Debate

Evidence-Based Decision-Making: Should the General Dentist Adopt the Use of the VELscope for Routine Screening for Oral Cancer?

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The VELscope (Visually Enhanced Lesion Scope) is currently being marketed to general dentists. Advertisements claim that this handheld device visually enhances a clinician's ability to detect oral cancer. The technology is based on the premise that normal cells will glow when exposed to fluorescent light, whereas abnormal cells (not necessarily only cancer or precancerous cells) will absorb fluorescent light and appear dark. The light-reflecting property of normal cells and the light-absorbing property of abnormal cells allow visual distinction of the two.

Currently the manufacturer (LED Dental Inc., White Rock, B.C.) is marketing this device to general dentists in the following way: "The VELscope examination takes only one or two minutes and is easy to incorporate into your workflow" and "an increasing number of insurance companies are recognizing VELscope as an adjunctive screening device."[1]

Although the vast majority of oral soft tissue lesions are not cancerous,[2] it is standard practice for all dentists to screen every patient thoroughly for possible oral cancer lesions.[3] Currently, dentists do this by direct visual inspection as part of their complete and recall examinations.

The annual incidence of oral cancer is reported to be 12 new cases in 100,000 people;

a third of the 12 will die of the disease in 5 years.[4] To put this into perspective, the average general dental practitioner will identify a single case of oral cancer about every 7–10 years, and lose a patient to oral cancer about every 20–30 years.

Important clinical factors like male gender, smoking, age and immunosuppressant disorders increase the risk of oral cancer 2–7-fold.[5,6] Also, the stage at which oral cancer is diagnosed plays a significant role in the likelihood of the patient surviving. For example, 80% of patients diagnosed early (stages I and II) are likely to survive for 5 years, whereas only 20% who are diagnosed in the more advanced stages (III and IV) will survive 5 years.[7]

Unfortunately, the survival rates associated with oral cancer have not changed significantly in the last 30 years.[7] Recently, the dental profession has promoted itself as the logical primary health care provider to screen for oral cancer with the goal of increasing the survival rate through early diagnosis. The manufacturers of VELscope claim that dentists can reach this goal with the routine use of their device in general practice.

Dentists have been given the privilege of professional status. Therefore, we have the responsibility to place the best interests of society, including our patients, foremost in our

Table 1 Critical appraisal of studies cited by the manufacturers of VELscope[10]

Citation	Study design	Outcome	Results	Critique
Poh and others[11]	Case study[a]	Detection of oral premalignant and malignant lesions	Direct fluorescence visualization was effectively used to detect a new lesion in 3 patients during follow-up	• All cases were people whom the investigators knew had a history of oral dysplasia or carcinoma in situ • Case studies generally not used to change clinical practice
Poh and others[12]	Observational (cross-sectional) study[a]	Detection of the extent of visibly identified premalignant or cancerous oral lesions	102 margins established Sensitivity = 97% Specificity = 94%	• Pilot study • Spectrum and test-referral bias • Participants limited to those already known to have had cancer; results in overestimate of VELscope's sensitivity and specificity • No blinding of investigators • No discussion of agreement in VELscope readings among clinical investigators (i.e., no kappa value cited) • Premature to use this pilot study as basis for routine use of the device in clinical practice
Lane and others[13]	Observational (cross-sectional) study[a]	Normal tissue; abnormal tissue (severe dysplasia, carcinoma in situ, squamous cell carcinoma)	50 lesions detected Sensitivity = 98% Specificity = 100%	• Pilot study • Shows that device may be able to distinguish between normal and abnormal tissue, but not necessarily between oral cancer and other forms of abnormal oral tissues • Spectrum and test-referral bias • Participants limited to those already known to have had cancer; results in overestimate of VELscope's sensitivity and specificity • No blinding of investigators • No discussion of agreement in VELscope readings among clinical investigators (i.e., no kappa value cited)
Kois and Truelove[14]	Case study[b]	Detection of oral premalignant lesions	Direct fluorescence visualization was effectively used to detect a new lesion in 3 patients during follow-up	• All cases were people whom the investigators knew had a history of oral dysplasia or carcinoma in situ • Case studies generally not used to change clinical practice

[a]*Patients from oral cancer clinic (British Columbia Cancer Agency).*
[b]*Patients from oral dysplasia clinic (University of Washington).*

clinical decision-making.[8] Evidence-based dental practice promotes clinical decision-making that is based on scientific research, available clinical skill sets and patients' preferences and values. All 3 factors must be favourable before any new clinical protocol is adopted into dental practice.[9] The objective of this paper is to determine whether these factors support the use of the VELscope for the routine screening of oral cancer.

The Scientific Evidence

I reviewed and critically appraised all clinical papers (excluding abstracts) cited on the VELscope website (**Table 1**). All studies included patients seen in referral clinics that are specialized in the diagnosis and management of oral pathology. This population is not representative of the patient mix in a general dental practice and, thus, there is a risk of test-referral bias (i.e., the bias of only including people in the study who were referred for definitive diagnostic procedures) in the interpretation of the results of these studies.[15]

The 2 case studies demonstrated the potential benefit of the VELscope during follow-up of already diagnosed (high-risk) patients to check for new lesions.[11,14] However, case studies are generally not meant to change clinical practice, but rather to identify an area worth further investigation.[16] Furthermore, the 2 observational studies may be giving an artificially high true-positive rate (sensitivity) and true-negative rate (specificity) because of "spectrum bias."[12,13] This bias occurs when there is a significant difference between the study population and the general population that the device is intended for, i.e., general practice.[15] In addition, all studies were limited to the detection of premalignant or cancerous lesions, not other oral lesions more commonly seen in general practice. In other words, there is no evidence that this device can distinguish between oral cancer and aphthous ulcers, lichen planus and pemphigoid to name a few.

Finally, there is no long-term evidence that this device actually saves lives. The company's claim that it saves lives by detecting cancer early is premature and possibly invalid. For example, studies have shown that some commonly used early cancer screening methods are not saving the lives they were once believed to.[17,18] Also, it is important to consider the potential risk of harm from a false-positive reading before adopting the VELscope in general practice.

Clinician's Skill Set

I had the opportunity to try out the VELscope. Although the device is generally easy to use, I was uncertain of its usage heuristics. In other words, how consistent was my interpretation of the VELscope's positive test results? In addition, would all clinicians agree on what was a positive reading from the VELscope? Inter-observer and intra-observer agreement on a diagnostic test is determined by statistically assessing its kappa value, which ranges from 0 (no agreement) to 1 (perfect agreement). Neither a review of the literature nor of the manufacturer's information revealed any evidence that such an assessment of the clinical performance of the VELscope was carried out. Such problems further the risk of false-positive interpretations and, therefore, erroneous diagnosis of oral cancer.

Patient Preferences and Values

There are no quantitative data assessing patients' perceived concern of oral cancer or of its treatment outcomes. Without such data, I took it upon myself to conduct a quasi-scientific marketing survey. I asked people what they thought of paying about $50 for oral cancer screening with the VELscope. I sampled 52 people between the ages of 22 and 60, of which more than half (30) were women. All but 1 were willing to pay for such a service. Comments included, "I trust you," "$50 is worth peace of mind," "[I knew someone] who died of cancer."

This suggests that people generally trust dentists and that they want to know that they are being screened for oral cancer. The question is: does the VELscope offer patients the sense of security that they think they are getting for their $50?

Shortcomings of the VELscope

Of the 3 principles of evidence-based dental decision-making, only 1 is satisfied by the VELscope. Specifically, the desire by the public to know that they are being screened for oral cancer. Currently, neither the scientific evidence nor the level of clinical skill justifies the routine use of the VELscope in a general dental practice. Scientific studies have been carried out on people known to have oral cancer. The device may be effective in distinguishing between normal and abnormal tissue, but there is no evidence that it can distinguish between different types of abnormal tissue. In other words, the device is more likely to detect the more common abnormal oral tissue lesions (aphthous ulcers, lichen planus and pemphigoid) than oral cancer. Also, intra- and inter-operator agreement in the interpretation of test results has not been verified.

The VELscope's inability to distinguish between oral cancer and other abnormal tissue and the lack of a kappa value to assess its intra- and inter-operator reliability raise the potential for many false positives and, therefore, overdiagnosis of oral cancer. This would cause unnecessary stress and fear among patients, as well as increasing morbidity through unnecessary surgical biopsy procedures. It would also increase costs for the patient and contribute to the financial burden that is already on the health care system with no evidence of a net benefit to the patient or society.

In conclusion, there is no evidence that routine use of the VELscope in general dental practice saves lives. However, there are compelling reasons to be concerned about the risk of harm this device may cause if routinely used in general practice. Therefore, adoption of the VELscope as a routine cancer-screening device in general practice at this time may be premature. On the other hand, there is evidence that the VELscope may be of value in a clinic that is specialized in the management of oral cancer. ❧

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Editor's Note: *When Dr. Balevi submitted an article to* JCDA *questioning the benefit of the VELscope in the general practice setting, we sent his article to members of the British Columbia Oral Cancer Prevention Program for response. Their reply can be found on p. 607.* JCDA *is publishing these articles side by side in the interest of fostering discussion on timely issues affecting the dental profession. CDA members are encouraged to continue this discussion by logging on to the Members' Forum at* www.cda-adc.ca/forum.