Spring 2013

Fluorescent Technology Versus Visual and Tactile Examination in the Detection of Oral Lesion: A Pilot Study

Hadeel Mohammed Ayoub
Old Dominion University

FLUORESCENCE TECHNOLOGY VERSUS VISUAL AND TACTILE EXAMINATION IN THE DETECTION OF ORAL LESIONS: A PILOT STUDY

by

Hadeel Mohammed Ayoub
B.S.D.H. August 2006, King Saud University, Saudi Arabia

A Thesis Submitted to the Faculty of
Old Dominion University in Partial Fulfillment of the
Requirements for the Degree of

MASTER OF SCIENCE

DENTAL HYGIENE EDUCATION

OLD DOMINION UNIVERSITY
May 2013

Approved By:

Tara Newcomb (Director)

Gayle McCombs (Member)

Marshall Bonnie (Member)

ABSTRACT

FLUORESCENCE TECHNOLOGY VERSUS VISUAL AND TACTILE EXAMINATION IN THE DETECTION OF ORAL LESIONS: A PILOT STUDY

Hadeel Mohammed Ayoub
Old Dominion University, 2013
Director: Prof. Tara Newcomb

Purpose: The purpose of the study was to compare the effectiveness of the VELscope® Vx, versus a visual and tactile intraoral examination in detecting oral lesions in an adult, high risk population. **Methods:** A convenience sample of 30 participants (17 cigarette smokers and 13 dual addiction smokers) was enrolled. For the purpose of this study, dual addition was defined as cigarettes plus hookah usage. Two trained and calibrated dental hygienists conducted all examinations. Visual and tactile intraoral examinations were conducted, followed by VELscope® Vx florescence examinations. All subjects received an inspection of the lips, labial mucosa, buccal mucosa, floor of the mouth, dorsal, ventral and lateral sides of the tongue, as well as the hard and soft palate. Both evaluations took place in one visit. All participants received oral cancer screening information, recommendations and referrals for tobacco cessation programs and material on the two types of examinations provided. **Results:** Thirty subjects, between the ages 18-65 were enrolled (23 males and 7 females). The duration of tobacco use was significantly higher in cigarette smokers (14.1 years) than dual addiction smokers (5 years). The average numbers of cigarettes smoked per day were 13.5 compared to 14.2 cigarettes for dual addiction smokers. Neither the visual and tactile intraoral examination nor the VELscope® Vx examination showed any positive lesions. No lesions were detected; therefore, no referrals were made. **Conclusion:** Study participants were

considered high risk based on demographics (current smokers & males). These results support data from the American Cancer Society, which indicates that males smoke more cigarettes than females, and are at a higher risk of oral cancer. Furthermore, individuals who have dual smoking addictions are on the rise, and are also at increased risk for oral cancer. Results from this study suggest the visual and tactile intraoral examination produced comparative results to the VELscope® Vx examination.

ACKNOWLEDGEMENTS

I would like to recognize my extraordinary thesis committee for their love, encouragement, support, patience, and for the wonderful opportunity to learn at this eminent and unique dental hygiene research facility. I would like to express gratitude for Professor. Tara Newcomb, my thesis director. Thank you very much for the professional direction and substantial support. You have been a benefactor without whom this would not have been accomplished. Always available even in your busiest times, you directed me step by step and nurtured a sense of confidence in me, which enabled me to go above and beyond my perceived abilities. When I first learned that we would be working together, I can recall your excitement to work with an international student and from day one you gave me the lead. You have been nothing short of passionate and inspiring throughout this journey with a delightful personality. I greatly appreciate the numerous personal and professional lessons learned from you.

Acknowledgment is due to Professor Gayle McCombs, my thesis committee member and Graduate Program director, for the appreciation, inspiration, encouragement, valuable time and guidance given to me without any limits. You are more than a graduate program director; you are a mentor and a friend. I will never forget how you always have been by my side from when I first came to the United States. You provided me with distinctive opportunities that made me expanded my skills for my dental hygiene career and thus, I cannot thank you enough.

To Dr. Marshall Bonnie, thank you very much for your reassurance and support and for your assistance in facilitating communication with Eastern Virginia Medical School.

To my friend and co-researcher Ms. Amanda Kimball, and to my colleague and research assistant Mr. Yasser AlMaree, it was a pleasure working with you. I also would like to thank Ms. Clair Richardson for her help in statistical analysis.

I would like to take this opportunity to express my appreciation to King Saud University, College of Applied Medical Sciences and the Ministry of Higher Education in Saudi Arabia for providing me with this once in a lifetime opportunity to pursue a Masters degree through sponsorship.

To my beloved parents, who showered me with their prayers, love, and support every step of the way. You have raised me to be a self-directed, independent, and positive caring person. You stood beside me through my ups and downs and enabled me to accomplish my academic aspirations. I would have not reached my goals and be where I am in now without your support. To my sisters Hanadi and Muneerah, and my brothers Hasan, Khalid and Fisal, We missed precious moment during my stay here, yet I have felt your presence with me in my heart. I love you all.

To my best friend, who was with me during the most difficult times in my life, Hanan Bajaaman, always bestowing upon me her wisdom, care and love. She has always been a supportive friend in my times of need and I carry her presence close to my heart. I am dedicating my success to Hanan, although she is not here to share this moment with me.

Last but not least, I would like to thank the Chair of the Old Dominion University School of Dental Hygiene, Professor Michele Darby. Your calming presence and humble nature has been essential during the demanding thesis process. You supported my novel ideas and provided insightful and constructive feedback to develop a visionary product. You have been an inspirational professional model and it has been an honor to collaborate with you and acquire irreplaceable lessons.

Above all, I give my greatest thanks to *Allah* "God" for giving me the strength, courage, guidance and blessings throughout my life and through this educational process.

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CHAPTER I

INTRODUCTION

The importance of oral cancer screening is widely documented in the research 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] Oral potentially malignant (OPM) lesions manifest replication of nuclear DNA at an accelerated rate; therefore, the DNA mass increases and becomes a greater percentage of the total cell volume. The ratio between the nucleus and the cytoplasm can increase until the nucleus takes up nearly 100% of the cell volume.[5] Evidence supports earlier diagnosis reduces morbidity and mortality rates.[1,3] Although numerous studies have been conducted to compare and validate oral cancer screening techniques,[1,3-9] minimal gains have been made in the area of standardization and ways to promote regular oral cancer screening.

Dental professionals are seeking ways to improve traditional oral cancer screenings. Adjunctive oral cancer screening tools such as the VELscope® Vx, LED (Dental Inc, Burnaby, BC, Canada); Identafi® (StarDental, Lancaster, PA); ViziLite® Plus with TBlue, ZILA™ (Fort Collins, CO); and the Microlux™/DL, (AdDental Inc, Danbury, CT), are optical devices available for use in private practice and public health settings.[4] These technology-based devices are approved by the U.S. Food and Drug Administration (FDA).[4] Each device has individual defining features that highlight submucosal cells which have mutated from normal to cancerous; this is a limitation of the traditional oral cancer screening.

Technology-based devices can aid oral health care professionals' oral cancer screening protocol and may help identify, evaluate, and monitor abnormal oral lesions going through these dysplastic changes not visible during a traditional oral cancer screening.

The latest technology-based devices include hand-held operating systems that use different types of light to enhance the visual inspection of intraoral tissues and help distinguish healthy areas versus OPM lesions. The VELscope® Vx elicits a green, homogeneous fluorescence of normal tissue (Figure 1). Tissue fluorescence means the ability of the fluorophobes in healthy tissue to produce color variants when exposed to fluorescent light. A reduction in the green fluorescence indicates abnormal tissue (Figure 2). A digital camera attachment option allows for a photographic recording of any findings.

The Identafi® system uses three light modes; a white light mode for a cursory examination of the oral cavity; a fluorescent violet light mode to detect surface lesion; and an amber reflectance mode to examine deeper abnormal vascular growth of a lesion. 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.[3] Dehydrated tissues distinguish cellular changes more readily.[3,8] Normal tissue appears healthy pink, while abnormal tissue appears as acetowhite in color. TBlue is a toluidine blue based dye that binds to dysplastic and malignant epithelial cells. According to literature, the use of

TBlue in conjunction with the ViziLite® Plus increases the accuracy of lesion detection through enhancing the Vizilite® illumination.[4]

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. The Microlux™/DL system also requires a dehydrating type of pre-rinse for an extended 60 seconds. Abnormal tissue will appear as acetowhite, while normal tissue will appear as a healthy pink in color.[3]

The research literature concluded there is insufficient evidence to support the exclusive of either traditional visual examination or technology-based screening tools for early detection of oral cancer in the general population.[1,3,4,6,9-14] 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 submucosal abnormal lesions or OPM lesions at earlier stages.[4]

Current literature does not support exclusive use of technology-based screening protocols in reducing mortality rates in smokers. Additional research is needed to evaluate the true benefits of using the technology-based techniques as an adjunct to traditional oral cancer screening.[1,3-5]

According to Healthy People 2020, detecting oral and pharyngeal cancers at the earliest stages (stage I and II) is a critical objective.[15] In 2007, 32.5 % of the oral and pharyngeal cancers detected were at their earliest stages.[15] This suggests that by the year 2020 the percentage of oral and pharyngeal cancers diagnosed at early stages should

reach a 10% improvement.[11] Early detection is critical and the emergence of new technology may influence cancer detection and mortality rates in a positive way.

Currently, the most accurate differential diagnosis is through invasive scalpel biopsy and expensive histologic examination.[7] The Oral Cancer Foundation is encouraging the development and research of technology to include minimally invasive early detection techniques and devices. Fluorescent-based optical screening systems do not require acetic acid pre-rinse or invasive incision.[16] The VELscope® Vx is an adjunctive, optical oral device which is noninvasive; however, minimal research has been conducted on its capabilities as a standalone oral cancer screening device.

This study supports the need for more research using new technologies. 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.[5,6] While the exact etiology of the oral and oropharyngeal squamous cell carcinomas is multifactorial[17], the American Cancer Society has ranked and identified the most common risk factors for oral cancer as tobacco use (smoking or smokeless tobacco), heavy drinking of alcohol, heavy drinking and smoking, HPV infection, gender, age, prolonged exposure to ultraviolet (UV) light, poor nutrition, and immune system deficiencies.[18] Specifically, cigarette smoking has been firmly established as a direct causal link to oral cancer. In the U.S., tobacco contributes to an estimated 30% of all cancers, and the use of tobacco products accounts for an estimated 75% of oral cancers.[17] Since tobacco is the most common modifiable known risk factor of oral cancer, researchers in this study chose cigarette smokers as the target population.

Problem Statement

Is the VELscope® Vx effective in identifying oral cancer lesions in high risk populations? Does the VELscope® Vx improve detection of OPM lesions versus visual and tactile intraoral examination alone? Available research suggests VELscope® Vx may detect the extended borders of known cancerous lesions, but not typical submucosal cancerous lesions.[5,6]

The research project aimed to answer the following questions:

1. Does the VELscope® Vx detect OPM lesions lesions more readily than traditional visual examination in cigarette smokers?
2. What is the comparative difference in OPM lesions detected by the VELscope® Vx versus visual and tactile intraoral cancer examination?

Definition of Variables/Terms

VELscope® Vx: VELscope® Vx technology utilizes fluorescence technology that uses specific blue light wavelengths, transmitted through a halide lamp. Histologically, fluorescent light excites the cells in the epithelial tissue, then the basement membrane and stroma. Once excited, the tissues emanate a green fluorescene (sometimes referred to as autofluorescene) that is not visible to the naked eye. The VELscope® Vx filters out the blue light from the green, only the green fluorescence remains. Intraorally, the difference in degrees of green fluorescence reveals abnormalities. The variations are differed based on visual color and shape:

1. Healthy tissue: pale, lime green that will shine with fluorescent light
2. Abnormal tissue: dark green to dark rust due to the absorption of the light.

The wavelength of the VELscope® Vx light is 400-600 nanometers, which results in 98% sensitivity, and 100% specificity, in a high risk population.[9]

Oral Cancer: For this study purposes, oral cancer is defined as cancer that affects the oral cavity, which includes lips, labial and buccal mucosa, gingiva, dorsal, ventral and lateral sides of the oral tongue, floor of the mouth, hard and clinically visible portion of the soft palate.

Oral Potentially Malignant Lesions (OPM): In this research study, OPM stands for one or more of the following:

1. Lesions persist for more than 14 days
2. Red, white, or mixed lesions that resemble leukoplakia, erythroplakia, or erythroleukoplakia.

Traditional 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 consumption, HPV infection, frequent exposure to ultraviolet light, poor nutrition, and genetic factors.[19] The National Institute of Dental and Craniofacial Research (NIDCR) developed an oral cancer screening protocol for the clinicians to use with every patient as a part of the regular periodic appointment (Appendix A).[19] The examination consists of two parts: extraoral examination; perioral and intraoral soft tissue examination. The extraoral examination includes visual inspection of the face, ears, neck and the lymph nodes areas. The examination also includes bilateral palpation of the regional lymph nodes areas. Presence of tissue changes such as fissuring, abnormal growth, or color changes may indicate abnormality.

Comprehensive intraoral soft tissue examination requires a bidigital evaluation of the lips, labial mucosa, right and left buccal mucosa, visual inspection of the gingiva, bidigital 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 soft palate, and visual inspection of the oropharynx and uvula.[19] Evidence of any of the following is viewed as potential cancerous lesion:

1. Presence of oral mucosal ulcerations that do not resolve within 2 weeks
2. Red/white patchy lesions that do not resolve within 2 weeks
3. Persistent localized pain in the mouth
4. Persistent sore throat or a feeling that something is caught in the throat
5. Difficult or painful chewing and/or swallowing
6. Difficulty moving the jaw or tongue
7. Numbness of the tongue or other areas of the mouth with no previous history of trauma
8. Localized swelling of the jaw that causes dentures to fit poorly or become uncomfortable

Visual and Tactile Intraoral Examination: For the purpose of this study this term is defined as a comprehensive visual and tactile inspection of intraoral areas including lips, labial mucosa, right and left buccal mucosa, gingiva, dorsal, ventral and lateral sides of the tongue, floor of the mouth, hard and soft palate, the oropharynx and uvula. Excludes extraoral examination. Excludes anatomy in neck area.

High Risk Population: According to the literature, gender and smoking habits are considered risk factors for oral cancer.[16,18] In this research study, high risk population are defined as males, and people who currently smoke either cigarettes only or cigarettes with hookah smoking.

Dual Addiction: For the purpose of this study this term is defined as study participants who smoke cigarettes in addition to hookah smoking.

Cancer Stages: Different staging systems exist; the following system can be used to describe oral cavity and lip cancers:

Stage I- The cancer does not span more than 2 cm, and has not metastasized (spread) to local lymph nodes

Stage II- The cancer spans between 2-4 cm, and has not metastasized to local lymph nodes

Stage III- The cancer spans more than 4 cm, or the cancer is any size but has metastasized to a single, lymph node in the neck region ipsilateral to the original cancer. The dimensions of the involved cancerous lymph node do not exceed 3 cm.

Stage IV- Any of the following applies:

a. The cancer has spread within the oral cavity or to the lips; the local lymph nodes may or may not be involved;
b. The cancer measures any size, and has spread: to multiple, local lymph nodes ipsilaterally, to lymph nodes on one or both sides of the neck, or to any lymph node exceeding 6 cm;
c. The cancer has metastasized to other body regions

Recurrent- The cancer returned after treatment to the same or different part of the body

In stage I and II of oral cancer the size of the lesion will be between 2-4 centimeters. The lesion will not be spread from the lymph nodes, thus, visual inspection of the lesion may be difficult in some areas of the oral cavity. However, the lesion will be larger than 4 centimeters and easier to distinguish in stage III and IV.[3]

Research Hypotheses

The following hypotheses were tested at the .05 level of significance:

HO_1: There is no statistically significant difference in the oral cancer lesions detected in cigarette smokers by the VELscope® Vx compared to the visual and tactile intraoral examination, as measured by the number of oral potentially malignant lesions detected.

HO_2: There is no statistically significant difference in the oral cancer lesions detected in cigarette smokers by the VELscope® Vx compared to the visual and tactile intraoral examination, as measured by the stage of lesions detected.

CHAPTER II

REVIEW OF THE LITERATURE

Oral Cancer Prevalence and Diagnosis

The Oral Cancer Foundation indicates the incidence and mortality rates for oral cancer are still significantly higher than other cancers, such as cervical and laryngeal.[16] The oral cancer incidence rate in 2009 was 10.89 per 100,000 compared to cervical cancer (6.88 per 100,000). The mortality rate of oral cancer in 2009 was 2.37 (per 100,000), compared to the laryngeal cancer that was 1.09 (per 100,000).[15] According to the most current statistics by Surveillance Epidemiology and End Results database (SEER) 16.1 per 100,000 males and 6.2 per 100,000 females are diagnosed with oral cancer every year in the US.[20] In January 2009, 172,708 males and 91,734 females were diagnosed with oral cancer.[20] Since the reduction of incidence and mortality rates is occurring with other cancers and regular screening protocols exist, it should be a priority in oral cancer research to improve the 5 year survival rates.

Demographic data indicates oral cancer occurs mostly in people over 55 years of age.[16] Oral cancer occurs in males more than females (2:1 ratio) and occurs in black population more than white.[16] The key to reducing incidence and mortality rates is through early detection. Early diagnosis of oral cancer results in minimally invasive procedures and better prognosis.[3] Early cancerous lesions (premalignant lesions, stage I and II) can remain undetected until advanced stages and when symptoms present clinically.[1,3]

Early cancer or premalignant lesions can mimic benign lesions, appearing as asymptomatic white and red lesions, diagnosed precancerous lesions, and do not always progress into malignant.[1,7]

The two main problems associated with late diagnosis are large disfigurement and recurrence.[7] Safe, cost effective technologies could improve diagnosis and early treatment, and would decrease mortality rates while minimizing disfigurement.[3] In addition to the recommendations from the Oral Cancer Foundation, Marzouki et al., and Balevi concluded that the VELscope® Vx may be useful in early detection of oral lesions in patients who are considered high risk.[6]

Oral Cancer and Survival Rates

Between 2002-2008, oral cancer 5 year survival rate reached 67.7%.[8] This number is significantly higher than in the 1970s, when only 49.1% of cancer patients survived.[20] This dramatic shift in mortality rates is due to advances in screening methods and early detection.[21] Implementing early screening options for patients needs to be a priority in all health fields. Early diagnosis means the subclinical detection of OPM lesions (stage I and II cancers) before they metastasize (stage III and IV).

Patient education should be included in screening protocol to include regular self-identification of changes in the oral cavity and oral cancer sites.[1] Patients should be educated on common lifestyle risk factors, such as cigarette smoking, benefits of early detection and smoking cessation.[1] Additional education of other risk factors, such as diet and Human Papilloma Virus (HPV) should be reviewed.[22-24] The dental hygienist has an important role in oral cancer detection by providing, educating, and performing a thorough oral cancer screening.

If diagnosed early, oral cancer patients have an 80% to 90% survival rate.[3] The 5-year survival rate for oral cancer varies among individuals, based on the stage and location of the lesion. According to a 2013 statistics by the American Cancer Society, the highest survival rate in early cancerous lesions (stage I and II) is for stage I lip cancer (96%), whereas the lowest survival rate is for stage II tongue cancer (59%).[25] When comparing these findings to previous studies that show survival rates ranging between 21% (advanced stages) and 82% (early stages), findings suggest a greater survival rate when cancers are detected at an early stage.[2,8,9]

Smoking and Oral Cancer

The Healthy People 2020 report identified tobacco and alcohol consumption as priorities for the prevention of cancer.[26] More than 80% of oral cancer patients use tobacco.[3,4] Smokers have an average of 2 to 18 times increased risk of developing oral cancer compared to nonsmokers.[16,27] Smoking is a primary risk factor for oral cancer.

Thirty-seven percent of oral cancer individuals who continue to smoke after their cancer is cured will redevelop a recurrence of oral cancers.[17] In former smokers, recurrent cancer will possibly occur in 6% of patients who quit.[17]

Histologically, body tissues absorb tobacco components, and oral mucosal keratinocytes are the cells primarily affected by these. Keratinocytes are responsible for allowing the growth of premalignant lesions; it was proposed that the tobacco induced abnormal alteration of oral mucosal keratinocytes would contribute to the development of premalignant oral white lesions.[28]

Based on tobacco history and histological effects of tobacco, the need for early diagnosis and intervention is needed. New screening technologies need to be tested,

especially with high risk populations, to facilitate the early detection of precancerous and OPM lesions.

Current Screening Methods

Practicing dental hygienists and dentists are using mixed oral cancer screening protocols or none at all. 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. Research shows long-term effects of late diagnosis, including aggressive treatments and disfigurement, xerostomia, chewing and swallowing difficulties, dental caries, and depression.[4] The similarity in appearance between benign and premalignant oral lesions makes it difficult to rely on the traditional oral cancer screening.

New optical technologies such as the VELscope® Vx, ViziLite® Plus with TBlue, Identafi®, and the Microlux™/DL, show promise to improve the early detection of premalignant and malignant lesions.[7] Roblyer et al., suggests that more accurate discrimination between oral premalignant and benign lesions is possible by using technologies such as Spectroscopy, Fluorescence Imaging and Visualization, Optical Coherence Tomography, and Nanotechnology.[7] These technologies are safe and inexpensive compared with other medical imaging technologies, such as magnetic reasonance imaging (MRI), and can be integrated easily into clinical practice.[7]

In a systematic review by Patton et al., the effectiveness of traditional oral cancer screening and optical screening methods was described.[12] Patton et al., concluded that there is insufficient evidence to support or refute the exclusive use of either traditional

oral cancer examination or technology-based, optical screening examinations as beneficial or harmful for oral cancer screening in the general population.[12] No evidence exists to suggest that other methods of screening, toluidine blue, fluorescence imaging or brush biopsy, are effective as diagnostic tool, hence, these devices should only be used as an adjunct diagnostic tool.[10]

The VELscope® Vx

In 2001, The VELscope® Vx was initially approved by the FDA as an oral mucosal examination device.[29] The VELscope® Vx is used in the early detection of oral cancer as an adjunct to a clinical visual and tactile examination.[29] The VELscope® Vx also gained the FDA approval to be used to help identify diseased margins of clinically visible lesions.[29] The handpiece device emits safe blue light into the oral cavity that penetrates the stratified squamous epithelium, inducing fluorescence in normal cells.

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 to photograph lesions. The VELscope® Vx is a non-magnifying, wide-field imaging device, allowing to view larger areas in the oral cavity.

Dysplastic and malignant cells will appear as a dark area of abnormality as they interrupt and cause a loss of fluorescence.[5] Preliminary studies showed that the sensitivity and specificity of the VELscope® Vx were both higher than 90%.[6,9] However, the evidence support the effectiveness of the VELscope® Vx in identifying extended boarders of known lesions but not early oral cancer lesions in general populations.[6,9]

In summary, early detection and diagnosis of oral cancer is the key to the best possible prognosis. Devices such as the VELscope® Vx need further investigations, yet,

the VELscope® Vx is considered to be an effective tool in the identification of oral cancer lesions.[6] The VELscope® Vx has shown to have high sensitivity and specificity. Even though the VELscope® Vx is promoted as an effective part of routine oral cancer screening, there is no evidence of its effectiveness in identifying subclinical lesions.[6]

CHAPTER III

METHODS AND MATERIALS

Research Design

An Institutional Review Board approved study was conducted at Old Dominion University's Dental Hygiene Research Center to investigate the effectiveness of two methods of oral cancer screenings. The oral cavity was assessed using visual and tactile intraoral cancer examination and a fluorescence-based oral cancer examination. Two dental hygienists served as examiners. One examiner conducted the visual and tactile manual examination and the second examiner conducted the VELscope® Vx examination. Examiners were calibrated and trained to perform traditional and fluorescence examinations to control the interrater reliability. All participants received both visual and tactile intraoral and the VELscope® Vx examinations to assess oral potentially malignant (OPM) lesions.

Confidentiality was maintained throughout the study through the protection of the records and information. All study documents were kept in a locked cabinet in the Dental Hygiene Research Center. Subjects signed informed consent prior to study initiation (Appendix B). Subjects were coded to maintain confidentiality.

Sample Description, Selection and Enrollment

Recruitment flyers were distributed electronically through the University faculty and staff email announcement. Recruitment flyers were posted at various locations in the local community.

Data collection took place on the campus of Old Dominion University and at three senior citizens nursing homes. The convenience sample of 30 cigarette smokers, 18

years of age or older, were included in the study. Participants were eligible if they were current cigarette or dual addiction smokers. People who used other types of tobacco such as smokeless tobacco only without cigarette smoking or individuals who were photosensitive were excluded from participation.

Procedures and Materials

A visual and manual oral cancer screening examination is the current standard of care for most practicing oral health professionals. In this research study, the oral cancer screening protocol for both examinations was derived from the NIDCR protocol excluding the extraoral examination.[20]

The sequence of examination was:

- Examination #1- Visual and tactile intraoral examination.
- Examination #2- The VELscope® Vx examination.

Each examination was blinded to the other and conducted in one appointment. All findings from the visual and tactile intraoral examination were recorded on the Mucosal Examination Charts (See Appendix D, E and F). All findings from the VELscope® Vx examination were recorded on the VELscope® Examination Charts (See Appendix G, H and I).

Findings from both examinations were discussed with each participant. Each subject also received recommendations regarding tobacco cessation and information on the two examinations performed (See Appendix J and K).

During the examination, if suspicious lesions were detected photographs would be taken using extraoral digital camera (Canon EOS macro lens with ring flash and 140 magnification digital camera) or the VELscope® Vx camera.

The protocol included scheduling a follow up appointment for any patient with detected OPM lesion persisted for more than 14 days from the initial appointment to Eastern Virginia Medical School (See Appendix L). The study planned for financial coverage the expenses of any biopsies needed; however, participants were informed that any subsequent investigations would not be covered by the study.

Data collection

All records were kept confidential in a locked cabinet. Identifications were removed from data collection sheets. All participants completed a health information and medical history (See Appendix C). Demographic data included age, gender, and ethnicity/race. The health history included history of cancer, chemotherapy, HPV infection and current medications. Smoking habits were calculated according to the number of cigarettes/ packs per day and the length of smoking in years. Translators were made available to individuals with language barriers; interpreters trained in medical and dental terminology were used specifically with Arabic speaking participants.

Clinical findings were recorded using six data collection forms; three for visual and tactile intraoral examination and three for the VELscope® Vx examination (See Appendix D, E, F, G, H and I). Examination sequences were standardized according to size, shape, color, and texture of the lesion. The sequence of the visual and tactile intraoral examination included bidigital evaluation of the lips, labial mucosa, right and left buccal mucosa, visual inspection of the gingiva, bidigital 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 performing a palpation.

CHAPTER IV

RESULTS

Demographic and medical health risk behaviors were identified in individuals who smoke tobacco. The VELscope® Vx was compared to visual and tactile intraoral examination in the detection of oral lesions.

The study included 30 participants with a mean age of 42 years; 17 participants were cigarettes smokers, while 13 participants reported dual addiction (See Table 2). Cigarette smokers consisted of 23.5% females and 76.5% males. For the dual addiction smokers, 23% were females and 77% were males.

Racial/ethnic distribution was 50% Asian, 33.3% White (Caucasian), 10% African American, and 3.3% recorded Hispanic and 3.3% Native Americans (See Table 2).

In participants who smoke cigarettes, the average length of time smoking was 14.1 years, whereas the average length of time smoking for dual addiction smokers was 5.0 years (See Table 3).

The number of alcohol drinks consumed per month for tobacco cigarette smokers was an average of 5.0 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 (See Table 3).

Hypotheses

HO_1: There is no statistically significant difference in the oral cancer lesions detected in cigarette smokers by the VELscope® Vx when compared to visual and tactile

intraoral examination, as measured by the number of oral potentially malignant lesions detected.

Results showed no differences between findings in either traditional examination or the VELscope® Vx examination. No lesions were identified in either group; therefore the null hypothesis was accepted.

HO_2: There is no statistically significant difference in the oral cancer lesions detected in cigarette smokers by the VELscope® Vx when compared to visual and tactile intraoral examination, as measured by the stage of lesions detected.

Although the study protocol included taking intraoral photographs and referral to Eastern Virginia Medical School (EVMS) for biopsy, no lesions were detected using either type of examination. There were no intraoral photographs taken and no referrals were made. Neither visual and tactile, nor VELscope® Vx examinations identified any lesions. Therefore, the null hypothesis was accepted.

T-test was performed and data were analyzed at the .05 level. Results demonstrated a statistically significant difference in the average length of time smoking (in years) between the cigarettes smokers (14.1 years) and the dual addiction smokers (5 years).

Results showed that there was no statistically significant difference between cigarette smokers and dual addiction smokers in either average number of alcoholic drinks per month (5 for cigarette smokers and 13.9 for dual addiction) or average number of cigarettes smoked per day (13.2 for cigarette smokers and 14.5 for dual addiction) (See Table 3).

CHAPTER V

DISCUSSION

All participants in this study presented one or more health risk behaviors, or factors for developing potentially malignant oral lesions; however, researchers found no difference in findings in comparing the VELscope® Vx examination and the visual and tactile intraoral examination. This pilot study enrolled a small sample size and results should be interpreted within that context. Mostly males were enrolled in this study, and the research suggest overall males account for the majority of smokers.[18,20] The literature identifies black populations as a high risk racial group who smoke cigarettes,[18,20] this study found Asians to be majority of cigarette and dual addiction smokers.

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.[18,20] In this study, 13 of the 30 participant recorded dual addiction. The literature indicates hookah smoking is becoming a trend within adolescents and young adults,[27] and this study supports that fact.

The VELscope® Vx was initially approved by the FDA in 2001 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."[29] The results 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 oral examination. The VELscope® Vx is an optical device is used intraorally; its limitation includes a lack of a comprehensive palpatory examination of head and neck and an extra oral examination.

Limitations

Limited funding and time impeded the development of a cohort study to investigate any changes or alterations in the oral soft tissues throughout a long period of time in high risk populations. Patient recruitment efforts were limited to a three month time period, contributing to a small sample size. A larger study would allow for a greater representation of high risk population. Recruitment and time needed to conduct the research was limited and future studies will need a more longitudinal research design. The age range of the majority of the sample was between 19-34 years, which indicates a young low risk population. Enrollment was limited to 30 subjects, which can be considered a nonrepresentative population.

Participation in the study was low. Research suggests the general and even high risk populations are not very worried about oral cancer.[30] 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 oral cancer screening.[31]

CHAPTER VI

SUMMARY AND CONCLUSIONS

Recommendations for future studies include, designing a cohort study to observe high risk population over a longer period of time, including a broader spectrum of high risk individuals of older participants, and inclusion of a larger number of high risk ethnic groups. Future studies are recommended to address the importance of incorporating adjunctive technologies that image submucosal tissues in early detection of oral malignant and premalignant lesions to improve morbidity and mortality rates.

Table 1. Oral Cancer Screening Devices

Product Name	Company	Dispensing Method	Unique Features
VELscope® Vx	LED Dental Inc.	• Lighted device focused into oral cavity • Emits safe blue-light • Clinician views oral cavity through the VELscopeß® lens.	• Cordless, portable device with digital camera attachment • Uses blue light to simulate natural fluorescence. • No solutions used; no tissue staining.
Identafi®	DentalEZ group StarDental	• Hand-held mirror emits 3 different type of lights • Safe blue light, white light and amber light into the oral cavity; • Clinician views tissue discoloration using the three modes.	• Cordless, portable device. • Ability to examine tissue vasculature. • No solutions used; no tissue staining.
ViziLite® Plus	ZILA Pharmaceuticals , Inc.	• Uses low energy blue-white light source • Clinician activates the light source by bending the vial container then insert it to a holder.	• Cordless, portable device • Requires with Microlux/DL pre-rinse for 30 seconds. • Can be used in conjunction with TBlue (Tuludine blue-based dye).
Microlux™/DL	AdDent	• Produces blue-white LED light source • Clinician views white lesions.	• Cordless, portable device • Requires with ViziLite® Plus pre-rinse for 60 seconds.

Table 2. Demographics

Smoking Habit	AA	A	H	NA	C	Age 19-34	Age >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

Table 3. Health Determinants

	Mean ± SE	p-value
Length of Time Smoking (Years)		
Cigarette Smoking	14.1 ± 3.11	0.005
Dual Addiction	5 ± 0.89	0.005
Number of Alcoholic Drinks per Month		
Cigarette Smoking	5 ± 1.79	-
Dual Addiction	13.9 ± 7.63	-
Number of Cigarettes Smoked per Day		
Cigarette Smoking	13.2 ± 2.56	-
Dual Addiction	14.5 ± 2.92	-

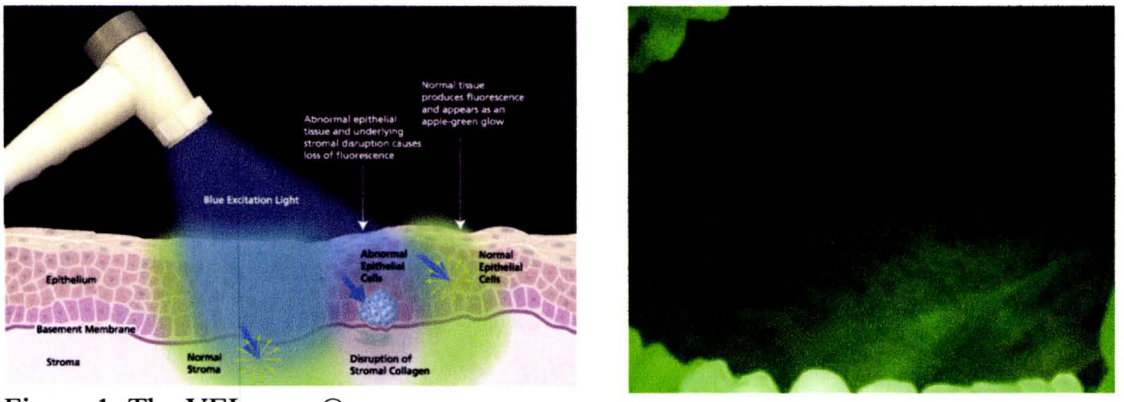

Figure 1. The VELscope®

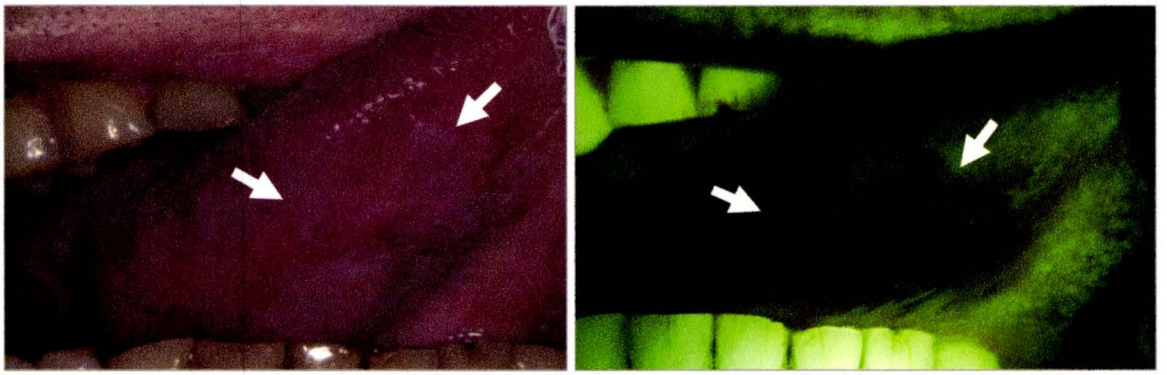

Figure 2. VELscope® Green Fluorescence Indicates Abnormal Tissue

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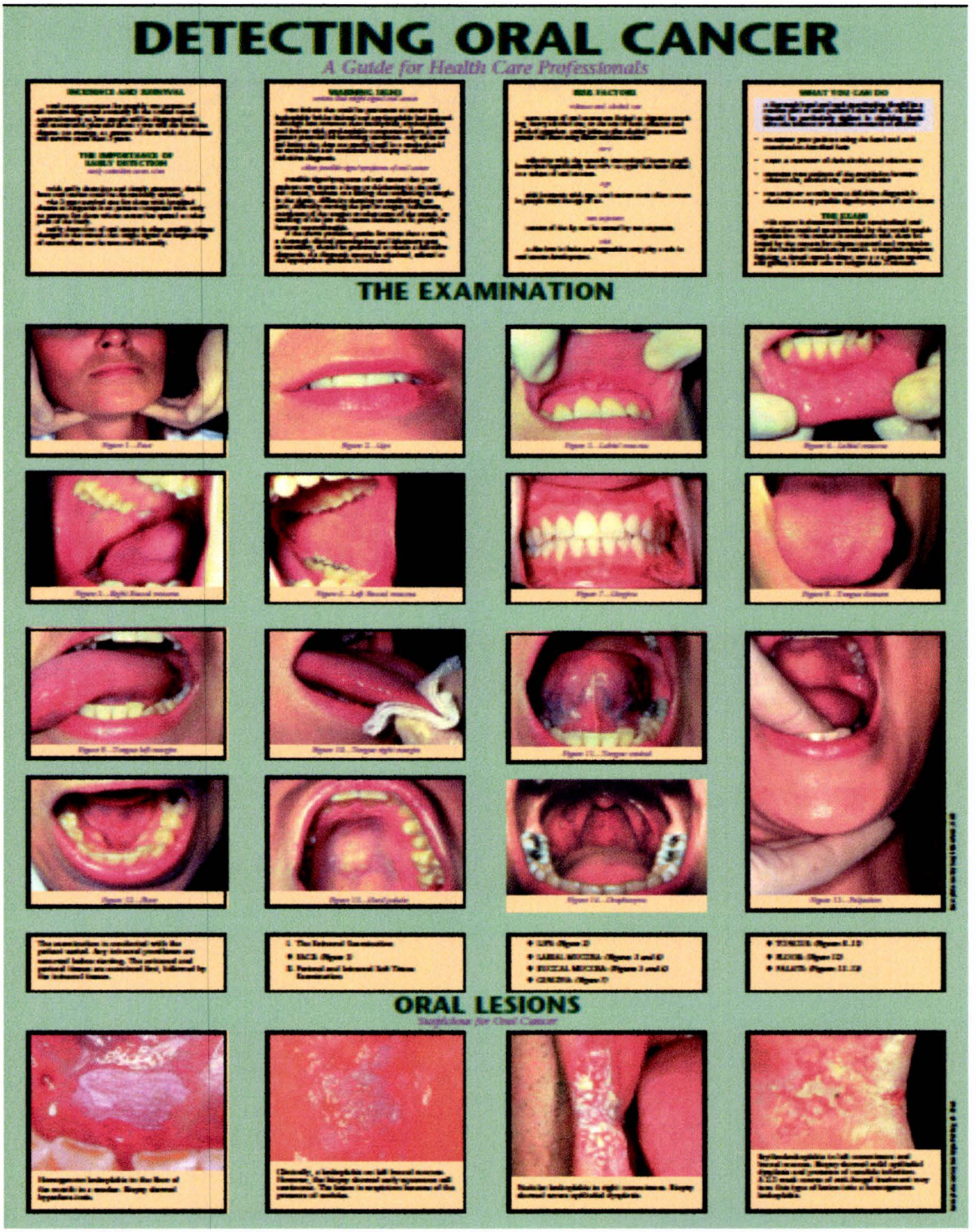
APPENDIX A

THE NIDCR ORAL CANCER SCREENING GUIDE



APPENDIX B

INFORMED CONSENT DOCUMENT

INFORMED CONSENT DOCUMENT
OLD DOMINION UNIVERSITY

PROJECT TITLE: THE EFFECTIVENESS OF VELSCOPE VERSUS THE CLINICAL EXAMINATION IN DETECTING ORAL CANCER IN CIGARETTE AND HOOKAH SMOKERS

INTRODUCTION
The purposes of this form is to give you information that may affect your decision whether to say YES or NO to participation in this research, and to record the consent of those who say YES. This project entitled "**THE EFFECTIVENES OF VELSCOPE VERSUS THE CLINICAL EXAMINATION IN DETECTING ORAL CANCER IN CIGARETTE AND HOOKAH SMOKERS**" will be conducted in the dental hygiene simulation lab, Old Dominion University, Health Sciences building, room 1101.

RESEARCHERS
(Responsible Project Investigator) Margaret Lemaster, BSDH, MS, Assistant Professor, School of Dental Hygiene, College of Health Sciences.
(Co-investigators) Tara Newcomb, BSDH, MS, Assistant Professor, School of Dental Hygiene, College of Health Sciences.
Amanda Kimball, BSDH, Dental Hygiene Graduate Student
Hadeel Ayoub, BSDH, Dental Hygiene Graduate Student

DESCRIPTION OF RESEARCH STUDY
Several studies have been conducted looking into the subject of early detection of oral cancer. This study uses a device that uses a fluorescent light that is reflected back by your tissue. If there is a positive result, there will be a follow-up appointment 2 weeks after the initial appointment. If the tissue is abnormal, you will be referred to a local oral surgeon for evaluation and possible biopsy.
If you decide to participate, then you will join a study involving research of the effectiveness of using a device to detect oral cancer early in addition to a traditional oral cancer screening. If you say YES, then your participation will last for one or two visits with maximum 40 minutes of time involved per appointment at the Dental Hygiene Research Center located in the Health Sciences Building Of Old Dominion University. Approximately 150 of tobacco and hookah smokers will be participating in this study.

EXCLUSIONARY CRITERIA
You should be 18 years old or above, and either a cigarette or hookah smoker.

RISKS AND BENEFITS
RISKS: There might be some physical risks: if you are photosensitive, or taking medications that have photosensitivity as a side effect, you will not be able to participate. The device used may cause a sunburn-like reaction, rash or eye pain. Detection of some lesions that are questionable may cause you to feel emotionally stressed. If you feel you need to speak to a counselor, you may contact Norfolk Community Services Board at (757) 823-1617. If you are an Old Dominion University student, you may contact the ODU Counseling Center at (757) 683-4401.

BENEFITS: The main benefit to you for participating in this study is you will have a free oral cancer screening. If you present with any questionable soft tissue lesions, you will be referred to EVMS for further evaluation and if a biopsy is necessary, researchers will incur the expense. This evaluation is important for the early detection of oral cancer.

COSTS AND PAYMENTS
You will have a chance of winning a Target gift card for $100.00.
The researchers want your decision about participating in this study to be absolutely voluntary. Yet they recognize that your participation may pose some inconvenience, such as time and travel. The researchers are unable to give you any payment for participating in this study.

NEW INFORMATION
If the researchers find new information during this study that would reasonably change your decision about participating, then they will give it to you.

CONFIDENTIALITY

The researchers will take reasonable steps to keep private information confidential. The results of this study may be used in reports, presentations, and publications; but the researcher will not identify you. Of course, your records may be subpoenaed by court order or inspected by government bodies with oversight authority. For any further information, please contact the Office of Research, Old Dominion University at (757) 683-3460.

WITHDRAWAL PRIVILEGE

It is OK for you to say NO. Even if you say YES now, you are free to say NO later, and walk away or withdraw from the study -- at any time. Your decision will not affect your relationship with Old Dominion University, or otherwise cause a loss of benefits to which you might otherwise be entitled. The researchers reserve the right to withdraw your participation in this study, at any time, if they observe potential problems with your continued participation.

COMPENSATION FOR ILLNESS AND INJURY

If you say YES, then your consent in this document does not waive any of your legal rights. However, in the event of harm or injury arising from this study, neither Old Dominion University nor the researchers are able to give you any money, insurance coverage, free medical care, or any other compensation for such injury. In the event that you suffer injury as a result of participation in any research project, you may contact Margaret Lemaster at 757-683-5230 or Dr. George Maihafer the current IRB chair at 757-683-4520 at Old Dominion University, who will be glad to review the matter with you.

VOLUNTARY CONSENT

By signing this form, you are saying several things. You are saying that you have read this form or have had it read to you, that you are satisfied that you understand this form, the research study, and its risks and benefits. The researchers should have answered any questions you may have had about the research. If you have any questions later on, then the researchers should be able to answer them:

Margaret Lemaster at 757-683-5230

If at any time you feel pressured to participate, or if you have any questions about your rights or this form, then you should call Dr. George Maihafer, the current IRB chair, at 757-683-4520, or the Old Dominion University Office of Research, at 757-683-3460.

And importantly, by signing below, you are telling the researcher YES, that you agree to participate in this study. The researcher should give you a copy of this form for your records.

Subject's Printed Name & Signature	Date

INVESTIGATOR'S STATEMENT

I certify that I have explained to this subject the nature and purpose of this research, including benefits, risks, costs, and any experimental procedures. I have described the rights and protections afforded to human subjects and have done nothing to pressure, coerce, or falsely entice this subject into participating. I am aware of my obligations under state and federal laws, and promise compliance. I have answered the subject's questions and have encouraged him/her to ask additional questions at any time during the course of this study. I have witnessed the above signature(s) on this consent form.

Investigator's Printed Name & Signature	Date

APPENDIX C

HEALTH INFORMATION AND HISTORY FORM

Health Information and History **Today's Date:** _____

Name: _____ **Date of Birth:** _____

Phone #1: _____ Phone #2:_____

_____Male _____Female

Race or Ethnicity:__ African American ___ Asian __ Hispanic/Latino ___ Native American ___ Pacific Islander ___Caucasian ___ Other:_____

1. Are you taking any medications?

Yes No ,If yes, please list: _____

2. Are you photosensitive or do any of your medications have a side effect of photosensitivity? Yes No

3. Do you have any other conditions, diseases, or medical problems, or is there ANY other information that you would like us to know about, or that we should be made aware of?

Yes No

If yes, please explain: _____

4. Do you smoke or have you EVER smoked (Check all that apply)?

_ Smoke less than 1 pack of cigarettes/week
_Smoke 1-10 cigarettes per day
_Smoke 10-19 cigarettes per day
_Smoke 1 pack of cigarettes per day
_ Smoke 2 or more packs of cigarettes/day
_ Smoke hookah (shisha) less than once/ month
_ Smoke hookah (shisha) once a month
_ Smoke hookah (shisha) 2 - 3 times a month
_ Smoke hookah (shisha) 2 - 3 times a week
_Smoke hookah (shisha) daily

5. How many years have you smoked?

___Less than 2 years ___2-5 years ___5-10 years ___10-20 years ___Over 20 years

6. Approximate average amount of alcoholic beverages presently consumed per week:

__None __ <1 drink __1-5drinks __6-11drinks __11-20drinks __Over 20 drinks

7. Do you have or have you ever been informed that you have been infected with the Human Papilloma Virus (HPV)? Yes No

8. Do you have a history of cancer? Yes No

If yes, please explain:

_____

9. Are you having or have you ever had radiation or chemotherapy treatments? Yes No

If Yes, for how long? _____ Name of facility performing the treatment: _____

10. Other concerns and considerations: _____

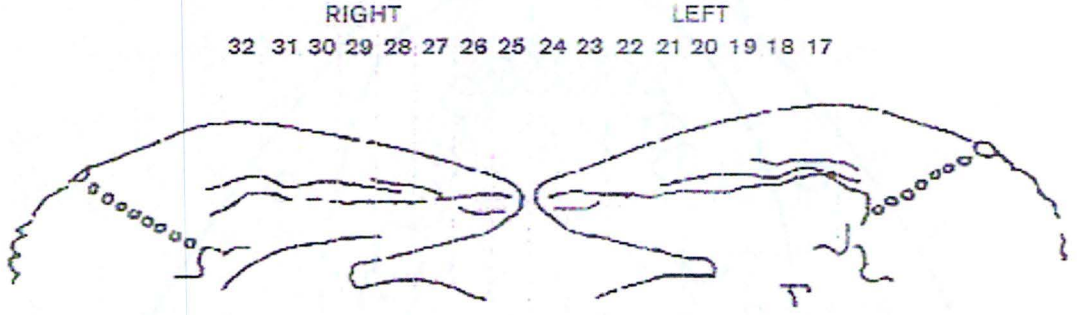
Signature_____ Date _____

APPENDIX D

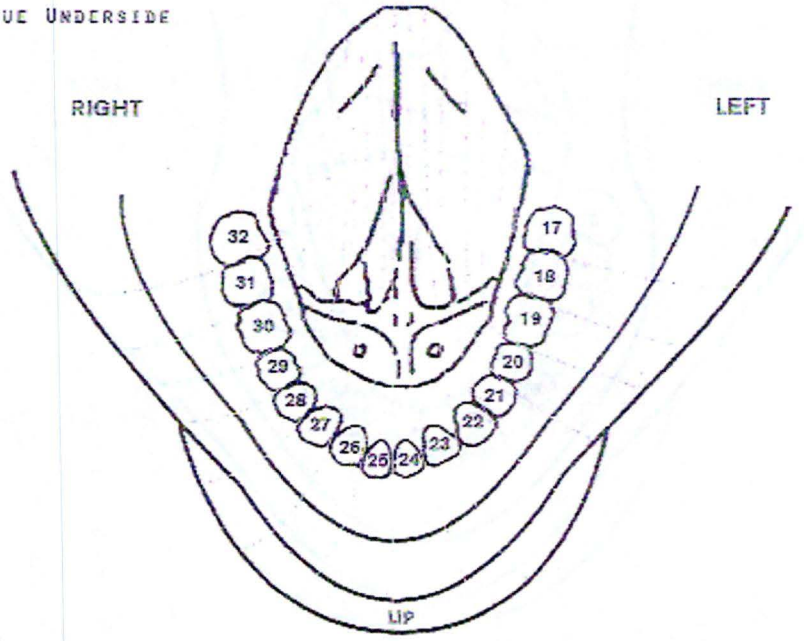
VISUAL AND TACTILE EXAMINATION CHART-I

MUCOSAL EXAMINATION CHART
PATIENT NAME:
CASE NUMBER:
EXAM DATE:
CLINICIAN:

FORM B: TONGUE-LATERAL VIEW



FORM C: TONGUE UNDERSIDE



CLINICAL IMPRESSION: _____

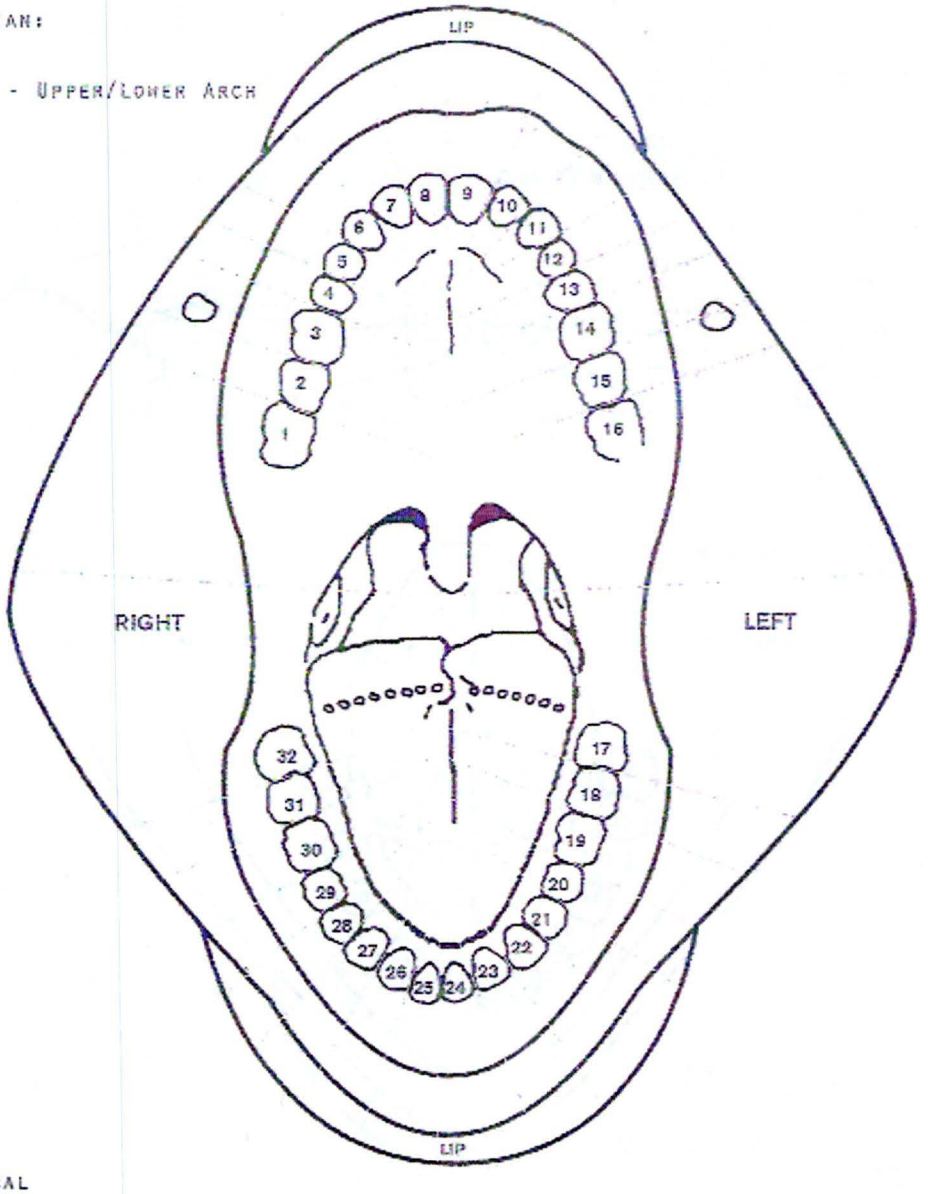
 01-06-07

APPENDIX E

VISUAL AND TACTILE EXAMINATION CHART-I

Buccal Examination Chart
Patient name:
Case Number:
Exam Date:
Clinician:

Form A - Upper/Lower Arch



Clinical
Impression:

 01-08-07

APPENDIX F

VISUAL AND TACTILE EXAMINATION CHART-II

Patients Name: _____ N=Normal O=Other

Date: _____

Intra oral examination

	N	O	N	O
Labial Mucosa	□	□	□	□
Labial Vestibules	□	□	□	□
Anterior Gingivae	□	□	□	□
Buccal Vestibules	□	□	□	□
Buccal Gingivae	□	□	□	□
Tongue-Dorsal	□	□	□	□
Ventral	□	□	□	□
Lateral	□	□	□	□
Lingual Tonsils	□	□	□	□
Floor of Mouth	□	□	□	□
Lingual Gingivae	□	□	□	□
Tonsillar Pillars	□	□	□	□
Pharyngeal Wall	□	□	□	□
Soft Palate	□	□	□	□
Uvula	□	□	□	□
Hard Palate	□	□	□	□
Palatal Gingivae	□	□	□	□
Submandibular Glands	□	□	□	□

Directions:
Visually examine all tissues
Using a sequence from the list, palpate all tissues
Record all findings in the note section (signs/ symptoms of oral cancer)

- ☐ Persistent pain in the mouth
- ☐ A sore, irritation, lump or thick patch in the mouth, lip, or throat
- ☐ Persistent sore throat/ a feeling that something is caught in the throat
- ☐ Difficulty chewing or swallowing
- ☐ Difficulty moving the jaw or tongue
- ☐ Numbness in the tongue or other areas of the mouth
- ☐ Swelling of the jaw that causes dentures to fit poorly or become uncomfortable
- ☐ Loosening of the teeth or pain around the teeth or jaw
- ☐ Hoarseness or change in voice quality
- ☐ Pain in one ear without hearing loss
- ☐ Trismus
- ☐ Presence of a neck mass not resolving after antibiotic therapy

NOTES:

Follow-up Taken:
Lesion after two weeks:

_____

_____

Biopsy : Referred on _____

Results _____ date: _____

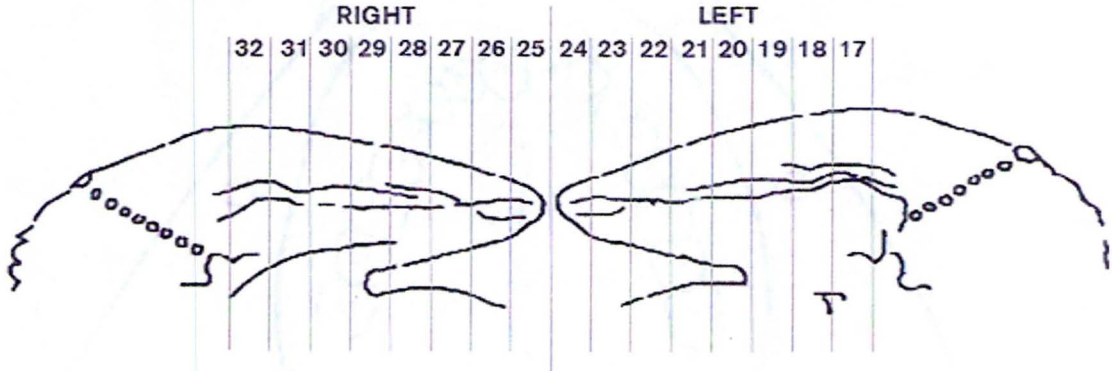
APPENDIX G

VELscope® Vx EXAMINATION CHART-I

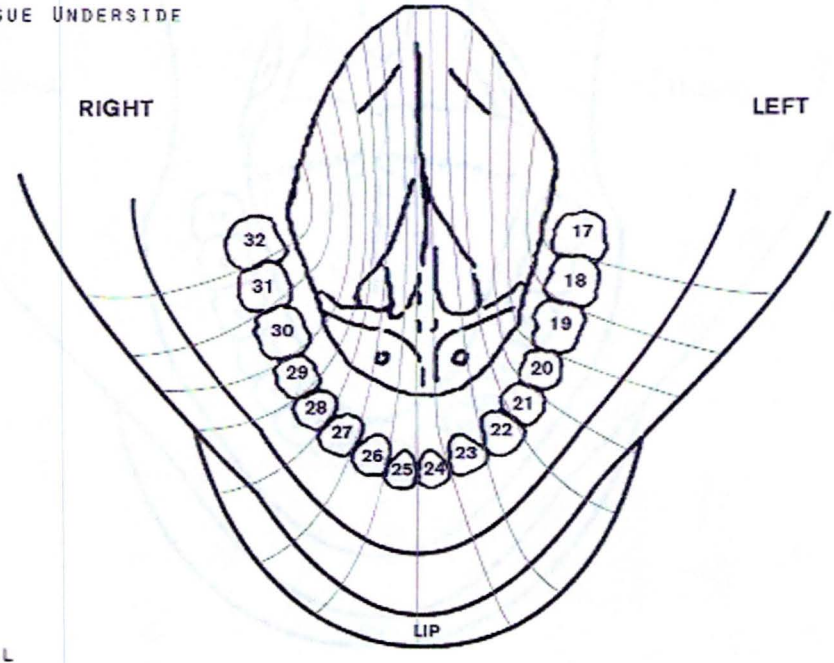
MUCOSAL EXAMINATION CHART
PATIENT NAME:
CASE NUMBER:
EXAM DATE:
CLINICIAN:

VELscope®
THE MUCOSAL EXAMINATION SYSTEM
www.velscope.com

FORM B: TONGUE LATERAL VIEW



FORM C: TONGUE UNDERSIDE



CLINICAL IMPRESSION: _____

 01-08-07

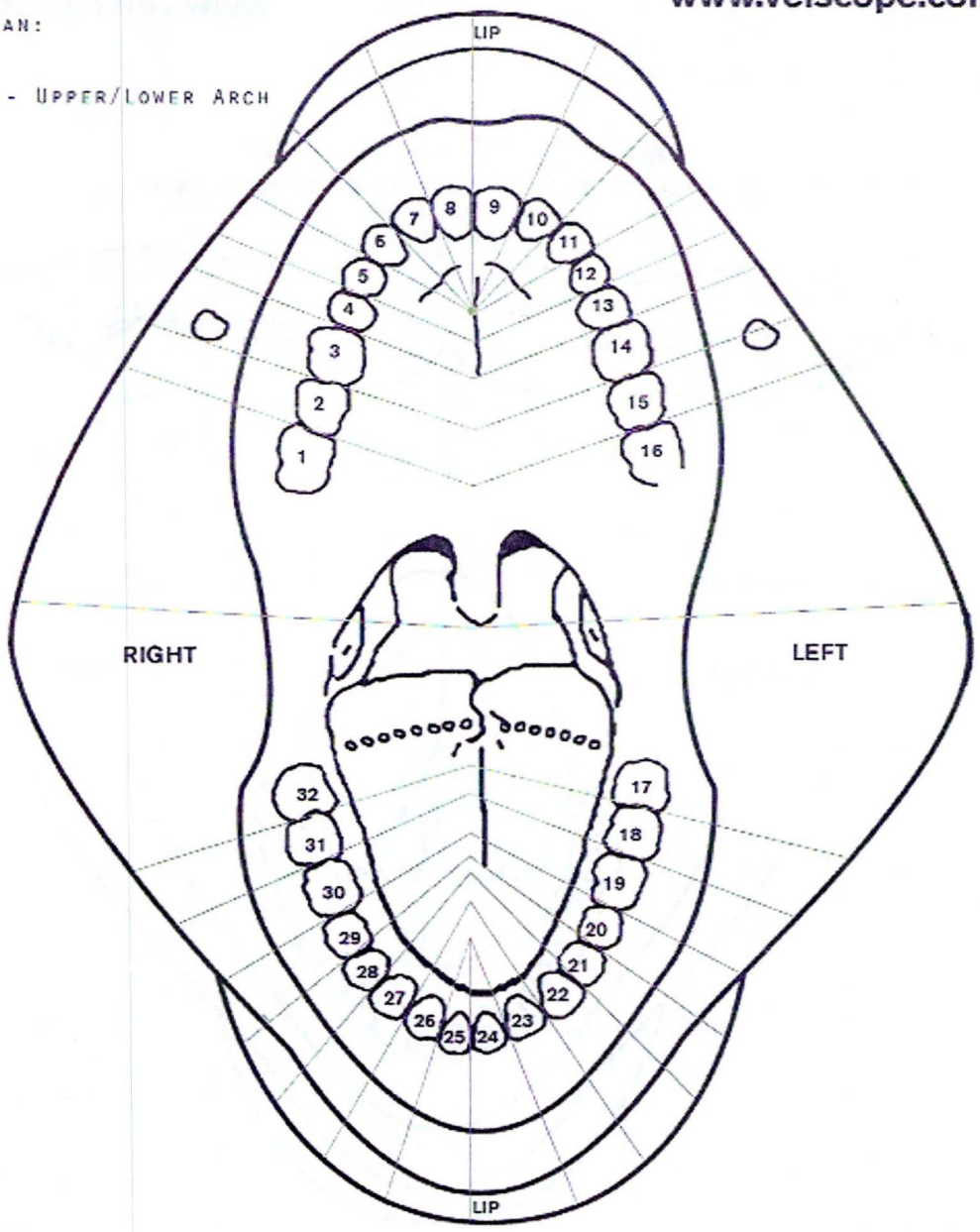
APPENDIX H

VELscope® Vx EXAMINATION CHART-I

MUCOSAL EXAMINATION CHART
PATIENT NAME:
CASE NUMBER:
EXAM DATE:
CLINICIAN:

FORM A - UPPER/LOWER ARCH

VELscope®
THE MUCOSAL EXAMINATION SYSTEM
www.velscope.com



CLINICAL IMPRESSION: _____

 01-08-0

APPENDIX I

VELscope® Vx EXAMINATION CHART-II

Patients Name: _____ N=Normal O=Other

Date: _____

VELscope® examination

	N	O	N	O
Labial Mucosa	□	□	□	□
Labial Vestibules	□	□	□	□
Anterior Gingivae	□	□	□	□
Buccal Vestibules	□	□	□	□
Buccal Gingivae	□	□	□	□
Tongue-Dorsal	□	□	□	□
Ventral	□	□	□	□
Lateral	□	□	□	□
Lingual Tonsils	□	□	□	□
Floor of Mouth	□	□	□	□
Lingual Gingivae	□	□	□	□
Tonsillar Pillars	□	□	□	□
Pharyngeal Wall	□	□	□	□
Soft Palate	□	□	□	□
Uvula	□	□	□	□
Hard Palate	□	□	□	□
Palatal Gingivae	□	□	□	□
Submandibular Glands	□	□	□	□

Directions:
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- ☐ Persistent sore throat/ a feeling that something is caught in the throat
- ☐ Difficulty chewing or swallowing
- ☐ Difficulty moving the jaw or tongue
- ☐ Numbness in the tongue or other areas of the mouth
- ☐ Swelling of the jaw that causes dentures to fit poorly or become uncomfortable
- ☐ Loosening of the teeth or pain around the teeth or jaw
- ☐ Hoarseness or change in voice quality
- ☐ Pain in one ear without hearing loss
- ☐ Trismus
- ☐ Presence of a neck mass not resolving after antibiotic therapy

NOTES:

Follow-up Taken:
Lesion after two weeks:

_____

_____

Biopsy : Referred on _____

Results _____ date: _____

APPENDIX J

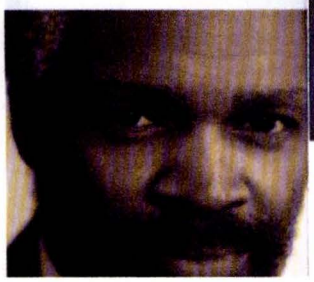
ORAL CANCER BROCHURE

ch year in the US alone, approximately
,000 individuals are newly diagnosed with
al cancer. If you add throat cancers to the
mber (which have the same risk factors),
at number will increase to about 48,000
ople. The death rate from oral cancer is
y high; about 43% of those diagnosed will
t survive more than five years. While these
tistics are alarming, this high death rate is
ectly related to two factors. These may be
ectly influenced by your choices.

e first is to be aware. Knowing that
estyle choices you make, such as tobacco
e and other risk factors listed in this
ochure, are causes of this disease, is part
that process. Avoidance of risk factors
eatly reduces your chance of developing
al and throat cancers. Knowing the signs
d symptoms of the disease is also part
awareness. It is one that will help you
cide to seek professional advice should
u recognize symptoms in yourself. Just by
ading this brochure you are engaging in an
ucational process that will keep you, and
ose you share the information with, aware
d educated about the disease.

Early detection is the second factor that will reduce your risk. Once knowledgeable, you will wish to engage in a regular annual screening to look for signs and symptoms at your doctor's office, ensuring early detection. Most oral cancer can be caught early, even as a pre-cancer. With early detection, survival rates are high, and side effects from treatment are at their lowest. These screenings are painless, quick, and inexpensive. Like other screenings you engage in such as cervical, skin, prostate, colon, and breast examinations, oral cancer screenings are an effective means of finding cancer at its early, highly curable stages. Make them part a of your annual health check-ups.

- **Be aware**
- **Avoid risk factors**
- **Get an annual screening**

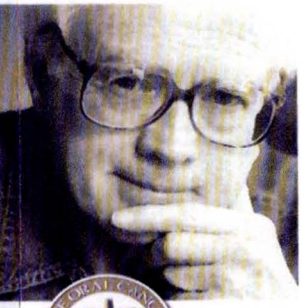


Oral Cancer
What you need to know.

THE ORAL CANCER FOUNDATION, INC.
3419 Via Lido #205
Newport Beach, CA 92663

Website: http://www.oralcancer.org

The foundation is an IRS registered 501(c)3 non-profit charity.



The printing and distribution of this brochure was made possible by a generous grant from LED Dental, manufacturer of the VELscope Early Detection Device

lisk Factors
actors you can control

. Tobacco use. In all its forms, tobacco is a
ajor contributor to the development of oral
r mouth cancers. Not using tobacco is the
ngle most important thing you can do to
void oral cancers.

. Excessive alcohol consumption. More
an 15 alcoholic beverages per week may
ut you at greater risk. If you drink, do so in
oderation.

**. The combined use of tobacco and
lcohol.** This significantly increases the risk of
al cancer more than either by itself.

**. Excessive unprotected exposure to
un.** Unprotected exposure to sun will
crease the likelihood of lip cancers. Use at
ast SPF 30 sunblock on your lips.

. Low intake of fruits and vegetables.
diet that does not contain the protective
utrients of these foods increases the risk of
eveloping a variety of illnesses including oral
ncer.

. Use of betel nut and bedis. When
ewed or smoked, these are causative agents
mouth cancers. Avoid their use.

**isk factors not in your control, or in
hich control is limited**

. Age. Older individuals tend to develop
ore disease in general, including oral cancer,
their immune system becomes less efficient.

. HPV16 viral infection. Increasing numbers
f young, non-smoking individuals are being
iagnosed with oral cancer. The causative
ctor is persistent HPV16 viral infection, the
me virus responsible for more than 95%
f all cervical cancer. While testing for the
rus at the time of cervical examinations
d PAP smears is becoming more common,
individuals carrying this virus are not likely to know that they have it, as there are no outward symptoms. Currently there are no preventative or avoidance measures that will prevent sexual transmission of this virus. However, limiting the number of sexual partners decreases your risk of contracting the virus.

3. Race, ethnicity, and economics. There are socio-economic factors that influence the development of cancers in different groups of people. For instance, while not related to biology, blacks are diagnosed with oral cancer 2 to 1 over other races. In addition, people who live in areas with poor access to healthcare, or for economic reasons do not routinely visit a dentist or doctor, are also at increased risk.

4. Recurrence. Previous head and neck cancer patients have a higher risk of a cancer recurrence which may occur in the mouth or other areas of the aero-digestive tract.

5. Gender. Statistically males get oral cancer more often than females. Again, this is not related to biology but lifestyle issues.

Signs and Symptoms

In the early stages of oral cancer's development, it often is painless, and the physical signs may not be obvious. This makes it a very dangerous disease. Regular screenings by a qualified medical or dental professional, combined with a person's knowledge of the warning signs and symptoms, will allow its discovery in the earliest possible stages, when cure and survival are most likely. Even pre-cancerous tissue changes can often be detected by a trained professional.

Early indicators

1. Red and/or white discolorations of the soft tissues of the mouth.
2. Any sore which does not heal within 14 days.
3. Hoarseness which lasts for a prolonged period of time.

Advanced indicators

1. A sensation that something is stuck in your throat.
2. Numbness in the oral region.
3. Difficulty in moving the jaw or tongue.
4. Difficulty in swallowing.
5. Ear pain which occurs on one side only.
6. A sore under a denture, which even after adjustment of the denture, still does not heal.
7. A lump or thickening which develops in the mouth or on the neck.

The good news: It can often be found early in its development.

Today while you are at the doctor's office, in just 3 to 5 minutes, you can receive a comprehensive oral cancer examination. This exam should include a visual and tactile exploration of the interior of your mouth, as well as the underside of your chin and neck. Some doctors may use a special light or a special dye to aid in the discovery of tissues which are suspicious. If an area of concern is located, the doctor may use a small brush to collect cells from that area for examination under a microscope. If the doctor suspects that something is abnormal, it is standard procedure to refer you to a specialist for another opinion, and perhaps even a small, painless biopsy of the tissue in question. Referral for a second opinion should not alarm you, but assure you that the doctor wants to conclusively determine what any abnormality may be. Most abnormalities turn out to be benign conditions. This quick and inexpensive cancer examination will allow any serious condition to be caught at the earliest possible time, when treatments are the most effective. An oral cancer screening such as this should be conducted every year, and is easily incorporated into your routine visits for health check-ups, or cleanings and regular exams at the dental office. For thos who engage in known risk factors such as the use of tobacco, it should be done more frequently. In the future, new discovery and diagnostic tools currently being tested and developed may be used. However, the visual and tactile screening techniques available today are more than adequate to find oral cancers in their most highly curable stages. The entire healthcare team at the office, including the nurse or the dental hygienist, may be involved in portions of this examination. All are concerned with seeing that any area of suspicion is caught.

APPENDIX K

VELscope® Vx Brochure

VELscope Vx: The Two-Minute Exam That Could Save Your Life

How many little sores do we find in our mouths? Dozens? Hundreds? More? Most of the time we ignore them, and they simply go away.

But sometimes our mouths keep secrets. That's why we use the VELscope Vx Enhanced Oral Assessment system.

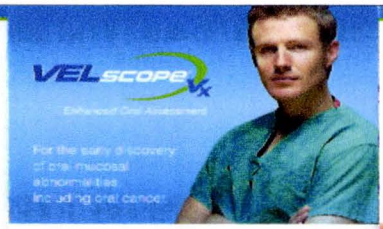
Ask us about a VELscope Vx exam.

The VELscope Vx Helps Us:

- Improve our assessment of your overall oral health.
- Ensure that the delicate tissues of your mouth are healthy.
- Protect you from oral disease, including oral cancer.

All this in two minutes, with no rinses, stains or discomfort.

For more information, please visit: www.velscope.com



As seen on *"The Doctors"* and *"Dr. Oz"*

Our dental office is proud to provide the most advanced standards of care available. Please ask us about a VELscope Vx exam.

VELscope Vx

www.velscope.com

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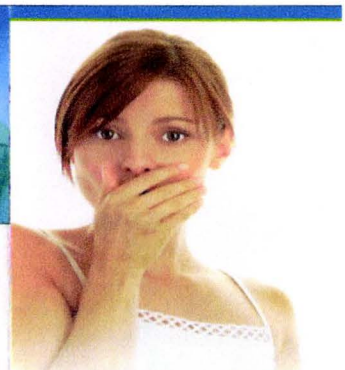
LED Dental Inc.
235-5589 Byrne Rd, Burnaby, BC Canada V5J 3J1
North America Toll Free: +1 888-541-4614
Phone: +1 604-434-4614
FAX: +1 604-434-4612

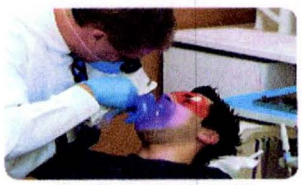


Your Mouth Can Hide a Secret...

That's Why We Use the VELscope Vx.

VELscope Vx – for a Clean Bill of Health

- Helps dental professionals find oral mucosal abnormalities, including oral cancer
- Over 10,000,000 examinations performed
- Recognized by the World Health Organization
- The most powerful tool available for assisting in the discovery of oral abnormalities



The VELscope Vx exam: quick, painless, effective

"Adding the VELscope to our diagnostic protocol has been extremely useful and resulted in detection of dangerous lesions that would have otherwise been undetected."

– **Edmond L. Truelove** DMD, MSD. Chair & Professor, Oral Medicine, School of Dentistry, University of Washington

LED-3250 Rev.A

Oral Cancer and Oral Disease

The VELscope Vx helps us identify oral disease early, while it's still easy to treat.

One of the VELscope's most important tasks is to help locate areas that might, if not treated, progress to oral cancer.

- Found early, oral cancer's 5-year survival rate is good: approx. 83%.
- Found late, oral cancer's 5-year survival rate is poor: approx. 32%.
- Clearly, finding oral cancer in its early stages is key to survival.

The VELscope Vx offers hope for the early discovery of oral disease, including precancer and cancer.

Risk Factors

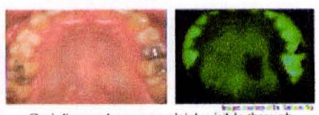
Tobacco and chewing tobacco, along with alcohol, are the leading causes of oral cancer. Over the last four decades, the Human Papilloma Virus (HPV), known for its role in cervical cancer, has been showing up in increasing numbers of oral cancer cases.

"Dentists saving lives? Now more than ever a reality with the development of VELscope. Every dental office needs this instrument."

– **Ken Neuman** DMD, FAGD, FADI, FICD, FACD

Why Use the VELscope Vx?

- The VELscope's blue light stimulates natural fluorescence in the soft tissues of your mouth.
- Natural fluorescence, seen through the VELscope Vx, allows dental professionals to see disease not visible with the naked eye.
- The VELscope Vx helps us discover oral disease BEFORE it can be seen under ordinary light.



Oral disease becomes plainly visible through the VELscope Vx.

"I find the VELscope to be an invaluable tool for the detection of oral cancer. The response from my patients has been overwhelmingly positive. In my opinion, this technology will be part of the standard of care in a short period of time."

– **Tony Hewlett, DDS** Standwood, WA

APPENDIX L

BIOPSY REFERRAL FORM

DEPARTMENT OF OTOLARYNGOLOGY - HEAD & NECK SURGERY
EVMS HEARING & BALANCE CENTER
WWW.EVMSENT.ORG
500 Gresham Drive, Suite 1100 □ Norfolk, VA 23507-1904 | Phone: 757.388.6200 □ Fax: 757.388.6201

Teaching. Discovering. Caring.

EVMS
Eastern Virginia Medical School

AUTHORIZATION FOR RELEASE OF MEDICAL RECORDS

I, _____ hereby authorize and request the following to be sent to and/or released from EVMS Department of Otolaryngology-Head and Neck Surgery:

☐ **Complete medical record.** I understand that all information contained in my record including but not limited to: information relating to psychiatric treatment, drug/alcohol abuse, and HIV/AIDS testing and/or treatment shall be released.

☐ **Specific medical information** that is **limited** to the following date(s) or date range: _____.

If requesting specific medical records, please check all that apply.

☐ Discharge Summary
☐ History & Physical
☐ Operative Notes
☐ Office Notes
☐ Inpatient/Outpatient Notes
☐ Laboratory Results
☐ Pathology Results
☐ Radiology Results
☐ Audio/Balance Testing
☐ Other_____

I authorize my records to be released to the following:

Name: _____

Address: _____

City, State, and Zip: _____

Phone #: _____ Fax#: _____

I request the information be: _____Mailed _____Faxed _____Picked up

This authorization shall remain valid for 90 days unless otherwise specified. I understand that I may cancel this authorization at any time but disclosures made prior to this cancellation would not be affected. I understand that my cancellation is not in effect until delivered in writing to the custodian of my medical record. I understand that if my medical information is disclosed to someone who is not required to comply with federal privacy regulations that such information may be re-disclosed and would no longer be protected. I understand that I do not have to sign this authorization and that my refusal to sign will not affect my ability to obtain treatment at Eastern Virginia Medical School unless that treatment is tied to a research related treatment.

_____ _____
Patient's Full Name **Date of Birth**

_____ _____
Patient/Guardian Signature **Date**

SSN (If other than patient): _____

_____**Photo ID Confirmed by EVMS Representative (if other than patient)**

□ C.H.K.D.
601 Children's Lane
Norfolk, VA 23507
Phone: 757.668.9327
Fax: 757.668.9848

□ Virginia Beach Office
933 First Colonial Road, Suite 102
Virginia Beach, VA 23454
Phone: 757.422.9300
Fax: 757.625.6118

APPENDIX M

RAW DATA

	Cigarette Smoking n=17	**Dual Addiction** n=13
Gender		
Male	13	10
Female	4	3
Race		
African American	2	1
Asian	8	7
Hispanic	0	1
Native American	0	1
Pacific Islander	0	0
Caucasian	7	3
Age		
19-34	11	13
Above 35	6	0

	Cigarette Smoking n=17	**Dual Addiction** n=13
Medications	6	5
History of Cancer	4	2
History of Chemotherapy	0	1
Other Medical	2	2
Less than 1 pack of cigarettes a week	3	4
1 pack of cigarettes per day	5	3
2 or more packs of cigarettes per day	2	1
Smoke hookah less than once a month	1	2
Smoke hookah once a month	-	2
Smoke hookah 2-3 times a month	-	5
Smoke hookah 2-3 times a week	-	3
Smoke hookah daily	-	3

VITA

HADEEL MOHAMMED AYOUB, B.S.D.H.
Old Dominion University Department of Dental Hygiene
4608 Hampton Blvd. Norfolk, VA 23529

EDUCATION:

Bachelor of Science in Dental Hygiene 2006
King Saud University, Riyadh, Saudi Arabia

Master of Science in Dental Hygiene
Specialization: Education and Research Expected 2013
Old Dominion University, Norfolk, Virginia

EXPERIENCE

Teaching

Sep 2012-Present	Adjunct Instructor – Gene. W. Hirschfeld School of Dental Hygiene, Old Dominion University, Norfolk, VA
May 2011-Dec 2011	Graduate Teaching Assistant – Department of Dental Hygiene Old Dominion University, Norfolk, Virginia
Jul. 2007- Jul 2010	Teaching Assistant- Dental Health Department, King Saud University, Riyadh, Saudi Arabia

Research

March 2005-Dec 2005	*Oral Health Care and Dental Status of Children with Special Needs in Private School in Riyadh, Saudi Arabia*

Clinical Practice

August 2007- March 2009	Volunteer Dental Hygienist (College of Dentistry, King Abdulaziz University Hospital) part-time

HONORS, AWARDS, & SCHOLARSHIPS:

2013	DENTSPLY/ADHA Graduate Student Clinicians Dental Hygiene Research Program
2010	Outstanding Teaching Assistant, Dental Health Department, College of Applied Medical Sciences, Riyadh, Saudi Arabia
2006	Best intern performance, King Khalid University Hospital, Riyadh, Saudi Arabia