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A comparison of near-infrared imaging and computerized tomography scan for detecting maxillary sinusitis

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Abstract

Objective: To investigate the use of near-infrared (NIR) imaging as a tool for outpatient clinicians to quickly and accurately assess for maxillary sinusitis and to characterize its accuracy compared to computerized tomography (CT) scan.

Methods: In a prospective investigational study, NIR and CT images from 65 patients who presented to a tertiary care rhinology clinic were compared to determine the sensitivity and specificity of NIR as an imaging modality.

Results: The sensitivity and specificity of NIR imaging in distinguishing normal *vs.* maxillary sinus disease was found to be 90% and 84%, normal *vs.* mild maxillary sinus disease to be 76% and 91%, and mild *vs.* severe maxillary sinus disease to be 96% and 81%, respectively. The average pixel intensity was also calculated and compared to the modified Lund-Mackay scores from CT scans to assess the ability of NIR imaging to stratify the severity of maxillary sinus disease. Average pixel intensity over a region of interest was significantly different ($P < 0.001$) between normal, mild, and severe disease, as well as when comparing normal *vs.* mild ($P < 0.001$, 95% CI: 42.22–105.39), normal *vs.* severe ($P < 0.001$, 95% CI: 119.43–174.14), and mild *vs.* severe ($P < 0.001$, 95% CI: 41.39–104.56) maxillary sinus disease.

Conclusion: Based on this data, NIR shows promise as a tool for identifying patients with potential maxillary sinus disease as well as providing information on severity of disease that may guide administration of appropriate treatments.

Keywords

maxillary sinusitis; near-infrared imaging; CT scan; average pixel intensity; sensitivity; specificity; accuracy

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Conflicts of Interest: None

Introduction

Sinusitis is responsible for billions of dollars in direct healthcare costs and lost productivity in the United States each year.¹ It is also one of the most common diseases affecting North Americans, affecting about 1 in every 8 individuals.² Chronic rhinosinusitis alone is responsible for over 4 million primary care physician visits, over 300,000 emergency room visits, and approximately \$20 billion in direct and indirect costs annually.^{3–5} Despite the prevalence of sinusitis, diagnosis can be challenging and costly to the patient due to the non-specific nature of its symptoms. Maxillary sinusitis (the most commonly affected sinus) is often diagnosed clinically, particularly in the primary care or urgent care settings where cultures and imaging may not be readily available. Up to 66% of patients who present acutely to primary care clinics with mild maxillary sinusitis symptoms are given antibiotics;⁶ however, a meta-analysis by Young *et al.* found that for antibiotic use within a two week period, the number needed to treat is 15, meaning that for every one patient who benefitted from antibiotics, 15 did not.⁷ This contributes to unnecessary side effects, development of resistance, and increased healthcare cost.

Previous studies have shown that individual symptoms have limited value when diagnosing maxillary sinusitis.^{8,9} This may place more importance on objective modalities to provide timely diagnosis. Previous studies on accuracy of nasal endoscopy determined that its specificity when compared to computerized tomography (CT) scan was 75%.¹⁰ Together with a prevalence of 0.4–0.56,¹¹ this can result in a noticeable false negative rate when nasal endoscopy is used for diagnosis. With respect to imaging, conventional methods are not always optimal as a screening method for maxillary sinusitis in patients with typical symptoms.

With rising healthcare costs in the United States, there is a need for more cost-effective and accessible methods for timely diagnosis and stratification of maxillary sinusitis, particularly in primary care settings where conventional imaging modalities such as CT scan and magnetic resonance imaging (MRI) may not be readily available or affordable for the patient. Near-infrared (NIR) spectroscopy is one such method that has shown promise for use in screening for maxillary sinusitis.^{12,13} We have previously published preliminary results using an earlier version of an original NIR-emitting probe in combination with a camera able to capture NIR light.¹² Here, we report a pilot study comparing NIR imaging to CT scans for the diagnosis of maxillary sinusitis using an updated NIR probe device.

Materials and Methods

Patients

Following Institutional Review Board approval from the University of California Irvine, 65 patients with chronic maxillary sinusitis were recruited from a tertiary care rhinology clinic. The cohort consisted of healthy subjects and those who fulfilled a more succinct and specific set of symptom criteria of chronic maxillary sinusitis recommended by the American Academy of Otolaryngology–Head and Neck Surgery in 2007.¹⁴ Inclusion criteria were also age ≥ 15 years old and concurrent CT scan of sinuses available within a 2-week interval of NIR imaging. Exclusion criteria included patients with previous sinus

surgery. This is important given that sinus surgery could alter the anatomy of multiple structures evaluated by the NIR, while it could also potentially yield edema, crusting, and inflammation surrounding the structures.¹⁵ Given that the purpose of the current study is to demonstrate the crude capacity of NIR to diagnose maxillary sinusitis, such anatomical outliers were deemed inappropriate for inclusion. For patients who underwent a CT scan prior to the recruitment visit, enrollment was permitted if no new therapy of any nature, including over the counter medications, was initiated between the time of the CT scan and the visit. For patients for whom a CT scan was ordered upon recruitment, no new therapy was prescribed or allowed until the CT scan was complete. Patients were permitted to continue any existing daily therapy such as nasal steroid sprays, antihistamine, and saline irrigations, provided that they were already using such therapies prior to the visit.

Imaging Setup

The imaging setup consists of a light source that transmits light to a probe with high power NIR light-emitting diodes (LEDs) that is held intraorally against the hard palate by the patient and a detector (camera) that can capture NIR light (Figure 1). The probe contains diodes that emit NIR-wavelength light which are surrounded by acrylonitrile butadiene styrene foam to help with light diffusion and patient comfort. To aid in infection control, the entire probe is placed in a disposable polyethylene bag that is replaced with each new patient. These LEDs are able to be digitally controlled with regard to intensity and activation time. Typically, LEDs were activated for three seconds to allow time for a camera to obtain sufficient images. A digital single-lens reflex (DSLR) camera with its infrared blocking filter removed (Canon ELPH) was used to capture the emitted NIR light in a darkened room with no windows. The camera was positioned 18 inches from the patient's face and captured pictures of the face in quick sequence at three different pre-set exposure times with a fast-aperture lens (f/3.5) during the three seconds of LED activation time. A single imaging session could be completed in about 10–30 seconds.

Image Processing and Statistical Analysis

NIR images of the maxillary sinuses and CT scans of the maxillary sinuses were obtained for all patients. To ensure that interpretations of NIR images could be reliably correlated with CT scan readings, we performed a comparison of our NIR scoring system with a modified Lund-Mackay CT scoring. CT scans were evaluated and each maxillary sinus was assigned a Lund-Mackay score between 0–2.¹⁶ The scoring system is as follows for each maxillary sinus: 0 = fully aerated with no opacification (normal), 1 = partial opacification or mucosal thickening present, 2 = complete opacification. To compare NIR image results with the Lund-Mackay scores, each NIR image was processed to include iso-intensity contour lines along pixels of equal intensity, the shape of which was used to determine normal *vs.* mild or severe maxillary sinus disease (Figure 2). From this, a sensitivity and specificity for the NIR images *vs.* the CT images was calculated.

In addition, we calculated the average pixel intensity within a region of interest (ROI) on the NIR images. The ROI, which we mapped using an image analysis tool (MATLAB, The MathWorks, Inc.), was determined as the area adjacent and lateral to the area of peak intensity for each patient on the affected side (Figure 3). This region was selected based

on the consistently similar pixel intensity patterns and regions of maximum transmittance (e.g., the area of least resistance to the NIR light) found in our sample of patients without maxillary sinus disease. The maximum intensity peak is always observed in the area where the NIR light path has least resistance, and each subject's ROI was systematically determined based on the location of the peak as analyzed via MATLAB analysis toolbox. The average pixel intensity of the ROI was compared between different maxillary sinus conditions (i.e., normal, mild, and severe) using analysis of variance (ANOVA) and post-hoc Tukey analysis. SPSS 17.0 software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis with a 0.05 alpha considered significant.

Results

A total of 65 patients with a median age of 51 years (range, 20–83 years) were included. Based on NIR iso-intensity contour line imaging, 38.5% (25/65) of patients were determined to have no maxillary sinus disease, 23.1% (15/65) mild maxillary sinus disease, and 38.5% (25/65) severe maxillary sinus disease. The sensitivity and specificity of NIR imaging vs. CT scan for normal, mild, and severe disease is shown in Table 1. The average pixel intensity of the ROI for each patient was also compared to the modified Lund-Mackay scores (Figure 4). One-way ANOVA showed that the average pixel intensity over the ROI is significantly different ($P < 0.001$) between the three CT-based scores corresponding to the severity of maxillary sinusitis (i.e., normal, mild, and severe). Post-hoc Tukey analysis also showed that the average pixel intensity in the ROI is different when comparing normal vs. mild ($P < 0.001$, 95% CI: 42.22–105.39), normal vs. severe ($P < 0.001$, 95% CI: 119.43–174.14), and mild vs. severe ($P < 0.001$, 95% CI: 41.39–104.56) maxillary sinus disease.

Discussion

Our study serves as an update to the preliminary report on the use of NIR light in the diagnosis of maxillary sinusitis by Coughlan *et al.*¹² We build on that study by testing this technique in a larger cohort of patients and providing additional data on its validation parameters, including sensitivity and specificity, which have not been previously reported. Our results add further support for the potential of NIR imaging as a quick, reliable, and cost-effective imaging modality for use in the primary care setting to detect the presence and extent of maxillary sinusitis and to possibly monitor response to treatment. Since the use of CT scan is largely limited to assisting in surgical planning and examination of underlying malignancy, there is a need for an alternative technique for detecting maxillary sinusitis in the outpatient point-of-care setting. Given its lower cost, ease of use, and lack of radiation exposure, NIR imaging could be used for serial monitoring of disease and reduce inappropriate antibiotic administration and subsequent CT imaging in patients without maxillary sinusitis.

Although NIR imaging would not replace CT scan where indicated, it may still provide valuable diagnostic information and allow for confirmation of maxillary sinusitis when combined with a complete history in the office setting, particularly at the hands of primary care providers without access to nasal endoscopy. Furthermore, while findings of maxillary sinus disease on NIR imaging would not necessarily alter the therapeutic plan if similar

conclusions are formed based on nasal endoscopy, this novel imaging tool may still serve as an easy to administer, and cheaper initial diagnostic step in the work-up of patients with suspected disease. NIR imaging may also provide clinicians with an alternative to CT scan in assessing the severity of the disease and monitoring response to treatment.

Our results revealed that NIR imaging has the ability to be both sensitive and specific, particularly when distinguishing between mild and severe maxillary sinus disease (sensitivity 96%, specificity 81%) and between normal and presence of any maxillary sinus disease (sensitivity 90%, specificity 84%). This is competitive with the sensitivity (85–94%) of sinus CT scans, while having higher specificity (vs. 41–59%)¹⁷ than CT scan and costing less. NIR imaging could therefore be a powerful tool for identifying patients who have more severe disease and who may require more extensive confirmatory imaging.

Given the higher specificity of NIR imaging found in our study in distinguishing between normal and presence of maxillary sinus disease compared to CT scan, we suggest that NIR may be less prone to incidental findings. The difference in specificity between CT scan and NIR imaging is a noteworthy observation that may have a few explanations. Incidental findings occur in the sinuses in up to 42.5% of CT scans and account for most of the decreased specificity of the modality.¹⁸ For example, maxillary sinus retention cysts exist in up to 9.6% of the population and are easily identified on CT scan.¹⁹ Incidental findings may be misinterpreted as diagnostic of disease, and have little to no correlation with symptoms and are generally not sufficiently large enough to result in sinus ostial obstruction.²⁰ NIR imaging, on the other hand, yields a result relating to both the contour of the sinuses and the degree of opacification, and may correlate more directly with Lund Mackay scores without picking up incidental findings.

Our analysis of average pixel intensity also shows promise that NIR imaging may be used diagnostically. We found a significant difference ($P < 0.001$) between the average pixel intensity values between normal, mild, and severe maxillary sinus disease by Lund-Mackay score. Average pixel intensities obtained from NIR imaging may prove useful in quickly stratifying patients in terms of disease severity so that appropriate treatments can be started promptly. Our analysis did reveal some outlying overlapping values of average pixel intensity, particularly between normal and mild disease – these cases may represent cases that can be better stratified with further refinement of the ROI, or they may represent cases that require further imaging such as a CT scan for improved characterization. Despite the potential need for further work-up for a small number of cases, NIR imaging could potentially reduce the number of CT scans for maxillary sinusitis patients, thereby reducing both patient costs and radiation exposure.

NIR imaging ultimately also has the potential to be much cheaper and faster than conventional imaging, allowing for expanded use in primary care offices and rural communities. The typical cost to the healthcare system for a single x-ray of the sinuses is up to approximately \$45 and for a single CT scan of the sinuses up to approximately \$185, according to 2020 Medicare physician fee schedules.²¹ This can reach thousands of dollars in upfront costs to uninsured patients, who make up 8.5% of Americans.²² These imaging modalities can also require significant time and travel investment. We estimate the

upfront cost of our imaging set-up to the clinician to be less than \$500 including the cost of the camera and polyethylene bags and with additional indirect costs only with respect to time. For this study, we used a Canon ELPH camera; this camera is able to capture light at a wavelength of 850 nm while being affordable (about \$200) to the typical outpatient clinic. All NIR imaging can potentially be done in-office at point of care, thereby avoiding an additional episode of care and associated direct and indirect costs.

NIR technology is one of many emerging imaging techniques being investigated for the diagnosis of various otorhinolaryngological issues, including maxillary sinusitis, otitis media, airway stenosis, head and neck cancers, and more.²³⁻²⁵ Optical coherence tomography (OCT), spectroscopy, and thermal imaging are all being considered as tools that may aid providers in identifying maxillary sinusitis.²⁶⁻²⁸ OCT utilizes NIR light to capture images of tissues on a microscopic level, providing a final product similar to a histological slide. Though also used in other fields within otolaryngology, within the rhinological sphere, OCT has been investigated for its ability to identify bio-films or defects in ciliary clearance that may contribute to maxillary sinusitis, as it can provide near-microscopic levels of detail when used on samples of tissue such as polyps.^{26,29} Currently, widespread use of OCT imaging is limited primarily by its cost: one device capable of capturing OCT images can cost between \$50,000-\$300,000.²⁶ Additionally, tissue samples or cultures are required if one wants to obtain information on a microscopic level, and the significance of this information in diagnosing or stratifying maxillary sinusitis is not yet established.

Spectroscopic imaging uses a laser to detect differences light absorption and scattering in gas, water vapor, and solid structures within and around the sinuses. Similar to NIR imaging, spectroscopy can detect the difference between aerated, gas-filled and opacified sinuses. It is also non-invasive and does not involve any ionizing radiation. Lewander *et al.* determined that the sensitivity and specificity of laser spectroscopy for the maxillary sinuses was 93% and 61%, respectively, placing it on par with CT scans as a potential diagnostic tool.²⁷ Similar to OCT imaging set-ups, the diode laser, photodiode, and spectrometer may cost thousands to tens of thousands of dollars and may not be ergonomic for some primary care clinics.

Thermal imaging has also been investigated as a potential cost-effective measure for diagnosing maxillary sinusitis. Thermal images are images of body surface temperatures taken with the thought that inflammation causes increased temperature, and thus maxillary sinusitis should be visible as areas of higher body temperature. Kalaiarasi *et al.* determined the sensitivity and specificity of thermal imaging for the maxillary sinuses to be 70% and 85%, respectively.²⁸ However Mansfield *et al.* did not find thermal imaging to be viable modality as it was confounded by surface lesions such as acne and did not show significant differences between affected and unaffected sides.³⁰ Although thermal imaging is less costly than either OCT or spectroscopy, its use may be limited by the presence of other inflammatory conditions in the facial area and the specifications of the imaging setup.

There remain some limitations to our method of NIR imaging that will warrant further study and development in the future. This method requires a learning curve in regard to the amount of exposure required for the camera, which can change depending on the patient's

age. Underexposure of images may be common until the operator becomes more familiar with exposure settings. Additionally, a small number of patients may not tolerate a device held inside the mouth, even if only for a short amount of time. Although we found no statistically significant variations in average pixel intensity among our sample of patients without maxillary sinus disease, it should be noted that individual anatomic variations may contribute to differences in pixel intensities. Furthermore, isolated and clinically insignificant opacification of sinus floor as well as history of prior endoscopic sinus surgery could alter diagnostic outcomes. Future studies in larger, more anatomically diverse cohorts of normal individuals (e.g., without maxillary sinus disease or of varying body mass index) should be performed to determine how the confounding anatomic variations in facial bones and soft tissue can be controlled and calibrated via NIR imaging. Doing so will help us both refine the technique of NIR imaging and improve the accuracy of this diagnostic modality in the future.

NIR imaging, as an initial screening tool with high sensitivity and specificity for disease, could be used as a powerful tool for identifying patients who have more severe disease and who may require more extensive confirmatory imaging. However, at present, we do not advocate for NIR imaging as the sole imaging technique used in surgical planning for maxillary sinusitis, due to the lack of anatomic details that can be provided. Despite this potential limitation, our study succeeds in further characterizing the imaging modality by utilizing NIR imaging in a larger cohort than reported in previous studies,¹² as well as being the first study to provide data on both the sensitivity and specificity of NIR imaging compared to CT scan in distinguishing between the presence of no disease, mild disease, and severe maxillary sinus disease in patients.

It is important to recognize that the technique assesses only extent of opacity in the maxillary sinuses. We used the Lund-Mackey scoring merely as a means to quantify opacity of maxillary sinus on CT such that we can compare and evaluate the capacity of NIR to output similar results. However, the Lund-Mackey scoring has not been validated for evaluating clinical significance of disease based on individual sinuses. Consequently, it does not yet have ability to determine what the opacity represents and differentiate between specific diagnoses resulting in maxillary sinus disease. Nonetheless, the merits of this technology are: (i) low cost (ii) quick (iii) easy to administer (iv) simple diagnostic measure. It seems plausible that NIR imaging of the maxillary sinus has potential utility in point-of-care screening in primary or urgent care settings for possible maxillary sinus infections *vs.* other etiologies of similar symptoms or as a monitoring tool for treatment efficacy (i.e., response to drug therapy).

Conclusion

Near-infrared imaging is an emerging tool for the stratification and potential diagnosis of maxillary sinus disease in the outpatient environment. NIR imaging can provide a quick, cost-effective, and radiation-free way to determine basic severity of maxillary sinus disease to guide the next steps in management.

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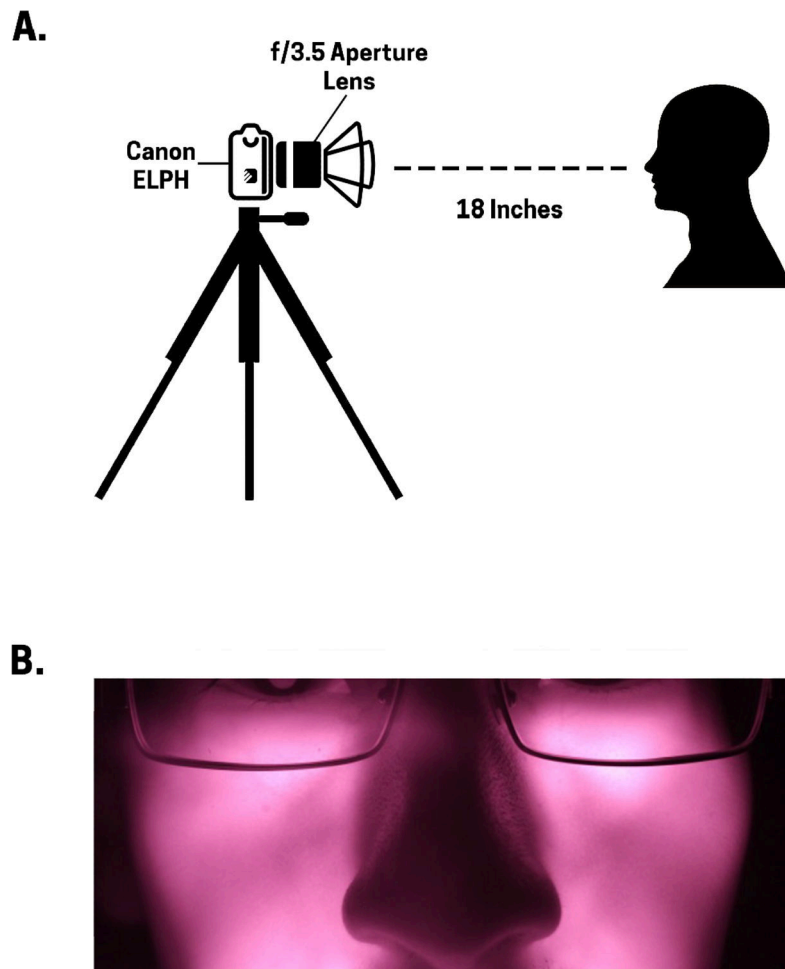


Figure 1.
(A) Imaging set-up consists of a Canon ELPH camera with a fast aperture lens (f/3.5) placed 18 inches away from the patient. (B) A sample of raw NIR image in a normal patient with no maxillary sinus disease where light can be seen transilluminating the maxillary sinuses.

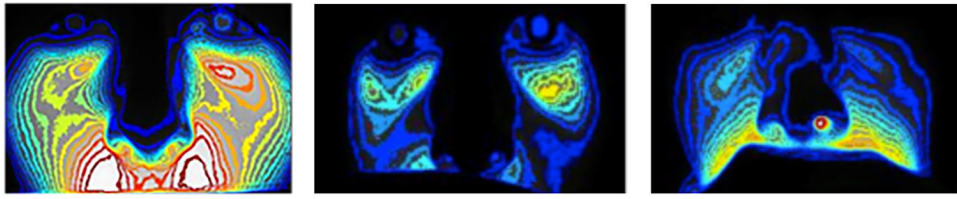


Figure 2.

Iso-intensity contour lines represent lines of equal pixel intensity, that is, areas where the intensity of light is the same. Red represents intense light (aeration of sinuses) and blue represents low or no light (opacification, mucus, inflammation, bone, etc.). The iso-intensity contour images are shown in a normal patient (left) and a mild (middle) or severe (right) cause of maxillary sinusitis showing reduced intensity.



Figure 3. Example of determination of region of interest (red circle) used to calculate average pixel intensity in a normal patient (left), a patient with mild maxillary sinus disease (middle), and a patient with severe maxillary sinus disease (right). Notice that the intensity of light is stronger in a normal patient, representing aeration of sinuses, and weaker in the patient with severe disease, representing opacification via mucus or inflammation that blocks the NIR light.

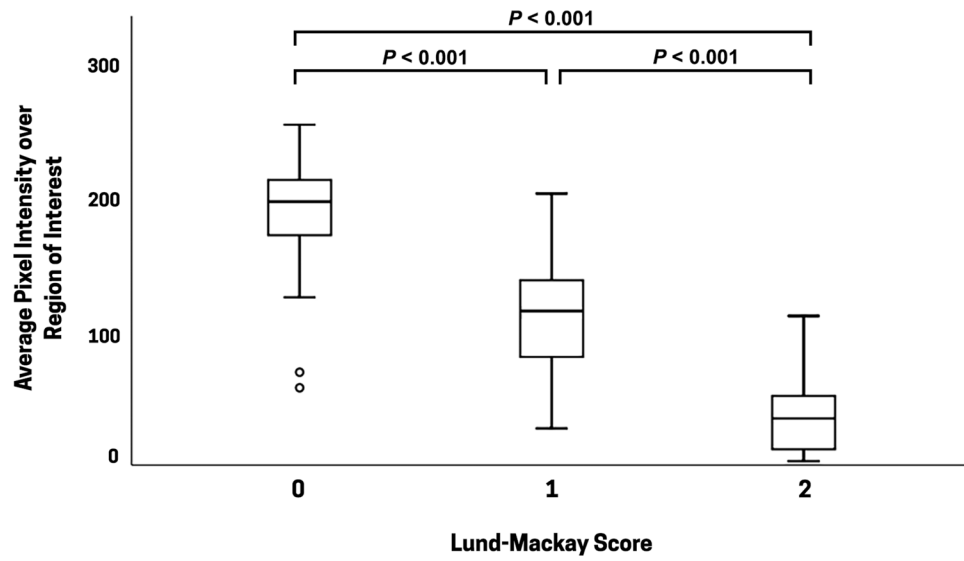


Figure 4. Comparison of average pixel intensity over region of interest from NIR imaging for Lund-Mackay scores assigned to CT scan images.

Table 1.

The sensitivity and specificity of near-infrared imaging vs. CT scan for different severities of maxillary sinus disease.

	Normal vs. any disease severity	Normal vs. mild maxillary sinus disease	Mild vs. severe maxillary sinus disease
Sensitivity	90%	76%	96%
Specificity	84%	91%	81%

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