Introduction & objectives: The Novoglan balloon tissue expander has been developed for non-surgical treatment of phimosis. This device stimulates the growth of new skin cells by applying regular controlled pressure between the foreskin and the glans, thereby expanding the foreskin tissue, allowing it to retract properly. We conducted a clinical trial assessing the efficacy, safety and tolerability of this treatment and compared its findings to the results of the post-marketing survey completed earlier.

Materials & methods: The Novoglan-01 clinical trial is a multicenter (2 sites), observational study that has been approved by the Human Research Ethics Committee of Macquarie University and by the Queensland Metro South Health Human Research Ethics Committee and enrolled twenty patients. The post-marketing surveillance survey was undertaken by Callor8 Consulting Pty Limited to independently survey consenting Novoglan device users with adult phimosis. Eight hundred and three Novoglan users agreed to participate in the survey of which 461 individuals had used the identical Novoglan device used in the Clinical trial. The remainder used an older version of the device and have been excluded from this study. In both instances, users were questioned about the treatment efficacy, safety and tolerability. These measures were self-reported in the post-market survey and independently assessed in the clinical trial.

Results: Both post-marketing survey and clinical trial showed very high efficacy and tolerability of the treatment with 93% and 100% of patients, respectively, achieving foreskin retraction and being satisfied with the treatment. No patients experienced adverse events or serious side effects in both studies. Mild side effects were reported by 10% of the clinical trial participants and were not reported by anyone in the post-marketing survey. Importantly, 85%-95% of users reported reduction in level of their phimosis-related anxiety after the Novoglan treatment.

Outcomes	**Clinical Trial**	**PMS Study**
Efficacy / Satisfaction With Treatment Outcome	100%	93%
Safety - Significant Side Effects	0%	0%
Safety - Mild Side Effects	10%	0%
Adverse Events Reported	0%	0%
Device Usability (Comfort and Usability)	90%	92%
Reduced Anxiety	95%	85%
Consider Future Circumcision if Relapse	20%	N/A
Recommend Novoglan Treatment to Other Phimosis Patients	95%	N/A

Conclusion: Results from the independent Novoglan-01 clinical study are strongly in concordance with the Post Marketing Survey, confirming the novel Novoglan foreskin tissue expander balloon device is a safe, effective and well tolerated conservative treatment for adult phimosis.

FINAL SUBMISSION TO MEET CHARACTER LIMITATIONS

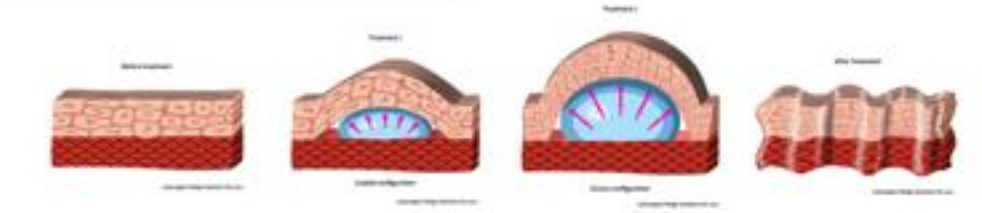
Title:

Comparative review of independent clinical trial data and post marketing surveillance data of the novel foreskin tissue expander balloon device for phimosis in adult males

Topic: Non-Disease specific
Sub topic: Affordable medicine/New Technology
Clinical step: Treatment

Introduction & Objectives:

The Novoglan balloon tissue expander has been developed for non-surgical phimosis treatment. The device stimulates new skin cell growth by applying regular controlled pressure between foreskin & glans, thereby expanding foreskin tissue, allowing it to retract properly. We conducted a clinical trial assessing efficacy, safety & tolerability of treatment & compared findings to results of post-marketing survey completed earlier.



Materials & Methods:

Novoglan-01 clinical trial is a multicenter 2 sites observational study approved by Human Research Ethics Committee of Macquarie University & Queensland Metro South Health Human Research Ethics Committee - enrolled 20 patients.

Post-marketing surveillance survey undertaken by Collabor8 Group Pty Ltd to independently survey consenting Novoglan device users with adult phimosis. n=803 Novoglan users agreed to participate in the survey of which n=461 individuals used the identical Novoglan device as per the Clinical trial. The remainder used an older device version thus excluded from the study. In both cases, users were asked about treatment efficacy, safety & tolerability. All measures were self-reported in the post-market survey & independently assessed in the clinical trial.

Results:

Both post-marketing survey & clinical trial showed very high treatment efficacy & tolerability with 93% & 100% of patients, respectively, achieving foreskin retraction & being satisfied with treatment. No patients experienced adverse events or serious side effects in both studies. Mild side effects were reported by 10% of clinical trial participants but not reported by anyone in post-marketing survey. 85%-95% of users reported reduction in level of their phimosis-related anxiety after the Novoglan treatment.

	Clinical Trial	PMS Study
Efficacy / Satisfaction - Treatment Outcome	100%	93%
Safety - Serious Side Effects	0%	0%
Safety - Mild Side Effects	10%	0%

Adverse Events	0%	0%
Device Usability (Comfort & Usability)	90%	92%
Reduced Anxiety	95%	85%
Consider Future Circumcision if Relapse	20%	-
Recommend Novoglan Treatment to Other Phimosis Patients	95%	-

Conclusions:

Results from the independent Novoglan-01 clinical study are strongly in concordance with the Post Marketing Survey, confirming the novel Novoglan foreskin tissue expander balloon device is a safe, effective & well tolerated conservative treatment for adult phimosis.