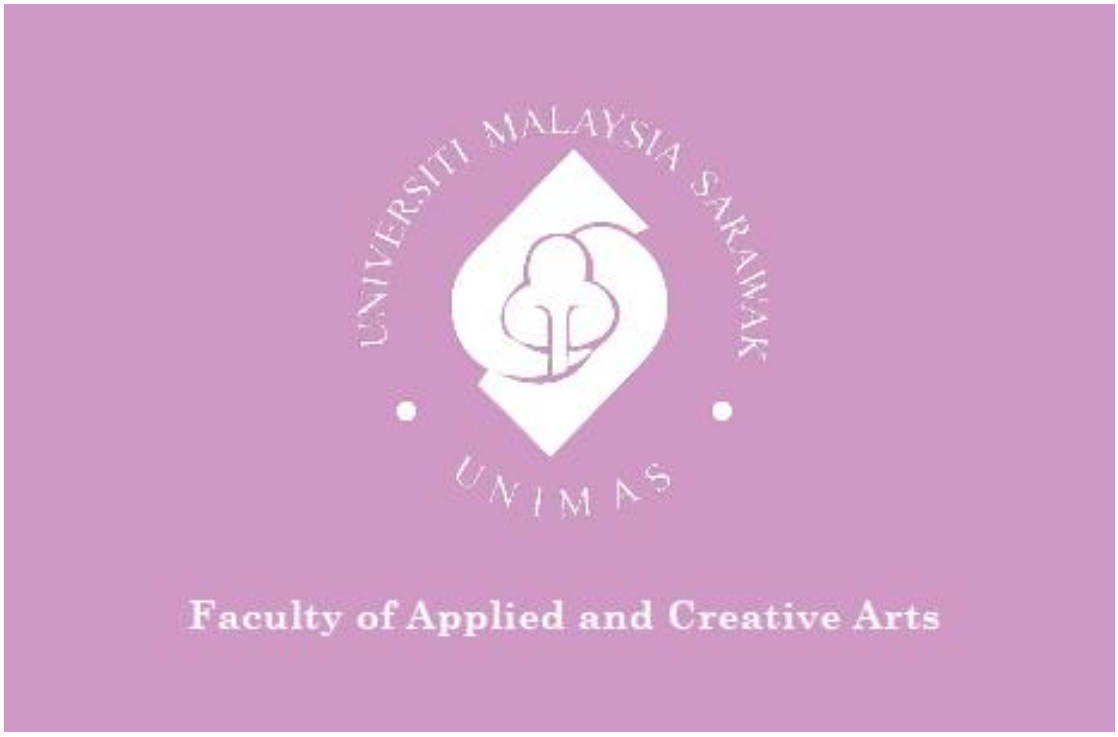

Exploration of Medical Product Design in Treating the Amblyopia

Tan Choon Ho

Bachelor of Applied Arts with Honours
(Design Technology)
2019

UNIVERSITI MALAYSIA SARAWAK

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Exploration of Medical Product Design in Treating the Amblyopia

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This project is submitted in partial fulfilment of the
requirement for degree of Bachelor of Applied Arts with Honours
(Design Technology)

Faculty of Applied and Creative Arts
UNIVERSITI MALAYSIA SARAWAK
2019

The project entitled 'Exploration of Medical Product Design in Treating the Amblyopia' was prepared by Tan Choon Ho and submitted to the Faculty of Applied and Creative Arts in partial fulfilment of the requirements for a Bachelor of Applied Arts with Honours (Design Technology).

Received for examination by:

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Date: ……

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CHAPTER 1
INTRODUCTION

1.1 Abstract

Amblyopia affects approximately 2 to 4 percent of the population and clinically defined as a vision development disorder which is most commonly associated with causes of strabismus, refractive anisometropia and visual deprivation. The visual suppression of areas of differ images by the brain can happen caused by those situations. The critical period for developing amblyopia is within ages of 7 to 8 years old. The earlier amblyopia is diagnosed and treated, it increases the possibility to be better vision compared to the current situation. Otherwise, the visual acuity of amblyopic eye will be decreased and blur permanently if not treated well. The resistance for the treatment of amblyopia is higher with increasing of ages in 2013. Eventually, the living condition of the children with amblyopia will be affected and unfair due to the poorly performance in education, jobs, sports and even the socioeconomic achievement in future. To increase the visual outcome of amblyopic eye, the characteristics of product design have to be explored and created based on the need of children with amblyopia. This research is an attempt to generate a good idea of product design in order to ensure the normal visual development for children under 8 years old. Through the qualitative research, the result revealed that the most people's choice for treating the amblyopia is adhesive eye patch or eye patch for glass design compared to wear special glass design or use atropine. In case, financial constraint is a problem for them and there is no strongly evidence to prove the effectiveness of special glass in increasing the vision. The concept of ergonomic and economic would be a good exploration in the medical product design to enable the compliance use of them among children.

1.2 Research Background

Amblyopia is commonly known as ‘lazy eye’ to the public which is a form of cortical visual impairment and affect 2 to 4 percent of the population according to the Dr. Tamara Petroysan who is an associate clinical professor at SUNY College of Optometry and East New York Diagnostic and Treatment Center. Lazy eye develops because of abnormal visual experience early in life that either no transmission or poor transmission of the visual stimulation through the optic nerve to the brain affects the neurologically active process. And it even changes the nerve pathways between retina at the back of the eye and the brain. Thus, the amblyopic eye receives the fewer visual signals.

Clinically, amblyopia will reduce visual acuity which is most commonly associated with the amblyogenic causes, such as strabismus, refractive anisometropia and visual deprivation (Birch, 2012). Although amblyopia can be bilateral, but it commonly affects one eye of children with refractive anisometropia, strabismus, or both. The best corrected vision cannot achieve 20/20 or 6/6 when amblyopia existed. It has to be treated within the critical period which is from 7 to 8 years old. It is not an typically eye disease and even can be treated effectively if diagnosed early.

Based on the American Optometric Association, amblyopia represents a syndrome of concessive deficiency, rather than merely decrease in quality of vision. The ability of eye tracking, contrast sensitivity, monocular fixation and others are degraded but the sensitivity of contour interaction effects will be increased. Eventually, the ability of the eyes to work together decreases, and the brain suppresses or ignores input from the amblyopic eye.

The risk of getting amblyopia is increased due to the factors of family history (Yasmin, 2013) and premature, small size at birth when born. Amblyopia will not disappear unless it is treated. Otherwise, it can lead to permanent visual problems, behaviours’ problem, social stigma, slow in learning process and even causes trauma in life.

The early detection and treatment of amblyopia is preferred for normal visual development and the best visual outcomes from amblyopia treatment. There are various of

treatment for amblyopia such as employing eyeglasses, atropine, vision therapy or eye patching. Some existing product for treating the amblyopia are high cost and may not aesthetic enough for children. The aspects of ergonomic, usability, safety, aesthetic, cost and other considerations need to take an insight into the medical product design for treating the amblyopia. Due to the economic downturn, the financial problem occurs in the poor family. They might not afford to get the treatment immediately. Thus, this research is to focus on exploration of medical product design in treating the amblyopia in order to create good medical product design for the children who suffered amblyopia under 8 years old.

1.3 Problem Statement

Many people do not realize the importance of treating amblyopia. In 2011, it is around 10 million of people under 8 years old suffered from the amblyopia in whole world. Some people feel discriminated by others when they going through the treatment such as eye patching. Thus, it gives the burden and stress to the parent and child. If not improve the compliance for the treatment, it may influence the effective result in treating the amblyopia. According to the study of Dr. Maria Namono Wanyonyi, the resistance for the treatment of amblyopia is higher with increasing of ages in 2013. The financial problem is also another main point for poor family due to the economic downturn. If the amblyopia is not treated well, visual acuity of amblyopic eye will be deteriorative and permanently blur.

1.4 Research Questions

The research will be based on a few questions :

1. What are the problems of existing product design of treating the amblyopia faced by the children?
2. What are the characteristics need to put in the medical product design for the treatment of amblyopia?
3. What is the best medical product design to improve the vision?

1.5 Research Objectives

1. To identify the problems of existing product in treating the amblyopia for children under 8 years old.
2. To analyze the characteristics of the existing product for the treatment of amblyopia.
3. To design an ergonomic medical product design for the treatment of amblyopia.
4. To validate the medical product design for children.

1.6 Scope of the Study

The research main location is at children eye care clinic (Pusat Jantung Sarawak General Hospital) in Kota Samarahan as there are eye specialists and many children with eye problem such as the strabismus, amblyopia and other else. Optical shop is also one of the locations to be chosen. The validation will be carried out at the optical shop.

1.7 Significance of the Study

A good medical product design is essential to the children under ages of 8 years old. The properties of product design will affect the effectiveness of the treatment such as the eye patch design, eyeglasses design or atropine. Improper medical product design will influence the improvement of visual acuity. The aspect of safety, ergonomic design, economics, sustainability, aesthetic and others need to be considered in designing the product to increase the effectiveness of treatment. Inappropriate materials used of medical product make child allergic and feeling of uncomfortable instead of providing a skin friendly and long lasting product to save the cost. The concept of aesthetic and ergonomic for product design is significant to make their children willing to use it while training their amblyopic eye. To improve the vision of children is the main goal of designing the medical product but to consider their financial problem is also another main concern. Therefore, the medical product design will be suited to the children's need in order to getting a good treatment.

CHAPTER 2
LITERATURE REVIEW

2.1 Overview of Amblyopia

2.1.1 Amblyopia

Amblyopia or commonly referred as lazy eye which is reduced visual acuity in unilateral or infrequently bilateral condition due to the abnormal visual experience during infancy or childhood. The nerve pathways between the brain and retina are improper stimulated. Amblyopia develops during the visual path within the ages of 7 to 8 years old in life called critical period. According to the American Optometric Association, amblyopia represents a symptom of compromising deficiency, rather than merely decreased the visual acuity, including :

i. Imprecise accommodating reaction
ii. Contrast sensitivity decreased
iii. Unusual spatial distortions and unpredictability
iv. Poor eye tracking capability
v. Sensitivity to contour interaction result enhanced
vi. Unstable and inaccurate monocular fixation

2.1.2 Differential Diagnosis of Case in Decreased the Visual Acuity

Based on the American Optometric Association, these are the causes of functional amblyopia, psychogenic and its structural below:

Functional amblyopia causes

i. Constant one-sided strabismus
ii. Combined aniso-strabismus
iii. Amblyopiogenic unadjusted refractive errors
    - Isoametropia
    - Anisometropia (astigmatic or round)
iv. Form deprivation
    - Early complete blepharoptosis
    - Hyphema
    - Uncontrolled occlusion treatment
    - Uncontrolled penalization treatment
    - Corneal opaqueness

Psychogenic causes

i. Malingering
ii. Conversion hysteria

Structural causes

i. Coloboma
ii. Macular pathology
iii. Prematurity's retinopathy
iv. Degenerative nearsightedness
v. Media's opacities
vi. Myelinated retinal nerve fibers
vii. Optic atrophy
viii. Hypoplastic optic nerve

2.1.3 Type of Amblyopia

Based on the Dr. Gary Heiting who has the cinical experience included positions at Ophthalmic Surgeons & Physicians, Ltd., in Tempe, Arizona; Park Nicollet Medical Center in Minneapolis; and Eau Claire LASIK in Eau Claire, Wisconsin, the abnormal visual experience will be happened due to these three types of amblyopia, based on the potential factors:

1. **Strabismic amblyopia**

Strabismus (crossed eye) is a most common factors of amblyopia. It is a condition of both eyes are not looking in the same visual direction, the crossed eye‘turns off’. To prevent double vision caused by the poor alignment of eyes, the brain disregard the visual input from the improper alignment of eyes. This leads to the amblyopia.

The starting point and seriousness of strabismic amblyopia will be varied. It depends on the category of strabismic amblyopia and the started age. There have different kind of strabismic amblyopia such as esotropia, exotropia, hypotropia, hypertropia, incyclotorsion and excyclotorsion according (P. Rutstein et al., 2011). For new born babies, they are not instantly use their eyes. Normal children will develop binocular cooperation’s stereopsis standard and fusion. The term of binocular rivalry is vital to develop the stereopsis. The children will perceive the double vision if the image cannot be fused. In this case, one of the eyes has to be repressed in order to eliminate the binocular rivalry. Patient will use different eyes which needs to take turn for suppression, or it may be monocular which could cause one sided amblyopia.

Misalignment of the eyes in strabismus can be categoried in a lots of ways (P. Rutstein et al., 2011):

i. Size (small, medium, big)
ii. Deviation varies with the direction of gaze or equal in all direction
iii. Direction (convergent, divergent, or vertical)
iv. Laterality (unilateral or alternating)
v. Frequency (intermittent or constant)
vi. Involvement of accommodative system (accommodative or non-accommodative)
vii. Time of onset (congenital or alternating)
viii. State of vergence system

According to the Royal College of Ophthalmologists in 2012, the following are the purposes of strabismus treatment below:

i. To restore eye alignment
ii. To restore optimal vision in each eye
iii. To get rid of double vision
iv. To correct abnormal head posture
v. To detect severe underlying optic or neurological disease
vi. To restore correct eye alignment

Esotropia

The term of esotropia can be defined as a condition where one or both eyes turn inward. Generally, most of the patients aged between 2 to 3 years will present esotropia. It is always constant. Intermittent esotropia happens firstly in association with decompensated esophoria which is an condition of tendency of one eye deviate inward or accommodative esotropia. Intermittent esotropia becomes constant if do not be treated (P. Rutstein et al., 2011).

Image 2.1.3.1 : Esotropia (eye turns inwards).
(Source : http://medpic.org/)

Esotropia can be sorted in many methods, normally based on the age of onset or underlying factors:

i. Infantile esotropia
ii. Acquired esotropia
    - Accommodative esotropia
        - Accommodative refractive esotropia
        - Accommodative refractive esotropia with a high accommodative convergence to accommodative ratio (AC/A).
        - Accommodative non-refractive esotropia with a high accommodative convergence to accommodative ratio (AC/A).
    - Partially accommodative esotropia
    - Non-accommodative esotropia
iii. Other

Infantile Esotropia

Infantile esotropia (IE) is the esotropia with a start before the age of six months, with a large-angle esodeviation, no or minimal amblyopia, small to medium hyperopia, separated vertical divergence, absent or decreased binocular visual acuity, latent nystagmus, and others, in the absence of nervous system problems according to the doctor of medicine, Joshua Schliesser, Derek Sprunger and Eugene Helveston in 2016.

Acquired Esotropia

Acquired esotropia is esotropia that occurs at a later age of infantile esotropia. One of the leading complaints of those suffered with this condition is double vision. The effectiveness of work is lower down because they have difficulty to finish the tasks every day. Although surgery may be undergone for treatment of this esotropia, but it can also be treated successfully with using glasses and vision therapy based on the doctor of optometry, Ann Marie Griff. The acquired esotropia is divided into four types of esotropia which are accommodative esotropia, non-accommodative esotropia, acute esotropia and mechanical esotropia.

Symptoms

People with esotropia cannot focus their eyes on same location at the same time. They may be able to see thing clearly by using one eye. The following are the signs of esotropia based on the expert in the field of optometry, Ann Marie Griff:

i. Crossed eyes
ii. Eyes turn inwards
iii. Lazy eye

Exotropia

Exotropia is a misalignment of eyes which one or both eyes turn outwards. It is a condition of opposite of crossed eyes. This can affect anyone at any ages, but it is normally diagnosed early in life. Most are intermittent exotropia although it may be constant or intermittent based on the American Optometric Association in 2011.

Image 2.1.3.2 : Exotropia (eye turns outwards).
(Source : https://davisjeeny.wordpress.com/)

There are other clinical categorization of exotropia in the following according to the American Optometric Association:

i. Infantile exotropia
ii. Acquired exotropia
    - Intermittent exotropia
    - Acute exotropia
    - Mechanical exotropia
iii. Secondary exotropia
    - Sensory exotropia
    - Consecutive exotropia
iv. Microexotropia

Infantile Exotropia

Within the first six months, a diverse strabismus begins that is called infantile exotropia. In the comparison with infantile esotropia, the infantile exotropia is less common. During the infancy, some cases of constant exotropia may relate to the craniofacial signs, flaw of eyes in structure and neurological syndromes or defect.

Acquired Exotropia

After six months of ages, an exotropia happens that has considered as acquired exotropia. There are a various of acquired exotropia such intermittent exotropia, acute, exotropia, sensory exotropia and others.

Secondary Exotropia

This exotropia results from a primary sensory defect or happens as an outcome of some form of treatment for the esotropia is referred to secondary exotropia.

Microexotropia

Microexotropia occurs less regularly compared to the microesotropia. A constant microexotropia is less than 10 PD.

Symptoms

There are a few symptoms described below may not representative towards the child has exotropia. If the child has one or more of those signs, the parent has to bring them for a check for eye. The following are the signs of exotropia according to the Kellogg Eye Centre :

- Outward deviation of the eyes, often periodically at first.
- Depth perception is decreased.
- The vision is reduced.
- Sensitivity of closing one eye in bright light.

Hypotropia

Hypotropia is a situation of abnormalities of eyes' alignment whereby one of the eyes looks downwards. Differential diagnosis is from double elevator paralysis. This will show hypotropia in primary position and absence of Bell's sign based on the Eye 2 Eye Optometrists.

Image 2.1.3.3 : Hypotropia (eye turns downwards).

(Source : http://pugetsoundeyecare.com/)

Hypertropia

Hypertropia is a situation of misalignment of eyes which is called strabismus. The visual axis of one eye is higher than another fixating eye. One of the eyes will turn upwards which is usually caused by paresis of one of the muscles that either uplift or depress the eye according to the doctor of optometry, Dr. Jeffrey Cooper and Dr. Rachel Cooper.

Image 2.1.3.4 : Hypertropia (eye turns upwards).

(Source :https://www.cehjournal.org/)

2. Refractive amblyopia

Refractive anisometropia, a condition which both eyes have unequal refractive power. It is not easily to detect immediately. One eye may experience the significant different farsightedness or nearsightedness, but the fellow eye does not according to the Kellogg Eye Center in 2014. Due to the poor development of visual function, the vision will be decreased and blurred. If a child born with significant uncorrected refractive errors, that child need to get glass early on.

Image 2.1.3.5 : Eyes have unequal refractive power.
(Source :https://spinoff.nasa.gov/)

3. Deprivation amblyopia

Visual deprivation will be occurred when the cataract blurs the visual axis. This is less common causes of amblyopia. The light will not allow to enter in caused by something obstructed when being focused by baby's eyes such as congenital cataract. To ensure the normal visual development, the treatment of congenital cataract must be implemented promptly.

Image 2.1.3.6 : In the right eye, the pupil appears white due to the cataract. Cataract blocked the light from entering the eyes.
(Source :https://spinoff.nasa.gov/)

2.1.4 Signs and Symptoms of Amblyopia

According to the National Collaborating Centre for Aboriginal Health, the signs of amblyopia are hard to be noticed for parent or guardian. It is commonly only one eye is affected. The following syndromes of amblyopia are:

i. Crying when one of the eyes is covered
ii. Rubbing the eyes
iii. Squinting
iv. Tilting the head
v. Saggy upper eyelid
vi. Eyes do not work together
vii. Immoderate blinking
viii. Drifting the eye when the child is tired, sick, or in bright sunlight
ix. Eyes that turn inward or outward
x. Closing or covering one eye
xi. Problems with depth perception

2.1.5 Way to Diagnose the Amblyopia

According to the website of 'All About Vision', if the eye is turned over or both eyes are not proper aligned, the guardian or parent needs to bring their child to meet up with optometrist or ophthalmologist, who specializes in the field of children's eye. Another way to test amblyopia is to simply cover the child's one of the eyes. If that child feel anxiety, the amblyopia may develop on their children.

2.1.6 Risk Factors of Amblyopia

The risk factor of amblyopia is ophthalmic circumstances that cause amblyopia. It includes strabismus, refractive error and situations which intervene with obvious retinal image formation.

Refractive error can be measured during infancy and is a common risk factor for both unilateral and bilateral amblyopia. Anisometropia, specifically hyperopic anisometropia, is a significant prophet of amblyopia. In common, the hyperopic anisometropia is referred to the farsightedness. If greater than 1.00 D of hyperopic anisometropia, it is considered possibly amblyogenic, with enhancing risk as the significance of anisometropia increases.

Myopia is an abnormal eye situation. It is also known as nearsightedness. Myopia may cause to amblyopia if a greater interocular difference is reached. If the myopic anisometropia is in lower degree, it does not associate with amblyopia. The levels for astigmatic anisometropia that can lead to amblyopia when it is lower than 1.50-2.00 D. Preschool children with bilateral astigmatism of ≥2.00 D or hyperopia of ≥4.00 D SE are 17 and 11 times respectively, to have bilateral amblyopia. Bilateral farsightedness will increase risk of esotropia on infants and younger children. Farsightedness between 2.00 and less than 3.00 D presents more than a 6-fold enhance in risk of esotropia.

The younger child or infant is recognized as being at risk may have not develop the approaching amblyopia. The refractive error is partly or wholly allocated by the majority of amblyopia. Major risk factor for one sided reduced vision of children who aged 2.5 to 6 years old when it was greater than or equal to 2.00 D same anisometropia in the combined results of the Baltimore Pediatric Eye Study (BPEDS) and Multi-Ethnic Pediatric Eye Study (MEPEDS).

Furthermore, another detectable risk factor is the strabismus. Strabismus is hard to be identified by guardians or families, specifically when the strabismus is one sided and fixed. Refractive risk factors individually do not satisfy for recognition of strabismus. It is because children with strabismus can obtain refractive errors in normal range. Strabismus is