Pilot Study of Normative Range of Field of Binocular Single Vision in Adults in Singapore (NORVIBAS)

Study Site: Tan Tock Seng Hospital, Singapore

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Background:

The assessment and monitoring of the field of binocular single vision is a crucial aspect of ophthalmological care, particularly in the management of oculoplastic and strabismus. Currently, clinicians worldwide, including those in Singapore, rely on the normal boundary of the field of binocular single vision established by Doctor Robert M. Feibel & Gill Roper-Hall in 1974 as the gold-standard parameter for clinical assessment. However, this long-standing standard raises several significant concerns regarding its applicability to our current population.

The original study by Feibel & Roper-Hall was conducted in St Louis, Missouri, United States of America, with participants who were likely of Caucasian descent. This demographic composition presents a potential limitation when applying these standards to Asian populations, particularly in Singapore, where ethnic and genetic factors may influence ocular characteristics. Furthermore, the study's methodology involved only "several" normal individuals, suggesting a sample size of more than two but fewer than ten participants. A sample size of this limited scope significantly increases the likelihood of Type II errors, potentially compromising the statistical power and reliability of the established normative values.

The temporal gap of over five decades since the original study adds another layer of concern. Population characteristics, environmental factors, and lifestyle patterns have undergone substantial changes during this period, potentially affecting ocular health parameters. Additionally, advances in measurement techniques and an understanding of ocular physiology suggest the need for updated normative data that reflect current population characteristics and incorporate modern assessment methodologies.

Given these limitations, there is a pressing need to establish population-specific normative data for the field of binocular single vision in Singapore's adult population. This would not only provide more relevant reference values for clinical assessment but also potentially improve the accuracy of diagnosis and monitoring of various ocular conditions in our local context.

Study Objectives

The primary purpose of this pilot study is to address these gaps in current clinical practice through two main objectives. First, we aim to establish the normative range of the field of binocular single vision specifically for adults in Singapore, creating a locally relevant reference

standard. This will provide clinicians with more appropriate benchmarks for assessing their patients.
Secondly, we seek to determine whether a significant difference exists between these local normative values and the currently used standards established by Feibel & Roper-Hall in 1974. We hypothesise that there will be a significant difference in the normative range of the field of binocular single vision in our current adult population in Singapore compared to the historical standards. This hypothesis is based on the understanding that genetic, environmental, and temporal factors may influence ocular characteristics.

The findings from this study could have substantial clinical implications. If significant differences are identified, it would justify the adoption of new, population-specific normative values for clinical practice in Singapore. This could lead to more accurate assessment and monitoring of subjects, potentially improving the quality of eye care delivered to our population. Furthermore, this study could serve as a model for other Asian countries to establish their population-specific normative values, contributing to the broader field of ophthalmology in the region.

2. STUDY DESIGN

This research will be conducted as a single-centre, pilot study at Tan Tock Seng Hospital, designed as an observational investigation regulated under the Human Biomedical Research Act (HBRA) of Singapore. This study will employ a cross-sectional design, with each participant completing all assessments in a single visit lasting approximately 60 minutes. This approach has been chosen to minimise participant burden while ensuring comprehensive data collection.

The study will span a total duration of one year, with active data collection scheduled from 1 November 2025 to 31 October 2026. This timeline allows for adequate recruitment, data collection, and subsequent analysis while accounting for potential scheduling challenges and the need for careful quality control of the collected data. The single-visit design also helps minimise dropout rates and ensures consistency in data collection procedures.

Study Design:

***Study population*:** This study aims to recruit a balanced sample of adult participants from Singapore's population, with a target enrolment of 32 participants, equally distributed between males and females (16 of each gender) and of Asian descent. This sample size has been

carefully determined to provide sufficient statistical power while remaining feasible within the study's resources and timeline.

Participants will be recruited primarily by word of mouth at the TTSH Ophthalmology Specialist Outpatient Clinic's, focusing on accompanying next-of-kin of existing patients, TTSH staff members, or any other availably healthy volunteers after meeting the inclusion and exclusion criteria. The recruitment process will be conducted with careful attention to avoiding any coercion or undue influence, particularly in cases involving dependent relationships. All potential participants will be given adequate time to consider their participation and will be required to provide informed consent in the presence of a witness in compliance to the Declaration of Helsinki, as well as other prevailing laws and guidelines regulating clinical research.

***Inclusion Criteria*:**

1. Age: 21 to 59 years old
2. Gender: Males or females
3. Ethnicity: Asian descent.
4. Language comprehension: Able to understand verbal spoken instructions in:
    - British/American English
    - Mandarin Chinese
    - Bahasa Melayu
5. Protocol compliance: Ability to comply with the study protocol, as determined by the investigator's judgment
6. Consent capacity: Must be able to understand and provide informed consent, with signed informed consent form required before any study assessments

***Exclusion Criteria*:**

1. Communication barrier: Unable to understand verbal spoken instructions
2. Medical history:
    - Any facial trauma
    - Any ocular trauma
    - Any head trauma
    - Any history of ocular disease
    - Any history of ocular surgery
    - Systemic condition(s)

3. Near visual acuity:
    - Right eye & Left eye monocularly, binocularly unaided near vision: worse than N6 at 40cm from participant's nose
4. Ocular alignment:
    - Prism cover test at near (30cm) of equal or greater than 10 prism diopters at these positions of gaze:
        - Primary gaze
        - Right gaze
        - Left gaze
        - Up gaze
        - Down gaze
5. Extraocular movement:
    - Extraocular movement of over-action or under-action of equal or greater than 0.5 in any of the nine cardinal positions of gaze
6. Confrontational Visual field:
    - Abnormal monocular visual field on confrontational visual field test
7. Hess chart test
    - Abnormal or asymmetry in pattern of extraocular muscle action in Hess chart test
8. Pregnant woman will be excluded from this study.

Study Procedure:

This cross-sectional study will involve 1 study visit.

***Pre-specified clinical outcome*:** The primary outcome is the establishment of a normative range of field of binocular single vision measurements in Singapore adults. These measurements will be taken using the Takagi MT-325UD Projection Perimeter. The secondary outcome is the comparison with the normal boundary of the established field of binocular single vision by Feibel & Roper-Hall (1974) and the analysis of any significant differences between the two sets of measurements.

Clinical Validation will be a cross-sectional study design to determine the normative range of the field of binocular single vision measurements in participants who are Singapore adults focusing on accompanying next-of-kin of existing participants and TTSH staff members after meeting the inclusion and exclusion criteria.

Research Procedures:

1) *Medical history assessment*

A comprehensive medical history will be obtained from each participant through a structured interview. The investigator will specifically inquire about any history of facial trauma, ocular trauma, head trauma, ocular disease, ocular surgery or any systemic condition(s), documenting the nature, timing, and severity of any reported incidents. Particular attention will be paid to any previous ocular diseases and surgical interventions. All responses will be recorded in standardized case report forms, with detailed documentation of the type, date, and outcome of any reported conditions or procedures. Participants should not have any history of facial trauma, ocular trauma, head trauma, ocular disease, ocular surgery or any systemic condition(s). This thorough screening is essential to ensure participants meet the study criteria for establishing normative values.

2) *Near Visual Acuity Testing*

Near visual acuity will be assessed right eye and left eye monocularly & binocularly using a standard near vision chart held at 40cm from the participant's nose. Testing will be conducted under standardized lighting conditions with monocularly and binocularly and unaided. A measuring stick will be used to maintain the precise testing distance. The examiner will record the smallest line that can be read accurately, with participants required to achieve N6 or better to be included in the study. Any participant with near vision worse than N6 will be excluded from the study.

3) *Ocular Alignment Assessment*

A prism cover test will be performed at near of approximately 30cm from participant's nose to evaluate ocular alignment. The examiner will systematically assess alignment in five positions of gaze: primary gaze (straight ahead), right gaze, left gaze, up gaze, and down gaze. Measurements will be taken using loose prisms or a prism bar, with deviations recorded in prism diopters. Any deviation equal to or greater than 10 prism diopters in any of the five positions of gaze will result in exclusion from the study. The examiner will ensure consistent testing distance using a measuring stick and maintain standardized testing conditions throughout the assessment.

4) *Extraocular Movement Testing*

Extraocular muscle function will be examined by having the participant follow a fixation target through the nine cardinal positions of gaze. The examiner will assess and grade any overaction or underaction of the extraocular muscles using a standardized scale, where 0 represents normal movement. Participants demonstrating overaction or underaction equal to or greater than 0.5 units in any direction will be excluded from the study. The examination will be conducted methodically, ensuring smooth pursuit movements are carefully observed and documented.

5) *Confrontational Visual Field Testing*

Monocular confrontational visual field testing will be performed separately for each eye. The examiner will sit at one meter distance, directly facing the participant at eye level. Each quadrant of the visual field will be tested systematically using standardized targets, while the participant maintains fixation on the examiner's nose. Any abnormality in the visual field will be documented and will result in exclusion from the study. The testing sequence will remain consistent for all participants to ensure standardization of the assessment.

6) *Hess Chart Testing*

The Hess chart test will be conducted using a standard Hess screen at the recommended testing distance. This test will evaluate the action of each extraocular muscle, with results plotted on the Hess chart. The examiner will assess for any asymmetry or abnormality in the pattern of extraocular muscle action. Any abnormal findings on the Hess chart will be documented in detail and will result in exclusion from the study. The test will be performed following standardized protocols to ensure consistency and accuracy of results.

7) *Field of binocular single vision*

Participants perform the field of binocular single vision test binocularly and pursue a single round light stimulus presented in the bowl of the Takagi MT-325UD Projection Perimeter, and participants will need to look and follow through the single light stimulus as it moves throughout the bowl, and participants will press the buzzer if two distinct light stimuli are seen. Scores will be recorded and plotted on the recording sheet based on participants' responses during the test. Eye dilation will not be required for this research study.

All examinations will be performed by trained orthoptists, with results recorded immediately in standardised documentation forms. The testing sequence will remain consistent across all participants, and any exclusion criteria met will be documented with specific measurements and observations.

As part of the clinical evaluation of participants during the analysis phase, access and extraction of data will be limited to TTSH's NGEMR and Zeiss Forum Viewer. Clinical information collected for this study would include medical & ocular histories along with prior visual assessments documented by orthoptists.

Additionally, NEHR cannot and will not be used for research. Access of medical records for the purpose of data collection will also be limited to the period dated from 1 November 2025 to 31 October 2026. Clinical information/data collected will be done once off during, or retrospectively after the study visit.

Sample size calculation

This is a pilot study. Due to resource constraints, a total of 32 healthy participants will be recruited for this study.
Based on the literature, the standard deviation (SD) of normal values for the selected binocular single vision measure ranges from 5.3 to 6.9. Assuming an SD of 6 in our study, a sample size of 29 will allow us to estimate the mean of normal values with a precision of 2.2 at the 95% confidence level. We expect drop out rate to be no more than 10%, 32 participants will be sufficient.

References:

1 Feibel RM, Roper-Hall G. Evaluation of the field of binocular single vision in incomitant strabismus. Am J Ophthalmol. 1974; 78(5):800-805.
2 Kakizaki H, Umezawa N, Takahashi Y, Selva D. Binocular Single Vision Field. Ophthalmology. 2009; 116(2):364-364.e2.