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Two-Year Follow-Up of NOVOGLAN-01 Open Label Multicentre Clinical Trial: Efficacy and Safety of Novoglan for Adult Phimosis

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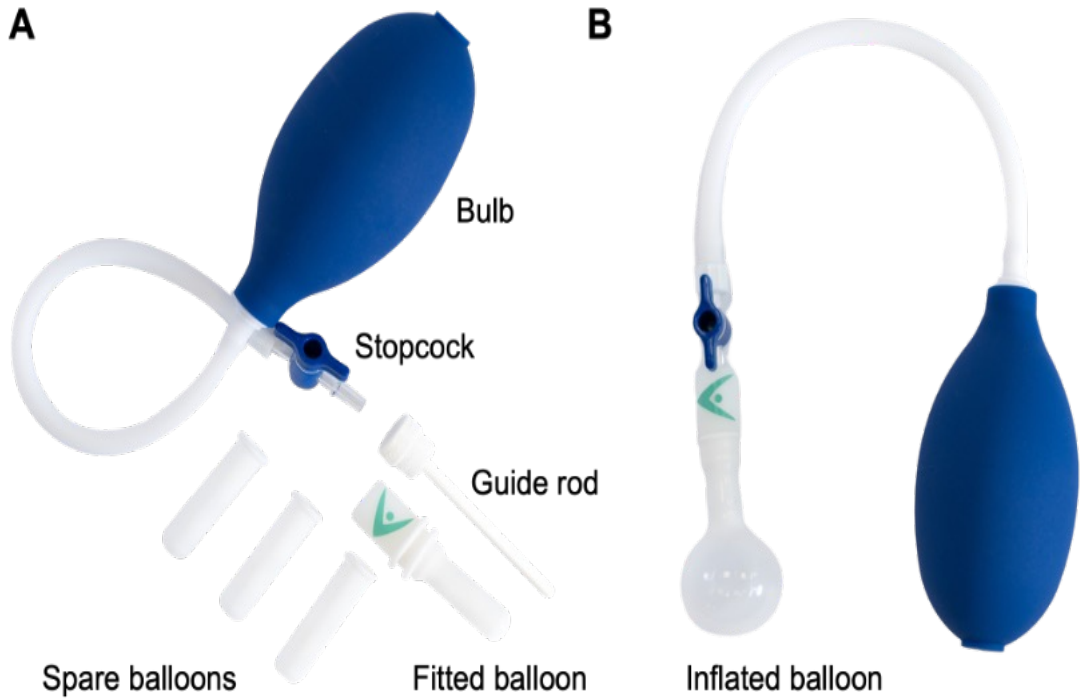
Novoglan device

- Novoglan is a device for non-surgical treatment of phimosis
- It includes a balloon that patient places under the foreskin and inflates to stretch the foreskin and promote the generation of new cells
- The inflation is controlled by the patient via a squeeze bulb
- Application for 15 min twice daily for 6-8 weeks

Application



Novoglan device and its components

The Novoglan-01 clinical trial

- **Twenty men** aged between 20 and 62 with **phimosis** were recruited across 2 sites - Macquarie University Hospital (Sydney, NSW) and Princess Alexandra Hospital (Brisbane, QLD)

- Apart from the **safety** and **efficacy** of the Novoglan, we aimed to assess the impact of phimosis and the treatment on patient's **quality of life**

- All men had the degree of phimosis **assessed by a urologist** before and after the treatment (6-8 weeks) and had several phone/face-to-face follow up during the treatment to assess progress and complete **quality-of-life questionnaires**

- A **two-year follow up** was performed face-to-face or via telehealth to assess the long-term efficacy of the treatment

The Novoglan-01 clinical trial – Results

Safety

- No adverse events or major side effects were reported
- Two patients reported transient pain or discomfort when using Novoglan

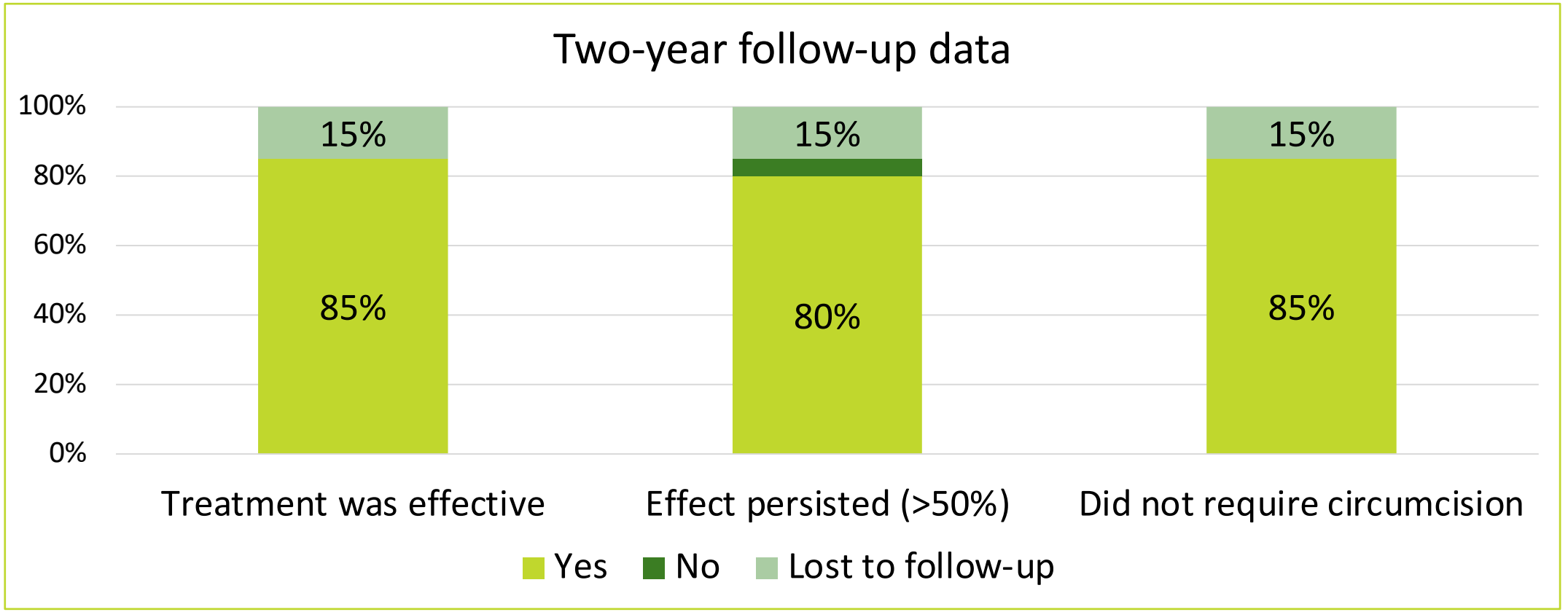
Efficacy

- Novoglan was effective in reducing the degree of phimosis in 90% of patients
- All patients had full retraction of the foreskin after the treatment (Grade 5 or 6 phimosis)

Quality-of-life

- The treatment significantly reduced the level of patient-reported anxiety/depression and relieved pain/discomfort during sexual intercourse in most participants

The Novoglan-01 clinical trial – Follow-Up



Conclusions

- The effects of Novoglan treatment persisted in most patients from the Novoglan-01 clinical trial
- Despite one patient reporting relapse of the symptoms, no patients required circumcision
- This data highlights the potential of the Novoglan treatment as a safe and effective alternative to circumcision
- Additional data is needed to better identify patients that would be more likely to respond to treatment

Thank you

Original Article

Novoglan device for treatment of adult phimosis: Novoglan-01 open-label clinical trial on safety, efficacy and tolerability

Eric Chung[1], Dmitry Polikarpov[2]^, Hubert Mazure[3], Andrew James[4], Hassan Doosti[5], Douglas Campbell[6], David Gillatt[7]

Phimosis grade	Before, n	After, n
1- Absolutely no retraction	1	-
2 - Slight retraction with neither meatus nor glans exposed	7	-
3 - Partial retraction, just sufficient to see the glandular meatus	6	-
4 - Partial retraction, exposing part of the glans	3	-
5 - Full retraction of the foreskin, tight behind the glans	3	10
6 - Full and free retraction of the foreskin, no tightness behind the glans	-	10

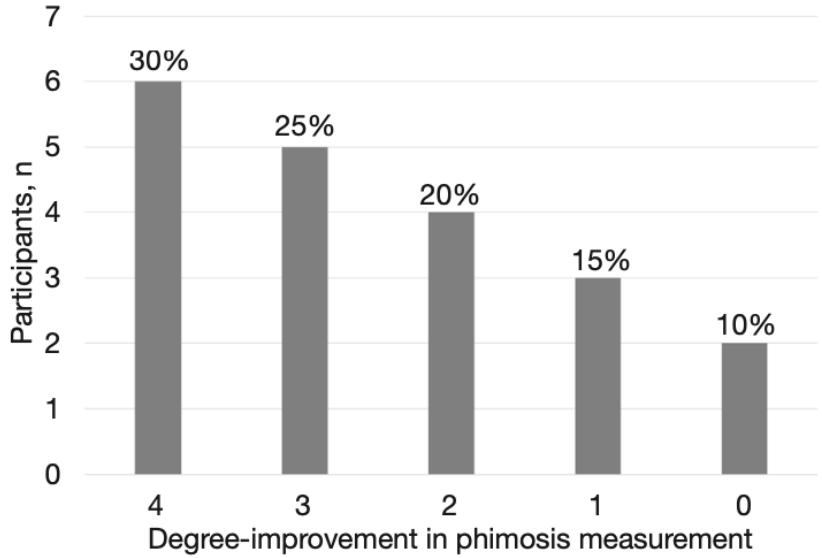


Figure 4 Bar-chart representing the number of participants with 4-, 3-, 2- and 1-degree improvement or no change of their phimosis measurement.

Table 5 The number of participants with phimosis measurement rank 1–6 at first visit and their respective distribution at final visit (count and percent)

Score at Visit 1	Number of patients, Visit 1	Score at Final Visit		
		1–4	5	6
1	1 (5%)	–	1	–
2	7 (35%)	–	2	5
3	6 (30%)	–	3	3
4	3 (15%)	–	2	1
5	3 (15%)	–	2	1
6	–	–	–	–
Total	–	–	10 (50%)	10 (50%)