

The novel foreskin
tissue expander non-
surgical phimosis
treatment:
safe, effective in adult
males and improves
patient quality of life.

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Class 1 Medical Device
TGA, CE, MHRA, FDA listed



INTRODUCTION

Men with phimosis can endure pain during sexual activity or simply arousal, due to the tightness of the foreskin.

This often leads to:

**anxiety or depression,
impacting the patient's
quality of life.**

While the mainstay of adult phimosis treatment is circumcision, many men are apprehensive due to:

**perceived risk of pain,
bleeding, hypersensitivity
& reduced sexual
pleasure.**





“We know there's a lot of literature about circumcision to treat phimosis and the benefit of circumcision, but there was really no good scientific study looking at treating phimosis while preserving the foreskin”



PROFESSOR

Eric Chung

Independent Investigator



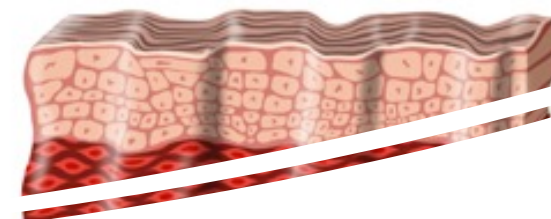
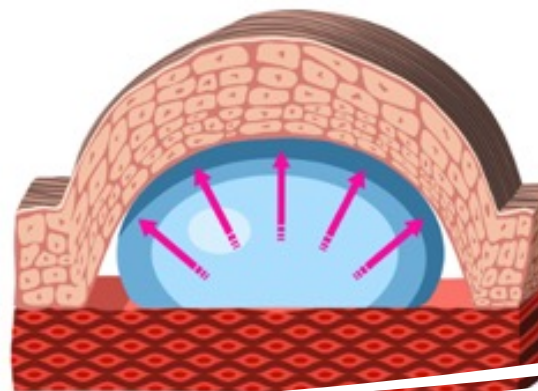
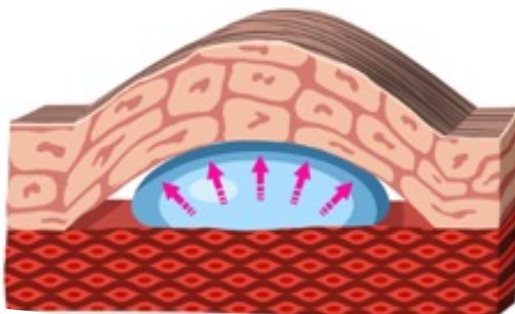
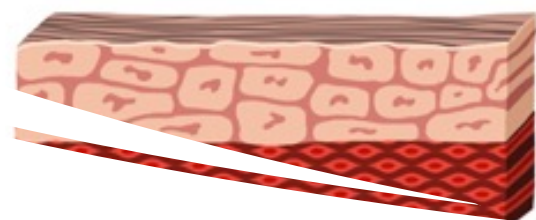
OBJECTIVE

Independent investigator initiated clinical study to establish

a) treatment efficacy in retraction

b) safety and satisfaction
of the novel balloon-based foreskin
tissue expander

c) QOL improvement - comparing patient
pain, discomfort & anxiety during sexual
activity, pre & post treatment.



> 30 mins daily for 6 weeks

> 45,000 patients treated globally

The novel silicone balloon device stimulates the growth of new foreskin cells by applying regular controlled pressure between the foreskin and the glans.

With increased tissue volume, the foreskin is loosened & can then retract properly.



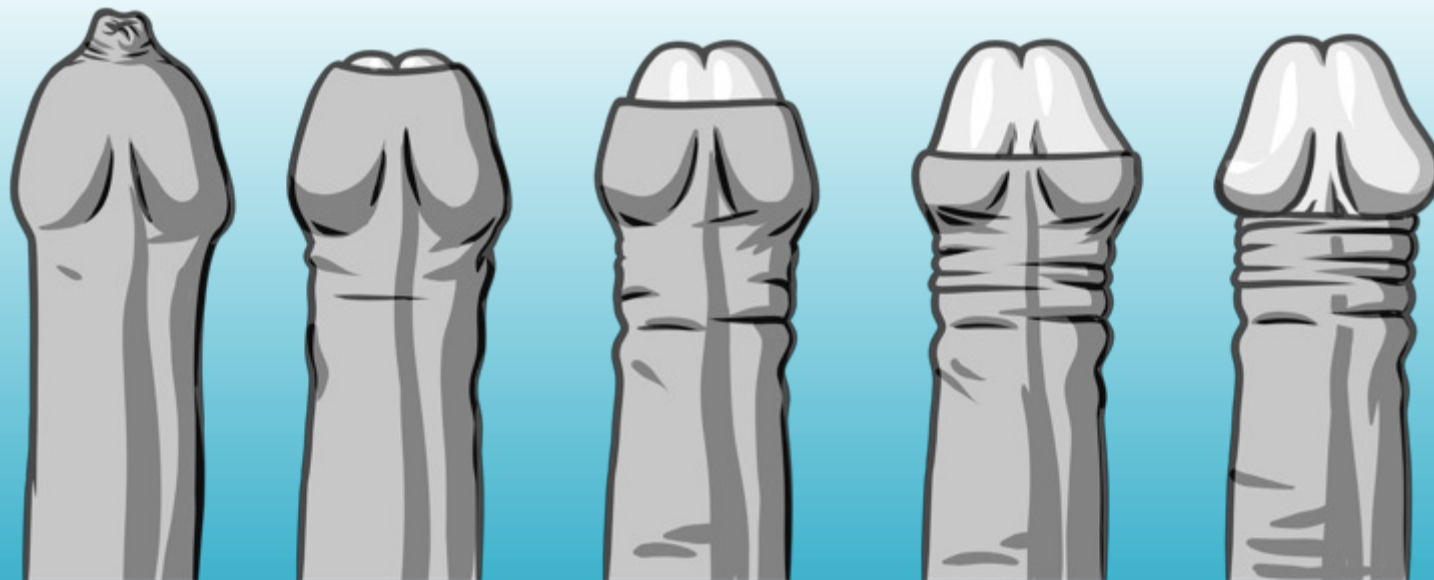
METHODS

The clinical trial used ordinal & scalar outcome variables plus descriptive participant variables.

Participation involved 2 initial visits to a urology clinic, patients were consented, trained on how to deploy the daily treatment and their grade of phimosis determined; 2 phone follow-ups and a final study visit, where their grade of phimosis was reassessed.

Grades of Phimosis were **independently assessed by Consultant Urologist** on a 1-to-6 scale, where grade 1 represents absolutely no foreskin retraction and grade 6 represents full free foreskin retraction.

Participant quality of life with phimosis were surveyed at visit 1 & again at the final Visit, with measures based on general pain / discomfort; pain / discomfort during sexual function and anxiety.



Gillatt Chung Grading
Kikiros scale

Grade 1
5

Grade 2
4

Grade 3
3

Grade 4
2

Grade 5
1



RESULTS

interim review of initial 20 patients. Results in concordance with Independent PMS n=809

Efficacy

- 100% of participants observed **full retraction** of their foreskin (Phimosis measurement 5 or 6) by the final study visit compared with 15% after the first visit. **Zero adverse events**

Tolerability

- 90% reported **no pain** during treatment.

Sexual activity

- 65% experienced **no pain during sexual activity** by the final visit vs 5% at the initial visit.
- 10% experienced moderate pain during sexual activity by the final visit vs 50% at the initial visit.

Anxiety

- 95% reported **reduced level of anxiety** post treatment
- 80% no longer considered circumcision an option post treatment



PROFESSOR
Eric Chung
Independent Investigator



PROFESSOR
David Gillatt
Independent Principal Investigator



CONCLUSIONS

Both investigators, Profs Gillatt & Chung concluded that the novel foreskin tissue expander balloon device is a **safe, effective, well tolerated conservative treatment** for adult phimosis in selected patients, **enabling quality of life improvement** measured by reduced levels of pain, discomfort & anxiety during sexual activity.

REFERENCES

- [1] M. Czajkowski et. al. Male Circumcision Due to Phimosis as the Procedure That Is Not Only Relieving Clinical Symptoms of Phimosis But Also Improves the Quality of Sexual Life
- [2] Kikiros D.S. et al. The response of phimosis to local steroid application. *Paediatric Surgery International*, 1993 8:329-332
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