

The Magnetic Levator Prosthesis for Temporary Management of Severe Blepharoptosis: Initial Safety and Efficacy

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Purpose: We further optimized and evaluated the safety of the magnetic levator prosthesis (MLP) for temporary management of severe blepharoptosis, and compared efficacy and comfort against the ptosis crutch.

Methods: The interpallebral fissure (IPF) of participants ($n = 12$) with ptosis was measured during attempted eyelid opening, volitional closing, and spontaneous closing with no device, ptosis crutch, or the MLP. A 10-point scale documented comfort. Additionally, a 20 minute and then 1 week trial of the MLP was offered. Safety measures were skin erythema rating, change in visual acuity, and change in corneal staining.

Results: The MLP and crutch opened the eye (IPF 11.2 and 9.3 mm), but the MLP allowed better volitional closure (IPF 1.0 vs. 4.9 mm, $P = 0.009$), but was no better in allowing spontaneous blink (IPF 7.5 vs. 7.7 mm, $P = 0.722$). Both devices were equally comfortable (both median 8/10 comfort, $P = 0.46$). With extended use, opening with the MLP showed IPF 9.24 mm at 20 minutes and 9.46 mm at 1 week, and volitional closure was IPF 0.95 and 0.52 mm, respectively. Closure on spontaneous blink improved with extended wear to IPF 5.14 and 5.18 mm, respectively ($P = 0.002$). Two participants exhibited moderate skin erythema and one had increased corneal staining without change in acuity.

Conclusions: The MLP is safe and feasible for temporary correction of severe ptosis.

Translational Relevance: First group data in patients showing successful reanimation of the eyelid with magnetic force.

Introduction

Blepharoptosis, defined as incomplete elevation of the upper eyelid, occurs due to abnormalities in muscle function, muscle structure, nerve function, or anatomic limitations.¹ Etiologies include congenital abnormalities, stroke, traumatic brain injury, tumors of the brain or face, viral illnesses, diabetes, myasthenia gravis, and general aging mechanisms.¹ The

prevalence of blepharoptosis within the United States general population is unknown; however, in Korean and United Kingdom general populations it has been reported to be 11%.^{2,3} This suggests that approximately 30 million people may have the disorder in the United States.

The most common methods used currently to correct ptosis involve either surgical advancement of the levator palpebrae superioris muscle (levator advancement) or shortening the Muller muscle

Table 1. Patient Characteristics

ID	Age, y	Affected Eye	Severity, mm IPF (SD)	Sex	Cause
S1	45	Right	Complete	F	Craniopharyngioma
S2	52	Right	Complete	F	Meningioma
S3	18	Right	9.7 ± (1.3)	F	Traumatic brain injury
S4	66	Right	Complete	M	Traumatic brain injury
S5	73	Both	Complete	F	Cavernous hemangioma
S6	39	Left	5 ± 1	M	Traumatic brain injury
S7	26	Left	4.2 ± (1.1)	F	Traumatic brain injury
S8	77	Both	1.1 ± (1.4) ^a	F	Myasthenia gravis
S9	50	Right	Complete	F	Traumatic brain injury
S10	72	Both	1.6 ± (1.4) ^a	M	Stroke
S11	19	Left	Complete	M	Traumatic brain injury
S12	39	Right	Complete	F	Traumatic brain injury
Mean	40 ± (20)		2.6 ± (4)		

IPF, interpalpebral fissure (in complete ptosis the IPF = 0); SD, standard deviation.

^a Measurement refers to the eyelid to be treated (bilateral ptosis).

(conjunctiva-mullerectomy). In cases of levator muscle paralysis or impaired function, a “sling” is implanted to attach the eyelid to the eyebrow, using the action of the frontalis muscle to elevate the eyelid (frontalis sling).¹ While these procedures are a mainstay of treatment, in our experience they have disadvantages in that they do not always restore normal blink function and overcorrection may result in exposure keratitis. Substantially less attention has been given to nonsurgical approaches, which has led to lack of effective options during the early recovery period from neurological etiologies, in cases with daily variability in the ptosis such as myasthenia gravis, or other cases where surgery is contraindicated. The ptosis crutch has been available for many decades and consists of a wire attached to the patient’s spectacle frame to provide a tonic mechanical elevation of the eyelid.⁴ However, we observed major problems with the ptosis crutch, including the need for frequent adjustment to maintain lid elevation, inability to close the eye completely, and increased risk of eye injury during spectacle adjustment or if the patient were to fall.

We recently demonstrated successful correction of eyelid ptosis using magnetic force in a case series of complete unilateral third nerve palsy.⁵ The device elevated the eyelid while allowing a volitional blink. In the present study we expanded on this prior work to perform further optimization and test the safety, feasibility, comfort, and efficacy of the magnetic

levator prosthesis (MLP) against the ptosis crutch in a larger patient sample.

Methods

The protocol was approved by the institutional review board of Partners Healthcare and the study was conducted in accordance with the tenets of the Declaration of Helsinki. Informed consent was obtained from the participants following detailed explanation of the nature and possible consequences of the study. Participants were inpatients at Spaulding Rehabilitation Hospital in Boston, MA. Twelve participants (Table 1) were screened, enrolled, and met the inclusion criteria of having paralytic ptosis and ability to provide informed consent or assent. Selection was not affected by age or sex. Median age of participants was 45 years (interquartile range [IQR] 39–66) and 67% were female. The right eye was affected in six patients, left eye in three, and bilateral in three. The most common etiology was traumatic brain injury with cranial nerve III injury. Participants with third nerve palsy and double vision were treated using 8 prism diopter base-in press-on prism (3M, St. Paul, MN) on the nondominant eye. Patients also were encouraged to move the eyes away from the paretic motor field by turning the head opposite to the affected eye, which reduced the angle of strabismus and further minimized double vision. Three participants had severe bilateral eyelid ptosis, but only one



Figure 1. Participant S11 with left paralytic ptosis, shown here with the predicate nonsurgical device, the ptosis crutch. The wire is coated in black shrink tubing. Frequent adjustment of the crutch was necessary to keep the eyelid open.

eyelid was treated; selected using a clinical decision-making process involving consideration of acuity, motility, and eyelid function.

Cross-Over Intervention Methods

Participants were informed that the study was investigating the relative effectiveness of two devices to help open the affected eyelid, but they were masked as to which device was the predicate (crutch) and novel (MLP) device. The devices were mounted on similar spectacle frames to avoid participant bias based on appearance or comfort. The order of the interventions was not counterbalanced (MLP trial always was performed after the crutch trial) to avoid repeated removal and reapplication of the magnet array adhesive, which could irritate the eyelid skin. Participants were asked to choose one device over the other (or no device), after which they were debriefed and informed that the MLP was the experimental device. Participants were not permitted to wear the crutch for an extended trial due to risk of self-injury during crutch readjustment or if they were to have a fall.

Device Development and Fitting Techniques

The ptosis crutch was constructed with a semirigid wire coated in thermoactive shrink tubing (Versafit, TE Connectivity, St. Paul, MN) and attached to the bridge of a spectacle frame (Fig. 1). A clinician experienced in fitting ptosis crutches (KH) adjusted the wire to match the contour and position of the upper eyelid and ensured that the device effectively elevated the eyelid. The clinician could not be masked by nature of experience needed to fit the crutch and because this study included continued optimization of fitting techniques for the MLP. Two nonclinician study staff, who were masked to which device was experimental, performed the video image processing

and eyelid measurements offsite at Schepens Eye Research Institute, Boston, MA.

The MLP consisted of a 1.27 (diameter) \times 1.27 mm (length) axially-magnetized cylindrical neodymium (NdFeB) magnet (SM Magnetics, Pelham, AL) mounted on a spectacle frame (Fig. 2) using thermoactive shrink tubing (Versafit, TE Connectivity, St. Paul, MN). Magnetic eyelid arrays were fabricated at the Boston Keratoprosthesis Laboratory, Schepens Eye Research Institute by embedding rectangular NdFeB (N-52) micro-magnets ($2 \times 3 \times 1$ or $2 \times 4 \times 1$ mm; thickness \times length \times width) in polydimethylsiloxane (PDMS) biocompatible elastomer using three-dimensional (3D) printing molds and soft lithography techniques (Fig. 2C). The magnets were encapsulated in PDMS, providing flexibility, biocompatibility, and conformation to the eyelid curvature (Fig. 2C). The eyelids were prepped before application of the array with either a warm washcloth, alcohol swab, or with eyelid scrub (OCuSOFT, Richmond, TX). The array was attached to the upper eyelid by trimming Tegaderm (3M, St. Paul, MN) and in participants S11 and S12 IV 3000 (Smith & Nephew, London, UK) to a size just smaller than that of the upper eyelid, draping it over the top of the array and then peeling the backing off using contact lens tweezers (Bernell Corp, Mishiwaka, IN; Fig. 2E).

Study Procedure

Immediate Measurements and Cross-Over

First, baseline visual acuity with best correction and a clinical assessment of the cornea was performed using biomicroscopy with sodium fluorescein. Corneal staining was documented for each corneal zone using a scale of 0 (no staining) to 3 (dense staining).⁶ Next, video was recorded of eyelid kinematics for 1 minute, initially without any device, then with the ptosis crutch, and finally with the MLP. At the end of the 1-minute recording the participants were asked to close their eyes and hold for 3 seconds, representing a volitional blink trial, which was repeated three times. A 10-point Likert-type scale was administered during the 1-minute recording to document subjective comfort with 10 being best and 1 worst comfort.

Extended Trials of the MLP

At the completion of the crossover trial described in the preceding paragraph, each participant was given the option to participate in a 20-minute trial with the MLP, after which the same outcome measures were repeated. Additionally, the eyelid skin

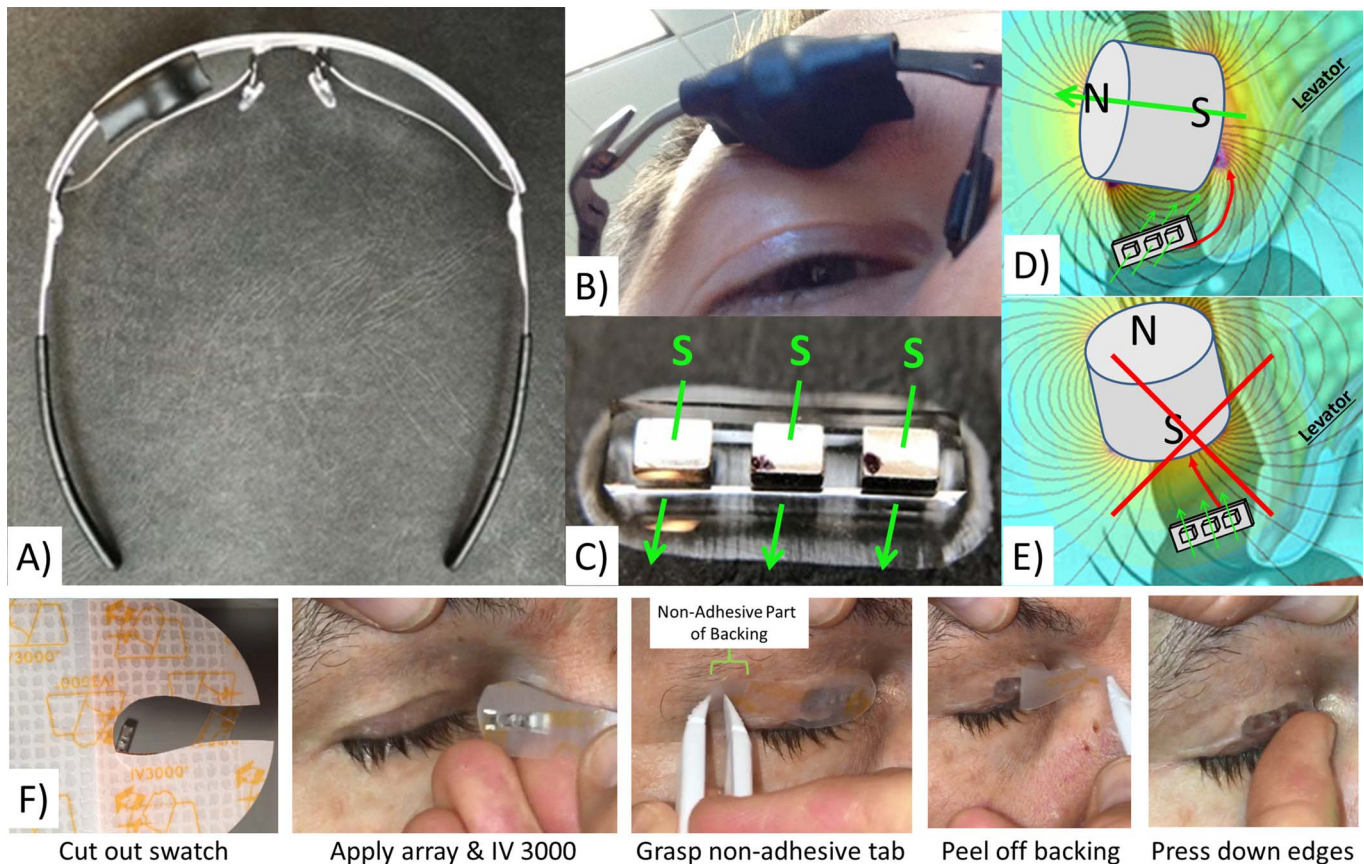


Figure 2. (A) Photo of the MLP spectacle with magnet attached to the upper eye-wire of a Bolle Silium frame with clear safety lenses and adjustable nose pads, and (B) a similar frame with lenses removed as done for video recordings. The MLP frames could be worn over the prescription glasses as needed. (C) Magnified view of a three-magnet PDMS lid array showing through-thickness polarization (arrows). (D) Schematic of the MLP showing orientation of magnetic poles and primary force vectors as were used in the study. Orienting the spectacle magnet poles perpendicular to the frontal plane as shown in (D), rather than directly aligning them as shown in (E), provided a primary force vector more similar to the natural levator's primary force vector and seemed to provide better opening and eyelid apposition to the globe. (F) Photo illustration of lid array application method.

erythema was assessed by the clinical study staff using the industry scale⁷ (scale truncated at 4).

The option for a 1-week trial was given to participants if comfort rating was equal or above 6 of 10, there were no adverse events in the 20-minute trial, and the clinical study team (KH, NF) agreed that it was safe and appropriate to proceed. If so, participants were instructed to wear the MLP glasses for 2 hours per day or less during occupational therapy (eyelid array remained attached all day), after which video and other outcome measurements were performed. If the eyelid array became loose or detached, it was reapplied by one of the clinical study staff who documented the length of the adhesion (days). After the 1-week trial the study ended and the participants were given the option to continue with the MLP until discharge from the rehabilitation hospital at which time they were scheduled for

follow-up with an oculoplastic surgery specialist (MY). Participants were not allowed to take the MLP upon discharge from the hospital.

Video Analysis Methods

National Eye Institute ImageJ software (available in the public domain at <https://imagej.nih.gov/ij/index.html>) was used to measure blink kinematics. The primary outcome measure was interpalpebral fissure size IPF (Fig. 3). Two masked raters with medical and research training but unfamiliar with the MLP or ptosis crutch were trained to classify video frames by blink condition as resting state (time between blinks when eyelids were resting open), spontaneous blink, and volitional blink trials. Criteria for classification of blink types were predetermined and available to the raters in a written protocol. The raters were trained on the protocol before making the

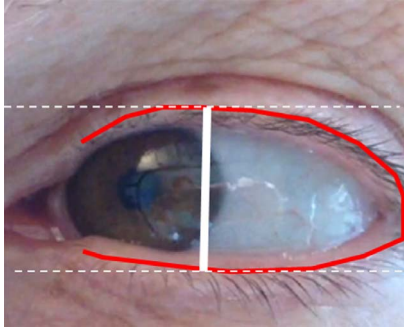


Figure 3. Method used to make interpalpebral fissure measurements.

measurements. IPF was defined as the greatest distance between the upper and lower eyelid margins at the base of the eye lashes (Fig. 3). Marginal reflex distance, used commonly to quantify mild to moderate ptosis, was not a suitable option considering the severity of the ptosis in our sample. Height of the interpalpebral fissure in normal eyes varies between 8 and 11 mm in normal individuals¹ and so this should be the target range of any treatment.

Calibration of Biometric Measurements

Measurements were calibrated using the adult population norm white-to-white, sometimes called horizontal visible iris diameter (HVID) of 11.7 mm.⁸ In our prior study⁵ a ruler held in the recording frame was used to calibrate measurements, but this may generate error if the ruler is not held right at the plane of the iris. Since the iris is fixed very near the plane of the eyelid and population-based studies have shown the adult HVID only varies approximately 0.2 mm with sex and race (11.70 mm \pm 0.26), the HVID was used to calibrate measurements.^{8,9}

Outcomes

The primary outcome was interpalpebral fissure size (IPF) when opening and during maximum closure on volitional blink compared between no treatment, ptosis crutch, and MLP. Secondary outcomes were IPF during spontaneous blink (maximum closure), comfort ratings, change in visual acuity in the treated eye (LogMAR), and frequency and severity of adverse events. We also determined the average size and shape of the adhesives used to attach the arrays to the eyelids by tracing the adhesive within a video frame for each participant, scaling to actual physical size, mirroring left eye tracings (in participants where the left eye was treated), setting fill transparency to 1/12, overlaying tracings of all participants, and using an

approximately 50% density to estimate an average shape and size.

Statistical Methods

Primary analysis compared, among no treatment, crutch, and MLP, the mean IPF outcomes from the repeated measures. We used a longitudinal general linear mixed effects model with the compound symmetry longitudinal covariance structure wherein the subject level baseline levels were random effects and the treatment effects were fixed effects (xtreg, Stata 14.2; StataCorp, College Station, TX). We hypothesized that age and sex may affect the response to the MLP due to differences in skin laxity and orbital structure; thus, these variables were included in the model as adjusting covariates. The model was fit for each different blink condition (resting open, volitional blink, spontaneous blink). Secondary analyses included comparison of the median comfort ratings between the crutch and MLP. We also evaluated for any change in LogMAR or comfort with extended wear of the MLP. Adverse events were logged and reported.

Results

Of the 12 participants enrolled, nine completed the entire 1-week protocol and three only performed the immediate crossover portion of the study. For two of these three participants (S8 and S9) a clinical decision was made to discontinue after the immediate MLP measurement (Table 2, measure 1) because of (S8) extremely thin and fragile eyelid skin (Fig. 4, middle column) and (S9) inability to position the MLP spectacle frame adequately. S9 was of Asian descent and the nose pads could not be adjusted adequately to elevate the MLP to the necessary height. S7 declined to continue after the immediate MLP measurement reporting that the affected eye was open enough without the MLP (mean affected eye IPF 9.7 mm without treatment). These three participants have data for baseline, crutch, and the immediate MLP trial only.

For the remaining nine participants, a full data set was available aside from S6, where the 20-minute video data failed to record. Three participants had been reported in a previous proof of concept paper,⁵ and one in a case report.¹⁰

Graphical representation of the primary analysis can be found in Figure 5, and output in Table 3. These data revealed that the MLP and crutch provided

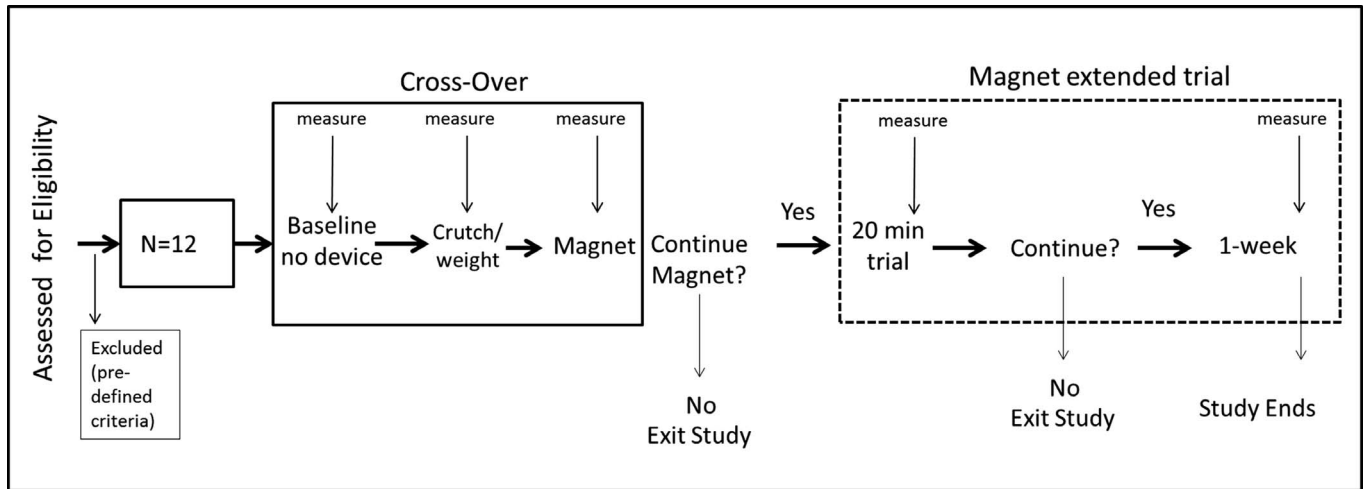
Table 2. Study Procedures Diagram**S6- Left Ptosis
Trauma****S8 – Bilateral Ptosis
Myasthenia Gravis****S10 – Bilateral Ptosis
Stroke**

Figure 4. Three participants with (A) no device, (B) resting open with the ptosis crutch, (C) volitional blink with the crutch, (D) resting open with the MLP, and (E) volitional blink with the MLP. The volitional blink is complete with the MLP but not with the ptosis crutch. For S8, a felt pad is attached to the outside of the spectacle magnet to reduce force at the spectacle magnet surface. This “buffer” also can be added inside the black heat-shrink tubing so it is not visible. Also for S8, another felt pad was used to raise the frame up, since this frame model did not have adjustable nose pads. This issue was solved later in S10 using with adjustable nose pads (Bolle Silium Safety Glasses, Fig. 2A).

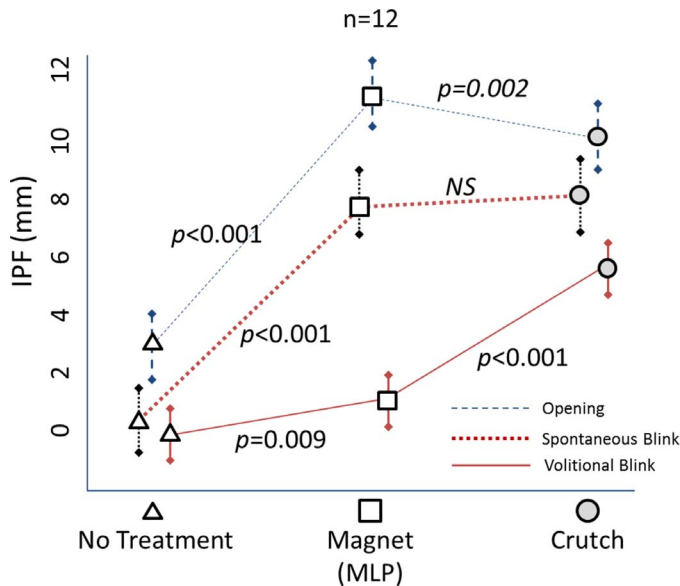


Figure 5. (a) Longitudinal linear mixed effects model predicted means and 95% CI for IPF in each of the treatment and blink conditions. The MLP provided improved opening better than the ptosis crutch and was better at allowing volitional blink. The MLP was no better than the crutch in allowing a spontaneous blink.

significantly improved eyelid opening compared to no treatment, with IPF improvement from a mean of 2.3 mm (95% confidence interval [CI], 1.1–3.5 mm) to MLP 11.2 mm (95% CI, 10–12.4 mm; $P < 0.001$) and

crutch 9.3 mm (95% CI, 8.1–10.5 mm; $P < 0.001$). There was significantly less opening with the crutch compared to the MLP ($P = 0.002$), but both means exceeded the lower end of the target range (8 mm). The MLP allowed better eyelid closing than the crutch for the volitional blink (mean, 1.0 mm; 95% CI, 0.1–2.0 mm vs. mean, 4.9; 95% CI, 3.9–5.9 mm; $P = 0.009$), but was no better than the crutch in allowing a spontaneous blink (IPF 7.5; 95% CI, 6.5–8.5 mm vs. 7.7; 95% CI, 6.6–8.7 mm; $P = 0.722$; Figs. 5, 6). The impacts of age and sex on IPF were not significant for any of the blink conditions. There was less closure with spontaneous blink when wearing the MLP or crutch compared to no device: MLP 7.5 (95% CI, 6.5–8.5 mm; $P < 0.001$), Crutch 7.66 (95% CI, 6.6–8.7 mm; $P < 0.001$); no device 0.61 (95% CI, –0.4 to 1.6 mm).

Extended Trials of the MLP

All nine participants who started the 1-week trial completed it. The array remained adhered to the eyelid for a median of 5 days (IQR 3–7). Graphical representation of the primary analysis can be found in Figure 7, and output in Table 4. Eyelid opening with the MLP at the immediate time point was mean IPF 11.3 (95% CI, 9.7–12.9 mm) larger means more opening. There was less opening at 20 minutes, mean IPF was 9.24 (95% CI, 7.5–11.0 mm; $P = 0.001$) and

Table 3. Output from the Primary Analysis (Crossover)

		β	95% CI		P Value
		Effect Size, mm	Lower Bound	Upper Bound	
Model 1:	No treatment	Other conditions compared against no treatment			
Resting open	Crutch	7.0	5.8	8.2	< 0.001
	MLP	9.0	7.8	10.1	< 0.001
	Age ^a	–0.01	–0.06	0.04	0.732
	Male	0.15	–1.9	2.2	0.887
Model 2:	No treatment	–6.86	–7.87	–5.85	< 0.001
Spontaneous blink	Crutch	0.18	–0.85	1.22	0.722
	MLP	Other conditions compared against MLP condition			
	Age ^a	0.02	–0.03	0.06	0.430
	Male	0.66	–1.1	2.4	0.460
Model 3:	No treatment	–1.1	–1.9	–0.28	0.009
Volitional blink	Crutch	3.9	2.9	4.8	< 0.001
	MLP	Other conditions compared against MLP condition			
	Age ^a	–0.03	–0.07	0.01	0.139
	Male	–0.33	–2.12	1.46	0.720

One longitudinal multiple linear regression model was fitted for each blink type. Output corresponds to the plots in Figure 5.

^a Per year increase.

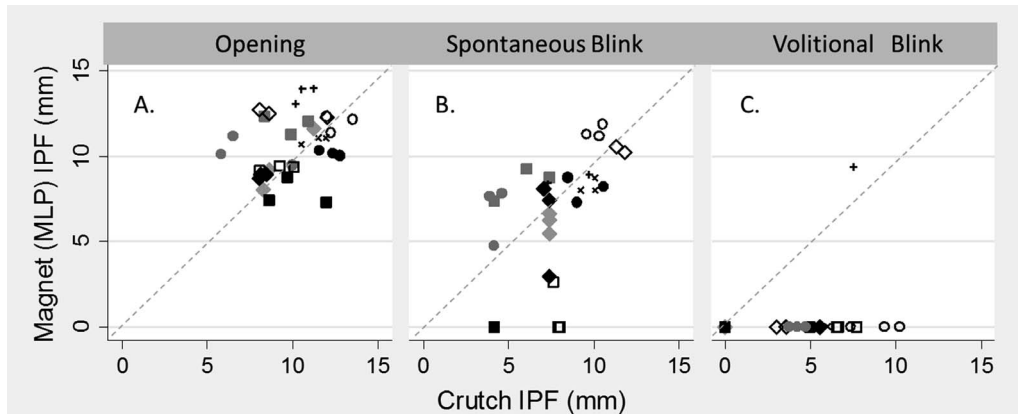


Figure 6. Scatterplots of the IPF for each blink type with each data point representing one measurement. Each participant is indicated by a different marker type. Each marker type appears multiple times due to multiple measurements of each blink type. (A) Points above the line indicate more opening with the MLP. (B, C) Points below the line indicate better closure with the MLP. The mixed-effects model determined the MLP was better at opening (A) and volitional closure (C) than the crutch ($P < 0.001$).

this amount of opening was maintained at 1 week, mean IPF was 9.46 (95% CI, 7.77–11.14 mm; $P = 0.726$). For volitional blink, the affected eyelid mean IPF with the MLP at the immediate time point was 1.11 (95% CI, –0.23 to 2.36 mm), which was not different at 20 minutes, mean IPF was 0.95 (95% CI, –0.38 to 2.27 mm; $P = 0.655$), but was better at 1 week, mean IPF was 0.52 (95% CI, –0.80 to 1.85 mm; $P = 0.052$). For spontaneous blink, the MLP-treated eyelid mean IPF at the immediate time point was 7.55 (95% CI, 5.97–9.12 mm), which was improved at 20 minutes, mean IPF was 5.14 (95% CI, 3.25–7.02 mm; $P = 0.002$). This did not change at 1 week, mean IPF was 5.18 (95% CI, 3.44–6.92 mm).

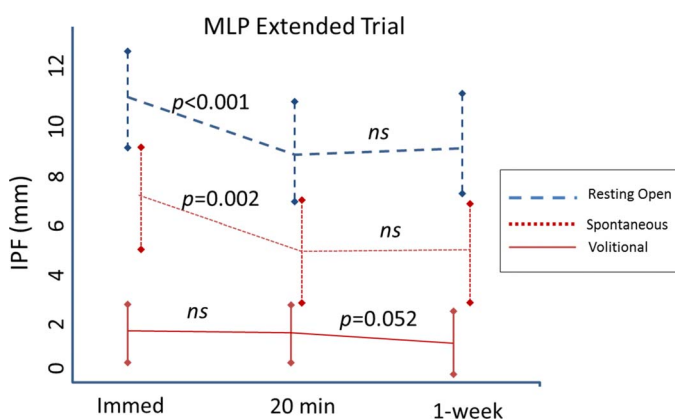


Figure 7. Model predicted means and 95% CI for IPF with the MLP for the extended trials. After 20 minutes of use, opening was less, volitional closure was maintained, and spontaneous closure was more complete compared to the immediate time point. At 1 week, the amount of opening and spontaneous closing was maintained, and volitional closure was further improved.

Comfort of the MLP and crutch was acceptable to most participants with a median comfort rating of 8 (IQR 8–9) and 8 (IQR 5–9), respectively (Wilcoxon, $P = 0.20$; Fig. 8, immediate). The median comfort with the MLP did not change after 20 minutes or 1 week (Kruskal-Wallis, $P = 0.46$). There also were no differences when comparing the comfort change scores (Δ): immediate to 20 minutes Δ versus immediate to 1-week Δ , $P = 0.59$, and 20 minutes to 1 week Δ versus immediate to 20 minutes Δ , $P = 0.813$ (Wilcoxon paired signed-ranks test).

Median visual acuity of the affected eye at baseline was LogMAR 0.32 (IQR 0.18–0.4) and did not change after 1 week of MLP use (median, 0.35; IQR, 0.2–0.5; Wilcoxon, $P = 0.70$).

Adverse Events

No serious adverse events occurred. There was no skin erythema in any of the MLP participants after the immediate or 20-minute trials. Three minor adverse events were identified in two participants with severe bilateral ptosis after 1 week of MLP use (S5 and S10). Both participants had severe bilateral ptosis and wore the MLP longer (5–8 hours per day) than instructed (≤ 2 hours per day). S5 had a grade II increase in inferior corneal punctate keratopathy and grade II skin erythema, but without reported discomfort (9 of 10 comfort rating) or reduction in visual acuity. S10 had grade III erythema and a comfort rating at 1 week of 2/10, but still expressed a desire to continue wearing the MLP citing “inability to open my eyes otherwise.” Skin erythema resolved without treatment or any reported complications. Images of the lid after the 1-week MLP trial for all participants

Table 4. Output from the Extended Use Trial of the MLP, Corresponding to Figure 7

		β	95% CI		P Value
		Effect Size, mm	Lower Bound	Upper Bound	
Model 1: Resting open	Immed	Other time points compared to the immediate time point			
	20 minutes	-2.03	-3.20	-0.86	0.001
	1 week	-1.81	-2.94	-0.70	0.726
	Age ^a	-0.01	-0.09	0.07	0.782
	Male	0.96	-2.25	4.17	0.558
Model 2: Spontaneous blink	Immed	Other time points compared to the immediate time point			
	20 minutes	-2.41	-3.97	-0.85	0.002
	1 week	-2.37	-3.75	-0.98	0.001
	Age ^a	0.01	-0.06	0.09	0.749
	Male	1.19	-1.91	4.29	0.450
Model 3: Volitional blink	Immed	Other time points compared to the immediate time point			
	20 minutes	-0.12	-0.64	0.40	0.655
	1 week	-0.54	-1.09	0.01	0.052
	Age ^a	-0.05	-0.12	0.01	0.118
	Male	-0.86	-3.57	1.86	0.536

One longitudinal multiple linear regression model was fitted for each blink type.

^a Per year increase.

are shown in Figure 9, and for S5 and S10 documented at higher magnification in Table 5. S5 was allowed to continue with the MLP after the study until discharge from the hospital; S10 was not allowed to continue.

Adhesive Size

The average adhesive size was estimated by finding the areas of 50% density, illustrated in Figure 10 as a dashed gray line. The average size was 1.2 cm vertical \times 2.5 cm horizontal.

Discussion

Our hypothesis that the MLP would effectively open the paralyzed eyelid while still allowing volitional closure was supported by our findings. The MLP was shown to have substantial advantages over the predicate ptosis crutch in this patient population, providing similar opening and better ability to close the eye volitionally. The MLP was very well tolerated by participants with high comfort ratings and no serious adverse events. No participant who began the 1-week trial dropped out, supporting the value and comfort of treatment when used during inpatient rehabilitation for 1 week at 2 hours per day or less. Adhesion of the device was excellent (median 5 days). Application was very challenging with the Tegaderm,

becoming substantially easier when switching to IV 3000, which has a backing making it easy to trim to the size needed while still being easy to handle and apply. Frames with adjustable nose pads that wrapped around worked the best (Bolle Silium Safety

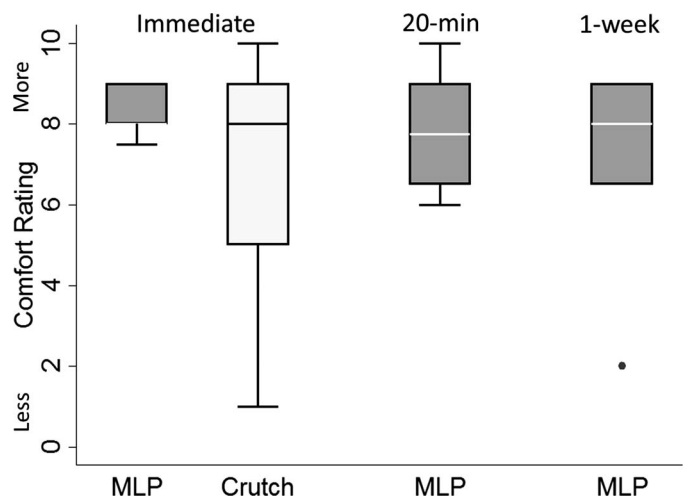


Figure 8. Comfort ratings of the Crutch and MLP at the three time points. Comfort of both devices was acceptable to most participants during the short immediate trial, and not significantly different. Comfort with the MLP did not decrease with extended wear of 20 minutes or 1 week. One participant reported poor comfort with the MLP at the 1-week time point (outlier point, S10), due to overwear or overcorrection resulting in grade III skin erythema (see adverse events Table 3).

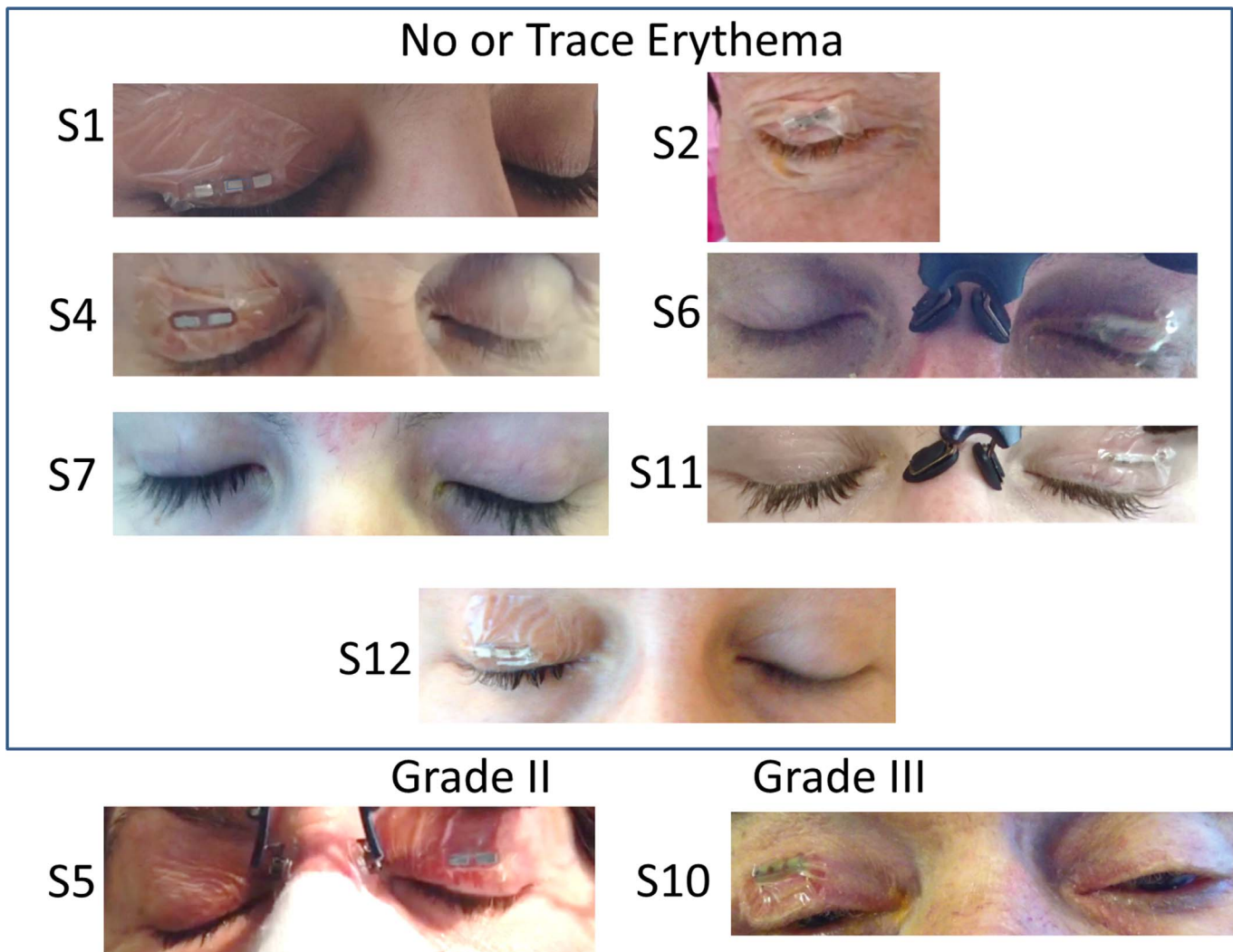




Figure 9. Video frames after 1 week of MLP wear with eyelids closed to photo-document eyelid skin integrity, shown for most participants with the lid array attached. S2 did not have video frames where both eyelids were visible and so only the treated eyelid is shown. S7 does not have the MLP on – the left eye was the treated eye. Lower: Two participants experienced more than trace skin erythema.

Glasses). They could fit over habitual spectacles, at least with the safety lens removed (not shown in photos). Adjustable nose pads are rare on a wrap-around frame design, but were critical to allow proper positioning of the spectacle magnet. The wraparound design was not critical, but seemed to distribute the weight better than standard frames. For some participants, an eyewear strap was needed to prevent sliding.

While IPF during opening at the immediate time point was greater with the MLP compared to the crutch (11.2 vs. 9.3 mm), 11.2 mm was not necessarily better and might suggest some overcorrection. However, by the 20-minute time point opening IPF with the MLP had reduced significantly to 9.2 mm (Fig. 7),

similar to the crutch and perhaps a better amount of opening. Reduction of opening may reflect adjustment of the frame by the patient or some stretching of the adhesive. At the 1-week time point, this amount of opening was maintained; however, most patients had the MLP reapplied at some point during the week (mean adhesion time 5 days) and so the 1-week measurement reflects an adhesion duration of approximately 2 days. While it is useful to know there was no change by 2 days, efficacy with longer intervals remains unconfirmed and it is possible that there would be some further stretching of the adhesive (although patients and therapist reported consistent efficacy). This will need to be determined before a definite replacement schedule can be recommended.

Table 5. Adverse events

ID	Increase Staining	Acuity Baseline	Acuity 1 week	Erythema 1 week	Comfort 1 week	High Mag Image of Lid
S5	II ^a	20/50	20/40	Grade II ^a	9	
S10	0	20/30	20/63	Grade III ^a	2 ^a	

^a Adverse event.

Over the 1 week of use skin erythema occurred in only two participants, increase in punctate staining in only one, and there was no reduction in visual acuity from ocular surface drying. S5 and S10, who experienced skin erythema, had severe bilateral ptosis and felt the need to wear the MLP much longer than instructed. Also, some eyelid skin erythema was present at baseline, as S5 and S10 had been taping the eyelid open before the study. Despite the minor adverse events, both participants requested to continue using the MLP at the end of the 1-week trial due to marked functional improvement provided by the MLP. Perhaps, using the MLP as a first treatment and avoiding taping of the eyelid open would have prevented erythema despite the longer MLP wear times. S12 used the MLP longer than instructed but did not suffer eyelid skin erythema, perhaps because tape was not used before enrollment in the study.

Neither age nor sex were predictive of efficacy due to thin lid skin or other factors; however, the sample was fairly small and wear times were only 2 hours per day: we recommend future studies continue to evaluate these factors. One Asian patient participated in the study and could not be fitted with the MLP or crutch due to low nose bridge anatomy. This problem might be addressed using low bridge fit nose pads, available for standard spectacles. It is worth noting

that when the frame was held manually in the correct position, the blink was restored effectively.

Spontaneous blink during MLP use was possible by some participants, but was not significantly better than with the ptosis crutch. The decreased spontaneous blink had no adverse effect on the cornea, at least over the 1-week trial duration. Improvement in spontaneous blink should be an aim of future studies. Improving the spontaneous blink may be possible by increasing the thickness of the magnet coating to reduce force at the surface.

Before our study, data on nonsurgical correction of ptosis and magnetic correction of ptosis (surgical and nonsurgical) were limited to case series and opinion pieces.^{4,11-16} Our study begins to fill a significant gap in terms of nonsurgical correction during inpatient rehabilitation while not excluding use

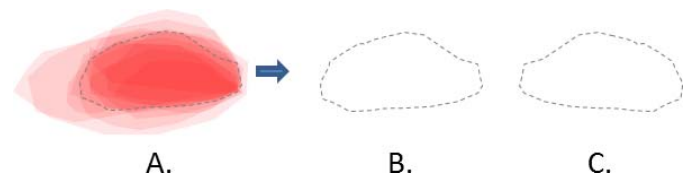


Figure 10. (A) Heat map of the adhesive size for all participants with dashed outline at 50% density to derive an average size of 1.2 cm vertical by 2.5 cm horizontal. (B) The recommended medium-sized swatch template for the right and (C) the left eyelid.

of data and methodology to advance success with surgical implantation or nonsurgical chronic use. Chronic use for myasthenia gravis, a condition where ptosis often is variable throughout the day and where surgery typically is not offered, is a population that stands to benefit greatly from such technology. However, evaluation of safety for chronic daily use and limitations of wear must be examined with further optimization.

In terms of United States Food and Drug Administration (FDA) approval, the predicate ptosis crutch was exempt from the premarket notification 510(k) submission (similar to glasses and low vision aids), and so the MLP should fall in the same category. However, inquiry with the FDA is recommended before any attempts to translate the technology for clinical use. We expect the cost in the market will be comparable to other spectacle-mounted visual devices but substantially less than for surgery.

This study has several limitations. First, it examined use of the MLP in a very select population of inpatients recovering from neurological disease or trauma with very severe ptosis. Use of the MLP in the community or for longer wear times cannot be endorsed at this time; however, we have begun examining longer term outpatient use with positive results (Singh et al. *Optom Vis Sci.* 2016;93: AAO E-abstract 16118). Secondly, as our present study included continued optimization of the MLP, it required that the clinician fitting the MLP not be masked. Now that methods for fitting are more standardized and initial safety has been established, a clinical trial with randomization where the fitter also is masked and with longer wear times would be possible. Third, the ptosis crutch always was trialed before the MLP, and so order effect is possible and relative efficacy results should be viewed as preliminary. Fourth, MRD is a preferred method for measuring mild-to-moderate ptosis, but had a poor outcome for this study, where ptosis was near total for most patients (Table 1), and a common outcome for opening and closing was desirable. Finally, we did not measure brow position and so the influence of opening from frontalis recruitment is unknown; however, frontalis recruitment cannot fully explain the large improvement in opening from the crutch and MLP.

Conclusion

The MLP represents a simple, inexpensive, and feasible device for temporary correction of severe

ptosis. Longer wear times and chronic use require investigation and are warranted considering the positive results of this trial.

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