Zacks Small-Cap Research

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LED Medical Diagnostics (V.LMD)

V.LMD: LED Imaging Revenue Expected To Ramp. Revenue Guidance of 260%+

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/20/2014
Current Price (09/04/2014)	$0.42
Target Price	**$2.50**

OUTLOOK

LED Medical's VELscope is the world's leading device used for oral cancer screening with 13k units sold and 25 million scans done since the 2006 launch. Demand is fueled by a quantity of clinical data and recommendations from influential sources supporting use of the device as well as increased awareness of the dangers of oral cancer. Despite their leading position, the market remains barely penetrated, offering significant upside opportunity.

LED recently revamped its sales strategy to one with multiple distributors and complemented by a direct sales force. This is expected to further expand their footprint, drive utilization and increase profitability. LED also continues to expand their product line - contribution from which is expected to make a significant impact in the near term. Applications for their technology into other cancers including skin and cervical provide potential market-expansion and additional growth opportunities. We value LMD.V at $2.50/share.

SUMMARY DATA

52-Week High	**$0.59**
52-Week Low	**$0.35**
One-Year Return (%)	**36**
Beta	**N/A**
Average Daily Volume (sh)	**158,589**
Shares Outstanding (mil)	**75**
Market Capitalization ($mil)	**32**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**N/A**
Dividend Yield (%)	**N/A**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**Large-Growth**
Industry	**Med/Dental-Supp**

ZACKS ESTIMATES

Revenue
(in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	$310 A	$1083 A	$911 A	$216 A	$2519 A
2014	$1055 A	$1590 A	$1910 E	$5027 E	$9582 E
2015					$14225 E
2016					$26499 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.03 A	-$0.05 A	-$0.03 A	-$0.02 A	-$0.13 A
2014	-$0.04 A	$0.00 A	-$0.02 E	-$0.02 E	-$0.08 E
2015					-$0.03 E
2016					-$0.00 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Q2 2014 Results: *Big Beat On Revenue But Bigger News is Guidance of 260% Revenue Growth*

LED filed their Q1 2014 financials for the period ending June 30, 2014. Similar to Q1 of this year, revenue increased significantly on both a sequential and yoy basis and was again well ahead of our estimate. And while the company did not provide specifics relative to the impetus for the continued strength in sales, they did note that the recent change to non-exclusive distribution as well as the newly established digital imaging product line were contributors. Even more striking than the recent beat on revenue relative to our estimates, however, is the company's full-year guidance. In the Q2 earnings release LED is providing revenue guidance - a first for the company - LED expects full-year 2014 revenue in the range of $9.0M - $11.0M. The company further implies that this guidance could prove conservative depending on the impact of their sales and marketing programs.

And as we noted previously, the recent shift in strategy, which also included key executive hires, adding direct sales reps, opening a sales office in Atlanta and development work on new products, has also had the effect of increasing operating expenses. At the end of June 2014 LED had 38 employees, including 27 in sales and marketing - this is up from just 14 employees including 8 in sales and marketing at June 2013.

Q2 revenue was $1.59M, well ahead of our $929 estimate and up 47% and 51% from Q2 2013 ($1.08M) and Q1 2014 ($1.06M), respectively. Operating expenses also significantly increased, from $1.5M in Q1 2014 to $2.3M in Q2 and mostly reflects the substantial increase in sales and marketing investments in support of both VELscope and the newly established LED Imaging business. So despite the significant sequential revenue growth, the jump in operating expenses resulted in Q2 operating loss about $400k greater ($1.6M vs $1.2M) than Q1. Net income and EPS were $83k and $0.00 but excluding a $1.8M positive mark-to-market adjustment, net income and EPS were ($1.7)M and ($0.02), compared to our ($1.2)M and ($0.02) estimates.

Cash used in operating activities was $2.0M in Q2. Excluding changes in working capital, cash used in operating activities was $1.5M. Cash balance stood at $1.8M. Subsequent to quarter end the company generated gross proceeds of $2.2M via the exercise of warrants.

Board Appointments
Following quarter-end, LED announced that Darryl Yea, President of Investco Capital Management, was appointed LED's Chairman of the Board . In addition, Lamar Roberts, President of LED Dental, and Al Fiore, Chairman and CEO of PowerWorks, were appointed to the board of directors. Commensurate with this, Peter Whitehead, LED's former CEO who recently took the role of Chief Scientific Officer, will step down as a director and act as a consultant to the company for the next year.

Al Fiore was a colleague of Messrs. Roberts and Ganes at PracticeWorks, one of the largest software/technology companies in the dental care segment which was purchased by Eastman Kodak. We think Mr. Fiore should be a great fit for the company's focus on expanding their LED Imaging business in particular.

Model Update
We have made meaningful changes to our model following the release of Q2 results. As we noted in previous reports, we had yet to model any contribution from sources other than VELscope (and related consumables) given the lack of clarity surrounding the timing of launch of new products (mostly from LED Imaging) and pace of introduction throughout LED's distribution footprint. So while we have made no changes to our forecasted VELscope-related sales, we have updated our model to now include revenue from new products - namely, RAYSCAN-Expert, the company's imaging software, the IS100 intraoral sensor and two models of intraoral cameras. With RAYSCAN-Expert retailing for approximately $100k, the instrument could be a very significant revenue source for LED. The company expects to continue to look further expand their product suite. And while LED noted in the Q2 release that they are now mothballing their oral cancer genetic test development program as they dedicate resources to other products, this decision has no impact on our model as we had yet to incorporate any potential contribution from the test.

LED's $9.0M - $11.0M revenue guidance for 2014 includes the expectation that sales of their digital imaging products show a substantial ramp in late Q3 and throughout Q4, facilitated by seasonal dental industry buying patterns. As noted, the company implied that this guidance could end up being conservative and they expect that the digital imaging products will continue to be a significant contributor to total sales going forward.

Revenue fell 60% in 2013 but has since done an about-face, increasing 90% through the first half of 2014. We think it is now clear that the initial portion of the company's shift in strategy, which includes a major focus on expanding distribution and complementary revenue opportunities, has already been well established - and has been done in much more rapid fashion than we had initially anticipated it would be. The architects, namely David Gane and Lamar Roberts who came to LED from Carestream with highly relevant experience in the dental products industry sales, have made obvious substantive progress (in a very short period of time) with broadening the distribution footprint, revamping the sales strategy, growing the product portfolio and returning the company to positive revenue growth. The $9.0M - $11.0M revenue guidance implies yoy growth of 260% - 340% and would best the company's previous annual revenue record of $5.7M (2011) by at least 50%.

The update to our model to include contribution from LED Imaging has pushed our 2014 forecasted revenue up from $4.3M to $9.6M. Continued investment in sales/marketing infrastructure and other costs related to the roll-out of the LED Imaging product suite as well as an increase in sales-related commissions will have the effect of pushing up operating expenses, although we model a flatter rate of growth in opex as compared to that of revenue.

The update to our model has also pushed our DCF-generated price target up from $2.00 to $2.50 per share. We are maintaining our Outperform rating.

Strategy Shift Taking Shape…

The company continues to make substantive progress in its efforts to revive growth of its flagship VELscope product as well as in developing revenue sources from complementary products and services. As a reminder, in 2013 LED began charting an updated strategy to address its flagging revenue and consistent net losses. Despite a rapid placement rate since initial introduction and holding the title as the world's leading adjunctive screening device for oral cancer, VELscope sales began to tumble in late 2012 with the loss of a key distributor. The company then began a shift in strategy which culminated in the Fall of 2013 when new management experienced in dental product sales was brought on to outline and execute the new plans.

Additional hand-picked hires have been made including direct sales reps as well as management-level personnel. Just recently Dr. Jeff Brooks, an oral surgeon and colleague of Dr. David Gane while at Carestream Dental, was hired for the position of V.P. of Imaging of LED Dental, a recently formed subsidiary of LED Medical. We expect that Dr. Brooks, who is also an associate professor and 3D Imaging Director in the department of Oral and Maxillofacial Surgery at the University of Tennessee at Memphis, comes armed with potentially valuable knowledge of the oral cancer diagnostics market as well as industry contacts. In the V.P. of Imaging role Dr. Brooks will be directly involved in implementation of the company's recent strategy shift - including reigniting sales growth of VELscope as well as the introduction of new complementary products. More recently, another Carestream colleague, Tom Kearney, was brought on to drive the orthodontic channel for LED Imaging.

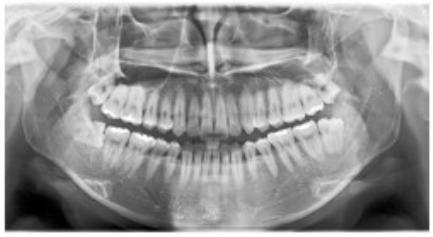
And while the transformation is still very much a work in progress, substantive changes have already been put in place to re-ignite sales of VELscope. Instead of the prior sales and marketing strategy which relied almost exclusively on third party distribution (and with a heavy reliance on a single distributor), the company is moving towards a combination of direct and distributor sales (using several distributors). In the last several months the company has signed distribution agreements with several new distributors covering Canada and the U.S. At Q2 quarter-end the company had 9 distributors selling their products - this compares to just one in mid-2013. They also opened an office in Atlanta to facilitate easier access to the U.S. market and where the sales team will also coordinate the ongoing international commercialization efforts.

LED has also made meaningful headway with efforts to supplement VELscope revenue with complementary products including partnership with a Samsung subsidiary to market that company's dental imaging system. These complementary products are already expected to make a major contribution to revenue and are clearly the major impetus for management guiding to 2014 revenue of $9.0M - $11.0M - which compares to just $2.5M in all of 2013 and implies revenue in the second half of 2014 will be in the range of $6.5M - $8.5M (compared to $2.7M in 1H 2014).

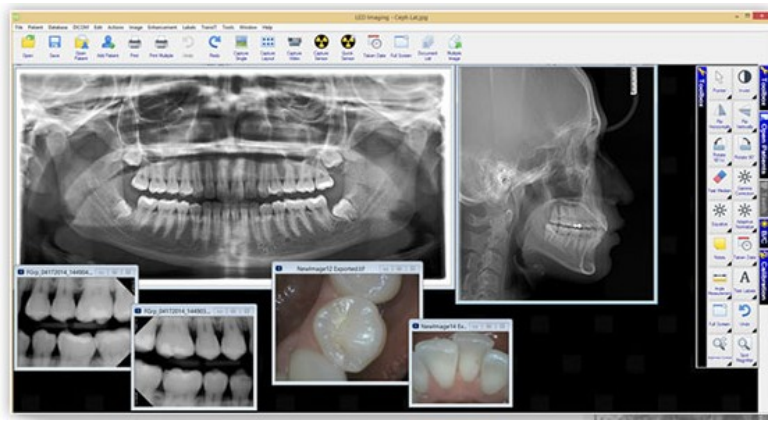
> In early April the company announced that it entered an agreement with Ray Co, Ltd, a subsidiary of Samsung, to sell that company's RAYSCAN-Expert dental imaging instrument. With LED's vast installed base and beefed-up customer reach via build-out of its sales and distribution infrastructure, the RAYSCAN-Expert offers a synergistic revenue opportunity. LED also just announced launch of its LED Imaging Software which is compatible with RAYSCAN and captures and records oral pictures and videos from a variety of imaging devices. The software easily integrates with all dental practice management programs, supports HIPPA compliance and is seamlessly installed and updated.

***RAYSCAN - Expert* and Sample Images** *(SOURCE: rayscanamerica.com)*





LED Imaging Software *(SOURCE: leddental.com)*



> In May LED announced the introduction of its newest products in their LED Imaging division. LED IS100 is a digital radiography intraoral sensor which replaces traditional dental film for the imaging of teeth and oral bone structures. LED IC100 and LED IC200 are high resolution cameras. With these products LED expects to capitalize on the shift from film to digital imaging as the latter provides certain important benefits including faster results, very high resolution, seamless integration across various software and imaging platforms and use with a wide variety of dental applications including endodontics, cavities, periodontics and others.

Intraoral Sensor



IC100 Intraoral Camera *(SOURCE: leddental.com)*



BACKGROUND

LED Medical Inc. (LMD.V) is a British Columbia, Canada based medical device company. The company went public in late 2011. LED's VELscope is the world's leading adjunctive screening device for oral tissue abnormalities, including oral cancer. The tissue fluorescence visualization technology on which the VELscope is based was developed in partnership with the British Columbia Cancer Agency and is supported with more than $50 million in research provided by the National Institutes of Health and other leading institutions and universities. After only about seven years on the market, there are already more than 13k VELscope devices in use and more than 25 million scans have been performed to date. The device is approved for sale in the U.S., Canada and over 20 other countries.

Sales of VELscope have been driven from several angles including greater awareness of the threat posed by oral cancer which has been spurred in part by increased incidence of the human papillomavirus among young people, clinical evidence indicating that conventional and widely used current oral cancer diagnostic methods are lacking, a substantial amount of clinical evidence documenting the efficacy of VELscope technology, endorsements of and awards for VELscope from dental organizations as well as celebrity physicians, broadening insurance reimbursement, favorable economics for dental practices (including quick capex payback period), the launch of a new handheld wireless VELscope model and distribution by dental and medical device distributor heavyweight, Henry Schein.

Despite their success to-date in quickly ramping their installed base of VELscope systems, LED is currently in the midst of somewhat of a change in strategy. While the company remains focused on continuing to increase their installed base and market penetration (which they estimate at only about 6% currently in North America and substantially less in ROW), they are now in a position to leverage their customer base and increase profitability. The company recently brought on two ex-Carestream Dental sales executives to lead LED's revamped sales and marketing strategy which is expected to revive sales of VELscope, increase utilization (i.e. - razor blade sales in their razor/razor blade revenue model) and facilitate the synergistic opportunities afforded with the introduction of new products, specifically those from the company's newly formed LED Imaging business (which includes the RAYSCAN-Expert dental imaging instrument, as well as others). LED is also on the front-end of expanding the indicated uses of its existing technology beyond just oral applications and into skin cancer, a market many times the size of oral cancer. Longer-term, the company may also look to enter other cancer applications including for prostate and cervical cancers.

The CEO role has recently been filled by Dr. David Gane, DDS, the former V.P. of the Dental Imaging business of Carestream Dental, LLC, a division of Carestream Health. Carestream Health was formed in 2007 with the purchase of Eastman Kodak Company's Health Group, was named Frost & Sullivan's 2010 Medical Imaging Company of the Year, has been an innovator in medical imaging and has operations in 170 countries. Lamar Roberts was brought on as LED's V.P. of Sales and Marketing in October 2013. Lamar was a colleague of Mr. Gane for ten years at Carestream Dental and comes armed with significant experience and potentially valuable contacts in the dental products and services market. Gane and Roberts have already implemented changes related to distribution, optimized sales and marketing and been instrumental in expanding the product portfolio - all of which have culminated in the expectation that revenue will begin to significantly accelerate in the back half of 2014.

We think LED's strategy shift along with additional clinical evidence supporting the use of VELscope and the ongoing opportunity to exploit a largely untapped market will put the company in a position to re-accelerate revenue growth and, for the first time since going public, generate positive net income and cash flow.

INVESTMENT THESIS

ORAL CANCER

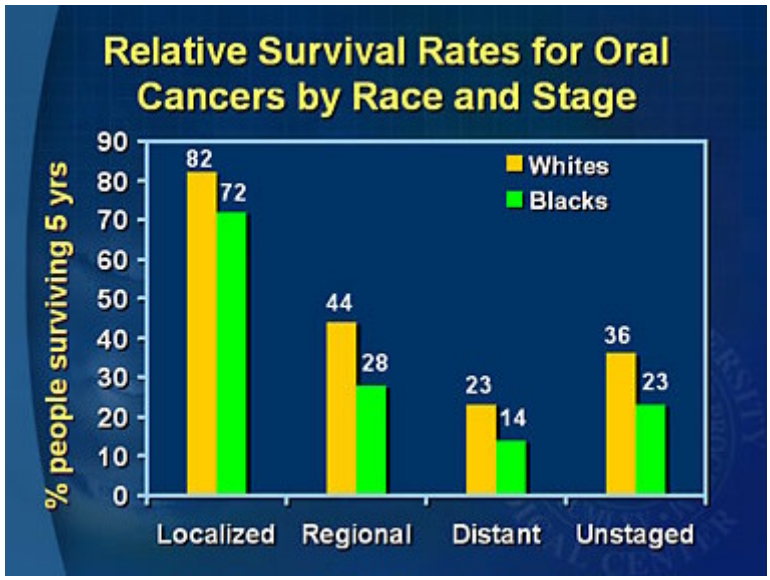
About 42k new cases of oral cancer are diagnosed in the U.S. every year. Worldwide the figure is about 640k new cases. About 8k people die every year in the U.S. from oral cancer. For those that do survive a late-stage battle with oral cancer, the disease and surgeries to remove tumors can leave them severely disfigured. Survivability of oral cancer is relatively low compared to other major cancers (see graphic below) with five-year survivability at only about 57%. Characteristic of all cancers is the later the stage, the poorer the prognosis. The relatively general poor

prognosis of oral cancer relates to that the disease is usually not found until later stages. Specifically, approximately 60% of oral cancer cases are not found until the distant (III and IV) stage when the five-year survival rate is under 50%. When discovered in early stages, however, the five-year recurrence-free survival rate is about 82%; earlier detection of oral cancer is the primary goal of VELscope technology. Another issue that exacerbates oral cancer metastasizing is the relatively high rate of development of second primary tumors in patients with a history of oral cancer. The rate of development of second tumors (new tumors which develop after an initial diagnosis) in oral cancer is 3.7%, the highest among all cancers. This means that people who have survived an initial bout with oral cancer have up to a 20x higher risk of developing a second tumor (a risk that is maintained for up to five to ten years). A study titled "Second Primary Tumors in Patients with Oral Cancer"[1] and published in the journal *Cancer*, concluded, "The exceptionally high rate of cancer recurrence among patients with oral cancer (exceeding that for all other cancers) points to the need for close medical surveillance."

Estimates of relative survival rates, by cancer site

	% survival rates and their standard errors			
	5 year	10 year	15 year	20 year
Prostate	98.8 0.4	95.2 0.9	87.1 1.7	81.1 3.0
Thyroid	96.0 0.8	95.8 1.2	94.0 1.6	95.4 2.1
Testis	94.7 1.1	94.0 1.3	91.1 1.8	88.2 2.3
Melanomas	89.0 0.8	86.7 1.1	83.5 1.5	82.8 1.9
Breast	86.4 0.4	78.3 0.6	71.3 0.7	65.0 1.0
Hodgkin's disease	85.1 1.7	79.8 2.0	73.8 2.4	67.1 2.8
Corpus uteri, uterus	84.3 1.0	83.2 1.3	80.8 1.7	79.2 2.0
Urinary, bladder	82.1 1.0	76.2 1.4	70.3 1.9	67.9 2.4
Cervix, uteri	70.5 1.6	64.1 1.8	62.8 2.1	60.0 2.4
Larynx	68.8 2.1	56.7 2.5	45.8 2.8	37.8 3.1
Rectum	62.6 1.2	55.2 1.4	51.8 1.8	49.2 2.3
Kidney, renal pelvis	61.8 1.3	54.4 1.6	49.8 2.0	47.3 2.6
Colon	61.7 0.8	55.4 1.0	53.9 1.2	52.3 1.6
Non-Hodgkin's	57.8 1.0	46.3 1.2	38.3 1.4	34.3 1.7
Oral cavity, pharynx	56.7 1.3	44.2 1.4	37.5 1.6	33.0 1.8
Ovary	55.0 1.3	49.3 1.6	49.9 1.9	49.6 2.4
Leukemia	42.5 1.2	32.4 1.3	29.7 1.5	26.2 1.7
Brain, nervous system	32.0 1.4	29.2 1.5	27.6 1.6	26.1 1.9
Multiple myeloma	29.5 1.6	12.7 1.5	7.0 1.3	4.8 1.5
Stomach	23.8 1.3	19.4 1.4	19.0 1.7	14.9 1.9
Lung and bronchus	15.0 0.4	10.6 0.4	8.1 0.4	6.5 0.4
Esophagus	14.2 1.4	7.9 1.3	7.7 1.6	5.4 2.0
Liver, bile duct	7.5 1.1	5.8 1.2	6.3 1.5	7.6 2.0
Pancreas	4.0 0.5	3.0 1.5	2.7 0.6	2.7 0.8

SOURCE: edwardtufte.com



SOURCE pamodules.mc.duke.edu/Oral_Health

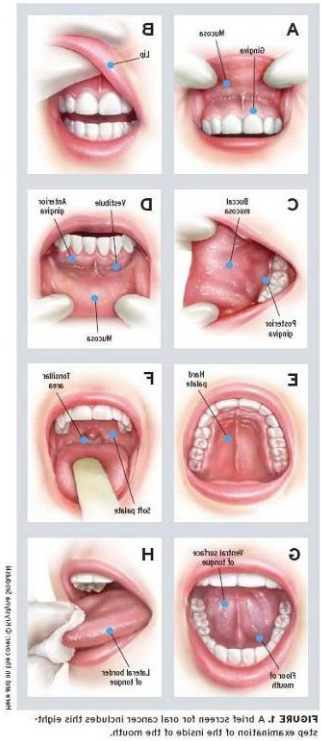
Risk Factors Heighten Incidence Among Younger Population

The risk of becoming afflicted with oral cancer is relatively low, roughly just less than 1%. Similar to most cancers, the risk of oral cancers increases with the use of alcohol and tobacco. Similarly, the older one's age, the higher the risk. Historically, oral cancer occurs most often over the age of 40. However, recently the fastest growing segment of the oral cancer population has become non-smokers under the age of 50. Meanwhile, while most cancers are declining in incidence, the overall incidence of oral cancer has remained fairly static. The reason appears to be that while the percentage of people that smoke has regularly declined, the incidence of another risk factor has rapidly grown, that being the human papillomavirus (HPV), particularly type 16 (HPV16). HPV16 is now the primary risk factor for oral cancer. HPV16 (along with HPV18) is the virus responsible for the majority of all cervical cancers as well and is the most common sexually transmitted infection in the U.S. People that engage in oral sex with more than one partner are particularly at risk of developing oral cancer from the transmission of HPV16 - which has been the cause of the shift of oral cancer occurrence from the older to the younger population. This also means that a much greater proportion of the population is at relatively higher risk of oral cancer than just those that smoke, drink, and are over the age of 50.

[1] Day GL, Blot WJ. Second primary tumors in patients with oral cancer. Cancer. 1992;70(1):14–19

Oral Cancer Examination

An oral cancer examination is recommended during every routine visit to the dentist and at any time that certain symptoms are present such as lesions in the mouth that don't heal, thickening in the cheek, white or red patches on the gums, tongue, or lining of the mouth, and swelling of the jaw. The typical visual exam that dentists perform is relatively straightforward and involves looking with the naked eye over the inside of the mouth to check for red or white patches or sores. The dentist will also feel with their hand inside the mouth and palpate the neck and face to check for lumps. White or red patches and sores most often are not cancerous and can usually be attributed to other causes such as cheek/tongue biting or food burns.



SOURCE: beautydentalchicago.com

Need For Better Methods

A review of eight oral cancer detection studies by MC Downer and colleagues titled, *A Systematic Review of Test Performance in Screening for Oral Cancer and Precancer*[2], indicated conventional visual oral exams have sensitivities of between 60% and 97% and specificities between 75% and 99%. A manuscript titled, *Advances in Fluorescence Imaging Techniques to Detect Oral Cancer and its Precursors*, published in the July 2010 edition of the journal Future Oncology, in citing the Downer study, notes that, "Oral cancer specialists can often recognize subtle visual changes associated with early lesions, but community practitioners or general dentists may lack the experience to identify early lesion development."[3] And while specialists are more attuned to finding cancer, other studies found that long wait times[4] to see a specialist (in some cases up to 10 months[5]) can contribute to later stage diagnosis of the disease. Given that the great majority of oral exams are done during regular visits to the ~200k general dentists (in the U.S.) and oral cancer specialists would likely be involved only when cancer is already suspected (and potentially at a later, less treatable stage), we think this adds additional support for the use of an adjunct, such as VELscope, to aid dental practitioners in the oral exam process.

Authors of another study titled, *Narrow Band (Light) Imaging of Oral Mucosa in Routine Dental Patients. Part I: Assessment if Value in Detection of Mucosal Changes,* also believe adjunctive methods are called for to improve oral cancer detection, particularly given the increase in dental care over the last 50 years without a proportional decrease in oral cancer deaths. The study, which we provide more detail about later, was conducted to determine the value of using narrow band light (using VELscope) to detect mucosal changes. The authors note in the study manuscript which was published in the journal General Dentistry, "Existing data suggest that current examination methods are not sufficient for the earliest detection of mucosal changes that could represent inflammatory damage or the presence of very early dysplasia. This could partly account for the only modest reduction in oral cancer deaths since 1960. There are several possible explanations for why oral cancer deaths and the stage of oral cancer at the time of diagnosis have not changed dramatically in the past 50 years. The lack of improvement could relate to a number of factors, but when considering that the percentage of the population that receives regular dental care has increased in the past 50 years, it appears obvious that current diagnostic methods could benefit from one or more adjunctive approaches. Early detection of dysplasia in other organ systems has been acknowledged to be an important component in improving survival, so it is difficult to believe that early detection of potentially significant mucosal changes, whether they are inflammatory or dysplastic, would not lead to improvements in cancer-related outcomes[6]."

[2] Downer MC, Moles DR, Palmer S, Speight PM. A systemic review of test performance in screening for oral cancer and precancer. Oral Oncol. 2004;40:264–273.

[3] Shin D, Vigneswaran N, Gillenwater A, Richards-Kortum R. Advances in fluorescence imaging techniques to detect oral cancer and its precursors. Future Oncol. 2010 July; 6(7): 1143–1154

[4] Epstein JB, Sciubba JJ, Banasek TE, Hay LJ. Failure to diagnose and delayed diagnosis of cancer: medicolegal issues. J Am Dent Assoc. 2009;140(12):1494–1503

[5] Peacock ZS, Pogrel MA, Schmidt BL. Exploring the reasons for delay in treatment of oral cancer. J Am Dent Assoc. 2008;139(10):1346–1352

[6] Truelove EL, Dean D, Maltby S, Griffith Ma, Huggins K, Griffith Mi, Taylor S. Narrow Band (Light) Imaging of Oral Mucosa in Routine Dental Patients. Part I: Assessment if Value in Detection of Mucosal Changes. General Dentistry. 2011 Jul/Aug. 281-289

The most recent notable review that concluded that standard oral exam is insufficient and that adjuncts should be employed to improve the detection of oral cancer, titled, *The Limitations of the Clinical Oral Examination in Detecting Dysplastic Oral Lesions and Oral Squamous Cell Carcinoma*, was published in the Journal of the American Dental Association in December 2012. The authors conducted a review of clinical trials and studies from 1966 to 2010 in order to determine the quality of the clinical oral examination (COE - the standard, naked-eye visual exam) as a diagnostic method for predicting dysplasia and oral squamous cell carcinoma (OSCC). The authors concluded that, "On the basis of the available literature, the authors determined that a COE of mucosal lesions generally is not predictive of histologic diagnosis. The fact that OSCCs often are diagnosed at an advanced stage of disease indicates the need for improving the COE and for developing adjuncts to help detect and diagnose oral mucosal lesions."[7]

VELSCOPE

Co-developed by Peter Whitehead, founder of LED Medical, and the British Columbia Cancer Agency (BCCA) in the early 2000's, VELscope launched in the commercial market in 2006 in the U.S. and Canada and quickly became the leading oral cancer screening device with over 13k units sold and 25 million screens performed by more than 8k dentists in 23 countries since the initial launch. VELscope is approved by the FDA, Health Canada and European regulators and has been recognized by the World Health Organization as a device that addresses global health concerns. The VELscope Vx recently was named “Best in Class” by the highly respected Pride Institute, which recognizes highly innovative and effective dental products. Out of thousands of dental products under consideration, the VELscope Vx was one of only a few products to have received this prestigious honor for three consecutive years. Demand for and awareness of VELscope among the dental community has been catalyzed by a regular and ongoing stream of clinical studies supporting use of the device as a means to improve earlier detection of oral cancer, a relatively rare but often deadly and disfiguring disease.

VELscope Vx





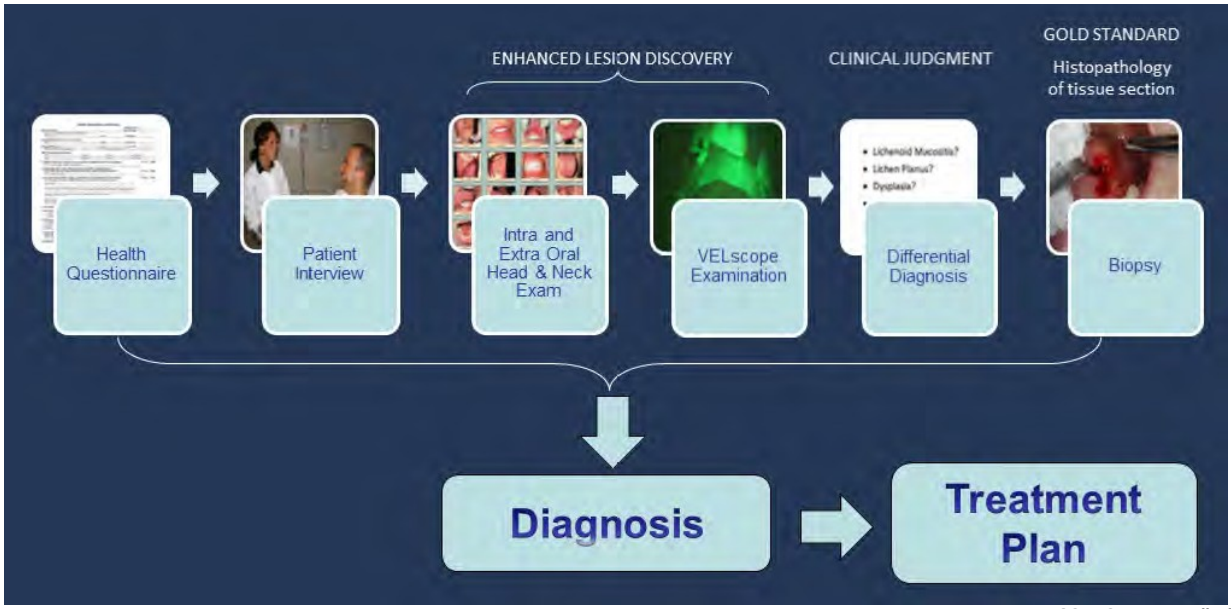
The VELscope technology integrates four concepts: light, sophisticated filtering, natural tissue fluorophores and human optical and neural physiology. The technology platform is based on the direct visualization of tissue fluorescence and the changes in fluorescence that can result when abnormal tissue is present. This technology helps clinicians visualize abnormal oral tissue that is often not apparent under white light (i.e., the naked eye). Screening with the VELscope is non-invasive and quick - with the average procedure taking approximately 2.5 minutes to perform.

The first generation VELscope was introduced in 2006. A newer model, the VELscope Vantage, was released in 2008 and the most current model, VELscope Vx was launched in early 2011. VELscope Vx is a portable,

[7] Epstein J, Guneri P, Boyacioglu H, Abt E. The limitations of the clinical oral examination in detecting dysplastic oral lesions and oral squamous cell carcinoma. JADA, Dec 2012, 143;1332-1342

rechargeable (wireless) unit and sells for significantly less than the legacy models (price of Vx is about 60% less than what Vantage sold for).

VELscope is used as an adjunct to standard oral exam

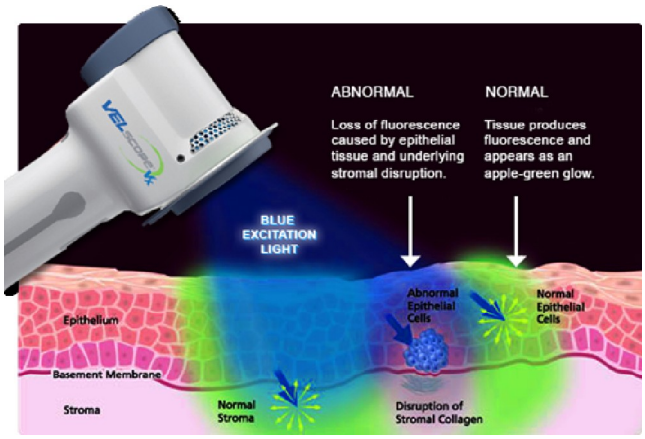


SOURCE: LED Medical

✧**Tissue Fluorescence Visualization Technology**

Fluorescence is the emission of light by a substance that has absorbed light or energy. Fluorescence occurs when after that substance has absorbed light, its molecules become excited and emit light at a longer wavelength than the excitation light. Fluorescence of a particular substance is dependent on the wavelength of the excitation light and on the biological make-up of the substance being examined. Human tissue and organs contain various fluorophores which are the compounds that re-emit light when exposed to an excitation light. Different human tissues, containing certain fluorophores, will re-emit light at different wavelengths. Most of the fluorescence comes from collagen which is in the basement membrane and stroma. Unhealthy epithelial tissue (which lines the surface), such as cancer, cause a disruption to the stromal collagen which in-turn causes loss of fluorescence (see graphic below).

VELscope's Tissue Fluorescence Visualization Technology



SOURCE: LED Medical

Peter Whitehead and researchers at the BCCA found that blue excitation light (in the 400nm to 460nm wavelength) effectively excites molecules in the mucosal cells and causes them to re-emit it as visible green fluorescence. VELscope uses this blue excitation light during an oral exam to distinguish unhealthy tissue from healthy tissue by identifying abnormal fluorescence patterns. Healthy tissue is reflected back as green in color

while unhealthy tissue will appear as dark irregularly-shaped areas due to loss of fluorescence. Both oral cancer and pre-cancer will show up as dark areas.



Figure 3. Image of normal tongue. (Figures 3 to 6 courtesy of the British Columbia Cancer Agency.)

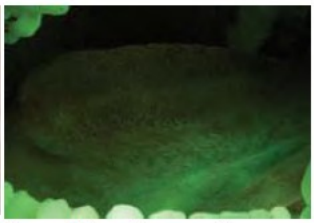


Figure 4. Normal tongue as it appears under the VELscope.



Figure 5. Area appearing normal under white light.



Figure 6. Figure 5 as seen under the VELscope. Dark area is VEL-scope-positive, which was confirmed by biopsy as carcinoma in situ.

SOURCE: British Columbia Cancer Agency. Dentistrytoday.com, October 2006

✧Clinical Studies

Almost two dozen clinical and case studies using VELscope have been performed and respective manuscripts published in peer-reviewed publications since 2006. In addition, several studies that pre-date these have been done using natural tissue fluorescence for the detection of oral cancer – with largely positive results, indicating tissue fluorescence has significant utility in oral cancer detection applications. The majority (although not all) of the VELscope-related studies documented support for VELscope in its indicated use, which is "intended to be used by a dentist or health-care provider as an adjunct to traditional oral examination by incandescent light to enhance the visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or pre-malignant dysplasia." VELscope can be of particular benefit in finding abnormalities at early stages such as cellular changes that may eventually develop into a lesion but may not be visible at their earliest stages under normal white light. Given the poor prognosis of late-stage oral cancer and high survivability if found early, an adjunct to find potentially cancerous abnormalities at their earliest stage has obvious benefits.

We think these studies, several of which we list below, adds significant and credible support for the use of VELscope in the detection of oral cancer. We also note that the few studies (most notably the two studies titled, "A cross-sectional study evaluating chemiluminescence…." and "Evaluation of an autofluorescence based imaging system…") that concluded VELscope added little or no benefit were arguably faulty in design relative to the indicated use of VELscope. In particular these studies appear to have erred by comparing VELscope as a stand-alone diagnostic to a definitive test for cancer (i.e. – biopsy), clearly an unfair comparison given that biopsy is the only definitive diagnosis and VELscope's indicated use is as an adjunct to standard oral exams to help determine if a suspicious area should be biopsied. Said another way, the VELscope is a detection device, not a diagnostic device. VELscope's job is to help clinicians discover suspicious lesions - it is up to the clinician to decide if the lesions should be submitted for diagnosis via a surgical biopsy.

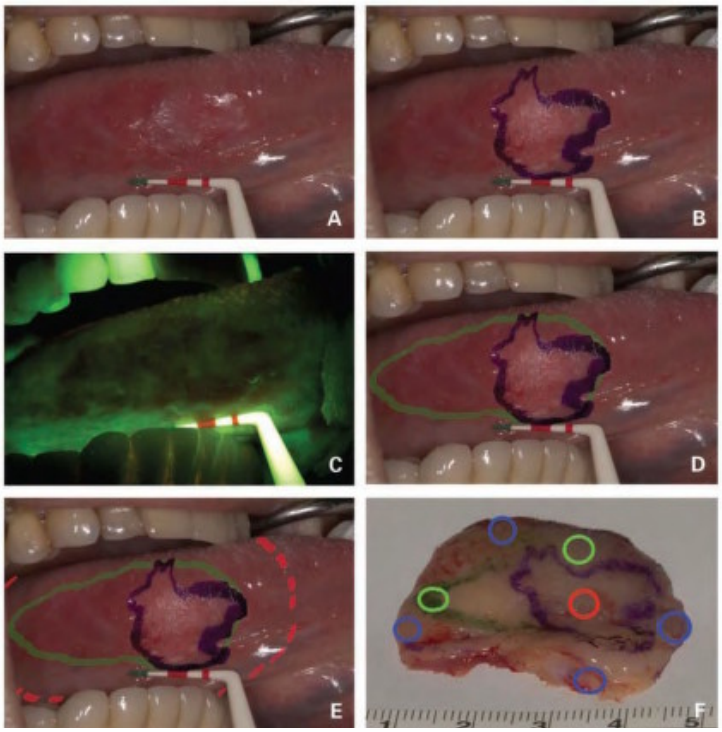
Sensitivity and specificity along with negative predictive value and positive predictive value are the oft-used measures used to provide some context to help determine the clinical utility of a medical device or diagnostic test. While these metrics have proven to be of substantial and meaningful value when comparing a particular device or test with a binary or quantitative result against a definitive diagnostic in large study populations (particularly populations where homogeneousness is less important) in conditions with relatively high incidence rates, their utility becomes much more questionable when applied to situations where the output involves interpretation, the control (comparator) similarly is not a definitive diagnosis, study populations are not particularly large, homogeneousness is of greater importance, and relative incidence of the condition is low. So while sensitivity and specificity can provide real value in comparing, for example, a novel HIV rapid test to a standard ELISA HIV test followed by a Western Blot test to determine if someone in sub-Sahara Africa (where HIV incidence is as high as 20%) has HIV, it makes no sense to attempt to measure how an adjunct detection

device, such as VELscope stacks up against biopsy in diagnosis of oral cancer (incidence of which is less than 1%). So while sensitivity/specificity of studies using VELscope have ranged from lows of 50%/39% and 84%/15% to highs of 98%/100% in various clinical studies (with various comparators and patient populations), it seems clearly more meaningful to ascertain clinical utility by evaluating outcomes in clinical practice and demand and utilization rates of the device from practitioners – with more than 13k units sold and over 25 million scans done to-date, we think there's substantial evidence that dentists find significant utility of VELscope. This is further reinforced by independent surveys of dentists that have used VELscope, which indicate extremely high user satisfaction levels.

The bulk of the study data does support the use of VELscope, however and we point to two studies in particular that offer significant support for the use of VELscope in the detection of oral cancer;

- "**Fluorescence visualization detection of field alterations in tumor margins or oral cancer patients**" (Catherine Poh, et al. Paper published in Clinical Cancer Research, 2006). This was the pivotal study supporting the eventual FDA approval of VELscope for determination of surgical margins. It was also important as it was one of the first studies offering substantial evidence that VELscope can significantly improve on normal white light visualization of detection of oral cancer. This study will also almost certainly be a pivotal piece of LMD's marketing for commercialization of their technology for determination of surgical margins for skin cancer – a near-term goal.

  The study compared VELscope to assessment under normal lighting to determine the surgical margins (i.e.- where the lesion should be excised). The majority of oral cancer surgeries inadvertently leave some cancerous tissue behind, due in large part to the fact that some tissue is beneath the surface and not visible to the naked eye of the surgeon. The respective margins determined by normal light and by VELscope were marked with a surgical pen. 122 oral mucosa biopsies were obtained from 20 surgical specimens (20 from the clinically apparent tumors, 36 from the margins determined to be abnormal by VELscope, and 66 from margins determined to be healthy by VELscope). Results showed that 32 of the 36 "abnormal" identified margins did indeed show histological changes (7 squamous cell carcinoma, 10 severe dysplasia, and 15 mild-to-moderate dysplasia). Meanwhile 65 of the 66 "healthy" identified margins were indeed normal with one showing mild-to-moderate dysplasia. Of the 20 clinically apparent tumors, 19 had abnormal margins that extended beyond what was clinically apparent (i.e. – apparent under normal light). In addition, the investigators found that if a conventional 10mm clearance of the clinical tumor had been used, 50% of the tumors in the study would have had cancer or dysplasia at the margin, 30% of which showed severe dysplasia or carcinoma in situ (i.e. – abnormal cells that may become cancer).



Clinical Cancer Research Paper: stepwise protocol for surgical field assessment. Image E shows the clinically apparent tumor outlined in blue; the loss of fluorescence (FVL) area outlined in green; the boundary of surgical specimen in red (based on both white light and FVL); and the locations of punch biopsy sites from clinically visible tumor (red circle), from tissue showing FVL, placed directly abutting FVL boundary (green circle), and, from tissue showing retained fluorescence (FVR), placed directly abutting the boundary of surgical specimen (blue circle).
SOURCE: Clinical Cancer Research, 2006. Poh et al.

- "**Narrow band (light) imaging of oral mucosa in routine dental patients. Part I: Assessment of value in detection of mucosal changes**." The study was conducted at the University of Washington and led by Dr. Edmund Truelove, professor in the Department of Oral Medicine at the university. The study was published in the July/August 2011 edition of General Dentistry. The purpose of the study was to determine the value of adding narrow band light (using VELscope) to a standard oral exam to detect mucosal change. The study is particularly important as its design is very similar to the way VELscope is intended to be used in clinical practice, it showed that VELscope was able to correctly identify areas of suspicious pathology that were missed with standard white light, and the study concluded that VELscope did improve the quality and outcome of the examination process.

  The study examined 620 patients using both normal white light (using the naked eye) and narrow band light (using VELscope). VELscope identified 69 patients as having areas of loss of fluorescence (LOF), all of which were determined to be normal during the white light examination. After an immediate re-evaluation, 41 of the 69 were determined to have subtle LOF that could be explained to be of normal variation. Of the remaining 28, nine were found to have tissue changes that were significant enough to warrant further follow-up – all of which had a biopsy. Of these, five patients were found to have either mild or mild-to-moderate dysplasia. These five cases of dysplasia, all of which had lesions missed under normal white light but were identified with VELscope, are at significantly higher risk of progressing to cancer and requiring additional treatment. We believe that this study lends additional support for the use of VELscope as an adjunct to conventional oral examination and indicates it can reduce the number of precancerous and cancerous lesions that go undetected. And given the aggressive nature of oral cancer, it suggests VELscope may reduce death from oral cancer by finding it at an earlier, more treatable stage.

Title	Publication	Investigators	Conclusion/Summary
Simple device for the direct visualization of oral cavity fluorescence	Journal of Biomedical Optics 11 2 , 024006 March/April 2006	Lane PM, Gilhuly T, Whitehead P, Zeng H, Poh CF, Ng S, Williams PM, Zhang L, Rosin MP, MacAulay CE.	Using histology as the gold standard for 50 sites, the device achieved a sensitivity of 98% and specificity of 100% when discriminating normal from high-risk oral premalignant lesions and invasive oral squamous cell carcinoma. It is envisioned that such a device would be used as an adjunct to conventional white-light screening to increase the sensitivity of white-light screen alone but not reduce the specificity.
Detecting Oral Cancer: A New Technique and Case Reports	Dentistrytoday.com. October 2006	John C. Kois and Edmond Truelove	The VELscope is an important aid in patient assessment, and when added to a well-thought out clinical assessment process that takes into consideration the age of the patient and risk factors that include tobacco, alcohol, and immunologic status, it increases the clinician's ability to detect oral changes that may represent premalignant or malignant cellular transformation. False positive findings are possible in the presence of highly inflamed lesions, and it is possible that use of the scope alone may result in failure to detect regions of dysplasia, but it has been our experience that use of the VELscope improves clinical decision making about the nature of oral lesions and aids in decisions to biopsy regions of concern.Where tissue changes are generalized or cover significant areas of the mouth, use of the scope has allowed us to identify the best region for biopsy. As with all clinical diagnostic activities, no single system or process is enough, and all clinicians are advised to use good clinical practice to assess patients and to recall and biopsy lesions that do not resolve within a predetermined time frame. Lesions that are VELscope-positive and absorb light need to be followed with particular caution, and if they do not resolve within a 2-week period, then further assessment and biopsy are generally advised. It is much better to occasionally sample tissue that turns out to be benign than to fail to diagnose dysplastic or malignant lesions. In our fight to protect patients from cancer, the VELscope improves our odds for early detection, hopefully resulting in fewer deaths from oral cancer.
Fluorescence Visualization Detection of Field Alterations in Tumor Margins of Oral Cancer Patients	Clinical Cancer Research. November 2006	Catherine F. Poh, Lewei Zhang, Don W. Anderson, J. Scott Durham, P. Michele Williams, Robert W. Priddy, Ken W. Berean, Samson Ng, Olivia L. Tseng, Calum MacAulay, and Miriam P. Rosin	The current study is an important step in the development of a potential integration of optical technology into the management of patients with oral cancer.The device will need to be integrated with information from other sources, both histologic and molecular, and experience with the device will have to be associated with clinical outcome before its clinical value can be established.However, as a proof-of-principle, our data has, for the first time, shown that direct FV can identify subclinical high-risk fields with cancerous and precancerous changes in the operating room setting.
Direct Fluorescence Visualization of Clinically Occult High-Risk Oral Premalignant Disease Using a Simple Hand-Held Device	Head & Neck. January 2007	Catherine F. Poh, Samson P. Ng, P. Michele Williams, Lewei Zhang, Denise M. Laronde, Pierre Lane, Calum MacAulay, Miriam P. Rosin	This is the first report of the diagnosis of occult oral disease using a simple noninvasive device. These early examples indicate the potential value of this technology to guide the management of patients with oral lesions, facilitating the detection of high-risk changes not apparent with white-light visualization.
Direct Fluorescence Visualization as Adjunct for Identification of High-Risk Oral Premalignancies	Poster Presentation at 2007 AACR	Lewei Zhang, Catherine F. Poh, Samson P. Ng, Michele Williams, Denise Laronde, Calum MacAulay, Miriam P. Rosin. University of British Columbia, BC Cancer	The data support the use of VELscope as an adjunct tool to identify high-risk oral lesions.
Sensitivity of direct tissue fluorescence visualization in screening for oral premalignant lesions in general practice	General Dentistry. January 2009	Kevin Huff, Paul C. Stark, Lynn W. Solomon	In the present study, routine incorporation of the VELscope in the examination protocol for low-risk adolescents and adults in a general dental practice proved useful in identifying occult, potentially premalignant lesions
Tracing the "At-Risk" Oral Mucosa Field with autofluorescence: Steps Toward Clinical Impact	Cancer Prevention Research. May 2009	Catherine F. Poh, Calum E. MacAulay, Lewei Zhang and Miriam P. Rosin	Autofluorescence and other such imaging processes have the potential to make a significant impact on standards of care, influencing not only surgical margin assessment but also the evaluation of tissue alterations during chemoprevention, which relies on establishing lesion boundaries. Autofluorescence imaging has already begun to shed new light on tissue changes during cancer development. Other visualization technologies (e.g., in vivo confocal microscopy, molecular targeted optical contrast agents alone and in combination) are poised to enter this field and will be integrated in the future with molecular findings to further advance our understanding of disease processes.
Assessment of the VELscope as an Adjunctive Examination Tool	Dental Journal. June 2009	Michaell A. Huber	In a comparative observational study of 130 subjects who smoked at least one package of cigarettes per day, 10 suspicious oral lesions requiring follow-up monitoring or biopsy were discovered through routine clinical examination. No occult suspicious lesions were discovered using the VELscope. VELscope interpretation did not enhance or otherwise alter the clinical management of the suspicious lesions. Several commonly occurring conditions such as mucosal pigmentations, ulcerations, irritations, and gingivitis were associated with a loss of fluorescence. More study is indicated to determine the true value of routine use of the VELscope in routine dental examinations.
A cross-sectional study evaluating chemiluminescence and autofluorescence in the detection of clinically innocuous precancerous and cancerous oral lesions	The Journal of the American Dental Assocaition. February 2010	Ravi Mehrotra, Mamta Singh, Shaji Thomas, Preeti Nair, Shruti Pandya, Niraj Shakti Nigam, Pankaj Shukla	Although ViziLite and VELscope have been promoted as valuable adjuncts in the early detection of oral precancerous and cancerous lesions, the results of our study indicate that they do not add any benefits to a conventional screening examination involving the use of a standard overhead light. Additional clinical studies are needed to evaluate the effectiveness and costs of light-based oral cancer screening aids before they can be recommended.
Evaluation of an autofluorescence based imaging system (VELscope) in the detection of oral potentially malignant disorders and benign keratoses	Oral Oncology. 2011	K.H. Awan, P.R. Morgan, S. Warnakulasuriya	Our study demonstrated a relatively high sensitivity (84%) and a low specificity (15%) in discriminating high-risk (dysplasias) from benign lesions. Further well designed studies are needed to examine the role of VELscope as an oral examination system in primary care.
Autofluorescence imaging of potentially malignant mucosa lestons	Oral Surg., Oral Med., Oral Path., Oral Rad., & Endod. May 2011	Martin Scheer, Joerg Neugebauer, Ali Derman, Julianne Fuss, Uta Drebber, Joachim E. Zoeller	Autofluorescence imaging is an easy and fast approach for obtaining additional information of suspicious mucosa lesions. As shown previously by other groups, malignant and dysplastic lesions present as areas with fluorescence loss. Although all carcinoma and dysplastic lesions in our series were identified with the VELscope, autofluorescence imaging results have to be interpreted with caution, because benign reactive lesions may show similar autofluorescence patterns, just as dysplasia or invasive carcinoma. Additional histology controlled prospective studies in a general population are required to assess the role of autofluorescence imaging as a screening adjunct.
Narrow band (light) imaging of oral mucosa in routine dental patients. Part I: Assessment of value in detection of mucosal changes	General Dentistry. July 2011	Edmond L. Truelove, David Dean, Samuel Maltby, Matthew Griffith, Kimberly Huggins, Mickealla Griffith, Stuart Taylor	The findings of this study support the use of narrow band (light) imaging (NBI) as a simple adjunctive diagnostic device that, when used as one component of a standard diagnostic protocol, could help clinicians to detect inflammatory and dysplastic tissues. Use of this technology could improve clinicians' ability to monitor and follow initially detected changes, and to better judge progression versus resolution and response to nonsurgical treatments. These findings need to be further explored in other settings to determine overall utility in general practice, but based on these findings, NBI appears to have the potential to assist general practitioners in assessment and decision-making related to mucosal tissues and lesions.
Efficacy of Tissue Autofluorescence Imaging (VELscope) in the Visualization of Oral Mucosal Lesions	Head & Neck. 2011	Camile S. Farah, Lidija McIntosh, Anastasia Georgiou, Michael J. McCullough	In order to improve patient prognosis, early detection and treatment of malignant and potentially malignant oral lesions is essential. VELScope seems to be of use at aiding the visualization of potentially malignant, malignant, and inflammatory conditions; however, it cannot accurately or consistently differentiate between them, even in the hands of experienced oral medicine specialists. VELScope is a useful clinical tool for visualizing abnormalities of the oral mucosa, but cannot provide a definitive diagnosis as to the presence or otherwise of dysplastic tissue change. Its use requires a significant understanding of mucosal pathology, and interpretation of results requires skill and training. Although clinical inspection and histopathology have certain limitations, they remain the gold standard for determining a definitive diagnosis.
Effectiveness of autofluorescence to identify suspicious oral lesions—a prospective, blinded clinical trial	Clinical Oral Investigations. August 2010	Felix Peter Koch & Peer W. Kaemmerer, Stefan Biesterfeld, Martin Kunkel, Wilfried Wagner	With a high sensitivity and negative predictive value, but a low specificity and positive predictive value (PPV), oral mucosal lesions could be detected by autofluorescence. The autofluorescence examination, however, is not able to differentiate between benign and malignant oral lesions. Red autofluorescence should be an indication for scalpel biopsy due to a high PPV for cancer.
Clinical evaluation of an autofluorescence diagnostic device for oral cancer detection: a prospective randomized diagnostic study	European Journal of Cancer Prevention. 2011	Majeed Ranaa, Antonia Zapfb, Marco Kuehlea, Nils-Claudius Gellricha and Andre´ M. Eckardta	Early diagnosis of oral cancer is a major requirement for multidisciplinary oncologic physicians. Detection should lead to less damage from cancer therapy and to better prognosis. The VELscope device, which uses visible light of 430nm wavelength to cause fluorescent excitation of certain compounds in the tissues, will play a major part in prevention of oral cancer diseases.
Use of Fluorescent Light in detecting Malignant and Premalignant Lesions in the Oral Cavity	Journal of Otolaryngology-Head & Neck Surgery. June 2012	Hani Z. Marzouki, Thien Tuong Vi Vu, Rania Ywakim, Peter Chauvin, James Hanley, and Karen M. Kost	Our data support the use of the VELscope Vx device as a noninvasive, user-friendly screening tool and as an adjunct in identifying dysplastic lesions of the oral cavity in high-risk patients. This safe, non-invasive device may be particularly useful for dentists, family physicians, and general otolaryngologists as an adjunct in identifying malignant or dysplastic lesions of the oral cavity in high-risk patients.

✧**Surgical Margin Study Expected to Read-Out In 2015**

In addition to the already completed studies supporting use of VELscope, an ongoing study titled, *Efficacy of Optically-guided Surgery in the Management of Early-staged Oral Cancer*, is expected to show that fluorescence visualization guided surgery can increase recurrence-free survival in oral cancer patients. This is the first randomized, multi-site trial to validate the effectiveness of the fluorescence visualization -guided surgery. The phase III 400-patient study is being sponsored by the University of British Columbia in collaboration with the Terry Fox Research Institute and the BCCA. Lead investigator is Catherine Poh, who was also the lead investigator of several other VELscope-related studies including the tumor margin study that we highlighted above. The study is built on the premise that a major cause of oral cancer recurrence is abnormalities that extend beyond the surgical margin (similarly detailed in the tumor margin study) and go unrecognized under normal white light. The study will enroll ~160 patients with severe oral dysplasia or carcinoma in situ and ~240 with invasive squamous cell carcninoma at nine sites in Canada. Patients will be randomized to FV-guided (VELscope) surgery or white light-guided surgery. The primary endpoint is recurrence at or 1cm within the previous surgery site with either 1) the same or higher grade histology compared to the initial diagnosis or 2) further treatment due to the presence of severe dysplasia or higher degree of change at follow-up. The study protocol, which was first published in October 2011 on biomedcentral.com[8], notes that anticipated timelines are as follows; August 2013 for completion of patient recruitment, follow-up completed two years later, initial results sometime in 2014 and full results available by 2015. Assuming positive results, we think this could be another catalyst to drive awareness, interest, reimbursement and demand for VELscope, particularly for use during excision/surgery. This study should also provide additional credence to an indication of VELscope for a dermatological application, potentially including for use in determination of surgical margins for skin cancer.

✧**IP / Patent Protection**

The technology underlying the VELscope was developed by the BC Cancer Agency and Peter Whitehead, founder of LED Medical. The base patents covering the technology (covering four concepts; light, sophisticated filtering, natural tissue fluorophores and human optical and neural physiology) were awarded in 2000 and acquired by LED Medical in 2003. The patents are expected to be valid until at least 2017. Additional patents have been submitted and are pending.

✧**Awareness / Publicity of Oral Cancer and VELscope**

Demand for and awareness of VELscope has also been aided by mainstream media attention highlighting LED Medical's device as a way to effectively increase the chance of finding oral cancer before it metastasizes. This has included VELscope being featured on over 100 local and regional news channels and talk shows throughout the country over the last few years. More significantly it was also featured on well known national programs focused on health, namely "The Dr. Oz Show" in June 2011 and "The Doctors" show in separate segments in November 2008 and January 2012.

- "The Dr. Oz Show" ran a segment approximately 8 minutes long on oral cancer in which VELscope was demonstrated (OralCDx, a competing technology which we discuss later, was also featured). Dr. Oz called VELscope a "groundbreaking oral screening test" that is "changing dramatically how we can quickly screen and identify cancers". He also noted that it is "very helpful in aiding the eye (in areas that) are not normal". Dr. Oz suggested that everyone demand that their dentists perform the VELscope exam. A YouTube video of the segment is available here, http://www.youtube.com/watch?v=8GUOn0Pbzjg

- In November 2008 VELscope was featured on "The Doctors" show in a segment highlighting the risks of oral cancer and stressing how important regular screenings are in order to catch the disease as early as possible. Dr. Bill Dorfman, a Beverly Hills cosmetic dentist who has been interviewed extensively on major TV programs and talk shows noted that early diagnosis of oral cancer is key and that VELscope is easy to use (VELscope is used in his practice). He also demonstrated how it is used, indicated that it is an effective tool to identify oral cancer and suggested that everyone demand that their dentists examine them for oral cancer by using VELscope. Dr. Dorfman concluded by saying "I think this (VELscope) is the best system on the market today (for oral cancer screening)." A YouTube video of the segment is available here, http://www.youtube.com/watch?v=dZZWksiU-9U. VELscope was again featured on The Doctors show in a segment in January 2012 titled *Twelve Tricks to Save Your Life in 2012.*



SOURCE: thedoctorstv.com

[8] http://www.biomedcentral.com/1471-2407/11/462

- VELscope has also been the recipient of several awards over the recent past. These includes; named "Best New Diagnostic/Imaging Device" by DrBicuspid.com in January 2012, named "Best of Class" by Pride Institute in June 2013 (for the third consecutive year), and chosen by Dentistry Today magazine as one of its "Top 50 Technology Products" in November 2012. In addition, in 2010 VELscope was recognized by the World Health Organization as a device to address global health concerns. The latest professional public recognition came in March 2014 when REALITY Review (similar to a Consumer Reports for dental products with evaluations done by practicing dentists) announced VELscope received 4.5 out of 5 stars when it was evaluated on several features including clinical utility, ease of use and camera system, among others

✧**Reimbursement**

LED estimates that approximately 35% of insurers currently cover VELscope exams and that this is growing as more insurers are realizing the value of VELscope. VELscope scans can be covered under the CDT code D0431 which the American Dental Association approved in 2005. D0431 relates to adjunctive tests to aid in oral mucosal exams and reads, "Adjunctive pre-diagnostic test that aids in the detection of mucosal abnormalities including pre-malignant and malignant lesions not to include cytology or biopsy procedures."

✧**Dental Practice Economics**

LED notes that the average billing for a VELscope scan by dentists is approximately $35. The VELscope unit retails for $2,700. Each scan requires the use of a disposable cap which retails for $1.80/each. This means payback on the cost of the unit to the dental practice can be achieved in less than 100 exams. Assuming on average a dentist would see 15 patients per day and just 25% of these are examined with VELscope, break-even on the cost of the unit would be achieved in about one month, which indicates a low-risk capital equipment investment for the dental practice. From that point on, VELscope exams become a potentially significant profit generator for the practice. Dental practices considering a purchase of VELscope should be further encouraged by the fact that the device already has a track record of significant utilization, with 25 million scans performed to-date.

LED has also indicated that dental practices are seeing ancillary and non-direct economical benefits from offering VELscope scans. This includes growth in the client base, patient referrals and being the beneficiary of patients switching from other dentists that do not offer VELscope scans. LED cites a recent survey that indicated dental practices that use VELscope Vx added on average four patients during the first year of use, with some practices adding more than 20 new patients. Further, they note that roughly one-third of practices that have VELscopes offer the scans for free, and despite offering these complimentary scans, these practices have still seen a positive financial benefit (from additional patient flow).

✧**Installed Base**

Current installed base is approximately 13k units with about 8k dentists in 23 countries using the device. This is up considerably from just the end of 2011 when 9k units had been placed. Sales are benefitting from the recent and ongoing clinical data and other publicity supporting the use of VELscope (and also clearly benefitting from the distribution reach that Henry Schein provided). Recent significant sales orders and customer wins include; in December 2011 it was announced that Heartland Dental Care, which represents over 350 dental practices in 18 states, approved use of VELscope, in March 2012 it was announced that AppleWhite Dental Partners, which provides services to 17 dental practices in IA, IL and MN, approved use of VELscope, in May 2012 it was announced that Pacific Dental Services, Inc. agreed to purchase up to 400 VELscope Vx systems over three years, and in January 2013 it was announced that Chicago Otolaryngology Associates will use VELscope to assist in oral cancer surgeries. In addition to corporate customers LED notes that over 50% of U.S. dental colleges own at least one VELscope.

✧ **Distribution**

In late 2010 LED signed an exclusive distribution agreement for the U.S. market with major medical device company, Henry Schein. While LED had supplemented this with a small sales force of their own which included three reps covering the Canadian market and seven covering the U.S. market and also handled some of the marketing functions, Schein was for the most part, LED's sales force. Bringing on Henry Schein was a clear benefit in terms of increasing system sales and growing the installed base. In a strategic move, however, LED decided to greatly reduce reliance on Schein and in September 2012 signed an exclusive distribution agreement (the agreement was subsequently modified to be exclusive OUS and non-exclusive for the U.S. market) with DenMat Holdings, LLC (Schein will still sell some consumables). The rationale

being that while Schein was successful in growing the installed system base, there was perhaps less attention provided towards nurturing utilization and the related consumables sales, which is where the bulk of profitability lies in a razor/razor-blade sales model. Henry Schein is a relative behemoth in dental and medical device distribution compared to DenMat but DenMat's strengths provide more customer hand-holding and the ability to nurture long-term client relationships. These strengths of DenMat include: an entire focus on dental-related products with close relationships with dental practices, an extensive offering of training/continuing education courses, being very active in tradeshows/marketing, and staffing a large call center for product support. LED sees these as particularly important now with a significant base of installed units to feed consumables to. The ability to leverage these customer relationships should also facilitate the sale of complimentary products such as RAYSCAN, the genomic oral cancer test (assuming successfully developed and launched) and other products that may be added to the company's portfolio in the future.

In November 2013 LED announced that the DenMat distribution agreement would remain exclusive OUS but become non-exclusive in the U.S. This was just weeks after the hiring of two ex-Carestream Dental sales executives to lead LED's new sales and marketing strategy (more below). David Gane and Lamar Roberts have already begun implementing their strategy to reignite sales which, along with modifying the DenMat agreement, has included consummation of a distribution agreement with dental products heavyweight Sinclair Dental for Canada. The company has quickly moved to bring on additional distribution in the U.S. as well. In early December 2013 the company announced non-exclusive distribution agreements for the U.S. market with Burkhart Dental Supply (announced Dec. 3rd) and Benco Dental (announced Dec. 10th). In 2014 LED brought on other distributors, including Patterson Dental (U.S./Canada), Atlanta dental Supply (U.S.) and Nashville Dental (U.S.). We expect additional distribution agreements for the U.S. market will be penned, which, along with other recent changes to the sales and marketing strategy, will result in a significant increase in revenue.

✧**Ex-Carestream Dental Execs Brought On As CEO and VP of Sales**

In October 2013 LED announced the hiring of David Gane as the company's new CEO with Peter Whitehead voluntarily transitioning to a role focused on R&D and business development. Dr. David Gane, DDS, was the former V.P. of the Dental Imaging business of Carestream Dental, LLC, a division of Carestream Health. Carestream Health was formed in 2007 with the purchase of Eastman Kodak Company's Health Group, was named Frost & Sullivan's 2010 Medical Imaging Company of the Year, has been an innovator in medical imaging and has operations in 170 countries.

Dr. Gane was clearly hand-picked not only for his management skills but also for his ~25 years' worth of sales experience with dental products and services which he can use to lead LED's efforts in restructuring their sales and marketing strategy. This includes not only beefing up distribution capabilities and reach but also expanding the breadth of products and services under LED's umbrella as well.

Then in November LED hired Lamar Roberts for the position of V.P. of Sales and Marketing. Roberts was a colleague of Mr. Gane for ten years at Carestream Dental and comes armed with significant experience and potentially valuable contacts in the dental products and services market. As part of the revamped sales and marketing strategy, LED opened an office in Atlanta, Georgia to facilitate easier access to the U.S. market and where the sales team will also coordinate the ongoing international commercialization efforts.

✧**Skin Cancer**

In March 2013 LED announced that it is looking to expand the indicated uses of their tissue fluorescence visualization technology for the detection of dermatological diseases including skin cancer. The initial focus will be for the determination of surgical margins during excision of basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), the two most common cancers of the skin. Combined, SCC and BCC account for approximately 96% of all skin cancers.

Skin cancer is the most common form of cancer. In the U.S. there are approximately 2.8 million diagnosed cases of BCC of every year, accounting for about 80% of all skin cancer cases. While BCC rarely metastasizes, it can be highly disfiguring if left to grow and, in rare occasions can be fatal.[9] In the U.S. there are approximately 700k diagnosed cases of SCC of every year, accounting for about 16% of all skin cancer cases and accounting for about 2.5k deaths.[10] With more than 3.5 million cases of skin cancer occurring

[9] http://www.skincancer.org/skin-cancer-information/basal-cell-carcinoma
[10] http://www.skincancer.org/skin-cancer-information/squamous-cell-carcinoma

every year in the U.S., LED sees this as a particularly attractive market and highlights that this market is about 85 times as large as the oral cancer market (with about 42k cases per year).

LED holds a patent for a “fluorescence scope system for dermatologic diagnosis.” And while not directly applicable to skin cancer, at least two completed clinical studies (which we detailed earlier) with VELscope have shown that the technology has potential real-world applications and significant utility in the delineation of surgical margins. LED envisions the technology would be used to aid surgeons in determining exactly where the margins are between the diseased and healthy tissue. This could be a clear benefit given the pitfalls of missing some of the diseased tissue (heightened risk of cancer recurrence) and the pitfalls of removing more tissue than necessary (additional and unnecessary scarring).

COMPLEMENTARY PRODUCTS AND SERVICES

Gane and Roberts wasted no time in beefing up the product portfolio for which it can leverage its distribution reach and VELscope installed base. In just the last few months they have added four dental imaging-related products in their newly created LED Imaging business. The addition of these new products, particularly the RAYSCAN-Expert, were the major reason that the company recently announced 2014 full-year revenue guidance of $9.0M - $11.0M, an implied yoy increase of at least 260%. The company expects to continue to look for additional products that will complement their distribution.

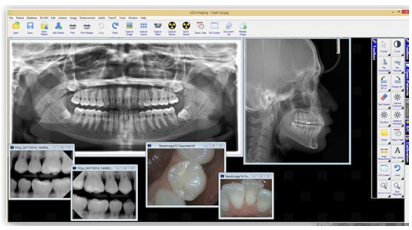


RAYSCAN-Expert

In April 2014 the company announced that it entered an agreement with Ray Co, Ltd, a subsidiary of Samsung, to sell that company's RAYSCAN-Expert dental imaging instrument. With LED's vast installed base and beefed-up customer reach via build-out of its sales and distribution infrastructure, the RAYSCAN-Expert, which retails for approximately $100k, offers a very attractive synergistic revenue opportunity.

LED Imaging Software

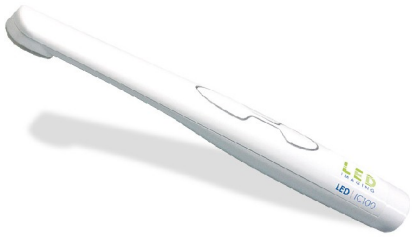
Also announced in April, LED Imaging Software captures and records oral pictures and videos from a variety of imaging devices, including RAYSCAN. The software easily integrates with all dental practice management programs, supports HIPPA compliance and is seamlessly installed and updated.



LED Intraoral Sensor and High Res Cameras

In May LED announced the introduction of its newest products in their LED Imaging division. LED IS100 is a digital radiography intraoral sensor which replaces traditional dental film for the imaging of teeth and oral bone structures. LED IC100 and LED IC200 are high resolution cameras. With these products LED expects to capitalize on the shift from film to digital imaging as the latter provides certain important benefits including faster results, very high resolution, seamless integration across various software and imaging platforms and use with a wide variety of dental applications including endodontics, cavities, periodontics and others.





COMPETITION

Competition to VELscope in the adjunctive oral cancer screening market comes mainly from three products; ViziLite TBlue from Zila, Inc., OralCDx from CDx Diagnostics, and Identafi from DentalEZ Group. The Identafi system is the most similar competitor to VELscope.

Privately-held Zila, Inc. manufactures **ViziLite TBlue**, a toluidine blue dye product. Toluidine blue has been used for over forty years to aid in the detection of cervical and oral cancers. The blue dye is applied to the inside of the

mouth - areas that are highlighted by the dye are considered suspicious for abnormalities, including potentially cancer. The ViziLite TBlue system consists of the blue dye along with a small chemiluminescent-light source which, following the application of the dye, is inserted into the mouth to inspect for any highlighted areas. Similar to VELscope scans, ViziLite TBlue is covered under CDT code D0431 and is covered by at least a portion of insurance carriers.



SOURCE: zila

Clinical data on toluidine blue staining is somewhat mixed. The most recent study that we found, published in the Journal of Craniofacial Surgery in March 2012[11], included 30 patients and 40 lesions which were examined separately with chemilumiscent light and toluidine blue and were then biopsied. The study indicated that chemilumiscent light may be effective in improving the visual properties (brightness, sharpness, etc) compared to white light and showed toluidine blue had a sensitivity and specificity of 82% and 38% in identification of premalignant and cancerous lesions. We do note, however, that this study used ViziLite Plus, which is the legacy product and does not combine chemilumiscent light with toluidine blue as the ViziLite TBlue product does, which potentially could have produced different results. We also note that VizaLite Plus exams are roughly twice as costly for patients as are VELscope exams, and they require patients to rinse with a vinegar-based solution that has elicited numerous patient complaints. The device also does not have the same FDA or Health Canada clearances as does VELscope.

Privately-held CDx Diagnostics, manufacturer of **OralCDx**, claims to be the "world's leader in the detection and prevention of cancers of the esophagus, oral cavity, pharynx, and larynx". OralCDx Brush Biopsy is an oral brush used to swab the inside of the mouth, collecting cells from all three layers of the epithelium (superficial, intermediate, and basal). The sample is then placed on a glass slide which is sent to CDx for analysis. The sample is examined under a computer microscope which is driven by sophisticated technology and software which renders a result. From what we can tell OralCDx is not covered by insurance and instead the cost of the test is borne by the practitioner or patient. Clinical studies of OralCDx have largely had positive results, indicating the test has a relatively high sensitivity and specificity in detection of oral cancer. OralCDx was part of the Dr. Oz segment which also featured VELscope.



SOURCE: cdxdiagnostics

It is important to note a key differentiation between VELscope and OralCDx in terms of how and when they are used in oral cancer screening. VELscope has utility in screening the general population and in examining the entire mouth, whether or not signs or symptoms of cancer are present. In contrast, OralCDx is typically used when signs or symptoms (such as visible lesions) are already present (which was the protocol of OralCDx clinical studies). In other words, VELscope is a detection device and OralCDx is a first step diagnostic service that cannot be used until a lesion has been detected by a VELscope or some other means. This is a major reason why we do not view OralCDx as a direct competitor to VELscope.

CDx Diagnostics notes that OralCDx has been used by over 30k U.S. dentists. The number of dentists currently using the product on a regular basis is likely much lower than this, however. CDx's marketing materials include citation of a 945-patient study conducted in 1999 and published in the Journal of the American Dental Association[12]. Results showed OralCDX identified 100% of the 131 lesions deemed (via biopsy) to be precancerous or cancerous and correctly identified 93% of the 196 benign lesions as having no features of dysplasia or cancer. OralCDx also found that 4.5% (n=29) of the sample base (n=647) that was visually diagnosed as benign, showed precancer or cancer with biopsy. However, OralCDx also flagged another 99 (15%) of this 647 sample base (considered benign by visual inspection) as precancerous but these were not biopsied as in the opinion of investigators, they did not require histological evaluation (which may suggest these were false positive results).

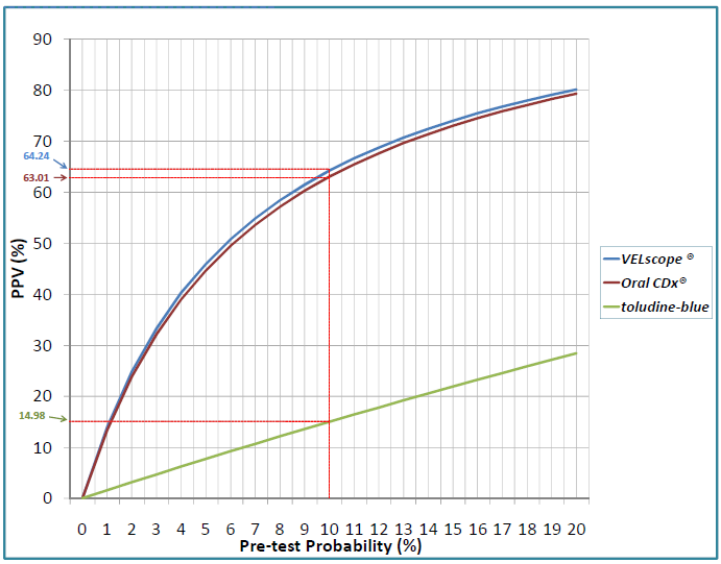
VELscope vs. toluidine blue, OralCDx

[11] Mojsa I, Kaczmarzyk T, Zaleska M, Stypulkowska J, Zapala-Pospiech A, Sadecki D. Value of the ViziLite Plus System as a Diagnostic Aid in the Early Detection of Oral Caner/Premalignant Epithelial Lesions. J Craniofac Surg, Mar 2012

[12] Sciubba J. Improving Detection of Precancerous and Cancerous Oral Lesions. JADA, Vol 130, Oct 1999

While no formal head-to-head studies have been published comparing these three products in oral cancer screening, one study was done comparing the devices based on data from respective studies of each. The study titled, *Assessing the Usefulness of Three Adjunctive Diagnostic Devices for Oral Cancer Screening: A Probabilistic Approach*[13], and published in Community Dentistry and Oral Epidemiology in 2011, compared VELscope, toluidine blue, and OralCDx on sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV). The comparison was made under three different scenarios; screening the general population, screening only adults over 39, and screening only adults over 39 with intra-oral visible lesions (OralCDx data was only for the visible-lesion population as that is its indicated use). The analysis showed VELscope produced the highest PPV's of 1.27%, 2.53% and 8.11%, in these respective scenarios with false positive rates of between 92% and 99%. Toluidine blue false positive rates were between 99% and 100% and OralCDx false positive rate was 92% (and potentially benefitting from only being used with the visible-lesion population). While the authors' conclusion was that all three devices have high false positive rates when used to routinely screen for oral cancer in the general population, they noted that they may be beneficial in screening higher risk populations. We would again caution about relying too heavily on the high false positive rates as an indicator of utility in cancer screening as this is comparing each device to biopsy - a diagnostic procedure - which is not the indicated or intended use of VELscope (or, for that matter, the other devices). A more fair comparison would be against white light examination as VELscope's intended use is as an adjunct to white light exam for purposes of detection rather than diagnosis. Nonetheless, this study may provide some insight into the relative performance and utility of the devices amongst each other, which indicated that VELscope was superior.

PPV vs. Pre-Test Probability [13]



PPV & False-Pos: visible lesions [13]

Device	PPV (%)	False Positive (%)
toludine blue staining	0.90	99.10
VELscope	8.52	91.48
Oral*CDx**	8.11	91.89

Sensitivity & Specificity [13]

Diagnostic device	Sn (%)	Sp (%)
toludine-blue staining [9]	77	67
VELscope ® [10]	97	94
Oral*CDx*® [11]	92	94

VELscope vs. ViziLite Plus, ViziLite TBlue, Microlux DL, Orascoptic DK, OralCDx

Another, somewhat more dated study also compared clinical trial data of various devices used for oral cancer screening. It included VELscope, ViziLite Plus, ViziLite TBlue, Microlux DL, Orascoptic DK, and OralCDx. Microlux DL is made by AdDent Inc, a small CT based company that manufactures dental products. Microlux DL is a small handheld LED light. Orascoptic DK is also a small handheld light but, from we can tell, is primarily used to look at tooth fractures. There is very limited information on both Microlux DL and Orascoptic DK leading us to believe that neither is of significance in terms of competition to VELscope. In fact the authors of this study noted that they were not able to find any clinical studies using either of these devices.

This study, titled, *Adjunctive Techniques for Oral Cancer Examination and Lesion Diagnosis*[14], and published in the Journal of the American Dental Association in July 2008 was a fairly exhaustive review of respective studies of each device with the goal of assessing the devices' utility in detection of oral premalignant and malignant oral lesions (OPML) among adults during routine oral examinations. Among the authors' conclusions were that toluidine blue is effective as an adjunct diagnostic for use in high-risk populations, OralCDx has utility in detecting dysplastic changes in high-risk mucosal lesions but data are insufficient to assess its utility in low-risk populations,

[13] Balevi B. Assessing the Usefulness of Three Adjunctive Diagnostic Devices for Oral Cancer Screening: A Probabilistic Approach. Community Dent Oral Epidemiol 2011; 39: 171-176

[14] Patton L, Epstein J, Kerr AR. Adjunctive Techniques for Oral Cancer Examination and Lesion Diagnosis. JADA, Vol 139 July 2008

and that there is not enough evidence to support or refute the use of visually-based adjuncts (including ViziLite and VELscope - note that Identafi was not part of this review). We note that the authors had specific inclusion and exclusion criteria relative to which studies of which device were to be used in this study. The result was fifteen toluidine blue studies, three ViziLite studies and just two VELscope studies. The authors conceded the significant difference in number of studies among the devices as a limitation. For reference, we have included the tables listing the included studies in the Appendix at the end of this report. We also note that this study is now somewhat dated and several VELscope studies have been completed since the 2008 publication date (reference the list of studies earlier in this report - the majority were completed in 2009 or later) which have concluded that the use of VELscope as an adjunct to white light visual exam does provide significant utility in detecting mucosal abnormalities including precancer and cancer.

Identafi, manufactured by DentalEZ Group, is the most similar to VELscope. Identafi uses multi-spectral fluorescence and reflectance to identify mucosal abnormalities. DentalEZ notes that the three distinct color wavelengths (white, violet and amber) produced by Identafi make it easier to identify abnormalities compared to other technologies. The process involves first using the white light, then switching to violet, then to amber to enhance the difference in reflectance between each wavelength in determining if tissue appears abnormal. The supposition includes that the higher wavelength (i.e. - amber, ~590nm) can differentiate between cancer and other types of lesions such as abrasions, burns, inflammation and viral infections. The device is compact and wireless with a mirror on the end to help in viewing hard to reach areas of the mouth. Identafi received FDA approval in early 2009.



SOURCE: wowdentalinnovation

Identafi retails for $3,995 in the U.S. with consumables (disposable mirrors) priced at $2.44 for each procedure. This is considerably more expensive than VELscope Vx cost of $2,749 and $1.80 for the system and per-procedure disposable, respectively.

We have found only limited clinical research using multi-spectral fluorescence and even less specifically with Identafi. Most of the research to-date with fluorescence in oral cancer encompasses blue/violet light. So while the supposition with Identafi is that multi-spectral fluorescence is superior to VELscope (i.e. - only blue light) due to the potential to differentiate between cancer and non-cancerous lesions, we have found no specific clinical evidence to support this. Another meaningful advantage of VELscope is that whereas suspicious lesions detected by the VELscope can be easily photo-documented by attaching a digital camera to the device, this is not possible with Identafi.

FINANCIALS

Balance Sheet / Cash Flow

As of the most recent reporting period (ending 6/30/2014) the company had $1.8M in cash and equivalents. Subsequent to quarter end the company generated gross proceeds of $2.2M via the exercise of warrants. Cash used in operating activities was $2.0M in Q2 but excluding changes in working capital, cash used in operating activities was $1.5M. Capex has been fairly immaterial.

The company has no preferred stock outstanding and, aside from normal trade payables, has no debt.

Recent Financial Performance

From November 2010 to September 2012 LED had an exclusive distribution agreement with medical device distribution heavyweight, Henry Schein. As discussed above, in September 2012 shifted most of its distribution to DenMat Holdings, a much smaller organization compared to Schein.

Revenue in 2012 was $6.3 million, up almost 11% from the $5.7 million generated in 2011. The shift from Schein to DenMat, as LED had anticipated, caused a hiccup in VELscope sales. Q4 2012 sales fell just 3% yoy but were down 60% for the full year in 2013. This hiccup may be fairly short term, however, given the company's revamped sales and marketing strategy which has already resulted in the signing of several new distributors and adding to its direct sales force.

In addition, new complementary products and services, which have yet to make much of a contribution could be a very significant driver of revenue beginning as early as the second half of 2014. As noted, with the Q2 earnings release (8/24/2014) management provided revenue guidance for the full current year of $9.0M - $11.0M. We think much of the anticipated 260%+ yoy revenue growth will be driven by sales of these new products (RAYSCAN-Expert and others) in the LED Imaging business.

OUTLOOK

Shift In Strategy
LED is now in the early stages of its shift in strategy - from a major focus on building out the installed base via Henry Schein to a more relationship-driven approach facilitated by multiple, non-exclusive distributors and led by a new and highly experienced sales and marketing team. This will be complemented by its own direct sales force. We expect this will offer the advantages of continuing to expand the installed base and at the same time help to facilitate consumable sales. The new strategy also has a determined focus on bringing new products and services to market which has already included RAYSCAN and other products in the LED Imaging business.

This strategy shift has been somewhat painful in terms of financial performance over the last several quarters but is expected to pay significant dividends - beginning in the very short term. We think this results in VELscope utilization (i.e. - high margin consumable sales) increasing, a growing and significant ancillary source of revenue (new products and services) and greater operating leverage. If all goes to plan, this should also provide the additional benefit of solidifying the stickiness of their customer base. The more value-added services that LED can provide should increase the opportunity to gain market share and reduce the risk of customer churn.

Clinical Evidence
Clinical evidence in the form of a multitude of studies, trials and professional reviews supporting the use of VELscope has helped catalyze both awareness and sales of the device to-date and also highlighted misgivings of the standard naked-eye visual exam. Reimbursement, while still somewhat spotty, appears to be growing and should also benefit from additional evidence in favor of VELscope and other adjunctive devices for the detection of oral cancer. The 400-patient surgical margin study, which could have initial results sometime in 2014 and fully read out in 2015, is one of potentially several studies that could provide additional significant credibility to the use of VELscope. Initial feedback from the study is positive which could bode well for showing significance on endpoints.

Expanded Indications
LED's technology and intellectual property can potentially be relatively seamlessly expanded into other indications including for the detection of other cancers such as prostate and cervical. The most near-term endeavor, per recent public announcements by LED, is likely to be for the determination of surgical margins for skin cancer. Existing clinical data could potentially support FDA approval in the relatively near-term. Other dermatological applications remain possibilities as well which we think LED will likely be actively exploring.

International Market Expansion
LED penned an agreement with Sinclair Dental in late October. Sinclair Dental is a significant player in Canada and we expect this agreement will benefit VELscope sales there. And while the U.S. market will remain the largest contributor to LED's revenue for the foreseeable future, LED will likely look to beef up their international presence beyond just Canada and their existing small footprint in Europe. International sales should become more meaningful over the next several years as the company begins to penetrate other areas of the world including parts of Asia, where tobacco use and hence oral cancer rates are much higher than in North America. Countries with largely nationalized dental services which ease the distribution function and potentially accommodate bulk orders could also be of particular interest.

Longer Term Catalysts To Drive Sales
Into mid-to-late 2014 and beyond we see a number of catalysts to increase sales. For one, we expect additional distribution agreements will be in place in the near term. Supplemental revenue from complementary products such as RAYSCAN are expected to be highly meaningful beginning in Q4 of this year.

Expanded applications of the VELscope technology into other cancers and for surgical margins is a very real possibility and could dramatically increase the target markets and user base. In addition, expanded reimbursement for oral and other applications would also help catalyze sales - additional clinical data expected to be released in the near along with increasing awareness of the benefits of the technology may aid in this regard.

The increasing awareness of the importance of oral cancer screening in the general population, partly due in part to the risk posed by HPV which largely afflicts the younger generation, provides another catalyst to driving demand for VELscope. International markets, which are almost completely untapped, provide a potentially lucrative area for rapid sales growth - something that LED expects to provide a greater focus on.

Given the historic relatively low consumable sales per device, we only model a very moderate uptick in this going forward. However, as the installed user base grows the overall number of consumables sold should continue to grow as well and should be the major driver of revenue over the longer term, particularly with even a modest increase in paid utilization (i.e. - single exam per consumable).

VALUATION / RECOMMENDATION

We model $9.6 million in revenue in 2014 with a significant contribution from the expanded product portfolio from the LED Imaging business beginning in Q4. Expansion of the product suite has ramped very rapidly and, along with a change in distribution model, has been the work of the new management team. This recent shift in strategy appears to already be the turning point for the company in terms of returning it to positive revenue growth. Revenue is up 90% yoy through the first half of 2014 and is expected to increase by at least 260% for the full year.

We expect moderate growth of the VELscope installed system base in the U.S. and accelerating growth in international markets. While we think the U.S. market remains the largest base for LED and at only about 6% penetrated, still provides significant upside for the company, international markets, which are almost completely untapped, offer potentially steep growth curve opportunities over the next several years. Current paid utilization is well below reasonable expectations but is likely at floor level with upside (potentially significantly so) possible now with a new and experienced sales team onboard and additional distribution expected in the near term. We model only somewhat modest increases in paid utilization over the next several years - we think this is a fair estimate given the lackluster consumables in the past but also giving credit for LED's change in strategy to take hold. The modest increase in paid utilization, where the greater margin lies, is also reflected in our somewhat modest estimated uptick in gross margin over the next few years.

Meanwhile, the company will further capitalize on their distribution reach and leverage their sales infrastructure through a larger product portfolio. The RAYSCAN agreement already looks like a winner for LED and the company expects to continue to look to add complementary products to their sales forces' bags. Per our discussions with management relative to the potential of the LED Imaging business, this segment holds great opportunity to grow over the long-term. The recent released revenue guidance for 2014 could pale in comparison to 2015 - which we expect will show significant growth in both the VELscope and LED Imaging businesses.

We value LED using a 10-year discounted cash flow model. We have revenue CAGR of about 50% from 2014 through 2018, then dropping to a low-double digit average through 2024. These estimates could prove conservative particularly if paid utilization, the major revenue driver in razor/razor blade business models, substantially outpaces our estimates. We also note that growth in the the LED Imaging business could outpace our current estimates - these will also be subject to updating as the potential for these products becomes more clear. This could provide revenue upside to our model, particularly over the mid-to-long-term time frames. We use a 10% discount rate and 2% terminal growth rate. Based on DCF, LED is value at $2.53/share - we round to $2.50.

We are maintaining out Outperform rating.

FINANCIAL MODEL

LED Medical Inc.

	2013 A	Q1A	Q2A	Q3E	Q4E	2014 E	2015 E	2016 E	2017 E
Revenue	$2,519	$1,055	$1,590	$1,910	$5,027	$9,582	$14,225	$26,499	$35,617
YOY Growth	*-60.1%*	*240.7%*	*46.9%*	*109.6%*	*2232.0%*	*280.3%*	*48.5%*	*86.3%*	*34.4%*
Cost of sales	$1,348	$526	$724	$1,038	$3,026	$5,314	$7,398	$12,380	$15,915
Gross Income	$1,171	$529	$866	$872	$2,001	$4,269	$6,827	$14,119	$19,702
VELscope related GM				*54.6%*	*54.2%*	*54.7%*	*55.3%*	*60.0%*	*61.2%*
Total Gross Margin	*46.5%*	*50.2%*	*54.5%*	*45.7%*	*39.8%*	*44.5%*	*48.0%*	*53.3%*	*55.3%*
SG&A	$4,369	$1,478	$2,251	$2,610	$3,250	$9,589	$10,050	$12,980	$15,100
% SG&A	*173.4%*	*140.1%*	*141.6%*	*136.6%*	*64.6%*	*100.1%*	*70.6%*	*49.0%*	*42.4%*
R&D	$442	$259	$247	$265	$280	$1,051	$1,154	$1,218	$1,336
% R&D	*17.6%*	*24.5%*	*15.6%*	*13.9%*	*5.6%*	*11.0%*	*8.1%*	*4.6%*	*3.8%*
Operating Income	($3,641)	($1,207)	($1,633)	($2,003)	($1,529)	($6,371)	($4,377)	($79)	$3,266
Operating Margin	*-144.5%*	*-114.4%*	*-102.7%*	*-104.9%*	*-30.4%*	*-66.5%*	*-30.8%*	*-0.3%*	*9.2%*
Total Other Income	($3,302)	($1,687)	$1,715	$20	$20	$68	$60	$70	$85
Pre-Tax Income	($6,943)	($2,894)	$83	($1,983)	($1,509)	($6,303)	($4,317)	($9)	$3,351
Taxes (benefit)	$12.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*-0.2%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($6,955)	($2,894)	$83	($1,983)	($1,509)	($6,303)	($4,317)	($9)	$3,351
Net Margin	*-276.0%*	*-274.3%*	*5.2%*	*-103.8%*	*-30.0%*	*-65.8%*	*-30.3%*	*0.0%*	*9.4%*
EPS	($0.13)	($0.04)	$0.00	($0.02)	($0.02)	($0.08)	($0.03)	($0.00)	$0.02
YOY Growth	*455.5%*	*14.3%*	*-102.2%*	*-28.4%*	*-20.4%*	*-40.8%*	*-58.8%*	*-99.8%*	*-35616.4%*
Diluted Shares O/S	53,131	73,574	74,593	82,000	95,000	81,292	135,000	140,000	145,000

Brian Marckx, CFA

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APPENDIX

SOURCE: Patton L, Epstein J, Kerr AR. Adjunctive Techniques for Oral Cancer Examination and Lesion Diagnosis. JADA, Vol 139 July 2008

SUPPLEMENTAL DATA

This material is an online-only supplement to the following article: Patton LL, Epstein JB, Kerr AR. Adjuncts for oral cancer examination and lesion diagnosis: A systematic review of literature. JADA 2008;139(7):896-905.

Evidence for effectiveness of vital tissue staining with toluidine blue (TB) for detection of oral premalignant and malignant lesions.*

AUTHOR	STUDY SITE†	NO. OF SUBJECTS/ LESIONS	SUBJECT INCLUSION CRITERIA	ADJUNCTIVE TEST USED‡	STUDY POPULATION PREVALENCE OF OPML§ (NO. [%])	SENSI-TIVITY (%)	SPECI-FICITY (%)	PPV¶ (%)	NPV# (%)	QUALITY SCORE (± SD**) (0-100)
Shedd and colleagues, 1967[4]	United States	62/62	Some form of known or suspected SCCa†† or nonneoplastic lesions of oral mucosa	TB vital dye: 10-second application and 5-milliliter rinse as needed	42 (68%) biopsy diagnosis of CIS‡‡ or invasive SCCa	100	85	93	100	27.5 ± 2.5
Meyers, 1970[5]	United States	70/70	Had lesions of the oral cavity	TB vital dye: topical swab application (no duration given)	51 (73%) biopsy diagnosis of malignancy	98	100	100	95	15 ± 5
Vahidy and colleagues, 1972[6]	West Pakistan	1,190/1,030	Subjects enrolled in oral cancer study with oral lesions; authors excluded160 doubtful results	TB vital dye: 10-second application of 5-mL rinse as needed	535 (45%) biopsy diagnosis of SCCa	86	76	76	86	32.5 ± 2.5
Mashberg, 1980[7]	United States	187/235	Subjects referred from hospital admission examinations; persistent lesion at 10-to 14-day reevaluation with clinical diagnosis of SCCa, CIS or atypia	TB vital dye: topical swab application (no duration given)	117 (50%) biopsy diagnosis of SCCa, CIS, or atypia	86	93	93	87	42.5 ± 2.5
					105 (45%) biopsy diagnosis of SCCa, CIS only	93	92	90	94	
Mashberg, 1983[9] (includes data from Mashberg, 1981[8])	United States	134 /179	Subjects referred from hospital admission examinations; persistent lesion at 10-to 14-day reevaluation with clinical diagnosis of SCCa, CIS or atypia	TB vital dye application	88 (49%) biopsy diagnosis of SCCa, CIS, or atypia	91 for TB application	90 for TB application	91 for TB application	91 for TB application	52.5 ± 2.5
				TB vital dye: sequence of three oral rinses	88 (49%) biopsy diagnosis of SCCa, CIS or atypia	83 for TB rinse	93 for TB rinse	93 for TB rinse	85 for TB rinse	
Silverman and colleagues, 1984[10]	United States	132/132	Oral medicine clinic attendees suspected of having oral cancer or precancerous lesions	TB vital dye: 30-second application	99 (75%) biopsy diagnosis of dysplasia or SCCa	98	70	91	92	52.5 ± 2.5
Epstein and colleagues, 1992[11]	Canada	59/59	Clinically suspicious lesion among 33 new cancer agency referrals and 26 patients previously treated for oral cancer	TB vital dye application	40 (68%) biopsy diagnosis of dysplasia, CIS, SCCa or mucoepidermoid cancer	93	63	84	80	42.5 ± 2.5
Warnakulasuriya and Johnson, 1996[12]	Asia, Sri Lanka, Pakistan††	102/145; 86 lesions biopsied	Oral mucosal lesions	TB vital dye: single rinse with ready-to-use kit	57 (66%) biopsy diagnosis of dysplasia or SCCa	86	45	75	62	77.5 ± 2.5
Epstein and colleagues, 1997[13]	Canada	46/81	Patients with previous treatment for oropharyngeal cancer; new clinical lesions	TB vital dye: 30-second application	55 (68%) dysplasia, CIS and SCCa	83	69	85	69	57.5 ± 2.5
					27 (33%) CIS and SCCa only	100	52	51	100	
Onofre and colleagues, 2001[14]	Brazil	50/50	Subjects with potentially malignant epithelial lesions; subjects willing to undergo biopsy	TB vital dye: sequence of three oral rinses	13 (26%) biopsy diagnosis of dysplasia or SCCa	77	65	43	89	67.5 ± 2.5
Epstein and colleagues, 2003[15]	Canada	32/39	Subjects with suspected premalignant lesions; with or without history of oral cancer; willing and able to provide a 50ng biopsy sample large enough to provide DNA for at least 10 loss-of-heterozygosity analyses	TB vital dye: sequence of three oral rinses	25 (64%) biopsy diagnosis of dysplasia	64	36	64	36	57.5 ± 2.5
Studies using pharmaceutical-grade TB										
Epstein and colleagues, 2003[16]	Multicenter; United States, England, Canada (Multicenter study)	81/96	Aged 18 years or older; treatment for upper aerodigestive tract or pulmonary carcinoma in past two years but not past three months; capable of providing informed consent; willing and able to follow instructions	TB vital dye: five-rinse sequence, including 20-second rinse/gargle with 10 mL of 0.5% TB: Dye retention at two visits 10 to 21 days apart or lesion that second investigator deemed in need of biopsy.	30 (31%) biopsy diagnosis of CIS or SCCa	97	9	33	86	75 ± 5
Zhang and colleagues, 2005[17]	Canada (Retrospective longitudinal study)	100 /100	Histologically confirmed oral dysplasia but no head and neck cancer; availability of a biopsy specimen with concurrent TB assessment for the biopsy; at least six months' follow-up after biopsy	TB vital dye: five-rinse sequence, including 20-second rinse/gargle with 10 milliliters of 0.5% TB	81 (81%) biopsy diagnosis of dysplasia	38	74	86	22	60 ± 0

* The study by Ram and Siar, 2005,[18] is reported in Table 2.
† Unless specified, studies were prospective, convenience-sample, single-center, case-series studies.
‡ Unless specified, positive rest results are positive or equivocal dye retention at a single application.
§ True-positive results are obtained by means of scalpel biopsy of dysplasia, carcinoma in situ or squamous cell carcinoma unless specified. OPML: Oral premalignant and malignant lesions.
¶ PPV: Positive predictive value.
# NPV: Negative predictive value.
** SD: Standard deviation.
†† SCCa: Squamous cell carcinoma.
‡‡ CIS: Carcinoma in situ.

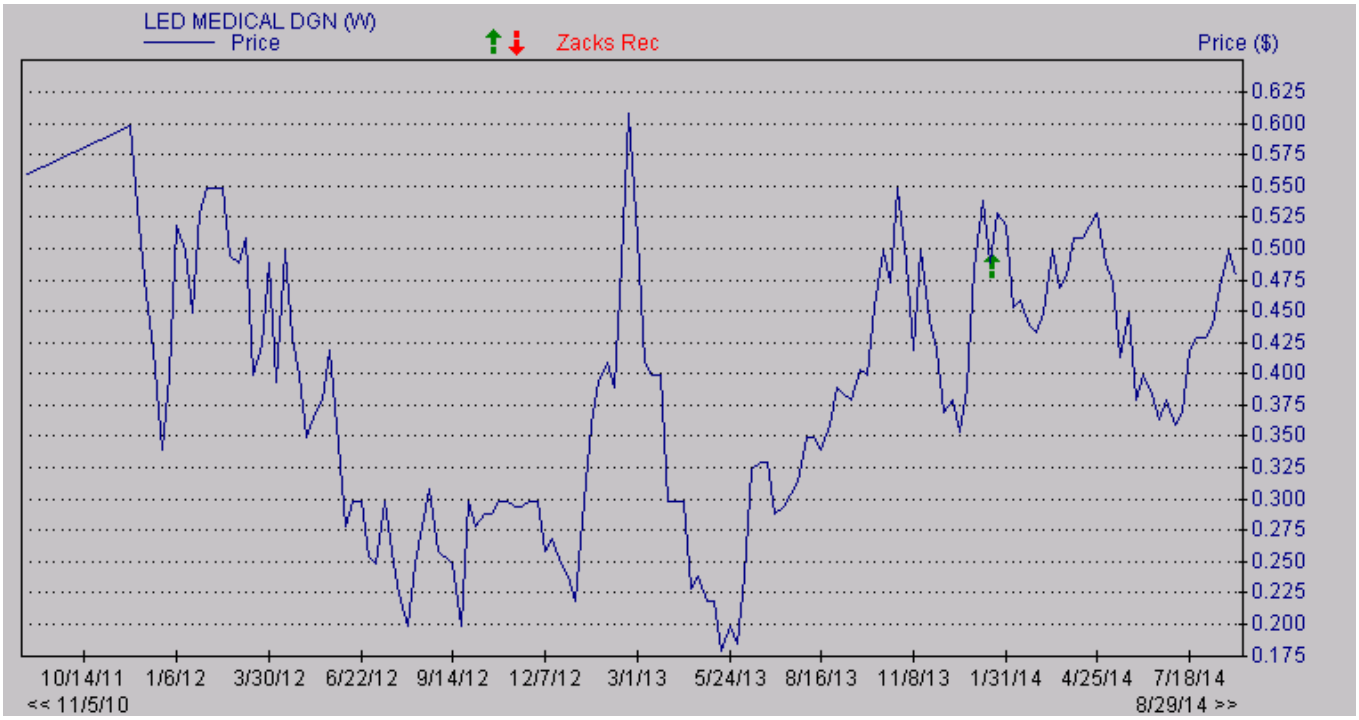
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Evidence for effectiveness of visualization aids Vizilite, VELscope and Vizilite Plus With TBlue for detection of oral premalignant and malignant lesions.*

AUTHOR	STUDY SITE†	SCREENER TYPE AND TRAINING	NO. OF SUBJECTS/ LESION BIOPSIES	SUBJECT INCLUSION CRITERIA	ADJUNCTIVE TEST USED	ORAL LESION DIAGNOSTIC CRITERIA	STUDY POPULATION PREVALENCE OF OPML‡ (NO. [%])	SENSITIVITY (%)	SPECIFICITY (%)	PPV§ (%)	NPV¶ (%)	QUALITY SCORE (± SD#) (0-100)
Studies of ViziLite												
Ram and Siar, 2005[18]	Malaysia	Providers in the specialty departments of oral pathology, oral medicine, periodontology and oral and maxillofacial surgery	40/31	Aged 35 years and older; one or more of following: current, suspected or history of treatment for oral cancer or potentially malignant epithelial lesions, history of high-risk habits (smoking or chewing of tobacco, use of betel nuts, alcohol consumption)	ViziLite-aided visual examination	Clinical appearance with reflection of blue-white light	24 (77%) biopsy diagnosis of dysplasia or SCCa**	100	14	80	100	32.5 ± 2.5
					Toluidine blue 1% mouthrinse	Clinical appearance and retention of dark blue stain		70	25	86	13	
Farah and McCullough 2007[19]	Australia	Two trained oral medicine specialists	55/55	Referral for examination of an oral mucosal white lesion	ViziLite-aided visual examination	Clinical appearance with reflection of blue-white light	10 (18%) biopsy diagnosis of dysplasia or SCCa	100	0	18	0	42.5 ± 2.5
Study of ViziLite Plus with TBlue												
Epstein and colleagues, 2007[22]	United States, Canada (multicenter study)	Clinical experts in oral medicine and oral pathology	84/97	History of oral cancer or white lesions or high risk of developing oral cancer (prior or current tobacco use or daily alcohol use)	ViziLite-aided visual examination	Clinical appearance with reflection of blue-white light	54 (66%) biopsy diagnosis of severe dysplasia, CIS†† or SCCa	100	0	21	0	55 ± 5
					ViziLite Plus With TBlue	Clinical appearance and dye retention		100	55	37	100	
Studies of Technology Behind VELscope‡‡												
Lane and colleagues, 2006[20]	Canada	Providers (training and type not specified) from oral dysplasia clinic and head and neck oncology group	44/50	Patients in the Oral Health Study (ongoing longitudinal study of oral leukoplakia) with history of biopsy-confirmed oral dysplasia or SCCa	Device for direct fluorescence visualization (technology of VELscope; authors from LED Medical Diagnostics although proprietary product not mentioned)	Clinical appearance with fluorescence visualization loss	44 (88%) biopsy diagnosis of severe dysplasia, CIS or SCCa	98	100	100	86	42.5 ± 2.5
Poh and colleagues, 2006[21]	Canada (case control study)	Head and neck oncology surgeon	20/122 (punch biopsies from tumor [n = 20] and tumor margin [n = 102]; at least one in all four directions)	Patients with biopsy-confirmed primary cancer of the oral cavity; tumors to be resected in the operating room with intent to cure; aged 18 years or older	Device for direct fluorescence visualization (technology of VELscope); proprietary product not mentioned	Clinical appearance with fluorescence visualization loss	37 (30%) biopsy diagnosis of high-grade dysplasia, CIS or SCCa; if low-grade dysplasia is included, 52 (43%)	100; if low-grade dysplasia is included, 98	78; if low-grade dysplasia is included, 94	66; if low-grade dysplasia is included, 93	100; if low-grade dysplasia is included, 98	60 ± 0

* VELScope is manufactured by LED Dental, White Rock, British Columbia, Canada. ViziLite is manufactured by Zila Pharmaceuticals, Phoenix, Ariz. ViziLite Plus With TBlue is manufactured by Zila Pharmaceuticals, Phoenix, Ariz.
† Unless specified, studies were prospective, convenience-sample, single-center, case-series studies.
‡ True-positive results are obtained by means of scalpel biopsy of dysplasia, carcinoma in situ or squamous cell carcinoma unless specified. OPML: Oral premalignant and malignant lesions.
§ PPV: Positive predictive value.
¶ NPV: Negative predictive value.
# SD: Standard deviation.
OPML: Oral premalignant and malignant lesions.
** SCCa: Squamous cell carcinoma.
†† CIS: Carcinoma in situ.
‡‡ No studies have been published about the currently marketed VELscope product.

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