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GOCCLES
(Glasses for Oral Cancer – Curing Light Exposed – Screening)
A new medical device for the prevention of oral cancer

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Background: oral cancer is responsible for 128,000 deaths per year, and nearly all of them are preventable. There are currently no recommended screening tests, but studies on low-cost examinations are ongoing. These include the examination of oral cavity autofluorescence (loss of fluorescence may be related to dysplasia or cancer). The GOCCLES device (fig. 1), patented at the Catholic University of the Sacred Heart of Rome, consists of filters that show oral mucosal autofluorescence abnormalities when used together with any dental curing light. The aim of the study is to demonstrate that GOCCLES allows an effective examination of autofluorescence in the dental practice.

Methods: data from two trials (including a multicenter clinical trial, not yet published) on consecutive patients at risk for oral cancer (heavy smokers/heavy alcohol drinkers/history of oral cancer/presenting with potentially malignant lesions of the oral cavity). All patients underwent naked eye inspection followed by autofluorescence examination with GOCCLES and four curing lights with different technical characteristics. All fluorescence loss areas and all potentially malignant lesions persisting for three weeks underwent excisional biopsy, regardless of being visible to the naked eye.

	NE-	NE+
AF-	-	1 (2.3%)
AF+	4 (9.1%)	39 (88.6%)

	Not visible to AF	AF margins not infiltrated	AF margins infiltrated
Not visible to the NE	-	0 (0%)	1 (3.1%)
NE margins not inf.	1 (3.1%)	3 (9.4%)	6 (18.8%)
NE margins infiltrated	0 (0%)	4 (12.5%)	17 (53.1%)

Table 1 (left). True positive lesions identified by autofluorescence examination with GOCCLES (AF) and naked eye inspection (NE). **Table 2 (right).** Margins correctly identified by AF and NE in true positive lesions (margins were studied on 32 true positive patients).

Results: overall, 78 lesions were sampled. The device allowed the visualization of fluorescence loss in all moderate to severe dysplasias and cancers and in 93,3% of mild dysplasias (fig. 2). In 4 cases the device allowed to identify otherwise invisible lesions (including one oral cancer, tab 1). In 10 cases the device allowed complete resections of lesions with infiltrated naked-eye-visible margins (tab. 2). False positives at naked eye examination: 37.2%. False positives with GOCCLES: 39,7%. The device worked properly with all tested curing lights. Of nineteen patients at risk of oral cancer excluded from the study because showed no lesions at both autofluorescence and naked eye examination, no one developed oral cancer during the follow up (at one year).

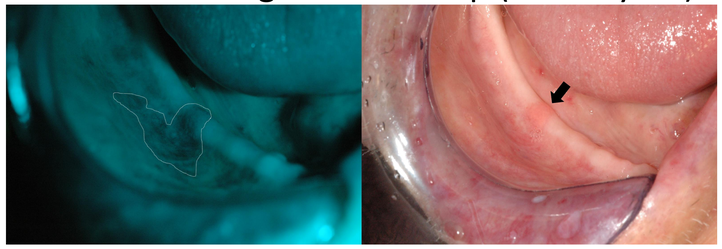

Figure 1 (left). The GOCCLES medical device. **Figure 2 (right).** Oral cancer in an edentulous patient in follow-up after surgical resection of a malignant lesion. Autofluorescence examination (left) vs. conventional visual examination (right). The lesion is barely visible if the oral examination is performed with superficiality. Loss of fluorescence increased contrast making it easier to see the tumor. Also visible in this figure is a clear difference in the extension of the margins of the lesion: fluorescence loss (margins highlighted) extended beyond the margins which were visible to the naked eye. Arrow points to the main lesion.

Conclusions: GOCCLES has high sensitivity and allows an easy and low-cost oral cancer screening in the dental practice. It is recommended as a complementary inspection following the naked eye examination on patients at risk and in follow-up for oral cancer. The device may also be used in the surgical setting (excision of dysplasias/tumors of the mouth).

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