Title:
Long-Term Efficacy and Safety of Novoglan for Adult Phimosis: Staged Comparison of Post-Marketing Study, Clinical Trial, and Two-Year Follow-Up

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Introduction and Objective:
Phimosis in adults is traditionally managed by circumcision, but the Novoglan device provides a non-surgical option for prepuce dilation. Data from both a post-marketing study and a clinical trial previously highlighted Novoglan's effectiveness and user satisfaction. This abstract stages the comparison of post-marketing study data with clinical trial findings and incorporates two-year follow-up results to further evaluate long-term efficacy and safety.

Methods:
The post-marketing study included de-identified survey responses from 461 Novoglan users, assessing efficacy, usability, safety, and mental wellbeing. Following this, the NOVOGLAN-01 clinical trial enrolled 20 patients with adult phimosis, who received twice-daily applications of the device for 4-8 weeks. Participants in the clinical trial underwent evaluations by urologists at baseline, post-treatment, and follow-ups at 6-8 weeks and two years. The data comparison of both cohorts was conducted to analyze trends in efficacy, tolerability, and patient-reported outcomes, with additional data collected on transient side effects in the clinical trial.

Results:
In the post-marketing study, 93.5% of respondents reported effective treatment outcomes, with 91.8% finding the device easy to use and 85.3% experiencing positive mental health impacts. The clinical trial findings were consistent, with 90% of participants achieving improved foreskin retraction post-treatment and 95% reporting reduced anxiety levels. Transient side effects, such as discomfort and itching, were reported by 5-15% of clinical trial participants, aligning with broader post-market results.

The two-year follow-up demonstrated sustained outcomes, with 95% of clinical trial participants maintaining foreskin retraction and no need for further interventions or circumcision. No new symptoms were observed, and the sustained positive impact further supports the device's long-term effectiveness and safety profile.

Conclusions:
The Novoglan post-marketing study, clinical trial, and two-year follow-up collectively affirm the device’s efficacy and safety for adult phimosis management. The consistency between post-marketing and clinical trial data, coupled with the long-term follow-up results, underscores the reliability of Novoglan as a sustainable non-surgical alternative to circumcision. These findings highlight the device’s potential for broad patient application, with enduring therapeutic and mental health benefits.