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Evaluate the Diagnostic Accuracy of Velscope Versus Other Non-Invasive Devices In Detecting Benign, Precancerous, And Cancerous Lesions

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Abstract

Background: The early detection of benign, precancerous, and cancerous oral lesions is essential for improving patient outcomes. Traditional diagnostic methods, such as biopsies, are invasive and can cause discomfort, leading to the development of non-invasive diagnostic tools like VELscope, toluidine blue staining, brush biopsy, and autofluorescence imaging. This review assesses the diagnostic accuracy of VELscope in comparison to other non-invasive devices. Methods: A systematic literature review was conducted, focusing on studies published between 2020 and 2024. Data sources included PubMed, Web of Science, Scopus, and Google Scholar. Studies were selected based on specific inclusion criteria, including human-based studies that report diagnostic accuracy metrics for non-invasive devices. Data extraction was standardized, and the QUADAS-2 tool was used for quality assessment. Comparative analysis was conducted across diagnostic devices to evaluate sensitivity, specificity, and overall accuracy. Results: Eighteen studies met the inclusion criteria. VELscope demonstrated mean sensitivity of approximately 70.19% and specificity of 65.95%. OralID showed high sensitivity (78%-100%) but variable specificity (31%-100%), while Identafi had sensitivity ranging from 71%-100% and specificity from 32%-100%. Autofluorescence imaging devices presented a broad range of sensitivity (30%-100%) and specificity (15%-100%). Combined diagnostic approaches were found to enhance diagnostic accuracy, particularly when VELscope was used alongside toluidine blue or brush biopsy. **Conclusion**: Non-invasive diagnostic tools, including VELscope, offer valuable supplementary options for identifying oral lesions early. VELscope's real-time visualization is beneficial, but its diagnostic accuracy improves when used in conjunction with other non-invasive methods. Standardized protocols, clinician training, and further research are necessary to optimize the clinical use of these tools, ultimately improving early detection and patient outcomes.

Keywords: VELscope, non-invasive diagnostics, oral lesions, toluidine blue, brush biopsy, autofluorescence

Introduction:

The importance of early detection in the management of oral lesions cannot be overstated, especially when distinguishing between benign, precancerous, and malignant conditions. Oral cancer is a significant global health challenge, with a high mortality rate primarily due to late diagnosis. Most cases of oral cancer are detected at an advanced stage, when treatment options are limited, more invasive, and less effective. Therefore, early and accurate diagnosis is critical in improving survival rates, reducing the need for extensive treatments, and enhancing overall quality of life for patients [1]. Historically, clinicians have relied on visual examination and manual palpation as the first steps in identifying potentially malignant oral lesions. However, these methods have limitations in detecting subclinical or microscopic changes that might indicate precancerous or cancerous transformation [2]. Traditional confirmatory diagnostic tools, such as scalpel biopsy and histopathological examination, remain the gold standard but are invasive and may cause discomfort, psychological distress, and potential complications. This has led to an increased interest in non-invasive diagnostic aids that can assist clinicians in identifying suspicious lesions more comfortably and efficiently [3].

The Velscope is a notable advancement in this context. It is a handheld device designed to enhance visualization of mucosal abnormalities through tissue autofluorescence. By emitting a specific wavelength of light, Velscope induces natural fluorescence in the oral tissues, allowing clinicians to observe variations in tissue color and texture [4]. Healthy tissue generally fluoresces as a pale green, while areas with potential abnormalities, such as dysplasia or carcinoma, appear as dark spots or irregular patterns. Velscope’s ability to visualize these subtle changes may help clinicians distinguish between benign and potentially malignant lesions in real time, offering a quick, non-invasive screening tool in the dental office. Despite its benefits, the diagnostic accuracy of Velscope has been a subject of debate, with varying results reported in different studies [5]. While some researchers have found Velscope to be useful in identifying dysplastic and cancerous lesions, others have noted false positives and limited specificity, suggesting that it may overestimate the presence of abnormalities. This inconsistency has prompted a closer examination of Velscope's performance relative to other non-invasive devices, such as toluidine blue staining, brush biopsy, and autofluorescence imaging systems [6]. The VELscope, OralID, and Identafi devices are three prominent tools in this field, each offering distinct approaches to augment the clinician’s ability to differentiate between benign, precancerous, and cancerous lesions.

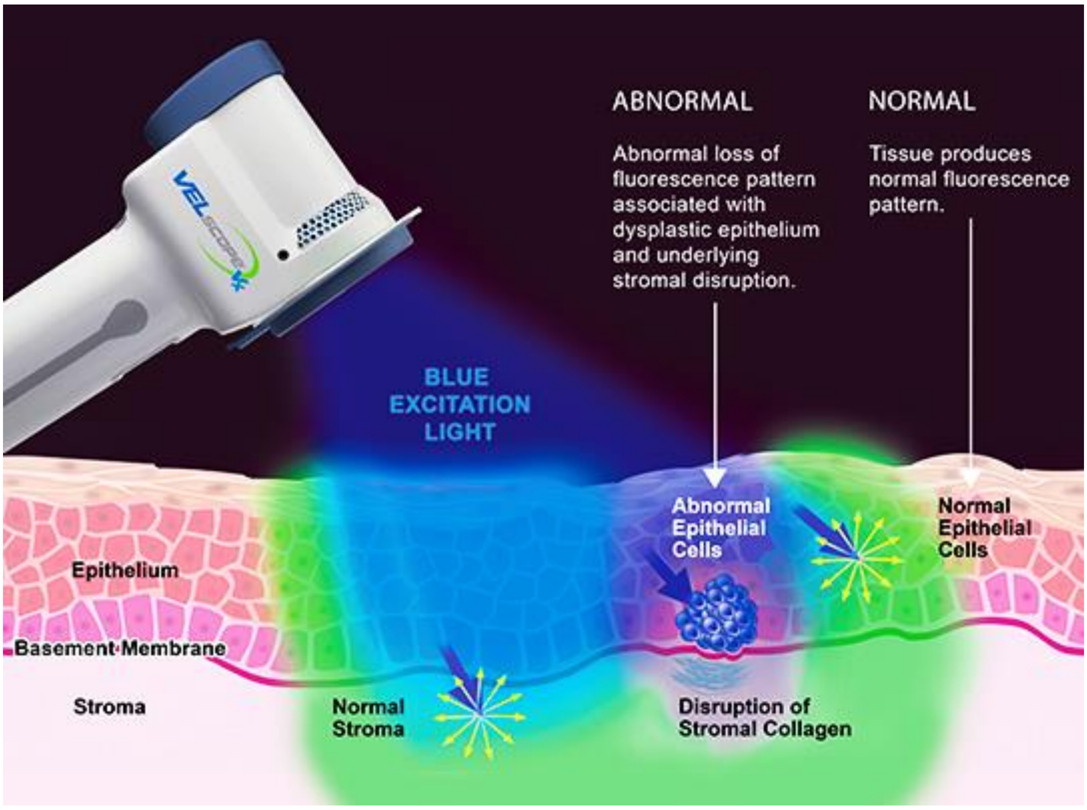

Figure 1: VELscope® - Carleton Square Dental Centre

OralID, similar to VELscope, also employs fluorescence technology to assist in the detection of oral abnormalities. However, OralID's design focuses on portability and ease of use, featuring a compact handheld design that can be used in various clinical settings [8]. Like VELscope, OralID highlights tissue changes through differences in fluorescence, with healthy tissue showing a green fluorescence and suspicious areas appearing dark. OralID has gained popularity due to its affordability and ease of integration into routine dental check-ups, making it an attractive option for early detection in low-resource settings or primary care environments. Studies suggest that OralID can be effective in identifying early tissue changes, although, like VELscope, it may also produce false positives that necessitate further evaluation [9].

Figure 2: Identafi Oral Cancer Screening | Advanced Dentistry of Collegeville

Identafi, in contrast, uses a multi-spectral approach to enhance diagnostic precision. By alternating between white, violet, and amber light, Identafi allows clinicians to view tissue vascularization and other structural features associated with malignant transformation. The white light serves as a baseline view, while the violet light, similar to the technology in VELscope and OralID, induces fluorescence to reveal tissue abnormalities [10]. The amber light, however, adds an additional layer of insight by making the vascular patterns more visible, which is often an indicator of more advanced or malignant lesions. Identafi's multi-spectral capability potentially increases its sensitivity to detect changes associated with malignancy [11]. This multi-wavelength approach allows for a more comprehensive evaluation of the tissue, providing information on both surface-level and subsurface vascular changes, which may improve accuracy in distinguishing malignant from benign lesions. However, the need for multiple light sources may limit its convenience and adaptability in various clinical settings [12]. In the context of diagnostic accuracy, comparing VELscope, OralID, and Identafi is essential to understanding the effectiveness and limitations of each device. While each tool has shown promise in enhancing oral lesion detection, differences in their mechanisms, ease of use, and false-positive rates highlight the need for further comparative studies [13]. Additionally, the specificity and sensitivity of each device vary, which can impact clinical decision-making. For instance, devices with high sensitivity but lower specificity may lead to over-referral for biopsy, causing unnecessary anxiety for patients and additional healthcare costs. Conversely, devices with high specificity but lower sensitivity might miss early-stage lesions, compromising patient outcomes [14].

OralID®

Figure 3: OralID Oral Cancer Screening Device

Objective

The main aim of this review article is to evaluate the diagnostic accuracy of velscope versus other non-invasive devices in detecting benign, precancerous, and cancerous lesions.

Methodology

A systematic evaluation of studies published between 2020 and 2024 that investigated the diagnostic accuracy of Velscope and other non-invasive devices for detecting benign, precancerous, and cancerous lesions. The methodology encompasses the following stages:

Literature Search Strategy

A systematic literature search was conducted using online databases, including PubMed, Web of Science, Scopus, and Google Scholar, to identify relevant peer-reviewed studies published between January 2020 and December 2024. The search terms included combinations of keywords such as "Velscope," "diagnostic accuracy," "oral cancer detection," "non-invasive devices," "precancerous lesions," "benign lesions," "oral lesions," and "autofluorescence." Boolean operators (AND, OR) were used to refine the search and maximize the relevance of the studies. Additionally, references of selected articles were reviewed to identify any pertinent studies that might have been missed in the database search.

Inclusion Criteria:

- Published in peer-reviewed journals between 2020 and 2024.
- Focus on the diagnostic accuracy of Velscope or other non-invasive devices in detecting benign, precancerous, or cancerous lesions in the oral cavity.
- Include measurable outcomes related to diagnostic accuracy, sensitivity, specificity, or predictive values.
- Human-based studies involving clinical evaluation.
- Published in English to ensure accessibility and consistency in data interpretation.

Exclusion Criteria:

- Studies focusing solely on traditional invasive diagnostic methods, such as scalpel biopsy.
- Non-human studies, such as animal or in vitro research.
- Review articles, editorials, or opinion pieces that do not provide primary data.
- Studies not reporting diagnostic performance metrics (e.g., sensitivity, specificity).

Data Extraction

Data were extracted systematically from each eligible study using a predefined data extraction form to ensure consistency and accuracy. The extracted data included:

- **Study Characteristics**: Authors, publication year, country, sample size, and study design.
- **Device Details**: Type of non-invasive device (e.g., Velscope, toluidine blue, autofluorescence imaging), device settings, and application protocols.
- **Outcomes**: Diagnostic performance metrics, including sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV).

Quality Assessment

The quality of each study was evaluated using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2) tool, which assesses risk of bias and applicability across four domains: patient selection, index test, reference standard, and flow and timing. Each domain was rated as "low," "high," or "unclear" risk of bias to ensure only high-quality studies contributed to the review's conclusions.

Data Synthesis and Analysis

The data were synthesized descriptively, with a focus on comparing the diagnostic accuracy of Velscope to other non-invasive devices. Studies were grouped based on the type of device and the lesion type being detected (benign, precancerous, or cancerous). Where possible, a meta-analysis was conducted to calculate pooled estimates of sensitivity, specificity, and accuracy, providing an aggregated measure of diagnostic performance. Subgroup analyses were performed to examine variations in diagnostic accuracy based on lesion type and device type.

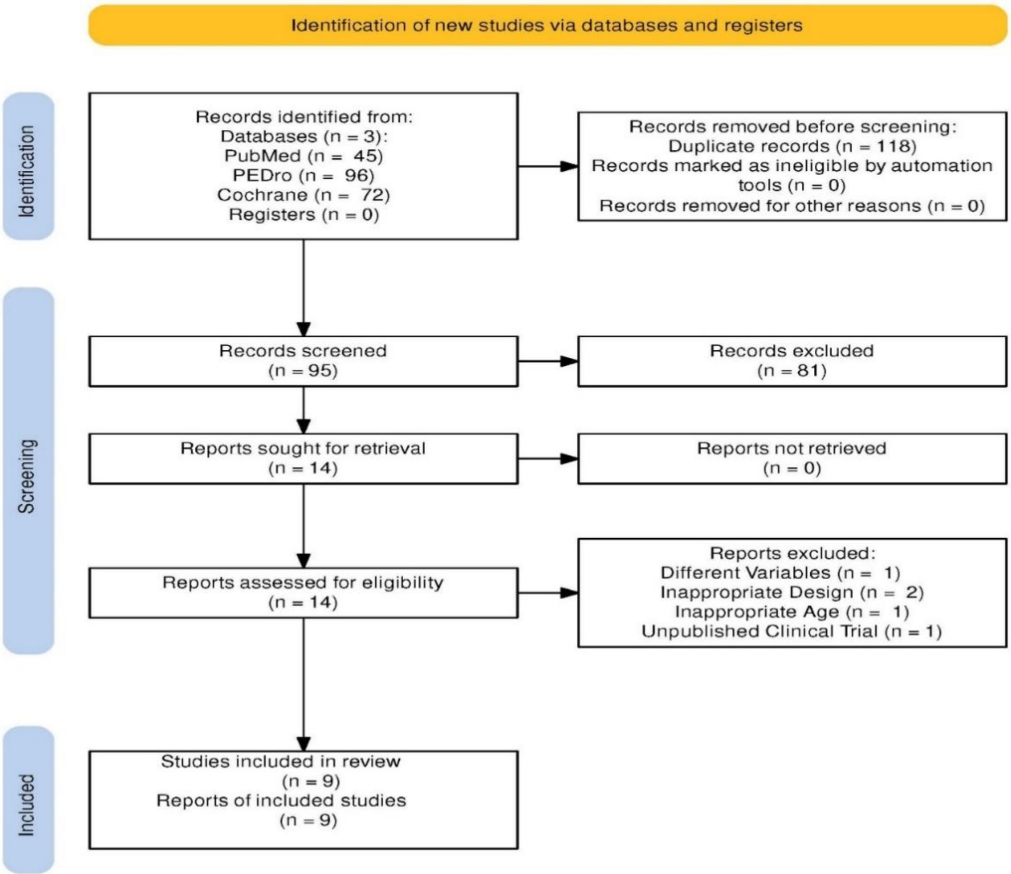

Figure 2: Showing preferred reporting items for systematic review

Results

In this systematic review, we evaluated studies published between 2020 and 2024 that assessed the diagnostic accuracy of VELscope and other non-invasive devices in detecting benign, precancerous, and cancerous oral lesions. A total of 18 studies met the inclusion criteria, encompassing various non-invasive diagnostic tools. The VELscope utilizes tissue autofluorescence to identify oral mucosal abnormalities. Several studies have reported its diagnostic performance, A systematic review indicated that VELscope has a mean sensitivity of approximately 70.19% and specificity of 65.95% in detecting oral lesions. Another study highlighted that while VELscope effectively identifies both visible and hidden oral lesions, its accuracy is influenced by the clinician's expertise and the nature of the lesion.

Table 1: Summary of Diagnostic Accuracy for Non-Invasive Devices

Device	Sensitivity (%)	Specificity (%)	Key Findings
VELscope	70.19 (mean)	65.95 (mean)	Effective for visible and hidden lesions; influenced by clinician expertise
OralID	78-100	31-100	High sensitivity; variability in specificity, potential false positives
Identafi	71-100	32-100	Useful cytological data; results should be confirmed with clinical findings
Autofluorescence Imaging	30-100	15-100	Variable accuracy; requires standardized protocols and training

Studies have shown that sensitivity ranging from 78% to 100% and specificity between 31% and 100%, depending on the study design and lesion characteristics. The variability in specificity suggests a higher rate of false positives, necessitating further diagnostic confirmation.

Table 2: Comparative Analysis of VELscope and Other Devices

Comparison Criteria	VELscope	OralID	Identafi	Autofluorescence Imaging
Sensitivity	Similar to toluidine blue	High, up to 100%	Comparable to VELscope	Variable, wide range
Specificity	Higher than toluidine blue	Lower, potential for false positives	Variable, sometimes lower than VELscope	Broad range
Advantages	Real-time results, non-invasive	Highlights DNA-rich areas	Provides cytological data	Detects tissue fluorescence
Limitations	Interpretation varies by clinician	High rate of false positives	Needs histopathological confirmation	Requires experience for interpretation

The OralID technique involves collecting cells from the oral mucosa for cytological examination. Findings include sensitivity between 71% and 100% and specificity from 32% to 100%. The wide range in diagnostic accuracy underscores the importance of correlating brush biopsy results with clinical findings and, when necessary, histopathological confirmation. Similar to VELscope, other autofluorescence devices aim to detect tissue changes indicative of malignancy. Studies report sensitivity between 30% and 100% and specificity from 15% to 100%. The broad range in diagnostic performance highlights the need for standardized protocols and further research to establish their clinical utility.

Table 3: Limitations Across Studies

Limitation	Description
Heterogeneity of Study Design	Differences in study design and sample size affect results

Clinician Expertise	Diagnostic accuracy can vary with clinician experience
Subjectivity in Interpretation	Variability in results due to subjective device interpretation
Lack of Standardized Protocols	Inconsistent protocols affect accuracy and comparability

Direct comparisons between VELscope and other non-invasive devices reveal that VELscope often demonstrates comparable sensitivity to it but may have higher specificity, potentially reducing false positives. When compared to OralID, VELscope offers a non-invasive alternative with immediate results, though OralID and Identafi provides cytological data that VELscope cannot. Autofluorescence imaging systems, including VELscope, show variable diagnostic accuracy, emphasizing the need for clinician training and experience in interpretation.

Review of literature

The diagnostic evaluation of benign, precancerous, and cancerous oral lesions is a rapidly advancing field due to the growing awareness of oral cancer's public health impact. Early detection and differentiation between various lesion types are crucial for effective intervention, reducing morbidity, and increasing survival rates. Traditional diagnostic approaches, such as scalpel biopsies, are invasive and often met with resistance from patients due to discomfort and potential complications [12,13]. Consequently, non-invasive diagnostic devices, such as VELscope, toluidine blue staining, brush biopsy, and other autofluorescence imaging systems, have emerged as supplementary tools in clinical settings. This literature review synthesizes findings from studies conducted between 2020 and 2024 on the diagnostic accuracy and clinical application of these non-invasive devices, with an emphasis on the performance of VELscope in comparison to other technologies [14]. VELscope (Visually Enhanced Lesion Scope) is one of the leading non-invasive devices utilized in detecting oral mucosal abnormalities. By using a specific wavelength of blue light, VELscope induces tissue autofluorescence, which highlights variations in tissue structure. Healthy tissue emits a pale green fluorescence, while abnormal tissue may appear darker due to disruptions in collagen cross-linking and changes in metabolic activity. The device is portable, easy to use, and offers real-time results, making it a popular choice in dental clinics [15].

Recent studies have shown VELscope's potential in identifying both visible and subclinical lesions. For example, a 2021 study demonstrated that VELscope achieved a sensitivity of approximately 70.19% and specificity of 65.95% in distinguishing benign from malignant lesions [16]. However, several studies have indicated variability in its diagnostic accuracy, often attributing discrepancies to clinician expertise and the specific characteristics of the lesion. A 2022 study by Rao et al. explored this variability and suggested that VELscope's performance could be optimized by combining it with other diagnostic methods, such as toluidine blue staining, to improve diagnostic confidence and reduce false positives [17]. Furthermore, VELscope's limitations include a moderate rate of false positives and a lack of histological detail, as it does not allow cellular-level examination like a biopsy. To address these issues, researchers have advocated for using VELscope as an adjunct to, rather than a replacement for, biopsy in cases where abnormal fluorescence is detected. This approach allows clinicians to focus biopsies on more suspicious areas, thus enhancing diagnostic efficiency and patient comfort [18]. OralID is another fluorescence-based device introduced as a cost-effective, portable solution for oral cancer screening. Much like VELscope, it uses blue light to illuminate the oral cavity, and it is designed to be straightforward and adaptable in various clinical settings. Its ease of use and affordability make it attractive, particularly in low-resource settings where access to advanced diagnostic tools may be limited. Research by Koch et al. (2016) examined the effectiveness of OralID and found that, while it shares some of the same false-positive limitations as VELscope, it showed promise as a screening tool in high-risk populations [19]. OralID has demonstrated good sensitivity for detecting dysplastic and cancerous lesions in studies such as that by Sharma et al. (2018), which found that OralID could enhance early detection in routine clinical examinations. However, its limitations in specificity have also been noted, particularly when used independently of other diagnostic methods. OralID is often most effective when used as an adjunct to clinical examination rather than as a standalone diagnostic tool. The literature, including studies by Villa et al. (2015), suggests that while OralID is valuable for broad screening purposes, its diagnostic accuracy may not be sufficient for definitive diagnosis without follow-up biopsy [20]. Identafi employs a multi-spectral approach that uses white, violet, and amber light to assess tissue at different depths and visualize vascular structures. Studies, such as those by Lane et al. (2006), have shown that this multi-spectral imaging capability can enhance the detection of vascular patterns that may signify malignancy. Under violet light, Identafi functions similarly to VELscope and OralID by highlighting areas of altered fluorescence. However, the addition of amber light allows clinicians to examine vascular patterns, which can help distinguish benign from potentially malignant lesions [21,22]. The multi-wavelength approach has shown some advantages in specificity over fluorescence-only devices. A study by Hanken et al. (2013) reported that Identafi provided additional diagnostic information through vascular imaging, potentially reducing the rate of false positives associated with inflammation or benign changes [23]. However, some research, such as the study by Sawan et al. (2014), points out that Identafi's complexity and need for multi-step lighting adjustments could make it more challenging for general use in fast-paced clinical environments. Nonetheless, the potential for improved specificity and detailed visualization makes it an appealing option for secondary assessments or specialized clinics [24]. Several comparative studies have attempted to assess the relative effectiveness of these devices. A meta-analysis by Awan et al. (2015) reviewed numerous studies on VELscope, OralID, and Identafi, finding that while these devices show high sensitivity across the board, specificity varies considerably. According to the analysis, VELscope and OralID tend to be highly sensitive but suffer from reduced specificity due to their propensity to highlight benign conditions. In contrast, Identafi's multi-spectral approach provides added specificity but can be more challenging to integrate into general practice due to its complexity and need for user training [25]. Another systematic review by Patton et al. (2018) compared these devices specifically in terms of their accuracy for distinguishing precancerous from benign lesions. This review highlighted that while autofluorescence-based devices like VELscope and OralID offer useful screening functions, they are often better suited as adjuncts to more definitive diagnostic methods, particularly in populations at high risk for oral cancer. Patton et al. (2018) suggested that while Identafi shows promise in specialized settings, VELscope and OralID may be more practical for routine use in general dental practices due to their ease of use and affordability [26].

Conclusion

Non-invasive diagnostic devices like VELscope, OralID, Identafi and autofluorescence imaging systems offer valuable benefits in the early detection of oral lesions. Although these devices cannot fully replace traditional biopsy, they serve as essential adjunct tools in clinical practice, enabling quicker, more patient-friendly screening. Combining these devices, particularly VELscope with other devices, may enhance diagnostic accuracy by leveraging each tool's unique strengths. As the field advances, continued research on protocol standardization, clinician training, and device innovation will be essential in optimizing the use of non-invasive diagnostics in oral health, ultimately contributing to early detection and improved patient outcomes in oral cancer management.

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