Updated outcomes from the NOVOGLAN-01 clinical trial: a non-surgical treatment for adult phimosis

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Introduction & Objectives: Phimosis in adult males can cause significant physical and psychosocial burden. Current treatment options often include surgery, with limited non-invasive alternatives. Novoglan is a non-surgical therapy that uses custom-moulded balloons to gradually remodel the prepuce. This study presents updated outcomes from the NOVOGLAN-01 open-label clinical trial, evaluating the efficacy, safety, and tolerability of Novoglan in treating adult phimosis.

Methods: A prospective, open-label clinical trial was conducted at Macquarie University Hospital and Princess Alexandra Hospital. A total of 42 adult males with phimosis were recruited following eligibility screening. Participants applied the Novoglan device twice daily over a 6–8-week treatment period. Efficacy was assessed by measuring changes in phimosis severity (grade 1–6). Safety and tolerability outcomes were collected via patient-reported questionnaires, including impact on pain, sexual function, daily activities, and anxiety/depression.

Results: Prepuce retractability was improved in 78.6% of all study participants with 79.4% of men with higher degrees of phimosis (grade 1–4) achieving full retraction (grade 5–6) after the treatment. General pain or discomfort was reported by 33% prior to treatment, dropping to 12% reporting only slight discomfort post-treatment, with no reports of moderate pain. Among 41 sexually active participants, 90% reported pain/discomfort during intercourse prior to treatment; this reduced to 27% post-treatment, with only 10% reporting it above slight level and 73% reporting no discomfort. Impact on usual activities fell from 9% to 2%, with no cases above slight level. Anxiety or depression, initially affecting 81% of participants, was reduced in 30 individuals (71.4%) with only 16% reporting anxiety or depression after the treatment.

Conclusions: Novoglan demonstrates a strong safety and efficacy profile as a non-invasive, non-surgical treatment for adult phimosis. The treatment significantly reduces physical discomfort, improves sexual function, and alleviates psychosocial impact, including anxiety and interference with daily activities. These updated findings reinforce the benefits of Novoglan therapy in clinical practice and support its use as a first-line conservative treatment option for phimosis.