Report for the Australian and New Zealand Head and Neck Cancer Society Foundation Grant 2024 (General Fund)

Principal Investigator: A/Prof Hubert Low MBBS[1,2,3] (Hons), BSc Med(Hons), FRACS
Associate Investigators: Prof Jonathan Clark[1,3,4], Prof Gregg Suaning[5,6], Dr Jacinta Cleary[6], Dr Orsolya Kekesi[6]

1. Department of Head and Neck Surgery, The Chris O'Brien Lifehouse, Sydney, Australia
2. Department of Otolaryngology – Head & Neck Surgery, Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia
3. Central Clinical School, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
4. Royal Prince Alfred Institute of Academic Surgery, Sydney Local Health District, Sydney, Australia
5. School of Biomedical Engineering, University of Sydney, Sydney, Australia
6. FRIAS/FRESCO Fellow, University of Freiburg, Freiburg, Germany

Title: Overcoming Facial Paralysis - Bionic Lid Implant for Natural Closure (BLINC)

Introduction:

Facial nerve palsy (FNP) affects approximately 2.5 million people worldwide each year and can result in significant functional and psychosocial consequences. Loss of the blink reflex is particularly debilitating, as inadequate eyelid closure compromises corneal lubrication and protection, potentially leading to corneal injury and vision loss. Current approaches, such as lid loading, rely on passive gravitational forces and often result in slow, incomplete and asynchronous eye closure. There remains a significant unmet need for a reliable approach capable of restoring functional and natural-appearing blinking.

The Bionic Lid Implant for Natural Closure (BLINC) is an innovative implantable electromechanical device designed to actively generate eyelid closure. A synthetic sling connected to a magnetic actuator generates downward movement of the upper eyelid, while the natural anatomy facilitates reopening. A previous chronic ovine implantation study established proof-of-concept, demonstrating the feasibility of mechanically generating a blink. The next stage of development required refinement of the surgical approach and implant positioning to improve eyelid movement and establish a reproducible method for achieving effective eye closure.

The aims of this project were to:

1. Refine the surgical implantation approach for positioning the BLINC device within the temporal fossa and routing the synthetic sling to the upper eyelid.
2. Determine the optimal sling pathway and angle to maximise force transfer to the eyelid and minimise mechanical resistance.
3. Characterise the force required to generate eyelid closure in human anatomy and determine whether the force range identified in previous studies was sufficient.

Results:

A human cadaver study was undertaken to evaluate the implantation approach and determine the optimal pathway for transferring force from the BLINC actuator to the upper eyelid. The BLINC device was positioned within the temporal fossa, with access to the upper eyelid established through the lateral orbital wall. Two approaches for routing the synthetic sling were investigated: a 2 mm drilled tunnel through the lateral orbital wall at either 0° or 45°, and removal of a section of the lateral orbital wall to permit a more direct sling pathway. For the latter approach, the implant was positioned at either 45° or 90° relative to the eyelid (Figure 1A). The sling was tunnelled through the upper eyelid superficial to the tarsal plate and secured at the medial canthal ligament.

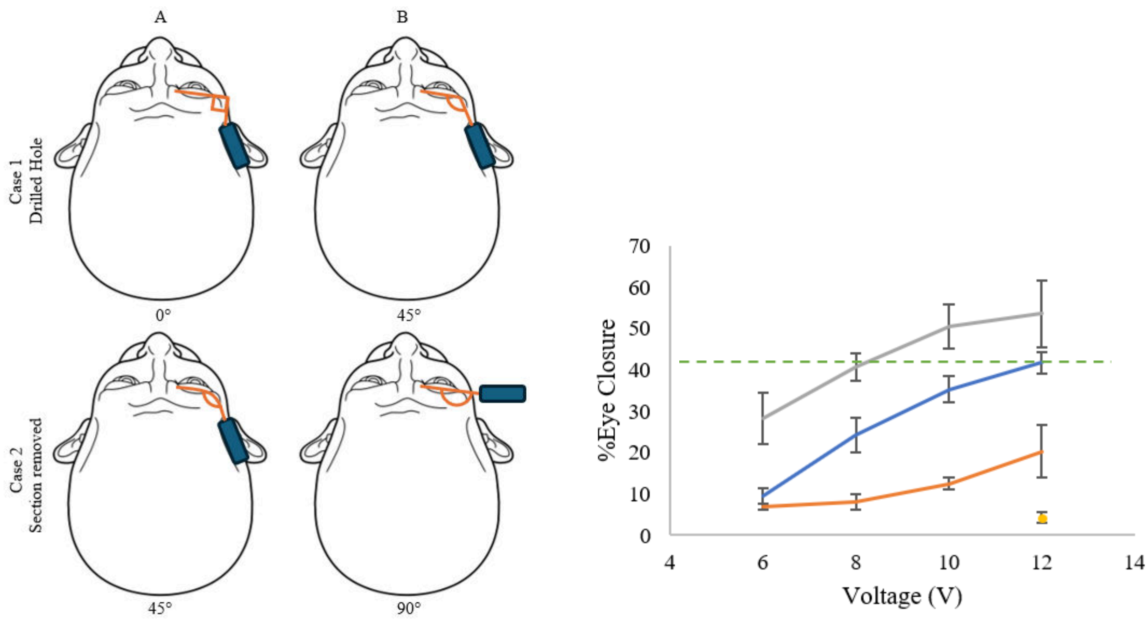

Figure 1: A. The implant and sling positions. Case 1 had a 2mm tunnel drilled through the lateral orbital wall, at either Case 1A: a 0° (perpendicular to the bone), or Case 1B: 45°. Case 2 had a section of bone removed from the lateral orbital wall, equal to the diameter of the medial surface of the implant. The implant position was moved to create a sling angle of Case 2A: 45° or Case 2B: 90°. Right: The percentage of eye closure achieved using different access methodologies. Grey: Case 2A, section removed, 45°. Blue: Case 2B, section removed, 90°. Orange: Case 1B, drilled hole, 45°. Yellow: Case 1A, drilled hole 0°. Green: Maximum value of spontaneous eye closure using lid loading techniques [1, 2]. Mean ± STDEV. N=18 for each data point.

The results demonstrated that the pathway of the sling had a substantial effect on eyelid closure. The configuration involving removal of a section of the lateral orbital wall performed better than the drilled-tunnel configurations. The optimal configuration was achieved when the implant was positioned at 45° to the eyelid, allowing the sling to follow a more gradual pathway around the globe. In contrast, the drilled tunnels introduced sharp changes in sling direction, increasing tension within the sling and reducing the force effectively transferred to the eyelid (Figure 1B). The 0° drilled configuration produced no observable movement until the highest voltage was applied.

Eyelid closure increased with increasing actuator force across the tested configurations. The greatest closure was achieved using an 800 mN horizontal force, producing 53.5 ± 8% eye closure in the optimal 45° configuration. This exceeded the maximum spontaneous eye closure reported for conventional lid-loading approaches (2 - 42 % [1, 2]), demonstrating the potential of BLINC to improve upon existing treatment strategies. However, complete eye closure was not achieved. The force required for maximum closure was also greater than the previously reported range of 470–755 mN [3, 4], although this may partly reflect the greater stiffness and reduced compliance of cadaver tissue compared with living tissue.

<u>Conclusion:</u>

The cadaver study successfully addressed the key biomechanical and surgical considerations identified in the funded project proposal. The results demonstrated that an unrestricted sling pathway with a gradual change in angle, following the contour of the globe, provides the most favourable configuration for generating eyelid closure. Positioning the implant at approximately 45° to the eyelid within the temporal fossa produced the greatest closure and provides a practical configuration for future implant development.

The study achieved 53.5 ± 8% eye closure using an 800 mN horizontal force, exceeding the reported performance of current lid-loading approaches and providing evidence that active mechanical eyelid closure is feasible in human anatomy. While complete closure was not achieved, the findings have established important design and surgical parameters for subsequent development of BLINC. Further optimisation of the force range, sling pathway and device design will be required to achieve consistent and complete eye closure and to more closely reproduce the functional and aesthetic characteristics of a natural blink. These outcomes provide an important foundation for progression towards subsequent preclinical evaluation and, ultimately, clinical translation of BLINC for patients with chronic FNP.

<u>References:</u>

1. D. B. Chepeha, J. Yoo, C. Birt, R. W. Gilbert, and J. Chen, “Prospective evaluation of eyelid function with gold weight implant and lower eyelid shortening for facial paralysis,” Arch Otolaryngol Head Neck Surg, vol. 127, no. 3, pp. 299 - 303, 2001, DOI: 10.1001/archotol.127.3.299.
2. J. K. Terzis and S. A. Kyere, “Experience with the gold weight and palpebral spring in the management of paralytic lagophthalmos,” Plast Reconstr Surg, vol. 121, no. 3, pp. 806 - 815, 2008, DOI: 10.1097/01.prs.0000299919.18076.b4.
3. S. Hasmat, S. McPherson, G. J. Suaning, N. H. Lovell, T. H. Hubert Low, and J. R. Clark, “Recreation of eyelid mechanics using the sling concept,” J Plast Reconstr Aesthet Surg, vol. 73, no. 5, pp. 942 - 950, 2020, DOI: 10.1016/j.bjps.2019.12.007.
4. C. W. Senders, T. T. Tollefson, S. Curtiss, A. Wong-Foy, and H. Prahlad, “Force requirements for artificial muscle to create an eyelid blink with eyelid sling,” Arch Facial Plast Surg, vol. 12, no. 1, pp. 30 - 6, 2010, DOI: 10.1001/archfacial.2009.111.