Point of Care Device/Lab based assay for Screening and Diagnosis of Oral Cancer

Aaron Weinberg, DMD, PhD, Santosh Ghosh, PhD, Umut Gurkan, PhD
School of Dental Medicine, School of Engineering, UH/CWRU School of Medicine
Case Western Reserve University

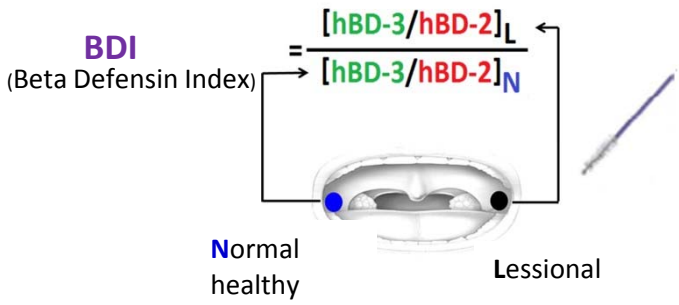
BACKGROUND

Oral cancer is the 6th most common cancer in the world today, with 350,000 annual deaths worldwide (11,000 in US). In India, it is number 1 cancer in males and number 3 cancer in females, partly as a result of the widespread use of gutka, a carcinogenic stimulant similar to nicotine. Unfortunately, most oral cancers are not diagnosed until they have reached an advanced stage. At present, oral cancer is diagnosed by scalpel biopsy, followed by a pathology review. This diagnosis is costly, invasive and subjective, which creates an unmet need for a **rapid, low-cost, non-invasive, objective screening of oral cancer**.

Researchers at Case Western Reserve University discovered that the ratio between the proteins, **human beta defensin 3 (hBD-3) and human beta defensin 2 (hBD-2)** can detect early signs of oral cancer in suspicious lesions of the oral cavity. Based on this discovery, they are developing **a Lab based assay** along with a **point-of-care test that are cost-effective, reliable and non-invasive.**

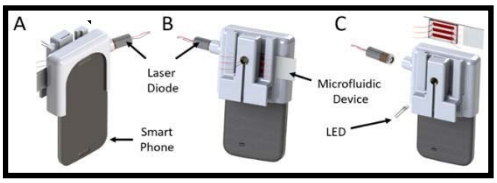
TECHNOLOGY

The proposed point of care device consists of a microfluidic chip to analyze cell samples collected with a cytobrush from 1) a suspected lesion and 2) healthy tissue on the opposite side. The ratio of two analytes (hBD-3:hBD2) is measured in the samples to provide a score that can indicate whether the lesion is cancerous or not. Results can be analyzed with a handheld device coupled to a smart phone.



Cyttobrush samples

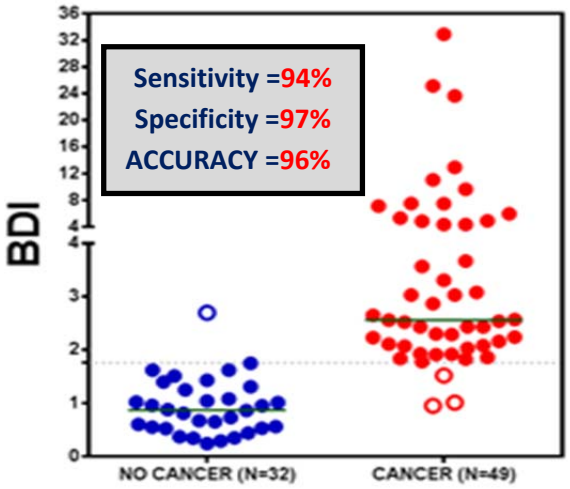
Since the assay **relies on two analytes** (hBD-3 and hBD-2), it is more robust and specific than assays based on single analytes. In addition, each subject is her/his own control, promoting increased sensitivity and specificity.



Hand held microfluidic chip analyzer

DATA

The biomarker test is currently being validated in a clinical trial (81 subjects, US cohort) with very favorable results to date.



ADVANTAGES

Non-invasive Biomarker Test

- Robust and specific assay
- Can allow oral cancers to be identified at a much earlier stage to improve survivability
- Can determine whether a biopsy is needed
- Can be used for continued monitoring of lesions

Lab based Assay/Point of Care Device

- Can be performed in any dental or ENT clinic as part of oral health check-up
- Provides **rapid, objective results in one day (Lab based)/30 minutes (POC)**
- **1/10th cost of biopsy**.

INTELECTUAL PROPERTIES

- U.S. Patent 8,076,088
- **PCT/US2016/066972**

For more information, contact:
Stephanie Weidenbecher
Licensing Manager, Technology Transfer Office
saw43@case.edu | (216) 368-6191 |

CASE WESTERN RESERVE UNIVERSITY EST. 1826