A COMPARISON OF NEAR STRABISMUS MEASUREMENTS WITH DIFFERENT FIXATION TARGETS

by

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ABSTRACT

It has been reported that there is a significant difference in the size of esodeviations when using letters compared to pictures or lights as a fixation target. In many clinics, small picture stickers are used as a target for preliterate or uncooperative children. In this study, experimental stickers with detailed pictures were compared to the Lang fixation cube and a monochromatic circle to assess their suitability as near fixation targets for the measurement of near deviations. Participants were 3-5 years of age and had an esodeviation. The near angle of deviation was measured using the three targets and compared to determine if treatment would be affected. Significance is based on a difference of 5 prism diopters (PD) as this could potentially change the treatment plan. The results of the study show no clinically significant difference when using the experimental sticker, Lang cube or red circle as the near target.

LIST OF ABBREVIATIONS AND SYMBOLS USED

A	Alternating
AC/A	Accommodative convergence/accommodation ratio
APCT	Alternate prism and cover test
AV	Average
BI	Base in
BO	Base out
cm	Centimeter
Coop.	Cooperation
D	Diopters
DVD	Dissociated vertical deviation
E	Esophoria
ET	Esotropia
ID	Identification
L	Left
LE	Left eye
LogMAR	Logarithm of the minimum angle of resolution
Mm	Millimeter
NPA	Near point of accommodation
PD	Prism diopters
R	Right
RE	Right eye
SD	Standard deviation

VA	Visual acuity
(T)	Intermittent tropia

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Chapter 1 INTRODUCTION

Strabismus is defined as a deviation of the visual axes relative to each other due to a sensory or motor anomaly. A heterophoria is a latent deviation that is controlled by fusional mechanisms, whereas a heterotropia is a manifest deviation (von Noorden & Campos, 2002). A deviation can also be intermittent when a person has some ability to control it. According to a population-based study by Friedman et al. (2009), 2-3% of children aged 6-71 months old of African-American and White descent in the United States of America have strabismus. Early detection and treatment of strabismus in children is essential for the normal development of the visual system, as misalignment of the eyes has been found to be the most common cause of amblyopia and loss of binocular vision. Amblyopia is defined as decreased vision unilaterally or bilaterally caused by abnormal binocular interaction or pattern vision deprivation (Taylor & Hoyt, 2017). 3% of western populations are affected by amblyopia (Astle, Webb & McGraw, 2011). Strabismus has been reported to have a significant impact on a person's quality of life, as they can suffer from emotional or psychosocial problems because of the misalignment of their eyes. For children this includes, but is not limited to low self-esteem, bullying and social anxiety (Ribeiro et al., 2014).

It has been determined that the critical period for visual development differs for different visual aspects. Stereopsis, for example, is normally established before the age of three, whereas the critical period for amblyopia due to monocular deprivation extends to nine years of age (Astle, Webb & McGraw, 2011). There is a sudden onset of stereopsis development at three months of age, followed by a period of rapid maturation that can continue up to 18 months of age. There is then a gradual improvement to continues until

approximately age three years old, as previously mentioned (Fawcett, Wang & Birch, 2005). This shows the importance of proper alignment of the eyes at a young age so as to diminish the risk of strabismic amblyopia and give the child the best chance to develop stereopsis.

1.1 ACCOMMODATION and CONVERGENCE

Mechanisms of control for ocular alignment can include accommodation, convergence and divergence fusional amplitudes, with these entities interacting. Three mechanisms are at work to ensure a clear and single near image. These three components are accommodation, convergence and miosis and they are collectively known as the near triad (Miller, Walsh & Hoyt, 2005). Accommodation and convergence will be further discussed in order to illustrate their importance in proper ocular alignment and hence their importance for this study.

1.1.1 Accommodation

Accommodation is a process that steepens the curvature of the lens in order to increase the effective refractive power of the eye; this is controlled by a complex sensorimotor system. The peripheral motor effector in the accommodative pathway is the ciliary muscle. In a summarized overview, this muscle is innervated by preganglionic parasympathetic fibers of cranial nerve III with the fibers being relayed through the mesencephalon synapse of the ciliary ganglion from the midline nucleus (Edinger-Westphal) of the oculomotor complex. The afferent pathway involves an accommodative stimulus initiating a response due to blurred retinal images, travelling via the optic nerve/chiasm/tract to the visual cortex and ends with the neurons in the Edinger-Westphal nucleus of the oculomotor nerve. The supra-oculomotor nuclei then send the motor

control signals which travels from the Edinger-Westphal nucleus in the fibers of cranial nerve III to the orbit where they synapse with the ciliary ganglion. Postganglionic fibers travel via the short ciliary nerves to the peripheral motor effector which results in the change of accommodation. It has also been determined that there is a supranuclear aspect in the control of accommodation. Jempel confirmed that the cerebral cortex is involved in accommodation along with the stimulation of convergence and miosis, as well as other studies suggesting that the lateral supra-sylvian visual cortex is the cortical control of accommodation (Miller, Walsh & Hoyt, 2005).

Accommodative amplitudes are measured in diopters (D) and is calculated by using the reciprocal of the fixation distance (von Noorden & Campos, 2002). Accommodation is first detected at two months of age and is fully developed by eight months of age (Taylor & Hoyt, 2017). The average resting state refractive power of the lens is +10 D. The lens power can increase to +18 D, which takes place precisely and instantaneously when needed so as to create a clear image on the retina. The change in the eye's refractive power between a state of non-accommodation and maximum accommodation is defined as the amplitude of accommodation. The near point of accommodation (NPA) is the point closest to the eye at which the eye can maintain a focused image on the retina.

There are several types of accommodation including tonic, reflex, proximal and convergence accommodation. The cues that will initiate the proper accommodative response include spherical and chromatic aberrations, blur, target size, spatial frequency, brightness and contrast (Thiagarajan, Lakshminarayanan & Bobier, 2008). The primary stimulus for accommodation is reflex, which is the response to retinal blur to create a

clear, sharp image. Tonic is defined as the tonus from the ciliary muscle; this means that the resting state of the lens, with no stimulation, will focus images at an intermediate distance, not infinity. This has also been referred to as "dark focus" or "dark accommodation" and has been found on average to be 0.78 D (Liu, Drew, Borsting, Escobar, Stark & Chase, 2016). Proximal accommodation is stimulated by the awareness of an object being near. Convergence-accommodation is accommodation that is associated with the convergence of the two eyes and is governed by the accommodative-convergence/accommodation (AC/A) ratio (Miller, Hoyt & Walsh, 2005).

1.1.2 Convergence

Convergence is a disjunctive, simultaneous vergence movement of the two eyes that increases the angle formed by the visual axes (von Noorden & Campos, 2002). It is stimulated by retinal image position and with normal convergence amplitudes will allow for single vision and stereoscopic viewing (Horwood & Riddell, 2012). Vergence movements are mediated by the same ocular motoneurons as versional movements, but the individual neurons differ. The frontal cortex and the cerebellum are also involved in regulation of these movements, as well as play a role in accommodation. Together they create a negative feedback control system (Miller, Hoyt & Walsh, 2005).

The three sets of neurons in the midbrain reticular formation that only discharge for vergence movements are burst, tonic and burst-tonic cells. These cells are intermixed in the reticular formation, one to two millimeters away from the oculomotor nucleus and generate the position as well as velocity commands for the vergence movement. For convergence, the oculomotor neurons send a signal for the medial recti to contract while

the abducens motorneurons decrease their firing to the lateral recti, allowing it to relax proportionally (Miller, Hoyt & Walsh, 2005).

There are various types of convergence that play a role including voluntary, fusional, proximal, tonic, and accommodative convergence. Voluntary convergence is the conscious effort made to bring the two eyes together without an external stimulus, whereas tonic convergence is the innate response of the extraocular muscles to overcome the anatomical divergence of the two eyes and orbits in order to maintain proper alignment. The extraocular muscles are never without electrical activity in a resting eye (von Noorden & Campos, 2002). Fusional convergence is an involuntary movement initiated by the image of an object on non-corresponding parts of the two retinas. This can be stimulated by introducing a prism under binocular viewing. By optically moving the image, this induces retinal disparity without changing the position of the target (Miller, Hoyt & Walsh, 2005). Proximal convergence is induced by the awareness of an object coming close to the face, and is elicited to prevent diplopia. It is believed that two-thirds of convergence is accommodative-convergence, the direct result of retinal blur (Rowe, 2012).

Schor (1983) has described the interactions between the two feedback loops of accommodation and convergence when blur or binocular disparity are introduced to the visual system. Both can be isolated by opening up the feedback loop of the other, for example monocular occlusion to open up convergence and viewing through a pinhole to open up accommodation. Figure 1.1 illustrates the theory that blur and disparity simultaneously stimulate accommodative convergence and convergence accommodation. This theory predicts a higher demand on accommodation and convergence under

binocular (closed-loop) conditions when compared to monocular (open-loop) conditions. Meaning Schor found that the amount of accommodation and convergence found when each test monocularly would result in a lower amount than when tested with the same stimuli under binocular conditions.

One of the relationships between accommodation and convergence is expressed as the AC/A ratio, the ratio of accommodative convergence in prism diopters (PD) to accommodation in diopters (D). This is the amount of accommodative convergence induced by each diopter of accommodation exerted. The normal range of the AC/A ratio when calculated using the gradient method is between 3 to 5:1. There are two methods to calculate the AC/A as seen in Figure 1.2 and Figure 1.3. The resulting ratio is usually larger when using the heterophoria method, the gradient method is therefore considered to give a better estimate of the AC/A ratio (von Noorden & Campos, 2002).

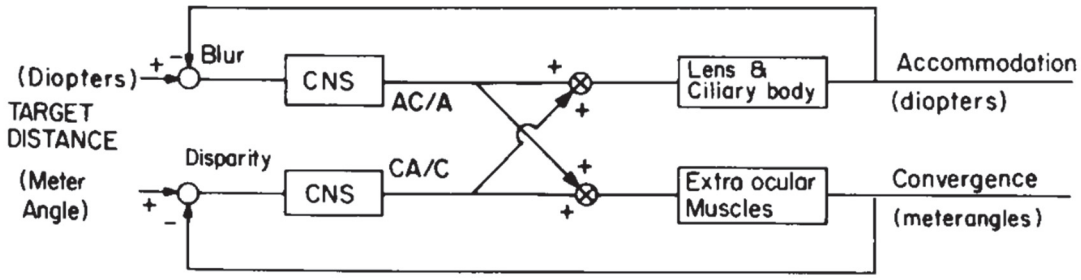

Figure 1.1 Mutual interactive model of accommodation and convergence by Schor (1983). This model involves parallel forward crosslinks with controller outputs being used as stimuli simultaneously for accommodative convergence and convergence accommodation.

$$\text{AC/A} = \frac{\Delta_1 - \Delta_0}{\text{D}}$$

Figure 1.2 The gradient method is used to calculate the AC/A ratio by changing the stimulus to accommodation while keeping the fixation distance the same. Plus lenses would be placed in front of each eye to relax accommodation, whereas minus lenses would be used to increase accommodation. This is calculated by the original deviation (Δ_0) subtracted from the strabismic deviation with the lenses (Δ_1) divided by the power of the lens (D) (von Noorden & Campos, 2002).

$$\text{AC/A ratio} = \text{IPD(in cm)} + \frac{(\text{Near PCT}) - (\text{Distance PCT})}{\text{Amount of accommodation exerted}}$$

Figure 1.3 Heterophoria Method: The distance strabismus measurement is subtracted from the near strabismus measurement in PD, this is then divided by the amount of accommodation exerted in D. The resulting value is then added to the interpupillary distance in centimeters (cm) (Rowe, 2012).

The AC/A ratio is an important consideration when diagnosing and treating strabismus, as it can be permanently altered by strabismus surgery and temporarily altered with the use of lenses or drugs. Calculation of this ratio can help properly categorize esodeviations as well as exodeviations (Rowe, 2012). The close association between accommodation and convergence has led those in the field of strabismus to create a near target that stimulates accommodative effort by employing letters ranging from 20/200 to 20/20 to ensure a standardised, accurate strabismus measurement for near.

1.2 ESODEVIATIONS

To narrow the scope of the research, this study is specifically studying only one form of strabismus: esodeviations. An esodeviation is the tendency for one eye to deviate medially due to a mechanical cause, an innervational cause, or a combination of the two. The deviation can be latent, intermittent or manifest. One classification of esodeviations is shown in Table 1.1. The deviation is classified not only by the medially deviated eye, but by completing a thorough ophthalmic exam to determine if any other abnormalities accompany the strabismus. This includes, and is not limited to, abnormal movements on ocular motility, the presence of a refractive error, nystagmus and dissociated vertical deviation (DVD). Timing of onset is also important when diagnosing the type of esodeviation.

I. Comitant esodeviations
  A. Accommodative esotropia
    1. Refractive accommodative esotropia (normal AC/A)
    2. Nonrefractive accommodative esotropia (high AC/A)
    3. Hypoaccommodative esotropia (reduced NPA)
    4. Partially accommodative esotropia
  B. Nonaccommodative esotropia
    1. Infantile esotropia
    2. Nonaccommodative convergence excess (normal AC/A)
    3. Acquired (basic) esotropia
    4. Acute-onset esotropia
    5. Divergence insufficiency or paralysis*
    6. Cyclic esotropia*
    7. Recurrent esotropia
  C. Microtropia
    1. Primary microtropia
    2. Secondary microtropia
  D. Nystagmus "blockage" syndrome*
II. Incomitant esotropia*
  A. Paralytic
  B. Nonparalytic
    1. A- and V-pattern esotropia
    2. Retraction syndrome
    3. Mechanical-restrictive esodeviations
      a. Congenital fibrosis of extraocular muscles
      b. Acquired restriction (endocrine myopathy, trauma to orbital wall, excessive resection of medial rectus muscle(s), myositis, strabismus fixus)
III. Secondary esodeviations
  A. Sensory
  B. Consecutive

AC/A, accommodative convergence/accommodation ratio; NPA, reduced near point of accommodation.
*Forms of esotropia discussed in other chapters of this book.

Table 1.1 Classification of esodeviations (von Noorden & Campos, 2002)

The classifications of esodeviations that could potentially meet the inclusion criteria (see section 6.2.2) for this study are refractive accommodative, non-refractive accommodative, partially-accommodative, infantile, non-accommodative convergence excess and acquired esodeviations.

Refractive accommodative esotropia is defined as an esotropia that is restored to orthotropia at all fixation distances when the hypermetropic refractive error is fully corrected. The esotropia is the result of insufficient fusional divergence amplitudes, along with an increased accommodative effort in order to see clearly leading to excessive accommodative convergence.

Non-refractive accommodative esotropia is defined as an esotropia that is unrelated to an uncorrected refractive error with a deviation that is greater at near when compared to distance fixation, caused by a high AC/A with a normal NPA. A partially-accommodative esotropia has an accommodative component, but it does not account for the entire deviation. It is essential for all esodeviations, this type in particular, to be corrected with the patient's full cycloplegic refraction to ensure optimal visual acuity and alignment.

Infantile esotropia is defined as a large angle (minimum 30 PD) manifest deviation with an onset between birth and six months of age, alternation on cross fixation and no apparent central nervous system abnormalities. Other clinical features that can accompany these features are amblyopia, motility patterns, DVD, manifest-latent nystagmus and abnormalities on adduction or abduction.

Non-accommodative convergence excess has a normal AC/A ratio and measures larger at near than distance (minimum difference 10 PD) while wearing full optical

correction. Acquired non-accommodative esotropia is comitant with a gradual onset after six months of age and the near deviation is within 10 PD of the distance deviation. A significant hypermetropic refractive error is not present in these cases and the AC/A ratio is normal (Taylor & Hoyt, 2017; von Noorden & Campos, 2002).

When determining the diagnosis for patients with esotropia, it is very important to consider all aspects of the ophthalmic exam in order for the deviation to be properly categorized. As previously described, the refractive error, ocular motility, near point of accommodation, age of onset as well as the near and distance deviation measurement all need to be considered. In the context of this research, the two classifications that can commonly be misdiagnosed as the other are non-accommodative convergence excess and non-refractive accommodative esotropia. Both are esodeviations that measure greater at near when compared to distance fixation, but one results from a high AC/A ratio and the other does not. Non-refractive accommodative esotropia is the result of abnormal synkinesis between accommodation and accommodative convergence, whereas non-accommodative convergence excess esotropia has a normal AC/A, and the larger esotropia at near is thought to be due to excessive tonic innervation (von Noorden & Campos, 2002). To differentiate between the two, the most valuable test is measuring the near esodeviation using convex lenses to relax accommodation and comparing this to the near deviation without the lenses. These measurements are then used in the gradient method (Figure 1.2) to determine if the AC/A is within normal limits. Von Noorden & Campos (2002) emphasize the need for accommodation to be fully controlled to obtain an accurate calculation. It is a common diagnostic error to not use a fixation target that requires a full accommodative effort to see clearly, or full relaxation of accommodation

through the convex lenses. This example illustrates the importance fixation target choice can have when it comes to making an accurate diagnosis of esodeviation.

1.3 QUANTIFYING AND TREATING STRABISMUS

1.3.1 Quantifying

There are various methods to quantify strabismus including the Hirschberg method, Krimsky test, modified Krimsky test, Maddox rod test, simultaneous prism and cover test and alternate prism and cover test. These methods all demand different levels of cooperation from the patient. The Hirschberg method requires the least amount of cooperation, as it estimates the number of millimeters the corneal light reflex is displaced in the misaligned eye when a prism cannot be used. As seen in

Figure 1.4, the average corneal diameter is 12 mm for an adult and the average indoor pupil size is 4 mm, therefore based on this information the strabismic deviation can be quickly estimated. Each millimeter is said to be equivalent to 15 PD for this method (von Noorden & Campos, 2002). The Hirschberg estimation is very useful for strabismic patients who have poor vision, who are unsettled by having objects approach their face, or who have a limited attention span.

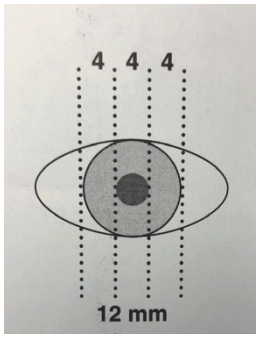

Figure 1.4 Illustration of the three segments used to estimate the strabismic deviation based on the average corneal diameter and pupil size. Each segment is 4 mm horizontally (Cassin, 1995).

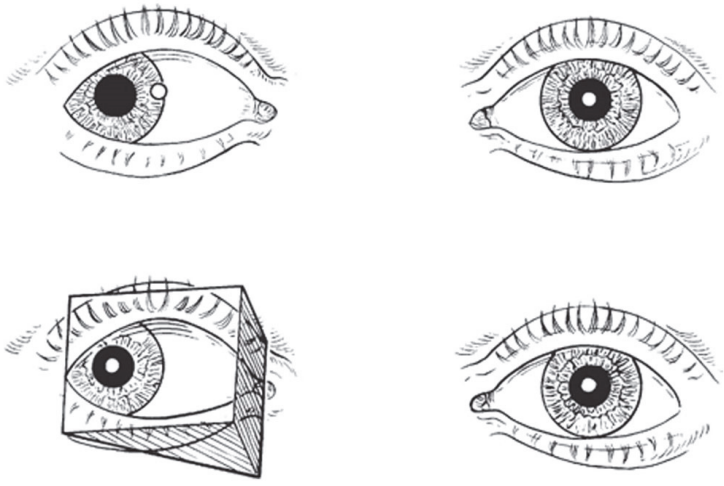

Figure 1.5 The Krimsky test uses a prism to optically move the position of the corneal reflex of either the fixing eye or the misaligned eye (Simon & Calhoun, 1997).

The next test requiring minimal levels of cooperation for measuring strabismus is the Krimsky test. The location of the corneal reflex on the fixing eye is noted. A prism of the proper orientation is then placed in front of the misaligned eye to move the corneal light reflex. The light reflex will move towards the apex of the prism. When the light reflex of the misaligned eye matches that of the fixing eye, as seen in Figure 1.5, the deviation has been neutralized. This test is particularly valuable for patients who have very poor vision in one eye, rendering them unable to perform an alternate prism and cover test. The modified-Krimsky test can then be used, which involves the prism being placed in front of the fixing (non-deviated) eye to move the light reflex of the deviated eye to a point slightly nasal to the center of the pupil.

The Maddox rod test involves placing the Maddox rod distorting filter over one eye with the cylinders in the horizontal direction while using a muscle light as a fixation target. The patient aligns the image of the distorted vertical line with the image seen by the fellow eye. This method cannot distinguish between a tropia and a phoria as it is a dissociative test (American Academy of Ophthalmology).

The simultaneous prism and cover test is used to measure the manifest portion of strabismus by placing the occluder in front of the fixing eye and a prism of the proper orientation in front of the deviating eye simultaneously. When there is no movement of the deviating eye (looking through the prism) the manifest deviation has been neutralized. The most accurate and preferred method for the measurement of the total phoria and tropia is the alternate prism and cover test (APCT), but this requires a greater degree of

patient cooperation (Cassin, 1995; Mehta, Kushner & Morton, 1998; PEDIG, 2009). When measuring strabismus, the patient must be fixing on an accommodative target to obtain the most reliable results (Cassin, 1995). A cover test is performed with the patient's eyes in primary position with the fixation target at their eye level: one eye is covered, and the uncovered eye is observed for any refixation movement. It is used to assess whether the strabismus is constant, intermittent or alternating. If movement is seen with the cover test, the cover/uncover test can be skipped and the alternate prism cover test can be performed. If there is no movement of the uncovered eye, then a cover/uncover test is performed to test for a phoria: the covered eye is observed for movement when the occluder is removed.

The alternate cover test is performed by occluding each eye in turn. It is essential that the patient is given several seconds to pick up fixation with the uncovered eye, then the occluder is moved once again, back and forth over the two eyes. If a movement of the eyes is seen, a prism of the appropriate orientation is then used to neutralize the deviation. Neutralization of the deviation is defined as the largest prism that stops the movement before reversal of direction of the refixation movement. As APCT is the preferred method to measure strabismus for participants with no amblyopia and no restriction of ocular motility, it was used in this study (Cassin, 1995; Johns et al., 2004; PEDIG, 2009).

1.3.2 Treatment of Esodeviations

This research is also relevant when considering the treatment of esodeviations. In order to determine the appropriate treatment modality, accurate strabismus measurements must be obtained at near and distance. All scientifically proven testing must be employed to reveal the largest deviation as well as any differences in the measurements obtained

when fixing at 6m and 1/3m. Examples of commonly used methods include using a muscle light as a target or placing convex lenses in front of each eye at near for exodeviations (Wright, 2003).

After completing the orthoptic evaluation of the patient, a cycloplegic refraction is performed to determine whether there is a refractive error that can be corrected as this may reduce the esodeviation. Cycloplegic refraction is performed by using a parasympatholytic eye drop to temporarily paralyze the ciliary muscle. These medications also result in the temporary paralysis of the iris sphincter muscle. The loss of accommodation and dilation of the pupil facilitate an easier examination, with less variability in the light reflex and the ability to uncover a latent refractive error (Cassin, 1995).

Wearing spectacles alone can straighten the eyes in a case of refractive accommodative esotropia, but a deviation at near can persist if there is a high AC/A. Ophthalmologists may approach treatment for this type of deviation with either bifocal glasses or strabismus surgery. The purpose of bifocals is to reduce the accommodative demand and consequently correct the residual deviation at near with the use of plus lenses (in addition to their full cycloplegic refraction) so as to obtain some degree of binocular single vision (von Noorden & Campos, 2002). Accurate near and distance strabismus measurement with an accommodation-stimulating target is essential to determine whether bifocals are an appropriate treatment.

Strabismus surgery involves strengthening or weakening one or multiple extraocular muscles to better balance their effective power. Esodeviations and exodeviations are usually treated by operating on the horizontal rectus muscles (medial

and lateral) to varying degrees depending on the clinical strabismus measurements. Strabismus measurements are performed at near and in the cardinal positions whilst focusing on a distance target. A surgical dose table is used to determine how many millimeters to move the muscles based on the size of the deviation. An example of a surgical dose table used can be seen in Table 1.2. The surgical dose increases as the angle of deviation increases in steps of 5 PD. A difference of 5PD would therefore be clinically significant as it is very likely to change the surgical plan. Consequently, 5PD was determined to be the level of clinical significance when considering measured angles of deviation for this research project.

Angle	MRc	LRs
15^{Δ}	3.0 mm	4.0 mm
20^{Δ}	3.5 mm	5.0mm
25^{Δ}	4.0 mm	6.0 mm
30^{Δ}	4.5 mm	7.0 mm
35^{Δ} - 40^{Δ}	5.0 mm	8.0 mm
$> 40^{\Delta}$	see Cong ET Table	

Table 1.2 A table created by W.E. Scott that is used to determine how many millimeters (mm) the medial rectus is to be weakened (MRc) and the lateral rectus to be strengthened (LRs) based on the esodeviation angle in prism diopters (Δ) (Scott & Wright).

Generally, surgery for esotropia is performed when the manifest deviation exceeds 10 PD in the primary position at near and/or distance with the patient wearing their full refractive correction. This number is generally accepted as an angle too large for comfortable binocular single vision and acceptable cosmesis (Sandercoe, Beukes & Martin, 2014; Holmes, Beck, Kip, Droste, Leske & PEDIG, 2000). Binocular vision is best achieved when the postsurgical alignment is within 10 PD of orthotropia, with varying levels of stereopsis achieved dependent on factors such as best-corrected visual acuity of each eye, timing of onset of strabismus etc. (Pageau, Guise & Saint-Amour, 2011).

Not only is the size of the strabismic deviation to be considered when doing surgery, but the difference between the near and distance measurements must also be considered. If there is a greater deviation at near when compared to distance then the surgeon may opt for a different surgical technique. For an esotropia with a high AC/A ratio the most common surgical procedures include a greater amount of recession (weakening) of the medial rectus, recessing the medial rectus with a slanted insertion, and medial rectus recession with additional posterior scleral fixation sutures. These techniques have resulted in better outcomes when compared to surgery that is solely based on the distance deviation as in Table 1.2 (Ellis, Pritchard, Baham & Babiuch, 2012).

1.4 PURPOSE OF THE STUDY

The objective of this study is to expand upon previous research on the importance of the choice of fixation target used for strabismus measurements at near fixation. As it can be difficult to have a young child reliably hold the fixation stick, and the majority are

not yet literate, it is common practice among orthoptists and ophthalmologists to use a picture sticker as a near fixation target. A sticker can be a hands-free target that holds the attention of young children well, and can contain details that can stimulate accommodation. Possible problems with these are that different stickers are used inconsistently and present more variability in the size and colour, as well as the level of detail of the pictures used on these stickers. These factors could potentially have an effect on the accommodative effort of the patient, and thus the measured deviation. As previously discussed, the accommodation and convergence pathways have significant interaction, therefore when measuring one the other must be considered and controlled as well.

The purpose of this study is to investigate novel stickers with a picture and symbols. The size, colour and amount of detail will all be controlled, as well as the presentation distance and the instructions given (Cassin, 1995; Lovasik & Kergoat, 1988; Mehta et al., 1998). An experimental sticker (Figure 3.1,

Figure 3.2 & Figure 3.3), the cat picture on the Lang fixation cube (Figure 3.4) and a red circle (
Figure 3.5) will be compared.

When wearing appropriate refractive correction, the eye's focal point is considered infinity. Therefore, the blur of symbols or letters at 1/3m would induce an accommodative response. The experimental stickers incorporate symbols that have Snellen equivalence so they are therefore accommodation-inducing targets (Scott, Mash & Redmond, 1976). The three sizes of symbols are Snellen equivalent of 20/30 (0.18 logMAR), 20/40 (0.3 logMAR) and 20/60 (0.48 logMAR).

1.4.1 Research question

When quantifying esodeviations at 33 cm, is the measurement statistically and clinically significantly different when using detailed picture stickers as an accommodative target for preliterate children when compared to the very popular cat picture on the Lang fixation cube, or a simple red circle sticker?

1.4.2 Hypothesis

It is hypothesized that an experimental sticker with a detailed picture as a near fixation target will result in significantly different strabismus measurements when compared to the cat picture on the Lang fixation cube, or a red circle.

Chapter 2 LITERATURE REVIEW

In the literature, there is no universally-agreed fixation target standard for measuring strabismus at near for pre-literate patients. Rowe (2012) does not define the meaning when using the term accommodative target, whereas Cassin (1995) advises the use of "an accommodative target of some type, usually a toy on or around a fixation light". Von Noorden & Campos (2002) go into more detail in their text, suggesting a 6/9 visual acuity symbol or a figure on a tongue depressor. Having figures on both sides of the depressor allows for a longer span of attention by reversing the faces; the child is also able to easily hold the depressor, freeing both of the examiner's hands. A small card can also be clipped to the bridge of the examiners' glasses. The textbook Pediatric Ophthalmology and Strabismus (Taylor & Hoyt, 2017) suggests using the Lang fixation cube, small detailed toys or pictures with fine detail that will stimulate accommodation. In comparison, there is a very well-defined target that is commonly used in clinical practice for the literate population that has optotypes ranging from 20/200 to 20/20 Snellen acuity.

A retrospective study of patients seen between the years of 1984 to 1994 studied the factors affecting the outcome of strabismus surgery. Various factors such as age, visual acuity, refractive error and pre-operative deviation magnitude were all compared to the success of the surgery. The populations studied were those that had recess-resect strabismus surgery for an acquired esotropia or exotropia, with success being defined as a deviation of five degrees or smaller from orthotropia, with or without binocular single vision. It was found that a statistically significant factor was the pre-operative deviation in both esotropia and exotropia (Abbasoglu, Sener & Sanac, 1996). They discovered that

patients with larger pre-operative deviations had poorer surgical results with the recess-resect surgery, representing a higher percentage of residual deviations greater than five degrees. In the methods, the authors note that for visual acuity testing as well as their strabismus measurements, they included data from three different methods. Snellen, the illiterate E chart and a forced choice preferential looking test were all used to measure visual acuity. For the strabismus measurements, either synoptophore, APCT or the Krimsky test was used. As the strabismus measurement and visual acuity were both variables that were studied in this retrospective study, I believe that the accuracy and reliability may differ between the methods of testing and thus may introduce error in the data. The authors did recognize there may be errors in the pre-operative measurements, but do not mention the fact that multiple methods relying on subjective and objective responses were included. Overall, this study is one of many illustrating the importance of an accurate pre-operative strabismus measurement in order to create an appropriate surgical plan. It is also important in order to facilitate proper informed consent for surgery, so that the risks and expectations of potentially more than one surgery are accurately discussed with the best evidence at hand.

As accommodation and convergence play a significant role in strabismus, it has been the focus of research looking at the importance of different fixation targets for stimulating these mechanisms fully. Scott, Mash & Redmond (1976) conducted a study using a non-accommodative target (light) compared to an accommodative target (20/30 Snellen equivalent letters) at near and distance to determine whether horizontal measurements would be significantly different. They included 85 participants between the ages of 5 and 26 years old. They found that there was a significant target-dependent

difference in measurements for 39% of the esodeviation group and 56% of the exodeviation group.

Inspired by the previous work by Scott, Mash & Redmond (1976), Mehta, Kushner & Morton (1998) evaluated the difference in the angle of deviation when using an accommodative target compared to other commonly used non-accommodative targets, to determine if the choice of target alters the amount of surgery to be performed. They chose a difference of 3 prism diopters (PD) to be clinically significant in their study as they argued such a difference would change the surgical dose; strabismus surgery tables increase by increments of 5 PD, so they argued that a difference of 3 PD would prompt the surgeon to round up and use an incrementally higher surgical dose from the table.

The study included 48 partially accommodative esotropic patients aged between 4.5 and 22 years old, with a mean age of 9.6 years old. They also included 23 intermittent exotropia patients aged between 4.5 and 51 years old, with a mean age of 16.3 years old. Participants were asked to fixate on each of three different targets for the distance measurements: reading a 20/40 Snellen optotype line, fixing on a motorized toy animal and watching a cartoon video. These were presented in a random order. For near fixation, the participant was asked to read the Jaeger 3 Snellen optotype line, as this would induce a sustained accommodative effort. This was compared to the participant fixing on a clown sticker. The Snellen optotype line was considered the gold-standard target for this study. Their results can be seen in

Patient Type	Distance Deviation On Optotype, Mean ± SD (Range)	Distance Deviation on Optotype minus Deviation on Toy Mean ± SD (Range)	Distance Deviation on Optotype minus Deviation on Cartoon* Mean ± SD (Range)	Near Deviation on Picture Mean ± SD (Range)	Near Deviation on Optotype minus Deviation on Picture Mean ± SD (Range)
Accommodative Esotropes N=48	7.6 Δ±5.4 (0 to 20)	3.1 Δ ± 3.5 (–4 to 16)	3.4 Δ ± 3.6 (–4 to 16)	17.0 Δ ± 10.2 (0–45)	3.0 Δ ± 3.3 (–6 to 18)
Intermittent Exotropes N=23	15.6 Δ ± 6.3 (4 to 25)	4.3 Δ ± 4.2 (–14 to 10)	3.2 Δ ± 3.5 (–14 to 10)	14.0 Δ ± 9.6 (0 to 30)	2.7 Δ ± 3.0 (–8 to 10)

Table 2.1. For the esotropic population, they found that 50% of the patients had a clinically significant difference when looking at letters compared to the cartoon at distance fixation, and 48% when comparing letters to the motorized toy. There was a trend towards an underestimation of the esodeviation when letters were not the target. For near, 42% had a significant difference when looking at letters compared to the sticker. There was a trend towards an underestimation of the esodeviation when fixing on the sticker. The authors do not state what percentage of the intermittent exotropia group had a 3 PD difference between the optotype and toy for distance or the optotype and cartoon, only that there was a 4.3 PD mean difference with a standard deviation of 4.2 PD, and 3.2 PD mean difference with a standard deviation of 3.5 PD respectively. For near fixation, the authors report 44% having a mean difference of 3 PD or greater, but there was no trend towards under or over estimation while fixing on the picture target.

There are a few weaknesses in the methodology by Mehta et al. that I believe should be avoided to achieve significant results. To begin, they are basing a clinically significant difference (3 PD) off an assumption that a strabismus surgeon would choose to round up. As there are several surgery dose tables, and all of them go up by 5 PD increments, I believe 5 PD is a more appropriate difference to use to define clinical significance. Also, based on the presented data, they did not have a minimum deviation requirement to be included in this study. The range for esotropia was 0-20 PD for distance and 0-45 PD for near fixation. The range for exotropia was 4-25 PD for distance and 0-30 for near fixation. If they are expecting a difference based on which target is used and classifying 3 PD as a significant difference there should be a minimum strabismic deviation assigned to have meaningful results. Another weakness of this study includes

not considering the accommodative status of the participants they included. For the intermittent exotropia participants, there were four participants that have the potential to be presbyopic due to their age. It was not stated that any measurement of accommodation was performed to check for hypo-accommodation. They also included children who routinely wear bifocals, which by decreasing accommodative demand can lead to weak accommodative ability (Shainberg, 2014). I believe both of these factors who have induced error to the resulting strabismus measurements and thus both were excluded from our study.

This study states that for the literate population a Snellen optotype line is considered the gold-standard for measuring strabismus. As to not repeat their work, a pre-literate population was chosen for this novel study in order to determine if a gold-standard accommodative near target would be valuable when measuring strabismus.

Patient Type	Distance Deviation On Optotype, Mean ± SD (Range)	Distance Deviation on Optotype minus Deviation on Toy Mean ± SD (Range)	Distance Deviation on Optotype minus Deviation on Cartoon* Mean ± SD (Range)	Near Deviation on Picture Mean ± SD (Range)	Near Deviation on Optotype minus Deviation on Picture Mean ± SD (Range)
Accommodative Esotropes N=48	7.6 Δ±5.4 (0 to 20)	3.1 Δ ± 3.5 (–4 to 16)	3.4 Δ ± 3.6 (–4 to 16)	17.0 Δ ± 10.2 (0–45)	3.0 Δ ± 3.3 (–6 to 18)
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Table 2.1 Comparison of strabismus measurements for partially accommodative esotropia and intermittent exotropia at near and distance when fixing on different targets: 20/40 Snellen optotypes, a toy, a cartoon and a picture (Mehta, Kushner & Morton, 1998).

An accommodation-related study was also performed on patients with intermittent exotropia by Le et al. in 2010. According to the authors when classifying a divergence excess intermittent exotropia, an important clinical test is assessing the AC/A ratio as it is useful in determining whether the patient has a true or simulated divergence excess. A true divergence excess exotropia refers to the deviation being greater when measured at distance fixation when compared to near. It is considered simulated type when the smaller near measurement is increased with further testing. This includes using prolonged monocular occlusion or accommodation-relaxing convex lenses.

According to Le et al., the gradient method (as seen in Figure 1.2) has been quantified as the most accurate technique to calculate the AC/A ratio. This method relies on the use of plus or minus lenses to control the patient's accommodation (relax or stimulate, respectively), but based on their results they add that the target being used for this test is important to achieve the proper accommodative response. This study included 25 participants between the ages of 4 and 15 years old, and its purpose was to compare the AC/A ratio when calculated using strabismus measurements obtained with two different fixation targets: N5 print and a picture target subtending a visual angle equivalent to N60 (as seen in Figure 2.1). They chose these targets as both are commonly used in clinic and the authors believed that the print would induce sustained accommodative effort. Conversely, they believed that there would be minimal accommodative effort exerted to fix on the larger picture target. They also argued that a change in accommodation would not be necessary to properly identify the large picture, whereas the small print would be too blurred if the appropriate accommodative response did not occur. Tenacious proximal fusion, a term defined by Kushner (2001), refers to a

"fusional vergence aftereffect". This possible confounding factor was eliminated by using 45-minute monocular occlusion for all participants prior to testing. The target presentation was not randomized; measurements with the large picture were first made and were followed with the N5 letters; the authors did not want the relaxed accommodation from the N5 print to affect the N60 target results. The average deviation measured with the picture was 26.8 PD (SD ± 10.6); when using the N5 print, the average measured deviation was 35.6 PD (SD ±10.8). This difference of 8.8 PD was found to be statistically significant. The resulting AC/A ratio was therefore 6.6:1 D when calculated with measurements obtained with the N5 print and 3.5:1 D with the picture target. This difference resulted in 56% of the participants shifting to a higher AC/A category for the N5 target (Le, Koklanis & Georgievski, 2010).

The main weakness of this study in my opinion is not randomizing the targets being used for the strabismus measurement to calculate the AC/A ratio. The authors have given their reasoning for this decision, but learning effect or attention should be taken into consideration. If the targets were to be randomized the results could have been studied to determine if the target order had any significant trend on the results.

These authors concluded from their results that when measuring the AC/A ratio with intermittent exotropia, the N5 target size is to be used and N5 print is preferred as a fixation target to elicit the appropriate accommodative relaxation with convex lenses. Patients with exodeviations are known to over-accommodate to maintain binocular single vision, decreasing their ability to see stereo-tests at a distance for example (Walsh, LaRoche & Tremblay, 2000) and it must be considered that patients with esodeviations can be under-accommodating to achieve also maintain their binocular vision. Therefore,

accommodation needs to be appropriately stimulated when measuring the maximum esodeviation at near, hence the relevance of our study of accommodative targets for the measurement of esotropia at near.

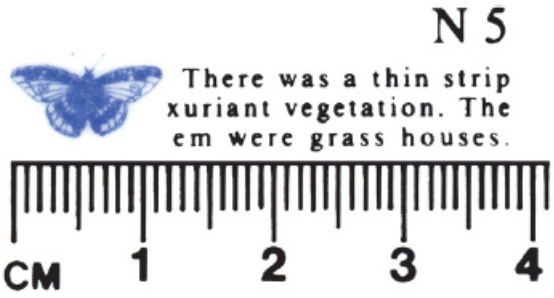

Figure 2.1 The blue butterfly target was considered to be N60 equivalent. This was compared to the N5 print that patients needed to continuously read while measurements were taken (Le, Koklanis & Georgievski, 2010).

The research in this field reviewed for this study, including the papers discussed above, use participants who are able to read letters or words as an accommodative near target. This is not an option for pre-literate children. As well, they compare optotypes to pictures that, as far as we know, were not all quantitatively analyzed for their visual resolution characteristics as the letter/print targets would have been.

There is no standardized alternative (non-Snellen) accommodation-inducing near target for the pre-literate children. There is a limited body of evidence stating that the use of an accommodative target is important as it has a clinically significant impact on the measured deviation, but there is no target is considered to be the gold standard for pre-literate strabismic patients. It is believed that this study will fill this gap in the literature in determining the most appropriate target to be used in the pre-literate population for the measurement of esodeviations at near.

Chapter 3 **PRE-STUDY METHODOLOGY**

3.1 PRE-STUDY RESEARCH DESIGN

A non-interventional, pilot prospective cohort study was completed. This pilot pre-study was performed in order to validate an equivalent VA resolution value for the experimental stickers designed for this study. Ethics approval was obtained from Dalhousie University, the University of Manitoba research ethics boards, and the Health Sciences Centre Pediatric Research Coordinating committee.

Sixteen patients (32 eyes) were enrolled and completed this pilot study. The age range for the participants was 3 to 5-years-old. A minimum age of 3 years old was chosen to facilitate cooperation for the duration of the examinations necessary for the study. Each participant underwent monocular measurement of their near vision with the LEA symbols® near chart, followed by testing of the near vision with the experimental stickers. The visual acuities obtained by these two testing methods were statistically analyzed to determine if the experimental stickers correlated with a corresponding LEA logMAR visual acuity. In study on the visual acuity of pre-school age children (3 to 6-year olds) using the LEA symbols® near chart by Sanker, Dhirani & Bhakat (2013), they define a real change in visual acuity to be 0.2 logMAR. Therefore, for this study 0.2 logMAR was chosen as a significance difference between the visual acuity measured using the LEA symbols® near chart and the experimental stickers.

3.1.1 Experimental Stickers

The experimental stickers were designed by the primary investigator to correlate with the Snellen acuities of 20/30 (0.2 logMAR), 20/40 (0.3 logMAR) and 20/60 (0.5 logMAR). These three acuity levels were chosen as they are the second, third and fourth

smallest lines on the Snellen fixation stick widely used with literate patients. The smallest optotypes line target of 20/20 was not used as it is beyond the Snellen equivalent threshold for this age group (Table 3.2.

Table 3.1) (Pan et al., 2009). The following converter was used to determine the millimeter (mm) to pixel conversion:
https://www.pixelto.net/px-to-mm-converter

In the Microsoft Paint® program used to design the stickers, the dots per inch (DPI) was 120. DPI signifies the resolution of an image, meaning how many dots fit into a linear inch. Therefore, according to the pixel conversion website, at this resolution one pixel is equal to 0.211667 mm. The conversions from Snellen acuity from the fixation stick to pixels used to create the stickers can be seen in Table 3.2.

Age (mos)	Mean VA(Male)	Mean VA (Fem.)	Mean (s.d.) VA	5th %ile(Snellen equiv.)*	Snellen equiv. threshold†
30–35 (N=100)	0.24	0.22	0.23 (0.14)	0.46 (20/58)	20/63
36–47 (N=460)	0.16	0.18	0.17 (0.13)	0.38 (20/48)	20/50
48–59 (N=567)	0.07	0.10	0.08 (0.11)	0.26 (20/36)	20/40
60–72 (N=595)	0.01	0.03	0.02 (0.09)	0.17 (20/30)	20/32

Table 3.1 Mean visual acuity for children 30-72 months of age (Pan et al., 2009).

Snellen Equivalent (ft)	**Size of letters on Snellen Fixation Stick** (horizontal x vertical) (mm)	**Pixels** (rounded to the nearest whole number)
20/200	5.5 x 5	26 x 24
20/100	3 x 3	14 x 14

20/80	2 x 2	9 x 9
20/60	1.5 x 1	7 x 5
20/40	1 x 1	5 x 5
20/30	0.75 x 0.75	4 x 4
20/20	0.5 x 0.5	2 x 2

Table 3.2 Dimensions, in pixels, used for creation of appropriately sized symbols of experimental stickers

Each experimental sticker was 1.50 cm in diameter with three symbols incorporated. Due to the limitations of the program being used to create the stickers, the range of symbols that could be incorporated was limited. The symbols used were circle, square, triangle, diamond and heart. As previously mentioned, the stickers were created on Microsoft Paint® by the pixel, making them as standardized as possible. As the symbols became smaller, the lines that make the symbols and the spacing between components were also altered to correlate with a Snellen optotype. For example: with the 20/60 cat, the representation of the eyes and nose are each seven pixels tall and five pixels wide. To create a standard crowding effect each of these components has one pixel of white above and below, and two pixels of white on each side to keep the dimensional comparison with the Snellen optotype arrangement the same. The black outline of the eyes and nose were all three pixels wide on the top and bottom, and four pixels wide on the side.

A cat's face was used for the experimental target in an effort to be comparable to the cat picture on the widely-used Lang fixation cube (LANG-STEREOTEST AG, Fähnlibrunnenstraffe 5, CH-8700 Küsnacht, Switzerland) (Figure 3.4). The red, white and black colour scheme of the experimental sticker was designed to be similar to the images on the Lang fixation cube as well. It was found by Atchison, Strang and Stark (2004) that the

accommodative responses of the study subjects were not more variable when focusing on a black and white vs. coloured (i.e. red) targets, therefore to be more interesting for the participant this colour scheme was used for the experimental stickers.

The Lang cube is also 1.50 cm in height and width, with the cat picture being 1.0 cm in height and 1.0 cm at its widest part (body and tail). The yellow eyes have no symbol or optotype in them and are approximately 1.0 mm in height and width. No Snellen equivalent has been assigned by the manufacturer, the cat picture would be equivalent to a Snellen optotype that is greater than 20/200 according to the measurements in Table 3.2.

The Lang cube was created as a fixation target for children with pictures considered appealing to this age population. An advantage of the Lang cube is the presence of one different picture on each of five faces of the cube, each one presented at will and quickly without changing the direction of gaze of the patient. This allows for a longer distraction-free period to measure strabismus at near and therefore has become a standard near fixation target (Lang, 1987; Taylor & Hoyt, 2017).

In this study, the experimental sticker (Figure 3.1,

Figure 3.2 & Figure 3.3) was also compared to a red circle (
Figure 3.5), which was selected so as to stifle accommodation as much as possible. The diameter of the red circle was also 1.50 cm. The colour red was chosen to be similar to the red color of the components of the experimental sticker. As we are only looking to manipulate the accommodation/convergence pathway, having all the targets black, white and red means the same retinal components (such as the long wavelength cones) will be stimulated each time (Purves, Augustine, Fitzpatrick et al, 2001).

Figure 3.1 The experimental sticker designed to correlate with 20/30 Snellen equivalent.

Figure 3.2 The experimental sticker designed to correlate with 20/40 Snellen equivalent.

Figure 3.3 The experimental sticker designed to correlate with 20/60 Snellen equivalent.

Figure 3.4 The "cat": the only picture used on the Lang fixation cube.

Figure 3.5 Non-accommodative red circle fixation target.

3.2 PRE-STUDY POPULATION

3.2.1 Participants

All participants of the pre-study were patients followed at a local busy eye clinic of a pediatric hospital. Potential participants were found by the PI through the review of 45 ophthalmology charts for patients with upcoming appointments in the clinic. After initial review, the family of patients who met the inclusion criteria were contacted by phone to determine if they were interested in participating. If they expressed interest, the pre-study information handout (Appendix A) was sent for review prior to their next scheduled appointment. If a patient was deemed to be eligible on the day of the appointment, the parent/guardian was given the same information handout to read through prior to any experimental testing. Informed consent was obtained on the day of the appointment by an independent orthoptist for those families agreeing to participate. This orthoptist has no other involvement in the study and has not seen any patient data from previous visits.

3.2.2 Inclusion Criteria

The inclusion criteria for the pre-study stipulated that participants be between the ages of 3 and 5 years old, with no strabismus and normal vision for their age in both eyes according to Table 3.2.

Table 3.1.

3.2.3 Exclusion Criteria

Patients who had manifest strabismus or an interocular vision difference of 10 optotypes or more when tested with the LEA symbols® (Good-lite®, Elgin, IL) near vision chart were excluded from the study. Patients taking any systemic medication that might have an effect on their accommodation were excluded (The Compendium of Pharmaceuticals and Specialties 2016 volume 1 and 2 was chosen to determine whether ocular side effects were associated with any systemic medications). Any patient with a condition that could affect their accommodation was excluded: this included Trisomy 21 (Woodhouse et al., 2000), traumatic brain injury (Green et al., 2010), Adie's tonic pupil syndrome, 3rd nerve palsy, Wilson disease, irido-cyclitis, large colobomas, buphthalmos, and direct eye trauma (Taylor & Hoyt, 2017).

3.2.4 Sample size estimation

The sample size was estimated on the basis that a 95% confidence level was selected with 80% power, to have an appropriate sample size in the proposed timeline

(Kadam & Bhalerao, 2010). The planned acceptable standard deviation was 5 PD. These premises were used to calculate the required sample size using the following tool: http://www.openepi.com/v37/SampleSize/SSMean.htm

The estimated sample size for this pre-study pilot was 12 participants. More subjects were actually recruited due to the population being studied (3 to 5-year-old children) as not all those participating were expected to be capable of accurately performing the task.

3.2.5 Ethical Considerations

As this study added only two additional methods of testing the near visual acuity above a normal orthoptic evaluation, little variation from a normally planned assessment of the participants took place with this pre-study's protocol. There was no potential for any harmful side effects, no extra visits to the clinic and no compromise to patient care. This was an observational study as no treatment was prescribed. Patient confidentially was ensured as all study information was encrypted and password protected in files stored on a secure hospital server. Patient identifiers were dispensed with on all but the master file. Any hard copies of study data utilized participant ID numbers to avoid the need for any patient identifiers.

Policies set by the Winnipeg Regional Health Authority (see Appendix E) were followed.

3.2.6 Informed consent

An information handout (Appendix A) was sent to the parent/guardian to read through in advance of the child's appointment. This document contained the contact information for the PI, as well as the supervisors, in case there were any questions.

Before the appointment began, the details of the study were discussed with the participant and their family, and any outstanding questions were answered at that time. All parties were aware that the pre-study was voluntary and that they could withdraw during the appointment or contact the PI within one month to withdraw. If both parent/guardian and child were still willing to enroll, parental consent was obtained by the independent orthoptist.

3.2.7 Risk analysis

There were no identified potential sources of harm associated with participation in this study other than the potential for breach of confidentiality. To prevent this from occurring, each participant was assigned a study ID number that was stored in a password-protected master file, accessible by the primary investigator alone, and no identifiers were used in the study documentation.

3.2.8 Benefit analysis

There was no guarantee that the participant would personally experience any benefits from participating in this study. There was no treatment prescribed during the appointment.

3.2.9 Funding/Reimbursement

Participation in this study did not result in any extra expenses to the participant or their family, therefore there was no reimbursement offered to the family.

3.3 PRE-STUDY OVERVIEW OF THE PROTOCOL

For the pre-study a population of non-strabismic children were recruited from the Winnipeg Children's Hospital eye clinic. Each test was performed monocularly, using an eye patch on spectacles worn or directly on skin for occlusion. The visual acuity of the

right eye was tested first with a LEA symbols® near visual acuity chart, followed by the left eye. The visual acuity was then tested with the experimental stickers in the same order. To ensure the participant was aware of the names for the potential shapes on the LEA symbols® near card and the experimental stickers, subjects were given the opportunity to briefly practice before beginning each test. First the LEA symbols® were reviewed once on a practice card. Each symbol found on the experimental sticker was printed on a practice card as well and the PI asked the participant the name of each shape once. The 20/60 line of the LEA symbols® near acuity chart was attempted first, continuing until the child could not correctly name three successive optotypes at a given acuity level.

For the experimental stickers, the subject was presented with six stickers per eye, two for each visual acuity level. This means that there were six possible optotypes (three for each sticker) for subjects to identify at each acuity level, but only five were asked as this is the number of optotypes found on each level of the LEA symbols® near chart. The test was performed with the largest optotypes first to engage the participant with symbols easier to see, continuing to smaller levels if a minimum of three optotypes were correctly named. Visual acuities were recorded in logMAR, with each optotype representing 0.02 logMAR. The subject's age and gender were also recorded.

3.4 PRE-STUDY DATA ANALYSIS

In order to validate the stickers, the visual acuity measured with the LEA symbols® near chart was compared to the visual acuity measured with the experimental stickers. The primary outcome of the pre-study was to determine whether any difference in the measured visual acuities was clinically significant.

A Bland-Altman plot was used to compare the results between the two testing techniques and assess if there was agreement (Giavarina, 2015). This plot compares the difference between the two paired measures (Y axis) against the gold standard method of measuring visual acuity in this age group, namely, the LEA symbols® near chart (X axis) (Krouwer, 2008). It is recommended that 95% of the resulting measurements be within two standard deviations of the mean difference. This plot constructs the limits of agreement, which is calculated comparing the measurement using the gold standard method to test visual acuity in 3 to 5-year-old children and the standard deviation of the difference between the experimental sticker measurement and the LEA symbols® near chart measurement (Giavarina, 2015).

Chapter 4 **PRE-STUDY RESULTS**

A total of 16 patients were enrolled in the pre-study, of the 16 participants, only 12 were deemed to give a reliable visual acuity measurement by the PI and 7 (44%) were males. The age range was 3 to 5 years old (mean= 4.4 years old, SD ± 0.72). There were 21 eyes that had a visual acuity measurement using both the LEA symbols® near chart and the experimental sticker symbols that were deemed reliable by the PI. Those deemed unreliable were participants who made no effort to name the correct shape, or would not make any guess at all. For example, poor effort would be documented if a subject were presented with a circle and would name it as a car, a totally different shape then a circle.

The raw data from all participants can be found in

Table **4.1**.

Patient ID	Sex	Age (years)	Near visual acuity using LEA symbols near vision chart (logMAR)		Smallest experimental target size resolvable (logMAR)	
			RE	LE	RE	LE

The mean difference between the LEA symbols® near chart visual acuity versus sticker visual acuity was 0.031 logMAR (SD ± 0.048), which is equivalent to a two optotype difference. The participants achieved two optotypes better when using the LEA symbols® near chart when compared to the experimental stickers. A graphical representation of the pre-study results is seen in Figure 4.1. The two methods of testing visual acuity were compared for each eye.

01	M	4	0.18	0.20	0.26	0.24
02	F	5	0.22	0.22	0.24	0.24
03	M	5	0.34	X	0.34	X
04	F	3	0.30	0.34	X	X
05	F	5	0.10	0.20	0.22	0.22
06	F	5	0.02	0.00	0.24	0.24
07	F	4	0.20	X	0.24	X
08	M	4	X	X	X	X
09	M	5	0.08	0.00	0.26	0.24
10	F	5	0.00	0.00	0.22	0.20
11	M	4	0.10	0.00	0.20	0.24
12	M	4	0.24	0.24	0.34	0.24
13	F	4	0.20	0.34*	0.34*	0.54*
14	F	5	0.02	0.20	0.22	0.24
15	M	5	0.42	X	0.46	X
16	F	3	0.40	0.14	>0.50*	>0.50*

Table 4.1 Data collected from pre-study participants.

X Unable to obtain a measurement

**deemed an unreliable measurement*

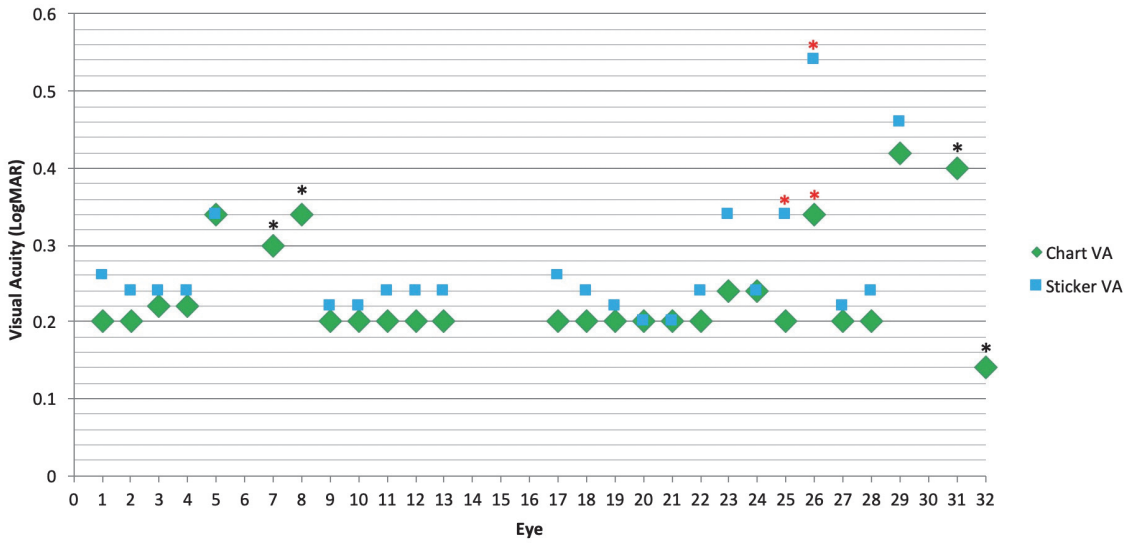

Figure 4.1 Pre-study data comparing visual acuity measured with the LEA symbols near chart and the experimental stickers.

** Deemed an unreliable measurement*
** Participant only had reliable measurement with LEA symbols near chart*

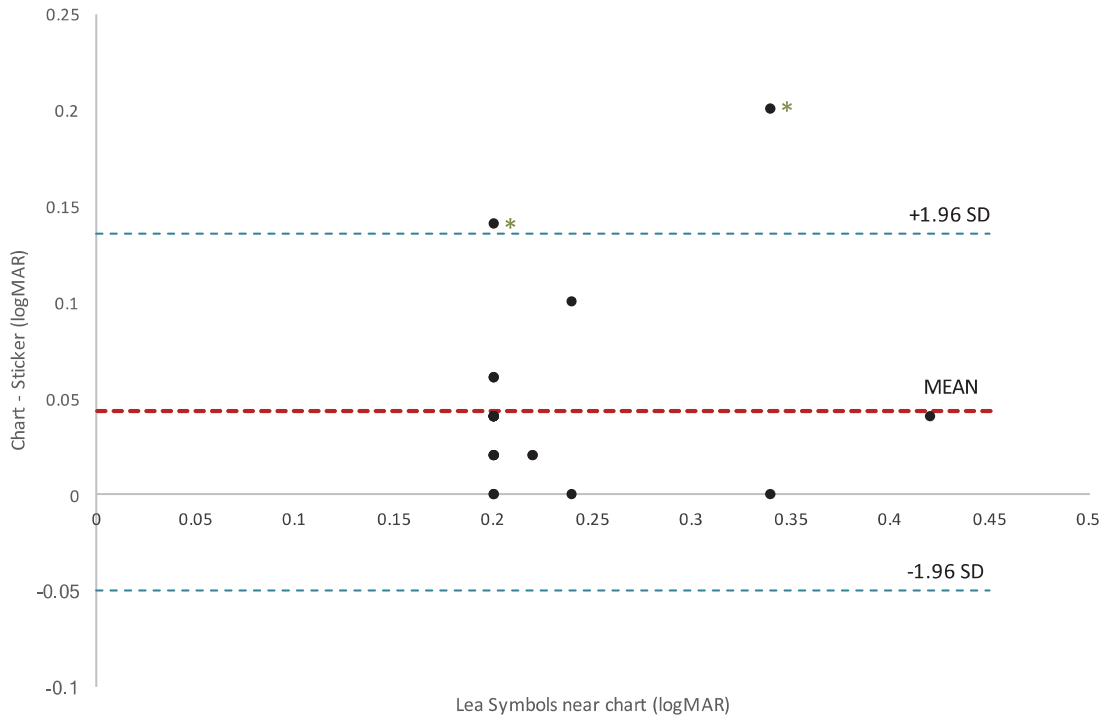

Figure 4.2 Bland-Altman plot comparing visual acuity (logMAR) measured using LEA symbols® near chart to the resulting logMAR difference when the experimental visual acuity is subtracted from the visual acuity using LEA symbols® near chart. *Deemed an unreliable participant

Chapter 5 PRE-STUDY DISCUSSION

There was good correlation when comparing the visual acuities as measured with the experimental stickers to the LEA symbols® near chart in the pre-study. The stickers slightly underestimated the acuity with a mean difference of 0.031 logMAR, less than a two optotype difference. As the smallest optotype on the experimental stickers was designed to be a 0.2 logMAR equivalent, all visual acuities of 0.0-0.2 logMAR measured with the LEA symbols® near chart were ascribed an acuity of 0.2 logMAR. It was decided that it would be a misrepresentation of the data set to have differing visual acuity end-points depending on the test used.

As previously mentioned, a study performed by Sanker, Dhirani & Bhakat (2013) states that a significant visual acuity difference using the LEA symbols® near chart is 0.2 logMAR, therefore this was used to define a significant difference in visual acuity between the two tests. The two different tests of visual acuity were found to have a two optotype difference; this falls well below the eight optotype cut-off and is therefore clinically insignificant.

It must be remembered that the purpose of this study is not to measure visual acuity; it is to test different near targets that present different accommodative challenges to determine if there is a clinically significant difference in the measured near angle of deviation. As such, this pre-study was important to prove that the experimental stickers could be used as an effective substitute for an established near accommodative target by using acuity as a surrogate for accommodation.

The pre-study results were analyzed using a Bland-Altman plot (Figure 4.2). The purpose of this plot is to compare the experimental stickers as a type of near visual acuity

test, to the pediatric gold standard LEA symbols® near chart. This means the difference between the two measurements for each eye is plotted against the visual acuity measured using the LEA symbols® near vision test. To determine if the two tests are in agreement, it is advised that 95% of the data points are within ±1.96 standard deviations (SD) of the mean (Giavarina, 2015). In this data set, 2 of the 24 data points are not within ±1.96 SD, but both had been deemed an unreliable measurement by the primary investigator due to poor participant cooperation. Excluding these data points, all of the data points fall within the limits of agreement.

After the data was collected, it became clear that a secondary outcome that needed to be studied was the cooperation and reliability of the population. There were participants who would not answer what shape they saw, would stop looking at the test or would guess a shape that is not comparable to the correct answer. Based on the primary investigator's experience testing visual acuity, they determined the unreliable data that was collected. Also, as the participants are known patients in the clinic, their visual acuity had been measured previously to be normal for their age.

One factor that was considered for the reliability of the pre-study was the children who would cooperate for the LEA symbols® near test but not the experimental sticker (eyes 7/8 and eyes 31/32 in Figure 4.1). This was the case with two of the sixteen children tested. There were also three children who would cooperate with each test for one eye, but their attention was lost for the second eye. As the testing order was not randomized, this could be a factor as the LEA symbols® near chart was always performed first. It was determined by the PI and thesis supervisors that the experimental stickers

designed could be used for their intended purpose in the study as 87.5% (21 of 24 eyes) of the study population had similar cooperation for each test.

It was also acknowledged that test subject cooperation would likely be an issue in the study, just as it was in the pre-study. It was determined that recruitment would continue until the sample size was met for the study with cooperative participants and that the study measurements would be performed at the beginning of their regularly scheduled appointment.

Chapter 6 **STUDY METHODOLOGY**

6.1 STUDY RESEARCH DESIGN

Ethics approval was obtained from Dalhousie University and University of Manitoba research ethics boards. It was also obtained from the Health Sciences Centre Pediatric Research Coordinating committee.

The age range of the participants was 3 to 5-year-old children. Each participant in the study had their near vision tested monocularly with the LEA symbols® near chart followed by three near strabismus measurements by an external examiner at 1/3m. The resulting strabismus measurements for the study were statistically analyzed to determine if there was a clinically or statistically significant difference when measuring with the three different fixation targets. A difference of 5 PD was considered to clinically significant as this would change the surgical treatment plan for the patient.

6.2 STUDY POPULATION

6.2.1 Participants

All participants were established patients at the local pediatric hospital's eye clinic and cared for by the clinic's ophthalmologists. Potential participants were identified by their direct eye care provider. The patients' information was given to the PI and the parents/guardians of the participants were then contacted by phone. The study's purpose and requirements were explained to determine if they were interested in participating and further information was offered in the form of the information and authorization handout (Appendix B). The parent/guardian was asked to review this handout prior to their child's next scheduled appointment. Informed consent using the

information and authorization handout, as well as verbal assent from the participant, was obtained on the day of the appointment by the PI. Using the script (Appendix D), the study was reviewed with the parent/guardian and child on the day of the appointment by the PI.

The study population was three to five-year-old children, as the study required that they would be able to cooperate with the tests, and most children of this age are pre-literate.

6.2.2 Inclusion criteria

Patients were included if they were between the ages of 3 to 5-years-old with a manifest, intermittent or phoric esodeviation of 10 PD or greater when measured at 1/3m. A vertical deviation of no more than 4 prism diopters was acceptable. They were not permitted to have more than a 10 optotype difference between the visual acuity of the two eyes on the LEA symbols® near chart. They were required to be able to cooperate with the APCT, meaning they allow prisms close to their eyes and would allow each eye to be occluded from the duration of the testing. Patients who had been prescribed glasses must have been wearing their full cycloplegic refractive correction prescribed by their pediatric ophthalmologist for a minimum of sixteen weeks (Zhou, Feng, Lin & Hess, 2016), and their glasses had to be up-to-date (i.e. based on a cycloplegic refraction that was less than one year old).

6.2.3 Exclusion criteria

Patients who had been given cycloplegic eye drops within the last two weeks, aphakic/pseudophakic/dislocated lens patients, or the presence of any vertical or horizontal restriction on ocular motility testing. The presence of nystagmus, botulinum

toxin injections into the extra-ocular muscles in the past six months, or the use of any systemic medication that might have an effect on the patient's convergence or accommodation (Compendium of Pharmaceuticals and Specialties 2016 volume 1 and 2 would have been used to discern whether there are ocular side effects of any system medications being taken). Also, any patients with a condition that could affect their accommodation were excluded: this included Trisomy 21 (Woodhouse et al., 2000) and traumatic brain injury (Green et al., 2010), Adie's tonic pupil syndrome, 3rd nerve palsy, Wilson's disease, irido-cyclitis, large colobomas, buphthalmos, and direct eye trauma (Taylor & Hoyt, 2017).

6.2.4 Sample size estimation

The confidence level to be used in this study was 95% and the power was set to 80%, as is standard in research and it allows for the sample size to be met in an appropriate timeline (Kadam & Bhalerao, 2010). It was determined in a study by PEDIG that for near strabismus measurements using the APCT in children ages 2 to 60 months old, the 95% limits on agreement of a measurement 20 PD or greater was ±8.3 PD and between 10-20 PD was 4.7 PD (PEDIG, 2009). Therefore, the approximate standard deviation was set at 10 PD. The calculated minimum sample size estimation for the study was 34 participants. This calculation was performed by the statistics department at the University of Manitoba. As discussed in the protocol, the study testing was performed before the standard orthoptic exam. Therefore, after the study measurements were completed not all participants met the inclusion criteria. More participants were recruited to have 34 participants that met all the study criteria.

6.2.5 Ethical Considerations

As this study involved the addition of only one near visual acuity test and two extra near deviation measurements (as one near measurement of strabismus is always performed) to the normal orthoptic evaluation, there would be little variation from the patient's normal orthoptic assessment. There was no potential for any harmful side effects, no extra visits to the clinic and no compromise to patient care. This was an observational study as no treatment was prescribed. Patient confidentially was ensured as all study information was encrypted and password protected in files stored on a secure hospital server. Patient identifiers were dispensed with on all but the master file. Any hard copies of study data utilized participant ID numbers to avoid the need for any patient identifiers.

Policies set by the institution where the study was conducted were to be followed (see Appendix E).

6.2.6 Informed consent

An information handout (Appendix B) was sent to the parent/guardian to read through in advance of the child's appointment. This document contained the contact information for the PI, as well as the supervisors, in case they wanted to ask any questions. Before the appointment began, the details of the study were discussed with the participant and their family, and any outstanding questions were answered at that time. Due to the fact that 3 to 5-year-old children are unable to give informed consent, the PI would read the assent script, which can be found in Appendix D. This is standard practice when conducting research with children of this age. All parties were made aware that the study was voluntary and that they could withdraw at any time during the appointment, or

contact the PI within one month to withdraw. If both parent/guardian and child were willing to enroll, parental consent was obtained by the PI.

6.2.7 Risk analysis

There were no identified potential sources of harm associated with participation in this study other than the potential for breach of confidentiality. To prevent this from occurring, each participant was assigned a study ID number that was stored in a password-protected master file, accessible by the primary investigator alone, and no identifiers were used in the study documentation.

6.2.8 Benefits analysis

There was no guarantee that the participant would personally experience any benefit from participating in this study. There was no treatment prescribed during the appointment.

6.2.9 Funding/Reimbursement

Participation in this study did not result in any extra expenses to the participant or their family, so no reimbursement was offered to the family.

6.3 STUDY PROTOCOL OVERVIEW

At the beginning of the participant's regularly scheduled appointment in the eye clinic, a different examiner (defined as "external" examiner) than the PI began by testing the monocular near visual acuity using the LEA symbols® near card at the standard testing distance of 40 cm. The smallest level tested was the 20/30 line and the testing order of the eyes was randomized. To gain the line, three of the five symbols must be correctly identified. The experimental sticker for each subject was selected so as to match their measured near acuity of their worst eye (in the event that a one line difference in

visual acuity was found). The external examiner then performed a cover test with the participant's eyes in the primary position using the first fixation target at a test distance of 33 cm. The fixation target was always at the same fixation distance so as to induce 3D of accommodation whilst wearing their cycloplegic refractive correction. A measuring tape was used by the PI to ensure that the target was presented at this distance. The cover test assessed whether the deviation was constant, intermittent or alternating. The cover/uncover test was omitted if movement was seen with the cover test, and the examiner proceeded to the APCT. If there was no movement of the uncovered eye, then a cover/uncover test was performed to test for a phoria. The covered eye was observed for movement with the cover/uncover test.

The alternate prism and cover test is the accurate method for the measurement of strabismic deviations (Mehta et al., 1998) so this technique was employed in this study to accurately measure the near deviation. The test was performed in the standard manner, such that the patient had time to pick up central fixation prior to occlusion of the fellow eye. Once movement of the eyes to pick up central fixation had been noted then a base out prism was used to neutralize the deviation. Neutralization of the deviation is defined as the largest prism that stops movement before reversal of the deviation is noted (Cassin, 1995). Prisms were held in the proper orientation for plastic prisms (frontal plane), with the base parallel to the lateral wall of the orbit (Egbert & Fantin, 1999). For measurements between prism values found on the prism bar, loose prisms were used as they can be stacked to allow for more accurate measurements with smaller increments (instead of increasing by 5 PD on a prism bar). Table 6.1 was used for the accurate

dioptric value of the prisms when they are being stacked in front of the same eye, as published by Thompson & Guyton (1983).

Added Prism (labeled value in prism diopters)	Initial Prism (labeled value in prism diopters)											
	10	12	14	16	18	20	25	30	35	40	45	50
1	11	13	15	17	19	21	27	32	37	43	48	54
2	12	14	16	18	20	23	28	33	39	45	50	56
3	13	15	17	19	22	24	29	35	40	46	52	58
4	14	16	18	21	23	25	30	36	42	48	54	61
5	15	17	20	22	24	26	32	38	44	50	56	63
6	16	19	21	23	25	27	33	39	45	52	59	66
7	17	20	22	24	26	29	35	41	47	54	61	68
8	19	21	23	25	28	30	36	42	49	56	63	71
9	20	22	24	27	29	31	37	44	51	58	66	74
10	21	23	25	28	30	33	39	46	53	60	68	77
12	23	25	28	30	33	35	42	49	57	65	74	84
14	25	28	30	33	35	38	45	53	61	70	80	91
16	28	30	33	36	38	41	49	57	66	76	87	100
18	30	33	35	38	41	44	52	61	71	82	95	110
20	33	35	38	41	44	47	56	66	76	89	104	122
25	39	42	45	49	52	56	66	78	93	110	133	165
30	46	49	53	57	61	66	78	94	114	141	183	264
35	53	57	61	66	71	76	93	114	144	195	315	—
40	60	65	70	76	82	89	110	141	195	339	—	—
45	68	74	80	87	95	104	133	183	315	—	—	—
50	77	84	91	100	110	122	165	265	—	—	—	—

Table 6.1 Summed value of prisms stacked in front of the same eye in prism diopters

Each participant was tested with the red circle (
Figure 3.5), the experimental sticker (Figure 3.1,

Figure 3.2 & Figure 3.3) and the cat on the Lang fixation cube (Figure 3.4) in a randomized order. This was done by listing all the permutations of possible order for the targets, assigning them a number, then randomly assigning them to each participant. A random number generator (random.org) was used for this task. The proper permutation was then recorded on the data collection page of each participant. For example: "ELR" would signify that the external examiner should start the measurement of the near deviation with the experimental sticker, followed by the Lang cube fixation stick, and finally the red sticker.

Subjects were asked detailed questions regarding the targets during testing. It is recognized that accommodative effort is influenced by the instructions given to a patient (Stark & Atchison, 1994) and their cognitive effort (Kruger, 1980). Subjects were therefore asked the same questions for all three targets to minimize variations in results that may be attributable to these factors. The questions were designed to ensure the attention of the participant, and then to attract their visual attention (fixation) to the small details of the target. This was followed by attracting their attention to larger aspects of the target during the cover testing as prismatic blur would be expected to become a factor with stronger prisms. At least five questions were asked in the same order and the questions were continued until the angle of strabismus was neutralized with the prism. The APCT was continued until the fifth question even if the angle was neutralized before this. This was done to ensure each participant's attention is drawn to the Snellen-equivalent symbols of the experimental target. The same order of questions was restarted for each new target introduced.

The following questions were asked for the targets:

1. What is this a picture of?
2. How many ears does it have?
3. What colour are the eyes?
4. Take a really good look, what is the shape on its nose?
5. Which shapes are in its eyes?
6. What colour are the ears?
7. Is it wearing glasses?
8. Does it look happy or sad?

6.4 STUDY DATA ANALYSIS

The primary outcome of this study was the mean difference between the strabismus measurements obtained with the three fixation targets. This was analyzed to determine if there was a clinically significant difference when comparing the resulting strabismus measurements while fixing on the experimental sticker and the Lang cube, the experimental sticker and the red circle as well as a comparison between the Lang cube and the red circle sticker.

The data was also analyzed to determine if there was a statistically significant difference using a Wilcoxon signed rank test with continuity correction. This test was used as we did not assume a normal distribution and the data samples are matched.

The data was also analyzed for trends when split into age categories (3, 4 and 5-years-old). The Kruskal-Wallis rank sum test, also known as one-way ANOVA on ranks, was performed to determine if the independent data samples are identical without assuming that they follow a normal distribution.

Chapter 7 STUDY RESULTS

A total 34 patients met the inclusion criteria and completed the testing. Of these participants, 17 (50%) were female. The age range was 3 to 5 years old (mean=4.1, SD± 0.87). Of the 34 participants, 31 (91%) had hyperopia that was deemed significant by their primary ophthalmologist, and they were suitably corrected as per the inclusion criteria. The three participants that did not need glasses had no significant anisometropia and were within 0.50 D of plano. The results can be found in Table 7.1.

Three strabismus measurements were obtained for each subject; these are graphically represented in Figure 7.1. The percentage of participants that represent each strabismus measurement difference between the three targets is found in Table 7.2, and Figure 7.3 is the graphical representation of this.

The mean difference between the resulting strabismus measurement using the experimental target and the Lang cube was 1.12 PD (SD ± 2.51) with a range of -5 PD to +5 PD. There were 8 participants (24%) with a clinically significant difference between the two measurements.

The mean difference between the strabismus measurements using the experimental target and the red circle sticker was 3.06 PD (SD ± 3.19) with a range of -2 PD to +10 PD. There were 12 participants (35%) with a clinically significant difference between the two measurements.

The mean difference between the strabismus measurements using the Lang cube target and the red circle sticker was 1.88 PD (SD ± 2.58) with a range of -2 PD to +10 PD. There were 7 participants (21%) with a clinically significant difference in the

measurements obtained with these two targets. The graphical representation of this data can be found in Figure 7.2.

The results of the Wilcoxon signed rank test can be found in Table 7.3. Based on a p-value of less than 0.05, there is a statistically significant difference for all three target comparisons.

ID #	Gender	Age (years)	Cycloplegic Refraction (D)	S (PD)	L (PD)	R (PD)	S-L (PD)	S-R (PD)	L-R (PD)
1	F	4	+3.50 +3.50	16	16	14	0	2	2
2	F	5	+3.75 +0.75 060 +4.25 +0.25 100	25	30	25	-5	0	5
3	F	4	+5.25 +5.25 +0.25 080	30	25	20	5	10	5
5	M	3	+3.50 +0.50 090 +3.50	30	30	20	0	10	10
6	F	3	+2.75 +1.50 080 +0.75 +4.25 105	16	14	12	2	4	2
7	F	3	+6.25 +0.75 095 +6.00	35	30	27	5	7	2
8	M	3	+4.25 +5.75	25	25	18	0	7	7
9	M	5	+3.50 +0.75 070 +3.50	30	30	30	0	0	0
11	F	4	+4.50 +2.00 100 +4.50 +1.75 080	18	16	16	2	2	0
12	M	5	+1.75 +0.75 090 +1.75 +0.75 090	10	10	10	0	0	0
14	F	4	+3.75 +3.25	35	32	30	2	5	2
15	M	5	+3.50 +1.75 105 +4.50 1.00 080	30	30	30	0	0	0
16	M	5	+1.50 +1.00 080 +2.00+1.00 085	32	35	30	-2	2	5
17	M	3	+5.50 +5.25	30	25	27	5	2	-2
18	F	3	+3.00 +0.75 100 +3.50+0.50 090	27	25	25	2	2	0
19	M	3	+1.50 +1.75 120 +0.75 +1.25 080	35	30	25	5	10	5
20	M	4	+3.50 +2.75	30	25	25	5	5	0
21	F	3	+5.25 +0.25 090 +5.50 +0.25 090	45	42	40	2	5	2
22	F	4	Plano Plano	13	14	12	-1	1	2
23	M	5	+0.50 +0.50	30	30	25	0	5	5
24	F	5	+2.25 +2.25	10	12	10	-2	0	2
25	F	5	+2.75 +2.75	14	12	12	2	2	0
26	M	5	Plano +0.25	32	32	30	0	2	2
28	F	3	+3.25 +0.50 090 +4.50 +0.50 090	20	22	20	-2	0	2
29	M	4	+6.50 +1.00 090	20	18	18	2	2	0

ID #	Gender	Age (years)	Cycloplegic Refraction (D)	S (PD)	L (PD)	R (PD)	S-L (PD)	S-R (PD)	L-R (PD)
			+6.50 +0.75 090						
30	M	5	+4.50 +1.00 180 +4.50 +1.00 180	25	25	25	0	0	0
31	M	3	+4.50 +1.50 090 +4.00+2.00 090	25	20	20	5	5	0
32	F	4	+1.00 +0.25 090 +1.50	40	40	37	0	2	2
33	M	5	+5.75 +1.75 100 +6.25 +1.25 080	30	25	25	5	5	0
34	F	5	+3.25 +3.25 +0.25 090	25	22	20	2	5	2
35	F	4	+5.25 +1.25 100 +5.25 +0.25 090	12	14	12	-2	0	2
36	M	5	+7.50 +3.50 090 +7.50+3.50 090	14	14	16	0	2	-2
37	M	3	+3.50 +0.50 100 +3.50	20	20	20	0	0	0
39	F	5	+2.00 +2.00	15	14	12	1	3	2
AV		4.08		24.82	23.65	21.70	1.12	3.06	1.88
SD							2.51	3.19	1.88

Table 7.1 Data collected from participants including their gender, age, cycloplegic refraction and their strabismus measurements using the experimental sticker (S), the Lang cube (L) and the red sticker (R). The difference between the measurements obtained with the experimental sticker and Lang (S-L), experimental sticker and the red sticker (S-R) and the Lang cube and the red sticker (L-R) are also included in the table.

STRABISMUS MEASUREMENT DIFFERENCE (PD)	**EXPERIMENTAL STICKER –LANG CUBE** (%)	**EXPERIMENTAL STICKER –RED CIRCLE** (%)	**LANG CUBE – RED STICKER** (%)
-5	3	-	-
-2	12	3	6
-1	3	-	-
0	35	26	38
1	3	3	-
2	23	26	29
3	-	3	6
4	-	3	-
5	21	21	15
7	-	3	3
8	-	3	-
10	-	9	3

Table 7.2 Participants organized by percentage for each strabismus measurement difference between the three fixation targets.

– signifies no participants with that strabismus measurement difference

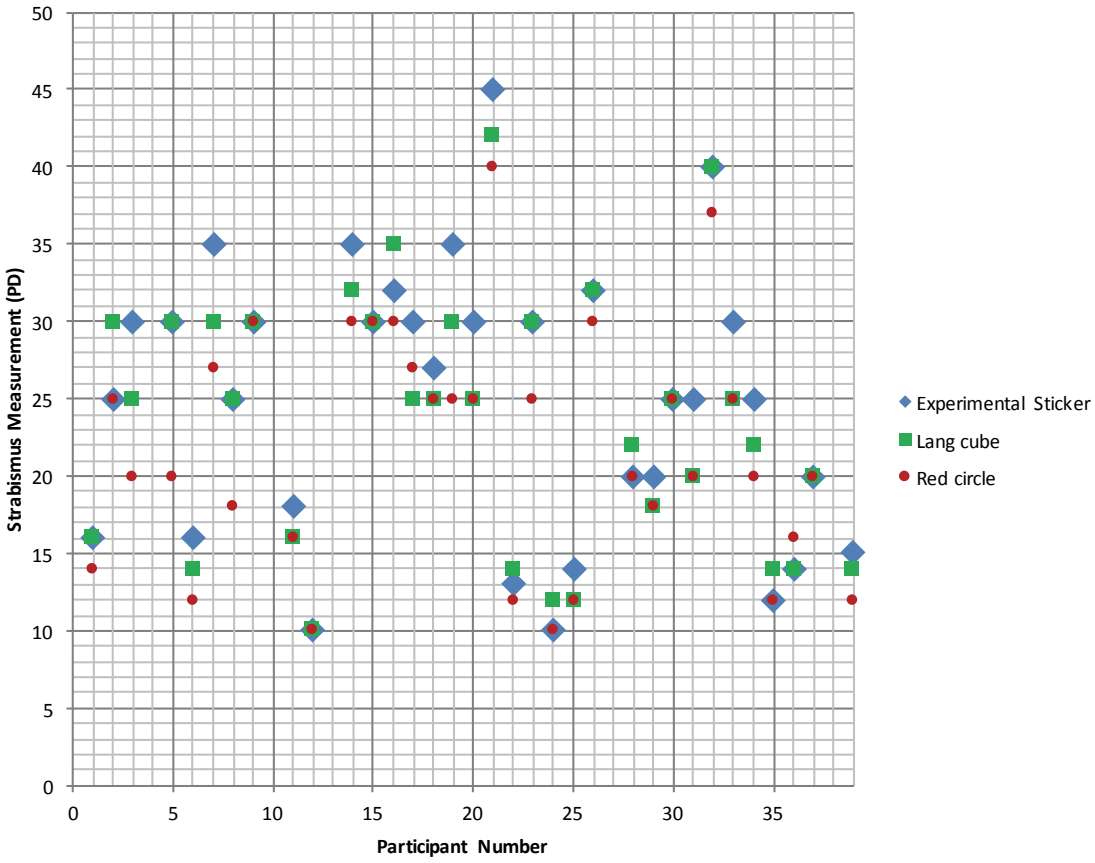

Figure 7.1 An illustration of the strabismus measurement (PD) using the experimental sticker, the Lang cube and the red circle organized by participant.

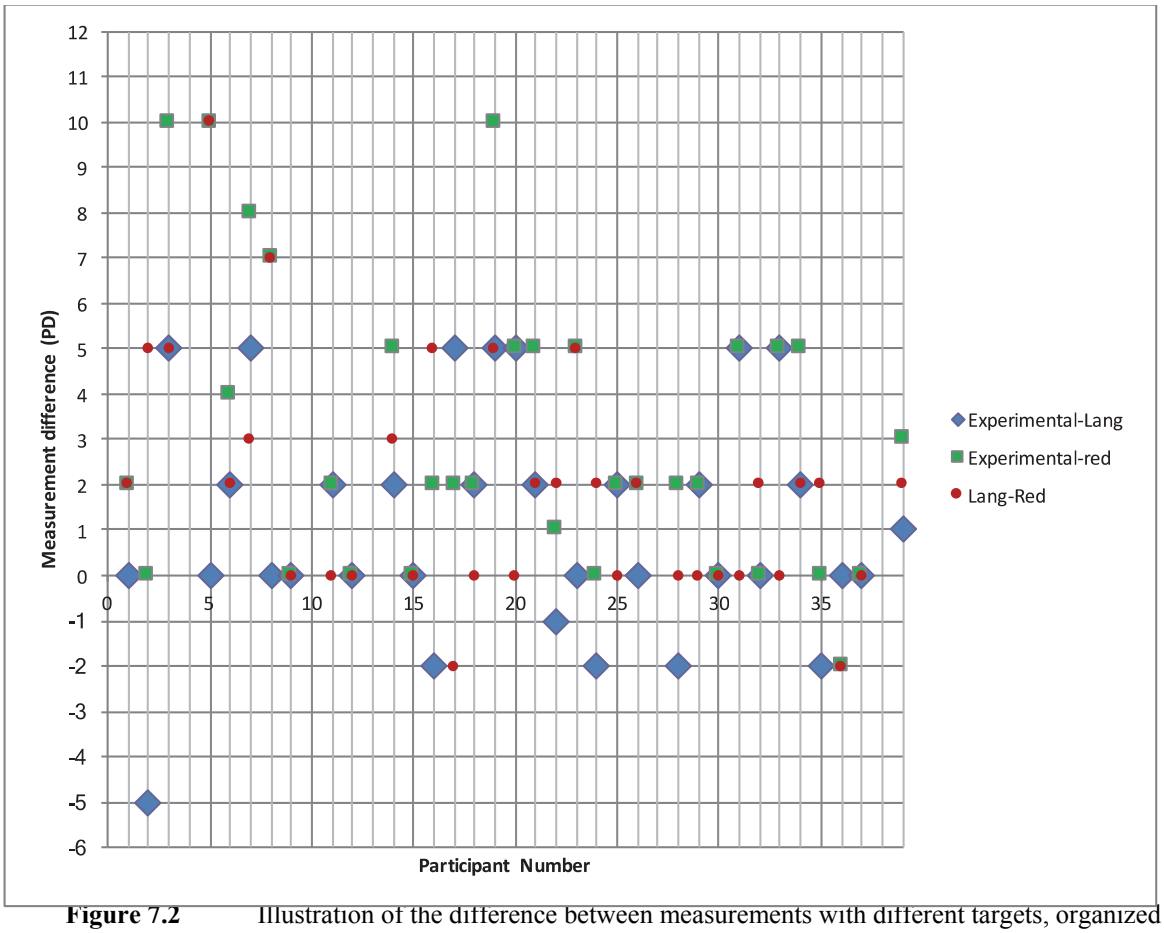

Figure 7.2 Illustration of the difference between measurements with different targets, organized by participant: the strabismus measurement using the Lang cube subtracted from the experimental target; the red sticker measurement subtracted from the experimental sticker; and the red sticker subtracted from the Lang cube measurement.

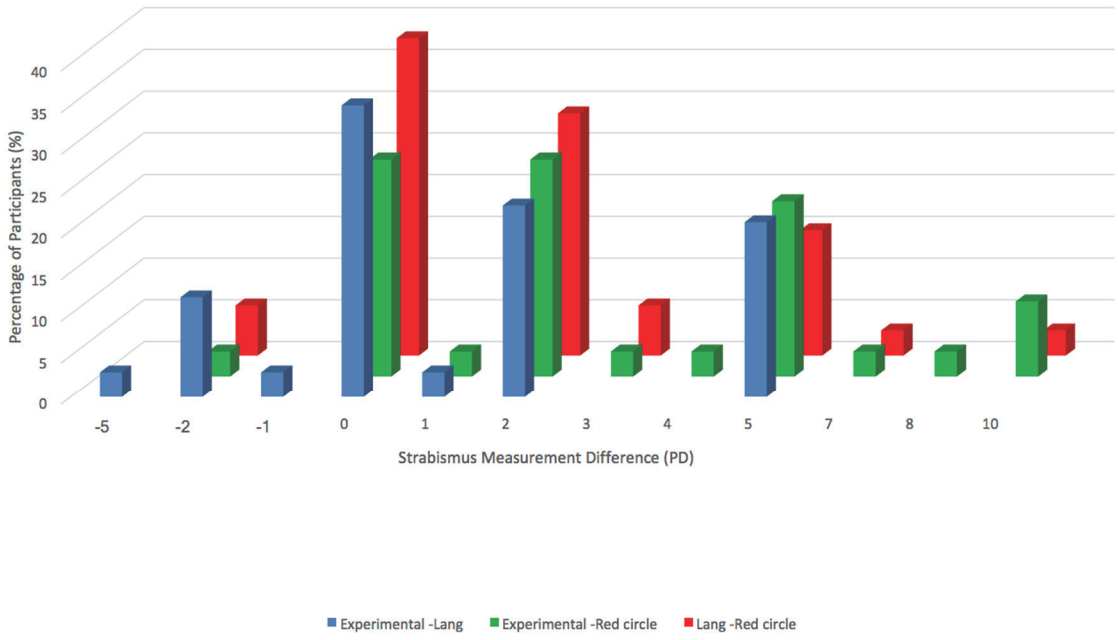

Figure 7.3 Illustration of participants organized by percentage for each strabismus measurement difference between the three fixation targets.

	p-value
Experimental – Lang cube	0.01504
Experimental – Red sticker	$2.241e^{-05}$
Lang cube – Red sticker	0.0001899

Table 7.3 Results from the Wilcoxon signed rank test when comparing the near strabismus measurements using the experimental sticker to the Lang fixation cube, the experimental sticker to the red circle sticker and the Lang cube to the red circle sticker.

The data was also divided by age to determine if there was a statistical and clinically significant difference. There were 11 three-year old participants, 9 four-year olds and 14 five-year old participants. As the sample sizes are much smaller when split into age categories, concrete conclusions should not be drawn with this data set, but potential trends could be studied. The mean differences can be seen in Table 7.4 and the graphical representation of the mean differences, subdivided by age, can be seen in Figure 7.4. The difference in the measurements obtained using the experimental sticker and the red sticker were found to be clinically significant for three years-old participants. The red circle resulted in an underestimation of the size of the esodeviation when compared to the experimental sticker as a fixation target. No other group was found to have a clinically significant result.

The same trend was found for each set of targets when the data was divided into age groups: younger patients demonstrated larger differences in the strabismus measurements obtained with any two targets. This trend was analyzed using Kruskal-Wallis rank sum test to determine if the trend was statistically significant. The results for this test can be seen in Table 7.5. There was no statistically significant difference found, but the difference between the experimental sticker and the red circle based on age is approaching significance.

	S-L (PD)	S-R (PD)	L-R (PD)
3 YEARS OLD	2.18	5*	2.45
N=11	*SD=2.52*	*SD=3.40*	*SD=3.59*
4 YEARS OLD	1.44	3	1.78
N=9	*SD=2.45*	*SD=3.2*	*SD=1.64*
5 YEARS OLD	0.07	1.57	1.50
N=14	*SD=2.27*	*SD=2.24*	*SD=2.21*

Table 7.4 The difference in the strabismus measurements for each set of fixation targets organized by age. The Lang cube subtracted from the experimental sticker (S-L), the red circle subtracted from the experimental sticker (S-R) and the red circle subtracted from the Lang cube.

*clinical significance

	CHI-SQUARED	P-VALUE
S-L BY AGE	4.0513	0.1319
S-R BY AGE	4.6131	0.0996
L-R BY AGE	0.53132	0.7667

Table 7.5 Results of the Kruskal-Wallis rank sum test when comparing the difference between the experimental sticker to Lang cube, experimental sticker to the red sticker and the Lang cube to the red circle by age group.

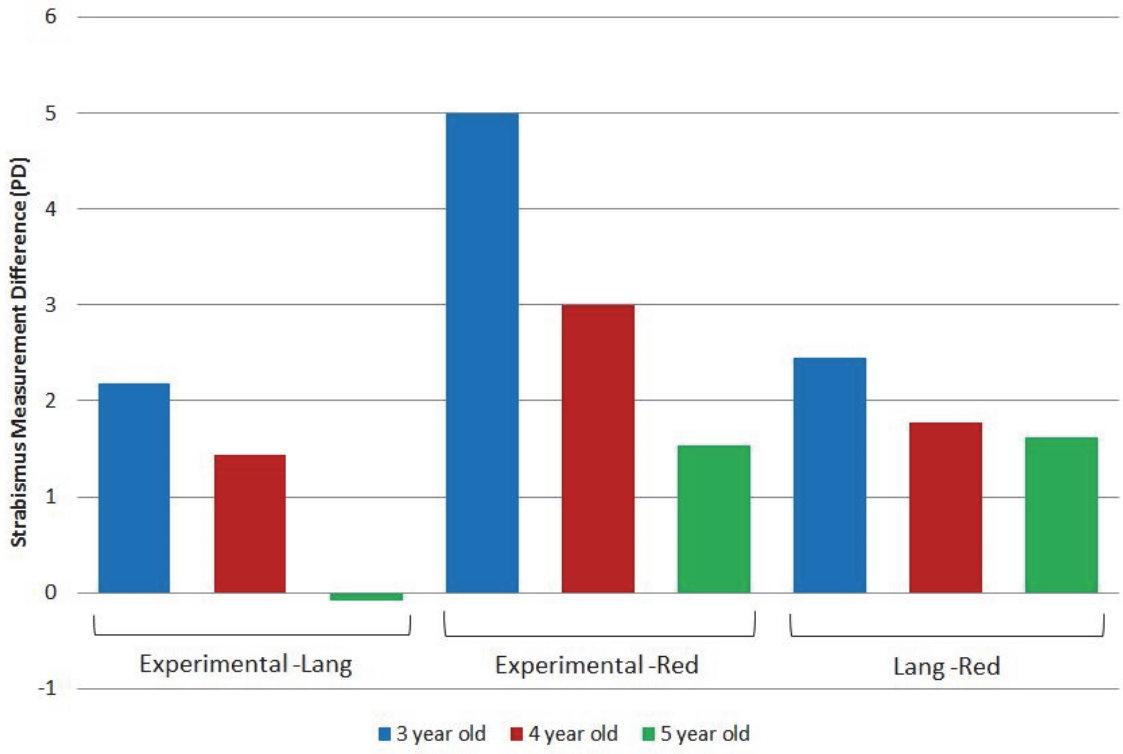

Figure 7.4 The mean difference in the measured angle of strabismus with the three fixation targets based on age.

Chapter 8 **DISCUSSION**

The objective of this study was to better understand the influence of near fixation targets in the measurement of strabismus. Specifically, the aim was to determine if there is a statistical and clinically significant difference in the measured angle of esodeviations when using near fixation targets with varying levels of detail, and thus making varying accommodative demands. Scott, Mash & Redmond published a study in 1976 stating that there was a reasonably high degree of agreement between the measurements obtained using an accommodative target and a non-accommodative target. Nevertheless, they went on to conclude that even though there was only a mean difference of 0.4 PD for esodeviations at distance fixation and -0.25 PD for near fixation, "the results of this study clearly show the importance of using an accommodative controlled target". From their data, Mehta, Kushner & Morton concluded in their observations on literate participants (1998) that the use of cartoons, pictures or toys to control fixation of a young child is not advisable, as they do appear not elicit the proper accommodation needed when measuring strabismus at near. They found that 42% of partially accommodative esotropia participants and 44% of intermittent exotropia participants had a 3 PD difference in the strabismus measurements when using letters compared to a picture at near and.

For the literate strabismic population, Snellen linear optotypes are widely used as a near accommodative target (Mehta, Kushner & Morton, 1998). When using this target, there is literature that suggests focusing on the 20/30 or 20/40 Snellen-equivalent line gives the most accurate results (Von Noorden & Campos, 2002; Mehta, Kushner & Morton, 1998). This is an appropriate form of fixation target as most patients would be able to hold the target, accurately focus on the target, and cooperate fully with the test.

When it comes to a younger, pre-literate population, different considerations need to be taken into account when selecting a fixation target. Young patients are less reliable when it comes to holding a target steady, their reach is not as long, their cooperation and attention can be limited, and they may not know the alphabet. To mitigate against this, examiners often use colourful picture stickers on their nose, they may ask a parent to hold a picture target, or they may attach a picture target to their glasses. The target details vary between stickers and examiner preference; they are not standardized. The Lang cube is commonly used as a near fixation target for the pre-literate population, but due to the larger size of the pictures on the cube, this would not induce the desired degree of accommodative effort that 20/30 or 20/40 optotypes would.

Based on the previously discussed literature, we thought that there should be a clinically significant difference in the strabismus measurements dependant on the level of accommodation induced by the near fixation target being used. As previously mentioned, there was a statistically significant difference between all three target comparisons. This finding provides evidence that the experimental sticker induces more accommodation when compared to the Lang cube and red circle sticker, as well as the Lang cube inducing more accommodation than the red circle sticker, as was expected. Based on this evidence, the three targets should not be used interchangeably for near strabismus measurements in the pre-literature population. Our results however show that when studying the mean difference of the study participants there is no clinically significant difference between the Lang cube fixation stick, the non-accommodative red circle target and the experimental sticker. There was a trend towards underestimation of the size of the esodeviation when using the red circle sticker when compared to the

experimental sticker. Another aspect to consider is the percentage of participants that did have a clinically significant difference between two targets. For the experimental sticker compared to the red circle, 35% of the participants had a clinically significant difference in the near strabismus measurement. When comparing the experimental sticker and Lang cube, 24% had a clinically significant difference and 21% of the participants had clinically significant difference between the Lang cube and red circle sticker. I believe it is clinically relevant to consider that even though the overall mean difference between the experimental sticker and red circle was not significant, more than one third of the study participants had a difference of 5 PD or greater.

When our data was analyzed using Mehta et al.'s standard of clinical significance of 3 PD, the mean difference in strabismus measurements between the experimental sticker and the red circle becomes clinically significant. The percentage of participants with a clinically significant difference in strabismus measurements would be very similar to the results in their study when comparing the resulting esodeviation measurement using their accommodative target (Jaegar 3 Snellen optotype line) to the non-accommodative picture target. They reported 42% of their participants having a minimum of 3 PD difference, and 41% of our participants have a minimum of 3 PD difference when comparing the experimental sticker to the red circle. However as previously discussed, we chose a clinical significance of 5 PD difference between measurements as it represents the real threshold used in most surgical practices to define a different quantitative approach when indicated in these children (Scott & Wright, n.d.; Ansons & Davis, 2014).

A trend in our data that should be noted is the significant proportion of the study population that had a 0, 2 or 5 PD difference between the strabismus measurements using two targets. As seen in Figure 7.3, this is the case for all three target comparisons. We believe this is due to the horizontal prism bar being used for the majority of the strabismus measurements. From 2-18 the prism value increases in increments of 2 PD. From 20-40 the prism value increases in increments of 5 PD. At times, loose prisms were stacked when the external examiner felt the measurement was not neutralized by a prism value on the bar, but this was not deemed necessary by the examiner often. It requires precise fixation to notice the target being optically shifted by small prism increments and we believe this may be a factor in this pre-literate population.

Our data was also broken down by age, as attention and cooperation are more of an unknown factor with younger children under five years old. There was a trend suggesting correlation between the age of the participant and the mean difference in strabismus measurement. A greater mean difference between the targets corresponded to a younger age. As 34 participants was calculated to be the sample size needed to reach significance, this cannot be definitively concluded, but it raises the question as to what is the driving force behind the differences in strabismus measurements in this age group.

8.1 LIMITATIONS

Three to five-year old children cannot be relied upon consistently to concentrate and cooperate with strabismus testing. In this study, we used the same questions for all three targets as cognitive demand can have an effect on accommodation (Kruger, 1980). Due to our clinical experience of measuring strabismus in the target population, these questions were created in an attempt to keep the attention of the participant throughout

the three measurements and have them focus on certain aspects of the targets. Having the same questions for all three targets was confusing for some children: for example, when it came to asking about the "symbol in the nose" on the red circle, the subjects would sometimes look to their parent in confusion and wouldn't be as willing to respond to the next questions. The answers to the standardized questions (pg. 61) were not recorded, so they could appear to be cooperating by answering the question but still be making no voluntary accommodative effort to see the small symbols clearly. This would be the most significant limitation in this study. Although as there was a statistically significant difference in the target comparisons, we believe that it does not bring the reliability of our results into question. Unfortunately, if the responses were recorded and the only strabismus measurements included in the study were those that responded to the answers correctly, the timeline of the study would have significantly increased in order to obtain the sample size needed. As well I believe the participants would consist of a higher proportion of the upper age range of our target population as they have better cooperation, better developed verbal skills and have potentially attended more exams in the clinic thus being more comfortable with the tests.

It was also predicted that this population would need continual encouragement to complete the task. Therefore, some encouraging words were written into the questions (e.g. "Take a really good look"). On the other hand, the clinical setting would potentially present a friendlier environment making it easier to obtain an accurate measurement by allowing a much more encouraging encounter than the limited study protocol script; it is indeed possible to tailor questions to the child being examined based on the situation at hand (e.g. "Is the circle red like your boots?"); depending of the age, it is also easier

when using a Snellen fixation stick for patients who can read the letters from the largest to the smallest so one has a good indication of the patient's accurate visual attention toward the target.

Examiners were not masked to the target that was being used for the measurement in this study, but were aware of the purpose of the measurements. This bias could have potentially been avoided by having a muted video of each measurement with an outside examiner responsible for deciding on the point of neutralization, but this would not be transferable to the clinical setting.

Due to the age of the participants, an accurate measurement of accommodation was not acquired. In several of the previously discussed literature on an older population, accommodation was also not measured therefore they would have the same limitation. To prevent this affecting the study results the near visual acuity was measured, the fixation distance was standardized, and cycloplegic refractive error corrections were controlled. The accommodative amplitude of children 6-10 years old is known to be 14.6 D (Chattopadhyay & Seal, 1984), therefore our study subjects should have ample accommodative reserves to produce the 3D needed for the task when their refractive error was fully corrected. In retrospect, dynamic retinoscopy could have been performed on each participant to at the beginning to determine if hypo-accommodation was an issue.

8.2 FUTURE RESEARCH

Accommodative effort was not measured throughout each of the three strabismus measurements in this study. If this were to be monitored then it would allow us to see if there is a difference in the amount the participant accommodates when fixing on an "accommodative target" when compared to a "non-accommodative target", as well as

whether this accommodative effort is maintained to the end of the measurement. I believe there would be a measurable difference in the amount of accommodation induced by the two targets and that there would be a high variability in whether the effort was maintained until the end of the measurement in this population.

This research could be repeated on participants who have exodeviations using the same targets for the pre-literate population. As previously discussed (pg. 29-30), accommodation plays a significant role in exodeviations in terms of control and size of the manifest deviation therefore it would be very interesting to determine if a similar result would be found.

A larger sample size could possibly help determine whether age is a significant factor when measuring strabismus in the pre-literate population. Our results were separated into three age categories but due to the small sample size in each group concrete conclusions could not be made. This would be helpful for orthoptists and ophthalmologists measuring strabismus to know if a certain target in clinic should be used based on the age of the patient. Also, instead of separating the population by year, it would be important to analyze by months of age. Behaviorally a 36-month-old child could be quite different from a 47-month-old but they would both be 3-years-old.

A comparison between our experimental sticker, a Snellen fixation stick and a non-accommodative target like the red circle or a light in an older population could help determine a relation with accommodation and its influence on measurements obtained with these targets. This population would have more reliable cooperation and potentially more experience with the task and thus the potential limitation of cooperation would be lower.

8.3 CONCLUSIONS

We conclude that there is a statistically significant difference in the measured esodeviation when comparing the experimental sticker to the Lang fixation cube, the experimental sticker to the red circle sticker, and the Lang fixation cube to the red circle sticker as near fixation targets. This indicates that the experimental sticker induces the most accommodation, followed by the Lang fixation cube and then the red circle sticker. Although none of the mean differences between the target comparisons reached the clinically significant threshold that we set, it should be considered in clinical practice that over one third of participants had a clinically significant difference in the esodeviation measurement at 33 cm when using the detailed picture sticker when compared to the red circle sticker for three to five-year old children.

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APPENDIX A: Pre-study Informed Consent Document

Study Title: A comparison of near eye-turn measurements with different targets

Investigator(s):

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Study Title: A comparison of near eye-turn measurements with different targets

Introduction

The goal of this document is to explain the purpose of the pre-study, how it may affect the participant, the risks and benefits of taking part and what you will be asked to do. After going through this information, you will be able to make an informed decision on whether your family would like to take part. This informed consent document is to help you decide if it is in the participant's best interest to be involved, as participation is completely voluntary. If you have any questions that this form does not answer, the principal investigator (Liz Armstrong) will be happy to give you any further information.

Purpose of the Pre-study

There will be a study in the Winnipeg Children's Hospital eye clinic to determine an appropriate target for the measurement of eye-turns at near in children between the ages of 3&5 years old. The target we are testing is multiple detailed stickers designed specifically for the study, with symbols that compare to the participant's best corrected vision.

To validate the size of the symbols on the stickers, this pre-study is being performed on children with straight eyes and good vision. The information gathered from this pre-study will only be used to prove the stickers can or cannot be used for the study.

Study Design

There will be 12 current patients of Dr. Ian Clark in the Winnipeg Children's Hospital eye clinic between the ages of 3&5 years old invited to participate. Eligible patients will

be identified through chart review, and then the patient's family will be called by the primary investigator to explain the study. A copy of the informed consent document will be mailed to the participant along with the document for assent. This form will then be signed at the next scheduled appointment if the parent agrees for their child to become a participant.

Once enrolled in the pre-study the participant will receive the same treatment as their usual follow-up appointments with Dr. Clark, there will just be two extra tests added to the appointment.

What Participation Involves

Taking part in this study will involve a one-time assessment with the participant's regularly scheduled follow-up appointment. Each participant will undergo their standard eye exam. Once this part of the appointment is completed then the participant will have their near vision tested followed by identifying symbols on the experimental stickers. The extra tests will add approximately ten minutes to the appointment.

Potential Harms

There are no identified potential harms associated in participation of this study.

Potential Benefits

There are no benefits to the participant from participating in this pre-study. There is no intervention prescribed during this one time appointment. However, the knowledge gained from this study will help determine the best way to measure near strabismus.

Alternatives to the Study

Before deciding to participate in this study, you should know that your child does not have to take part in the study. If your child does not participate in the study they will receive the same standard of care.

Withdrawal from Participation

Participation in the study is entirely voluntary. You may decide not to enroll your child, or if you do choose to participate you may withdraw from the study at any time. This will not affect your child's eye care at the Winnipeg Children's Hospital eye clinic in any way. If the study is changed in any way that could affect your decision to continue to have yourself or your child participate, you will be informed of the changes and you may be asked to sign a new consent form.

Confidentiality

Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as Dalhousie University Research Ethics Board and the Pediatric Research Coordinating Committee. The University of Manitoba Health Research Ethics Board may review records related to the study for quality assurance purposes.

A number will be given to anyone participating and therefore no names will be used in the documentation of the results. Information gathered in this research study may be published or presented in public forums, however your name and other identifying

information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. All records will be kept in a locked secure area and only those persons identified will have access to these records. If any of your ophthalmology/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the Children's Hospital eye clinic.

Costs and Reimbursement

Participation in this study will not result in any expenses to the participant or their family.

Duty to Disclose

Please note that as with any patient seen by Dr. Clark, the research team has a duty to disclose if they should become aware of a client/ resident/patient who may be experiencing abuse and be in need of assistance or protection. Policies set by the Winnipeg Regional Health Authority will be followed.

Research Rights

Your signature on this form will show that you have understood to your satisfaction the information about the research study. By signing this document you are not waiving any of your child's legal rights, nor are you releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

If you have any questions at any time during or after the study about these legal rights or about research in general and you would like an independent opinion, you may contact the Bannatyne Research Ethics Board office at 204-789-3389.

Contact Person

The principal investigator (Liz Armstrong) will be available to answer any questions or concerns that you have from Monday to Friday between 8 am to 4 pm at 204-787-8524 OR e-mail – EL498822@dal.ca

Study Title: A comparison of near eye-turn measurements with different targets

Participant ID:_____ **Participant INITALS**: _____

Parental or Guardian Consent - I have read or had read to me this informed consent document and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand that I have the right to withdraw my child from the study at any time without affecting my child's care in any way. I have received a copy of the Informed Consent document for future reference. I freely agree to have my child participate in this research study and have verbal consent from my child to participate.

_____

Name of Participant (Print):

_____ _____

Name of Parent/Guardian (Print) Signature of Parent/Guardian

Date:_____ Time: _____

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY AND OBTAINING CONSENT

I have explained the nature and demands of the research study and judge that they understand that participation is voluntary and that they/their child may withdraw at any time from participating.

Name (Print):_____ Position: _____

Signature:_____ Date: _____Time_____

Other people present at time of signing:

Name (Print):_____ Position: _____

Signature:_____ Date: _____Time_____

Communication of Results

Research results will be made available to you at the completion of the study. If you wish to have a copy of the results please print your address here:

_____

_____

APPENDIX B: Study Information and Authorization Document

Study Title**:** **A comparison of near eye-turn measurements with different targets**

Investigator(s):

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Study Title: A comparison of near eye-turn measurements with different targets

Introduction

Your child is being invited to take part in the research study named above. The goal of this form is to describe the purpose of the study, how it may affect your child, the risks and benefits of taking part and what your child will be asked to do. After going through this information, you will be able to make an informed decision on whether your family would like to take part. This informed consent document is to help you decide if it is in your child's best interest to be involved, as participation is completely voluntary. If you have any questions that this form does not answer, the principal investigator (Liz Carson) will be happy to give you any further information.

Purpose of the Study

The purpose of this study is to see if there is a difference in the measurement of an eye-turn (strabismus) when using three different types of targets up close. The goal is to find a good target for children who do not know their letters or have a limited attention span due to their age.

The information gathered in this study could be used in the future to help with the planning of eye muscle surgery for other patients. If a patient is having surgery, the measurements done before are used to construct the surgical plan, therefore having the most accurate measurements is helpful in hopes of having a successful end result.

Study Design

A minimum of 34 participants between the ages of 3&5 years old, who are current patients in the Winnipeg Children's Hospital eye clinic with an inward turning eye will be invited to participate. Eligible patients will be identified by their direct care provider,

and then the patient's family will be called by the primary investigator to explain the study. This form will be signed at the next scheduled appointment if you agree for child to become a participant.

Any questions or concerns can be brought up at any point in this process. Once a participant is signed up for the study they will receive the same treatment as their usual follow-up appointments, the only changes are three extra measurements of the near eye-turn using three different targets and near visual acuity testing added to beginning of the appointment.

What Participation Involves

Taking part in this study will involve a one-time assessment included at the beginning of your child's regularly scheduled follow-up appointment. The near visual acuity testing and three strabismus measurements will add approximately ten minutes to the time and will take place an examination lane in the eye clinic (CE216H).

The primary investigator will be helping with the accuracy of the measurement while another examiner performs the measurements. This will be followed by the tests regularly performed at your child's eye assessment.

Potential Harms

There are no identified potential harms associated in participation of this study. If your child is unable to complete all the tests, this will be recorded in the study results. This could result from disinterest in the task, less encouragement than previous testing by the examiner as it is for a study, or fatigue. It will not affect the standard of care by any Orthoptist or Ophthalmologist in the eye clinic. If they are unable to complete the regularly scheduled appointment, their follow-up will be scheduled at the discretion the

Ophthalmologist. This will be avoided if possible by more encouragement, rewarding after tasks by the examiner and allowing more time for the regularly scheduled appointment.

Potential Benefits

There is no guarantee that your child will personally experience any benefits from participating in this study. There is no treatment prescribed during this one time appointment. The knowledge gained from this study will help determine the best way to measure near strabismus in the future.

Alternatives to the Study

Before deciding to participate in this study, you should know that your child does not have to take part in the study. If your child does not participate in the study he/she will receive the same standard of care.

Withdrawal from Participation

Participation in the study is entirely voluntary. You may decide not to enroll your child, or if you do choose to participate, your child may withdraw from the study during the appointment or up to one month after the assessment. This will not affect your child's eye care at the Winnipeg Children's Hospital eye clinic in any way. If the study is changed in any way that could affect your decision to continue to have your child participate, you will be informed of the changes and you may be asked to sign a new consent form.

Confidentiality

Medical and research records that contain your child's identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. The

primary investigator and the supervising ophthalmologist will have access to your child's internal ophthalmology chart as well as the data collected during the study. Only the glasses prescription will be recorded from the chart, all other data will be collected at the upcoming appointment. This includes their gender, age, near visual acuity and three measurements of their eye turn. Research and medical records may be reviewed by staff involved with the Winnipeg Regional Health Authority and the University of Manitoba Health Research Ethics Board to ensure research is being performed properly. A number will be given to anyone participating and therefore your child's name will not be used in the documentation of the results. If the results of the study are published in a medical journal it will not have any information that would identify the participant. Study records will encrypted and stored in a password protected file.

Costs and Reimbursement

Participation in this study will not result in any extra expenses to your family.

Duty to Disclose

Please note that as with any patient seen in the Winnipeg Children's eye clinic, the research team has a duty to disclose if they should become aware of a client/ resident/patient who may be experiencing abuse and be in need of assistance or protection. Policies set by the Winnipeg Regional Health Authority will be followed.

Research Rights

Your signature on this form will show that you have understood to your satisfaction the information about the research study. By signing this document you are not waiving any of your or your child's legal rights, nor are you releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

If you have any questions during or after the study about these legal rights or about research in general and you would like an independent opinion regarding the research study, you may contact the University of Manitoba Bannatyne Research Ethics Board office at 204-789-3389.

Contact Person

The principal investigator (Liz Carson) will be available to answer any questions or concerns that you have from Monday to Friday between 8 am to 4 pm at 204-787-8524 OR e-mail – ecarson2@exchange.hsc.mb.ca

Study Title: A comparison of near eye-turn measurements with different targets

Participant ID: _____ Participant INITALS: _____

Parental or Guardian Consent - I have read or had read to me this informed consent document and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand that I have the right to withdraw my child from the study at any time without affecting my child's care in any way. I have received a copy of the Informed Consent document for future reference.

_____

Name of Participant (Print)

_____ _____

Name of Parent/Guardian (Print) Signature of Parent/Guardian

Date: _____ Time: _____

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY AND OBTAINING CONSENT

I have explained the nature and demands of the research study and judge that the Parent/Guardian named above understands the nature and demands of the study.

Name (Print): _____Position: _____

Signature:_____ Date: _____Time_____

Other people present at time of signing:

Name (Print): _____Position: _____

Signature:_____ Date: _____Time_____

Communication of Results

Research results will be made available to you at the completion of the study. If you wish to have a copy of the results please print your address here:

_____

_____

_____

APPENDIX C: Data Collection Form

Date:_____ **Patient ID #**:_____

Age:_____ **Gender:**____ **Consent obtained:** **Yes** **No**

	Near visual acuity
RE	
LE	

	Lensometry	Cycloplegic refraction
Right		
Left		Date performed: _____

Strabismus Measurement:

	Measurement
Lang cube cat picture	
Red circle	
Experimental sticker (size symbol:_____)	

Notes:_____

_____

_____

APPENDIX D: Child Assent Script

Today I would like to do a couple extra games with you. We would start by testing your eyes up close with the shape naming game, then we will show you three different pictures while measuring your eye turn. Then we will do the tests that you do every time you come to the eye clinic.

Being in the study may not help your eyes, but it won't harm them. We hope that we will learn things in the study that will help us take better care of other children with same eye problem in the future. You do not have to be in this study if you don't want. No one will be mad at you and it will not affect how your doctor looks after you if you decide not to be in the study. If you don't want to be in this study, tell us. Even if you say yes now, you can change your mind later.

APPENDIX E: WRHA Abuse Reporting Policy

Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg — Caring for Health / À l'écoute de notre santé	**REGIONAL**	Level: 1
	Policy Name:	Policy Number: / Page
	Approval Signature:	Section: CLIENT / RESIDENT /
	Date: April 2006	Supercedes: HSC 80.140.1, HSC 80.140.3, HSC 80.140.6, HSC 80.140.7

1.0 **PURPOSE:**

1.1 To advise all WRHA Medical staff, employee, students and volunteers of the appropriate action should they become aware of a client/ resident/patient who may be experiencing abuse and be in need of assistance or protection.

1.2 To ensure that staff actions are in accordance with legislation or guidelines on identifying and reporting situations involving abuse.

2.0 **DEFINITIONS**:

2.1 *The Child and Family Services Act (Manitoba):*

2.1.1 Abuse: An act or omission of a parent, guardian or person having care, custody, control or charge of a child, where the act or omission results in:

a) physical injury to the child

b) emotional disability of a permanent nature or is likely to result in such a disability,

c) sexual exploitation of a child with or without the child's consent

2.1.2 *Child: A person under the age of majority or 18 years of age.*

2.1.3 In Need of Protection: A child in need of protection may include, but is not limited to, situations where the child:

a) is without adequate care, supervision or control;

b) is in the care, custody, control or charge of a person

i) who is unable or unwilling to provide adequate care, supervision or control of the child, or

ii) whose conduct endangers or might endanger the life, health, or emotional well being of the child, or

iii) who neglects or refuses to provide or obtain proper medical or other remedial care or treatment necessary for the health or well being of the child or who refuses to permit the provision of such care or treatment to the child as recommended by a duly qualified medical practitioner;

c) is abused or is in danger of being abused;

d) is beyond the control of a person who has the care, custody, control or charge of the child;

e) is likely to suffer harm or injury due to the behavior, condition, domestic environment or associations of the child or of a person having care, custody or control of the child/

f) is subjected to aggression or sexual harassment that endangers the child's life, health or emotional well being of the child;

g) being under the age of 12 years, is left unattended and without reasonable provision being made for the supervision and safety of the child; or

h) is the subject, or is about to become the subject, of an unlawful adoption or of an unlawful sale.

2.2 *The Vulnerable Persons Living With A Mental Disability Act (Manitoba):*

2.2.1 Abuse: Mistreatment, whether physical, sexual, mental, emotional, financial or a combination thereof, that is reasonably likely to cause death or that causes or is reasonably likely to cause serious physical or psychological harm to a vulnerable person, or significant loss to his or her property.

2.2.2 Neglect: An act or omission whether intentional or unintentional, that is reasonably likely to cause death or that causes or is reasonably likely to cause serious physical or psychological harm to a vulnerable person, or significant loss to his or her property.

2.2.3 Mental Disability: Significantly impaired intellectual functioning existing along with impaired adaptive behaviour and manifested prior to the age of 18 years, but excludes a mental disability due exclusively to a mental disorder as defined in section 1 of The Mental Health Act.

2.2.4 Service Provider: A person who provides care, support services or related assistance for a vulnerable person in the course of professional or employment duties, as a student in a training placement, as a volunteer, or as an owner, operator or manager of a facility or business which provides such care, support services or related assistance.

2.2.5 Vulnerable Person: An adult living with a mental disability who is in need of assistance to meet his or her basic needs with regard to personal care or management of his or her property.

2.3 *The Protection For Persons In Care Act (Manitoba):*

2.3.1 Abuse: Mistreatment, whether physical, sexual, mental, emotional, financial or a combination of any of them, that is reasonably likely to cause death or that causes or is reasonably likely to cause serious physical or psychological harm to a person, or significant loss to the person's property.

2.3.2 *Health Facility:*

a) A hospital designated by regulation under The Health Services Insurance Act;

b) A personal care home designated by regulation under The Health Services Insurance Act;

c) An institution or organization designated as a health facility by regulation under section 13 of the Act;

2.3.3 Mistreatment:

a) A single act or series of acts of physical aggression. b) A verbal or written threats (s) against a patient.

c) Use of patient/dependant finances/assets other than to support patient/dependant

d) Non responsive to patient needs

e) Intentionally giving the wrong treatment

2.3.4 Patient: An adult resident, in-patient, client, or person receiving respite care in a Health Facility, but does not include a vulnerable person within the meaning of The Vulnerable Persons Living with a Mental Disability Act.

2.4 *Family Violence, Domestic Abuse and Elder Abuse:*

2.4.1 Abuse: Mistreatment, whether physical, sexual, mental, emotional, financial or a combination of any of them".

2.4.2 Domestic Abuse: Abuse or violence that occurs between intimate partnerships.

2.4.3 Elder Abuse: Any act or lack of action by someone in a position of trust that harms the health or well-being of an older person.

2.4.4 Family Violence: Abuse or violence that occurs in relationships of intimacy, kinship, dependency, or trust.

2.4.5 Mistreatment:

a) A single or a series of acts of physical aggression.

b) A verbal or written threat (s) against the patient.

c) Use of patient/ dependant finances/assets other than to support patient/dependant.

3.0 **POLICY:**

3.1 General:

3.1.1 Under the mandatory reporting legislation below, the duty to report is an individual responsibility and does not require staff consensus or the approval of any supervisor or physician.

3.1.2 Where there is mandatory reporting legislation, the obligation to report supersedes any restrictions respecting the disclosure of information, in legislation, including The Personal Health Information Act (Manitoba), or otherwise. There may be a need for multiple reporting based on the situation.

3.1.3 If unable or if uncertainty exists respecting the requirements or advisability to report, the individual shall contact the program/team manager for consultation or direction. If uncertainty still exists, legal counsel may be contacted for further direction.

3.1.4 For any of the reporting requirements below, the individual shall consult with the appropriate agency, as identified below, regarding measures to ensure the safety of the client/resident/patient

3.1.5 The individual shall advise his or her supervisor/manager as soon as possible regarding actions taken, as appropriate.

3.1.6 Confidentiality regarding the identities of the individuals involved in allegations of abuse shall be maintained to the greatest extent possible. Information shall be shared only as required for the investigation.

3.1.7 The individual shall complete appropriate documentation, including the assessment and action. This can include but is not limited to:

a) description of the client/resident/patient, including any abuse that may be noted (drawings may be useful to pinpoint the area, size, and colour of injuries for physical abuse);

b) the client/resident/patient behaviour with and without the person suspected of abuse;

c) the client/resident/patient statement of what happened to him/her, in their own words. The interview should be in the absence of the persons suspected of committing the abuse;

d) consultation with other health professionals;

e) the name of the agency and persons contacted.

3.1.8 This policy does not apply to situations where there is a complaint about the nature or effect of a routine procedure performed by a responsible health care professional that has followed established WRHA policies. The Client Complaint Management System Policy 10.50.010 should be consulted in such situations for further guidance.

3.2 *The Child And Family Services Act (Manitoba):*

3.2.1 An individual having information causing him/her to believe that a Child is or might be In Need of Protection by anyone (including WRHA staff) shall:

a) Immediately report the information to the Child and Family Service agency; or to a parent or guardian of the child. Where the individual reporting:

- does not know the identity of the parent or guardian of the child; or
- has information that leads the person recording to believe that the parent or guardian is responsible for causing the child to be in need of protection or is unable or unwilling to provide adequate protection; or
- has information that leads the individual to believe that the child is or might be suffering Abuse by a parent or guardian or by a person having care, custody, control or charge of the child, then the individual shall report only to Child and Family Services.

b) Consult the Child Protection Centre or legal counsel if further assistance or direction is required.

3.2.2 If the Child is in a WRHA facility or WRHA funded facility, the individual shall inform their immediate supervisor, who will ensure appropriate security measures are taken.

3.3 *The Vulnerable Persons Living With A Mental Disability Act (Manitoba):*

Any individual Service Provider who believes, on reasonable grounds, that a Vulnerable Person to whom he or she provides service is or is likely to be Abused or neglected, shall immediately report the belief and information upon which it is based to the Executive Director appointed under this Act, by phoning the Family Services Intake for the Supportive Living Program or Family Services After Hours.

3.4 *The Protection For Persons In Care Act (Manitoba):*

3.4.1 Any individual who has a reasonable basis to believe that a Patient is or is likely to be Abused shall promptly report the belief and the information on which it is based, to the minister or his/her delegate, by phoning the Protection for Persons in Care Office.

3.4.2 When reporting is based on a belief that the patient is likely to be Abused the individual must have a reasonable basis on which the belief is based, including but not limited to awareness of a verbal or written threat against a patient, actions though incomplete that are suggestive of an intent to harm, (ie. raising a fist against a patient) or a combination thereof.

3.4.3 If unsure the Protection Office may be contacted in consultation. The Protection Office will assure the anonymity of the person making the report if requested.

3.5 *Family Violence, Domestic Abuse and Elder Abuse:*

3.5.1 Reporting of Family Violence, Domestic Abuse or Elder Abuse is not mandated by legislation, unless a mandatory reporting obligation applies.

3.5.2 Reporting may be permissible under The Personal Health Information Act (Manitoba) including under Section 22(2) by disclosure without an individual's consent.

3.5.3 Routine screening questions for Domestic Abuse, Family Violence and Elder Abuse should be part of a client/resident/patient initial routine health assessment in all WRHA programs and services, particularly when the presenting injuries are consistent with the indicators of Family Violence, Domestic Abuse or Elder Abuse.

3.5.4 The health care providers primary responsibility should be to identify the problem, provide information about appropriate resources, refer the client/resident/patient to an appropriate resource and provide support if needed.

4.0 PROCEDURE:

Facilities/Sites shall develop process and procedures, as appropriate, to support this policy.

5.0 REFERENCES:

5.1 WRHA Client Complaint Management System Policy 10.50.010.

5.2 Health Sciences Centre Reporting Child Abuse or Children in Need of Protection Policy 80.140.003.

5.3 WRHA PHIA Policy, Protection of Privacy During Use and Disclosure of Persona Health Information 10.40.100.

5.4 WRHA Vulnerable Persons Policy, Vulnerable Persons Living with a Mental Disability Act, Policy, 10.40.200.

5.5 The Child and Family Services Act (Manitoba).

5.6 The Protection for Persons in Care Act (Manitoba).

5.7 The Vulnerable Persons Living With A Mental Disability Act (Manitoba).

5.8 The Personal Health Information Act (Manitoba).

Policy Contact: Sandra Loewen, WRHA Regional