Title:
Short and Long-Term Efficacy, Safety, and Usability of Novoglan for Adult Phimosis: Clinical Trial Data vs. Real-World Outcomes from 811 Patients

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Introduction:

Adult phimosis is commonly managed with topical corticosteroids or circumcision. Novoglan, a custom-moulded balloon device for foreskin tissue expansion, offers a non-surgical alternative. While clinical trials report high efficacy, safety, and tolerability, post-marketing surveillance (PMS) provides real-world insight. This review consolidates findings from a clinical trial (TAU 2023), a PMS study involving 811 patients (UAA 2023), and a 2-year long-term follow-up study (USANZ NSW 2024).

Methods:

Three datasets were analyzed:

- **Novoglan-01 Clinical Trial (TAU 2023):** Open-label, multi-center trial (n=20) assessing phimosis resolution over 6–8 weeks of once-daily Novoglan use.
- **Post-Marketing Surveillance (UAA 2023):** Large-scale real-world study (n=811) evaluating usability, safety, and patient-reported efficacy.
- **Long-Term Follow-Up (USANZ NSW 2024):** 2-year post-treatment evaluation of Novoglan-01 participants assessing sustained success and need for further intervention.

Primary endpoints included phimosis resolution, safety, tolerability, and usability. Secondary outcomes examined mental well-being and long-term satisfaction.

Results:

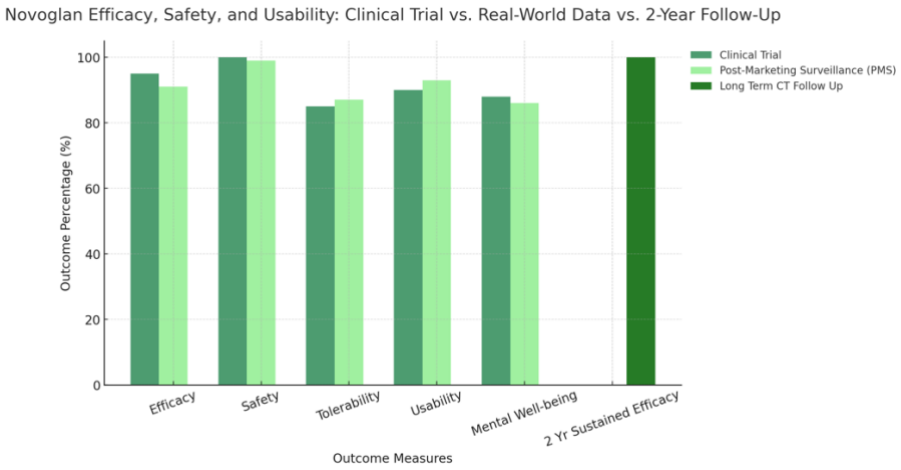
Short-Term (6–8 weeks):

- Clinical trial: 95% (19/20) achieved full prepuce retraction without surgery.

- PMS (n=811): 91% reported successful outcomes, with higher satisfaction linked to the updated device design.
- 15% of trial participants reported mild, transient discomfort at treatment initiation.

Long-Term (2 years):

- 95% (19/20) maintained resolution with no recurrence.
- None of the successfully treated patients required circumcision or further intervention.
- No new adverse effects were reported.



Conclusions:
Combined data from clinical trial, post-marketing, and long-term follow-up confirm Novoglan as a safe, effective, and well-tolerated non-surgical treatment for adult phimosis. High short-term success (91–95%) was sustained at 2 years (95%) with no recurrence or surgical requirement. Minor discomfort was self-limiting and did not affect adherence. These findings support Novoglan as a viable long-term alternative to circumcision and highlight the importance of integrating real-world evidence with clinical trial data in urological device evaluation.