

Title: Efficacy, tolerability, and safety of two generations of Novoglan device designed for conservative treatment of adult phimosis.

Author(s):

Dmitry Polikarpov

Organization(s) Department of Urology, Royal Prince Alfred Hospital

Position(s) Urology SRMO

Address: Royal Prince Alfred Hospital, Camperdown, NSW, Australia.

Phone number: +61 04 1347 4975

Fax number: +61 02 9812 3836

Email address: dpol7646@uni.sydney.edu.au

Eric Chung

Organization(s) Department of Urology, Princess Alexandra Hospital

Position(s) Urologic surgeon

Address: Princess Alexandra Hospital, Woolloongabba, QLD, Australia

Phone number: +61 (07) 3832 1168

Fax number: +61 (07) 3832 8889

Email address: ericchg@hotmail.com

Hubert Mazure

Organization(s) HGM Consultants

Position(s) Director

Address: HGM Consultants, Winston Hills, NSW, Australia.

Phone number: +61 (0) 404 199 146

Fax number: +61 (0) 404 199 146

Email address: humazure@hotmail.com

Andrew James

Organization(s) Platigo Solutions

Position(s) CEO

Address: Platigo Solutions Pty Ltd, Roseville, NSW, Australia.

Phone number: +61 401987047

Fax number: +61 401987047

Email address : andrew.james@novoglan.com

Hassan Doosti

Organization(s) School of Mathematical and Physical Sciences, Macquarie University, NSW, Australia.

Position(s)

Address: School of Mathematical and Physical Sciences, Macquarie University, NSW, Australia.

Phone number:

Fax number:

Email address:

Douglas Campbell

Organization(s) Minomic International Ltd., Sydney, NSW, Australia.

Position(s)

Address: School of Mathematical and Physical Sciences, Macquarie University, NSW, Australia.

Phone number:

Fax number:

Email address:

David Gillatt

Organization(s) Macquarie University Hospital

Position(s) Urologic surgeon

Address: Macquarie University Hospital, Macquarie University, NSW, Australia

Phone number: +61 02 9812 3838

Fax number: +61 02 9812 3836

Email address: David.gillatt@mq.edu.au

Presenter: Dr Dmitry Polikarpov is a medical practitioner in Sydney, Australia, aiming to join a urological training program. He has experience in basic, translational and clinical urology research and holds a Master of Research and a Doctor of Philosophy degrees focusing on urologic oncology.

Purpose:

Novoglan is a device for non-surgical treatment of phimosis. It consists of a balloon that is placed under the foreskin and inflated by the patient in a controlled manner to produce stretching of the foreskin and promote generation of new skin cells. The inflation had been originally controlled by an air plunger, which was later replaced by a bulb and a stop cock, while the balloon was changed from latex to medical-grade silicone. We conducted a post-marketing survey to compare the two generations of the device, assess patient-reported efficacy of the Novoglan treatment as well as its usability, tolerability, safety and impact on mental wellbeing.

Methods:

Specifically designed questionnaires were emailed to 9700 Novoglan customers. Complete responses from 811 customers were de-identified and included in the analysis.

Results:

The use of Novoglan with a bulb and a stop cock instead of an air plunger and change of the balloon material produced an improvement in patient-reported efficacy from 85.0% to 93.5%. Usability was also improved, with the number of patients reporting difficulty in Novoglan use dropping from 13.8% to 6.7%. Similarly, the number of patients willing to recommend Novoglan treatment to other men increased from 92.2% to 98.1%. Neither group reported any side effects that required cessation of the treatment or medical intervention and 96.3% of all patients were able to tolerate the treatment. Of note, 97.7% reported that phimosis had a negative impact on their mental wellbeing and 88.8% reported that treatment with Novoglan had improved it.

Conclusion(s):

The Novoglan post-marketing study revealed improvement in patient-reported efficacy, usability, tolerability and overall satisfaction with introduction of the bulb and stop cock into the Novoglan device. It demonstrated exceptional safety of the Novoglan treatment with no significant side effects reported and improvement in mental wellbeing of almost 90% of patients. These findings highlight the role of Novoglan treatment in non-surgical management of phimosis.

Ethical Approvals.

Macquarie University HREC approval letter reference 520193 3799 8816 dated 11 June 2019 and approval letter reference 52020 3799 21701 dated 16 October 2020) and Royal Alexandra Hospital (Queensland Health Metro South HREC approval letter dated 17 November 2020 under reference HREC/2020/QMS/66682.

Funding acknowledgements:

The work was financially supported by Platigo Solutions.

Publication/previous presentation/award(s):

This work has not been previously published or presented.