



**The World's Leading Adjunctive  
Oral Exam Technology**

# Wayne Rees

Vice President VELscope Imaging  
LED Dental Inc.



# The Problem

The Mortality Rate for Oral Cancer  
has not decreased in over 30 years.\*

U.S. Department of Health and Human Services. Oral Health in America: A Report of the Surgeon General. Rockville,  
MD: U.S. Department of Health and Human Services, NIDCR, NIH, 2000

# Who Get's Oral Cancer?

Traditional risk factors were males over age 40, heavy smokers, heavy drinkers, and those with a previous history of cancer.

In the last 10 years we've seen a 60% increase in Oral Cancer in adults under the age of 40.

25% of these cases have no traditional risk factors

*Oral Cancer in America: A Report from the Surgeon General 2000*

# Oral Cancer

In 2019, it is estimated that there will be 53,000 new cases of oral cancer in the United States – approximately 4 times that of cervical cancer (13,170).

Age-adjusted (AA) Rate per 100,000 Oral cancer incidence had been decreasing for about 20 years due to increased awareness of the dangers of tobacco. However, since the year 2000, oral cancer incidence has been on the rise again due to the increasing number of oral cancer cases related to the HPV-16 virus.

25% of these cases have no traditional risk factors

# May 10, 2007



## The NEW ENGLAND JOURNAL of MEDICINE

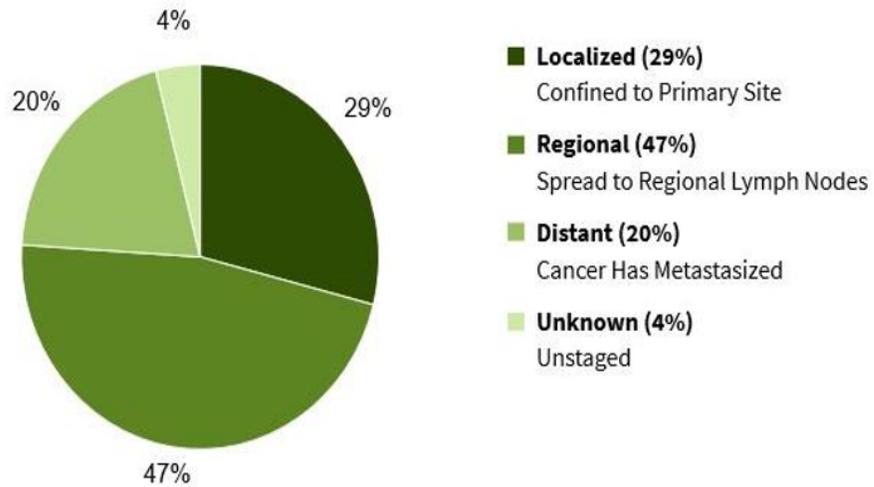
*Case–Control Study of Human Papillomavirus and Oropharyngeal Cancer*  
Gypsyamber D'Souza, Ph.D., Aimee R. Kreimer, Ph.D., Raphael Viscidi, M.D., Michael Pawlita,  
M.D., Carole Fakhry, M.D., M.P.H., Wayne M. Koch, M.D., William H. Westra, M.D., and Maura L.  
Gillison, M.D., Ph.D.

### CONCLUSION:

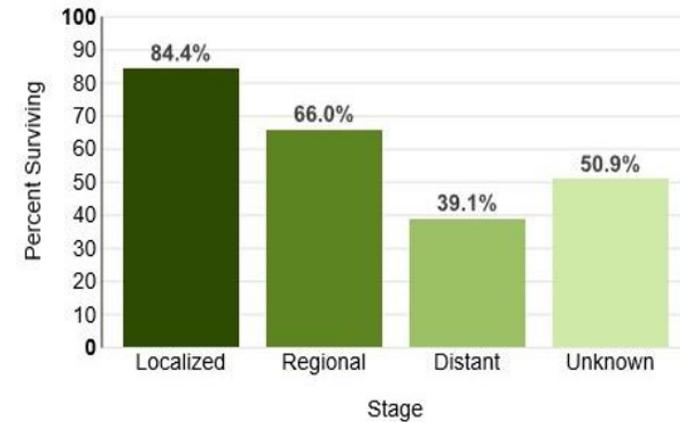
“Oral HPV infection is strongly associated with oropharyngeal cancer among subjects with or without the established risk factors of tobacco and alcohol use.”

# Oral Cancer – Early Detection is Critical

Percent of Cases by Stage



5-Year Relative Survival



# ADA Changes Screening Policy

The ADA has amended their policy on early detection and prevention of oral cancer to include oropharyngeal cancer and cover all patients, not just those previously thought to be at an increased risk because of tobacco and alcohol use. What are the implications to dentistry and how should our oral cancer screening be adjusted to compensate for this new profile?



# “I’ll Never See It In My Practice . . .”

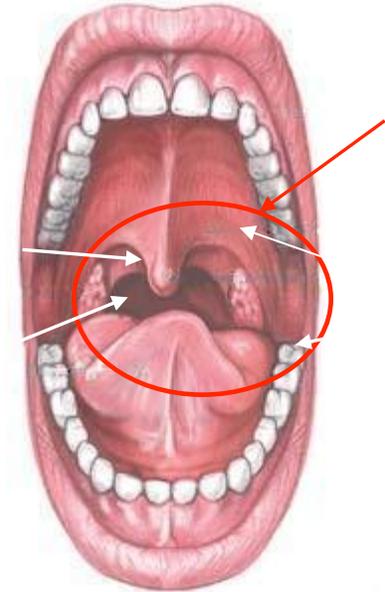
- US pop over the age of 14: 240,000,000
- New cases (2013): 41,380
- 1 in 5,800 individuals
- Average practice sees 2,000 patients per year
- Therefore, a case roughly every 3 years
- How common is dysplasia?
  - A reasonable estimate is 20-40 times more common
  - 1 in 210 patients – 5-10 cases of dysplasia/year

Refer to Huff and Benjamin Data and the American Cancer Society

# Oral Cancer – Basic Facts

## HPV-16 and 18

The FDA estimates that 70% of cervical cancers are associated with HPV-16 or 18. In the oral environment these HPV's manifest themselves primarily in the oropharynx regions - such as the back of the throat, base of the tongue, tonsils, tonsillar pillars and soft palate.



# ORAL CANCER: Clinical Awareness

## National Cancer Institute Statistical Facts - United States Only

NCHS - National Center for Health Statistics 2008 Vs 2005 SEER Report (*Surveillance Epidemiology and End Results*)

sorted by: **Incidence Forecast 2008**

### 32 Cancer Categories Measured

	Caner Type	Incidence 2008	Deaths 2008	5-yr Survival	Die within 5-ysrs	Death Rate
1	Lung	215,020	161,840	15.2%	182,337	84.80%
2	Prostate	186,320	28,660	98.9%	2,050	1.10%
3	Breast	182,460	40,480	88.7%	20,618	11.30%
4	Colon	148,810	49,960	64.4%	52,976	35.60%
5	Urinary Bladder	68,810	14,100	79.8%	13,900	20.20%
6	Non-Hodgkin's Lymphoma	66,120	19,160	84.8%	10,050	15.20%
7	Melanoma of the Skin	62,480	8,420	91.2%	5,498	8.80%
8	Kidney	54,390	13,010	66.5%	18,221	33.50%
9	Corpus and Uterus	40,100	7,470	82.9%	6,857	17.10%
10	Pancreas	37,680	43,290	51.0%	35,758	94.90%
11	Thyroid	37,340	1,590	96.9%	1,158	3.10%
12	Oral and Pharynx*	35,310	7,590	59.7%	14,230	40.30%
13	Brain	21,810	13,070	34.1%	14,373	65.90%
14	Ovarian	21,650	15,520	45.5%	11,799	54.50%
15	Stomach	21,500	10,880	24.7%	16,190	75.30%
16	Liver	21,370	18,410	11.7%	18,870	88.30%
17	Esophagus*	16,470	14,280	15.8%	13,868	84.20%
18	Chronic Lymphocytic Leukemia	15,110	4,390	79.9%	3,037	20.10%
19	Acute Myeloid Leukemia	13,290	8,820	21.9%	10,379	78.10%
20	Larynx*	12,250	3,670	62.5%	4,594	37.50%
21	Cervical	11,070	3,870	71.2%	3,188	28.80%
22	Heart	10,390	3,680	66.7%	3,460	33.30%
23	Hodgkin's Lymphoma	8,220	1,350	64.5%	2,918	35.50%
24	Testis	8,090	380	95.5%	364	4.50%
25	Small Intestine	6,110	1,110	57.8%	2,578	42.20%
26	Acute Lymphocytic Leukemia	5,430	1,460	64.6%	1,922	35.40%
27	Non-Epithelial Skin	5,240	2,780	87.7%	645	12.30%
28	Anal	5,070	680	66.5%	1,698	33.50%
29	Chronic Myeloid Leukemia	4,830	450	50.2%	2,405	49.80%
30	Vulva	3,460	870	79.6%	706	20.40%
31	Eye and Orbital	2,390	240	83.8%	387	16.20%
32	Bone and Joint	2,380	1,470	68.1%	759	31.90%
	Ranking	12th	16th	22nd	9th	11th

# ORAL CANCER: Clinical Awareness

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Sorted by: **Deaths within 5-yr**

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# ORAL CANCER: The Scope and the Problem

In North America, someone dies of Oral Cancer every hour of every day.

The 5-year survival rate is only 52%, but when diagnosed early, can be as high as 80% to 90%.

**Late diagnosis leads to high death rate.**

*U.S. Department of Health and Human Services. Oral Health in America: A Report of the Surgeon General. Rockville, MD: U.S. Department of Health and Human Services, NIDCR, NIH, 2000*

# Debilitating Effects on Quality of Life

Oral Cancer is One of the Most Disfiguring Diseases **Affecting the Ability to Speak, Eat, Breathe & Socialize.**

Often the Physical Deformity of Treatment Prevents People from Returning to Work

**Patients Treated for Head and Neck Cancer Have the Highest Rate of Work Disability & Unemployment\***

Early Detection Enables Conservative Treatment Producing Fewer Complications & Permanent Disfigurements.

Source--[http://www.deltadentalmi.com/media/newsReleases/2006/04\\_14\\_06\\_OralCancerAwarenes/](http://www.deltadentalmi.com/media/newsReleases/2006/04_14_06_OralCancerAwarenes/)  
Accessed 4/15/2007

# Visual and Tactile Examination (COE)

- Traditional method, practiced by Dentists, Periodontists, OMS's, PCP's and ENT's.
  - ✓ Visual inspection of oral cavity, with attention to tongue, soft and hard palate, gums, inner cheeks, lips, and throat using white incandescent light.
  - ✓ Palpation of lymph nodes, inner structures, neck, and throat.
  - ✓ Duration, two to three minutes.
- All practitioners, dental and medical, reported using this screening method on their patients
- Detection of discrete tumors, mucosal abnormalities, white lesions (Leukoplakia), red lesions (erythroplakia), changes in pigmentation.
- There is inadequate detection of dysplasia or stage I or II malignancy.
- **This technique is conventional but not always accurate**



## *The limitations of the clinical oral examination in detecting dysplastic oral lesions and oral squamous cell carcinoma*

Joel B. Epstein, DMD, MSD, FRCD(C), FDS RCS(Edin)<sup>1</sup>  
, Pelin Güneri, DDS, PhD<sup>2</sup>  
, Hayal Boyacioglu, PhD<sup>3</sup>  
, Elliot Abt, DDS, MS, MSc

**The Problem:** Late Stage Discovery Oral Cancer and Dysplastic Progression: “On the basis of the available literature, the authors determined that a COE of mucosal lesions generally is not predictive of histologic diagnosis. The fact that OSCCs often are diagnosed at an advanced stage of disease indicates the need for improving the COE and for developing adjuncts to help detect and diagnose oral mucosal lesions”.



# True or False?

**The majority of patients referred to an Oral Surgeon or ENT Otolaryngologist for suspected oral cancer diagnosis are referred by a dental healthcare provider.**

# True or False?

**FALSE**

In 2007, Primary Care Physicians referred 310,000 patients with abnormal oral tissue lesions to Oral Surgeons or Otolaryngologists.

Dentists referred 220,000

Only 14% of patients in the United States  
over age 40 claim to have  
**ever been screened for Oral Cancer.**

*Horowitz AM, Drury TF, Goodman HS, Yellowitz JA Oral Pharyngeal Cancer Prevention and Early Detection Dentists'  
Opinions and Practices J Am Dent Assoc (JADA) April 2000;131(4):453-62*

# Whose Job Is It?

The Discovery and Diagnosis of Oral Cancer is Primarily the Responsibility of Dentists and the Dental Profession!!!

You **ARE** the Healthcare Specialist of the Mouth!





# MEDICAL

## Legal community is tuning in...

Meet Brian Hill

Founder - Implant Support Systems, Inc.

Sold to Life Core Biomedical in 1993

4 time Oral Cancer survivor

Founder - Oral Cancer Foundation

Brian was deposed 16 times in 2007.

All 16 cases were settled in the plaintiffs favor.

The average settlement for failure to detect Oral Cancer in the US in 2007 is \$874,500.



Brian Hill  
Founder/Executive Director  
Oral Cancer Foundation  
Image taken from OCF website

# For Those Who Do Survive Late-Stage Discovery . . .



Rick Bender,  
Former Baseball Player



Rod Stewart,  
Throat & Thyroid Cancer



Roger Ebert,  
Papillary Thyroid Cancer



Colleen Zenk Pinter,  
Stage 2 Oral Cancer

## Life will never be the same:

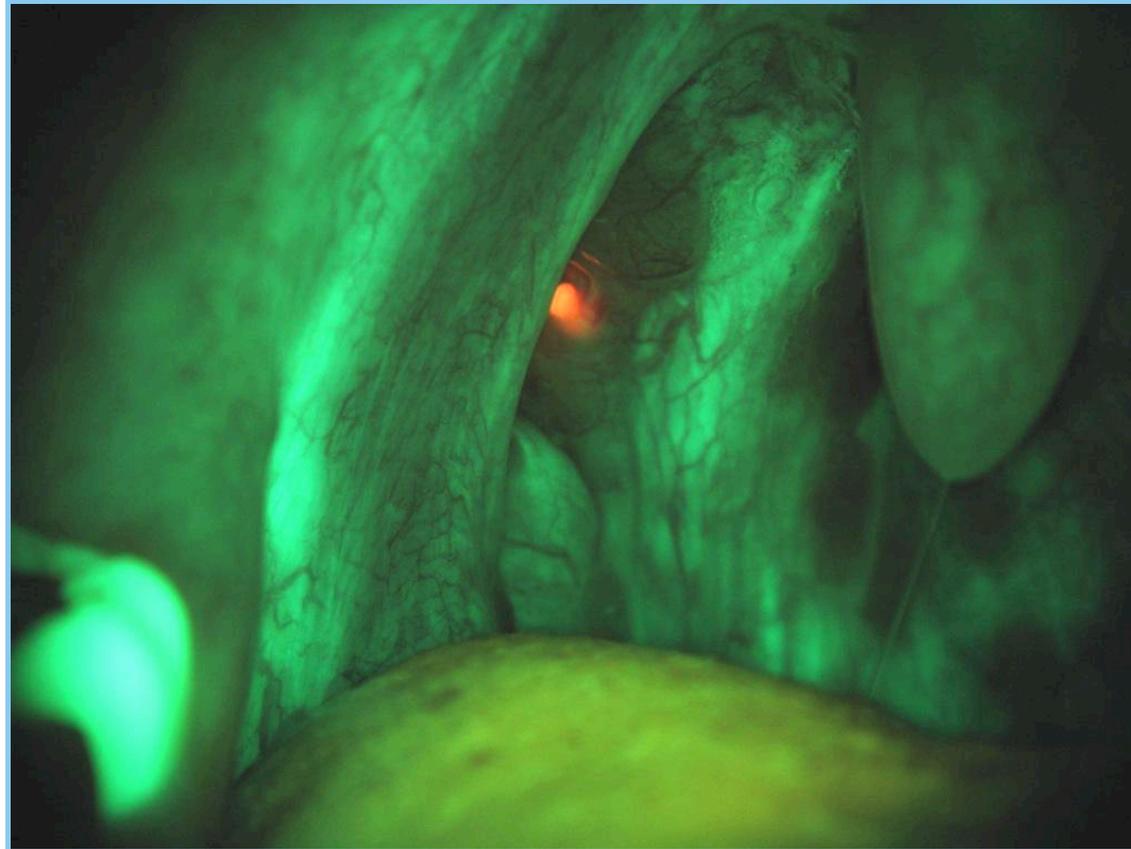
- Loss of palate, mandible, tongue, and can no longer eat
- Oral cancer has a high death rate – 50% will die within 2-5 years

**When it comes to examining soft tissue, do you sometimes feel like things haven't changed?**





# Look Again.



# Tissue Fluorescence – The Research Team

## Ongoing Trials and Research Science Team

### Univ. of Texas M.D. Anderson Cancer Center

#### **Ann M. Gillenwater, M.D., F.A.C.S.**

Associate Professor, Associate Surgeon,  
Department of Head and Neck Surgery  
Clinical Assistant Professor, Department of Otolaryngology,  
Baylor College of Medicine, Houston, Texas

#### **Randal S. Weber, M.D., F.A.C.S.**

*Chairman, Department of Head and Neck Surgery*  
Professor of Surgery  
Distinguished Professor in Cancer Research

### University of Texas Dental Branch - Houston

#### **Catherine M Flaitz, DDS, MS**

Dean, University of Texas Dental Branch at Houston  
Co-director of Oral and Maxillofacial Pathology Laboratory, Professor  
of Oral and Maxillofacial Pathology, Professor of Pediatric Dentistry,  
Department of Diagnostic Sciences

#### **Mark E. K. Wong, DDS**

Chairman and Program Director  
Department of Oral and Maxillofacial Surgery  
Professor, Division of Oral and Maxillofacial Surgery

#### **Nadarajah Vigneswaran, BDS, DMD, Dr. Med.Dent.**

Professor of Oral and Maxillofacial Pathology  
Department of Diagnostic Sciences  
Adjunct Professor, Department of Pathology, University of Texas  
School of Medicine at Houston

#### **Mark S. Chambers, D.M.D., M.S.**

Associate Professor of Head and Neck Surgery and Radiation  
Oncology  
Associate Dental Oncologist and Prosthodontist (Maxillofacial)  
*Deputy Chief, Section of Oncologic Dentistry and Prosthodontics*

### University of BC Medical School

### British Columbia Cancer Agency

#### **Miriam P Rosin**

Professor, Dept. Pathology & Lab Medicine, University of BC  
Director, BC Oral Cancer Prevention Program & Oral Health Research  
Network, Professor, Cancer Prevention Laboratory, Faculty of Applied  
Science, Simon Fraser University  
Senior Research Scientist, Cancer Control Research Program, BC  
Cancer Agency

#### **Catherine Fang-Yeu Poh, DDS, Ph.D., Cert. Oral Pathology, FRCD(C), Dip ABOMP**

Department of Surgery, Faculty of Medicine, University of BC  
Assistant Professor Faculty of Dentistry, Assistant Pathologist  
Department of Anatomical pathology, Vancouver Hospital and Health  
Sciences Centre, Staff Dentist Oral Mucosa Disease Program,  
Vancouver Hospital & Health Sciences Centre  
Clinical Scientist British Columbia Oral Cancer Prevention Program,  
Cancer Control Research, BCCRC



# Intraoral Exam: *What is the PROPER Sequence?*

- \* Lips
- \* Buccal mucosa
- \* Mucobuccal fold
- \* Palate
- \* Uvula and Oropharynx
- \* Tongue (dorsal/ventral and lateral surfaces)
- \* Floor of the mouth
- \* Gingiva
- \* Teeth



***Lips:*** Observe the outer lips (vermilion border) and the inside of the lower lip (labial mucosa)



***Lips*** (labial mucosa) : Observe the inside of the upper lip and note the color, texture and any surface abnormalities



***Buccal Mucosa*** (inside cheek): Visually examine the left cheek extending all the way back; note any change in color, texture and mobility



***Buccal Mucosa:*** Palpate using fingers and thumb to detect any lumps and evaluate for the mobility and consistency of the tissues





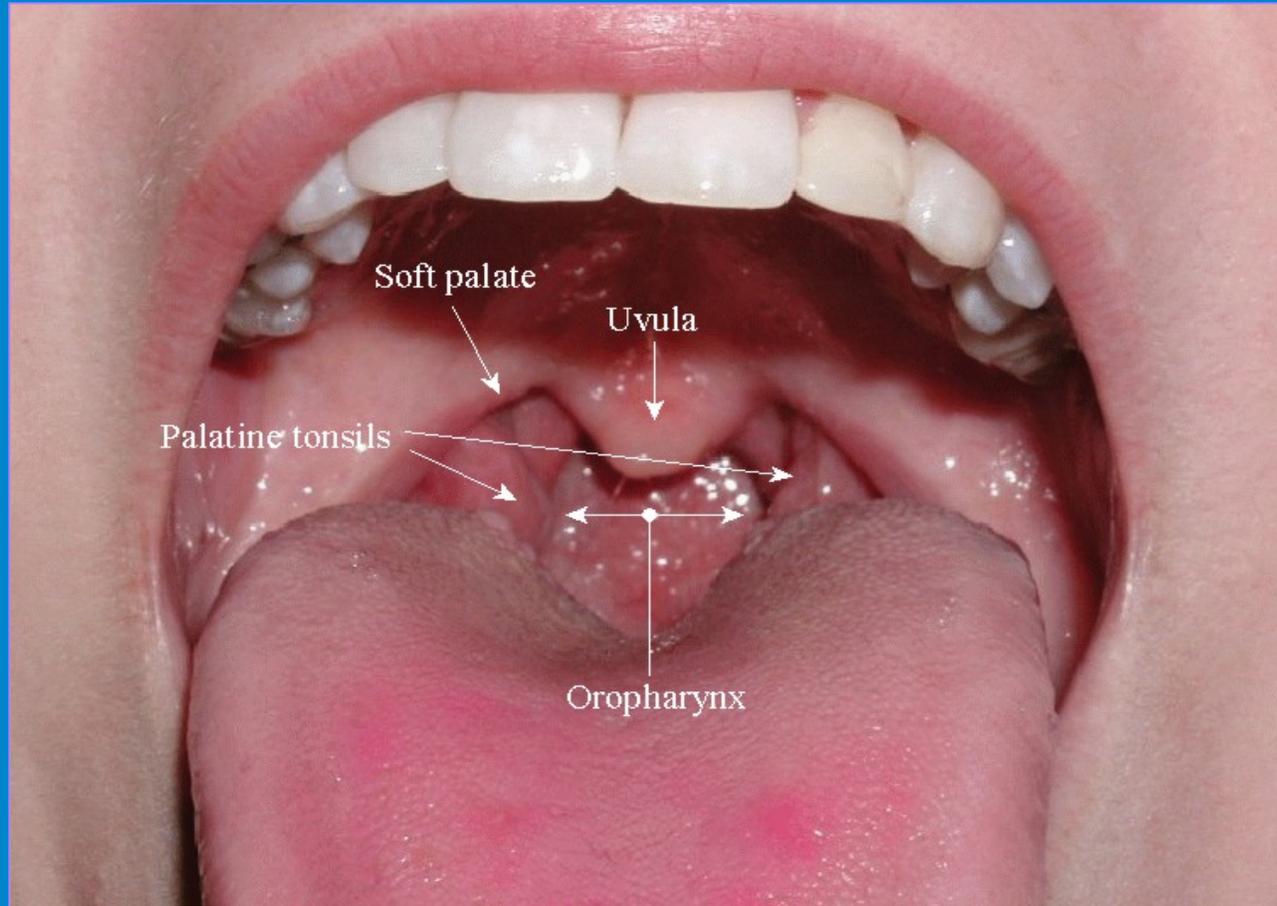
***Buccal Mucosa*** (inside cheeks): Repeat on the right side



***Buccal Mucosa:*** Palpate using fingers and thumb to check on the right side



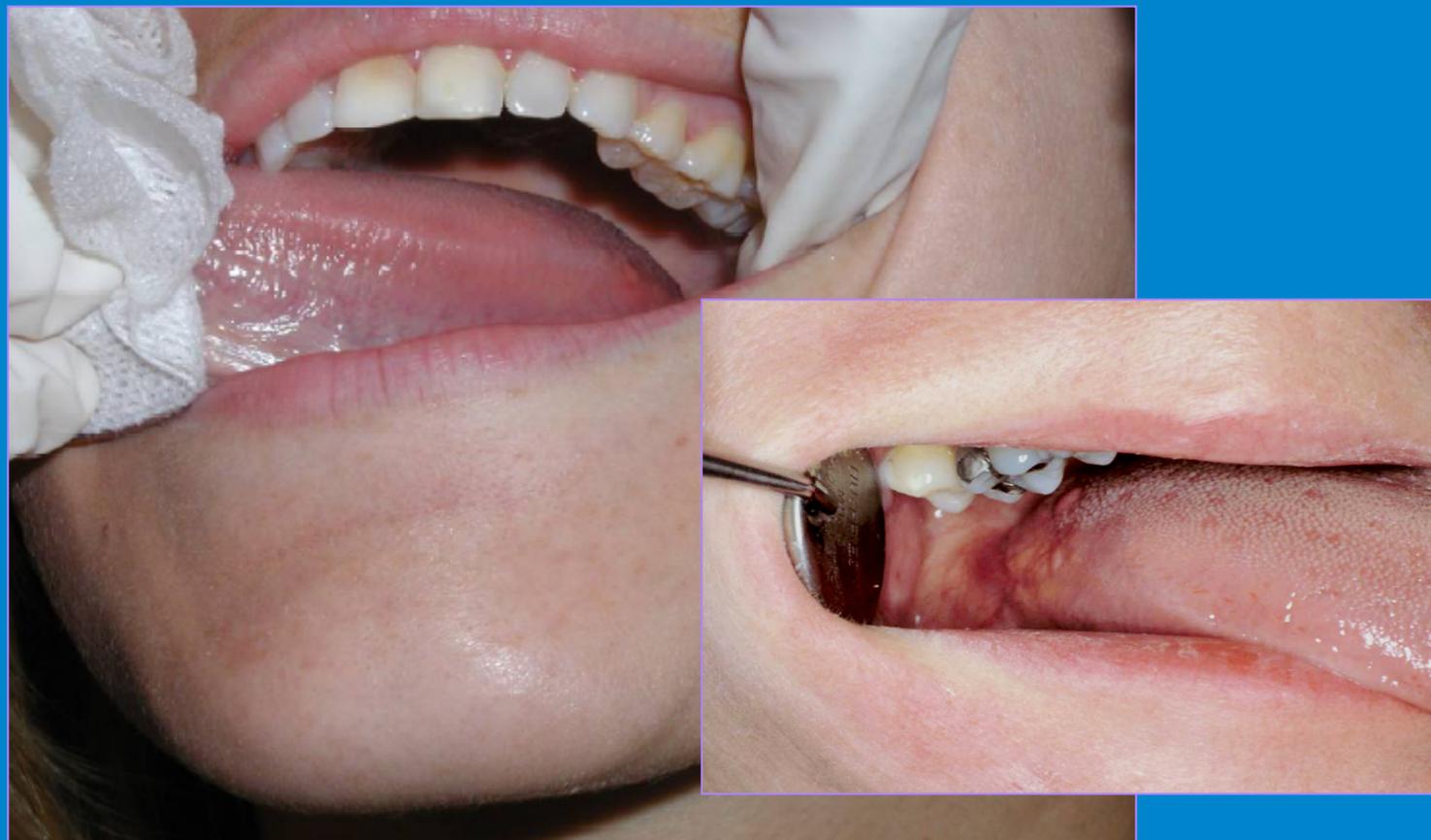
***Palate*** (roof of the mouth): Inspect hard and soft palate



***Soft Palate and Oropharynx*** (back of the inside of the mouth and throat): Inspect for changes



***Tongue:*** Check for any swelling, ulcers, coating or variation in size, color or texture



***Tongue:*** Grasping the tip of the tongue with a piece of gauze will aid examination of the more posterior aspects of the tongue's lateral borders

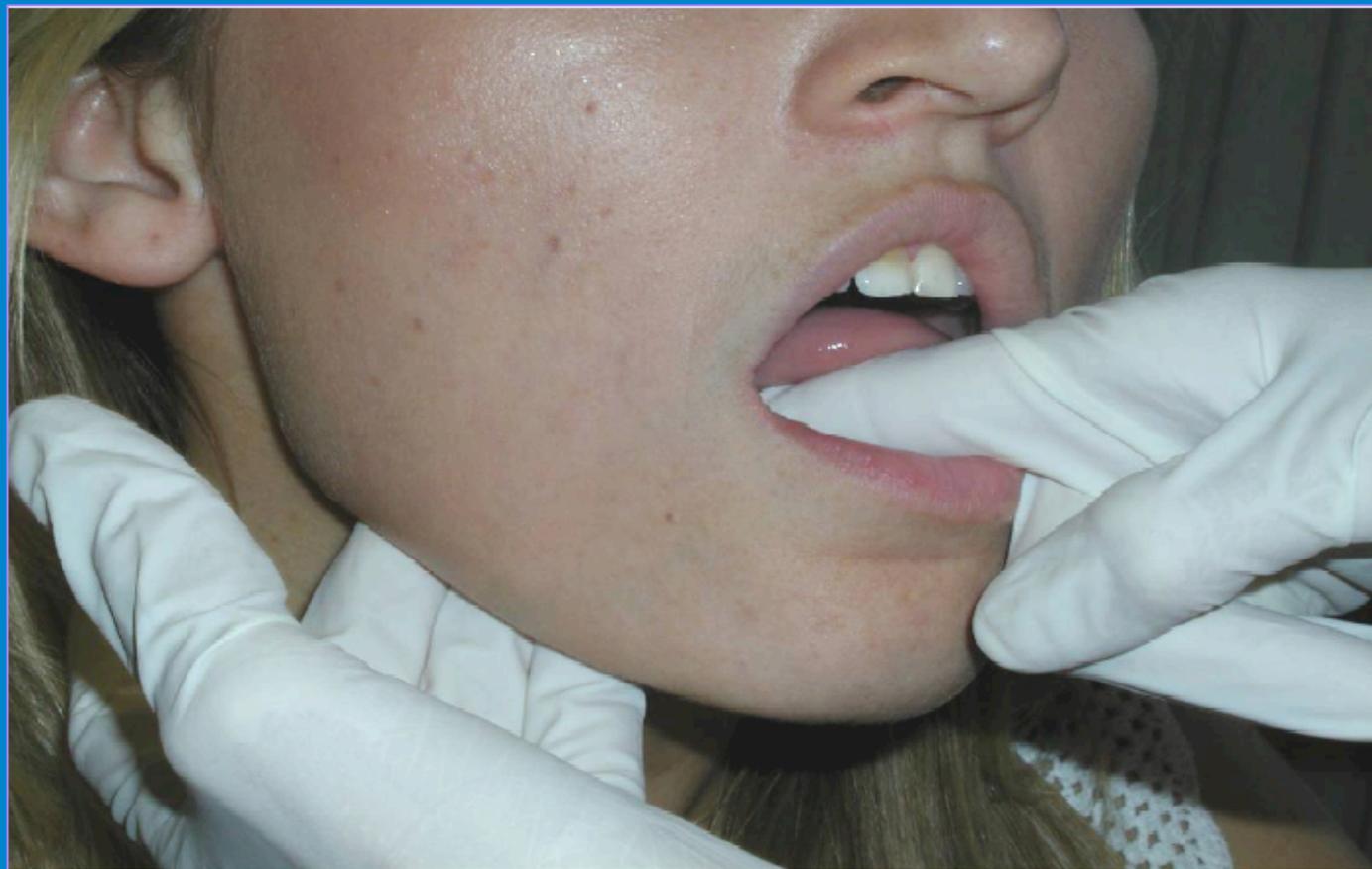


***Floor of the Mouth and Ventral Tongue:*** Elevate the tongue and look for abnormalities



***Floor of the Mouth and Ventral Tongue:*** With the tongue elevated, inspect for changes in color, texture, swellings or other surface abnormalities



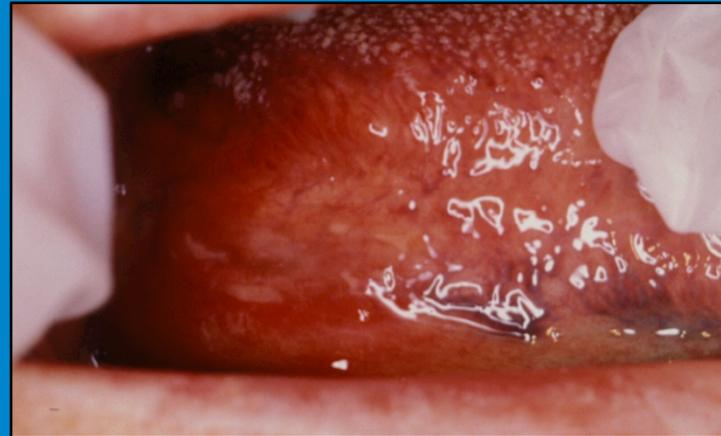
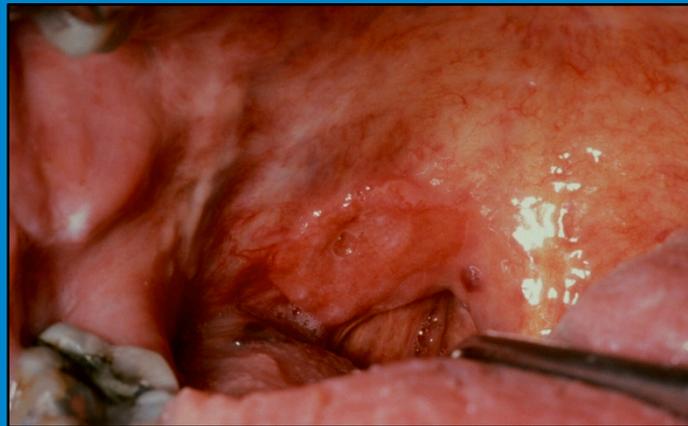


***Floor of the Mouth:*** Palpate for any abnormalities



***Gingivae* and surrounding tissues: Outer  
and inner surfaces**

# Oral Cancer: *High Risk Sites*



# Early Signs and Symptoms

- Persistent white patch with thick surface
- Persistent red patch, granular surface
- Non healing, firm ulcer
- Firm enlargement with surface changes
- Sudden tooth mobility without cause
- Prolonged hoarseness (laryngeal site)

# Late Signs and Symptoms

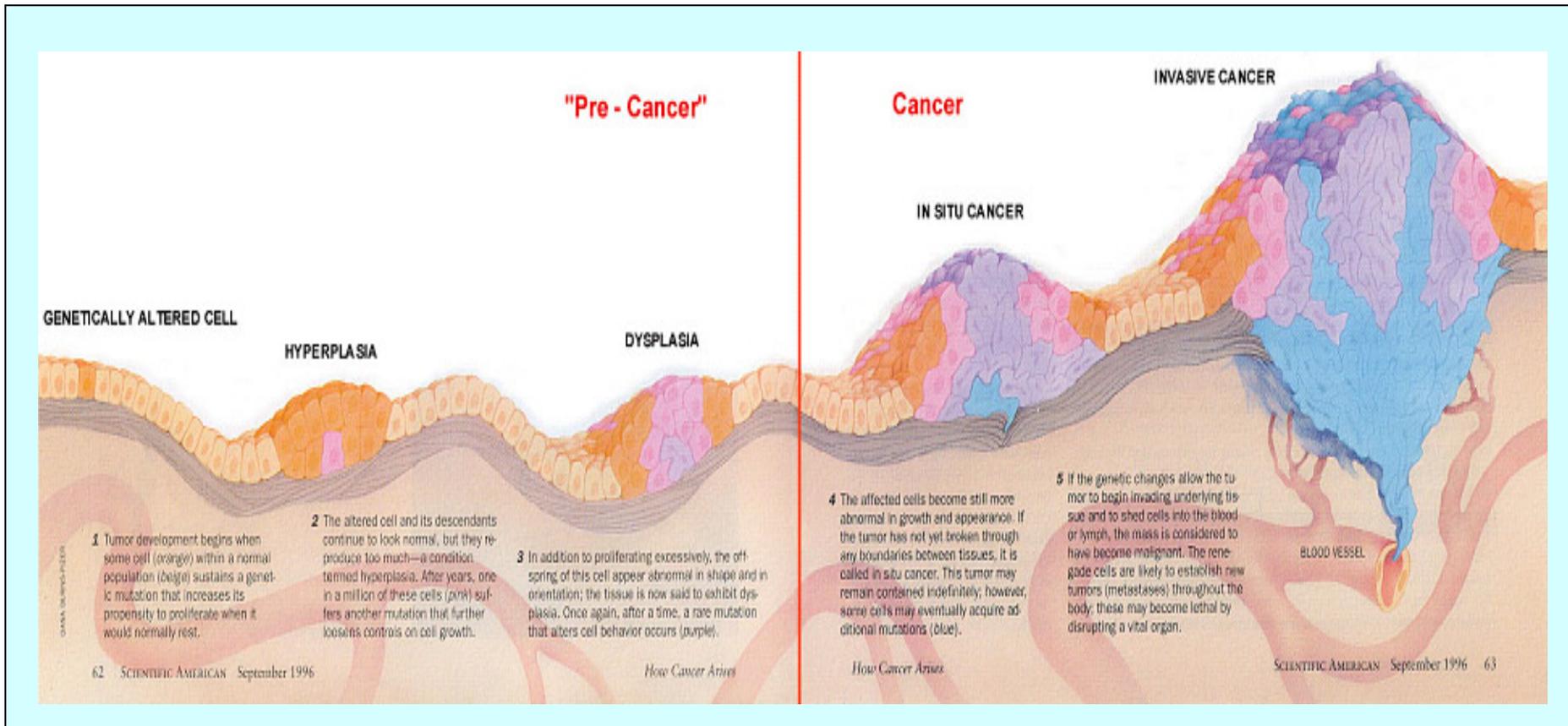
- Fixed, indurated mass
- Restriction of tongue, jaw movement, trismus
- Persistent or referred pain; chronic earache
- Firm, nontender lymph nodes of the neck
- Speech changes
- Swallowing difficulties



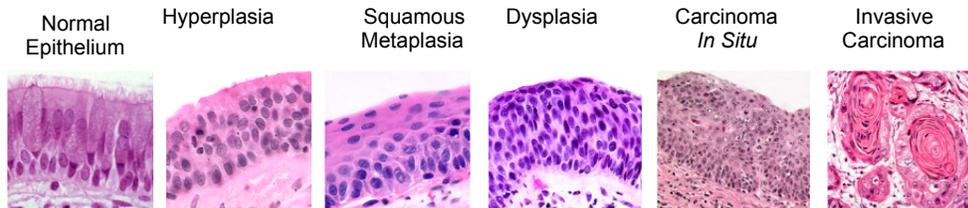
## See Prevention in a New Light

- Portable
- Cordless
- Affordable: \$1695.00





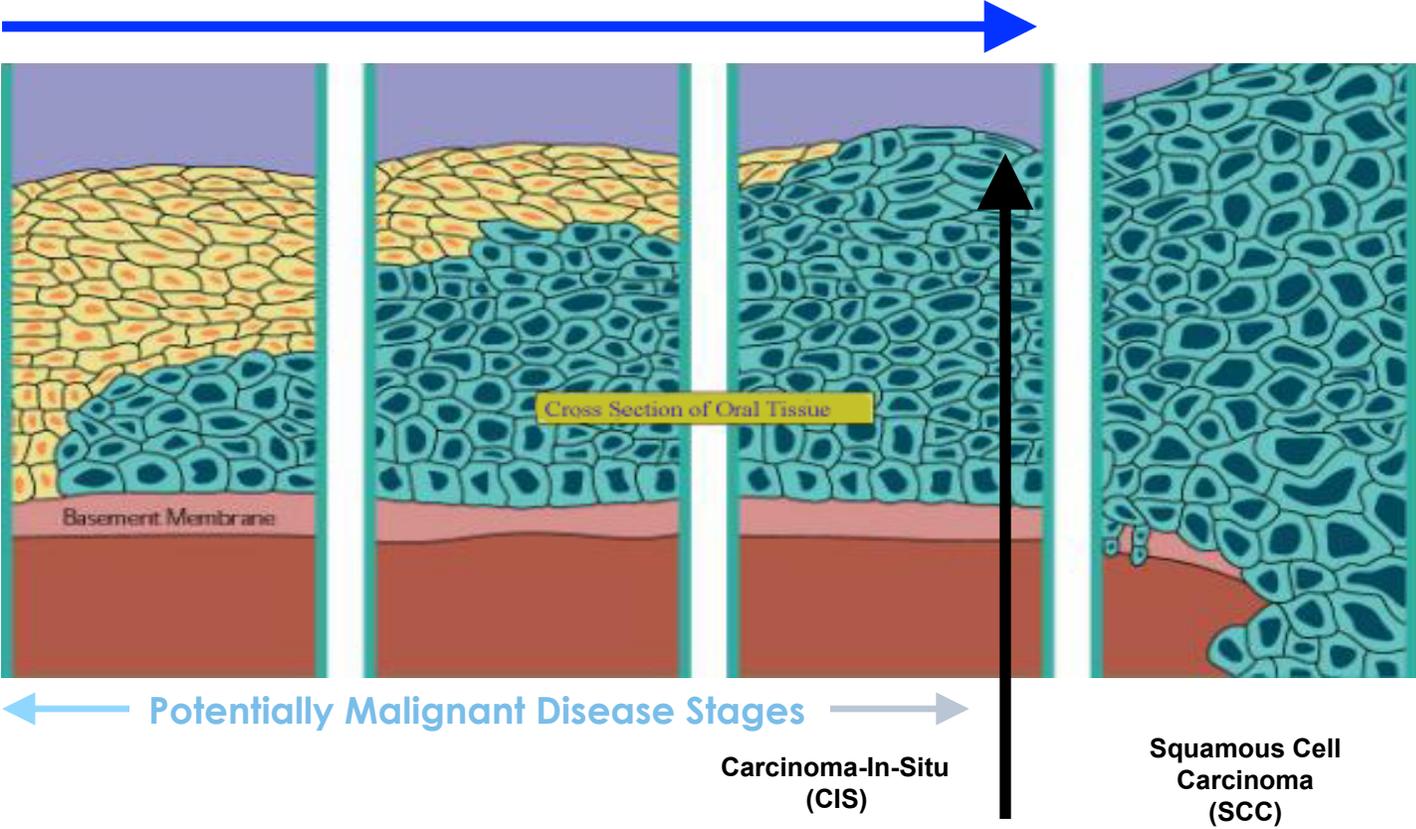
## Neoplastic Lesions



Stage I - IV

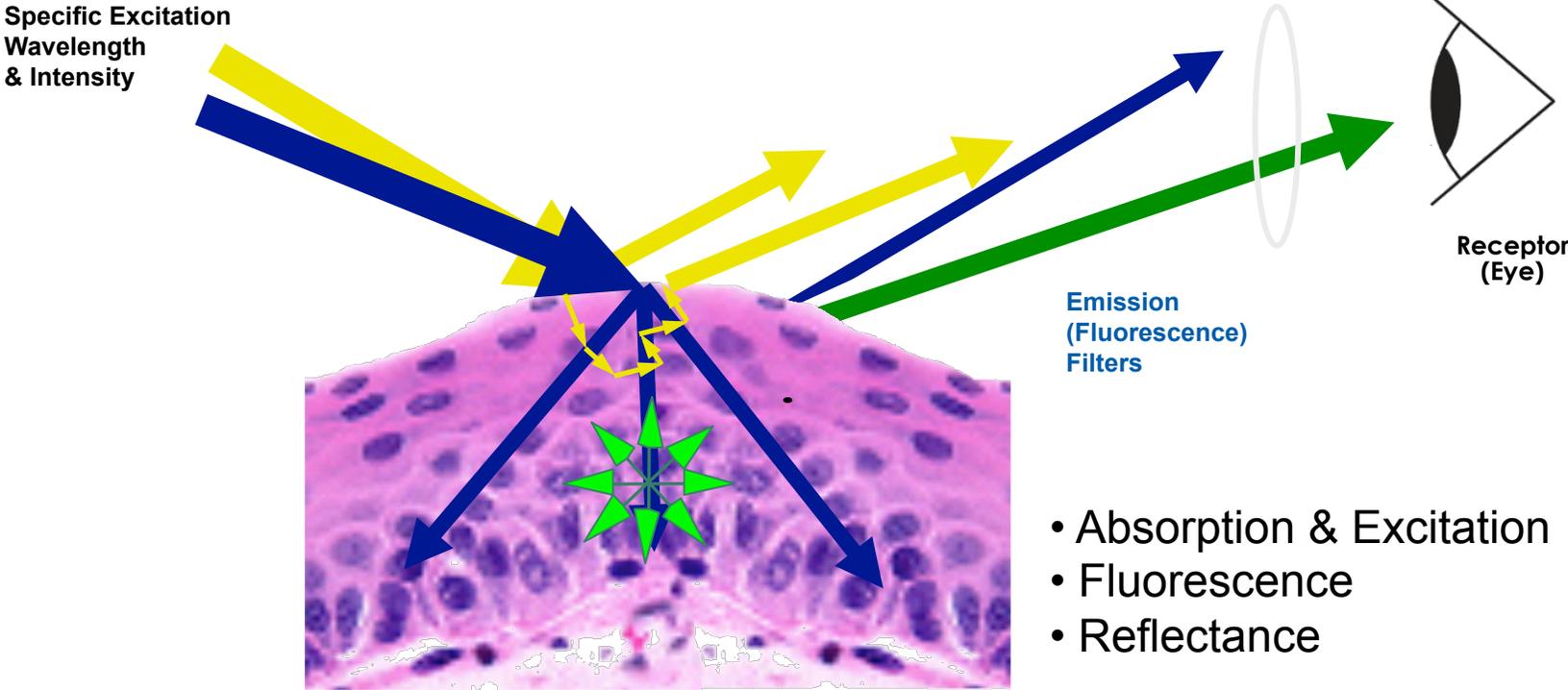
# Oral Cancer & Dysplastic Progression

Ideal time for discovery & intervention is in the Premalignant stages

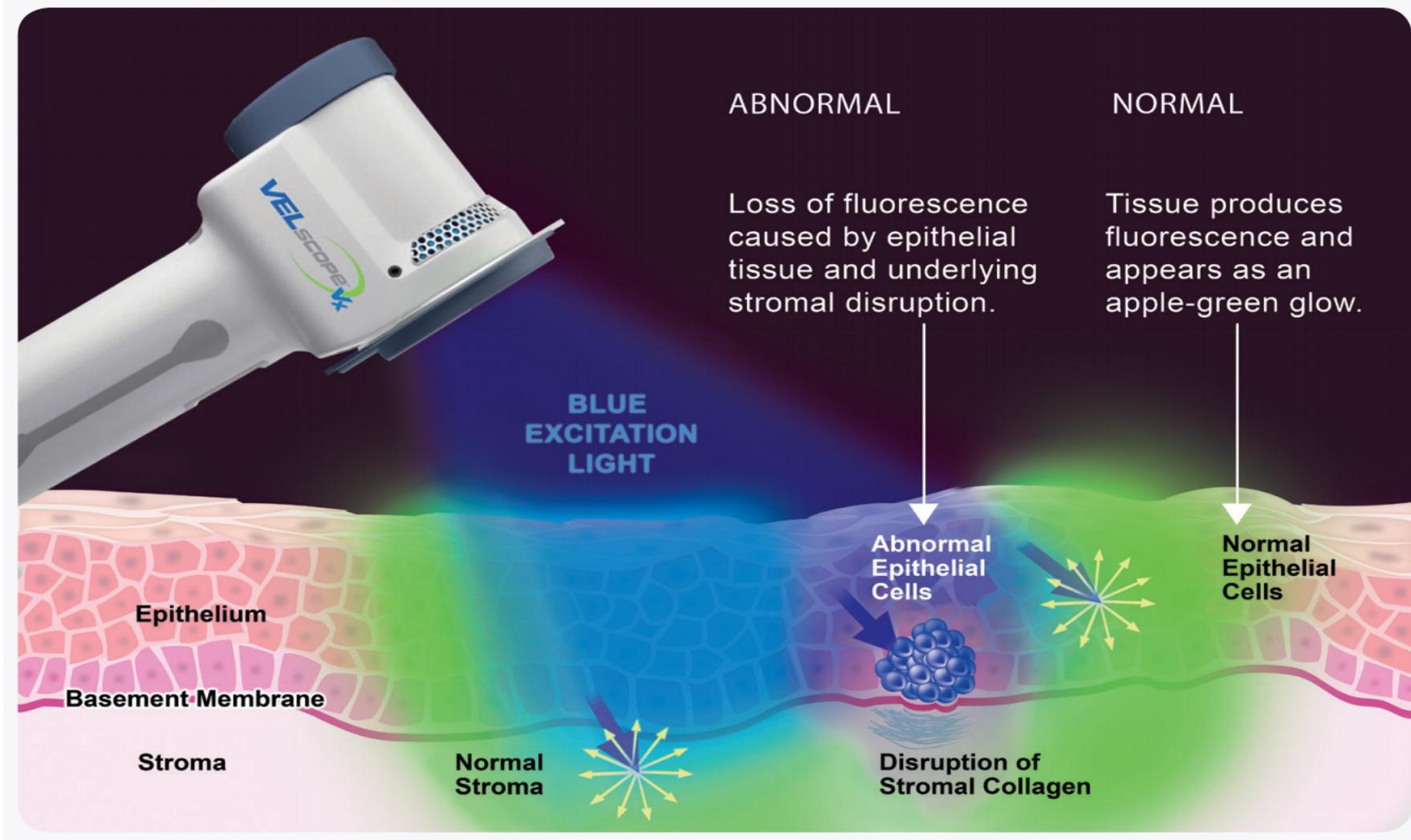




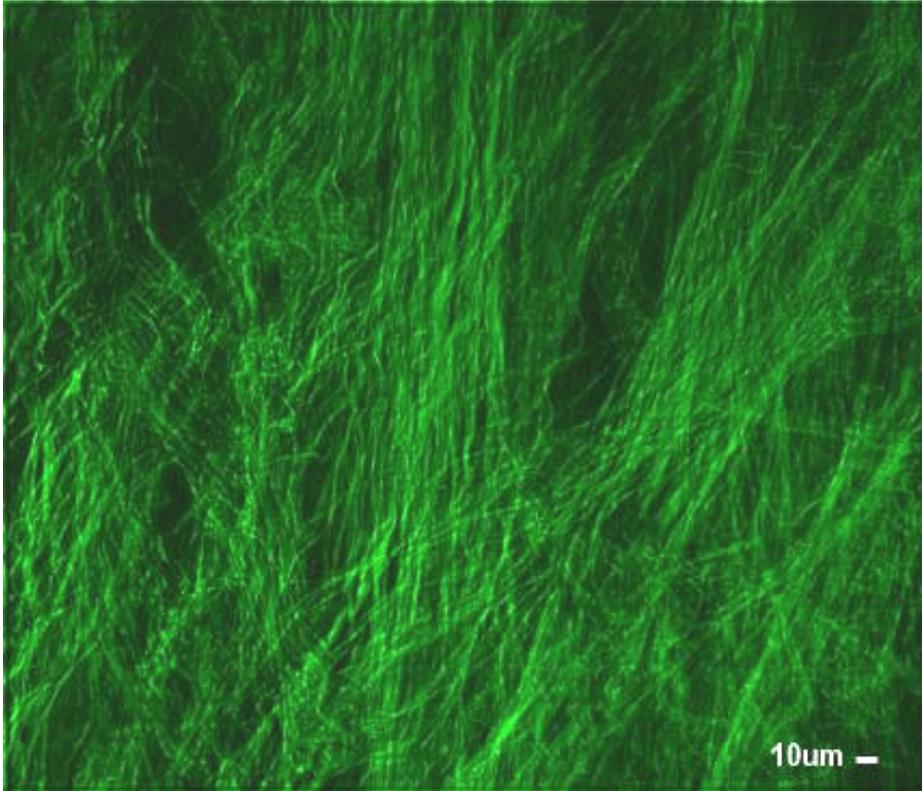
# Direct Tissue Fluorescence Visualization



# Tissue Fluorescence



# Natural Fluorophores Excited by the VELscope:



Breakdown of the collagen matrix in the stroma increases as dysplasia and cancer progress, and is naturally associated with decreased numbers of collagen cross-links, and therefore decreased fluorescence.

# In Summary:

- INCREASED METABOLIC ACTIVITY

More NADH, less FAD, - less fluorescence

- EPITHELIAL THICKENING & INCREASED NUCLEAR SCATTERING

- Decreases penetration & absorption of blue light, less fluorescence

- INCREASED MICRO VASCULARIZATION – blood highly absorbs the blue light (410 nm)  
- less fluorescence

- RESTRUCTURING OF COLLAGEN MATRIX,- Collagen Crosslinks Disappear - less fluorescence

# Psychological Habituation – Our minds see what we expect to see:

I cdnuolt blveiee taht I cluod aulacly uesdnatnrd waht I was rdgnieg. Tihs is an emaxlpe of the phaonmneal pweor of the hmuan mnid. Aoccdrnig to rscheearch at Cmabrigde Uinervtisy, it deosn't mttar in waht oredr the ltteers in a word are, the olny iprmoatnt tihng is taht the frist and lsat ltteer be in the rghit pclae. The rset can be a taotl mses and you can sitll raed it wouthit a porbelm. Tihs is bcuseae the huamn mnid deos not raed ervey lteter by istlel, but the wrod as a wlohe. Amzanig huh?

# Fluorescence can Enhance the Discovery and Recognition of Many Conditions:

- **Neoplastic Lesions**
  - **Potentially Malignant Lesions (Dysplasias)**
  - **Cancerous Lesions**
- **Reactive Lesions (such as Inflammation) Due to:**
  - **Trauma from Physical Irritation or Abuse**
  - **Chemical Irritation**
  - **Medication Side Effects**
  - **Allergic Responses**
  - **Thermal Damage**
  - **Fungal, Viral, or Bacterial Irritation**
  - **Systemic Conditions with Oral Manifestations**
- **Developmental / Congenital Abnormalities**

# All the Other Types of Oral Lesions!



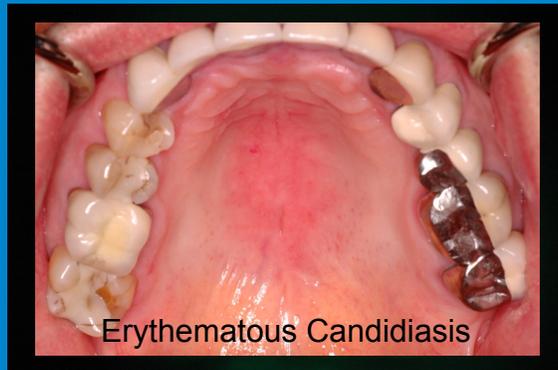
Lichenoid Mucositis



Squamous Papilloma



Reticular Lichen Planus



Erythematous Candidiasis



Irritation Fibroma



Geographic Tongue



White Hairy Tongue



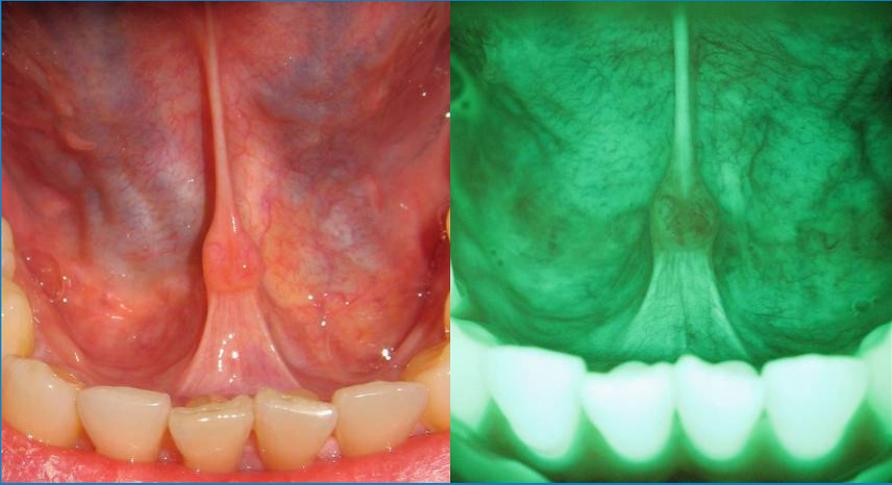
Erosive Lichen Planus



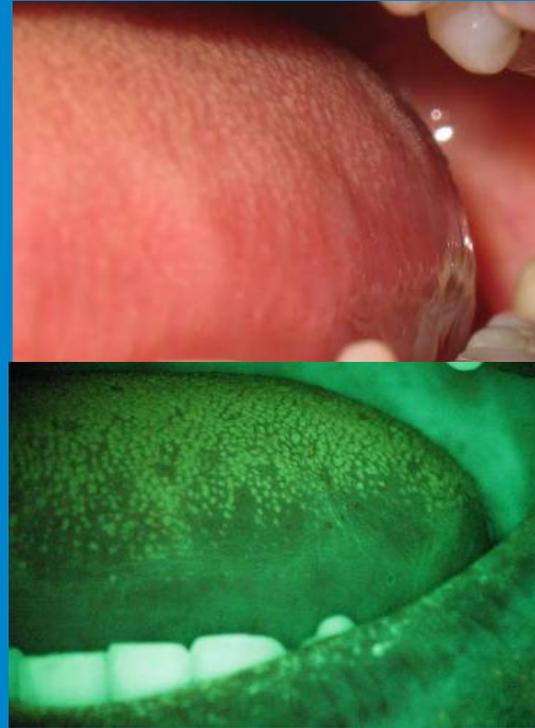
Mucoepidermoid Carcinoma

A brighter homogeneous green colour is usually indicative of healthy tissue...

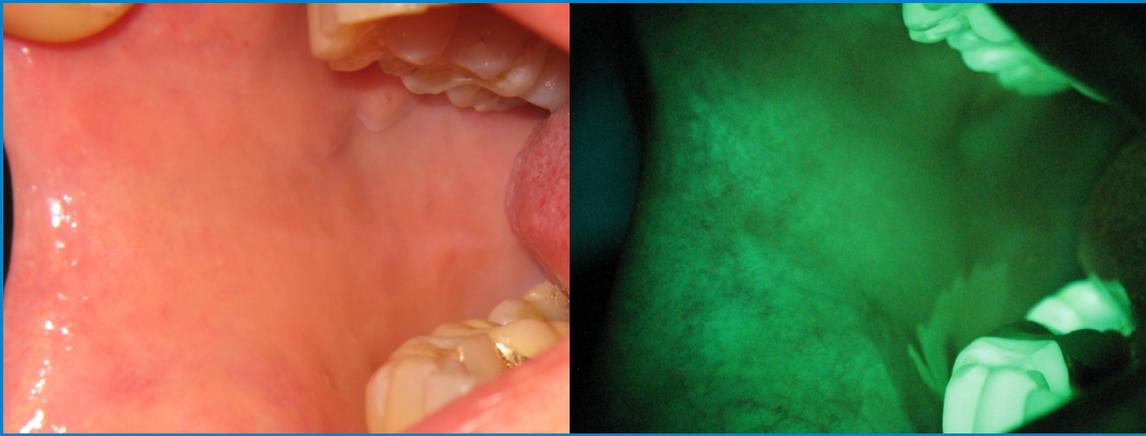
Floor of the Mouth



Lateral Border Tongue



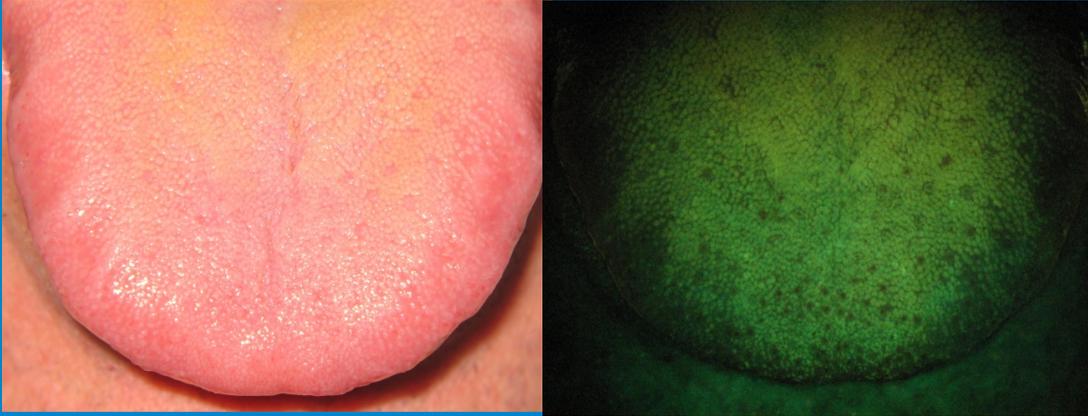
Buccal Mucosa





# Sometimes healthy tissue has a normal fluorescence pattern of both bright and dark areas ...

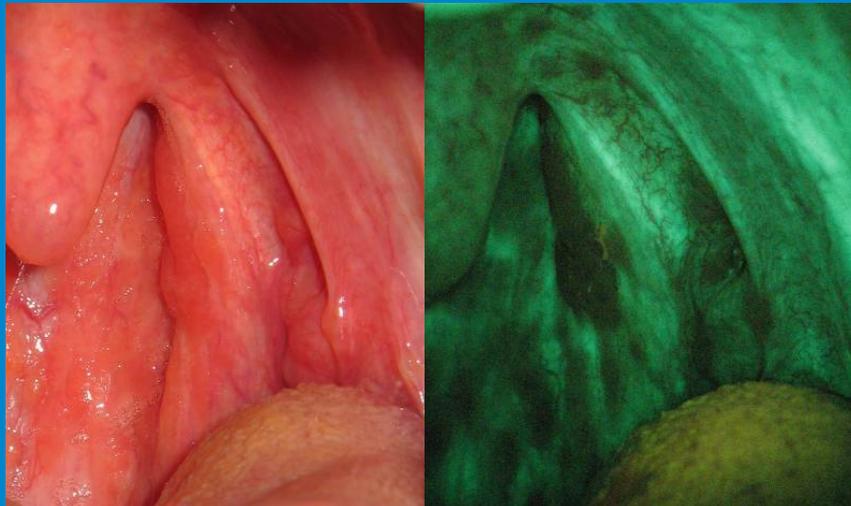
Fungiform/Filliform Papillae on Dorsal Tongue



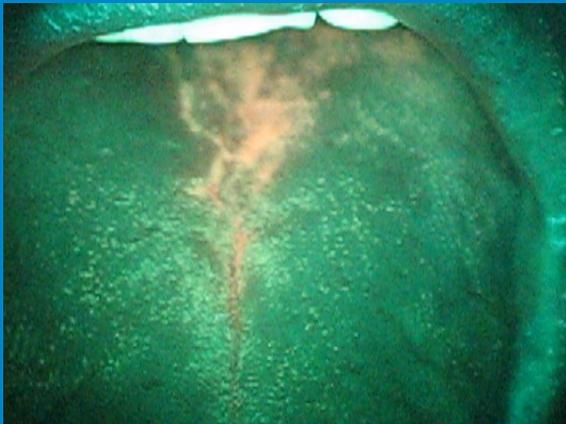
Attached / Unattached Gingiva



Palatine Tonsil / Lymphoid Aggregates

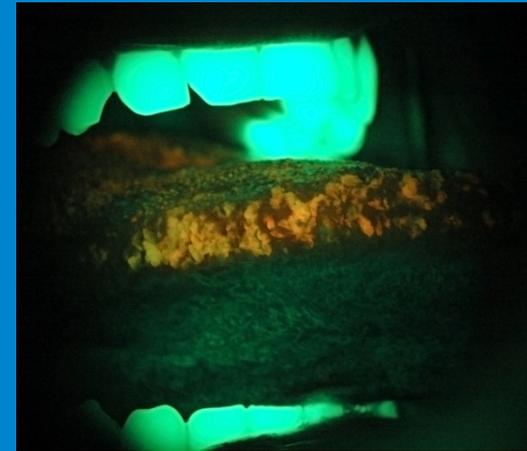


# Bacteria & the Porphyrin Response

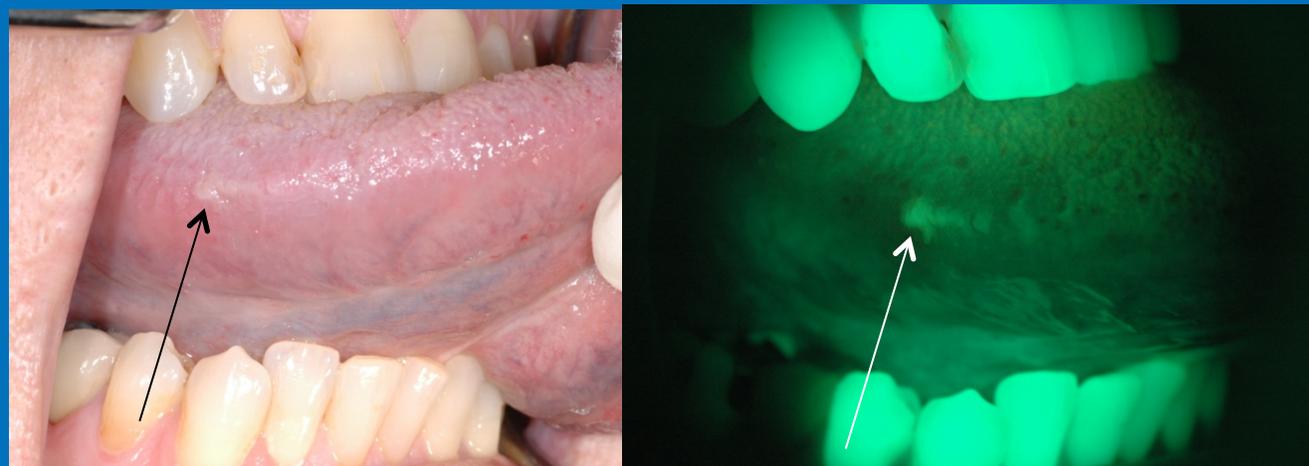
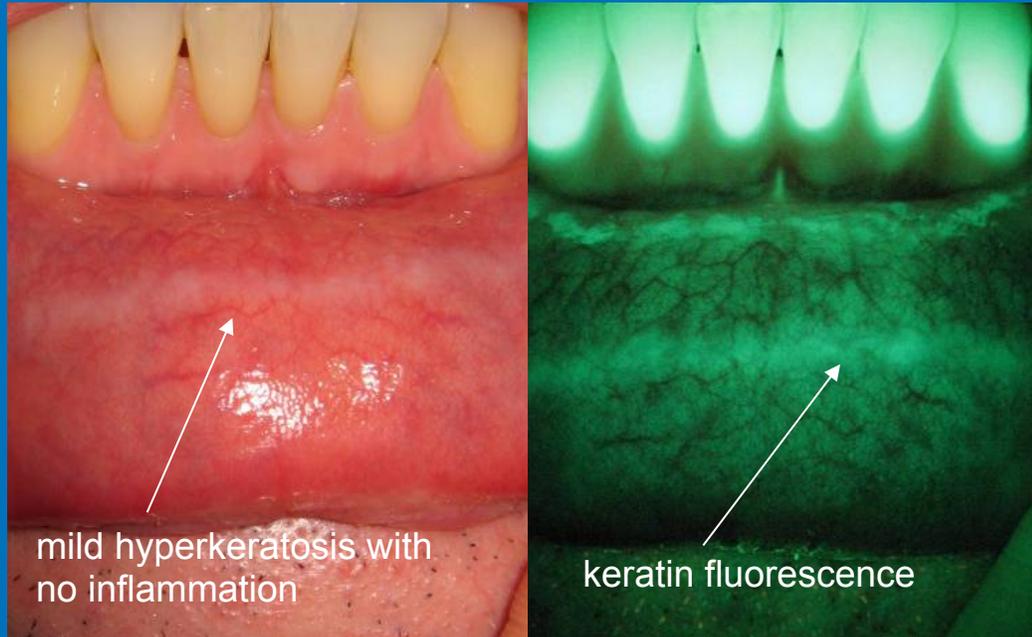


The yellow/orange/red colours often seen in the oral cavity are from porphyrins that are a byproduct of bacterial presence.

You tend to see this in areas of non-smooth mucosa where bacteria can collect, e.g. fissures in the tongue, fungiform papillae, hyperkeratotic areas, palatine tonsil.



# Hyperkeratosis (minimal inflammation)



# Pigmented Areas / Lesions

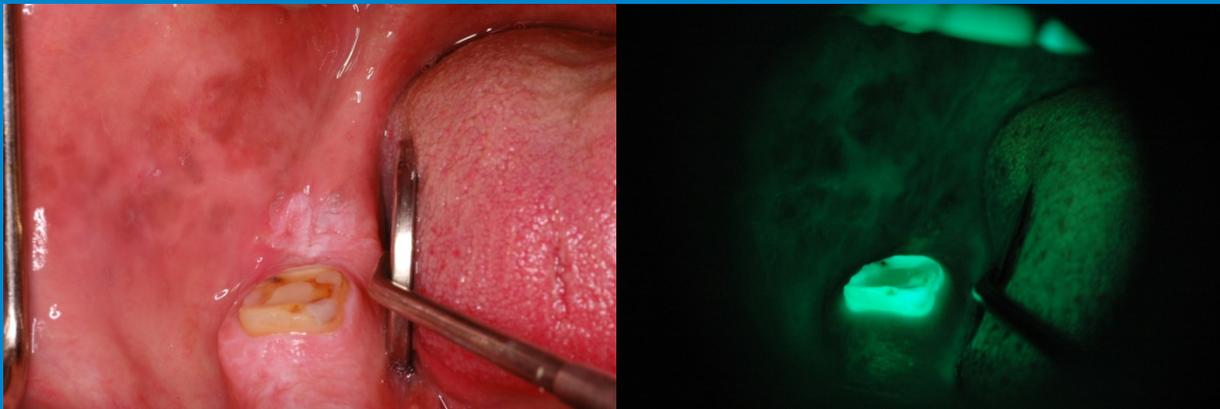
Melanin Pigmentation on Gingiva



Amalgam Tattoo

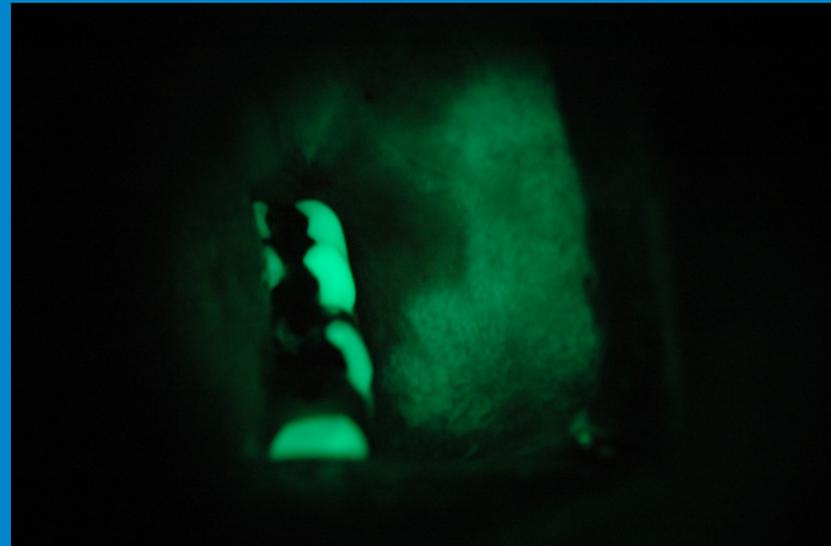


Melanin Pigmentation on Buccal Mucosa



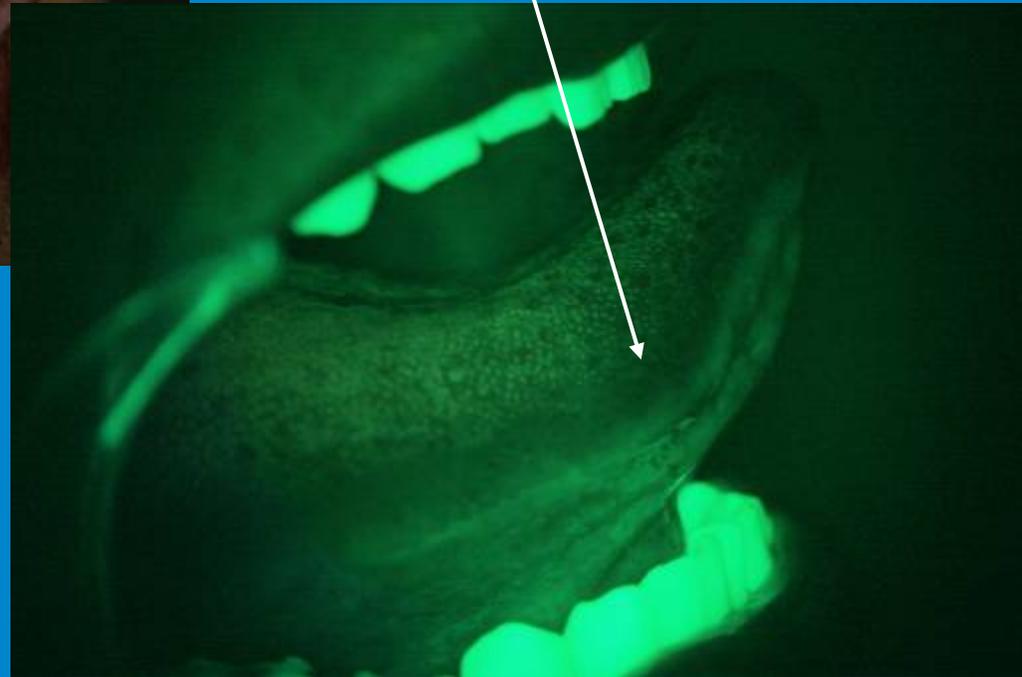
# Fluorescence Visualization & Inflammation

- Blood vessel dilation associated with inflammation results in a higher blood content in the tissue, the net result being a darkened area at the inflamed site due to increased absorption of light.





Chronic mild inflammation is quite common on the lateral border of the tongue



UNIKLINIK  
KÖLN

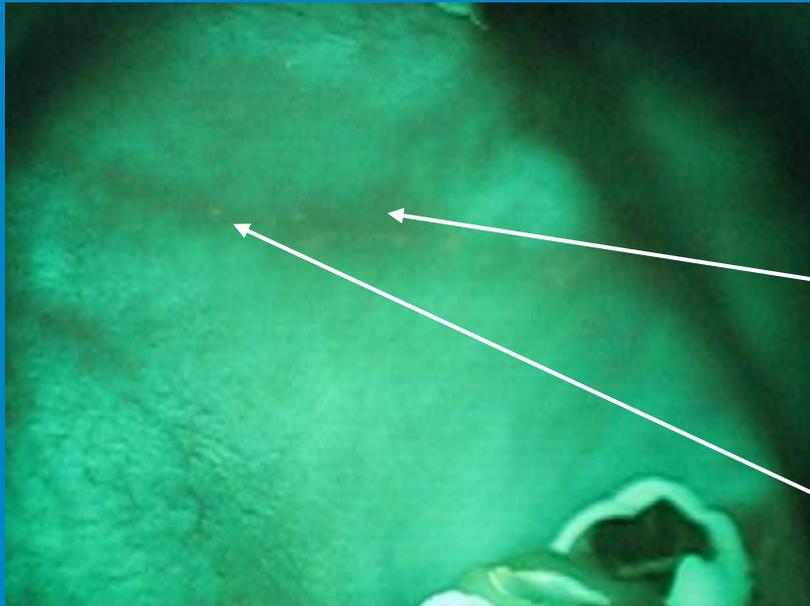
Larger dark spots can sometimes be seen on the dorsal surface of the tongue



*This is likely due to the patchy wearing down of the filiform papillae and a consequent loss of keratin fluorescence*



The Buccal mucosa is quite often an area of chronic irritation and mild inflammation...



***Classic Linea Alba***

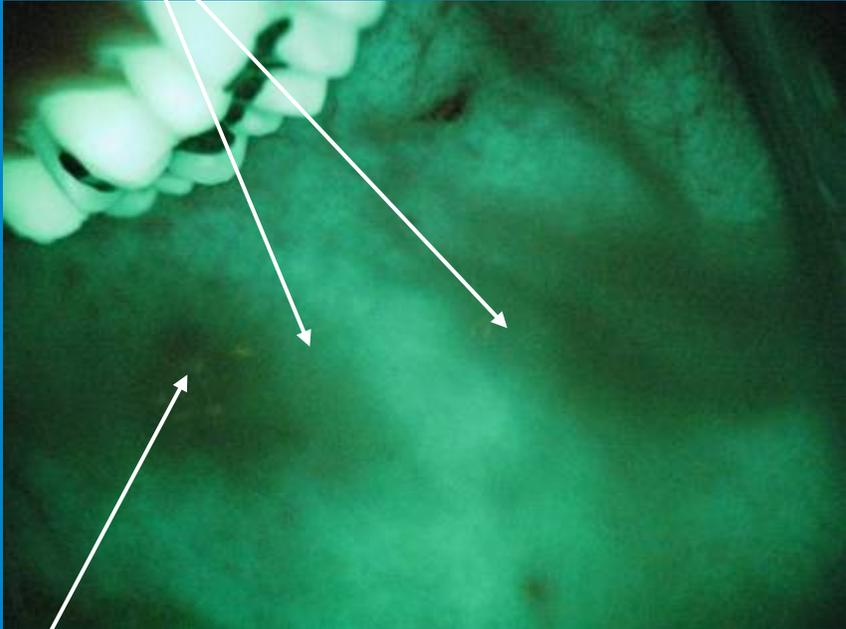
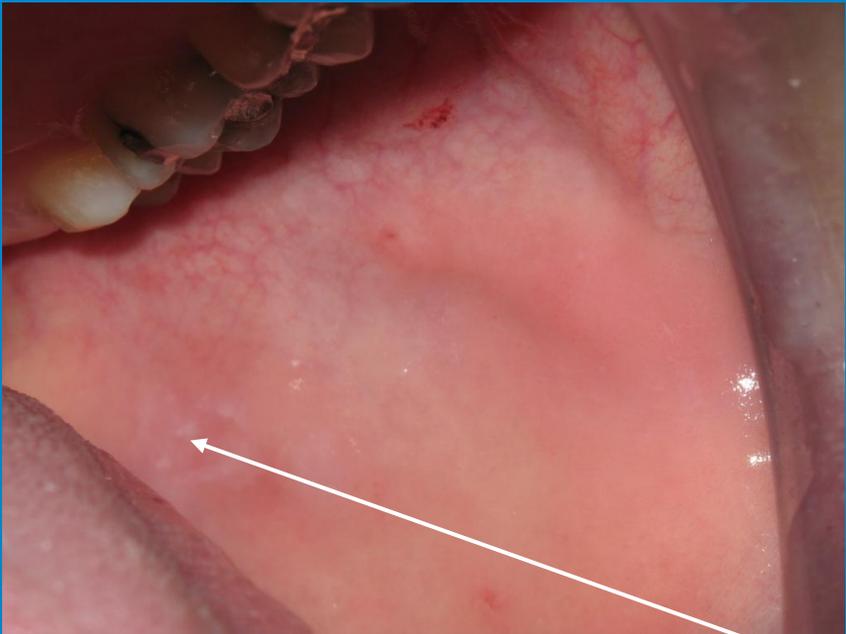
***Inflammation along bite line shows up as a dark area***

***Bright spots due to keratinization are also evident***



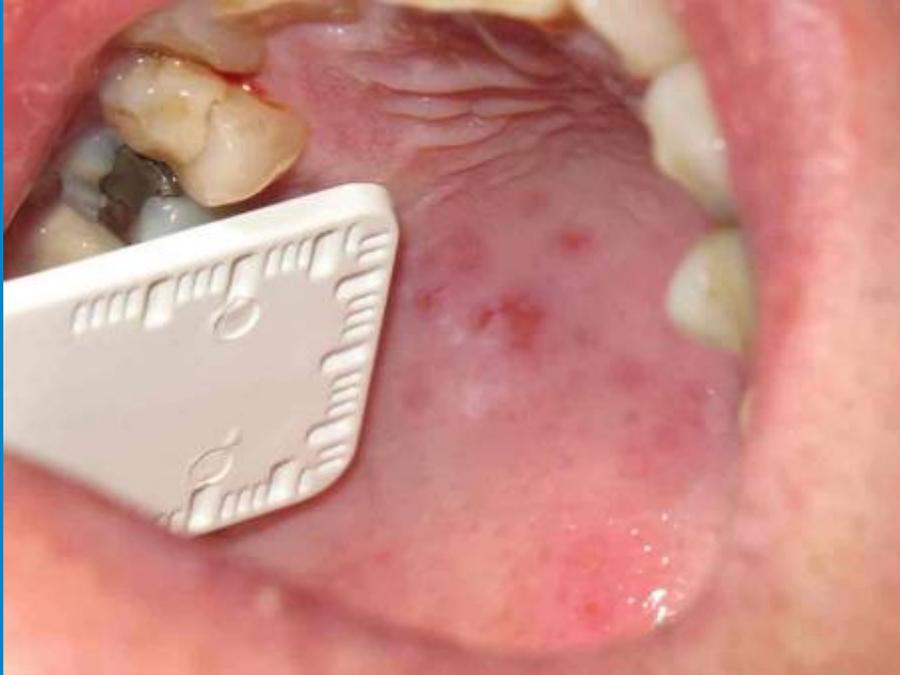
**Chronic irritation of the Buccal mucosa from the teeth has in this case led to two pronounced dark patches**

*Diffuse borders of the darkened areas under VELscope  
– typical of an inflammatory response*



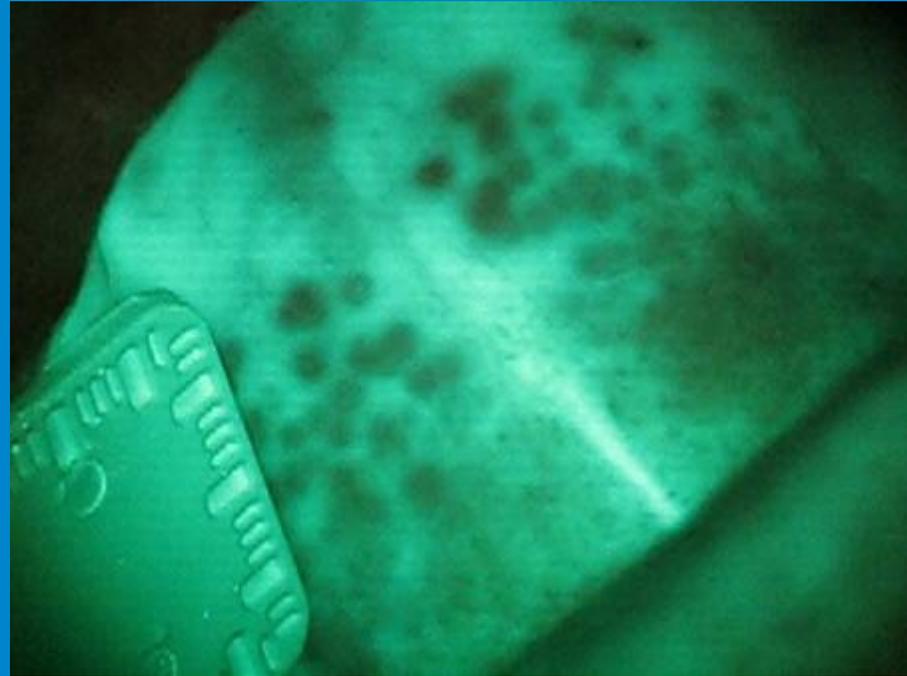
***Keratinization***

The hard palate is quite a common area for irritation and local trauma



*The patient had been sucking on hard candies prior to the appointment*

# Inflamed Salivary Glands on the Hard Palate

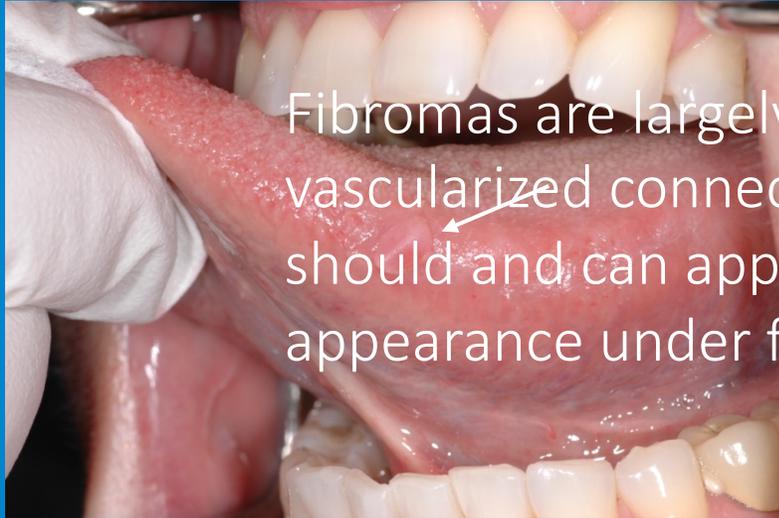


Images courtesy the Benjamin Dental Group

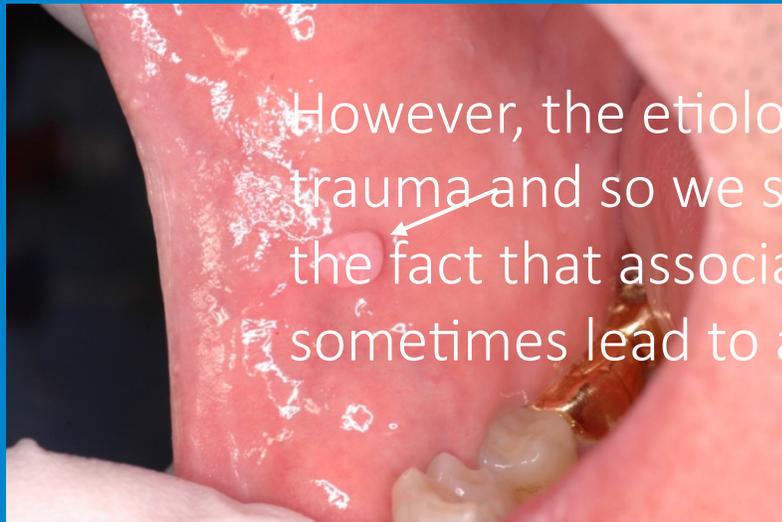
# Abnormal Oral Mucosa

- Look for tissue that has a reduction of normal green fluorescence compared to surrounding tissue of the same type
- Particular danger signs:
  - *Unilateral as opposed to bilateral presentation*
  - *Irregular and/or non-symmetrical shape*
  - *Well-demarcated borders*
  - *Abnormal patterns that appear “out of context”*
  - *Abnormal patterns that spread across different anatomical structures*

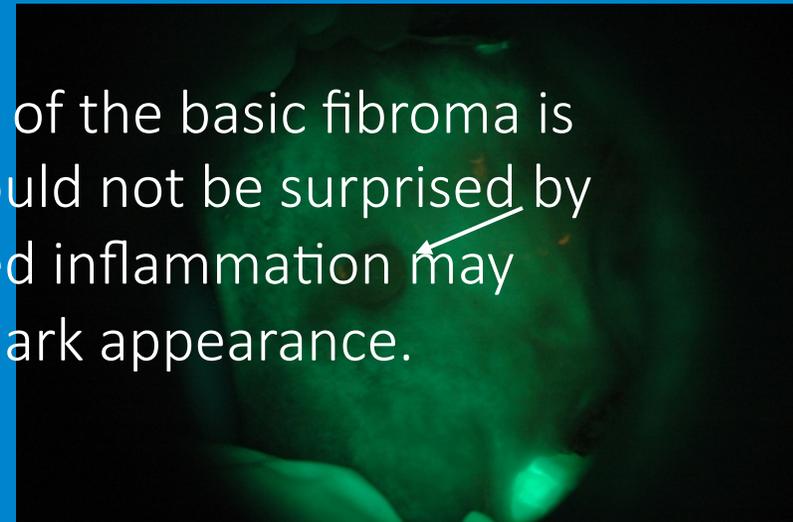
# Fibroma



Fibromas are largely composed of poorly vascularized connective tissue, and thus should and can appear bright or neutral in appearance under fluorescence.



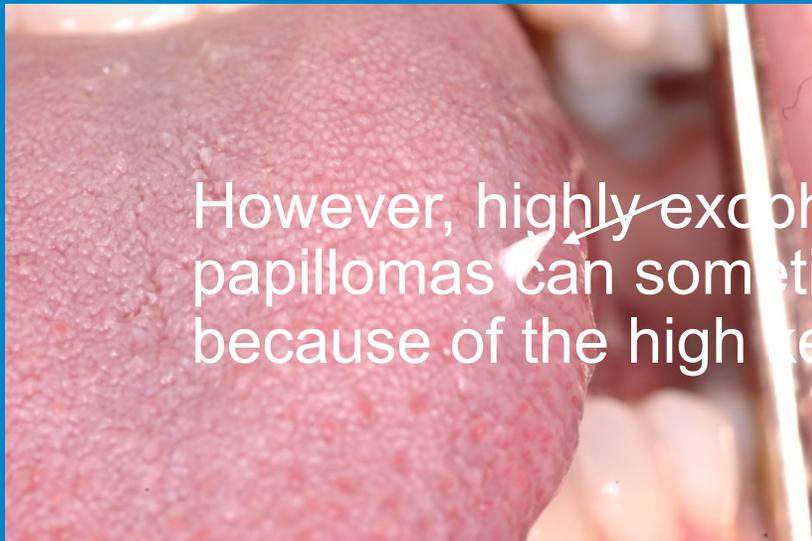
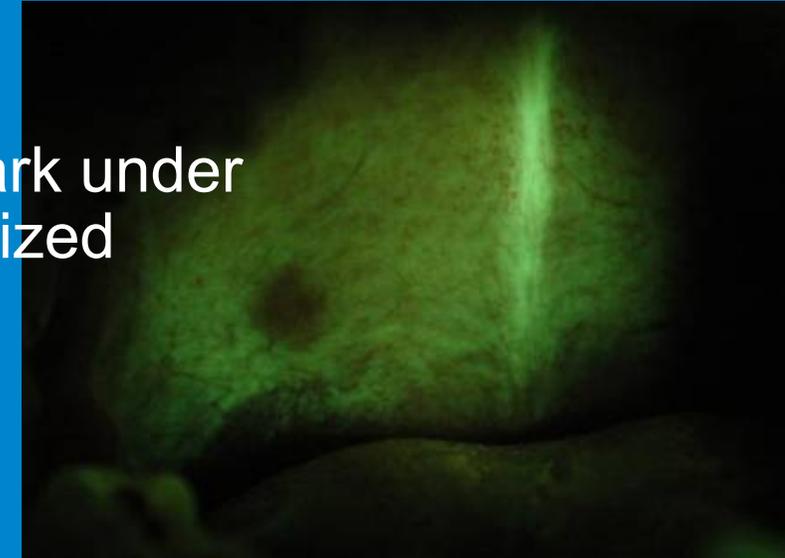
However, the etiology of the basic fibroma is trauma and so we should not be surprised by the fact that associated inflammation may sometimes lead to a dark appearance.



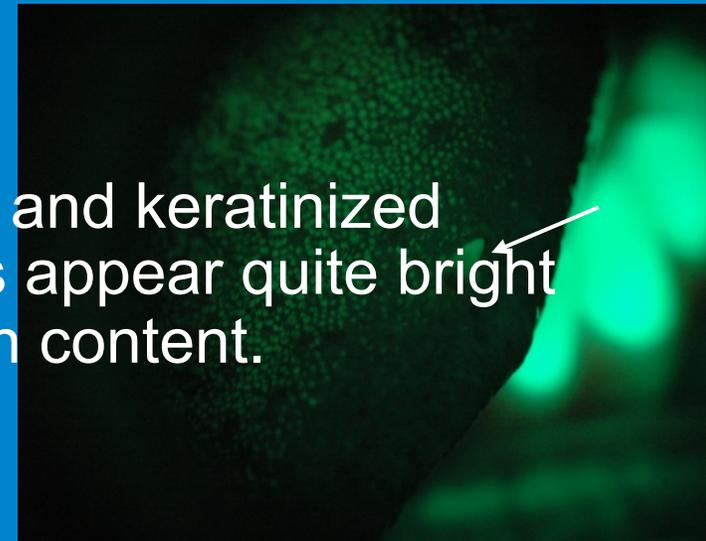
# Viral Induced Lesion - Squamous Papilloma



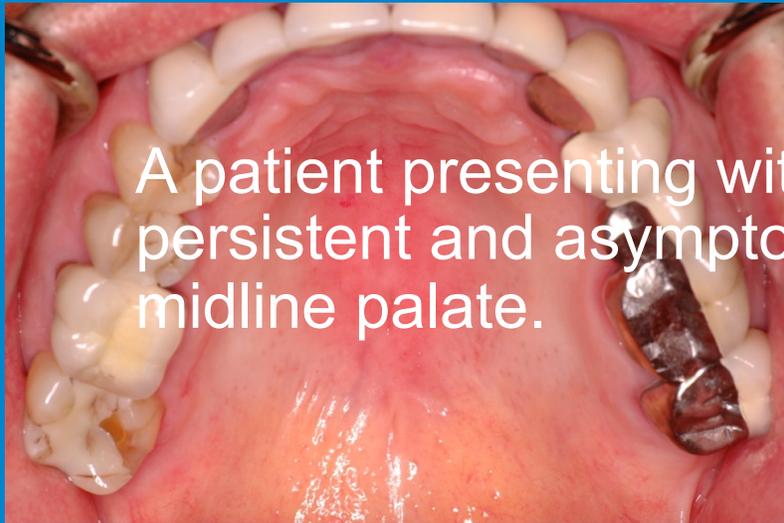
Squamous papillomas typically appear dark under VELscope because of the highly vascularized fibro-connective cores that are part of the structure of the papilloma.



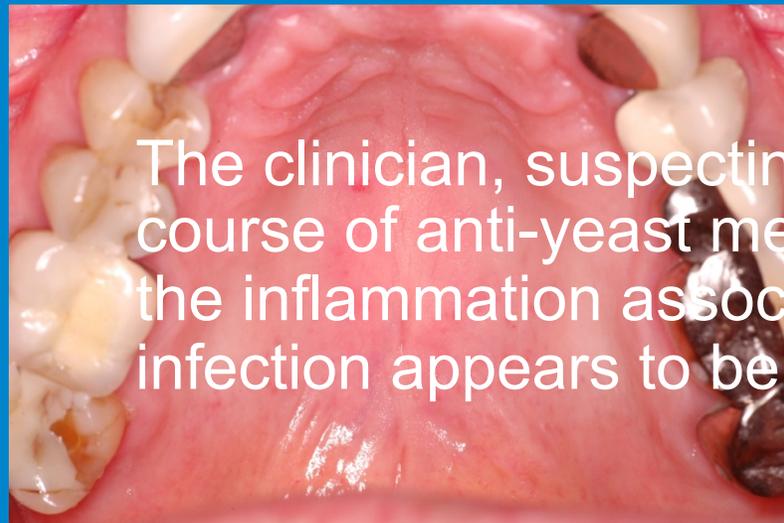
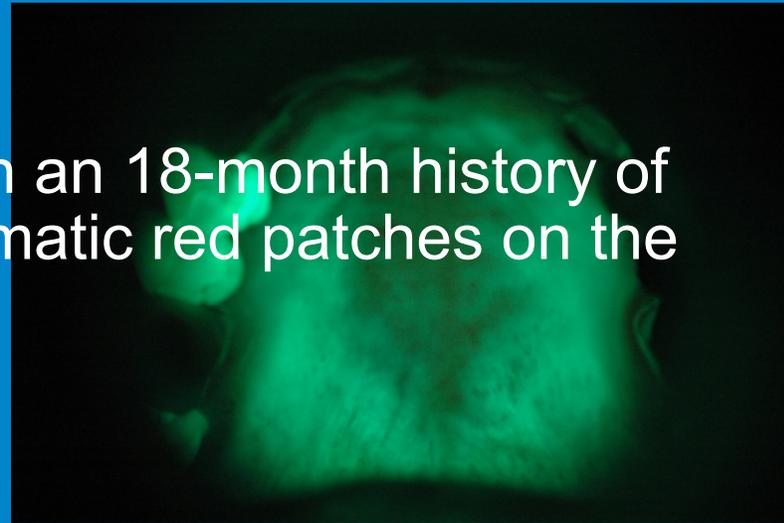
However, highly exophytic and keratinized papillomas can sometimes appear quite bright because of the high keratin content.



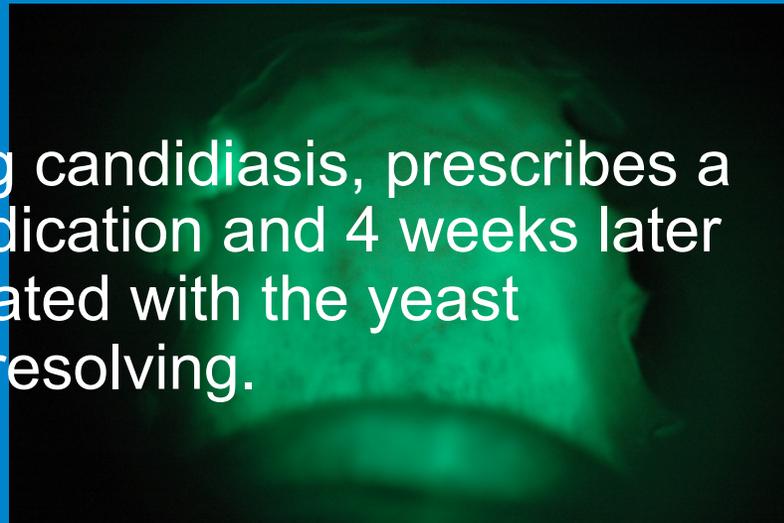
# Candidiasis



A patient presenting with an 18-month history of persistent and asymptomatic red patches on the midline palate.



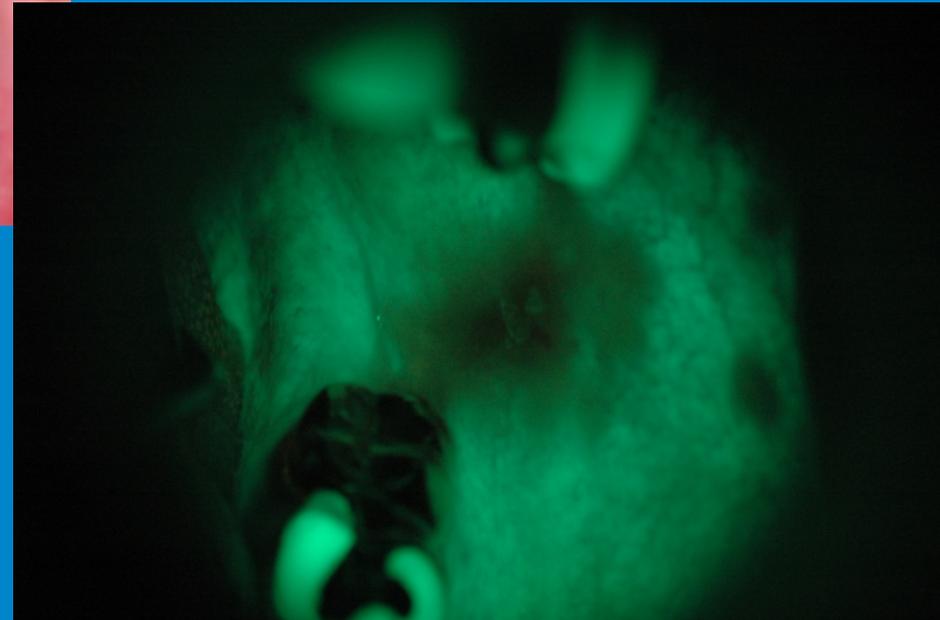
The clinician, suspecting candidiasis, prescribes a course of anti-yeast medication and 4 weeks later the inflammation associated with the yeast infection appears to be resolving.



# Lichenoid Mucositis



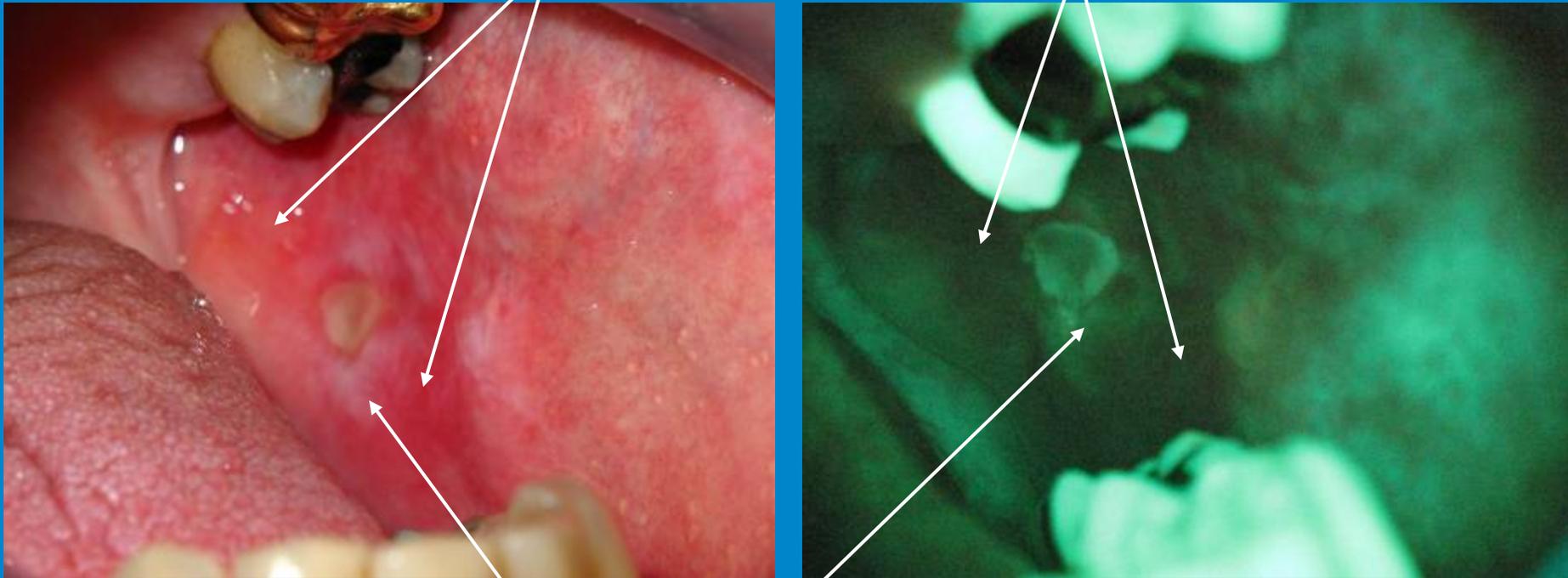
Enhanced visualization of a lichenoid reaction to a gold crown using the VELscope





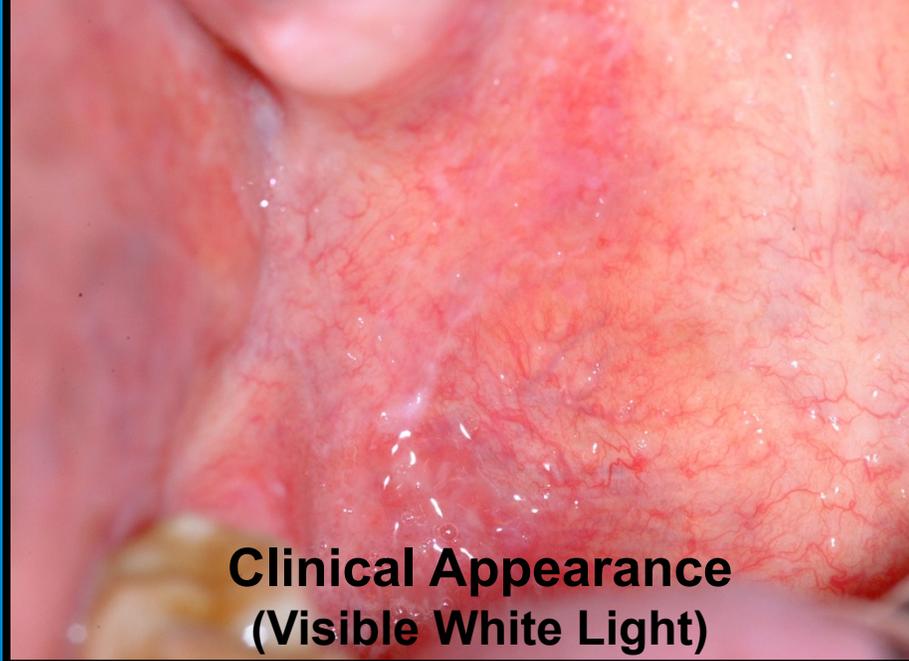
# Erosive Lichen Planus

Not surprisingly, the inflammation around the central ulceration shows up as dark under VELscope

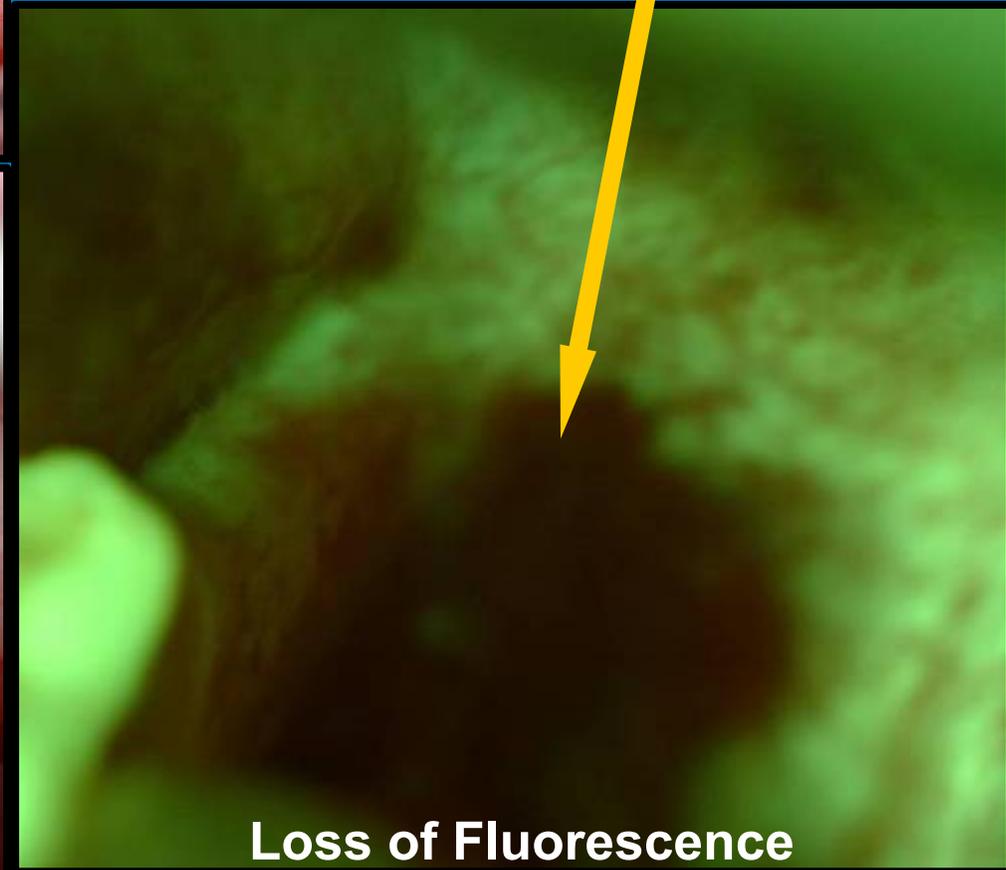


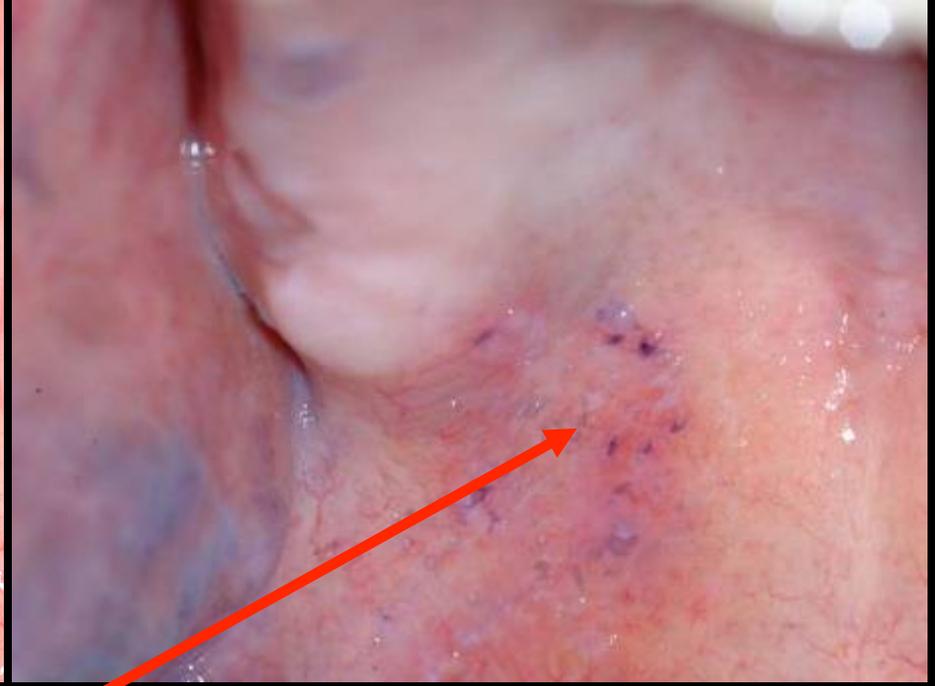
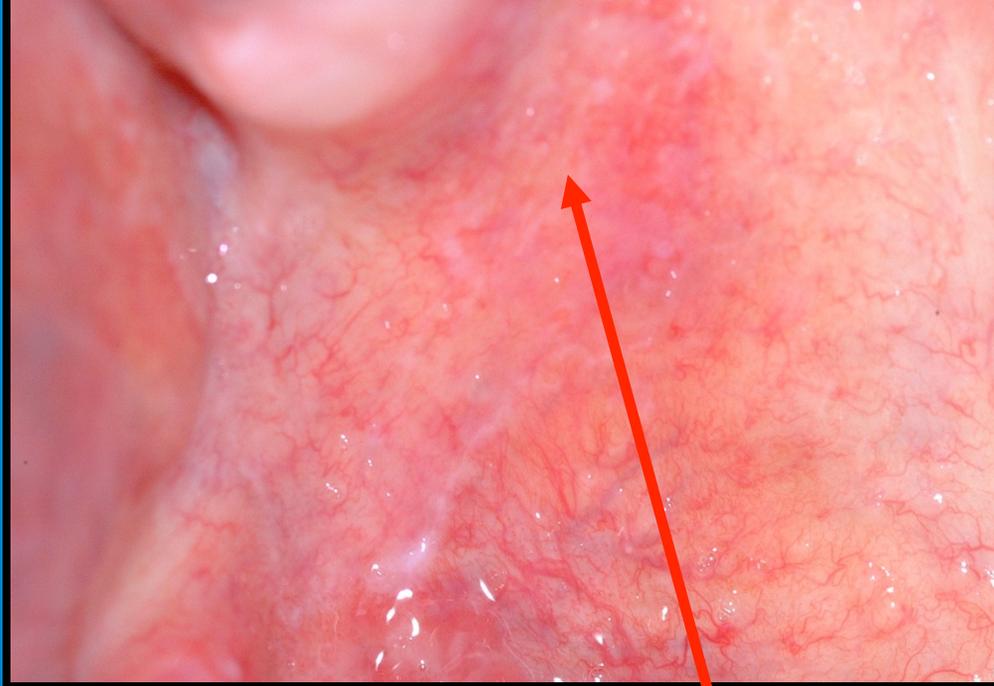
*Notice also that the keratinized (white) tissue and fibrin clot show up brighter compared to the surrounding inflammation*

# Fluorescence Visualization

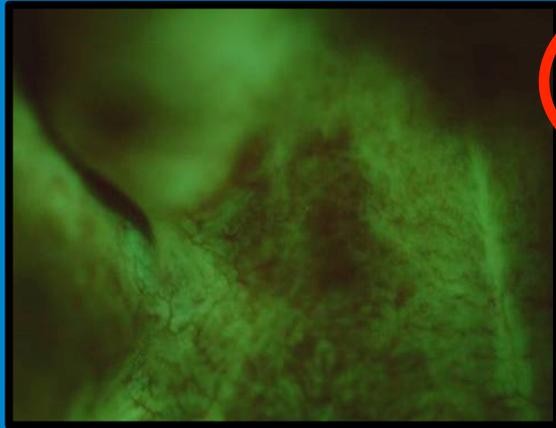


Carcinoma-In-Situ  
(CIS)



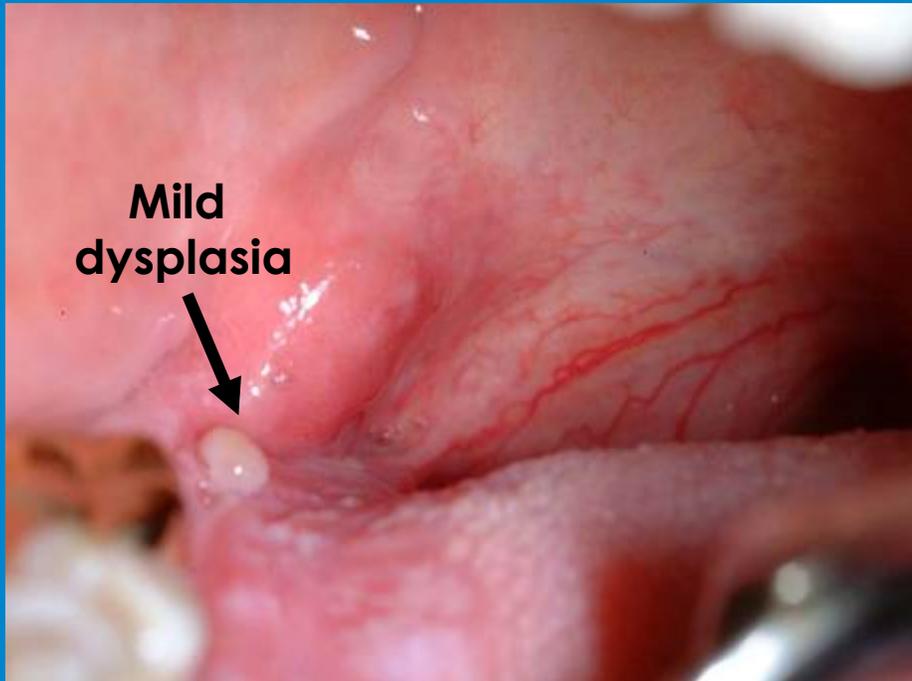


**Severe  
Dysplasia**

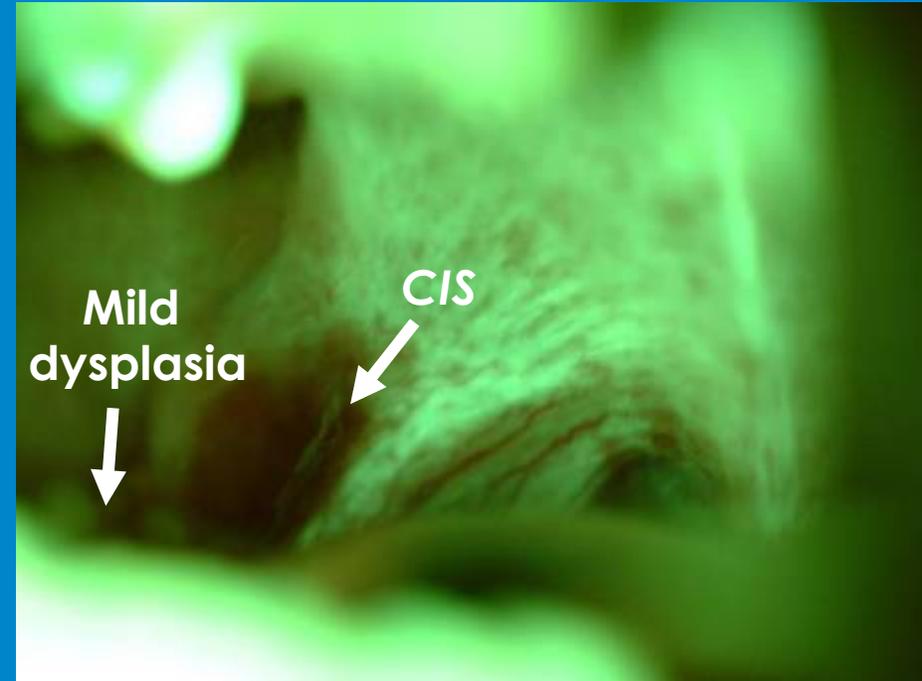


Same Patient  
(2nd Site)

# Dysplasia & Oral Cancer



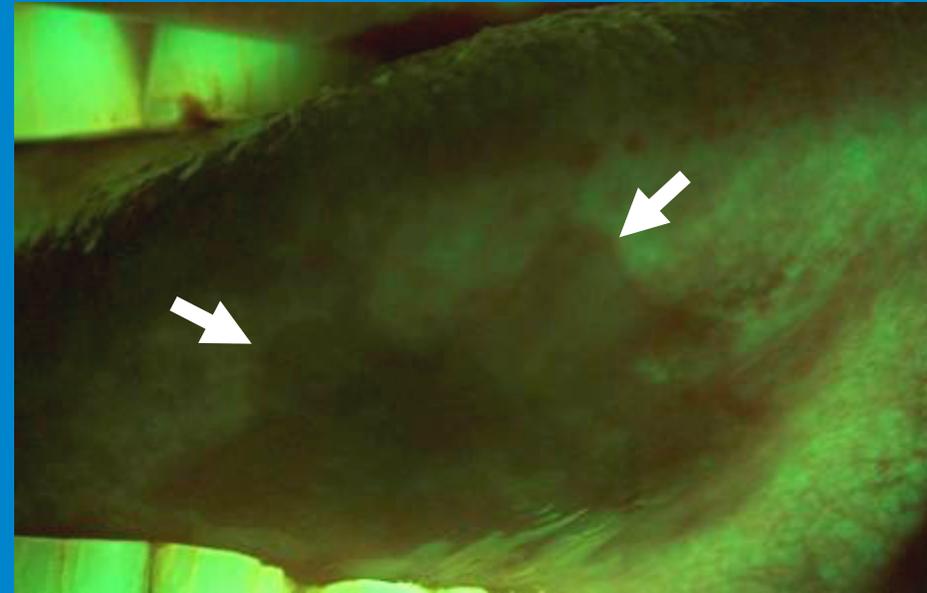
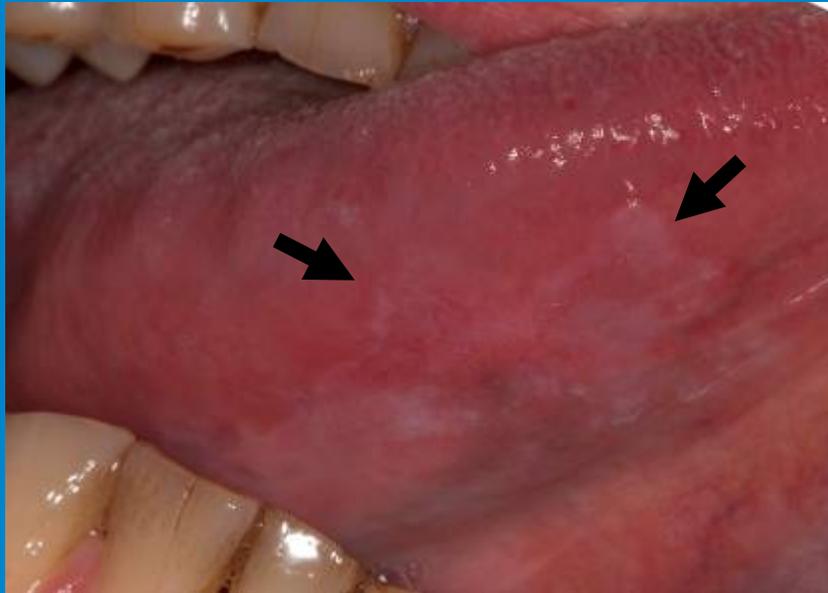
Clinical Appearance



Loss of Fluorescence:  
Region of CIS is now clearly visible

# Severe Dysplasia - Lateral border of Tongue

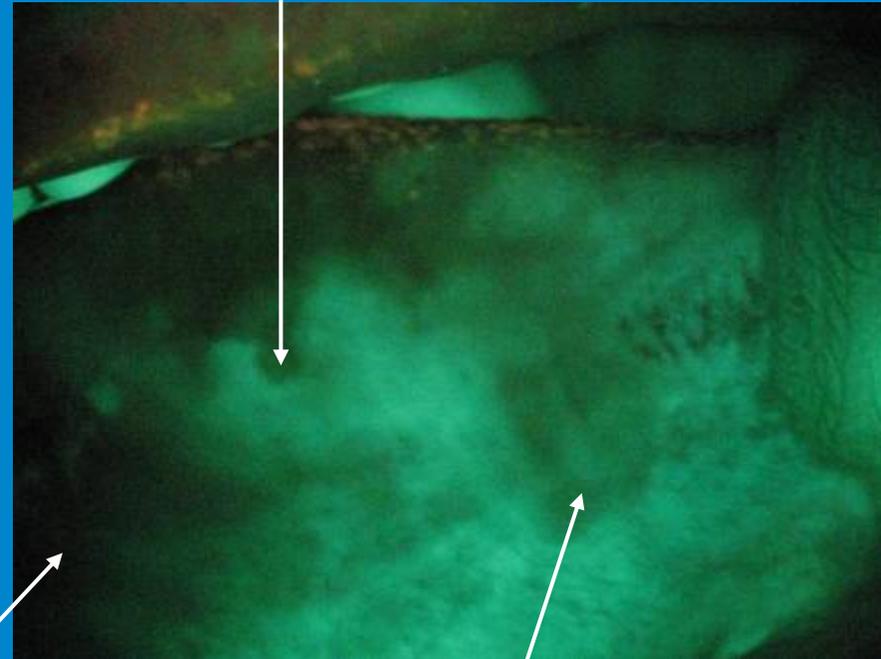
Biopsy Confirmed as Severe Dysplasia



# Dysplasia & Oral Cancer - Lateral Border of Tongue



Invasive Squamous Cell  
Carcinoma



Severe dysplasia

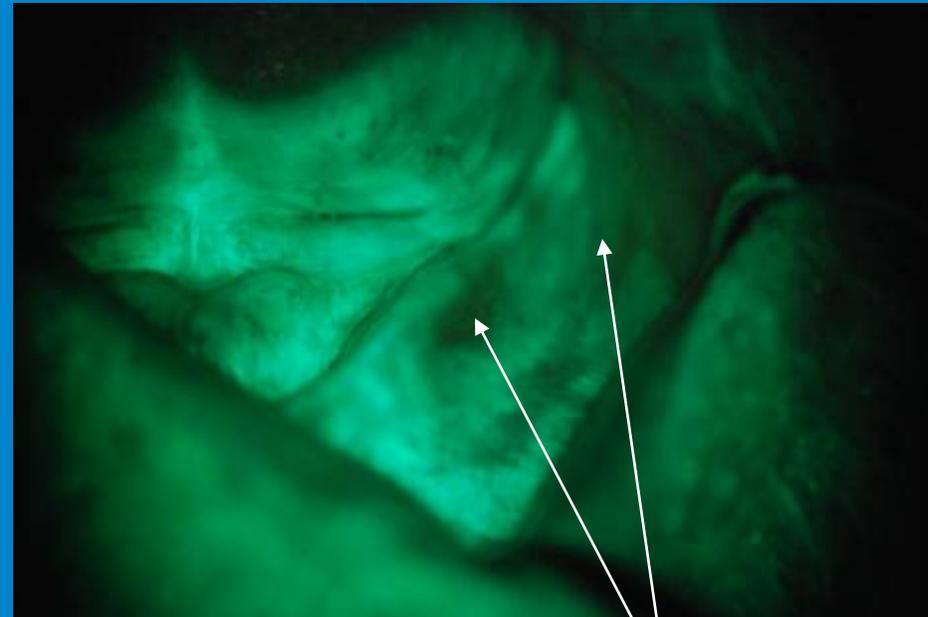
Moderate dysplasia

# Severe Dysplasia on Alveolar Ridge

Clinical Impression: Denture Trauma?



*Inflammation resolved in 2 weeks  
after removal of denture*

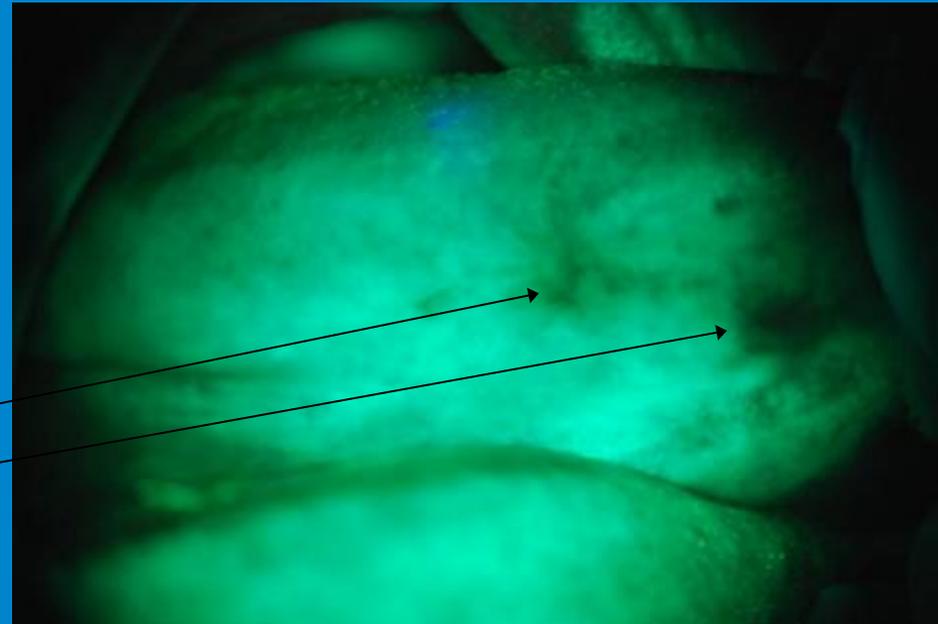


*Excisional Biopsy: Severe Dysplasia*

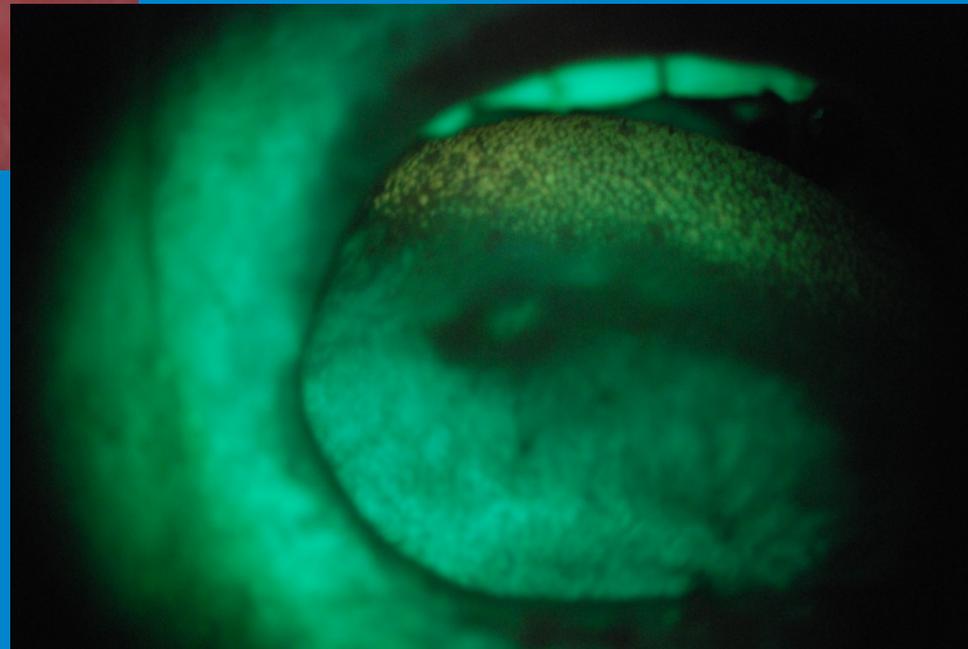
# Clinical Findings – Leukoplakia



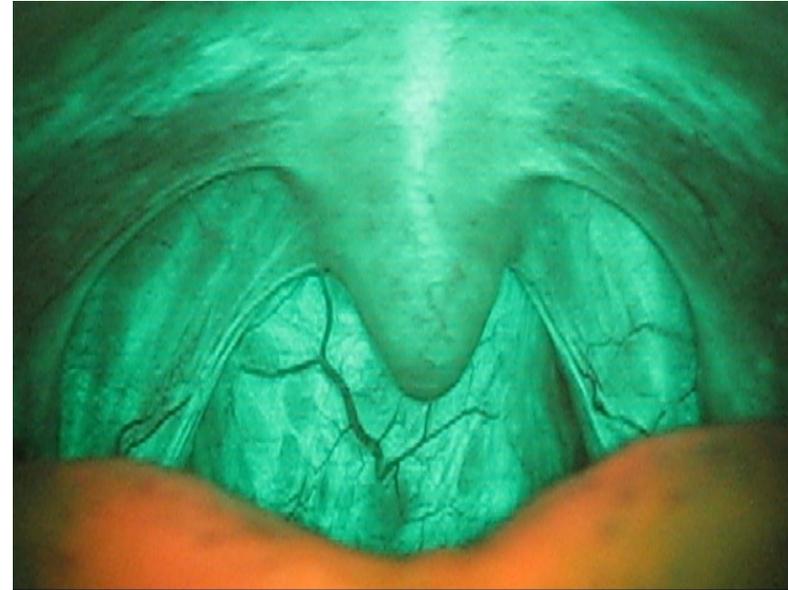
Moderate  
dysplasia







# Bilateral Presentation is a Good Thing

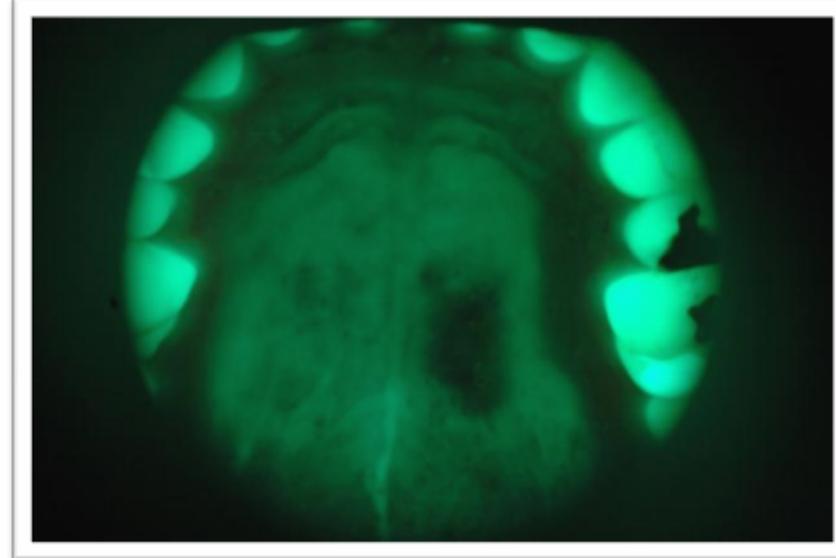


# Pre-Clinical Discovery

34 year-old male presents with 'funny' feeling on palate

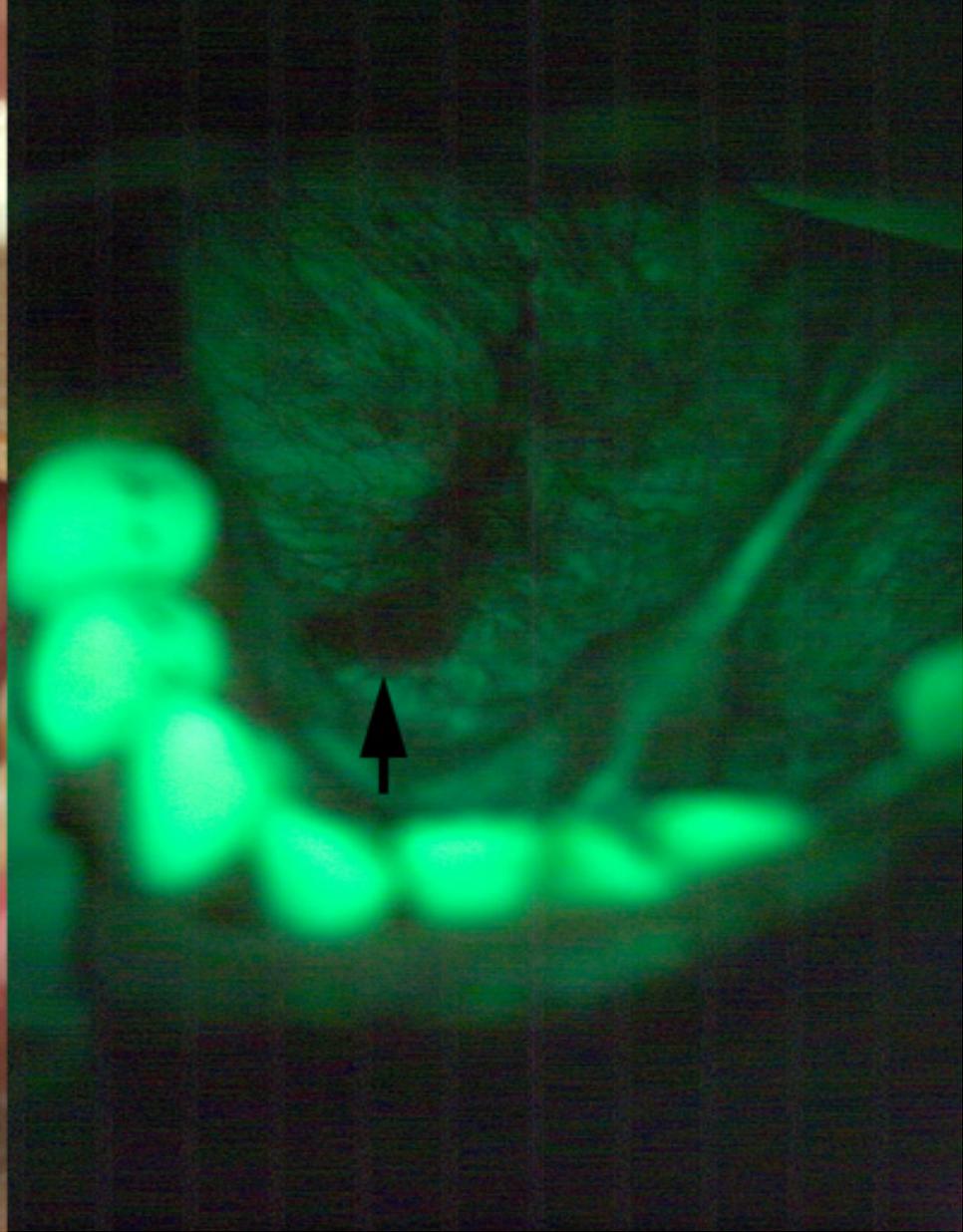
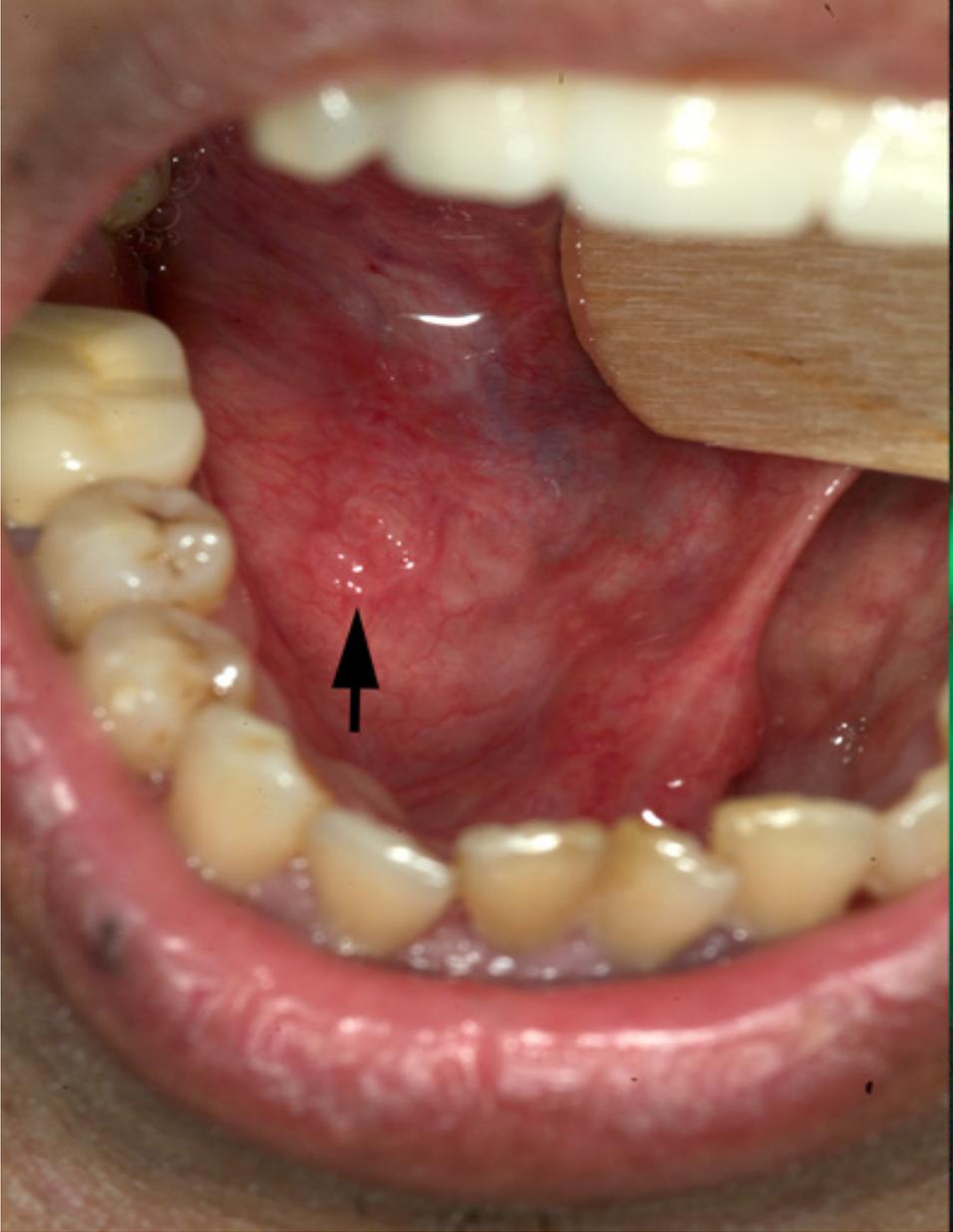


**Clinical Appearance  
(Visible Under White Light)**

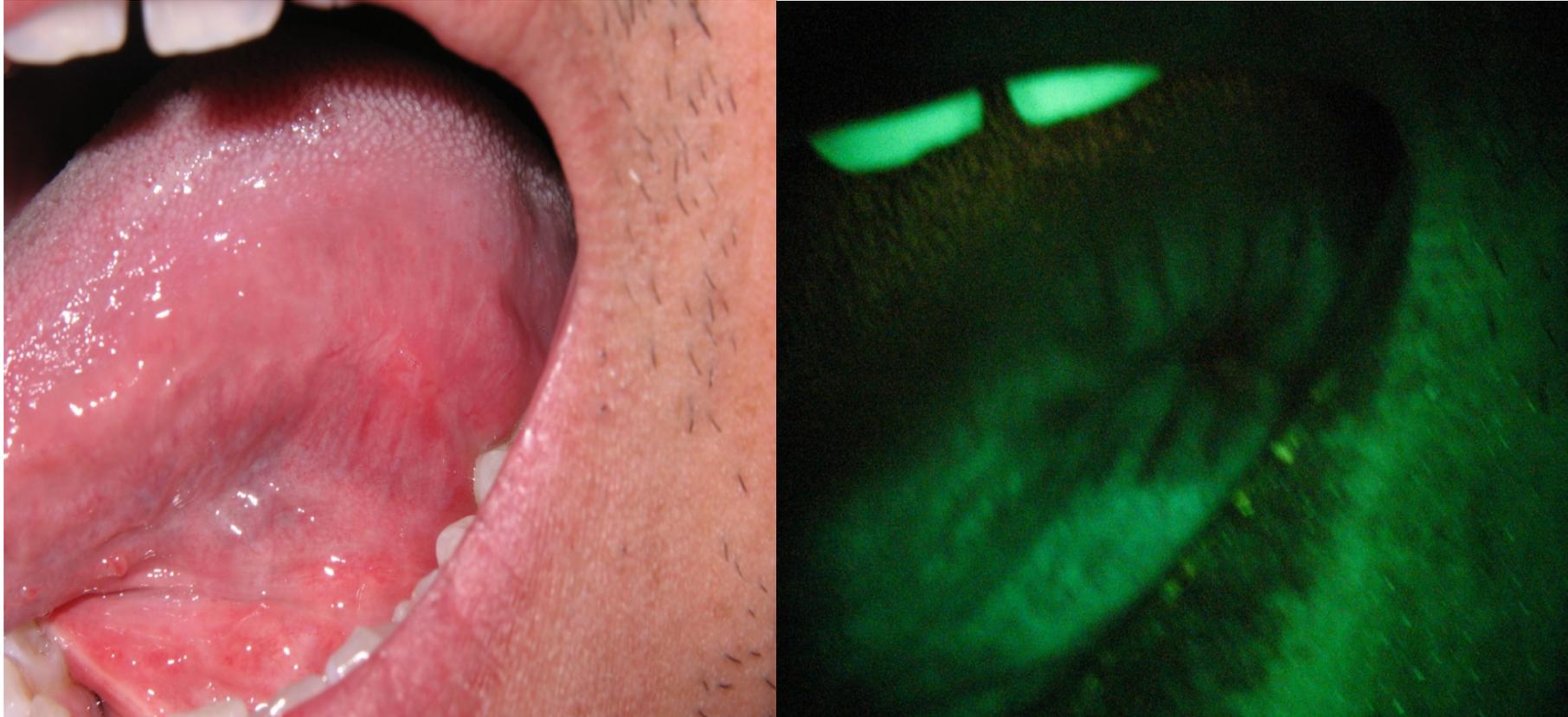


*Images courtesy of the British Columbia Oral Cancer Prevention Program.*

*Images courtesy of Dr. Samson Ng*



# Moderate Dysplasia

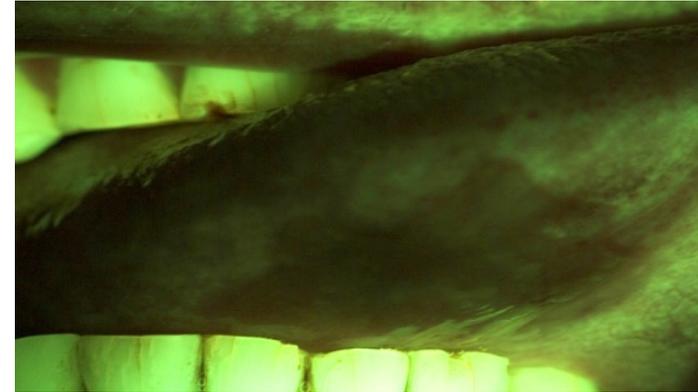


Dept. of Oral Medicine, University of Washington

Patient referred for biopsy.  
Result: Severe dysplasia.



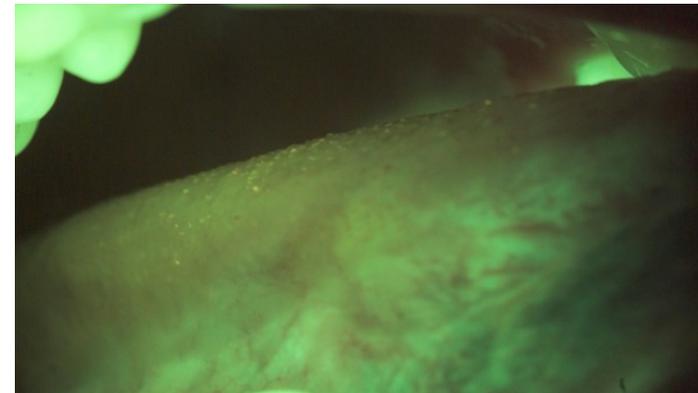
Visible Leukoplakia



Irregular, Dark Area



Visible Leukoplakia



Normal Fluorescence Pattern

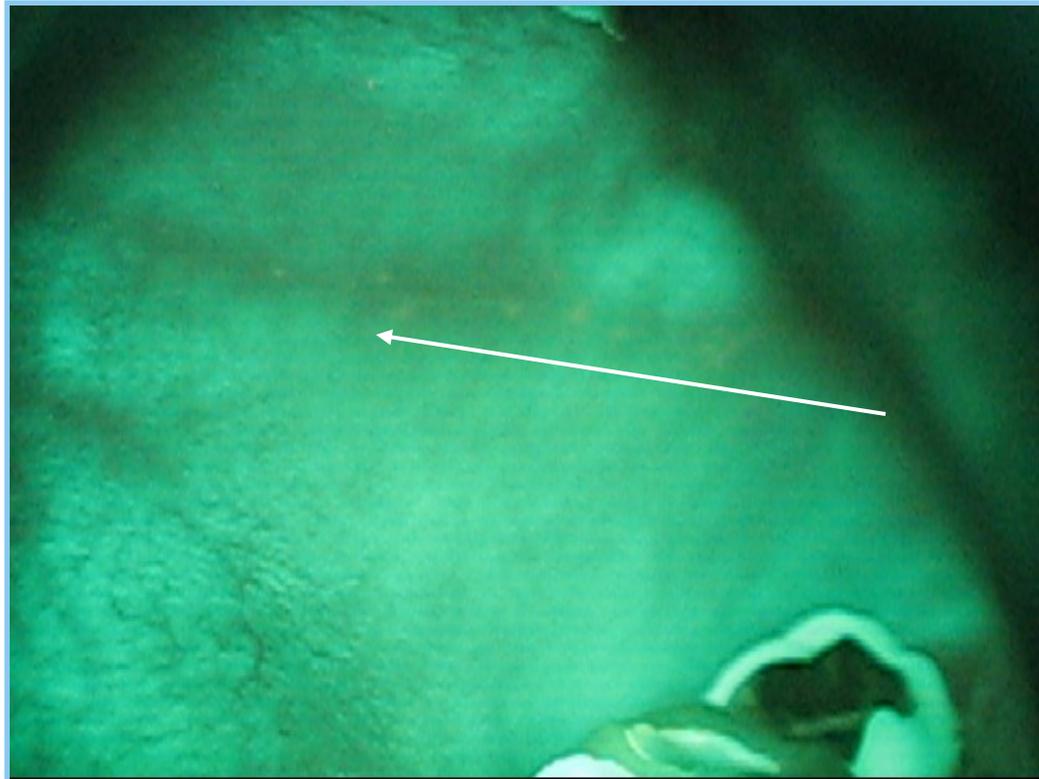
*Images courtesy of the University of Washington Oral Medicine Program*

# VELscope® Vx: The Proven Solution

Journal of Oral Pathology and Medicine:

- **NEW STUDY:** Oral Cancer Screenings are dependent upon the experience of the clinician and can vary widely. Deciding when a patient needs to be referred is a critical and difficult decision.  
(2404 patients studied)
- **CONCLUSION:** Integrating VELscope into a process of assessing and reassessing lesions significantly improved this model

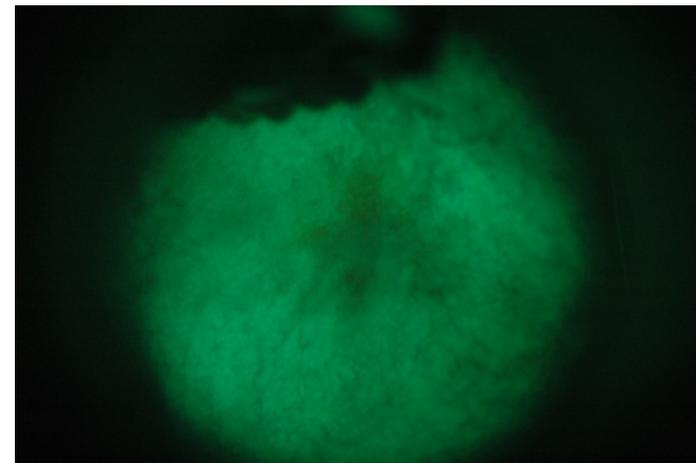
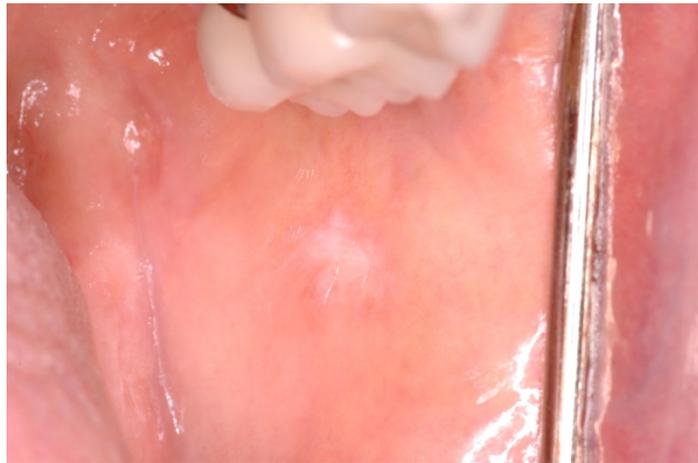
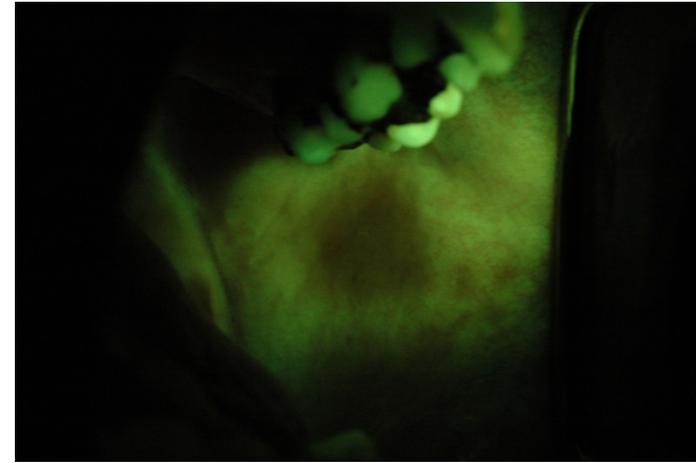
# The Buccal mucosa is quite often an area of chronic irritation and mild inflammation...



Classic Linea Alba



# Inflammatory Response & Trauma



# Blanching Under Diascopic Pressure



*This particular area is inflammation and blanches completely. Treatment and follow-up in two weeks showed complete resolution.*

1. Rudd M, Eversole R, Carpenter W. "Diascopy: a clinical technique for the diagnosis of vascular lesions", *Gen Dent.* 2001 Mar-Apr; 49(2):206-9.

# Some Important Things to Remember

**Tissue fluorescence is adjunctive:** combine what you see under FV with your white light visual & tactile exam.

**A comprehensive patient history** can be the key to helping you understand what you're seeing with VELscope.

**Understand the basics of oral cancer** – knowing where it is most likely to occur and how it presents

# Some Important Things to Remember

Recognize normal and abnormal *patterns* - **your brain is good at pattern recognition!**

Beware of a **unilateral** presentation vs. bilateral - this can help you decide what “doesn’t belong”.

Carefully **examine non-symmetrical lesions with irregular and/or well-delineated border**

# Specialist Referral & Biopsy

## You should refer when:

- A lesion is thought to be premalignant or malignant/high risk.
- You suspect a non-cancerous lesions that requires a biopsy for definitive diagnosis.
- You're not sure what it is and it does not respond to conservative therapy.

# Time Limits After Discovery (Lesions with unknown etiology)

- HIGH RISK (suspected premalignant or malignant lesions):
  - No more than 2-3 weeks before evaluation by a specialist.
- LOWER RISK Lesions:
  - No more than 5-6 weeks before a definitive diagnosis.

# What Do You Say if the Patient Asks, "Do You Think It's Cancerous?"

- “The only way to diagnose cancer is with surgical biopsy.”
- “At this time I would recommend...”

# VELscope Indications for Use

## FDA 510(k) Clearance April '07

- *VELscope is intended to be used by a dentist or health-care provider as an adjunct to traditional oral examination by incandescent light to enhance the visualization of oral mucosal abnormalities that **may not be apparent or visible to the naked eye**, such as oral cancer or pre-malignant dysplasia.*
- *VELscope is further intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion and thus **aid in determining the appropriate margin for surgical excision**.*



# How Should We View the VELscope?

- Discovery!
- Q: Is it a “False Positive” if I discover a lesion with VELscope and it isn’t pre-cancer or cancer?  
A: No more than if you discovered it with a conventional exam.
- Did this discovery lead to a positive therapeutic intervention for the patient?
- Most lesions in the Lexicomp guide have some clinical treatment recommendation after discovery.

# VELscope Can Also Help to Discover These Conditions:

- Lichen Planus
- Lichenoid mucositis
- Squamous Papillomas
- Candidiasis
- Viral and bacterial infections
- Inflammation from a variety of causes (e.g. trauma)
- Salivary gland tumors

# See Prevention in a New Light VELscope® Vx Imaging Adapter

The newest imaging solution for the VELscope Vx is designed for ease of use:

- Simple configuration via a free application
- Intuitive functionality
- Improved wireless network performance
- Image tagging with clinical description
- Fluorescence and white-light exam documentation



# Sample Consultation

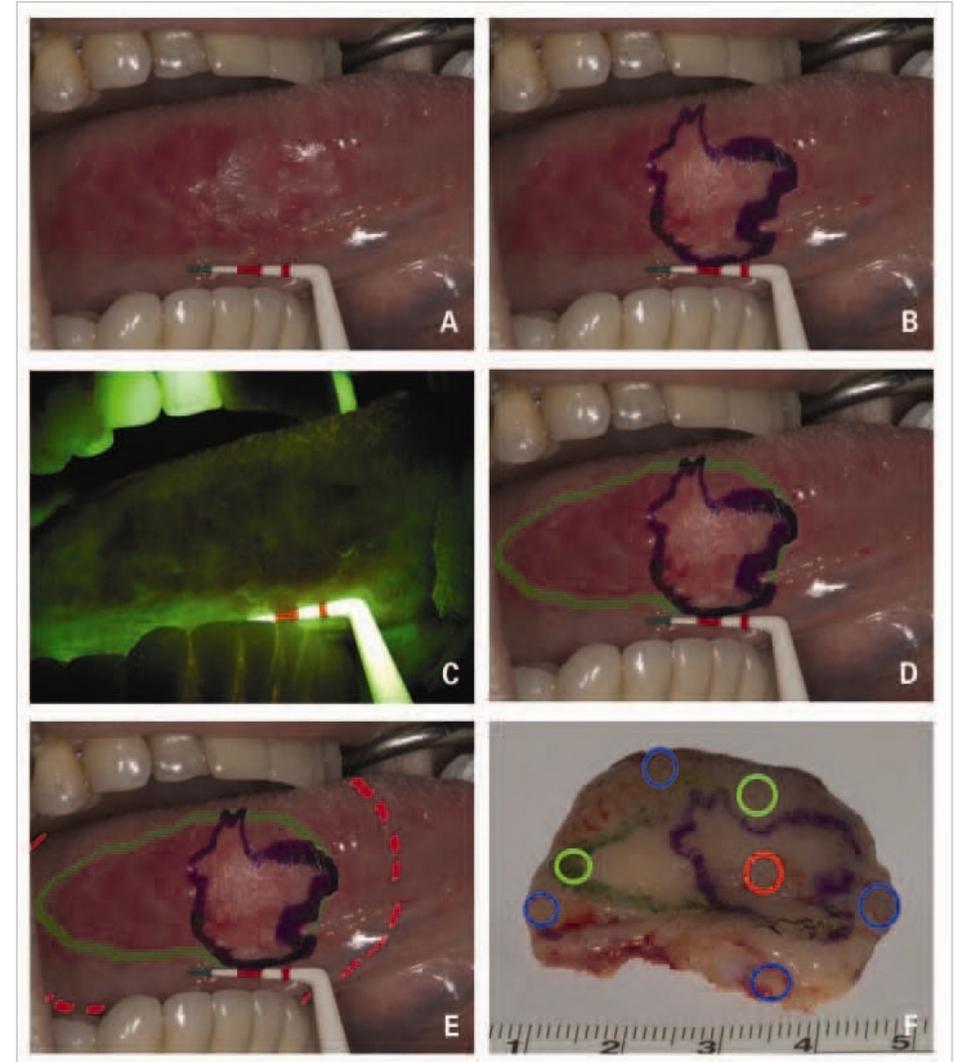
Thanks for the case. The area is highly suggestive of chronic atrophic candidiasis but could also represent another inflammatory reaction to microflora (bacterial or mixed bacterial-fungal infection, or dysplastic change associated with increased risk post lymphoma treatment including bone marrow transplant. That procedure also increases risk of chronic candidiasis and other low grade forms of stomatitis/mucositis. My recommendations for the Doctor to consider:

1. Ask about type of treatment for lymphoma (chemo, radiation with chemo, bone marrow transplant, other).
2. Development of any other cancers since lymphoma (skin cancer, throat, esophagus, other).
3. History of any other chronic infections (bacterial, fungal, yeast)
4. Presence and severity of dry mouth (hyposalivation)
5. Current medications
6. Presence of any other oral change such as any changes of the dorsum of the tongue toward the back half of the tongue

Based on the limited findings and lack of additional information I would suggest consideration of treatment to a presumed case of chronic atrophic candidiasis and treat with an antifungal as part of the diagnostic process. If the lesion clears after 2 weeks of treatment or is dramatically better, a diagnosis will be confirmed but the next question would be, why did it develop. Options include reduced immune system competence from prior lymphoma or its treatment, recent antibiotics, dry mouth, use of an inhaler.

Best presumptive treatment for candidiasis in this case would be fluconazole 100mg per day for 5 days and then 100mg every 2 days for 2 weeks and then clinical visit with new imaging. Culture is not very specific because about 50% of adults carry candida, biopsy can also be considered but I normally select presumptive treatment first in cases of this type of palatal change because candidiasis is much more likely diagnosis.

# 19 of the 20 Patients Showed Dysplasia or Cancer Beyond the Clinically Visible Lesion



Images courtesy of the British Columbia Oral Cancer Prevention Program.

# VELscope® Vx: The Proven Solution

- **STUDY:** *Tracing the ‘At-Risk’ Oral Mucosa Field with Autofluorescence: Steps Toward Clinical Impact”*
  - Published in *Cancer Prevention Research* in 2009
  - Shows that the VELscope helps delineate the margins of lesions during surgery.
  - After 12 months follow-up, a control group had a 25% recurrence of oral cancer while a group that had been operated on by surgeons with the aid of a VELscope had a 0% recurrence of oral cancer.

# Studying the Effectiveness of Fluorescence Visualization

A \$4.7 million study at the British Columbia Cancer Agency aims to quantify fluorescence visualization's effectiveness in treating oral squamous cell cancers relative to their recurrence.



## NEW STUDY RESULTS:

*Use of VELscope Tissue Fluorescence Visualization when determining surgical margins for excision significantly reduced the rate of local recurrence in preinvasive high-grade and early-stage oral cancers.*







# Fluorescence Visualization-Guided Surgery for Early-Stage Oral Cancer

- Study led by Dr. Catherine Poh, Provincial Oral Medicine Leader for Oral Oncology at the BC Cancer Agency.
- Results published January 14, 2016 in the **Journal of the American Medical Association** ([goo.gl/QyIVtn](http://goo.gl/QyIVtn)).
- Retrospective, case-control observational study that was conducted on 246 patients between September 1, 2004, to August 31, 2009.
- Showed a **significant reduction in the rate of local recurrence of early-stage squamous cell carcinoma and high-grade precancerous lesions** in patients where VELscope tissue fluorescence visualization was used to assist in determining the surgical margin for excision, compared to those patients where conventional methods were used.

**JAMA**<sup>®</sup>

The Journal of the American Medical Association

**VELSCOPE**<sup>®</sup>  
Enhanced Oral Assessment **Vx**



# Fluorescence Visualization-Guided Surgery for Early-Stage Oral Cancer

- Among the 156 patients with squamous cell carcinoma, **the 92 patients in the FV group showed significant reduction in the 3-year local recurrence rate**, from 40.6% (26 of 64 patients) to 6.5% (6 of 92 patients).
- Among the 90 patients with high-grade lesions, **the 62 patients in the FV group showed a reduction in local recurrence rate** from 11 of 28 patients (39.3%) to 5 of 62 patients (8.1%).
- The data also indicated that, **compared with conventional surgery, the FV-guided approach for squamous cell carcinoma was associated with less regional failure** - 14 of 92 patients (15.2%) vs. 16 of 64 (25.0%) and death - 12 of 92 patients (13.0%) vs. 13 of 64 (20.3%), although these differences were not statistically significant.

**JAMA**<sup>®</sup>

The Journal of the American Medical Association

**VELSCOPE**<sup>®</sup>  
Enhanced Oral Assessment **Vx**



# Fluorescence Visualization-Guided Surgery for Early-Stage Oral Cancer

- ***“This is really a revolutionary way for surgeons to visualize a diseased region. We are now working with head and neck surgeons across Canada to conduct a multi-center trial that will convince the world to change practice and improve the treatment of oral cancer.”***

~ Dr. Poh of the BCCA

- ***“The results of this important clinical study will be of great interest to oral cancer patients and practitioners alike. It adds to the growing body of peer reviewed literature that corroborates the use VELscope as an effective adjunct in oral cancer treatment, while further supporting its use in concert with a comprehensive oral examination to screen for the presence of oral cancers and pre cancers.”***

~ Dr. David Gane, CEO of LED

**JAMA**<sup>®</sup>  
The Journal of the American Medical Association

**VELSCOPE**<sup>®</sup>  
Enhanced Oral Assessment **Vx**



# Fluorescence Visualization-Guided Surgery for Early-Stage Oral Cancer

- Dr. Catherine Poh is an associate professor in the Faculty of Dentistry at the University of British Columbia, a clinician scientist at the BC Cancer Agency, and an oral pathologist and researcher at the Vancouver Coastal Health Research Institute. She is also a Canadian Institutes of Health Research clinician scientist and a Michael Smith Foundation for Health Research Scholar.
- Dr. Poh is one of two practicing oral maxillofacial pathologists in British Columbia, Canada, and an active staff member of the Oral Oncology Department of the BC Cancer Agency as well as the Oral Mucosal Disease Program at Vancouver General Hospital.
- Dr. Poh's primary research focus involves application of molecular and imaging tools for community screening, early detection, and management of cancerous and precancerous oral lesions.



**BC Cancer Agency**  
CARE + RESEARCH



# Does Fluorescence Visualization (FV) Technology Make a Difference?

A summary of peer reviewed research from a General Dental Practice.

*Huff, K., Stark, P., Solomon, L.. Sensitivity of Direct Tissue Fluorescence Visualization in Screening for Oral Premalignant Lesions in a General Dental Practice. January/February 2009 . General Dentistry.*



# Two consecutive years of screening everyone (over 12 yrs. old) in the practice. A decidedly low-risk population, right?

## WITH TEN PRE-MALIGNANT LESIONS!

### Year ONE – Visible Light only:

- ZERO pre-malignant lesions found.
- ZERO “success” rate with biopsy referrals.
- 25% “success” rate with brush biopsy.

### Year TWO – VELscope added to protocol:

- TEN pre-malignant lesions found.
- 83% “success” rate with biopsy referrals.
- 100% “success” rate with brush biopsy.

# Clinical Research



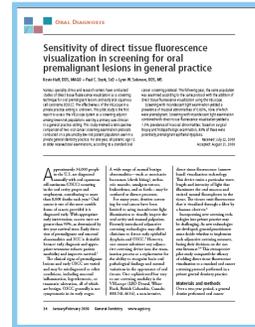
*J. Biomed. Opt.*  
11(2) Mar/Apr 2006



*Head & Neck*  
Jan 2007 Vol 29, Issue 1



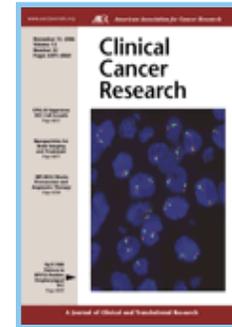
*Oral Maxillofac Surg*  
67:471-476, 2009



*General Dentistry*  
Jan/Feb 2009



*JCDA*  
Sept 2007, Vol. 73, No. 7



*Clin Cancer Res.*  
Nov 2006, Vol 12, Issue 22



*Cancer Prev Res*  
2009;2(5) May 2009

# Clinical Studies

- Impressive new findings for VELscope Vx:
  - Recent 620-patient study at University of Washington found that 11.1% of patients had lesions only detected by the VELscope exam.
- In addition to oral cancers and pre-cancers, VELscope Vx was powerful in detecting:
  - Viral, fungal and bacterial infections
  - Inflammation – including lichen planus, other lichenoid reactions
  - Squamous papillomas
  - Salivary gland tumors



# VELscope Endorsements

- June 30, 2010 – World Health Organization recognizes VELscope Vx a “an innovative device” that addresses global health concerns.
  - 1 of 8 commercial devices to be so honored.
  - The only dental device to be honored.
- AGD – partnership with LED Dental / VELscope
  - 12 oral cancer screening courses with CDE.
  - Includes advertising for VELscope Vx.
- University of Washington study led by Dr. Ed Truelove
  - Impressive new findings with use of VELscope Vx by GPs.
  - Clear case for expanded/routine usage in clinical practice.
- Many NA teaching hospitals and over 100 thought leaders are “VELscope lovers.”

# WINNER - OVER & OVER & OVER ... AGAIN

- Winner of 8 consecutive Cellerant (formerly Pride) “Best of Class” Technology Awards
- Awarded the DentalTown “Townie Choice” for the Oral Cancer Screening Category for the past 6 years
- Still #1! Used by more practices and DSOs than all other screening technologies combined



# VELscope® Vx

There are many reasons to feel good about giving your patients regular enhanced oral soft tissue exams (featuring both white light and VELscope Vx screenings)

- You're taking actions that most practices aren't.
- You're giving your patients—and yourself—peace of mind.
- You're letting patients know that you care about their health.
- It won't disrupt your practice.
  - The two exams take 5 minutes combined.
  - The VELscope Vx exam is free of rinses, dyes and discomfort.
- You're using a proven adjunctive technology trusted for millions of exams
- You'll significantly increase your bottom line.
- You'll reduce the risk of lawsuit.
- **YOU JUST MIGHT SAVE A LIFE OR TWO!**

# Implementation in Your Practice

## VELscope Vx Provides Extensive Training

- DVD Recorded Modules
- Recorded Webinar Training
- Training and Case Studies on the VELscope Vx Website, [www.VELscope.com](http://www.VELscope.com)
- Regular Seminars and Courses

# Suggested Examination Protocol

- All new adult patients and at recall patients:
  - Enhanced intra and extra oral head and neck exam including VELscope Vx exam.
  - Medical history and risk factor assessment.
- Patients with a positive risk factor:
  - At every recall appointment (e.g. every 6 months)

# Who and How Often?

- All patients 14+ should have an enhanced annual oral soft tissue exam.
- Tobacco users, heavy alcohol users and patients with a prior history of cancer should have exams every 6 months.
- The exam should have two key components:
  - Conventional white light exam with palpation
  - VELscope Vx examination

# What Should You Charge?

## CDT D0431

Direct Florescence Covered Rate is \$33.50 + E

- *Even without reimbursement, at \$15 per exam, 4 exams/day, ROI in only 8 weeks.*

# What Should You Charge?

- BC is the first province to designate a specific insurance code for the VELscope Vx examination.
  - BC Dental Code is 04403  
Direct Florescence Covered Rate is \$35.50 + E

***Even without reimbursement, at \$15 per exam, 4 exams/day, ROI in only 8 weeks.***



# You Are Doing a Potentially LIFE-SAVING EXAM.

This is a non-negotiable part of the exam

# Send a Letter to the Physicians in the Area

- Inform them you have this amazing technology in your office, and that they can reach out if they happen to find a patient with an area of concern.
- Great way to raise the level of Oral Cancer awareness in the community and build your practice.

**WHY WOULD YOU NOT ADD THIS TECHNOLOGY TO YOUR PRACTICE AS IT IS A “WIN-WIN” FOR ALL INVOLVED?**

# VELscope User Directory

## VELscope User Directory

Dear VELscope User:

Congratulations! Your decision to incorporate the VELscope® Oral Cancer Screening System into your practice is proof of your commitment to fulfilling your responsibility as the first line of defense in the fight against oral cancer.

It is our goal to assist you in any way possible in the implementation of the VELscope system in your practice. Your ongoing success will help ensure that more and more oral cancer patients will be receiving timely screening, diagnosis and treatment.

This is why we would like to invite you to be added to our VELscope User Directory. This Directory consists of an online searchable database of VELscope users, and it is intended to link oral healthcare professionals, including general practitioners and specialists, such as oral surgeons and oral pathologists, so you can share your oral cancer screening and Fluorescence Visualization knowledge and experiences with other experts. We trust you will find the Directory to be an invaluable source of information that will assist you in making the most of your VELscope experience.

The Directory is also available to the general public so patients in your area who are looking for a local dental office offering oral mucosal examinations with the VELscope system can find you. We help turn patient inquiries into customers for your dental practice.

If you agree to be added to the VELscope User Directory, the basic contact information of your dental practice will be posted on our online searchable database and it will be made instantly available to thousands of healthcare providers. This contact information consists of your name, specialty, business address, and phone number. (You can also specify an office or company name, email address, website URL, and fax number.)

All you need to do to accept this invitation is complete and sign this letter in the space provided below and return it to LED Dental Inc. by fax or mail (see contact information below). Adding your name to the Directory is totally free of charge, there is no compensation, and you can have your name withdrawn from the database at any time by just sending a written request to us directly.

Please do not hesitate to contact us should you have any questions regarding this invitation. Thanks in advance and we look forward to having you in our VELscope User Directory.

Sincerely,

LED Dental Inc.

### Invitation Acceptance

By signing below, I hereby accept the invitation to be added to LED Dental's VELscope User Directory under the conditions indicated above.

Signature: \_\_\_\_\_

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Specialty:

General Practitioner     Endodontist     Prosthodontist     Orthodontist     Periodontist  
 Oral Surgeon     Pathologist     Denturist     Other: \_\_\_\_\_

Dental Office / Company Name: \_\_\_\_\_ Phone No.: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State/Province: \_\_\_\_\_

Country: \_\_\_\_\_ Zip/Postal Code: \_\_\_\_\_ VELscope Serial #: \_\_\_\_\_

Email: \_\_\_\_\_ Website: \_\_\_\_\_

LED Dental Inc.  
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T +1 888 541 4614 F +1 604 541 4613 www.velscope.com



LED 0129 Rev D

# Why We Screen

Hey Heartland Family!

This is my first ever Heartland email, woot woot!

I have had quite an amazing week and I wanted to share it with all of you. I had a patient come in this week with a beautiful bouquet of flowers and the note read “Dr., Thanks for saving my life.” This patient then proceeded to tell me that he has been undergoing treatment for the oral cancer I detected 6 months ago and he has officially gotten the “cancer free” label from his oncologist. WOAH. \*\*\*Cue the tears\*\*\* I want to preface this with the fact that I have been practicing dentistry now for 11 months and feel so blessed to be in such a rewarding and amazing profession with such amazing people on my team! You know how to keep a patient for life? Help keep them alive! (That was his joke by the way)

I want to remind you doctors that every single one of you changes and literally SAVES lives when you do an oral cancer/soft tissue exam so go UTILIZE your Velscope! If you’ve been letting yours collect some dust, go get it out!

There’s something I believe in my life and it’s that you impact peoples lives in unforgettable ways but you may never know it. You’ll be very blessed if some of those people share those moments with you. I’m thankful that my patient shared this moment with me and I hope it encourages you all to share this with your team and go off and SAVE LIVES!

Don’t forget that every one of you changes the world in your own way every single day.

Cheers to the best profession ever, Lisa Kallis

To: All Doctors <AllDrs@heartland.com>

Subject: For Those Doubting the Velscope

I've heard a lot of people talk about the Velscope being a 'sales tactic,' and that it doesn't make any clinical difference for our patients. I'd like to share a recent experience with everyone.

We've been with Heartland for almost a year now, and have been using the Velscope for our OCSs most of that time. I recently sent out a pt to get a biopsy on his R cheek because it looked funny in the Velscope's light.

Long story short, the OS said he wouldn't have opted to do a biopsy by looking at it and was reluctant to do so, but did so because we were insistent. Upon this, he was referred out to head and neck surgeon who removed it and found an early stage carcinoma in the lesion.

The 34 y/o patient has a sore cheek for a few weeks, but is cancer-free, largely thanks to the Velscope and my 'pushy' hygienist who kept calling the pt and OS office to get the biopsy done. That certainly beats having part of his face resected...

As has been said, the Velscope isn't a miracle worker, but it is a heck of a tool in helping save our patients lives. That's my \$0.02

Pako

# “Be Part of the Change”™

And Receive a  
FREE VELscope Vx System



"Be Part of  
the Change"<sup>™</sup>  
and  
Get a Free



Screening is the Beginning of the End of Oral Cancer.



LED Dental is proud to partner with the Oral Cancer Foundation in support of their "Be Part of the Change"<sup>™</sup> program.

Routine Screening for oral disease and oral cancer is the first step toward earlier detection and better patient outcomes.

To learn how you can qualify for a free VELscope<sup>®</sup> Vx Enhanced Oral Assessment and "Be Part of the Change,"<sup>™</sup> visit [go.leddental.com/change](http://go.leddental.com/change).



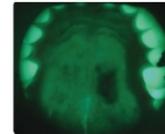
You Can "Be Part of the Change."<sup>™</sup>

- 65% of oral cancer is found late when the five-year survival rate is 54%.
- Only 31% of oral cancer is found early when the survival rate jumps to 83%.



Together we can make a difference.

Commit to regular patient screening & add a free VELscope<sup>®</sup> Vx to your practice.



Here's how it works:

- Make a commitment to perform 15 examinations per week for the next 3 years.
- Pay only for the consumable asepsis barriers at \$2.50 per patient.
- Receive your VELscope<sup>®</sup> Vx Enhanced Oral Assessment System at no charge.
- An attractive return on investment can make this commitment profitable for your practice.

For details, please call

844-952-7327

or visit

<http://go.leddental.com/change>.



# Help LED Dental and the Oral Cancer Foundation Stop Oral Cancer and “Be Part of the Change.”™

- The Oral Cancer Foundation developed the “Be Part of the Change”™ initiative to promote routine comprehensive oral examinations and earlier detection of oral cancer.
- Early detection is the best way to stop any form of cancer. And no one is better poised to spot early symptoms of oral cancer than dental healthcare providers.
- Dental professionals are uniquely positioned to take the lead in this fight. The free VELscope program was designed to encourage routine oral screening - and provide an incentive of a complimentary VELscope Vx Enhanced Oral Assessment System (retail value \$2749.00).

**In This Fight, Everyone Wins.**



# Effects of Adjunctive Screening Technology on Death Rates

Disease	Adjunctive Screening Technology Introduced	Decrease in the Death Rate	Time Period
Prostate CA	PSA Test (1986)	17.6%	1993 - 2002
Breast CA	Mammogram (1972)	45%	1972 - 1992
Cervical CA	Pap Smear (1952)	70-80%	1950 - 1990
Oral CA	Adjunctive Screening (2006) Fluorescence Visualization	unknown	2006 - now

# WHO'S AT RISK?

- Who will you screen on Monday morning?
- What might you miss?
- What will be the consequences?

***Don't let this be one of your patients.....***



**You Can Do It**  
**As a profession, you can make a difference !!**

***GET IT EARLY! GET IT ALL!***

***WITH OR WITHOUT VELscope***  
***ALWAYS SCREEN YOUR PATIENTS***



**Thank you**