## Research

# The Influence of Patient Education by the Dental Hygienist:

### Acceptance of the Fluorescence Oral Cancer Exam

Marie Paulis, RDH, BS Introduction

Most oral cancer is discovered in stages III or IV.1 It is usually not discovered until it has reached a secondary site, such as the lymph nodes. By this time, there is a mere 50% five-year survival rate.<sup>1</sup> Although the incidence of oral cancer is estimated to be very low (approximately 0.01%),<sup>1</sup> 25% of people with oral cancer have no known risk factors for the disease.<sup>2</sup> This demonstrates the importance of early screening for every patient. If patients were better educated about the risk factors for oral cancer, they may be able to recognize some of the early signs of oral cancer and dysplasia and seek diagnosis and treatment while still in stage I, the most curable of the disease process.<sup>3</sup>

The screening of patients for signs of oral cancer has traditionally relied upon the conventional oral examination. In recent years, there has been increased interest in new technologies for the detection of oral cancer.<sup>4</sup> What is not known is how patients accept these technologies. The purpose of this study was to assess the effect of patient education on the patient's decision to accept or refuse the use of a technology for oral cancer detection, the fluorescence oral cancer examination.

#### **Review of the Literature**

Detecting oral cancer in its early stages is crucial to prolonging the lives of patients with this disease. Knowledge about oral cancer is lack-

#### Abstract

**Purpose:** Oral cancer frequently goes undetected in its early and most curable stages because no clinical signs or symptoms usually exist. This study assessed the effect patient education had on the patient's decision to accept or refuse a fluorescence oral cancer examination.

**Methods:** Along with providing a routine clinical and white light oral cancer exam, a Visually Enhanced Lesion Scope (VELscope<sup>®</sup>) was used to evaluate the patient's oral cavity. After gaining written consent, 100 patients at a university dental hygiene clinic were provided a survey that evaluated their risk factors, opinions, and knowledge regarding oral cancer. Upon assessing the patient's willingness to receive a free oral fluorescence examination, the survey questioned if being charged a fee for the exam would serve as a deterrent to receiving it. Regardless of acceptance or refusal of the exam, the patient was educated, first by a brochure, and then by discussion with the researcher, about oral cancer.

**Results:** Overall, 92% of participants agreed to pay a fee for the VELscope<sup>®</sup> exam. Of those who initially refused the VELscope<sup>®</sup> exam, 78% agreed to the exam after being educated about oral cancer. Patients were very appreciative of both the education and technology offered to them.

**Conclusions:** Dental professionals have a responsibility to educate their patients about oral cancer in order to enable them to make informed decisions about their oral and overall health. Additionally, patient education has a significant impact on patient acceptance of the VELscope<sup>®</sup> exam.

**Key Words:** VELscope<sup>®</sup>, patient education, oral cancer, human papilloma virus

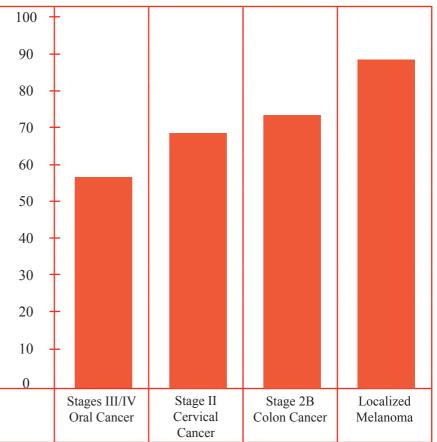
ing among some dentists and dental hygienists, as is transmission of that knowledge from provider to patient. Both dental professionals and the general public need to be better educated about the risk factors for oral cancer, its signs and symptoms, and the benefits of early oral cancer detection.<sup>1</sup> A review of the literature shows the number of deaths from oral cancer to be higher than many other types of cancers, such as breast cancer, skin melanoma, and ovarian cancer.<sup>5</sup> Due to lack of outward signs in its early stages, oral cancer is most often discovered in its later stages, by which time the 5-year survival rate is only 50% (Table 1). The American Cancer Society estimates that approximately 30,000 people are diagnosed with oral cancer each year, and approximately 7,000 of those people will die from the disease.<sup>1</sup> Surprisingly, oral cancer is actually more curable than most other cancers, but only with early detection.<sup>6</sup> Therefore, it is critical that oral health care providers become more adept at recognizing it.

Despite the fact that many medical professionals observe their patients' oral cavities,<sup>7</sup> 60% of oral cancers are in stages III or IV when they are detected.<sup>8</sup> In a national study conducted in 2000, only 66% of dental hygienists reported providing oral cancer screenings for adults over 40 years old at their initial appointment.<sup>9</sup> Eighty-two percent of all physicians and 17% of all dentists surveyed in Illinois in 2005 stated they did not perform routine oral cancer exams on most of their patients.<sup>10</sup>

According to a 2000 survey conducted at the University of Maryland School of Dentistry, lack of knowledge appears to be the reason why many physicians, dentists, and dental hygienists do not perform thorough oral cancer exams. Therefore, dental and dental hygiene programs have a responsibility to properly educate their students about oral cancer.<sup>11</sup>

An important aspect of educating oral health care professionals about oral cancer is teaching them about risk factors for the condition. The known risk factors include: tobacco use, alcohol abuse, the combination of alcohol and tobacco use, sun exposure, age over 40, poor diet, immunosuppression, presence of the human papilloma virus (HPV), male gender, and being of African American descent.<sup>2,12</sup> Even though there are established risk factors for oral cancer, 25% of patients with oral cancer have no known risk factors.<sup>2</sup> However, the lack of exhibiting risk factors should not eliminate suspicion from the observant clinician conducting an oral cancer examination.<sup>10</sup>

Screenings for oral cancer not only detect disease but also serve as a learning experience for patients. In Table 1. Comparison of Percentage of 5 Year Survival Rates for Various Cancers



2005, during an oral cancer screening of over 800 people in New York and New Jersey, it was discovered that most people did not recognize alcohol abuse as being a risk factor for oral cancer, despite it being the second highest risk after smoking.<sup>10</sup> Dental professionals have an ethical responsibility to educate their patients, and patient education should be performed during all phases of dental treatment. This education may include photos, handouts, pamphlets, books, videos, computer programs, and conversations. Patients must be given the necessary knowledge in order to make informed decisions about their own health care<sup>13</sup>

## VELscope<sup>®</sup> – a new technology for oral cancer detection

In recent years, new technologies for oral cancer detection have been designed and marketed for oral health care professionals.<sup>4</sup> One of those is the VELscope<sup>®</sup>, a handheld device that was developed in British Columbia, Canada by the British Columbia Cancer Agency in collaboration with MD Anderson Cancer Center. It received U.S. Food and Drug Administration approval in November 2001. VELscope® uses oral fluorescence technology to detect both precancerous and cancerous lesions in the oral cavity. The fluorescent light makes healthy tissue appear green and potentially cancerous lesions dark magenta or brown/black.14 This device was designed to detect changes in tissue while the changes are still subepithelial and not yet detectable by a white light oral cancer exam.

Not all positive findings by VELscope<sup>®</sup> indicate oral cancer, as it is a screening device and does not provide a definitive diagnosis. Certain areas may appear dark during an examination, such as normal oral anatomy (tonsillar pillars and linea alba) or areas where blood is under the epithelial surface, such as a hematoma. Typically, a dark area that is bilateral and uniformly shaped is not a concern. Therefore, the clinician must be able to distinguish between "normal" or "abnormal" findings under oral fluorescence visualization.<sup>14</sup> The VELscope<sup>®</sup> assists the clinician in determining if any lesions are present that require further intervention.<sup>5</sup> Suspicious lesions must be biopsied to provide a definitive diagnosis.9

Patients who previously had oral cancer are at increased risk of developing it a second time.<sup>15</sup> However, the tissue damage incurred from the first cancer may prevent the secondary cancer from being detected. With the assistance of oral fluorescence technology, the previous tissue damage will not obscure the view of a new tumor or dysplasia. Therefore, this technology is often utilized midbiopsy, to determine if all of the cancerous area has been removed.<sup>15</sup>

Although the scalpel biopsy is the "gold standard" for the diagnosis of oral cancer<sup>4</sup>, VELscope<sup>®</sup> has been investigated as an appropriate screening tool for the identification of suspicious lesions. Lane et al used the VELscope<sup>®</sup> to investigate its ability to identify precancerous and cancerous lesions.<sup>16</sup> Results demonstrated a 98% sensitivity and a 100% specificity for VELscope<sup>®</sup> in identifying dysplasia and cancers from normal oral mucosa. However, all of the lesions were observed using incandescent light alone. Also, the majority of the lesions included in the study appeared to be Class 1 or "suspicious" lesions. Poh et al reported anecdotal observations of 3 lesions that were identified using VELscope<sup>®</sup> that could not be seen using normal (incandescent) light.17 However, it should be noted that these cases were not part of a controlled clinical trial with a larger number of subjects. Another study by Poh et al investigated the use of the VELscope® for the detection of surgical tumor margins for oral cancer when used in the operating room.<sup>18</sup> The results found that VELscope<sup>®</sup> may be useful in oral cancer screening due to its ability to identify lesions that cannot be seen by a conventional oral examination (COE). However, the authors noted that the lesions identified in the study (Class II lesions) were found within the background of Class I lesions so it was not clear if VELscope<sup>®</sup> is able to identify Class II lesions. Although new technologies for oral cancer screening such as VELscope<sup>®</sup> may be useful for screening, oral health care practitioners still lack data to support their use over a COE alone.<sup>4</sup> However, their usefulness is promising, and may be helpful in educating patients about oral cancer and follow up with suspicious lesions.

The oral health care practitioner who routinely screens for potentially cancerous lesions using fluorescence has the opportunity to offer patients early education about the risk factors associated with oral cancer and to refer them for appropriate treatment if needed. The research site for the following investigation, the University of Bridgeport Fones School of Dental Hygiene, provides treatment for many patients who may be considered at high risk for this disease. Therefore, this study sought to educate these patients and provide them with the service of a technologybased oral cancer exam, even though it is recognized that a biopsy is the only definitive diagnosis of a suspicious lesion.<sup>4</sup> The specific purpose of the study was to assess the effect of patient education and fees associated with oral cancer screenings on patients' willingness to agree to the use of the VELscope<sup>®</sup> technology.

#### Methodology

In October 2007, the first 100 patients over the age of 21 who presented for treatment in the Fones

School of Dental Hygiene, University of Bridgeport dental hygiene clinic were provided with a pre-study survey form to evaluate their self reported oral cancer risks and their willingness to receive a VELscope<sup>®</sup> exam with or without an additional fee. The study was approved by the Institutional Review Board of the University. All subjects who enrolled were provided an informed consent document outlining the benefits and risks of the study. The form included information about the VELscope<sup>®</sup> technology, a disclaimer stating that they would not be eligible for the use of VELscope<sup>®</sup> if they were photosensitive (since it emits fluorescent light), and that the patient would need to wear tinted safety glasses during the VELscope<sup>®</sup> examination. Subjects were informed that all information would be confidential. The principal investigator also requested permission from subjects to receive follow-up information concerning the results of any referrals.

The research was conducted by the principal investigator (PI) and the research assistant (RA), both registered dental hygienists. Recruited subjects were 100 new and recall patients. Inclusion criteria was that the subjects were over 21 years of age and had one identified risk factor for oral cancer as determined by the prestudy survey. Along with questions about the subject's age and ethnicity, the survey asked about smoking history and alcohol intake. Oral cancer risk factors were dependent upon participants' self report.

Subjects were also asked if they would agree to a non-invasive oral cancer exam whether it were free or if they were charged a fee of \$20. Finally, the survey posed questions about the patient's knowledge level of oral cancer. If the subject agreed to have the VELscope<sup>®</sup> examination, either with or without a fee charged, the subject was invited to enroll in the study.

All subjects obtained education about oral cancer via a list of oral

cancer facts and a brochure about oral cancer obtained from the American Cancer Society. To evaluate the value of education on a subject's decision to have a VELscope<sup>®</sup> examination, all patients who originally agreed to have the VELscope<sup>®</sup> exam for no charge, but did not agree to an exam if a fee were attached, were studied to see if the role of education made them change their mind. If, after the examination, the patient still refused an examination for a fee, the PI asked the patient for the reason for the refusal. Potential reasons could be the added fee, fear of the examination, time restraints or other reasons. Regardless of the response, all patients who wanted the VELscope<sup>®</sup> examination received it for no fee. If the patient refused the examination under any circumstances, the VELscope<sup>®</sup> examination was not done and the patient received the regular dental hygiene treatment and conventional oral examination (COE).

The PI and RA conducted all VELscope<sup>®</sup> exams. Training occurred by reading an instruction manual, discussion with VELscope<sup>®</sup> company representatives, and viewing an informative step-by-step DVD supplied with the VELscope<sup>®</sup>. The PI first conducted a visual oral cancer examination using a mirror, dental light, palpation, and gauze to assist in tongue retraction. A VELscope<sup>®</sup> examination followed, and the PI discussed the risk factors, signs, and symptoms of oral cancer with the patient. The dentist on staff evaluated examination findings and confirmed the need for any referral. At the conclusion of the examination, positive and negative findings were discussed with the patient and, when necessary, the patient was referred to an oral surgeon. The PI or RA documented all findings in the patient's chart and on the VELscope<sup>®</sup> examination form. In addition, all potential positive findings were photographed. Two photos were taken, one showing the clinical view under

white light and one demonstrating the view through the VELscope<sup>®</sup>. Participants with potential positive findings were referred to an oral surgeon, dentist, or medical doctor.

After the examinations were complete the data was analyzed. Frequencies and percentages were calculated for each response. The most relevant statistics were those representing the difference in the patient's agreeing to a VELscope<sup>®</sup> exam prior to and after being educated about oral cancer. In order to compare these results, the number of patients who refused an exam prior to education was translated into a percentage and compared to the percentage of participants who refused an exam post-education.

#### Results

Of the 100 participants who completed the survey, 97 consented to a VELscope<sup>®</sup> exam. The remaining 3 did not have the exam because 1 was photosensitive and 2 refused for an unknown reason, speculated to be a language barrier.

Table 2 displays the survey including study demographics. Most subjects were between 40-59 years of age, Caucasian and male. Thirty seven percent were current smokers while 35% previously smoked. Out of the patients who currently smoke, 59% (n=22) were very interested in quitting, 27% (n=10) were slightly interested, and 14% (n=5) were not interested. A smoking cessation program was initiated for any patients who wanted to participate. Of the 37 participants who currently smoke, 59% (n=22) smoke while consuming alcoholic beverages.

The incidence of a positive history of cancer among the participants was 8% (n=8), with 1 participant having had throat cancer, 2 breast cancer, 1 prostate cancer, 1 colon cancer, and 2 not disclosing the type of cancer. Among the 100 research participants, 6 had an immediate family member who was diagnosed with oral cancer.

Upon being offered a free oral fluorescence exam, 93% (N=93) of respondents accepted, while 7% (N=7) declined. However, upon learning there might be a \$20 fee for the fluorescence exam, only 63% (n=63) accepted it and 37% (n=37) refused the exam (Table 3). Out of the 37 participants who declined the exam, the majority refused due to cost (73%, n=27), followed by fear (14%, n=5), other (8%, n=3), photosensitivity (3%, n=1), and lack of time (3%, n=1)n=1). Of those who refused the exam if there were a fee, 47% (n=17) were female and 53% (n=20) were male.

Of the participants who initially refused the exam, 78% (n=29) agreed to the exam after being educated about oral cancer. In describing their own opinion of their oral cancer knowledge prior to being educated by the researcher, 52% (n=52) considered themselves not at all knowledgeable, 43% (n=43) somewhat knowledgeable, and 5% (n=5) very knowledgeable.

After completing 97 VELscope® and white light oral cancer exams, 8% (n=8) of respondents were referred for further examination by an oral surgeon, dentist or medical doctor. One subject was followed for 2 weeks and with no changes, was referred to an oral surgeon. The surgeon decided to re-evaluate in 6 months since it did not appear to be serious. Four subjects were referred due to white findings on the tongue, all found to be innocent by VELscope<sup>®</sup> and the oral surgeon. A female patient was referred to the oral surgeon for an evaluation of a 7 mm pink, pedunculated, irregularly shaped pink lesion on the right side of the soft palate, which appeared suspicious through VELscope<sup>®</sup>. The biopsy indicated normal mucosal tissue, although the tissue sample contained HPV. Again, the patient will have a 6-month follow-up with the oral surgeon. The oral surgeon suspected the area might have been precancerous, although no dysplasia was noted by the biopsy. No photos

Table 2. Oral dise	ase risk assessment
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1) Age	# of patients	2) Gender	# of patients	3) Ethnicity	# of patients
21-29 years	25	Male	62	African American	7
30-39 years	8	Female	38	Asian	9
40-59 years	41			Caucasian	61
Over 60	26			Hispanic	14
				Native American	2
				Other	7
4) Do you smoke cigarettes?	# of patients	5) Do you chew tobacco?	# of patients	6) If "yes" to #4 or #5, how interested are you in quitting?	# of patients
Yes	37	Yes	2	Not at all	5
No	63	No	98	Slightly	10
If yes, how many per day?	Avg. – 10	If yes, how many containers per day?	Avg. – ½ pack	Very	22
For how many years?	Avg. – 30 years	For how many years?	Avg. – 6 years		
7) Did you use tobacco in the past and quit?	# of patients	8) Besides you, do any other members of your household smoke?	# of patients	9) How many alcoholic beverages do you drink per week?	# of patients
Yes	65	Yes	52	0 to 1	62
No	35	No	48	2-7	32
				8-14	4
				Over 15	2
10) Do you smoke while drinking alcoholic beverages?	# of patients	11) Have you been diagnosed with cancer?	# of patients	12) Have any of your family members been diagnosed with oral cancer?	# of patients
Yes	22	Yes	8	Yes	5
No	78	No	92	No	95
13) Would you agree to having a free, non-invasive oral cancer exam that takes less than 5 minutes?	# of patients	14) If you answered yes to #13, would you agree to the exam if there were a fee of \$20	# of patients	15) Are you knowledgeable about oral cancer?	# of patients
Yes	73	Yes	49	Not at all	52
No	7	No	31	Somewhat	43
				Very	5

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were taken of this participant. The remaining 2 subjects who were referred did not have malignancies.

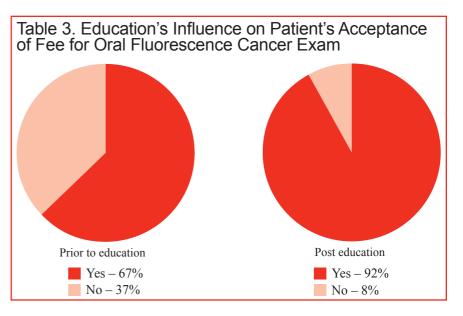
#### **Discussion**

The purpose of the study was to determine if educating a patient about oral cancer had an impact on accepting and paying for an oral fluorescence cancer exam. It was found that 63% of participants accepted the fee prior to being educated. However, out of those who refused the exam, patient education about oral cancer did improve patient acceptance of the exam by 78%. In order to educate patients about oral cancer, it is imperative that oral health care professionals first be educated about the risk factors and clinical manifestations of the disease. In a study conducted in 2003, 85% of medical doctors and 63% of dentists cited receiving insufficient training to correctly identify oral pathologic conditions.<sup>5</sup> Similarly, in a survey conducted in Texas in 2006, only 15% of dentists and dental hygienists reported educating new patients about risk factors and symptoms for oral cancer.<sup>6</sup> Dental professionals have a legal and ethical responsibility to educate their patients to enable them to make informed decisions about their own care. All participants of the study accepted the oral cancer informational brochure presented to them, regardless of whether they accepted the fluorescence examination.

Although risk factors such as smoking and high alcohol consumption contribute to the incidence of oral cancer, 25% of those diagnosed have no known risk factors.<sup>1</sup> In the current study population, 37% were current smokers and 35% were previous smokers. Of those who currently smoke, 59% drink alcohol while smoking. The combination of smoking and drinking increases oral cancer risk by 15%.19 New research indicates that HPV, in particular HPV-16, may be linked to oral cancer.<sup>16</sup> A study completed in 2003 found that 18% of females between 14 and 19 years of age were infected with HPV.17 Therefore, incidences of oral cancer are expected to rise, making early detection an increasingly important goal.<sup>19</sup>

The results of the study have direct implications on dental hygiene practice, as the dental hygienist is one of two practitioners in most dental offices who can provide an oral examination. Every dental hygienist should be informed about risk factors for oral cancer and this information should be relayed to their patients. All patients should receive a conventional oral examination in the dental office. The dental hygienist should also stay informed about new technologies for oral cancer screening such as the VELscope<sup>®</sup> and use those that have clear evidence to support their use.

Several studies support the use of VELscope<sup>®</sup> as a screening tool for oral cancer.<sup>16-18</sup> Even though large clinical trials have yet to be reported, these technologies that have benefit might be considered for use in practice. While our study did not find malignancies with the VELscope<sup>®</sup>, several subjects were identified as having suspicious lesions and were readily referred for more extensive



evaluation. This situation is common in private dental practice and the technology may assist practitioners in determining which suspicious sites need to be re-evaluated or referred at a later appointment.

Since patient education was the only variable introduced between the refusal of the VELscope<sup>®</sup> exam and acceptance, it is likely that patient education was the main determining factor in changing the patient's decision. However, it is also possible that the patient felt more comfortable with the physical surroundings, the student dental hygienist, and the researchers after spending time in the clinic. This may have had an impact on the patient's choice to have or not have the exam. This same or even greater comfort level would be achieved in the dental practice.

The initial cost of VELscope<sup>®</sup> is approximately \$5,000, and the maker, LED Dental, recommends charging the patient approximately what is charged for 4 bitewing radiographs. The American Dental Association approved the CDT code, D0431: "Adjunctive prediagnostic test that aids in the detection of mucosal abnormalities including pre-malignant and malignant lesions not to include cytology or biopsy procedures," which applies to VELscope<sup>®</sup>. Although not all insurance companies are currently reimbursing for such procedures, it is recommended that the claims be submitted to the insurance company for review so the companies can access the increase in use and the need for coverage of these screenings. As of October 2008, at least one major dental insurance company has announced its decision to reimburse its members for the cost of a VELscope<sup>®</sup> examination.<sup>20</sup>

#### Limitations

Participants in this study were limited to the first 100 willing participants, with one risk factor for oral cancer, over 21 years of age, who presented for dental prophylaxis at the Fones School of Dental Hygiene. Those under the age of 21 were not included as oral cancer incidence is very low in this population<sup>1</sup> and testing participants of that age would have necessitated the need for parental consult. Participants with photosensitivity were not eligible for a VELscope<sup>®</sup> examination, as the fluorescent light may have posed a health risk.<sup>5</sup> Also, this study did not compare the incidence of oral cancer found by traditional white light examination with that found by oral fluorescence technology. Finally, since alcohol abuse and tobacco use are not widely accepted practices, patients may have not disclosed their use upon self report.

#### Conclusion

The study results demonstrate that patient education by the dental professional is a relevant factor in the patient's acceptance of a VELscope<sup>®</sup> oral cancer examination. In addition, the use of the VELscope<sup>®</sup> was well accepted by the study subjects. Dental hygienists have an obligation to provide comprehensive care to their patients and, in the case of oral cancer detection, this care may be life saving. VELscope® is a new technology that may provide the dental professional with a more exact means to detect oral cancer in its earliest stages when it is most curable.

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At the time of this writing, Marie Felker-Paulis, RDH, BS was in the Bachelor's Degree online completion program at the Fones School of Dental Hygiene at the University of Bridgeport. Currently, she is pursuing her MS Degree in Dental Hygiene Education at the University of Bridgeport, where she is employed as a second year dental hygiene clinical instructor. She is also Trustee for the Bridgeport Component of CDHA and served as a CT Delegate to ADHA in Washington D.C.

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