Does Occlusion Therapy Improve Control in Non-Diplopic Patients with Intermittent Exotropia?

by

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To my father, mother, brothers Abdulla & Omer, grandmother and friends for your unlimited support, encouragement and endless love, Thank you

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Abstract

The aim of this pilot study is to evaluate the effectiveness of occlusion therapy in the control of intermittent exotropia (IXT) in children between 4 and 10 years in Saudi Arabia. A clinical, prospective cohort pilot study was performed on 21 untreated IXT patients. The deviation angle, amplitudes, stereopsis and control of IXT were evaluated before, during and after occlusion therapy. Using established clinical tests, 11% of the subjects had a decrease in the deviation angle by 50% while 55.5% attained normal ranges for base-out fusional amplitudes and 77% attained success for the control. The results of this limited study suggests that occlusion therapy does not improve the angle of deviation but may improve sensory status and strengthen fusional amplitudes. Occlusion therapy may be a useful method for the postponement of surgery in young children with IXT.

List of Abbreviations Used

X	Latent Exotropia
IXT	Intermittent Exotropia
XT	Manifest Exotropia
AC/A	Accommodative Convergence to Accommodation Ratio
VA	Visual Acuity
PD	Prism Diopters
DS	Diopters Sphere
BVA	Binocular Visual Acuity
BOFA	Base-Out Fusional Amplitudes

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CHAPTER 1: INTRODUCTION

In most populations, exodeviations occur less frequently than esodeviations and are reported more among females (Friedman, Neumann, Hyams & Peleg,1980). They occur more frequently in the Middle East, subequatorial Africa, and the Orient than the United States and central Europe (Von Noorden & Campos, 2002). In this chapter, we will be reviewing the etiology, classifications, assessment and management of Intermittent Exodeviations (IXT).

1.1 Background

Exotropia is an eye condition where the two eyes are not aligned along the same visual axes, but instead the axes diverge. Exodeviations can be classified as pseudoexodeviation when the eyes appear to be deviated outward but the fact is the eyes are properly aligned, latent (X), where the deviation is controlled by fusion under conditions of normal binocular vision, intermittent (IXT), which is a latent deviation that is sometimes manifest, and manifest (XT) where the deviation is manifest all the time. IXT is the most common form of exotropia found in children with a prevalence ranging from 9.4 to 18.7/1000 population (Jenkins, 1992). Intermittent exotropia (IXT) is an exodeviation intermittently controlled by fusional mechanisms and spontaneously breaks down into a manifest exotropia. At other times the eyes are aligned and binocular single vision is maintained. IXT tends to occur during distance viewing and often during periods of inattention, fatigue or illness (Ansons & Davis, 2001). Some investigators suggest that IXT is a large phoria that is controlled by fusional convergence part of the time and spontaneously breaks into a manifest exotropia (Costenbader, 1950). During the phoric phase, the eyes are aligned and binocular single vision and stereopsis are present. When

the deviation manifests (tropic phase), there is suppression of the temporal retina. However, a minority of IXT patients may demonstrate monofixation with abnormal bifoveal fusion and stereopsis (Nawratzi & Jampolsky, 1958; Pratt-Johnson & Wee, 1969; Wright & Spigel, 2003).

1.11 Etiology

The etiology of exodeviation remains unknown although investigators have proposed anatomical, mechanical, innervational and hereditary factors (Burian, 1971; Costenbader, 1950; Mitsui, 1978). Duane in 1897 proposed that exodeviations are caused by innervational imbalance that unsettles the reciprocal relationship between active convergence and active divergence mechanisms. Bielschowsky argued that Duane did not account for anatomical and mechanical factors in the occurrence of exodeviation and sensory exotropia after fusional disruption such as the effect of an abnormal resting position, shape and size of the orbits/ globes, function of the eye muscles according to their insertion and properties of the extrabulbar tissues (Bielschowsky, 1934). On the other hand, Worth, (1903) stated that defective fusion is the cause of inward or outward deviation. Worth explained that inadequate fusion faculty can cause the state of unstable equilibrium of the eyes. High AC/A ratio were thought to have a role in the etiology of IXT as suggested by Cooper and Medow (1993). Another theory suggests that affected patients develop large bilateral, bitemporal hemiretinal suppression which therefore allows the eye to diverge (Knapp, 1953; Jampolsky, 1954). In addition, uncorrected refractive errors contribute to the pathogenesis of exotropia. Uncorrected myopia causes under stimulation of convergence due to the constant reduced accommodative effort and therefore can cause an exodeviation to develop (Donders, 1899).

Unequal clarity of retinal images contributes to the pathogenesis of exotropia in that the fusion is disrupted; therefore, anisometropia has a role in the development of exodeviations (Jampolsky, 1955).

1.12 Classification

IXT was first classified by Duane in 1897 according to distance/near differences in measurements. Duane suggested three classifications of exodeviation including divergence excess (deviation larger at distance than near), convergence insufficiency (deviation larger at near than distance) and basic exotropia (deviation at near and distance is equal). Divergence excess is subdivided into simulated divergence excess and true divergence excess. Simulated divergence excess is a deviation that is larger for distance than near but with prolonged monocular occlusion the near deviation increases to become similar to or larger than the distance deviation. True divergence excess is when the deviation is greater at distance than near even after monocular occlusion (Duane, 1897). Scobee (1952) reported that the angle of deviation is usually greater at distance than near and the size of deviation often equalized after 24 hours of occlusion in IXT cases. However, Burian (1958) found that 30 to 60 minutes of occlusion was enough to equalize near and distance deviation. Burian, (1965) classified intermittent exotropia into basic IXT, divergence excess IXT, convergence insufficiency IXT, and simulated or pseudo divergence excess IXT. Kushner (1988) suggests that the mechanism for the distance-near disparities seen in patients with IXT are due to superimposed convergence on the basic exodeviation. Tenacious proximal fusion, accommodative convergence and proximal convergence are the convergence mechanisms that play an important role in determining distance-near disparities in IXT. Based on the convergence mechanisms and

the distance-near disparity, Kushner classified IXT as follow; Basic IXT, High AC/A ratio, proximal convergence, tenacious proximal fusion (pseudo-high AC/A ratio), low AC/A ratio, fusional convergence insufficiency and pseudo convergence insufficiency.

1.13 Epidemiology and Genetics

In most countries, exodeviations occur less frequently than esodeviations in a ratio of 1:3 and are more common in latent or intermittent form than are esodeviations. Of all the exotropias, IXT comprises about 50-90% of the cases and is usually preceded by a stage of exophoria. It usually affects about 1% of the general population (Govindan, Mohney, Diehl & Burke, 2005). Exodeviations occur more commonly in the Middle East, subequatorial Africa and the Orient than in the United States and central Europe (Von Noorden & Campos, 2002). Exodeviation is found more frequently in latitudes with higher levels of sunlight (Eustace,Wesson & Drury, 1973). Jenkins, (1992) made the interesting observation that the nearer a country is to the equator the higher the prevalence of exodeviations.

Thirty five percent to 40 % of exodeviation cases are seen before the second year of life and are more associated with neurological and craniofacial anomalies (Good & Hoyt, 1996). Exodeviations are more common in females (Friedman, Neumann, Hyams & Peleg, 1980). Heredity plays a role in exodeviations and genetics of the disorder are thought to be multifactorial (Good & Hoyt, 1996). A positive family history is also a risk factor for the disorder. An autosomal dominant pattern of constant XT has been documented in a single case report (Brodsky & Firtz, 1993; Burian & Spivey, 1965).

1.14 Signs and Symptoms

Signs and symptoms vary according to the type of exodeviation. The tropia phase of IXT is noticed more when patients are sick or day-dreaming or fatigued. Patients with exophoria can complain of eye strain, episodes of blurry vision, transient diplopia and headaches. Patients with exotropia may be less symptomatic due to suppression unless the onset is recent (Joosse, Simonsz, Van Minderhout, Mulder, & De Jong, 1999). Common complaints of IXT are photophobia and monocular eye closure. The mechanism of photophobia in IXT patients has not been extensively investigated. Current thought is that fusion is disrupted in bright light causing the deviation to manifest and the patient to close one eye to avoid diplopia (Manley, 1971). An alternate explanation is that changes due to bright light can cause perceptual visual field changes which can be mitigated through monocular eye closure (Jampolsky, 1958). Micropsia, another symptom of IXT, is a visual disorder in which objects appear much smaller than they actually are, and this occurs because IXT patients attempt to use accommodative convergence to control the deviation (Von Noorden & Campos, 2002).

1.15 Clinical Assessment

Exodeviation assessment warrants an eye examination including orthoptic work-up, refraction and examination by an ophthalmologist to rule out other pathologies. The orthoptic work-up is performed in an order to minimize dissociation of the deviation and it includes history taking, visual acuity, deviation measurements at near and distance, ocular motility, sensory tests for binocular function, base-out fusional amplitudes for near and distance, near point of convergence and control assessment. Accommodative convergence, proximal convergence and tonic convergence affect the management of

exodeviation and should be noted during patient examination. Several testing procedures will reveal this effect and assess the control of the patient, such as measurements during accommodation, measurements to light, distance measurements at more than 6 meters, measurements with +3.00 D spherical lenses, patch test and binocular visual acuity testing (Von Noorden & Campos, 2002; Ansons & Davis, 2001). The patch test involves occluding an eye for approximately 30-45 minutes and then measuring the deviation prior to restoration of binocular fusion to negate the effect of tonic fusional convergence. Measurements at distance greater than 6 meters can be performed by having the patient fixate on an object past 6 meters so that the proximal convergence effect is suspended enabling measurement of the maximum deviation. A +3.00 lens test is a measure of the deviation at near with the lens in front of both eyes to rule out the effect of accommodative convergence. The effect of AC/A ratio will mask the true magnitude of near deviation and therefore needs to be detected. The heterophoria method can be used for this purpose. The ratio is calculated as follows:

[1.511] $$AC/A=IPD+ (n-d)/D$$

Where AC is accommodative convergence; A is accommodation; IPD is interpupillary distance; n is prism cover test measurements at near; d is prism cover test at distance, D is the accommodation in diopters based on the reciprocal of the focal distance. The IPD is measured in centimeters and the patient should wear his refractive correction. The deviation is measured at near and distance (Ansons & Davis, 2001).

It is important to perform the patch test before the +3.00 lens measurements to avoid misdiagnosing a high AC/A ratio because the +3.00 lenses measurements suspend normal accommodative convergence whereas the patch test relaxes fusional convergence.

Measurement of exodeviation to light rather than an accommodative target reduces the effect of accommodative convergence (Ansons & Davis, 2001; Helveston, 1974; Kushner, 1988).

Lateral gaze measurements are important in the work-up of IXT patients as they determine whether to modify the amount of surgery on horizontal rectus muscles or not. Lateral incomitance and its effects on strabismus surgery were first described by Moore (1969). It is the difference in size of deviation in lateral gaze compared to the primary position. This difference was described as a 5% change to 60% change in lateral gaze measurements defined by different authors; each had a different definition of the change (Von Noorden & Campos, 2002; Burke, 1985; Knapp, 1971).

Because of the intermittency nature of IXT, it has a different sensorial adaptation than other types of ocular misalignment. Normal binocular vision is established in IXT and it varies from a gross to excellent according to the control and manifestation of the deviation. Anomalous retinal correspondence and normal retinal correspondence may coexist (Burian, 1947) but some authors state that anomalous retinal correspondence occurs primarily with constant XT (Holland, 1964)

Variability of fusional control in patients with IXT should also be considered. As previously mentioned, several assessment methods are available, some are subjective and others are objective. Home control and office control assessments are subjective methods which were developed to detect early signs of deterioration of IXT and therefore institute timely intervention. Home control assessment depends on information given by the parents. It is usually divided into few categories; excellent control, good control, fair control and poor control. Excellent control indicates that the tropic phase is rarely noticed

when day-dreaming or when fatigued. Good control is when the deviation is noticed less than five times a day and only at distance. Fair control is a deviation that is manifest more than five times a day at distance. Poor control is when the patient breaks at near and distance frequently during the day. Office control is assessed by the clinician and categories include well, good, fair and poor. Good control is when the patient breaks only after fusion disruption and resumes fusion rapidly. When the patient needs to blink to resume fusion then we describe it as fair control. Poor control is when the patient breaks spontaneously without any form of fusional disruption. Some of the objective methods to assess control of IXT are measuring stereoacuity at near and distance, binocular visual acuity (BVA) and fusional amplitudes on every visit to monitor the progression and/or regression of the control (Rosenbaum, 1996; Zanoni & Rosenbaum, 1991). In this study, we used the control score scale (Mohney & Holmes, 2006) subjectively to quantify the fusional control of the patients as outlined below in chapter 3. However, the control of fusion in intermittent exotropes is influenced by general health, attention, alertness, the anxiety level of the patient during evaluation and time of the day test is administered may also play a role (Von Noorden & Campos, 2002).

1.16 Management and Prognosis

Treatment of exodeviations is indicated if the patient is symptomatic and binocular function is affected. Surgical or non-surgical treatments aim to reduce episodes of manifest exotropia by reducing the angle of deviation and improving control of fusion (Von Noorden & Campos, 2002). The decision to perform surgery remains a contentious issue and each case has specific indications including the age of the patient, angle of deviation, symptoms, cosmesis, fusion potential, history, onset, prognosis, etc. The

reasons for non-surgical correction also vary, including patients who want to avoid surgery and clinicians/patients who want to delay surgical intervention for clinical / personal reasons. Occasionally non-surgical treatment alleviates symptoms such that surgical invention is unnecessary (Karlsson, 2009).

Non-surgical management involves observation, spectacle prescription including under-corrected hyperopia, base-in prisms, minus lens therapy, occlusion therapy and orthoptic exercises such as pen push-ups, base-out prism exercises, stereograms, etc (Karlsson, 2009). Regular observation of the control of the deviation is also considered management. During the observation process, the patient's control needs to be assessed at home and in the office, as previously mentioned.

Full correction is advised for myopic patients including the correction for astigmatism to ensure a sharp retinal image. The choice of full or partial correction remains debatable for hyperopes. Factors such as age, degree of hyperopia and the accommodative convergence/accommodation (AC/A) ratio must be considered to determine whether full or partial correction is warranted. There are two opposing concepts for treating exotropes with moderate to high hyperopia. The first concept is to provide a clear retinal image and therefore stimulate fusion despite the fact that mild hyperopes tend to have clear VA without correction (Haldi & Mets, 1997). The other concept proposes that correction of any hyperopia will decrease the demand on accommodative convergence and thus increase the exodeviation (Von Noorden & Campos, 2002). Iacobucci et al. (1993) studied the response of exotropic children to full hyperopic corrections and found that spectacles improved deviation and binocular sensory status in all patients assuming spectacles were the cause for the improvement. Iacobucci et al. (1993) concluded that full

spectacle correction is warranted in exotropic children with moderate to severe hyperopia, hyperopia with low AC/A ratio or evidence of hypo-accommodation. Alternately, Von Noorden advised against hyperopic correction for some levels of hyperopia (< +2.00), in children with exodeviations in order to avoid worsening of the exodeviation due to the relaxation of accommodation (Von Noorden & Campos, 2002). Therefore the treatment of hyperopia in patients with exodeviation should be evaluated on an individual basis.

The use of over-minus lens therapy induces accommodation and accommodative convergence by the induced retinal image blur. Over-minus lens therapy is sometimes used as temporizing therapy to promote fusion and to prevent the development of suppression. This therapy can be curative in cases of small angle consecutive exotropia after strabismus surgery but may result in asthenopia in older children. Caltrider and Jampolsky (1983) reported initial success with over-minus lenses as primary treatment for IXT which lasted less than a year after therapy was discontinued. There is also a concern that the use of over-minus lenses might induce or increase the development of myopia (Figueira & Hing, 2006; Dyer, 1979; Zylbermann, Landau & Berson 1993). Other studies have not supported this observation (Kushner, 1999; Dunlap, 1963; Kennedy, 1954).

Base-in prisms for exotropes compensate for strabismus, enabling binocular single vision and alleviating asthenopia. Some ophthalmologists use prisms for the management of postsurgical over/under correction (Ansons & Davis, 2001) while others use prisms preoperatively to improve fusional control (Pigassou, 1966).

Orthoptic therapy aims to stimulate the patient's awareness of diplopia, improve his/her control of diplopia and alleviate symptoms. Patient cooperation and comprehension play an important role in the success of orthoptic therapy. Orthoptic therapy involves antisuppression therapy, physiologic diplopia exercises, prism therapy, fusion and convergence exercises (Ansons & Davis, 2001). Convergence exercises increase the magnitude of fusional convergence and are useful in treating IXT associated with convergence insufficiency (Cooper & Leyman, 1977) but are relatively unsuccessful in treating IXT (Wright & Spigel, 2003).

Indication of surgical intervention is determined by the state of fusional control, the size of the deviation angle, asthenopic symptoms, visual confusion and diplopia. There are signs for the progression of IXT that allow the ophthalmologist to evaluate the case and decide the appropriate timing for surgical intervention. Such signs include; worsening of the angle of deviation at near and/or distance, worsening of the deviation control, development of secondary convergence insufficiency, increase in the size of basic deviation, development of suppression and decrease in stereoacuity. The factors that affect the response to surgery include the patient's age, the degree of control, the sensory destabilizing factors such as vision and micro deviations and tenacious fusion at near. Various surgical procedures are used for the goal of IXT alignment, lateral rectus recession, recess-resect procedures and medial rectus resection. It is the ophthalmologist's decision to use the appropriate procedure for every individual case (Rosenbaum & Santiago, 1999). It is difficult to determine the outcome of the current treatment of IXT due to the variety of the treatment approaches and variability of classification systems. Some authors suggest that the longer the follow-up, the higher the incidence of the

postsurgical undercorrection, i.e., the incidence of exotropia recurrence increases with time (Richard & Parks, 1983; Hardesty, 1990). However, Kushner (1988, 1998) concluded the following: a high AC/A ratio is an indicator of poor surgical prognosis, tenacious proximal fusion is an indicator of good prognosis, if distance deviation increased in size (after patching test or measurements at more than 6 m) then the surgery should be performed for the largest deviation that can be documented consistently.

Occlusion therapy is considered an antisuppression therapy to prevent or eliminate suppression and to induce diplopia in some cases and therefore stimulate sensory and motor fusion. However, not all patients complain of diplopia in antisuppression therapy (Von Noorden & Campos, 2002). Part-time or full-time occlusion of the dominant eye, or alternate occlusion in patients without ocular preference, has been used for this therapy. In this study, we initiated antisuppression (occlusion) therapy in an attempt to remove the suppression mechanism present under binocular conditions and therefore stimulate and/or improve binocularity by the end of treatment.

1.2 Purpose of the Study

The aim of this study is to evaluate the effectiveness of occlusion therapy in the control of IXT and the angle of deviation in children between 4 and 10 years old in Saudi Arabia. To our knowledge, occlusion therapy has not been studied extensively in the literature and to address this gap, the objective of the current study was to provide clear methodology and success criteria for this type of therapy.

1.3 Research Question

Does occlusion therapy improve control in non-diplopic patients with IXT?

1.4 Significance of Study

In this pilot study, we initiated occlusion therapy through eye patching in an attempt to reduce the suppression mechanism and therefore stimulate and/or improve binocularity (binocular single vision, resulting in depth perception). Occlusion therapy limits the inhibitory process present under binocular conditions, eventually eliminating the suppression mechanism altogether (Von Noorden & Campos, 2002).

This pilot study adds to the body of the knowledge of the non-surgical management of IXT patients. Results of this pilot study suggest how occlusion therapy in IXT may affect control of the deviation, binocular single vision, stereoacuity, angle of deviation and fusional amplitudes. There is a lack of such studies in the literature, particularly prospective ones.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Exodeviations are more common in latent or intermittent form than are esodeviations. IXT is the most common form of exodeviation, comprising approximately 50-90% of the cases. It is usually preceded by exophoria and affects approximately 1% of the general population (Govindan, Mohney, Diehl & Burke, 2005). The natural history of IXT remains obscure due to a lack of longitudinal prospective studies. In some cases, an exophoria progresses to an IXT that eventually becomes constant but in other cases the deviation may remain stable for many years, and rarely, it may improve. Von Noorden and Campos (2002) found that 75% of 51 untreated patients with IXT showed progression over an average follow-up period of 3.5 years whereas 9% did not change and 16% improved.

Occlusion therapy for IXT has not been studied extensively. Some studies, as will be discussed later in this chapter, used unclear methodology or vague treatment strategies and ambiguous success criteria. In this chapter, literature review was performed to examine the objectives, methodology and results of each study. To address this gap in the literature, one objective of the current study was to provide a clear methodology and success criteria.

2.2 Review of Literature

Newman and Mazow (1956) compared the management of IXT in 60 patients. 50% of the cohort underwent surgical treatment and the other 50% were medically managed with minus lenses, alternate patching and orthoptic exercises. Newman and Mazow defined success as a conversion of an IXT to an asymptomatic phoria or a decrease of the size of

deviation less than 15 prism diopters. Of the 26% of the cohort that underwent occlusion therapy, there was an 87% success rate.

Iacobucci and Henderson (1965) showed a beneficial effect of occlusion therapy alone on exodeviations, both in exodeviation type and magnitude but found that some patients with initial IXT subsequently decompensated to constant exotropia after full time occlusion. 53% of their subjects converted from IXT to exophoria while the deviation increased in control subjects during the study period. Limitations of the Iacobucci and Henderson study include a small sample size (17 patients), reporting data related to motor status and a poor definition of the criteria for success.

Asbury (1968) studied a group of patients with IXT and applied alternating occlusion therapy to all subjects. Asbury found that 94% of subjects obtained stereopsis with enhanced fusional vergence amplitudes at near and distance. Additionally, Asbury noted that primary occlusion improved the postoperative capabilities of enhancing fusion.

Niederecker and Scott (1975) studied the effectiveness of diagnostic occlusion from 24 hours to five days prior to strabismus surgery on a series of 28 patients. 8 of whom were occluded for 5 days. Niederecker and Scott found that one of the 8 patients reported improved control of the deviation despite the increased angle of exotropia. This observation led others to investigate the therapeutic effect of occlusion.

Flynn, MeKenney and Rosenhouse (1976) treated 31 IXT patients (average age 7.6 years) with full time occlusion therapy for a period of 6 to 12 weeks. In the Flynn et al. study, 29% of the cohort was postsurgical IXT. The results were divided into motor effects and sensory effects. Success for sensory effect was described as improved awareness of diplopia and disappearance of suppression scotoma. Success for the motor

effect was described as improved control of exodeviation that was detected by a decrese in the angle of deviation measurements and a 50% increase in fusional vergence range. After completing treatment, 68% of the subjects showed positive (sensory and motor) change. The magnitude and frequency of the deviation worsened in 39%. Limitations for the Flynn et al. study include the lack of statistical analysis and the inclusion of postsurgical subjects which may have had a confounding effect on the outcomes.

In a retrospective chart review in 637 patients, Cooper and Leyman (1977) compared different treatment modalities for IXT. They divided the cohort into four groups according to the type of treatment. The first group included 11 subjects who received occlusion therapy of whom 36% had normal sensory and motor function after treatment and 27% had fair binocular function after treatment. A poor response was reported in 36% of the subjects. Despite the small sample size used, Cooper and Leyman found that occlusion therapy is useful in breaking down suppression. However, the treatment regimen was poorly defined and no statistical analysis was performed.

Chutter (1977) studied the effect of occlusion therapy on suppression, visual acuity and fusional amplitudes in a cohort of 46 IXT patients with an age range of 4 to 10 years using both full-time and part-time occlusion for 3 to 12 weeks. Based on cover testing and synoptophore fusion ranges, 76% demonstrated stronger fusion of which 55% became exophoric. In addition, Chutter concluded that intermittent occlusion therapy is a straightforward, safe and effective method of treatment for IXT but not for manifest exotropia or monofixational phorias. Chutter presented outcomes in a cogent manner with clearly defined tables and treatment regimen. However, the lack of statistical analysis

weakened the outcomes of this study. Chutter used occlusion as an amblyopia treatment as well.

A prospective evaluation of occlusion therapy in a group of 38 infants and young children was performed by Spoor and Hiles (1979). All patients underwent 3 to 6 hours/day of part time occlusion for a mean duration of 15 months (range, 3 to 42 months). The mean duration of follow up was 2 years and 3 months. The mean magnitude of exodeviation prior to occlusion therapy was 18 prism diopters (PD) at distance and 7 prism diopters at near. Spoor and Hiles found a decrease of exodeviation after occlusion therapy to 12 prism diopters for distance and 4 prism diopters for near. Spoor and Hiles reported an improvement in 54% of the patients from manifest tropia to latent deviation at distance and 50% showed an improvement from manifest tropia to latent deviation at near. Four patients experienced conversion from an initial latent exodeviation to manifest exodeviation as a result of occlusion therapy. Spoor and Hiles concluded that occlusion therapy in infants and young children decreases the size and constancy of the exodeviations and improves the fixation reflex which results in a maintained fixation in either eye. However Spoor and Hiles included 3 postsurgical subjects, a subject with aniridia, a subject with ocular albinism with nystagmus and 4 subjects with developmental neurologic delay. The authors also did not perform statistical analysis.

Reynolds and Wackerhagen (1988) studied 25 IXT patients under 26 months of age including neurologically normal and abnormal subjects. Of the original cohort, 16 patients completed at least 3 months of part-time occlusion successfully. Reynolds and Wackerhagen reported initial improvement in 4 of their 16 patients and only one (6%)

achieved a persistent improvement in angle size and pattern. The small sample size, poorly-defined success criteria and lack of statistical analysis were all limitations of the Reynolds and Wackerhagen study. The inclusion of neurologically affected subjects was another limitation of this study as patients are unable to cooperate or communicate with the examiner and the outcomes were only objective, not subjective.

Freeman and Isenberg (1989) investigated the effect of part time occlusion therapy for early onset unilateral exotropia, intermittent or constant exotropia, on a series of 11 patients aged between 9 months to 5 years. Treatment was applied to the non-deviating eye for 4 to 6 hours per day. Initial follow-up was after 3 to 6 weeks and then adjusted according to each patient's needs. Freeman and Isenberg reported that 27% of the patients became orthophoric and 27% of the patients underwent surgery for exotropia because they were unresponsive to occlusion therapy. The remaining patients (45.5%) had asymptomatic exophoria at last visit. Freeman and Isenberg concluded that part-time occlusion therapy for preschool patients with predominantly unilateral exotropia can postpone surgical intervention and convert exotropia to exophoria or orthophoria. A clear methodology and treatment regimen was provided in the Freeman and Isenberg study. A larger sample size would have strengthened the outcomes of their study. Additionally, only one investigator was responsible of all measurements and fixation patterns which may have biased the results. Freeman and Isenberg did not perform an organized, consistent follow up for each patient which may have caused variation and conflicting results. Freeman and Isenberg depended on deviation angle measurements only as an improvement measure and neglected to assess stereopsis, fusional amplitudes and control.

Berg, Lozano and Isenberg (1998) prospectively studied 29 patients with IXT. Part time occlusion of 6 hours/day for the preferred eye was applied for a maximum of 4 – 8 weeks. Patients were then followed-up every 4 – 8 weeks to a maximum of 120 months. Berg et al. divided the patients into two groups according to treatment outcome, group A in which patients were controlled with occlusion, and group B in which patients failed to obtain a good response to occlusion and underwent surgery. Berg et al. (1998) found that in group A, the deviation decreased from mean 20.9 prism diopters to 9.2 prism diopters at distance (56%), which was a significant decrease (P= 0.0005), and from 8.2 prism diopters to 1.9 prism diopters at near (77%). Berg et al. found that the interval between the onset of IXT and initiating occlusion therapy was longer in the group of patients who eventually underwent surgery (group B). Group B also had an earlier onset of exotropia. Based on these observations, Berg et al. considered the interval between the onset of deviation and the initiation of treatment as an important factor. It has been suggested that group B had a deeper scotoma thus the occlusion therapy may have not been as effective as in group A. Berg et al. concluded that occlusion can be curative or at least postpone surgery in unilateral IXT and aid in establishing better binocularity preoperatively.

Figueira and Hing (2006) investigated treatment options for IXT including surgical and non-surgical modalities, dividing their sample into four groups according to the treatment they received; group 1: surgery with orthoptic/occlusion therapy, group 2: surgery alone, group 3: orthoptic/occlusion therapy and group 4: observation. Patients were observed for a total of four follow-up visits at 6 months, 1 year, 2 years and 5 years. The purpose of the Figueira and Hing's retrospective study was to identify the most successful form of treatment for a cohort of 150 IXT patients. Figueira and Hing defined

success based on the motor alignment for distance and near (orthophoria or < 10 PD esotropia), near stereopsis (Lang stereotest) and cosmesis (based on the parent/guardian impression). They concluded that surgery in addition to occlusion therapy had the highest success rate and that preoperative orthoptic therapy probably prepares the motor and sensory systems to maintain postoperative binocular alignment more effectively than surgery alone. However, the success observed in patients treated by occlusion therapy alone was 6% (3/50), 8.57% (3/35), 5.26% (1/19) and 0% (0/5) at 6 months, 1, 2 and 5 year follow-up, respectively. Also, Figueira and Hing did not clearly illustrate the treatment regimen for occlusion therapy or the patient compliance over the five year study period. Additionally, one investigator performs all measurements during the follow-up visits which may have biased the clinical assessment. The lack of the significant differences indicated the need for a larger sample size within the subgroups and prospective comparison of each treatment. The long term follow-up of the Figueira and Hing study was an advantage.

Suh, Kim, Lee & Cho (2006) evaluated the effect of part-time occlusion therapy on basic IXT and convergence insufficiency IXT. Their study included 70 patients who underwent 3 hours of daily patching for the non-deviating eye for 3 continuous months. Suh et al. (2006) found that part-time occlusion therapy resulted in a significant reduction of the deviating angles at near and distance. Post-patching evaluation showed that 32% of the basic type IXT patients converted to pseudo-divergence excess type and 69% of the convergence insufficiency type patients converted to the basic type. This indicates that the near angle improved more than the distance angle. However, this correlation requires further study with long-term follow-up to determine if the change is transient. In addition

Suh et al. performed only one follow-up visit to assess the changes in measurements of the deviation after occlusion therapy, which is insufficient to evaluate effectiveness in IXT. Suh et al. did not monitor patient compliance during the three months of therapy. Additionally Suh et al. did not show the effect of the treatment on stereopsis and control of the deviation.

2.3 Summary and Critical Analysis of the Literature

As outlined in the sample studies above, many previous studies had unclear methodology, a poorly-defined schedule for occlusion therapy or poorly-defined success criteria. In addition, patient compliance was not monitored in many studies as investigators mostly relied on general monitoring, by parents, which may be inaccurate. There were significant intervals between follow-up visits in some studies which may have reduced patient cooperation. In addition, long intervals between visits caused some patients to convert into constant exotropia as reported by Spoor and Hiles (1979) mostly because of patching. Many studies focused on the deviation angle as the only variable of the study. However, occlusion therapy affects other important variables such as control, amplitudes and stereopsis, that are of clinical importance and that warrant investigation.

2.4 Positioning Current Study in Reference to the Literature

In the current study, we provide a detailed schedule of occlusion therapy and clear success criteria for all the variables that were investigated. A calendar was provided to each family to facilitate easier and more accurate monitoring of daily patching compliance. The use of a calendar mitigated the need to rely on the parent's rough recollection during each follow-up visit. A clear schedule of follow-up visits was planned with adequate duration of occlusion to assess the effect of therapy without risking

occlusion amblyopia or decompensated manifest exotropia. Lastly, the interval between follow-up visits was short to keep patients motivated so that we could immediately address any questions or concerns that may arise during the study.

CHAPTER 3: METHODOLOGY

3.1 Research Design

A clinical, prospective cohort pilot study was performed. Thirty-six children were initially enrolled and 21 (58%) of them were able to complete the study. The 21 children were from 4-10 years old and had untreated IXT. The angle of the deviation and the child's ability to control the deviation were measured and compared before, during and after occlusion therapy. The before and after test results were statistically analyzed in order to assess the effectiveness of occlusion therapy on IXT.

3.11 Research Questions and Hypothesis

1. Does occlusion treatment decrease the magnitude of deviation in IXT at near and distance by a minimum of 50%?
2. Does occlusion treatment increase fusional amplitudes in IXT to within normal range at near and distance?
3. Does occlusion treatment increase stereopsis in IXT to within normal range at near and distance?

Additional research question: Are the benefits of treatment stable one month after cessation of treatment?

The primary outcome measure is the change in the magnitude of deviation at distance in IXT. We define a minimum 50% decrease of the deviation at distance as the success criterion of occlusion treatment.

3.12 Rationale for Chosen Methods

A prospective study was chosen as it is the most powerful way to demonstrate results of a treatment. Difficulty with patient recruitment limited us to a pilot study. A review of

the literature showed most studies were retrospective in nature and we believe that a prospective design is more valuable in terms of results and methods. We do not have a control group because of the difficulty we face with recruiting patients as the numbers of IXT patients who fit our inclusion criteria is relatively small. The investigator is also aware of the limitations that are caused by the fact that she is the only person to provide patient care during this investigation.

The children were given occlusion therapy by wearing an eye patch alternately on either eye for 6 hours/day each day. This was chosen because no prescribed international guideline or standard for this treatment exists so the intervention chosen was based on clinical standards and experience in Halifax and Saudi Arabia. It was decided to follow this standard intervention for the part time occlusion.

The clinical tests were chosen based on clinical experience to evaluate the sensory and motor status of every patient at each visit. Tests were performed by the primary investigator using a specific sequence, starting with the least dissociating tests to ensure there was no loss of fusion at the onset of evaluation. The sequence of the tests is presented in section 3.33.

3.13 Success Criteria

Success criteria in this study are:

- The decrease of the deviation angle at distance by at least 50%.
- The decrease of the deviation angle at near by at least 50%.
- Improvement to 40 seconds of arc for near stereopsis and 60 seconds of arc for distance stereopsis.

- Improvement to a minimum of 35 prism-diopters for near base-out fusional amplitudes and a minimum of 20 prism-diopters for distance base-out fusional amplitudes (Wright & Spiegel, 2003).
- Improvement of binocular visual acuity to 20/20 (0 Log MAR) or better.
- Improvement to the rate of 0 or 1 for the total control score scale. The scoring system of the control scale is explained in section 3.33 of this chapter.

The success criteria were evaluated at the time of the last assessment which is the fifth visit. This provided at least some data regarding a trend towards long term effectiveness as it is the longest period from the start point of the treatment in our study.

3.2 Cohort

3.21 Study Population

Pediatric Ophthalmology and Orthoptic clinics at King Khaled Eye Specialist Hospital (KKESH) and King Abdulaziz University Hospital (KAUH) were asked to identify potential participants based on the inclusion/exclusion criteria. The Medical Records Department screened charts/records for patients who met the inclusion/exclusion criteria. When a potential participant was identified, the patient's name and hospital record number were forwarded to the principal investigator. The principal investigator, who has access to patient clinical data through her position in the clinic, then re-reviewed the charts for compliance with the inclusion/exclusion criteria. Patients who met the required criteria had their names and contact information forwarded to the Research Office at KKESH and KAUH to contact the candidate by telephone. The Research Office representative did not have access to patient clinical data, but called the parent/caregiver, provided the topic of the study and asked if they were interested in having their child

participate. The research officer provided a detailed explanation of the study, and verbally clarified the patient information sheet, the purpose of the study, description of the research and provided all information regarding number of clinical visits and occlusion therapy; risks and confidentiality were also explained. The participant's parents/caregivers were thus well-informed prior to making a decision to participate. Upon consent of the potential participant's parent/caregiver, an appointment was booked with the principal investigator at the research clinic of the hospital.

3.22 Inclusion Criteria

- Diagnosed near and/or distance IXT. Deviation can be constant at distance if near deviation is intermittent or phoric.
- A deviation of at least 8 PD of distance angle.
- Age range 4 – 10 years.
- Visual acuity at least 20/40 (0.3 Log Mar) for each eye.
- Patients diagnosed as emmetropic, myopic, hyperopic (maximum +1.00 DS either eye) or astigmatic and fully corrected.
- Patients with no history of previous ocular treatment including amblyopia treatment
- Patients who live in Riyadh, Saudi Arabia.

3.23 Exclusion Criteria

- Patients with any mental disability and/or neurological impairment.
- Patients with any coexisting ocular pathology.
- Patients with limitations of ocular rotations due to paretic or restrictive strabismus.
- Patients with manifest or latent nystagmus.

- Patients with convergence insufficiency IXT type because distance deviation angle is a primary outcome measure.

- Patients who underwent previous strabismus surgery.

- Patients with unilateral or bilateral or significant bilateral ametropic amblyopia, visual acuity has to be at least 20/40 (0.3 Log Mar).

- Patients with subjective diplopia in any gaze.

3.24 Sample Size

A clinical prospective pilot study was performed. Thirty six children were enrolled aged 4 years to 10 years. Twenty-one patients completed the study and 15 patients failed to follow-up. Lack of early childhood screening programs in Saudi Arabia limits the available number of patients with IXT due to late referral resulting in progression to constant exotropia.

3.25 Participants

Participants were children 4-10 years of age, presenting with IXT with no previous ocular treatment except for the correction of the refractive errors. All participants lived in Riyadh to allow easy access to the clinic at KKESH and KAUH. The age group selected was based on sufficient cooperation with testing procedures, yet still visually immature so as to minimize the risk of producing intractable diplopia.

3.26 Risks Analysis

Occlusion therapy is one of the routine therapies that patients with IXT may be assigned. While there are some risks associated with this therapy, such as occlusion amblyopia and intractable diplopia, these risks would be the same for standard clinical care and are not specific to participation in this research study.

The Pediatric Ophthalmology Department was responsible for seeing patients who might experience complications and this would be through direct referral from the research clinic. This treatment was free for research patients as it is for all KKESH and KAUH regular patients. Letters of cooperation from pediatric ophthalmology heads in both KKESH and KAUH were signed.

3.27 Benefit Analysis

Subjects who met the inclusion criteria were treated with occlusion therapy, one of several treatment methods utilized for antisuppression management of IXT. These patients had the advantage of receiving treatment sooner than average clinic patients. They received four monthly follow-up appointments unlike regular patients to both KKESH and KAUH who usually have delayed appointments and long waiting periods due to the high patient load and long waiting lists.

3.28 Ethical Considerations

Personal clinical data regarding the visual function of the children participating in the study were collected. Recording of patient data in hospital medical records even for research purposes is obligatory according to KKESH and KAUH policy. Data was recorded directly onto a data collection sheet at the time of testing and subjects were identified by an ID study number. A separate master list linked study ID numbers with patient medical record numbers. The master list and data sheets were stored in a locked filling cabinet in the research department at KKESH. Records could only be accessed by the principal investigator, research assistant, co-supervisors and regulatory authorities for the conduct of research at the hospitals involved. On completion of the study, records

were placed in locked storage within the research department and remained on file indefinitely, according to the policy of the hospital.

This study required four follow-up visits by each participant. Clinical data was anonymous to the investigator at the time of the visit for the four months of their participation but data were known to the investigator later on for analysis. During the analysis stage participants were referenced by study identification number only. No participant was named or identified in any presentation or publication of the research results or data.

3.281 Informed Consent

All research participation visits were conducted by the principal investigator. The initial visit provided the participant with a detailed description and the reasons for the study, the potential risks, benefits and requirements, that participation was voluntary and that the patient could choose to withdraw at any stage during treatment. The subject's parent/caregiver was given a copy of the patient information sheet and consent form to read and was allowed to ask any questions and clarify any concerns. If the subject and parents were willing to participate, the parent/caregiver was required to sign the consent form.

At this stage, the researcher explained the process to the participating child using the child's assent script, thus gaining the child's assent. At each follow-up visit the researcher reminded the parent/guardian and the child of the research involved at each visit and how many visits remained. The researcher needed to secure that both parent/guardian and child remained willing to participate at each visit. The researcher verbally asked for continued consent from the parent/caregiver and assent from the child.

If consent was withdrawn at any visit or the patient failed to attend appointments after being contacted by the principal investigator, the child was removed from the study and this happened in 15 cases due to failure in attending their booked appointments.

3.3 Experimental Procedures

3.31 Methodology

All subjects were patients of either KKESH or KAUH, both in Riyadh, Saudi Arabia. Patients selected to participate were examined and followed up at KKESH or KAUH, whichever hospital the subject was already attending.

The consulting rooms at both hospitals had the standard 6 meter exam lanes and were fully equipped for orthoptic and ophthalmic examination. Privacy during examination was maintained at all times.

Participants were asked to undergo a series of vision and binocularity tests. All ocular tests were non-invasive and required no medication or eye drops. All of the tests were standardized tests used routinely in ophthalmic and orthoptic clinics at KKESH and KAUH. Occlusion therapy began after the first assessment, which required the subjects to wear an adhesive eye patch alternatively over either eye for an average of half the child's waking hours per day, which is approximately 6 hours/day. Occlusion therapy continued for three months, with follow-up assessments every month. After three months of occlusion therapy with good compliance, the occlusion was discontinued. A final assessment was performed after one month of discontinuing the treatment. Longer follow-up was not possible due to the lack of time the principal investigator had to accomplish this study and difficulties with patient recruitment.

This study differs from standard care in that more thorough visual assessments were performed and there were more frequent follow-up visits.

It is also important to note that effectiveness of the treatment is dependent on subject compliance with occlusion therapy. Subjects were given a calendar (Figure 1) to take home and the parents/caregivers were asked to record the number of hours of daily occlusion and return the calendar to the principal investigator at each follow up visit. This calendar aided in compliance with treatment and provided an approximation of compliance for utilization during data analysis.

Patient's code:

Year of treatment:

Jan.2010	Sun	Mon	Tue	Wed	Thu	Fri	Sat
Patched eye:		-	-	-	-	1	2
Patching hours: (total hours)							
Patched eye:	3	4	5	6	7	8	9
Patching hours: (total hours)							
Patched eye:	10	11	12	13	14	15	16
Patching hours: (total hours)							
Patched eye:	17	18	19	20	21	22	23
Patching hours: (total hours)							
Patched eye:	24	25	26	27	28	29	30
Patching hours: (total hours)							
Patched eye:	31	-	-	-	-	-	-
Patching hours: (total hours)							

Figure 1. Example of the January monthly calendar that was provided to the subject's parent/caregiver to record the duration of patching (hours) and the eye patched on each day of the month for the purpose of monitoring the compliance to occlusion therapy.

3.32 Experimental Apparatus

All measurements were performed by the principal investigator to maintain consistency. Bias was mitigated by masking the data of the previous visit from the principal investigator at each return visit. Assessment of the various visual functions was performed using standardized clinical tests with a standardized testing protocol. In addition, a standardized consistent testing format was used and is explained in section 3.33 of this chapter.

3.33 Clinical Tests

Patients' testing was performed in a standardized manner to minimize dissociation of the eyes. The following was the testing order:

After history taking, the investigator performed the near stereoacuity test (40 cm) with the Titmus test (manufacturer Stereo Optical, Chicago IL) that grades the near stereoacuity from 3000 seconds of arc to 40 seconds of arc using Polarized lenses. Subsequently, the distance stereoacuity test was performed at 6 meters using the vectograph test (manufacturer Stereo Optical, Chicago IL), with Polarized lenses in place. The vectograph test grades the distance stereoacuity from 240 seconds of arc to 60 seconds of arc (240, 180, 120 and 60 seconds of arc). Dimmed room illumination was used for stereoacuity testing at distance and normal room illumination for near testing. Principal investigator watched for dissociation under the polarized glasses while testing the patient. The investigator then performed the base-out fusional amplitudes test for near (40 cm) then for distance (6m) with the horizontal prism bar asking the patient to focus on a Lang fixation stick at near and a 0.3 LogMar target size (20/40) at distance and the patient's break point was recorded. The binocular visual acuity test (BVA) was then

performed at distance (6 m) with both eyes opened to measure the control of the patient using the Snellen chart with the full letters line displayed (all letters in each acuity line are displayed). Each patient was asked to read the lines starting from a 1.3 LogMar letter size (20/400) moving gradually to smaller lines while the investigator was watching the alignment and the control of the eyes. Once the patient broke his/her fusion and one of the eyes drifted out, the line he/she reached was recorded as the measure for the BVA and then was converted to LogMar for analysis purposes. Deviation was measured at distance (6m) followed by near (40 cm) measurement using the prism bar or lose prisms and occluder. Lang fixation stick was used at near and a 0.3 LogMar target size at distance (20/40). Alternate prism cover testing was used to assess the deviation at both near and distance. Monocular visual acuity was evaluated at distance starting with the right eye and followed by the left eye using the Snellen test and occluder. Patients were asked to distinguish the letters monocularly and the last line they recognize was recorded as the visual acuity of that eye. Visual acuity measures were then converted from feet to LogMar for statistical analysis. The control score scale was then recorded for near and distance after all previous testing and VA where the patients were given a break of few minutes before assessing the control score scale to regain fusion. Control score scale was assessed by the office based scale as described by Mohney and Holmes (2006). This scale was applied to each patient for both distance (6m) and near (40 cm) fixation. The sum of both distances results gave an overall control score ranging from 0 to 10. Levels 3 to 5 were assessed by observing the patient for the initial 30 seconds of the test for near and distance. If no score was recorded for the first 30 seconds, levels 0 to 2 were then assessed by three trials of 10 seconds of occlusion of either eye. The right eye was first

occluded for 10 seconds and then the occluder was removed and the length of recovery after uncovering the eye was recorded. The left eye was then occluded for ten seconds and the length of recovery after uncovering the eye was also recorded. A third trial of 10-second occlusion was performed on the eye that required the longest time to re-establish fusion. The worst level of control observed following the three 10-second trials was recorded as the score for that visit. The worst level of the three trials was defined by the longest duration that the eyes took to re-establish fusion.

Intermittent exotropia control scale scores definition:

5 = Constant exotropia

4 = Exotropia >50% of the 30-second period before dissociation

3 = Exotropia <50% of the 30-second period before dissociation

2 = No exotropia unless dissociated, recovers in >5 seconds

1 = No exotropia unless dissociated, recovers in 1–5 seconds

0 = No exotropia unless dissociated, recovers in <1 second (phoria)

The office based scoring system is not a routine tool but we felt it would be a useful additional tool to assess control as it can be easily applied and characterizes the wide range of control in intermittent exotropia.

All examinations were performed with full spectacle correction (of a full cycloplegic refraction). Cycloplegic refraction was performed for every patient at the screening clinic prior to the research clinic visit by a maximum of six months and spectacles were prescribed if necessary. Refraction then was performed at the optometry clinic by the principal investigator at the initial visit to the research clinic to ensure that there was no under-correction or over-correction of the myopia and astigmatism. If any under-

correction or over-correction was detected the principal investigator then compared it to the cycloplegic refraction and gave a prescription for spectacle correction as required. The maximum hyperopic correction that could be included in this study was +1.00 DS. The optometry clinic is close to the Orthoptic clinic in both hospitals, KKESH and KAUH. Spectacle power was measured at every visit with manual lensometry at the Orthoptic clinic by the principal investigator.

Types of patches used for therapy were Ortopad and Nexcare eye patches, both of which contained an adhesive and were hypoallergenic to allow application directly on the skin.

The treatment regimen of occlusion was 6 hours a day. Alternate occlusion therapy was applied to all patients even if there was dominant fixation or fixation preference. Patches were worn on alternate eyes on alternate days. Each patient was assessed at four consecutive month intervals during occlusion treatment plus reassessment after one month without occlusion treatment. Angle of deviation and quality of control were evaluated and recorded at each follow up visit.

The final assessment after one month without occlusion was used to assess whether the outcome remained stable or deteriorated over this short-term follow-up.

The primary end-point of the study was the last visit with patching, and the final follow-up visit after a month with no patching was designed to answer a secondary question: Are the benefits of treatment stable 1 month after cessation of treatment?

CHAPTER 4: RESULTS

4.1 Analysis Technique

Data were collected during the period from April 2009 to September 2010. A specific database was designed and all data were entered and stored into this database. Data were analyzed using SPSS software version 17.0 and MedCal version 8.0.

Descriptive and analytical statistics were performed. The Wilcoxon signed ranks test was used to compare means for successive follow-ups. General linear model analysis of variance (ANOVA) for repeated measures was used to determine differences between follow-up visits. A *P* value less than 0.05 was considered statistically significant.

Variables were analyzed to compare the results of the first visit to the second visit, the second visit to the third visit, the third visit to the fourth visit, the fourth visit to the fifth visit, the first visit to the fourth visit and finally, the first visit to the fifth visit. The results of the deviation measurements were analyzed differently because the mean prism diopter was measured for every visit and a comparison was performed to determine statistical significance. A *P* value less than 0.05 was considered statistically significant. Individual interpretation of the data was performed for more accurate analysis as each case was monitored individually throughout the five visits and an overall interpretation was made. Individual interpretation was thought to reflect a more accurate impression about the progression/regression of the data for the treatment duration. Table 1 presents the data of each subject for each visit.

Serial #	Visit #	Age	Sex	Stereopsis in sec. of arc		BOFA* In prism diopter		Deviation in prism diopter		BVA** in logMAR	VA		Control Score Scale		
				Near	Distance	Near	Distance	Near	Distance		OD	OS	Distance	Near	Total
1	1	9	Male	40	60	8	2	X***2	X(T)****16	0.3	0	0	1	0	1
	2			40	60	25	25	ortho*****	X(T)16	0.8	0	0	1	0	1
	3			40	60	40	30	X2	X(T)14	0	0	0	1	0	1
	4			40	60	30	25	ortho	X(T)14	0	0	0	1	0	1
	5			40	60	40	25	X2	X(T)10	0	0	0	1	0	1
2	1	6	Male	40	60	4	1	X(T)20	X(T)18	0.1	0	0	1	1	2
	2			40	60	16	20	X(T)6	X(T)14	0	0	0	1	1	2
	3			40	60	40	14	X(T)14	X(T)14	0	0	0	2	1	3
	4			40	60	30	16	X(T)8	X(T)12	0	0	0	1	1	2
	5			40	60	40	18	X6	X(T)12	0	0	0	1	0	1
3	1	10	Female	40	60	14	10	X(T)6	X(T)14	0	0	0	2	1	3
	2			40	60	20	18	X(T)14	X(T)14	0	0	0	3	2	5
	3			40	60	40	20	X(T)12	X(T)12	0	0	0	3	2	5
	4			40	60	40	25	X(T)10	X(T)10	0	0	0	1	1	2
	5			40	60	40	20	X(T)8	X(T)18	0	0	0	1	1	2
4	1	6	Female	40	180	18	1	X(T)25	X(T)16	0.7	0.1	0.1	4	2	6
	2			40	60	18	12	X(T)20	X(T)12	0	0.1	0.1	2	2	4
	3			40	60	30	6	X(T)20	X(T)10	0	0	0	2	2	4
	4			40	60	25	1	X(T)20	X(T)10	0	0	0	2	2	4
	5			40	60	30	1	X(T)14	X(T)14	0	0	0	1	0	1
5	1	9	Female	40	120	30	12	X(T)20	X(T)20	0.1	0.2	0.2	1	1	2
	2			40	120	40	16	X(T)18	X(T)14	0	0.1	0.1	1	1	2
	3			40	60	40	20	X(T)4	X(T)14	0.1	0.1	0.1	1	0	1
6	1	8	Male	40	180	40	30	Ortho	X(T)20	0.4	0	0	1	0	1
	2			40	60	35	30	Ortho	X(T)18	0.1	0	0	1	0	1
	3			40	60	40	35	Ortho	X(T)16	0	0	0	1	0	1
	4			40	60	40	35	Ortho	X 18	0	0	0	0	0	0
	5			40	60	40	40	Ortho	X 18	0	0	0	0	0	0
7	1	8	Female	40	0	1	1	X(T) 20	X(T) 20	1.3	0.2	0.1	4	1	5
	2			40	0	25	14	X(T) 6	X(T) 16	0.2	0.1	0.1	2	1	3
	3			40	180	40	30	X 4	X(T)14	0	0	0	1	0	1
	4			40	120	20	20	X(T)14	X(T)16	0	0	0	1	1	2
	5			40	60	40	25	X(T)10	X(T)14	0	0	0	1	0	1
8	1	10	Female	80	120	18	14	X(T)6	X(T)18	0.3	0.1	0	2	0	2
	2			50	60	16	10	Ortho	X(T)18	0	0	0	2	0	2
	3			40	60	40	14	Ortho	X(T)16	0	0	0	2	0	2
	4			40	60	25	14	Ortho	X(T)18	0	0	0	1	0	1
	5			40	60	40	20	Ortho	X(T) 14	0	0	0	1	0	1
9	1	9	Male	40	60	1	1	X(T)25	X(T)25	0.2	0.1	0.1	4	2	6
	2			40	60	18	12	X(T)14	X(T)18	0.3	0.1	0.1	3	1	4
	3			40	60	20	18	X(T)12	X(T)14	0.2	0.1	0.1	2	1	3
	4			40	60	35	18	X(T)16	X(T)14	0	0	0	2	1	3
	5			40	60	40	18	X(T)16	X(T)16	0	0	0	1	1	2
10	1	7	Male	400	0	1	1	X(T)35	XT30	1.3	0	0	5	4	9
	2			200	0	35	14	X(T)14	X(T)18	0.2	0	0	2	1	3
	3			40	0	35	16	X(T)8	X(T)14	0	0	0	1	1	2
	4			40	240	30	18	X(T)8	X(T)10	0	0	0	2	0	2
	5			40	180	16	12	X(T)8	X(T)8	0.1	0	0	3	0	3
11	1	10	Female	40	0	25	6	X(T)25	X(T)25	0.1	0.1	0	2	1	3
	2			40	240	25	20	X2	X(T)16	0.1	0	0	1	0	1
	3			40	60	40	30	Ortho	X(T)14	0	0	0	1	0	1

Serial #	Visit #	Age	Sex	Stereopsis in sec. of arc		BOFA* In prism diopter		Deviation in prism diopter		BVA** in logMAR	VA		Control Score Scale		
				Near	Distance	Near	Distance	Near	Distance		OD	OS	Distance	Near	Total
	4			40	60	40	30	Ortho	X(T)12	0	0	0	1	0	1
	5			40	60	25	25	X8	X(T)18	0	0	0	1	0	1
12	1	10	Male	40	120	1	1	X(T)18	X(T)18	0.4	0	0	3	1	4
	2			40	60	25	6	X(T)16	X(T)18	0	0	0	1	1	2
	3			40	60	40	6	X(T)12	X(T)12	0	0	0	1	0	1
	4			40	60	40	16	X6	X(T)12	0	0	0	0	0	0
	5			40	60	40	14	X(T)10	X(T)18	0	0	0	1	1	2
13	1	6	Male	40	180	25	12	X6	X(T)12	0.1	0.1	0.1	1	0	1
	2			40	60	25	30	ortho	Ortho	0	0	0	0	0	0
	3			40	60	30	25	ortho	Ortho	0	0	0	0	0	0
	4			40	60	30	20	ortho	Ortho	0	0	0	0	0	0
	5			40	60	25	16	X4	X2	0	0	0	0	0	0
14	1	10	Female	100	60	1	14	X(T)8	X(T)20	0	0	0	1	1	2
	2			80	60	20	30	X(T)8	X(T)16	0	0	0	1	0	1
	3			40	60	35	30	X(T)8	X(T)16	0	0	0	1	0	1
	4			40	60	40	35	X8	X(T)16	0	0	0	1	0	1
	5			40	60	40	40	X6	X(T)16	0	0	0	1	0	1
15	1		Female	100	0	20	1	X(T)20	X(T)20	1.3	0.1	0.1	4	2	6
	2			40	240	30	16	X(T)12	X(T)16	0.3	0.1	0.1	2	1	3
	3			40	60	35	16	X4	X(T)8	0.2	0.1	0.1	0	0	0
	4			40	60	40	18	Ortho	X(T)12	0.1	0.1	0.1	1	0	1
16	1	8	Female	50	120	8	1	X(T)4	X(T)8	0	0	0	1	1	2
	2			40	60	25	20	X2	X(T)6	0	0	0	1	0	1
	3			40	60	14	20	X4	X(T)8	0	0	0	1	0	1
	4			40	60	30	25	X2	X(T)6	0	0	0	0	0	0
	5			40	60	40	25	X6	X(T)8	0	0	0	1	0	1
17	1	7	Male	140	120	25	1	X(T)6	X(T)30	0.5	0	0	4	1	5
	2			50	60	25	12	X(T)6	X(T)30	0.1	0	0	3	1	4
	3			50	60	18	2	X(T)6	X(T)30	1.3	0	0	4	1	5
	4			50	60	30	1	X10	X(T)25	0	0	0	4	0	4
	5			40	60	40	4	X(T)6	X(T)35	0	0	0	4	0	4
18	1	10	Male	140	120	20	10	X(T)12	X(T)20	0	0	0	1	1	2
	2			40	60	35	16	X(T)12	X(T)25	0	0	0	1		2
	3			40	60	40	35	X(T)10	X(T)20	0	0	0	1	1	2
	4			40	60	40	35	X8	X(T)18	0	0	0	1	0	1
	5			40	60	40	35	X4	X(T)20	0	0	0	2	0	2
19	1	10	Female	50	120	35	1	X6	X(T)20	0.4	0	0	2	0	2
	2			50	120	40	14	ortho	X(T)20	0	0	0	2	0	2
	3			40	60	40	20	ortho	X(T)16	0	0	0	2	0	2
	4			40	60	30	16	ortho	X(T)16	0	0	0	2	0	2
	5			40	60	35	12	ortho	X(T)20	0	0	0	3	0	3
20	1	8	Male	100	240	30	20	X(T)12	X(T)25	0	0	0	2	1	3
	2			40	180	35	10	Ortho	X(T)25	0	0	0	2	0	2
	3			40	60	40	25	Ortho	X(T)20	0	0	0	1	0	1
	4			40	60	40	25	Ortho	X(T)30	0	0	0	1	0	1
	5			40	60	35	20	Ortho	X(T)30	0	0	0	1	0	1
21	1	9	Female	40	180	20	2	X(T)25	X(T)25	0	0	0	4	2	6
	2			40	120	25	8	X(T)16	X(T)16	0	0	0	1	1	2
	3			40	60	25	1	X(T)16	X(T)16	0	0	0	1	1	2

Table 1. Individual patient data over five follow up visits. *BO/FA: base-out fusional amplitudes **BVA: binocular Visual Acuity.***X: exophoria. ****X(T): intermittent exotropia. *****Ortho: orthophoria

Success treatment for the size of the deviation was indicated by a 50% decrease in the deviation angle at near and distance. This number was chosen based on the clinical experience of the supervisory committee of this project, and was chosen based on a pilot project of 18 patients with varying angles of strabismus ranging from 8 – 30 PD. Success for stereopsis at near was 40 seconds of arc, for stereopsis at distance success was 60 seconds of arc both of which are considered within the normal range. Success for base-out fusional amplitudes at near was 35 PD and 20 PD for distance which are considered within the normal range (Wright & Spiegel, 2003). Success for binocular visual acuity was 0 LogMAR (20/20) or better. Success for the control score scale was a rating of 0 or 1 for the distance and near control score separately.

Thirty-six IXT patients were enrolled in this study; fifteen patients did not attend after the first follow-up visit and were therefore excluded from the study. Twenty one patients attended most of the follow-up visits as three of them did not complete the full duration of therapy and failed to attend follow-up visits at the second or third follow-up visits while the remaining eighteen patients were success to complete the treatment duration and attended all follow-up visits. Eleven of the twenty-one patients were females (52%) and 10 were males (48%). The mean age of the patients was 8.50 ± 1.47 years (mean ± standard deviation) as the minimum age was 6 years and the maximum age was 10 years. The mean age of onset of the IXT was 4.7 years and the standard deviation was 1.59 ranging from 2 years to 7 years as determined by parents questioning during history taking. The spherical equivalent of the refractive errors of the selected patients showed 10 emmetropic patients (47.6%), 2 hyperopic patients (9.5%) and 9 myopic patients

(42.8%). The spherical equivalent ranged from - 3.80 D to + 0.37 D in the right eye and from -3.75 D to + 0.25 D in left eye (Table 2).

variable	Mean	Standard Deviation	Min. range	Max. range
Age	8.50	1.47	6.00	10.00
Age of onset	4.70	1.59	2.00	7.00
OD SE	-1.25	1.30	-3.80	0.37
OS SE	-1.29	1.24	-3.75	0.25

Table 2. Cohort demographics and refractive error of intermittent exotropes who underwent occlusion therapy.

4.2 Deviation Analysis

For our 21 cases, eighteen patients completed the full duration of treatment. For deviation interpretation at distance, two patients reached the set success criterion (11 %) where deviation decreased by 50% at the completion of the treatment in their fifth visit (case 10 and 13). Sixteen (88.8 %) of the 18 patients did not reach the set success criterion of 50% reduction in deviation, with 25% of them having the same deviation measurements from the first visit until the last visit (cases 12, 16, 18 and 19) and 18.7 % had an increase of their distance deviation by 5 PD (cases 3, 17 and 20). The remaining nine patients (56%) of the sixteen cases showed a decrease in their deviation measurements between 2 – 9 PD but attained less than 50% measurement decrease and therefore were not considered successful (cases 1, 2, 4, 6, 7, 8, 9, 11 and 14). The three patients who did not complete the full duration of treatment (cases 5, 15 and 21), did not reach the set success criterion of 50% reduction in deviation but deviation measurements at distance did decrease by 6, 8 and 9 PD for cases 5, 15 and 21 respectively. Cases 6 and 13 had an exophoria at distance in the last visit of the treatment. The success rate for the decrease size of deviation at distance of the four follow-up visits was 4% (1/21), 14% (3/21), 15.7% (3/19) and 11% (2/18) for the second visit, third visit, fourth visit and fifth visit respectively (Figure 2).

For deviation interpretation at near, 44.4% of the eighteen patients who completed their treatment duration were successful, whereby the deviation decreased by 50% at their last visit compared with the first visit (cases 2, 7, 8, 10, 11, 18, 19 and 20). However, 55.5% of the eighteen patients did not reach the set success criterion of 50%, and 33% measured the same as what they started with (cases 1, 6 and 17). Two cases had

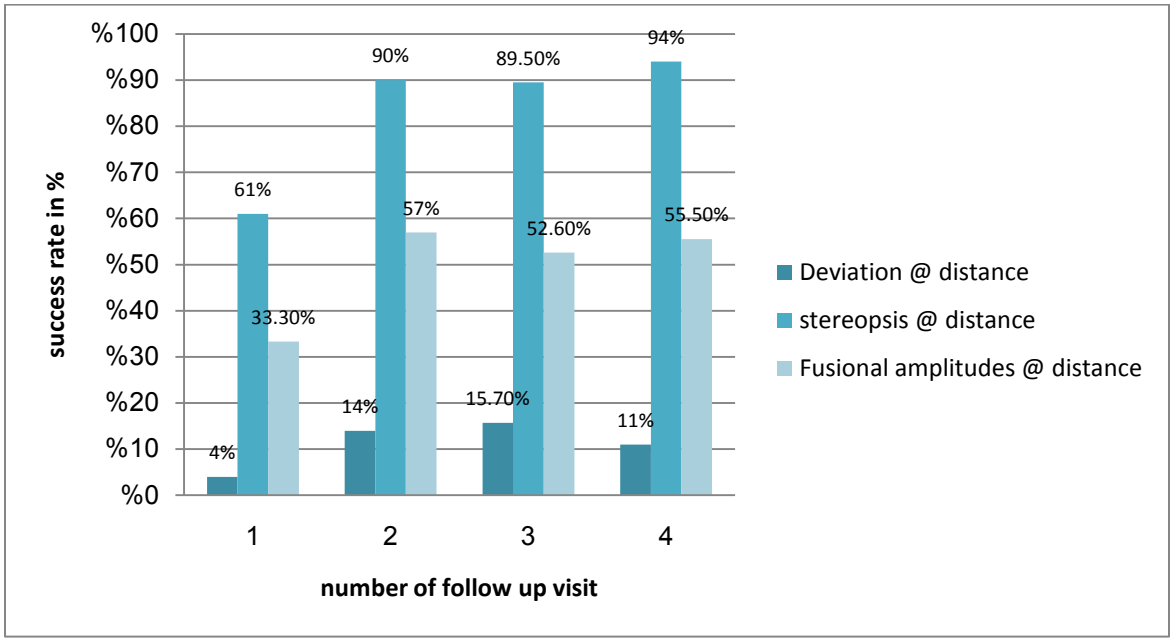

Figure 2. The change in success rate from one visit to the successive visit for deviation at distance, distance stereopsis and base-out fusional amplitudes at distance of intermittent exotropes who underwent occlusion therapy.

an increase of 2 PD (case 3 and 16) although case 16 improved to exophoria. The remaining cases of the 55.5% (no successful cases) had a decrease in their near deviation measurements but not to the range of the set success criterion (cases 4, 9, 12, 13 and 14). Of the three patients who did not complete the full duration of treatment, two were successful (cases 5 and 15) indicated by decreases in near deviation of 16 and 20 PD respectively. However, treatment for case 21 was not successful as the patient did not reach the set success criterion of 50%. Cases 1, 2, 6, 8, 11, 14, 16 and 18 had exophoria at last visit although cases 1 and 6 had an exophoria at first visit as well.

Deviation at near and distance was analyzed in the five visits and the mean value was measured at each visit. The mean deviation at distance at the first visit (before treatment commenced) was 20 PD (range, 8 PD to 30 PD) (Table 3). The mean deviation at the fourth visit (after treatment was completed) was 13.9 PD (range, orthophoria to 30 PD). There was a significant improvement between the first and fourth visits ($P = 0.001$) but the average improvement was below the expected rate of 50%. The mean deviation at the fifth visit (after treatment discontinuation) was 16.2 PD (range, 2 PD to 35 PD) (Figure 3). There was a significant improvement between the first and fifth visits ($P = 0.025$) but a comparison of visits 4 and 5 shows that on average, there was a decline in the achieved rate of improvement in distance deviation.

The mean deviation at near for the first visit (before treatment was applied) was 14.3 PD (range, orthophoria to 35 PD) (Table 4). The mean deviation at near for the fourth visit (after treatment was completed) was 5.8 PD (range, orthophoria to 20 PD). There was a significant improvement between the first visit and the fourth visit ($P = 0.001$).

The mean deviation at near for the fifth visit (after treatment discontinuation) was 6 PD (range, orthophoria to 16 PD) (Figure 3). There was a significant improvement between the first visit and the fifth visit ($P = 0.002$).

Deviation at distance				
Visit number	**Mean (prism diopters)**	**Standard Deviation (prism diopters)**	**Minimum (prism diopters)**	**Maximum (prism diopters)**
1	20.0	5.4	8	30
2	16.0	7.0	0	30
3	14.2	5.7	0	30
4	13.9	6.6	0	30
5	16.2	7.6	2	35

Table 3. Deviation measurement changes (at distance) for all five follow-up visits of intermittent exotropes who underwent occlusion therapy.

Deviation at near				
Visit number	**Mean (prism diopters)**	**Standard Deviation (prism diopters)**	**Minimum (prism diopters)**	**Maximum (prism diopters)**
1	14.3	9.7	0	35
2	7.9	7.0	0	20
3	6.5	6.1	0	20
4	5.8	6.3	0	20
5	6.0	4.7	0	16

Table 4. Deviation measurement changes (at near) for all five follow-up visits of intermittent exotropes who underwent occlusion therapy.

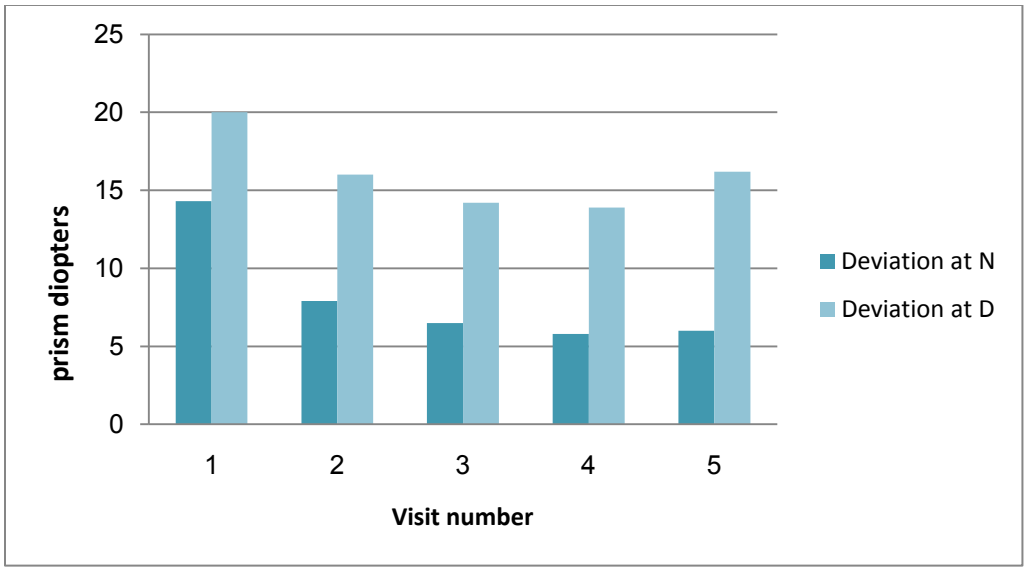

Figure 3. The mean deviation angle measurements at near and distance throughout the five follow-up visits of intermittent exotropes who underwent occlusion therapy.

4.3 Stereopsis Analysis

Stereopsis was interpreted for near and distance for the five visits (Table 1). For near stereopsis there was no room for improvement as 10 cases of the 18 (55.5%) started with normal near stereopsis (40 seconds of arc). For the remaining three cases, (patients who did not complete their treatment duration), two started with normal stereopsis (cases 15 and 21) and the third case started with 100 seconds of arc. All the twenty one cases improved to 40 seconds of arc at their last visits.

For distance stereopsis, five (27.7%) of the eighteen patients had normal stereopsis of 60 seconds of arc at first visit. Six (33.3%) of the eighteen patients had 120 seconds of arc at first visit. Three (16.6%) of the eighteen patients had 180 seconds of arc at first visit. Distance stereopsis was 240 seconds of arc for one (5%) of the eighteen patients at first visit. Three (16.1%) of the eighteen patients began with a 0 measurement. One patient with a 0 score on distance stereopsis progressed to 180 seconds of arc without further improvement (case number 10). The remaining seventeen patients progressed to normal stereopsis providing a success rate of 94.4% for patients who completed the full duration of treatment. Cases 5, 15 and 21 who did not complete their treatment, began with 120, 0, 180 seconds of arc respectively and all reached 60 seconds of arc at last visit. The success rate for stereopsis at distance of the four follow-up visits was 61% (1/21), 90% (19/21), 89.5% (17/19) and 94% (17/18) for the second visit, third visit, fourth visit and fifth visit respectively (Figure 2).

Stereopsis was analyzed at distance and near for the five consecutive visits. The mean near stereopsis for the first visit was 78.10 ± 81.16 seconds of arc and 40 ± 0.0 seconds of arc at the fifth visit (Table 5) (Figure 4). Individual interpretation showed no room for

improvement for near stereopsis in 10 of 21 cases. There was a significant difference in mean near stereopsis between the first and second visits ($P = 0.012$), the first and fourth visits ($P = 0.007$) and the first and fifth visits ($P=0.011$) (Table 6). The general linear model ANOVA for repeated measures showed statistical significance for near stereopsis ($P=0.008$).

The mean distance stereopsis at first visit was 100 ± 69.28 seconds of arc and was 66.7 ± 28.3 seconds of arc for the fifth visit (Figure 4) (Table 7). There were no significant changes in distance stereopsis between any of the other visits ($P>0.05$, all comparisons) (Table 8). The general linear model ANOVA for repeated measures was not statistically significant for distance stereopsis ($P= 0.251$). There was a 94.4% success rate for distance stereopsis.

Stereopsis at near		
Visit number	Mean (seconds of arc)	Standard deviation
1	78.10	81.16
2	50.95	35.34
3	40.5	2.2
4	40.5	2.3
5	40.00	0.00

Table 5. Near stereopsis over five follow-up visits of intermittent exotropes who underwent occlusion therapy.

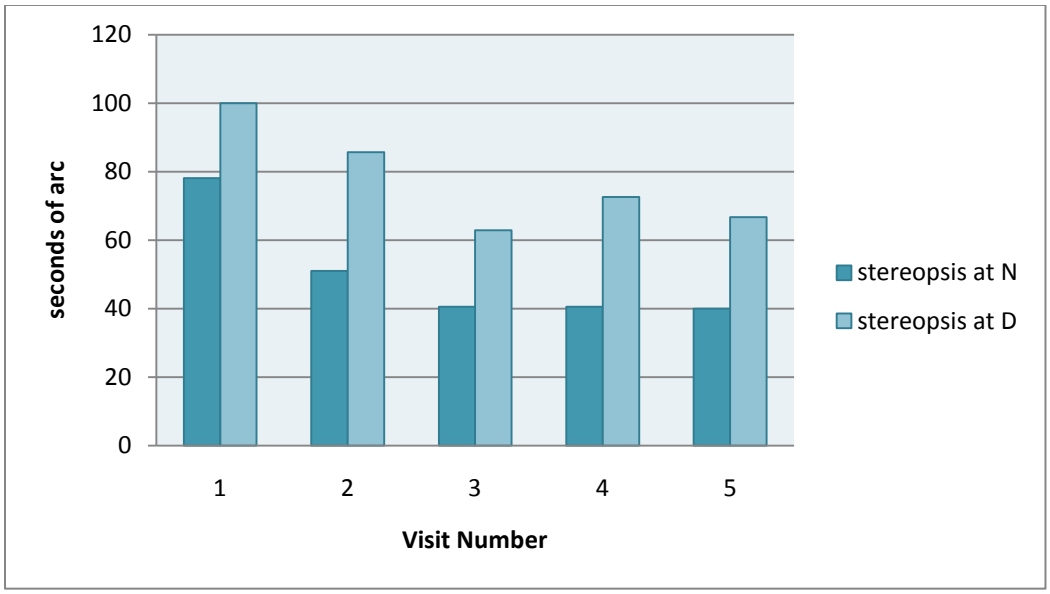

Figure 4. Mean distance and near stereopsis measured throughout five follow-up visits of intermittent exotropes who underwent occlusion therapy.

Number of the compared visits:	*P* value
1st visit to the 2nd visit	.012
2nd visit to the 3rdvisit	.066
3rd visit to the 4th visit	1.000
4th visit to the 5th visit	.317
1st visit to the 4th visit	.007
1st visit to the 5th visit	.011

Table 6. Statistical significance of the changes in near stereopsis between successive visits and the first and fourth visit and the first and fifth visit of intermittent exotropes who underwent occlusion therapy.

Stereopsis at distance (seconds of arc)		
Visit number	Mean	Standard deviation
1	100.00	69.28
2	85.71	64.54
3	62.86	29.86
4	72.63	42.80
5	66.67	28.28

*Table 7***.** Distance stereopsis for five follow-up visits of intermittent exotropes who underwent occlusion therapy

Number of the compared visits:	*P* value
1st visit to the 2nd visit	.199
2nd visit to the 3rdvisit	.170
3rd visit to the 4th visit	.655
4th visit to the 5th visit	.157
1st visit to the 4th visit	.222
1st visit to the 5th visit	.085

Table 8. Statistical significance of changes in distance stereopsis between successive visits and the first visit and fourth visit and the first and fifth visit of intermittent exotropes who underwent occlusion therapy.

4.4 Base-Out Fusional Amplitudes Analysis

For near base-out fusional amplitudes, 94.4% of the patients who completed their treatment duration improved to a normal range and were considered success at their last visits. Additionally, 38.8% of eighteen patients gradually improved from less than 10 PD to a normal range and 27.7% improved from 10 - 25 PD to a normal range. Five (27.7%) of eighteen patients remained stable throughout the five visits; three were within normal limits at their initial visit (case 6, 19 and 20). One case improved to a normal range during treatment duration but then the fusional amplitudes decreased below normal at the fifth visit (case 10) (Table 1).

Distance base-out fusional amplitudes increased to normal levels in 55.5% of the patients who completed the full duration of treatment (cases 1, 3, 6, 7, 8, 11, 14, 16 and 18). In these successful cases fusional amplitudes reached 20 PD or more at the fifth visit. The remaining eight (44.4%) of eighteen patients did not reach the normal distance fusional amplitudes. The three patients (cases 5, 15 and 21) who did not complete treatment, did not achieve normal distance fusional amplitudes at the last visit (Table 1). The success rate for the distance fusional amplitudes for the four follow-up visits was 33.3% (7/21), 57% (12/21), 52.6% (10/19) and 55.5% (10/18) for the second visit, third visit, fourth visit and fifth visit respectively (Figure 2).

The mean base-out fusional amplitude at near was 16.8 ±11.9 PD, for the first visit and 35.9 ±7.2 PD for the fifth visit (Table 9) (Figure 5).

There was a significant improvement in the near fusional amplitudes between the first and second visit (P=0.001), the second and third visit (P= 0.003), the fourth visit compared to the first visit (P= 0.000), and the last visit compared to the first visit (P=

0.001) (Table 10). General linear model ANOVA for repeated measures was significant for the near base-out fusional amplitudes (P=0.0001).

The mean distance fusional amplitudes (Table 11), was 7.3 ± 7.9 PD for the first visit and 21.9 ± 13.1 PD for the fifth visit (Figure 5). There was a significant improvement in the distance fusional amplitudes between the first and second visit (P< 0.001), and fourth visit compared to the first visit (P< 0.001) and in the fifth visit compared to the first visit (P< 0.001) (Table 12). General linear model ANOVA for repeated measures was significant for base-out fusional amplitudes at distance (P= 0.0001).

BO fusional amplitudes at near				
Visit number	**Mean (prism diopters)**	**Standard deviation(prism diopters)**	**Minimum (prism diopters)**	**Maximum (prism diopters)**
1	16.76	11.95	1.00	40.00
2	26.57	7.53	16.00	40.00
3	34.38	8.36	14.00	40.00
4	33.95	5.67	25.00	40.00
5	35.89	7.16	16.00	40.00

Table 9. Base-out fusional amplitudes measurements at near of intermittent exotropes who underwent occlusion therapy.

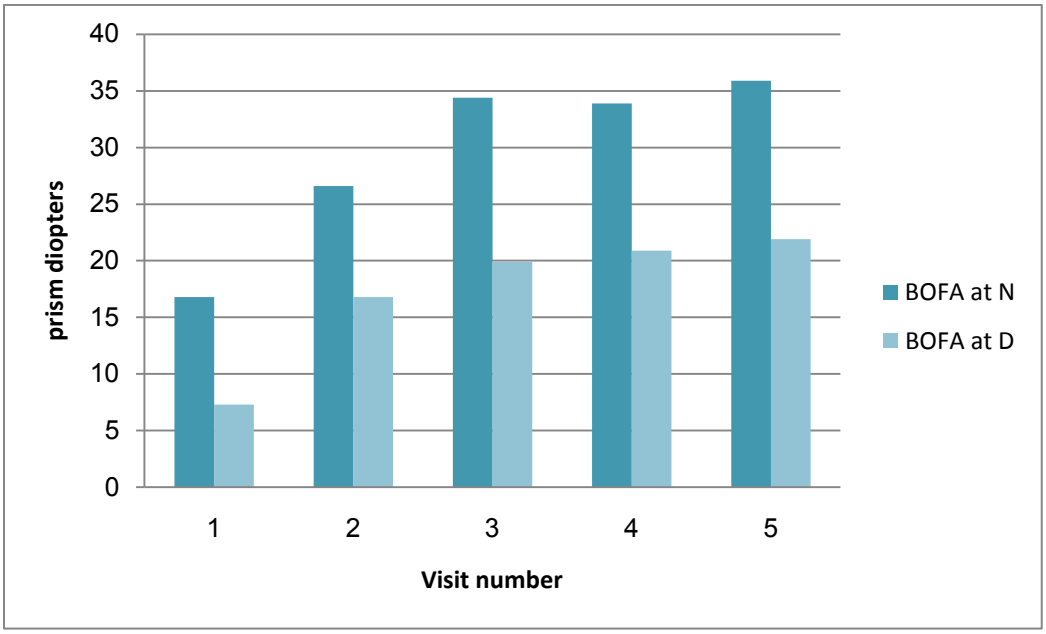

Figure 5. Mean base-out fusional amplitude measurements at near and distance throughout five follow-up visits of intermittent exotropes who underwent occlusion therapy.

*BOFA: base-out fusional amplitudes

Number of the compared visits:	P value
1st visit to the 2nd visit	.001
2nd visit to the 3rdvisit	.003
3rd visit to the 4th visit	.843
4th visit to the 5th visit	.257
1st visit to the 4th visit	.000
1st visit to the 5th visit	.001

Table 10. Statistical significance of the changes in base-out fusional amplitudes (at near) between successive follow-up visits and the first and fourth visit and the first and fifth visit of intermittent exotropes who underwent occlusion therapy.

BO fusional amplitudes at distance				
Number of follow up visit	**Mean (prism diopters)**	**Standard deviation (prism diopters)**	**Minimum (prism diopters)**	**Maximum (prism diopters)**
1	7.29	7.94	1.00	30.00
2	16.81	7.08	6.00	30.00
3	19.89	9.97	1.00	35.00
4	20.95	9.16	1.00	35.00
5	21.94	13.05	4.00	60.00

Table 11. Base-out fusional amplitude measurements at distance of intermittent exotropes who underwent occlusion therapy.

Number of the compared visits:	*P* value
1st visit to the 2nd visit	.000
2nd visit to the 3rdvisit	.118
3rd visit to the 4th visit	.479
4th visit to the 5th visit	.972
1st visit to the 4th visit	.000
1st visit to the 5th visit	.000

Table 12. Statistical significance of the changes in base-out fusional amplitudes (at distance) between successive follow-up visits and the first and fourth visit and the first and fifth visit of intermittent exotropes who underwent occlusion therapy.

4.5 Binocular Visual Acuity Analysis

Success for distance binocular visual acuity was attained in 94.4% of patients, all of whom had 0 logMAR at the last visit with the exception of case number 10 who attained 0.1 logMAR (20/25). In cases where treatment was not completed, distance binocular visual acuity was 0.1 logMAR for two cases (cases 5 and 15) and 0 logMAR for one case (case 21) (Table 1).

Binocular visual acuity over the five follow-up visits was analyzed. The mean binocular visual acuity was 0.4 (20/50) ± .4 logMAR at the first visit and 0.0 ± 0.0 logMAR at the last visit (Table 13) (Figure 6). There were significant changes in binocular visual acuity at the first visit compared to the second visit (P= 0.002), the fourth visit compared to the first visit (P= 0.001) and the fifth visit compared to the first visit (P= 0.001) (Table 14). General Linear Model ANOVA for repeated measures was statistically significant for binocular visual acuity (P = 0.002).

BVA		
Visit number	**Mean (logMAR)**	**Standard deviation (logMAR)**
1	0.4	0.4
2	.1	0.1
3	0.1	0.3
4	0.0	0.0
5	0.0	0.0

Table 13. Binocular visual acuity of intermittent exotropes who underwent occlusion therapy.

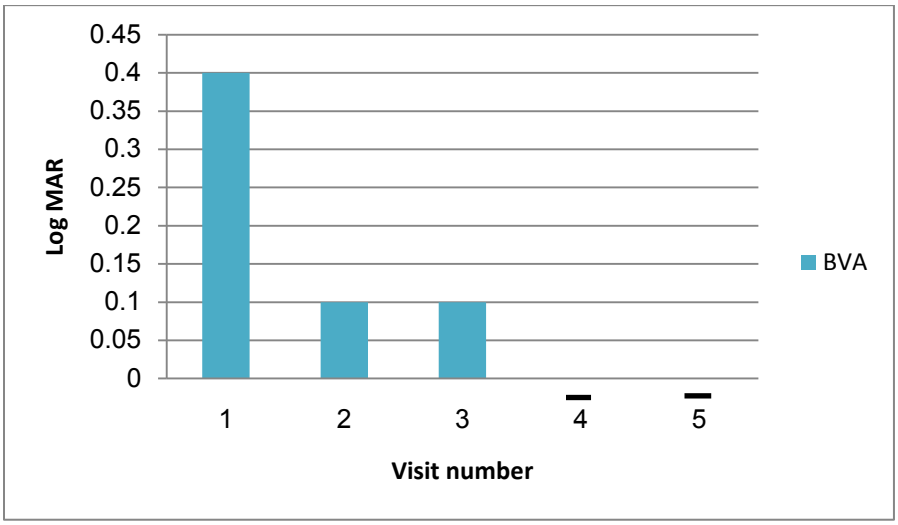

Figure 6. Binocular visual acuity throughout five follow-up visits of intermittent exotropes who underwent occlusion therapy.

*BVA: binocular visual acuity

Number of the compared visits:	*P* value
1st visit to the 2nd visit	.002
2nd visit to the 3rdvisit	.221
3rd visit to the 4th visit	.109
4th visit to the 5th visit	.317
1st visit to the 4th visit	.001
1st visit to the 5th visit	.001

Table 14. Statistical significance of the changes in binocular visual acuity over successive follow-up visits and during the first and fourth visit and the first and fifth visit of intermittent exotropes who underwent occlusion therapy.

4.6 Control Score Scale Analysis

The near control score scale indicates success in all cases including the cases that did not complete full treatment. Success of the distance control score to 0 or 1 was attained in 77.7 % of the 18 patients, who completed the full duration of treatment at their fifth visit, and all the cases that did not complete treatment duration (Table 1). A successful distance control score was not attained in 22.2% of 18 patients.

The control score scale mean was measured for near, distance as well as the total of both measurements. The control score scale graded from 0 to 5 for near, 0 to 5 at distance and the sum of distance and near is the total measure as per Mohney and Holmes (2006). In this study, we analyzed the distance and near score separately rather than analyzing the total score for the purpose of reflecting a detailed picture about the status of each measure separately and not to combine them in one total score mixing the near with the distance. The mean distance control score improved from 2.3 from the first visit to 1.3 in the fifth visit (Table 15) (Figure 7). There was a significant change in the distance control score between the first visit compared to the second visit (P= 0.006), the first visit compared to the fourth visit (P= 0.002) and the first visit compared to the fifth visit (P= 0.015) (Table 16). General Linear Model ANOVA for repeated measures was significant for control score at distance (P = 0.002).

The mean near control score improved from 1.1 at the first visit to 0.2 at the fifth visit (Table 17). There was a significant change in the near control score between the first visit compared to the second visit (P= 0.021), the second visit compared to the third visit (P= 0.46), the first visit compared to the fourth visit (P= 0.003) and the first visit compared to

the fifth visit (P= 0.001) (Table 18). General Linear Model ANOVA for repeated measures was statistically significant for the control score at near (P = 0.002).

Control score scale (Distance results)				
Number of follow up visit	**Mean**	**Standard deviation**	**Min. range**	**Max. range**
1	2.3	1.4	0.0	4.0
2	1.5	0.9	0.00	3.0
3	1.3	1.0	0.0	4.0
4	1.2	1.0	0.00	4.0
5	1.3	1.0	0.00	4.00

Table 15. Control score scale at distance of intermittent exotropes who underwent occlusion therapy. Score ranges from 0 to 5

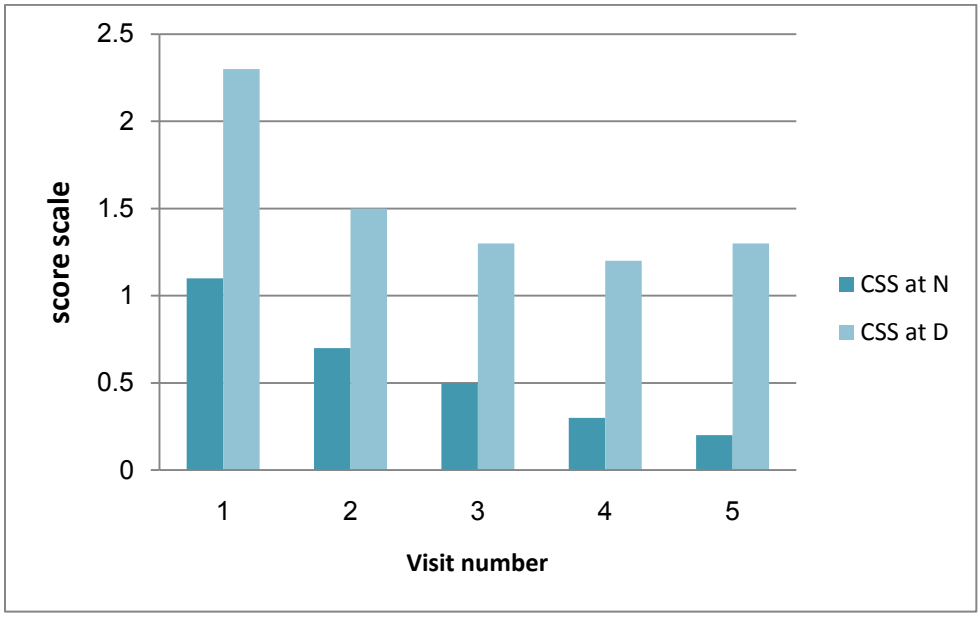

Figure 7. The control score scale results at near and distance throughout the five follow-up visits of intermittent exotropes who underwent occlusion therapy.
*CSS: control score scale

Number of the compared visits:	*P* value
1st visit to the 2nd visit	.006
2nd visit to the 3rdvisit	.206
3rd visit to the 4th visit	.206
4th visit to the 5th visit	.257
1st visit to the 4th visit	.002
1st visit to the 5th visit	.015

Table 16. Statistical significance of the change in control score at distance between follow-up visits of intermittent exotropes who underwent occlusion therapy.

Control score scale (Near results)				
Visit number	**Mean**	**Standard deviation**	**Min. range**	**Max. range**
1	1.1	0.9	0.0	4.0
2	0.7	0.7	0.0	2.0
3	0.5	0.7	0.0	2.0
4	0.3	0.6	0.0	2.0
5	0.2	0.4	0.0	1.0

Table 17. Control score scale at near between follow-up visits of intermittent exotropes who underwent occlusion therapy. Score ranges from 0 to 5

Number of the compared visits:	*P* value
1st visit to the 2nd visit	.021
2nd visit to the 3rdvisit	.046
3rd visit to the 4th visit	.180
1st visit to the 4th visit	.003
1st visit to the 5th visit	.001

Table 18. Statistical significance of the change in control score at near between follow-up visits of intermittent exotropes who underwent occlusion therapy.

4.7 Primary Outcomes Measure – Analysis and Interpretation of Results

4.71 Percentage Analysis of Distance Deviation Data

To better understand the effect of the applied occlusion therapy, the results of treatment were analyzed and expressed as percentages of the initial distance deviation values of every individual patient at visit 1 (Table 19). For example, patient number 1 showed improvement at the last treatment of 12.5% compared to the first visit and the improvement 1 month after the last treatment was 37.5% compared to the first visit.

Figure 8 shows the results divided into percentage categories. It can be seen that while only 3 cases have achieved higher than 50% improvement rates, the highest number of patients (5 cases) improved between 10% and 20% (category 10-20%). The second highest number of cases (4 cases) improved between 30% and 40% (category 30-40%). The mean improvement rate between visits 1-4 for all cases was 28.92 % (SD 25.92) with a calculated lower limit of 16.43% and upper limit of 41.42%. The frequency distribution of the improvement rates between visits 1 and 5 shows an increase in the magnitude of distance deviation as compared to visit 4. It demonstrates that the improvement cannot be considered permanent. According to the observed data, the mean improvement rate decreased from 28.92% to 18.76% within one month of no treatment in comparison with the initial distance deviation level of the patients. The standard deviation of the results increased to 31.79 from 25.92 at visit 4 (Table 20).

Patient number	Distance deviation	Distance deviation (%)	Improvement at last treatment (%)	Improvement 1 month after last treatment (%)
1	16	100.0		
	16	100.0		
	14	87.5		
	14	87.5	12.5	
	10	62.5		37.5
2	18	100.0		
	14	77.8		
	14	77.8		
	12	66.7	33.3	
	12	66.7		33.3
3	14	100.0		
	14	100.0		
	12	85.7		
	10	71.4	28.6	
	18	128.6		-28.6
4	16	100.0		
	12	75.0		
	10	62.5		
	10	62.5	37.5	
	14	87.5		12.5
5	20	100.0		
	14	70.0		
	14	70.0		
6	20	100.0		
	18	90.0		
	16	80.0		
	18	90.0	10.0	
	18	90.0		10.0
7	20	100.0		
	16	80.0		
	14	70.0		
	16	80.0	20.0	
	14	70.0		30.0
8	18	100.0		
	18	100.0		
	16	88.9		
	18	100.0	0.0	
	14	77.8		22.2
9	25	100.0		
	18	72.0		
	14	56.0		
	14	56.0	44.0	
	16	64.0		36.0
10	30	100.0		
	18	60.0		
	14	46.7		
	10	33.3	66.7	
	8	26.7		73.3
11	25	100.0		
	16	64.0		
	14	56.0		
	12	48.0	52.0	
	18	72.0		28.0
12	18	100.0		
	18	100.0		
	12	66.7		
	12	66.7	33.3	
	18	100.0		0.0

Table 19. Data table of the results of treatment expressed as percentages of the initial distance deviation values at visit 1.

Patient number	Distance Deviation	Distance deviation (%)		Improvement at last treatment (%)		Improvement 1 month after last treatment (%)
13	12	100.0				
	0	0.0				
	0	0.0				
	0	0.0		100.0		
	0	0.0				100.0
14	20	100.0				
	16	80.0				
	16	80.0				
	16	80.0		20.0		
	16	80.0				20.0
15	20	100.0				
	16	80.0				
	8	40.0				
	12	60.0		40.0		
16	8	100.0				
	6	75.0				
	8	100.0				
	6	75.0		25.0		
	8	100.0				0.0
17	30	100.0				
	30	100.0				
	30	100.0				
	25	83.3		16.7		
	35	116.7				-16.7
18	20	100.0				
	25	125.0				
	20	100.0				
	18	90.0		10.0		
	20	100.0				0.0
19	20	100.0				
	20	100.0				
	16	80.0				
	16	80.0		20.0		
	20	100.0				0.0
20	25	100.0				
	25	100.0				
	20	80.0				
	30	120.0		-20.0		
	30	120.0				-20.0
21	25	100.0				
	16	64.0				
	16	64.0				

Table 19. Data table of the results of treatment expressed as percentages of the initial distance deviation values at visit 1.

Statistical measures of distance deviation	Visit 4	Visit 5
Mean (% of the initial value at visit 1)	28.92	18.76
Standard deviation	25.92	31.79
Median	25.00	16.25

Table 20. Statistical measures of the observed distance deviation data in percentage change

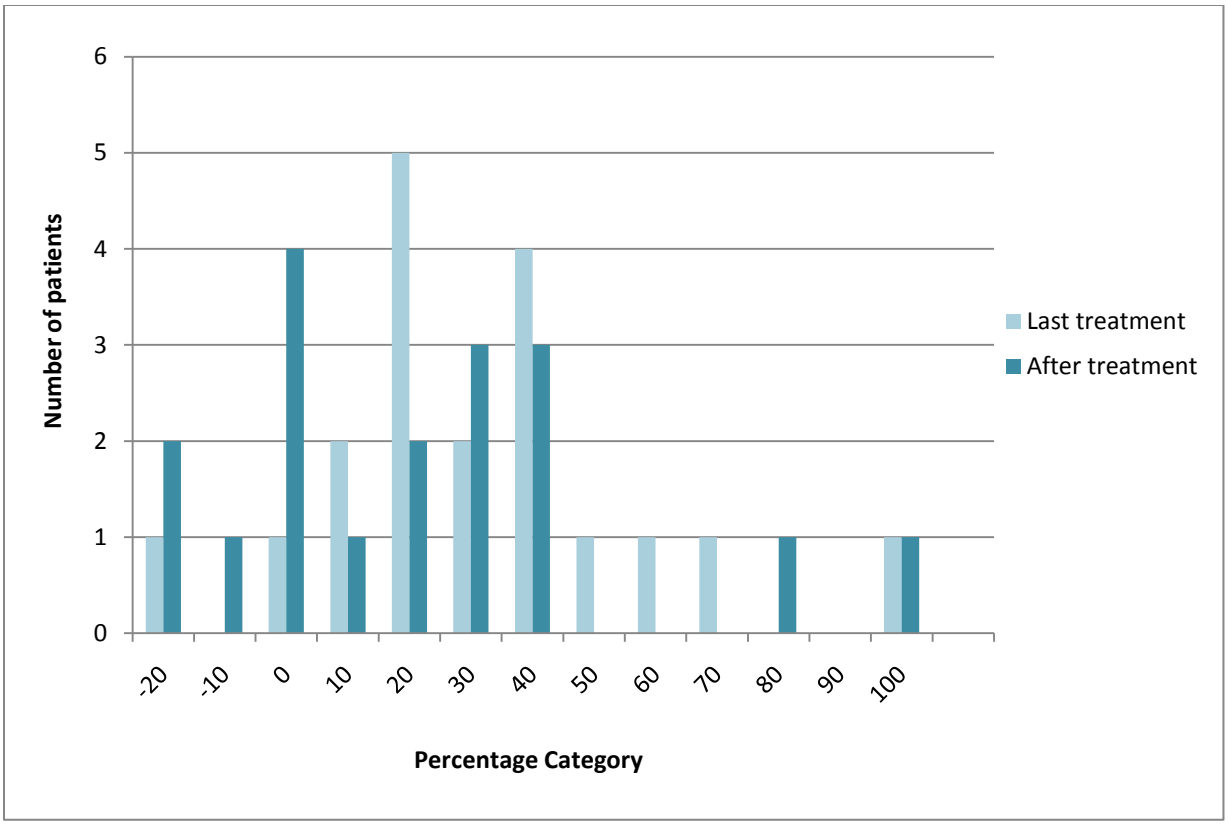

Figure 8. Number of patients by percent of improvement between visits 1-4 and 1-5

4.72 Sample Size

The observed results of sample proportions for the outcome measure (mean improvement rate of the distance deviation) between visits 1-4 obtained from the 18 patients show very high variability with a +/-43% interval around the mean of 28.92 % (SD 25.92). It is important to know what sample sizes would be needed to approximate the population mean with lower margins of error.

We have applied the Q-Q (quantile - quantile) plot technique to compare the distribution of the observed data with theoretical population data obtained by assuming normal distribution. As the resulting line demonstrated an acceptable fit, we base our estimations on parametric methods.

By using formula [4.7.2.1] describing the relationship between sample size and error of estimate, we can calculate the sample sizes that would be needed to reduce the margin of error to select levels:

[4.721] $$N = \left(\frac{Z_{\alpha/2} \bullet SD}{E} \right)^2$$

where N is the sample size, $Z_{\alpha/2}$ is 1.96 (at 95% confidence level), SD is the standard deviation of the mean and E is the maximum error of estimate. At this confidence level, 95% of the sample means will fall into the interval of the population mean plus or minus the error value.

According to our calculations in order to reach a margin of error of 20% around the mean difference between visits 1-4 (28.92 %±5.784) a minimum sample size of 78 is needed. A 10% margin of error would necessitate a sample size of 309.

By increasing the sample size we could enhance the precision of our conclusions about the effectiveness of occlusion therapy. Fifty percent or higher improvement rates in distance deviation that we have set as sufficient levels in correcting IXT were found to occur in less than 20% of the patients. In addition, the resulting reduced distance deviation did not remain at the achieved levels in all of the cases after the therapy was discontinued.

CHAPTER 5: DISCUSSION AND CONCLUSION

5.1 Discussion

The efficacy of occlusion therapy for IXT remains contentious. Some studies have been performed but they fail to provide sufficient evidence to substantiate the significance of improvement in the size of deviation and control of IXT with occlusion therapy. In the current prospective study we evaluated the effectiveness of occlusion therapy in improving the control and the size of deviation of IXT in children between 4 and 10 years of age in Saudi Arabia.

In this study, a number of variables were evaluated and analyzed to test the effectiveness of occlusion therapy including the angle of deviation at distance and near, stereopsis at distance and near, base-out fusional amplitudes at distance and near, binocular visual acuity and the control score scale. A *P* value less than 0.05 was considered statistically significant.

For individual deviation interpretation at distance, only three patients achieved success (15.7 %) where the deviation decreased by 50% at the completion of the treatment, while only two patients (11%) attained success one month after treatment was discontinued. The success rate throughout the four follow-up visits was 4% (1/21), 14% (3/21), 15.7% (3/19) and 11 % (2/18) for the second visit, third visit, fourth visit and fifth visit respectively. Although significant changes for the deviation at distance occurred at the first visit to the fourth and the first visit to the fifth visit, we will rely on our individual interpretation as it reflects a more detailed evaluation of our data for every individual throughout the five visits. The statistical analysis calculated the mean value of the deviation angle for all the patients in every visit and compared them as an average which reduces the strength of the findings. According to our individual interpretation, a low

success rate was found for deviation measurements at distance after the end of the treatment. However, for individual interpretation of deviation at near, success was achieved in 44.4% of the eighteen patients who completed the full duration of treatment and there were significant changes when comparing the first visit to the fourth visit and the first visit to the fifth visit.

The success rate for stereopsis at distance was high starting from the third visit to the last visit. The minor differences between the third to the fifth visits in stereopsis at distance explain lack of significance between visits. Additionally, 27.7 % of the patients had within normal stereoacuity at the outset therefore this may explain the lack of statistical significance calculated by the Wilcoxon signed ranks test. However, individual interpretation indicated a success rate of 94% at the last visit where 17 cases out of eighteen improved to normal stereoacuity. More than 50% of the subjects had normal near stereoacuity at the first visit which therefore warranted minor discussion or analysis.

Base-out fusional amplitudes at distance attained successful levels in 55.5% of the cases. The difference between the first and fourth visit and first visit and fifth visit were significant ($P < 0.001$, both comparisons). There were no significant differences between other visits *(*$P>0.05$, all comparisons). In reviewing the data individually throughout the four follow-up visits, results of the fusional amplitudes measures were very similar during successive visits starting from the second follow-up visit. Sixteen out of nineteen patients had within 5 PD changes from visit three to visit four and seventeen patients out of eighteen had within 5 PD changes from visit four to visit five. This may explain the lack of significance between these visits. Additionally, figure 2 (Chapter 4), plots the improvement between the first follow-up visit to the second follow-up while smaller

differences occur between subsequent visits indicating the little room for improvement at last visit.

Base-out fusional amplitude at near improved successfully in 94.4% of our cases. However, only the first (P=.001) and second (P= .003) follow-up were statistically significant. When data were reviewed, eleven patients had within 5 PD changes from visit three to visit four and ten patients had 5 PD changes from visit four to visit five which explains the lack of significant change as these values were slightly more than 50 % of the cases. In addition, significant improvement was attained comparing the first visit to the fourth (P< .001) and to the fifth (P=.001) follow-up visits.

Successful binocular visual acuity was attained in 94.4 % of our cases with significant improvement between the first visit to the fourth visit (P=.001) and the fifth (P=.001) follow-up visits. There was significant change in the first follow-up as well (P=.002). Individual analysis indicates the consistency of the data from one visit to another which explains the lack of significance in the second (P=.221), third (P=.109) and fourth (P=.317) follow-up visits.

Data for the control score scale at distance indicated a 77.7% success rate. Significant changes occurred between the first visit to the fourth (P =.002) and to the fifth (P =.015) visits. There was a significant difference in the first (P= .006) follow-up. Individual analysis of the data indicates the consistency of the data between the remaining follow-up visits, explaining the lack of statistical significance for the second (P=.206), third (P=.206) and fourth (P=.257) follow-up visits.

There was a 100% success rate for the control score scale at near. There was a significant difference between the first visit to the fourth (P=.003) and the fifth (P=.001)

visits. There was a significant difference in the first (P=.001) and second (P= .046) follow-up visits as well. In the remaining follow-up visits, consistency of the data is evident from visit to visit when the data are individually evaluated. This consistency explains the lack of significance.

In conclusion, all of our variables under study indicated moderate to high success except for the deviation angle at distance. Near stereoacuity was excluded from this analysis as discussed above. Our distance deviation findings are similar to those reported by Figueira and Hing (2006) who treated their subjects with occlusion therapy alone for near and distance and reported improvement rates of 6% (3/50), 8.57% (3/35), 5.26% (1/19) and 0% (0/5) at 6 months, 1, 2 and 5 year follow-ups, respectively, with no significant difference. Due to the differences in the clinical testing methods, comparison of other variables between our study and Figueira and Hing's study is not possible. Our results concur with Reynolds and Wackerhagen (1988) who reported 6% of their patients achieved a persistent improvement in angle size. Similarly, Flynn, MeKenney and Rosenhouse (1976) reported a 68% success rate for sensory and motor effects of occlusion. Alternately, 39% of the cohort in the Flynn, et al. study worsened in the size and frequency of the deviation. Asbury (1968) found that 94% of subjects obtained stereopsis with enhanced fusional vergence amplitudes at near and distance which agrees with our findings.

Contrary to our observations, Suh et al. (2006) found that part-time occlusion therapy resulted in a significant reduction of the deviating angles at distance as 32% of the basic type IXT patients converted to pseudo-divergence excess type and 69% of the convergence insufficiency type patients converted to the basic type. However the data for

near deviation in the Suh et al. study concurs with our results. Similarly, 27 % of patients in the Freeman and Isenberg (1989) study became orthophoric and 45.5% had an asymptomatic exophoria at the last examination which differs from our deviation angle results at distance. Furthermore, Iacobucci and Henderson (1965) showed a beneficial effect of occlusion therapy on exodeviations, both in pattern type and size of deviation, where 53% of their 17 IXT patients demonstrated stronger fusion as they converged from IXT to exophoria on cover/uncover testing which also disagrees with our results for deviation at distance. In addition, Spoor and Hiles (1979) reported an improvement of 54% in the deviation angle at distance and concluded that occlusion therapy decreases the size of the deviation as the overall mean exodeviation had decreased by 6 PD at distance and 3Δ at near. However, Berg, Lozano and Isenberg (1998) found that occlusion therapy decreases deviation angle at near from the mean of 8.2 PD to 1.9 PD (77%) and at distance from the mean of 20.9 PD to 9.2 PD (56%). Newman and Mazow (1956) found that 87% of their subjects who were treated with occlusion therapy reported decrease in the deviation size or converted to phoria, which differs from our findings.

A few studies concur with part of our results. Other studies however used different methodology than ours and compared occlusion therapy to other treatment modalities. Cooper and Leyman (1977) found that occlusion therapy is useful in breaking down suppression, with 63% of the cohort who were treated with occlusion therapy showing fair to good results for stereopsis and fusional amplitudes as well as improvement in the angle of deviation which conflicts with the results of the present study. Chutter (1977) found that the size of the deviation decreased after treatment application, which differs

from our findings, however the fusional ranges were improved and the fusional recovery (control) was strengthened which is similar to our findings.

Age of the patients may have played a role in the improvement in angle of deviation achieved by occlusion therapy in this study. The average age of all participants in our study was 8.4 years with mean improvement in angle of deviation of 28.9%. The average age of participants whose distance deviation has improved by more than 50% between visits 1-4 was 7.7 years (ages 6, 7 and 10 years). The only participant who improved to orthophoria (and stayed the same during one month with no treatment) was 6 years old. These results concur loosely with the findings of Wilson, Saunders and Trivedi (2008) who stated that occlusion therapy improves the control of IXT and is more effective for younger children, while it becomes less effective by age seven.

5.2 Future Plans:

A long-term observation of a similar study with a larger sample size is needed to determine whether occlusion therapy is a valid treatment modality for IXT and to confirm the results of the current study. The effectiveness of fewer patching hours should also be addressed in future studies.

Perhaps future studies can be made by grouping the patients with a stop after cycle one, another group stopping after cycle two and a third group after cycle three of treatment and evaluate/ compare which would be most effective shortest treatment duration to be applied to the patients.

The impact of age on the effectiveness of occlusion therapy could also be an area of further investigation.

5.3 Limitations

The lack of a sufficient number of cases in our study cohort is a limitation of this investigation. Fifteen cases were lost as they failed to attend follow-up visits and therefore were excluded from the study. Additionally, long-term observation of the patients to determine the efficacy of therapy over time was not possible in this study and represents a limitation due to the lack of time the principal investigator had to accomplish this project as well as difficulties in patient recruitment; therefore there was only one month follow-up after treatment discontinuation. Long term investigation should be conducted in the future.

The use of one investigator could cause bias although we tried to mitigate this by masking the data of the previous visit during follow-up visits. Lastly, IXT were not classified according to the type of deviation because the patient would be included regardless of the type of the deviation if he/she met the inclusion criteria. Therefore, classification of the deviation was avoided in this study.

5.4 Conclusion

Success rate was evaluated at the last visit of the patients to provide the effect of occlusion therapy at the longest period from the starting point of the treatment in this study. According to our success criteria mentioned in section 3.13, very few (11%) of our patients had a decrease of the deviation angle at distance while almost half of them (44%) reported a decrease in the angle of deviation at near. Sixty seconds of arc was reached by the majority of our cases for distance stereopsis (94.4%) and forty seconds of arc was reached by all the cases for near stereopsis. Improvement of base-out fusional amplitudes to normal ranges was attained by almost all of the patients at near and half of the patients

at distance. Improvement of binocular visual acuity to 0 Log MAR or better was attained by almost all of the patients (94.4%). An improvement to the rate of 0 or 1 for the distance control score scale was attained in three quarters of our subjects (77.7%) and in all cases for the near control score scale.

This prospective pilot study of IXT patients treated with alternate occlusion therapy suggests that alternate occlusion therapy can improve the sensory status and strengthen the fusional amplitudes at near and distance. In addition, we suggest that occlusion therapy can improve the deviation control but does not improve the size of the angle of deviation, although it does not worsen it in most cases. Therefore, we suggest that occlusion therapy can be used as a safe treatment modality to postpone surgery and improve sensory status, fusional abilities and control of deviation for younger age group patients in Saudi Arabia. Three months of treatment application are suggested to be enough to improve the patient's sensory status and strengthen the fusional ability and deviation control for IXT patients between 4 to 10 years of age.

Study question 1- Does occlusion therapy improve control in non-diplopic patients with intermittent exotropia? Yes, but not the size of the deviation.

Study question 2- Are the benefits of treatment stable one month after cessation of treatment? Improvement in success rates occurred over consecutive visits for fusional amplitudes, stereopsis and control of the deviation and final levels were maintained at one month after therapy was discontinued, except for the angle of deviation.

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Appendix A

Patient Information Sheet

Title: eye-patch therapy in children.

PURPOSE OF THE RESEARCH:
The aim of this study is to evaluate the effectiveness of eye-patch therapy in the control of this type of deviation in children from 4 - 10 years.

DESCRIPTION OF THE RESEARCH :
Eye-patch therapy will be used as a therapy to this type of deviation (intermittent exotropia). Measurement of the deviation will be performed in four follow up visits. Commitment of appointments is highly important and missing visits will lead to excluding from the project. However, commitment to patching therapy hours is expected and a calendar for patching will be provided to parents for daily recordings. Patching hours will be 50% of waking hours per day alternating between the right and the left eye i.e. Saturday patch the right eye and Sunday patch the left eye.

POTENTIAL RISKS AND DISCOMFORTS:
The tests to be done for the research do not use drugs or touching the eye. There is no expected risk from these tests. However, with all research there is a chance of unexpected risks.

POTENTIAL BENEFITS:
Benefits are not guaranteed.

COSTS/REIMBURSEMENTS:
The participant will not incur any costs for the visits/tests and will not receive any reimbursement. However, transportation costs for the five visits will be under the patients/parents responsibility.

TERMINATION OF PARTICIPATION:
You may discontinue participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled.

COMPENSATION/TREATMENT:
If you believe that you have suffered an injury relating to this research as a participant in this study, you should contact the Optometrist/orthoptist: Lina alkahmous at telephone# 01-4821234. Ext. 1157

INFORMATION SHEET FOR RESEARCH WITH NO DIRECT BENEFITS TO PARTICIPANT
This Information Sheet is approved for use by the Human Ethics Committee/Institutional Review Board of KKESH for a validity period of 1 year starting 3 October 2009.

ورقة معلومات للمشارك في البحث

عنوان البحث: علاج تغطية العين للأطفال.

الغرض من البحث:
إنّ هدفَ هذه الدراسةِ أنْ تُقيّمَ فعاليةَ علاجِ التغطيةِ في السيطرةِ على الحول الوحشي المتقطع في الأطفالِ بين 4 -10 سنةً.

وصف البحث:
العلاج بالتغطية سَيَستخدم لعلاج هذا النوع من الحول (الحول الوحشي المتقطع). قياسات الإنحراف وتقييمِ مستوى السيطرةِ سَيُؤدّيانِ في أربعة زيارات متابعةً. الالتزام بالمواعيد يعد في غاية الاهمية وعدم الالتزام بالمواعيد سيؤدي الى الاستبعاد من البحث. الاتزام بساعات التغطية متوقع من المرضى وسيزود الوالدان بتقويم خاص لتسجيل ساعات التغطية لكل يوم. عدد ساعات التغطية سيكون 50% من ساعات استيقاظ الطفل يوميا بالتبادل بين العين اليمين واليسار. مثال: يتم تغطية العين اليمنى يوم السبت ومن ثم اليسرى يوم الاحد.

المخاطر ومصادر الإزعاج المحتملة:
الفحوصات التي ستجرى في هذا البحث لا تحتوي استخدام لأي ادوية او تحتاج لملامسة العين. لا يوجد اي مخاطر متوقعه من هذه الفحوصات. كما انه ومع كل بحث يجرى هناك فرصة لحدوث اخطاء غير متوقعه.

الفوائد الممكنة:
الفوائد ليست مضمونة.

التكاليف والتعويضات:
لن يدفع المشارك في الدراسة أية تكاليف مالية للزيارات او الفحوصات كما لن يحصل على أي تعويض مادي. تكاليف التنقل الى المستشفى للخمس زيارات ستكون من مسؤولية المريض\ذويه.

إنهاء المشاركة في الدراسة:
بإمكانك عدم الاستمرار في المشاركة في الدراسة في أي وقت دون دفع أية غرامة مالية أو خسارة أي فوائد مستحقة لك خلاف ذلك.

التعويض والعلاج:
إذا كنت تعتقد قد تعرضت لأية إصابات متعلقة بهذا البحث بصفتك مشاركاً في هذه الدراسة فيجب عليك الاتصال بأخصائية البصريات/تقويم البصر : لينة الكهموس

ورقة معلومات خاصة بالبحث ولا تنطوي على منافع مباشرة للشخص المشارك في البحث
ورقة المعلومات هذه معتمدة للاستخدام وذلك من قبل لجنة أخلاقيات الأبحاث البشرية/هيئة المحكمين بمستشفى الملك خالد التخصصي للعيون وهي صالحة لمدة عام اعتباراً من October 3 2009

VOLUNTARY PARTICIPATION:
Participation in the study is voluntary. If you decide not to participate this will not affect your ability to receive medical care at KKESH, or to receive any benefits to which you are otherwise entitled.

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

CONFIDENTIALITY:
Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. Your medical record in connection with this study will be kept confidential to the extent permitted by the law. However, your medical record may be reviewed by government agencies or the agency sponsoring this research, if required by applicable laws or regulations.

CONTACT PERSON(s):
If you have any questions, at any time, about this research, please contact optometrist/orthoptist: Lina Alkahmous at telephone # 01-4821234. Ext.1157. If you still have questions, you may discuss them with a member of the section of Assurance & Compliance, Office of Research Affairs, telephone # 01-4821234. Ext. 1362 or with Ms. Patricia Lindley, Director, Office of Research Ethics Administration, Dalhousie University, Halifax, NS Canada, telephone 902-494-1462

About the principal investigator:
Lina S. Alkahmous, optometrist/orthoptist and a graduate student at Dalhousie university. This project is being conducted by a Masters Candidate in a degree program at this university.

King Khaled Eye Specialist Hospital
PO Box 7191, Riyadh 11462
Kingdom of Saudi Arabia
Form: 389-028

على هاتف رقم: 01-4821234 تحويلة 1157

المشاركة التطوعية:
إن المشاركة في هذه الدراسة هي عمل تطوعي, ولا يؤثر قرار عدم مشاركتك في هذه الدراسة على امكانية تلقيك للعناية الطبية في مستشفى الملك خالد التخصصي للعيون أو على الحصول على أية فوائد مستحقة لك خلاف ذلك.

وسيتم إبلاغك فورا بجميع المستجدات خلال الدراسة والتي قد تؤثر على قرار مشاركتك فيها.

كما سيتم تزويدك بنسخة موقعة من نموذج الموافقة هذا.

السرية:
سوف تظل هويتك كمشارك في هذا البحث سرية وذلك خلال أي عملية نشر لنتائج هذه الدراسة، وسيتم الحفاظ على سرية ملفك الطبي المتعلق بهذه الدراسة حسب الوقت المسموح به قانونياً. ولكن قد يتم الاطلاع على ملفك الطبي من قبل الجهات الحكومية أو الجهة الراعية لهذا البحث عند الحاجة وذلك وفقاً للأنظمة والقوانين السارية في هذه الحالة.

الأشخاص الممكن الاتصال بهم:
إذا كان لديك أي سؤال في أي وقت عن هذا البحث يُرجى الاتصال بأخصائية البصريات /تقويم البصر: لينة الكهموس على تليفون رقم: 01-481234 تحويلة 1157 وإذا كان لديك المزيد من الأسئلة بإمكانك مناقشتها مع أحد أعضاء قسم الضمان والالتزام، مكتب شؤون الأبحاث تليفون رقم: 01-4821234 تحويلة 1362 او السيدة باترشيا ليندي, مديرة, المكتب الداري للابحاث: جامعة هاليفاكس: كندا. تليفون: 902 494 1462.

معلومات عن الباحث:
لينة الكهموس, أخصائية بصريات وطالبة دراسات عليا في جامعة دالهاوسي بتخص تقويم البصر. هذا البحث هو بحث درجة الماجستير للباحثة.

هـ ع/ح ف

INFORMATION SHEET FOR RESEARCH WITH NO DIRECT BENEFITS TO PARTICIPANT	ورقة معلومات خاصة بالبحث ولا تنطوي على منافع مباشرة للشخص المشارك في البحث
This Information Sheet is approved for use by the Human Ethics Committee/Institutional Review Board of KKESH for a validity period of 1 year starting 3 October 2009.	ورقة المعلومات هذه معتمدة للاستخدام وذلك من قبل لجنة أخلاقيات الأبحاث البشرية/هيئة المحكمين بمستشفى الملك خالد التخصصي للعيون وهي صالحة لمدة عام اعتباراً من3 October 2009

Appendix B

موافقة على الاشتراك في دراسة بحثية

Consent to Participate in Research

I have been asked to participate in the following research study:

Project 0840-P

Project Title: "Occlusion Therapy in Intermittent Exotropia"

Principal Investigator Name: Lina Alkahmous

The purpose of the research, potential benefits, risks, complications and alternatives have been explained to me.

I have been given an information sheet explaining these factors, and the expectations for my participation.

I understand that my participation in the research study is voluntary, and I may choose to withdraw from the study at any time. If I withdraw, my refusal will not affect my continued access to KKESH services.

I understand that my personal information will remain confidential in any publication of the research.

☐ I agree ☐ Do not agree to the use of medical photographs for publication of this research. I understand I will not be identified in these photographs.

I understand that I am to contact the Principal Investigator, or other people designated in the information sheet I have been provided, to answer additional questions or to report possible complications or adverse events.

I understand that I will not be paid or compensated for my participation in the research study or any subsequent care.

All my questions have been answered to my satisfaction, and I agree to participate in the above study.

Patient Name

Signature

OR

Person Consenting on Behalf of the Patient:

Name

Signature

Relationship

Researcher Obtaining Consent
I verify that I have given the information sheet to the patient.

Researcher Name

Signature

لقد طلب مني الاشتراك في الدراسة البحثية التالية:

مشروع رقم:

عنوان البحث:

اسم الباحث الرئيسي:

لقد تم إيضاح الغرض من هذا البحث والفوائد والمخاطر والمضاعفات التي يمكن أن تنجم عنه، وكذلك البدائل الأخرى المتوفرة.

ولقد تم إعطائي ورقة معلومات توضح هذه الأمور وما يمكن أن أتوقعه من خلال مشاركتي في البحث.

وإنني أدرك أن اشتراكي في هذه الدراسة البحثية هو أمر تطوعي، وأنني قد أقرر الانسحاب من هذه الدراسة في أي وقت، وإذا قمت بالانسحاب منها، فإن رفضي المشاركة لن يكون له أي تأثير على استمراري في الاستفادة من هذا المستشفى.

وإنني أدرك أن المعلومات والبيانات الشخصية الخاصة بي ستبقى دائماً معلومات سرية وذلك في أي أنشطة تعليمية أو عند نشر هذا البحث.

☐ أوافق ☐ لا أوافق على استخدام الصور الطبية في الأغراض التعليمية أو لأغراض نشر هذا البحث. وإنني أدرك أنه لن يتم التعريف بشخصي في هذه الصور.

وإنني أدرك أنه يمكنني الاتصال بالباحث الرئيسي أو الأشخاص الآخرين الموضحين في ورقة المعلومات التي أعطيت لي، وذلك للإجابة على أية استفسارات إضافية أو لإبلاغهم عن أية مضاعفات محتملة أو أي ظروف غير مواتية.

وإنني أدرك أنه لن يتم دفع أية مبالغ نقدية أو تعويضي بأي شكل مقابل اشتراكي في الدراسة البحثية المذكورة، أو في أي رعاية أخرى لاحقة.

لقد تمت الإجابة على جميع استفساراتي بالشكل الذي يرضيني وأوافق على الاشتراك في الدراسة المذكورة عاليه.

اسم المريض:

التوقيع:

أو

الشخص الذي قام بالموافقة نيابة عن المريض:

الاسم:

التوقيع:

صلة القرابة:

King Khaled Eye Specialist Hospital
P.O. Box 7191 Riyadh 11462
Kingdom of Saudi Arabia
Form: 389-028 (Revised May 2001)

Patient ID:

This Research Project has been approved by the Human Ethics Committee/Institutional Review Board of KKESH for a validity period of 1 year starting 12 January 2009

Appendix C

Patient's information letter

The number of first and follow up visits for each patient are five. The time of appointments will be set with every patient's parent before the appointment in about a week so that it is convenient to the patient, the parents and the principal investigator. Every follow up visit will take from 20 to 30 minutes according to patient cooperation. These will be done in the normal exam chair. They don't require the use of medicines or direct contact with the eye. In each visit, there will be about ten tests performed on the patient. Eight of these are part of the normal care for the patient. Two extra tests are just for the purposes of the research. These are: 1) A test to measure the child's ability to hold his or her eyes straight after covering either eye. The eyes are covered one at a time and the researcher observes how long it takes for the eye to drift out.2) A test to measure how well the eyes work together. The child will read a letter chart with both eyes open while the researcher watches to see if the eyes drift out. Each test will be explained to the child if cooperation is needed and principal investigator will provide clear illustration. Vision will be tested for each eye. Information about patching will be provided at the end of each visit and time for any more clarifications will be allowed. As a research participant you will also be asked to record the use of the eye patch on a calendar and to bring the competed calendar back at each follow-up visit.

First visit	Follow up #1	Follow up #2	Follow up #3	Follow up #4
- 8 clinical tests. - 2 research tests. - 20 – 30 min. - Occlusion therapy starts.	- 8 clinical tests. - 2 research tests. - 20 – 30 min. - Occlusion therapy continues.	- 8 clinical tests. - 2 research tests. - 20 – 30 min. - Occlusion therapy continues.	-8 clinical tests. - 2 research tests. - 20 – 30 min. - Occlusion therapy stops.	- 8 clinical tests. - 2 research tests. - 20-30 min. - Final evaluation.

عدد الزيارات الاساسية وزيارات المتابعة لكل مريض سيكون خمس زيارات. وقت المواعيد سيحدد مع أحد الوالدين قبل كل زيارة بحوالى الاسبوع وذلك ليناسب المريض, الوالدين والباحث. كل زيارة متابعة ستستغرق من 20 الى 30 دقيقة وذلك بحسب تعاون المريض. ستقام الفحوصات في كرسي الفحص. لا توجد حاجة لاستخدام ادوية او ملامسة العين. في كل زيارة متابعة سيكون هناك حوالى العشر اختبارات ستجرى للمريض. ثمانية من عشر فحوصات هي فحوصات الزامية لاي زيارة متابعة. الفحصان المتبقيان سيكونان لهدف الابحاث. 1- فحص لقياس قدرة الطفل على السيطرة على الحول ويقاس بتغطية عين واحدة ثم كشفها. يتم ذلك بحساب الثواني او الدقائق. 2- فحص قياس النظر وكلتا العينين مكشوفة. فحص النظر سيجرى لكل عين على حدى. بعض الفحوصات ستجرى لحركة العين وذلك بالنظر الى صورة على المسافة القريبة – 40 سم- ومسافة بعيدة. اثناء النظر الى الصورة سيقوم الباحث باخذ القياسات بالاجهزة المعتادة. ستجرى ايضا فحوصات لوظائف العينين حيت سيعطى الطفل نظارة من نوع معين وسيسأل عن بعض الصور التي سيراها. في نهاية كل زيارة, سيكون هناك فرصه لشرح كيفية التغطية ووقت كافي للوالدين لطرح أي استفسارات حول الحالة. كمشارك في البحث سيطلب منك تعبئة جدول كيفية لبس الاغطية واحضاره في كل زيارة متابعة.

الزيارة الأولى	المتابعة الاولى	المتابعة الثانية	المتابعة الثالثة	المتابعة الرابعة
-8 فحوصات روتينية -فحصان ابحاث -30 – 20 دقيقة -يبدأ علاج التغطية	8 فحوصات روتينية فحصان ابحاث - 30-20 دقيقة -علاج التغطية يستمر	8 فحوصات روتينية فحصان ابحاث -30-20 دقيقة -علاج التغطية يستمر	8 فحوصات روتينية فحصان ابحاث -30-20 دقيقة -علاج التغطية يتوقف	8 فحوصات روتينية فحصان ابحاث -30-20 دقيقة -التقييم النهائي

Appendix D

Child's assent/ موافقة الطفل

You are invited to join a research study. It is a study for kids to wear an eye patch to help your eyes get better. You don't have to join the study – you can say "NO" - and no one will be mad at you if you don't.

If you join the study, I will do some extra eye tests each time you come to the hospital. The extra tests are like the ones you do usually. You will sit in the chair and look at the things I ask you to. I may ask you to tell me what you see. You don't have to take any medicine and I won't need to touch your eyes. The extra tests will take some more time – about 20 to 30 minutes.

You can decide to stop the study at any time. The doctor will still take good care of you, but we will stop doing the extra tests. If you have any questions about the research you can call me or my assistant at 01- 4821234. Ext. 1157

انت مدعو للانضمام الى دراسة ابحاث. ستقوم بارتداء اغطية للعين لتساعد عيناك لتصبح افضل. اذا انضممت للدراسة قد تستفيد او لا تستفيد. ليس عليك الانضمام لهذه الدراسة - وبامكانك قول لا اريد- ولن يجبرك احد عليها.

اذا قررت الانضمام لهذه الدراسة, سنقوم بأخذ بعض المقاسات لعينيك في كل زيارة لك. ليس عليك اخذ اي ادوية ولن اقوم بلمس عينيك مباشرة خلال الفحص. الفحوصات ستأخذ مزيدا من الوقت مقارنة بزيارتك العادية للعيادة, حوالى 20 الى 30 دقيقة.

يمكنك ان تقرر التوقف عن المشاركة في اي وقت.سيستمر الطبيب بمتابعة علاجك حيث انك ستستمر بتغطية عينيك ولكننا لن نقوم باجراء فحوصات اضافية. اذا كان لديك اي اسئلة تستطيع مكالمتي او مكالمة مساعدي على الرقم 01-4821234 تحويلة 1157

Appendix E

Occlusion therapy in intermittent exotropia

(Data collection sheet)

1 -Patient #: 2- File #:

3-Follow up visit #: 4 - Date:

5- Age: 6 - Age of onset of X(T):

7-History according to parents compared to previous visit:

2☐ Better 3 ☐Worse 1 ☐ Same

8- Refraction:

9- Given glasses:

10- Near stereopsis: 11 -Distance stereopsis:

12- BO /FA @ N: 13 - BO/ FA @ D:

14- BVA:

15- Deviation at D: 17 - Deviation at N:

18- VA: OD:

OS:

19- Fixation preference: 20 - Patching hours:

21-Control score scale:

1-Distance: ☐0 ☐1 ☐2 ☐3 ☐4 ☐5

2-Near: ☐0 ☐1 ☐2 ☐3 ☐4 ☐5

3-Total score: