

dentaltown®

March 2009 • Volume 10, Issue 3

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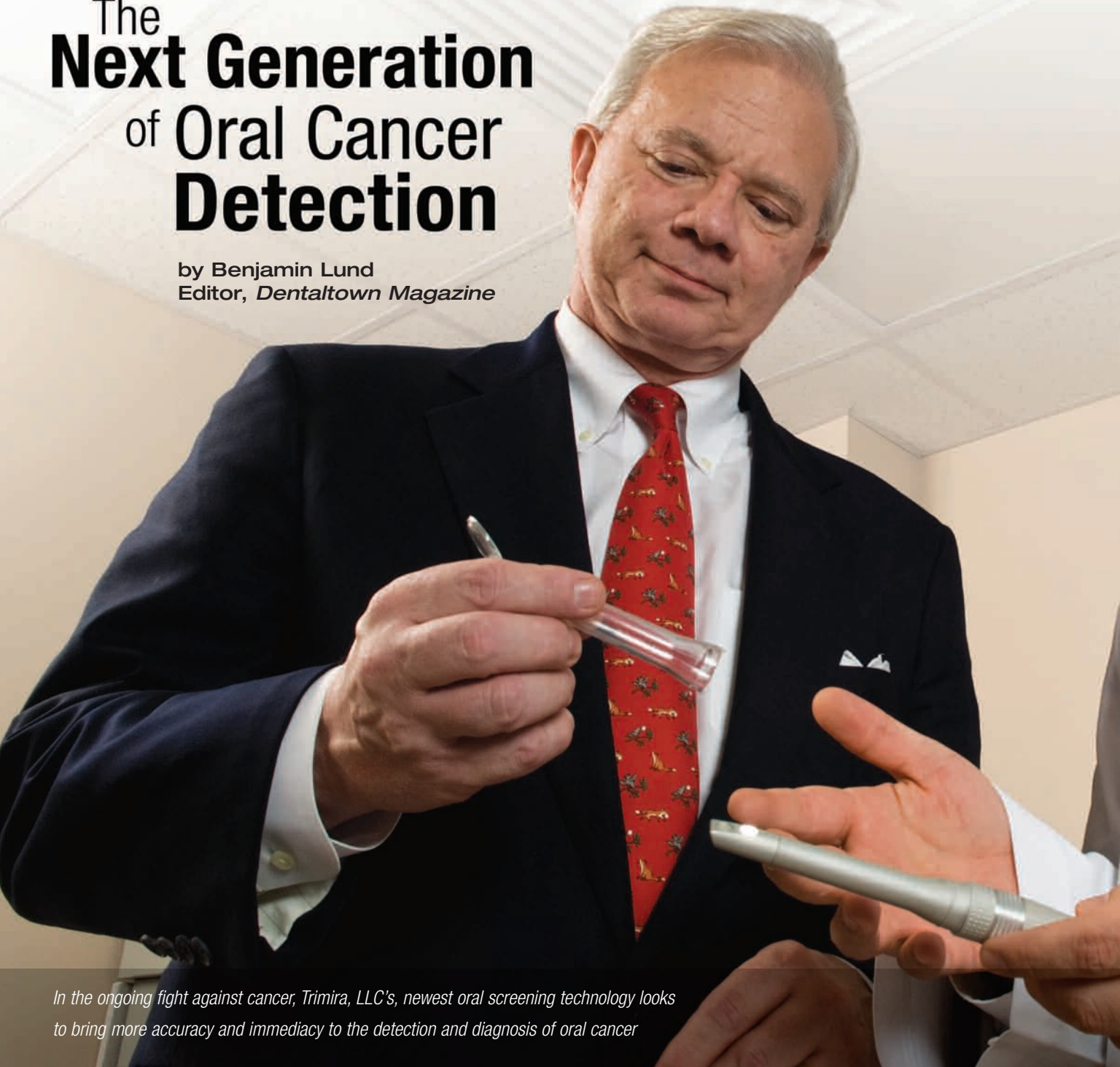
Trimira
Joins the
Fight Against
Oral Cancer



*Williams, M.
Department of
Head Neck Surgery*

The Next Generation of Oral Cancer Detection

by Benjamin Lund
Editor, *Dentaltown Magazine*



In the ongoing fight against cancer, Trimira, LLC's, newest oral screening technology looks to bring more accuracy and immediacy to the detection and diagnosis of oral cancer



According to the Oral Cancer Foundation, more than 34,000 Americans will be diagnosed with oral or pharyngeal cancer this year – and of those newly diagnosed patients, only half of them will be alive in five years.



The reason the death rate for oral cancer is so high is due to the acute difficulty of detection, and for those who do detect it, it's usually too late. Oftentimes oral cancer is located after it has metastasized to another area, and once it has reached that point the patient's prognosis is poor at best. As with all forms of cancer, early detection is key to successful treatment and when it comes to oral cancer screening, dentists are the vanguard. Oral cancer screening systems are becoming more and more sophisticated, cost effective and accurate with every new commercial and scientific innovation. Trimira LLC, a subsidiary of Remicalm LLC, has developed Identafi 3000, the newest oral cancer screening system for dentists to include in their oncological arsenal. *Dentaltown Magazine* spoke with David A. Burns, chairman and CEO of Trimira, to learn more about his company's new technology as it joins the battle against oral cancer from the broad base of science on which Trimira and Remicalm were founded.

David, where and how did Trimira get its start?

Burns: The technology and patents created by Drs. Rebecca Richards-Kortum, Michele Follen and Calum MacAulay and their respective teams at the University of Texas (now Rice University), M. D. Anderson Cancer Center and British Columbia Cancer Center.

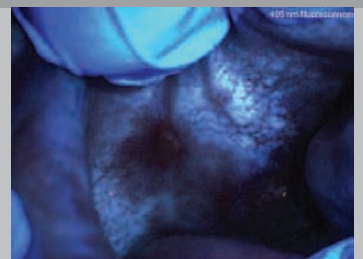
What was the impetus for developing an oral cancer screening system?

Burns: The research effort by the scientists included much work with mucosal tissue and naturally led to work with oral mucosal tissue. The technology is readily adaptable to cervical, esophageal, gastrointestinal and other areas of tissue. We are working toward both screening and diagnostic devices in other organ sites as well.

Fifteen years and \$40 million have been spent in the development of this multispectral screening technology, which is finally ready for com-

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*Above: Trimira Chairman and CEO David A. Burns (left) and Dr. Andres Zuluaga (right).
Below: A suspect area of the mouth illuminated in white, amber and violet light.*



mercial use. Can you please explain how you developed it, who worked on it and how it differs from other oral cancer screening systems?

Burns: Funding for this science has come from both public and private sources. The three scientists developed the basic science and patented it through their university affiliates. We obtained a license of approximately 25 patents jointly held by the three educational and medical centers and have taken the science forward with private funding and industrial engineering. Trimira has also created products in specific areas of this multispectral technology and has patented products such as the Identafi 3000 and other dental devices are also now in development or testing.

We have been fortunate to involve Dr. Andres Zuluaga, a former student of Drs. Richards-Kortum and Follen, in this effort. Dr. Zuluaga has worked on Trimira's projects from the beginning and is Trimira's vice president of research and development. He has been in charge of the design of the Identafi 3000 and other products. In addition we very much appreciate the work and testing of the Identafi 3000 by Drs. Ann Gillenwater, Miriam Rosin, Catherine Poh, Michele Williams and Nadarajah Vigneswaran.

There are two other types of oral cancer screening systems on the market. One is a dye-based oral lesion marking system used as an oral rinse, which performs much like acetic acid used in other parts of the body – that is to increase contrast in tissue. The other is a scope using a blue light to create fluorescence in the mouth. The Identafi 3000 uses violet light to create fluorescence, a white light for viewing similar to normal ambient light, and amber reflectance which permits the health care professional to see the morphology surrounding a lesion. We believe the violet lightwaves to be more efficacious than blue. The amber light (which is actually a combination of green and red wavelengths but perceived by the eye as amber) aids the health care professional in differentiation between the tissue that is cancerous or precancerous and tissue (such as inflamed tissue) that has a similar appearance as cancerous tissue under violet light but is not in fact cancerous or precancerous. The minimization of false positives, which has previously created problems in oral screening, is important to the credibility of the dentist, doctor and other health care professionals.

According to a recent report by the World Health Organization, cancer will overtake heart disease as the world's top killer by 2010, which is part of a trend that should more than double global cancer cases and deaths by 2030. With this trend in mind, how do you expect your technology to be received in the coming years and what impact do you hope it will have on world health?

Burns: The Trimira technology will help alleviate the problems of cancer in three ways. First, early detection of precancerous conditions or detection of cancer before metastasis greatly



Identafi 3000: General Overview

Trimira's Identafi 3000 is a battery-operated, hand-held multispectral oral examination light used in conventional and specialized oral examinations (patents pending). Accessories include filtered glasses for both the clinician and the patient; single use, disposable mirrors; rechargeable batteries and charger.

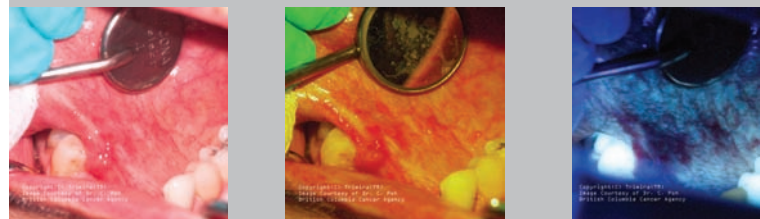
Eyewear

The Identafi 3000's reusable and filtered eyewear is worn by a health-care professional to enhance the visual effects of violet light during oral exam. The eyewear has been designed to allow transmission of 430-580nm light.

Violet and Amber Light

Identafi 3000's violet and amber lights each excite the oral tissues in distinct and unique ways. Specifically, biochemical changes can be monitored with fluorescence, while morphological changes can be monitored with reflectance. Violet light enhances normal tissue's natural fluorescence where suspicious tissue appears dark because of its loss of fluorescence. The clinician's filtered glasses block the violet excitation light and allow the observance of the tissue's natural fluorescence. Amber light enhances normal tissue's reflectance properties where the clinician can directly observe the difference between normal and abnormal tissue's vasculature.

Below: A suspect area of the mouth illuminated in (from left) white, amber and violet light.



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improves the odds of a favorable outcome for the patient. Second, the speed of an optical screen in comparison with the current methods of taking and reading biopsies happens in minutes rather than days or a week. Optical screening is faster, less expensive and more acceptable. Third, when this optical technology is developed to its full potential with algorithmic diagnosis, the efficacy of both screening and diagnosis will be greatly enhanced, will be faster and will be available to a much broader population in the world.

In relation to other forms of cancer, why is early detection so important when it comes to oral cancer?

Burns: The need for screening and earlier detection in oral cancer is high because of the frequent lack of pain or symptoms in oral cancer that would normally alert a patient to a disease. In the past, a patient's age and use of alcohol and tobacco were thought to be the key indications for screening for oral cancer. Today, oral and cervical cancers are rising at alarming rates because of the effect of the human papilloma virus (HPV), so a new part of the population is at risk.

Why should a general dentist interested in incorporating oral cancer screening into his/her practice invest in your technology?

Burns: Because of affordability, accuracy, availability and advisability. The Identafi 3000 system is less than half the cost of the competing optical screener. It is more compact, easier to use and contains a multispectral screening capability designed to permit both identification of suspicious areas of tissue and differentiation of those areas between cancer and confounders. The dentist can offer this screening service for less than half the fee currently being offered for the competing scope or the mouth-wash and have a profitable addition to his practice.

What sort of support and training do you offer those who have purchased your technology?

Burns: Trimira in conjunction with Learn HealthSci, Inc., is creating a series of continuing education courses for health care professionals. The dedicated site will feature course curriculums developed by globally recognized academic researchers. Researchers and private clinicians are working with Trimira to construct an Internet-based library that will be accessible to clinicians who utilize the Identafi 3000 technology in their practices or institutions. Training is a priority for Trimira. To that end, the company is working with three world-renowned institutions creating training modules for dentists and hygienists as well as otolaryngologists and primary care physicians. In addition, Learn HealthSci, Inc., has created training modules for the dentists and industry sales professionals.

Looking to the future and aside from detecting cancerous lesions or pre-cancerous tissue, are there any other applications this new technology can be used for?

Burns: With a change to the form of the head cover of the Identafi 3000, the device will be usable as a transilluminator. In addition, we will be introducing a device that will be adjunctive to the Identafi 3000 and will give the clinician a more detailed view of cell morphology in areas where disease is suspected. We shall not introduce either of these devices until further study and regulatory compliance has been accomplished.

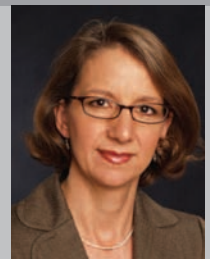
I ask this question with a hint of optimism, but, as an end note, do you think we will ever see a cure for cancer in our lifetime?

Burns: The capabilities of humans to seek and find a solution for mankind's problem should never be doubted. Nevertheless you should screen early and often.

Dentists can purchase the Identafi 3000 through their dental distributors. For more information on Trimira, please visit www.trimira.net. ■



Left: Trimira Vice President of Sales & Marketing Jerry S. Trzeciak (back left), Chairman and CEO David A. Burns (front left), President H. Kirby Atwood, Jr. (front right) and Dr. Andres Zuluaga (back right). Below: (From left) Founding Scientists Michele Follen, MD, Ph.D.; Calum Macaulay, Ph.D.; Rebecca Richards-Kortum, Ph.D.



In the war against oral cancer,
you just got a better weapon.

- Equipped with single use examination mirror to eliminate the need for autoclaving.
- Proprietary Identafi™ Technology employs THREE Multi-Spectral color wavelengths to minimize false positives and unnecessary biopsies.
- Compact, lightweight design more comfortable for the professional conducting the procedure and the patient.
- Eliminates the need for messy, bad tasting dyes or solutions.
- Space saving holder, with wall mount option, provides convenient, ready access in any treatment room layout.

Identafi™
3000

Compact and lightweight
with three Multi-Spectral
color wavelengths

Three Multi-Spectral Color Wavelengths



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Oral Cancer is a killer that claims one life every hour of every day with a shocking growth rate of 11% in 2007.¹ Sexually transmitted HPV, oral cancer's dangerous new ally, is putting younger and younger patients at risk. Now you have a better way to catch Oral Cancer with the Identafi™ 3000.

Unlike other fluorescence technologies and dye systems, the Identafi™ 3000 is Multi-Spectral with three distinct color wavelengths, making it easier to distinguish lesion morphology thereby reducing false positives. Coupled with its compact, lightweight design, in office training and reasonable price, the Identafi™ 3000 ensures the highest standard of care.

Shed more light on early detection.