**Introduction**

- 80% of oral cancers are preceded by OPML and biopsy and histopathological grading of dysplasia is considered as gold-standard for diagnosis.
- Being an invasive procedure and the need for expert pathologist, biopsies and conventional histology are not a feasible tool for screening and surveillance in a large volume, high-risk population.
- OCT technology uses near infrared light to obtain real-time images of in-vivo tissue microstructure. This is proved to be effective in ocular pathology.
- The goal of the present study is to develop an OCT probe compatible to image oral cavity and to determine its effectiveness to diagnose OPML and malignant lesions.

**Objectives**

- Re-engineer a small, robust portable diagnostic system for oral cancer on OCT
- Develop and test the diagnostic algorithm for OCT

**Methodology**

**Work flow**

- Re engineer the OCT device
- Develop initial algorithm
- Test and improve the algorithm and OCT device
- Validate in large cohort

**Study design**

- Normal
- Benign OPML
- Malignant
- OCT imaging
- Incision biopsy (if indicated)
- Histopathology diagnosis
- OCT diagnosis
- 2 Observers
- Algorithm
- Alpha value

**Data Collection**

Field screening was performed over 1 year by field workers in India with 3rd-grade equivalent education. They were trained for 1 day, and observed continuously over the first month of this study. They were provided with a wireless-enabled cell phone for data upload, as well as direct communication link with an oral oncologist at the Mazumdar Shaw Cancer Center in Bangalore.

De-identified images as well as clinical, photographic and medical history data mages were automatically transmitted every night via Drobo system to a server at the University of California, Irvine. There, images were analyzed visually by 2 pre-standardized blinded scorers and (2) scored by an automated diagnostic algorithm. Gold standard was histopathology.

**Results**

- Normal
- Lichen planus
- Pyogenic granuloma
- Hyperkeratosis
- Severe dysplasia
- OSCC
- OSCC

**Histopathology**

- Clinical image
- OCT image

<table>
<thead>
<tr>
<th>Alpha values</th>
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<tbody>
<tr>
<td>Normal</td>
</tr>
<tr>
<td>Dysplasia</td>
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<tr>
<td>Malignant</td>
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</tbody>
</table>

For differentiating SCC and high grade dysplasia from normal/benign/low grade dysplasia

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
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<tr>
<td>80</td>
<td>66</td>
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<tr>
<td>Alpha value cut off = &gt;1.52</td>
<td></td>
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</tbody>
</table>

**Sensitivity and specificity**

**Inter-observer agreement**

- Sensitivity: 90.0
- Specificity: 77.8
- Criterion: >1.335
- Sensitivity: 80
- Specificity: 66
- Alpha value cut off = >1.52

**Discussion**

Our novel device demonstrated the potential for detecting oral dysplasia and malignancy earlier and improving oncologic outcomes in low-resource, remote, non-specialist settings. It is ideal for non-invasive, point-of-care community-based screening of high-risk subjects enabling earlier detection of premalignant and malignant lesions in patients.

**Conclusion**

A simple, non-surgical imaging-based approach may greatly improve screening and detection of oral pre-cancer and cancer.