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A modular and adjustable ptosis crutch as a non-surgical solution to elevating the upper eyelid of myasthenia gravis patients

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Abstract

Myasthenia Gravis (MG) is a treatable autoimmune disorder that affects the neuromuscular junction. MG is characterised by fatigable muscle weakness of voluntary skeletal muscles with the most commonly affected muscles being the eye and facial muscles. Patients of African genetic ancestry, particularly juveniles, are more likely to develop ocular muscle complications of MG compared to their European counterparts. MG ophthalmoplegic complications include persistent difficulty with moving the eyes and blepharoptosis, despite treatment. Blepharoptosis, or ptosis, describes the condition of a lowered upper eyelid(s), beyond its normal anatomic position. Surgical correction of ptosis is often contraindicated in MG patients with severe weakness of the muscles involved in eye closure and in patients with active disease. In these cases, a non-surgical solution to elevating the ptotic eyelid above the visual axis is required. **Objective:** To design a patient specific, modular and low cost ptosis crutch to elevate the eyelid(s) of myasthenia gravis patients. The ptosis crutch should be low cost, modular and adjustable in nature. **Method:** 16 MG patients (42 ± 23 years) volunteered to participate in the pre-design phase of the project. Initial eye measurements of each participant were taken using photographic measurement. A bottom-up approach was followed for the design of the ptosis crutch. 3D CAD models of the modular ptosis crutch were created in SolidWorks, according to the measured dimensions and the predefined design parameters. The ptosis crutch was prototyped using 3D printing. Eighty-seven design failures were observed before the final design was realised. A design feedback loop lead to the discovery of a device that satisfied the specified requirements. The final ptosis crutch was tested, in the clinical setting, on 12 MG patients (43 ± 24 years). **Results:** The ptosis crutch was designed to fit onto the superior border of the spectacle frame. The ptosis crutch is adjustable along the x- axis to cater for the inter-individual variability of globe protrusion. The crutch bar is adjusted along the z-axis and elevated the ptotic eyelid by 1.96mm (±1.11mm). All of the participants indicated that they would be interested in using the ptosis crutch on a long-term basis. **Conclusion:** The immediate feedback on the ptosis crutch from the MG patients has shown a positive outcome for the device. Future work will include obtaining long term feedback on the ptosis crutch from all of the users as well as investigating manufacturing methods using materials with increased durability.

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List of abbreviations

MG	Myasthenia gravis
3D	Three-dimensional
MRD	Marginal reflex distance
VPF	Vertical palpebral fissure
HPF	Horizontal palpebral fissure
NEI-VFQ	National Eye Institute Visual Function Questionnaire
CAD	Computer assisted design
ABS	Acrylonitrile butadiene styrene
PEG	Polyethylene glycol
PVC	Polyvinyl chloride
FMEA	Failure Mode Effects Analysis
STL	Stereolithography

1. Introduction

1.1 Background to the study

Myasthenia gravis (MG) is a treatable autoimmune disorder that affects the neuromuscular junction. MG is characterised by fatigue and generalized weakness of voluntary skeletal muscle, with the eye and facial muscles being the most commonly affected (Pruitt & Ilsen, 2010; Nemet, *et al.,* 2014). The cause of muscle weakness is a defective neuromuscular junction, whereby the receptors responsible for initiating muscular contraction are blocked by the autoimmune antibodies (Pruitt & Ilsen, 2010).

Estimates from North American data indicate that the prevalence of MG is 200 per million (Phillips, 2003). The incidence within South Africa population is similar to the rest of the world (Mombaur, *et al.,* 2015). While MG affects individuals of all racial groups, patients of African genetic ancestry, particularly juveniles, are more likely to develop an ocular muscle complication of MG compared to their European counterparts (Heckmann, 2012). The most common symptoms of the ophthalmoplegic complications of MG are difficulty with moving the eyes and blepharoptosis.

Figure 1. A photograph of a myasthenia gravis patient with ptosis [photograph used with permission from the patient].

1.2 Description of the clinical problem

Blepharoptosis, abbreviated to ptosis, describes the condition of a lowered upper eyelid(s), beyond the normal position [*Figure 1*] (Ahmad, *et al.*, 2011; SooHoo, *et al., 2014;* Walsh*, et al.*, *2006)*. Ptosis may present as a unilateral or bilateral condition. Additional aetiologies of ptosis include muscle disorders as well as aging and muscular-aponeurotic disorders (SooHoo et al., 2014). Regardless of the type or presentation of ptosis, when it obstructs vision, it is disabling.

Figure 2. A photograph of the ptotic eyelid manually elevated to clear the visual axis [photograph used with the permission from patient].

Surgical correction of ptosis is often contraindicated in MG patients with severe weakness of the muscles involved in eye closure and in patients with active disease. In these cases, a non-surgical solution to elevating the ptotic eyelid above the visual axis is required [*Figure 2*] (Moss, 1982). An external device that mechanically elevates the upper eyelid seems to offer an appropriate solution to clearing the visual axis.

1.3 Significance of the clinical problem

Ptosis as a symptom of MG, or other muscular disorders, is a debilitating condition that can be improved by using an assistive device to elevate the eyelid. A ptosis crutch offers such a solution. Although the ptosis crutch itself is not a novel idea, there is no record of a commercial ptosis crutch that is developed and available in South Africa. Furthermore, no evidence could be found of a modular or adjustable ptosis crutch in the global market. The literature suggests that crutches are currently manufactured and fitted on a case-by-case basis (Moss, 1982; Lapid, 2000; Kumar, 2010).

Unfortunately, custom making crutches require the patient to have access to the appropriate facilities as well as the funds to supports this option. These are two luxuries that a large proportion of the South African population, as well as other developing countries, do not have.

The ptosis crutches that are available are permanently fixed to the frame or lens of the spectacle, thus limiting the use of the crutch to one pair of spectacles [*Figure 3*].

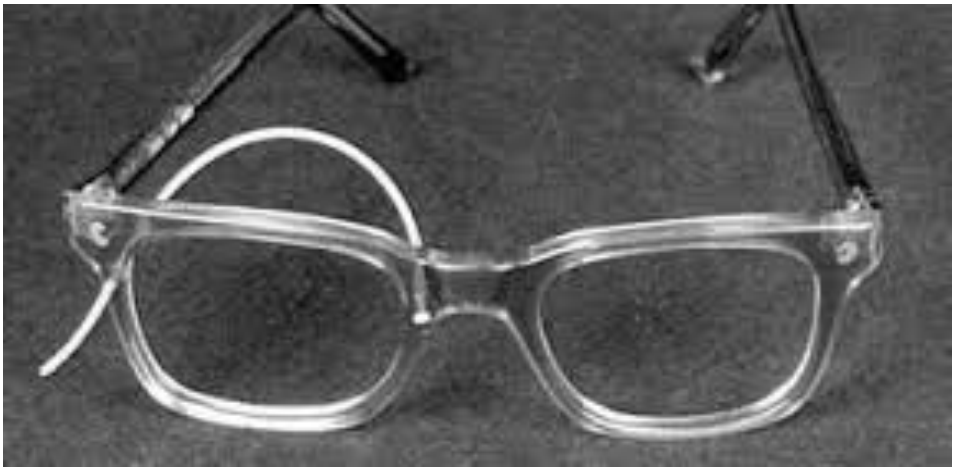


Figure 3. A ptosis crutch permanently attached to the spectacle frame [taken from Walsh, 2006].

MG affects individuals of all racial groups, however, the outcome of therapy of the disease differs across races. Patients of African genetic ancestry, particularly juveniles, are more likely to develop ocular muscle complications of MG when compared to their European counterparts. Despite the presentation of ptosis in MG patients, there is no record of a crutch that has specifically been designed for the MG population. The association of treatment resistant and ocular muscle complication in MG patients of African ancestry emphasizes the need for a South African solution all the more.

1.4 Research approach

The current research project includes both clinical and design aspects. Each aspect was carried out according to the normal practice of their respective fields. The design component followed the method of an iterative design approach. The clinical component followed the procedures of a quasi-experimental design. A one group pre-

test/post-test design was used to determine the effect, if any, that the ptosis crutch had on elevating the eyelid.

1.5 Research hypothesis

It is hypothesized that a modular and adjustable ptosis crutch will elevate the ptotic eyelid to clear the visual axis.

1.6 Study aim

The aim of the present study was to design and construct a modular ptosis crutch for the South African myasthenia gravis population. The crutch should elevate the upper eyelid to clear the visual axis.

1.7 Objectives of the study

1. To determine the anthropometric measures that will inform the ptosis crutch design.
2. To design and prototype a modular and adjustable ptosis crutch suitable for the MG population.
3. To verify the efficacy of the ptosis crutch within the clinical setting.
4. To investigate low cost manufacturing methods for producing the ptosis crutch.

1.8 Key project parameters

From an innovative/academic perspective, this project allowed for the development of a solution to a problem that is much needed in South Africa. From a social aspect, the aim of this product is to design a ptosis crutch that meets the needs and expectations of the user including the elements of effectivity, practicality, comfort and affordability as well as considering the aesthetic appearance of the crutch.

The clinical parameters were:

1. To determine the amount of eyelid elevation required to clear the visual axis.
2. To determine the size of the crutch that is required to provide upper eyelid elevation for children, adolescents, and adults.
3. To determine the effect that ptosis has on performing activities of daily living.

The design parameters were:

1. To determine the methods of tri-axial adjustment.
2. To investigate an easy method for attachment and detachment of the crutch.
3. To select materials to prototype and construct the crutch that will not cause skin irritation.
4. To determine the method of manufacturing the crutch.
5. To investigate a material with the strength to support eyelid elevation but allow for some blinking to occur.

1.9 Scope of the study

The present study was limited to investigating an appropriate method for elevating the upper eyelid of MG patients. This is a proof of concept investigation. The scope of the present study did not go beyond describing a working prototype. In the event that the long-term feedback from the MG patients was positive, the appropriate methods of manufacturing the device for long-term use were to be investigated.

1.10 Dissertation overview

This document describes the research, clinical and design methodologies of the study. Chapter 2 (Literature Review) provides an overview of the clinical problem as well as contextualises the need for the described solution. Chapter 3 (Clinical and Design Methodologies) describes the iterative design process as well as the clinical testing of the device that were carried out in order to achieve the design objectives. Chapter 4 (Design Outcome) refers to the final ptosis crutch design as well as the statistical analysis of the clinical results. A comparison of the ptosis crutch to existing designs as well as highlighting the socio-economic impact of the devices is highlighted in Chapter 5. Finally, Chapter 6 discusses the conclusions and limitations of the study, as well as suggesting recommendations for future research.

2. Review of Relevant Literature

This chapter is concerned with uncovering the need for the ptosis crutch. It seeks to present information regarding existing ptosis crutch devices as well as expanding on the practices that formed the clinical and design methodologies.

2.1 Myasthenia gravis

MG is a treatable autoimmune disorder that affects the neuromuscular junction. MG is characterised by fatigue and generalized weakness of voluntary skeletal muscle (Nemet, *et al.,* 2014; Pruitt & Ilsen, 2010). The most commonly affected muscles include those of the eye, neck, limbs as well as the respiratory muscle. The eye muscles involved in eyelid elevation and eye movements are among the first areas to display muscle weakness. The cause of the muscle weakness is a defective neuromuscular junction, whereby the receptors responsible for initiating muscular contraction are blocked by the autoimmune antibodies (Pruitt & Ilsen, 2010).

The estimates from North American data suggests that the prevalence of MG is around 200 per million (Phillips, 2003). The prevalence within the South Africa population is similar to the rest of the world (Mombaur, *et al.*, 2015). While MG affects individuals of all racial groups, patients of African genetic ancestry and particularly juveniles of this lineage are more likely to develop treatment resistance of their ocular muscle complications, compared to their European counterparts (Heckmann *et al*., 2012). The most common ophthalmoplegic complications of MG are difficulty with moving the eyes and blepharoptosis.

2.2 Ptosis

Blepharoptosis, or ptosis, describes the condition of a drooping upper eyelid(s), beyond the normal anatomic position [*Figure 4*] (Walsh, *et al.*, 2006).The most common symptoms of ptosis include; the inability to fully elevate the eyelid, disruption to the visual field (especially loss of superior vision) and difficulty completing activities

of daily living. Previous studies have found that visual field impairment to be present in individuals with a marginal reflex distance (MRD) of 1.5mm-2mm or less, with more severe ptosis resulting in proportionately greater visual impairment (Meyer, *et al.*, 1989). Non-specific symptoms of ptosis include blurred vision and frontal headaches due to fatigue of the forehead muscles in an attempt to lift the upper eyelids.

Figure 4. A photograph of a myasthenia gravis patient with bilateral ptosis [photograph used with permission from the patient].

2.2.1 Types of ptosis

Ptosis may present as either an isolated disorder or in conjunction with other ocular and systemic disorders (Sakol, *et al.*, 1999). Although ptosis associated with MG is the foundation for this research project, it is important to acknowledge the other pathologies of ptosis. The cause of congenital and acquired ptosis can be classified as either; myogenic, neurogenic, aponeurotic or mechanical (Sowka, *et al.*, 2001; Finsterer, 2003; Edmonson & Wulc, 2005).

Aponeurotic ptosis is the most common cause of acquired ptosis in adults. It involves an abnormality (dehiscence, disinsertion or stretching) of the levator aponeurosis from its attachment to the tarsus and pre-tarsal orbicularis muscles (Fujiwara, *et al.*, 2001). Myogenic ptosis is attributed to several various muscular disorders involving the levator palpebrae superioris. Neurogenic ptosis describes ptosis that results from disruption to the innervation of the muscles involved in upper eyelid elevation (Sowka *et al*., 2001). Resistance to the action of the levator palpebrae superioris muscle results in mechanical ptosis. The most common causes of mechanical ptosis include; trauma to the eyelid and surrounding tissues, benign or malignant tumours of the eyelid, dermatochalasis and conjunctival scarring (Sudhakar, *et al.*, 2009).

Treatment of ptosis is necessary to reduce visual disruptions caused by the ptotic eyelid covering the pupil of the eye, as well as to eliminate aesthetic abnormalities (Conway, 1973). Ptosis is usually treated by surgically elevating the eyelid to a fixed position. There are a number of situations where surgery is unsuccessful or not possible due to additional medical concerns (severe weakness of the muscles involved in eye closure) a lack of funding and accessibility for the procedure. While there is a vast body of research describing the surgical correction of ptosis, there is currently a lack of effective and long lasting non-surgical alternatives for alleviating the symptoms of ptosis.

2.2.2 Visual obstruction

The eyelid is considered to obstruct the visual axis when it is below the superior border of the pupil. The severity of obstruction of the visual axis will, therefore, be influenced by pupil size (Cohen & Weinberg, 2010).

Patients with untreated ptosis may need to hold their head in a chin-up position, elevate their eyebrows or manually lift their eyelids using their hands in an attempt to clear the visual axis [*Figure 5*] (Finsterer, 2003).

Figure 5. A photograph of a ptosis patient holding their head in an elevated position, to clear the visual axis [photograph used with permission from the patient].

2.3 Existing ptosis crutches

The crutches that have been developed thus far are scarcely available as they are produced for patients on a case-by-case basis (Walsh, *et al.*, 2006). Previously described ptosis crutches are permanently mounted to the frame or lens of the spectacle [*Figure 6]*. These devices include a straight or convex crutch bar that elevates the eyelid. The patient feedback on these devices indicated that the bar exerts uncomfortable pressure on the globe and inhibits the blinking mechanism.

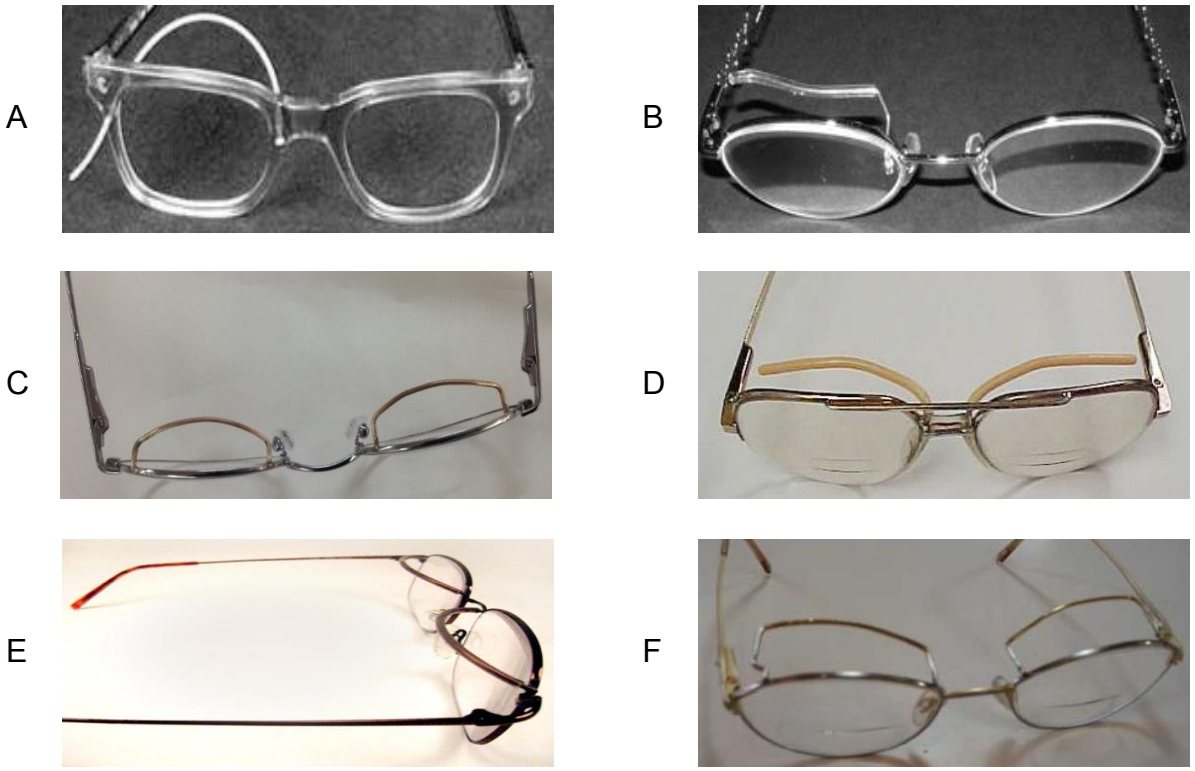


Figure 6. Images of existing ptosis crutch devices. A] Walsh, 2006. B] Kumar, 2008. C] Muller Optical. D] Vision Care. E & F] World Optic.

The lundie loop is an alternative device that was initially developed for blepharospasm patients but the application of the device was later extended to include ptosis patients. The design uses a loop of wire (usually stainless steel) that is the same size as the spectacle lens, thus permitting the user to look through the centre of the loop [*Figure 7 &8*]. The top of the loop is covered with silicone tubing, which holds the upper eyelid in an elevated position (Ramasamy, *et al.*, 2007). Although widely described in the literature as an assistive device, the lundie loop has been reported as an ineffective device for elevating the eyelid (Ahmad *et al*., 2011). An additional setback of the lundie

loop design is its inability to be mounted on different types and shapes of spectacle frames (Walsh, *et al.*, 2006).

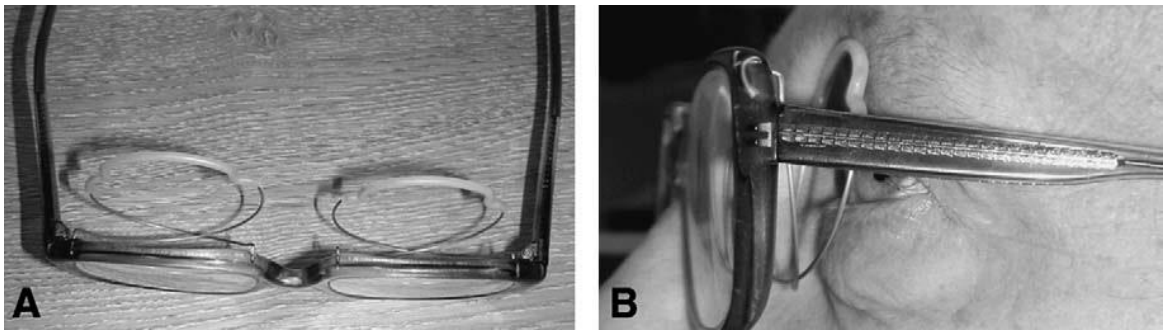


Figure 7. The lundie loop permanently attached to the spectacle frame [taken from Ramasamy, et al., 2007].

Figure 8. The lundie loop elevating the ptotic upper eyelids. [Taken from Ahmad, 2013].

The ptosis crutch is not a new method of elevating the upper eyelid, however, there are only a handful of practitioners that are still manufacturing the devices. The practitioners that manufacture ptosis crutches, do so on an individual request basis. No record of a standard ptosis crutch as a solution to elevating the upper eyelid could be found.

2.4 Other eyelid devices

The eyelid weight is a device that performs the opposite function to the ptosis crutch. It is designed to fit the shape of the globe and close the eyelid [*Figure 9*] (Jobe, 2001). While the function of the device has little relevance to the current study, the shape and size of this device are of interest to the design of the ptosis crutch.

Figure 9. A photograph of platinum eyelid weight with a radius of curvature of 12.7mm [Taken from Silver, 2009].

2.5 Eye measurements

The size, shape and position of the eye were important aspects to consider in the design of the ptosis crutch. Several eye measurements have been documented to quantify the position of the upper eyelid as well as the shape and size of the eye globe, contour and fissure. *Figure 10* provides an illustration of the dimensions of a normal eye, in ambient lighting conditions.

There is no evidence of a consistent method to evaluate and compare pre and post-ptosis treatment (surgical or device) (Koushan et al., 2008). Nevertheless, there are several gross but available methods for assessing upper eyelid position. The most widely used methods to determine the position of the upper eyelid include the marginal reflex distance and the vertical palpebral fissure (McCulley, *et al.*, 2003; Flynn, *et al.*, 2011).

2.5.1 Marginal reflex distance

The marginal reflex distance (MRD) is a measure of the vertical distance from the centre of the pupil to the centre of the upper eyelid margin in primary gaze. Clinically ptosis is recognized by an upper marginal reflex distance of less than 2mm or asymmetry of more than 2mm between the eyes (Ahmad et al., 2011).

2.5.2 Vertical palpebral fissure.

The vertical palpebral fissure (VPF) is the vertical distance between the top of the lower eyelid margin and the bottom of the upper eyelid margin.

Ptosis is described by the extent of which the upper eyelid covers the corneal limbus, or the vertical fissure height or the distance from the centre of the pupil to the upper eyelid (Small, *et al.*, 1989).

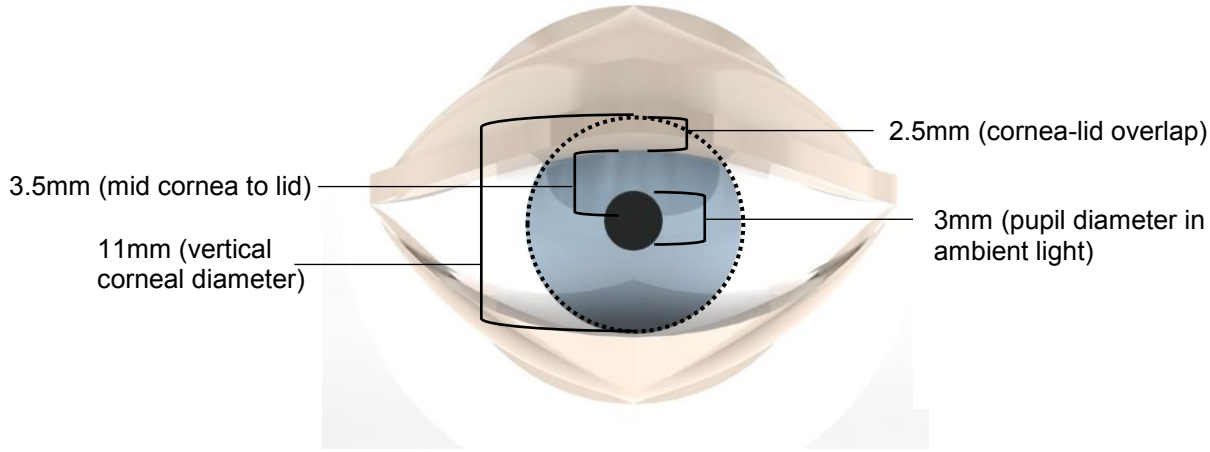


Figure 10. A model of the human eye in ambient lighting conditions. [Values taken from Small, R. 1989].

2.5.3 Horizontal palpebral fissure

The horizontal palpebral fissure (HPF) is the measured distance between the lower margin of the upper eyelid and the upper margin of the lower eyelid (Barretto & Mathog, 1999). Normal HPF values are illustrated in *Table 1.*

Table 1. Horizontal palpebral fissure [values taken from Barretto & Mathog, 1999].

Population	Horizontal palpebral fissure (mm)
Black adult male	32.29
White adult male	29.51
Black adult female	31.46
White adult female	29.40

2.5.4 Fissure obliquity

Fissure obliquity, or palpebral slant, describes the relative position of the medial and lateral canthi (Hanada, *et al.*, 2001). Fissure obliquity is determined by the angle of inclination of an imaginary line connecting the medial and lateral canthi of the same eye (Packiriswamy, *et al.*, 2012). The direction of the slant (upward or downward) influences the shape of the contour (Beden & Beltram, 2012). It has been suggested that ptosis inhibits the ability accurately assess fissure obliquity.

2.5.5 Eyelid contour

The upper eyelid contour is described by the curved shape of the lower margin of the upper eyelid. The eyelid contour is a complex line that has a dimension along the anteroposterior line. The z-axis component arises as a result of the three-dimensional nature of the palpebral fissure as well as the posterior position of the lateral relative to the medial canthi (Malbouisson, *et al.*, 2000). The palpebral fissure shape is dependent on a number of anatomical features including, the contour of the eyelid, the location of the eyeball within the orbit as well as the location of the upper and lower eyelid creases (Hanada, *et al.,* 2001).

2.5.6 Corneal diameter

The horizontal corneal diameter is remarkably consistent between age, sex and racial groups (Van den Bosch, *et al.*, 1999; Augusteyn, *et al*., 2012). Horizontal corneal diameter is reported to be around 11mm on average while the vertical corneal diameter is 12mm (Mashige, 2013). The intersection of the horizontal and vertical cornea measurements is approximated to the centre of the pupil (Small, *et al.,* 1989).

2.5.7 Globe projection

Globe projection is a measure from the deepest portion of the lateral orbital rim to the apex of the cornea (Barretto & Mathog, 1999). It is widely accepted that globe protrusion is determined by the depth of the orbital cavity, the vertical inclination of the orbit as well as the thickness and orientation of its upper rim (Wilkinson & Mautner, 2003).The literature suggests that the Caucasian population have lower values of globe projection when compared to a similar Black population (de Juan, *et al.*, 1980).

No difference in globe protrusion between sexes has been reported by previous studies (Meazzini, *et al.*, 2015). *Table 2* shows normative values for globe protrusion measurements.

Table 2. Globe protrusion measurements from the literature.

Author	Normal value of globe projection (mm)			
	Male		Female	
	Black	Caucasian	Black	Caucasian
Dunsky, 1992	18.20 ± 2.97		17.46 ± 2.64	
Migliori, *et al*., 1984	18.5	16.5	17.8	15.4
de Juan, *et al*., 1980	17.4 ± 2.8	15.3 ± 2.2	17.4 ± 2.8	15.3 ± 2.2
Barretto & Mathog, 1999	18.23 ± 2.26	17.00 ± 2.65	17.27 ± 1.44	15.98 ± 2.22

2.6 Methods of eye measurement

Despite the eyelids being three-dimensional structures, their topographic anatomy has only been described in the frontal plane (Van den Bosch *et al*., 1999; Malbouisson *et al.,* 2000). The two measurement methods that have been described by previous studies include digital and manual measurement.

2.6.1 Digital photograph measurement

The measurement of eyelid position using a millimetre ruler has been described as the gold standard for the assessment of ptosis (Khandwala, *et al.*, 2011). However, this method of measurement has been challenged by (Coombes, *et al*., 2007), who found a greater level of reproducibility of digital measurement compared to the manual handheld ruler measurement of the eyelid position.

Computerized image processing has been described as a precise non-invasive procedure for determining a variety of eye measurements (Cruz et al., 1998). There is, however, no specified method of digital image analysis, in that a variety of different programs have been used in previous studies.

2.6.2 Manual measurement

Traditionally the anthropometry of the eye has been measured using manual measurement. There are two common methods of manual measurement. The first involves manually measuring various eye dimensions using a millimetre ruler. The second method involves taking a photograph of the patient with a known scale in the image. The photograph is scaled accordingly, printed and the dimensions are measured on the photograph using a millimetre ruler.

2.7 Materials and methods of manufacturing

This study includes the use of Acrylonitrile Butadiene Styrene (ABS) as the three-dimensional (3D) printed material as well as a stainless-steel wire coated in polyvinyl chloride tubing. A brief description of these materials is discussed below.

2.7.1 3D printing as a prototyping method

3D printing is fast becoming a popular term within health care. It provides a sophisticated prototyping method that is capable of customization, increases that accessibility of devices and is cost effective when compared to other prototyping methods (Ventola, 2014).

Rapid prototyping is advantageous in the design process of user-centred devices as it is ultimately the interaction with the user that confirms or rejects the design. 3D printing is the gold standard of rapid prototyping as it seamlessly integrates the CAD software with the printer software to create a 3D model of the design (Berman, 2012).

2.7.2 Polyvinyl chloride

Polyvinyl chloride (PVC) is an inexpensive plastic material that has a wide array of domestic and industrial applications. Within the health sector, PVC is the material used for manufacturing. PVC tubing has a greater flexibility when compared to silicone and polyethylene tubing. Additionally, there are no reports of PVC causing skin irritation. The PVC tubing used in the current study is provided by *Figure 11*.

Figure 11. An image of the polyvinyl chloride tubing, from an Alaris© Products extension set. The tubing was used to coat the galvanized wire crutch bar.

2.7.3 Acrylonitrile butadiene styrene

Acrylonitrile butadiene styrene (ABS) is a low-cost plastic that has good strength and stiffness properties (Plastics International, 2016). ABS has good aesthetic qualities that are further improved by applying acetone vapour based smoothing to the printed product.

2.8 Summary

Ptosis associated with myasthenia gravis is a debilitating condition that may result in obstruction to the visual field of the patient. Surgical correction of ptosis is often contraindicated in MG patients with severe weakness of the muscles involved in eye closure and in patients with active disease. In these cases, a non-surgical solution to elevating the ptotic eyelid above the visual axis is required. A ptosis crutch, which is attached to the patient's spectacle frame offers such a solution. The ptosis crutch is not a novel device, however, there is no evidence of a modular and adjustable ptosis crutch. Furthermore, there is no evidence of a ptosis crutch that specifically considers the MG population.

A modular and adjustable ptosis crutch, using cost-effective materials and manufacturing methods could provide a valuable assistive device to the MG population.

3. Methodology

The present study investigated the design of a modular ptosis crutch as a low-cost solution for elevating the upper eyelids of MG patients. The intended function of the device is to elevate the upper eyelid above the visual axis [*Figure 12*].

The novelty of this project includes designing a ptosis crutch for young children, adolescents and adults that will be comfortable to use on a long-term basis. The design considered both individuals who do and do not wear spectacles as well as accommodating for both unilateral and bilateral conditions.

This chapter is subdivided into three sections namely, I] clinical methodology, II] design methodology and III] the iterative design process. An overview of the methodology is provided by the methodology flowchart in *Figure 13.*

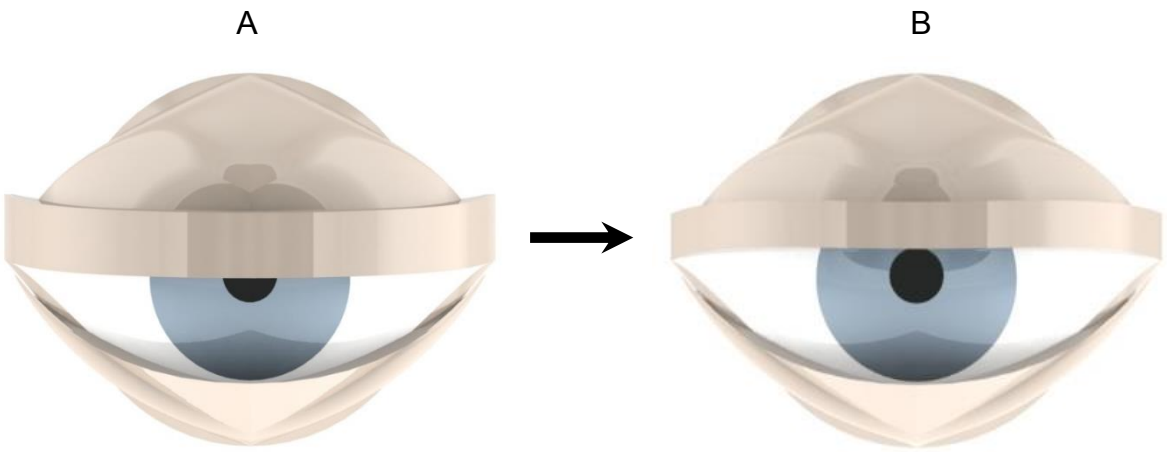


Figure 12. A model illustrating the desired outcome of the ptosis crutch. The ptosis crutch was intended to elevate the eyelid from the position illustrated by image A to the position illustrated by image B. Image B does not represent a normal eyelid position, but rather an eyelid elevated to a position that clears the visual axis.

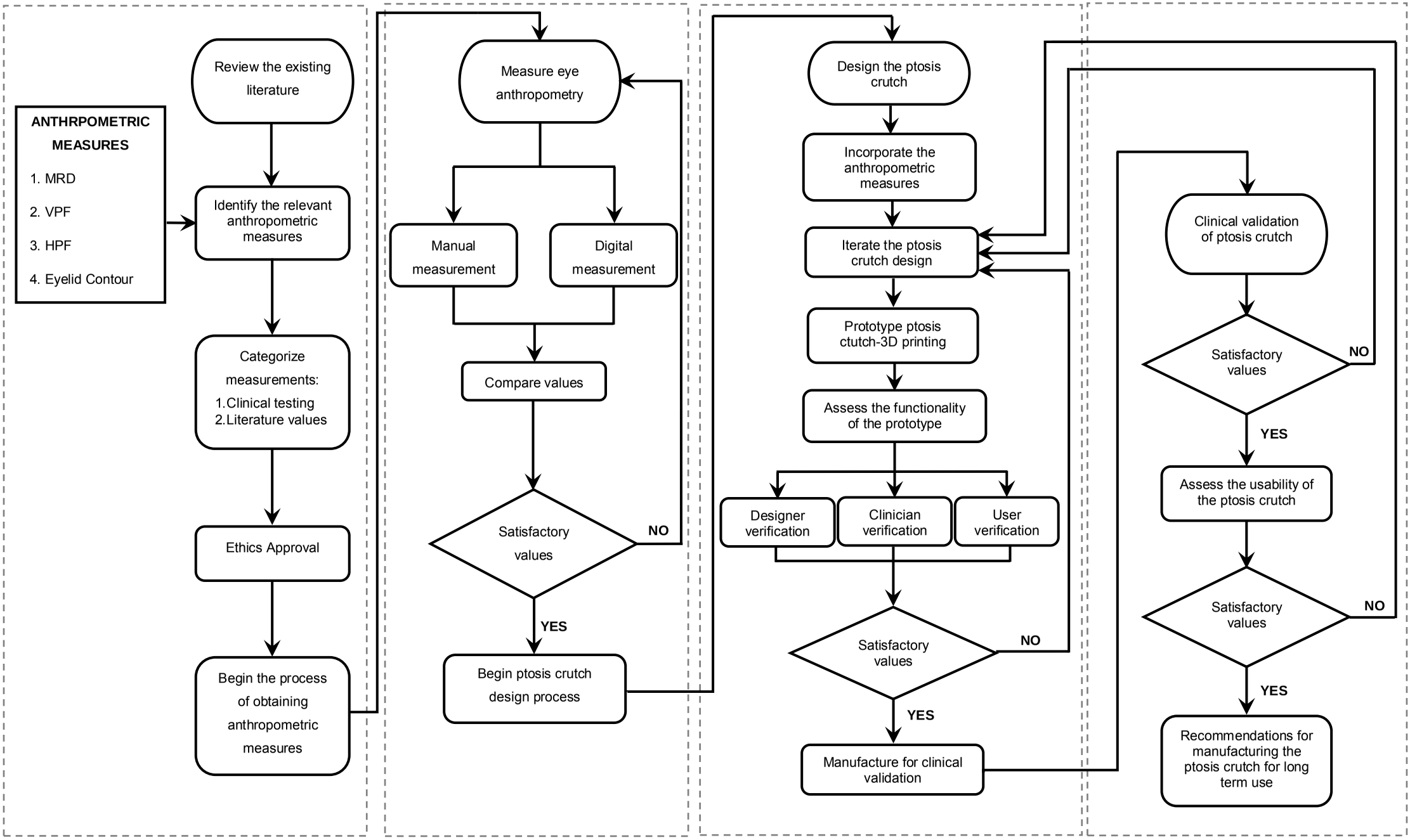


Figure 13. Methodology flowchart

Section I: Clinical methodology

The purpose of the clinical testing was twofold; pre-design testing sought to gain information of the amount of eyelid elevation required as well as qualitative information on the effect that ptosis has on their lives. The post design testing sought to verify the ptosis crutch functionality. This section will outline the clinical methodology that was followed in both the pre and post- design procedures.

3.1 Variables of interest

3.1.1 Independent variables

1. The marginal Reflex distance.
2. The vertical palpebral fissure.
3. The horizontal palpebral fissure.

3.1.2 Dependent variables

1. The upper eyelid elevation required to clear the visual axis.
2. The horizontal length of the ptosis crutch.
3. The obliquity of the ptosis crutch.

3.1.3 Assumptions

1. The shape of the globe is consistent across all individuals.
2. Inter-individual variability of globe projection beyond the lateral canthi exists.
3. There is no inter-individual variability of the dimensions of a healthy cornea.
4. The pupil diameter varies according to different lighting conditions as well as automatic nervous system activity.

3.1.4 Controlled criteria

1. The gaze of the participants was in primary position.
2. The spectacle frame used for testing.
3. The camera type as well as the setup and position.
4. The lighting conditions of the room where the crutch was tested.

3.2 Research hypotheses

The null hypothesis (H_0) states that a modular and adjustable ptosis crutch will elevate the upper eyelid above the current position.

The alternative hypothesis (H_A) states that a modular and adjustable ptosis crutch will not elevate the eyelid above the current position.

3.3 Experimental procedure

3.3.1 Participant recruitment

The participant population differed between the pre-design and post-design testing. Three patients from the pre-design sample group were unable to participate in the post-design testing due to unforeseen circumstances. Three additional patients were recruited for the post-design testing. The specific details of each sample group are displayed in *Table 3*. All of the participants included in the current study met the inclusion criteria for the study. Prior to testing the participants gave informed consent, in the case of minor's consent was provided by the guardian [HREC REF: 240/2015]. Both male and female participants were included in this study as ptosis, associated with MG, is not isolated to a specific sex.

Table 3. Participant information for the pre-design and post-design clinical testing.

Pre-design Testing	**Participant Information**
Number of participants	Total: 16 Male: 6 Female: 10
Age	42 ± 23 years
Post-design Testing	
Number of participants	12 Male: 3 Female: 9
Age	43 ± 24 years

3.3.2 Experimental setup

The clinical testing involved capturing photographs of the participant's eyes in primary position. The participants were photographed using three Canon EOS 1000D cameras with a 18-55mm variable lens. The cameras were secured onto a frame. Each camera was connected to a Canon ACK-E5 AC adapter kit, to ensuring that the cameras were continuously online. The camera lenses were clamped in position to ensure that the focus and focal length were fixed. A trigger switch, mounted to the camera frame ensured that all three cameras were fired simultaneously. The images had a resolution of 3888 x 2592 pixels. The cameras were set to a high shutter speed (1/60) and an aperture of f/5.6.

3.3.3 Experimentation

Clinical testing was carried on two separate occasions, namely pre-design testing as well as post-testing of the ptosis crutch. The specific procedures carried out during each testing session are outlined below.

Photographs were captured of the participants seated in a marked frame. The purpose of using the measurement frame was to provide a fixed frame of reference to standardize the measurements.

3.3.3.1 Pre-design clinical testing

The initial testing session involved measurement of the natural eyelid position in primary gaze, to determine the amount of eyelid elevation that was required. The position of the eyelid was measured using the measures of VPF as well as the MRD. The additional eye measurements that were recorded and the reason for noting these measurements is described in *Table 4*. Three photographs of each participant were taken, the best quality photograph was used for analysis, and the remaining photographs were discarded. The participants were required to fixate their gaze on the lens of the centre camera, thus standardizing the direction of gaze to primary gaze. The position of eye gaze was standardized to primary position to reduce the direction of gaze altering the position of the upper eyelid (Coombes et al., 2007).

Each participant was issued with a qualitative questionnaire to determine the impact that ptosis has on their visual field, activities of daily living and quality of life [*Appendix 1.2*]. The questionnaire focused on activities and symptoms that might be adversely

affected by ptosis. The design of the questionnaire was based on the National Eye Institute Visual Function Questionnaire (NEI-VFQ-25) (Mangione, *et al.,* 2001*)* and the 10-item Neuro-Ophthalmic Supplement to the NEI-VFQ-25 surveys. An item was not required to be answered if the patients did not perform the activity.

Table 4. The anthropometric measures that were recorded for each participant.

Measurement	Description of measurement	Reason for observation
Vertical palpebral fissure	The distance from the bottom of the upper eyelid margin to the top of the bottom eyelid margin	Upper eyelid position
Marginal reflex distance	The vertical measurement between the centre of the pupil and the upper eyelid margin	Upper eyelid position
Horizontal palpebral fissure	The distance from the lateral to the medial border of the eye aperture	Length of the crutch.
Vertical corneal diameter	A vertical line measuring the limbus to limbus distance	The centre of the cornea is approximated to the centre of the pupil. The measurement informed the elevation required to clear the visual axis

3.3.3.4 Post-design clinical testing

The post design testing involved the functional assessment of the ptosis crutch. The clinical testing of the ptosis crutch involved digital photograph analysis of the participant's ptotic eye under two conditions, specifically with no crutch and when wearing the ptosis crutch. The ptosis crutch was fitted to a standard spectacle frame that was used during all of the testing sessions. The reason for using a standard frame was to reduce any confounding influence that the spectacle frame may have on measurements. The experimental setup and procedures for capturing the photographs were consistent with that carried out in the pre-design testing.

Following the photographic assessment, each participant was required to complete a questionnaire [*Appendix 1.3*]. The questionnaire was intended to gain qualitative

feedback on the functionality and user experience of the ptosis crutch. The questions related to the visual ability of the patient while wearing the crutch as well as the ease of use and aesthetic appearance of the crutch.

Following the clinical testing, each participant was issued with a crutch/ pair of crutches that was fitted to their spectacle frame. In the circumstance that the participant did not wear spectacles, the participant was given a pair of spectacles with a clear lens, to which the crutch was fitted. Following a minimum of a one-month period, the participants were contacted to find learn whether they were using the crutch. The reasons for disuse were noted. Patients that were using the crutch were required to answer questions relating to the user experience of the crutch.

3.4 Photograph analysis

3.4.1 Digital analysis

Digital image analysis was used to measure the position of the eyelid(s) with and without the aid of the ptosis crutch. All photographs and clinical measurements were taken by the author.

The digital photographs were imported into Adobe Photoshop 2015 for processing. Adobe Photoshop has been reported as an effective tool for measuring various dimensions of the eye (Choi & Eo, 2014). The participant photographs were scaled according to the pixel/millimetre ratio [*Equation 1*]. The pixel/ millimetre ratio was established by measuring the number of pixels per white sphere on the calibration frame (5.5mm). After the photographs had been correctly scaled, the eye measurements were determined using the software's millimetre ruler tool [*Figure 14*]. All measurements were recorded to the nearest 0.1mm. MRD, the vertical and horizontal palpebral fissures and the corneal diameter measurements, were recorded for both eyes of each of the participants. The cameras were recalibrated before each testing session to ensure accurate measurements were recorded.

$$px\ mm = px(5.5mm)$$

Equation 1. Determining the pixels per millimetre ratio, of the patient photographs, where px= pixels.

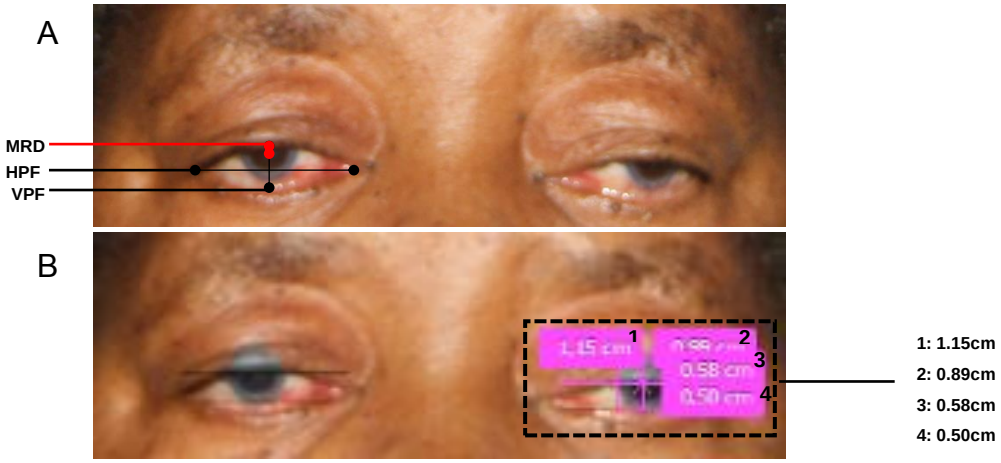


Figure 14. A photograph of the digital measurements. A] Illustrates the MRD, VPF and HPF measurements. B] The measurements generated using the Photoshop ruler tool.

3.4.2. Manual analysis

Scaled images (1:1) of the same patient photographs that were used for digital analysis were printed for manual measurement. White spheres, on the calibration frame, with a 5.5mm diameter were used as the reference measurement for scaling the images.

The scaling of the images was cross-checked with a 14mm ellipse that was placed on the participant's forehead [*Figure 15].* The photographs of each participant were printed using an HP DeskJet Ink Advantage 3525 printer. The vertical and horizontal palpebral fissure, fissure obliquity and the distance between the medial and lateral canthi were measured using a standard ruler. The manual measurements were performed by the same individual. The measurements were recorded to the nearest 0.1mm.

Figure 15. A photograph of the manual measurements performed using a millimetre ruler.

The reason for performing both manual and digital measurement was to determine whether any difference existed between these methods of measurement. It has previously been suggested that digital measurements exhibit greater inter-observer variability when compared to measurements obtained by a handheld ruler (Coombes

et al., 2007). Should no difference of the values obtained in the manual and digital measurement in this study, only the digital analysis will be used in the post- design clinical testing.

3.5 Determining the amount of eyelid elevation required

The MRD was used to determine the amount of eyelid elevation that would be required to clear the visual axis. Both the MRD and the VPF measurements are reported as measurements indicating the position of the upper eyelid (Flynn et al., 2011). Although both measurements were recorded in this study, the MRD measurement was used for determining the amount of eyelid elevation that was required. It was decided the MRD would be a more appropriate measure was as it acknowledges the position of the eyelid in relation to the visual axis, while the vertical palpebral fissure provides a measurement of the fissure aperture.

The visual axis was defined as the border of the pupil. It is appropriate at this point to acknowledge that the pupil diameter is variable in nature and adjusts according to the amount of available light as well as automatic nervous system activity. The pupil diameter is well researched and has been reported as having a range between 2 – 8 mm (Walker, *et al.*, 1990; Watson & Yellott, 2012). Previous studies indicate the diameter of the pupil in ambient light to be 3 – 4mm (Small *et al.,* 1989).The functional requirement of the ptosis crutch is to elevate the ptotic eyelid above the superior pupillary border, thus clearing the visual axis.

The ptosis crutch was designed to elevate the eyelid, above the superior border of the pupil, in ambient lighting conditions, however, the adjustable component along the z-axis allowed the eyelid to be elevated, to clear the visual field, in all lighting conditions. The amount of eyelid elevation required to clear the visual axis in ambient light was calculated using *Equation 2*. In the current study, the superior visual axis is synonymous with the superior pupil border. The eyelid must be positioned above the superior border of the pupil.

$$x = \left(\frac{c}{2} + 1.5\right) - e$$

Equation 2. Determining the vertical elevation of the eyelid in ambient lighting conditions. Where x refers to the amount of elevation required to clear the visual axis; c refers to the vertical corneal diameter; e refers to the current position of the eyelid measured from the centre of the limbus border.

3.5.1 Assumptions

The following assumptions were made when determining the amount of elevation required to clear the visual axis.

1. The centre of the limbus can be approximated to the centre of the pupil (Small *et al*., 1989).
2. The centre of the pupil is located at the height of ½ the vertical diameter of the cornea.
3. The pupil diameter ranges between 2 – 8mm (Watson & Yellott, 2012).
4. The diameter of the pupil in ambient light is 3mm (Small, *et al.,* 1989).

3.6 The usability of the ptosis crutch

The ISO 13407: 1999 Human-centred design processes for interactive systems defines usability as, 'the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of user'. In the context of this study effectiveness, efficiency and satisfaction were defined with the following criteria 1] Effectiveness referred to the efficacy of the ptosis crutch to satisfy the design requirements. 2] Efficiency focussed on the minimum and effective use of resources, i.e. a low-cost device. 3] Satisfaction referred to the user's perceived satisfaction of the ptosis crutch.

The usability of the ptosis crutch was assessed after 8 participants had used the device for a minimum of one month. The reason for omitting 3 participants from the usability testing was due to the participants not having used the device for a sufficient period of time before. The purpose of the usability questionnaire was to determine the initial user compliance as well as the usability of the device. The simplest method of determining the user compliance of the device is to ask the user the question, "Are you using the device?" In the circumstance that the participant was not using the device, the reasons for non-use were explored.

3.7 Statistical Analysis

3.7.1 Pre-design clinical testing

A two-tailed t-test ($p<0.05$) was performed on the manual and digital measurements to determine whether there was a difference in the values obtained. Descriptive

statistics were used to describe the recorded eye measurements. The results from the questionnaire were tabulated and analysed using nonparametric sign-ranked tests.

3.7.2 Post-design clinical testing

The data collected in the post-design clinical testing were analysed in STATISTICA, where a one-way factor analysis of variance (ANOVA) test ($p<0.05$) was conducted to identify significant differences in eyelid elevation for the two conditions. The results from the questionnaire were tabulated and analysed using descriptive statistics and using nonparametric sign-ranked tests.

3.8 Ethical Considerations

3.8.1 Informed consent

Prior to testing, the participants were informed about the background and aims of the study, as well as the procedures that were involved during the testing session. This information was provided in writing as well as verbally upon arrival at the testing session. The participants signed a consent form agreeing to voluntarily participating in the study as well as acknowledging the risks and benefits to the participants during the testing procedure [*Appendix 1.1*]. Prior to the initiation of the study ethics approval (HREC REF: 240/2015) was granted by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee [*Appendix 4*].

3.8.2 Privacy and anonymity of results

All of the participants were identified using a code, rather than by their names, in order to ensure that all of the data remained confidential. The participant's data was stored until statistical analysis was complete.

Section II: Design Methodology

3.9 Design Specifications

The requirements for each of the functional components of the ptosis crutch were specified to ensure that the final product met the user's needs. The design specifications were informed by the patient's needs, clinician's advice and the design considerations of material selection, ergonomic considerations and failure analysis. The balance between the clinician, designer and user requirements was of utmost

importance in ensuring a successful product. A detailed list of the design specifications can be found in *Appendix 2*. The order of importance of each of the requirements was determined through a literature search, patient input as well as analysis of existing ptosis crutch devices. From the critical analysis of the requirements, it was established that the elevation of the eyelid above the visual axis was the most important consideration. Adjustability along the x and y-axes, modularity, comfort and aesthetic appearance were other important considerations.

The ptosis crutch was broken down into modular components. Each of the components carried out a specific function, which together would ensure optimal functionality of the ptosis crutch. The components were divided according to the following functions; elevate eyelid (movement along the z-axis), adjust for globe projection (movement along the y-axis), adjust the horizontal position of the eye (movement along the x-axis) and allow for blinking to occur [*Figure 16*]. In addition to these requirements the ptosis crutch needed to satisfy the usability requirements of effectiveness, efficiency and user satisfaction [*see section 3*].

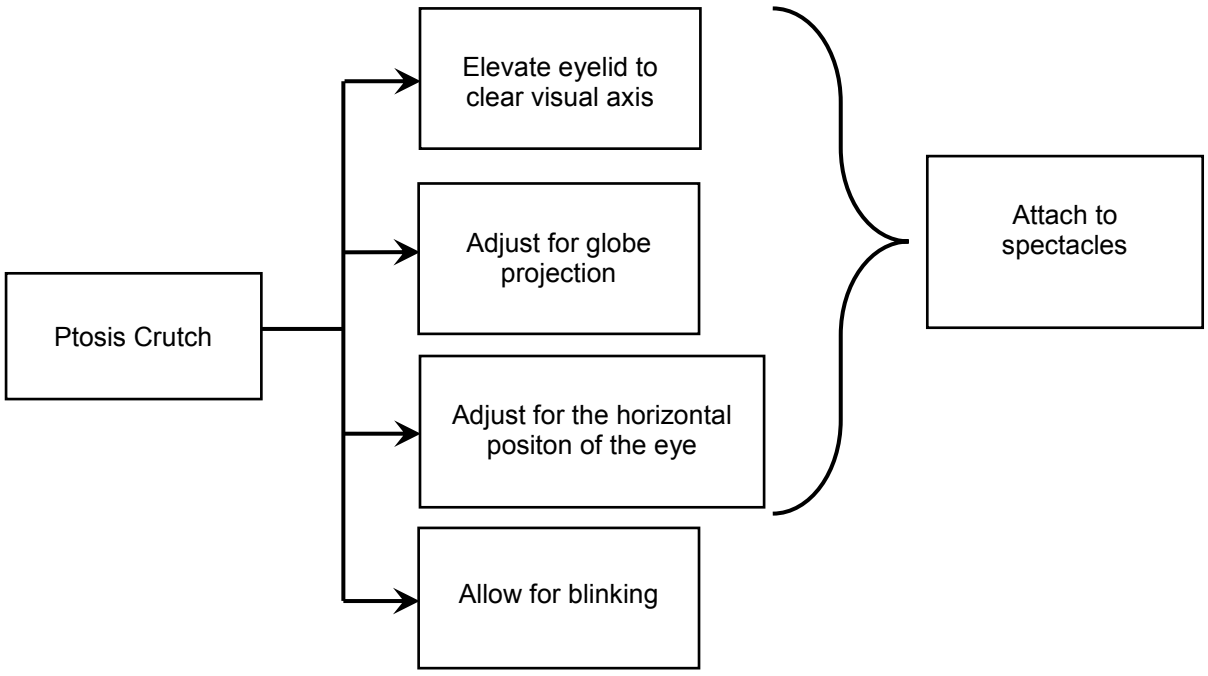


Figure 16. A schematic representation of the design functions of the ptosis crutch components.

The data from the pre-design clinical testing as well as the clinician and designer requirements were the primary input for the design specifications outlined below:

Function

1. The primary function of the ptosis crutch is to elevate the upper eyelid to clear the visual axis.
2. The device must be capable of accommodating for different degrees of ptosis. Thus, the device must be adjustable along the z-axis.
3. The device must accommodate for the inter-individual variability of globe projection. Thus, the ptosis crutch must be adjustable along the y-axis.
4. The device must cater for differences in the horizontal position of the eye.
5. The device should allow for some blinking effort to occur.

Ergonomics

1. There should be god skin-crutch coupling.
2. The device should be comfortable.
3. The ptosis crutch must be easily attached to the spectacles by the user.
4. The device should be easily and intuitively adjusted by the user.
5. The device should be efficient in that it should not be resource intensive.

Safety

1. The device should not subject the user to any danger.
2. The device should not provide the opportunity for misuse.
3. The device should be consistent with the user's intuition on how the device should function.

3.11 Ptosis crutch design

The ptosis crutch design process was informed by the patient, clinicians and designer. The initial measurements recorded in the pre-design clinical testing as well as the HPF, crutch depth and fissure obliquity values, obtained from previous studies, informed the size and elevation specifications of the crutch. The measurements are displayed in *Table 5*. It is important to note that ptosis associated with MG varies throughout the course of the disease. The inclusion of an adjustable component along the z-axis was thus essential as the user needs to adjust the height of the eyelid

according to the severity of ptosis. *Figure 17* illustrates a step-by-step walk through of the ptosis crutch design.

Table 5. The measurements that were used to inform the ptosis crutch design specifications.

Measurement	Value	Source
Marginal Reflex Distance	-1.4mm	Clinical testing
Vertical palpebral fissure	4.2mm	Clinical testing
Measured horizontal palpebral fissure	22.83	Clinical testing
Desired horizontal palpebral fissure	30mm	Barretto & Mathog, 1999
Fissure obliquity	± 2º	Van den Bosch,W.A. 1999
Depth of the curve	8.5mm	Young, A. 2012

The ptosis crutch followed an iterative design process. SolidWorks 2015 was used to create the computer assisted design (CAD) models of the modular crutch components. Eighty-seven design iterations resulted in a final design that satisfied the specified device requirements. It was ultimately the iterative design process that lead to the discovery of a device that satisfied the requirements. The crutch design evolved with a clear selection mechanism whereby the crutch needed to satisfy all of the specified criteria before it was considered to be successful. In the circumstance that the crutch failed to meet the requirements, the reason for failure was noted and the necessary iterations were made. Every failure of the design resulted in an improved iteration to the successive ptosis crutch.

The specifications of the final ptosis crutch components are described in the subsections below. The engineering drawings for the component can be found in *Appendix 3*.

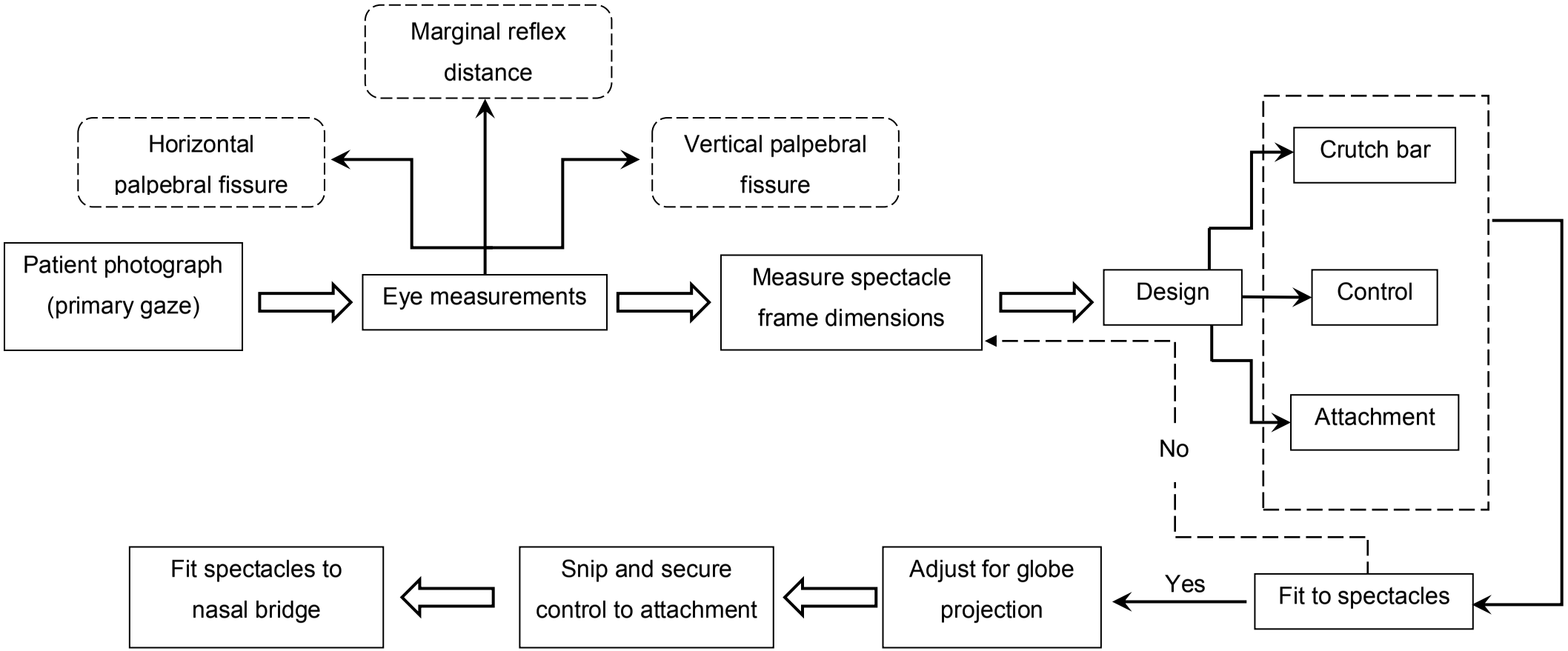


Figure 17. The design process of the ptosis crutch.

3.11.1 The crutch bar

The crutch bar is the component responsible for elevating the eyelid to clear the visual axis. The crutch bar mechanically elevates the upper eyelid when the user manually pulls the control in a vertical direction [*Figure 18]*. While the amount of required eyelid elevation was determined during the clinical testing, the shape of the crutch was determined using a combination of the anthropometric measures and dimensions of existing devices [*see section 2.3.2*]. The method for calculating the shape of the crutch is outlined in the subsections below.

Figure 18. The ptosis crutch bar. The concave bar is moulded to the shape of the eye globe. The congruency between the upper eyelid and the crutch bar, allowed the crutch bar to make full contact with the eyelid. The vertical lever allows for the amount of elevation.

3.11.1.1 The length of the crutch bar

The length of the crutch bar was determined by the measurement of the desired fissure width [*see section 2.4.3*]. The optimal HPF, of 30mm, was used to inform the design as the ptosis crutch intended to increase the width of the palpebral fissure by elevating the eyelid (Krishnakumar, 2013). The crutch bar makes full contact with 2/3 of the eyelid and tapers off on the outer edges of the fissure [*Figure 19]*. The length of the crutch determined the depth of the crutch bar.

3.11.1.2 The depth of the crutch bar

The ptosis crutch bar is designed to mirror the shape of the eye globe. The depth of the concave curve was determined according to the shape of an existing assistive device, namely an eyelid weight [*see section 2.3.2*]. The eyelid weight is a device that

serves the opposite purpose to the ptosis crutch. It is placed on the upper eyelid and forces the eyelid to close. The design of the eyelid weight encompasses a 12.7mm radius of curvature that conforms to the curvature of the eye globe (Blackmore & Jobe, 1996; Young & Blackmore, 2012). The concave curve of the ptosis crutch was designed to have a 12.7mm radius of curvature, the length of the curve was 24mm, determined by the horizontal measurement of the eye globe [*see section 2.4.8*]. The height of the curve was calculated as 4.87mm, using *Equation 3*.

$$h = r - \sqrt{r^2 - l^2}$$

Equation 3. The calculation that was used to determine the height of the curved crutch bar., where h= the sagitta; r= the radius; l= ½ the width (w). The height of the curve was calculated as 4.87mm, where r- 12.7 and l=24mm.

The reason for using a 24mm length was twofold. Firstly, it would cater for the palpebral fissure of all individuals (i.e. it would not extend beyond the canthi). Secondly, it was chosen to be longer than the length of the eyelid weight in order to distribute the force of the ptosis crutch over the globe. Excessive pressure on the globe may limit the blinking ability and/or cause double vision. The concave crutch bar was fitted to a CAD model of an emmetropic eye in SolidWorks [*Figure 19*], to assess the congruency of the crutch and globe curvatures.

A B

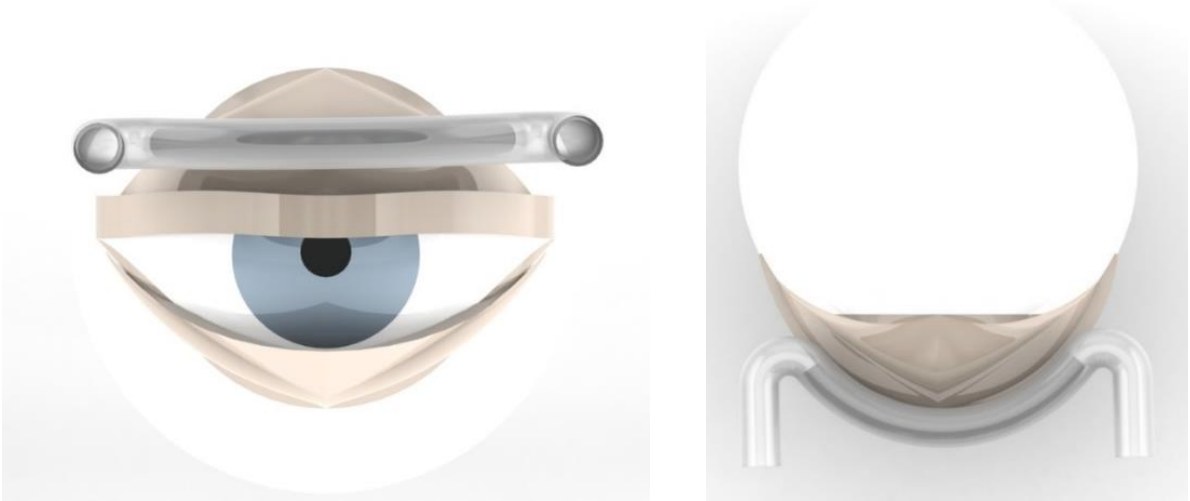


Figure 19. A model of the ptosis crutch bar fitted to the contour of the globe. A] Front view, B] Top view.

3.11.2.3 The slant of the crutch bar

The direction and degree of the palpebral slant differ between individuals (Odunze, *et al.*, 2008). The ptosis was designed for a palpebral slant of ± 1.5mm. The directions and magnitude of the crutch slant are illustrated in *Figure 20.*

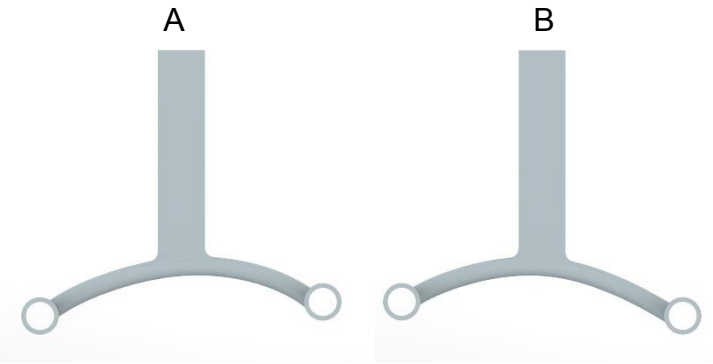


Figure 20. A model of the crutch bar illustrating the different bars used for upward and downward palpebral slants. A] The crutch bar for a downward slanting fissure (right eye). B] The crutch bar for an upward slanting fissure (right eye).

3.11.1.4 Additional considerations

An important consideration was to ensure that the crutch did not exert excessive pressure on the globe while elevating the eyelid. This was achieved by having maximum contact between the eyelid and the crutch, thus distributing the force over a greater area. The device described herein used a concave crutch bar that mirrored the shape of the globe [*Figure 19*].

The eyelid contour is a complex line that includes a y-axis component [*see section 2.4.5 for details*]. *Figure 21* illustrates the 1mm offset of the ptosis crutch along the y-axis, to ensure that the crutch bar made full contact with the eyelid surface.

Figure 21. A model of the ptosis crutch bar indicating the 1mm between the medial and lateral canthi.

3.11.2 Attachment to spectacle frame

The attachment component, as the name suggests, is the component responsible for attaching the device to the spectacle frame [*Figure 22*]. This component enabled the user to independently attach and detach the device to their spectacle frame. The distance between the eyes differs between individuals. The crutch would, therefore, need to be adjustable along the x-axis to allow the device to accommodate for the inter-individual variability of horizontal eye position. The device adjusts for the horizontal position of the eye by clipping the crutch onto the superior spectacle border at a position where the medial and lateral canthi are aligned with the outer edges of the crutch bar.

The ptosis crutch attachment is 18mm in length.The height and width of the component vary according to the size of the spectacles frame. The attachment is secured to the spectacle border through the use of a clip mechanism. The angle of deformation is 67 degrees. This allows for sufficient flexibility in the clip while maintaining enough rigidity to hold the attachment in a secure position on the spectacle frame. The attachment is the only component of the device that is customized according to patient specific dimensions. The CAD model can be modified in SolidWorks to adjust the height and depth of the spectacle frame.

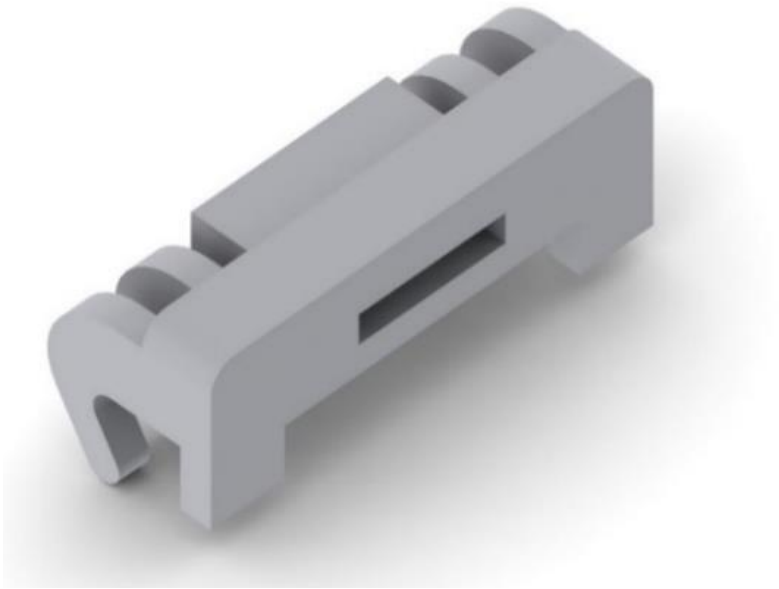


Figure 22. The attachment component that connects the ptosis crutch to the superior border of the spectacle frame. The attachment is a standard length; the height and width of the clip are adjusted according to the dimensions of the spectacle frame.

3.11.3 Globe projection component

The two primary functions of this component were 1] to act as a connection between the crutch bar and the attachment component and 2] to allow the device to be adjusted along the y-axis, thus accommodating for the inter-individual variability of globe projection. The user is able to adjust the position of the crutch bar along the y-axis to the position where the crutch bar makes full contact with the eyelid. The control, displayed in *Figure 23*, fits into a rectangular slot (1.25mm x 5.5mm) in the centre of the attachment component [*Appendix 3].*

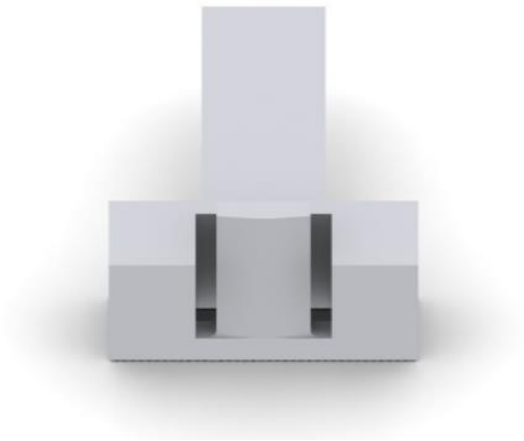


Figure 23. The globe projection control. The component is responsible for connecting the crutch bar to the attachment component.

3.12 Prototyping

The ptosis crutch was prototyped using a combination of 3D printing and manual manufacturing. The ptosis crutch was prototyped and tested from the first generation. It was the rapid production and interaction with the world that lead to the development of the final product. The components of the crutch were 3D printed using several different materials before failure testing of each material was performed. The failure testing involved testing the durability of the device when being attached/ detached to the spectacles as well as when operating the adjustable components. The materials that were tested are listed with their corresponding outcome in *Table 6*.

3.13 Failure Modes and Effect Analysis

Following the clinical validation of the ptosis crutch, a Failure Modes and Effect Analysis (FMEA) was performed. FMEA is a tool that uses a bottom-up approach to

analyse a system or device. A design FMEA was performed to determine any possible failures of the device that may occur in the prototyping process as well as during the use of the ptosis crutch.

Table 6. Thermoplastics that were tested for 3D printing the modular components of the ptosis crutch

Material	Outcome
ABS	Attachment – successful Crutch bar housing - successful Control – successful
Ultrat	Attachment - failed, did not provide sufficient flexibility for the clip mechanism Crutch bar housing - successful Control – successful
Polyethylene glycol (PEG)	Attachment – failed, the clip was brittle and broke when attached to the spectacles. Crutch bar housing - successful Control – successful
Glass	Attachment – failed, the clip was brittle and broke when attached to the spectacles. Crutch bar housing – successful, however, smoothing the surface was difficult. Control – successful, successful, however, smoothing the surface was difficult.

SECTION III: Iterative design process

The design of the ptosis crutch followed an iterative process. 87 design iterations lead to a ptosis crutch that satisfied the specific requirements of the device. The crutch design evolved with a clear selection mechanism. The crutch needed to satisfy all of the specified criteria. In the circumstance that the crutch failed to meet the requirements, the reason for failure was noted and the necessary iterations were made. Every failure of the design resulted in an improved iteration to the successive ptosis crutch.

The major iterations of each component are outlined below. For a comprehensive breakdown of the design process and a full list of the iterations involved, refer to *Appendix 2*.

3.14 Crutch bar iterations

The crutch bar underwent a number of iterations during the course of the study. Following the determination of the shape of the crutch bar, the method of elevating the eyelid was determined.

Concept 1: The crutch bar was attached to the housing on the spectacle temple. The bar was prototyped using ABS.

Reason for failure: The feedback from the patients indicated that the crutch bar was exerting pressure on the medial portion of the eyelid and that they were having trouble blinking *[Figure 24*].

Figure 24. A myasthenia gravis patient wearing an early design of the ptosis crutch, on the left eye. Although the ptosis crutch elevated the eyelid it disrupted the blinking mechanism. The crutch failed to adjust along the z axis.

Concept 2: To overcome these design flaws, the design was iterated to include two units joined by a spring. The idea was that the curved bars would be attached together via a spring [*Figure 25*]. The bars would pull the eyelid upwards, thus elevating it above the visual axis. When the user initiated a blinking force the lower bar would 'give' and move down with the eyelid while the upper bar maintained a fixed position at the level of the eyelid crease. When the blinking contraction ceased, the lower bar would return to the upper bar via the spring mechanism.

Figure 25. A model of the double bar ptosis crutch. The concave crutch bars were connected by a spring mechanism.

Reason for failure: the design was too bulky. A method of using a single bar to allow for blinking to occur was be investigated.

Concept 3: Following the rejection of the double bar design, the single curve was readopted and refined. The bar was further curved along the z-axis to mimic a natural eyelid contour as well as allowing the crutch to make contact with the eyelid at a slightly lower position on the lateral side.

Reason for failure: The bar applied excessive pressure to the globe, thus disrupting the blinking mechanism.

Concept 4: The crutch bar was iterated to include a flexible eyelid contact surface rather that the rigid bar [*Figure 26*]. The flexible bar was a combination of a galvanized wire that was coated in polyvinyl chloride tubing. The galvanized wire was moulded to fit the shape of the globe. The wire maintained the structural integrity of the crutch bar while the PVC ensured that the bar depressed and elevated with the blink of the eye. Additionally, the PVC tubing provided good skin-crutch bar coupling. A full description of how the crutch bar was prototyped can be found in section 4.2.

Reason for failure: The reason for failure was a result of the attachment position (*see section 3.15*)

Figure 26. The crutch bar positioned on the upper eyelid. The concave crutch bar makes full contact with 20mm of the eyelid, at the centre of the horizontal palpebral fissure. The contact between the crutch bar and the eyelid tapers off on the outer edges of the horizontal palpebral fissure length.

Concept 5: The crutch bar generated as concept 4 was used. The iteration involved the attachment point to the spectacle frame.

3.15 Attachment to spectacle frame

Concept 1: The first concept was to design a spectacle temple that incorporated the ptosis crutch. This design involved removing the existing temple from the spectacles and attaching the temple housing the fixed crutch. The initial appeal of this design was the secure attachment of the crutch to the spectacles. The concerns with this concept were that 1] the adjustment along the Y-axis would cause complications and 2] the attachment/detachment of the crutch would be timely.

Concept 2: The shortcomings of the first concept were overcome by simplifying the attachment of the ptosis crutch fitting on to the existing spectacle temple rather than replacing the temple in its entirety. This design allowed the crutch to be adjusted along the x, y and z-axes.

Several iterations were made to the spectacle temple attachment component (see *Appendix 2.4* for details).

Reason for failure: The attachment worked well and adjustment along the x and y-axes functioned as intended. The adjustment along the z axis had been designed via a rotational control [*Figure 27].* The rotational control aimed to adjust the amount of eyelid elevation by moving the crutch bar over the eye globe i.e. following the contour of the globe. The problem with this design was that the crutch was attached to the temple of the glasses, thus when the control was rotated the crutch pivoted on the eyelid and pushed the spectacles off the nose of the user.

Figure 27. A model of a failed crutch bar design that was adjusted along the z-axis using a rotational control.

Concept 3: The rotational control was iterated to include a control that moved the crutch along the y-axis and secured the crutch position according to fixed intervals *[Figure 28]*.

Reason for failure: Although the device was functional, it was not performing optimally as the amount of elevation required could not be categorized into fixed intervals.

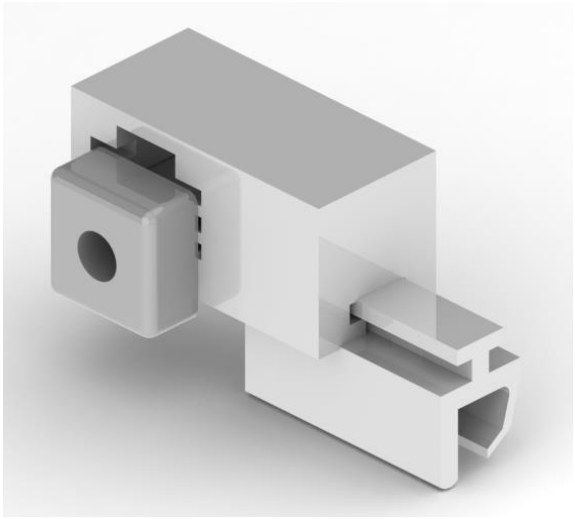


Figure 28. The rejected crutch attachment that adjusted the elevation provided by the crutch. The design was rejected as the amount of elevation required differs between individuals and cannot be categorized into fixed intervals.

Concept 4: The difficulties incurred with attaching the crutch to the spectacle temple suggested that a new approach needed to be adopted. The proposed solution was to change the location of crutch attachment. It was decided that the crutch would be attached to the superior border of the spectacle. The new site of attachment allowed the crutch to pull the eyelid towards the origin when elevating the eyelid, thus making the design biomechanically sound.

3.16 Globe projection component iterations

The ptosis crutch was required to accommodate for the difference in globe projection between users.

Concept 1*:* The initial concept was a slide design that moved the crutch bar along the y-axis [*Figure 29]*.

Reason for failure: The design satisfied the requirement of y-axis adjustment, however, the method of securing the slide component when in the correct position was unclear.

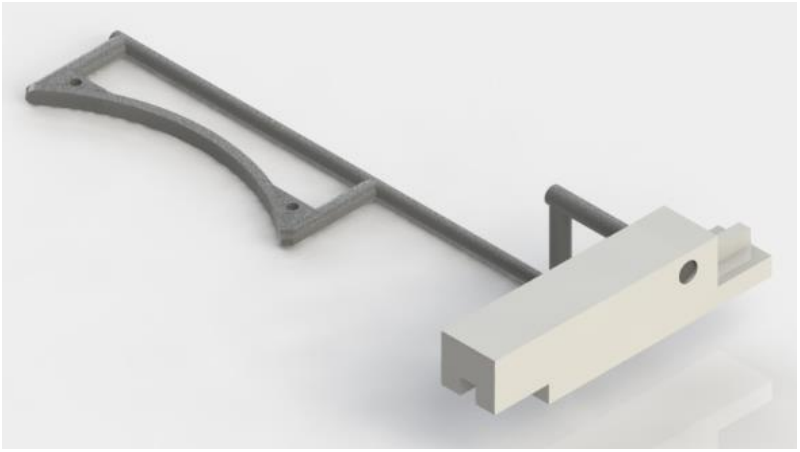


Figure 29. A model of an early design for y axis adjustment. The method of securing the slide adjustment to the spectacles was unclear. The design was iterated and later readopted.

Concept 2: A second method of adjusting along the y-axis was designed whereby the crutch bar was positioned in different slots on the housing component [*Figure 30*].

Reason for failure: The design was rejected as it only allowed the crutch to be adjusted according to the predefined fixed intervals. The inter-individual variability of globe projection could not be accurately categorized into fixed intervals and therefore the crutch would not cater for the entire patient population.

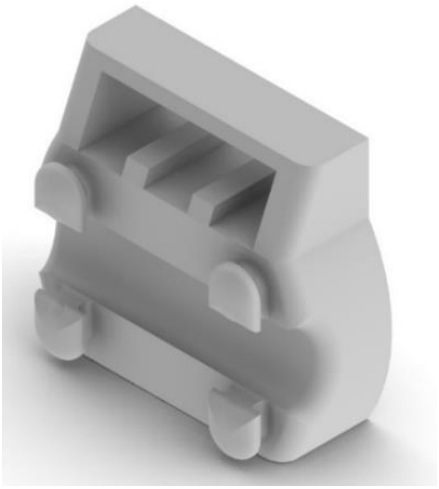


Figure 30. The rejected crutch attachment that adjusted for globe projecion by fixed intervals. The design was rejected as globe projection differs webteen indiciduals and cannot be categorized into fixed intervals.

Concept 3: The slide mechanism was readopted. The relocation of the attachment, to the superior border of the spectacles, allowed the slide mechanism for the adjustment of globe projection to be maintained.

3.17 Additional considerations

The horizontal position, as well as the obliquity of the eye, were additional design requirements that lead to the iteration of the ptosis crutch components. The design iterations associated with each of these device requirements are discussed in detail below.

3.17.1 Horizontal position of the eye

Adjusting the ptosis crutch bar along the x-axis was necessary to allow for the inter-individual difference in the horizontal position of the eye.

Concept 1: The crutch bar was adjusted along the x-axis using a thread mechanism [*Figure 31*].

Reason for failure: The concept worked well in a scaled-up model of the device, however, 3D printing a thread of the required size was not possible using the available resources.

Figure 31. A model of the thread mechanism to adjust the horizontal position of the ptosis crutch along the x axis. The design was rejected as 3D printing a thread of this size was not possible.

Concept 2: The crutch bar was adjusted along the x-axis using a zip tie mechanism. The crutch bar was pushed along the x-axis, until it was correctly positioned above the eye crease. The protruding portion of the crutch bar was snipped off.

Reason for failure: 3D printing a zip tie mechanism with the required precision was not possible using the available resources.

Concept 3: The crutch bar was adjusted along the x-axis using a press fit mechanism. When the crutch bar was correctly positioned above the crease of the user's eyelid, the protruding end of the crutch bar was snipped off.

Reason for failure: The relocation of the ptosis crutch attachment from the spectacle temple to the superior border of the spectacle frame required an alternative method of x-axis adjustment.

Concept 4: The ptosis crutch was adjusted along the x-axis by clipping the attachment component onto the spectacle frame at the position above the user's eyelid crease.

3.17.2 The obliquity of the crutch bar

It has previously been suggested that it is difficult to measure the fissure obliquity of ptosis patients, due to the obstruction to the palpebral aperture (Moorfields Eye Hospital, 2015). The first generation of the crutch curve was tangent to the x and y-axes. As was expected the crutch did not make full contact with the eyelid and when the eyelid was elevated it caused the eyelid to adopt an unnatural contour. The design was iterated to include an offset of 1mm and 2mm along the z and x-axes respectively. The offset was designed to cater for an upward sloping palpebral fissure. During the clinical testing of the ptosis crutch, it was evident that upward sloping crutch bar was not compatible with all of the participants as there were participants that had a downward sloping aperture. This finding was supported by previous studies, which have illustrated that the direction and degree of the palpebral slant differ between individuals (Odunze, *et al.*, 2008). The crutch was further iterated to include an upward and downward inclination of the crutch bar.

4. Design Outcome

This chapter presents the results of the final ptosis crutch design. The results were analysed and interpreted. A discussion of the results is presented in Chapter 5. This chapter is divided into subsections according to the design and the clinical methodologies. Subsection 4.1 illustrates the ptosis crutch design outcome with relevant CAD drawings and models. *Subsection 4.2* is focussed on the clinical testing of the ptosis crutch. The eyelid elevation provided by the crutch as well as initial qualitative feedback from the participants is displayed.

4.1 Final ptosis crutch design

The final ptosis crutch, displayed in *Figure 32*, was comprised of three separate components; the crutch bar, the housing and the control. The ptosis crutch requirements and corresponding design features are summarized in *Table 7.*

Table 7. The design requirements of the ptosis crutch with the corresponding design features of the final design.

Design Requirements	Design Features
Elevate the upper eyelid above the visual axis.	The curved crutch bar pulls the eyelid in a vertical direction to clear the visual axis.
Adjust for the variation in eyelid elevation	The crutch has vertical adjustment along the z-axis, allowing for variation in the degree of ptosis.
Attach to spectacles	The crutch is attached to the superior border of the spectacles via a clip mechanism.
Modular	The ptosis crutch is categorized into three functional components, namely the crutch bar, the globe projection control as well as the attachment to the spectacle frame. The globe projection control is responsible for connecting the crutch bar to the attachment component.
Adjust for globe projection	The crutch has a slide mechanism along the y-axis, allowing for variation in globe projection.

4.1.1 Functionality

The intended function of the device is to elevate the droopy eyelid(s) of MG patients. The device elevates the upper eyelid. The ptosis crutch elevates the eyelid by applying upward and backward pressure on the eyelid. The crutch is positioned on the eyelid, just above the upper eyelash margin. The crutch bar maintains continuous contact with the upper eyelid, while it is elevated to the appropriate position using the vertical lever. The ptosis crutch can be adjusted by the user to fit the globe projection, by sliding the connection component along the y-axis. The adjustable components enable the ptosis crutch to be fitted according to the patient's individual requirements, thus making the device patient specific.

Patients that do not wear spectacles were issued with a pair of spectacle frames with clear glass lenses, to which the crutch was attached. Should the user no longer require the ptosis crutch it can be detached by the user and the spectacles will be restored to their original state.

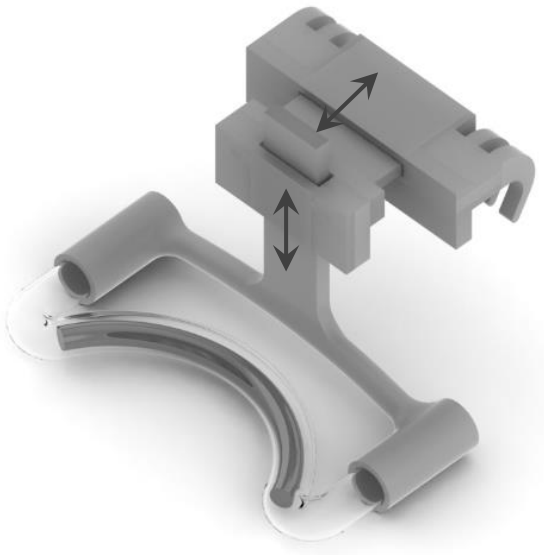


Figure 32. A model of the ptosis crutch. The arrows indicate the direction of movement that each component allows.

4.1.2 Prototyping

The final ptosis crutch was prototyped using a combination of 3D printing and manual manufacturing. The method of prototyping the components is tabulated in *Table 8.* 3D printing was the primary methodology of prototyping the ptosis crutch, as it is a low-cost prototyping method for a device of this size (Berman, 2012).

The concave crutch bar was manually moulded using 1.5mm galvanized wire. The crutch bar was coated in polyvinyl chloride (PVC) tubing. The tubing used to coat the crutch bar was from an Alaris©Products extension set, a Food and Drug Administration (FDA) approved product. The PVC tubing containing the crutch was threaded through the crutch bar housing component, after which it was cut to size and secured in position using steel pins. The steel pins were manufactured by sanding 2mm steel nails to size. A visual illustration of the crutch bar assembly is provided in *Figure 34.*

Table 8. The three modular components of the ptosis crutch and their respective prototyping methods.

Component	Prototyping method
Attachment to spectacles	3D Printed
Globe projection control	3D Printed
Crutch bar	
1. Housing	3D Printed
2. Curved crutch	Galvanized wire coated with polyvinyl chloride tubing

Although the manufacturing of the ptosis crutch was simple and the initial patient feedback has been positive [*see section 4.2*], it is important to highlight the challenges that were faced during prototyping the device. The 3D printer was unable to print the parts according to a consistent size, the ambient temperature and the colour of the ABS filament greatly impacted the quality and consistency of the print. Despite the CAD model being scaled appropriately to accommodate for the 0.05mm variability of the 3D printer, there was an unknown margin of oversized components that needed to be filed down.

After the components had been filed down, hot air was used to restore the original colour of the ABS. Finally, acetone vapour based smoothing was applied to the 3D printed components to remove any rough edges and provide a smooth appearance. Despite the improved aesthetics of the components after acetone vapour based smoothing, the parts were considerably more flexible. This proved to me problematic for the attachment component that required a certain degree of rigidity in order to

effectively clip onto the spectacle border. Through trial and error, it was found that satisfactory surface smoothing was obtained when the control and crutch bar housing were placed in the acetone chamber for 20 minutes while the attachment component was placed in the chamber for 10 minutes. The acetone chamber is illustrated in *Figure 33*. 45 ml of acetone was placed on the lining of the chamber prior to inserting the components.

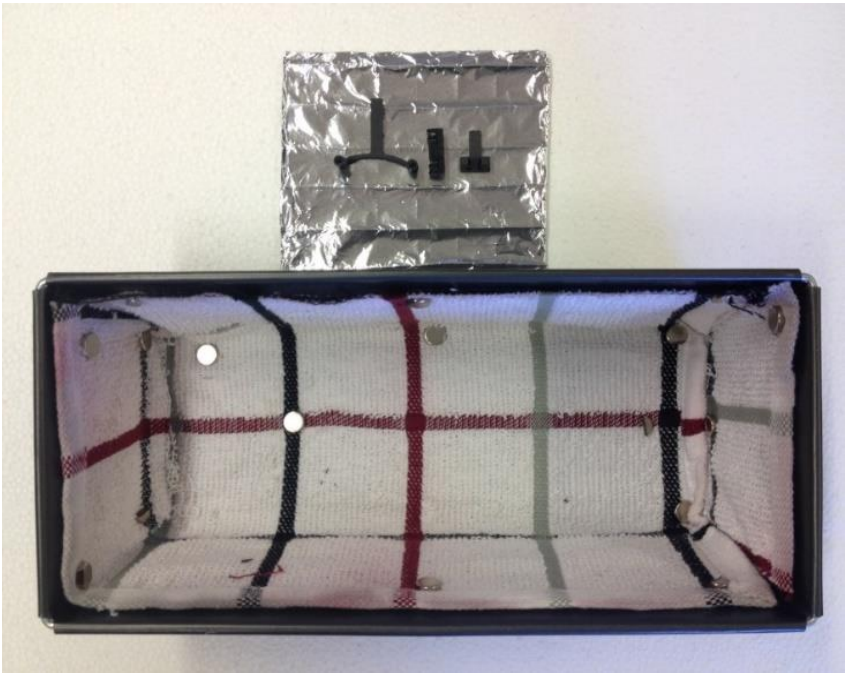


Figure 33. The acetone chamber with the device components placed on the aluminimum platform. The acetone is applied to the cloth using a syringe. The chamber is then placed over the aluminium platform for 10 – 20 minutes. The acteone vapour based smoothing is a process that gives the ABS plastic a smooth and glossy appearance.

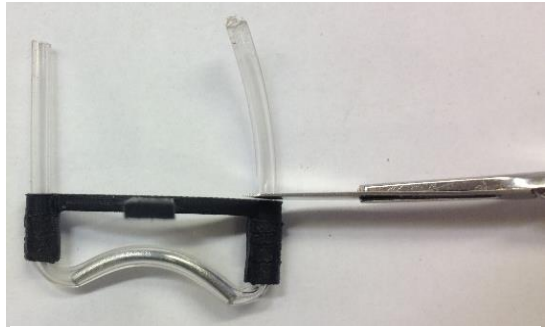
Using the described prototyping methods, a single ptosis crutch unit is estimated to cost R13 (± 0.90 USD, at the time of the study) to manufacture. This is considerably less than the cost of existing ptosis crutch devices, which are reported to cost between 30 – 100 USD (World Optic, 2016; Porter & Salter, 2005; Pelak, *et al.,* 2001).

Alternative methods of manufacturing were researched (press and die and laser cutting). Despite the minor constraints of 3D printing the ptosis crutch, it was evident that the benefits of using 3D printing as the method of prototyping outweighed the costs.

Galvanized wire shaped to the dimensions of the eye globe.

The moulded wire is threaded through the PVC tubing.

The PVC tubing, containing the wire bar, is threaded through the cylindrical openings in the crutch bar housing unit.



The excess PVC tubing is snipped at the edge of the crutch bar housing unit.

Image displaying what the crutch bar should look like after the PVC tubing has been trimmed.

The 2mm tip of a stainless-steel nail is removed using pliers.

The 2mm tip of the stainless-steel nail.

The nail tips are inserted into the PVC tube opening and pushed into the bore of the tube. The purpose of the nail tips is to secure the PVC tubing within the housing unit.

Figure 34. Step-by-step illustration of the methodology employed to construct the ptosis crutch bar.

4.1.3 Adjusting the ptosis crutch to fit the user

The attachment component is adjusted to the specifications of the user's spectacle before manufacturing, The CAD model of the attachment component is tweaked according to the dimensions of the patient's spectacle border. Adjusting these dimensions before the component is 3D printed ensures that the ptosis crutch is firmly attached to the spectacles. The dimensions that are adjusted are displayed in *Figure 35.* The crutch bar and globe projection control are standard components that are adjusted when fitting the crutch to the patient. *Figure 36* illustrates the ptosis crutch being fitted to a participant.

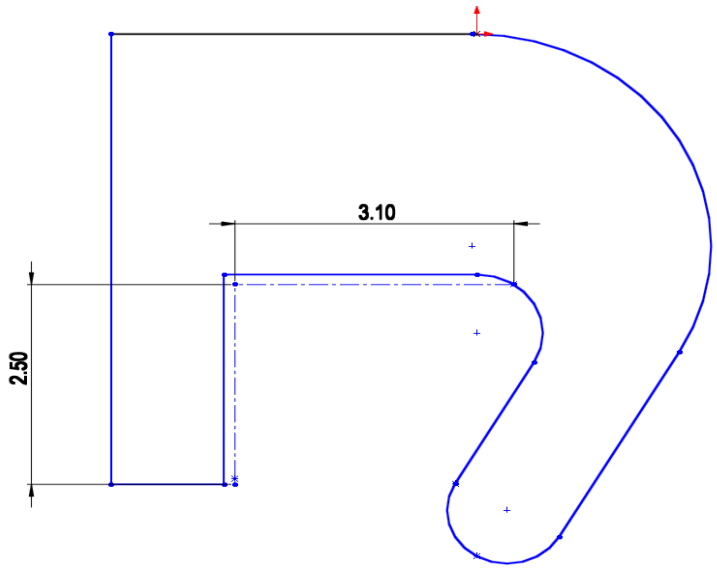


Figure 35. A drawing illustrating the dimensions of the attachment that are altered according to the height (H) and width (W) of the spectacle frame. The dimensions are altered in SolidWorks before the file is exported in STL format. The institution where the device will be 3D printed should be able to adjust these dimensions for the user, should the user not have access to the SolidWorks software.

The ptosis crutch will be made available on an open source platform in a manner that is easy to fabricate using a common 3D printing setup, i.e. STL files with simple instructions. The reason for making the device available on open source was to increase the accessibility of the crutch to ptosis patients as well as interested institutions. The open source platform and its potential benefit for the users are further discussed in Section 5.

Figure 36. A photograph illustrating the ptosis crutch being fitted to the participant's spectacle frame for permanent use.

4.1.4 Failure Mode Effects Analysis

FMEA is a systematic approach for evaluating a product to identify the areas and reasons where failure may occur (Institute for safe medication practices, 2016). In the context of this study, each component of the ptosis crutch was evaluated to identify potential areas of failure. The FMEA of the ptosis crutch is displayed in *Table 11*. The severity and occurrence of the failure were assigned subjective ratings by the designer. A description of each of the ratings is provided in *Table 9 and Table 10.*

Table 9. The description of the FMEA severity ratings

Minor (Rank 1)	Low (Rank 2)	Moderate (Rank 3)	High (Rank 4)	Very high (Rank 5)
The failure will have no noticeable effect on the performance of the device. The user will most likely not be able to detect the failure	The user will experience slight annoyance as a result of the failure. The user will notice a slight inconvenience when using the device.	Failure causes some user dissatisfaction which may include discomfort or annoyance. The performance of the device is compromised	High degree of user dissatisfaction due to the nature of the failure. Failure may result in serious hindrance to the performance of the device	Failure affects the safety of the user. The device will not perform its function as intended.

Table 10. The description of the FMEA occurrence ratings.

Remote (Rank 1)	Low (Rank 2)	Moderate (Rank 3)	High (Rank 4)	Very high (Rank 5)
Failure unlikely. No failures of this nature have been reported	Isolated failures	Occasional failures	Often occurring failures	Inevitable failures

Table 11. The Failure Mode Effects Analysis (FMEA) for the ptosis crutch.

Item ID	Function	Failure Mode	Cause of failure	Effect of the failure	Severity	Occurrence
Crutch bar	To elevate the eyelid	The bar does not make full contact with the upper eyelid.	The curved shape of the galvanized wire curve has been compromised	1. The crutch bar exerts excessive pressure on the eye globe at the point of contact. **OR** 2. The crutch does not elevate the eyelid **OR** 3. The crutch bar causes the upper eyelid to adopt an unnatural contour.	3	2
		The user is not able to grip the lever in order to adjust the elevation.	The lever does not provide sufficient coupling to allow for a firm grip by the user.	The user is not able to adjust the amount of eyelid elevation provided by the crutch bar.	2	3
Control	1. To adjust for globe projection. 2. Connection between the attachment and the crutch bar	The length of y-axis adjustment provided by the control is not sufficient for the user.	1. The user wears their spectacles at a low position on their nasal bridge. 2. The globe projection of the user exceeds the normal values as specified by the literature.	The crutch bar will not make full contact with the upper eyelid.	3	2
		The mechanism for securing the crutch bar in position is faulty.	1. The crutch bar does not fit securely within the provided slot on the control component. 2. The crutch bar is secured too tightly in the provided slot on the control component.	1. The crutch bar will not be secured to the spectacle frame via the control. **OR** 2. The amount of elevation provided by the crutch bar will not be adjustable.	4	3
		The mechanism for securing the control in position is faulty.	1. The control does not fit securely within the provided slot on the attachment. 2. The control is secured too tightly in the provided slot on the attachment.	1. The control will slip out of the slot provided on the attachment component. **OR** 2. The control will not be adjustable along the y-axis.	4	3
Attachment	To attach the device to the border of the spectacle frame	The component is not secure on the border of the spectacle frame.	1. The dimensions of the attachment component are not compatible to dimensions of the spectacle frame.	The attachment component disconnects from the spectacle border	4	2
		The component breaks during the attachment process to the spectacle border.	The components break when pressure is applied to attach the component to the frame.	The unit cannot be attached to the border of the spectacle frame.	4	3

4.2 Clinical results

Clinical testing was carried out before and after the ptosis crutch design process. Outside of these formal testing sessions, the various designs were presented to the participants and the clinician. Both parties expressed their thoughts on the components of the crutch that needed further development. In this manner, the design was fed through continuous iterations, informed by the participants, clinician as well as the designer.

The pre-design testing intended to gain anthropometric measures to inform the design specifications. Additionally, questionnaires were completed by the participants to gain insight into the effect that ptosis had on the visual function, activities of daily living and quality of life of the patients.

The post- design clinical testing aimed to quantify the functionality of the ptosis crutch. Furthermore, the subjective effect of the crutch on the participant's visual ability as well as the ease of use and aesthetic appearance of the crutch, was determined.

4.2.1 Pre-design anthropometric measurements

The measurements recorded in the pre-design testing included the resting position of the upper eyelid in primary position and the HPF [*Table 12*]. Additionally, the patients were required to complete a questionnaire regarding the initial user experience.

16 MG patients volunteered to participate in the study. The mean MRD measurement was -1.44mm (±2.17mm), for 32 eyes. There was no difference in the values for manual and digital measurement [*Figure 37*]. The digital measurement values were used to inform the design parameters.

Table 12. The pre-design anthropometric measures of 16 MG patients.

	Marginal reflex distance (mm)	**Vertical palpebral fissure (mm)**	**Horizontal palpebral fissure (mm)**	**Corneal diameter (mm)**
x	-1.44	4.23	22.83	10.6
SD	2.17	2.31	3.02	0.48

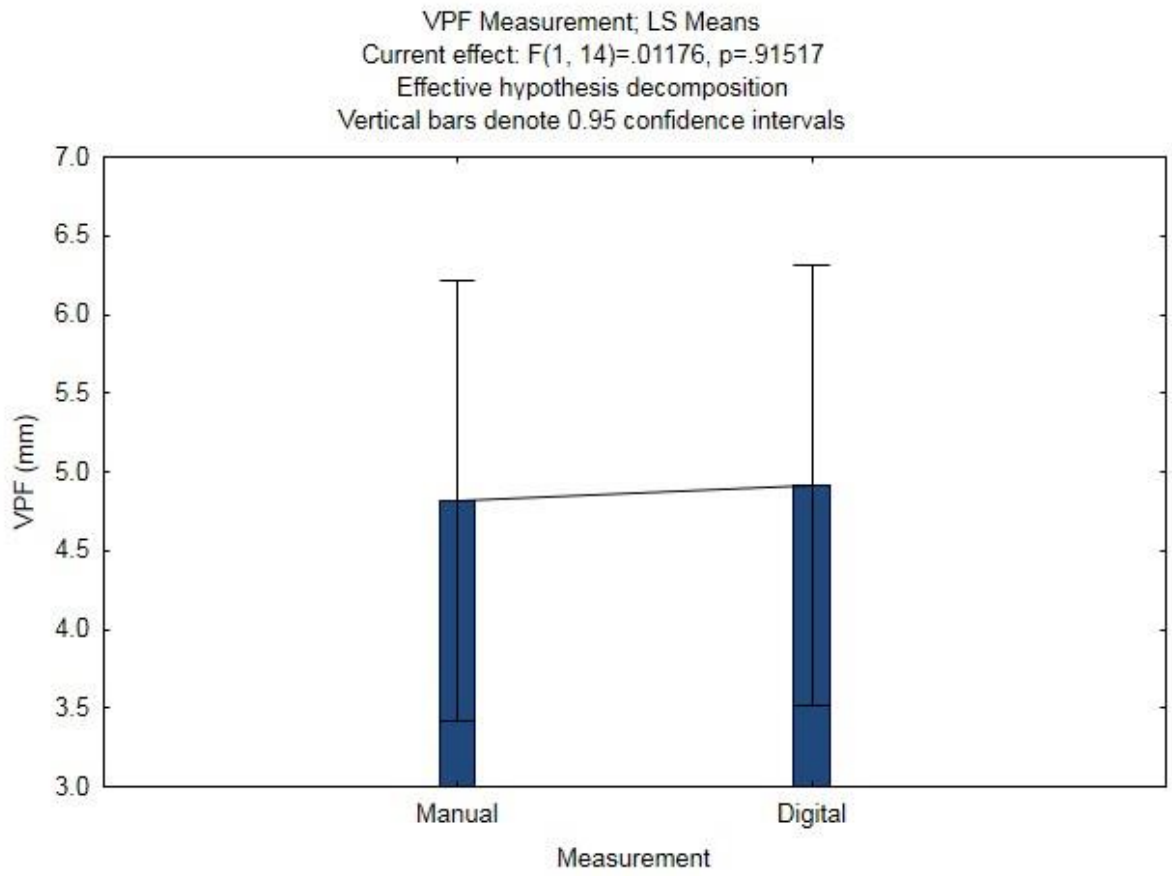


Figure 37. The vertical palpebral fissure (VPF) values measured using manual and digital methods. There was no significant difference between the two methods of measurement (p>0.05).

4.2.2 Predesign qualitative results

The purpose of the qualitative assessment was to determine the impact that ptosis has on the participants, visual field, activities of daily living and quality of life.

With reference to the results displayed in *Table 13* Visual function, specifically, the superior field of vision, was reported as poor. The patients perceived their eyelid appearance as being fair.

Table 14 displays a comprehensive overview of the perceived impairment that ptosis has on the participant's ability to complete activities. The activities that were perceived as having the greatest impairment included reading, watching television as well as walking up/down stairways. The activities that were least affected were identifying objects as well as shaving and styling hair.

Table 13. Mean scores of the impairment that ptosis has on symptoms in a group of 16 myasthenia gravis patients.

Symptom	No. Responses[1]	Mean Score	Mode
General visual function	14	3	4
Superior visual field	14	4	4
General health	14	2	2
Eye or eyelid appearance	14	3	3

[1]. No. responses refers to the number of respondents

Table 14. Mean scores of the impairment that ptosis has on activities in a group of sixteen myasthenia gravis patients.

Activities	No. Responses[1]	Mean Score	Mode
Reading	15	3	3
Watching television	12	3	4
Working on a computer	6	3	4
Walking up/down steps or around curbs	15	3	1
Identifying objects	15	1	1
Hanging or reaching objects	13	2	1
Performing occupation	7	1	1
Shaving, styling hair	14	2	1

[1]. No. responses refers to the number of respondents

4.2.3 Ptosis crutch clinical testing

Functional testing of the ptosis crutch was performed within the clinical testing. The amount of eyelid elevation that the ptosis crutch provided was measured using the same experimental setup that was used for the pre-design testing. The values for manual and digital measurement were found to be the same ($p < 0.05$) [*see section 3.1.4*]. Previous studies have reported similar results, thus the decision to only perform digital analysis for the final crutch testing was justified (Coombes, *et al.*, 2007).

12 patients volunteered to take part in the post-design testing. *Figure 38* displays the MRD of the participant's eyes when unassisted and when wearing ptosis crutch. The mean pre-crutch MRD measurement was -0.83 (±1.38mm), for 19 ptotic eyes. The

measurement differs from the MRD recorded in the pre-design clinical testing as ptosis associated with MG is variable in nature.

The MRD when wearing the ptosis crutch was 0.86mm (±1.33mm) compared to -0.83mm (±1.38mmmm) for 19 ptotic eyes. The difference in the MRD resulted in 1.69mm (±1.15mm) of elevation to the upper eyelid. The difference in the MRD between the two conditions was significant [*Table 15*].

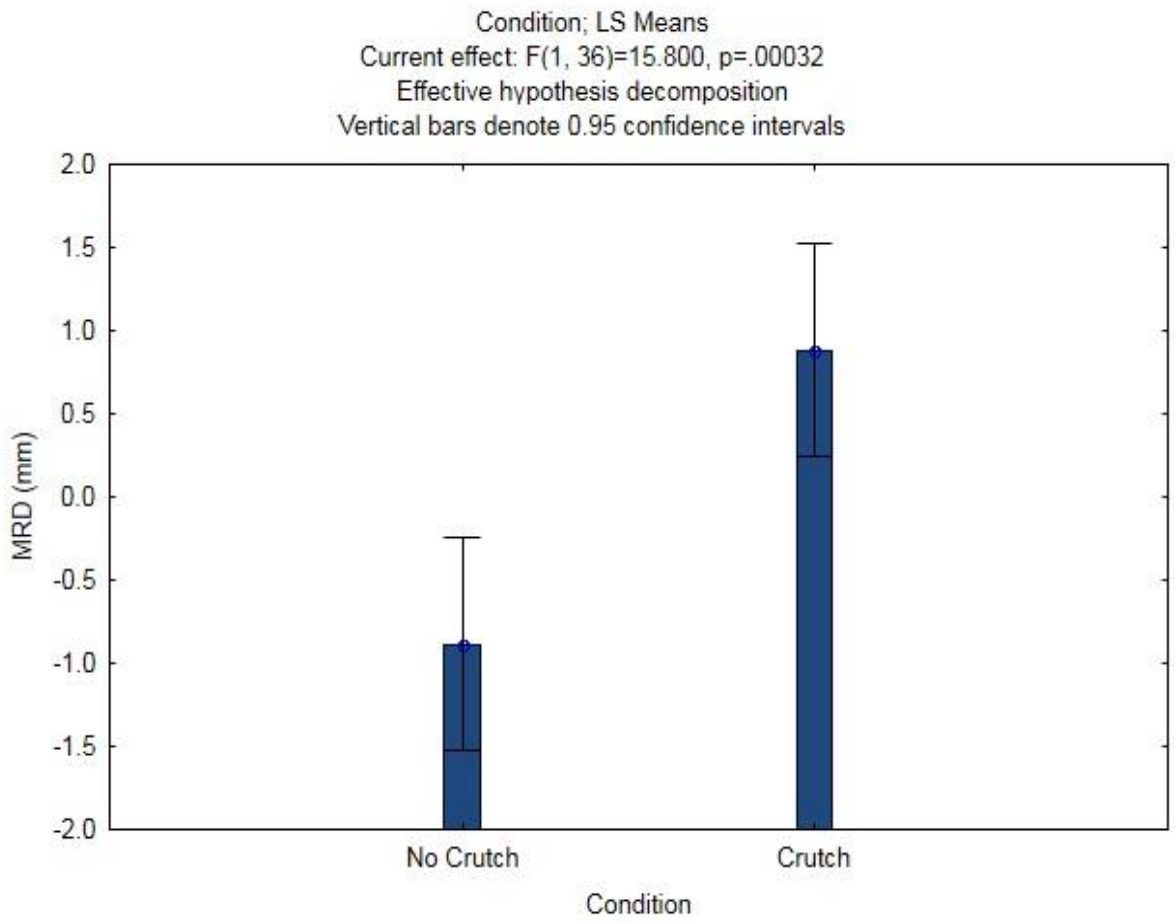


Figure 38. The marginal reflex distance (MRD) without the aid of the ptosis crutch and while wearing the ptosis crutch, recorded from 12 patients (19 ptotic eyes).

Table 15. One- Way ANOVA of the Marginal Reflex Distance between wearing a ptosis crutch and when not wearing a ptosis crutch; measured on 19 ptotic eyes.

Effect	SS	Degr. of	MS	F	p
Intercept	0.00007	1	0.00007	0.00003	0.995317
Condition	29.76255	1	29.76255	15.79975	0.000324
Error	67.81448	36	1.88374		

The results of the additional measurements that were recorded during the clinical testing of the ptosis crutch can be found in *Table 16.* The increase in the MRD and VPF when wearing the ptosis crutch compared to when not wearing the ptosis crutch.

Table 16. The marginal reflex distance (MRD), vertical palpebral fissure (VPF) and horizontal palpebral fissure (HPF) measurements for 12 myasthenia gravis patients with and without the ptosis crutch.

	No Crutch			**Crutch**		
	MRD (mm)	VPF (mm)	HPF (mm)	MRD (mm)	VPF (mm)	HPF (mm)
X	-0.83	4.72	18.67	0.86	5.96	24.11
SD	1.38	2.34	7.05	1.33	1.86	4.28

4.2.4 Qualitative assessment during the clinical testing

The purpose of the qualitative assessment was to gain initial patient feedback on the functionality of the ptosis crutch as well as the comfort, aesthetic appearance and the willingness to use the device.

Table 17 displays the participant's feedback on the ptosis crutch, during the testing session. All of the participants indicated that the crutch did not cause and pain or skin irritation during the testing session. While all of the participants indicated that they were interested in using the ptosis crutch on a long-term basis, there was a concern about the aesthetic appearance of the device, particularly from the younger participants.

Table 17. Mean scores of the feedback on the ptosis crutch in a group of 12 myasthenia gravis patients. The responses were recorded from a questionnaire administered during the clinical testing of the ptosis crutch.

Characteristic	**No. Responses**	**Mean Score**	**Mode**
Comfort	12	4	4
Visual Function	12	5	5
Ability to blink	12	4	4
Ease of attachment	12	4	4
Fit (congruency of crutch curve to the shape of the globe)	12	4	5
Eyelid/eye appearance	12	4	4

[1.] No. responses refers to the number of respondents

4.2.5 Usability of the ptosis crutch

The usability feedback from the 8 MG patients that had been using the crutch for a month or longer reflected a variety of results. The outcome of the usability testing is presented in *Table 18.*

Table 18. The ptosis crutch frequency of use by 8 participants. The frequency of use was reported after the participants had been using the crutch for a minimum of one month.

Frequency of crutch use	Number of patients
Used full time	0
Used occasionally (4 hours per day)	6
Used minimally (<4 hours per day)	2
Not used	0

The reasons for non-use included 1] the crutch broke, 2] wearing the crutch caused the eye to tear, 3] The user was not accustomed to wearing the crutch/wearing glasses and 4] the user had trouble adjusting the crutch appropriately thus the crutch was uncomfortable to wear for long periods of time.

The reasons noted for occasional and minimal used included 1] the patient was not yet accustomed to wearing the ptosis crutch, 2] the patient's eyes were watering when the eyelid was elevated.

5. Discussion of the Design Outcomes

The design of the ptosis crutch was successful, in that all of the requirements were met. The functionality of the ptosis crutch prototype was tested within the clinical. Initial feedback on the crutch was noted during the clinical testing as well as after the crutch had been used for a minimum of one month.

5.1 Functionality

12 MG patients tested the functionality of the ptosis crutch, within the clinical setting. The initial feedback on the device showed a promising outcome for the device.

5.1.1 Eyelid elevation

The ptosis crutch increased the MRD of the ptotic eyelid by 1.69mm (± 1.66mm). The elevation is sufficient to clear the visual axis in ambient lighting conditions when the diameter of the pupil is 3-4mm [*see section 2.4.1*]. During the clinical testing of the crutch, the eyelid was not elevated to a maximum position [*Figure 39*]. The reason for only elevating the eyelid to clear the visual axis was to ensure that the blinking mechanism was not disrupted. Additionally, the participants experienced tearing of the eye when the eyelid was elevated above the necessary position. It is thought that the tearing of the eye will settle down as the user becomes accustomed to the device.

The reason for reporting the MRD as the primary indicator of the upper eyelid position is due to the inter-individual variability of the position of the pupil within the eye aperture.

5.1.2 Adjustability

The device is adjustable along the x, y and z-axes. The described method of adjustment along the z-axis was effective but cumbersome. The mechanism requires a portion of the component to be visible above the superior border of the spectacle

frame [*Figure 40*]. Operating the mechanism requires the user to exert a pinch grip on the lever and push or pull the crutch in the desired direction.

The mechanism that allows the device to be adjusted along the y-axis, requires the user to slide the control along the y-axis as described in section. Once in the correct position the control is snipped and fixed in position. As previously mentioned [*see section 2.3*] there is no evidence of a ptosis crutch that provides the user with the autonomy to fit and adjust the crutch themselves. Although simple, the method of adjusting and securing the crutch, when fitting the crutch for the first time, requires a certain amount of patience and finesse. The user will need to pay careful attention to the instructions that accompany the open source file in order to ensure that the device is secured and adjusted correctly.

A

B

Figure 39. Photographs of a participant A] without the aid of the ptosis crutch and B] with the ptosis crutch attached to the spectacle frame provided by Muller's Optometrists.

5.2 Anthropometric measures

In addition to the MRD, several other anthropometric measures were taken. The effect that the ptosis crutch had on the VPF and HPF distances, as well as the shape of the eyelid contour, are discussed below.

5.2.1 Vertical palpebral fissure

The VPF was recorded despite it not being the primary measurement for determining eyelid elevation. The VPF increased significantly when wearing the ptosis crutch compared to when the ptosis crutch was not worn ($p<0.05$). Although interesting, the increase I the VPF does not indicate whether the visual axis was cleared as the measurement does not consider the position of the pupil.

5.2.2 Horizontal palpebral fissure

The HPF showed a significant increase in length when wearing the ptosis crutch, compared to when the ptosis crutch was not worn ($p<0.05$). With this in mind, it is important to note that the HPF when wearing the ptosis crutch was still less than that described in the literature (Barretto & Mathog, 1999).

5.2.3 Eyelid contour

The eye contour varies between individuals. Previous studies have indicated that the position and height of the peak of the eyelid margin as well as the length and obliquity of the fissure, influence the appearance of the eyelid contour (Beden & Beltram, 2012). The device described herein acknowledged that both upward and downward sloping fissures exist in that both upward and downward slanting designs are available. The design is based on the normal fissure obliquity of ± 1.5mm. Should the fissure obliquity of the user differ from this value, the slant of the crutch bar can be adjusted in SolidWorks.

Figure 40. The ptosis crutch elevating the right upper eyelid of the user. The vertical lever used, used to control the degree of elevation offered by the ptosis crutch is visible above the spectacle border. The reason for using a 25mm lever was twofold; firstly, to allow the crutch to cater for the variability in the degree of eyelid elevation required. Secondly, it provided a large enough surface area for the user to find a firm grip to adjust the eyelid elevation.

5.3 Technical challenges

Several technical challenges were incurred during the design and prototyping of the ptosis crutch [*Table 19*]. The challenges were overcome through the iterative design process that was described in *section 3.*

Table 19. The technical challenges incurred during the design of the ptosis crutch.

	Technical Challenge
1	3D printing the device
2	Ensuring that some blinking effort is possible
3	Allowing for adjustment along the x, y and z-axes
4	Aesthetics of the device

The device described herein was intended to be a standard solution ptosis crutch design rather than an ad-hoc device. For the most part the device fulfilled this requirement, however, there were three circumstances that required the design to be altered to cater to the specific needs of the user.

Case 1

The participant's spectacle frame had a 12° curve. The CAD model of the attachment was altered to include a curve along the x-axis [*Figure41*]. The crutch bar and control were not altered.

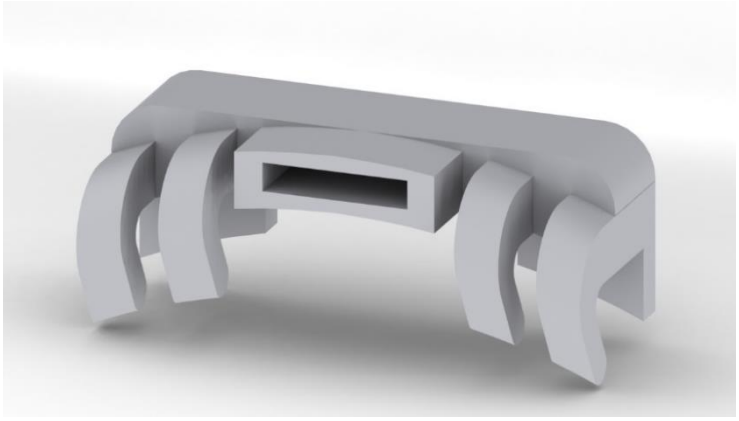


Figure 41. A model of the attachment component that was altered to include a 12-degree curve along the x axis in order to ensure a secure clip onto the user's spectacle frame.

Case 2

The participant's spectacles did not fit securely on the nasal bridge. As a result, the glasses slipped down the nasal bridge when the crutch was positioned on the eyelid. This resulted in the crutch applying superior pressure to the eyelid and thus closing the eye. The spectacles need to be tightened by an optometrist before the crutch can be fitted comfortably.

5.4 Visual function and activities of daily living

The qualitative assessment aimed to determine the effect (if any) that wearing the ptosis crutch on the user's ability to perform activities of daily life. The initial patient feedback on the ptosis crutch shows a promising outcome for the ptosis crutch. The qualitative questionnaire [*Appendix 1.3*] assessed the comfort, effect on the visual axis, ability to blink, among other factors.

5.5 Comparison to existing ptosis crutch devices

All of the existing ptosis crutches refer to a crutch design that requires the practitioner to custom fit the crutch to the patient's spectacles. The crutch is permanently mounted to the user's spectacle frame or lens. Unfortunately, custom making crutches require the patient to have access to the appropriate facilities as well as the funds to supports this option, a criterion that is often not available to a large portion of the South Africa population. Although the ptosis crutch itself is not a new idea, none of the filed patents, scientific literature or practitioner designs are similar to our invention in that they are not modular or adjustable in nature.

As indicated by the literature ptosis associated with MG is predominantly an African clinical problem. There is no evidence of a ptosis crutch that has been designed and produced in South Africa or the African continent as a whole. Previous studies support the idea that there is an unmet need for a low-cost, non-invasive device that alleviates the symptoms of ptosis (Jin Tan, *et al.*, 2012; Lamina & Hanif, 2009; Walsh, *et al.*, 2006).

The specific differences between the proposed ptosis crutch design and the existing ptosis crutch devices are outlined below:

5.5.1 Modular

The ptosis crutch is modular in design in that the design is compartmentalized into functional components. The specific components as illustrated in *Figure 42* include; the crutch bar (A), the crutch housing (B) and the attachment component to the arm of the glasses (C).

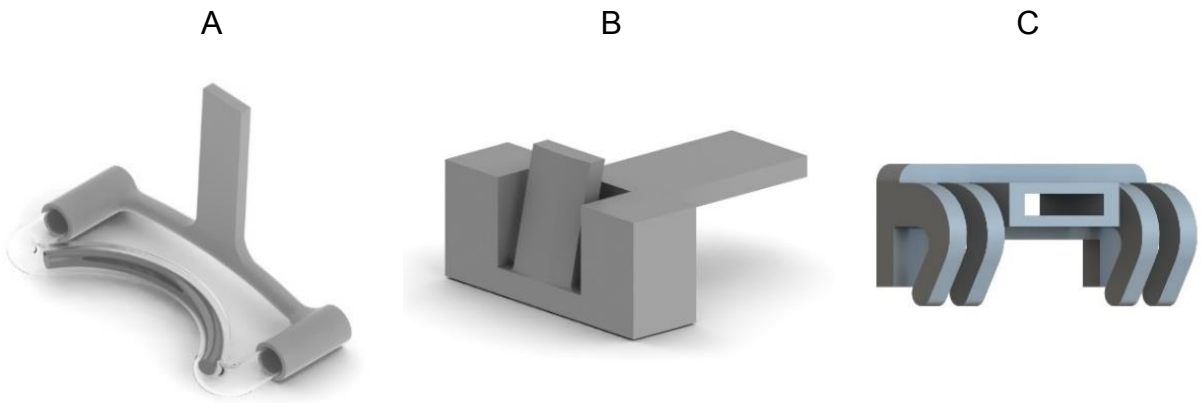


Figure 42. The modular components of the ptosis crutch. A] Crutch bar. B] Control and connection between the spectacle attachment and the crutch bar. C] Attachment to spectacles.

5.5.2. Adjustable

The ptosis crutch is adjustable along the x, y and z-axes. The amount of globe projection varies between males and females, as well as across racial groups [*see section 2.4.7*]. The differences in globe projection stimulated the need for the crutch to be adjustable along the y-axis.

The distance between the medial canthus and the nasal bridge differs between individuals. It was, therefore, important for the crutch to be adjustable along the x-axis. The adjustability is achieved through the position of attachment on the spectacles. The crutch is clipped onto the spectacle border above the patient's eye crease.

The crutch bar is adjustable along the z-axis. The crutch bar is adjusted to elevate the eyelid 2-5mm to clear the visual axis. The adjustable component of the crutch is particularly beneficial to MG patients, as they experience fluctuating severity of ptosis throughout the day and during the course of the disease.

5.5.3. Material selection

Previous ptosis crutch devices have been manufactured using metal wire (stainless steel, bronze, gold or copper-aluminium) or nylon. User feedback on these designs indicated that the wire exerts pressure on the globe, resulting in double vision as well as causing skin irritation at the site of crutch-eyelid contact. The ptosis crutch described by this research was prototyped using a combination of ABS and a galvanized wire covered in PVC tubing. The PVC coated crutch bar allows for good skin-crutch coupling and no skin irritation has been reported by the patients.

Figure 43. A superior view of the ptosis crutch attached to the right and left sides of the spectacle frame. The spectacles are setup to elevate the eyelids of a person with bilateral ptosis.

5.5.4. Affordability

The ptosis crutch prototype, described by this project, cost 0.9 USD per unit to produce. This is markedly lower than the 30 – 100 USD cost of existing devices on the market (World Optic, 2016; Porter & Salter, 2005; Pelak, *et al.,* 2001). The project is currently undergoing the necessary procedures towards launching the ptosis crutch on an open source innovation platform. This will ensure that the ptosis crutch is easily available, by allowing ptosis patients or interested institutions to download the ptosis crutch STL file free of charge.

5.5.5. Ability to blink

The ptosis crutches that have previously been used often interfere with the patient's ability to produce any blinking effort, resulting in the patient experiencing cornea drying. The blink mechanism may be inhibited by one of two reasons; the crutch may

exert an upward force that is too great for the muscles involved in eye closure to overcome or the crutch positions the eyelid at an ‘over-elevated’ position. The ptosis crutch described in the current project has been manufactured using materials with sufficient flexibility to allow for some blinking effort to occur. It is important to note that the crutch does not elevate the crutch to a ‘normal’ anatomic position but rather to a position that is just enough to clear the visual axis.

Figure 44. A ptosis crutch unit fitted to the superior border of two different spectacle frames.

5.6 Socio-economic impact

MG affects individuals of all racial groups, however, the outcome to therapy of the disease differs across races. Patients of African genetic ancestry, particularly juveniles, are more likely to develop ocular muscle complications of MG when compared to their European counterparts. Despite the presentation of ptosis in MG patients, there is no record of a crutch that has been designed for the MG population. Surgical correction of ptosis is possible; however, it is often contraindicated in MG patients with severe weakness of the muscles involved in eye closure and in patients with active disease. In these cases, a non-surgical solution to elevating the ptotic eyelid above the visual axis is required.

The association of treatment resistant and ocular muscle complication in MG patients of African ancestry emphasizes the need for a local, low-cost solution to elevate the eyelid. This need is not isolated to Africa as there appears to be an unmet need for such a device in developing countries worldwide (Jin Tan, *et al*., 2012; Lamina & Hanif, 2009).

The ptosis crutch described by this project provides an important step in offering a standard rather than an ad-hoc solution to elevating the ptotic eyelid of MG patients. The ptosis crutch design offers a standardized manufacturing method for the ptosis crutch. The device will be made available on an open source innovation platform. This will ensure that the ptosis crutch is easily available, by allowing ptosis patients or interested institutions to download the ptosis crutch STL design file free of charge.

Although, the device described herein is a solution to alleviating ptosis associated with MG, the application of the ptosis crutch could be of use to individuals with ptosis of other aetiologies.

5.7 Usability requirements

The usability requirements of effectiveness, efficiency and user satisfaction were explored to determine whether the ptosis crutch could be considered as successful in meeting the needs of the user. Each of these components is outlined in detail below.

5.7.1 Effectivity

Effectivity was defined as the ability of the ptosis crutch to effectively elevate the upper eyelid to clear the visual axis. The ptosis crutch was successful in elevating the eyelid to clear the visual axis. There were circumstances where the ptosis crutch needed to be altered to the specific requirements of the user [*see section 5.3*]. While the clinical testing of the ptosis crutch showed a promising outcome for the device, it is ultimately the long-term feedback on the device that will provide a more valuable indication on the usability of the device.

5.7.2 Efficiency

The efficiency of the ptosis crutch describes the device's use of resources. The term resources referred to the materials and manufacturing methods that were utilized. The ptosis crutch can be considered as efficient as it cost a 0.9 USD to produce. This is noticeably less than the rate of existing devices, which cost between 30-100 USD (World Optic, 2016; Porter & Salter, 2005; Pelak, *et al.,* 2001).

5.7.3 User satisfaction

User satisfaction describes the user's subjective feeling of the ptosis crutches usefulness. The device needed to meet the user's performance expectations as well

as being comfortable and easy to use. For the purpose of the current study, it was important to communicate to the participants that the ptosis crutch was not intended to restore the functionality of the muscles involved in eyelid elevation, but rather to act as an aid to manually elevate the eyelid in order to improve their visual function.

The initial feedback from the participants indicated that the ptosis crutch improved their vision. The participants reported the device as being comfortable and indicated that they were interested in using the device on a long-term basis.

The participant feedback after the crutch had been used for a minimum of one month showed mixed results. One participant found the crutch useful when reading and completing tasks around the house. Four participants indicated that they were no longer using the crutch as it had broken, however when they had been wearing the crutch, they had found it to be useful. Two participants indicated that they were not yet accustomed to wearing the ptosis crutch. One participant indicated that they were experiencing tearing when their eyelid was elevated. It is thought that manufacturing the device with more durable materials will improve the adjustment mechanisms as well as resulting in fewer crutch breakages.

6. Conclusions and Future Work

The present study sought to design a low cost, modular and adjustable ptosis crutch for the MG patient population. Although the ptosis crutch is not a new device, the final crutch described herein has several novel aspects. The design of the ptosis crutch followed a bottom-up design strategy, in that the design was continuously iterated with the input from the users, clinician and designer.

The use of ptosis crutches in South Africa has been limited due to cost, device scarcity and poor patient - device compatibility. Furthermore, no evidence was found of a ptosis crutch that is designed specifically for the MG population. The motive for developing an MG patient specific crutch was due to the patients not being candidates for surgery. The variable nature of ptosis associated with MG further supported the need for the development of the ptosis crutch described within this study. The device described herein is a simple, cost effective solution that has had positive initial feedback from the users.

This study suggests that the use of the ptosis crutch results in a reported improvement in the visual field as well as an improvement in several aspects of subjective visual function. The ptosis crutch appears to offer a step in the right direction to improving the visual function and quality of life of MG patients with ptosis. Although the ptosis crutch described herein was designed for the MG patient population, there is reason to believe that the use of the ptosis crutch could be extended to persons with ptosis from other aetiologies.

This multidisciplinary project used a bio-psychosocial approach, in that it acknowledged the anatomy and biomechanics of the eye as well as the social and psychological considerations of the MG patients.

6.1 Limitations

1. The study did not quantify the effect of the ptosis crutch on the patient's visual field. The effectivity (if any) of the ptosis crutch on the improving the visual field was determined by the subjective rating of the user. Further investigations should consider quantifying improvement (if any) of the user's visual function.
2. The diameter of the pupil is subject to change according to varying lighting conditions. Although the device is adjustable, the amount of elevation was determined according to a 3mm pupil (ambient lighting conditions).
3. The same spectacle frame was used to test the ptosis crutch for all of the participants. The frame was not customized to fit the facial features of each participant.
4. The use of 3D printing as the manufacturing method had several limitations. The choice of material and surface finishes of the material was limited. The 3D printer had a lower precision measurement when compared to other technologies, which limited the size of the ptosis crutch. The strength of the ptosis crutch is limited to the strength of the printable material.

6.2 Future Work

The clinical verification of the ptosis crutch was successful in that device satisfied the design requirements. That being said, there is future work that would be beneficial to the success of the device. The areas for future work, as suggested by the primary researcher, are listed below:

1. Initial MG patient feedback has shown promising results for the ptosis crutch. Keeping this in mind it is ultimately the long-term feedback from all of the users that will confirm the success of the device design.
2. The possibility of manufacturing the ptosis crutch using durable materials should be explored. The costs versus the benefits of a new manufacturing method should be investigated, once the long-term feedback from all the users has been determined.
3. The application of the ptosis crutch to persons with ptosis with aetiologies other than MG should be explored.

It appears as though the ptosis crutch, described by this project, has the potential to offer a much-needed biomechanical solution to an African clinical problem. It is suggested that the recommended future work is explored, to facilitate the use of the ptosis crutch on a long-term basis.

Reference list

Ahmad, K.; Wright, M., & Lueck, C. J. (2011). Ptosis. *Practical Neurology, 11*(6), 332-340.

Augusteyn, R. C.; Nankivil, D.; Mohamed, A.; Maceo, B.; Pierre, F., & Parel, J. (2012). Human ocular biometry. *Experimental Eye Research, 102*, 70-75.

Barretto, R. L. & Mathog, R. H. (1999). Orbital measurement in black and white populations. *The Laryngoscope, 109*(7), 1051-1054.

Beden, Ü. & Beltram, M. (2012). Periorbital anthropometric measurements. *Handbook of anthropometry* (pp. 641-654) Springer.

Berman, B. (2012). 3-D printing: The new industrial revolution. *Business Horizons, 55*(2), 155-162.

Blackmore, J. M., & Jobe, R. P. (1996). U.S. Patent No. 5,542,437. Washington, DC: U.S. Patent and Trademark Office. Choi, Y. & Eo, S. (2014).

Two-dimensional analysis of palpebral opening in blepharoptosis: Visual iris-pupil complex percentage by digital photography. *Annals of Plastic Surgery, 72*(4), 375-380.

Cohen, A. J., & Weinberg, D. A. (Eds.). (2010). Evaluation and management of blepharoptosis. Springer Science & Business Media.

Conway, J. S. (1973). Alleviation of myogenic ptosis by magnetic force. *The British Journal of Ophthalmology, 57*(5), 315-319.

Coombes, A. G.; Sethi, C. S., Kirkpatrick, W. N., Waterhouse, N., Kelly, M. H., & Joshi, N. (2007). A standardized digital photography system with computerized eyelid measurement analysis. *Plastic and Reconstructive Surgery, 120*(3), 647-656.

Cruz, A. A.; Coelho, R. P.; Baccega, A.; Lucchezi, M. C.; Souza, A. D.; & Ruiz, E. E. (1998). Digital image processing measurement of the upper eyelid contour in graves disease and congenital blepharoptosis. *Ophthalmology, 105*(5), 913-918.

De Juan, E.; Hurley, D. P. & Sapira, J. D. (1980). Racial differences in normal values of proptosis. *Archives of Internal Medicine, 140*(9), 1230-1231.

Edmonson, B. C. & Wulc, A. E. (2005). Ptosis evaluation and management. *Otolaryngologic Clinics of North America, 38*(5), 921-946.

Failure Modes and Effects Analysis (FMEA) Tool (2016) Retrieved from http://www.ihi.org/resources/pages/tools/failuremodesandeffectsanalysistool.aspx

Finsterer, J. (2003). Ptosis: Causes, presentation, and management. *Aesthetic Plastic Surgery, 27*(3), 193-204.

Flynn, T. H.; Rose, G. E., & Shah-Desai, S. D. (2011). Digital image analysis to characterize the upper lid marginal peak after levator aponeurosis repair. *Ophthalmic Plastic and Reconstructive Surgery, 27*(1), 12-14.

Fujiwara, T.; Matsuo, K.; Kondoh, S. & Yuzuriha, S. (2001). Etiology and pathogenesis of aponeurotic blepharoptosis. *Annals of Plastic Surgery, 46*(1), 29-35.

Hanada, A. L.; de Souza Jr, E. N.; Moribe, I. & Cruz, A. V. (2001). Comparison of palpebral fissure obliquity in three different racial groups. *Ophthalmic Plastic & Reconstructive Surgery, 17*(6), 423-426.

Heckmann, J. M.; Hansen, P.; Van Toorn, R.; Lubbe, E.; Janse van Rensburg, E. & Wilmshurst, J. (2012). The characteristics of juvenile myasthenia gravis among South Africans: Research. *South African Medical Journal, 102*(6), 532-536.

Heckmann, J.; Owen, E. & Little, F. (2007). Myasthenia gravis in South Africans: Racial differences in clinical manifestations. *Neuromuscular Disorders, 17*(11), 929-934.

Institute for safe medication practices, Retrieved from https://www.ismp.org/tools/FMEA.asp.

Jin Tan, M. C.; Young, S.; Amrith, S. & Sundar, G. (2012). Epidemiology of oculoplastic conditions: The Singapore experience. *Orbit, 31*(2), 107-113.

Jobe, R. P. (2001). U.S. Patent No. 6,309,418. Washington, DC: U.S. Patent and Trademark Office.

Khandwala, M., Dey, S., Harcourt, C., Wood, C., & Jones, C. A. (2011). Ptosis assessment spectacles: A new method of measuring lid position and movement in children. *Ophthalmic Plastic and Reconstructive Surgery, 27*(2), 111-113.

Koushan, K.; Skibell, B. C.; Harvey, J. T.; Jankowski, H. K.; Deangelis, D. D., & Oestreicher, J. H. (2008). Digital photography as a novel technique of measuring ocular surface dimensions. *Orbit, 27*(4), 259-265.

Krishnakumar, S. (2013). Clinical evaluation and management of ptosis. *AECS Illumination, 13*(4), 1-7.

Kumar, N. (2008). Ptosis Spectacle. Canadian Journal of Optometry, 70(3), 81.

Lamina, S., & Hanif, S. (2009). Pattern of ptosis in Kano north-west Nigeria. *African Health Sciences, 8*(4), 253-255.

Lapid, O. (2000). Eyelid crutches for ptosis: A forgotten solution. *Plastic and Reconstructive Surgery, 106*(5), 1213-1214.

Malbouisson, J. C.; Baccega, A., & Cruz, A. A. (2000). The geometrical basis of the eyelid contour. *Ophthalmic Plastic & Reconstructive Surgery, 16*(6), 427-431.

Mangione, C. M., Lee, P. P., Gutierrez, P. R., Spritzer, K., Berry, S., & Hays, R. D (2001). Archives of Ophthalmology, 119, 1050-1058)

Mashige, K. (2013). A review of corneal diameter, curvature and thickness values and influencing factors. *African Vision and Eye Health, 72*(4), 185-194.

McCulley, T. J.; Kersten, R. C.; Kulwin, D. R. & Feuer, W. J. (2003). Outcome and influencing factors of external levator palpebrae superioris aponeurosis advancement for blepharoptosis. *Ophthalmic Plastic & Reconstructive Surgery, 19*(5), 388-393.

Meazzini, M. C.; Miccoli, C.; Fastuca, R.; Panzi, S.; Mangano, F.; Mortellaro, C. & Caprioglio, A. (2015). Measurements of orbital protrusion from childhood to young adulthood. *The Journal of Craniofacial Surgery, 26*(3), 760-763.

Meyer, D. R.; Linberg, J. V.; Powell, S. R. & Odom, J. V. (1989). Quantitating the superior visual field loss associated with ptosis. *Archives of Ophthalmology, 107*(6), 840-843.

Mombaur, B.; Lebowski, M.; Liebenberg, L.; Vreede, H. & Heckmann, J. (2015). Incidence of acetylcholine receptor-antibody-positive myasthenia gravis in South Africa. *Muscle and Nerve, 51*(4), 533-537.

Moorfields Eye Hospital (2015) *Ptosis,* Retrieved from http://www.moorfields.nhs.uk

Moss, H. L. (1982). Prosthesis for blepharoptosis and blepharospasm. *Journal of the American Optometric Association, 53*(8), 661-667.

Nemet, A.; Kaiserman, I.; Mimouni, M.; Segal, O. & Vinker, S. (2014). High prevalence of myasthenia gravis among rural adult populations. *Journal of Clinical Neuromuscular Disease, 16*(2), 47-50.

Odunze, M.; Rosenberg, S. & Few, J. W. (2008). Periorbital aging and ethnic considerations: A focus on the lateral canthal complex. *Plastic and Reconstructive Surgery, 121*(3), 1002-1008.

Packiriswamy, V.; Kumar, P. & Rao, K. G. (2012). Photogrammetric analysis of palpebral fissure dimensions and its position in Malaysian south Indian ethnic adults by gender. *North American Journal of Medical Sciences, 4*(10), 458-462.

Pelak, V. S., & Galetta, S. L. (2001). Ocular myasthenia gravis. *Current treatment options in neurology*, 3(4), 367-376.

Porter, N. C., & Salter, B. C. (2005). Ocular myasthenia gravis. Current treatment options in neurology, 7(1), 79-88.

Phillips, L. H. (2003). The epidemiology of myasthenia gravis. *Annals of the New York Academy of Sciences, 998*(1), 407-412.

Pruitt, J. A. & Ilsen, P. F. (2010). On the frontline: What an optometrist needs to know about myasthenia gravis. *Optometry-Journal of the American Optometric Association, 81*(9), 454-460.

Ramasamy, B; Rowe, F; Freeman, G; Owen, M & Noonan, C. (2007). Modified lundie loops improve apraxia of eyelid opening. *Journal of Neuro-Ophthalmology: The*

Official Journal of the North American Neuro-Ophthalmology Society, 27(1), 32-35.

Sakol, P. J; Mannor, G & Massaro, B. M. (1999). Congenital and acquired blepharoptosis. *Current Opinion in Ophthalmology, 10*(5), 335-339.

Small, R. G; Sabates, N. R & Burrows, D. (1989). The measurement and definition of ptosis. *Ophthalmic Plastic & Reconstructive Surgery, 5*(3), 171-175.

SooHoo, J. R; Davies, B. W; Allard, F. D & Durairaj, V. D. (2014). Congenital ptosis. *Survey of Ophthalmology, 59*(5), 483-492.

Sowka, J. W; Gurwood, A. S & Kabat, A. G. (2001). *Handbook of ocular disease management* Jobson Publishing.

Sudhakar, P; Vu, Q; Kosoko-Lasaki, O & Palmer, M. (2009). Upper eyelid ptosis revisited. *American Journal of Clinical Medicine, 6*(3), 5 -14.

Van den Bosch, W. A; Leenders, I & Mulder, P. (1999). Topographic anatomy of the eyelids, and the effects of sex and age. *The British Journal of Ophthalmology, 83*(3), 347-352.

Ventola, C. L. (2014). Medical applications for 3D printing: Current and projected uses. *PT, 39*(10), 704-711.

Walker, H. K.; Hall, W. D & Hurst, J. W. (1990). The pupils. In R. H. Spector (Ed.), *Clinical methods: The history, physical, and laboratory examinations.* (3rd ed., pp. Chapter 58). Boston: Butterworths.

Walsh, G; Rafferty, P. R & Lapin, J. (2006a). A simple new method for the construction of a ptosis crutch. *Ophthalmic and Physiological Optics, 26*(4), 404-407.

Walsh, G; Rafferty, P. R & Lapin, J. (2006b). A simple new method for the construction of a ptosis crutch. *Ophthalmic and Physiological Optics, 26*(4), 404-407.

Watson, A. B. & Yellott, J. I. (2012). A unified formula for light-adapted pupil size. *Journal of Vision, 12*(10), 12-12.

Wilkinson, C. M. & Mautner, S. A. (2003). Measurement of eyeball protrusion and its application in facial reconstruction. *Journal of Forensic Science, 48*(1), 1-5.

World Optic (2016). About ptosis eye crutches, Retrieved from http://www.worldoptic.com/eyewear-modifications/eyeglasses-ptosis-drooping-eye-lid-crutches.php#.V9gFS_l95QJ

Young, A., & Blackmore, J. (2012). U.S. Patent No. 8,241,352. Washington, DC: U.S. Patent and Trademark Office.

Appendix One

A1.1(a) Patient Information and consent document

Study title: Design and development of a “ptosis crutch”

Researcher and designer: Ms Megan Findlay

Project supervisors: Dr Sudesh Sivarasu and Prof Jeannine Heckmann

Summary of the research

Thank you for considering being a participant on my study. The overall aim of this study is to develop a ptosis crutch that may provide a simple and effective solution to alleviating the drooping upper eyelid symptoms of ptosis. The basic aim of the study is to design, construct and test a ptosis crutch that is effective, user friendly and cosmetically acceptable.

You are reading this document because you have a problem with drooping eyelids or ptosis. In plain language, this project aims to develop a device called a ptosis crutch, which will lift the drooping lids by a few millimetres so that it is easier to see out of the eye. This will allow you to see better whilst the medicines take effect on the eyelids - which can take several months to years. In some patients, the current medicines do not help the eyelids or ptosis even if it does help the other muscles- the ptosis crutch may then become a long-term device to help you read and live an active fulfilling life.

In order to find an effective solution to this problem we will ask individuals like yourself who present with ptosis symptoms (either on one or both sides), whether you wish to participate in this research. The research will require that you participate in three separate assessments. All assessments will include filling out a questionnaire as well the investigator taking three portrait photographs of you (eyes in up gaze, down gaze and primary gaze/looking straight ahead). The photographs will be used for the research purpose of taking eye measurement only and will not be stored on any public data bases. Following the termination of the current project the photographs will be safely discarded should the patient not give consent to using the photograph in the write-up of the study.

The questionnaire relates to how much difficulty you experience with your vision during your everyday life and how much it impacts on your life experience. We will then follow with a questionnaire after you have been fitted with a ptosis crutch to assess how much benefit or not, there has been

You may decide not to take part in this study. It is entirely voluntary to take part. If you decide against taking part, you will still be part of the MG clinic and receive care like all the other patients. You can also decide to leave the study at any time without telling us the reason and it will not affect your care. If you are less than 18 years of age you and a parent will need to sign your consent to take part.

Once the design and development of the crutches are complete we will make a few pairs for participants to try. We are hoping that all the patients (whether you took part in the study or not) will eventually have access to the ptosis crutches.

The risks associated with the crutch are expected to be similar to the risk of wearing reading glasses. You have to place it carefully on the face. Although this is a low risk study the University of Cape Town (UCT) does have no-fault insurance in case, unexpectedly something goes wrong with the ptosis crutch.

What if Something Goes Wrong?

UCT has insurance cover for the event that research-related injury or harm results from your participation in the trial. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI) in the event of an injury or side effect resulting directly from your participation in the trial. You will not be required to prove fault on the part of the University.

The University **will not be liable** for any loss, injuries and/or harm that you may sustain where the loss is caused by:

- The use of unauthorised medicine or substances during the study
- Any injury that results from you not following the protocol requirements or the instructions that the study doctor may give you
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the study medication
- An injury that results from negligence on your part

[Researchers must bear in mind that it is unacceptable to impose a burden on participants who may not recognize symptoms or have the ready means to take action.]

“By agreeing to participate in this study, you do not give up your right to claim compensation for injury where you can prove negligence, in separate litigation. In particular, your right to pursue such a claim in a South African court in terms of South African law must be ensured. Note, however, that you will usually be requested to accept that payment made by the University under the SA GCP guideline 4.11 is in full settlement of the claim relating to the medical expenses. “

An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.

If you have questions about your rights as study participant, and in the event of trial-related injury, please contact: The head of the UCT Faculty of Health Sciences Research Ethics Committee, Prof Marc Blockman, Tel: 021 406 6496

If you have questions about the study, please contact:

Megan Findlay
Tel: 0764124608
Email: fndmeg001@myuct.ac.za
Prof Jeannine Heckmann
Tel: 021-404-3263
Email:jeanine.heckmann@uct.ac.za

Participant consent

I _____ do hereby voluntarily consent to participate in this study. I realize that my anonymity will be protected at all times, and agree to allowing the information gathered in the study to be used and published for scientific purposes. I have read and understand the information above and all questions have been answered to my satisfaction. I am willing to have photographs taken of me for the research purpose of obtaining my eye measurement. I am willing to have the photographs taken of me used in the final publication of this study, under the condition that only the identifiable features that will be visible will be my eyes. Should I not be willing for my photograph to be published I will indicate in the space provided below.

(Please tick the appropriate box)

YES	

NO	

_____ _____

Signature of participant Date

(Legal guardian should the participant be younger than 18)

_____

Name of person taking consent

_____ _____

Signature of person taking consent Date

A1.1(b) Assent form for participants younger than 18 years

I am Megan, a student at the University of Cape Town. My project is to design and develop a 'ptosis crutch' and I am asking you to take part in this study – but only if you want to. You may say yes or no – it is up to you. There is no right or wrong choice- as long as you understand what it involves and it is your choice. The main aim is to develop a device called a 'ptosis crutch' that will help lift up your drooping eyelid(s) so that it is easier for you to see. The figure shows an old design attached to a pair of reading glasses. I will try and develop a few different styles and types and will then ask your opinion as to which one you prefer wearing, and why you prefer it. The idea is to design it so that you will use it and that it will help you in your everyday life.

Figure: A pair of glasses with the 'ptosis crutch' attached.

What will I have to do?

If you take part in this study we will need to ask you questions on three different occasions and you have will need to fill in a form. We will also need to take 3 photographs of you face (of your eyes and nose). The photographs will be used for taking the eye measurements that are needed for designing the 'ptosis crutch'.

The question forms will be used to gather information about the difficulties that you may experience due to your drooping eyelids. After the crutch has been designed and you have used it we will ask you more questions to find out if the crutch has helped you. You can choose to leave out any questions that you feel are not necessary to your situation or if they make you feel uncomfortable.

Will participating in this study hurt or help me in any way?

Participating in this study should not hurt you. The ptosis crutch, like any pair of reading glasses, must be looked after and used with care when playing games.

By participating in this study you will contribute towards developing a device that will hopefully be beneficial to you and other patients in the future. We are hoping to give each of our patients with longstanding ptosis one of these crutches even if you have not been part of the study. However, if you take part we will use your suggestions and requests in the design process.

If you have any questions about your rights as study participant, and in the event of you getting hurt in the trial, you must please contact:

Prof Marc Blockman (The head of the UCT Research Ethics Committee)
Tel: 021 406 6496

What will you do with information about me?

We will be very careful to keep your answers to the questions as well as the photographs taken published in a magazine (known as scientific paper) which is only read by doctors and scientists. However, no-one will be able to recognize you. If you are happy for us to use the photos of your eyes for a scientific paper then please say yes. If you would rather not, you can say no. It will look something like this picture:

Yes, you can use my photo in the journal ☐ or no thanks ☐

If you have questions about the study please contact:

Megan Findlay
Number: 0764124608
Email: fndmeg001@myuct.ac.za

Prof Jeannine Heckmann
Number: 021 404 3263
Email:jeanine.heckmann@uct.ac.za

Agreement

If you decide you want to be in this study, please print/write your name.

I, _____ (print your name) would like to take part in this ptosis crutch design study.

_____ _____

(Signature) (Date of assent

A1.2 The adapted NEI-VFQ-25

The following is a survey with statements about problems which involve your vision or feelings that you have about your vision condition. After each question please choose the response that best describes your situation. Please answer all the questions as if you were wearing your glasses or contact lenses (if any). Please take as much time as you need to answer each question. All your answers are confidential and will be seen only by Prof Heckmann or Ms Findlay. However, Prof Heckmann will correlate your examination findings with your responses to these questions so that we can understand your disability better. In order for this survey to improve our knowledge about vision problems and how they affect your quality of life, your answers must be as accurate as possible.

INSTRUCTIONS

1. In general we would like to have people try to complete these forms on their own. If you find that you need assistance, please feel free to ask the researcher to assist you.

2. Please answer every question.

3. Answer the questions by circling the appropriate number.

4. If you are unsure of how to answer a question, please give the best answer you can and make a comment in the left margin.

STATEMENT OF CONFIDENTIALITY

All information that would permit identification of any person who completed this questionnaire will be regarded as strictly confidential. Such information will be used only for the purposes of this study and will not be disclosed or released for any other purposes without prior consent, except as required by law.

Name: _____ Age: _____

Date: _____ MG composite eye score: _____

GENERAL VISION

Please rate the following questions as Excellent, Good, Fair, Poor or Very poor, according to your personal situation.

1. Is your current vision using both eyes (with glasses or contact lenses, if you wear them) …….?

1	2	3	4	5
Excellent	Good	Fair	Poor	Very poor

2. Is your current upper visual field …….?

1	2	3	4	5
Excellent	Good	Fair	Poor	Very poor

3. Is your current general level of health …….?

1	2	3	4	5
Excellent	Good	Fair	Poor	Very poor

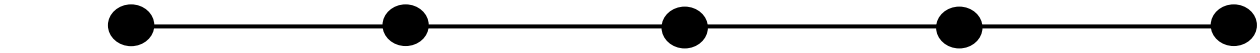
4. Is your current eye/eyelid appearance …….?

1	2	3	4	5
Excellent	Good	Fair	Poor	Very poor

DIFFICULTY WITH ACTIVITIES

The next questions are about how much difficulty, if any, you have doing certain activities with ptosis.

5. How much difficulty do you have when reading due to the position of your eyelid(s)?



1	2	3	4	5
No difficulty	A little difficulty	Moderately difficult	Extremely difficult	Cannot due this due to my drooping eyelids

7. How much difficulty do you have when watching TV due to the position of your eyelid(s)?

1	2	3	4	5
No difficulty	Occasional difficulty	Mild difficulty	Moderate difficulty	Severe difficulty

8. How much difficulty do you have using a computer due to the position of your eyelid(s)?

1	2	3	4	5
No difficulty	Occasional difficulty	Mild difficulty	Moderate difficulty	Severe difficulty

9. How much difficulty do going down steps, stairs or around curbs due to the position of your eyelid(s)?

1	2	3	4	5
No difficulty	A little difficulty	Moderately difficult	Extremely difficult	Cannot due this due to my drooping eyelids

10. How much difficulty do you have identifying objects due to the position of your eyelid(s)?

1	2	3	4	5
No difficulty	A little difficulty	Moderately difficult	Extremely difficult	Cannot due this due to my drooping evelids

11. How much difficulty do you hanging or reaching objects (plants, light bulbs, dishes) due to the position of your eyelid(s)?

1	2	3	4	5
No difficulty	Occasional difficulty	Mild difficulty	Moderate difficulty	Severe difficulty

12. Do you get less done (accomplish less) than you would like because of your ptosis?

In other words, do you think your ptosis/lid drooping prevents you from doing everything you would like to do?

1	2	3	4	5
All of the time	Most of the time	Some of the time	A little of the time	Never

13. How much difficulty do you have performing your occupation as a (fill in) …… due to the position of your eyelid(s)?

1	2	3	4	5
No difficulty	Occasional difficulty	Mild difficulty	Moderate difficulty	Severe difficulty

14. Because of your eyesight, how much difficulty do you have doing things like shaving, styling your hair, or putting on makeup?

1	2	3	4	5
No difficulty at all	A little difficulty	Moderate difficulty	Extreme difficulty	Cannot do this due to my drooping eyelids

15. How much of the time do you worry about your drooping eyelids?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

A1.3 Ptosis crutch usability questionnaire

NAME: DATE:

Please answer the following questions relating to the ptosis crutch you are currently wearing by circling the appropriate option. If you find that you need assistance, please feel free to ask the researcher to assist you.

---

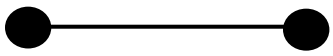
1. How comfortable is the crutch from unbearable to unnoticeable?

1	2	3	4	5
Extremely uncomfortable	Uncomfortable	Bearable	Comfortable	Extremely comfortable

2. How does wearing the crutch compare to not wearing the crutch?

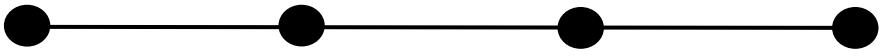
1	2	3	4	5
Much worse	Worse	No change	Somewhat better	Much better

3. Have you experienced any skin irritations/allergies caused by the crutch?



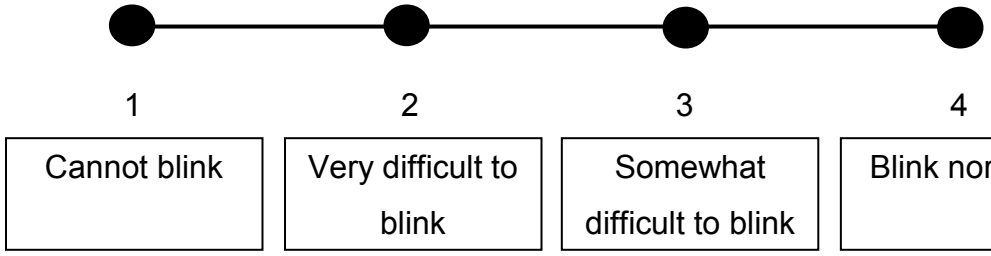
Yes	No

4. Does the crutch impose on your visual field?

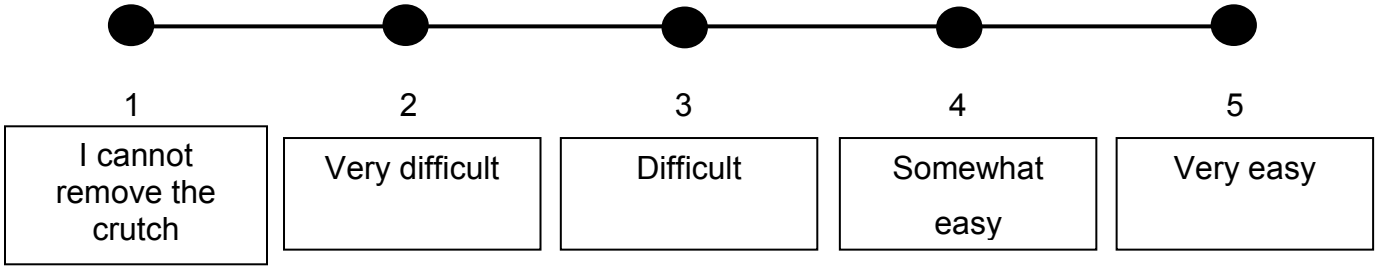


1	2	3	4
Completely distracting	Somewhat distracting	Somewhat noticeable	Not at all noticeable

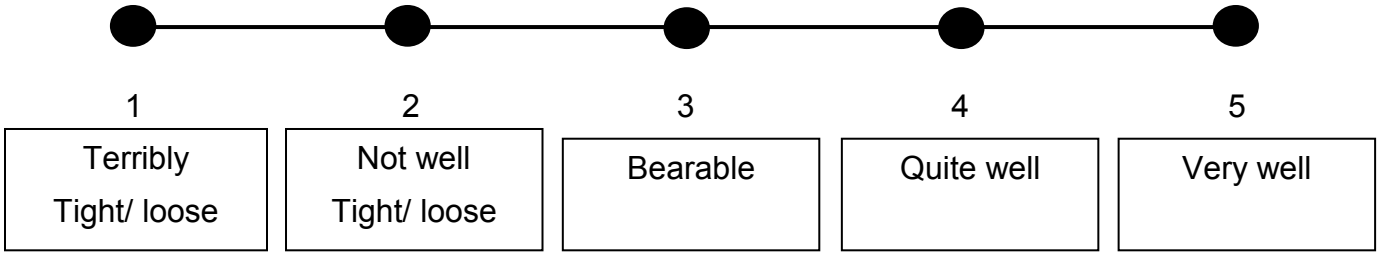
5. Has the crutch effected your ability to blink normally?



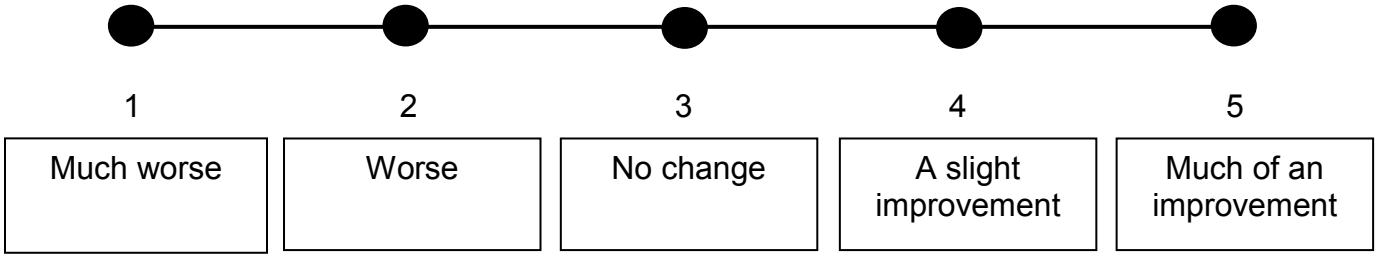
6. How easy or difficult was it to attach and remove the crutch from your glasses?



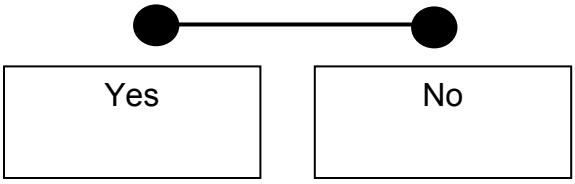
7. How well does the crutch fit you? (Please circle the tight or loose option if necessary)



8. How do you think the crutch effects your appearance?



9. Would you be interested in using a crutch such as this permanently?



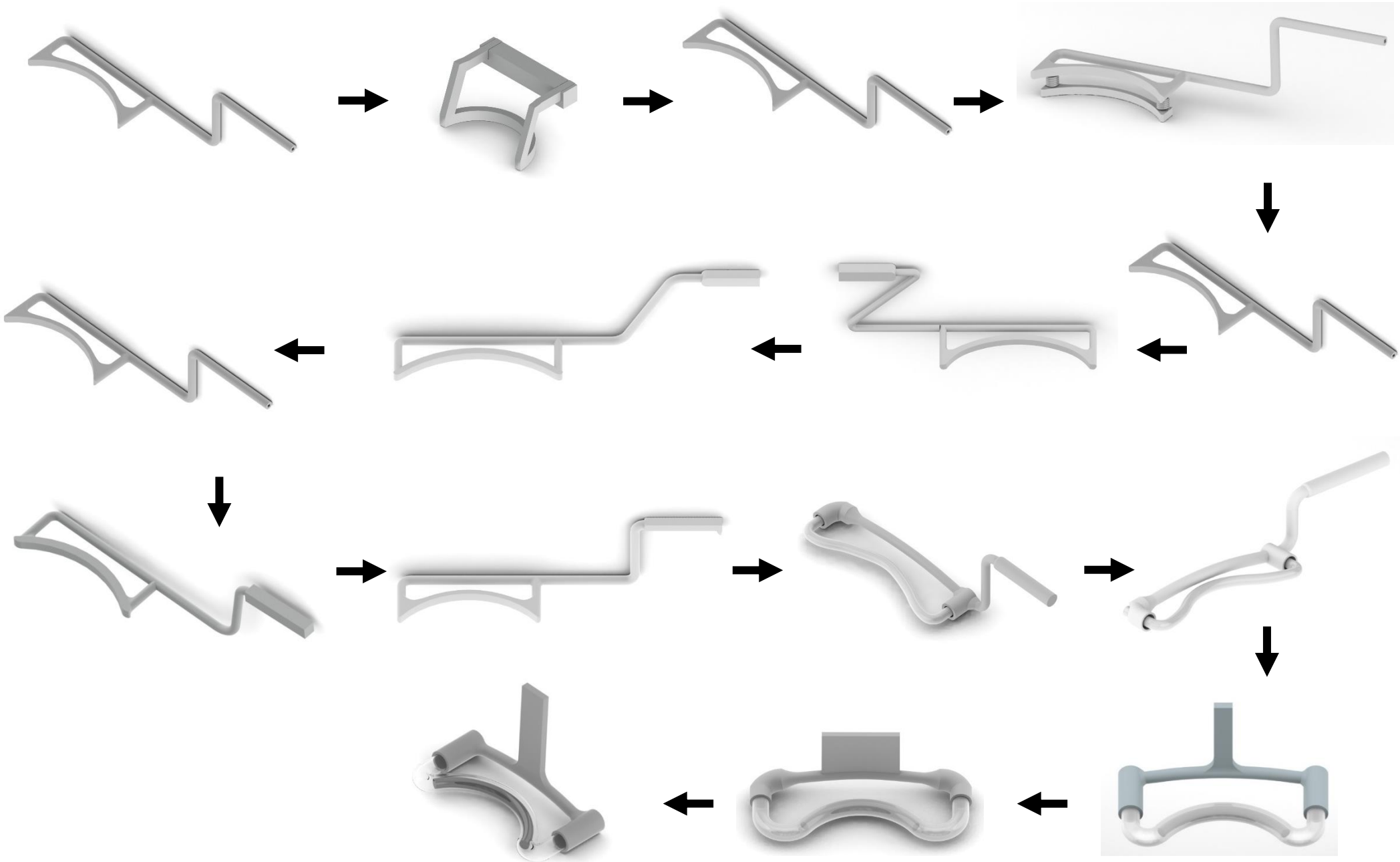
10. Please provide any additional information that you would like the researchers to know about this ptosis crutch design.

Appendix Two

A2.1 The ptosis crutch design specification form

What will it look like?	The appearance of the ptosis crutch cannot be likened to that of any existing device
What materials is the device made from?	The device is manufactured from different materials, depending on the function of the specific component: 1. **Attachment:** ABS 2. **Housing for crutch bar:** ABS 3. **Curved crutch bar:** galvanized wire coated with polyvinyl tubing 4. **Control:** ABS
What is the size of the device?	**Attachment:** length= 18mm; height = variable **Control:** width= 12.5mm; height= 15.75mm **Crutch bar:** width= 33.92mm; height= 30.25mm
	FUNCTION
What does the device do?	The product will provide the user with the ability to elevate their eyelid to clear the visual axis
How does it achieve its intended outcome?	The product is attached to the superior border of the user's spectacle frame. The device is adjusted to fit the horizontal position of the eye as well as the globe projection. The curved crutch bar should fit comfortably on the upper eyelid, above the eyelid margin. Once in place the crutch is able to adjust the eyelid position along the z axis using the lever.
What are the special features	The device is modular in that it is composed of three independent components. The device is adjustable along the x, y, and z axes by the user.
	USER
What is the device used for?	The device is used by Myasthenia Gravis patients with ptosis. The device is intended to elevate the upper eyelid of the user.
What does the user want to do with the device?	The user will attach to device to the superior border of their spectacle frame. They will fit the crutch to their eyelid when their spectacles are in position. The user hopes to use the device to elevate their eyelid to clear this visual axis.
Where will the device be used	The device will be used in in day to day activities. The device is intended to be worn by the user when required

A2.2 Iterations of ptosis crutch bar



A2.3 Iterations of the attachment to the spectacles