



## DROROSCOPE - "A NOVEL DIAGNOSTIC AID IN THE EARLY DETECTION OF ORAL POTENTIALLY MALIGNANT AND MALIGNANT LESIONS"

### Dental Science

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### ABSTRACT

**Aim:** The aim of the study was to evaluate the efficacy of DrOroscope (International patent publication no. WIPO/PCT WO2019/035024 A1) in the early detection of oral potentially malignant and malignant lesions

**Materials and Methods:** From a pool of 1000 patients, 170 subjects with oro-mucosal lesions were subjected to thorough clinical, blue light analysis and the suspicious lesions were subjected to histopathological evaluation. Considering the histopathological inference as a standard parameter, a comparison was made with the result obtained using DrOroscope to evaluate the efficacy of the latter.

**Results:** Of the 170 subjects 28.3% of the sample with lesions sounded dysplastic and the rest fell into pigmented, aphthous & traumatic ulcer's categories. A comparison amidst the diagnostic efficacy of DrOroscope & histopathological evaluation unveiled a sensitivity of 100% and a specificity of 98.3%. The analyzed data through statistics has put a P value which is much lower than 0.05 reinforcing the efficacy of DrOroscope as the results were in par with histopathological assay.

**Conclusion:** DrOroscope can be used as a clinical diagnostic aid in the detection of potentially malignant and malignant lesions of the oral cavity. Alongside, it also delineates the borders, while a biopsy or surgical excision is instituted.

### KEYWORDS

DrOroscope, Biopsy, fluorescent light, malignancy, pre-malignancy

### INTRODUCTION

Oral cancer includes a group of neoplasms affecting any region of the oral cavity, pharyngeal regions, and salivary glands. However, this term tends to be used interchangeably with oral squamous cell carcinoma (OSCC), which represents the most frequent of all oral neoplasms. It is estimated that more of 90% of all oral neoplasms are OSCC.<sup>1,2</sup>

Worldwide, oral cancer accounts for 2–4% of all cancer cases. In some regions, the prevalence of oral cancer is higher, reaching around 45% of all cancers in India and 10% in Pakistan.<sup>1,2</sup>

OSCC is a major health problem worldwide. It is among the most common cancers seen in both Indian men and women as can be gauged from the records of the National Cancer Registry Programme.<sup>3</sup>

Potentially malignant disorders (PMDs) are a group of lesions which have a thorough inclination to transform into malignancy if left untreated/observed. The subtle changes in their clinical presentation may demand histopathological evaluation leaving the patient morbid for a while in attaining a definitive diagnosis. In the process of minimizing the morbidity, precise evaluation of the lesion borders a new device was innovated in the DrOroscope (International patent publication no. WIPO/PCT WO2019/035024 A1).

### Early detection of the oral lesions

Clinical diagnosis remains the prime method for the early detection of oral cancers.<sup>4,5,6,7</sup> Clinical identification again depends on the knowledge and experience of the doctor. This suggests use of adjunctive diagnostic aids. Nevertheless, the use of diagnostic armamentarium is of paramount importance in conjunction to visual examination, such as the VELscope, OralID, ViziLite, Identafi etc.

### MATERIALS AND METHODS

A total of 1000 patients attending the outpatient department of SVS Institute of Dental Sciences, Mahabubnagar, Telangana & MNJ Institute of Oncology & Regional Cancer Centre, Hyderabad,

Telangana were screened for oral lesions after obtaining institutional ethical committee approvals (ECR/227/INST/AP/2013/RR-16). The study procedures were carried out in accordance with Helsinki declaration.

The study sample comprises of 170 subjects with oro-mucosal lesions.

The study took its progression after acquiring basic information yet precise in a specially designed format from every subject after obtaining an informed consent in their respective vernacular languages adhering to the Institutional ethical committee protocols.

The core of the study started with a thorough clinical examination of the lesion under aseptic and sterile environment and subsequently to DrOroscope. After a diagnostic evaluation with the device the lesions were subjected to biopsy and a comparative evaluation of the diagnosis is made to standardize the efficacy of the device.

### Device description:

The present device DrOroscope is a hand-held, portable, noninvasive cost effective device used for inspection of various malignant and PMDs.<sup>8</sup>

The device can be witnessed physically with 3 parts (Figure 1).



Figure 1: DrOroscope device.

1. Working end (Oral end)
2. The shaft/handle
3. Tail end/connector end

The working end/oral end of the device lodges an LED(Light emission diode) which can emit 3 different wavelengths of light(Blue, Red & amber) and a camera. The shaft connects the working end & the tail end facilitating easy grip. The shaft has a control switch with which the intensity of the emitted wavelength can be modulated to suite the illumination of screening area.

The camera of the device captures the images and can transfer the same to laptop or an android device.

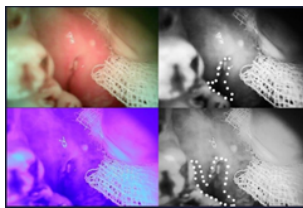
The tail end of the device has a cable with a provision to connect it to any android device (mobile or tablet) or a laptop computer and can be operated through an application software in which the inbuilt filters will facilitate the comparison of clinical pictures with those taken by the device.

It needs <1 min for its application cutback char side time. The device is supplied with disposable sleeves to make it safe from the cross-infection prospective.

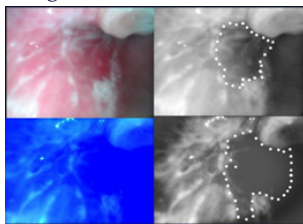
The device is supported by android application software with inbuilt features to enhance the lesion by various filters to aid in diagnosis.

**Analysis:**

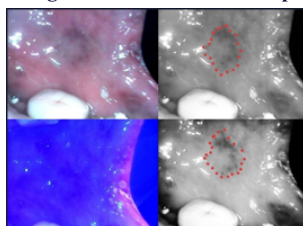
Captured images (both clinical and under the influence of the emitted light through device) were processed using filters in the software application and comparison was done by mapping the borders of visible dark area (Figures 2, 3, 4, 5). The pixels within the mapped area was calculated through software algorithm, and the values of clinical image and lesion captured under the influence of light were compared based on the percentage of difference the diagnosis was made.



**Figure 2: Filtered images of a case of oral cancer**



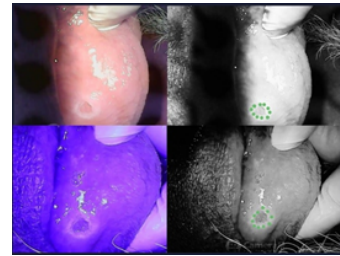
**Figure 3: Filtered images of a case of oral Lichen planus**



**Figure 4: Filtered images of a case of pigmentation**

**Table 2: Details paired differences between clinical vs blue light filtered pictures of lesions.**

Paired Samples Test		Paired Differences				t	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference			
					Lower			Upper
PMDs	Clinical vs. Blue light	-2.2550333	1.8608847	.7597030	-4.2079121	-.3021546	-2.968	.031
Non PMDs	Clinical vs. Blue light	1.48775	2.20986	1.10493	-2.02862	5.00412	1.346	.271



**Figure 5: Filtered images of a case of Traumatic ulcer**

**Statistical analysis**

Potentially malignant lesions observed in each patient were examined twice: The first examination consisted of a thorough visual and tactile examination followed by examination with DrOroscope instrument, second examination included surgical biopsy. The malignant potential of each detected lesion was determined;

A total of 50 cases were suspected for PMDs. Sensitivity, specificity, accuracy, positive predictive value, and negative predictive value were calculated using the following formulas:

$$\text{Sensitivity} = [\text{true positives}/(\text{true positive} + \text{false negative})] \times 100$$

$$\text{Specificity} = [\text{true negatives}/(\text{true negative} + \text{false positives})] \times 100$$

**RESULTS**

The patient distribution was statistically analyzed. Of the 170 patients, 93 were males and 77 females. The mean age is 39.6 years. The total data was categorized as PMDs and non-PMDs, where 50 patients were with PMDs and 120 were non-PMDs after clinical intra-oral examination. Of the 50 cases suspected for PMDs, 48 cases were diagnosed as high-risk lesions by histopathological confirmation after surgical biopsy.

When the sample distribution was analyzed, the incidence of PMDs was high in male compared to female subjects, its vice-versa in non PMDs. Of the PMDs majority of the lesions recorded were of lichen planus (n=20).

The mean area of the PMD lesions in clinically filtered pictures is 5.745±2.86 sq.mm while with blue light filter it is 8.0±3.71. In non-PMDs the area is 6.52 ±2.44 in clinically filtered pictures and 5.03±0.65 sq.mm using blue light filter. In the first group i.e. PMD group t value of -2.968, n non-PMD group t = 1.346. Table-1, details the statistics of area of the lesion with and without blue filter. Table 2 shows paired differences between clinical vs blue light filtered pictures of lesions.

**Table 1:Details the statistics of area of the lesion with and without blue filter**

		Paired Samples Statistics			
		Mean	N	Std. Deviation	Std. Error Mean
PMDs	Clinically Filtered	5.74580	48	2.8617232	1.1682936
	Blue Light filtered	8.00083	48	3.7148736	1.5165908
Non PMDs	Clinically Filtered	6.5228	122	2.44439	1.22219
	Blue Light filtered	5.0350	122	.65567	.32783

### Subjects' distribution according to the types of lesions.

Traumatic ulcer had the highest incidence and pemphigus vulgaris was the least common.

The percentage of benign lesions was 71.7% (122 patients). And in the suspected lesions were 48 (28.3%), which included 20 cases of lichen planus, 13 were leukoplakia, 6 Oral Submucous Fibrosis, 9 subjects with OSCC and a case of pemphigus.

The above mentioned cases were confirmed with histopathology reports.

Table 2 shows that P-value was much lower than 0.05, so we can conclude that at 95% confidence level, there were significant differences in DrOroscope results between benign in biopsy group and malignant/dysplastic in biopsy group subjects; percentage of benign subjects in benign in the biopsy group was greater than the percentage of benign subjects in malignant in the biopsy group. Also, the percentage of malignant subjects in benign in the biopsy group was lower than the percent of malignant subjects in malignant in the biopsy group.

The sensitivity and specificity of this device as per the sample were 100% and 98.3%. So, DrOroscope was statistically effective in detecting lesions' malignancy.

### DISCUSSION

The recent past has visualized the emergence of various adjunctive devices for the detection of oral cancer. This is because oral cancer has been the leading cause of death in both the developing and developed countries. Oral cancer being a broader term includes various malignant disorders. The cancer & its therapies are associated with morbidities and they affect the quality of life. Oral cancer is the 6<sup>th</sup> most common cancers in Asia<sup>9</sup> and Ranks top 3 of all the cancers in India.<sup>10</sup>

The survival rate of the patients suffering from oral cancer can be broadened by monitoring the following three main governing factors:

- Early detection of the lesion
- Proper diagnosis of the lesion
- The approach of treatment.

Elimination of the risk factors should be taken into consideration. Clinical intraoral examination of PMDs and proper radiographic study are important for the detection of the lesion. But unfortunately, they are not enough for detecting malignant and premalignant lesions.

Final diagnosis should be based on histopathological examination of the biopsied specimen. Several techniques have been introduced which aid in the early detection of malignant or premalignant lesions, such as OralCDx, Toluidine coloring, ViziLite, Identafi, and VELscope.<sup>11</sup> In the Current literature a number of articles explain the importance of these aids as atraumatic to surgical biopsy with pros & cons.

To fill the dearth with better properties DrOroscope - a novel diagnostic device was designed & the efficacy of the same is evaluated through the study. The machine's efficiency to act as a diagnostic aid for the differentiation of malignant and the premalignant lesions depends on the final decision made on the basis of the gold standard "surgical biopsy."

The results of our study are in accordance with the results of Poh et al. on VELscope who found in 2006 that in the differentiation between normal and defective mucosa, the sensitivity value was 97% and the specificity value was 94%.<sup>12</sup>

We obtained results similar to that of Kois and Truelove, (2006) with a sensitivity of 98% specificity 100% who used VELscope as an aid for visual inspection.<sup>13</sup>

In 2004, Scheifele et al.,<sup>14</sup> studied 80 cases for oral cancer screening with OralCDx, showed sensitivity of 92.3% and specificity of 94.3%. The present study too shows similar results with DrOroscope Balevi, (2007) in an opinion article described VELscope to be having sensitivity of 98% and specificity of 100%. The present study with DrOroscope too shows similar values.<sup>15</sup>

The present study results using DrOroscope, agreed with the study of Lee and Wong<sup>16</sup> who reported in their study that the sensitivity and

specificity of VELscope is high and almost absolute when it comes to the diagnosis of malignant lesions.

Our results are similar to the results of Farah et al.,<sup>17</sup> who studied 44 cases histologically and by VELscope clinically, and obtained a sensitivity of 100% and a specificity of 96%. Compared to the study piloted by Ganga R S et al.,<sup>18</sup> on VELscope, the current study employing DrOroscope exhibited superior sensitivity and specificity.

The statistical analysis of the device with a sensitivity of 100% & specificity of 96% marks its rigidity as a screening device. The hand held portable device with non-invasiveness in its nature makes its use more congenial for the evaluation of PMDs & malignant lesions in the early stages targeting a large scale population.

### CONCLUSION

Though the literature unveils the advent of various adjunctive diagnostic aids, each has its own limitations like high economicity, efficacy in terms of diagnosis & ease of use. DrOroscope can be considered as a novel diagnostic aid owing to its spectrum of advantages (low economicity, ease of handling and increased sensitivity & specificity reinforcing diagnostic accuracy). The availability of 3 different wavelengths in one further marks the concreteness of use which can be handled in lucid style which is effective in the detection of malignancy and potentially malignant lesions alongside the determination of accurate biopsy site.

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