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The Use of Fluorescence Technology versus Visual and Tactile Examination in the Detection of Oral Lesions: A Pilot Study

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Introduction

The importance of oral cancer screening is widely documented in the literature.¹ Oral cancer prevalence continues to increase every year, with an estimated 41,380 new oral cancer cases in 2013.² Over 7,890 of those cases are expected to include a negative prognosis or death from the disease.² In the U.S. alone there are 275,193 cases living with oral cancer, and the average 5 year survival rate for those people is 62.2%.² Late detection of oral cancer (when the cancer has reached stage III or IV) is a contributing factor in high morbidity and mortality rates.³ Several factors contribute to the late detection of cancerous lesions such as not conducting a comprehensive intraoral and extraoral oral cancer screening and the difficulty to detect early precancerous and cancerous lesions. Because of the difficulty in oral cancer early detection, lesions are often detected in advanced stages and show evidence of invasion and metastasis, which results in disfigurement from invasive treatments. Late diagnosis of the disease is unfortunate because oral cancer patients have an 80 to 90% survival rate when lesions are detected early (pre-malignant lesions, or when the lesion is on stage I) (Table I).² Early diagnosis of oral cancer results in minimally invasive procedures and better prognosis.⁴ Pre-malignant lesions, stage I and II oral cancers can remain undetected until symptoms present clinically.^{4,5} According to the National Cancer Institute, the

Abstract

Purpose: This study compared the effectiveness of the VELscope® Vx versus visual and tactile intraoral examination in detecting oral lesions in an adult, high risk population.

Methods: The pilot study compared the intra oral findings between 2 examination types. The sample was comprised of 30 participants who were addicted to either cigarettes or a dual addiction (cigarettes plus hookah). High risk population was defined as males who were current cigarette smokers or had a dual addiction. Two trained and experienced licensed dental hygienists conducted all examinations. Throughout the study, all visual and tactile intraoral examinations were conducted first by one dental hygienist first, followed by the VELscope® Vx fluorescence examinations by the second dental hygienist. All subjects received an inspection of the lips, labial and buccal mucosa, floor of the mouth, dorsal, ventral and lateral sides of the tongue, hard and soft palate, and visual inspection of the oropharynx and uvula. Both evaluations took place in 1 visit in the Dental Hygiene Research Center at Old Dominion University and external sites. All participants received oral cancer screening information, recommendations, referrals for tobacco cessation programs and brochures on the 2 types of examinations conducted.

Results: Participants were considered high risk based on demographics (current smokers and mostly males). Neither visual and tactile intraoral examination nor the VELscope® Vx examination showed positive lesions. No lesions were detected; therefore, no referrals were made. Data indicated the duration of tobacco use was significantly higher in cigarette smokers (14.1 years) than dual addiction smokers (5 years) ($p > 0.005$). The average numbers of cigarettes smoked per day were 13.5 compared to 14.2 cigarettes for dual addiction smokers.

Conclusion: Results from this study suggest the visual and tactile intraoral examination produced comparative results to the VELscope® Vx examination. Findings from this study support that the VELscope® Vx is still considered an adjunct technology and cannot be used exclusively for oral cancer screening.

Keywords: oral cancer, VELscope® Vx, dual addiction, oral potentially malignant lesions

This study supports the NDHRA priority area, **Clinical Dental Hygiene Care:** Investigate how dental hygienists use emerging science to reduce risk in susceptible patients (risk reduction strategies).

Table I: Five-Year Oral Cancer Relative Survival Rate, Based on the Data from the National Cancer Institute, SEER Program, NIH

Site	Stage			
	I	II	III	IV
Lip	96.3%	82.7%	56.7%	48.1%
Tongue	70.7%	58.6%	47.3%	36.7%
Floor of the mouth	72.5%	60.1%	35.8%	29.7%
Gingiva and other soft tissue	80.9%	62.2%	45.1%	40.0%

highest survival rate in early cancerous lesions is for stage I lip cancer (96.3%), whereas the lowest survival rate is for stage II tongue cancer (58.6%).⁵ According to Healthy People 2020, detecting oral and pharyngeal cancers at the earliest stages (stage I and II) is a critical objective.⁶ In 2007, 32.5% of the oral and pharyngeal cancers detected were at their earliest stages.⁶ This suggests that by the year 2020 the percentage of oral and pharyngeal cancers diagnosed at early stages should reach a 10% improvement.⁶ Since oral cancer is mostly detected in late stages, almost one-half of oral cancer survivors are at risk of developing local or regional recurrence and/or distant metastasis.⁷ In addition, up to 90% of treatment failures are for local and regional recurrences.⁷

Early cancer or premalignant lesions can mimic benign lesions, appearing as asymptomatic, white lesions (Leukoplakia) or red lesions (Erythroplakia). The surgical removal of leukoplakia is only obligatory when the dysplasia is diagnosed as moderate to severe. On the other hand, erythroplakia transforms to squamous cell carcinoma or carcinoma in situ in 90% of the cases. However, some of the red and white lesions do not always progress into malignant lesions.^{3,5} Safe, cost effective technologies could improve diagnosis and early treatment, and would decrease mortality rates while minimizing disfigurement.⁴ Research shows long-term effects of late diagnosis, including aggressive treatments and disfigurement, xerostomia, chewing and swallowing difficulties, dental caries, and depression.¹ Currently, the only accurate differential diagnosis is through scalpel biopsy and histologic examination which are gold standard diagnosing procedures but severely invasive and expensive.³

Intraoral and extraoral visual and tactile examination is still the standard of care for oral cancer screening. Traditional oral cancer screening includes taking an updated medical and dental history to identify risk factors including tobacco use (smoking or smokeless), alcohol consump-

tion, HPV infection, frequent exposure to ultraviolet light, poor nutrition and genetic factors.⁸ The National Institute of Dental and Craniofacial Research developed an oral cancer screening protocol for the clinicians to use with every patient as a part of the regular periodic appointment.⁸ The examination consists of 2 parts: extraoral examination, intraoral soft tissue examination. The extraoral examination includes visual and palpatory inspection of the face, ears, neck and the regional lymph nodes areas. Comprehensive intraoral soft tissue examination requires a visual and palpatory evaluation of the lips, labial mucosa, right and left buccal mucosa, gingiva, the dorsal, ventral and lateral sides of the tongue, the floor of the mouth, the hard and soft palate, and the oropharynx and uvula. Practicing dental hygienists and dentists are using mixed oral cancer screening protocols or none at all.⁸ There is little guidance for dental hygienists or dentists who are interested in improving their oral cancer detection because of the lack of standardization regarding the benefits of traditional oral cancer screenings versus optical or technology-based imaging in early detection of oral cancer. The similarity in appearance between benign and premalignant oral lesions makes it difficult to rely on the traditional oral cancer screening.

The Oral Cancer Foundation supports research and development of technology-based techniques and devices that are non-invasive to detect initial, asymptomatic cell change as soon as possible.⁹ Technology-based devices capabilities include increased ability by oral health care professionals to identify, contrast (abnormal versus abnormal), and monitor submucosal and dysplastic changes not visible during a visual oral cancer screening. While these screening devices do not differentiate between malignant and benign lesions, when used in conjunction with a traditional oral cancer screening, they may assist oral health professionals in recognizing abnormal lesions or oral potentially malignant lesions at earlier stages.¹

Oral cancer screening tools such as the VEL-

Table II: Oral Cancer Screening Devices

Product Name	Company	Dispensing Method	Unique Features
VELscope® Vx	LED Dental Inc.	<ul style="list-style-type: none"> • Lighted device • Emits blue-light • Clinician views oral cavity through the VELscope® Vx lens 	<ul style="list-style-type: none"> • Cordless, portable • Digital camera attachment • Uses blue light to simulate natural fluorescence • No solutions used
Identafi®	DentalEZ group StarDental	<ul style="list-style-type: none"> • Hand-held mirror emits 3 different type of light modes • Safe blue light, white light and amber light into the oral cavity • Clinician views tissue discoloration using the three modes 	<ul style="list-style-type: none"> • Cordless, portable • Ability to examine tissue vasculature • No solutions used
ViziLite® Plus	ZILA Pharmaceutical Inc.	<ul style="list-style-type: none"> • Uses low energy blue-white light source • Clinician activates the light source by bending the vial container then insert it to a holder 	<ul style="list-style-type: none"> • Cordless, portable • Requires, with Microlux/DL, a pre-rinse for 30 seconds • Can be used in conjunction with TBlue (Tuludine blue-based dye)
Microlux™/DL	AdDent Incorporated	<ul style="list-style-type: none"> • Produces blue-white LED light source • Clinician views white lesions 	<ul style="list-style-type: none"> • Cordless, portable device • Requires, with ViziLite® Plus, a pre-rinse for 60 seconds

scope® Vx, LED (Dental Inc, Burnaby, BC, Canada); Identafi® (StarDental, Lancaster, PA); ViziLite® Plus with TBlue, ZILATM (Fort Collins, Colo.); and the Microlux™/DL, (AdDental Inc, Danbury, Conn.), are technology-based devices available for use in private practice and public health settings (Table II). Technology-based devices include hand-held operating systems that use several chemiluminescence, blue-white LED and autofluorescence to penetrate epithelial tissue; light based systems enhance the visual inspection of intraoral tissues and help distinguish healthy areas versus oral potentially malignant lesions occurring at the submucosal layers and therefore not readily visible to the naked eye. Each device has individual defining features aimed to detect submucosal cell change or rapid destructive cell mutation and determine whether the lesion has metastasized to underlying connective tissue. This is a limitation of visual oral cancer screening examinations. More research is needed to support the use of technology-based screening tools for early detection of oral cancer in the general (low-risk) populations.¹⁰⁻¹³ Also, current literature does not support exclusive use of technology-based screening protocols in reducing mortality rates in smokers.¹²

VELscope® Vx is a non-magnifying, wide-field imaging device. The original VELscope® was primarily approved by the FDA on April, 2006 to be used as an adjunct oral mucosal examination device. In November 2010, the newer genera-

tion VELscope® Vx was approved by the FDA for the same purposes (Figure 1).¹⁴ The new VELscope® Vx is easier to carry, allows for broader intramural imaging and is cordless (utilizing a 12 hour battery). It does not require a dimmed light and can be used under incandescent light. VELscope® Vx has a higher intensity for a better visualization; an external camera attachment was added to facilitate a photo documentation of suspicious lesions during exams. Researchers choose the new generation VELscope Vx because of these advances in the technology and to provide research on the most current device.

The Identafi® system uses 3 light modes: a white light mode, a

Figure 1: Visual Enhanced Lesion Scope (VELscope® Vx)



Source: picture provided by LED dental Inc., the manufacturer of the VELscope® Vx

fluorescent violet mode and an amber reflectance mode. Identafi® fluorescent light makes an abnormal lesion appear dark brown or black, and healthy tissue reflect as blue fluorescence areas. ViziLite® Plus with TBlue system uses a low energy blue white light source, which requires a 30 second acetic acid pre-rinse that dehydrates the tissue. Normal tissue appears healthy pink, while abnormal tissue appears as acetowhite in color.

Microlux™/DL system uses a blue-white LED light source. It uses a bright light, illumination technology, but is currently recognized specifically for better discovery of keratotic lesions that might not be discovered using the chair-side light. Abnormal tissue will appear as acetowhite, while normal tissue will appear as a healthy pink in color. The VELscope® Vx elicits a green, homogeneous fluorescence of normal tissue (Figure 2). A reduction in the green fluorescence indicates abnormal tissue.¹⁵ However, the abnormality may indicate either pathological conditions (such as precancerous or cancerous lesions) or variation from normal structures (such as Linea alba in the buccal mucosa).

Unlike other types of light-based systems, the VELscope® Vx does not require a pre-rinse and does not contain a lesion-marking solution. The VELscope® Vx allows for the adaptation of a digital camera, which aids in monitoring and accessing submucosal parameters of suspicious lesions. In addition to the recommendations from the Oral Cancer Foundation,⁹ Marzouki et al¹⁶ concluded that "the VELscope may add sensitivity to the clinical examination and be a useful adjunct in high-risk patients."

Under the VELscope® Vx light dysplastic and malignant cells will appear as a dark area of abnormality as they interrupt and cause a loss of fluorescence.¹³ Preliminary studies showed that the sensitivity and specificity of the VELscope® Vx were both higher than 90%.^{10,11,16} The evidence support the effectiveness of the VELscope® Vx in identifying extended borders of known lesions but there is not enough evidence to support or refute its effectiveness in detecting early oral cancer lesions in general populations.^{10,11}

VELscope® Vx and other screening devices have high false positive rates.¹⁰ The positive and negative predictive values of the VELscope® Vx were found to be around 42 and 98%, respectively.^{3,16} For the ViziLite® Plus with TBlue, the sensitivity was found to be a median of 85%, the median specificity was 67%. The positive predictive value was 85% and the negative predictive

Figure 2: Tissue Appearance under the VELscope® Vx



Source: Photographs used by permission. Taken at the Dental Hygiene Research Center, Old Dominion University.

value was 83%.³ Therefore, the literature recommend the use of these devices may be useful as opportunistic screening protocol with high risk populations, where the pretest probability of oral cancer is above 10%.¹⁰

This study supports the need for more research using new technologies. According to a systematic review conducted by Kujan et al, no evidence exists to suggest that other methods of screening, toluidine blue, fluorescence imaging or brush biopsy, are effective as a diagnostic tool.^{10,12} VELscope® Vx is of particular interest because there are limited studies examining the effectiveness of the VELscope® Vx as an oral cancer screening tool in high risk populations. Unlike other technologies, the device has minimal contraindications; per manufacturer's instructions, individuals taking medications that cause photosensitivity or predisposed to photosensitivity are contraindicated for use of the VELscope® Vx because of the blue-white fluorescent light emitted by the device.¹⁰

High risk populations include those who smoke tobacco - smoking has been firmly established as a direct causal link to oral cancer.¹⁷ The risk of oral and oropharyngeal cancer increases with regular alcohol consumption.¹⁷ The Healthy People 2020 report identified tobacco and alcohol consumption as priorities for the prevention of cancer.⁶ According to the American Cancer Society, 7 out of 10 oral cancer patients are heavy drinkers.¹⁸ Since tobacco is one of the most common modifiable known risk factor of oral cancer, cigarette smokers were chosen in this study as the target population.

Methods and Materials

A convenience sample of 30 cigarette smokers or dual addiction (cigarette and hookah) smokers from the state of Virginia, Hampton Roads area (Norfolk, Virginia Beach, and Chesapeake) were recruited. Recruitment flyers were distributed electronically through the university faculty and staff email announcement. Recruitment flyers were also posted at various locations in the local community.

The inclusion criteria included participants 18 years of age or older and people who smoke cigarettes only or in combination with other type of tobacco use (hookah smoking). People who used other forms of smoking habits (without cigarette smoking) and individuals who were photosensitive were excluded from participation. Data collection took place on the campus of Old Dominion University, Norfolk, Virginia and at 3 local senior citizens nursing homes. Written informed consent was obtained from each participant. Translators trained in medical and dental terminology were made available to individuals with limited English proficiency.

Prior to data collection, the study was approved by Old Dominion University institutional review board. All participants completed a health information and medical history form. Demographic data included age, gender and ethnicity/race. The health history included questions to determine risk for oral cancer to include history of cancer or cancer treatments, HPV infection and current medications. Smoking and alcohol habits were calculated according to the frequency of tobacco and alcohol use: the number of cigarettes/packs, the number of times smoking hookah and the number of alcohol drinks consumed were calculated per day, per week or per month. The duration of smoking in years was also collected. At the completion of the study, all participants received recommendations regarding tobacco cessation and information on the two examinations performed.

Each participant received both a visual and tactile intraoral examination and a VELscope® Vx examination to assess oral potentially malignant lesions. Two licensed dental hygienists served as investigators - one investigator conducted the visual and tactile intraoral examination and the second examiner conducted the VELscope® Vx examination. The examination sequence was standardized for all study participants - visual and tactile intraoral examination was conducted first by investigator A, while investigator B conducted the VELscope® Vx examination second. All investigators were educated and trained on the use of the

VELscope® Vx and the interpretation of findings by a professional expert from LED Dental Inc, the manufacturer of the VELscope® Vx. Investigators also viewed a video tutorial on the proper use of VELscope® Vx technology and how to interpret findings. Because one examiner conducted each type of examination, no inter-rater calibration was necessary during the study. However, intra-rater reliability was measured for each investigator using test-retest reliability.

Clinical findings were recorded using 6 data collection forms - 3 for visual and tactile intraoral examination and 3 for the VELscope® Vx examination. Examination sequences were standardized according to size, shape, color and texture of the lesion. The sequence of the visual and tactile intraoral examination included bi-digital evaluation of the lips, labial mucosa, right and left buccal mucosa, visual inspection of the gingiva, bi-digital palpation and visual inspection of the dorsal, ventral and lateral sides of the tongue, digital palpation of the floor of the mouth, visual inspection and digital palpation of the hard palate, visual inspection of the visible portion of the soft palate, and visual inspection of the oropharynx and uvula. The VELscope® Vx examination followed the same sequence without palpation.

Statistical Analysis

To determine demographic and medical health risk behaviors in individuals who smoke tobacco, t-test were measured. This test analyzed the significant difference between cigarette smokers and dual addiction smokers by comparing the number of cigarettes smoked per day, number of alcoholic drinks consumed per month and length of time smoking per year. The significance level was set at 0.05.

Results

Thirty participants with a mean age of 42 years were enrolled. Seventeen participants were cigarette smokers and 13 participants reported dual addiction (Table III). Cigarette smokers consisted of 76.5% males (n=13) and 23.5% females (n=4). For the dual addiction smokers, 77% were males (n=10) and 23% (n=3) were females. Fifteen participants identified their ethnicity as Asian, 10 Caucasian, 3 African-American, 1 Hispanic and 1 Native American (Table III).

In participants who smoked cigarettes, the average length of time smoking was 14.1 years, whereas the average length of time smoking for dual addiction smokers was 5 years (Table IV).

Table III: Demographics

Smoking Habit	Ethnicity					Age		Gender	
	AA	A	H	NA	C	19 to 34	>34	Male	Female
Cigarette smoking n=17	2	8	0	0	7	11	6	13	4
Dual Addiction n=13	1	7	1	1	3	13	0	10	3
Total n=30	3	15	1	1	10	24	6	23	7

Key: AA=African American; A=Asian; H=Hispanic/Latino; NA=Native American; C=Caucasian
Dual Addiction=Cigarette + hookah smoking

Table IV: Health Determinants

Smoking Habit	Length of Time Smoking (Years)		Number of Cigarettes Smoked per day		Number of Alcoholic Drinks per month	
	Mean + SE	p-value	Mean + SE	p-value	Mean + SE	p-value
Cigarette Smoking n=17	14.1 + 3.11	0.005	13.2 + 2.56	-	5 + 1.79	-
Dual Addiction n=13	5 + 0.89	0.005	14.5 + 2.92	-	13.9 + 7.63	-

Key: Dual Addiction= Cigarette + hookah smoking

The number of alcohol drinks consumed per month for tobacco cigarette smokers was an average of 5 drinks. For dual addiction smokers, the average was 13.9 drinks per month. The number of cigarettes per day for tobacco cigarettes only smokers was an average of 13.2 cigarettes, whereas dual addiction smokers reported an average of 14.5 cigarettes per day (Table IV). Results demonstrated a statistically significant difference in the average length of time smoking (in years) between the cigarette smokers (14.1 years) and the dual addiction smokers (5 years).

Results showed there was no statistically significant difference between cigarette smokers and dual addiction smokers in the average number of alcoholic drinks per month (5 for cigarette smokers and 13.9 for dual addiction). The average number of cigarettes smoked per day did not show a statistically significant difference between the 2 groups (13.2 for cigarette smokers and 14.5 for dual addiction) (Table IV).

There were no statistically significant differences in the oral potentially malignant lesions detected in cigarette or dual addiction smokers by the VELscope® Vx when compared to visual and tactile intraoral examination. No lesions were identified in either group; therefore, results showed no differ-

ences between findings in either group. Although the study protocol included taking intraoral photographs and referral to Eastern Virginia Medical School for biopsy, no lesions were detected using either type of examination; therefore, no intraoral photographs or referrals were made.

Discussion

This study was conducted to determine if the VELscope® Vx examination lead to improved detection of early stage lesions in submucosal tissues. While results of the 2 examination types indicated no statistical difference, the majority of participants reported 1 or more high risk behaviors for oral cancer. Demographic information gathered supports current literature on high risk populations and an increase in the number of younger populations who become habitual smokers and also developing alcohol addiction and dual-addiction smoking habits (specifically those who smoke both cigarettes and hookah).¹⁹ All participants in this study presented 1 or more health risk behaviors, or factors for developing potentially malignant oral lesions.

This pilot study enrolled a small sample size and results should be interpreted within that context. Mostly males were enrolled in this study,

and less than one-third were females.^{17,20} Although the risk of oral cancer is increasing in females, the research suggest overall males account for the majority of smokers.¹⁷ Participants who consume alcohol in combination to smoking have an added risk of oral cancer; 7 out of 10 oral cancer patients are heavy drinkers, according to the American Cancer Society.¹⁸ The literature identifies black populations as a high risk racial group who smoke cigarettes.^{17,20} In this very specific group population, Asians were the majority of cigarette and dual addiction smokers.

The outcome of this study may have also been influenced by a short observational period. Patient recruitment efforts were limited to a 3 month time period, contributing to a small non-representative sample size of 30 subjects. Both examination types were conducted in 1 appointment. This research study was limited to 1 year; this did not allow time for scheduling periodic oral cancer screening appointments to observe any tissue changes. Limited funding and time impeded the development of a cohort study to investigate changes or alterations in the oral soft tissues throughout a long period of time in high risk populations.

The sample size used in this study was small and therefore limited the results. The age range of the majority of the sample was between 19 to 34 years, which indicates a young lower risk population. Almost two-thirds of the cigarette smokers enrolled were under 34 years old and none of the dual addiction smokers were above 34 years old. The research identifies adults above 55 years old as the highest risk age group.^{17,20} In this study, 13 of the 30 participants recorded dual addiction. The literature indicates hookah smoking is becoming a trend within adolescents and young adults,¹⁹ and this study supports that fact.

The lack of concern and education about oral cancer may have had an influence on the outcomes and participation of this study. Research suggests that the level of cancer concern ranges from low to moderate in general and high risk populations.²¹ There are no consistent findings concerning whether cancer worry in high-risk populations exceeds that for the general population.²¹ Overall, there is a lack of education on the importance of oral cancer screening. Paulis suggests dental hygienists have an important role in educating their patients regarding routine comprehensive intraoral and extraoral examination of the head and neck area for oral cancer early detection.²²

The VELscope® Vx was initially approved by the FDA in 2006 to “enhance the identification and visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia.”¹⁴ The results of the present study did not show a significant difference between the VELscope® Vx examination and the visual and tactile intraoral examination, thus supporting the importance of the thorough traditional intraoral and extraoral examination. The lack of the extraoral examination and the comprehensive palpatory examination of the head and neck and may have had an influence on the outcomes. The VELscope® Vx technology is an optical device that is only used intraorally; its limitation includes the lack of comprehensive soft tissue palpatory examination. This emphasizes the continued need for a thorough traditional visual and palpatory intraoral and extraoral examination of the head and neck, as well as the thyroid area.

Future studies should include a cohort research study design that includes a broader spectrum of high risk groups. For example, the inclusion criteria may include individuals having one or more oral cancer high risk parameters. Recruitment and time needed to conduct the research was limited and future studies should also consider longitudinal research design. This would allow for a greater representation of high risk population. To observe the effectiveness of the VELscope® Vx in the detection of the early lesions at subclinical levels, the cohort research study design should include scheduling periodic oral cancer screenings of the same participants every 6 months over a longer period of time that extends to several years.

Conclusion

In this particular study, no lesions were identified in either group. The absence of findings supports the need of further high-quality research evaluate very carefully the effectiveness of the 2 tested protocols in identifying the presence of oral potentially malignant lesions. This study did not produce statistically significant data to support or refute the use of the VELscope® Vx for use as an exclusive oral cancer screening device in cigarette smokers or those with dual addiction smoking habits. Therefore, the importance of conventional oral cancer screening is still significant especially that it includes intraoral and extraoral visual and tactile examination of the head and neck areas. Then, based on the given data, the use of adjunctive technologies, such as the VELscope® Vx is kept as the clinician’s choice.

Since the early diagnosis of oral cancer is the key for better prognosis and higher survival rates, more efforts should be made to enhance the effectiveness of the current technology-based adjunctive devices, including the VELscope® Vx, as oral cancer screening tools.

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