

A Prototype External Magnetic Eyelid Device for Blepharoptosis

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Purpose: To test a prototype magnet system (magnetic levator prosthesis) for the ability to comfortably and non-invasively provide eye opening with maintenance of the blink in people with paralytic ptosis and determine preliminary efficacy for short-term clinical application.

Methods: The prototype device consisted of a magnet on a spectacle frame and a micro-magnet array mounted externally on the eyelid. Participants with unilateral CN III palsy (n=3) trialed the predicate (ptosis crutch) and magnet device. Video analysis was used to quantify changes in eyelid opening and subjective responses were documented with a rating scale. A 20-minute and then a 1-week trial were offered.

Results: The magnetic levator prosthesis device was effective to provide eye opening while allowing, at minimum, a volitional blink without ill effects on the eyelid skin or ocular surface. Comfort scores ranged from 6 to 9 out of 10 over 3 evaluations. All patients chose an extended trial of the magnet device and reported continued 8-9/10 comfort and efficacy after the extended 1-week trial.

Conclusions: Comfortable and effective restoration of eye opening with maintenance of the blink is feasible using external static magnets and warrants further study.

Translational Relevance: This is the first careful documentation of the successful use of an externally mounted static magnet system to treat paralytic ptosis.

Introduction

Blepharoptosis, a complete or partial impairment of eye opening, has many etiologies from congenital to acquired. Surgery is a common treatment,¹ however it is not effective for all patients and currently lacks an effective and long-lasting, nonsurgical alternative. The only commercially available

external device is the ptosis crutch,² which uses a wire attached to the patient's eyeglass frame to mechanically hold the eyelid open. In the authors' experience, problems with this approach are that the crutch prevents the eye from fully closing causing ocular surface drying, it has to be continually adjusted, and intuitively might injure the eye if the patient were to fall or be struck by a blunt object.

Table 1. Participant Characteristics

	Age, y	Etiology	Acuity, logmar OD, OS	Estimated MRD, mm, OD, OS
1	45	Craniopharyngioma	0.40, 0.08	−5, 3
2	52	Meningioma	0.78, 0.08	−5, 4.7
3	66	Traumatic brain injury	0.40, 0.10	−5, 3.8

In many types of ptosis, while opening of the eye is impaired, the neuromuscular complex for eye closure (orbicularis oculi muscle and cranial nerve [CN] VII) is intact.¹ This includes many common types of ptosis such as aponeurotic ptosis, CN III palsy, and some types of congenital ptosis.¹ In these cases the ptosis might be alleviated using a permanent magnet system to pull the eye open.³ Ideally, the static force exerted by the permanent magnet to open the eye would be easily overcome by the orbicularis oculi, assuming the force of the magnet is not too great. This should restore the ability to open the eye while still allowing eye closure using widely available and inexpensive materials, and might be applied externally without surgery.

Despite this seemingly straight-forward application, thus far permanent magnets for ptosis have not become an available treatment. It is possible that earlier magnetic materials lacked the necessary strength (at sizes/weights that were acceptable to patients), or methods of implantation or external mounting were not effective. Using such a magnetic device, correction of ptosis with maintenance of eye closure may be possible either as a volitional eye closing or perhaps even as a reflexive blink.

A newer class of permanent magnets made of alloys of neodymium (Nd), iron (Fe), and boron (B) might provide the technology needed to develop a feasible external magnetic device for ptosis. They generate the strongest static magnetic fields yet possible, (1.3 T compared with 0.4 T of conventional ferrite magnets)⁴ with exceptional uniaxial magneto-crystalline anisotropy, which makes them resistive to demagnetization.⁵ The increased magnetic force at a fraction of the size has led to attempts for other medical applications including implantation for gastroesophageal reflux disease,⁶ dental prosthetics,⁷ ocular reconstructive surgery,⁸ and glaucoma.⁹

Difficulties achieving external nonsurgical adhesion to the skin of the eyelid may be solved with hydrocolloid-based medical adhesives (e.g., Tegaderm; 3M Corporation, St. Paul, MN),¹⁰ already used for intravenous (IV) catheter securement, wound dressing, and as a protective eye covering.¹¹ Hydrocolloids are extremely thin, transparent, and oxygen permeable

with an established safety profile for days to weeks of wear. The hydrophilic properties¹¹ are beneficial on the eyelids, which are often moist.

The primary aim of the research reported in this manuscript was to determine the feasibility of alleviating ptosis using an externally mounted, static magnet system to provide opening of the eyelid while maintaining the ability (at minimum) to volitionally close the eye. Secondary aims were to gather preliminary data on safety and patient comfort and perceived function of the magnetic device compared with the ptosis crutch.

Methods

Participants were inpatients at Spaulding Rehabilitation Hospital Boston with paralytic ptosis. The study was approved by the institutional review board of Partners Healthcare Human Research Committee, and research adhered to the tenets of the Declaration of Helsinki. Three patients were screened, enrolled, and completed the study; characteristics are provided in Table 1. All three cases involved complete right cranial nerve III (CN III); two were caused by brain tumor and one by trauma. Unilateral CN III palsy is a good model for testing the development of a magnetic system since it is a relatively common severe unidirectional paralysis of eye opening (26% of ocular cranial nerve palsies),¹² and the intact eye provides a reference. Visual acuity was measured at baseline (Table 1) and the end of the 1-week assessment.

Marginal reflex distance (MRD), or the distance between the corneal light reflex/reflection and the upper eyelid margin, is a measurement for presence and degree of blepharoptosis. In our subjects, there was complete eyelid ptosis, which prevented MRD measurement. Therefore, a “negative” MRD was estimated based on the position of the upper eyelid below the corneal light reflex/reflection (Table 1).

The “magnetic levator prosthesis” device consisted of a ½ × ½ inch neodymium-52 (NdFeB) axially-magnetized cylinder (K&J Magnetics, Pipersville, PA) mounted on a spectacle frame (Fig. 1) using thermoactive shrink tubing (Versafit; TE Connectiv-

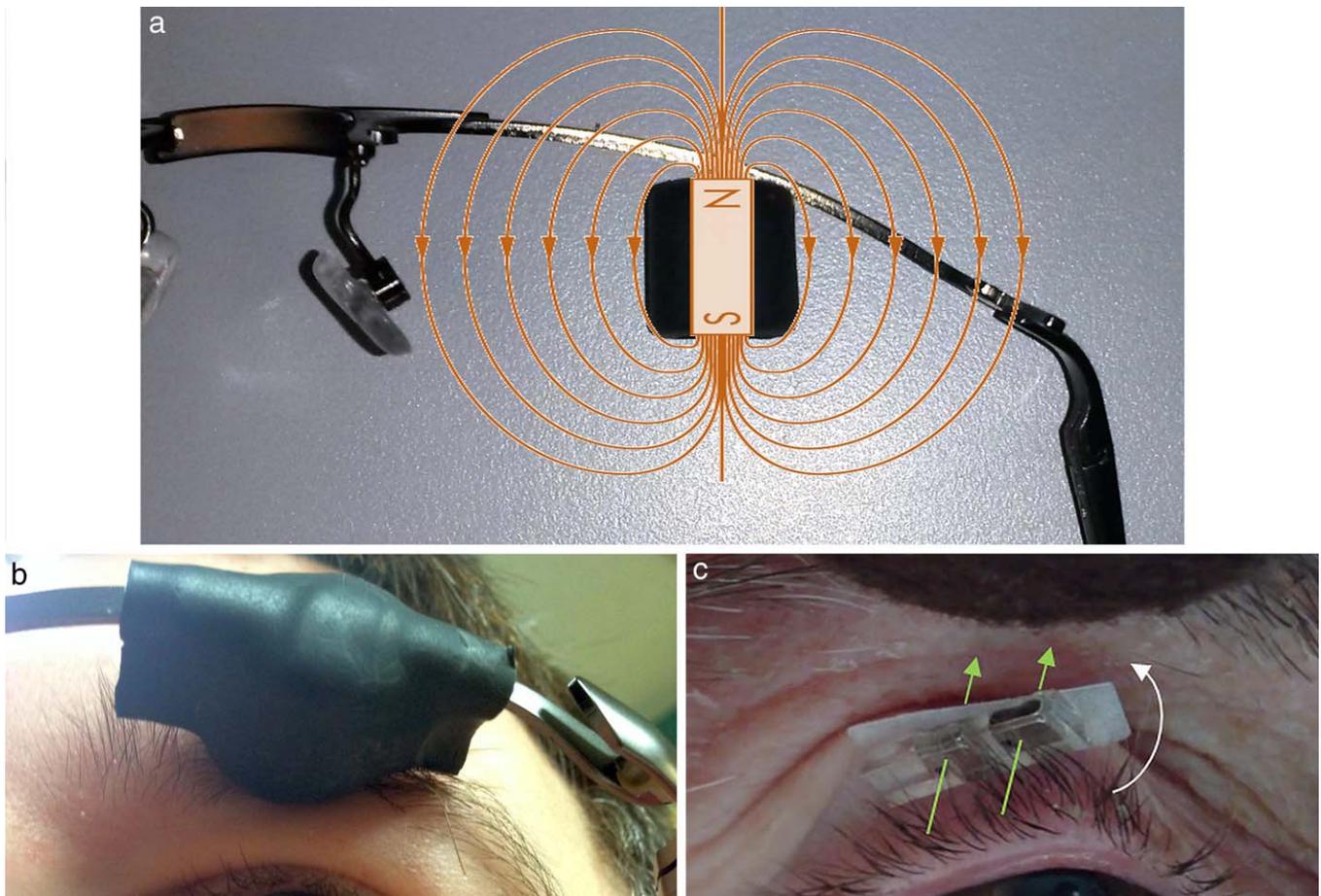


Figure 1. Photo schematic of the spectacle magnet design. (a) The magnet shown without the shrink tubing to illustrate the orientation. The magnetic lines are positioned perpendicular to the upper eye wire. (b) When worn, the magnet is in physical contact with the brow. (c) When combined with the lid magnet array, which is magnetized through thickness (*straight arrows*), a curvilinear force is generated, which moves the lid back toward the globe and then up under/against the superior orbital rim (*curved arrow*). Early prototypes that placed the poles toward each other were not effective as it pulled the lid out away from the globe, was susceptible to adhesion, and was less comfortable. Note: A double-sided tape was used for this photo rather than the Tegaderm in order to provide a better view of the lid magnet.

ity, St. Paul, MN). The eyelid magnets were produced by embedding permanent NdFeB (N-52) micro-magnets (1/8 in \times 1/8 in) in polydimethylsiloxane (PDMS) biocompatible polymer using soft lithography techniques. The magnets were separated by PDMS, providing a flexible strip that could conform to the lid shape. In addition, this allowed on-demand trimming of the strip (using scissors or artist's knife) and adjustment of the magnetic force according to the severity of the ptosis. The PDMS micromagnet array was attached to the lids by trimming Tegaderm (3M) adhesive to a size just smaller than that of the upper eyelid and draping it over the top of the array. Part of the Tegaderm backing was preserved to aid in handling. The lids were prepped prior to application with a warm wash cloth and an alcohol swab.

Characterization of the force/distance relationship generated by the prototype magnet system is provided (Fig. 2), measured using a scientific grade laboratory scale (Mettler BB 2400; Mettler-Toledo LLC, Columbus, OH). Measurements were obtained by mounting the lid magnet array on top of the scale and slowly (\sim 1 mm/sec) advancing the spectacle magnet toward the micro-array (along a millimeter rule) with the magnet axes arranged as illustrated in Figure 1. Video images which captured the millimeter rule and the scale read-out were used to document the measurement.

Study Procedure

Patients first trialed the ptosis crutch (Wilson Ophthalmics, Mustang, OK) followed by the mag-

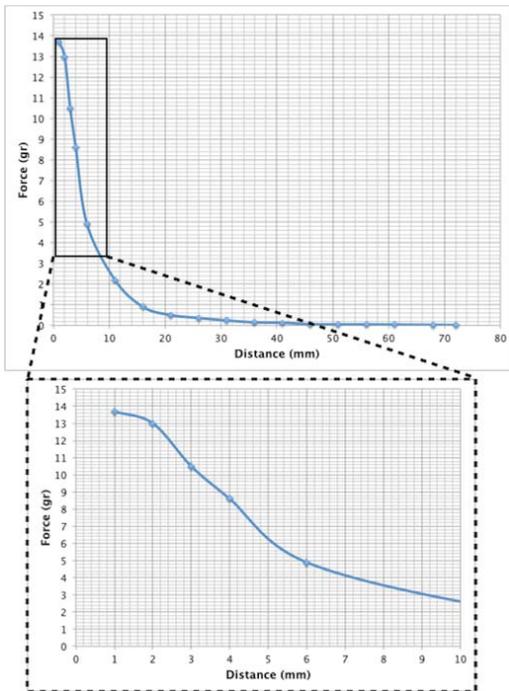


Figure 2. Force to distance plot using the prototype magnetic device. The x-axis represents the distance from the spectacle magnet to the lid magnet (mm) and the y-axis represents the force between the two magnets (g). The *lower panel* is an exploded view of the force generated at the distance range 1 to 10 mm.

netic levator device. The patient was not told which was the experimental and which was the predicate device. Video recording of the blink was performed, and a survey was used to document subjective response including a 10-point rating system for comfort and efficacy. At the completion of the initial fitting, the patient was asked if they would like to continue wearing the device for an additional 20 minutes. The same data was collected at the end of the trial. If ratings were 6 of 10 or better, the patient was

given the opportunity to participate in an extended 1-week trial, after which the video and rating scale data were again collected. The clinician evaluated the cornea with sodium fluorescein and rated the eyelid skin integrity.

Video Analysis

The interpalpebral difference was measured by two ophthalmologists not familiar with either device, and compared for inter-rater agreement. The first rater selected three clips from each video file where the fellow eye was resting open naturally, and then measurements were taken by both raters on those same clips. The separation (mm) between the upper and lower lids (interpalpebral fissure size) was measured at the point of largest separation between the lid margins at the insertion of the lashes (**Fig. 3**), averaged for the three clips selected from each video. The interpalpebral fissure difference was calculated as the difference between the right and left eye interpalpebral sizes. These measurements were performed in an identical manner for trials with the ptosis crutch and for trials with the magnet device (for full protocol, see [Supplemental Materials](#)).

Statistics

Inter-rater agreement was assessed by intraclass correlation coefficient (ICC), concordance correlation coefficient (CCC) and plotted using scatter diagram. The Statistical Package for the Social Sciences (SPSS, IBM, NY, USA) v17 was used for statistical analysis.

Results

Inter-rater agreement using ICC for single measures was 0.984 (95% confidence interval [CI]: 0.9718–0.991) and using CCC was 0.9836 (95% CI: 0.9713–

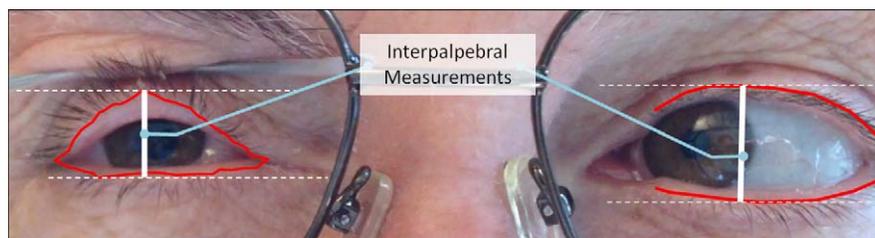


Figure 3. Example of a video clip used for measurement of the interpalpebral fissure difference in a patient with right CN III palsy, when wearing the ptosis crutch. Interpalpebral size was measured (*thick white line*) as the amount of greatest lid separation (*horizontal dashed line*) from the point of insertion of the lashes (*red lines*) when the fellow eye (*left*) was resting open naturally. In this example, the right lid is propped up with the crutch, but still not fully open relative to the fellow eye.

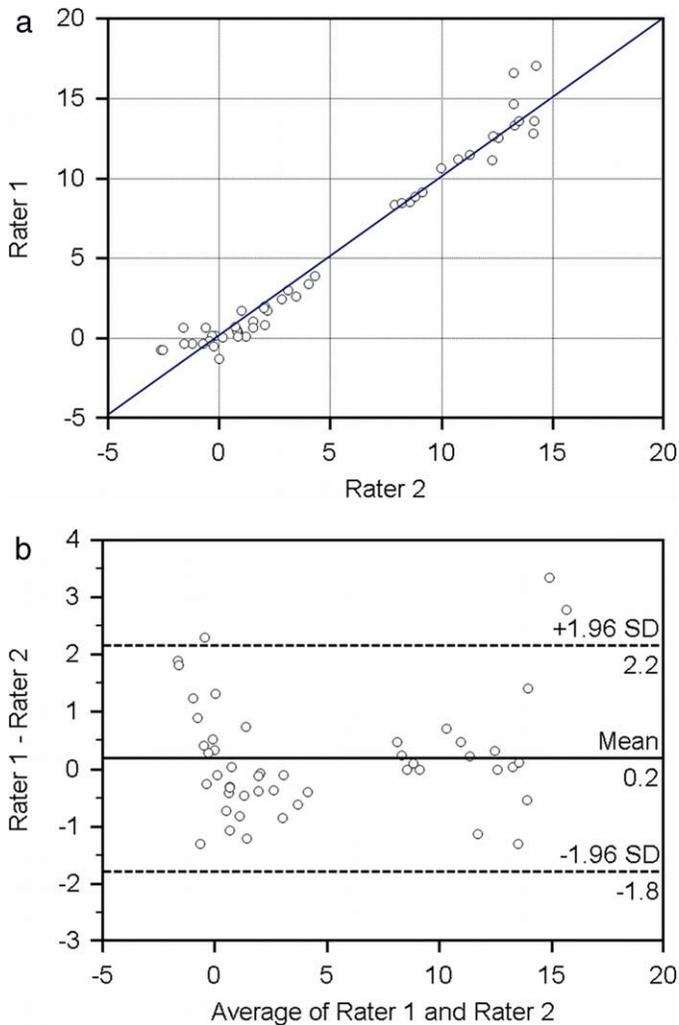


Figure 4. Graphical analysis of inter-rater reliability. (a) Inter-rater scatter plot showed excellent concordance between raters. (b) Bland Altman plot showed that almost all measurements were within ± 1.96 of the SD of the differences.

0.9907). Pearson's r for precision was 0.9845 and bias correlation factor C_b for accuracy was 0.9991. Inter-rater scatter plot showed excellent concordance between raters, Figure 4A, with Bland Altman plot showed that almost all measurements were within ± 1.96 of the SD of the differences, Figure 4B. The data in Table 2 represent the pooled interpalpebral measurements of both raters.

Immediate Response

All three patients showed improved eye opening with the magnetic levator device and the ptosis crutch, Table 2, (Figs. 5, 6) Supplementary videos. The interpalpebral difference was reduced by both devices

and slightly better with the magnet than the ptosis crutch for all three patients (Table 2).

All three patients reported good comfort and efficacy with the magnetic levator device. Efficacy of the ptosis crutch was also rated highly for two of the patients, however S2 reported poor efficacy of the crutch compared with the magnet device (Fig. 6). S3 responded well to both devices reporting similar initial comfort and efficacy between the crutch and the magnet (Table 2). S3 reported efficacy one point higher for the crutch (9/10 compared with 8/10 for the magnet device). For S3, there was some under-correction with the crutch and over-correction with the magnet.

Extended Trials

All three patients chose to wear the magnet device for an extended 20-minute trial. Objective measures of eye opening were still good at 20-minutes and 1-week (there was a small fluctuation [~ 1 – 2 mm] in interpalpebral difference related to positioning of the glasses), see Table 2. Comfort and efficacy at the end of the 20-minute trial were still good (Table 2), and eyelid skin irritation and corneal staining were rated as 0 of 10 for all patients.

After the 20-minute trial, all three patients chose to wear the magnet device for a 1-week trial. They were advised to wear the device 30 to 60 minutes per day. After 1-week, the first patient reported approximately 1 hour of wear per day with a comfort rating of eight and efficacy of nine. The lid magnet became detached on two occasions, and was successfully reapplied by the patient or the caregiver. The second and third patients also had a successful 1-week trial with 30 to 60 minutes of wear per day with comfort and efficacy ratings of nine and eight respectively, without eyelid skin irritation or ocular surface staining. The lid magnet remained adhered for the entire week. Interestingly, none reported double vision during the short or extended trials. There were some reports of visual confusion, consistent with the strabismus.

Discussion

This work provides proof of concept for the feasibility of reversible, nonsurgical correction of ptosis with maintenance of blinking using externally mounted micro-magnets on the eyelids of patients with paralytic ptosis for up to 1 week for 30 to 60 minutes per day. While these short wear times may be immediately beneficial for some patients (i.e., bilateral

Table 2. Interpalpebral Fissure Difference With and Without the Devices and Participant Comfort and Efficacy Ratings Immediately, After 20 Minutes of Wear, and After 1 Week of Wear

Patient	Trial	Interpalpebral Fissure Difference, mm			Ratings (x/10)			
		No Device	Crutch	Magnet	Magnet		Crutch	
					Comfort	Efficacy	Comfort	Efficacy
S1	Immediate	14.8	0.9	0.1	9	5	5	9
	20 min				9	5		
	1-week				8	9		
S2	Immediate	10	3.6	1.3	8	8	5	6
	20 min				9	9		
	1-week				9	9		
S3	Immediate	13.1	0.5	−0.7	8	8	8	9
	20 min				6	10		
	1-week				8	8		

CN III, myasthenia gravis), longer wear times of 5 to 7 hours per day would be ideal. Further investigation is needed before longer wear times can be recommended.

A challenge encountered during the application of the prototype lid device was attaching the lid magnet. We first attempted using a double-sided adhesive (Eyeclose; FCI Ophthalmics, Pembroke, MA) as has been reported previously.¹³ However, the adhesion was insufficient to withstand the continuous force provided by the external magnet. The next attempt was using Transpore tape (3M) over the top of the lid magnet, however this was also not ideal in terms of comfort and only provided a modest increase in adhesion time. Tegaderm was the most effective adhesive tested, however it is extremely thin and so application required some skill.

Maintaining apposition of the lid to the globe was a problem in early prototypes. If not addressed, this could cause irregularities in the tear film leading to desiccation of the cornea and discomfort with extended wear. The most effective method was to orient the lid magnet poles along the anterior/posterior axis rather than superior/inferior (up toward the spectacle magnet). This caused the lower margin of the lid magnet (and attached eyelid) to rotate toward the globe before lifting, as illustrated in Figure 7 and photo documented in Figure 1C. Still it is evident, for example, in patient S2 in Figure 6C that apposition was still potentially a problem. More sophisticated video analysis of the eyelid is planned to confirm the benefit of this technique and to continue to improve lid apposition.

This investigation also allowed a second look at

the conventional wisdom that patients after unilateral CN III palsy are better off with the ptosis to prevent diplopia. In this small sample, the patients were either not aware of diplopia or it was not a critical factor in satisfaction using the device. It is possible that one of the diplopic images was not as salient due to the large strabismic angle of deviation (and therefore large separation of the diplopic images). The blur resulting from pupil mydriasis is another possibility, however the acuities were fairly good for two of the patients (Table 1) making this explanation insufficient. Accommodative paralysis causing blur in the affected eye may help with suppression of the diplopic image during reading or other near tasks, where diplopia is most likely to be an issue. It is also possible the patients learned to adapt their head posture (turning their head away from the affected eye) to achieve single vision. Alternatively they may have had the strabismus and visual confusion, but found it less bothersome than being monocular, although this was not explicitly expressed by any of the patients. In addition to reduced depth perception, the monocular field is approximately 20° smaller than the binocular field, which might be relevant to the patient's mobility. Even if diplopia is bothersome, there may be a benefit for mobility as well as from attempted or passive movement of the paretic eyelid for recovery of function, similar in concept to repetitive robotic therapy for hemiparetic limbs.^{14,15}

One of the limitations of this device is the incompatibility with static magnetic fields, such as those generated by magnetic resonance imaging (MRI) systems or high voltage direct current (HVDC) lines (e.g., lines from power plants). The use of heavy and

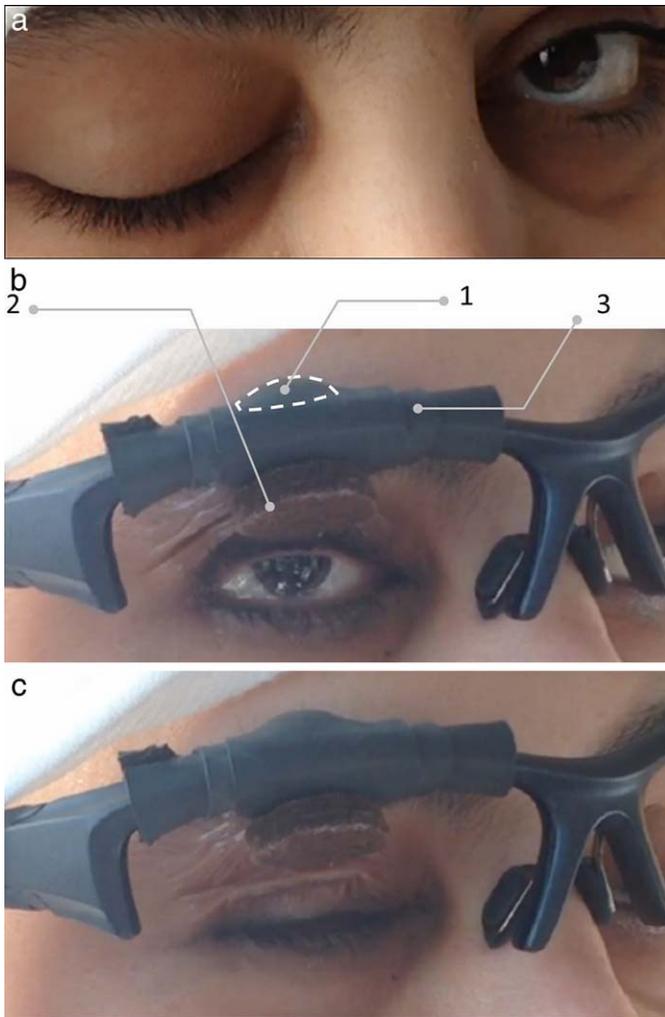


Figure 5. Still-frame images from a video documenting the magnetic levator device on a patient with unilateral third nerve palsy. (a) Inability to open the right lid due to right cranial nerve III palsy. (b) Same patient wearing the magnet system. The spectacle magnet (1) pulls the lid mounted magnet up under the superior orbital rim (lid magnet not visible). A felt pad (2) is an additional precautionary measure to protect against adhesion of the lid magnet to the spectacle magnet. The shrink tubing (3) used to attach the spectacle magnet. (c) Still-frame of the patient midblink. Since the Orbicularis muscle is intact, the patient can overcome the force of the magnet to close the eye.

dangerous equipment or vehicles with this device is not advised. The pragmatic intention of this device is the correction of ptosis (with maintenance of blinking and corneal integrity) during activities of daily living, such as reading, using computers, and watching television. The use of this device in nonoffice occupations as well as for driving requires further evaluation and approval. Walk-through metal detectors, such as those in airports, do not generate static magnetic fields, hence

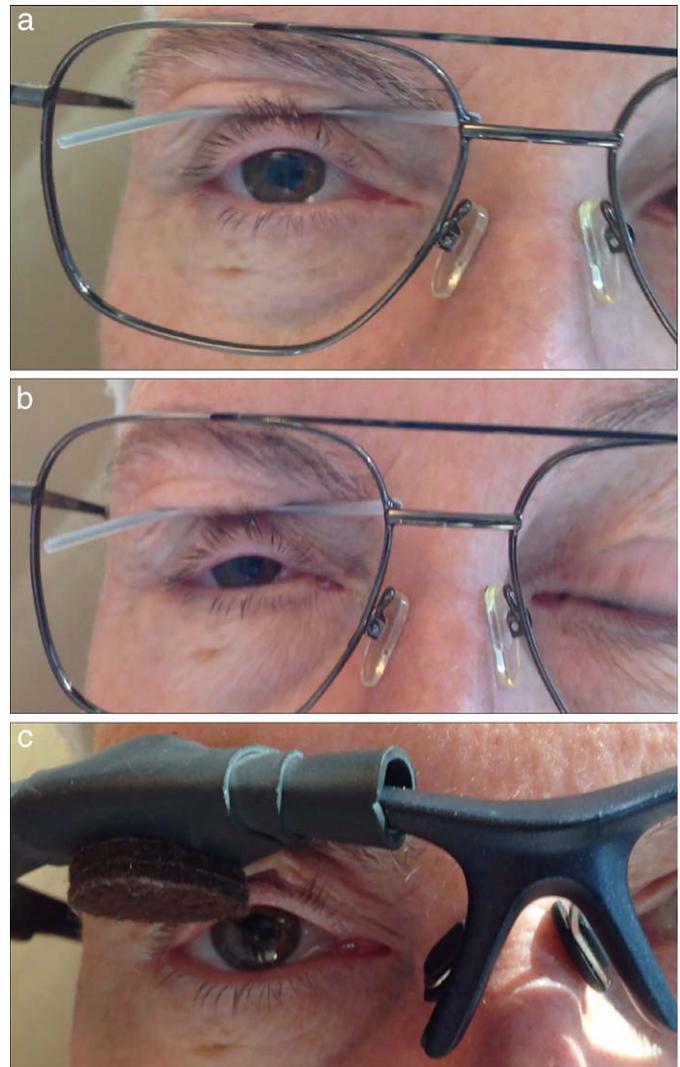


Figure 6. Clips providing a comparison between a ptosis crutch trial and magnet trial on the same patient. (a) Incomplete opening of right ptotic lid, and (b) incomplete closure on the blink (same patient, a few frames apart). (c) Near complete opening using the magnet device.

cannot interfere with this device. However, MRI that generates strong static magnetic fields can only be performed after removal and storage of the magnetic lid magnet and spectacle frame.

In any device study, there are biases that may result in device tolerance exceeding that which might be expected in clinical practice. Biases may also arise from failure in our attempt to mask the patient for the experimental (magnet) versus the predicate device (crutch), making the interpretation of the comparison difficult. For example, it is possible that the patients realized that the magnet device was new technology,

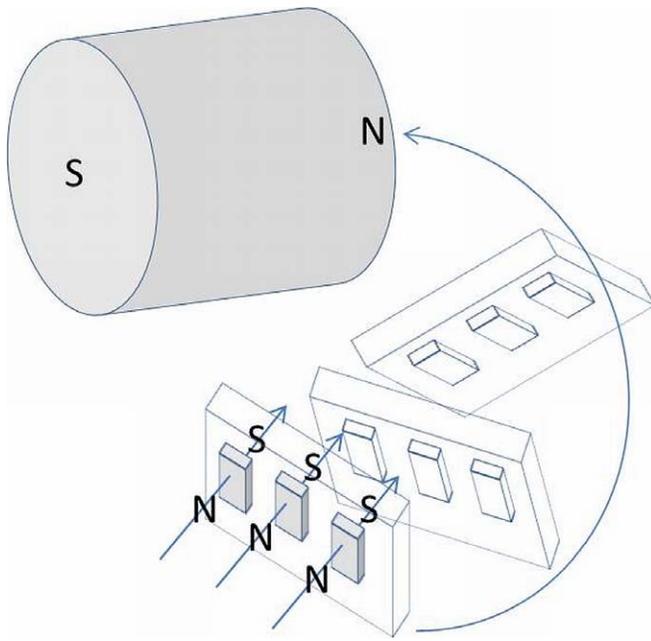


Figure 7. Illustration of the lid array to spectacle magnet orientation, which results in rotation of the array in toward the eye at the inferior edge while being pulled up toward the spectacle magnet.

and therefore desired to engage in an extended trial. S3's choice to do a trial with the magnet device might reflect this bias since he actually rated the comfort and efficacy of the crutch equivalent to the magnet device, possibly for reasons that were not identified by the questionnaire.

Future studies with larger sample size are necessary to further assess patient tolerance using the magnetic device.

Conclusions

Externally mounted NdFeB magnets are a promising, noninvasive technique to comfortably provide eye opening with maintenance of eye closure in paralytic ptosis, and further investigation is warranted. Our current results suggest that this could be an alternative and feasible option compared with conventional treatment using a ptosis crutch or surgery. Further work with larger sample size and with various types of disorders is planned.

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