COMPARING EFFECTIVENESS OF INTRAORAL SCANNER IN CARIES DETECTION

A Thesis
Submitted to
the Temple University Graduate Board

In Partial Fulfillment
of the Requirements for the Degree
MASTER OF SCIENCE

---

by
Mohand Alruwaili
May 2025

Thesis Approvals:

Geraldine Weinstein, Thesis Advisor, Restorative Dentistry
Salwa Mekled, Restorative Dentistry
Sungwoo Lim, Oral Health Sciences

ABSTRACT

Background

Dental caries is the most common oral health conditions globally, necessitating the development of a diagnostic tool which is most accurate and reliable diagnostic for timely detection and intervention. Traditional diagnostic methods like visual checks and X-rays are not always the most reliable. They can miss details, give false positives, or vary depending on who is interpreting them. That is where digital intraoral scanners (IOS) come in. These scanners offer high-resolution imaging and real-time analysis, making them a promising tool for spotting cavities more accurately. However, concerns regarding their diagnostic accuracy, specificity, and agreement with traditional methods remain under investigation. This study evaluates the performance of the TRIOS 5 intraoral scanner in detecting carious lesions compared to examiner-based assessments and radiographic findings.

Objectives

The primary objective of this study was to assess how accurately the TRIOS 5 intraoral scanner can detect cavities. It also compared the scanner's sensitivity and specificity to traditional examiner-based assessments and X-rays, which served as the gold standard. Another key objective was to evaluate inter-examiner variability in caries detection and determine the level of agreement between different diagnostic modalities.

Methods

A comparative diagnostic accuracy study designed to assess the performance of the TRIOS 5 intraoral scanner in detecting dental caries. A total of 21 patients were evaluated using three diagnostic modalities: visual-tactile examination by independent

examiner, TRIOS 5 intraoral scanner assessment, and radiographic evaluation. Each patient underwent an examination by two calibrated clinicians, followed by scanning with the TRIOS 5 intraoral scanner. The radiographic findings were used as the gold standard to determine the accuracy of the other methods.

Statistical analysis was performed to compare the diagnostic modalities. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated to assess the performance of each method. Cohen's Kappa test was applied to measure agreement between the TRIOS 5 scanner and radiographic findings. McNemar's test was conducted to assess the significance of discordant diagnoses between the scanner and radiographic findings.

Results

The TRIOS 5 intraoral scanner had a high sensitivity of 89.4%, meaning it was very effective at detecting actual caries. However, its specificity was considerably low at 26.4%, leading to a significant number of false-positive results. The positive predictive value (PPV) was 31.1%, indicating that only 31.1% of caries cases detected by the scanner were truly present. The negative predictive value (NPV) was 87.0%, demonstrating high reliability in correctly identifying non-caries cases.

The agreement analysis showed poor concordance between the TRIOS 5 scanner and radiographic findings, with Cohen's Kappa score of 0.100, indicating substantial discrepancies in diagnostic outcomes. McNemar's test revealed a statistically significant difference ($p = 4.648$) between the scanner and radiographic findings, suggesting that the scanner tends to over-diagnose caries.

Conclusion

The TRIOS 5 intraoral scanner can be a useful tool for improving cavity detection. Its high sensitivity but low specificity means it works best when combined with traditional diagnostic methods for more accurate results. More research is needed to create standardized protocols that ensure consistent diagnoses.

Clinical Implications

The TRIOS 5 intraoral scanner could be a helpful tool for early cavity detection, but radiographs are still necessary to avoid overtreatment. Future improvements in AI-driven diagnostic algorithms might boost the scanner's accuracy and clinical usefulness. Standardized training and calibration for clinicians could also help reduce subjectivity in visual exams, leading to more consistent and reliable diagnoses.

ACKNOWLEDGEMENTS

I would like to express my profound gratitude to **the Kingdom of Saudi Arabia** for its unwavering support of education and scientific advancement. I extend my deepest appreciation to **King Salman bin Abdulaziz**, and His Royal Highness Crown Prince **Mohammed bin Salman**, for their visionary leadership and generous investment in human capital, which have enabled tens of thousands of Saudi students to pursue academic and professional development around the world.

My sincere thanks also go to **the Ministry of Education and the Saudi Arabia Cultural Mission** in Washington, D.C., for their continued commitment to supporting Saudi students abroad and for their tireless efforts in facilitating our educational journeys.

I am indebted to **my family**. To **my mother**, the source of my strength and inspiration, whose unconditional love and prayers have carried me through every challenge. To **my father**, whose wisdom, support, and encouragement have guided my steps throughout life. To **my brothers and sisters**, whose constant support, motivation, and belief in me have been invaluable.

I would like to extend my heartfelt thanks to my **colleagues and friends** at Temple University. Being part of such a dynamic and collaborative research group has been one of the most enriching aspects of my experience. The knowledge shared, the academic discussions, and the meaningful friendships formed will remain treasured memories.

This work would not have been possible without the continued encouragement and support of those closest to me. as well as **the academic mentors** whose contributions have shaped every part of this project.

I am especially grateful to my thesis advisor **Dr. Geraldine Weinstein**, whose vast experience and profound knowledge have greatly enriched this research. Her accessibility, generosity, and mentorship throughout the program have been invaluable. It has been an honor and a privilege to work with such a pioneering figure in the field of restorative dentistry.

I also extend my sincere thanks to **Dr. Salwa Mekled**, for her thoughtful feedback, insightful suggestions, and generous participation as a member of my thesis committee. Her contribution has significantly enhanced the quality of this work.

I would like to thank **Dr. Sungwoo Lim** for his expert statistical guidance and constructive input, which were instrumental in shaping the final structure of this project .

To all those who supported, inspired, and believed in me throughout this journey **thank you.**

TABLE OF CONTENTS

Page

LIST OF FIGURES

Table **Page.no**

LIST OF TABLES

Table **Page**

CHAPTER 1

INTRODUCTION

1.1 Background

Dental caries is a common global oral health issue that can significantly impact overall well-being. It is a complex disease influenced by factors like diet, oral hygiene, and individual characteristics such as saliva composition and tooth structure (Selwitz et al., 2007). Catching cavities early is a key since the initial stages can often be treated with non-invasive methods, helping to avoid more extensive dental work (Fejerskov et al., 2015).

Traditionally, dentists detect cavities through visual and tactile exams, often backed up by radiographs. While these methods are considered the gold standard, they have notable drawbacks (Ismail AI, 2004). Visual-tactile assessments, for example, rely heavily on the clinician's experience and judgment, which can lead to inconsistencies in diagnosis (Nyvad & Fejerskov, 1997). Similarly, radiographic imaging, though effective for identifying interproximal and occlusal caries, has limitations in detecting early non-cavitated lesions and caries in regions obscured by overlapping anatomical structures (Mejàre et al., 2014).

Traditional methods also have trouble detecting cavities in hard-to-reach areas, like between teeth. Because of this, researchers have been looking into additional diagnostic tools to improve early detection. Newer technologies are being developed to overcome these challenges by providing more objective, reliable, and precise results. These advancements aim to make cavity detection more accurate, helping dentists catch problems earlier and treat them in a timely manner. (Al-Khalifa et al., 2024).

Interproximal caries, which develops between adjacent teeth, presents a significant challenge due to the inaccessibility of these areas for traditional visual and tactile examinations. Dental floss is widely recommended as a preventive measure, as it effectively disrupts and removes interproximal plaque—a biofilm known to be more acidogenic than plaque on other tooth surfaces (Zero, 1999). Since flossing helps remove plaque between teeth, it plays a key role in preventing cavities in those hard-to-reach areas. But the problem is that many people do not floss regularly. That is why patient education and targeted behavioral strategies are so important for promoting better oral hygiene habits (Jackson et al., 2006).

Thanks to widespread fluoride use and better awareness of oral health, cavities have become less common overall. But they are still a major public health concern, especially for children and vulnerable groups. In fact, dental caries is the leading cause of tooth loss in baby teeth, affecting around 530 million children worldwide (Global Burden of Disease Study, 2017). Among children, untreated caries has far-reaching consequences, affecting not only oral health but also nutritional status, growth, and overall quality of life (Sheiham, 2006). These challenges highlight the need for continued preventive measures and equitable access to dental care.

Effective management of dental caries requires addressing both the underlying disease process and the lesions it produces. Preventive strategies play a central role, including fluoride application, dietary counselling, and oral hygiene education, which aim to reduce risk factors and halt disease progression (Giacaman et al., 2022). Moreover, integrating oral health screenings into non-dental primary care settings has demonstrated potential in enhancing access to preventive care for vulnerable populations, such as the elderly and socioeconomically disadvantaged groups. This

approach promotes early detection and intervention, helping to bridge gaps in dental care access (Manski & Magder, 2016).

Modern dental care focuses on a more conservative approach to treating cavities, aiming to preserve as much of the natural tooth as possible while avoiding unnecessary invasive procedures. This shift emphasizes early detection and management of cavities at a microscopic level, allowing dentists to treat early-stage lesions before they cause serious damage (Kidd & Fejerskov, 2004). Because of this, innovative diagnostic tools play a key role in supporting minimally invasive and more effective treatments.

New advancements in cavity detection technology are helping to improve accuracy and reliability, addressing the shortcomings of traditional methods. Some of the most notable innovations include:

1.2 Raman Spectroscopy and Near-Infrared (NIR) Fluorescence Imaging

Raman Spectroscopy: This non-invasive technique identifies molecular changes in enamel and dentin, giving detailed insights into mineral loss linked to cavity development. By detecting these microscopic changes early, it helps support preventive treatments (Amaechi et al., 2012).

NIR Fluorescence Imaging: This method highlights demineralization in enamel and dentin, making it especially useful for spotting early-stage cavities before they turn into full-blown lesions. Its ability to detect subtle structural changes makes it a valuable tool for proactive cavity management (Neuhaus et al., 2010).

1.3 Artificial Intelligence (AI) in Dental Diagnostics

AI technologies, like Artificial Neural Networks (ANNs) and deep learning, have revolutionized cavity detection, especially when it comes to analyzing X-rays. These systems can recognize complex patterns in radiographs with impressive accuracy, often outperforming traditional diagnostic methods. Their use has significantly improved the precision and reliability of caries detection (Lee et al., 2018).

These advancements mark a major step forward in cavity management, allowing for earlier and more accurate detection, reducing the need for invasive treatments, and ultimately improving patient outcomes.

Intraoral scanners have become essential in modern dentistry, mainly for their role in digital workflows for restorative and prosthetic treatments. These high-tech devices create detailed digital impressions of a patient's teeth, generating stereolithography (STL) files that can be used for various diagnostic and treatment planning needs, including detecting structural changes like cavities (Ender et al., 2013).

While originally designed to improve efficiency in restorative procedures, intraoral scanners are now being explored for their potential in cavity detection. Researchers are evaluating their ability to identify carious lesions with high precision, opening new possibilities for their use in diagnostics.

1.4 Notable Innovations in Intraoral Scanners for Caries Detection

3Shape TRIOS 5 Scanner:

FDA-approved for caries detection in 2022, this scanner marks a significant milestone in integrating caries diagnostics with digital impression technology. Its ability to detect caries enhances diagnostic precision, particularly in early-stage detection, offering a promising tool for improving patient care (Fleming et al., 2022).

1.5 Objectives of the Study

Comparative Diagnostic Accuracy:

The study aims to compare the diagnostic accuracy of intraoral scanners with that of a calibrated clinician in detecting caries on occlusal and smooth tooth surfaces. This comparison seeks to evaluate the reliability and consistency of these advanced technologies relative to traditional clinical expertise.

Evaluation of Specific Scanner:

3Shape TRIOS 5: The first intraoral scanner to receive FDA approval for caries detection (2022), recognized for its innovative diagnostic capabilities.

1.6 Study Implications

By focusing on these objectives, the study aims to assess the diagnostic performance of these intraoral scanners, particularly in early-stage caries detection. The findings are expected to provide valuable insights into the potential of these technologies to enhance diagnostic precision, supporting more effective and timely clinical interventions. If successful, the integration of such tools could significantly improve patient outcomes by enabling earlier and more accurate identification of carious lesions.

CHAPTER 2

REVIEW OF THE LITERATURE

2.1 Overview of Caries Detection

2.1.1 Historical Context

Caries detection has evolved significantly over the centuries, reflecting advancements in both scientific understanding and clinical technologies. Early methods relied primarily on visual-tactile examinations, a practice that dates back to the 18th century when Pierre Fauchard, often considered the father of modern dentistry, first described methods for identifying and treating dental decay (Spielman et al., 2007). These early techniques were rudimentary, focusing on macroscopic signs of decay, such as discoloration and cavitation.

With the introduction of radiography in the 20th century, dental caries diagnosis experienced substantial advancement, establishing this technology as a fundamental tool in the field. Bitewing radiographs allowed dentists to detect interproximal caries that were not visible to the naked eye (Mileman & van der Weele., 1990). Although radiography is a valuable diagnostic tool, it has limitations, such as failing to detect early non-cavitated lesions and exposing patients to ionizing radiation (Dehghani et al., 2017).

With the turn of the 21st century, advancements in dental materials and digital technologies paved the way for new diagnostic tools, such as laser fluorescence devices and optical coherence tomography (OCT). These methods aimed to improve sensitivity and specificity in caries detection, particularly in the early stages of lesion development (Schwendicke et al., 2015).

2.2 Importance of Early Detection

Early detection of cavities is crucial for effective treatment and preventing further damage. In the beginning, cavities start as a reversible demineralization process, which means they can often be treated without drilling—using methods like fluoride therapy and dietary changes (Pitts et al., 2017). But if cavities go unnoticed for too long, they can cause permanent damage, leading to the need for fillings or other restorative treatments that weaken the tooth and increase the risk of future decay (Fontana and González-Cabezas, 2000).

Beyond individual treatment, early cavity detection also has a big impact on public health. Cavities are one of the most common chronic diseases worldwide, affecting people of all ages (Kassebaum et al., 2015). Catching them early not only helps reduce the overall burden of dental disease but also lowers healthcare costs and improves patients' quality of life.

2.3 Current Trends in Diagnostic Technologies

Contemporary caries detection leverages a variety of technologies to improve accuracy and reliability. Intraoral scanners have emerged as a promising tool, providing real-time, three-dimensional images of the tooth surface. These devices utilize optical imaging technology to detect surface irregularities associated with caries and have the added benefit of being non-invasive and radiation-free (Machoy et al., 2017).

Another promising innovation in cavity detection is fluorescence-based technology, like DIAGNOdent and Quantitative Light-Induced Fluorescence (QLF). These tools detect structural changes in teeth by measuring variations in fluorescence, making them highly sensitive for spotting early enamel lesions (Lussi et al., 2004). Similarly,

Optical Coherence Tomography (OCT) allows dentists to see cross-sectional images of dental tissues, providing detailed views of subsurface cavities with high resolution (Janjua et al., 2023).

AI is also playing a bigger role in diagnostics. Machine learning algorithms are being developed to analyze data from intraoral scans, X-rays, and other imaging techniques, potentially improving accuracy while reducing the workload for dentists (Schwendicke et al., 2020).

Overall, cavity detection has evolved from subjective visual assessments to more precise, technology-driven methods. These advancements highlight the importance of using reliable diagnostic tools to improve patient care and long-term dental health.

2.4 Evolution of Intraoral Scanning

Intraoral scanning technology has completely changed modern dentistry, giving clinicians digital tools for diagnostics, treatment planning, and patient education. The first intraoral scanners appeared in the late 1980s as a way to replace traditional impression materials like alginate or silicone. One of the earliest systems, the CEREC system by Sirona, introduced chairside digital scanning, allowing dentists to create ceramic restorations on the spot (Mörmann, 1987).

Over the decades, technological advancements have improved the precision, speed, and usability of intraoral scanners. Second-generation systems in the 2000s introduced laser-based imaging for higher accuracy. By the 2010s, optical triangulation and confocal laser scanning technologies became the standard, allowing for the acquisition of highly detailed three-dimensional models (Logozzo et al., 2014).

Modern systems now incorporate artificial intelligence (AI) for real-time error correction and enhanced image processing (Michou et al., 2021).

The miniaturization of hardware and software integration has also played a critical role in making intraoral scanners more accessible and user-friendly. Today, scanners like TRIOS 5 and Medit i700 exemplify this evolution, offering high-speed imaging, improved ergonomics, and compatibility with CAD/CAM systems (MEDIT i700).

2.5 Applications in Dentistry

Intraoral scanners have diverse applications across dental specialties, transforming workflows and improving patient outcomes. Key applications include:

Digital Impressions for Restorative Dentistry

- Intraoral scanners replace traditional impressions, creating accurate digital models for crowns, bridges, inlays, and onlays (Patel et al., 2016).

Orthodontics

- Scanners are integral to aligner therapy, such as Invisalign, where they capture precise dental arch data to fabricate custom aligners (Weir, 2017).

Implantology

- Digital scans guide surgical planning and prosthetic design in implant dentistry, enhancing accuracy and reducing chairside adjustments (Mangano et al., 2017).

Periodontology and Diagnostics

- Advanced imaging capabilities enable monitoring of gingival health, measuring recession, and detecting wear facets or caries (Rekow, 2020).

Patient Communication and Education

- Real-time 3D visualizations from scanners improve patient understanding and engagement in treatment planning (Ahmed et al., , 2024).

2.6 Advantages and Limitations

2.6.1 Advantages:

Accuracy and Precision:

- Intraoral scanners offer superior accuracy in capturing fine details compared to traditional impression materials (Mangano et al., 2017).

Efficiency and Comfort:

- Scanning is faster and more comfortable for patients, especially those with gag reflexes or allergies to impression materials (Rekow, 2020).

Digital Workflow Integration:

- Seamless integration with CAD/CAM systems reduces laboratory turnaround time, enabling same-day restorations (Afrashtehfar et al., 2022).

Cost-Effectiveness in the Long Term:

- While initial investment is high, scanners eliminate recurring costs of impression materials and reduce remakes due to errors (Ahmed et al., 2024).

Environmentally Friendly:

- Digital impressions reduce the environmental burden associated with disposable impression trays and materials (Alkadi & Ruse, 2016).

2.6.2 Limitations:

Learning Curve:

- Clinicians require training to achieve optimal results, especially in scanning challenging areas like subgingival margins (Logozzo et al., 2014).

Initial Cost:

- The high cost of acquiring and maintaining an intraoral scanner can be a barrier for smaller practices (Alqahtani et al., 2024).

Limitations in Accuracy for Certain Cases:

- Complex cases involving deep subgingival margins or edentulous arches may still require traditional methods for accuracy (Mangano et al., 2017).

Dependence on Software and Updates:

- Regular updates and potential software compatibility issues can disrupt workflows (Rekow, 2020).

Surface Reflection Issues:

- Glossy or wet surfaces may cause scanning errors, requiring additional preparation such as drying or the application of scanning sprays (Logozzo et al., 2014).

2.7 Caries Etiology and Pathophysiology

2.7.1 Caries Development

Dental caries is a multifactorial disease resulting from the interplay between host factors, dietary sugars, and the oral microbiome. It begins with demineralization of enamel caused by acids produced by bacterial metabolism, primarily by

Streptococcus mutans and Lactobacilli (RAthee and Sapra., 2024). Over time, if demineralization outweighs remineralization, this leads to the formation of cavitated lesions. Salivary flow and composition play crucial roles in buffering acids and facilitating the repair of early lesions through remineralization (Marsh, 2003).

The carious process progresses through enamel, dentin, and eventually to the pulp if untreated. The balance between protective factors, such as fluoride and oral hygiene, and pathological factors, such as frequent sugar consumption, determines the pace of progression (Featherstone, 2008).

2.7.2 Clinical Manifestations on Occlusal and Smooth Surfaces

On occlusal surfaces, caries typically begins in the pits and fissures, where plaque accumulation is greatest due to the complex anatomy. Lesions on these surfaces often appear as chalky or stained areas before progressing to visible cavitation (Naaman et al., 2017).

Smooth surface caries, on the other hand, primarily affects areas along the gingival margin or between teeth. These lesions are usually the result of prolonged plaque accumulation and often appear as opaque, whitish spots that may later darken as demineralization progresses (Nyvad & Fejerskov, 1997).

2.8 Traditional Methods of Caries Detection

2.8.1 Visual-Tactile Inspection

Visual-tactile inspection is still a key method for detecting cavities in dental practice. Dentists use a mirror and an explorer to check for changes in tooth color, texture, and structure. Signs like opacities, discoloration, or small cavities, along with the feel of the explorer on the tooth, help in diagnosis (Pitts, 2004). However, this

approach is subjective and isn't always effective at spotting early-stage or subsurface cavities.

2.8.2 Radiographic Techniques

Radiographic imaging, particularly bitewing radiographs, is widely used for detecting interproximal and occlusal caries that are not visible clinically. Radiographs provide information about the extent and depth of the lesion, especially in areas inaccessible to visual-tactile examination (Ritter, 2013). However, limitations include exposure to ionizing radiation and reduced sensitivity for detecting early lesions or small caries (Pitts & Longbottom, 1995).

2.8.3 Comparison with Modern Methods

Traditional cavity detection methods are still common, but they have limitations, especially when it comes to spotting early or subsurface lesions. Their sensitivity and specificity aren't always reliable. Newer technologies like fluorescence-based detection and Optical Coherence Tomography (OCT) provide higher accuracy and can catch cavities much earlier (Bader et al., 2001). However, factors like cost, required training, and accessibility can make it challenging to fully integrate these tools into everyday dental practice.

2.9 Role of Technology in Caries Detection

2.9.1 Fluorescence-Based Detection

Fluorescence-based systems, such as DIAGNOdent and Quantitative Light-Induced Fluorescence (QLF), detect caries by measuring changes in the fluorescence properties of tooth enamel. These tools are particularly sensitive for early enamel lesions and provide quantitative data, making them useful for monitoring lesion

progression over time (Lussi et al., 2004). However, their accuracy can be affected by extrinsic stains and plaque (Amaechi et al., 2002).

2.9.2 Optical Coherence Tomography (OCT)

OCT is a non-invasive imaging technology that uses near-infrared light to create high-resolution cross-sectional images of dental tissues. It enables the detection of subsurface carious lesions and assessment of their depth and severity (Janjua et al., 2023). While promising, OCT systems are not yet widely available in dental practice due to high costs and the need for specialized training.

2.9.3 Intraoral Scanning Systems

Intraoral scanners, such as TRIOS 5 and Medit i700, have emerged as versatile tools for caries detection. These systems provide three-dimensional imaging of the tooth surface, allowing for the visualization of surface irregularities and early-stage caries. Additionally, the integration of AI into scanning workflows enhances diagnostic accuracy by identifying patterns indicative of caries (Michou et al., 2021).

2.10 Evaluating Intraoral Scanners

2.10.1 Features and Specifications

2.10.1.1 Technology Overview

The TRIOS 5 **intraoral scanner**, developed by 3Shape, is a fifth-generation device that improves on previous models with upgraded hardware and software. It uses advanced optical and AI-driven technology to capture high-resolution, 3D images of dental structures. Designed with a lightweight build and ergonomic handle, it’s user-friendly and helps reduce fatigue during long scanning sessions.

One of its key features is Ultrafast Optical Sectioning technology, which captures up to 7,000 3D images per second, allowing for fast and highly accurate scans (3Shape, 2024). The scanner also includes autoclavable scanning tips, improving infection control in clinical settings. Its wireless functionality offers greater flexibility, and its compatibility with various CAD/CAM systems ensures smooth integration into digital workflows (Mangano et al., 2017).

2.10.1.2 Workflow in Clinical Practice

In clinical practice, the TRIOS 5 scanner improves efficiency by eliminating the need for traditional physical impressions. Its real-time visualization feature lets dentists immediately assess scan quality, reducing errors and the need for retakes (Medit, 2024).

The scanner also includes an AI-powered caries detection tool, which helps identify potential cavities on both occlusal and smooth surfaces. This enhances diagnostic accuracy and makes it easier for dentists to explain findings to patients (Medit, 2024). Additionally, its compatibility with 3D printers and milling machines enables same-day restorations, cutting down on patient visits and overall chair time (Mangano et al., 2017).

2.11 Performance Metrics for Caries Detection

*2.*11.1 Sensitivity and Specificity

The diagnostic performance of intraoral scanners is often evaluated based on their sensitivity and specificity in detecting caries. Sensitivity refers to the scanner's ability to correctly identify carious lesions, while specificity measures its ability to exclude healthy areas. Studies comparing TRIOS 5 have reported sensitivity values

ranging from 75% to 90% for occlusal caries detection and slightly lower values for smooth surface caries (Lussi et al., 2006).

2.11.2 Diagnostic Reliability in Clinical Settings

In clinical practice, the diagnostic reliability of intraoral scanners depends on multiple factors, including operator expertise, scanner calibration, and the presence of confounding factors such as saliva or plaque. The TRIOS 5 have demonstrated high reproducibility across various operators and clinical scenarios, with minimal inter-operator variability (Logozzo et al., 2014).

The use of AI-powered diagnostic tools in scanners like the TRIOS 5 improves reliability by minimizing human error in cavity detection (Al-Hassiny, 2024). These advancements make intraoral scanners a valuable part of modern clinical workflows, providing accurate, non-invasive, and efficient diagnostic solutions.

2.12 Advancements in Intraoral Scanner Technology

In recent years, intraoral scanners have undergone significant advancements, improving their accuracy, speed, and ease of use. One of the most notable innovations is the incorporation of artificial intelligence (AI) algorithms that help enhance the diagnostic capabilities of these devices. AI can assist in real-time error correction, caries detection, and tissue differentiation, making intraoral scanners more efficient and reliable for everyday clinical use (Schwendicke et al., 2020). Moreover, newer scanners like TRIOS 5 feature high-speed scanning capabilities, with scan times reduced to under a minute for full-arch impressions, streamlining workflows (Mangano et al., 2017).

New advancements in intraoral scanning include the development of portable and wireless scanners, giving dentists more flexibility and improving patient comfort.

These improvements are making intraoral scanners more practical across different fields of dentistry, including restorative treatments, orthodontics, and implantology (Logozzo et al., 2014).

Another key innovation is the integration of cloud-based platforms for storing and sharing digital impressions. This makes it easier for dentists and labs to collaborate, leading to better treatment planning and more efficient workflows (Mangano et al., 2017).

2.13 AI Integration in Caries Detection

The integration of AI technology is revolutionizing intraoral scanners, especially in enhancing caries detection capabilities. By using machine learning algorithms, AI systems can analyze scanned images for patterns indicative of caries, providing clinicians with enhanced diagnostic accuracy. These systems are capable of detecting even subtle changes in the enamel structure, which may be missed by the human eye (Schwendicke et al., 2020). AI-based algorithms also improve the specificity and sensitivity of caries detection, reducing the chances of false positives and false negatives, which are common limitations of traditional methods (Zimmermann et al., 2020).

In addition to caries detection, AI is being utilized to predict lesion progression, assisting clinicians in making more informed decisions regarding the treatment and monitoring of carious lesions. The integration of AI in intraoral scanners represents a significant step toward automating and enhancing diagnostic workflows, ultimately improving clinical outcomes and reducing the likelihood of diagnostic errors (Schwendicke et al., 2020). An example of this advancement is the Patient Monitoring feature in 3Shape, which facilitates the longitudinal assessment of

changes in tooth structure and position. Advancements in intraoral scanner technology are expected to expand their use beyond just capturing digital impressions. Future developments may allow scanners to track carious lesion progression, helping dentists monitor how cavities change over time and adjust treatment plans accordingly (Angelone et al., 2023).

2.14 Emerging Trends

Several trends are shaping the future of intraoral scanner technology:

- Multi-Functional Devices: A major shift is toward scanners that integrate additional diagnostic tools, like radiographic imaging or 3D imaging. These hybrid devices would give dentists a more complete picture of a patient's oral health in a single scan, improving accuracy while reducing chair time (Eggmann & Blatz, 2024).
- Expanding Applications: While originally designed for restorative dentistry, intraoral scanners are now widely used in orthodontics for designing aligners, planning treatments, and tracking progress (Eggmann & Blatz, 2024). In the future, they may also play a key role in detecting and monitoring oral diseases like periodontitis, where early identification of tissue changes could improve treatment outcomes (Logozzo et al., 2014).
- Greater Accessibility & Affordability: The market is seeing an increase in smaller, more budget-friendly scanners, making digital workflows more accessible to all types of dental practices (Mangano et al., 2017). This trend is likely to accelerate the widespread adoption of intraoral scanners, further integrating digital tools into everyday dentistry.

2.15 Best Practices for Technology Adoption

For dental practices transitioning to intraoral scanners, following a structured approach can help ensure a smooth shift to digital workflows.

- Staff Training: Proper training is key to making sure all team members feel confident using the new technology. Training should cover not just the technical operation of the scanner but also how to interpret scan results and troubleshoot common issues (Richert, 2017).
- Regular Maintenance & Calibration: Keeping the scanner in top condition is essential for accuracy and long-term use. Dental practices should schedule regular service checks, update software, and replace worn-out parts like scanning tips. Working closely with the manufacturer can help ensure the device remains reliable.
- Staying Up to Date: As software and AI technology continue to evolve, clinicians should stay informed about the latest advancements. This helps them make the most of the scanner's capabilities and integrate new features into their workflow for even better efficiency.

2.15.1 Enhancing Calibration Standards

Keeping intraoral scanners properly calibrated is essential for maintaining accuracy, especially in detecting cavities and other dental conditions. Calibration should follow strict standards, with regular re-calibrations to ensure reliable results. This process should include both internal and external validation, comparing scanner data against established benchmarks and real clinical outcomes (Mangano et al., 2017).

While intraoral scanners are valuable tools, clinicians should be mindful of their limitations. To improve diagnostic accuracy, scans should be used alongside other tools like radiographs to confirm findings and avoid misdiagnosis (Schwendicke et al., 2020).

A promising advancement in this area is the integration of AI-driven calibration features in modern scanners. These automated adjustments help maintain high diagnostic reliability by fine-tuning the scanner's accuracy over time.

CHAPTER 3

AIMS OF THE INVESTIGATION

3.1 Specific Aims

The aims of this study were as follows:

1. **To Evaluate Diagnostic Accuracy:** Assess the diagnostic accuracy of intraoral scanners in detecting dental caries, comparing their performance to calibrated clinicians, who serve as the gold standard in caries detection.
2. **To Compare Two Advanced Scanners:** Conduct a comparative analysis of two intraoral scanner, the 3Shape TRIOS 5 to determine its respective capabilities in identifying carious lesions on occlusal and smooth tooth surfaces.
3. **To Explore Non-Invasive Detection Methods:** Investigate the effectiveness of intraoral scanners as non-invasive diagnostic tools, highlighting their potential advantages over traditional methods, such as visual-tactile examinations and radiographs.
4. **To Address Technological Advancements:** Contribute to the growing body of research on digital diagnostics in dentistry by evaluating the role of advanced intraoral scanning technologies in enhancing caries detection.
5. **To Inform Clinical Practice:** Provide data-driven insights that could influence the integration of intraoral scanners into routine dental practice, emphasizing their potential to improve diagnostic outcomes and patient care.

3.2 Study Significance

This study has the potential to transform cavity detection and diagnosis by assessing how effective advanced intraoral scanners are as non-invasive diagnostic tools. Traditional methods, like visual-tactile exams and X-rays, often struggle to detect early-stage and interproximal cavities, which can lead to delayed diagnoses and unnecessary tooth damage.

By comparing the diagnostic accuracy of the 3Shape TRIOS 5 scanner with expert clinicians, this study aims to validate the scanner's ability to improve precision and consistency in caries detection. The results will contribute to the growing research on digital diagnostics in dentistry and offer valuable insights into how practical and efficient these tools are in real-world clinical settings.

Ultimately, this research seeks to guide clinical practice by promoting the use of innovative, non-invasive technologies that help detect cavities earlier, preserve tooth structure, and reduce the overall impact of dental caries on a global scale.

CHAPTER 4

MATERIALS AND METHODS

4.1 Setting of the Human Research

The study was approved by Temple University Kornberg School of Dentistry (TUKSoD) Institutional Review Board (IRB) under protocol #31694. Participants were recruited from the school's clinics, specifically the Triage Restorative Assessment Clinic and the Advanced Education General Dentistry Clinic. These clinics cater to new patients who underwent a medical history review and diagnostic radiographs as part of their initial visit. Patients meeting the study's inclusion criteria were approached in these clinics, and informed consent was obtained on-site. Recruitment efforts ensured that participants fully understood the study's purpose, procedures, and requirements.

4.2 Resources Available to Conduct the Human Research

The research utilized the expertise and resources of Temple University Kornberg School of Dentistry. The study team included the Principal Investigators (PI) and a Student Investigator (SI). The PI supervised the entire research process, ensuring compliance with study protocols, while the SI managed patient recruitment, data collection, and monitoring. Both the PI and SI were calibrated examiner for caries detection to maintain consistency and reliability in clinical assessments.

Temple Kornberg School of Dentistry is equipped with multiple state-of-the-art intraoral scanner, the 3Shape TRIOS 5. These scanners were integral to the school's digital workflows, enhancing the quality and efficiency of patient care. The availability of these advanced tools and the expertise of the research team ensured the study was conducted effectively.

4.3 Recruitment Methods

The recruitment process focused on new patients entering the school for treatment, as these individuals were more likely to present with undiagnosed and untreated caries. During their initial appointment, patients underwent the standard clinical examination and radiographic imaging required for all new patients. Eligible patients were invited to participate in the study.

For those who consented, additional intraoral scans using the 3Shape TRIOS 5 was performed to detect caries. These scans, along with the clinical examination, required approximately 60 extra minutes of the patient's time. Participants were informed of the additional time commitment during the consent process, and a detailed explanation of the study was provided using the recruitment script included in Appendix A.

4.3.1 Inclusion and Exclusion Criteria

Inclusion Criteria

- Age: Participants were adults aged 18 years or older.
- Dentition: Individuals had a minimum of 10 natural teeth present in a single dental arch.
- Consent: Participants provided informed consent to participate in the study, indicating their understanding and agreement.
- General Health: Participants were in good general health, without systemic diseases impacting oral health or participation.

- Oral Health Status: Participants were not undergoing treatments with orthodontic or orthognathic appliances that could interfere with scanning accuracy.
- Ability to Comply: Participants were able to attend scheduled appointments and cooperate with scanning procedures.
- Demographic Diversity: No participants were excluded or included based on demographic data, ensuring a diverse participant pool.

Exclusion Criteria

- Orthodontic Treatment: Participants currently undergoing orthodontic treatment or wearing orthodontic appliances were excluded.
- Recent Dental Treatment: Individuals with restorative procedures or extractions performed within the past year were excluded.
- Inability to Provide Informed Consent: Participants unable to provide informed consent due to cognitive impairment, language barriers, or other reasons were excluded.
- Pregnancy: Pregnant individuals were excluded due to hormonal changes and physiological alterations affecting oral health.

4.3.2 Screening Criteria and Sample Size

Screening Criteria	**Details**
Patient Selection	Patients were selected from new individuals seeking care at Temple University Kornberg School of Dentistry.

Eligibility	Selection was based on the previously established inclusion and exclusion criteria.
Radiographs Requirement	Patients had to provide radiographs that were no older than one year. Preferred radiographs included a full mouth series or a panoramic and bitewings.
Radiograph Payment	Patients were responsible for paying for their radiographs at the initial visit, consistent with standard school protocol.
Sample Size	The study recruited a total of 21 participants for the current sample.

4.3.3 Study Timeline

Study Timeline	**Activity**	**Timeframe**
Participant Recruitment	Recruitment of eligible participants and obtaining informed consent.	From Jan 2025
Data Collection	Conducting clinical assessments and intraoral scans.	From Jan 2025
Data Analysis	Analyzing collected data for accuracy and diagnostic outcomes.	February 2025
Thesis Finalization	Compiling findings and completing the thesis.	February–March 2025

4.3.4 Study Endpoints

Accuracy of Caries Detection

- Definition: The ability of the intraoral scanners to correctly identify the presence or absence of dental caries.
- Measurement: Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated to assess the overall accuracy of caries detection.

Detection Time

- Definition: The time required for each intraoral scanner to capture and process images for caries detection.
- Measurement: The duration of scanning procedures with TRIOS 5

User-Friendliness

- Definition: The ease with which the scanners could be operated by trained dental technicians.
- Measurement: User feedback and observations were gathered through surveys or interviews to assess the scanners' user-friendliness.

Diagnostic Variations

- Definition: Variations in diagnostic outcomes between the TRIOS 5 and calibrated examiner.
- Measurement: Discrepancies in caries detection results between the TRIOS 5 and calibrated examiner were documented and analyzed.

Clinician Calibration

- Definition: The accuracy and reliability of clinical assessments conducted by calibrated clinician.
- Measurement: Intra-examiner and inter-examiner reliability were determined through repeated assessments and inter-rater agreement analyses.

4.4 Procedures Involved in the Human Research

- Clinicians assigned to perform caries detection for the study were properly trained and calibrated. During clinician calibration for caries detection, based on the Temple Caries Detection criteria, the study concentrated on occlusal and smooth surface lesions. As intraoral scanners were not designed to detect interproximal lesions, the calibration process emphasized visual examination, radiographic analysis, and blunt-probing methods. The investigators were also calibrated in the use of intraoral scanners for caries detection.

Visual Assessment of Lesion Progression

Category	**Pits and Fissures**	**Proximal Tooth Surfaces**	**Buccal and Lingual Smooth Surfaces**
Sound surfaces (or undetectable caries) (ICDAS 0)	No visible carious changes when viewed clean and dry. Non-carious white or brown marks on tooth	Same as P&F	Developmental defects like enamel hypoplasia, fluorosis, tooth wear (attrition, abrasion, and

	surfaces must be differentiated from early caries lesions. *Due to the low sensitivity of visual methods, early lesions may not be detectable.*		erosion), and extrinsic or intrinsic stains are recorded as sound.
Medical care (ICDAS 1 & 2)	First visual change in enamel confined to the base of the fissure (opaque white seen only after air drying or when wet) OR a distinct visual surface change seen dry or wet that appears white or brown.	Opaque white and/or brown discolorations, as for P&F. These lesions are usually seen from the buccal or lingual directions but may be viewed from the O direction as well.	Opaque white and/or brown discolorations of the surface, as for P&F.
Surgical care (ICDAS 3 & 4) and extensive (advanced)	Localized enamel breakdown (incipient cavitation), widening of the pit	Initial breakdown of enamel surface integrity OR shadowing of dentin as for P&F. Lesions	Initial breakdown of enamel surface integrity OR shadowing of

stage caries (ICDAS 5 & 6)	or fissure without dentin exposure OR a shadow in enamel seen wet (may not always be clear). When dentin is exposed, cavitation is always evident. Distinct cavitation exposing visible dentin.	usually seen from the B and L directions but may also be viewed from the O direction as well. The shadowing is through intact marginal ridge enamel, or cavitated.	enamel, as for P&F.

- Patient recruitment commenced as soon as IRB approval was received to start the study. Patients were selected based on the inclusion and exclusion criteria. New patients entering the school daily were screened for eligibility. Each new patient was assigned a unique Axium Record Number (equivalent to a medical record number), which was utilized to identify patients if access to their radiographs or intraoral scans was required. Dental records for patients were securely password-protected, and access was restricted to specific patient pools for authorized providers only. Each patient was properly consented orally and provided with a copy of the signed consent form for their records.
- Each patient underwent a clinical assessment for caries detection by a calibrated examiner. The examiner recorded the teeth and surfaces that were visually and clinically identified as carious. The findings were documented in a structured

table, including details such as participant number, patient age, tooth number, number of carious surfaces identified radiographically, and number of carious surfaces identified through clinical examination.

- Each participant's number was matched with their Axium record number on a separate document to enable researchers to refer back to radiographs if needed. This matching chart was securely stored in a locked drawer in the primary investigator's office to ensure confidentiality. The table used for documentation was structured as follows:

Participant #	**Patient Age**	**Tooth #**	**# Carious Surfaces Radiographically**	**# Carious Surfaces by Clinical Examiner**

Similarly, the Axium record number mapping chart was structured as follows:

Participant #	**Axium Record #**

- A second researcher, different from the calibrated examiner, performed the scanning of patients the TRIOS 5 intraoral scanner. Patients were entered into the scanner as study participants, with their full names excluded to maintain anonymity. This second researcher, who was blinded to the caries findings recorded by the calibrated clinician, meticulously documented the carious teeth and surfaces identified by the scanner.

- The purpose of this step was to compare the diagnostic outcomes of the intraoral scanner against the benchmark set by the calibrated clinician. Findings from the scanning process were recorded in a structured table, such as the one below:

Participant #	**Tooth #**	**# Carious Surfaces Marked by TRIOS 5**	**# Carious Surfaces Marked by Calibrated examiner**

- After the scanning procedure, patients were dismissed and continued with their treatment for dental diseases in the assigned clinics. This marked the end of their participation in the study. The clinical findings recorded by the calibrated examiner and the intraoral scans were not included in the patients' dental records at the school, as this information was collected solely for research purposes. Patients participating in the study received the same standard examination and subsequent treatment as non-participant patients, ensuring equity in care.
- All data from the intraoral scanners were collected and securely stored on a HIPAA-compliant server until sufficient data was obtained for analysis. Similarly, all clinical assessment data from the calibrated examiner was stored in a locked cabinet in the primary investigator's office. The data collected for the study was not destroyed, in accordance with FDA compliance requirements, ensuring secure and appropriate handling of all research materials.

4.5 Data Management

Efficient data management is essential for ensuring the integrity and reliability of statistical analyses. The following strategies were employed to manage data effectively:

4.5.1 Data Storage

- All collected data were securely stored in a designated database or repository with restricted access. Patient scans were secured in a HIPAA-approved server.
- Regular backups were performed to prevent data loss.
- Collected study data were not included as part of the participants' dental records, ensuring they were solely used for research purposes.

4.5.2 Data Coding and Standardization

- Data coding was implemented to convert qualitative information into numerical values suitable for statistical analysis.
- Standardization procedures were applied to maintain consistency in data representation across the study.

4.5.3 Blinding Protocols

- Researchers involved in data analysis were blinded to the order of scanner use and specific outcomes to prevent bias.
- Strict adherence to blinding protocols was maintained throughout the analysis phase.

4.5.4 Data Analysis Software

- Specialized statistical software, such as SPSS or R, was utilized for data analysis.
- Statistical tests, including chi-square tests and t-tests, were conducted based on the nature of the variables.

4.5.5 Confidentiality Measures

- Participant confidentiality was upheld by anonymizing and aggregating data during collection and analysis.
- Personal and sensitive information was not stored with the collected data to maintain privacy.

4.5.6 Interim Data Checks

- Interim data checks were conducted periodically to identify and rectify any anomalies or inconsistencies in the dataset.
- Data cleaning procedures were implemented as necessary to ensure the accuracy and reliability of the data.

4.6 Data Analysis

The outcomes obtained from the TRIOS 5 scanner were systematically compared with the calibrated clinician's clinical assessments. Primary endpoints for analysis included the accuracy of caries detection, sensitivity, specificity, and the user-friendliness of the scanners. Statistical methods suitable for experimental studies, such as chi-square tests and t-tests, were employed to evaluate the data. The predefined significance level was set at $p<0.05$, ensuring rigorous statistical interpretation of the results.

4.6.1 Withdrawal of Subjects

Although the withdrawal of subjects was not anticipated, participants were encouraged to engage openly with the study staff if they experienced any distress or discomfort during the intraoral scanning process. Participants had the opportunity to discuss their concerns with the research team at any time and, if necessary, discontinue their participation without prejudice. Study staff provided full support for participants' decisions to withdraw, emphasizing the ethical priority of participant well-being. Maintaining open communication between participants and study staff was essential to ensuring ethical conduct and participant satisfaction throughout the research.

4.7 Risks to Subjects

Participants did not face any inconvenience beyond the additional time required for their participation in the study. All procedures were designed with participant safety and well-being in mind, and no physical risks or long-term adverse effects were anticipated. However, as with all research, there was a potential risk of breached confidentiality.

To mitigate the risk of confidentiality breaches, several safeguards were implemented:

- All study staff underwent training in human subject research and HIPAA regulations through CITI training.
- Data was collected and stored using secure servers and accessed only via password-protected computers.

- Access to study data was restricted to authorized personnel, and participant identifiers were limited to Dental Record numbers, excluding names or other personal identifiers.
- Access to the Axium Dental record database required specific password authentication, preventing unauthorized connections between Dental Record numbers and patient identities.

4.8 Privacy and Confidentiality

Participants were provided with a consent form outlining the study's efforts to maintain participant confidentiality and any potential risks of a breach of confidentiality. Upon enrollment, participants reviewed and acknowledged this form, ensuring informed consent.

Respecting patients' privacy was paramount throughout the research. All individuals involved in the study received training on the importance of upholding confidentiality and completed education on proper practices according to HIPAA regulations. Data files were accessible only to the investigators and research assistants directly involved in the study, and only members of the research team reviewed the data.

To ensure participant comfort, the student investigator and other staff emphasized participants' right to ask questions and to decline any aspect of the research that made them uncomfortable. Data were shared only with individuals associated with the project who obtained prior written consent from participants. When the results of the study were published, no participant was identified by name, ensuring anonymity.

4.9 Economic Burden to Subjects

Participants in this research did not incur any economic burden as a requirement for participation. No additional dental procedures were performed as part of this research study, maintaining the standard treatment protocols for all patients.

4.9.1 Subject Compensation

Participants were not compensated for their participation in the study.

4.10 Consent Process

Eligible participants were presented with a concise informed consent form (Appendix A). They had the opportunity to ask questions about the study or the consent form to the research staff. To signify agreement, participants acknowledged and clicked an agreement button electronically. Additionally, they received a copy of the consent form for their own records.

Participants retained the right to opt out of the study at any time by informing a research staff member. They were informed that participation in the study would add an additional hour to their visit to the school. Participants were also provided with HIPAA authorization forms (Appendix A), detailing who was authorized to access the information collected within the study, ensuring confidentiality. Only the patient’s age was recorded on the data collection form to further protect privacy.

4.10.1 Process to Document Consent in Writing

The process to obtain consent in writing for this study involved minimal risk to participants. Upon recruitment, participants were presented with a consent form detailing the study's purpose, procedures, and potential risks. Instead of collecting

signed documents, participants verbally acknowledged their consent and clicked "I agree" in the electronic survey.

This approach minimized any additional risk to confidentiality associated with collecting signed documents.

CHAPTER 5

Results

5.1. Descriptive Statistics

Table 1 presents the descriptive statistics for caries detection findings from Examiner and the TRIOS 5 scanner.

- The standard deviation (SD) values suggest that Examiner had greater variability (0.858) in caries detection than the TRIOS 5 scanner (0.352).

Table 1: Descriptive Statistics

	Examiner_ Findings	**TRIOS 5_Findings**
count	255.0	255.0
mean	0.945	0.854
std	0.858	0.352
min	0.0	0.0
25%	0.0	1.0
50%	1.0	1.0

Figure 1 illustrates the distribution of caries detection findings, visually representing the variance in caries detection rates among the three evaluators.

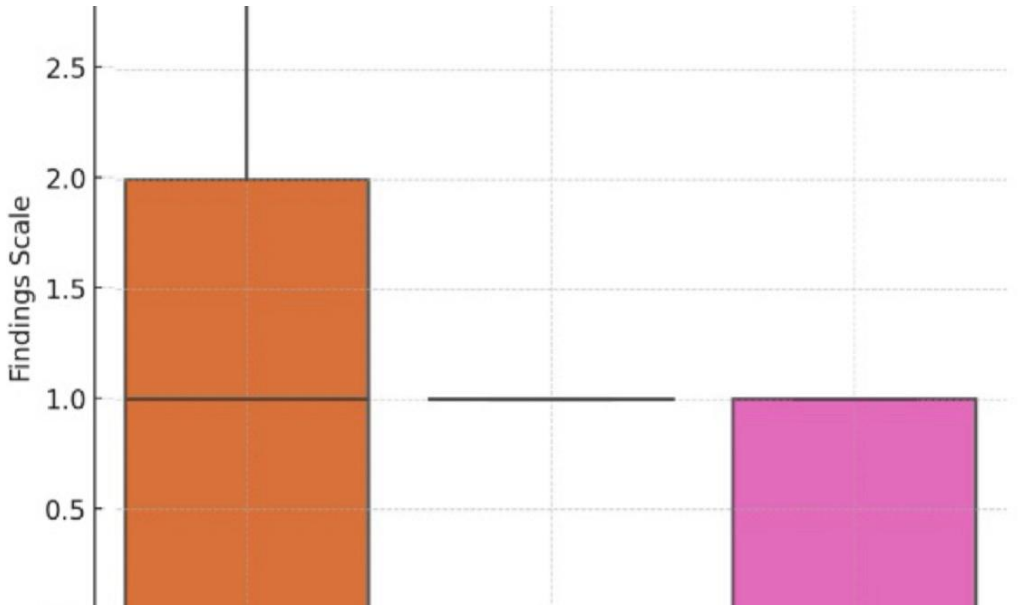


Figure 1: Distribution of Caries Detection Findings

5.2. Correlation Analysis

Table 2 presents the correlation matrix, which examines the relationship between different caries detection methods.

- The TRIOS 5 scanner findings had a weak negative correlation with Examiner (-0.052), suggesting limited agreement between manual detection and scanner-based detection.
- Radiographic findings correlated moderately with Examiner (0.450) but very weakly with the TRIOS 5 scanner (0.071), suggesting the scanner's findings do not align well with radiographic detection.

Table 2: Correlation Matrix

	Examiner_ Findings	**TRIOS 5 Findings**
Examiner_ Findings	1.0	-0.052
TRIOS 5_Findings	-0.052	1.0
Radiographic_ Findings	0.450	0.071

Figure **2**, the correlation Heatmap, visually represents these relationships, reinforcing the weak agreement between the TRIOS 5 scanner and traditional examiner.

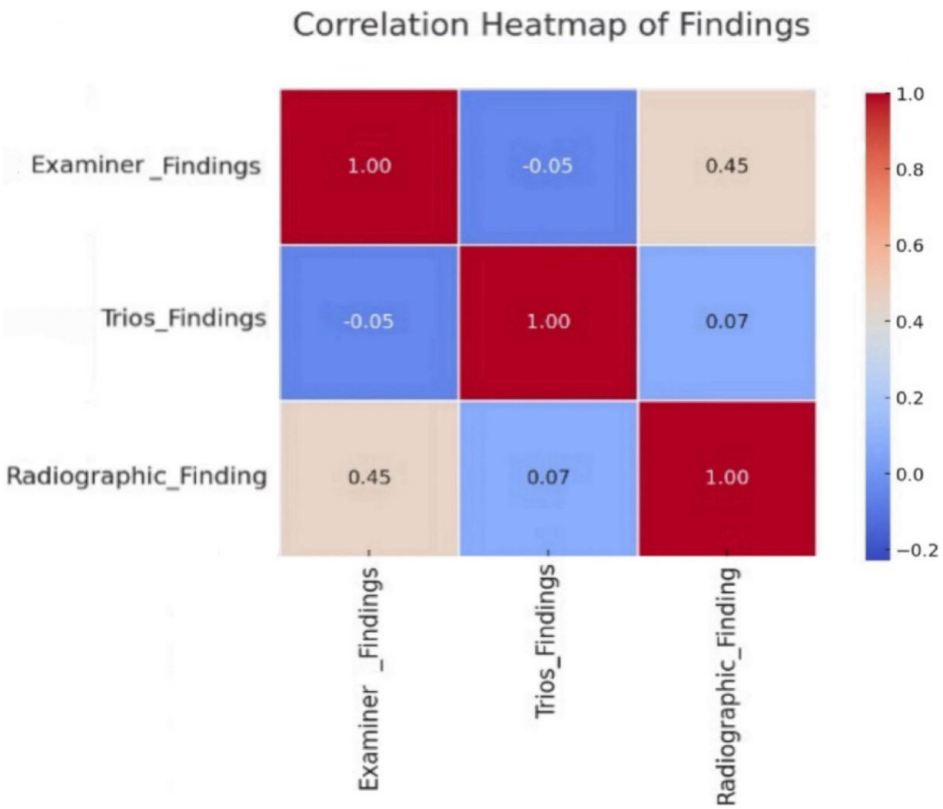


Figure 2: Correlation Heatmap of Findings

5.3. Chi-square Analysis

Table **3** presents the Chi-square test results, assessing the relationship between TRIOS 5 scanner and radiographic findings.

- The Chi-square statistic (0.885) with a p-value of 0.346 indicates no statistically significant association between the scanner's findings and radiographic diagnosis.
- This suggests that the TRIOS 5 scanner does not strongly align with radiographic diagnosis, which is often considered the gold standard.

Table 3: Chi-square Test Results

Chi-square Statistic	Degrees of Freedom	P-Value
0.8851058727244471	1	0.346

5.4. Contingency Table & Sensitivity-Specificity Analysis

Table 4 provides a contingency table, classifying cases based on TRIOS 5 scanner and radiographic findings.

- 68 surfaces were detected as caries-positive by both TRIOS 5 and radiographs, confirming agreement.
- 147 surfaces were classified as caries-positive by the scanner but negative by radiographs, indicating possible false positives.
- 8 surfaces were detected by radiographs but missed by the TRIOS 5 scanner, indicating false negatives.

Table 4: Contingency Table (TRIOS 5 vs Radiographic)

TRIOS 5_Findings	0.0	1.0
0.0	28	8
1.0	147	68

5.5. Agreement and Statistical Tests

Table 5 presents the performance metrics of the TRIOS 5 scanner:

Negative Predictive Value (NPV) 0.870

- Sensitivity (89.4%) indicates that the TRIOS 5 scanner correctly identifies 89.4% of actual caries surfaces.
- Specificity (26.4%) is low, suggesting that the scanner frequently misclassifies non-caries cases as carious.
- PPV (31.1%) means that only 31.1% of cases diagnosed as carious by TRIOS 5 were truly carious.
- NPV (87.0%) suggests that 87% of cases classified as non-caries were correctly identified.

Table 5: Sensitivity, Specificity, PPV, NPV

Metric	Value
Sensitivity	0.894
Specificity	0.264
Positive Predictive Value (PPV)	0.311
Negative Predictive Value (NPV)	0.870

Table 6 and Figure 3 presents the confusion matrix, showing that false positives (150 surfaces) significantly outnumber false negatives (8 surfaces).

Table 6: Confusion Matrix

	No Caries (Predicted)	Caries (Predicted)
No Caries (Actual)	54	150
Caries (Actual)	8	68

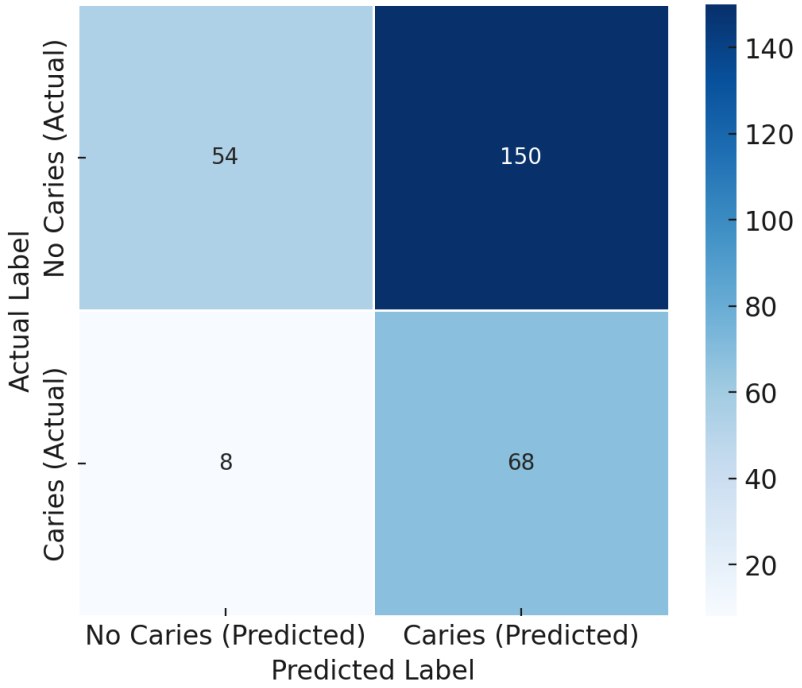


Figure 3: Confusion Matrix for TRIOS 5 vs Radiographic Findings

Figure 4 presents the ROC curve, which visually represents the diagnostic ability of the TRIOS 5 scanner.

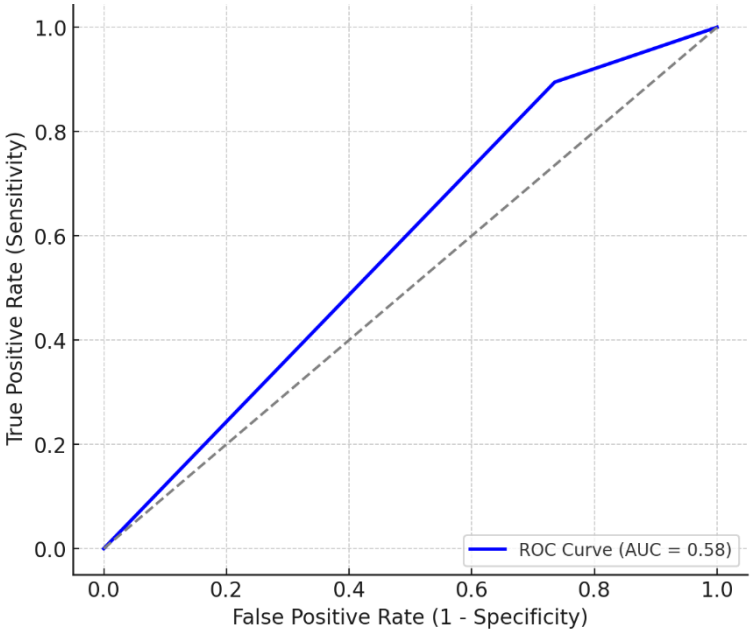


Figure 4: ROC Curve for TRIOS 5 vs Radiographic Findings

5.6 Cohen's Kappa Agreement

Table 7 presents Cohen's Kappa Score (0.100), which measures agreement between TRIOS 5 scanner and radiographic findings.

- A low agreement score of 0.100 suggests poor reliability in the scanner's caries detection compared to radiographic findings.
- This indicates that TRIOS 5 scanner findings do not strongly align with radiographic diagnosis.

Table 7: Cohen's Kappa Agreement

Statistic	Value
Cohen's Kappa Score	0.100

Figure 5 presents the Cohen's Kappa agreement Heatmap, visually reinforcing this weak agreement.

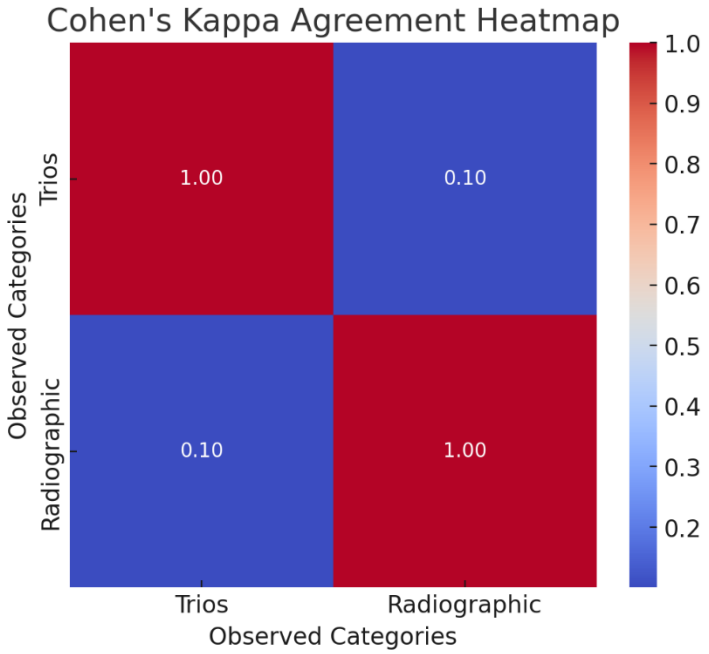


Figure 5: Cohen's Kappa Agreement Heatmap

5.7 McNemar’s Test for Paired Data

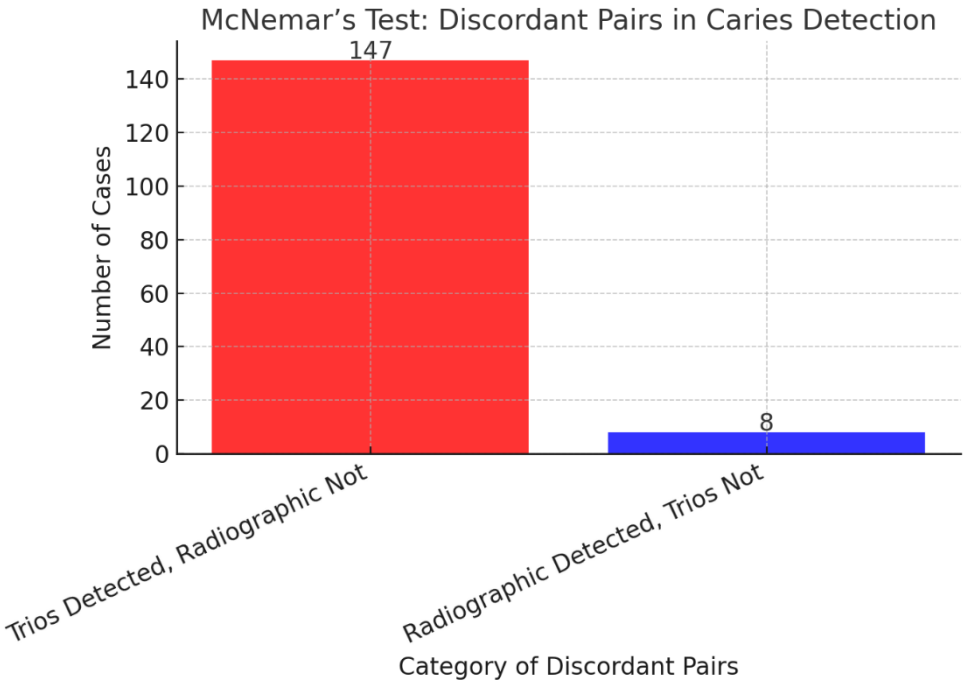
Table 8 presents McNemar’s test results, which evaluates the discrepancy between TRIOS 5 scanner and radiographic findings:

Table 8: McNemar's Test Results

Statistic	P-Value
McNemar's Test Statistic	4.648

- The significant p-value indicates that TRIOS 5 scanner and radiographic findings differ significantly.
- This suggests that the scanner and radiographic detection are not interchangeable, particularly in cases where the scanner detects caries that radiographs do not confirm.

Figure 6 presents the McNemar’s Test bar chart, showing the discordant pairs where TRIOS 5 detected caries while radiographs did not, and vice versa.


McNemar’s Test: Discordant Pairs in Caries Detection
Number of Cases
0
20
40
60
80
100
120
140
147
8
Trios Detected, Radiographic Not
Radiographic Detected, Trios Not
Category of Discordant Pairs

CHAPTER 6

Discussion

Dental caries is a significant global health concern, affecting approximately 2 billion people worldwide (WHO). This widespread prevalence underscores the critical need for accurate and reliable diagnostic methods to ensure timely intervention and optimal patient outcomes (Ghodasra et al., 2025).

Traditionally, caries detection has relied on visual-tactile examination (VTE) and radiographic imaging. While these methods are widely used, they have notable limitations. Studies have shown poor agreement between VTE and radiographic examinations in detecting caries, particularly in posterior teeth of caries-active adults. For instance, a study reported a kappa statistic of 0.18 for all surfaces, indicating low concordance between these two diagnostic methods. (Chong et al., 2003)

Additionally, radiographic techniques may underestimate the extent of carious lesions, as demineralization must reach a certain threshold before becoming radiographically apparent (Wenzel., 2021).

In recent years, digital intraoral scanners have emerged as promising tools for early caries detection (Lin et al., 2023). These devices offer non-invasive, real-time, and high-resolution imaging capabilities, potentially enhancing the accuracy of caries diagnosis (Kanar er al., 2024). However, their clinical validity and reliability compared to traditional diagnostic modalities remain under evaluation (2024).

Recent studies have evaluated the diagnostic performance of intraoral scanners (IOS) in caries detection, highlighting concerns regarding their specificity due to a tendency to produce false-positive results. For instance, a comparative study assessing the caries diagnostic capabilities of various IOS models found that both the TRIOS 5

and iTero Element 5D scanners exhibited higher percentages of false-positive diagnoses compared to false negatives. This indicates a propensity to over-diagnose carious lesions, thereby affecting their specificity (Schlenz et al., 2022).

Similarly, another clinical study focusing on occlusal caries detection in pediatric patients compared the performance of the TRIOS 5 and Emerald S intraoral scanners, as well as the Diagnocam device, against traditional visual examination methods. The findings revealed that while these devices are effective in detecting carious lesions, they also demonstrated a higher rate of false-positive results, leading to concerns about their specificity (Schulz-Weidner et al., 2024). These studies suggest that while intraoral scanners are valuable tools for caries detection, their tendency towards false-positive diagnoses necessitates cautious interpretation of results. Integrating IOS assessments with traditional diagnostic methods may help mitigate the risk of over-diagnosis and ensure more accurate patient evaluations.

This study aimed to assess the diagnostic accuracy of the TRIOS 5 intraoral scanner by comparing its caries detection performance with examiner-based assessments and radiographic findings. Understanding the strengths and limitations of this technology is essential for its integration into clinical practice and for improving patient care outcomes.

6.1 Overview of Findings

This study evaluated the diagnostic accuracy of intraoral scanning technology (TRIOS 5) for detecting dental caries, comparing its performance against human examiner and radiographic findings. The results indicate a high sensitivity (89.4%) but low specificity (26.4%), suggesting that while the scanner is effective at detecting true caries cases, it also produces a significant number of false positives. These

findings align with previous studies that have demonstrated similar trends in digital diagnostic technologies, where high sensitivity was reported (Zhang et al., 2024; Kanar et al., 2024).

In contrast, examiner-based assessments demonstrated stronger agreement with radiographic findings, highlighting the continued relevance of expert clinical judgment in caries diagnosis.

6.2 Diagnostic Accuracy of Intraoral Scanners

6.2.1 Sensitivity and Specificity

The TRIOS 5 scanner demonstrated an 89.4% sensitivity, indicating that it effectively detects carious lesions. This aligns with a systematic review highlighted that optical-based caries detection methods have been developed and intensively investigated over the past 20 years, enabling the diagnosis of early lesions. (Abdelaziz., 2023). However, The observed low specificity (26.4%) of the scanner, leading to an overestimation of caries presence, aligns with existing literature indicating that digital scanning technologies often produce false positives due to their heightened sensitivity to minor demineralization. For instance, fluorescence-based caries detection methods have been noted for their tendency toward false-positive results, which can lead to overdiagnosis (Chan et al., 2023). Similarly, a study comparing various caries diagnostic methods found that certain intraoral scanners exhibited higher sensitivity but lower specificity, resulting in an increased risk of false positives (Schlenz et al., 2022).

The high false-positive rate observed in intraoral scanners may be attributed to their detection of structural variations in enamel that do not necessarily indicate active caries. Amaechi et al. (2001) demonstrated that optical coherence tomography (OCT)

could detect demineralization in enamel, which might not correspond to active carious lesions. Similarly, Janjua et al. (2023) highlighted that non-cavitated enamel demineralization could be misinterpreted as caries in OCT studies, emphasizing the need for adjunctive confirmatory methods.

6.3 Comparison with Radiographic Findings

The Chi-square test results ($p = 0.346$) suggest no statistically significant association between the TRIOS 5 scanner and radiographic findings, indicating that these two diagnostic modalities may not align in caries detection. Radiographic techniques have long been considered the gold standard for diagnosing interproximal and advanced occlusal caries due to their ability to penetrate deeper into enamel and dentin layers. However, they have limitations in detecting early-stage, non-cavitated caries. In contrast, intraoral scanners, such as the TRIOS 5, can identify early demineralization on tooth surfaces, potentially leading to earlier interventions. This complementary capability suggests that while the TRIOS 5 scanner should not be used as a standalone diagnostic tool, it can serve as a valuable adjunct to radiographic and clinical assessments. Integrating digital imaging technologies into clinical workflows has been shown to enhance early detection of caries while maintaining specificity through confirmatory diagnostics (Schlenz et al., 2022).

6.4 Agreement Between Different Diagnostic Modalities

6.4.1 Cohen’s Kappa Analysis

The low agreement (Cohen's Kappa = 0.100) between the TRIOS 5 scanner and radiographic findings indicates poor reliability, suggesting that the scanner may detect non-cavitated demineralization or early lesions not visible on radiographs. This discrepancy highlights the potential role of intraoral scanners in identifying early

carious lesions before structural breakdown occurs. A study evaluating near-infrared light reflection for detecting proximal caries found poor consistency between this method and bitewing radiography, suggesting that near-infrared light reflection may detect early demineralization not visible on radiographs (Shen et al., 2025).

Fluorescence-based and optical scanning technologies have been shown to detect demineralized enamel more readily than radiographs, often leading to higher false-positive rates but better sensitivity for early intervention. A review on fluorescence devices for caries detection reported that these tools are more sensitive in identifying early enamel demineralization compared to traditional methods, though they may also result in increased false-positive detections (Macey et al., 2020).

Future research should explore whether intraoral scanners can be calibrated to distinguish between reversible enamel demineralization and active caries to reduce unnecessary overtreatment. A study assessing demineralized tooth lesions using optical coherence tomography emphasized the need for advanced diagnostic tools to differentiate between active and inactive lesions, which could help minimize overtreatment (Mohamad et al., 2022)..

6.4.2 McNemar’s Test and Discordant Pairs

The significant discrepancy between the Trios scanner and radiographic findings, as indicated by McNemar's test ($p = 4.648$), suggests that these two modalities diagnose caries differently. This aligns with findings from a study by Schwendicke et al. (2021), which reported that while the TRIOS 5 intraoral scanner demonstrated high sensitivity in detecting occlusal caries, it also exhibited a tendency to overestimate caries presence, leading to false positives. The authors noted that this overestimation could be due to the scanner's heightened sensitivity to surface

irregularities, such as minor demineralization or natural variations in enamel reflectivity. They concluded that while the TRIOS 5 shows promise as an adjunctive tool for caries detection, it should not replace traditional diagnostic methods (Michou et al., 2021).

Intraoral scanners (IOS) have been shown to misinterpret natural variations in enamel reflectivity as carious lesions, leading to false-positive detections. A study comparing the occlusal caries detection performance of IOSs, including the TRIOS 5 and Emerald S, found that these devices exhibited higher percentages of false-positive diagnoses than false negatives. The authors emphasized the importance of combining intraoral scanning with other diagnostic tools to improve specificity and reduce the likelihood of overtreatment (Schlenz et al., 2022).

Similarly, a narrative review highlighted that while IOSs with near-infrared imaging features offer promising capabilities in caries detection, they also have limitations, including high error rates in detecting enamel caries. The review suggests that IOSs should be used as adjunctive tools rather than primary diagnostic methods to enhance diagnostic accuracy and minimize false positives (Lin et al., 2023). These findings underscore the necessity for clinicians to integrate IOS technology with traditional diagnostic methods to ensure accurate caries detection and avoid unnecessary treatments.

Intraoral scanners have been proposed as tools to reduce subjectivity in caries detection by providing standardized criteria. However, studies have shown that certain scanners, such as those utilizing near-infrared imaging features, may overestimate the presence of proximal caries, leading to false positives. This overestimation is primarily due to heightened sensitivity to minor demineralization. Therefore, while

intraoral scanners hold promise for standardizing caries detection, their limitations must be addressed before they can be widely adopted as primary diagnostic tools (Lin et al., 2023).

Given these findings, intraoral scanners could provide standardized detection criteria, reducing subjectivity. However, TRIOS 5's overestimation of caries cases must be accounted for before widespread adoption as a primary diagnostic tool.

6.5 Clinical Implications

The findings from this study hold significant clinical implications for the diagnosis and management of dental caries. While TRIOS 5 intraoral scanner demonstrates high sensitivity (89.4%), its low specificity (26.4%) raises important considerations for its clinical application. Below are key clinical takeaways:

6.5.1. Role of Intraoral Scanners in Caries Detection

The results suggest that TRIOS 5 can be a valuable adjunct tool in clinical settings, particularly for early caries detection. However, its tendency to over-diagnose caries means that it should not be used as a standalone diagnostic tool.

- Clinicians may utilize TRIOS 5 scanning as an initial screening method, followed by radiographic and clinical confirmation to reduce the risk of false positives and unnecessary interventions.
- The scanner may be particularly useful for monitoring enamel demineralization over time, helping assess the effectiveness of remineralization therapies in preventive dentistry.

6.5.2. Minimizing Unnecessary Restorative Interventions

The low specificity of TRIOS 5 (26.4%) indicates a high number of false-positive caries detections, which can lead to unnecessary restorative treatments.

- Clinicians must be cautious when interpreting positive scanner findings, ensuring that early demineralization is not mistaken for active caries.
- Non-invasive interventions such as fluoride therapy, resin infiltration, or case-by-case observation should be considered before committing to restorative treatment.
- This is particularly important in minimally invasive dentistry, where the focus is on preserving natural tooth structure whenever possible.

6.5.3. Implications for Pediatric and Preventive Dentistry

Intraoral scanners could be highly beneficial in pediatric and preventive dentistry, where early intervention is crucial.

- Children and adolescents often present with incipient caries, which may not yet be visible on radiographs but could be detected by TRIOS 5 scanning.
- The scanner's ability to monitor early demineralization over time allows non-invasive preventive measures (e.g., fluoride application, dietary modifications, remineralization protocols) to be implemented before cavitation occurs.
- However, practitioners must avoid over-reliance on scanner results, ensuring that false positives do not lead to overtreatment in young patients.

6.5.4. The Need for Multimodal Caries Diagnosis

Given the poor agreement between TRIOS 5 and radiographic findings (Cohen's Kappa = 0.100, McNemar's p = 4.648), it is evident that no single diagnostic method is entirely reliable.

- Best clinical practice involves using multiple diagnostic modalities in combination:

  - Visual-tactile examination remains essential for assessing cavitation.
  - Radiographic imaging is crucial for detecting interproximal and deep dentinal caries.
  - Intraoral scanning can enhance detection of early-stage demineralization.

- The integration of AI-enhanced caries detection algorithms may further improve the accuracy and clinical reliability of intraoral scanners in the future.

6.5.5 Future Potential of AI in Caries Diagnosis

The low specificity of the TRIOS 5 scanner suggests that its diagnostic accuracy could be significantly improved with artificial intelligence (AI) and machine learning.

- AI-assisted intraoral scanners could help differentiate between active caries, arrested lesions, and sound enamel, thereby reducing false positives.
- AI models trained on large-scale clinical datasets may also enhance the scanner's ability to predict lesion progression, enabling early intervention strategies without overtreatment.
- Future research should focus on validating AI-assisted caries detection, ensuring it aligns with evidence-based clinical practices.

6.5.6 The Importance of Clinical Judgment

Despite advancements in digital diagnostics, clinical expertise remains irreplaceable.

- The findings emphasize the importance of practitioner judgment in interpreting intraoral scanner results alongside patient history, radiographic findings, and clinical examination.
- Training in digital diagnostic technologies should be incorporated into dental education, equipping clinicians with the skills to integrate new technologies into evidence-based practice.

6.6 Limitations

Despite the valuable insights gained from this study, several limitations must be acknowledged:

6.6.1 Lack of Gold Standard Validation

Although radiographic findings were used as a comparative benchmark, radiographs are not infallible in detecting early-stage caries.

- Histological validation (such as microscopic sectioning of teeth) could provide a definitive gold standard for assessing true caries status.
- Future studies should incorporate micro-CT analysis or histological verification to improve diagnostic accuracy comparisons.

6.6.2 Limited Sample Size and Study Population

The study's findings may be limited by the sample size and demographic distribution of the study population.

- If the sample primarily consisted of a specific age group or population subset, the findings may not be generalizable to other patient groups.
- Larger-scale multicenter trials are needed to confirm the reproducibility of these results in diverse clinical settings.

6.6.3 Lack of Longitudinal Follow-Up

This study was cross-sectional, meaning caries progression was not assessed over time.

- **Without longitudinal follow-up, it remains unclear whether the lesions detected by the TRIOS 5 scanner would have progressed into cavitated caries or remineralized naturally.**
- Future studies should implement long-term patient monitoring to validate whether scanner-detected lesions require intervention or remineralization therapy.

6.6.4 Influence of Scanner Calibration and Operator Technique

The performance of intraoral scanners can be influenced by operator technique and device calibration.

- Differences in scanning angle, pressure, and scanning duration could affect the detection accuracy of TRIOS 5.

CHAPTER 7

Conclusion

7.1 Summary of key findings

This study evaluated the diagnostic accuracy of the TRIOS 5 intraoral scanner for caries detection, comparing its performance with radiographic findings and examiner-based assessments. The findings indicate that while TRIOS 5 demonstrated high sensitivity (89.4%), it had low specificity (26.4%), resulting in a high false-positive rate.

7.1.1 TRIOS 5 is effective for early caries detection but not as a standalone tool –

The scanner's high sensitivity allows it to detect incipient caries, but its low specificity increases the risk of over-diagnosis. Radiographic and clinical confirmation remain essential before deciding on intervention.

7.1.2 Poor agreement between TRIOS 5 and radiographic findings –

Cohen’s Kappa (0.100) and McNemar’s Test (p = 4.648) indicate that TRIOS 5 findings do not strongly align with radiographic results, suggesting the scanner may overestimate caries presence.

7.2 Recommendations

7.2.1 Integration with multimodal diagnostic tools is necessary – Given its limitations, TRIOS 5 should be used in conjunction with other diagnostic methods, such as digital radiography, fluorescence-based imaging, and optical coherence tomography (OCT), to improve overall diagnostic accuracy.

7.2.2 Potential for AI-enhanced diagnostic improvements –

The study highlights the need for AI-driven calibration of intraoral scanners, which could refine their ability to differentiate between active caries, arrested lesions, and sound enamel, reducing false-positive detections.

7.3 Future Research Directions

This study provides valuable insights into the diagnostic accuracy of the TRIOS 5 intraoral scanner for caries detection. However, several areas require further research to enhance its clinical applicability:

7.3.1 AI-Enhanced Diagnosis –

Future studies should integrate artificial intelligence (AI) and machine learning to refine the scanner's specificity, reducing false positives while maintaining early detection accuracy.

7.3.2 Longitudinal Validation –

Follow-up studies should assess whether scanner-detected lesions progress into cavitated caries or remineralize, ensuring accurate treatment decisions.

7.3.3 Multicenter and Diverse Population Studies –

Large-scale, multicenter trials across different age groups and demographics are needed to confirm the generalizability of intraoral scanner performance.

7.3.4 Optimizing Scanner Calibration –

Refinements in scanner software and sensitivity thresholds are necessary to differentiate between active caries, arrested lesions, and enamel demineralization more accurately.

7.3.5 Multimodal Caries Detection –

Combining TRIOS 5 scanning with digital radiography, fluorescence-based imaging, and optical coherence tomography (OCT) could enhance diagnostic precision and compensate for individual modality limitations.

7.3.6 Standardized Scanning Protocols –

Operator-dependent variability should be minimized through protocol standardization, ensuring reproducibility across different clinical settings.

7.3.7 Influence of Oral Conditions –

Future research should evaluate how saliva contamination, restorations, and enamel translucency affect scanner performance under real-world conditions.

7.3.8 Economic and Patient-Centered Evaluations –

Studies should assess **cost-**effectiveness, patient comfort, and willingness to adopt intraoral scanning in routine dental practice.

REFERENCES

1. Abdelaziz M. Detection, Diagnosis, and Monitoring of Early Caries: The Future of Individualized Dental Care. Diagnostics (Basel). 2023 Dec 12;13(24):3649. doi: 10.3390/diagnostics13243649. PMID: 38132233; PMCID: PMC10742918.
2. Al-Khalifa KS, Ahmed WM, Azhari AA, Qaw M, Alsheikh R, Alqudaihi F, Alfaraj A. The Use of Artificial Intelligence in Caries Detection: A Review. Bioengineering (Basel). 2024 Sep 18;11(9):936. doi: 10.3390/bioengineering11090936. PMID: 39329679; PMCID: PMC11428802.
3. Amaechi BT, Higham SM, Podoleanu AG, Rogers JA, Jackson DA. Use of optical coherence tomography for assessment of dental caries: quantitative procedure. J Oral Rehabil. 2001 Dec;28(12):1092-3. doi: 10.1046/j.1365-2842.2001.00840.x. PMID: 11874506.
4. Angelone F, Ponsiglione AM, Ricciardi C, Cesarelli G, Sansone M, Amato F. Diagnostic Applications of Intraoral Scanners: A Systematic Review. J Imaging. 2023 Jul 3;9(7):134. doi: 10.3390/jimaging9070134. PMID: 37504811; PMCID: PMC10381333.
5. Chan EK, Wah YY, Lam WY, Chu CH, Yu OY. Use of Digital Diagnostic Aids for Initial Caries Detection: A Review. Dent J (Basel). 2023 Sep 28;11(10):232. doi: 10.3390/dj11100232. PMID: 37886917; PMCID: PMC10605137.
6. Chong MJ, Seow WK, Purdie DM, Cheng E, Wan V. Visual-tactile examination compared with conventional radiography, digital radiography, and Diagnodent in the diagnosis of occlusal occult caries in extracted premolars. Pediatr Dent. 2003 Jul-Aug;25(4):341-9. PMID: 13678099.
7. Dehghani M, Barzegari R, Tabatabai H, Ghanea S. Diagnostic Value of Conventional and Digital Radiography for Detection of Cavitated and Non-

Cavitated Proximal Caries. J Dent (Tehran). 2017 Jan;14(1):21-30. PMID: 28828014; PMCID: PMC5557993.

8. Fontana M, González-Cabezas C. Secondary caries and restoration replacement: an unresolved problem. Compend Contin Educ Dent. 2000 Jan;21(1):15-8, 21-4, 26 passim; quiz 30. PMID: 11199687.
9. Giacaman RA, Fernández CE, Muñoz-Sandoval C, León S, García-Manríquez N, Echeverría C, Valdés S, Castro RJ, Gambetta-Tessini K. Understanding dental caries as a non-communicable and behavioral disease: Management implications. Front Oral Health. 2022 Aug 24;3:764479. doi: 10.3389/froh.2022.764479. PMID: 36092137; PMCID: PMC9448953.
10. Ghodasra R, Brizuela M. Dental Caries Diagnostic Testing. [Updated 2023 Mar 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK574510/
11. Ismail AI. Visual and Visuo-tactile Detection of Dental Caries. Journal of Dental Research. 2004;83(1_suppl):56-66. doi:10.1177/154405910408301s12
12. Janjua OS, Jeelani W, Khan MI, Qureshi SM, Shaikh MS, Zafar MS, Khurshid Z. Use of Optical Coherence Tomography in Dentistry. Int J Dent. 2023 Dec 11;2023:4179210. doi: 10.1155/2023/4179210. PMID: 38111754; PMCID: PMC10727803.
13. Kanar Ö, Tağtekin D, Korkut B. Accuracy of an intraoral scanner with near-infrared imaging feature in detection of interproximal caries of permanent teeth: An in vivo validation. J Esthet Restor Dent. 2024 Jun;36(6):845-857. doi: 10.1111/jerd.13198. Epub 2024 Jan 24. PMID: 38263949.

14. Lee Y, Ku H-M, Jun M-K. Clinical Application of Intraoral Scanners in Dentistry: A Narrative Review. *Oral*. 2024; 4(4):639-652. https://doi.org/10.3390/oral4040049

15. Lin WS, Alfaraj A, Lippert F, Yang CC. Performance of the caries diagnosis feature of intraoral scanners and near-infrared imaging technology-A narrative review. J Prosthodont. 2023 Dec;32(S2):114-124. doi: 10.1111/jopr.13770. Epub 2023 Sep 24. PMID: 37701946.

16. Macey R, Walsh T, Riley P, Glenny AM, Worthington HV, Fee PA, Clarkson JE, Ricketts D. Fluorescence devices for the detection of dental caries. Cochrane Database Syst Rev. 2020 Dec 8;12(12):CD013811. doi: 10.1002/14651858.CD013811. PMID: 33319353; PMCID: PMC8677328.

17. MEDIT i700 - Intraoral Scanners and Dental Software. Available from: https://www.medit.com/medit-i700-intraoral-scanner/

18. Michou S, Lambach MS, Ntovas P, Benetti AR, Bakhshandeh A, Rahiotis C, Ekstrand KR, Vannahme C. Automated caries detection in vivo using a 3D intraoral scanner. Sci Rep. 2021 Oct 28;11(1):21276. doi: 10.1038/s41598-021-00259-w. Erratum in: Sci Rep. 2021 Dec 8;11(1):23951. doi: 10.1038/s41598-021-01926-8. Erratum in: Sci Rep. 2022 Aug 2;12(1):13240. doi: 10.1038/s41598-022-17576-3. PMID: 34711853; PMCID: PMC8553860.

19. Mohamad Saberi FN, Sukumaran P, Ung NM, Liew YM. Assessment of demineralized tooth lesions using optical coherence tomography and other state-of-the-art technologies: a review. Biomed Eng Online. 2022 Dec 3;21(1):83. doi: 10.1186/s12938-022-01055-x. PMID: 36463182; PMCID: PMC9719651.

20. Ritter AV, Ramos MD, Astorga F, Shugars DA, Bader JD. Visual-tactile versus radiographic caries detection agreement in caries-active adults. J Public Health

Dent. 2013 Summer;73(3):252-60. doi: 10.1111/jphd.12024. Epub 2013 Jun 17. PMID: 23772747.

21. Shen L, Yang X, Dong C, Tang X, Zheng S, Wang T, Wang L, Yang F, Zheng Y. Near-infrared light reflection for the early detection of proximal caries in posterior teeth: an in vivo study. BMC Oral Health. 2025 Jan 26;25(1):139. doi: 10.1186/s12903-025-05481-w. PMID: 39865218; PMCID: PMC11765916.
22. Schlenz MA, Schupp B, Schmidt A, Wöstmann B, Baresel I, Krämer N, Schulz-Weidner N. New Caries Diagnostic Tools in Intraoral Scanners: A Comparative In Vitro Study to Established Methods in Permanent and Primary Teeth. Sensors (Basel). 2022 Mar 10;22(6):2156. doi: 10.3390/s22062156. PMID: 35336328; PMCID: PMC8950989.
23. Schulz-Weidner N, Gruber M, Wöstmann B, Uebereck CF, Krämer N, Schlenz MA. Occlusal Caries Detection with Intraoral Scanners in Pediatric Dentistry: A Comparative Clinical Study. J Clin Med. 2024 Feb 6;13(4):925. doi: 10.3390/jcm13040925. PMID: 38398239; PMCID: PMC10889243.
24. Schwendicke F, Elhennawy K, Paris S, Friebertshäuser P, Krois J. Deep learning for caries lesion detection in near-infrared light transillumination images: A pilot study. J Dent. 2020 Jan;92:103260. doi: 10.1016/j.jdent.2019.103260. Epub 2019 Dec 9. PMID: 31821853.
25. Tichý A, Kunt L, Nagyová V, Kybic J. Automatic caries detection in bitewing radiographs-Part II: experimental comparison. Clin Oral Investig. 2024 Feb 5;28(2):133. doi: 10.1007/s00784-024-05528-2. PMID: 38315246; PMCID: PMC10844156.

26. van der Veen MH. Detecting Short-Term Changes in the Activity of Caries Lesions with the Aid of New Technologies. Curr Oral Health Rep. 2015;2(2):102-109. doi: 10.1007/s40496-015-0050-2. PMID: 26317065; PMCID: PMC4544495.
27. Wenzel A. Radiographic modalities for diagnosis of caries in a historical perspective: from film to machine-intelligence supported systems. Dentomaxillofac Radiol. 2021 Jul 1;50(5):20210010. doi: 10.1259/dmfr.20210010. Epub 2021 Mar 4. PMID: 33661697; PMCID: PMC8231685.
28. World Health Organization. Oral health. [Internet]. Available from: https://www.who.int/news-room/fact-sheets/detail/oral-health
29. Zhang JW, Fan J, Zhao FB, Ma B, Shen XQ, Geng YM. Diagnostic accuracy of artificial intelligence-assisted caries detection: a clinical evaluation. BMC Oral Health. 2024 Sep 16;24(1):1095. doi: 10.1186/s12903-024-04847-w. PMID: 39285427; PMCID: PMC11406783.

APPENDIX A

INSTITUTION REVIEW BOARD HIPAA WAIVER & APPROVAL (Protocol Number: 31694)

Temple University
Office of the Vice President for Research

Research Integrity & Compliance
Student Faculty Center
3340 N. Broad Street, Suite 304
Philadelphia PA 19140

Institutional Review Board
Phone: (215) 707-3390
Fax: (215) 204-4609
e-mail: irb@temple.edu

Approval for a Project Involving Human Subjects Research Requiring Continuing Review

Date: 13-Dec-2024

Protocol Number:	31694
PI:	GERALDINE WEINSTEIN
Review Type:	FULL COMMITTEE
Approved On:	13-Dec-2024
Approved From:	13-Dec-2024
Approved To:	12-Dec-2025
Risk:	Minimal risk
Committee:	A2
Sponsor:	NO EXTERNAL SPONSOR
Project Title:	Comparing Effectiveness of Intraoral Scanners in Caries Detection

The IRB approved the protocol 31694.

The study was approved under FULL COMMITTEE review for submission number **31694-0006**. The IRB determined that the research **does require a continuing review**, consequently there is an approval period that can be found above.

If applicable to your study, you can access your IRB-approved, stamped consent document or consent script through ERA. Open the Attachments tab within the approved submission (# **31694-0006**) and open the stamped documents by clicking the View link next to each document. The stamped documents are labeled as such. **Copies of the IRB approved stamped consent document or consent script must be used in obtaining consent.**

Before an approval period ends, you must submit the Continuing Review form via the ERA module. Please note that though an item is submitted in ERA, it is not received in the IRB office until the principal investigator approves it. Consequently, please submit the Continuing Review form via the ERA module 60 days before the study's expiration date.

Note that all applicable Institutional approvals must also be secured before study implementation. These approvals include, but are not limited to, Medical Radiation Committee ("MRC"); Radiation Safety Committee ("RSC"); Institutional Biosafety Committee ("IBC"); and Temple University Survey Coordinating Committee ("TUSCC"). Please visit these Committees' websites for further information.

Finally, in conducting this research, you are obligated to submit the following:

- **Amendments - All changes to the research must be reviewed and approved by the IRB.** Changes requiring approval include, but are not limited to, changes in the design or focus of the research project, revisions to the information sheet for participants, addition of new measures or instruments, increasing the subject number, changes to the research funding, and changes to research personnel. Changes made to eliminate apparent immediate hazards to subjects and implemented prior to IRB approval must be promptly reported to the IRB.
- **Reportable New Information** - Using the Reportable New Information e-form, report new information items such as those described in HRP - 071 Policy - Prompt Reporting Requirements to the IRB **within 5 days**.
- **Closure report** - Using a closure e-form, submit when the study is permanently closed to enrollment; all subjects have completed all protocol related interventions and interactions; collection of private identifiable information is complete; and analysis of private identifiable information is complete.

For the complete list of investigator responsibilities, please see the HRP–070 Policy – Investigator Obligations, the Investigator Manual (HRP-910), and other Policies and Procedures found on the Temple University IRB website: https://research.temple.edu/irb-forms-standard-operating-procedures.

Please contact the IRB at (215) 707-3390 if you have any questions.

If you would like to tell us how we are doing, please complete this 5-minute Satisfaction Survey: https://forms.gle/9EcgYGDEEANnvMw37

APPENDIX B:

SUMMARY OF SUBJECTS & RAW DATA COLLECTION

Patient_Tooth_Surface	Examiner_ Findings	TRIOS 5_Findings	Radiographic_ Finding
2 DO	2	1	1
15 O	2	1	1
14/o	0	1	0
18/o	0	1	0
19/o	0	1	0
31/o	0	1	0
(0)154790			
3 DOL	2	1	1
12 DOL	2	1	1
13 DO	1	1	1
32 O	1	1	1
1/ o	0	1	0
2/o	0	1	0
14/o	0	1	0
15/o	0	1	0
2510318			
10/ml	1	0	1
12/m	2	0	1
25/d	1	0	1
8/L	0	1	1

28/O	0	1	1
29/DO	0	1	1
2432587			
10/d	0	0	0
18/l	0	0	0
30/l	0	0	0
31/0	0	1	0
2432715			
1/O	2	1	1
2/O	2	1	1
3/O	2	1	1
4/O	1	0	0
14/O	0	1	0
15/O	1	1	0
16/O	1	1	0
17/O	2	1	1
18/O	2	1	1
20/O	1	1	0
32/O	2	1	1
2432807			
4/DO	2	0	1
12/D	1	1	
14/D	2	0	
18/o	2	1	

29/O	1	1	0
30/O	1	1	0
3/O	0	1	1
20/O	0	1	
28/O	0	1	0
31/O	0	1	0
2432704			
8/M	1	0	0
9/M	1	0	0
21/DO	1	0	0
20/O	0	1	1
28/O	0	1	1
28/B	0	1	0
2432703			
6/F	0	1	1
7/F	0	1	1
10/F	2	1	1
11/F	2	1	1
11/L	2	1	1
29/B	1	1	0
30/B	1	1	0
11/D	1	1	1
8/F	0	1	0
9/F	0	1	0

28/F	0	1	0
2416568			
1/O	2	1	1
3/O	1	0	0
8/F	1	0	0
9/F	1	0	0
6/F	1	0	0
7/F	1	0	0
14/L	2	0	0
15/O	1	0	0
16/O	2	0	1
31/O	1	1	0
32/O	1	1	0
18/O	0	1	0
20/O	0	1	0
31/B	0	1	0
2218382			
4/F	0	0	0
6/I	0	0	0
8/I	0	1	1
12/D	1	1	1
28/F	1	1	0
5/O	0	1	1
21/F	0	1	0

22/F	0	1	0
2433061			
8/ML	2	1	1
18/O	2	1	1
24/F	0	1	0
25/F	0	1	0
2/O	0	1	0
4/O	0	1	0
5/O	0	1	0
12/O	0	1	0
13/O	0	1	0
14/O	0	1	0
15/O	0	1	0
19/O	0	1	0
29/O	0	1	0
31/O	0	1	0
9/ML	0	1	0
(0)148058			
2/O	2	1	0
4/O	1	1	0
5/O	1	0	0
8/F	1	0	0
13/O	3	1	0
15/O	2	1	0

18/O	2	1	0
29/O	1	1	0
31/O	1	1	0
3/O	0	1	0
8/ML	0	1	0
10/M	0	1	0
10/D	0	1	0
28/O	0	1	0
1927010			
4/M	1	0	0
4/O	1	1	0
4/D	1	0	0
6/F	1	1	0
8/F	1	1	0
9/L	1	1	0
10/F	1	0	0
12/M	1	1	0
12/O	1	1	0
12/D	1	1	0
3/O	0	1	0
7/F	0	1	0
11/F	0	1	1
13/O	0	1	0
15/F	0	1	0

31/O	0	1	0
2314137			
2 entire tooth	2	1	1
3 entire tooth	2	1	1
4/L	1	1	0
5/I	2	0	0
6/ML	2	1	0
6/F	2	1	0
8/ML	2	1	1
8/DL	2	1	1
9/DL	2	1	1
10/ML	2	1	1
10/DL	2	1	1
11 entire tooth	2	1	1
12/D	1	0	0
13/O	1	0	0
14/entire tooth	2	1	1
15 entire tooth	2	1	1
18 entire tooth	2	1	1
19 entire tooth	2	1	1
22/F	1	0	0
24/F	1	0	0
28/O	1	1	0
29/O	1	1	0

31/O	1	0	0
31/B	1	1	0
32/O	1	1	0
7/DF	0	1	0
(0)154240			
2/O	1	1	0
15/O	1	1	0
2/L	0	1	0
15/L	0	1	0
2426764			
24/I	0	1	0
25/I	0	1	0
22/I	0	1	0
31/O	0	1	0
3/O	0	1	0
4/O	0	1	0
14/O	0	1	0
15/O	0	1	0
19/O	0	1	0
20/O	0	1	0
21/O	0	1	0
30/O	0	1	0
2315455			
2/O	2	1	0

5/O	2	1	0
9/DL	1	0	1
10/DL	1	1	1
11/D	1	0	1
14/O	1	1	0
15/O	2	1	0
17/O	2	1	0
20/O	1	1	0
28/M	1	0	1
29/L	1	1	0
32/O	2	1	0
3/O	0	1	0
14/L	0	1	0
16/o	0	1	1
29/O	0	1	0
(0)203474			
2/O	0	1	0
3/O	0	1	0
29/O	0	1	0
15/O	0	1	0