Assessment of a Handheld Near-Infrared Spectroscopy Device in Detecting Traumatic Intracranial Hemorrhage in Uganda

by

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Date: March 21st, 2025

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Thesis submitted in partial fulfillment of
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ABSTRACT

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Abstract

Background: Traumatic brain injury (TBI) is a leading cause of morbidity and mortality worldwide, particularly in low- and middle-income countries (LMICs) like Uganda, where the burden is disproportionately high due to factors such as the prevalence of motorcycle accidents and the limited neurosurgical resources. Computed tomography (CT) scans are essential to TBI care, though a limited resource in LMICs. This study aims to assess the diagnostic accuracy of the handheld near infrared device (NIRD), Infrascanner 2500™, in identifying traumatic intracranial hemorrhage in Uganda. The study will evaluate the device's sensitivity, specificity, and predictive values against CT scans in neurotrauma patients.

Methods: Patients with suspected head trauma at Mbarara Regional Referral Hospital (MRRH) and Mayanja Memorial Hospital (MMH) who received a head CT scan were included. Participants were scanned with the Infrascanner 2500™ within 30 minutes after their head CT scan. Participant demographics, presenting characteristics, and Infrascanner 2500™ output were recorded.

Results: Of the 137 participants included in this interim analysis, 62 (45%) were positive for intracranial hematoma. The Infrascanner 2500™ showed a sensitivity of 83.9% and a specificity of 25.3%. The positive predictive value and negative predictive value were 48.1% and 65.5% respectively. Results showed a high false positive rate across the cohort.

Conclusion: This study demonstrated the Infrascanner 2500™ with low specificity and sufficient specificity for detecting intracranial bleeds for patients with TBI in Uganda. The refinement of NIR devices and continued investigation into factors affecting the Infrascanner 2500™ diagnostic performance will be essential to its potential for improving TBI management.

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Our collaborative efforts help build and enhance neurosurgical systems. This work would not have been possible without the collective support, encouragement, and guidance of each one of you. Thank you all for your contributions.

1. Introduction

In 2018, an estimated 69 million individuals sustained traumatic brain injury (TBI), with most cases occurring in LMICs.[1,2] Approximately 90% of all injury-related vehicular deaths occur in LMICs.[3] The substantial contribution of TBI mortality is only expected to widen without substantial growth in legislative, municipal, and medical infrastructure capable of slowing the incidence of TBI.[3] The constrain of medical resources in sub-Saharan Africa is especially prominent in neurological care. As of July 2023, there were 0.15 neurosurgeons per 100,000 African people.[4] Outside of Africa, the world's population benefits from 12 times more neurological beds, 56 times more neurosurgeons per capita, and 30 times more neurologists.[5]

In Uganda, a low-income country in East Africa, motorcycles pervade the landscape with motorcycle accidents (MCAs) contributing to most of the country's TBI. Between 2010 and 2017, Mulago National Referral Hospital saw a doubling of fatal road traffic injuries, from 11.6% to 22.8%, mostly from MCAs.[6] Based upon the limited literature regarding TBI within SSA, Uganda experiences among the highest rates of TBI and TBI-related mortality in the world. Mortality outcomes at Mbarara Regional Referral Hospital (MRRH) are high and estimated to be 9.6%, with mortality rates of 4.7% for patients with mild and moderate TBI and 55% for patients with severe TBI in 2016.[7,8] As much as 50.4% of deaths at a secondary referral hospital in Uganda were found to be due to trauma, with a 7.4% mortality rate for those admitted. Head trauma, specifically, represented 68% of all trauma deaths and 34.3% of all deaths overall.[9] A recent study conducted in the intensive care unit (ICU) at Mbarara Regional Referral Hospital (MRRH), which serves the western region of Uganda, Rwanda, eastern region of Democratic Republic of Congo, and northwestern Tanzania, showed that head injury accounts for 74% of adult and 69% of pediatric trauma cases, with an overall mortality of 60% for patients admitted to the ICU with head trauma.[7] For comparison, a 2006 UK study showed that in head injury patients requiring intensive care, 77% survived to leave the ICU and 67% survived to leave the hospital, an ICU mortality rate nearly three-fold less than that seen in Mbarara.[10] Limited transportation and emergency services infrastructure compound existing challenges to CT accessibility.[11] Unfortunately, CT scanners are currently a modality of considerable financial burden for both patient and governmental sectors. With the number of lives lost due to inaccessibility of immediate brain imaging in LMICs, it is essential to identify and validate cost-effective alternatives to CT scans.

In 2013, the Infrascanner 2000™, a near infrared spectroscopy device (NIR) was introduced, prompting a study to validate it in a consecutive series of 500 head injury patients who obtained a head CT scan at Duke University Hospital (DUH).[12] For all patients with CT-proven bleeds (n=104), irrespective of size, initial NIR scans localized the bleed to the appropriate quadrant with a sensitivity of 86% and specificity of 96% compared to a CT scan as the gold standard. For extra-axial bleeds >3.5ml, sensitivity and specificity were 94% and 96%, respectively. For longitudinal serial rescans with the NIR, sensitivity was 89% (<4 days from injury: sensitivity=99%) and specificity was 96%.

After the DUH study, our group began a study of 684 TBI patients at Mbarara Regional Referral Hospital (MRRH) in Uganda using the Infrascanner 2000™.[13] For all patients with CT-proven bleeds (n=180), irrespective of size, initial NIR scans localized the bleed to the appropriate quadrant with a sensitivity of 89% and specificity of 38% compared to a CT scan. Of the 384 participants analyzed, 127 participants were identified as false positives, contributing to the low specificity. These findings greatly differ from the DUH data set, prompting our team to conduct a secondary analysis of the MRRH data. Lower specificity and positive predictive value were found in the Mbarara study as compared to DUH.[12] There is evidence to suggest skin tone variance, among other patient characteristics, affects the accuracy of the near-infrared-based device.[13] These factors are likely contributors to the lower specificity and positive predictive value found in the Mbarara study, as compared to DUH.[13]

Previous literature for similar NIR technology, such as pulse oximetry, has suggested an overestimation of SpO2 in dark-skinned individuals,[14–16] with the skin attenuating NIR more,[17] resulting in more variability in the signal readback.[15] These combined can contribute to a weaker detection by the pulse oximetry sensor and hence over-estimation of SpO2. In the Infrascanner 2000™, this higher NIR attenuation due to the dark color of the skin could have been the source of a false positive readout and may account for the high false positive results we encountered. This study will include representation of populations with darker skin tones within medical device testing and development, a matter that extends beyond NIR.[17–20] By addressing racial differences within device research and development, we can strengthen device applicability in broader contexts. The sensitivity and specificity of the newer version of the device, the Infrascanner 2500™, with its new algorithms adjusting for skin tone variance, have not been previously studied.

This study addresses the critical need for evaluating and optimizing the handheld near-infrared device performance in diagnosing intracranial bleeds within the diverse skin tone range prevalent in SSA, such as Uganda. This research is essential to ensure that NIR can be a highly sensitive, specific, and reproducible tool across all populations, regardless of skin tone. Given the higher prevalence and mortality rates associated with TBI in LMICs,[1,2] coupled with limited healthcare resources and access to CT scans,[21] the successful adaptation of NIR technology for use in these settings could improve TBI management and inform neurocritical and neurosurgical evidence-based decision making. This study aims to evaluate the diagnostic performance of the Infrascanner 2500™, in detecting traumatic intracranial bleeds to determine if diagnostic performance of a new model of NIR has improved in the Ugandan population. If able to detect intracranial hematomas with efficacy similar to CT in the Ugandan patient population, this data can be used to formulate a future trial using the device as a triage tool, and possibly as a diagnostic tool, to inform on the need for surgical management for patients in which obtaining CT scans is not feasible or timely. The Infrascanner 2500™ if shown to have high efficacy could be used as a triage management tool to triage patients that come into the healthcare facilities.

2. Methods

A prospective observational study was preformed to assess the diagnostic accuracy of the Infrascanner 2500™ for patients with TBI at two hospitals in Uganda. To collect quantitative data, three local research assistants were trained by a team from the device manufacturer, Infrascan Inc., in a two-day training seminar. The research assistants were also trained to annotate skin tones based on the Monk Skin Tone Scale (MST).[22] Physical sets of the MST scale were printed on premium non-glossy paper and laminated to enhance the durability of the paper displayed in the Appendix. The three research assistants screened, recruited, and consented patients in the emergency departments of the two study sites. Patients who presented with suspected TBI and consented to the study by themselves or by legally authorized representative (LAR) were recruited.

The quantitative difference in OD (optical density) measurements with the Infrascanner 2500™ were collected within 30 minutes of patients CT scan. Data collection involved using the Infrascanner 2500™ to measure optical absorption in eight scalp quadrants for approximately 10 minutes. The participant CT file from the radiology team were uploaded into a secure folder within Duke Box. When required, participant hair was parted with a pintail parting comb for Infrascanner 2500™ fiberoptic tip access to the scalp. Participants were compensated approximately 15,000 UGX ($4 USD) for their time. Patient characteristic data was collected and entered into REDCap. All CT scans were assigned and reviewed by one of two physicians on the study team at Duke all data was entered into REDCap.

2.1 Setting

The study was conducted at Mbarara Regional Referral Hospital (MRRH) and Mayanja Memorial Hospital (MMH) in Uganda. MRRH is a 600-bed capacity, government-owned referral and teaching hospital associated with Mbarara University of Science and Technology. MRRH is one of only two public hospitals in Uganda with facilities to support neurological surgery. MMH is a private, not-for-profit hospital with a 100-bed capacity. Both MRRH and MMH facilities included had a CT scanner dedicated to their facility.

2.2 Sample Size Calculation

Sample size calculations were based on achieving adequate power to detect differences in device performance, with a target enrollment informed by estimated prevalence rates of traumatic intracranial hemorrhages in similar settings. The sample size was calculated using 95% confidence interval for the sensitivity based on previous findings,[13] and the sample size calculator provided at http://wnarifin.github.io. [23, 24] With 84 patients with positive findings of hematoma (i.e. CT-proven intracranial hemorrhage), sensitivity can be estimated to be within at most +/- 0.099 with 95% confidence.[25] An assumed 46% of patients have true hematomas detected,[13] Overall, 171 participants with CT scans must be accrued, with 79 of them positive for intracranial bleeding. Accounting for an estimated 5% dropout rate, the required sample size for this trial was calculated to be **180** total subjects.[23, 24] We estimated 50% of patients with TBI would obtain CT scans, thus approximately 360 TBI patients will need to present to MRRH and/or MMH to reach our desired sample size.

2.3 Participants

Participants were recruited from the patient population presenting with suspected head trauma at MRRH and MMH. Inclusion criteria included patients aged 13 and above, able to give consent themselves or have a legally authorized representative (LAR) who could consent in English, Runyankole, or Luganda. Exclusion criteria excluded patients with large scalp wounds or where hair could not be appropriately parted to access the scalp. Patients for whom it was not possible to obtain complete Infrascanner 2500™ measurement within 30 minutes of their CT scan were also excluded from the study.

2.4 Ethical Approval

The study was reviewed, and all study procedures were approved by the ethical review boards at Duke University, Mbarara University of Science and Technology (MUST), Uganda National Council for Science and Technology (UNCST), and administrative approval was obtained from both Mbarara Regional Referral Hospital and Mayanja Memorial Hospital. The study was registered at ClinicalTrials.gov under identifier NCT06491173.

2.5 Measures

The primary outcome measures were the sensitivity and specificity of the Infrascanner 2500™ in detecting traumatic intracranial hemorrhages, with CT scans serving as the reference gold standard. Data on optical density (OD) differences between sides were collected directly using the device, and additional demographic and clinical data were recorded in REDCap. The CT scans were interpreted by experienced physicians blinded to the Infrascanner 2500™ results. The data was stored in a secure database at Duke University. The clinical staff were not informed of the Infrascanner 2500™ results and data output was not used to inform clinical decisions.

2.6 Analysis

Statistical analysis was conducted using RStudio software version 2024.12.1+563. Patients with mechanism of injury (MOI) documented as "Accidental Injury" were assigned to "Unknown." Patients with outcome "Absconded" or "Withdrew" were assigned to "Absconded/Unknown."

The sensitivity and specificity of the Infrascanner 2500™ were calculated, along with positive and negative predictive values with the CT scan results as the gold standard comparison. The participant demographics and injury were compared between participants with brain hematoma present and brain hematoma absent as shown in Table 1. Categorical variables were summarized with frequency, percentages, and totals of each group when appropriate.

3. Results

3.1 Study Sample

Research assistants screened 382 patients with TBI during the study period. Overall, 186 participants were consented to be included in the study. Data for three participants were excluded from analysis due to “Unstable Error” in the measurements from the Infrascanner device. One participant was excluded from analysis due to loss of CT scan data from radiology. An additional participant was excluded from analysis due to a plaited/braided hair style that prevented scalp access by the Infrascanner 2500™. This research thesis report is an interim analysis of the current data as data collection and data analysis of the larger data set is currently being analyzed. As reported the current study is underpowered to make definitive concluding statements as to the diagnostic performance of the device. The interim analysis of the data set in the reported results have includes 137 participants. Forty-four participants were not included in this interim analysis as CT scan collection and adjudication were not completed. The accrual process and exclusions are outlined via the flow chart in Figure 1.

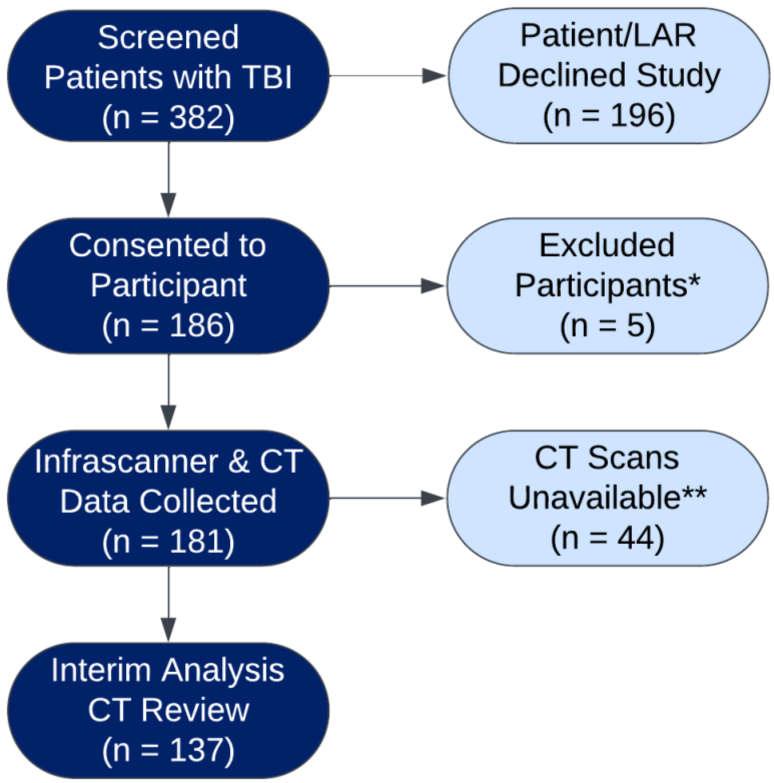

Figure 1 – Number of participants screened and included in the interim analysis

*One participant excluded from analysis due to a plaited/braided hair style that prevented scalp access to the Infrascanner 2500™. One participant was excluded from analysis due to loss of CT scan data from radiology. Three participants were excluded from analysis due to "Unstable Error" from the Infrascanner device. **Forty-four participants were not included as CT scans were unavailable at time of analysis.

Table 1 - Descriptive Statistics by Intracranial Bleed Status

	Absent *(n = 75)*	*Present* *(n = 62)*	*Total* *(n = 137)*
Sex			
Male	68 (54.4%)	57 (45.6%)	125 (91.2%)
Female	7 (58.3%)	5 (41.7%)	12 (8.8%)
Age			
Mean (SD)	33.0 (12.0)	34.7 (15.7)	33.8 (13.7)
Median	32.0	30.0	30.0
Q1, Q3	24.5, 38.0	24.0, 44.5	24.0, 33.8
Range	(13 – 76)	(13 – 90)	(13 – 90)
Site			
Mbarara Regional Referral Hospital (MRRH)	36 (48.0%)	36 (58.1%)	72 (52.6%)
Mayanja Memorial Hospital (MMH)	39 (52.0%)	26 (41.9%)	65 (47.4%)
Initial GCS (3–15)			
Mean (SD)	14.5 (1.4)	13.3 (2.7)	13.9 (2.2)
Median	15	15	15
Q1, Q3	15, 15	13, 15	13, 15
Range	(8 – 15)	(5 – 15)	(5 – 15)

Mechanism of injury (MOI)			
Road Traffic Injury	53 (56.4%)	41 (43.6%)	94 (68.6%)
Fall – Ground level	0	3 (100.0%)	3 (2.2%)
Fall – Elevated	3 (75.0%)	1 (25.0%)	4 (3.6%)
Assault – Blunt trauma	16 (61.5%)	10 (38.5%)	26 (19.0%)
Assault – Penetrative trauma	2 (40.0%)	3 (60.0%)	5 (3.6%)
Unknown	1 (20.0%)	4 (80.0%)	5 (3.6%)
Scalp hematoma present			
No	41 (54.7%)	29 (46.8%)	70 (51.1%)
Yes	34 (45.3%)	33 (53.2%)	67 (48.9%)
Scalp open injury present			
No	49 (65.3%)	42 (67.7%)	91 (66.4%)
Yes	26 (34.7%)	20 (32.3%)	46 (33.6%)
Skull Open Injury present			
No	74 (98.7%)	58 (93.5%)	132 (96.4%)
Yes	1 (1.3%)	4 (6.5%)	5 (3.6%)
In Hospital Mortality			
Alive	69 (92.0%)	52 (83.9%)	121 (88.3%)
Dead	2 (2.7%)	7 (11.3%)	9 (6.6%)
Absconded/Unknown	4 (5.3%)	3 (4.8%)	7 (5.1%)

3.2 Descriptive Statistics by Intracranial Bleed Status

Of the 137 participants with fully adjudicated CT data, 75 (54.7%) were negative for intracranial bleeding and 62 (45.3%) participants were positive for intracranial bleed (Table 1). Males represented 91.2% (n = 125) of total cohort and females accounted for 8.8% (n=12). The mean age of participants was 33.8 years (SD = 13.7 years), and age ranged from 13 to 90 years. Among clinical presentations, initial Glasgow Coma Scale (GCS) scores were higher for participants in the hematoma-negative group with an average of 14.5 (SD = 1.4), compared to the hematoma-positive group with an average of 13.3 (SD = 2.7). Participants were nearly evenly distributed between the two data collection sites with 72 (52.6%) from MMRH and 65 (47.4%) from MMH. A larger proportion of hematoma-positive participants was observed at MRRH (58.1%, n = 36) than at MMH (41.9%, n = 26).

The most common mechanism of injury (MOI) reported was road traffic injury (RTI) involving 94 (68.6%) participants. Scalp hematomas were reported in 48.9% (n = 67) of the total participants, with higher incidence in the hematoma-positive participants 33 (53.2%) compared to the hematoma-negative group (45.3%, n = 34). Open scalp injuries were close to evenly distributed across both groups. Open skull injuries occurred more in participants with hematoma-positive CTs (6.5%, n = 4), than without (1.3%, n = 1). Overall, mortality was reported in 9 participants and was higher in the hematoma-positive group (11.3%, n = 7) than the hematoma-negative group (2.7%, n = 2).

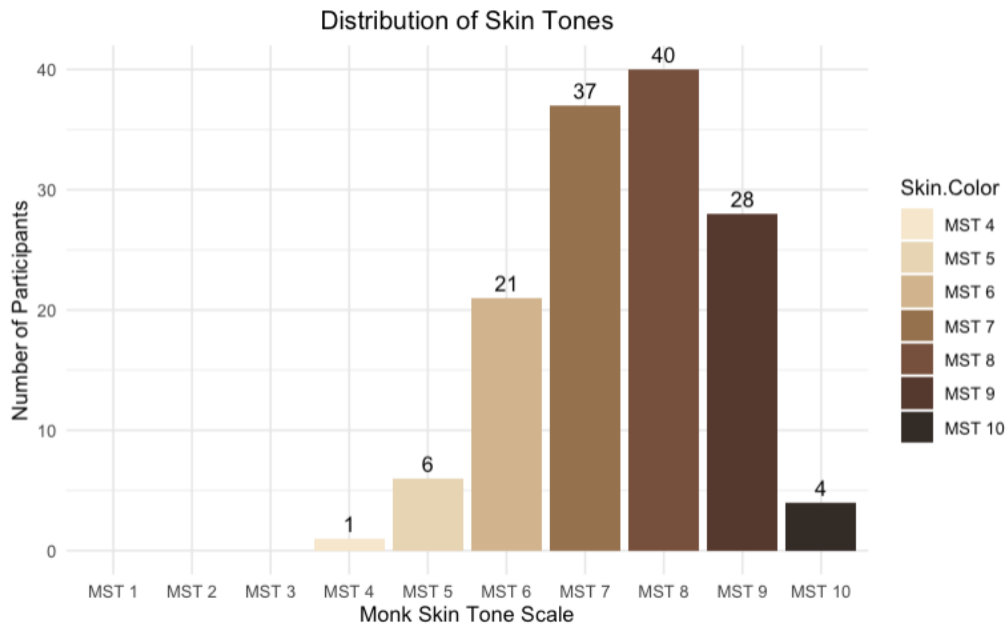

Figure 2: Distribution of Skin Tones using Monk Skin Tone Scale

3.3 Distribution of Skin Tones using Monk Skin Tone Scale

The distribution of skin tones among participants was categorized into the Monk Skin Tone Scale shows a left skew in the range from MST 4 to MST 10. The MST 8 category was the most represented category with 40 participants followed by MST 7 with 37 participants. In the extremities of the scale captured, MST 4 and MST 10 had fewer counts of participants with 1 and 4 participants respectively.

Table 2 – Device Diagnostic Performance for Infrascanner 2500™ vs CT

	Condition Present	Condition Absent	Totals
Test +	52	56	108
Test -	19	10	29
Totals	75	62	137

Table 3 - Performance Characteristics for Infrascanner 2500™ vs CT

	Estimated Values (95% confidence interval)
Prevalence	45.3% (36.8%, 54.0%)
Sensitivity	83.9% (71.9%, 91.6%)
Specificity	25.3% (16.3%, 36.9%)
Positive Predictive Value	48.1% (38.5%, 57.9%)
Negative Predictive Value	65.5% (45.7%, 81.4%)

Table 4 - Performance for Infrascanner 2500™ vs Infrascanner 2000™ in Uganda

	Estimated Values (95% confidence interval)	
	Infrascanner 2500™	Infrascanner 2000™
Sensitivity	83.9% (71.9%, 91.6%)	88.9% (84.3%, 93.5%)
Specificity	25.3% (16.3%, 36.9%)	37.7% (31.1%, 44.4%)
Positive Predictive Value	48.1% (38.5%, 57.9%)	55.7 (50.0%, 61.5%)

Negative Predictive Value	65.5% (45.7%, 81.4%)	79.4% (71.3%, 87.4%)

3.4 Diagnostic Performance for Infrascanner 2500™ vs CT

The prevalence of hematoma positive scans was 45.3% in the study cohort. The Infrascanner 2500™ demonstrated an overall sensitivity of 83.9% and specificity of 25.3% (Table 3). The positive predictive value was 48.1% and the negative predictive value was 65.5%. The diagnostic performance of the Infrascanner 2500™ in Uganda is similar to the previous model version of the device, Infrascanner 2000™, as shown in Table 4.

4. Discussion

This study is the first study to determine the diagnostic performance of the Infrascanner 2500™ in a hospital within an LMIC. The interim analysis showed that the Infrascanner 2500™ had a sensitivity of 83.9% and a specificity of 25.3%, which reflects a diagnostic performance comparable to its predecessor, the Infrascanner 2000™, tested previously at MRRH. The results did not support the hypothesis that updated Infrascanner 2500™ algorithm was sufficient to compensate for the differences between the DUH and MRRH/MMH subsets.

The low specificity indicates a high number of false positive results in the cohort and in practice would lead to inefficient resource allocation in Uganda or other resource-constrained environments. The performance characteristics from this study differ notably from those reported in the Duke University Hospital (DUH) study.[12] This study's specificity (25.3%) was substantially lower than that reported at DUH (96%). This discrepancy is consistent with the previous Infrascanner 2000™ findings,[13] suggesting that factors inherent to the Ugandan setting significantly influence device performance. Previous literature on NIR technology supports the notion that darker skin tones attenuate NIR signals more strongly, potentially leading to higher false-positive rates.[13] The clinical relevance of these findings supports the need for further algorithm adjustments and/or alternative adjunctive methods to enhance diagnostic accuracy of this device before use in LMIC contexts.

4.1 Study strengths and limitations

It is very important to note the limitations in the generalizability of these results outside of this study setting. This study is an interim analysis and underpowered at the 137-participant sample size. The smaller sample size could result in wider confidence intervals and reduced precision of the diagnostic performance estimates. Also, the categorization of skin tones using Monk Skin Tone Scale was subjective and could vary depending on differences in lighting conditions inside the facilities and the visual assessments of the local researchers who classified participants.

One key limitation was the challenge of participant recruitment given the high-stress conditions of emergency hospital visits for traumatic brain injury. Many potential participants and or their family members declined enrollment to the study due to the overwhelming concern for the status of their traumatic brain injury. This introduces a potential selection bias, as those who agreed to participate may have had less severe TBI conditions and greater capacity to engage with the study. As a result, the study cohort included, may not be fully representative of the full range of TBI severity encountered in emergency settings in Uganda. Another limitation was the reluctance of some individuals to participate because of concerns about the safety of the near-infrared light emitted by the device. While there is no scientific evidence to support these concerns the perception of risk still influenced enrollment decisions. This reflects a gap in understanding of the technology and may present a barrier to broader clinical application of the device and may introduce selection bias. Future research should consider strategies to improve participant education and minimize selection bias due to TBI severity of in participants.

4.2 Implications for further research

Skin color associated bias in near-infrared devices (NIR) should be further examined in future studies. Future analyses should include an assessment of variance in measurements and the consistency of measurements both within and between subjects, device operators, as well as across the full range of the Monk Skin Tone Scale. Evaluating these factors will be critical in addressing concerns related to end-user challenges and may provide further insight into the extent to which skin tone influences the near-infrared technology. Future research should determine whether adjustments to measurement protocols or device calibration are necessary to ensure equitable performance across populations.

5. Conclusion

This study demonstrated the Infrascanner 2500™ has sufficient sensitivity but low specificity for detecting intracranial bleeds for patients with TBI in Uganda. Further research into patient and user specific variables to inform further device optimization are needed to support the Infrascanner 2500™ as a triage tool for TBI treatment protocols in CT resource-constrained settings. The refinement of NIR devices and continued investigation into factors affecting the Infrascanner 2500™ diagnostic performance will be essential to its potential for improving TBI management.

Appendix

Figure A.1: Physical Version of Monk Skin Tone Scale with MST 1-5

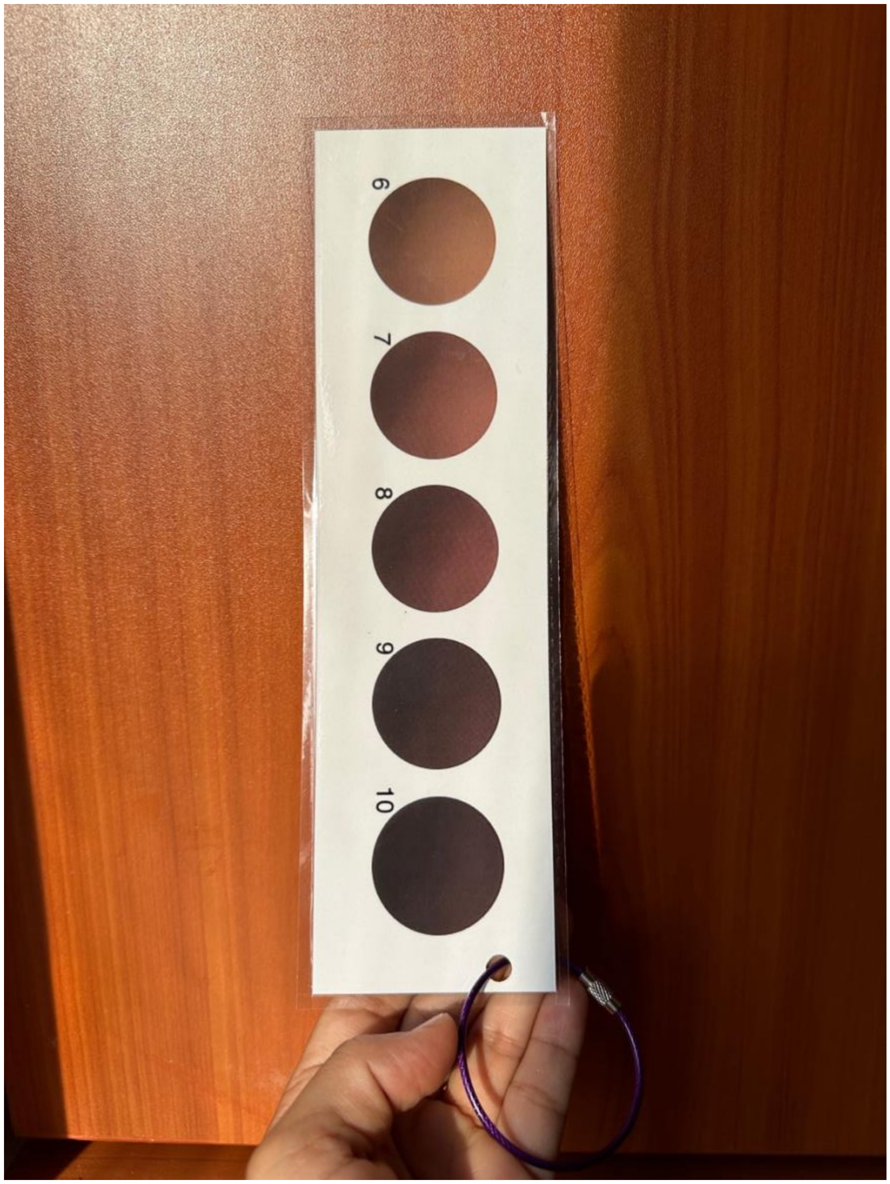

Figure A.2: Physical Version of Monk Skin Tone Scale with MST 6-10

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