Pathology Of Oral Leukoplakia/Erythroplakia: Is It Enough?

- **Histology alone is not able to predict malignant transformation.**
- Dysplasia grading is **subjective** with **poor reproducibility** and has **limited prognostic value**.

In a large retrospective study by Chaturvedi et al, of the leukoplakia patients that progressed to cancer **39.6%** had **no dysplasia whatsoever.**[1]

38-89% — **Range of sensitivity in dysplasia grading as prognostic factor.**[2]

69.9% — **Percent of time that 2 Pathologists reviewing same oral dysplasia cases agreed on the diagnosis.**[3]

LACK OF INDIVIDUAL RISK STRATIFICATION MAY LEAD TO UNDER OR OVER-TREATMENT.

Scan to learn more about **STRATICYTE™** and how the 5-year risk score can help improve care management plans for your OPMD patients.

STRATICYTE™ in Practice.

"Stratictye helps to guide clinical decision making by gaining insight into the potential behavior of premalignant oral lesion. Clinicans and patients can use this information to optimize and better personalize a treatment plan."

Dr Deepak Kademani, MD, DMD, FACS, Associate Professor Department of Oral and Maxillofacial Surgery,University of Minnesota

"Straticyte's real value is its ability to accurately & objectively identify and stratify elevated versus low-risk patients, guide OPMD patient management decisions and encourage better patient follow up compliance. Straticyte should reduce the number of patients presenting with advanced disease, thereby increasing 5-year survival rates, lowering direct and indirect health care costs and diminishing Oral Cancer morbidity."

James C. Melville, DDS FACS Professor Department of Oral & Maxillofacial Surgery Oral, Head & Neck Oncology and Microvascular Reconstructive Surgery University of Texas Health Science Center at Houston

References: 1. Chaturvedi et al, "Oral leukoplakia and risk of progression to cancer: A population-based cohort study." J Nat Can Inst. (112) 1047, 2020 **2.** Banoczy 1976, Lumerman 1995, Holmstrup 2006, Ardunio 2009, Bradley 2010, Warnakulasuriya 2011, Ho 2012, Zhang 2012, Sperandio 2013, Dost 2014. **3.** Speight et al "Interobserver agreement in dysplasia grading: toward and enhanced gold standard for clinical pathology trials" Oral Surg Oral Med Oral Pathol Oral Radiol. 2015 Oct;120(4):474-82.e2. doi: 10.1016/j.oooo.2015.05.023. Epub 2015 Jun 17. **4.** Kaur et al , S100A7 overexpression is a predictive marker for high risk of malignant transformation in oral dysplasia Int. J. Cancer 2014 134(6):1379 **5.** Assists Pathologists in Stratifying risk 5/ Hwang, JTK et al.Individualized five-year risk assessment for oral premalignant lesion progression to cancer. Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology 2017 **6.** Hwang, JTK et al. Individualized five-year risk assessment for oral premalignant lesion progression to cancer. Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology, 2017 Darling, MR et al. Assessing Oral Epithelial Dysplasia Risk for Transformation to Cancer: Comparison Between Histologic Grading Systems Versus S100A7 Immunohistochemical Signature-based Grading. 2023.

Proteocyte AI

www.proteocyte.com

For additional patient information or support please contact us at: proteocyte@patientcaresolutions.com or call 1-833-5-PROTEO (1-833-577-6836)

For all other inquiries please contact us at straticyte@proteocyte.com

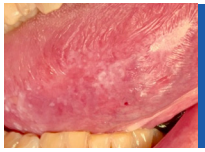
STRATICYTE is provided by Proteocyte Diagnostics Inc., a Canadian cancer diagnostics company with offices in Canada & US.

Supported by:

SPOHNC — SUPPORT FOR PEOPLE WITH ORAL AND HEAD AND NECK CANCER | EST. 1991

AAOM — The American Academy of Oral Medicine — INTEGRATING MEDICINE AND DENTISTRY

Proteocyte AI



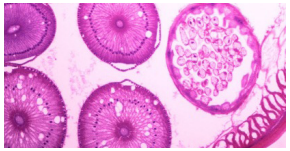
Will This Precancerous Lesion Become Invasive Cacinoma?

How STRATICYTE™ Can Help Avoid Trial and Error In Managing Precancerous Oral Lesions.

Order Your Patient's Personalized Risk Score, Today!

STRATICYTE

Predicting the Risk of Developing Oral Cancer



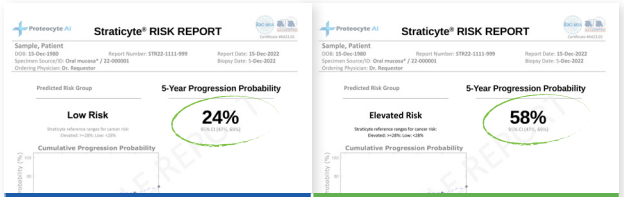
Biomarkers in Prognostic Oncology.

Why S100A7 is important and how it predicts future malignant transformation of Oral Pre-cancerous Lesions (e.g. Oral Potentially Malignant Disorders or OPMD).

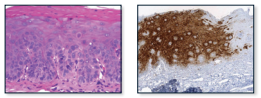
S100A7 is a calcium binding protein involved in cellular replication and cellular invasion. Found in high concentration in many human cancers, S100A7 content is associated with poor prognosis. In oral leukoplakia and erythroplakia, high lesional S100A7 is associated with malignant transformation regardless of dysplasia grading by a pathologist.

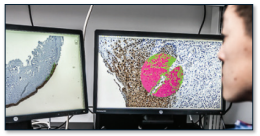
S100A7 was selected as a top performing biomarker from a panel of 811 candidate protein biomarkers.[4] This biomarker, along with several histomorphometric features, is the basis of the Straticyte test and is used to calculate a patient's individualized risk score.

Assists Physicians in Stratifying Patient Risk[5]



Low	Elevated
Patients confidently counseled on the low risk of malignant conversion and can be returned to their primary physician or dentist for routine care, following routine surveillance in the critical first 18 to 36 months (highest recurrence period).	Proactive, intense surveillance program and early interventional surgery to reduce the incidence of malignant conversion and minimize the morbidity from treatment. Patients remain under the care of the specialty clinician for 5 years during which they are examined every 3 months.





The STRATICYTE™ Test.

Using AI-driven digital technology, the S100A7 biomarker assay is used to calculate a personalized Risk Score (RS), providing guidance and peace of mind.

Your patient's RS is compared with a large cohort of patients with known clinical outcomes and at least five years of follow up.

Software identifies region of interest after cellular immunohistaochemistry staining for S100A7.

Cytomorphometrics & cellular S100A7 assay are used to compute RISK SCORE on a scale of 0-100.

Consider **STRATICYTE™** and personalize the management of your Oral Pre-cancer (OPMD) patients.

38-89%
Range of sensitivity in dysplasia grading.[2]

Dysplasia Grading

97% Sensitivity[6] **97%** NPV

With STRATICYTE™

Scan here to order and learn more about **STRATICYTE™**

The STRATICYTE™ Difference.

A personalized, signature-based cancer protection assay for Oral Cancer.

Current workflow remains same with the exception of simply ordering the **STRATICYTE™** test

Suspicious oral lesion identified during routine exam*

Biopsy performed by surgeon in office (awake patient, local anesthesia).

Simply order the STRATICYTE™ test.

Digital image of biopsy evaluated by STRATICYTE™ software.

Output	Result
Pathology lab returns report to surgeon.	Treatment plan developed for at-risk patients improving early cancer detection, leading to meaningful increase survival rates.
STRATICYTE™ report provides individual patient risk of developing oral cancer over 5 years.	

*Examine for suspicious oral lesions / oral cancer is a recommended practice standard by the American Dental Association

Simple Integration
Order the Test, **Proteocyte** does the rest!

No Additional Biopsy
Uses patient's original biopsy tissue

5-Year Risk Score
Accurate, objective, individualized.
Sensitivity of **97%** and a NPV of **97%.**