Clinical Management of Patients With Oral Epithelial Dysplasia And Elevated STRATICYTE™ Risk For Progression To Cancer

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INTRODUCTION

Approximately 90% or more of oral cancers are squamous cell carcinomas (SCCs)[1] which often begin as potentially pre-malignant oral epithelial lesions (PPOELs; leukoplakia or erythroplakia). These lesions may show a degree of oral epithelial dysplasia (OED), traditionally used as a predictor of risk for malignant transformation, however, a more objective assessment of progression risk for OED is highly desired. The management of PPOELs and OEDS remain a major challenge, but progress could be improved by understanding the molecular mechanisms and discovery of diagnostic, prognostic, and predictive biomarkers[2]. This poster highlights how a biomarker-driven prognostic modality, STRATICYTE[3], can be used in clinical practice to assess and manage patients with OED.

METHODS

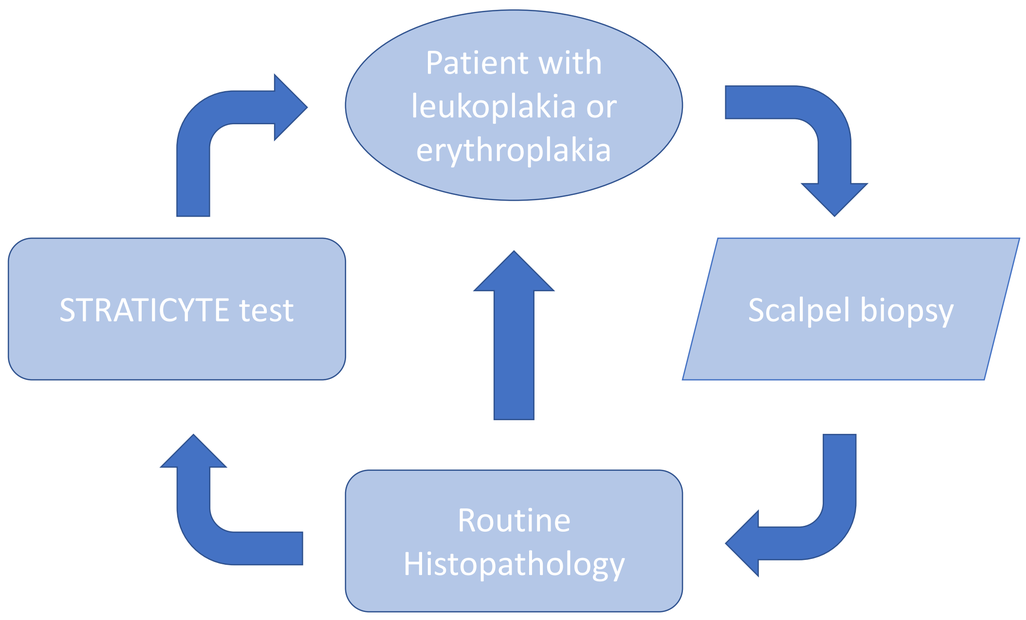

Figure 1. Addition of STRATICYTE testing does not disrupt process flow

- Patients presenting with leukoplakia or erythroplakia in the oral mucosal cavity are subjected to a scalpel biopsy.
- Biopsy specimen is submitted for routine microscopic examination by oral pathology.
- Additional unstained tissue sections are prepared (by oral pathology) from the same biopsy specimen and STRATICYTE Testing is performed:
  - Stained for S100A7 via immunohistochemistry.
  - Digitally scanned.
  - Images computationally analyzed resulting in the risk of progression to cancer score.
- Both Histopathology and STRATICYTE Risk reports sent to requesting clinician.

RESULTS

- Since 2015, 41 oral biopsy cases from 33 patients with lesions of clinical concern have been submitted for both routine histopathology and STRATICYTE testing. Patient's re-biopsied if lesion underwent suspicious changes.
- From the 33 patients, 19 patients initially presented (at first biopsy) with OED.
- Of the 19 patients, 4 patients' OED lesions progressed to cancer.
- STRATICYTE classified all 4 patients' (OED lesions which progressed to cancer) as "Higher Risk".

Table I. Summary of cases

Histopathology Diagnosis	# of cases
Hyperkeratosis no dysplasia	3
Hyperplastic candidiasis	2
Nicotine stomatitis	1
Chronic lichenoid mucositis	1
Ulcer	1
Mild dysplasia	15
Moderate dysplasia	4
Severe dysplasia	5
Carcinoma in situ	2
SCC	7
TOTAL	**41**

OED Progression Case

Figure 2. A – C, Clinical photographs of A, lesion at initial presentation; B, post-operative, left partial glossectomy; C, surgical site at 1-year post-operative follow-up; D – E, Immunohistochemistry staining of S100A7 biomarker in D, STRATICYTE Medium-Risk; E, STRATICYTE High-Risk.

Table II. Clinical timeline of OED lesion in patient above with corresponding histopathology diagnosis and STRATICYTE risk assessment.

Time (months)	Clinical Observation	Histopathology	STRATICYTE
0	White patch	Mild OED	31% Medium-Risk
6	White/red patch	Mild OED	61% High-Risk
30	Speckled white/red	Micro-invasive SCC	N/A

Patient follow-up was set to 3 month interval in light of STRATICYTE "Medium Risk" at initial biopsy.

CONCLUSIONS

- Patients with elevated STRATICYTE risk should be more closely monitored.
- STRATICYTE could become a valuable companion to the clinical exam and histopathology in establishing patient management.

REFERENCES

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CONFLICT OF INTEREST

BM Renick is an investor and currently Board Director for Proteocyte Diagnostics Inc.
MR Darling has no conflicts of interest to declare.

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