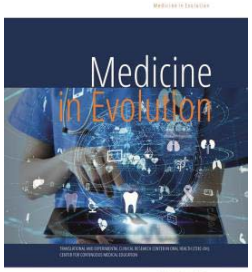
Efficacy of Goccles medical device in the screening of potentially malignant oral lesions- an experimental study



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Abstract

Oral cancer is characterized by the abnormal growth of cells that can invade any part of the mouth, including the gums, tongue, hard palate, and soft palate. GOCCLES® uses autofluorescence technology to aid in the early detection of oral cancer lesions. This non-invasive screening method is more effective than visual inspections and can detect even the slightest tissue changes. While traditional white lights decrease the dentist's ability to identify affected areas, GOCCLES® allows them to see subtle changes in intense fluorescent green light. With such advanced technology, dentists can more efficiently diagnose oral lesions at the first signs, thereby increasing the chances of successful treatment. Additionally, GOCCLES® can be used as a monitoring tool to ensure that patients have ongoing oral health.

Keywords: GOCCLES, oral cancer, fluorescent green light

INTRODUCTION

Oral cancer or malignant oral tumour, presents as a swelling or lesion of the oral mucosa that does not heal, caused by the uncontrolled growth and division of cells. The early symptoms of oral cancer are not visible to the naked eye. [1] The spread of oral cancer is rarely associated with severe pain. More than 2/3 of all oral cancers are diagnosed only in advanced stages. Early detection of oral cancer increases the survival rate to approximately 80% [1].

The screening procedure of oral cancer is painless, free of radiation risk, non-invasive, and quick to perform during routine visits to the dentist [2]. It is a test that uses clinically proven technology to detect oral lesions and is recommended at least once a year.

The screening requires a special effort to ensure the quality of services, as only some people invited to participate in cancer screening have the disease or incipient conditions that could lead to cancer [3].

In recent years, the number of cases of oral cancer have increased significantly, especially among men. This has led researchers to conduct studies to find out the etiological factor. The largest increases have been reported in throat and tongue cancer. [3] This has been attributed to the human papillomavirus (HPV) [4],[5].

The American Cancer Society estimates that approximately 50,000 people will be infected with this virus, and 9,500 of them will die of this, only this year [6].

Invasive squamous cell carcinoma [7] is often preceded by clinically recognizable premalignant changes [8], [9] of the oral mucosa. These lesions are often present as white or red patches, known as leucoplakia and erythroplakia. As the cancer develops, the patient may notice the presence of a persistent ulcer. [10] Symptoms in later stages include bleeding, tooth mobility, difficulty wearing dentures, dysphagia, and the development of a mass in the posterior region of the oral cavity [9].

Efforts should be made to establish a definitive diagnosis and maximize time for treatment of patients with more severe lesions, using a therapeutic protocol [11],[12].

GOCCLES® (Glasses for Oral Cancer - Curing Light Exposed - Screening) (PIERREL PHARMA, ITALY) is a medical device created to provide comfortable, easy, and low-cost direct visualization of abnormal tissue in the oral cavity [13].

GOCCLES® Medical Glasses (Glasses for Oral Cancer - Curing Light Exposed - Screening) (PIERREL PHARMA, ITALY) is a pair of glasses with a filter that highlights the autofluorescence of the mucosa when illuminated with a photopolymerizable lamp or the light from Oral ID that emits blue light (435-460nm) [18],[19].

The device was created to provide direct fluorescence with low costs, visualizing oral tissue abnormalities, and was introduced to the consumer market in 2015. Other fluorescence-based devices available on the market, such as VELscope Vx® (Visual Enhanced Lesion Scope, by LED Dental Inc, BC, Canada, do not require the use of dyes or rinses during the procedure [16].

The GOCCLES device represents a modern pair of glasses, reported to be less heavy and noisy than a device such as VELscope Vx [14], [21-31]. VELscope Vx has its own halogen tungsten light source over which current passes and heats very quickly. This design means that it needs to be charged frequently and has a cooling fan inside the device. The latter is responsible for the noise of the device [15], [20].

By comparison, GOCCLES® works efficiently with any light curing unit, which mostly are LED and, therefore, do not create heat, making them easier to use. These glasses are packaged in a special protective box, which makes them easy to transport if working in

multiple locations. VELscope Vx constantly requires single-use green filters, while the glasses have an incorporated filter, meaning that post-purchase costs are nil [14],[15].

Another aspect related to VELscope Vx is the device's design being too large, which requires the clinician to get too close to the patient's face. By using the special glasses, the clinician can stand in front of the patient and orient themselves well through peripheral and spatial awareness [17-23]. The only advantage of the VELscope Vx over Goccles is that the halogen has a higher light intensity than LED and is not as sensitive to ambient light [16-24].

However, a factor to consider for both devices is the possibility of reducing ambient light. The darker environment, reflect the better fluorescent tissues.

The research method involving analysis of the oral mucosa during a routine consult increases the early detection rate of oral cancer. Including screening in the daily routine of a physician treating their patients is perhaps the most important thing after pain relief.

Aim and objectives

The objective of this clinical study was to evidence the ability/ efficacy of the GOCCLES® medical device examining the autofluorescence of the oral mucosa, inpatients with different potentially malignant lesions.

The major objectives of oral screening include: detecting and recognizing lesions with malignant potential in the oral cavity, examining, collecting, and analysing samples for confirmation and differentiation, developing a presumptive, differential, and definitive diagnosis, and establishing treatment plan in accordance with the diagnosis.

MATERIAL AND METHOD

A clinical experimental study was conducted at the Discipline of Oral Pathology of the Faculty of Dental Medicine in Timisoara, respecting the regulations of the Declaration of Helsinki regarding the studies on humans. Different patients, referred to the department for an adjuvant screening for oral cancer were randomly tested, and those who presented lesions were prioritized. A number of 9 patients, aged 18-29, were taken in consideration for this experimental study. All participants signed inform consent upon their inclusion in the study.

Most of the patients presented oral lesions that were visible to the naked eye, but there were also patients who wanted to be screened even if they did not present lesions.

The research method is clinically non-randomized. Patients were placed in the dental chair, with protective glasses, and the dental assistant positioned the light from the lightcuring unit perpendicular to the lesion.

To capture the autofluorescence of the oral mucosa, we used the camera of the phone, and the GOCCLES® glasses were placed as a filter in front of the camera. The light was held at a distance of 20-40 cm from the mucosa. Some practitioners used the blue light from Oral ID.

We examined the entire oral mucosa as well as the dorsal and ventral surface of the tongue. Several pictures were taken from different incidences of the lesions. Some of the patients were recalled after two weeks for a follow-up in order to observe the evolution of the lesions.

RESULTS

The first case was that of a patient who did not present visible lesions with the naked eye. The patient wanted to benefit from an oral cancer screening in the absence of obvious lesions. We took pictures of the ventral and dorsal surface of the tongue, the left and right jugal mucosa using GOCCLES glasses (PIERREL PHARMA, ITALY). After examination, no

abnormal images were present, tissue autofluorescence was normal. The second patient examined was a young man with night-time bruxism who often bit his cheek. We took pictures of the upper and lower lip mucosa, the ventral and dorsal surface of the tongue, the hard and soft palate, and the left (Figure 1) and right jugal mucosa.

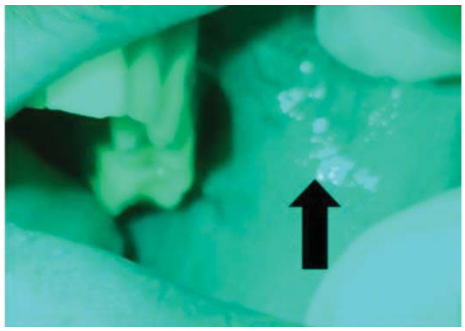

Figure 1. Left buccal mucosa visualized with GOOCLES (PIERREL PHARMA, ITALY), where the afferent vascularization can be highlighted

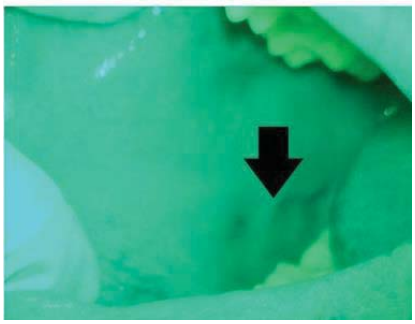

Figure 2. The right jugal mucosa with lesions on the surface. By viewing the lesions with the help of glasses, darker areas were highlighted indicating their presence

Upon visualization with the glasses, the lesions appeared with low fluorescence. Since the patient presented dark-colored lesions at the time of examination with the glasses, we asked the patient to come back for a follow-up in two weeks.

Upon his return, we only took pictures of the left and right jugal mucosa. Upon examination, we realized that the patient's lesions in the right jugal mucosa had healed but presented smaller ones in the left and right jugal mucosa. GOCCLES glasses (PIERREL PHARMA, ITALY) helped us confirm the presence of lesions. These are dark green to black. The patient still presented night-time bruxism.

The third patient did not present any visible pathology at the level of the oral mucosa that he knew of and that would be visible upon routine inspection. He requested an oral screening. Upon examination with the filter glasses, two areas were highlighted at the level of the left and right jugal mucosa that showed colour closures typical of a lesion. The patient recalled biting his cheek during a meal a few days after the examination, but the lesions appeared completely healed upon inspection without glasses.

After examination with the filter of the glasses, two areas were highlighted at the level of the left and right jugal mucosa that presented specific colour closures of a lesion. The patient remembered that a few days prior to the examination he bit his cheek during a meal, but on inspection without glasses, the injuries seemed completely healed.

Following this examination, in which lesions were detected that were not visible without GOCCLES glasses (PIERREL PHARMA, ITALY), we can conclude that it is a routine clinical stage that provides beneficial information for the patient as well as for the treatment plan.

After examining with the filter of the GOCCLES glasses, two areas were highlighted on the left and right jugal mucosa that showed color closures specific to a lesion. The patient remembered biting his cheek during a meal a few days before the examination, but upon inspection without the GOCCLES glasses, the lesions appeared completely healed.

As a result of this examination, which revealed present lesions that were not visible without the GOCCLES glasses, we can conclude that it is a routine clinical stage that provides beneficial information for the patient and the treatment plan.

The fourth examined patient is a young man who presents a jugal white line due to a deep bite. He wanted to check the degree of hyperkeratinisation of the oral mucosa and also if he had pathological lesions. At the level of the left jugal mucosa, the normal layer of

hyperkeratosis can be seen normally, slightly whiter than the surrounding mucosa. When we examined the dorsal surface of the tongue, the depapillated areas had low autofluorescence.

The fifth patient did not present obvious lesions upon inspection or palpation, but oral cancer screening was also performed with the GOCCLES glasses. In this patient, some darker areas were often evident, but this was due to intense vascularization. No pathological lesions were detected in the oral mucosa. Everything that appeared dark was due to rich vascularization.

Pictures were taken for oral screening at the level of the lip mucosa, the tongue Figure 3) the hard palate, and the jugal mucosa in the sixth patient. Depapillated areas were observed on the dorsal surface of the tongue. A lesion appeared on the right jugal mucosa due to the cheek bite, and the right jugal mucosa also had areas of hyperkeratosis next to the bite lesions.

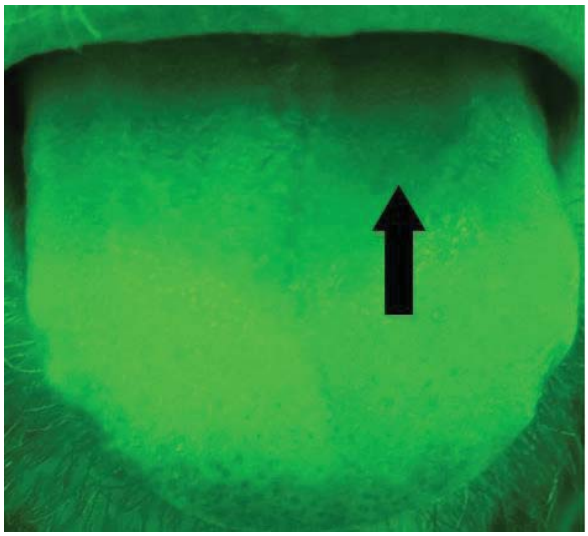

Figure 3. Dorsal view of the tongue with depapillated areas on the left side

The seventh patient had a history of a tongue piercing. Afterward, only a scar remained on the dorsal surface of the tongue, which was highlighted with the GOCCLES glasses as a darker area with hyperkeratinized margins. The eighth patient did not present visible lesions upon inspection or with the glasses. Tissue autofluorescence was normal with rich vascularization.

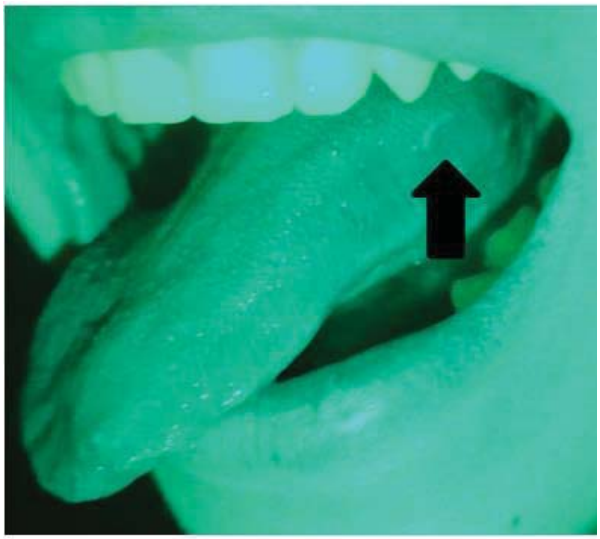

Figure 4. Following visualization with GOCCLES glasses (PIERREL PHARMA, ITALY), a lesion was detected on the lateral side of the tongue, which was the cause of the patient's pain

The last examined patient came for a consultation because she had painful sensitivity on her tongue when consuming different foods. Pictures were taken on the dorsal and lateral surfaces of the tongue Figure 4). Slightly darker and depapilated areas were observed. The patient had geographic tongue, and in certain periods of the Following the examination, slightly darker and depapilated areas were observed. The patient had a geographic tongue and it reappeared during certain periods of the mouth.

Following the analyses performed on the 9 patients, we have gathered a clinical picture with various signs after visualizing them with GOCCLES® glasses (Glasses for Oral Cancer – Curing Light Exposed – Screening) (PIERREL PHARMA, ITALY).

The first case was that of a patient who did not present visible lesions with the naked eye. The patient wanted to benefit from an oral cancer screening in the absence of evident lesions. We took pictures of the ventral and dorsal sides of the tongue left and right jugal mucosa using GOCCLES glasses (PIERREL PHARMA, ITALY). After examination, there were no abnormal images, and the tissue autofluorescence was normal.

The second patient examined was a young man who had night-time bruxism and often bit his cheek. We took pictures of the upper and lower lip mucosa, ventral and dorsal sides of the tongue, hard and soft palate, and left and right jugal mucosa.

When visualized with the glasses, the lesions appeared with low fluorescence. Since the patient presented dark-coloured lesions at the time of visualization with the glasses, we asked the patient to return for a check-up in two weeks.

DISCUSSIONS

It has been demonstrated internationally that these medical glasses, GOCCLES® (Glasses for Oral Cancer - Curing Light Exposed - Screening) (PIERREL PHARMA, ITALY), are used to detect the loss of tissue autofluorescence when affected.[22],[23] The glasses can detect moderate and severe dysplasia as well as oral cancer. This device can be used with the dental unit lamp but has also been tested with a halogen lamp. Another study was conducted with patients sitting in the dental chair and trying to reproduce the situation as closely as possible to the dental office [24]. According to the scientific literature, examination of autofluorescence determined characteristics of the mucosa that appeared invisible to simple inspection [27]. International studies are trying to encourage the acquisition of this type of

material, especially GOCCLES® (Glasses for Oral Cancer - Curing Light Exposed - Screening) (PIERREL PHARMA, ITALY), to increase the chances of detecting oral cancer and to increase the rate of oral screening. The glasses are a much more accessible device than other apparatus that act on the same principle [26]. Additionally, Nichola Tong in her articles [25] presents the advantages of the glasses and makes a comparison with Oral ID, arguing that a device such as glasses is much easier to use in day-to-day dental practice. Huang et al in one of their publications supported the fact that there is a very high rate of detection of oral cancer and premalignant lesions due to tissue autofluorescence [28], [29]. The new technology for early detection of oral cancer and malignant lesions is now accessible to all through various devices that use tissue autofluorescence and could save many patients [30], [31].

CONCLUSIONS

The lesions present in the oral cavity appear dark in color due to the loss of mucosal fluorescence;

Even post-piercing or other scar tissue appears with lost fluorescence;

Hyperkeratosis areas appear with increased fluorescence compared to surrounding unaffected tissue;

Incomplete healing lesions appear with lower fluorescence even if they are not visible on visual inspection;

GOCCLES® glasses (with a filter for visualizing fluorescence of affected and unaffected tissue proved to be a highly effective device for oral cancer screening.

The use of oral screening devices such as GOCCLES® glasses is essential for preventing and early detection of premalignant lesions and oral cancer.

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