Effectiveness of the Nictavi™ Tarsus Patch for managing lagophthalmos in children and adolescents

Sarah Guo, BA[1], Melinda Chang, MD[1,2], Mark Borchert, MD[1,2], Sandy Zhang-Nunes, MD[1], Jessica Chang, MD[1], Angeline Nguyen, MD[1,2]

[1]Keck School of Medicine of University of Southern California, Los Angeles, CA, United States.

[2]Children's Hospital Los Angeles, Department of Ophthalmology, Los Angeles, CA, United States.

PURPOSE

- The Nictavi™ Tarsus Patch (NTP) **(Figure 1)** is a new device designed to manage lagophthalmos by conforming to the upper eyelid, supporting the tarsus in maintaining eyelid closure. [1]
- Current treatments available range from medical tape to surgical tarsorrhaphies and eyelid weights, [2, 3, 4] which generally have not been well tolerated by patients.
- We aim to demonstrate NTP's effectiveness in managing lagophthalmos and hypothesize that it will be more effective among paralytic than mechanical types of lagophthalmos.

METHODS

- 20 patients <21 years old with lagophthalmos were prospectively enrolled. Palpebral fissure height (H) was measured in the eyes-closed and primary gaze positions before and after placing the NTP. **(Figure 2)** Measurements were compared using paired t-tests.
- Following a 3-night trial with the patch, parent perceptions of effectiveness, comfort, and complications with the patch were assessed using Likert-scale survey questions.

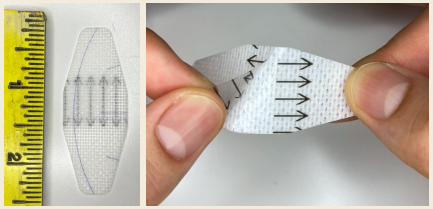

Figure 1: The NTP a) is designed to fit the upper eyelid and b) uses gentle adhesive with flexible backing

RESULTS

- 20 patients completed the study. Mean age was 10.2±5.0 years, 35% were female, 55% were Hispanic.
- 55% had paralytic lagophthalmos, 30% had mechanical reasons (e.g proptosis or scarring), and 15% had idiopathic lagophthalmos **(Table 1)**
- Average H in the eyes-closed and primary gaze positions significantly improved when using the NTP.
- Compared to non-paralytic reasons, paralytic lagophthalmos saw greater improvement in the eye closure with the NTP in the primary gaze positions. **(Table 2)**
- Non-paralytic lagophthalmos was associated with no significant improvement in the palpebral fissure height in the eyes- closed position **(Table 2)**
- Survey results revealed that on a scale of 0-(worst) to 4-(best), the NTP averaged 3.3±0.8 in comfort while wearing, 3.3±1.1 in comfort in removing, 3.6±0.6 in ease of use, and 3.3±1.0 in effectiveness.
- 92% of parents would use the NTP again over other methods tried.

Table 2: Efficacy of the Nictavi Tarsus Patch as measured by mean palpebral fissure height (H) in millimeters with and without the NTP in 2 gaze positions: a) eyes-closed and b) primary gaze

		H (mm) without Tarsus patch	H (mm) with Tarsus Patch	p-value
All (n=20)	Eyes closed	3.5	0.4	**P< 0.001**
	Primary Gaze	9.5	1.1	**P< 0.001**
Paralytic (n=11)	Eyes closed	3.7	0.1	**P< 0.001**
	Primary Gaze	9.4	0.6	**P< 0.001**
Non-paralytic (n=9)	Eyes closed	3.7	1.2	P= 0.12
	Primary Gaze	9.9	1.6	**P< 0.001**

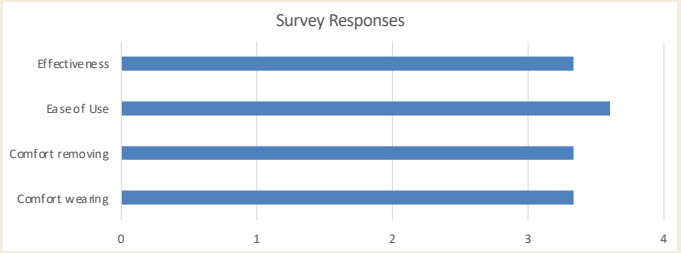

Table 1: Characteristics of the Study Population

Age (mean, SD)	10.2± 5.0
Sex	**Number of patients (%)**
Male	13 (65)
Female	7 (35)
Race	
Hispanic	11 (55)
White	3 (15)
Asian	1 (5)
Black	1 (5)
Other/unknown	4 (20)
Etiology	
Paralytic	11 (55)
Mechanical	6 (30)
Idiopathic	3 (15)

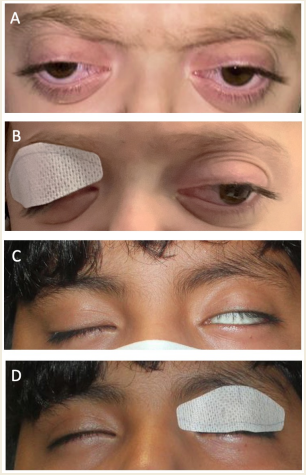

Figure 2: Eyelid position with and without the NTP in a patient with mechanical lagophthalmos from proptosis (A and B), and a patient with paralytic lagophthalmos from facial palsy (C and D).

CONCLUSION

- Nictavi™ is an effective method of eyelid closure for managing lagophthalmos in children and adolescents.
- The NTP is efficacious in managing both paralytic and mechanical lagophthalmos, with patients with paralytic lagophthalmos having greatest benefit.
- The majority of parents preferred the NTP, rating it more favorably in terms of comfort, ease of use, and effectiveness over other eyelid closure methods

REFERENCES

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DISCLOSURES

Knights Templar Eye Foundation (MSB, MYC), Children's Eye Foundation of AAPOS (MYC), Saban Research Institute (MYC), Blind Children's Center (MYC), NIH/NEI 1K23EY033790-01 (MYC)

Horizon (ad board consultant 6/2020), Tarsus (ad board 11/2021), Bruder (ad board 11/2021), and Sciton (consultant)