suggested that there might be a link between heart disease and oral health.

The association itself and the way in which bacterial inflammation in the mouth contributes to heart disease is still highly debated in the dental community. DT

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Dear reader,

Daniel Zimmermann
DTI

Being a dental trade journalist, I usually come to visit a lot of trade shows during the year. On many occasions I have heard Western manufacturers to complain about the registration of dental products in Asia.

While things have somehow improved in this regard, the regulatory situation here is still far from being perfect. Companies producing high-end equipment in particular find it difficult to roll-out their product simultaneously throughout the region and dentists are being forced to import devices by themselves for which they have to pay larger fees.

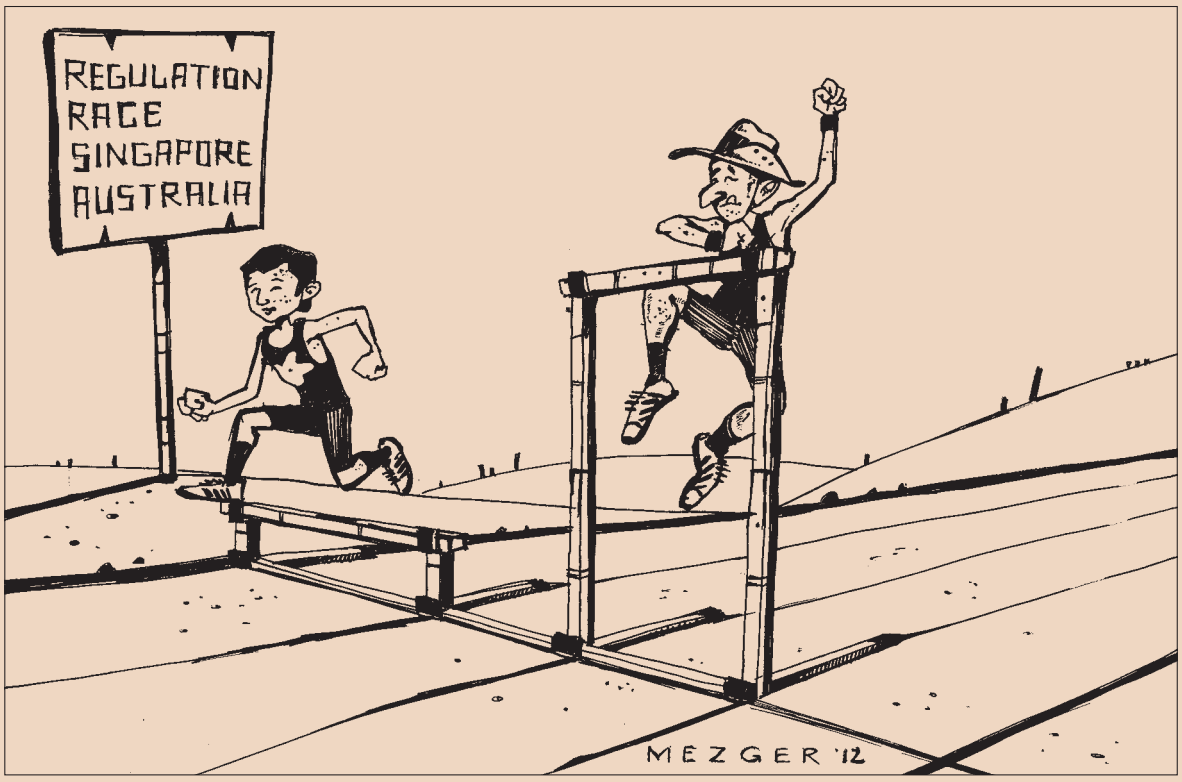
Unfortunately, the situation is unlikely to change in the years to come, despite efforts to establish common regional standards. It will hinder Asian professionals to keep up with international dentistry. DT

Yours sincerely,

Daniel Zimmermann
Group Editor
Dental Tribune International

Correction

In *Dental Tribune Asia Pacific* No.1+2, Vol. 10, the article on page 15 about IDEM included incorrect information. This year was the seventh time that the International Dental Exhibition & Meeting was held in Singapore.



A keener eye on post-market activities

Ing Loong Yang
Hong Kong/Singapore

The recent sweeping changes to the medical device regulations in Singapore are certainly a welcome relief for many medical practitioners and industry players. But the changes might not necessarily be good news for all those involved, in particular, diligent companies who had taken the initiative to have their products registered before these new rules were first announced.

Firstly, there will be no refund of application fees in respect of non-sterile Class A devices registered before 1 May 2012. It remains to be seen whether the registered non-sterile Class A devices, which now enjoy the exemption scheme, will be required to be de-registered. An immediate question that arises is whether the registrants are still subject to the registration conditions and duties, as prescribed in the medical device regulations. For instance, must these registrants ensure that the devices comply with the prescribed safety and performance requirements, or notify HSA of any change that may affect the safety, quality or efficacy of the devices? Technically, the answer is yes, until HSA decides to amend the law.

For Class B devices, industry players may have learnt to bide their time, as it has been announced that the registration fees for this risk class of devices will be reduced from September this year.

No news has been published yet regarding the potential issues HSA might see a need to address. In any case, the recent changes do not mean that dealers manufacturing and importing products that enjoy the product registration exemption or reduced registration fees can afford to be complacent. The HSA has already made it clear that dealers will continue to be required to declare the list of such products in the manufacturer's and importer's licences and update this list biannually. "We will manage risk by putting more emphasis on post-market vigilance, compliance, audit and enforcement," said Associate Professor John Lim, CEO of HSA.

The message is clear: while premarket approval requirements for medical devices have been relaxed, HSA will be casting a keener eye on post-market activities. DT

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The way forward

Prof. Urs Belser
Switzerland

General dentistry has undergone major changes during the last 20 years, not just in the way clinicians treat their patients, but particularly in the way patients request treatment and their increased expectations of outcomes. In particular, the practice of restoring patients' compromised teeth has become less complex in some ways, yet more challenging in others. Tooth replacement is increasingly being performed through the use of restorations supported by dental implants, and numerous elegant and predictable clinical approaches to this have been developed.

The increase in the use of dental implants is also partly due to the developments in the design of the implants themselves and of the components available to complete the restoration.

All of these advances, however, would be of little use without well-defined decision-making criteria when considering treatment in the context of either damaged or missing teeth. Accurate diagnosis is essential, and the clinicians involved must always have the aesthetic aspects of the treatment foremost in mind when dealing with sites located within the appearance zone. DT

Contact Info

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Implant failure may be related to bisphosphonate use

DTI

NEW YORK CITY, NY, USA: The results of a study conducted at the New York University College of Dentistry seem to confirm the hypothesis that the use of oral bisphosphonate is connected to dental implant failure. In the case-control study, more than 300 middle-aged female patients with failed dental implants were compared with woman from the same age group whose implants were still intact.

Clinical evaluations at the Department of Periodontology and Implant Dentistry were conducted between 1997 and late 2004. According to the researchers, the clinical data gathered from these examinations showed that in women whose implants had failed the odds of having taken bisphosphonate orally were almost three times higher. Dental implant failure related to the use of oral bisphosphonate also seemed to be more likely to occur in the maxilla.

Neither the quantity nor the duration of bisphosphonate use was evaluated.

Although the risk of implant failure is low, the researchers concluded that oral bisphosphonate could pose a risk to the success of dental implant therapy and should be prescribed with caution.

Earlier research on the association remains ambiguous, as results from Sweden and Australia have not found increased risks for implant failure when bisphosphonate was taken by patients before or after implant placement.

However, the majority of clinical organisations still recommend that long-term users stop taking bisphosphonate before undergoing dental implant procedures to avoid complications. DT

Teeth equally perceived by dentists

DTI

BERLIN, Germany: Several morphometric studies have proven sexual dimorphisms in human teeth, for example that women's teeth are smaller than men's teeth. The German Society for Sex-Specific Oral and Maxillofacial Surgery recently reported on a study that found no obvious differences between male and female teeth.

Headed by Prof. Ralf J. Radlanski from the Centre for Oral and Maxillofacial Surgery at the Benjamin Franklin Campus of Charité Universitätsmedizin Berlin, the researchers explored whether the sex of an individual could be identified if only the front teeth were considered. This was tested by having participants evaluate 50 images of the anterior oral region of men and women aged between seven and 75. The lip area was not shown.

The participants included dentists, dental technicians, dental students and dental professionals, as well as 50 people who had no professional dental background.

The results overall demonstrated that sex could be detected in only about 50 per cent of the images. Although there are anthropological studies that claim to prove measurable morphometric differences, the study proved that those are not even visible to experts' eyes.

While some tooth positions were correctly assigned by 70 per cent of the participants, others were wrongly assigned by the same number of participants. The assumption that women tend to have rounded teeth and men rather angular ones could not be confirmed by the study. Furthermore, contrary to what was expected by many of the participants, shape, size and colour of the canines were not meaningful indicators of sex.

"In everyday practice, it is relevant whether the restoration fits the patient's face but not whether the patient is male or female," Radlanski said. "Recognisable typical male teeth or female teeth do not exist." DT

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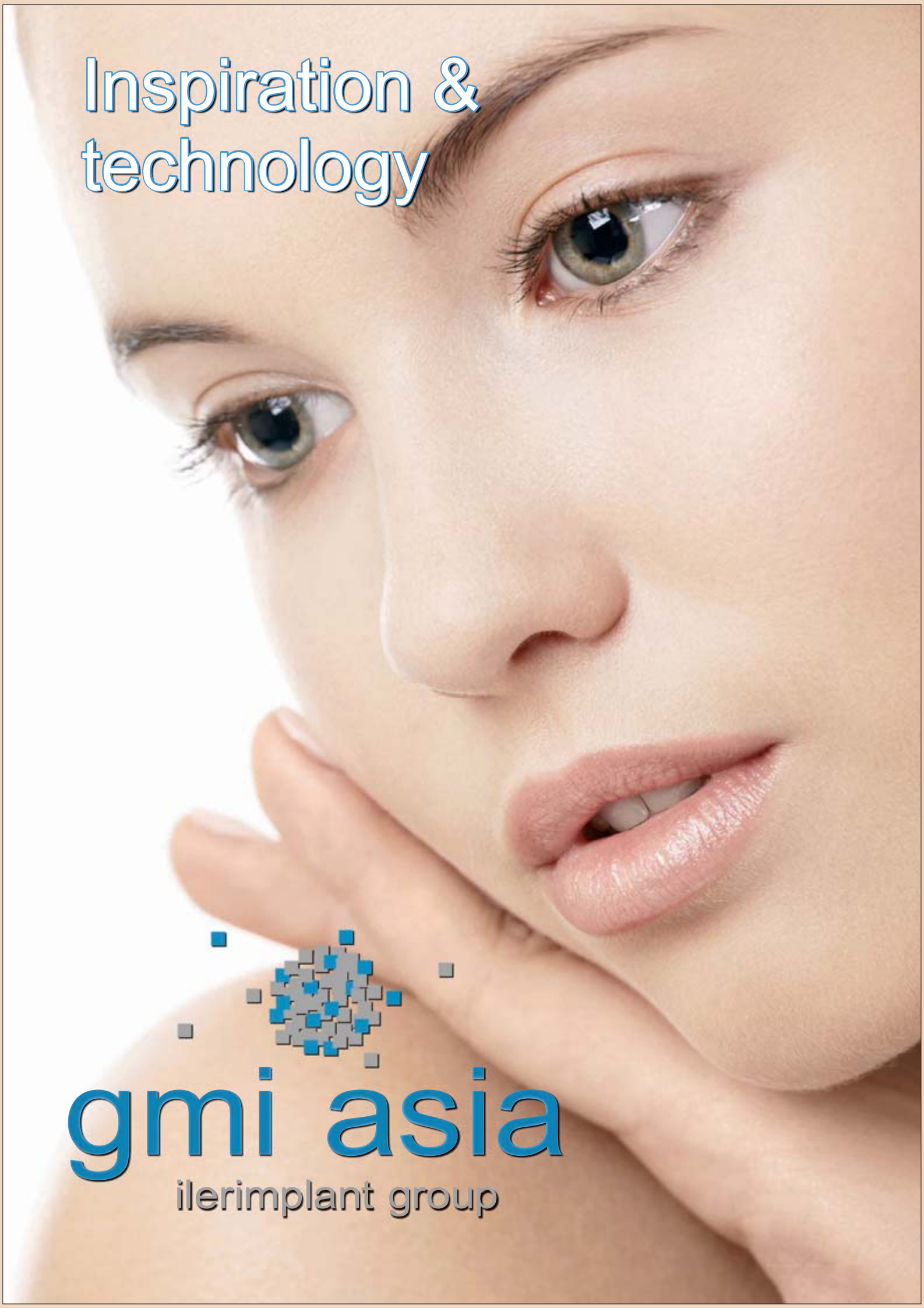

Dr Nigel Pitts at IDEM 2012. (DT/Photo Claudia Duschek, DT)

"A common language for all stakeholders to communicate about caries"

An interview with IDEM presenter Dr Nigel Pitts, UK

At this year's IDEM, Dr Nigel Pitts from the UK presented a lecture focusing on dental caries as a public-health issue, as well as the epidemiology and importance of understanding the science behind primary and secondary caries prevention. *Dental Tribune Asia Pacific* spoke with him about evidence-based approaches to planning care that can be utilised in dental practice.

Dental Tribune Asia Pacific: ***Caries is increasingly considered a serious public-health issue. Has the perception of the disease changed during the last few years and if so, what are the indications of this development?***

Dr Nigel Pitts: Yes, the perception has changed, but in what way, very much depends on which country one is considering. There is a growing awareness in many "developed" countries, where caries has been declining dramatically for decades, but there are still vulnerable groups, particularly young children, with a very high burden of preventable disease.

In other countries, caries in young children is thought to be increasing. In yet other traditionally low-caries "developing" countries, there are real concerns that changes in diet and lifestyle may be accompanied by an increasing caries problem for society and for individuals.

You are one of the developers of a caries classification and management system endorsed by dental organisations like the FDI World Dental Federation. What is the concept behind it and what is its potential for decreasing the burden of tooth decay in the world today?

ICDAS (International Caries Detection and Assessment System) is a simple, logical, evidence-based, detection and assessment system that classifies the stages of the caries process. It is designed for use in dental education, clinical practice, research and public health. It provides a common language for all stakeholders to communicate about caries, and facilitates valid, consistent comparisons of lesions at single and multiple time points.

ICDAS has evolved to comprise a number of approved, compatible formats for different needs and applications, including simplified forms for those wanting to work with fewer stages of caries. The potential for decreasing the burden of caries ranges from helping the transition to a more preventive approach to caries, helping in assessing health needs more realistically for populations and individuals, helping evaluate preventive programmes and helping to deliver more preventive caries control and better future products through research.

Apart from classification, what other advantages does such a system offer?

ICDAS leads to better quality information, derived from the assessment of caries severity and activity, to support decisions about diagnosis, prognosis and clinical management at both the individual and public-health levels. As we know more about

AD

the complexities of the caries process, informing sound clinical decisions is increasingly important for providing appropriate and high-quality caries care.

How can these concepts be applied to dental practice?

ICDAS has created the International Caries Classification and Management System (ICCMS), an open system developed specifically to meet the needs of those seeking a preventively orientated framework to support and enable comprehensive clinical caries management in the dental practice situation. This framework will help the dental team secure improved long-term outcomes for their patients.

There are improved means of detecting and assessing risks for early carious lesions. Has technology changed how we look at them?

The clinical visual detection and assessment of early lesions (using ICDAS-style approaches) is the foundation for planning care, but there is a continuing need for detection aids to help identify lesions that are difficult to detect visually and for effective risk assessment tools.

Examples of some of the newer approaches on the market for detection are enhanced electrical, optical and radiographic detection aids. These should be considered prudently as aids to preventive caries care, not just finding more cavities to fill.

There are also developments in risk assessment systems, such as CAMBRA, to accompany older established systems, such as cariogram. All of the information derived from these useful detection and risk assessment tools needs to be integrated into a holistic and personalised preventive treatment plan for each patient.

Concerning the management of early carious lesions, you promoted a study in 2010 on the best way to manage decay in children's teeth called FICTION (Filling Children's Teeth, Indicated or Not?). The study to be finished in 2018 is examining the different approaches (conventional restoration, preventive method and the Hall technique) to children of ages three to seven. Is there a tendency towards any of these approaches so far?

As you indicated, this exciting study will not be completed for some years. The feasibility stage is finished and the much-needed back-to-back comparison is getting underway—it is too soon to see results yet. The mounting evidence we do have (from multi-year randomised controlled trials in general practice) is that the approach of biological, preventive management with reduced surgical intervention (such as with the Hall technique) is showing results that are better than those achieved by the more conventional methods.

"I do see this move from a purely operative towards a more preventive-based approach."

What approaches to primary and secondary caries prevention are the most promising and what evidence do we have with regard to their clinical effectiveness?

The strongest evidence on caries prevention comes from high-quality systematic reviews of fluoride, whether in water, salt, toothpaste, varnish or other forms. In addition, there is strong evidence of the efficacy of sealants.

There are also some promising new developments with remineralisation, but it will inevitably take time to accrue further evidence of clinical effectiveness.

There is evidence that a purely restorative approach is not efficient but preventive caries control has been adopted rather slowly in many countries. Do you see a move from an operative towards a more preventive approach?

I do see this move from a purely operative towards a more preventive-based approach gathering pace. It has been a very slow change in some countries, despite the profession talking about it for decades. However, there are a number of countries that have been controlling caries in this way for years and an increasing number of countries that are in transition. Reform of payment systems and changes in patient expectations are important components of this change.

Thank you very much for this interview. DT

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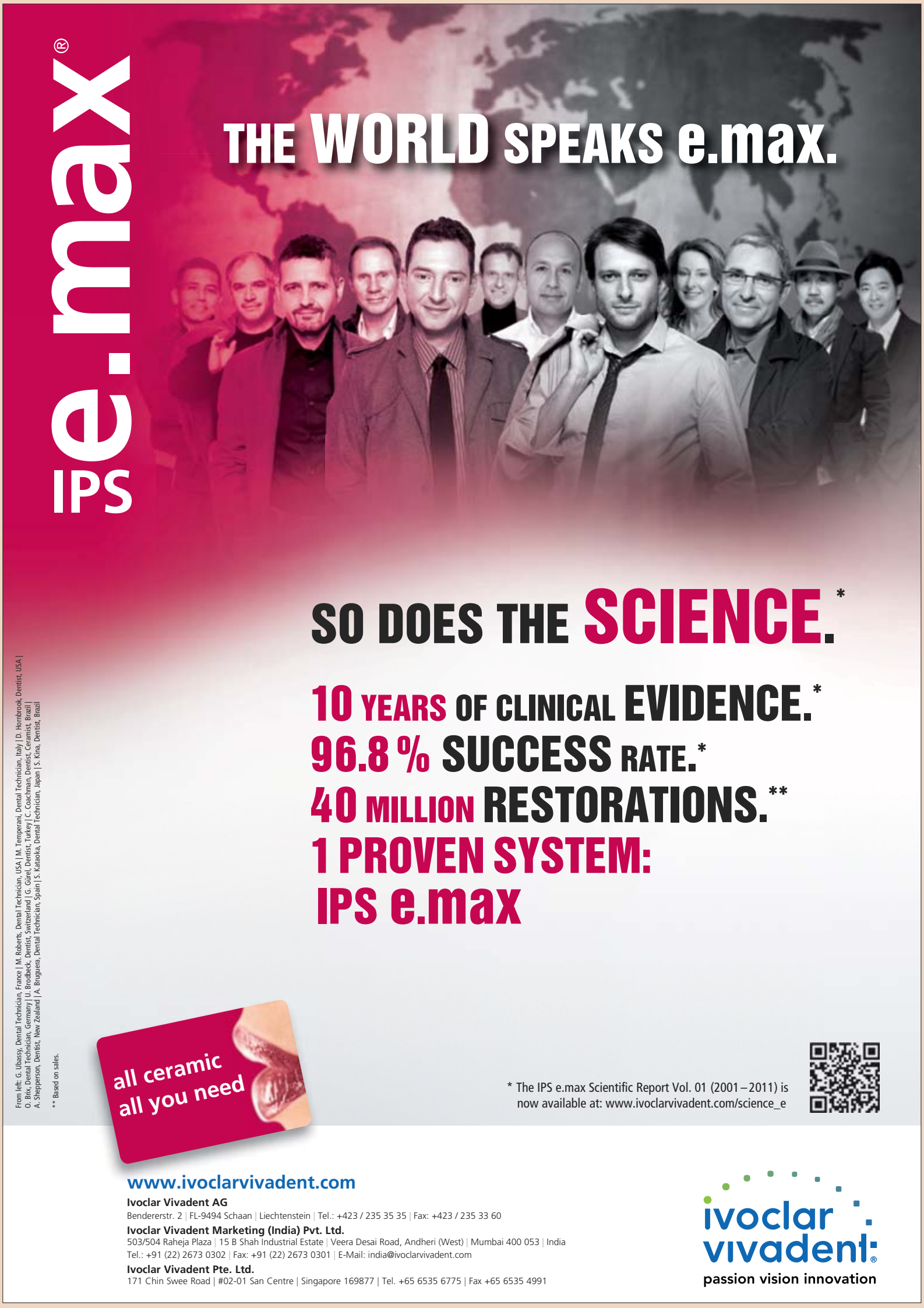

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Booming dental industry drives IDEM Singapore

Organiser Koelnmesse announces changes for 2014 edition of Asia dental show

More visitors than ever were swarming the aisles of the Suntec exhibition hall on Saturday. (DTI/Photo courtesy of Koelnmesse, Singapore)

Daniel Zimmermann
DTI

SINGAPORE: The International Dental Exhibition & Meeting in Singapore will be more integrated and even more comprehensive in future. According to Koelnmesse's Asia Pacific Vice-President, Michael Dreyer, his organisation plans to bring the exhibition and congress together in 2014, which will then both be held in close proximity on levels 4 and 6 at the Suntec Singapore International Convention & Exhibition Centre.

The range of topics covered by the congress programme will also be extended by issues concerning practice management, such as the marketing of dental care or the use of digital management systems, and future developments in dentistry, Dreyer said.

The next IDEM Singapore will take place from 4 to 6 April 2014.

This year's edition has been the most successful since the first IDEM was held in Singapore in 2000. According to figures of Koelnmesse, participation by dental professionals increased by 20 per cent compared to 2010, which was affected by air travel restrictions caused by a volcanic ash cloud in Europe.

Michael Dreyer (right) talking to Singapore's Minister of Health Gan Kim Yong. (DTI/Photo courtesy of Koelnmesse, Singapore)

Attendance by regional and overseas manufacturers and dealers also went up by 20 per cent this year.

Dreyer said that in order to facilitate this growth, his organisation is aiming at creating regional communities to attract more buyers from key countries in South-East Asia to future meetings. For this year's show, he said that Koelnmesse has been working closely with professional dental associations in countries like Thailand and Vietnam, who also brought more attendees to IDEM Singapore.

IDEM Singapore also collaborated with the Asia Pacific Students Dental Association this year. For the first time, fifteen students of dentistry from across the region were given the opportunity to come to Singapore and interact with exhibitors, speakers and attendees. Extra sessions moderated by Prof. Urs Belser, Switzerland, and Prof. Robert Boyd, USA, gave first-hand insights into the intricacies behind sophisticated patient treatment.

"Once again, we recorded an increased number of exhibitors and visitors, establishing IDEM Singapore as an important event in the region's calendar of dental events. As markets across the region prepare to embrace the globalization of dentistry and its opportunities, IDEM Singapore will continue to play a strategic role to facilitate this growth," Dreyer concluded.

"This year's event provided an all-round experience for participants with a good mix of trade exhibitions, scientific sessions and hands-on workshops. The knowledge and insights gained by participants over these three days will help accelerate the progress of the industry, probably resulting in more sophisticated dental offerings and a more robust dentistry market." DT

"We are looking for high-end clinics and the distributors selling high-quality products to them"

An interview with Sabine Nahme and Philip Y. K. Teng, Abrasive Technology

Sabine Nahme (right) and Philip Y. K. Teng, who will manage Abrasive's operations in Singapore. (DTI/Photo Claudia Duschek, DTI)

Global manufacturer Abrasive Technology has set up a new direct sales office in Singapore. *Dental Tribune Asia Pacific* spoke with Sabine Nahme, who was recently appointed to Abrasive Technology's business development team, and Philip Y. K. Teng, the General Manager for Asia Pacific.

Dental Tribune Asia Pacific: *Abrasive Technology is aiming at expanding into the dental sector, especially in Asia. How are you going to approach the market?*

Sabine Nahme: Although we have covered many other areas like optical, medical and aerospace applications in the last decades, we actually started out in dentistry. Now we would like to focus more intensively on our dental business by expanding our own quality line, Two Striper, which is manufactured through a unique P.B.S. diamond-particle bonding process, to the Asian market.

I was recently hired to support Abrasive Technology's international growth, and I will assist Philip with sales in Asia.

What are your expectations of the Asian market?

Sabine Nahme: The East Asian market is growing every year. There are a couple of large markets, with the biggest in China. We are also expecting a large increase in sales in this region.

Philip Y. K. Teng: We are also very confident that we will be able to achieve this goal in a short time.

How will you approach sales in Asia?

Sabine Nahme: At the moment, we are looking for high-end clinics and the distributors selling high-quality products to them, in particular.

Philip Y. K. Teng: To do effective networking, we are attending trade shows, conducting webinars and seminars, and collaborating with highly respected clinicians. At IDEM, we have already made good contacts in Korea, India and Singapore.

Thank you both for this interview. DT

Abrasive Instruments (DTI/Photo courtesy of Abrasive Technology)