ROLE OF LOW VISION DEVICES TO IMPROVE COMPLIANCE WITH OCCLUSION THERAPY IN CHILDREN WITH AMBLYOPIA

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This is to certify that this dissertation entitled “Role of low vision devices (LVD) to improve compliance with occlusion therapy in children with amblyopia” done towards fulfilment of the requirements of the Tamil Nadu Dr. M.G.R. Medical University, Chennai for the MS Branch III (Ophthalmology) examination to be conducted in May 2020, is a bonafide work of Dr. Santa Christina, post graduate student in the Department of Ophthalmology, Christian Medical College, Vellore.

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https://www.researchgate.net/publication/6683456_Anisometropic_Amblyopia_Treated_with_Spectacle_Correction_Alone_Possible_Factors_Predicting_Success_and_Time_to_Start_Patching
https://www.science.gov/topicpages/a/amblyopia
https://entokey.com/amblyopia-5/

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INTRODUCTION

Amblyopia is one of the most common causes of visual impairment among children. They are susceptible to amblyopia from birth, till when their visual cortex completes its development. The reason for this is, the abnormal visual experience during early childhood, the critical period of visual development. The earlier, the onset of this abnormal visual experience, the greater the amblyopia.

Children do not recognize and hence do not complain of amblyopia or decreased vision. Visual impairment is usually recognized by teachers or parents. Children are brought to an ophthalmologist for an eye check-up, only when they have a white reflex or a deviating eye. Occasionally they are brought by parents or teachers when they realize that the child reads very close to face. Hence, diagnosing amblyopia at the right time is challenging.

There are a few hypothesis regarding amblyopia. Chavasse et al., coined the term ‘amblyopia of arrest’. He believed disuse of one eye, resulted in arrested visual development of that eye. Linkszet al., expressed a similar thought and stated an eye remained amblyopic and did not become amblyopic.

The newer concepts of amblyopia have discarded these hypothesis and recent research and studies have introduced newer concepts on the etiology of amblyopia.

There are numerous causes of amblyopia and it could be unilateral or bilateral. Patients with amblyopia can have disorder of vision and visual perceptions as well. Hence, a child with amblyopia may not only have decreased visual acuity, but can have associated decreased grating acuity, vernier acuity, stereo-acuity, contrast sensitivity, brightness perception, motility defects in saccades and pursuit and fixation.

Amblyopia may be caused by organic or functional causes. These functional causes may be treated easily and residual amblyopia may respond to standard amblyopia treatment. The organic causes are difficult to treat and can have poor response to the standard amblyopia treatment.

Currently, the accepted management for amblyopia, is occlusion therapy. The response to occlusion is highly dependent on the patient's compliance to the recommended duration of occlusion. This variability in compliance is the major reason for the success or failure of treatment. Because children do not experience any disability or limitation in activities due to good vision in the non-amblyopic eye, the treatment compliance is highly under-rated and underestimated.

Various reasons for non-compliance with occlusion therapy have been reported. Various studies, on methods to improve compliance have also been studied and reported.

We designed our study to document the compliance and the improvement in compliance after intervention, in children with amblyopia. In this study we have attempted to

improve the compliance to occlusion therapy, by an interventional method. We structured and administered a counselling regime to the child and the parent/ care-taker. We advised maintenance of occlusion record book and regular follow-up. Documentation of vision and visual parameters were done at the beginning and at each follow-up visit. Our main intervention was, giving low vision devices to children who remained to have poor compliance with occlusion therapy in spite of counseling. Dedicated staff for counseling and administering occlusion therapy at hospital were also done during the study.

AIMS AND OBJECTIVE

AIM:

To assess improvement in compliance during occlusion therapy in children with amblyopia, with counseling and with low vision aids.

OBJECTIVE:

To assess improvement in compliance during occlusion therapy with counseling alone.

To assess improvement in vision and higher visual functions.

To assess improvement in compliance during occlusion therapy using low vision devices.

To develop a hospital-based occlusion therapy training for children which can be adopted at home.

LITERATURE REVIEW

AMBLYOPIA

The Greek word amblyopia means “dull vision”. It refers to poor vision caused by abnormal visual development secondary to inadequate or abnormal visual stimulation in early life(1). This may not be attributable to any structural abnormality of the eye or posterior visual pathways(2). “Critical period” was coined by Hubel and Wiesel et al., which is the period of early visual development, in the first 3 months. This critical or sensitive or susceptible period is the time where there is robust plasticity in the visual cortex during the infantile period. The retino-cortical connections continues to develop at a slower rate, with lesser plasticity as the child grows and plateaus at around 7-8 years of age(1). So children are susceptible to amblyopia from birth upto 7-8 years of age(1). Earlier, the onset of abnormal stimulation, greater the visual deficit. Amblyopia is predominantly a disease of central vision, usually the peripheral vision is normal(2).

The major maternal risk factors for amblyopia are smoking, fetal distress, prolonged labor, malnutrition, exposure to drugs or toxic agents or viral diseases. The major fetal causes for amblyopia are low birth weight, prematurity, delayed milestones and CNS disorders(3).

Amblyopia was defined by Von Noorden as, “Decrease of visual acuity in one eye caused by abnormal binocular interaction or occurring in one or both eyes as

a result of pattern vision deprivation during visual immaturity, for which no cause can be detected during the physical examination of the eye(s) and which in appropriate cases is reversible by therapeutic measures(4). In practical terms, it is defined as at least 2 Snellen lines difference in visual acuity between the two eyes(1). Two major forms of amblyopia, depending on the pathological causes are, organic and functional. Organic causes of poor vision include decreased visual output secondary to structural abnormalities, i.e. optic atrophy, macular scar, retinal diseases. These organic causes are difficult to treat. Functional amblyopia on the other hand is reversible, if treated with appropriate visual stimulation in childhood(1).

Amblyopia not only affects the visual acuity but also alters the visual recognition functions. There is decreased vernier acuity, contrast sensitivity(1), grating acuity, stereo-acuity, brightness perception and motility defects in saccades, pursuit and fixation(5).

PATHOPHYSIOLOGY OF AMBLYOPIA

The exact neurophysiological mechanisms causing amblyopia is unclear. The study of modified visual experience in laboratory animals and humans with amblyopia, reveal a profound level of visual disturbance in the neuronal functions due to abnormal visual stimulation. Cells in the primary visual cortex do not respond to stimulation of the eye and if responsive, have significant functional deficiencies(2).

Animal studies demonstrated that amblyopia induced changes occur in the lateral geniculate nucleus and striate cortex. There are six nuclear layers in the lateral geniculate body, 3 layers corresponding to right eye and 3 layers corresponding to the left eye. If one eye perceives blurred image, it is noticed that the layers corresponding to the eye perceiving clearer image stain darker and wider(1). Ocular dominance columns in the striate cortex are also damaged because of unilateral blurred image during early visual receptor development(1). Von Noorden, identified similar neural anatomic changes in human pathological studies in anisometropic and strabismic amblyopia(2).

Two specific pathways have been identified in animal studies, which are postulated to process visual information. The lateral geniculate body nuclei can be divided into parvo-cellular (P or small) cells and magno-cellular (M or large) cells. From the cortical areas, information from P cells go to temporo-occipital areas and information from M cells go to parieto-occipital areas.

P cells project to fovea and central visual field and are sensitive to colour, high spatial frequencies, stereopsis and two-point discrimination. M cells project to para-foveal and peripheral retina and are sensitive to gross binocular disparities, direction, motion, flicker and speed. In amblyopia of any cause, there is associated abnormal P and M-cell development(1).

Hence in amblyopia, the P cell functions like light detection thresholds, with different –sized spots and two-point discrimination is affected. This explains the crowding phenomenon(2).

Critical period corresponds to the period when the child's developing visual system is sensitive to abnormal input caused by stimulus deprivation, strabismus or significant refractive errors. Critical period for stimulus deprivation amblyopia is earlier than for strabismic or anisometropic amblyopia. This means the time period required for amblyopia to occur during the critical period is shorter for stimulus deprivation amblyopia than strabismic or anisometrophic amblyopia(2). Response to occlusion therapy varies based on the type of amblyopia.

PREVALANCE OF AMBLYOPIA

Amblyopia occurs in 2% of the general population and is one of the most common cause of decreased vision in children(1). The prevalence varies from 1.1% in the South Indian (Karnataka) population(6)to 1.75% in the North East Indian (Assameese) population to 10.4%(7) in developing country like Nigeria in Africa (8). In the South-Indian study, the percentage of boys with amblyopia was 57%, while only 43% girls had amblyopia(6).

The most common cause for amblyopia in the North-Eastern, Assameese population was refractive amblyopia(45.29%). In children below 5 years, deprivation amblyopia and strabismic amblyopia were more common(7).

TYPES OF AMBLYOPIA

During childhood, the eye is susceptible to amblyopia due to abnormal visual stimulation and immature visual centres in the brain. The two main forms of abnormal stimulation are: pattern distortion (blurred retinal image) and cortical suppression (constant suppression of an eye)(1). These two suppressions can occur simultaneously or independently. Pattern distortion includes any media opacities, which project a blurred image to the retina and cortical suppression include strabismus which constantly suppress the fellow eye(2).

As mentioned before - lateral geniculate nucleus has six nuclear layers (3 layers corresponding to right and 3 layers corresponding to left eye). In induced amblyopia, observed in animal studies, the 3 well developed layers corresponded to the eye perceiving clear retinal images(1).

In a study done by Ganekal et al, 90.9% amblyopia was due to refractive causes, amblyopia due to strabismus was 6.8% and amblyopia due to visual deprivation and combined causes were 4.5% and 2.2%, respectively(6). In a study done by Magdalene et al., large volume of children had refractive amblyopia (45.29%), followed by deprivation (40.36%) and strabismic amblyopia (14.35%)(7). In a study done by Singh et al., 50.7% had refractive amblyopia, 31.9% had mixed amblyopia, 11.6% had strabismic amblyopia and 5.8% had sensory amblyopia.

Strabismic amblyopia due to abnormal binocular interaction can occur in patients who have a constant ocular deviation (tropia), who show strong fixation preference for one eye and constant suppression of the deviated eye and hence its neuronal connections. In strabismus, amblyopia occurs due to competitive or inhibitory interaction between neurons carrying non-fusible inputs from both the eyes. Fixating eye dominates the cortical visual centres and there is reduced inputs from the non-fixing eye(2).Strabismic amblyopia occurs in 50% of patients with congenital esotropia with constant tropia and is very uncommon in patients with intermittent strabismus or in-commitant strabismus (fusion is intermittent or maintained by other mechanisms)(1).In infants with strabismic amblyopia, even grating acuity is decreased than Snellen, as the lines appear distorted, interfering with grating recognition(2). In strabismic amblyopia both binocularity and stereopsis are affected.

Children with strabismic amblyopia, use eccentric fixation for monocular viewing, by consistently using the non-foveal region of the amblyopic eye(2).

Pattern distortion amblyopia, occurs due to unequal refractive error (abnormal binocular interaction and deprivation of form) causing retinal image blur in one eye. So one eye is chronically defocussed and child loses his or her binocularity. This condition occurs due to direct effect of image blur on the affected eye and interocular competition(2).Mild anisometropic amblyopia (myopic anisometropia (less than -3D), hypermetropic or astigmatic anisometropia(1-2D)) allows development of peripheral fusion and stereopsis but a densely blurred image (unilateral high myopia >-6D or hypermetropic or astigmatic anisometropia>2D)

(2) can produce severe amblyopia. Myopic anisometropic amblyopia, usually responds to treatment. In contrast, hypermetropic anisometropic amblyopia is usually not amenable to treatment beyond 4-5 years(1). Children with anisometropic amblyopia usually look normal to the care-takers and primary physician, causing a delay in diagnosis and treatment.

In bilateral pattern distortion, a bilateral reduction in acuity which is usually mild, results from large, approximately equal, uncorrected refractive errors in both eyes. There is bilateral symmetrical image blur (hypermetropia>5D, myopia >6D and astigmatism >2D)(2). Depending on the extend of image blur, some binocular fusion can develop with good stereopsis in mild image blur and can extend to poor stereopsis with sensory nystagmus with severe image blur(1).

In stimulus deprivation amblyopia due to congenital or early acquired cataract or rarely corneal opacities or vitreous haemorrhage, the visual axis is obstructed so amblyopia develops. Deprivation amblyopia is the least common, but is most refractory to treatment(2).

Unilateral deprivation amblyopia (abnormal binocular interaction and form deprivation) is difficult to treat than a bilateral deprivation(form deprivation) of the same level, because interocular image difference adds to the quality of image degradation(2).

In children less than 6 years, dense congenital cataracts in the visual axis, cause severe amblyopia. Acquired cataracts after 6 years of age, are less harmful. Smaller polar cataracts and lamellar cataracts through which retinoscopy and a

reasonably good view to the fundus is possible can rarely cause amblyopia and if amblyopia is present, it is usually very mild(2).

DIAGNOSIS OF AMBLYOPIA

Amblyopia is diagnosed early, when a child with maternal or neonatal risk factors is identified or child has a condition which is known to increase the risk for amblyopia or a child with a parent or relative with amblyopia, has a reduced visual acuity which cannot be explained by physical abnormalities of the eye. Vision alone cannot be used to differentiate amblyopia from other forms of vision loss. Crowding is typical of amblyopia but not pathognomonic of amblyopia. Amblyopia rarely coexists with organic causes for visual loss, a trial of vision assessment with crowded letters and single optotypes can be done and improvement in vision with single optotypes can confirm the diagnosis of amblyopia and standard amblyopia treatment may improve vision in these patients(2).

Diagnosis of amblyopia is by assessing the visual acuity. Visual acuity is assessed by the linear acuity than single optotype presentation, as single optotype underestimates degree of amblyopia. Single optotypes can be used to confirm amblyopia, not to diagnose amblyopia.

When Snellen charts or similar symbol charts of a given size are used, as it is surrounded by similar letter forms, it becomes difficult for the child to identify the letters or objects. This is because of crowding phenomenon or contour

interaction. Crowding phenomenon is similar with alphabets, numbers and symbols. Crowding phenomenon arises because an amblyopic receptive field is abnormally large, resulting in increased spatial summation and lateral inhibition.(2).

At risk children should be identified early and advised early visual examination. In normally developed children as young as 2-3 months, amblyopia is assessed by examining the quality of monocular or binocular fixation preference. Central fixation develops by 2-3 months, with accurate smooth pursuit and saccadic refixation eye movements. Central fixation is examined by covering one eye and moving a target slowly in front of the child's eye and observing fixation and following the target. It indicates vision is better than 20/100(1).

Eccentric vision in older children is assessed using a visuscope. In patients with eccentric fixation, the patient will view with the parafoveal retina and the more peripheral the eccentric fixation, the denser the amblyopia(1). A visuscope projects a target with an open center surrounded by two concentric circles onto the retina, and patient is asked to fixate on the target. If the target is not directed at the fovea, the degree of eccentric fixation can be measured using the concentric circles as a guide(2). Another test to identify strabismic amblyopia is by fixation preference. Strong fixation preference is indicative of amblyopia and alternating fixation is indicative of equal preference and equal vision(1). In case of small-angle strabismus, in preverbal children, resenting to occlusion can diagnose amblyopia(1).

The amblyoscope method uses separate target illumination and the amount of deviation can be directly read from the amblyoscope scale when the corneal light reflex is centered.

GRADES OF AMBLYOPIA

The binocularity level and fixation pattern can affect the grade of amblyopia.

A variety of optotypes, are used to measure vision in children more than 3 years of age. Linear optotypes are a better option to measure visual acuity. Isolated symbols, usually tend to underestimate vision loss, due to crowding phenomenon(2).

Depending on the degree of amblyopia, unilateral amblyopia has been graded as mild, moderate and severe. Mild amblyopia is when the vision is 6/9 to 6/12, moderate when it is from 6/18 to 6/36 and severe when vision is worse than 6/36(9)(10). Depending on the grades of amblyopia, occlusion duration varies, so it is important to stratify the grades of amblyopia.

MANAGEMENT OF AMBLYOPIA

Natural history of amblyopia suggests that mild degree of amblyopia may resolve spontaneously(11),but active therapy can improve visual acuity(12). Amblyopia does not affect lifetime occupational opportunity, due to decrease in vision(13). There is an increased life-time risk of visual impairment in the better

eye of an amblyope due to injury (14). Prevention of future blindness in the good eye is also a reason warranting treatment of amblyopia.

The main aim of management of amblyopia is to correct ocular dominance, correct any obstacle to vision (cataract, vitreous hemorrhage and corneal opacity) and correct refractive error(2). Ocular dominance is corrected by occlusion therapy, penalization, pleoptic therapy and active stimulation of the amblyopic eye.

Cataracts significant enough to produce amblyopia, require surgery as early as possible. In newborn babies, removal of visually significant cataract during 4-6 weeks of life, is necessary for optimal recovery of vision. In babies, amblyopia may develop as quickly as 1 week per age of life. In bilateral symmetrical cases, interval of surgery between the two eyes, should not be more than 1-2 weeks. Rapidly progressing traumatic cataracts, should be operated as early as possible, especially in children less than 6 years of age. Post-operative vision assessment and initiation of occlusion therapy in-case of unilateral amblyopia in children should not be delayed. Refractive correction for aphakia following cataract surgery, also must be provided as early as possible to prevent a compound effect of visual deprivation caused by opacity and severe optical deficit. Same applies to all unilateral media opacity which requires surgery. Residual amblyopia needs to be addressed at the earliest.

REFRACTIVE CORRECTION:

Optical correction for amblyopic eyes, is provided as per the full cycloplegic refraction. An amblyopic eye tends to have impaired accommodation, so this eye cannot be expected to compensate for uncorrected hypermetropia.

Both anisometropic and ametropic amblyopia, might resolve over few months of constant spectacle wear. When resolution does not occur, treatment for amblyopia with spectacles and occlusion is mandatory(2).

OCCLUSION THERAPY

The main principle of occlusion therapy is to cover the good eye and to stimulate the amblyopic eye to see. Occlusion therapy can be part-time occlusion(PTO) or full-time occlusion(FTO)(2).

OTHER TREATMENT OPTIONS FOR AMBLYOPIA

PENALISATION

Penalisation can be optical or pharmacological. Optical penalisation is achieved by optical degradation- positive defocus (giving more plus power to the sound eye) and blurring the image, until patient can read letters as the amblyopic eye, thus enabling a force fixation with the amblyopic eye(15)(16).

Pharmacological penalization is done with cycloplegics, 1%atropine and 5% homatropine is administered to the better-seeing eye, so that eye is not able to accommodate. Better eye is unable to accommodate for near vision and has hypermetropia for distance viewing.(2) Advantages with atropine sulphate is that patient's have good compliance, more rapid improvement(15), easier administration, low cost, easily accepted by parents(17) and have more acceptance in terms of compliance and social stigma(18)(19). Another advantage with atropine is the once weekly dosing which is as effective as daily dosing(17)(18) and imperfect dosing also may not interfere much with duration of treatment(20). So in children who are resistant to compliance for occlusion, atropine treatment is a good strategy to improve treatment adherence rate(21)(19). The systemic side effects (allergy, rashes, photosensitivity and convulsions) for these pharmacological agents is the only limiting factor in their treatment. Penalization is successful to treat moderate amblyopia, with comparable results to occlusion.

PHARMACOLOGICAL TREATMENT OF AMBLYOPIA

Levodopa and citicoline are drugs which have been tried in amblyopia treatment. Levodopa is a pro-drug that acts in the central nervous system, where it is supposed to have a enhanced neurotransmission effect when added to occlusion and citicoline also has the same effect. Twenty five years of study with levo-dopa, has failed to produce any convincing result with its use(10). Citicoline has

neuroprotective effects and enhances neurotransmission, brain remodelling and is a brain stimulator. In an Indian trial, it had a favourable outcome when tried along with occlusion(22).

FULL-TIME OCCLUSION

Full-time occlusion of the better seeing eye is defined as occlusion during all waking hours (10).

FIGURE 1: VARIOUS TYPES OF OCCLUDERS

Full-time occlusion is performed with commercially available adhesive patches or with spectacle mounted occluders or opaque contact lenses(1). Strabismic

patients without binocular fusion are preferably treated with full-time occlusion. The major complication of full-time occlusion is reverse amblyopia, in children between 4-5 years of age. So child is re-examined at frequent intervals. i.e. 1 week per the child's age in years(1).

Initially, full-time occlusion was the only treatment practiced. With the stigma attached to occlusion in school going children, compliance to occlusion therapy was declining. After, the PEDIG studies were published, moderate amblyopics responded equally to 2 hours/day of patching as to full-time and severe amblyopes to 6 hour/day patching(10)(12). Various studies have showed 3-line improvement from baseline within 4 months of treatment. In the PEDIG studies, for severe amblyopia, 4-line improvement has been seen with 6 hour occlusion, which is as effective as full-time occlusion. Patching is considered to be safe as it does not affect the refractive status of the fellow eye(10).

FIGURE 2: CHILD OCCLUDING WITH ADHESIVE PATCH

FIGURE 3: CHILD OCCLUDING WITH A DOYEN'S OCCLUDER AND DOING NEAR WORK

PART –TIME OCCLUSION

Part-time occlusion is defined as occlusion for 2-6 hours per day(10). Part-time occlusion is the preferred treatment in patients with straight eyes (trophia<8PD) and peripheral fusion (anisometrophic amblyopia and microtropia monofixators). In anisometrophic amblyopia, initially spectacles are prescribed and child is followed up every month for visual assessment, most children have visual improvement upto 2 lines or more within 15 weeks of wearing spectacles(10). If vision improvement is not documented, then the child is started on part-time patching(1).

Due to the numerous compounded effects, numerous studies have established that part-time occlusion is as effective as full-time occlusion(1)(2)(10)(12). Hence part-time occlusion is the preferred choice of treatment, nowadays.

Depending on the degree of amblyopia, the duration of patch-on and patch-off intervals should be tailored(2). For mild to moderate amblyopia, a minimum of 2-3 hours of occlusion is recommended to work with additional near vision work(23). For severe amblyopia, part-time occlusion of upto 6 hours can be tried(24). Though visual plasticity is considered to be effective upto 6-7 years, recent studies have shown that there is a substantial visual improvement even in older children upto 18 years with occlusion(24), especially in children who were not treated previously(25). Treatment is beneficial beyond the plasticity age, especially when the child has not undergone previous occlusion(2).

Compliance can be graded into four categories depending on percentage of hours of actual patching to the hours of prescribed patching, as excellent(76-100%), good(51-75%), fair(26-50%) and poor(0-25%)(20). It can be either subjective compliance or objective compliance.

In subjective compliance parents or care-takers were advised to maintain a diary in which treatment hours of occlusion and performance of near work activities were noted and diary is reviewed in every follow-up visit(26).

In objective monitoring of compliance, duration is usually estimated with a monitoring device-occlusion dose monitor(ODM), which measures skin conductance with a wire or temperature with thermistors at the border of the

patch. These ODM's are being improvised, refined and miniaturized and they provide an accurate time precisely upto every minute and therefore provide the factual daily occlusion dose(dose rate) and cumulative dose(20).

It has also been noted that there is a statistically significant relation between acuity increase and compliance. The better the compliance, the better the visual acuity improvement(27). Compliance usually shows a dynamic variation within a child over time. It usually decreases with time and the dynamics of compliance might differ with interventions and also varies by days of the week(20).

COMPLIANCE WITH OCCLUSION

Compliance is the major factor preluding visual improvement in children initiated on occlusion therapy. Amblyopia can be refractory due to lack of compliance towards occlusion. Higher degree of non-compliance is seen in children with severe amblyopia(28).

Compliance has been shown to be influenced by various interventional materials. A Dutch study has established use of cartoon pamphlets, to improve compliance in children with low socio-economic status in a multi-lingual, non-Dutch speaking community(29). Intervention material significantly reduced the number of drop-outs and improved compliance(21). Another study showed that doing near work during the period of occlusion improved the visual outcome(21). Low level of parent education and poor acuity at the start of

treatment are predictors for low compliance(28).Older children have better compliance with part-time occlusion(2).

FACTORS AFFECTING COMPLIANCE

Factors affecting compliance vary from skin irritation, forced use of the eye with poor vision, poor cosmesis and lengthy treatment periods. It is reported that stress was induced to both the child and parent during patching therapy, which affects the occlusion compliance. As visual improvement takes few weeks to improve and because of the social and educational difficulties faced by the child, there is a tendency to abandon therapy. Occlusion therapy can be more successful, when there is a "concordance" between the parents belief's and wishes and the realistic approach for treatment, is discussed in detail by the physician to the parent(30). Limited improvement following treatment reflects poor compliance rather than ineffective treatment.

There are various interventions which have been tried to improve compliance in occlusion therapy. An intense motivational/ interventional programme can significantly reduce the number of poorly adherent patients and dropouts among study participants(31). Interventions include educational interventions as well as strategies advised by parents (32). In one study, children who received educational cartoons, reward chart and parents who received information sheet, occluded better and longer than those who did not receive these interventional measures(33). Knowledge and motivation of parents plays a major role in compliance(34). Good counselling plays a major role in increased compliance

rates(35)(20). Decorating the patch daily or playing video games are other treatment strategies to improve compliance(32). Frequent clinic visits are encouraged to clear doubts, monitor treatment adherence and tailor treatment regime depending on the patients requirements(30)(36). Wallace et al predicted the best attainable visual acuity, from the total effective dose of occlusion(TED)(36). Studies have shown that cumulative effect is good(36). There are some studies which show that direct supervision in an in-patient set-up improves compliance(37).

An RCT comparing semi-opaque Bangerter foils attached to spectacles alone or occlusion, there is no significant improvement in visual outcomes between the two groups and these foils produce less distress for the patient and therefore can be considered as an alternative(21).

It is reported that in about 13-24% of patients, a decrease in vision by 2 or more LogMAR lines, occur within the first year of completion of treatment. A number of factors have been associated with this recurrence including better vision at the end of treatment, greater improvement during treatment, history of recurrence and squint compounded with anisometropia or microtropia. So a period of maintenance or weaned occlusion has been suggested(21) to prevent recurrence of amblyopia.

NEWER MODALITIES AFFECTING COMPLIANCE:

A newer modality that can be tried for visual stimulation is computer programs, as they offer the option of shifting visual eye training to the home(35). The Amblyopia Treatment Study, is being conducted to compare effectiveness of binocular game play vs patching in 5-13 years and 13-17 years age group(10). These software-based vision training, combines background stimulation and thereby increasing attention retention and support amblyopia treatment(35). They were also acceptable to families as a standard of treatment for amblyopia. Videogames(38) (game boy/ Nintendo/ playstation) computers, mobile phone gaming, colouring in especially designed patterns, hand writing and school homework assignments were used as vision training aids(39)(23).Younger patients were rewarded on completion of tasks and older patients were motivated showing actual improvement in Snellen's charts and other patients motivational stories with occlusion was shared(39). Homework tracking and flexible timings also increase compliance(39). It is seen that constant encouragement to have a routine and do near work like crafts, colouring, tracing, cutting out shapes with scissors, completing workbook games while occluding increases compliance rates, thereby the visual outcome also, as early as 4 weeks after treatment initiation (21)(23)(39)(40)(41). In the PEDIG studies it has been demonstrated that near-vision work with occlusion group with severe amblyopia had greater improvement in visual acuity(26).

ENHANCEMENT OF AMBYLOPIA TREATMENT COMPLIANCE WITH OTHER DEVICES:

A newer venture in treatment of amblyopia would be using magnifiers in the poorly seeing eye along with occlusion to increase the rate of compliance(42).

Another modality introduced in the treatment of amblyopia, is stimulation of the neurons in the lateral geniculate nucleus and striated cortex, by stimuli of certain spatial frequency by the Cambridge stimulator (CAM therapy). This therapy is helpful in improving the rate of compliance and visual acuity(43).

Liquid crystal glasses have been recently developed for the treatment of amblyopia. A liquid crystal glass with appropriate correction, provides programmed, electronic, intermittent occlusion of the normal eye. The liquid crystal in the sound eye is used as an intermittent flickering shutter. This shutter switches on (i.e. occlusion mode) and off (i.e. transmits light) depending on patient's degree of amblyopia(44).

Opaque occluder contact lenses are used in children not compliant to occlusion otherwise. But a close follow-up is required to monitor anterior segment complications(45).

FOLLOW-UP IN OCCLUSION THERAPY:

Amblyopia treatment needs regular follow-up, to monitor reverse amblyopia, especially in full-time occlusion. With part-time occlusion, less frequent but

definite follow-up, is required. Parents of strabismic children, should be advised to look-out for switching of fixation preference and promptly report. Iatrogenic amblyopia, should be treated with judicious, frequently monitored alternating occlusion. Sometimes, stopping treatment for few weeks, equalises vision. (2)

REVERSE AMBLYOPIA:

The most unexpected result of occlusion therapy in amblyopia is reverse amblyopia. Reverse amblyopia is defined to have occurred when the visual acuity in the amblyopic eye is 3 LogMAR units better than the visual acuity of the initially sound eye. Children with dense, strabismic amblyopia under 4 years of age, were more prone to develop reverse amblyopia(46).

Amblyopia treatment always carries the risk of overtreatment, leading to amblyopia of the initially better eye. This is more common with full-time occlusion. With full-time occlusion, an infant usually requires follow-up within one week, after initiation of therapy and upto 1 week per year of age for older children. Subsequent follow up, can be scheduled after longer intervals.

BINOCULAR TREATMENT FOR AMBLYOPIA

Newer treatment modalities work on the principle that amblyopia is a binocular phenomenon and any treatment should involve both the eyes. Future modalities of treatment might be using dichoptic glasses while playing video games(10).

Recent modification of this therapy is to change it from a hospital-based therapy to a home-based, user-friendly, i-Pod based dichoptic therapy with stable head positioning(47)

LANDMARK STUDIES IN AMBLYOPIA

Occlusion is the classic treatment for amblyopia, though some studies have shown that atropine is the first step of treatment in certain cases(19)(17). In the PEDIG 2002 study, the mean improvement in visual acuity from baseline was slightly better in the patching group(3.16) than the atropine(2.84) group. They also found patching was faster than atropine in recovering amblyopia. The improvement in visual acuity did not depend on the cause of amblyopia or age of the patient or the baseline visual acuity. Faster recovery was noticed with children on patching for more than 10 hours/day(17).

In the PEDIG 2005 study, on observation of all the treatment groups (atropine, patching, atropine to patching and patching to atropine), at the end of two years revealed that one-third of patients were still under treatment and improvement with either therapy only happened after 6 months of treatment. A small subgroup analysis with the patients having anisometropic amblyopia suggested that binocular vision is better in patients on patching than on atropine therapy, contraindicating the classical hypothesis(26). For 7-12 years patients, part-time patching with near-vision work and atropine has been observed to improve visual acuity even when amblyopia has previously been treated. For patients within 13-

17 years, part-time patching with near tasks improves visual acuity only if not treated previously or with poor response during previous treatment(26).

UNRESPONSIVENESS TO TREATMENT:

Unresponsiveness to treatment, is usually seen in older children, despite completely following the treatment regimen. The decision to continue or discontinue treatment, depends on the care-takers decision and duration of occlusion therapy.

Before diagnosing, intractable amblyopia, refraction is rechecked, pupils reassessed, macula and optic nerve reassessed. Amblyopia associated with unilateral high myopia and extensive retinal nerve fibre layer myelination, may be refractive to treatment(2).

END POINT OF AMBLYOPIA THERAPY:

The ideal end point of treatment is free alternating fixation (although the better eye may be used frequently than the other), equal linear Snellen acuity or when difference in Snellen acuity less than 1 line between the two eyes.

The duration of completion of treatment depends on the degree of amblyopia, choice of therapeutic approach, compliance with the treatment regimen and patient’s age.

RECURRANCE OF AMBLYOPIA AFTER TREATMENT:

Recurrence is defined as a decrease in vision by 2 or more LogMAR lines, in a previously amblyopic eye.

Factors attributing to the recurrence of amblyopia are unclear. Poor initial visual acuity, strabismic amblyopia and low age at the end of treatment are major risk factors for recurrence(40).

Even after successful amblyopia treatment, after completion of occlusion therapy, around 20-25% of patients, have recurrence within the first year of completion of treatment, with higher rates seen within the first six months(2). A number of factors have been associated with this recurrence including better vision at the end of treatment, greater improvement during treatment, history of recurrence and squint compounded with anisometropia or microtropia. So a period of maintenance or weaned occlusion has been suggested(21) to prevent recurrence of amblyopia.

This can be reversed with renewed therapeutic effort. PEDIG studies have demonstrated higher recurrence in children who have abruptly discontinued treatment. Another significant finding is, there is no difference in recurrence in patients who underwent atropine treatment or patching therapy(10)(11).

After equalization of vision, slow weaning of occlusion therapy is known to reduce recurrence. Surveillance for amblyopia recurrence is mandatory after completion of therapy. Periodic monitoring 6 monthly, as long as vision remains stable is acceptable.

METHODOLOGY

DETAILED ALGORITHM OF THE STUDY

UNILATERAL AMBLYOPIC CHILDREN AGED 5-18 YEARS WHO VISITED OPD (old and new cases)

PATIENT FULFILLS INCLUSION & EXCLUSION CRITERIA

INFORMED CONSENT FROM PARENTS AND ASSENT FROM CHILD (WHEN APPLICABLE)

BEST CORRECTED VISUAL ACUITY - EACH EYE SEPERATELY

DISTANT VISION ASSESSMENT - AIDED & UNAIDED WITH LEA SYMBOL (LogMAR) CHART& NEAR VISION ASSESSMENT (N) CHART

CONTRAST SENSITIVITYASSESSMENT WITH PELLI-ROBSON CHART

STEREOPSIS WITH TITMUS FLY TEST

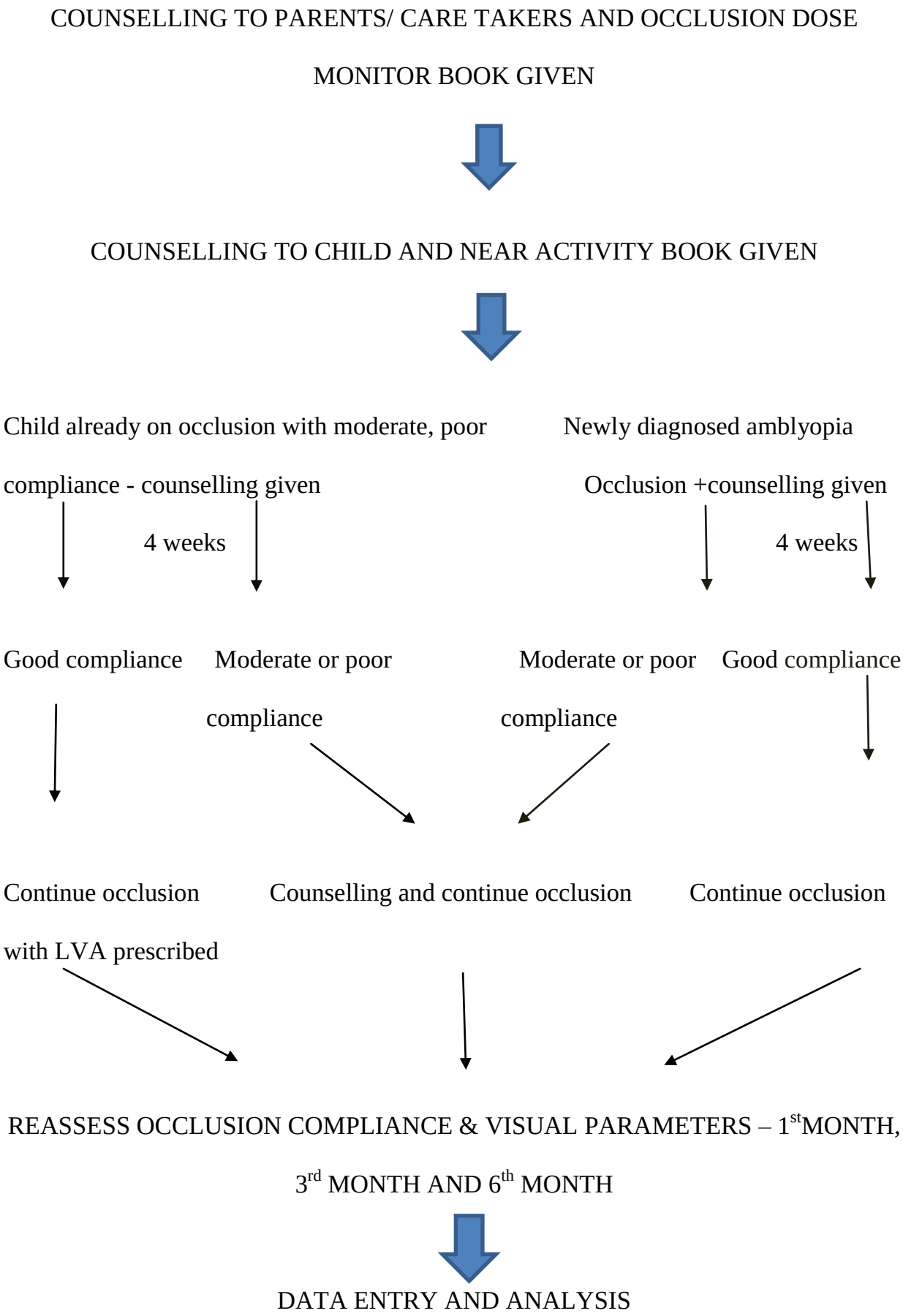

COUNSELLING TO PARENTS/ CARE TAKERS AND OCCLUSION DOSE MONITOR BOOK GIVEN
COUNSELLING TO CHILD AND NEAR ACTIVITY BOOK GIVEN
Child already on occlusion with moderate, poor compliance - counselling given
Newly diagnosed amblyopia Occlusion +counselling given
4 weeks
4 weeks
Good compliance
Moderate or poor compliance
Moderate or poor compliance
Good compliance
Continue occlusion with LVA prescribed
Counselling and continue occlusion
Continue occlusion
REASSESS OCCLUSION COMPLIANCE & VISUAL PARAMETERS – 1st MONTH, 3rd MONTH AND 6th MONTH
DATA ENTRY AND ANALYSIS

FIGURE 4: LEA PICTURE CHART (LogMAR)

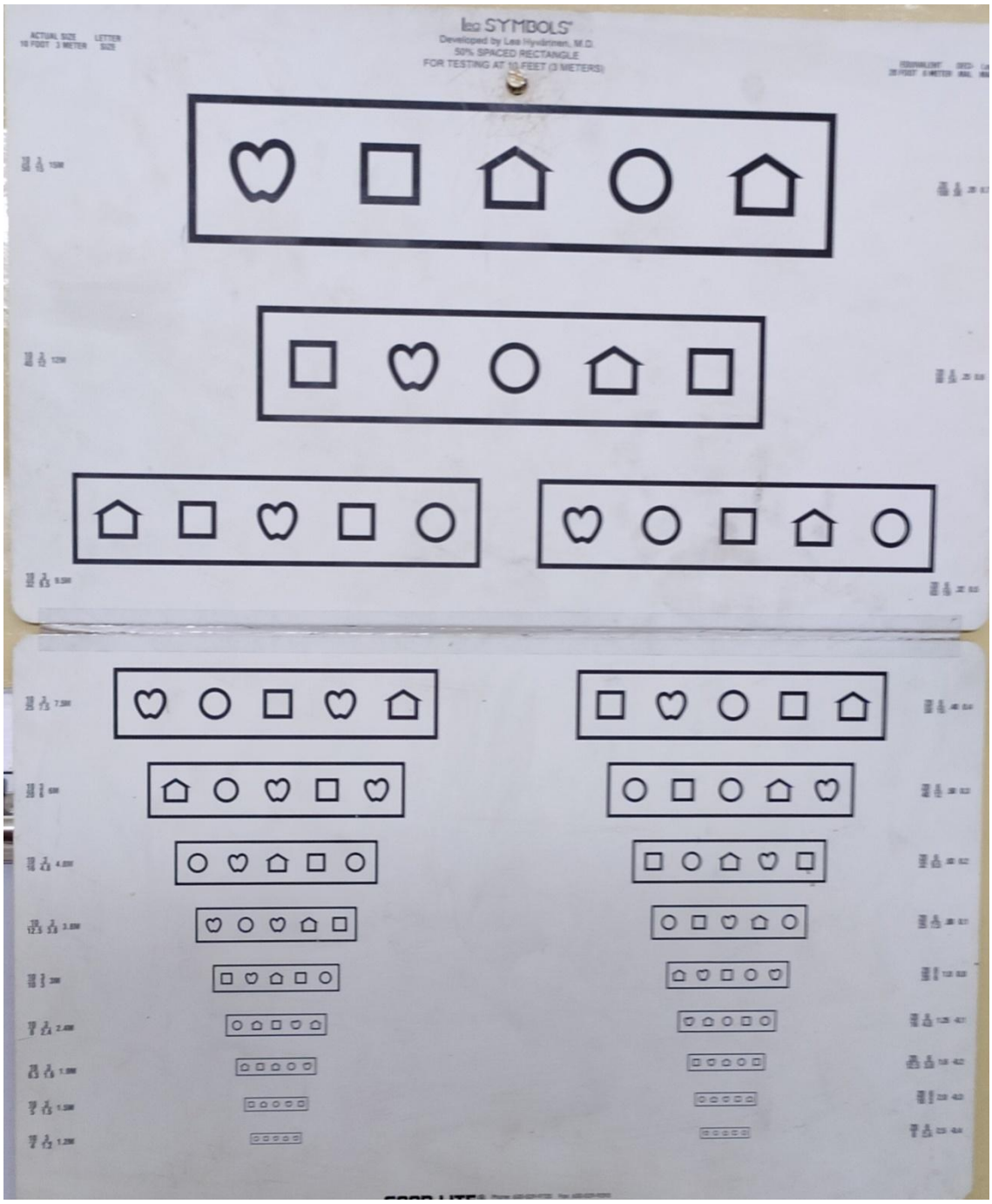


FIGURE 5: PELLI-ROBSON CONTRAST SENSITIVITY CHART

FIGURE 6: PRISMS FOR COVER TEST

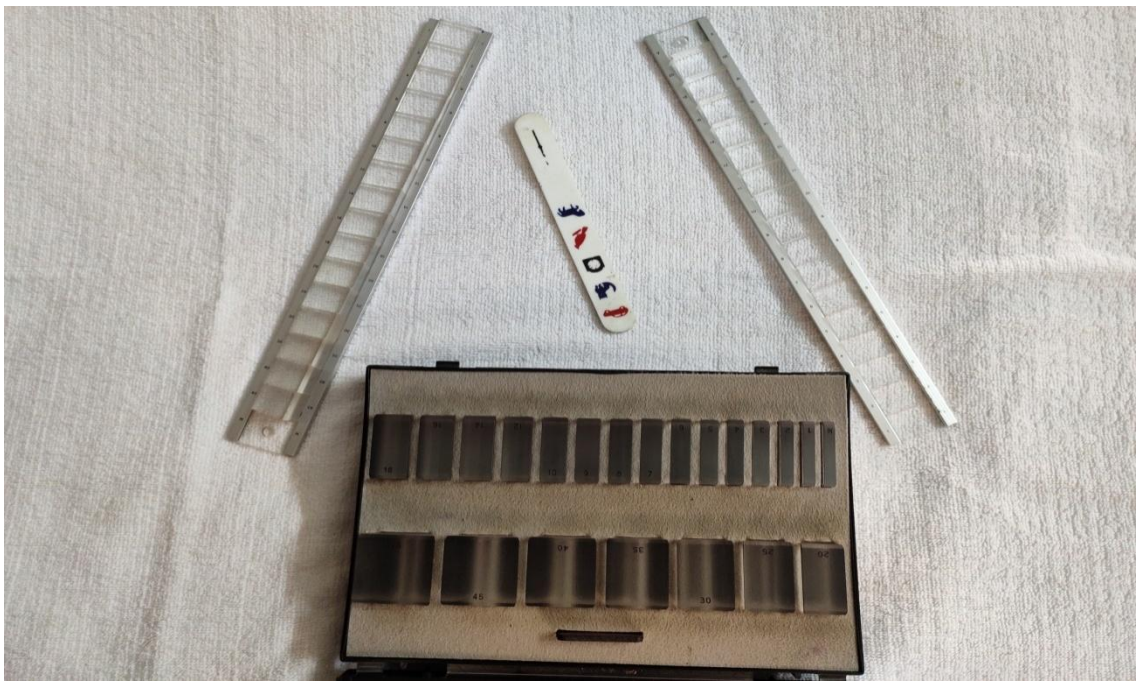


FIGURE 7: TITMUS FLY TEST FOR STEREOPSIS

SETTING:

Patients were recruited from general OPD. The study patients were followed up in the paediatric clinic and the low-vision clinic of the Department of Ophthalmology, Christian Medical College, Vellore. This was a hospital-based, prospective, cross-sectional study, done over a period of 12 months from 5th November 2018 to 7thOctober 2019.

PARTICIPANTS:

Children who were between 5 and 18 years and were amblyopic (two-line difference between the eyes) were recruited. Child who were verbal, who were able to read were recruited.

Children who were already on occlusion therapy as well as new cases of amblyopia - irrespective of causes and grades of amblyopia, were recruited after informed consent and assent.

INCLUSION CRITERIA:

Verbal children between 5 to 18 years with unilateral amblyopia

EXCLUSION CRITERIA:

Children unable to come for follow-up.

Patients not willing to enroll in the study

PRIMARY OUTCOME:

Improvement in compliance with occlusion therapy with counselling and with low vision devices (LVD).

SECONDARY OUTCOME:

Improvement in visual acuity in the amblyopic eye.

Improvement of higher visual functions.

POTENTIAL CONFOUNDERS/ EFFECT MODIFIERS:

Age of patient: Older children tend to co-operate better for occlusion, especially because they can understand the consequences of occlusion.

Type and grade of amblyopia: Children with mild grade of amblyopia and anisometropic amblyopia, have better occlusion rates.

Error in documentation by parent or care-taker

Observer bias

Learning curve effect: Children tend to do the visual charts and the higher visual acuity testing better, with experience.

STUDY DESIGN:

Distant vision is checked in Snellen's chart and Lea picture-LogMAR chart and near vision is checked with N (notation) chart. Then higher acuity tests like contrast sensitivity and stereopsis is measured by the principal investigator at the first visit.

Prism bar cover test for near and distance is done by the squint specialist. After initiation of occlusion therapy, visual parameters were repeated at the first, third and sixth month. The patient's condition of amblyopia was clearly explained to the patient and to his/her parents or care-taker in a language they could understand. They were counselled regarding the need for occlusion and the limited time available for the neural connections to be established and thus the benefits of occlusion. The child and the parent's or care-taker's are given a printout, regarding the study and benefits, in a language they could understand.

Distant vision was re-checked by the co-investigator, in Snellen's chart and Lea picture-LogMAR chart and near vision was checked with Snellen's chart. Then higher acuity tests like contrast sensitivity, stereopsis and prism bar cover test for near and distance was measured at the first visit and after initiation of occlusion therapy in the first, third and sixth month. The patient's condition of amblyopia was clearly explained to the patient and to his/her parents or care-taker in a language they could understand and counselled regarding the need for occlusion and the limited time available for the neural connections to be established and thus the benefits of occlusion. The child and the parent's or care-taker's are given a brochure, regarding the study and benefits, in a language they could understand.

Depending on the vision, the degree of amblyopia was graded as mild, moderate and severe.

Vision 6/9-6/12 -- Mild amblyopia

Vision 6/18-6/36 -- Moderate amblyopia

Vision worse than 6/36 -- Severe amblyopia.

Depending on the degree of amblyopia, the duration of occlusion is advised.

For mild amblyopia – 3 hours of occlusion was advised

For moderate and severe amblyopia – 6 hours of occlusion was advised.

Occlusion could be carried out in a stretch or could be split into smaller durations and cumulative period could be equivalent to the total duration advised.

Counselling was given to inform parents that child's one eye has poor vision(lazy eye), so they need to occlude(cover) the good eye, so the lazy eye will be forced to see and thus vision in the lazy eye might improve. Parents were informed that without occlusion, vision in lazy eye will not improve. The limited time available for occlusion due to the development of the visual system was also explained. Any doubts regarding the therapy was clarified. A dedicated person-relative/parent/care-taker for supervising the occlusion therapy at home was advised and was noted. Initially, they were asked to occlude for 1 hour to start with and slowly increase the time based on compliance. We recommend occlusion after school hours to avoid peer pressure.

In our study, the principal investigator administered counselling, as described above and also informed the limited time available for occlusion due to the development of the visual system. This information was reinforced by the co-investigator separately with documentation. Both parent and the child were counselled. Any doubts regarding the therapy was cleared on the initial visit.

An occlusion monitor record/diary to document daily occlusion, was given. We advised the family to have a dedicated person to supervise the child and advised to note down the duration of occlusion to the smallest minute on a daily basis. An activity book containing drawing, painting, activities were given and daily activities during occlusion were asked to be documented. Activities were divided and advised, depending on the total occlusion time. Near-work activities were encouraged during the period of occlusion. Some of the near-vision work advised during occlusion were drawing, painting, craft work, knitting, playing video games with phone or tablets or I-Pad's, depending on the child's interest.

Each child was asked about their daily routine and a personalized plan for occlusion was given, depending on the available free time at home. Parents are advised to supervise and modify the occlusion time depending on the day to day schedules of the child. During weekends, children are advised to occlude for a longer duration of time, beyond the prescribed duration of occlusion and to make-up for any missed occlusion time during the weekdays.

Those children who are already on occlusion, the duration of occlusion was advised and the duration of occlusion practiced was noted and the compliance of occlusion was graded.

Depending on the duration of occlusion, compliance graded was:

Good: >75% of the total required time

Moderate: 50 to 75% of the total required time

Poor: <50% of the total required time

Those with good compliance will be advised to continue occlusion. For patients with moderate or poor compliance with occlusion, re-counselling was given to the parents and the child.

After one month, those with improvement in occlusion therapy good compliance were asked to continue the occlusion and was reviewed again at 3 month and 6 months after initiation of treatment, to confirm consistence in good compliance with occlusion.

Inspite, of counseling and daily recording, those who had only moderate or poor compliance and those who failed to record the duration were recruited for occlusion of the good eye with low vision aids for the amblyopic eye.

Those who were recruited for use of low vision devices, were trained in the low vision clinic of the Ophthalmology department, regarding usage of optical and non-optical LVD, and also how to engage in near vision activities, which could be practiced at home. Children were given the LVD (hand magnifier/ stand magnifier/dome magnifier/ magnifying sheet, reading stand and electronic video magnifier) free of cost, as child's need and acceptance. Practice was given in various near-vision activities like reading, writing, drawing and coloring. Near activities from books or craft work to keep the child occupied during occlusion and thus to use the amblyopic eye was practiced.

The children were then reassessed at 1, 3 and 6 months to assess improvement in compliance, vision and other visual acuities.

For new cases also similar methods were administered.

VARIABLES	DATA SOURCE (Units)
Visual acuity– *Distance* *Near*	 Lea picture – LogMAR charts (log units) N Chart
Contrast sensitivity	Pelli-Robson Chart (log units)
Stereopsis	Titmus-fly test (seconds of arc)
Angle of deviation	Prism-bar cover test (degree)

BIAS:

To prevent bias, visual acuity and higher visual function were checked by the principal investigator and rechecked by co-investigator, at every visit.

Counselling was also administered by the investigator and co-investigator, separately.

DATA ANALYSIS

Our study was approved by the Institutional Review Board Committee

No: 11629, dated: 08.11.2018.

The data was analyzed using SSPS 23 statistics, with Windows 10 Version.

The categorical variables like sex, age, eye laterality, grade of amblyopia, type of amblyopia, occlusion period advised were analyzed and was described in percentage.

The continuous variables like vision in LogMAR, contrast sensitivity, stereopsis and occlusion duration were analyzed and was described as mean with standard deviation.

A two-tailed $P < 0.05$ was taken to be statistically significant and $P < 0.001$ was considered to be highly significant.

SAMPLE SIZE CALCULATION:

Sample Size was calculated with an expected 30% improvement in compliance during occlusion using counseling and LVD, with 90% power (1-beta) and 5% Alpha error a, sample size of 28 in each arm was calculated. Since there was no similar study using LVD, sample size was calculated for a pilot study.

SAMPLE SIZE CALCULATION:

Two Proportion - Hypothesis Testing - Large Proportion - Equal Allocation							
Proportion in group I	0.4	0.4	0.4	1	1	1	1
Proportion in group II	0.6	0.7	0.75	0.7	0.75	0.65	0.8
Estimated risk difference	-0.2	-0.3	-0.35	0.3	0.25	0.35	0.2
Power (1- beta) %	80	80	80	90	80	80	80
Alpha error (%)	5	5	5	5	5	5	5
1 or 2 sided	2	2	2	2	2	2	2
Required sample size for each arm	97	42	30	28	26	17	34

Formula

$$H_o : P_1 = P_2; \qquad H_a : P_1 \neq P_2$$

$$n = \frac{\left\{ Z_{1-\frac{\alpha}{2}} \sqrt{2\,\overline{P}\,(1-\overline{P})} + Z_{1-\beta} \sqrt{P_1\,(1-P_1) + P_2\,(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

Where,

$$\overline{P} = \frac{P_1 + P_2}{2}$$

P_1 : Proportion in the first group

P_2 : Proportion in the second group

α : Significance level

$1-\beta$: Power

A total of 35 patients were recruited in the study.

Among the total 35, 77.1 % (27 patients) were already on occlusion and did not have 100% compliance, hence included in the study, to enhance occlusion compliance.

22.9 % (8 patients) were new cases of amblyopia, to whom occlusion was advised after recruitment.

AGE:

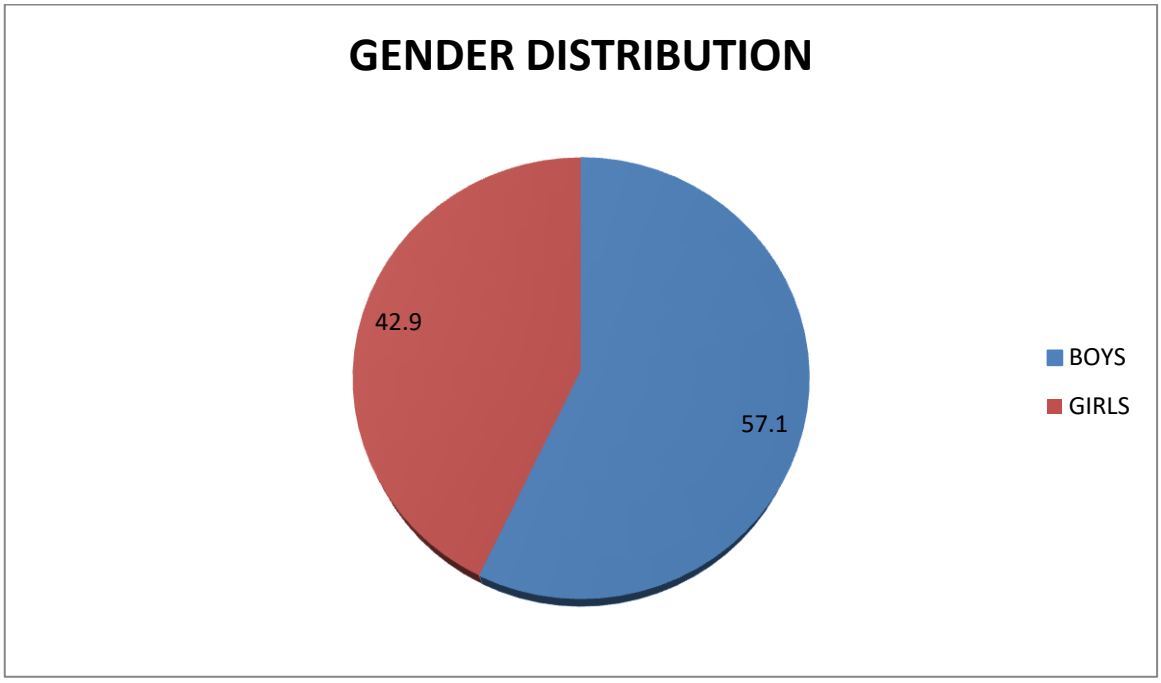
Age of subjects ranged from 5 – 18 years, with a mean age of 8.26 years (SD 3.25).

29 children (82.9%) belonged to the age group 5-12 years and 6 children (17.1%) enrolled in the study were more than 12 years.

TABLE 1: TABLE SHOWING THE AGE DISTRIBUTION OF THE STUDY POPULATION

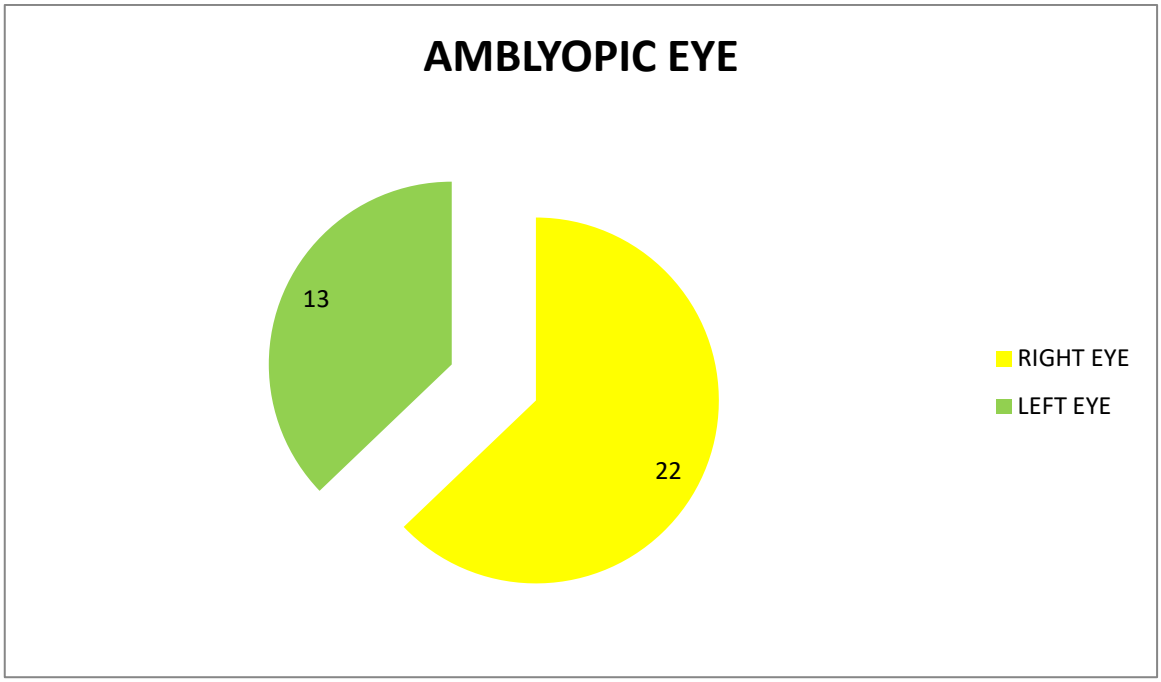
AGE	NO. OF CHILDREN	% PERCENTAGE
5-12 YEARS	29	82.9%
>12-18 YEARS	6	17.1%

FIGURE 8: GENDER DISTRIBUTION



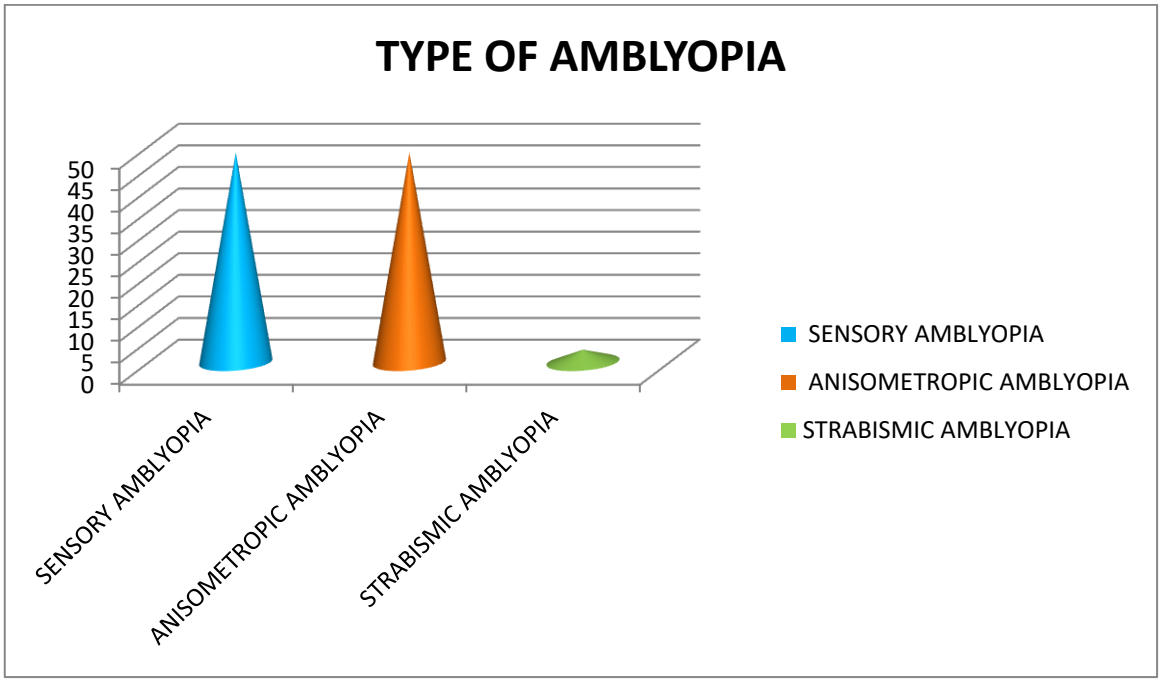
The number of boys 20 (57.1%) with amblyopia was higher than the number of girls with amblyopia 15 (42.9%)

FIGURE 9: LATERALITY OF THE AMBLYOPIC EYE



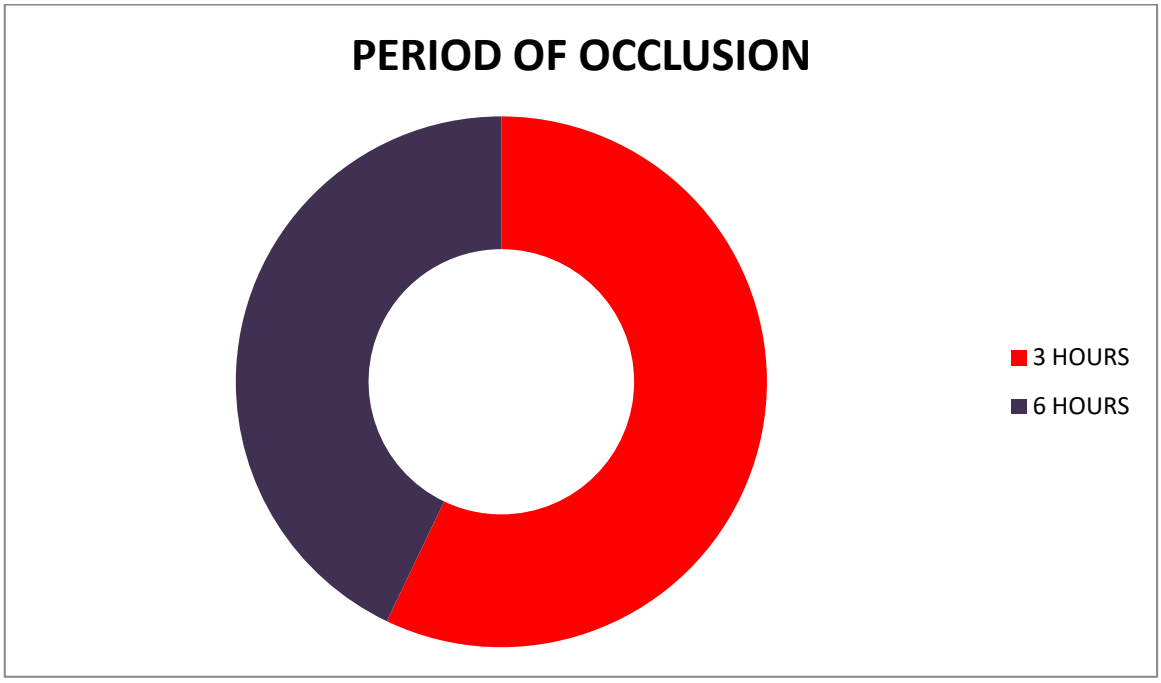
Most of our patients had right amblyopic eye (62.9%)

FIGURE 10: THE TYPES OF AMBLYOPIA IN OUR STUDY POPULATION



A total of 15 (42.9%) children had mild amblyopia, 12 (34.3%) had moderate and 8 (22.9%) had severe amblyopia. Underlying amblyogenic causes were sensory in (48.6%, n=17), anisometrophic (48.6%, n=17) and purely strabismic (2.9%, n=1). 51.49% (n=18) children had some degree of strabismus in the sensory and anisometropic group, but only one child had pure strabismic amblyopia.

FIGURE 11: OCCLUSION PERIOD PRESCRIBED

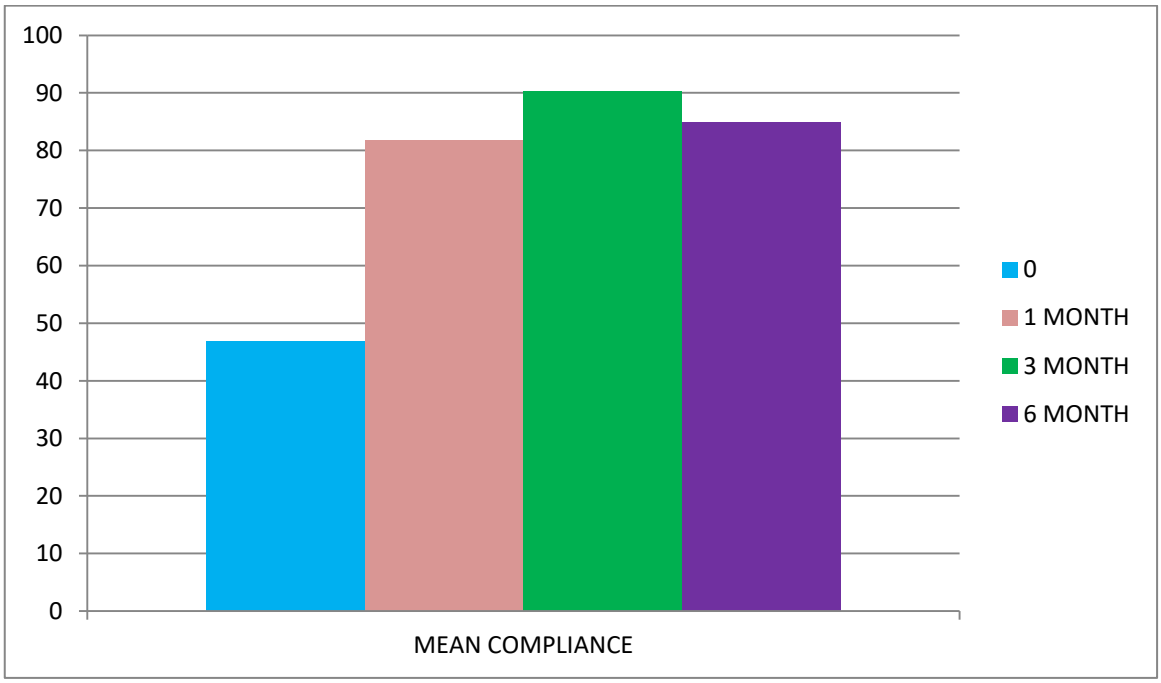


A total of 15 (42.9%) children had mild amblyopia and 3 hours of occlusion was advised. 12 (34.3%) children had moderate amblyopia and 8 (22.9%) children had severe amblyopia and were advised 6 hour occlusion. Those advised 6 hour occlusion, were started initially on 3 hour occlusion and then increased to 6 hour occlusion. In 5 moderate amblyopes, vision improved (better than 6/12) within 1 month of occlusion, so were advised to continue occlusion (mild amblyopes) for 3 hours per day. The remaining 7 moderate amblyopes, continued to occlude for 6 hours per day.

Finally, 3 hour occlusion was advised for 57.1% (n=20) children – 15 mild amblyopes and 5 moderate amblyopes and 6 hour occlusion was advised for 42.9% (n=15) children – 7 moderate amblyopes and 8 severe amblyopes.

Our study aimed primarily at enhancing the compliance rate. Among 35 patients, 26 came for 1 month follow-up, 29 came for 3 month follow-up and 25 came for 6 months follow-up.

FIGURE 12: MEAN COMPLIANCE IN PERCENTAGE AT THE BEGINNING OF STUDY, AT 1, 3 AND 6 MONTHS



The mean compliance for occlusion at the beginning of study, for children who were already on occlusion was 37.62% (SD 39.2) for patients, who were already on occlusion. Once occlusion was initiated for those who were newly initiated on occlusion and old patients already on occlusion, after counselling, at 1 month the compliance for occlusion was 81.73 % (SD 22.86), at 3 monthwas 90.18 (SD 19.91) and at 6 month was 84.93 (SD 22.49).

FIGURE 13: PRE & POST COUNSELLING COMPLIANCE

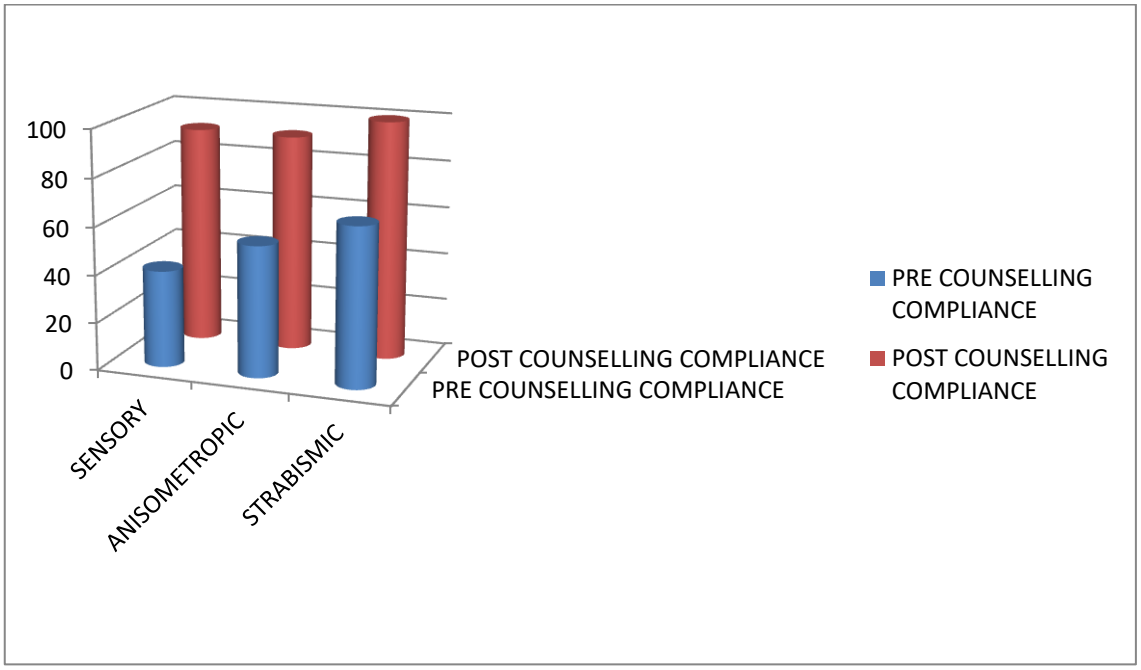


TABLE 2: COMPLIANCE IN VARIOUS GROUPS OF AMBLYOPIA PRE & POST COUNSELLING IN CHILDREN ALREADY ON OCCLUSION

(OLD CASES)

	PRE - COUNSELLING COMPLIANCE (mean± SD)	POST – COUNSELLING COMPLIANCE (mean ± SD)	P VALUE
ANISOMETROPIC (n=8)	55.00 ± 44.48	97.92 ± 5.89	0.785
STRABISMIC(n=1)	66.67 ± 0	100.00 ± 0	
SENSORY (n=16)	40.62 ± 37.00	91.98 ± 12.01	

The improvement in compliance was clinically significant, but not statistically significant.

TABLE 3: OCCLUSION COMPLIANCE POST-COUNSELLING

	POST – COUNSELLING COMPLIANCE (mean± SD)
ANISOMETROPIC (n=13)	91.03 ±18.78
STRABISMIC (n=1)	100
SENSORY (n=17)	91.47 ± 11.81

TABLE 4: COMPLIANCE PRE & POST COUNSELLING IN CHILDREN FROM 5-12 YEARS

	PRE -COUNSELLING COMPLIANCE (mean± SD)	POST – COUNSELLING COMPLIANCE (mean± SD)
ANISOMETROPIC (n=11)	42.31 ± 45.45	89.39 ± 20.10
STRABISMIC(n=1)	66.67 ± 0	100.00 ± 0
SENSORY (n=15)	42.22 ± 37.73	92.56 ± 12.20

TABLE 5: COMPLIANCE PRE & POST COUNSELLING IN CHILDREN >12 YEARS

	PRE -COUNSELLING COMPLIANCE (mean±SD)	POST – COUNSELLING COMPLIANCE (mean±SD)
ANISOMETROPIC (n=2)	0.0 ± 0.0	100.0 ± 0.0
SENSORY (n=2)	8.34 ± 11.79	83.33 ± 0.0

Among children from 5-12 years (n= 29) i.e. 82.9% of the study population had compliance of 91.54 (SD 15.52) and >12 years to 18 years (n= >12-18 years) i.e. 17.1% had a compliance of 91.67 (SD 9.62)

However, for the types of amblyopia and age, our small sample size was not enough to calculate Odds ratio (OR)

The pre-recruitment vision ranged from log 1.8 to log 0.2, with a mean of 0.72 ± 0.29SD.

The vision post-recruitment ranged from log1.6 to log 0.1, with a mean of 0.57 ± 0.31SD.

The difference was statistically significant ($p < 0.001$)

The pre-recruitment near-vision ranged from Nnil to N8

The near-vision post-recruitment ranged from Nnil to N6.

Among 35 patients, 18/35 (51.43%) had improvement in vision of 0.1 LogMAR, 11/35 (31.43%) had improvement in vision of atleast 0.2 LogMAR,5/35 (14.29 %) had improvement in vision of atleast 0.3 LogMAR.

TABLE 6: COMPARISON IN VISION PRE & POST COUNSELLING IN THE VARIOUS TYPES OF AMBLYOPIA

	PRE - COUNSELLING VISION (mean±SD)	POST – COUNSELLING VISION (mean±SD)	P VALUE
ANISOMETROPIC (n=13)	0.66 ± 0.27	0.47 ± 0.15	0.389
STRABISMIC (n=1)	0.20 ± 0	0.20 ± 0	
SENSORY (n=17)	0.80 ± 0.28	0.64 ± 0.34	

In children with anisometropic and sensory amblyopia, there was an improvement of vision, about 0.2 in logMAR which was clinically significant. However, it was not statistically significant.

FIGURE 14: VISION IN LogMAR IN THE BETTER EYE VS AMBLYOPIC EYE AT THE BEGINNING OF STUDY

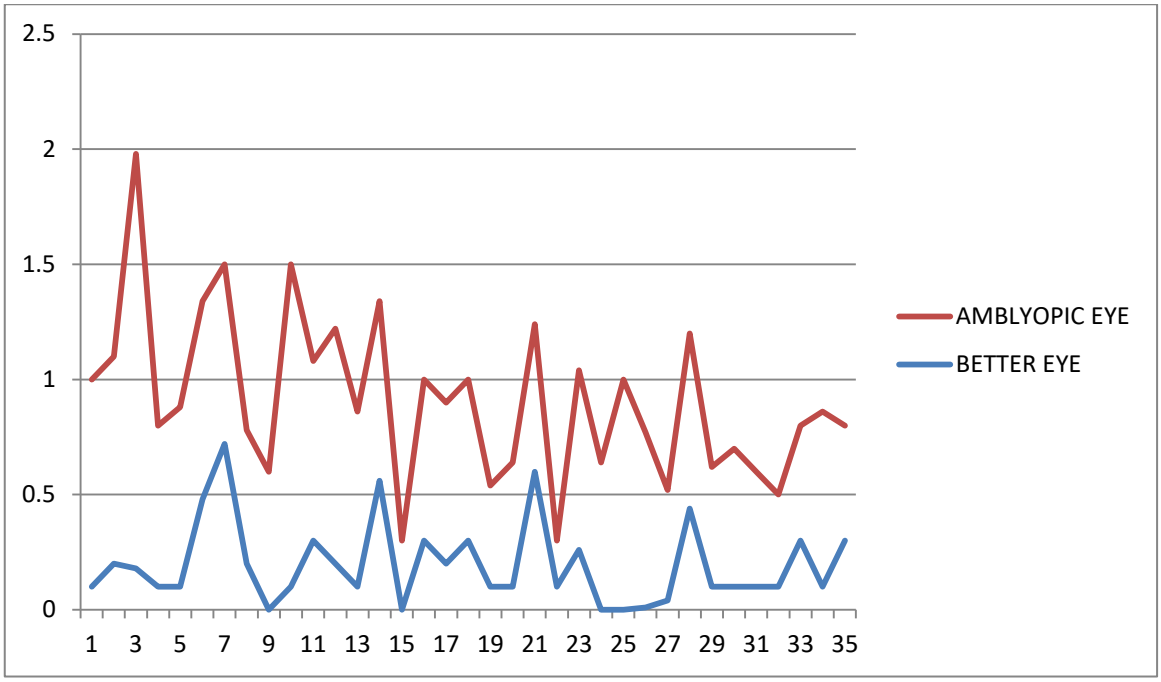


FIGURE 15: MEAN VISION IN LogMAR IN THE BETTER EYE VS AMBLYOPIC EYE AT VARIOUS PERIOD OF THE STUDY

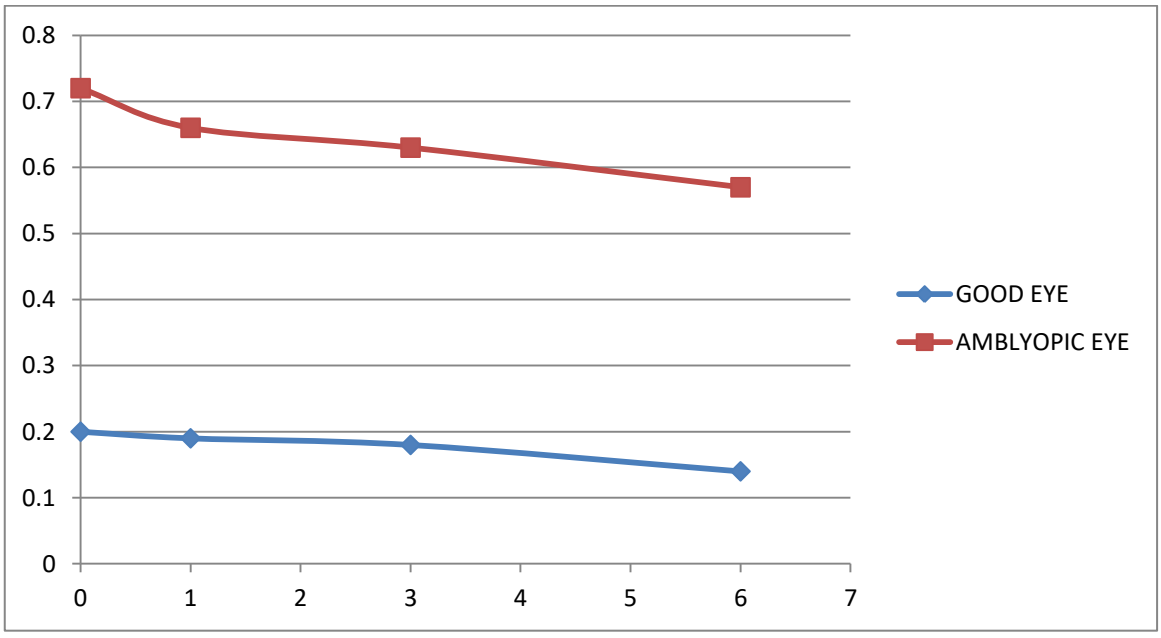
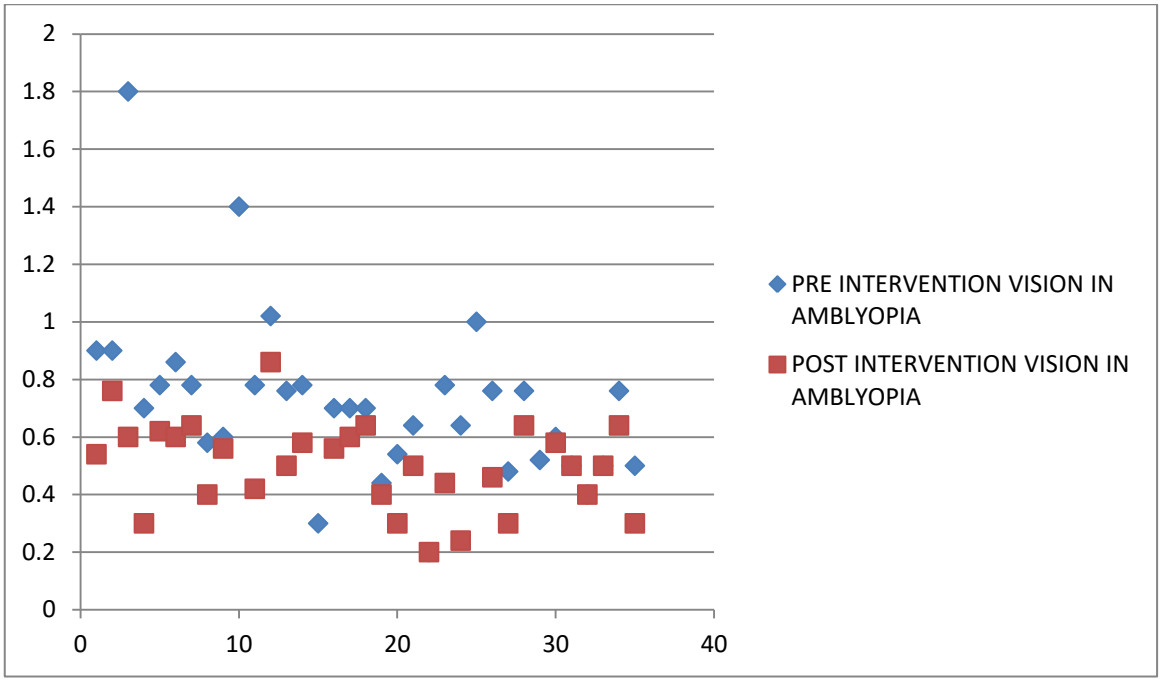
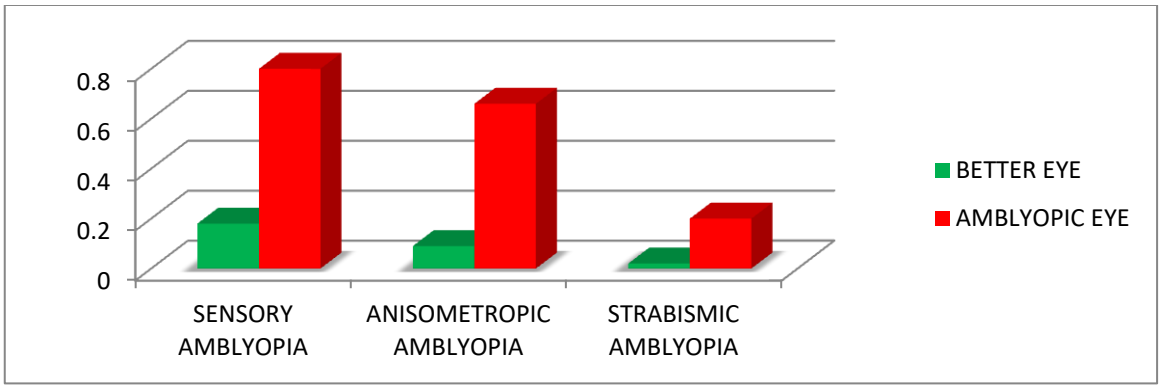


FIGURE 16: PRE – INTERVENTION AND POST – INTERVENTION VISION OF THE AMBLYOPIC EYE



The mean vision in the better eye was log 0.2 (with a SD of 0.18) and the mean vision in the amblyopic eye was 0.72 (with a SD of 0.29). The eyes were orthotrophic in 45.71% of the children for both distant and near, when measured by a prism bar cover test.

FIGURE 17: VISION IN THE BETTER EYE VS AMBLYOPIC EYE IN THE VARIOUS TYPES OF AMBLYOPIA PRE-COUNSELLING:



At the beginning of study, the mean vision in the better eye and amblyopic eye of the patients with sensory amblyopia was 0.26 (SD 0.21) and 0.91 (SD 0.39) and the p value was 0.001. The mean vision in the better eye and amblyopic eye of the patients with anisometropic amblyopia was 0.15 (SD 0.16) and 0.73 (SD 0.28) and the p value was 0.002. The mean vision in the better eye and amblyopic eye of the patient with strabismic amblyopia was 0.1 and 0.2 respectively.

FIGURE 18: VISION IN THE BETTER EYE VS AMBLYOPIC EYE IN THE VARIOUS TYPES OF AMBLYOPIA - PRE-COUNSELLING

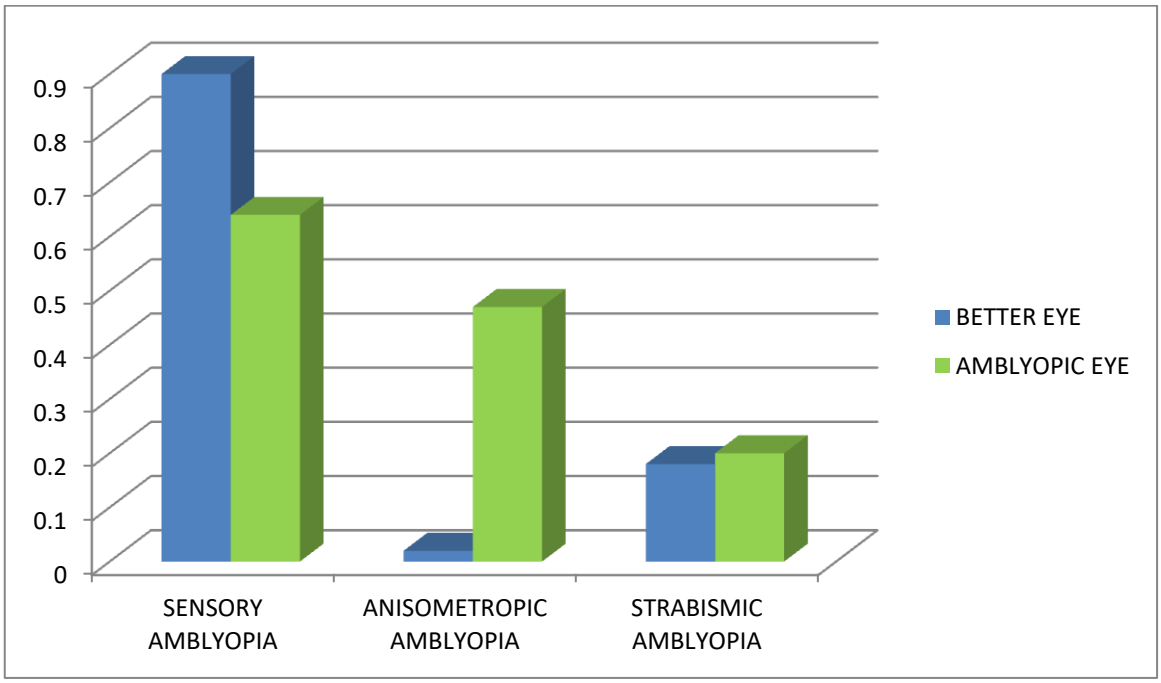
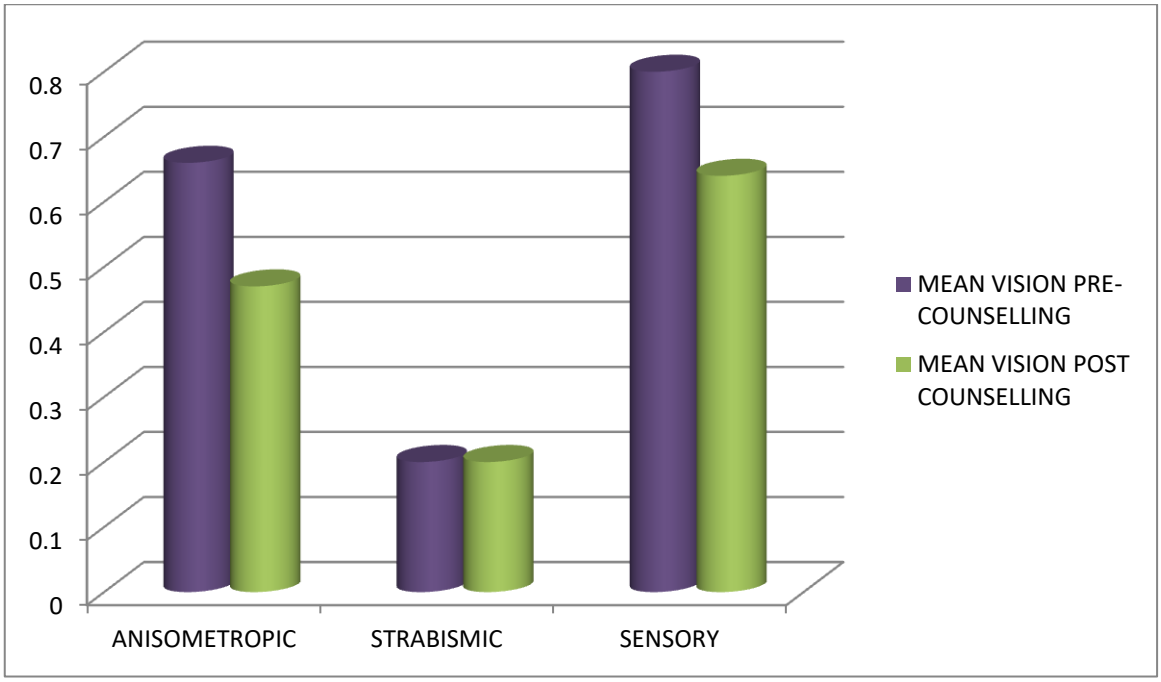


FIGURE 19: MEAN VISION IN THE AMBLYOPIC EYE – PRE & POST COUNSELLING



Among the 35 children, vision improved in 9/13 children with anisometropic amblyopia in a larger degree and 14/17 children with sensory amblyopia, had a moderate visual improvement.

Among 35 patients, 19/35 (54.28%) had improvement in contrast sensitivity, 20/35 (57.14 %) had improvement in stereopsis.

Hence, children with anisometropic amblyopia, had a better chance for good visual improvement.

Among children from 5-12 years (n=29) in 62.06% (n=18) had vision improvement, with a mean of 0.15 (SD±0.29) as compared to 83.33% (n=5) and >12 years to 18 years, with a mean of 0.17 (SD± 0.14.

So children among 12-18 years had vision improvement better than 5-12 age group.

TABLE 7: COMPARISON OF VISION PRE & POST COUNSELLING IN MALE & FEMALE

GENDER	PRE COUNSELLING VISION (mean±SD)	POST COUNSELLING VISION (mean±SD)	P value
MALE (n=18)	0.73 ± 0.36	0.57 ± 0.34	0.001
FEMALE (n=13)	0.70 ± 0.18	0.55 ± 0.15	0.001

TABLE 8: COMPARISON OF VISION PRE & POST COUNSELLING IN 5-12 &> 12 YEARS

AGE	PRE COUNSELLING VISION (mean ±SD)	POST COUNSELLING VISION (mean ±SD)	P value
5 – 12 YRS (n=27)	0.72 ± 0.28	0.57 ± 0.29	<0.001
>12 – 18 YRS (n=4)	0.68 ± 0.37	0.51 ± 0.14	0.066

The improvement in vision in logMAR among 5 to 12 yrs category was 0.15, while in the > 12 to 18 yrs group it was 0.17.

TABLE 9: COMPARISON OF VISION PRE & POST COUNSELLING IN THE VARIOUS GRADES OF AMBLYOPIA

GRADE OF AMBLYOPIA	PRE COUNSELLING VISION (mean ±SD)	POST COUNSELLING VISION (mean ±SD)	P value
MILD (n=13)	0.56 ± 0.19	0.44 ± 0.14	0.631
MODERATE (n=12)	0.69 ± 0.10	0.52 ± 0.11	
SEVERE (n=6)	1.05 ± 0.38	0.89 ± 0.45	

FIGURE 20: CHANGE IN VISION IN PRE TO POST COUNSELLING IN THE VARIOUS GRADES OF AMBLYOPIA

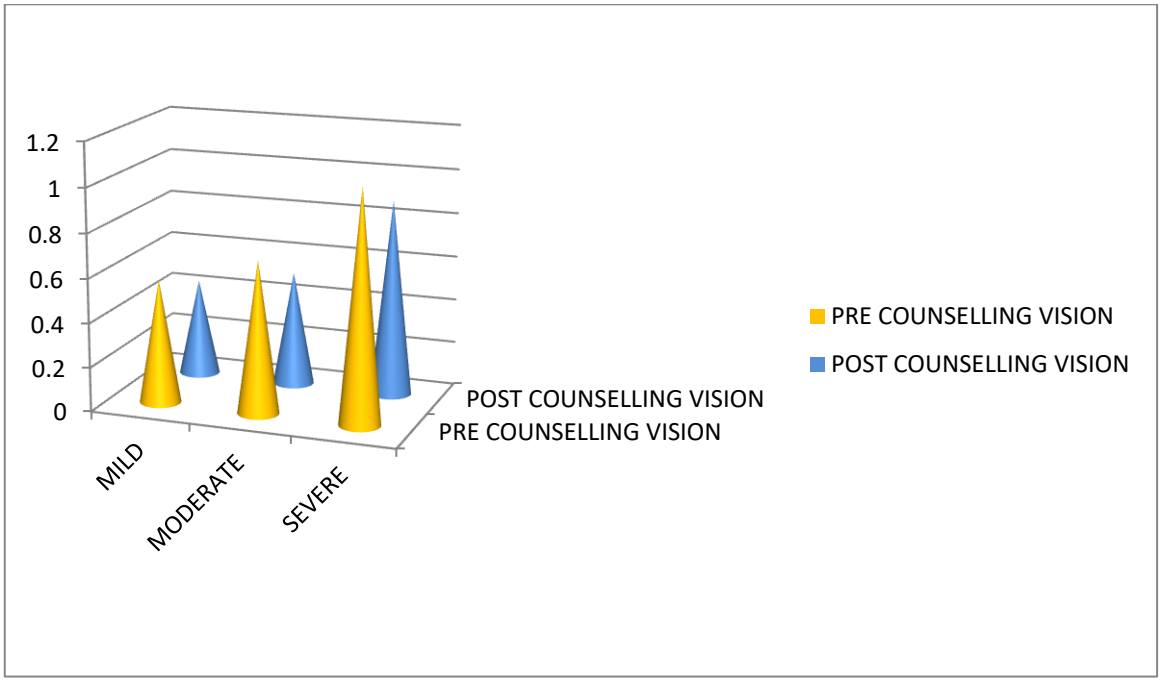


TABLE 10: MEAN VISION AT VARIOUS STAGES OF THE STUDY

VISION ASSESSMENT	MEAN (log)	S.D.	P value
AT RECRUITMENT	0.72	0.18	<0.001
1 MONTH	0.66	0.29	
3 MONTH	0.63	0.27	
6 MONTH	0.57	0.31	

TABLE 11: VISION AND HIGHER VISUAL FUNCTION, BEFORE AND AFTER 6 MONTHS OF OCCLUSION AND COUNSELLING

	PRE COUNSELLING (MEAN ± SD)	POST COUNSELLING (MEAN)	P VALUE
DISTANT VISION (LogMAR)	0.72 ± 0.29	0.57 ± 0.31	<0.001
STEREOPSIS (Seconds)	2176.57 ± 1789.16	836.83 ± 1356.08	<0.001
CONTRAST SENSITIVITY (LogMAR)	0.88 ± 0.56	1.05 ± 0.54	0.002

Normal vision(6/6) in LogMAR is 0.0, normal contrast sensitivity is 1.73-1.99 and 3000 at 4 years to 60 seconds at 10 years

The pre-recruitment contrast sensitivity in the amblyopic eye ranged from log nil to log 1.9, with a mean of 0.88 and ± 0.56SD.

The contrast sensitivity post-recruitment ranged from log nil to log 1.65, with a mean of 1.05 ± 0.54SD.

The difference was statistically highly significant (p 0.002)

FIGURE 21: MEAN CONTRAST SENSITIVITY WITHIN THE GROUPS, BETTER EYE VS AMBLYOPIC EYE

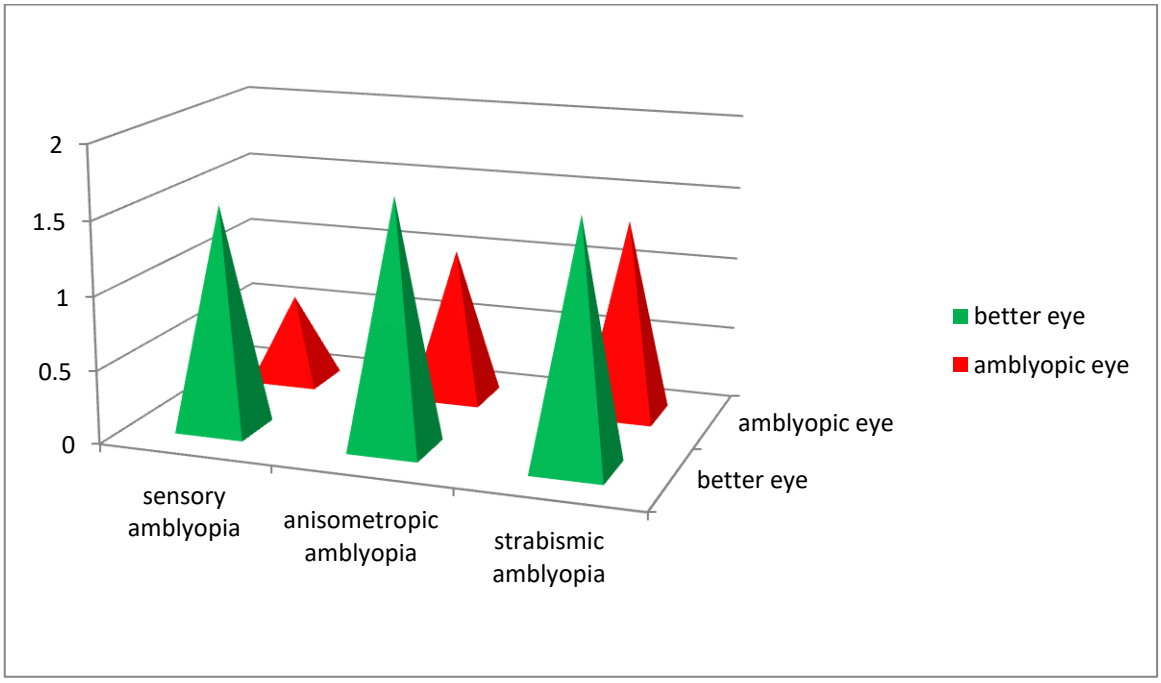


FIGURE 22: CONTRAST SENSITIVITY IN THE BETTER EYE AND AMBLYOPIC EYE DURING THE PERIOD OF STUDY

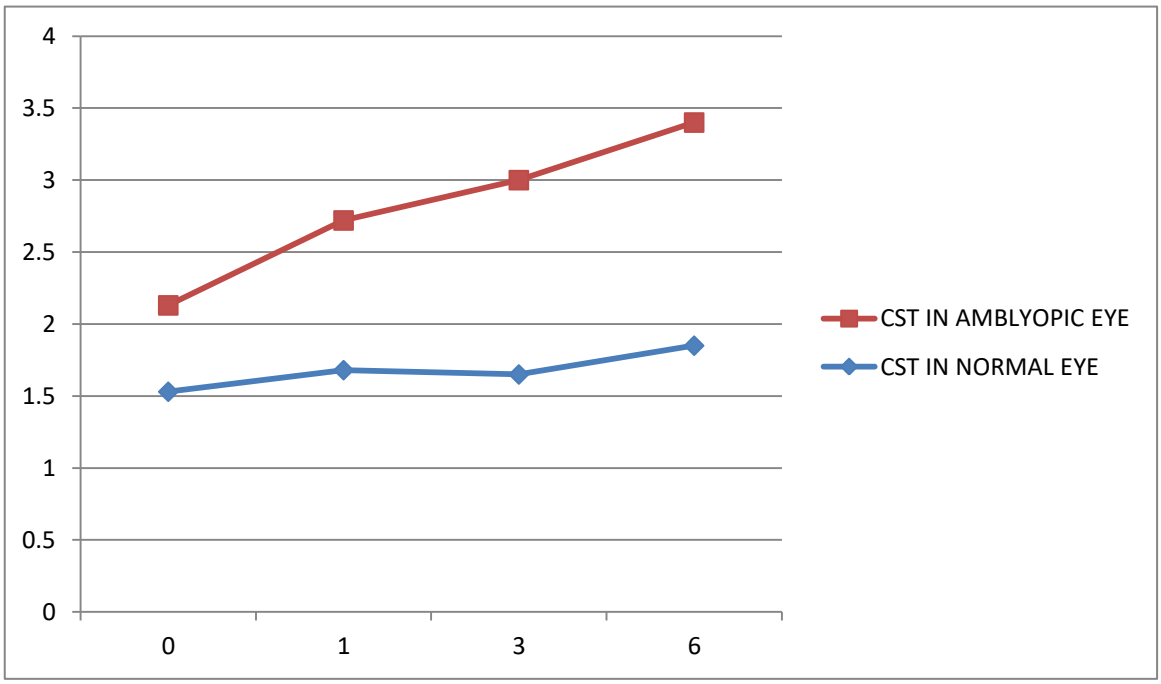


FIGURE 23: CONTRAST SENSITIVITY IMPROVEMENT DURING THE COURSE OF STUDY IN THE AMBLYOPIC EYE

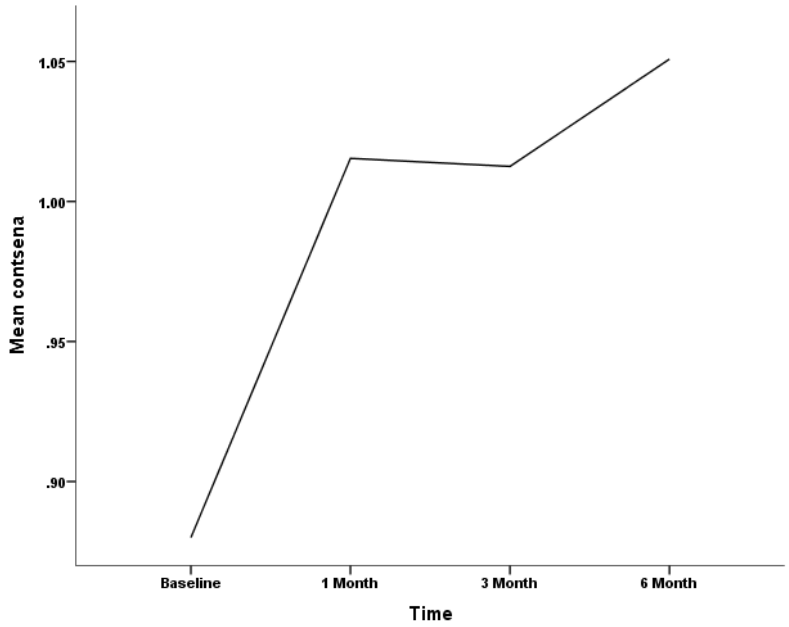


FIGURE 24: CONTRAST SENSITIVITY AT THE BEGINNING AND AT 6 MONTHS

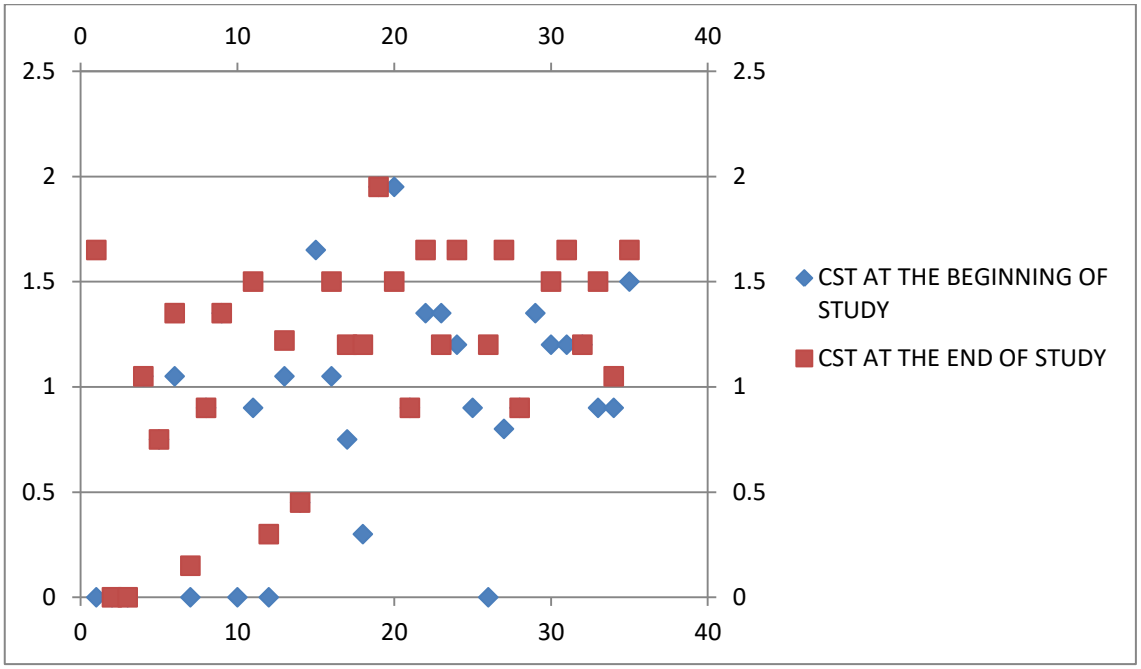


FIGURE 25: CHANGE IN CONTRAST SENSITIVITY IN PRE AND POST COUNSELLING IN THE VARIOUS TYPES OF AMBLYOPIA

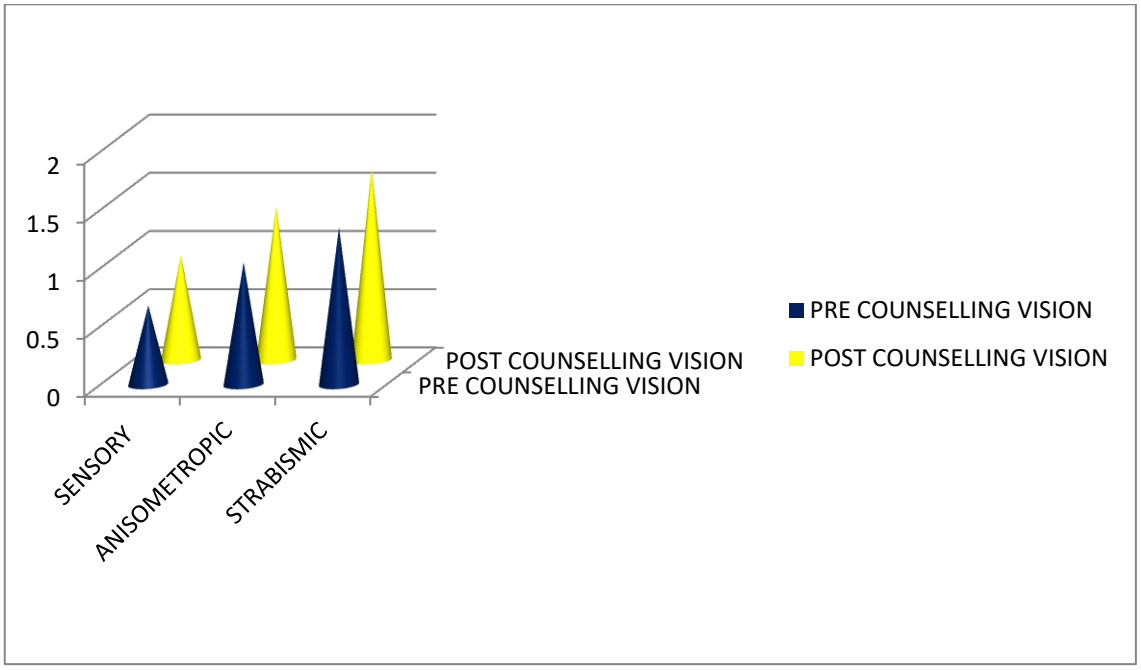
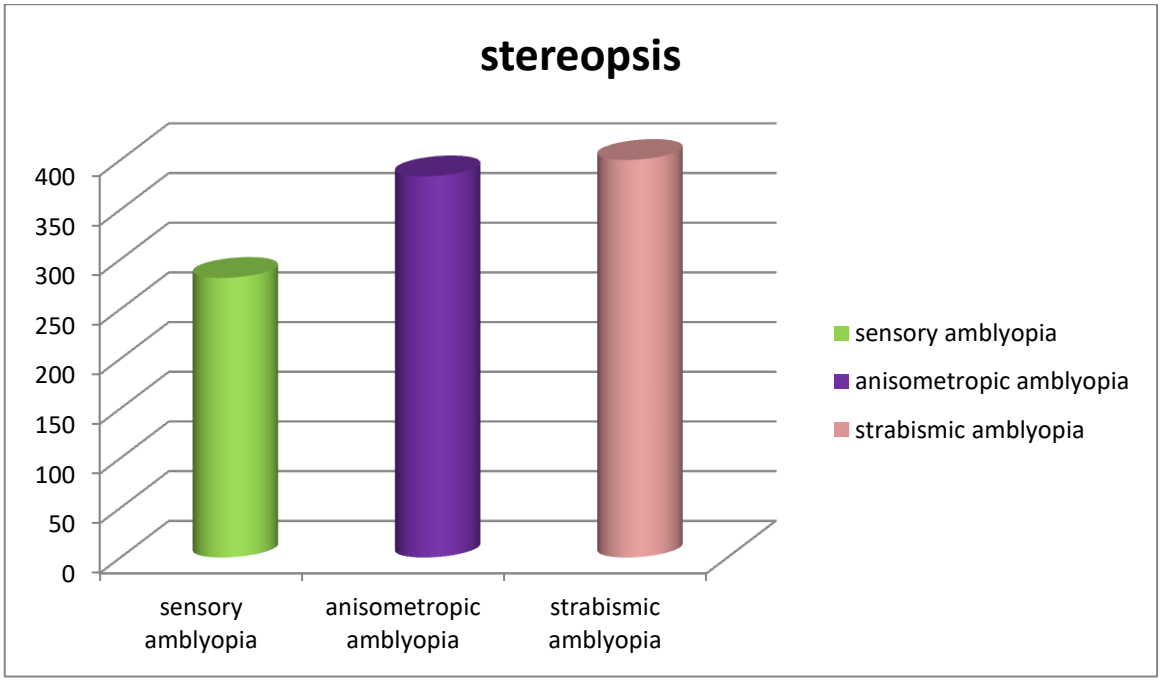


TABLE 12: CHANGE IN CONTRAST SENSITIVITY FROM PRE COUNSELLING TO POST COUNSELLING IN THE VARIOUS TYPES OF AMBLYOPIA

	PRE – CONTRAST SENSITIVITY	POST – CONTRAST SENSITIVITY	P VALUE
	Mean ± SD	Mean ± SD	
ANISOMETROPIC (n=13)	1.05 ± 0.58	1.32 ± 0.43	0.985
STRABISMIC (n=1)	1.35 ± 0.0	1.65 ± 0.0	
SENSORY (n=17)	0.68 ± 0.49	0.90 ± 0.55	

At the beginning of study, the mean contrast sensitivity of the better eye and amblyopic eye with sensory amblyopia was 1.53 (SD 0.26) and 0.60 (SD 0.51) with the p value of 0.001. The mean contrast sensitivity of the better and amblyopic eye in the anisometropic group was 1.68 (SD 0.41) and 1.04 (SD 0.56) with a p value of 0.002. The mean contrast sensitivity of the better and amblyopic eye in the strabismic group was 1.65 and 1.35.

FIGURE 26: MEAN STEREOPSIS BETWEEN VARIOUS GROUPS AT THE BEGINNING OF STUDY



At the beginning of the study, the mean stereopsis in the sensory amblyopia group was 3056.24 seconds, in the anisometropic amblyopia group was 1401.41seconds and 400 seconds in strabismic amblyopia. The pre-recruitment stereopsis ranged from nil seconds to 100 seconds, with a mean of SD. At the end of the study, the mean stereopsis in the sensory amblyopia group was 855.53 seconds, in the anisometropic amblyopia group was 256.92 seconds and400 seconds in strabismic amblyopia The stereopsis post-recruitment ranged from nil to 100 seconds, with a pre recruitment mean of 3466.67 (SD 1306.39) and post recruitment mean of 792 (SD 1354.48).

The difference was statistically significant ($p < 0.001$).

FIGURE 27: STEREOPSIS AT THE BEGINNING AND END OF STUDY

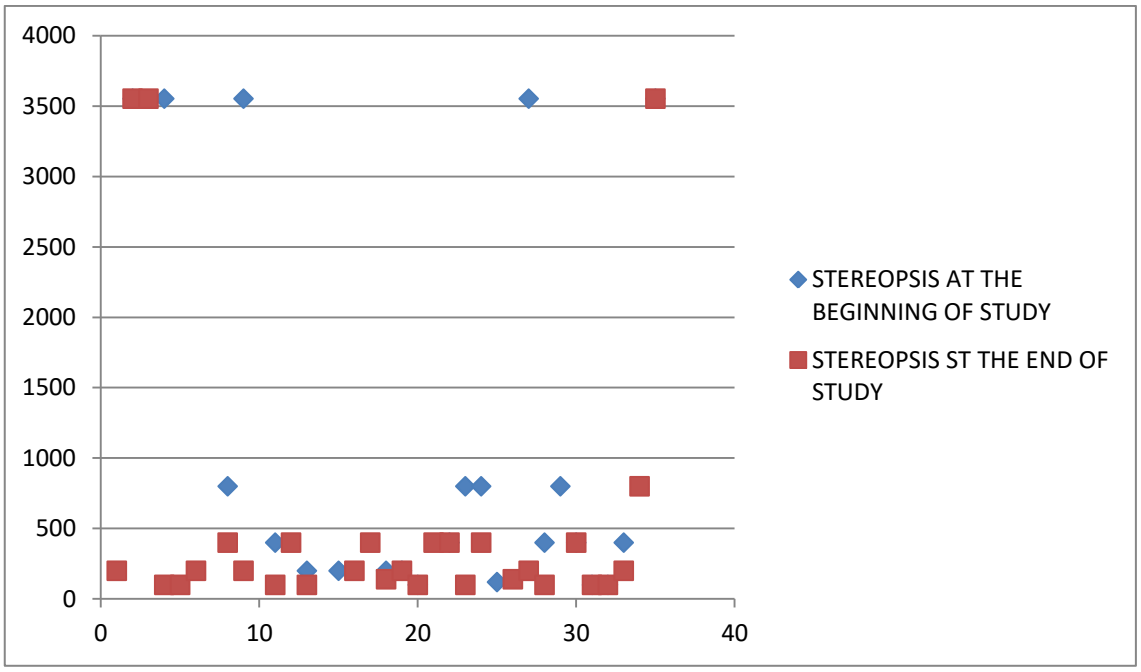


TABLE 13: CHANGE IN STEREOPSIS FROM PRE TO POST IN THE VARIOUS TYPES OF AMBLYOPIA

	PRE - STEREOPSIS	POST – STEREOPSIS	p VALUE
	Mean ± SD	Mean ± SD	
ANISOMETROPIC (n=13)	1401.41 ± 1634.79	256.92 ± 200.31	0.173
STRABISMIC(n=1)	400.00 ± 0.0	400.00 ± 0.0	
SENSORY (n=17)	3056.24 ± 1572.23	855.53 ± 1372.50	

FIGURE 27: PRE & POST COUNSELLING STEREOPSIS IN THE VARIOUS TYPES OF AMBLYOPIA

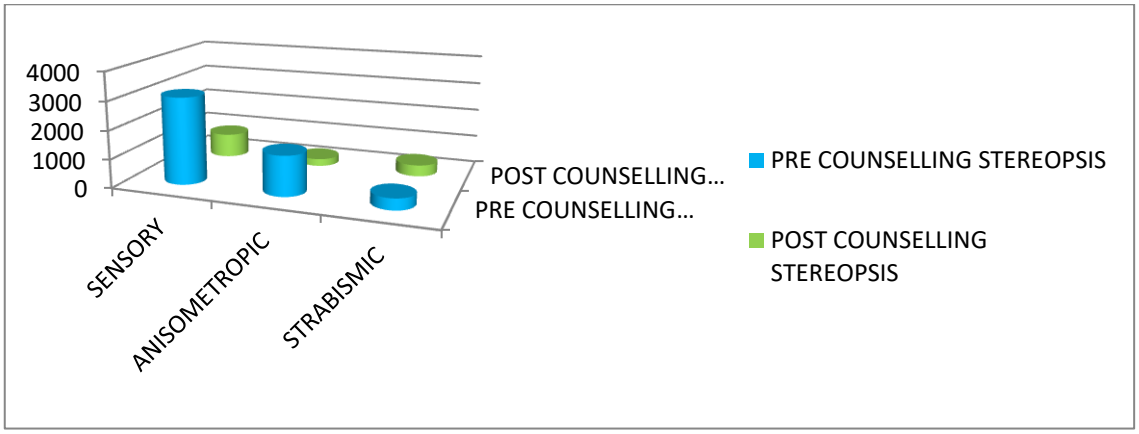


TABLE 14: PROGRESSION OF COMPLIANCE,VISION, CONTRAST SENSITIVITY AND STEREOPSIS OVER A PERIOD OF TIME

	BASELINE	1 MONTH	3 MONTH	6 MONTH	pVALUE
OCCLUSION GRADE (%)	37.62 ± 39.26	81.73 ± 22.86	90.18 ± 19.91	84.93 ± 22.49	**<0.001**
AMBLYOPIC EYE VISION (LogMAR)	0.72 ± 0.29	0.66 ± 0.29	0.63 ± 0.27	0.57 ± 0.31	**<0.001**
CONTRAST SENSITIVITY (LogMAR)	0.88 ± 0.56	1.02 ± 0.53	1.01 ± 0.51	1.05 ± 0.54	**0.002**
STEREOPSIS (seconds)	2176.57 ± 1789.16	1894.92 ± 1716.87	999.86 ± 1325.50	836.83 ± 1356.08	**<0.001**

LOW VISION DEVICES GROUP:

The pre-counselling compliance in 6 children before using low vision devices was 16.67% (SD 25.62) and post-counselling compliance in the children who used low vision devices to see better, when occluding the good eye was 83.33% (SD 21.08). The mean vision of these children in the amblyopic eye before the study was 0.97 (SD 0.43) and mean vision post counselling and use of low-vision devices was 0.85 (SD 0.48). The mean stereopsis at the beginning of study was 3466.67 (SD 1306.39) and mean stereopsis at the end of study was 792 (SD 1354.48). The contrast sensitivity in the amblyopic eye pre counselling was 0.38(SD 0.58) and post counselling with use of low-vision devices was 0.65(SD 0.73).

TABLE 15: PRE & POST COUNSELLING PARAMETERS IN CHILDREN WHO USED LOW VISION AIDS WITH OCCLUSION

PARAMETERS	PRE-COUNSELLING	POST-COUNSELLING
VISION IN AMBLYOPIC EYE (LogMAR)	0.97 ± 0.43	0.85 ± 0.48
CONTRAST SENSITIVITY (LogMAR)	0.38 ± 0.58	0.65 ± 0.73
STEREOPSIS (seconds)	3466.67 ± 1306.39	792 ± 1354.48
COMPLIANCE (PERCENTAGE (%)	16.67 ± 25.82	83.33 ± 21.08

DISCUSSION

Amblyopia refers to poor vision caused by abnormal visual development secondary to inadequate visual stimulation(1). The most critical period of visual development is the first three months, followed by a slower rate upto 7-8 years(1) and mounting evidence shows that even upto 18 years visual plasticity is active(25).

Amblyopia is graded based on vision. Treatment protocols for amblyopia are also based on vision. There are various other visual factors which are also affected along with vision. The amblyopic eye also may have deficits like poor contrast sensitivity, stereopsis, grating acuity and vernier acuity. Other disturbances like positional uncertainity, misperception of orientation and spatial distortion may also be present(5). Recent studies on amblyopes have failed to identify any functional limitation of work in amblyopes with some probable educational limitation. Further research has to be done for long term follow-up on functional and educational limitation of amblyopes(11). It is presumed that binocular vision is required for fine motor functions, hence amblyopes who lack stereopsis may have difficulty in performing fine tasks requiring three dimensional depth(5).

Children with sensory amblyopia are presumed to have denser amblyopia, hence difficult to treat(2), because of the interocular image resolution difference. In strabismic amblyopia, binocularity and stereopsis are grossly affected(1). Myopic amblyopia is easier to treat because of a clear near image in the myopic eye as compared to hypermetrophic amblyopia which does not have any clear image, hence is not amenable to treatment beyond 4-5 years(1). Children who

have hypermetropia, depending on the degree of hypermetropia, might have mild impairment of fine skills(5).

Once children with amblyopia were identified, the basic aim is to treat them as early as possible with persistant follow-up. Amblyopia is one disease which has very slow, but steady improvement with continuous treatment.

Our aim was to identify the children early and form an individualised treatment approach for each child and have a strict follow-up regimen. This close follow-up regimen is important to encourage the children to follow occlusion and monitor improvement in the visual parameters. Personalised interaction also helps to clear any doubts from the family and patient, regarding occlusion.

To remove any bias, at every visit, the vision and all visual parameters were checked by the principal investigator, followed by a co-investigator, blinded from the information collected by the principal investigator, and data was entered. For children who did not follow-up at the scheduled visit, frequent telephonic reminders were sent to the parents.

Age of subjects included in our study was only from 5-18 years. We did not include children below 5 years, so they can read, express their thoughts, can understand counselling better and probably handle low vision aids better. Our higher limit was 18 years, because of the extended limit of plasticity seen in an Indian study, done by Kavitha et al(25).

Vision examination was done with Lea symbol - LogMAR chart, as it was easy for children to recognise the symbols and verbalise. Contrast sensitivity was

examined using Pelli-Robson charts, as all children had started attending school and was able to identify alphabets. The stereopsis was measured using titmus fly test, irrespective of age, for uniformity. These were the conventional charts used in most of the studies for visual assessment in children(48) . Prism-bar cover test was used to assess the degree of strabismus for distance and near.

Depending on the degree of amblyopia, children were assigned their duration of occlusion, which was based on the PEDIG study(10). In a South Indian study by Ganekal et al, boys(57%) were more than girls(43%) as in our study were amblyopic boys(57.1%) outnumbered the girls(42.9%)(6). The degree of amblyopia was also comparable as in the study done by Ganekal et al., where 63.7% had mild-moderate amblyopia and 36.3% had severe amblyopia. In our study, mild amblyopia was seen in 42.9%, moderate amblyopia in 34.3% and severe amblyopia in 22.9%.

TABLE 16: COMPARATIVE TABLE SHOWING PERCENTAGE OF VARIOUS TYPES OF AMBLYOPIA

STUDY	MILD amblyopia	MODERATE amblyopia	SEVERE amblyopia
Ganekal et al(6)	63.7%		36.3%
Our study	42.9%	34.3%	22.9%

In our study population, 48.6% of our patients had sensory amblyopia, 48.6% had anisometrophic amblyopia and 2.9% had strabismic amblyopia. Our

proportion of sensory amblyopia was high, because our institute is a tertiary referral centre and we have a large clientele of sensory amblyopes due to congenital cataract and trauma, compared to the South Indian institutional study population by Ganekal et al., where refractive amblyopia was seen in 90.9% amblyopes, strabismus related amblyopia in 6.8% and 4.5% and 2.2%, due to visual deprivation and combined causes respectively. In a study done by Magdalene et al, in a North Eastern population, refractive amblyopia was seen in 45.01%, followed by deprivation amblyopia in 40.36% and strabismic amblyopia in 14.35%. In a study done by Singh et al., 50.7% had refractive amblyopia, 31.9% had mixed amblyopia, 11.6% had strabismic amblyopia and 5.8% had sensory amblyopia.

TABLE 17: COMPARATIVE TABLE COMPARING THE PECENTAGE OF THE VARIOUS TYPES OF AMBLYOPIA

STUDIES	SENSORY AMBLYOPIA	ANISOMETROPIC AMBLYOPIA	STRABISMIC AMBLYOPIA	COMBINED CAUSES
Ganekal et al(6)	4.5%	90.9%	6.8%	2.2%
Magdalne et al(7)	40.36%	45.01%	14.63%	
Wallace et al(30)		32.89%	28.95%	38.16%
Singh et al(24)	5.8%	50.7%	11.6%	31.6%
Our study	50%	46.4%	3.6%	

PEDIG studies demonstrated that occlusion is the most preferred treatment option for amblyopia, as the response rate was faster and better and held a slight edge over the other treatment options like pharmacological penalisation. We followed only occlusion therapy for our study.

We enforced our patient's parents or care-taker's to daily maintain a diary – the occlusion dose record/ diary, to chart the duration of daily occlusion. We advised parent or care-taker to bring the diary we provided at every scheduled out-patient visit, to monitor the compliance to occlusion and the compliance percentage was noted.

During the period of occlusion, we advised our patients to do near work activities like playing video games with phone, tablets and I-Pad, other written work from school, painting, colouring, art and craft work, cutting shapes with scissors, tracing, work book activities etc.,.(23)(21)(26)(38)(39)(40)(41). We also provided children with a work-book, encouraging them to use the work book and giving care-taker's an idea how to indulge children in near work activities during occlusion.

Occlusion compliance at initiation of our study in amblyopes already on occlusion was 38.12% (SD 37.58), there was sudden increase in compliance with counselling and on explaining the merits and de-merits and avoidable negative outcome of non-occlusion. In the first month there was a sudden increase in compliance to 81.73% (SD 22.86) and even higher compliance by the third

month to 90.18% (SD 19.91) and compliance thereafter decreases to 84.93% (SD 22.49) by 6 months.

TABLE 18: COMPARATIVE TABLE DEPICTING SAMPLE SIZE AND COMPLIANCE IN VARIOUS STUDIES

STUDY	NUMBER OF SUBJECTS	COMPLIANCE PERCENTAGE
Wallace et al(30)	152 patients	44%
Stewart et al(36)	86 patients	48%
Pradeep et al(31)	62 children	80.6%
Our study	35 children	84.93%

Various strategies were tried in various studies to improve compliance.

TABLE 19: COMPARATIVE TABLE SHOWING THE VARIOUS STATERGIES IN OTHER STUDIES AND COMPLIANCE %

STUDIES	STRATEGY USED	COMPLIANCE % POST INTERVENTION
LOUDON et al(27)	Educational intervention	78%
TJIAM et al(29)	Educational cartoon	89%
PRADEEP et al(31)	Educational/Motivational program.	81%
OUR STUDY	Counselling	84.93%

Our other secondary variables - vision, contrast sensitivity, stereopsis and prism bar cover test for distance and near, were checked and data was entered at every visit. With improvement in compliance, vision, stereopsis and even contrast sensitivity also improved in most children. El-Ghrably et al, in his study documented that vision improved as the rate of compliance increased (49). It was observed in our study also. As the rate of compliance increased, vision, stereopsis and contrast sensitivity also improved in our study patients. In an Indian study done by Singh et al, as the compliance improved(moderate amblyope-80%, severe amblyope-65%) and period of occlusion increased(3-6 months), the vision, accommodation, contrast sensitivity, stereopsis, mesopic visual acuity improved(50).

TABLE 20: COMPARATIVE TABLE SHOWING VARIOUS STUDIES AND THE VISUAL FACTORS MONITORED AND COMPLIANCE ACHIEVED

STUDIES	VISUAL FUNCTIONS STUDIED	COMPLIANCE PERCENTAGE
Singh et al(24)	VISION, ACCOMODATION, CONTRAST SENSITIVITY, STEREOPSIS, MESOPIC VISUAL ACUITY	65-80%
El Grahably et al(49)	VISION	77%
Our study	VISION, CONTRAST SENSITIVITY, STEREOPSIS, PRISM BAR COVER TEST	84.93%

Most of our study patients improved with counselling. Those who did not have improvement in compliance were mostly patients who had dense amblyopia. In patients whose compliance did not improve with occlusion, we introduced a novel method to improve compliance by enabling the densely amblyopic eye to see with low vision devices (hand magnifier, electronic video magnifier, magnifying sheet, magnifying stand), as per patients requirement, thereby improving compliance in these patients(42).

REVERSE AMBLYOPIA

Reverse amblyopia is a well-known side-effect of occlusion therapy. One of our patients, developed reverse amblyopia. During routine follow-up worsening of vision in the better eye was noticed hence further occlusion was stopped.

A6 year old, studying in Ist standard was diagnosed with both eyes, high myopic astigmatism with right eye congenital ptosis, that covers the visual axis. Her vision in the right eye was 6/24 (log 0.64) N12 and 6/12 (log 0.60) N6, she had no stereopsis and her contrast sensitivity was log 0.90 in both eyes.

She was counselled for occlusion of her right eye for 3 hours per day. On one month occlusion her visual parameters in the right eye had slightly improved. Her vision was 6/24 (log 0.6) and 6/12 (log 0.5), no stereopsis and contrast sensitivity was the same.

On the 3rd month follow-up, vision in both eyes were 6/18 N9 (log0.5), her stereopsis was 400 seconds and her contrast sensitivity was log 0.90 in the right eye and log 1.20 in her left eye. So her occlusion was stopped and is on constant follow-up.

During her last visit, her vision in the right eye was 6/18 (log 0.5) N9 and left eye was 6/18 (log 0.4) N6, her stereopsis was 400 seconds and her contrast sensitivity in the right eye was log 1.80 and left eye was log 1.50. She is currently under constant 1 monthly monitoring.

CHILDREN GIVEN LOW VISION DEVICES:

Our trial with low vision devices is a novel technique, attempting to show an enlarged image of the object of interest, to an amblyopic eye, thereby enabling the child to perceive a clearer image of the object, thereby increasing the interest for occlusion.

Most of our children were compliant with occlusion, with enhanced and enforced sessions of counselling at every scheduled visit. Some of the children, with denser amblyopia could not comply to the full period occlusion, due to very less vision in the amblyopic eye, which hindered them from doing any reasonable or productive work during the period of occlusion.

Our innovative idea was to forcing the amblyopic eye to see a clearer, well-defined and a better image, thereby enhancing the duration of occlusion.

Below are the case reports of some of our patients who are using low-vision devices with occlusion.

CASE I:

Ms. H, an eight year old girl, presented with unilateral congenital cataract in the left eye in 2011, at 4 months of age and underwent lens matter aspiration. She was started on occlusion, from the immediate post-operative period. In 2014, she underwent secondary intra-ocular lens implantation after appropriate intra-ocular lens power calculation. Despite post-operative best corrected visual acuity and spectacles her vision did not improve. She was advised to continue occlusion.

Initially, she was occluding the right eye for 3 hours per day. As the child started to attend school, her compliance to occlusion slowly decreased. Over the last 5 years she had slowly stopped occlusion.

Now with our counselling regime, she re-started occlusion for 6 hours per day and was compliant for 5 months. In the 6^{th} month, her compliance dropped to 3 hours per day. Her visual parameters also had showed marginal improvement. Her vision in the amblyopic eye improved from 2/60(log 0.90) to 4/60(log 0.72) with appropriate correction. She had no stereopsis and contrast sensitivity, but with time stereopsis improved to 3552 seconds and her contrast sensitivity increased to log 0.30. Post 6 months-follow-up, her compliance to occlusion slowly decreased to 3 hours and she was counselled to increase occlusion with low vision device (+16.0 D lens). With 16 dioptre lens her reading speed increased and could read upto N8 comfortably. Slowly on follow-up, her

occlusion rate increased to the prescribed 6 hours per day. 3 months post occlusion with + 16 dioptre lens, her vision improved to 6/36(log 0.54), her stereopsis improved to 200 seconds and her contrast sensitivity was log 0.30.

CASE II:

Mas. D, a 6 year old child studying 1st grade presented to us in 2015, with a corneal scar involved the visual axis, following corneal suturing. His vision in the amblyopic eye on presentation was counting fingers one and a half metre (log1.8), with no stereopsis nor contrast sensitivity and he was advised 6 hours of occlusion. Despite counselling, his compliance rate for occlusion did not increase. He was advised to occlude his good eye and to do near vision work with a low vision device – hand magnifier (+20 Dioptre lens). With 20 dioptre lens, his occlusion compliance improved upto 2 hours. Though vision did not improve, he gained gross stereopsis(3552 seconds).As he was not compliant enough with occlusion even with a hand magnifier, he was advised to use electronic video magnifier (EVM). With EVM, his occlusion time improved to 6 hours per day. With EVM, the vision in the amblyopic eye improved to 2/60 (log 1.6), he had gross stereopsis(3552 seconds) and no appreciable contrast sensitivity.

FIGURE 28:CHILD BEING TRAINED IN OUR LOW VISION CENTRE TO USE ELECTRONIC VIDEO MAGNIFIER TO DO NEAR-WORK

CASE III:

Ms. I, a 11 year old school going child, had both eyes congenital cataract, for which she underwent lens matter aspiration and intraocular lens implantation in both eyes in 2007. When she came to us in 2011, she had thick posterior capsular opacification in the left eye, for which she underwent surgical membranectomy in 2011. Her vision despite appropriate refraction in the amblyopic eye was 3/60(log 0.78) (could not read near print charts).Vision in her better eye was 6/36 (log 0.72) and N18. She had no stereopsis nor contrast sensitivity. She had been advised occlusion, but she had not occluded for more than 1 hour/day. She was

counselled for occlusion for 6 hours/day, as per our protocol. She had dense amblyopia, she occluded for 6 hours on weekdays and up to 8 hours during weekends. Her vision, stereopsis and contrast sensitivity, did not show much improvement. In view of which, she was started on occlusion to the better eye and doing near work using low vision device (electronic magnifier) in the amblyopic eye. With electronic magnifier and adequate illumination, her reading speed improved and she could write comfortably. With this her compliance was maintained and within three months, her vision improved to 3/60 (log 0.64) N36 and 6/24 (log 0.66) and N8, her stereopsis improved to 200seconds and her contrast sensitivity was log 0.15. She is currently following this therapy for 6 hours per day.

CASE IV:

Ms. S., a 7 year old 3rd grade student, was brought to hospital by her mother with complaints of recently noticed deviation in her left eye. Evaluation revealed right eye high myopic astigmatism and left simple myopia. She was diagnosed with anisometropic amblyopia. She was prescribed appropriate refraction with constant use of glasses for 3 months. Despite appropriate refraction, her vision did not improve. On her first visit to paediatric clinic, her vision in the amblyopic eye was 6/60 (log 1.0) N36, she had no stereopsis nor contrast sensitivity, with a left (alternate) divergent squint, with a near angle of 16 degree prism base in and a distant angle of 30 degree base in. Despite personalised counselling and telephonic monitoring, her period of occlusion never improved beyond 5 hours/day, during the 6 month follow-up period. She was counselled for

occlusion of the better eye with low vision device (+20 dioptre lens) for her amblyopic eye. With the +20 Dioptre lens for 3 hours per day, her vision improved to 6/18 (log 0.44) N24, her stereopsis improved to 400 seconds and contrast sensitivity was log 0.30, with a left (alternate) divergent squint, with a near angle of 16 degree prism base in and a distant angle of 25 degree base in. She continues to occlude with the +20 dioptre lens, for 3-4 hours per day.

CASE V:

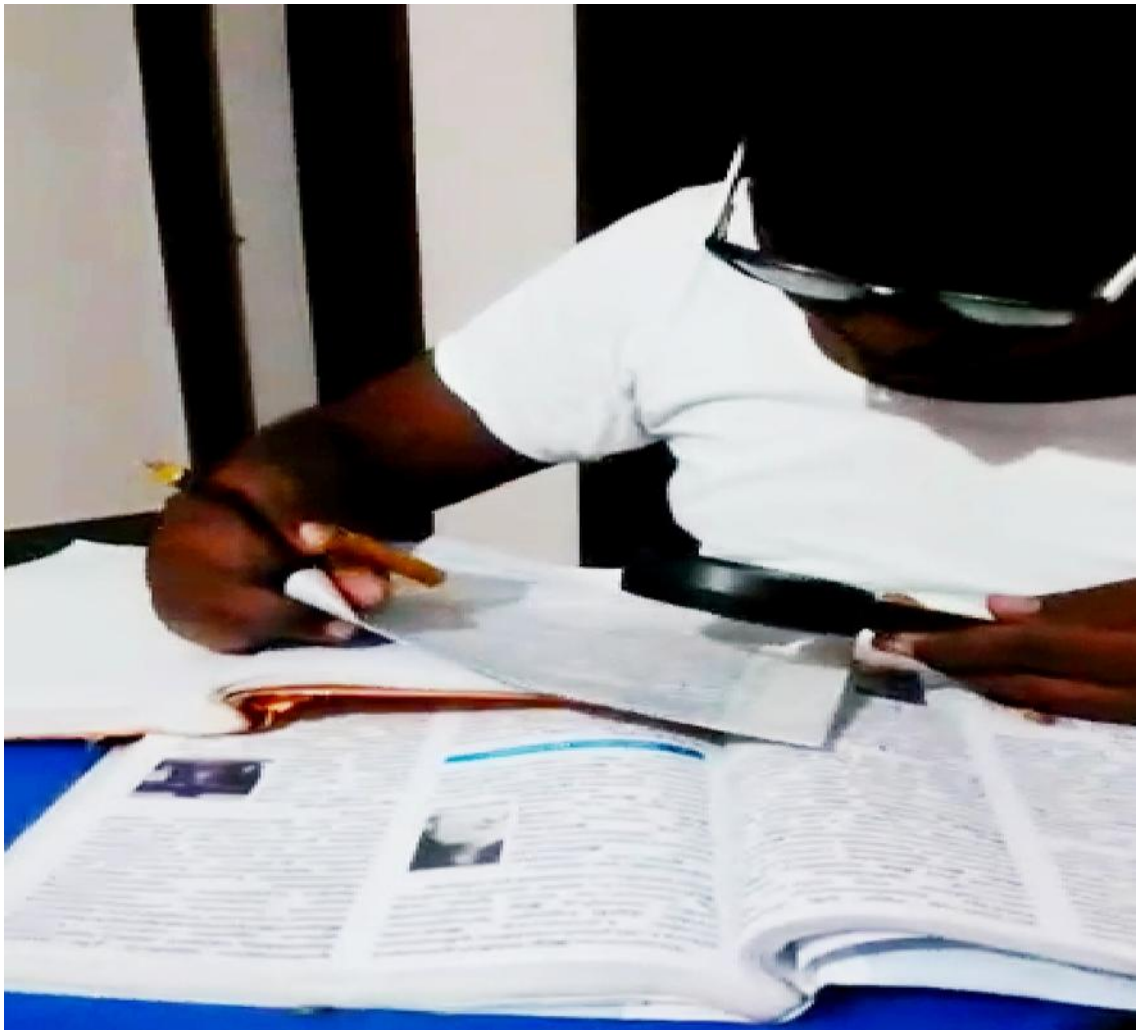
Mas. J., a 7 year old child attending third grade, was initially diagnosed with developmental cataract in both eyes in 2016. He underwent right eye lens matter aspiration with primary posterior capsulotomy with partial anterior vitrectomy with intraocular lens implantationin October 2016. Left eye had a faint posterior subcapsular cataract.

Despite clearing his visual axis, his vision in the right eye did not improve. He was diagnosed with right eye sensory amblyopia and advised occlusion. As both his parents were working, he was spending maximum time at home with his grand-mother and was not compliant with occlusion.

When we recruited him for occlusion, his best corrected visual acuity in the right eye was 6/24 (log 0.7) N12 and in the left eye was 6/9 (log 0.3) N6. He had no stereopsis. We re-counselled the parents and the child with an aunt who offered to help the parents in motivating and monitoring the child to occlude for 6 hours per day.

Initially, he occluded for 3-4 hours/day and by the third month he again stopped occlusion therapy. We restarted occluding the better eye and forcing him to use the amblyopic eye with low vision device (Hand magnifier - +16Dioptre lens), for 6 hours per day. His compliance to occlusion increased to 4-5hours per day and his vision improved to 6/18 (log 0.56) N6 and his stereopsis improved to 200 seconds. He is advised to continue occlusion, with usage of his low vision device.

FIGURE 29: CHILD USING HAND MAGNIFIER WITH OCCLUSION TO DO NEAR VISION WORK (HOME WORK)



CASE VI:

Mas. M, a 14 year old Xth standard student, presented with history of decreased vision in right eye noticed only 3 years ago. He was diagnosed as right eye hypermetropic amblyopia and prescribed spectacles. Despite wearing glasses constantly for 3 years, his vision did not improve and was referred to the paediatric ophthalmology clinic for further management.

His vision in the right amblyopic eye was improving upto 6/18 (log 0.64) N8 and was emmetropic in the other eye. His stereopsis was 800 seconds and his contrast sensitivity was 1.20 in the amblyopic eye. He and his mother were counselled for occlusion for 6 hours per day. As he was on high school, he was unable to occlude for more than one hour per day.

He was advised to occlude his left eye and use his right eye to see with low vision device (hand magnifier + 20 dioptre lens). With the hand magnifier, he started occlusion and his compliance improved to 5 hours per day. His vision in the amblyopic eye became 6/9 (log 0.24) N6, his stereopsis improved to 400 seconds and his contrast sensitivity improved to log1.65. He is advised to continue occlusion with hand magnifiers.

CONCLUSION

With good counselling and good occlusion compliance vision and higher visual functions improved.

LIMITATIONS

Some of our patients were lost to follow-up despite requests and phone reminders.

A longer follow-up is required to monitor compliance and visual parameters in children on occlusion therapy.

Due to the limited study period we could not follow-up our patients to assess their compliance beyond 6 months. As studies have shown that there could be a drop in compliance after an initial period of improvement, our patients need monitoring, which will be given from our clinic as a standard of care.

Visual improvement and other acuity improvements on occluding for more than six months could not be assessed. If there is visual acuity and other higher acuity improvement during the study period and if the patient discontinues treatment, there could be a drop in vision and higher acuity. Hence, we need to follow-up these patients for a period of 12 months, also even upto the end point of occlusion therapy to monitor these parameters.

REFERENCES

1. Wright KW.Visual Development and Amblyopia. Handbook of pediatric strabismus and amblyopia. 2006 edition, Volume 4: Chapter 35, 103-137.

2. Pediatric Ophthalmology and Strabismus. American Academy of Ophthalmology. 2011-12 edition. Section 6. Chapter 5, 61-70

3. Backman H. Children at risk of developing amblyopia: When to refer for an eye examination. Paediatr Child Health. 2004 Nov;9(9):635–7.

4. Von Noorden GK, Campos EC. Binocular vision and ocular motility: theory and management of strabismus. 6th ed. St. Louis, Mo: Mosby; 2002; 653

5. Webber AL et al. The functional impact of amblyopia.ClinExpOptom. 2018;101(4):443–50.

6. Ganekal S, Jhanji V, Liang Y, Dorairaj S. Prevalence and Etiology of Amblyopia in Southern India: Results from Screening of School Children Aged 5–15 years. Ophthalmic Epidemiology. 2013 Aug 1;20(4):228–31.

7. Magdalene D, Bhattacharjee H, Choudhury M, Multani PK, Singh A, Deshmukh S, et al. Community outreach: An indicator for assessment of prevalence of amblyopia. Indian Journal of Ophthalmology. 2018 Jul 1;66(7):940.

8. Olusanya BA, Ugalahi MO, Okoli CE, Baiyeroju AM. Refractive Amblyopia among children in Ibadan: the need for amblyopia screening programmes. Afr J Med Med Sci. 2015 Sep;44(3):237–42.

9. Williams C.et al. Amblyopia. BMJ Clinical Evidence- 2009 Sep 16 ;2009;709.

10. R.S. Braverman et al. PEDIG Studies: Quality Healthcare and Amblyopia Treatment. American Academy of Ophthalmology. 2015; 133(5):606-609.

11. Snowdon SK, Stewart-Brown SL. Preschool vision screening. Health Technol Assess. 1997;1(8):i–iv, 1–83.

12. Repka MX, Beck RW, Holmes JM, Birch EE, Chandler DL, Cotter SA, et al. A randomized trial of patching regimens for treatment of moderate amblyopia in children.ArchOphthalmol. 2003 May;121(5):603–11.

13. Chua B, Mitchell P. Consequences of amblyopia on education, occupation, and long term vision loss. Br J Ophthalmol. 2004 Sep;88(9):1119–21.

14. Tommila V, Tarkkanen A. Incidence of loss of vision in the healthy eye in amblyopia. Br J Ophthalmol. 1981 Aug;65(8):575–7.

15. Simons K, Stein L, Sener EC, Vitale S, Guyton DL. Full-time Atropine, Intermittent Atropine, and Optical Penalization and Binocular Outcome in Treatment of Strabismic Amblyopia.Ophthalmology. 1997 Dec 1;104(12):2143–55.

16. Pharmacologic versus Optical Penalisation in the treatment of Amblyopia.

17. B.J.Kushner et al,.Pediatric Eye Disease Investigator Group.A randomized trial of atropine vs. patching for treatment of moderate amblyopia in children.ArchOphthalmol. 2002 Mar;120(3):268–78.

18. S.A.Cotter et al,.Pharmacological Plus Optical Penalization Treatment for Amblyopia: Results of a Randomized Trial. Arch Ophthalmol. 2009 Jan 12;127(1):22–30.

19. Foley-Nolan A, McCann A, O'Keefe M. Atropine penalisation versus occlusion as the primary treatment for amblyopia. Br J Ophthalmol. 1997 Jan;81(1):54–7.

20. Wang J. Compliance and patching and atropine amblyopia treatments. Vision Research. 2015 Sep 1;114:31–40.

21. Maconachie GDE, Gottlob I. The challenges of amblyopia treatment.Biomedical Journal. 2015 Dec 1;38(6):510–6.

22. Pawar PV, Mumbare SS, Patil MS, Ramakrishnan S. Effectiveness of the addition of citicoline to patching in the treatment of amblyopia around visual maturity: A randomized controlled trial. Indian J Ophthalmol. 2014 Feb;62(2):124–9.

23. A Randomized Trial to Evaluate Two Hours of Daily Patching for Amblyopia in Children. Ophthalmology. 2006 Jun;113(6):904–12.

24. Singh I, Sachdev N, Brar GS, Kaushik S. Part-time occlusion therapy for amblyopia in older children. Indian J Ophthalmol. 2008;56(6):459–63.

25. Kavitha et al. Occlusion therapy in older children with amblyopia. Journal of Clinical Ophthalmology & Research 2016; 4(2) : 71-74.

26. Scheiman MM, Hertle RW, Beck RW, Edwards AR, Birch E, Cotter SA, et al. Randomized trial of treatment of amblyopia in children aged 7 to 17 years. Arch Ophthalmol. 2005 Apr;123(4):437–47.

27. Loudon SE, Polling JR, Simonsz HJ. A preliminary report about the relation between visual acuity increase and compliance in patching therapy for amblyopia.Strabismus. 2002 Jun;10(2):79–82.

28. Al-Zuhaibi S, Al-Harthi I, Cooymans P, Al-Busaidi A, Al-Farsi Y, Ganesh A. Compliance of amblyopic patients with occlusion therapy: A pilot study. Oman J Ophthalmol. 2009;2(2):67–72.

29. Tjiam AM, Holtslag G, Vukovic E, Asjes-Tydeman WL, Loudon SE, Borsboom GJJM, et al. An Educational Cartoon Accelerates Amblyopia Therapy and Improves Compliance, Especially among Children of Immigrants. Ophthalmology. 2012 Nov 1;119(11):2393–401.

30. Wallace MP, Stewart CE, Moseley MJ, Stephens DA, Fielder AR. Compliance With Occlusion Therapy for Childhood Amblyopia. Invest Ophthalmol Vis Sci. 2013 Sep 1;54(9):6158–66.

31. Pradeep A, Proudlock FA, Awan M, Bush G, Collier J, Gottlob I. An educational intervention to improve adherence to high-dosage patching regimen for amblyopia: a randomised controlled trial. Br J Ophthalmol. 2014 Jul;98(7):865–70.

32. Dixon-Woods M, Awan M, Gottlob I. Why is compliance with occlusion therapy for amblyopia so hard? A qualitative study.Arch Dis Child. 2006 Jun;91(6):491–4.

33. Dean S.E.et al.Assessing interventions to increase compliance to patching treatment in children with amblyopia: a systematic review and meta-analysis | British Journal of Ophthalmology 2016, Vol 100, Issue 2; 159-165.

34. Searle A, Norman P, Harrad R, Vedhara K. Psychosocial and clinical determinants of compliance with occlusion therapy for amblyopic children. Eye (Lond). 2002 Mar;16(2):150–5.

35. Newsham D. Parental non-concordance with occlusion therapy. British Journal of Ophthalmology. 2000 Sep 1;84(9):957–62.

36. Wallace MP, Stewart CE, Moseley MJ, Stephens DA, Fielder AR, MOTAS and ROTAS Cooperatives. Treatment of Amblyopia Using Personalized Dosing Strategies: Statistical Modelling and Clinical Implementation. Strabismus. 2016;24(4):161–8.

37. Kämpf U, Muchamedjarow F, Seiler T. [Supportive amblyopia treatment by means of computer games with background stimulation; a placebo controlled pilot study of 10 days]. KlinMonblAugenheilkd. 2001 Apr;218(4):243–50.

38. Tailor VK, Glaze S, Khandelwal P, Davis A, Adams GGW, Xing W, et al. Prescribed computer games in addition to occlusion versus standard occlusion treatment for childhood amblyopia: a pilot randomised controlled trial. Pilot Feasibility Stud. 2015;1:23.

39. Khan T. Is There a Critical Period for Amblyopia Therapy? Results of a Study on Older AnisometropicAmblyopes. J ClinDiagn Res. 2015 Aug;9(8):NC01–4.

40. de Zárate BR, Tejedor J. Current concepts in the management of amblyopia. ClinOphthalmol. 2007 Dec;1(4):403–14.

41. Holmes JM, Edwards AR, Beck RW, Arnold RW, Johnson DA, Klimek DL, et al. A randomized pilot study of near activities versus non-near activities during patching therapy for amblyopia. J AAPOS. 2005 Apr;9(2):129–36.

42. Hockenberry MJ, Wilson D. Wong's Essentials of Pediatric Nursing9: Wong's Essentials of Pediatric Nursing. Elsevier Health Sciences; 2013.1223 p.

43. Kuruca S, Niyaz L, Yucel OE, Erkan ND. Results of CAM therapy in amblyopic patients.VestnOftalmol. 2015;131(4):83–7.

44. BenEzra O, Herzog R, Cohen E, Karshai I, BenEzra D. Liquid Crystal Glasses: Feasibility and Safety of a New Modality for Treating Amblyopia. Arch Ophthalmol. 2007 Apr 1;125(4):580–1.

45. Eustis HS, Chamberlain D. Treatment for amblyopia: results using occlusive contact lens. J PediatrOphthalmol Strabismus. 1996;33(6):319–22.

46. Hainline BC, Sprunger DC, Plager DA, Neely DE, Guess MG. Reverse amblyopia with atropine treatment. Binocul Vis Strabismus Q. 2009;24(1):25–31.

47. Kraus CL, Culican SM. New advances in amblyopia therapy I: binocular therapies and pharmacologic augmentation. British Journal of Ophthalmology. 2018 Nov 1;102(11):1492–6.

48. Suliman IAM, Ali MSA. The effect of amblyopia on contrast sensitivity, color vision, and stereoacuity.Al-Basar International Journal of Ophthalmology. 2017 Jul 1;4(2):54.

49. El-Ghrably IA, Longville D, Gnanaraj L. Does compliance with amblyopia management improve following supervised occlusion treatment.Eur J Ophthalmol. 2007 Oct;17(5):823–7.

50. Singh V, Agrawal S. Visual Functions in Amblyopia as Determinants of Response to Treatment. Journal of Pediatric Ophthalmology and Strabismus; Thorofare. 2013 Nov;50(6):348–54.

ANNEXURES

ANNEXURE I : IRB APPROVAL LETTER/ FLUID RESEARCH LETTER

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

January 15, 2019

Dr. Santa Christina,
Department of Ophthalmology,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
Role of Low vision devices (LVD) to improve compliance with occlusion therapy in children with amblyopia.
Dr. Santa Christina, Employment Number: 21526, Post Graduate student, MS Ophthalmology, Dr. Deepa John, Employment Number: 20182, Ophthalmology, Dr Thomas Kuriakose, Employment number -14521, Ophthalmology, Dr. Padma Paul Employment number -14374, Dr. Lekha Mary Abraham, Employment number -20086, Ms. Rubia A, Employment number -53698 Ophthalmology, Ms. Malavika Babu, Employment number 31917, Biostatistics.

Ref: IRB Min. No. 11629 [INTERVEN] dated 08.11.2018

Dear Dr. Santa Christina,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Deepa John, Dept. of Ophthalmology, CMC, Vellore

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

ANNEXURE II : INFORMATION SHEET AND CONSENT FORMS IN TAMIL

நோயாளிகளின் தகவல் அறிக்கை கையோடு

கண் மருத்துவமனை

கிருத்துவ மருத்துவ கல்லூரி

குறைந்த பார்வை உடையவருக்கு உண்டான உபகரண'ண்களைக் கொண்டு பார்வை மேம்படுத்த ஒருகண் அடைப்பு மூலம் பார்வை தெரிவின்மை குழந்தைகளுக்கு சிகிச்சை அளிக்கும் முறை.

குழந்தைகளின் சோம்பல் கண்ணின் ஆய்வு பற்றிய பரிந்துரை அறிக்கை.

இந்த சிகிச்சையில் நன்றாக பார்வை உள்ள கண்ணை கண் அடைப்புப் செய்து சோம்பல் கண்ணிற்கு பார்வை அதிகரிக்கச் செய்யப்படும். மேலும் இந்த சிகிச்சை முறை பள்ளி முடித்து வந்த பிறகு மூன்று (அ) ஆறு மணிக்குள் அவர்களின் ஆய்வு முடிய செய்யப்படும். மேலும் சில குழந்தைகள் இந்த சிகிச்சையால் இணக்காமான பார்வையை பெற முடிவதில்லை. காரணம் குறைந்த பார்வையினால் உள்ள சோம்பல் கண்ணால்.

இந்த ஆய்வின் மூலம் குழந்தைகளுக்கும் பெற்றோர்களுக்கும் ஆலோசனை அளித்து மேலும் உருட் பெருக்கி கருவிகளையும் கண் அடைப்பு சிசிச்சை செய்து பார்வை குறைப்பாட்டை சரி செய்கின்றோம்.

கண் உருபெருக்கி கருவிகள் மூலம் சோம்பல் கண்ணிற்கு கண் அடைப்பு சிகிச்சை மூலம் பார்வையை அதிகரிக்க உதவலாம். மேலும் இந்த உருப்பெருக்கி கருவிகளை உபயோகிக்க பயிற்சிகள் அளிக்கிறோம்.

உங்கள் குழந்தைகளின் 1 (ம) 3 (ம) 6 மாதத்திற்கு ஒருமுறை பரிசோதனை செய்து கண் அடைப்பு செய்த சோம்பல் கண்ணிற்கு பார்வை அதிகரித்துள்ளதா என்று அறியாலம்.

குறைந்த பார்வை உடையவருக்கு உண்டான உபகரணங்களைக் கொண்டு பார்வை மேம்படுத்த ஒருகண் அடைப்பு மூலம் பார்வை தெளிவின்மை குழந்தைகளுக்கு சிகிச்சை அளிக்கும் முறை

நீங்கள் உங்கள் குழந்தைகளை தயவு செய்து இந்த சிகிச்சையில் பங்குபெற செய்வதின் மூலம் சோம்பல் கண்ணில் கண் பெருக்கி கண்ணாடி கொண்டு பார்வை குறைப்பாட்டை ஓரளவு சீர் செய்யலாம். மேலும் இந்த சிகிச்சையை கொடுக்கப்பட்ட கால அளவின்படி செய்தால் குழந்தைகளுக்கு குறைந்த பார்வையை மேம்படுத்தலாம்.

1. குறைந்த கண் பார்வை உடையவர்களுக்கு கண் வரும்பெருக்கியை உபயோகித்ததால் என்ன உபயோகம் இருக்கும்?

தாங்கள் உருபெருக்கி கண்ணாடியை சோம்பல் கண்ணிற்கு உபயோகிக்குமாறு பரிந்துரைச் செய்கின்றோம். தாங்கள் குறைந்த பார்வை உடையவர்களுக்கான உருப்பெருக்கியை உபயோகிக்க அறிவுறுத்தி பார்வை உள்ள கண்ணை அடைப்பு செய்து, சோம்பல் கண்ணிற்கு பார்வை அதிகரிக்க இந்த சிகிச்சையின் மூலம் உதவுகின்றோம்.

2. இந்த குறைந்த பார்வைக்கு உண்டான உருப்பெருக்கியை பக்க விளைவுகளை உண்டாக்குமா?

குறைந்த பார்வைக்கான உருப்பெருக்கி கண்ணாடி பக்கவிளைவுகளை ஏற்படுத்தாது.

3. உங்கள் குழந்தை இந்த சிகிச்சையில் பங்கேற்றால் உங்கள் பங்களிப்பு என்ன?

உங்கள் குழந்தை இந்த சிகிச்சை ஆய்வில் பங்கேற்கும் போது குறைந்த பார்வைக்கான கண்ணாடிகள் இலவசமாக உங்கள் குழந்தைகளுக்கு கொடுக்கப்படும் இதன் மூலம் உங்கள் குழந்தைகளின் அருகாமை பார்வை அடைப்பு பார்வை சிகிச்சையின் மூலம் அதிகரிக்கும்.

4. உங்கள் குழந்தை இந்த ஆய்வில் பங்கேற்று இடையில் விலகலாமா?

உங்கள் குழந்தை இந்த ஆய்வில் பங்கேற்க எந்த கட்டாயமும் இல்லை. நீங்களோ அல்லது உங்கள் குழந்தையோ இந்த ஆய்விலிருந்து விலகுவதற்கு முழுசம்மதம் உள்ளது. இதன் மூலம் உங்கள் வழக்கமான மருத்துவமனையின் சிகிச்சைக்கு எந்த இடையூறும் ஏற்படாது.

5. இந்த ஆய்வில் பங்கேற்கும் பொழுது ஏதாவது சிக்கல்கள் ஏற்பட்டால் என்ன செய்வது?

இந்த ஆய்வில் எந்த சிக்கல்களும் மற்றும் தேவையில்லா விளைவுகளும் ஏற்படாது. ஏதாவது சிக்கல் ஏற்பட்டால், நாங்கள் மேற்பட்ட எந்த இழப்பீட்டுற்கு பொறுப்பேற்க மாட்டோம்.

6. நீங்கள் குறைந்த பார்வைக்கான உபகரணங்களுக்கு கட்டணம் செலுத்த வேண்டுமா?

குறைந்த பார்வைக்கான உபகரணங்கள் இலவசமாக வழங்கப்படும். உங்கள் குழந்தைகள் ஆய்வு முடிவிற்கு பிறகும் நாங்கள் இந்த கண்

அடைப்பு சிகிச்சையினால் உங்கள் பார்வை அதிகரிக்கபடுகிறதா என்று கண் காணிப்போம்.

7. இந்த ஆய்வு முடிந்த பிறகு என்ன செய்ய?

இந்த ஆய்வில் குழந்தையின் கண்ணின் பார்வை கண் அடைப்பு சிகிச்சை மூலம் மேம்பட்டால் குறைந்த பார்வைக்கான உபகரணங்கள் மேலும் பயன்படுத்த அறிவுறுத்தப்படும். மேலும் நல்ல கண்ணை அடைப்பு செய்து, சோம்பல் கண்ணிற்கு குறைந்த பார்வைக்கு உண்டான உபகரணங்களை உபயோகிக்க அறிவுறுத்துவோம்.

8. உங்கள் குழந்தையின் சிகிச்சை முறைகளை ரகசியமாக வைக்கபடுமா?

இந்த ஆய்வின் முடிவுகள் மருத்துவ நாளிதழில் பெயர் வெளியிடாமல் வெளியிடப்படும். உங்கள் மருத்துவ ஆய்வுகள் இந்த ஆய்வில் பங்கேற்பவர்களால் ஆய்வுக்கு உட்படுத்தப்படும். உங்கள் அனுமதியில்லாமலே மேலும், உங்களுக்கு எந்தவிதமான சந்தேகங்கள் இருந்தாலும் தயவு செய்து சந்தேகங்களை நிவர்த்தி செய்து கொள்ளலாம்.

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கண் மருத்துவமனை

கிருத்துவ மருத்துவ கல்லூரி

குறைந்த பார்வையுடையவருக்கு உள்ளான உபகரணங்களை கொண்டு பார்வை மேம்படுத்த ஒரு அடைப்பு மூலம் பார்வை தெளிவின்மை குழந்தைகளுக்கு சிகிச்சை அளிக்கும் முறை.

குழந்தைகளின் சோம்பல் கண்ணின் ஆய்வு பற்றிய பரிந்துரை அறிக்கை.

இந்த சிகிச்சையில் நன்றாக பார்வை உள்ள கண்ணை கண் அடைப்புச் செய்து சோம்பல் கண்ணிற்கு பார்வை அதிகரிக்கச் செய்யப்படும். மேலும் இந்த சிகிச்சை முறை பள்ளி முடித்து வந்த பிறகு மூன்று (அ) ஆறு மணிக்குள் அவர்களின் ஆய்வு முடிய செய்யப்படும். மேலும் சில குழந்தைகள் இந்த சிகிச்சையால் இணக்கமான பார்வையை பெற முடிவதில்லை. காரணம் குறைந்த பார்வையினால் உள்ள சோம்பல் கண்ணால்.

இந்த ஆய்வின் மூலம் குழந்தைகளுக்கும் பெற்றோர்களுக்கும் ஆலோசனை அளித்து மேலும் உருட் பெருக்கி கருவிகளையும் கண் அடைப்பு சிகிச்சை செய்து பார்வை குறைப்பாட்டை சரி செய்கின்றோம்.

கண் உருபெருக்கி கருவிகள் மூலம் சோம்பல் கண்ணிற்கு கண் அடைப்பு சிகிச்சை மூலம் பார்வையை அதிகரிக்க உதவலாம். மேலும் இந்த உருப்பெருக்கி கருவிகளை உபயோகிக்க பயிற்சிகள் அளிக்கிறோம்.

உங்கள் குழந்தைகளின் 1 (ம) 3 (ம) 6 மாதத்திற்கு ஒருமுறை பரிசோதனை செய்து கண் அடைப்பு செய்த சோம்பல் கண்ணிற்கு பார்வை அதிகரித்துள்ளதா என்று அறியலாம்.

குறைந்த பார்வை உடையவருக்கு உள்ளான உபகரணங்களைக் கொண்டு பார்வை மேம்படுத்த ஒருகண் அடைப்பு மூலம் பார்வை தெளிவின்மை குழந்தைகளுக்கு சிகிச்சை அளிக்கும் முறை

நீங்கள் தயவு செய்து இந்த சிகிச்சையில் பங்குபெற செய்வதின் மூலம் சோம்பல் கண்ணில் கண் பெருக்கி கண்ணாடி கொண்டு பார்வை குறைப்பாட்டை ஓரளவு சரி செய்யலாம். மேலும் இந்த சிகிச்சையை கொடுக்கப்பட்ட கால அளவின்படி செய்தால் உங்களுக்கு குறைந்த பார்வையை மேம்படுத்தலாம்.

1. குறைந்த கண் பார்வை உடையவர்களுக்கு கண் வருப்பெருக்கியை உபயோகித்ததால் என்ன உபயோகம் இருக்கும்?

நாங்கள் உருபெருக்கி கண்ணாடியை சோம்பல் கண்ணிற்கு உபயோகிக்குமாறு பரிந்துரைச் செய்கின்றோம். நாங்கள் குறைந்த பார்வை உடையவர்களுக்கான உருப்பெருக்கியை உபயோகிக்க அறிவுறுத்தி பார்வை உள்ள கண்ணை அடைப்பு செய்து, சோம்பல் கண்ணிற்கு பார்வை அதிகரிக்க இந்த சிகிச்சையின் மூலம் உதவுகின்றோம்.

2. இந்த குறைந்த பார்வைக்கு உண்டான உருப்பெருக்கியை பக்க விளைவுகளை உண்டாக்குமா?

குறைந்த பார்வைக்கான உருப்பெருக்கி கண்ணாடி பக்கவிளைவுகளை ஏற்படுத்தாது.

3. நீங்கள் இந்த சிகிச்சையில் பங்கேற்றால் உங்கள் பங்களிப்பு என்ன?

நீங்கள் இந்த சிகிச்சை ஆய்வில் பங்கேற்கும் போது குறைந்த பார்வைக்கான கண்ணாடிகள் இலவசமாக உங்களுக்கு கொடுக்கப்படும் இதன் மூலம் உங்கள் குழந்தைகளின் அருகாமை பார்வை அடைப்பு பார்வையை சிகிச்சையின் மூலம் அதிகரிக்கும்.

4. நீங்கள் இந்த ஆய்வில் பங்கேற்று இடையில் விலகலாமா?

நீங்கள் இந்த ஆய்வில் பங்கேற்க எந்த கட்டாயமும் இல்லை. நீங்கள் இந்த ஆய்விலிருந்து விலகுவதற்கு முழுசம்மதம் உள்ளது. இதன் மூலம் உங்கள் வழக்கமான மருத்துவமனையின் சிகிச்சைக்கு எந்த இடையூறும் ஏற்படாது.

5. இந்த ஆய்வில் பங்கேற்கும் பொழுது ஏதாவது சிக்கல்கள் ஏற்பட்டால் என்ன செய்வது?

இந்த ஆய்வில் எந்த சிக்கல்களும் மற்றும் தேவையில்லா விளைவுகளும் ஏற்படாது. ஏதாவது சிக்கல் ஏற்பட்டால், நாங்கள் மேற்பட்ட எந்த இழப்பீட்டுற்கு பொறுப்பேற்க மாட்டோம்.

6. நீங்கள் குறைந்த பார்வைக்கான உபகரணங்களுக்கு கட்டணம் செலுத்த வேண்டுமா?

குறைந்த பார்வைக்கான உபகரணங்கள் இலவசமாக வழங்கப்படும். உங்கள் குழந்தைகள் ஆய்வு முடிவிற்கு பிறகும் நாங்கள் இந்த கண் அடைப்பு சிகிச்சையினால் உங்கள் பார்வை அதிகரிக்கபடுகிறதா என்று கண் காணிப்போம்.

7. இந்த ஆய்வு முடிந்த பிறகு என்ன செய்ய?

இந்த ஆய்வில் உங்கள் கண்ணின் பார்வை கண் அடைப்பு சிகிச்சை மூலம் மேம்பட்டால் குறைந்த பார்வைக்கான உபகரணங்கள் மேலும் பயன்படுத்த அறிவுறுத்தப்படும். மேலும் நல்ல கண்ணை அடைப்பு செய்து, சோம்பல் கண்ணிற்கு குறைந்த பார்வைக்கு உண்டான உபகரணங்களை உபயோகிக்க அறிவுறுத்துவோம்.

8. உங்கள் குழந்தையின் சிகிச்சை முறைகளை ரகசியமாக வைக்கபடுமா?

இந்த ஆய்வின் முடிவுகள் மருத்துவ நாளிதழில் பெயர் வெளியிடாமல் வெளியிடப்படும். உங்கள் மருத்துவ ஆய்வுகள் இந்த ஆய்வில் பங்கேற்பவர்களால் ஆய்வுக்கு உட்படுத்தப்படும். உங்கள் அனுமதியில்லாமலே மேலும், உங்களுக்கு எந்தவிதமான சந்தேகங்கள் இருந்தாலும் தயவு செய்து சந்தேகங்களை நிவர்த்தி செய்து கொள்ளலாம்.

டாக்டர் சண்டா கிறிஸ்டினா - 9442120677.
திருமதி.ரபியா - 9940778592.

மின் அஞ்சல் santachristina87@gmail.com

பெற்றோர்களின் ஒப்பந்த அறிக்கை

குறைந்த பார்வை உடையவருக்கு உண்டான உபகரணங்களைக் கொண்டு, பார்வை குறைவை மேம்படுத்த ஒரு கண் அடைப்பு மூலம் பார்வை தெளிவின்மை குழந்தைகளுக்கு சிகிச்சை அளிக்கும் முறை.

1. நான் இந்த படலத்தை படித்து புரிந்துக் கொண்டேன். மேற்கண்ட ஆய்வில் என் குழந்தையை பங்கேற்க்க அனுமதிக்கின்றேன். ஏற்படும் சந்தேகங்களை அறியும் உரிமையும் அளிக்கப்படுகிறது.

2. நான் இந்த ஆய்வில் என சொந்த விருப்பத்தில் என குழந்தை பங்கேற்க வைக்கிறேன். நான் எப்பொழுது வேண்டுமானாலும் இந்த ஆய்வில் இருந்து என் குழந்தையை விலகலாம் என்று அறிந்திருக்கிறேன். அப்படி விலகினாலும் என் மருத்துவ உரிமைகள் பறிக்கபடாது என்று புரித்திருக்கிறேன்.

3. நான் என் குழந்தையின் மருத்துவ படிவங்கள் மருத்துவ நிபுணர்கள் ஆய்வு / பரிந்துரை செய்வதற்கு எனது அனுமதி தேவையில்லை என்று அறிந்திருக்கிறேன். மேலும் இந்த ஆராய்ச்சிக்கு தேவைபடும் படிவங்கள் மற்றும் ஆய்வுகளை மருத்துவர் என் குழந்தை இந்த ஆய்விலிருந்து விலகிய பின்னும் படிக்க / ஆராய எனது அனுமதி தேவையில்லை இதனால் என் குழந்தையின் அடையாளம் மறும் அபாயம் எதுவும் இல்லை என்பதை நான் நன்று அறிந்துள்ளேன்.

இந்த ஆராய்ச்சியின் படிவங்கள் மற்றும் முடிவுகளை தடுக்க எனக்கு உரிமை இல்லை என்பதை நான் ஒப்புக்கொள்கிறேன். இந்த ஆய்வில் பங்கேறபதினால் என்னுடைய குழந்தையின் கண் பார்வையில் தேர்ச்சி வரலாம், வராமலும் போகலாம் என்பதை நன்கு புரிந்து கொண்டேன்.

இதனால் எனக்கோ / என் குழந்தைக்கோ எவ்வித பொருளாதார உதவியும் இல்லை என்பதை புரிந்து கொண்டேன்.

இந்த ஆய்வில் என் குழந்தை பங்கேற்க என் முழு மனதோடு சம்மதிக்கிறேன்.

குழந்தையின் பெயர் :

பெற்றோர் கையொப்பம் :

சாட்சி கையொப்பம் :

மருத்துவர் கையொப்பம் :

குழந்தைகளின் ஒப்பந்த அறிக்கை

குறைந்த பார்வை உடையவருக்கு உண்டான உபகரணங்களைக் கொண்டு பார்வை மேம்படுத்த ஒருகண் அடைப்பு மூலம் பார்வை தெளிவின்மை குழந்தைகளுக்கு சிசிக்சை அளிக்கும் முறை.

1. நான் இந்த படலத்தை படித்து புரிந்துக் கொண்டேன். மேற்கண்ட ஆய்வில் ஏற்படும் சந்தேகங்களை அறியும் உரிமையும் அளிக்கப்படுகிறது.

2. நான் இந்த ஆய்வில் என் சொந்த விருப்பத்தில் பங்கேற்கிறேன் நான் எப்பொழுது வேண்டுமானாலும் இந்த ஆய்வில் இருந்து என் குழந்தையை விலக்கலாம் என்று அறிந்திருக்கிறேன். அப்படி விலகினாலும் என் மருத்துவ உரிமைகள் பறிக்கபடாது என்ற புரிந்திருக்கிறேன்.

3. நான் என்னுடைய மருத்துவ படிவங்களை மருத்துவ நிபுணர்கள் ஆய்வு பரிந்துரை செய்வதற்கு எனது அனுமதி தேவையில்லை. மேலும் இந்த ஆராய்ச்சிக்கு தேவைபடும் படிவங்கள் மற்றும் ஆய்வுகளை மருத்துவர், நான் இந்த ஆய்விலிருந்து விலகிய பின்னும் படிக்க / ஆராய எனது அனுமதி தேவையில்லை இதனால் எனது அடையாளம் மாறும் அபாயம் எதுவும் இல்லை என்பதை நான் நன்கு அறிந்துள்ளேன்.

   இந்த ஆராய்ச்சியின் படிவங்கள் மற்றும் முடிவுகளை தடுக்க எனக்கு உரிமையில்லை என்பதை நான் ஒப்புக்கொள்கிறேன்.

   இந்த ஆய்வின் பங்கேற்பதினால் என்னுடைய கண் பார்வையில் தேர்ச்சி வரலாம், வராமலும் போகலாம் என்பதை நன்கு புரிந்துகொண்டேன். இதனால் எனக்கு, எவ்வித பொருளாதார உதவியும் இல்லை என்பதை புரிந்துகொண்டேன். இந்த ஆய்வின் பங்கேற்க நான் முழுமனதோடு சம்மதிக்கிறேன்.

குழந்தையின் பெயர் :

குழந்தையின் கையொப்பம் :

மருத்துவர் கையொப்பம் :

சாட்சி கையொப்பம் :

ANNEXURE III: CHILD'S ASSENT, PARENT'S CONSENT AND INFORMATION BROCHURE IN ENGLISH

CHILD'S ASSENT

Role of Low vision devices (LVD) to improve compliance with occlusion therapy in children with amblyopia.

(i) I confirm that I have read and understood the information sheet dated _____ for

the above study and I have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and I can withdraw myself

from it at any time, without giving any reason, without my medical care or legal rightsbeing affected.

(iii) I understand that the Ethics Committee and the regulatory authorities will not need mypermission to look at my health records both in respect of the current study and any

further research that may be conducted in relation to it, even if I withdraw from the

trial. I agree to this access. However, I understand that my identity will not be revealed

in any information released to third such a use is only for scientific purpose(s)

(iv) I agree not to restrict the use of any data or results that arise from this study provided

(v) I understand that by taking part in the study I may or may not receive any visual

benefit

(vi) I also understand that I will not receive any other financial compensation.

(vii) I agree to take part in the above study.

Name of Child:

Oral assent: Given / Not Given

Signature (or Thumb impression) of the Parent:

Date: _____/_____/_____ Place:

Signatory's Name: _____

Representative signature or thumb impression:

Date: _____/_____/_____ Place:

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____ Place:

Study Investigator's Name: _____

Signature or thumb impression of the Witness:

Date: _____/_____/_____ Place:

Name & Address of the Witness: _____

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: Role of Low vision device (LVD) to improve compliance with occlusion therapy in children with amblyopia.

Study Number:

Participant's name:

Date of Birth / Age (in years):

I_____

_____, father/mother of _____

I declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]

I also understand that my child's participation in this study is entirely voluntary and that I am free to withdraw my child's participation at any time without affecting my usual treatment or my legal rights [ ]

I understand, my child will receive free treatment for any study related injury or adverse event but will not receive and other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my child's health records even if he/she withdraws from the trial. I agree to this access [ ]

I understand that my child's identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree for my child to take part in this study [ ]

Signature (or Thumb impression) of the Parent:

Date: ____/____/_____ Place:

Signatory's Name: _____

Representative: _____

Date: _____/_____/_____ Place:

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____ Place:

Study Investigator's Name: _____

Signature or thumb impression of the Witness:

Date: _____/_____/_____ Place:

Name & Address of the Witness: _____

_____

INFORMATION BROCHURE FOR CHILDREN

Christian Medical College, Vellore Department of Ophthalmology

Role of Low vision devices (LVD) to improve compliance with occlusion therapy in children with amblyopia

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We are conducting a study in children with lazy eye.

As treatment you are advised to close/ occlude the good eye. So, the lazy eye will necessarily have to be used and thus can result in improvement in vision. This is advised after school hours, 3 to 6 hours based on the need. However, some of you are not compliant with this treatment probably due to poor vision in the lazy eye.

We are conducting this study in an attempt to improve the compliance to occlusion therapy by giving counselling to parents and children or by giving counselling and magnifying glasses.

Magnifying glasses might help you see better with the lazy eye during occlusion. If you require magnifying glasses, a training will be given to you by the staff regarding it's use, as how to do near activities with it, like drawing, colouring, sketching, painting etc.,. which can be continued at home.

You will also be advised a follow up at 1,3 and 6 months to assess the improvement in occlusion as well as improvement in vision in the lazy eye.

You are being requested to participate in a study to see if your lazy eye can be treated with magnifying glasses. This method has no side effects. When followed strictly for a prescribed period of time, might help improve your vision.

What does low vision devices (magnifying glasses) do when used in amblyopic patients?

We advise use of magnifying glasses for the lazy eye. We intend to encourage increase in the duration of occlusion/closing of the good eyes by giving low vision device/ magnifying glass to the lazy eye to see better and thus encourage you to do more near work.

Do low vision devices(magnifying glass) have any side effects?

Low vision devices(magnifying glass) have no potential side effects.

If you takes part what will you have to do?

If you agree to participate in this study, you will be given low vision device, free of cost to improve your vision for near work, with the lazy eye during occlusion therapy.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are free to decide to withdraw permission to participate in this study. If you do so, it will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related complications?

We do not expect any untoward incident with use of low vision devices, but if any untoward incident occurs we will not be liable to give you any compensation what so ever.

Will you have to pay for the low vision aids?

The low vision device will be provided free of cost and your child can continue using the device even after the study concludes, if we observe any improvement in occlusion compliance.

What happens after the study is over?

You may or may not benefit from the study. If the doctor notices improvement in your compliance with occlusion or vision with the low vision devices, she will advice you to continue occlusion/closure of your better eye and the low vision device for your lazy eye.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please free to clarify your doubts with Dr. Santa Christina(9442120677), Ms. Rabiya (9940778597) or email: santachristina87@gmail.com.

INFORMATION BROCHURE FOR PARENTS

Christian Medical College, Vellore Department of Ophthalmology

Role of Low vision devices (LVD) to improve compliance with occlusion therapy in children with amblyopia

---

We are conducting a study in children with lazy eye.

As treatment the children with lazy eye are advised to close/ occlude the good eye. So, the lazy eye will necessarily have to be used and thus can result in improvement in vision. This is advised after school hours, 3 to 6 hours based on the need. However, some children are not compliant with this treatment probably due to poor vision in the lazy eye.

We are conducting this study in an attempt to improve the compliance to occlusion therapy by giving counselling to parents and children or by giving counselling and magnifying glasses.

Magnifying glasses might help the child see better with the lazy eye during occlusion. If your child requires magnifying glasses, a training will be given to your child by the staff regarding it's use, as how to do near activities with it, which can be continued at home.

Your child will also be advised a follow up at 1 ,3 and 6 months to assess the improvement in occlusion as well as improvement in vision in the lazy eye.

Your child is being requested to participate in a study to see if his/her lazy eye can be treated with magnifying glasses. This method has no side effects.When followed strictly for a prescribed period of time, might help improve your child's vision.

What does low vision devices (magnifying glasses) do when used in amblyopic patients?

We advise use of magnifying glasses for the lazy eye. We intend to encourage increase in the duration of occlusion/closing of the good eyes by giving low vision device/ magnifying glass to the lazy eye to see better and thus encourage your child to do more near work.

Do low vision devices(magnifying glass) have any side effects?

Low vision devices(magnifying glass) have no potential side effects.

If your child takes part what will you have to do?

If you agree for your child to participate in this study, your child will be given low vision device, free of cost to improve his/her vision for near work, with the lazy eye during occlusion therapy.

Can your child withdraw from this study after it starts?

Your child's participation in this study is entirely voluntary and you or your child are free to decide to withdraw permission to participate in this study. If you do so, it will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related complications?

We do not expect any untoward incident with use of low vision devices, but if any untoward incident occurs we will not be liable to give you any compensation what so ever.

Will you have to pay for the low vision aids?

The low vision device will be provided free of cost and your child can continue using the device even after the study concludes, if we observe any improvement in occlusion compliance.

What happens after the study is over?

Your child may or may not benefit from the study. If the doctor notices improvement in your child's compliance with occlusion or vision with the low vision devices, she wil ladvice you to continue occlusion/closure of your better eye and the low vision device for your lazy eye.

Will your child's personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please free to clarify your doubts with Dr. Santa Christina(9442120677), Ms.Rabiya (9940778597) or email: santachristina87@gmail.com.

Informed Consent Form for Parents

Study Title: Role of low vision devices (LVD) to improve compliance with occlusion therapy in children with amblyopia

Patient hospital Number: _____Patient enrolment Number:: _____

Child's Initials: _____Child's Name: _____

Parent's Name:

Date of Birth / Age/Gender: _____

(Patient)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my child's participation in the study is voluntary and that my child is free to withdraw at any time, without giving any reason, without my child's medical care or legal rights being affected. [ ]

(iii) I understand that , the Ethics Committee and the regulatory authorities will not need my permission to look at my child's health records both in respect of the current study and any further research that may be conducted in relation to it, even if my child withdraws from the trial. I agree to this access. However, I understand that my child's identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree for my child to take part in the above study. [ ]

(vi) I am aware of the Audio-visual recording of the Informed Consent. [ ]

Signature (or Thumb impression) of the Parent

Date: _____/_____/_____ Place:

Signatory's Name: _____ Signature:

Representative: _____

Date: _____/_____/_____ Place:

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____ Place:

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: _____/_____/_____ Place:

Name & Address of the Witness: _____

PROFORMA

DEPARTMENT OF OPHTHALMOLOGY--CHRISTIAN MEDICAL COLLEGE, VELLORE

NAME: **DATE:**

AGE: **HOSPITAL NUMBER:**

GENDER:

BCVA RE: LE: AMBLYOPIC EYE

	RE	LE
LogMAR	**RE:**	**LE:**

FATHER'S EDUCATION: <8, 10, 12, DEGREE MOTHER'S EDUCATION: <8, 10,12, DEGREE

GRADE OF AMBLYOPIA MILD MODERATE SEVERE

TYPE OF AMBLYOPIA

ANISOMETROPIC STRABISMIC SENSORY

ENTRY NEW CASE OLD CASE

OLD CASE:

PRESCRIBED OCCLUSION TIME:

OCCLUSION PRACTISED

	GOOD COMPLIANCE	MODERATE COMPLIANCE	POOR COMPLIANCE
OLD CASE PRESENT GRADE OF COMPLIAI			
POST COUNSELLING& DOCUMENTATION COMPLIANCE			
NEW CASE POST COUNSELLING& DOCUMENTATION COMPLIANCE			

MODERATE AND POOR COMPLIANCE GROUP- POST INTERVENTION WITH LVD

GRADE OF COMPLIANCE GOOD MODERATE POOR

BCVA of amblyopic eye

In logMar

1 month

3 month

6 month

THOSE WITH GOOD COMPLIANCE POST COUNSELING FOLLOW UP

GRADE OF COMPLIANCE GOOD MODERATE POOR

BCVA of amblyopic eye

In log MAR

1 month

3 month

6 month

COUNSELING FOR OCCLUSION THERAPY

AMBLYOPIA – GRADE M/MOD/S HRS ADVISED 3/6 CURRENT

PI COMPLIANCE %

CAREGIVER - NAME AND RELATION

INFORM EYE IS LAZY EYE

NEED TO COVER THE GOOD EYE, SO LAZY EYE WILL BE FORCED TO SEE AND THUS VISION MIGHT IMPROVE

WITHOUT OCCLUSION VISON WILL NOT IMPROVE

LIMITED TIME AVAILABLE FOR OCCLUSION DUE TO THE DEVELOPMENT OF THE VISUAL SYSTEM

ANY DOUBT REGARDING OCCLUSION THERAPY

DEDICATED PERSON AT HOME TO SUPERVISE ADVISED

RELATION TO CHILD, TIME WITH CHILD AT HOME

ACTIVITY BOOK GIVEN

DIVISION OF ACVITITIES ADVISED

CHILD – NAME AND AGE

INFORM EYE IS LAZY EYE

NEED TO COVER THE GOOD EYE, SO LAZY EYE WILL BE FORCED TO SEE AND THUS VISION MIGHT IMPROVE

WITHOUT OCCLUSION VISON WILL NOT IMPROVE

LIMITED TIME AVAILABLE FOR OCCLUSION DUE TO THE DEVELOPMENT OF THE VISUAL SYSTEM

ANY DOUBT REGARDING OCCLUSION THERAPY

DEDICATED PERSON AT HOME TO SUPERVISE ADVISED

RELATION TO CHILD, TIME WITH CHILD AT HOME

ACTIVITY BOOK GIVEN

DIVISION OF ACVITITIES ADVISED

CO – INVG /GUIDE

CAREGIVER - NAME AND RELATION

INFORM EYE IS LAZY EYE

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RELATION TO CHILD, TIME WITH CHILD AT HOME

ACTIVITY BOOK GIVEN

DIVISION OF ACVITITIES ADVISED

CHILD – NAME AND AGE

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DEDICATED PERSON AT HOME TO SUPERVISE ADVISED

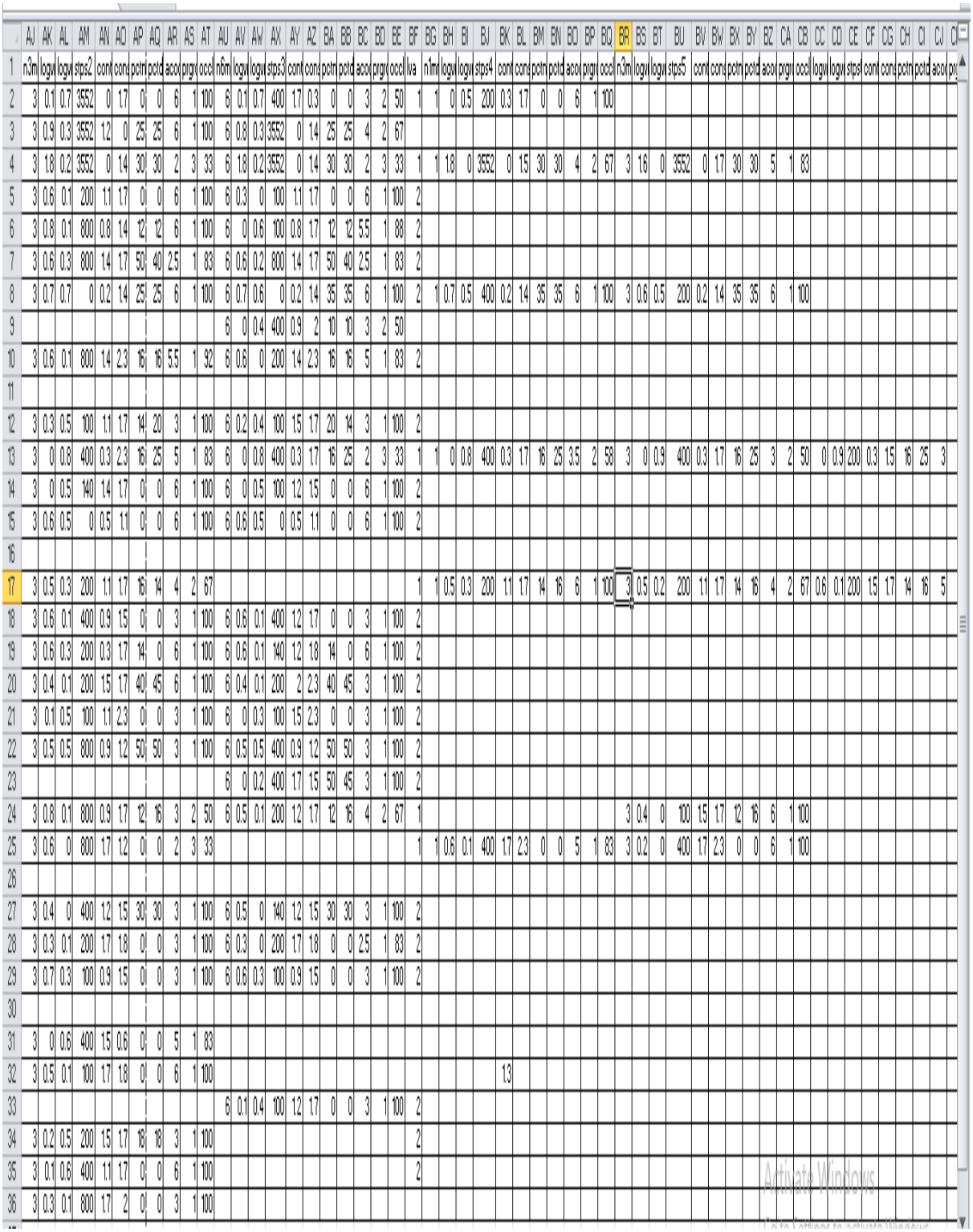
RELATION TO CHILD, TIME WITH CHILD AT HOME

ACTIVITY BOOK GIVEN

DIVISION OF ACVITITIES ADVISED

ANNEXURE III: DATA SHEET

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL
1	sin	hospno	doe	name	age	sex	amb	grad	type	entry	occl	n0m	logw	logw	good	amb	stps	cont	cons	pctn	pctd	acol	prgn	oocl	n1m	logw	logw	stps1	cont	cons	pctn	pctd	acol	prgn	oocl	n3m	logw	logw
2	1	334608	05-11-2018	harini	8	2	2	3	1	1	2	0	0.1	0.9	0.1	0.9	0	0	1.3	0	0	1	3	17	1	0.1	0.7	0	0	1.7	0	0	5	1	83	3	0.1	0.7
3	2	485041	10-12-2018	prajith	4	1	1	3	1	1	2	0	0.9	0.2	0.2	0.9	3552	0	1.2	25	25	0	3	0	1	0.9	0.2	3552	1.2	0	25	25	3.5	2	58	3	0.9	0.3
4	3	508715	26-12-2018	deepakra	6	1	1	3	1	1	2	0	1.8	0.2	0.2	1.8	0	0	1.7	25	25	1	3	17	1	1.8	0.2	0	0	1.7	25	25	2	3	33	3	1.8	0.2
5	4	520777	21-01-2019	reshma	5	2	1	2	1	1	2	0	0.7	0.1	0.1	0.7	3552	1.1	1.7	0	0	0	3	0	1	0.7	0.1	800	1.1	1.7	0	0	6	1	100	3	0.6	0.1
6	5	601057	16-02-2019	magilan	6	1	2	2	1	1	2	0	0.1	0.8	0.1	0.8	0	0.8	1.2	12	12	5	1	83	1	0.1	0.8	0	0.8	1.4	12	12	6	1	100	3	0.8	0.1
7	6	418853	#########	suji	6	2	1	1	1	1	1	0	0.9	0.5	0.5	0.9	0	1.1	1.7	45	40	0	3	0	1	0.6	0.2	0	1.2	1.7	40	50	2	2	67	3	0.6	0.3
8	7	340074	21-01-2019	ishwarya	11	2	1	3	1	1	2	0	0.8	0.7	0.7	0.8	0	0	1.4	25	25	0	3	0	1	0.8	0.7	0	0.2	1.4	25	25	5	2	83	3	0.7	0.7
9	8	681652	19-03-2019	kaviya	9	2	2	2	2	2	2	0	0.2	0.6	0.2	0.6	800	0.9	2	10	10	0	3	0														
10	9	153396	10-12-2018	sneha	13	2	1	2	1	1	2	0	0.6	0	0	0.6	3552	1.4	2.3	16	16	1	3	17	1	0.6	0	3552	1.4	2.3	16	16	4	2	67	3	0.6	0.1
11	10	686194	#########	aabid	17	1	1	3	2	2	2	0	1.4	0.1	0.1	1.4	0	0	1.7	0	0	0	0	0														
12	11	455644	#########	aamir ali	7	1	2	1	1	1	1	0	0.3	0.8	0.3	0.8	400	0.9	1.7	30	25	2	2	67	1	0.4	0.6	800	1.4	1.7	14	20	3	1	100	3	0.3	0.5
13	13	681412	#########	sadhana	7	2	2	3	2	2	2	0	0.2	1	0.2	1	0	0	2	16	30	3	2	50	1	0	1	3552	0	2.1	16	30	4	2	67	3	0	0.8
14	14	671608	#########	arun	7	1	2	2	2	1	2	0	0.1	0.8	0.1	0.8	200	1.1	1.7	0	0	4	2	67	1	0.1	0.5	60	1.4	1.8	0	0	6	1	100	3	0	0.5
15	15	535250	01-04-2019	arun	6	1	1	2	1	1	2	0	0.8	0.6	0.6	0.8	0	0.5	1.7	0	0	2	3	33	1	0.7	0.5	0	0.5	1.1	0	0	6	1	100	3	0.6	0.5
16	16	619866	#########	bhuvanes	15	2	1	1	2	1	1	0	0.3	0	0	0.3	200	1.7	2.1	0	0	0	3	0														
17	17	551545	#########	jagadees	7	1	1	2	1	1	2	0	0.7	0.3	0.3	0.7	0	1.1	1.7	14	16	4	2	67	1	0.6	0.4	200	1.1	1.7	14	16	4	2	67	3	0.5	0.3
18	18	437747	#########	om prakas	5	1	1	1	1	1	1	0	0.7	0.2	0.2	0.7	0	0.8	1.4	0	0	1	3	33	1	0.6	0.2	800	0.8	1.7	0	0	2.5	1	83	3	0.6	0.1
19	19	349252	19-11-2018	saicharan	7	1	1	2	2	1	2	0	0.7	0.3	0.3	0.7	200	0.3	1.7	14	0	3	2	50												3	0.6	0.3
20	20	663861	15-04-2019	sarvesh	8	1	1	2	2	1	2	0	0.4	0.1	0.1	0.4	200	2	2.3	30	30	6	1	100	1	0.4	0	200	1.7	2.3	40	40	6	1	100	3	0.4	0.1
21	21	167232	#########	jeslin	13	2	2	1	2	1	1	0	0.1	0.5	0.1	0.5	100	2	2.1	0	0	0	3	0	1	0	0.4	400	1.2	1.7	0	0	1	1	33	3	0.1	0.5
22	22	677814	#########	charisma	6	2	1	1	2	1	1	0	0.6	0.6	0.6	0.6	0	0.9	0.9	50	50	3	1	100	1	0.6	0.5	0	0.9	0.9	50	50	3	1	100	3	0.5	0.5
23	23	649167	#########	ram	7	1	2	1	3	1	1	0	0.1	0.2	0.1	0.2	400	1.4	1.7	50	45	2	2	67	1	0	0.2	400	1.5	1.5	50	45	2	2	67			
24	24	632887	#########	sivasarojin	7	2	1	2	2	2	2	0	0.8	0.3	0.3	0.8	800	1.4	1.7	12	16	0	3	0	1	0.8	0.2	800	1.4	1.7	12	16	2	3	33	3	0.8	0.1
25	25	560806	16-05-2019	mohamme	14	1	1	2	2	2	2	0	0.6	0	0	0.6	800	1.2	1.7	0	0	0	3	0												3	0.6	0
26	26	635048	#########	tamal dutt	10	1	2	3	2	2	2	0	1	0	0	1	120	0.9	1.7	0	0	0	3	0														
27	27	600001	#########	dhanuska	8	2	1	1	1	1	1	0	0.8	0	0	0.8	0	0	1.7	30	30	1	3	33	1	0.5	0	400	0.9	1.5	30	30	3	1	100	3	0.4	0
28	28	498140	13-06-2019	kamesh	12	1	1	1	2	1	1	0	0.5	0	0	0.5	3552	0.8	2	0	0	1	3	33	1	0.4	0.1	800	1.7	1.8	0	0	3	1	100	3	0.3	0.1
29	29	344856	#########	saichanth	8	2	1	1	1	1	1	0	0.8	0.4	0.4	0.8	400	0.9	1.4	0	0	2.5	1	83	1	0.7	0.4	100	0.9	1.5	0	0	3	1	100	3	0.7	0.3
30	30	646486	#########	haasini	8	2	2	1	2	1	1	0	0.1	0.5	0.1	0.5	800	1.4	1.7	0	0	3	1	100														
31	31	495502	s	naren kart	13	1	1	3	1	2	2	0	0.1	0.6	0.1	0.6	400	1.2	0.6	0	0	0	0	0												3	0	0.6
32	32	658522	#########	susith	5	1	1	1	1	1	1	0	0.5	0.1	0.1	0.5	100	1.2	1.2	0	0	6	1	100	1	0.5	0.1	100	1.7	1.8	0	0	6	1	100	3	0.5	0.1
33	33	557035	#########	stanley	7	1	2	1	2	1	1	0	0.1	0.4	0.1	0.4	100	1.2	1.7	0	0	0	3	0														
34	34	665040	15-07-2019	usman	5	1	2	1	2	1	1	0	0.3	0.5	0.3	0.5	400	0.9	1.5	18	18	3	1	100	1	0.2	0.5	400	1.5	1.7	18	18	3	1	100	3	0.2	0.5
35	35	665040	15-07-2019	esther	5	2	2	2	1	1	2	0	0.1	0.8	0.1	0.8	0	0.9	1.7	0	0	6	1	100	1	0.1	0.7	800	0.9	1.7	0	0	6	1	100	3	0.1	0.6
36	36	336821	#########	Ranjith Ku	7	1	1	1	2	2	1	0	0.5	0.3	0.3	0.5	3552	1.5	1.7	0	0	0	3	0	1	0.4	0.1	3552	1.7	1.8	0	0	2.5	1	83	3	0.3	0.1



ABBREVATIONS USED

LVD – Low Vision Devices

OPD – Out-patient Department

PEDIG – Paediatric Eye Disease Investigator Group

LogMAR – Logarithm of the minimum angle of resolution

N – Near vision notation

BCVA – Best-corrected visual acuity

CST – Contrast sensitivity

D – Dioptre

EVM – Electronic Video Magnifier

SSPS – Statistical Package for the Social Sciences

SD – Standard Deviation

P value – Probability value

n - number

CAM therapy – Cambridge Stimulator therapy

TED – Total effective dose

RCT – Randomised control Trial

ODM – Occlusion dose monitor

P cell – Parvocellular

M cell – Magnocellular

PTO – Part-time occlusion

FTO – Full-time occlusion

CNS – Central Nervous system

ABSTRACT

TITLE: ROLE OF LOW VISION DEVICES TO IMPROVE COMPLIANCE WITH OCCLUSION THERAPY IN CHILDREN WITH AMBLYOPIA

DEPARTMENT: DEPARTMENT OF OPHTHALMOLOGY

NAME: SANTA CHRISTINA .P.

DEGREE AND SUBJECT: M.S. OPHTHALMOLOGY

NAME OF GUIDE: DR. DEEPA JOHN

OBJECTIVES:

To assess improvement in compliance during occlusion therapy with counseling alone and with low vision devices.

To assess improvement in vision and higher visual functions after occlusion therapy.

METHODS:

Children with unilateral amblyopia on occlusion therapy (old cases with less compliance and new cases), between 5-18 years, were included into the study, after an informed consent

Distant and near visual acuity, contrast sensitivity and stereopsis were measured

Counselling for occlusion was given and near activity during occlusion was adviced

Occlusion compliance was assessed at 1st,3rd and 6thmonth as recorded in the occlusion monitor book

Children with good compliance continued occlusion and those with moderate and poor compliance were taught occlusion of the good eye with low vision devices for the amblyopic eye

Data analysis – SSPS 23 statistics

Categorical variables – Percentage

Continuous variables – Mean,Standard deviation

RESULTS:

Counselling improved occlusion compliance (37.62% to 84.93%) which was clinically significant

Mean vision improvement (log 0.72 to 0.57) and mean stereopsis improvement (2167.57 to 836.83) was statistically significant

Contrast sensitivity improvement (log 0.88 to 1.05) was highly significant

In the low vision device group, there was good improvement in compliance rate, vision, contrast sensitivity and stereopsis

KEYWORDS: Low vision device, compliance, amblyopia, occlusion therapy