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A patient centric review of the experiential & clinical data associated with the safety, efficacy, tolerability & usability of the Novoglan foreskin tissue expander to treat uncomplicated phimosis - post marketing surveillance program

Introduction:

A market review of foreskin tissue expander devices was conducted in 2005 to assess the availability of devices to treat uncomplicated adult phimosis and to gage their efficacy, tolerability, safety and usability via targeted online survey [27].

The results were analysed and it was concluded that existing devices were inappropriate or sub optimal [27]. A wide ranging review of the literature about phimosis as well as skin stretching generally, resulted in the development of the Novoglan medical device that uses a specialised balloon to stretch the foreskin and expand the delicate tissue[28]. The product prototype was developed in 2005 and was formally launched in 2006.

This paper provides a patient centric review of the experiential and clinical data associated with safety, efficacy, tolerability and usability of the Novoglan foreskin tissue expander to treat uncomplicated phimosis, as captured in the manufacturer and sponsors post marketing surveillance program.

Phimosis:

In simple terms, phimosis refers to “a condition in which the foreskin of the penis cannot stretch to allow it to be pulled back past the glans” [1]. More technically, Cold and Taylor refer to phimosis as being characterized by a stenosis of the foreskin resulting in the inability of the prepuce to retract over the glans. They also make a distinction between pathological phimosis and physiological phimosis. Pathologic phimosis can occur at any age among uncircumcised adult men and is frequently associated with infections such as balanitis. [2]

The incidence of adult phimosis is open to conjecture as research approaches have been inconsistent, however, some authors report an incidence of around 1% [3] but the incidence of adult circumcision typically linked to phimosis has been reported as high as 15.8% in the UK [4]. Schoberlein [5] found phimosis in 8.5% of 3,000 men mostly aged 18 to 22 and representing 10.4% of the uncircumcised men. Rickwood, as well as other authors, has suggested that true phimosis is over-diagnosed due to failure to distinguish between normal developmental non-retractability and a pathological condition [6].

Male phimosis is characterized by a stenosis of the foreskin resulting in the inability of the prepuce to retract over the glans. Physiological phimosis is a condition in infants and boys which usually disappears by the age of 10 [1,2].

Pathologic phimosis can occur at any age among uncircumcised adult men and is frequently associated with infections such as balanitis, chronic inflammation, repeated catheterization, forcible foreskin retraction and injury [1]. We refer to phimosis in the absence of infection, observable inflammation, injury, other disease, and scar tissue, as “uncomplicated phimosis’.

Grading Severity of Phimosis:

To assist with a more robust understanding of efficacy of Phimosis treatments, Kikiros, Beasley and Woodward developed a grading system to diagnose the severity of phimosis. [7]

- Grade 1: full retraction of foreskin, tight behind the glans.
- Grade 2: partial exposure of glans, prepuce (not congenital adhesions) limiting factor.
- Grade 3: partial retraction, meatus just visible.
- Grade 4: minimal retraction, with minor distance between tip and glans (notably, meatus nor glans exposed).
- Grade 5: No visible retraction of the foreskin

Phimosis Treatments:

Adult phimosis can cause significant and often painful symptoms such as urinary difficulties, frequent infections or ballooning of the foreskin during urination, sexual disfunction, disfigurement, pain during sex, mental health issues and partner dissatisfaction have all been documented in the literature [8].

The most common treatment for adult phimosis is circumcision [9].

Marco and Heil [10] conducted a review in support of circumcision and concluded that there was no consensus on whether or not circumcision resulted in more side effects than benefits. Their report covers the impact on infant circumcision on adult sexual function. However, In a very large study of 5552 people, reported by Frisch and Lindholm [11], they concluded that Circumcision was associated with frequent orgasm difficulties in men and with a range of frequent sexual difficulties in women, notably orgasm difficulties, dyspareunia and a sense of incomplete sexual needs fulfilment. McMahons [12] review of disorders of orgasm and ejaculation in men, reported that circumcised men were three times more likely than uncircumcised men to experience frequent orgasm difficulties which, according to an international expert panel, are either psychogenic or due to reduced penile sensitivity.

Bronselaer and colleagues [13], describe reduced penile sensitivity and sexual satisfaction subsequent to circumcision have been described by in a large cohort of 1,369 men of whom 1,059 were uncircumcised and 310 circumcised who reported less sexual pleasure than uncircumcised men.

A preliminary review of the literature results in dozens of studies referring to the adverse outcomes associated with circumcision and a summary is included in Table A

Table A - Reported Adverse Circumcision Outcomes

Authors	Adverse Circumcision Outcomes
Friedman and colleagues [9]	postoperative complications can involve pain, wound infection, edema, urinary retention, meatal stenosis, foreskin adhesion and fistulas
Adrienne Carmack [14]	bleeding, pain, meatitis, various surgical complications, delayed complications such as adhesion or skin bridges and infection notably associated with antibiotic resistant strains of Staphylococcus aureus.
Williams and Kapila [15]	Death, Bleeding, Infection, Loss of Skin/Wound Dehiscence, Trapped/Concealed Penis, Redundant Foreskin/Circumcision Revision, Preputial Adhesions/Skin Bridges, Meatitis/Meatal Stenosis, Urethrocutaneous Fistula, Glanular Necrosis/Glanular Amputation, Hypospadias
Gerharz and Haarmann [16]	Bleeding, injury to glans
Fekete and colleagues [17]	44% incidence among 48 men referred to them with dissatisfied results from an adult circumcision. Other complications included scar wrinkling (27%), redundant foreskin (23%) and paraphimosis (6%)

There is a major gap in our understanding of the consequences of adult circumcision on psycho-emotional impacts on patients. Carmack [14] identified that published studies on circumcision fail to report on this aspect or the aesthetic trauma of circumcision. However, there are clear descriptions [17] provided in the literature confirming patient anxiety following unsatisfactory adult male circumcision.

The area of medicolegal cases arising from circumcision is poorly documented in the scientific literature [16]. However, a google [18] search returns volumes of articles regarding the matter.

The impact of circumcision on a man's partner is an emerging and important area of investigation. Bensley and Boyle [19] provided the following abstract which highlights the need for a more rigorous academic investigation into this critical aspect of sexual fulfilment:

“Circumcised and genitally intact men, as well as female and gay partners having sexual experience with both circumcised and intact men, were surveyed in order to investigate the long-term effects of infant circumcision. Both circumcised men and the sexual partners of circumcised men reported a number of adverse physical, sexual, and psychological sequelae.

Logistic regression analysis revealed that circumcised men could be reliably classified as having penile scarring, need for use of lubrication when undertaking sexual activity, reluctance to use condoms, progressive decline in sexual sensitivity, as well as unhappiness with and reluctance to think about their circumcision status. Female and gay sexual partners reported that their circumcised partners were more likely to experience reduced sexual sensation as compared with their intact partners, as well as dissatisfaction with their orgasms and a wide range of negative emotions associated with being circumcised.

Evidently, there are many adverse physical, sexual and psychological effects from infant circumcision, which need to be acknowledged in any discussions pertaining to informed consent in relation to circumcision surgery”

Other treatments include topical steroids, manual stretching and foreskin tissue expansion.

Gillatt & Chung [20] describe manual stretching of the foreskin with topical cortico-steroid creams in order to minimise the symptoms of adult phimosis. They assert that this conservative initial treatment preferred by many clinicians and patients as an alterative to the higher side effects of adult male circumcision, has a poor efficacy. This treatment was first described in the literature in the 1990’s [6] and further described elsewhere [21-22]. Gillatt and Chung [17] report that the treatment is usually provided over a period of 4 to 8 weeks. Once the cream is applied to the foreskin, a progressive stretching of the prepuce over the glans can be undertaken with fingers or a skin retractor, in order to facilitate foreskin tissue expansion over time.

In there clinical experience this treatment has poor and variable efficacy often leading to circumcision with the significant problem of adverse events and outcomes as discussed above... In 2016, Gillatt and team began offerring different form of conservative treatment, the Novoglan product. This product has received generated an excellent safety profile and very high patient satisfaction rates. This is now considered a suitable alternative to circumcision or steroid creams in cases of adult phimosis. the team have initiated an independents clinical trial into the safety, efficacy and tolerability pf the Novoglan product.

The Novoglan Foreskin Tissue Expander:

The Novoglan foreskin tissue expander product is manufactured and distributed by Platigo Solutions Pty Ltd in Sydney, Australia [23] . Novoglan is indicated for use by patients 18 years and over for the treatment of phimosis or preferential loosening of the foreskin. The Novoglan devices uses a balloon system to apply pressure under the foreskin and applies distributed pressure. Persistent

treatment results in foreskin cell proliferation as an adaptive response leading to increased foreskin tissue and a looser foreskin permitting safe retraction for most patents.

A new generation liquid molded medical grade silicone foreskin stretching balloon has been developed for the specific purpose of stretching the foreskin[24]. Novoglan is designed to provide relief for tight foreskin in adults within 6 to 8 weeks. A significant number of patients have described normal retraction occurring after 14 days of continuous treatment twice per day [25].

Methodology:

A questionnaire was randomly sent to 9700 registered customers (emails) who had purchased the Novoglan foreskin tissue expander device . The recipients were de-identified. A total of 879 responses were received via the confidential online survey tool, with 68 responses being rejected for material incompleteness and 811 were included in the analysis. Of the 8821 that did not respond, they received a followup email survey with one question. 119 responses were received from the second attempt.

The questions have been grouped into tables and graphs and are described in the results section below.

Results

Table 1 - Use of instructions, device version, usability, expectations, experience, reuse.

Question	Yes	No	Undecided	Yes	No	Undecided
Did you use the Novoglan foreskin tissue expander as per the instructions	803	5	3	99.01%	0.62%	0.37%
Did you use the Novoglan foreskin tissue expander with the air plunger ?	334	463	14	41.18%	57.09%	1.73%
Did you use the Novoglan foreskin tissue expander with the squeeze bulb and stop cock?	463	334	14	57.09%	41.18%	1.73%

Did you use the Novoglan foreskin tissue expander with both the air plunger and the stop cock?	8	793	10	0.99%	97.78%	1.23%
Did you find the Novoglan foreskin tissue expander difficult to use?	82	713	16	10.11%	87.92%	1.97%
Did the Novoglan foreskin tissue expander treatment meet your expectations?	641	124	46	79.04%	15.29%	5.67%
Did you have a positive experience using the Novoglan foreskin tissue expander ?	721	81	9	88.90%	9.99%	1.11%
If your phimosis returned, would you use the Novoglan foreskin tissue expander again	663	76	72	81.75%	9.37%	8.88%

Graph 1:

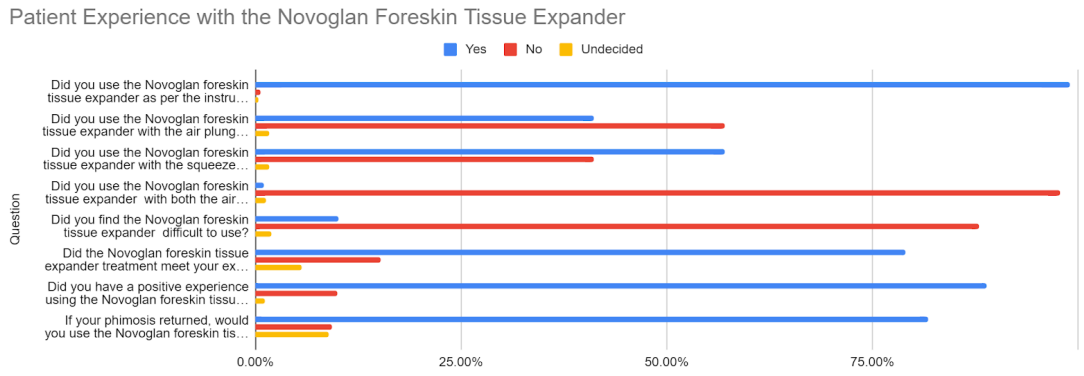
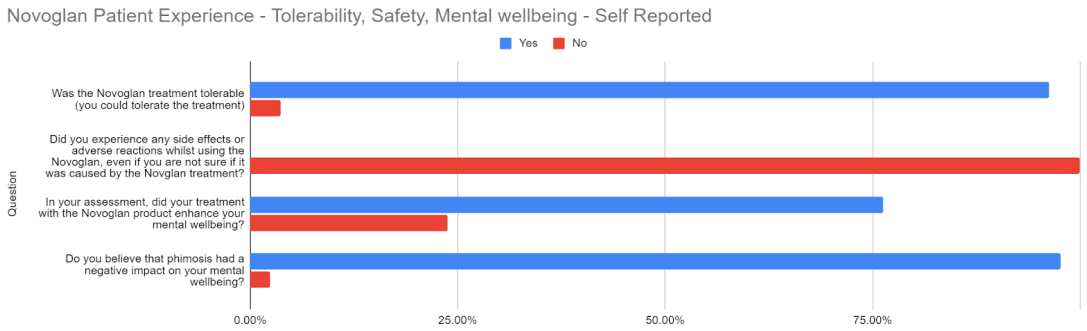


Table 2 - Tolerability, Safety & Mental Well-being

Question	Yes	No	Totals
Was the Novoglan treatment tolerable (you could tolerate the treatment)	781	30	811

Did you experience any side effects or adverse reactions whilst using the Novoglan, even if you are not sure if it was caused by the Novoglan treatment?	0	811	811
In your assessment, did your treatment with the Novoglan product enhance your mental wellbeing?	618	193	811
Do you believe that phimosis had a negative impact on your mental wellbeing?	792	19	811



Graph 2 (above)

Table 3 - Novoglan User Satisfaction / Dissatisfaction

Question	Very Unsatisfied	unsatisfied	indifferent	satisfied	very satisfied	Very Unsatisfied	unsatisfied	indifferent	satisfied	very satisfied
How satisfied were you with the Novoglan foreskin tissue expander device in	19	48	24	684	36	2.34%	5.92%	2.96%	84.34%	4.44%

treating your phimosis?										
How satisfied were you with your treatment outcome when using the Novoglan foreskin tissue expander device.	19	48	19	689	36	2.34%	5.92%	2.34%	84.96%	4.44%
How satisfied were you with the ease of use of the Novoglan foreskin tissue expan	16	52	27	691	25	1.97%	6.41%	3.33%	85.20%	3.08%

der device ?										
How satisfied were you with the overall experience with using the Novoglan foreskin tissue expander device ?	18	47	29	693	24	2.22%	5.80%	3.58 %	85.45%	2.96 %

Graph 3

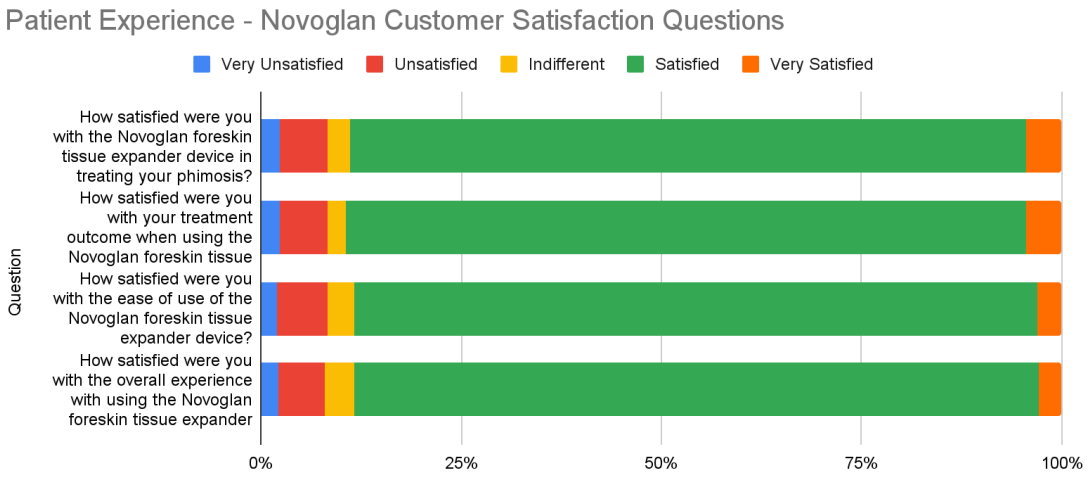


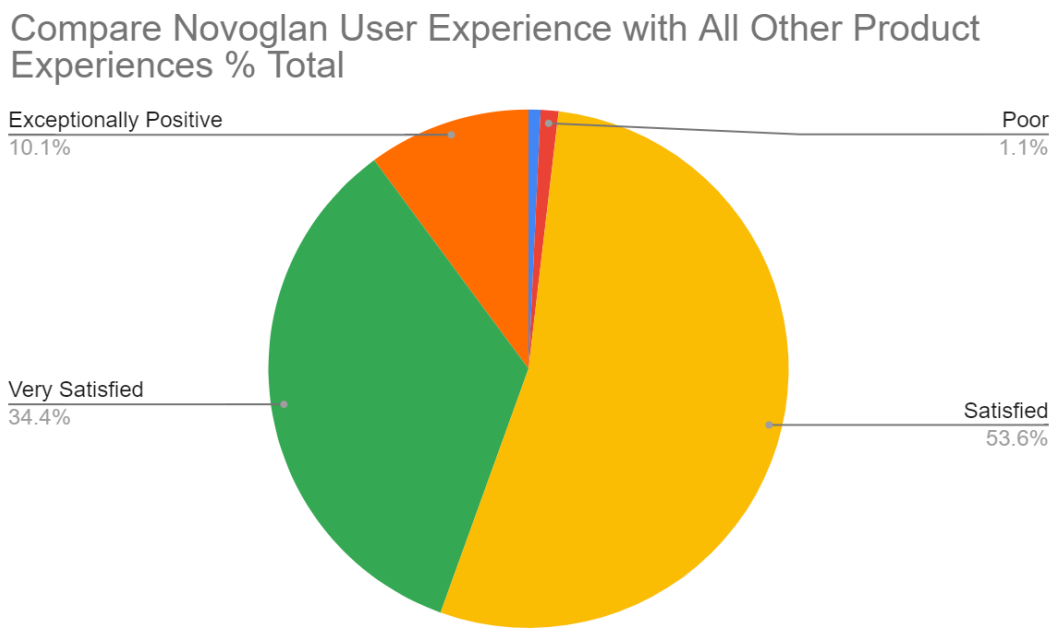
Table 4 - Reason for not responding to initial survey request

To help us with our quality control for future surveys, we would be grateful if you could please select one of the following reasons (the most important one) for not responding to our questionnaire about the Novoglan foreskin tissue expander	missed the survey email	generally do not respond to email surveys	wasn't interested	product didn't work	not satisfied with product	not satisfied with service	satisfied with product	none of the above	Total
Total #	14	62	12	3	5	6	11	6	119
% of total	11.76%	52.10%	10.08%	2.52%	4.20%	5.04%	9.24%	5.04%	100.00%

Table 5 - Comparison of Patient Experience with Novoglan Products and Service verses all their other online product and service experiences.

When you consider any or all of the products and services you have EVER purchased over the internet can you please compare how satisfied were you with the Novoglan experience (that is how would you compare the Novoglan experience to all your other online product and services experiences)?	Very Unsatisfied	Poor	satisfied	very satisfied	Exceptionally Positive	Total
Total #	6	9	435	279	82	811
% Total	0.74%	1.11%	53.64%	34.40%	10.11%	100.00%

Graph 4



Discussion

Limitations of both email based questionnaires and the survey instruments as we have used in this study have been described in the literature [26]. Furthermore it is noted that dichotomous and scaled responses options as used in this study, have their limitations. That being said, they remain an important and well established mechanism to collect data for evaluation [26].

It is well documented that survey response rates are often very poor, and there can be affirmation bias or other biases that stimulate respondents to participate [26] . In this study, we have used neutral language in the questions to reduce any unintended biases. We also followed up non respondents with a single question requesting a single reason for their lack of participation. From Table 4 we note that of the initial 8821 non respondents, 119 responded to the follow up single question survey. 62% of this group stated they either didn't generally respond to surveys or were not interested. Only 11% provided negative reasons related to the Novoglan product or service, in that the product didn't work, they were not satisfied with the product, or they were not satisfied with service. 9% were satisfied with the product. We infer from this data that the bulk of the non respondents in total do not generally participate or are not interested in the survey and that they are not driven by either satisfaction or dissatisfaction with the product or service. We suggest this reduces the risk of significant bias for or against the product or service by the initial respondents.

From Table 1 it can be summarised that just over half the respondents had used the Novoglan Kit with the squeeze bulb and stop cock system. 10% found the product difficult to use, however, it is unclear if that was to do with the older kit that uses the air plunger. The Squeeze bulb system was introduced to enhance

usability [27] . Around 80% of respondents indicated that the novoglan device met their treatment expectations, had a positive response to the Novoglan device, and would reuse the device again if the phimosis returned. Compliance with instructions was over 99%. This data can be extrapolated to allow an interpretation that the Novoglan device in general, meets patients expectations, is easy to use as per the instructions and most users would use the device again should the phimosis return.

From Table 2 we note that no adverse events or side effects were reported. This is a very remarkable result given it is common for treatments to have some side effects or adverse events reported, even if not caused by the treatment. We undertook a literature review to identify any reported or known side effects or adverse events associated with the use of the Novoglan foreskin tissue expander. No reports were located. This result alone highlights the key safety profile that the Novoglan product has developed over the 15 years on the market. Furthermore over 96% of respondents reported that they tolerated the treatment whilst 97% reported that phimosis had a negative impact on their mental well being. The fact that over 76% of respondents reported that Novoglan treatment enhanced their mental well-being provides strong evidence that Novoglan has a positive impact on the overwhelming majority of patients treated with the Novoglan device.

From Table 3 we note that over 88% of all respondents were either satisfied or very satisfied with novoglan treatment, outcomes, ease of use, and experience of using the Novoglan device. Indifference or dissatisfaction with the Novoglan device is less than 15% across the range of questions. This data can be interpreted as almost 9 out of 10 Novoglan users were satisfied with their Novoglan experience. The data from Table 5 also supports the positive patient experience with Novoglan. In fact, nearly 90% of users rated their experience with the Novoglan product or service as “satisfied”, “very satisfied”, or “extremely positive”, when compared to all their other online purchases of services or products. This data is even more compelling when it is received with the understanding that customers that have had a negative experience are significantly more likely to speak up and provide a poor review.

Conclusions

Real world data demonstrates that the Novoglan foreskin tissue expander device is a safe and well tolerated non surgical treatment for uncomplicated phimosis. User experience is significantly positive with respect to the treatment of phimosis and the overall user experience with the device and the related service.

With extremely high levels of patient satisfaction we conclude that the Novoglan device meets the efficacy expectations of patients and has a very significant role to play as a serious option in the non surgical conservative treatment of uncomplicated phimosis.

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Interim review of the Novoglan-01 foreskin tissue expander clinical study in adult males

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INTRODUCTION

The main therapeutic options for pathologic adult phimosis consist of circumcision, manual preputial stretching with steroid creams and foreskin tissue expanders such as the Novoglan product. Circumcision and preputial stretching with cortico-steroid creams can frequently be successful but are far from simple and can lead to severe complications that the Novoglan product is designed to prevent. The Novoglan-01 study is an investigator-initiated study that aims to demonstrate the safety, efficacy and tolerability of the Novoglan treatment.

AIM

The Novoglan-01 clinical trial primary objective is to confirm the efficacy of the Novoglan product as measured by the improvement in foreskin retraction against a standardised scale by the end of a typical 6 to 8 weeks treatment. The Novoglan-01 trial secondary objective is to confirm the safety and satisfaction with treatment as assessed by quality of life improvement and treatment tolerability questionnaires. .

METHOD

We analysed the case report files of the first 20 cases having completed the Novoglan-01 clinical trial treatment protocol. The statistical methods used in analyzing the data involve both ordinal and scalar outcome variables as well as descriptive participant variables.

RESULTS

Participant journey

Week 0 – Enrolment + informed consent

Week 1 – Study Visit 1 + Novoglan product training + Phimosis measurement + Quality of life (QOL) questionnaire

Week 2 – Study Visit 2 – Monitoring

Week 4 – Study Visit 3 – Monitoring

Week 6 – Final Study Visit + Phimosis measurement + QOL questionnaire + tolerability questionnaire

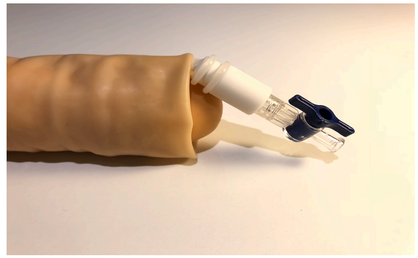
Phimosis measurement

Carried out by investigator – Assessment of degree of phimosis based on a 6 steps scale inspired by Kikiros et al. [1], ranging from:

1 = absolutely no foreskin retraction, to

6 = full and free foreskin retraction

Novoglan product



Treatment efficacy

The treatment efficacy observed by the end of treatment (Final Visit) was as follows.

- **All participants could fully retract their foreskin** (Phimosis measurement 5 or 6)
- **Participants with severe or partial phimosis** (Phimosis measurement 1, 2, 3 or 4) **observed the most improvement with full foreskin retraction** (Phimosis measurement 5 or 6)

Treatment safety

The Novoglan treatment shows a strong safety profile.

- **85% of participants did not report any side effects at all.** Only minor side effects were reported by 15% of participants.
- **No adverse event** was reported.

Treatment tolerability

- Participant questionnaires show that **95% of participants reported satisfaction** with the Novoglan treatment .

Other outcomes

Other study observed outcomes were as follows.

- **95% of study participants would recommend the Novoglan treatment to others.**
- **95% of study participants confirmed progressing well with the Novoglan treatment** during the study.
- **95% of participants observed reduced anxiety** following the Novoglan treatment.

The Novoglan-01 clinical trial is a multicenter (2 sites), observational study that has been approved by the Human Research Ethics Committee of Macquarie University and by the Queensland Metro South Health Human Research Ethics Committee. The Novoglan-01 clinical study is registered with the Australia and New Zealand Clinical Trial Register under the reference ACTRN12621000924853.

CONCLUSIONS

This interim review of the Novoglan-01 study confirms that the Novoglan foreskin tissue expander is safe, effective and well tolerated as a conservative treatment for adult phimosis.

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Original Article

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

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Background: At present, the only definitive treatment for adult phimosis is circumcision, which is a surgical removal of the prepuce. Novoglan is a novel device that could offer patients with phimosis an alternative to surgery. It is based on application of custom-moulded balloons for gradual skin remodelling and prepuce dilatation. This open-label clinical trial aimed to investigate the safety, efficacy and tolerability of the Novoglan treatment.

Methods: A prospective trial was conducted on 20 patients with adult phimosis recruited at Macquarie University Hospital and Princess Alexandra Hospital. After eligibility screening and enrolment, patients were provided with the Novoglan product and training. The treatment involved twice daily 10-minute applications for a duration of 4–8 weeks with patient's degree of phimosis assessed before and at 6–8 weeks after the initiation of the treatment. Participants were also asked to complete questionnaires aimed to assess the safety and tolerability of the Novoglan treatment.

Results: The treatment was successful with improved foreskin retraction in 90% of patients and all patients achieving full foreskin retraction after the treatment. Ninety-five percent of patients reported reduced level of anxiety, and over 60% of patients reported reduced pain/discomfort during sexual activity or in general. Similarly, 95% of patients were moderately-to-very satisfied with the treatment and would recommend Novoglan to others. No adverse events were observed and only 15% of participants reported minor side effects.

Conclusions: The Novoglan-01 trial demonstrated high safety, efficacy and tolerability of the Novoglan treatment for adult phimosis and its high potential as a conservative alternative to circumcision or steroid cream treatment.

Trial Registration: The Novoglan-01 study has been registered with the Australia and New Zealand Clinical Trial Registry under the reference ACTRN 1262 10009 24853, dated 15 July 2021.

Keywords: Phimosis; adult male phimosis; circumcision; conservative treatment of phimosis

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Introduction

Male phimosis is characterised by stenosis of the foreskin resulting in the inability of the prepuce to retract over the glans penis or tightness of the foreskin when retracted. Physiological phimosis is a condition in infants and boys which usually disappears by the age of 10 (1). Pathological phimosis can occur at any age in uncircumcised adult men and is frequently associated with lichen sclerosus (also known as Balanitis Xerotica Obliterans) or balanitis/balanoposthitis. Phimosis can be graded according to a scale originally developed by Kikiros, Beasley and Woodward (2). While the data on the prevalence of adult phimosis is limited, a recent systematic review by Morris *et al.* (1) estimated the risk of phimosis in males over 18 years of age to be 3.4% [95% confidence interval (CI): 1.8–6.6%] and its prevalence is expected to rise in the near future given decline in the rate of newborn circumcision (3). Adult phimosis often requires treatment as it can cause significant and often painful symptoms such as recurrent infections and ballooning of the foreskin during urination or pain during sexual intercourse (4).

Phimosis has been traditionally managed by circumcision. While this is effective and provides a permanent solution, it is not without complications. These can include pain, bleeding, swelling, inadequate skin removal, wound infection, oedema, urinary retention, meatal stenosis, foreskin adhesion and fistulas and have been reported to reach 2.4% to 17.7% (5-8). Patients with phimosis, therefore, often wish to trial other methods of treatment before proceeding with circumcision. These methods include preputioplasty, or surgical treatment of phimosis with preservation of the foreskin (9) or conservative treatments, such as use of corticosteroid creams (2,10) with progressive stretching of the prepuce and application of stretching devices (11,12).

Recently, a new conservative treatment option, the Novoglan product, has shown promising results, with a high success rate and satisfaction reported by users. Novoglan is a novel medical device for conservative treatment for adult phimosis that involves the use of a balloon that can be inserted underneath the opening of the foreskin (between the glans and the preputial mucosa), progressively inflated by a user and kept in place. The inflation is controlled by the user to ensure safe and painless application. The patient is advised to use the device twice daily for a period of 4 to 8 weeks until full normal prepuce retraction is achieved. The Novoglan-01 clinical trial aimed to confirm the safety, efficacy, and tolerability of the Novoglan product as a conservative treatment for adult phimosis. We present this article in accordance with the TREND reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-91/rc).

Highlight box

Key findings

- The Novoglan treatment is safe, effective and highly tolerable alternative to circumcision in adults with phimosis with all patients achieving foreskin retraction after the treatment.

What is known and what is new?

- Circumcision remains the standard of care for treatment of adult phimosis, however many patients would prefer non-surgical approach.
- Novoglan-01 clinical trial has shown that non-surgical Novoglan treatment could improve foreskin retraction in adults with phimosis without significant side effects or discomfort.

What is the implication, and what should change now?

- The findings of the Novoglan-01 clinical trial demonstrate high potential of Novoglan as a conservative first line treatment in adults with phimosis.

Methods

Novoglan device

The Novoglan product is a medical device commercialised in Australia since 2006 and listed with the Australian Therapeutics Goods Administration (ARTG 168962) as a conservative treatment option designed for adult patients with phimosis. As shown at *Figure 1A*, its main component is a small balloon that can be inserted underneath the opening of the foreskin and progressively inflated causing skin stretching by providing gentle and even pressure. The Novoglan balloon is guided under the foreskin between the glans and the prepuce using a purpose moulded rod (*Figure 1A*) and placed in the same position every time. Once the balloon is in place the rod is removed, a stopcock is attached, and balloon is inflated by the patient using an inflation bulb. The assembled Novoglan device with inflated balloon can be seen at *Figure 1B*. The pressure is under control of the user to ensure foreskin stretching with no discomfort (*Figure 2*). The Novoglan device is applied for 10 minutes twice daily for a total duration of 4–8 weeks. The Novoglan kits were provided for the study free of charge by Platigo Solutions Pty Ltd.

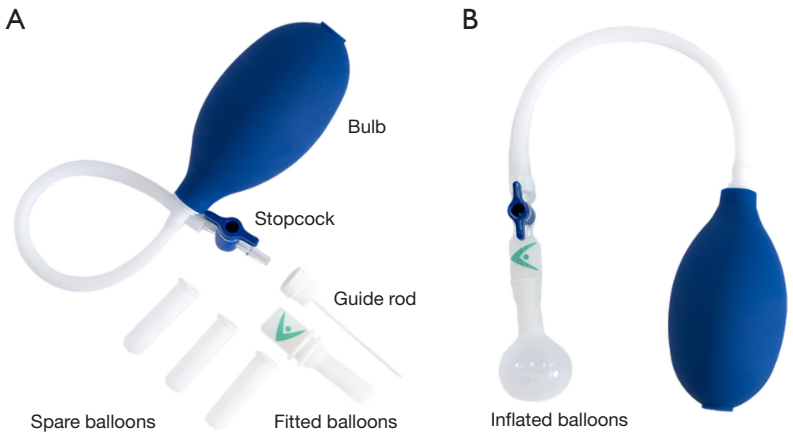

Figure 1 The components of the Novoglan device (A) and assembled device with balloon inflated (B).

Figure 2 Application of the Novoglan device with patient-controlled foreskin stretching.

Ethics

The Novoglan-01 clinical trial was approved by the Human Research Ethics Committees at Macquarie University (Macquarie University HREC, Reference Nos. 520193 3799 8816 and 52020 3799 21701) and Royal Alexandra Hospital (Queensland Health Metro South HREC, Reference No. HREC/2020/QMS/66682). Both Macquarie University HREC and Queensland Health Metro South HREC follow the Australian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). All participants gave informed consent before taking part in the study.

Participants

The Novoglan-01 clinical trial has been conducted at the Urology Department at Macquarie University Hospital, Sydney, NSW and at Princess Alexandra Hospital, Brisbane, QLD, Australia, where a total of 20 consecutive phimosis patients have been screened and enrolled. To take part in the study, these patients had to be male 18 or older, referred to the urology clinic, have symptoms of adult phimosis, report pain or discomfort, and be willing to provide informed consent as well as participate and comply with the study requirements. The exclusion criteria were: bleeding, ulcer or active infection of the penis, prior prepuce surgery, except for frenuloplasty, hypospadias, severe scaring of the glans or foreskin, history of penile cancer, and history of a psychological illness or other conditions which may interfere with their ability to understand the study requirements. Based on a power calculation, we required at least 18 participants to complete the treatment. Following an interim analysis after recruitment of the first 20 participants, a decision was made to analyse and publish the results given compliance and the size of the effect achieved.

Objectives and trial design

The hypothesis for the Novoglan-01 study is that the Novoglan product is an alternative conservative treatment for adult phimosis that is safe, effective and well tolerated by participants. The primary study objective was to determine the efficacy of the Novoglan treatment by measuring

Table 1 The Novoglan-01 trial timelines

Study visit	Timeline	Interventions in summary
Enrolment Visit	As scheduled with Site Investigator	Eligibility screening and enrolment
Study Visit 1	Minimum 1 week following Enrolment Visit	Phimosis measurement, quality of life questionnaire, Novoglan product supply and training
Study Visit 2 (phone)	1 week following Study Visit 1	Treatment progress and adverse events
Study Visit 3 (phone)	4 weeks following Study Visit 1	Treatment progress and adverse events
Final Visit	6–8 weeks following Study Visit 1	Phimosis measurement, quality of life questionnaire, tolerability questionnaire, trial completion

the degree of phimosis before and after the treatment. The first of secondary objectives was to assess the safety of the Novoglan treatment by observing and reporting any treatment discomfort or adverse event experienced by the participants. The adverse events were defined as per Therapeutic Goods Administration Medical device incident reporting & investigation scheme and included serious conditions that require hospitalisation, have risk of permanent damage, life-threatening or leading to death. (please see https://www.tga.gov.au/resources/resource/guidance/medical-device-incident-reporting-investigation-scheme-iris). The other secondary objective was to confirm the participant's satisfaction with the Novoglan treatment by assessing the quality-of-life improvement and treatment tolerability as reported by the participant at the end of the trial. The Novoglan-01 clinical trial is an investigator-initiated, multicentre, single arm, non-randomised, observational, prospective study.

Intervention

The interventions of the Novoglan-01 study included 5 contacts (*Table 1*), where every step concluded with confirmation of date and time for the next contact.

The first contact was the Enrolment Visit, where the Site Investigator collected patient's demographics and medical history with a particular focus on phimosis and conducted a general medical examination and penile examination to confirm phimosis. The Site Investigator then confirmed patient's eligibility for the study and invited them to participate. If the patient agreed to participate in the study, they were then asked to sign the Novoglan-01 Participant Informed Consent Form and assigned a Novoglan-01 Study unique participant identifier.

The second contact was the Study Visit 1, scheduled at a minimum of 1 week following the Enrolment Visit. During the Study Visit 1, the degree of patient's phimosis was determined using a revised measurement scale based on Kikiros *et al.* (2), an evaluation of the participant quality of life was carried out using the Novoglan-01 Quality-of-Life Questionnaire, and the Novoglan investigative product as well as printed how-to-use guide were supplied to the participant. The participants were then explained the various components of the Novoglan product and trained in its appropriate and safe use. The Novoglan-01 Quality-of-Life Questionnaire has been specifically designed for this study.

The third and fourth contacts were the Study Visits 2 and 3 conducted by telephone and scheduled at 1 and 4 weeks, respectively, following the Study Visit 1. During these contacts, the participants were offered the option to schedule an additional face-to-face training and asked about the overall progress with the treatment, problems in using the Novoglan product, adverse events, and changes to the concomitant medications.

The fifth and final contact was the Final Visit scheduled at 6–8 weeks following Study Visit 1. During that visit, the assessment of the participant's phimosis was conducted, the participant's quality of life was assessed using the Novoglan-01 Quality-of-Life Questionnaire, and participant's perceived tolerability of the Novoglan product was assessed using the Novoglan-01 Treatment Tolerability Questionnaire, both of which were specifically designed for the Novoglan-01 clinical study. The final outcomes of the treatment were then reviewed and discussed with participant by a Site Investigator.

The provisions for modifying allocated interventions included the option of organising additional training session of the use of Novoglan device either by phone or in person at Study Visits 2 or 3. Participants could terminate their participation in the trial at any time. The strategies to ensure adherence to the intervention protocols included

Table 2 The phimosis measurement scale used to assess the efficacy of the treatment

Phimosis grade	Description
1	Absolutely no retraction
2	Slight retraction leaving a gap between the tip of the prepuce and the glans, i.e., neither meatus nor glans are exposed
3	Partial retraction, just sufficient to see the glandular meatus
4	Partial retraction, exposing part of the glans
5	Full retraction of the foreskin, tight behind the glans
6	Full and free retraction of the foreskin, no tightness behind the glans

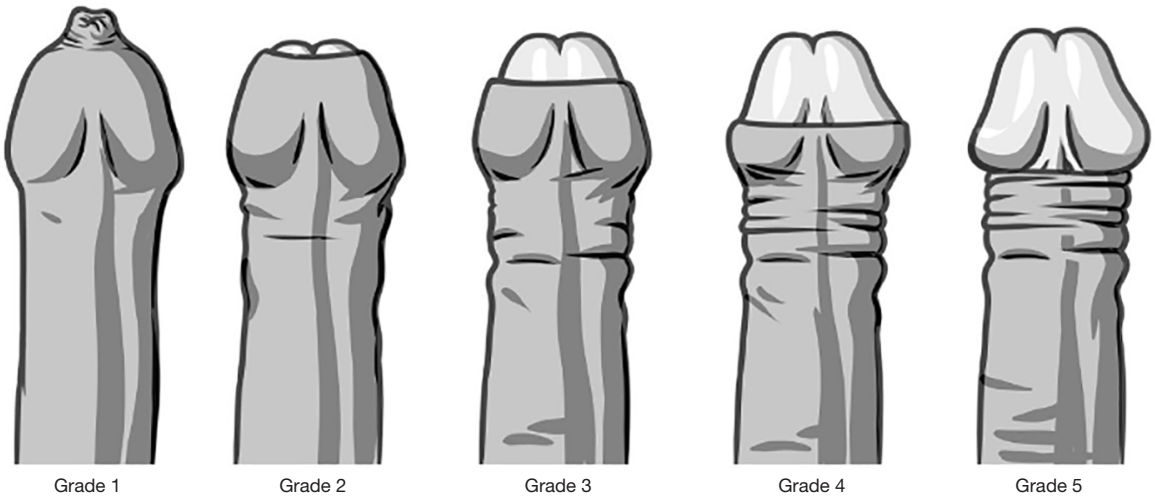

Figure 3 The phimosis measurement scale used to assess foreskin retraction and the efficacy of the treatment.

offering additional training sessions on the Novoglan device to participants identified as in need of it during Study Visits 2 or 3. There were no other specific concomitant care or interventions permitted or prohibited during the trial other than those specified in the eligibility criteria.

While at the Princess Alexandra Hospital participants were assessed by the site investigator at every step, at Macquarie University Hospital step 1 was conducted by the Site Investigator, steps 2–4 were conducted by a Clinical Trial Nurse and step 5 was conducted by both site investigator and the clinical trial nurse.

Outcome measures

The expected outcomes from the Novoglan-01 study were as follows:

- Confirmation of the ability of the Novoglan product to effectively relieve phimosis as measured by foreskin retraction before and after treatment against the Phimosis Measurement Scale (*Table 2*, *Figure 3*) at Study Visit 1 and Final Study Visit.
- Confirmation of the safety of the Novoglan treatment as evidenced by the lack of any adverse events or significant side effects during treatment.
- Confirmation of the satisfaction of participants with the Novoglan treatment as measured by the Quality-of-Life Questionnaire completed before and after treatment.
- Confirmation of the tolerability of the Novoglan treatment as measured by the treatment tolerability questionnaire filled in by the participants during the Final Visit.
- Confirmation of the Novoglan treatment as a valid conservative first line treatment alternative to steroid creams in adult males presenting with phimosis.

Table 3 Descriptive characteristics of the participants recruited in the Novoglan-01 clinical trial

Characteristic	N	Minimum	Maximum	Mean	SD
Age (years)	20	20.00	63.00	32.10	12.20
Weight (kg)	20	62.80	126.00	79.40	15.90
Height (cm)	19	164.00	189.00	178.70	6.60
BMI (kg/m^2)	19	20.30	40.70	25.16	5.30

SD, standard deviation; BMI, body mass index.

Table 4 Characteristics of participants recruited in the Novoglan-01 clinical trial

Characteristic	Frequency	Percent
Ethnicity		
Caucasian	13	65
Asian	7	35
Relevant medical history	4	20
Evidence of lichen sclerosus	7	35
Prior frenuloplasty	0	0

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%)

Statistical analysis

The Novoglan-01 data involved Phimosis assessment and the Quality-of-Life Questionnaire (both ordinal, scalar) completed pre- and post-treatment and treatment tolerability questionnaire completed by the participants after the treatment. The statistical analysis of the Novoglan-01 trial has also involved descriptive variables collected for each patient such as physical parameters (e.g., age, weight, height—numerical variables), medical history (categorical, binary) and record of adverse events (categorical, binary). Univariate analysis was used for these data.

The sample size was determined using a power analysis to achieve a power of 0.8 in a paired-samples *t*-test with an alpha level of 0.05. Based on an expected standard deviation of 1.5 for the paired differences, the computed Cohen's d for the size effect of the paired-samples *t*-test was 0.67. Using all the above inputs, the minimum required sample size for the paired-samples *t*-test was calculated to be 18.

Results

Patient recruitment and clinical characteristics

From September 2019 to May 2022, a total of 20 consecutive patients were screened as potential participants for this study. All 20 study participants met the inclusion criteria and decided to proceed with the study. As shown in *Tables 3*,*4*, the participant population was a mix of 65% Caucasians and 35% Asians of a mean age of 32.10 years and a mean body mass index (BMI) of 25.16 kg/m^2 which is considered as overweight by the Heart Foundation (see: https://www.heartfoundation.org.au). Eighty percent of participants had no relevant medical history, but 4 participants had some other condition or illness. There were 7 participants with evidence of lichen sclerosus and no evidence of prior frenuloplasty in any participant. It is important to note that the diagnosis of lichen sclerosus was based only on clinical examination, which has been shown to be inaccurate in some instances (13). In terms of concomitant drug use, one participant reported use of statin and one reported use of statin and a blood pressure medication.

Treatment efficacy

The degree of phimosis was assessed before the treatment and at the final visits at 6 to 8 weeks after the initiation of the treatment as a measurement of its efficacy. The findings can be seen in *Table 5*. Of note, while at the first visit 17

patients were classified as grades 1–4, three patients had grade 5 and no patients had their phimosis assessed as grade 6, all 20 patients have been assessed as either grade 5 or 6 at the final visit with 10 patients (50%) in each group.

As shown at *Table 5* and *Figure 4*, 6 participants (30%) had a four-degree improvement with improvement from phimosis measurement 1 to 5 (1 participant) and from 2 to 6 (5 participants). Five participants (25%) experienced a three-degree improvement with their phimosis score changing from 2 to 5 (2 participants) and from 3 to 6 (3 participants). Four participants (20%) had a two-degree improvement from phimosis measurement changing from 3 to 5 (3 participants) and from 4 to 6 (1 participant). Three participants (15%) had a one-degree improvement with phimosis score changing from 4 to 5 and from 5 to 6 in two and one participants, respectively. Only 2 participants (10%) had no improvement of the phimosis measurement, which remained at 5.

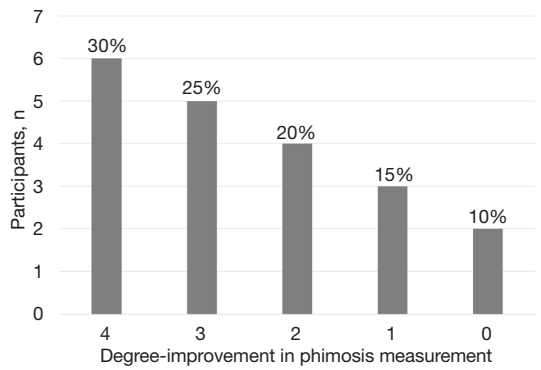

Figure 4 Bar-chart representing the number of participants with 4-, 3-, 2- and 1-degree improvement or no change of their phimosis measurement.

Quality of life

The effect of phimosis on patient's quality of life was assessed before and after Novoglan treatment in terms of general pain/discomfort, pain/discomfort during sexual activity, impact on usual activities, and anxiety by using specifically designed questionnaires (*Table 6*). The level of pain or discomfort of participants was none to moderate at Visit 1 and only none or slight at the Final Visit. Out of 8 participants reporting slight or moderate general

Table 6 The quality-of-life assessment before and after the Novoglan treatment

Ranking [scale 1 to 5]	Visit 1		Final Visit	
	Count	Percent	Count	Percent
General pain/discomfort				
None [1]	12	60	15	75
Slight [2]	5	25	5	25
Moderate [3]	3	15	0	0
Pain/discomfort during sexual activity				
No pain [1]	1	5	13	65
Slight [2]	8	40	5	25
Moderate [3]	10	50	2	10
Severe [4]	1	5	0	0
Impact of usual activities				
No problem doing usual activities [1]	19	95	19	95
Slight problems doing usual activities [2]	1	5	1	5
Anxiety/depression				
Not anxious/depressed [1]	0	0	17	85
Slightly anxious/depressed [2]	16	80	3	15
Moderately anxious/depressed [3]	4	20	0	0

Table 7 Novoglan tolerability and satisfaction

Ranking [scale 1 to 4]	Count	Percent
Usefulness of demonstration		
Very useful [1]	16	80
Useful [2]	4	20
Usefulness of User Guide		
Very useful [1]	16	80
Useful [2]	4	20
How easy to understand the use of Novoglan?		
Very easy [1]	15	75
Easy [2]	2	10
Moderately easy [3]	3	15
How easy to use did you find Novoglan?		
Very easy [1]	13	65
Easy [2]	4	20
Moderately easy [3]	3	15
How confident do you feel that you used Novoglan correctly?		
Very confident [1]	13	65
Confident [2]	5	25
Somewhat confident [3]	2	10
How painful was it to use Novoglan?		
Not painful at all [1]	12	60
Slightly [2]	6	30
Moderately [3]	1	5
Moderately-to-quite painful [3 to 4]	1	5
How overall satisfied are you with your Novoglan treatment?		
Very satisfied [1]	12	60
Satisfied [2]	4	20
Moderately satisfied [3]	3	15
Quite dissatisfied [4]	1	5
Novoglan treatment recommendation to others		
Maybe	1	5
Yes	19	95

pain/discomfort at the First Visit, 6 participants reported reduction in general pain/discomfort, while 2 participants reported their level of pain/discomfort remained unchanged at the Final Visit. Two participants (10%) reported new slight general pain or discomfort at the Final Visit. Nineteen participants (95%) reported pain (slight-to-severe) during sexual activity at Visit 1. Following Novoglan treatment 13 participants (68%) observed reduction to slight or no pain at all with no severe pain reported at the final visit. Phimosis did not appear to significantly affect usual activities with only one patient reporting slight problem at Visit 1. This patient reported no impact on usual activities after the treatment, while one other patient developed slight problems doing usual activities. In terms of anxiety or depression, all patients reported it at slight (16 participants, 80%) or moderate (4 participants, 20%) level at Visit 1 with 19 participants (95%) reporting reduced level of anxiety/depression following the treatment.

Overall, Novoglan treatment was found to reduce the level of anxiety in 95% of participants, level of general pain/discomfort during sexual activity in 68% of participants and in general pain/discomfort in 63% of participants, with no worsening anxiety or pain during sexual activity reported. Only 2 participants (10%) reported new slight general pain/discomfort after the treatment, however, no significant impact on usual activities was observed. Such slight pain/discomfort could be attributed to a period of desensitization needed for a newly exposed glans or to a short-term discomfort observed in a small minority of patients after skin stretching.

Treatment tolerability and satisfaction

As part of the Novoglan treatment assessment, at the final visit patients were asked to provide feedback on usefulness of the Novoglan demonstration and user guide, ease of understanding how Novoglan works, ease and confidence in Novoglan application, pain associated with Novoglan use, the overall satisfaction with the treatment and whether they would recommend it to others.

All participants found the demonstration and the user guide useful or very useful (*Table* 7). Seventeen participants

Table 8 Side effects reported by the participants

Side effect	Visit 2		Visit 3		Final Visit	
	Count	Percent	Count	Percent	Count	Percent
Any pain in using Novoglan						
No	18	90	18	90	18	90
Yes	2	10	2	10	2	10
Any itching of the foreskin in using Novoglan						
Missing	1	5	0	0	0	0
No	17	85	20	100	19	95
Yes	2	10	0	0	1	5
Any foreskin discoloration in using Novoglan						
Missing	1	5	0	0	0	0
No	18	90	20	100	20	100
Yes	1	5	0	0	0	0
Any foreskin discomfort in using Novoglan						
No	17	85	19	95	18	90
Yes	3	15	1	5	2	10
Any other side effect in using Novoglan						
No	20	100	20	100	19	95
Yes	0	0	0	0	1	5

Only one participant reported other side effect—discharge under foreskin.

(85%) found understanding how to use Novoglan easy or very easy and 18 participants (90%) felt confident they had used the product correctly. Similarly, 18 participants (90%) had only slight or no pain in using Novoglan and a total of 16 participants (80%) were satisfied or very satisfied with the treatment. While 3 participants (15%) were moderately satisfied and 1 participant (5%) reported dissatisfaction, a total of 19 participants (95%) would recommend the Novoglan treatment to others. The Novoglan treatment was reported as progressing well by 95% of participants with no participant requiring additional training.

Within the Quality-of-Life Questionnaire, participants were also asked about their perception of circumcision as a treatment option before and after the Novoglan treatment. The number of patients considering circumcision as a near future treatment option dropped by 69.2% following the treatment from 13 participants at Visit 1 to 4 participants at the Final Visit.

Side effects and adverse events

There was no adverse event reported during the trial period by any participant. The side effects assessed at Visits 2, 3 and Final Visit were pain in using Novoglan, foreskin itching or discoloration or other side effects (*Table 8*). Pain was reported by 2 patients at each visit. Similarly, 2 participants (10%) reported itching of the foreskin at Visit 2, however, no participants reported it at Visit 3 and only one at the Final Visit. Foreskin discoloration was experienced by one participant at Visit 2 and has not been reported by anyone at following visits. Foreskin discomfort has been reported by only three participants at Visit 2 and by one and two participants at third and final visits, respectively. Only one participant reported other side effect (discharge under foreskin) at the Final Visit with none reported at Visits 2 and 3.

Overall, the vast majority of participants did not

report any side effect in using Novoglan, with only 1 or 2 participants reporting side effect. Added to the lack of any adverse event, this confirms the strong safety profile of Novoglan.

Discussion

Circumcision offers a definitive treatment for adult phimosis. While it has a low rate of complications and they tend to be moderate and transient, patients may experience pain, bleeding, swelling, inadequate skin removal, wound infection, oedema, urinary retention, meatal stenosis, foreskin adhesion and fistulas (5-7). Of note, in a recent literature review, Bossio and colleagues noted that complications following circumcision are more frequent in adult than in children or infants and have been reported to reach 2.4% to 17.7% (8). A study by El Bcheraoui *et al.* later showed a similar trend with a very low rate of complications of 0.40% (95% CI: 0.39–0.41%) in infants, going up to 9.06% for circumcision performed between the ages of one and nine and 5.31% for males over 10 years of age (6). Additionally, several methods of preputioplasty, or surgical treatment of phimosis with preservation of the foreskin have been described (9).

Corticosteroid therapy has been introduced by Kikiros and colleagues (2) in the early 1990s as a conservative alternative treatment for phimosis. Such treatment is performed by the patient over a period of 4 to 8 weeks with application of the cream on the tip of the foreskin opening with gentle and progressive stretching of the prepuce over the glans, with an aim to stimulate the growth of the foreskin and its expansion over time (14,15). This form of phimosis treatment has been extensively studied and applied over the past three decades and has been effective in 71.1–91.1% of cases with a recurrence rate of up to 29.5% (10,14-17). Other methods of conservative treatment include recently developed devices for phimosis treatment, however, data on their application is very limited with some devices being suitable only for patients with low-grade phimosis, who can at least partially retract the foreskin and expose the glans (11,12). Due to higher prevalence of phimosis in children, some methods of phimosis treatment were validated in paediatric populations only and require careful interpretation and further assessment in adults.

The Novoglan treatment appears to be a potential alternative to existing methods of phimosis treatment with high levels of safety and efficacy and very low rate of side effects. It demonstrated outstanding efficacy in terms of the improvement of foreskin retraction with all patients achieving full foreskin retraction after the treatment. Unlike other methods, Novoglan has been most effective in patients with more advanced phimosis who had either no foreskin retraction or could only partially expose the meatus (grades 1–3) before the treatment and were all able to achieve full retraction (grades 5–6) after the Novoglan treatment. Grade 6 foreskin retraction has been achieved by 57% of patients with grades 1–3 disease and by only 33.3% of patients with grades 4 or 5 phimosis. The Novoglan treatment demonstrated significant improvement in quality of life of the participants reducing anxiety in 95% of participants, pain/discomfort in 63% of participants who initially reported general pain/discomfort and 68% of patients who reported pain/discomfort during sexual activity before the treatment. Only 2 participants (10%) reported new slight general pain/discomfort after the treatment. Similarly, Novoglan demonstrated high levels of tolerability and satisfaction with only 2 participants (10%) reporting more than slight pain during its use, only 1 participant (5%) reporting overall dissatisfaction and no participants requiring additional training on the use of Novoglan. Importantly, the Novoglan treatment demonstrated excellent safety with no adverse events reported and side effects reported by only 10–15% of participants throughout the visits.

This study successfully demonstrated the efficacy and safety of Novoglan treatment, its tolerability and patient's satisfaction. The study population was well-representative of phimosis patients as it included patients with all degrees of phimosis from absolutely no retraction (grade 1) to males whose foreskin was fully retractable, but tight behind the glans (grade 5). The main limitations of this study were relatively low number of participants, and lack of long-term follow up data available at this stage as other conservative methods of phimosis treatment have been reported to suffer from phimosis recurrence. Another potential limitation is that all participants of this study were recruited in Australia and could not be representative of populations in other parts of the world, although participants were recruited across 2 states with multiethnic demographics. To further address these limitations, the recruitment for a study with a larger number of participants and longer follow up is planned to commence with the aim to collect data needed

for consideration of the Novoglan product as part of the conservative treatment guidelines for adult phimosis.

Conclusions

The Novoglan-01 study has demonstrated Novoglan device to be a safe and effective treatment for adult phimosis with all patients being able to retract foreskin after the treatment. While larger studies and head-to-head comparison to current surgical and conservative methods of phimosis treatments are needed, results from the Novoglan-01 study clearly demonstrate the high potential of Novoglan as first-line phimosis treatment.

Acknowledgments

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Footnote

Reporting Checklist: The authors have completed the TREND reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-23-91/rc

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-23-91/coif). EC serves as an unpaid editorial board member of *Translational Andrology and Urology* from August 2018 to July 2024. EC reports that Platigo Solutions Pty Ltd. provided investigative product for the study. HM is a consultant of Platigo Solutions Pty Ltd. and received assistance from Platigo Solutions for the manuscript medical writing. AJ is an employee of Platigo Solutions Pty Ltd. and reports that Platigo Solutions Pty Ltd. provided investigative product for the study. DC is an employee of Minomic International Ltd. and received support from Platigo Solutions Pty Ltd. to attend the USANZ 2022 Conference. DG reports that Platigo Solutions Pty Ltd. provided investigative product for the study. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The Novoglan-01 clinical trial was approved by the Human Research Ethics Committees at Macquarie University (Macquarie University HREC, Reference Nos. 520193 3799 8816 and 52020 3799 21701) and Royal Alexandra Hospital (Queensland Health Metro South HREC, Reference No. HREC/2020/QMS/66682). Both Macquarie University HREC and Queensland Health Metro South HREC follow the Australian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). All participants gave informed consent before taking part in the study.

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

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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.

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This work has not been previously published or presented.

Abstract presented at UAA-2023

Title: Clinical trial and post-marketing data on the use of Novoglan for conservative treatment of adult phimosis

Dmitry Polikarpov, Eric Chung, Hubert Mazure, Andrew James, Hassan Doosti, Douglas Campbell, David Gillatt

Purpose:

Novoglan is a medical device designed for adults with phimosis who wish to avoid circumcision. We conducted a post-marketing study and a clinical trial focusing on the safety, efficacy, and usability of the Novoglan treatment as well as its impact on mental wellbeing. To assess the reliability of the data collected from the post-marketing study and real-world applicability of the clinical trial data, we compared the findings from both studies.

Methods:

For the post-marketing study, questionnaires were emailed to the Novoglan users. Complete responses from 461 patients were de-identified and included in the analysis. The Novoglan-01 clinical trial recruited 20 participants, who were similarly asked to completed questionnaires and were assessed by a urologist before and after the treatment to assess the treatment results.

Results:

The treatment efficacy was similarly high in both studies with 93.5% of the Novoglan users deeming their treatment effective in the post-marketing study and improvement in foreskin retraction observed by urologists in 90% of the trial participants. The Novoglan product was reported easy to use by 91.8% of the post-marketing study participants and by all clinical trial participants. Positive impact on mental wellbeing was reported by 85.3% of the users in the post-marketing study, while more detailed assessment conducted in the clinical trial revealed reduced anxiety level in 95% of participants. Similarly, while no significant side effects were reported in the post-marketing study, more detailed questionnaires used in the clinical trial revealed transient foreskin discomfort, pain, itching or discoloration in 5-15% of participants.

Conclusion(s):

Both Novoglan post-marketing study and clinical trial demonstrated very high level of safety, efficacy and usability of the treatment and its positive impact on mental wellbeing. The comparison of the findings revealed that while more data could be obtained from detailed questionnaires used in the clinical trial, the overall similarity of the findings supports the reliability of both studies.

treatment using RigiScan® that besides the frequency-, regi tumescence- (TAU) and rigidity (RAU) of erections at the base and tip of the penis during sleep. As a normal reference, RigiScan® -values from men of similar age and no ED were used. All 70 participants underwent liposuction of 200-360 ml from the abdominal subcutis and ADRCs were isolated using a Cytori Celution® System. Immediately after isolation, the patient received an injection into each corpus cavernosum of 2 ml with either Ringer`s lactate or ADRCs.

RESULTS: The two groups were similar regarding age and comorbidity. Patient-reported outcome measures showed no statistical difference between groups in either the IIEF-5 or EHS scores at baseline, 1, 3, 6, or 12 months. RigiScan® evaluation following method validation and reference setting, showed that for each of the four RAU/TAU parameters, more patients in the treatment group had a response beneficial effect compared to the placebo group with tip TAU being significantly higher (46% vs 11%; p=0.0097). We observed that the probability for improvement in EF remained higher in the treatment group independent of the time between surgery and treatment. No severe adverse events related to the treatment were reported during the follow-up period.

CONCLUSIONS: In conclusion, ADRCs had no measurable effect on IIEF-5 and EHS scores in this study. ADRCs injected into the corpora cavernosum had some effect as evaluated by Rigiscan®, which suggest a potential for ADRC in subgroups of patients despite negative clinical findings in this study.

Source of Funding: Innovation Found Denmark

PD11-10

PHOSPHODIESTERASE-5 INHIBITOR USE AND PROGRESSION TO HEART FAILURE IN MEN WITH CORONARY ARTERY DISEASE AND ERECTILE DYSFUNCTION

Albert Ha, New York, NY; George Wayne, Miami, FL; Mark Jacobs, Andreas Kalogeropoulos, Stony Brook, NY; Joseph Alukal, New York, NY*

INTRODUCTION AND OBJECTIVE: Coronary artery disease (CAD) and erectile dysfunction (ED) often co-occur due to shared vascular risk factors. Although phosphodiesterase-5-inhibitors (PDE5i) are first line treatments for ED, they have also been shown to improve myocardial perfusion and cardiac contractility. To date, information regarding PDE5i and their perceived cardiac benefits has been limited. We hypothesized that tadalafil, with its high affinity to PDE5 receptors compared with sildenafil, may provide greater clinical benefits in reducing major adverse cardiac events (MACE).

METHODS: A retrospective, propensity-matched cohort study was performed using the TriNetX Research Network. Patients with ICD-10 codes for CAD and ED but not pulmonary hypertension were captured (1/2011-12/2016). Patients were subdivided and analyzed via pairwise fashion according to known prescriptions for tadalafil (T), sildenafil (S), or no treatment (NT). Propensity matching was performed using baseline comorbidities of hypertension, ischemic heart disease, cerebral infarction, diabetes, and hyperlipidemia. Outcomes of interest included 5-year rates of heart failure (HF), acute myocardial infarction (MI), and mortality.

RESULTS: A total of 41,287 male patients were identified, with 6,751 with concurrent tadalafil use, 12,214 with sildenafil use, and 22,321 with NT. When compared with NT, both tadalafil and sildenafil were associated with reduced progression to HF, MI, and overall mortality (Figure 1). Most importantly, compared with sildenafil, tadalafil demonstrated lower progression to HF (HR: 0.85 [0.77-0.94]), MI (HR: 0.86 [0.76-0.97]) and mortality (HR: 0.85 [0.76-0.95]) (Table 1).

CONCLUSIONS: Tadalafil use was associated with a significant reduction in progression to HF, MI, and mortality compared with sildenafil or no treatment. These preliminary results may signal meaningful clinical differences in drug choice for men suffering from CAD and ED, and therefore require further inquiry.

Figure 1 – Kaplan-Meier Survival Curves for Tadalafil, Sildenafil, and No Treatment for Heart Failure, Acute Myocardial Infarction, and Mortality

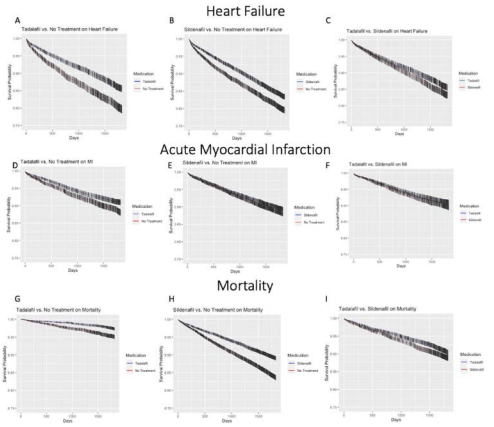


Table 1
Comparison of tadalafil, sildenafil, and no treatment with 5 year cardiac-specific outcomes

	Descriptive@		Propensity-score Matching
Comparison†	N (%)	P-value	HR [95% CI]
5 Year Heart Failure			
Tadalafil vs. No Treatment	711 (12.2) vs. 916 (17.0)	<0.001	0.67 [0.61-0.74]
Sildenafil vs. No Treatment	1,432 (14.5) vs. 1,643 (17.2)	<0.001	0.78 [0.72-0.83]
Tadalafil vs. Sildenafil	711 (12.2) vs. 795 (14.5)	0.002	0.85 [0.77-0.94]
5 Year Acute Myocardial Infarction			
Tadalafil vs. No Treatment	452 (7.7) vs. 553 (9.7)	<0.001	0.75 [0.67-0.85]
Sildenafil vs. No Treatment	935 (9.1) vs. 991 (9.7)	0.005	0.88 [0.80-0.96]
Tadalafil vs. Sildenafil	452 (7.7) vs. 518 (9.0)	0.017	0.86 [0.76-0.97]
5 Year Overall Mortality			
Tadalafil vs. No Treatment	553 (8.2) vs. 895 (13.3)	<0.001	0.59 [0.53-0.65]
Sildenafil vs. No Treatment	1,173 (9.6) vs. 1,687 (13.9)	<0.001	0.65 [0.60-0.70]
Tadalafil vs. Sildenafil	553 (8.2) vs. 664 (9.9)	0.003	0.85 [0.76-0.95]

† Propensity score matched using cardiac-specific comorbidities: Hypertension, Ischemic Heart Disease, Cerebral Infarction, Diabetes, and Hyperlipidemia
@Based on the Log-rank Test

Source of Funding: None

PD11-11

NOVOGLAN FORESKIN TISSUE EXPANDER TREATMENT IS SAFE & EFFECTIVE IN ADULT MALES WITH PHIMOSIS & IT REDUCES PAIN DURING SEXUAL ACTIVITY

Phil James, Sydney, Australia; Eric Chung, Brisbane, Australia; Dmitry Polikarpov, Hassan Doosti, Hurbert Mazure, Sydney, Australia; Andrew James, North Sydney, Australia; Douglas Campbell, Macquarie Park, Australia; David Gillatt, Sydney, Austrzalia*

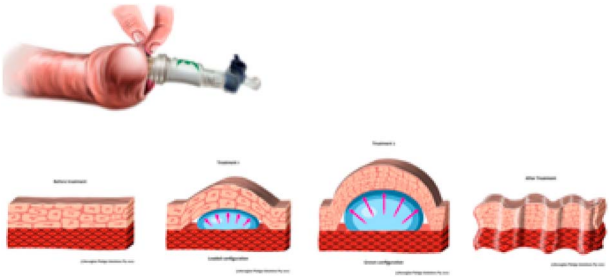
INTRODUCTION AND OBJECTIVE: Men with phimosis can endure pain during sexual activity due to phimosis. This can result in anxiety impacting the patients quality of life. While the mainstay of adult phimosis treatment is circumcision, many men are apprehensive of this intervention due to perceived risk of pain, bleeding, hypersensitivity & reduced sexual pleasure. The Novoglan device stimulates new skin cell growth by applying regular controlled pressure between foreskin & glans allowing it to retract properly. We conducted a clinical trial to establish treatment efficacy, safety & tolerability of the Novoglan foreskin tissue expander & compare patient pain, discomfort & anxiety during sexual activity, pre & post treatment.

METHODS: Analysis of the first 20 cases in the Novoglan-01 clinical trial used ordinal & scalar outcome variables plus descriptive participant variables. Clinical Trial Participation involved two initial visits to a urology clinic, where the patients were consented, trained & their degree of phimosis determined; two phone follow-ups & a final study visit to again determine the degree of phimosis. Phimosis grades were independently assessed by Consultant Urologist on a 1 to 6 scale, where #1 represents absolutely no foreskin retraction & #6 represents full free foreskin retraction. Participant quality of life with phimosis was measured at Visit 1 & again at Final Visit based on general pain / discomfort; pain / discomfort during sexual function, & anxiety.

RESULTS: Efficacy 100% of participants observed full retraction of their foreskin (Phimosis grade 5 or 6) by the final study visit compared with 15% after the first visit. Tolerability 90% reported no pain during treatment. Sexual activity 65% did not experience pain during sexual activity by the final visit vs 5% at the initial visit. 10% experienced

moderate pain during sexual activity by the final visit vs 50% at the initial visit. Anxiety 95% reported reduced level of anxiety post treatment 80% no longer considered circumcision an option post Novoglan treatment

CONCLUSIONS: Novoglan-01 study confirms foreskin tissue expander balloon device is an effective, well tolerated conservative treatment for adult phimosis, enabling quality of life improvement measured by reduced levels of pain, discomfort & anxiety during sexual activity.



Source of Funding: n/a

PD11-12

THE EFFECT OF CLOMIPHENE CITRATE ON PATIENT REPORTED OUTCOME MEASURES

Jessica Schardein, Kia Fendereski, Zane Randell, Soren Keihani, Joshua Horns, James Hotaling, Salt Lake City, UT*

INTRODUCTION AND OBJECTIVE: Clomiphene Citrate (CC) is a medication that can be used in hypogonadal men in lieu of testosterone to increase testosterone levels while preserving or improving fertility. Patient reported outcome measures for this medication are limited, especially regarding sexual functioning. Our objective is to assess whether self-reported changes in androgen deficiency symptoms and erectile function are observed along with changes in hormone levels and semen parameters in men taking CC.

METHODS: We performed a retrospective review of all patients on CC between 2014 and 2018 for hypogonadism and/or infertility. Patient characteristics including age and body mass index (BMI) along with hormone levels, semen parameters, and self-reported questionnaire scores were obtained. Patients who completed blood work for total testosterone and bioavailable testosterone, a semen analysis, and hypogonadism and erectile function questionnaires including Androgen Deficiency in Aging Male (ADAM) and Sexual Health Inventory for Men (SHIM) before and 3 months after the initiation of CC were included in the analysis. Patients with documented exogenous testosterone, human chorionic gonadotrophin, or anastrozole use were excluded. Changes in baseline and follow-up data were analyzed using paired-sample t-tests.

RESULTS: A total of 97 men were identified and included in the analysis. The mean age and body mass index (BMI) were 33.7 $\pm$ 6 years and 31.2 $\pm$ 7.3 kg/m^2, respectively. All patients were followed for at least 3 months. The use of CC significantly increased both mean total and bioavailable testosterone levels by 236.5 ng/dL and 115.6 ng/dL, respectively ($p<0.05$). Concentration, total progressive motility and morphology all significantly improved as well ($p<0.05$). Clinical manifestations included a significant improvement in ADAM scores ($p=0.025$) and no change in SHIM scores ($p=0.278$).

CONCLUSIONS: As more men are placed on CC for hypogonadism and/or infertility, characterizing patient reported outcomes regarding androgen deficiency symptoms and erectile function are important. The medication is able to raise testosterone levels while increasing semen parameters in addition to improving self-reported hypogonadal symptoms and maintaining erectile function scores.

Labs, Semen Parameters and Questionnaires Pre and Post Clomiphene Citrate (CC)

Labs	Before CC	3 months after CC	P-value
Total testosterone (ng/dL)	322.2 (207.8)	558.7 (271.8)	<0.001
Bioavailable testosterone (ng/dL)	138.9 (66.8)	254.5 (163.3)	0.011
Semen parameters			
Concentration, million/mL	22.3 (44.4)	33.4 (41.9)	<0.001
Morphology, %	1.8 (2)	1.9 (2.2)	0.034
Total progressive motility, %	30.8 (78.4)	48.1 (71.5)	0.001
Questionnaires			
SHIM	22.5 (3.2)	21.6 (4.1)	0.278
ADAM	4.2 (2.2)	2.7 (3)	0.025

Source of Funding: None

UROLOGICAL SOCIETY OF AUSTRALIA AND NEW ZEALAND

The novel foreskin tissue expander non-surgical phimosis treatment:

safe, effective in adult males and improves patient quality of life.

E. CHUNG [1], D. Polikarpov[2], H.DOOSTI[3], A.JAMES[4], H. MAZURE[5,] & **P.JAMES[6]** & D. GILLATT[7]

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Class 1 Medical Device
TGA, CE, MHRA, FDA listed

UROLOGICAL SOCIETY
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INTRODUCTION

Men with phimosis can endure pain during sexual activity or simply arousal, due to the tightness of the foreskin.

This often leads to:

anxiety or depression, impacting the patient's quality of life.

While the mainstay of adult phimosis treatment is circumcision, many men are apprehensive due to:

perceived risk of pain, bleeding, hypersensitivity & reduced sexual pleasure.

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"We know there's a lot of literature about circumcision to treat phimosis and the benefit of circumcision, but there was really no good scientific study looking at treating phimosis while preserving the foreskin"

PROFESSOR
Eric Chung
Independent Investigator

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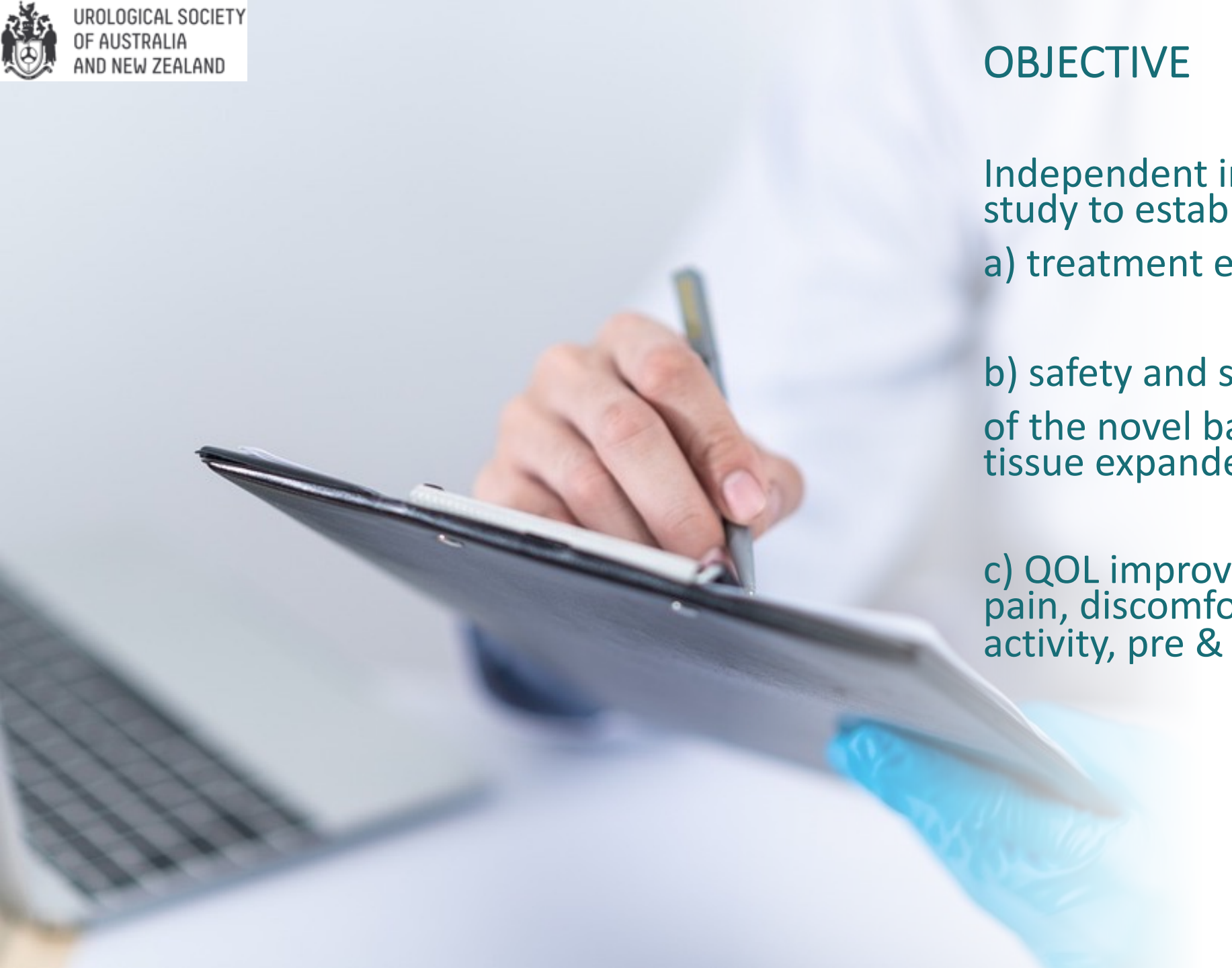

OBJECTIVE

Independent investigator initiated clinical study to establish

a) treatment efficacy in retraction

b) safety and satisfaction

of the novel balloon-based foreskin tissue expander

c) QOL improvement - comparing patient pain, discomfort & anxiety during sexual activity, pre & post treatment.

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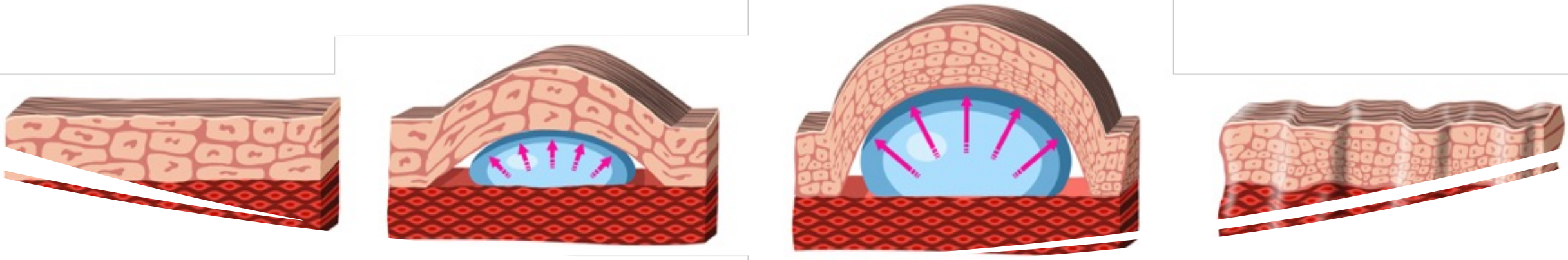

> 30 mins daily for 6 weeks

> 45,000 patients treated globally

The novel silicone balloon device stimulates the growth of new foreskin cells by applying regular controlled pressure between the foreskin and the glans.

With increased tissue volume, the foreskin is loosened & can then retract properly.

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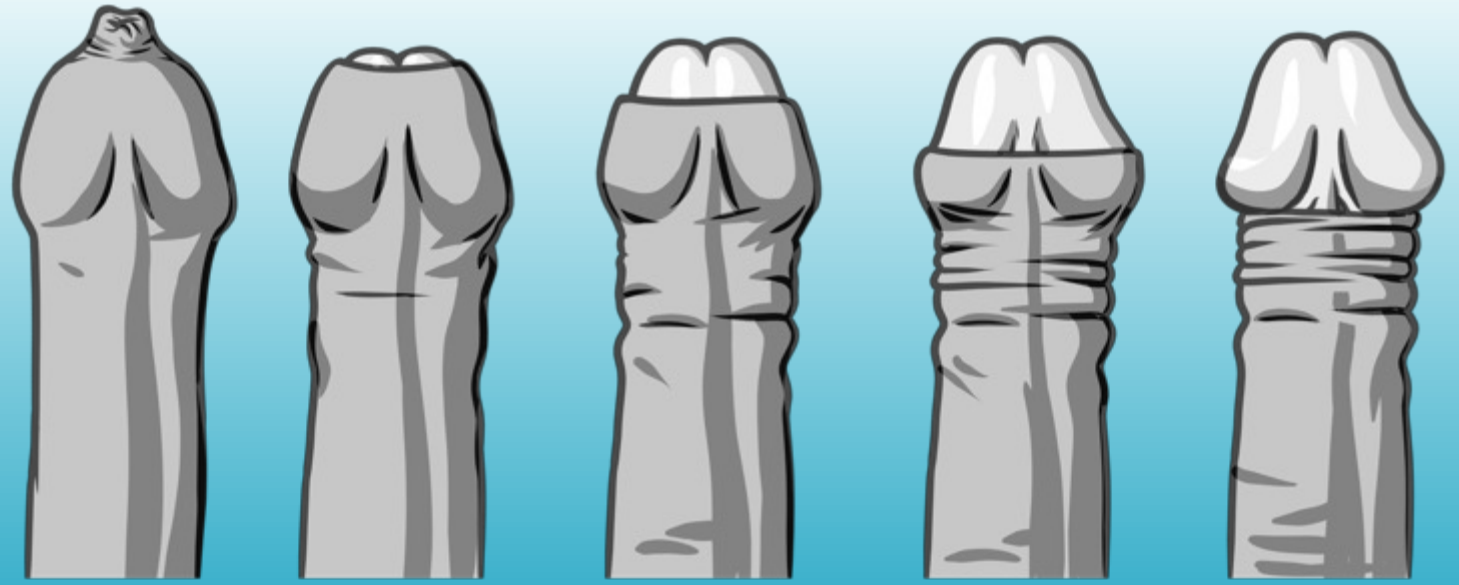
METHODS

The clinical trial used ordinal & scalar outcome variables plus descriptive participant variables.

Participation involved 2 initial visits to a urology clinic, patients were consented, trained on how to deploy the daily treatment and their grade of phimosis determined; 2 phone follow-ups and a final study visit, where their grade of phimosis was reassessed.

Grades of Phimosis were **independently assessed by Consultant Urologist** on a 1-to-6 scale, where grade 1 represents absolutely no foreskin retraction and grade 6 represents full free foreskin retraction.

Participant quality of life with phimosis were surveyed at visit 1 & again at the final Visit, with measures based on general pain / discomfort; pain / discomfort during sexual function and anxiety.



Gillatt Chung Grading	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Kikiros scale	5	4	3	2	1

UROLOGICAL SOCIETY OF AUSTRALIA AND NEW ZEALAND

RESULTS

interim review of initial 20 patients. Results in concordance with Independent PMS n=809

Efficacy

- 100% of participants observed **full retraction** of their foreskin (Phimosis measurement 5 or 6) by the final study visit compared with 15% after the first visit. **Zero adverse events**

Tolerability

- 90% reported **no pain** during treatment.

Sexual activity

- 65% experienced **no pain during sexual activity** by the final visit vs 5% at the initial visit.
- 10% experienced moderate pain during sexual activity by the final visit vs 50% at the initial visit.

Anxiety

- 95% reported **reduced level of anxiety** post treatment
- 80% no longer considered circumcision an option post treatment

PROFESSOR
Eric Chung
Independent Investigator

PROFESSOR
David Gillatt
Independent Principal Investigator

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CONCLUSIONS

Both investigators, Profs Gillatt & Chung concluded that the novel foreskin tissue expander balloon device is a **safe, effective, well tolerated conservative treatment** for adult phimosis in selected patients, **enabling quality of life improvement** measured by reduced levels of pain, discomfort & anxiety during sexual activity.

REFERENCES

[1] **M. Czajkowski et. al.** Male Circumcision Due to Phimosis as the Procedure That Is Not Only Relieving Clinical Symptoms of Phimosis But Also Improves the Quality of Sexual Life

[2] **Kikiros D.S. et al**. The response of phimosis to local steroid application. *Paediatric Surgery International,* 1993 **8**:329-332

[3] **E. Chung et.al.** Novoglan-01 Interim Review Report 27May22.pdf

Introduction & objectives: The Novoglan balloon tissue expander has been developed for non-surgical treatment of phimosis. This device stimulates the growth of new skin cells by applying regular controlled pressure between the foreskin and the glans, thereby expanding the foreskin tissue, allowing it to retract properly. We conducted a clinical trial assessing the efficacy, safety and tolerability of this treatment and compared its findings to the results of the post-marketing survey completed earlier.

Materials & methods: The Novoglan-01 clinical trial is a multicenter (2 sites), observational study that has been approved by the Human Research Ethics Committee of Macquarie University and by the Queensland Metro South Health Human Research Ethics Committee and enrolled twenty patients. The post-marketing surveillance survey was undertaken by Callor8 Consulting Pty Limited to independently survey consenting Novoglan device users with adult phimosis. Eight hundred and three Novoglan users agreed to participate in the survey of which 461 individuals had used the identical Novoglan device used in the Clinical trial. The remainder used an older version of the device and have been excluded from this study. In both instances, users were questioned about the treatment efficacy, safety and tolerability. These measures were self-reported in the post-market survey and independently assessed in the clinical trial.

Results: Both post-marketing survey and clinical trial showed very high efficacy and tolerability of the treatment with 93% and 100% of patients, respectively, achieving foreskin retraction and being satisfied with the treatment. No patients experienced adverse events or serious side effects in both studies. Mild side effects were reported by 10% of the clinical trial participants and were not reported by anyone in the post-marketing survey. Importantly, 85%-95% of users reported reduction in level of their phimosis-related anxiety after the Novoglan treatment.

Outcomes	**Clinical Trial**	**PMS Study**
Efficacy / Satisfaction With Treatment Outcome	100%	93%
Safety - Significant Side Effects	0%	0%
Safety - Mild Side Effects	10%	0%
Adverse Events Reported	0%	0%
Device Usability (Comfort and Usability)	90%	92%
Reduced Anxiety	95%	85%
Consider Future Circumcision if Relapse	20%	N/A
Recommend Novoglan Treatment to Other Phimosis Patients	95%	N/A

Conclusion: Results from the independent Novoglan-01 clinical study are strongly in concordance with the Post Marketing Survey, confirming the novel Novoglan foreskin tissue expander balloon device is a safe, effective and well tolerated conservative treatment for adult phimosis.

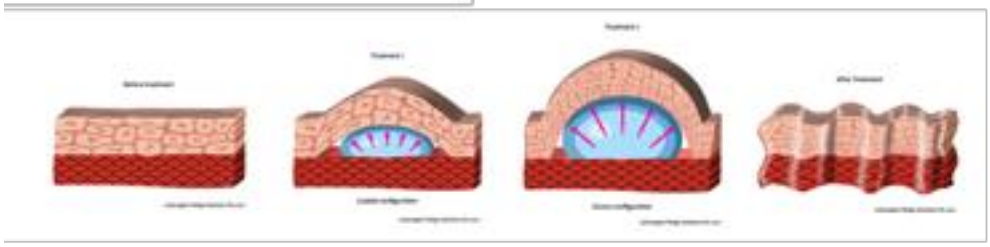
FINAL SUBMISSION TO MEET CHARACTER LIMITATIONS

Title:
Comparative review of independent clinical trial data and post marketing surveillance data of the novel foreskin tissue expander balloon device for phimosis in adult males

Topic: Non-Disease specific
Sub topic: Affordable medicine/New Technology
Clinical step: Treatment

Introduction & Objectives:

The Novoglan balloon tissue expander has been developed for non-surgical phimosis treatment. The device stimulates new skin cell growth by applying regular controlled pressure between foreskin & glans, thereby expanding foreskin tissue, allowing it to retract properly. We conducted a clinical trial assessing efficacy, safety & tolerability of treatment & compared findings to results of post-marketing survey completed earlier.



Materials & Methods:

Novoglan-01 clinical trial is a multicenter 2 sites observational study approved by Human Research Ethics Committee of Macquarie University & Queensland Metro South Health Human Research Ethics Committee - enrolled 20 patients.

Post-marketing surveillance survey undertaken by Collabor8 Group Pty Ltd to independently survey consenting Novoglan device users with adult phimosis. n=803 Novoglan users agreed to participate in the survey of which n=461 individuals used the identical Novoglan device as per the Clinical trial. The remainder used an older device version thus excluded from the study. In both cases, users were asked about treatment efficacy, safety & tolerability. All measures were self-reported in the post-market survey & independently assessed in the clinical trial.

Results:

Both post-marketing survey & clinical trial showed very high treatment efficacy & tolerability with 93% & 100% of patients, respectively, achieving foreskin retraction & being satisfied with treatment. No patients experienced adverse events or serious side effects in both studies. Mild side effects were reported by 10% of clinical trial participants but not reported by anyone in post-marketing survey. 85%-95% of users reported reduction in level of their phimosis-related anxiety after the Novoglan treatment.

	Clinical Trial	PMS Study
Efficacy / Satisfaction - Treatment Outcome	100%	93%
Safety - Serious Side Effects	0%	0%
Safety - Mild Side Effects	10%	0%

Adverse Events	0%	0%
Device Usability (Comfort & Usability)	90%	92%
Reduced Anxiety	95%	85%
Consider Future Circumcision if Relapse	20%	-
Recommend Novoglan Treatment to Other Phimosis Patients	95%	-

Conclusions:

Results from the independent Novoglan-01 clinical study are strongly in concordance with the Post Marketing Survey, confirming the novel Novoglan foreskin tissue expander balloon device is a safe, effective & well tolerated conservative treatment for adult phimosis.

Psychological Outcomes and Sexual Satisfaction Rates in Males with Phimosis following the Novoglan Foreskin Extender Treatment.

Eric Chung, Dmitry Polikarpov, Hubert Mazure, Andrew James, Hassan Doosti, Douglas Campbell, David Gillatt

Introduction:
Phimosis can be associated with sexual dysfunction since it often causes discomfort or pain on erection or during sexual intercourse. While circumcision is routinely advocated in patients with phimosis, many males would prefer conservative treatment and are keen to preserve their foreskins. Novoglan foreskin tissue expander is a non-surgical device that uses a balloon to produce gradual stretching of the phimotic foreskin.

Objective:
To assess the impact of phimosis and Novoglan treatment on sexual health and psychological domains.

Methods:
Following Institutional Ethics Board approval (HREC/2020/QMS/66682), 20 males with phimosis were recruited across two Australian sites. Inclusion criteria include male aged ≥ 18 years, who has phimosis and normal erectile function, while those with balanoposthitis and/or recurrent UTIs were excluded. All participants received informed consent and completed questionnaires before and after the Novoglan treatment. The questionnaires included questions on pain or discomfort during sexual activity and levels of anxiety or depression. Circumcision was offered to all patients at the start and end of the study period.

Results:
Nineteen (95%) patients with phimosis recruited in the Novoglan trial reported pain or discomfort during sexual activity, with one (5%) participant reporting pain or discomfort as severe, while moderate or mild levels were reported by ten (50%) and eight (40%) participants, respectively. The level of pain or discomfort during sexual activity improved significantly after the Novoglan treatment with no patients reporting severe level of pain or discomfort, with most males reporting mild or no pain or discomfort (80%). While all participants documented mild to moderate levels of anxiety or depression prior to treatment, 17 participants (85%) reported no anxiety or depression and only three (15%) men reported a mild degree of psychological distress. None of the participants elected for circumcision.

Conclusions:
The Novoglan foreskin tissue expander device significantly improves the psychological outcomes and sexual function in males with phimosis. All patients reported minimal or no pain or discomfort during sexual activity, had minimal or no anxiety or depression related to foreskin issues, and declined circumcision at the end of the study period.

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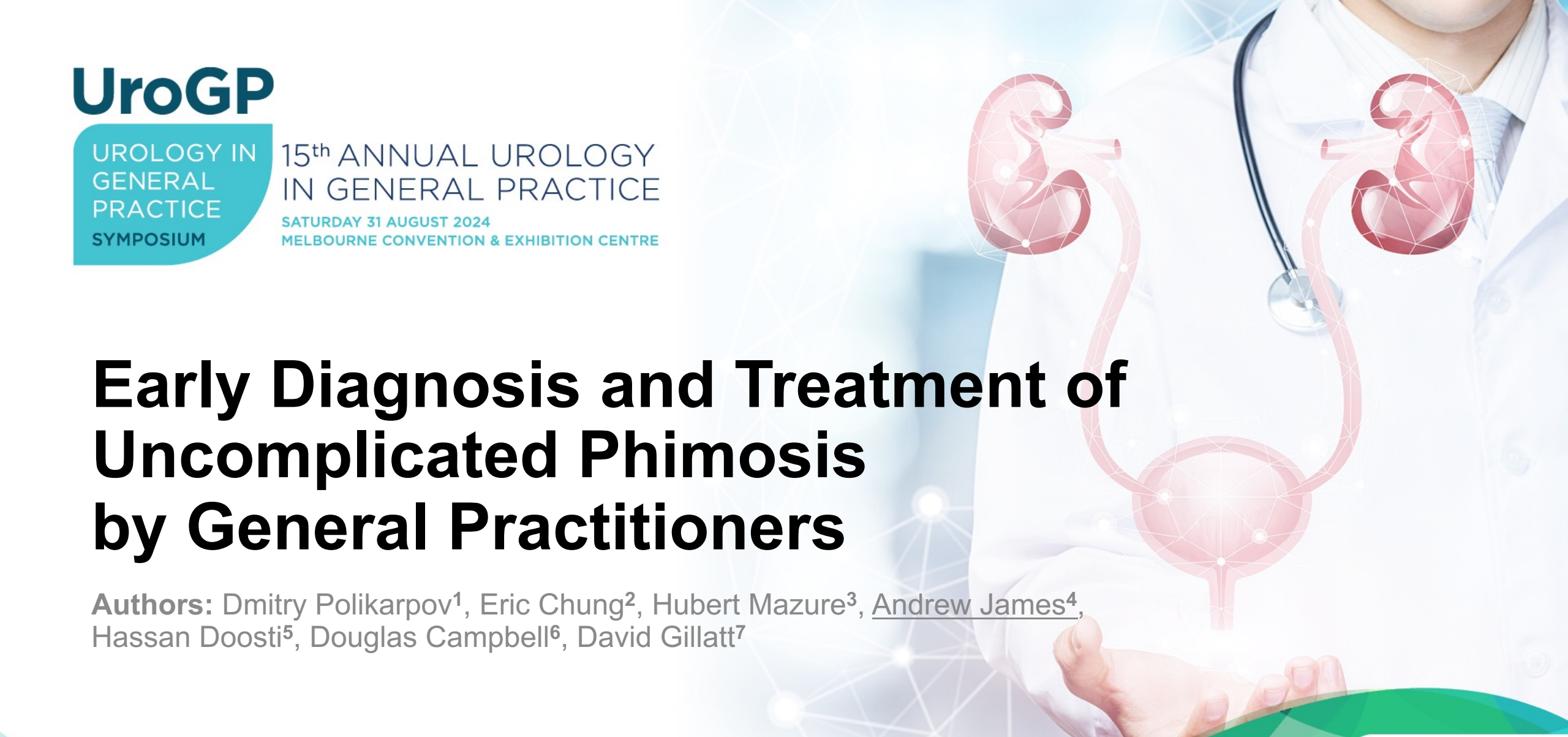
UROLOGY IN GENERAL PRACTICE SYMPOSIUM

15th ANNUAL UROLOGY IN GENERAL PRACTICE

SATURDAY 31 AUGUST 2024

MELBOURNE CONVENTION & EXHIBITION CENTRE



Early Diagnosis and Treatment of Uncomplicated Phimosis by General Practitioners

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

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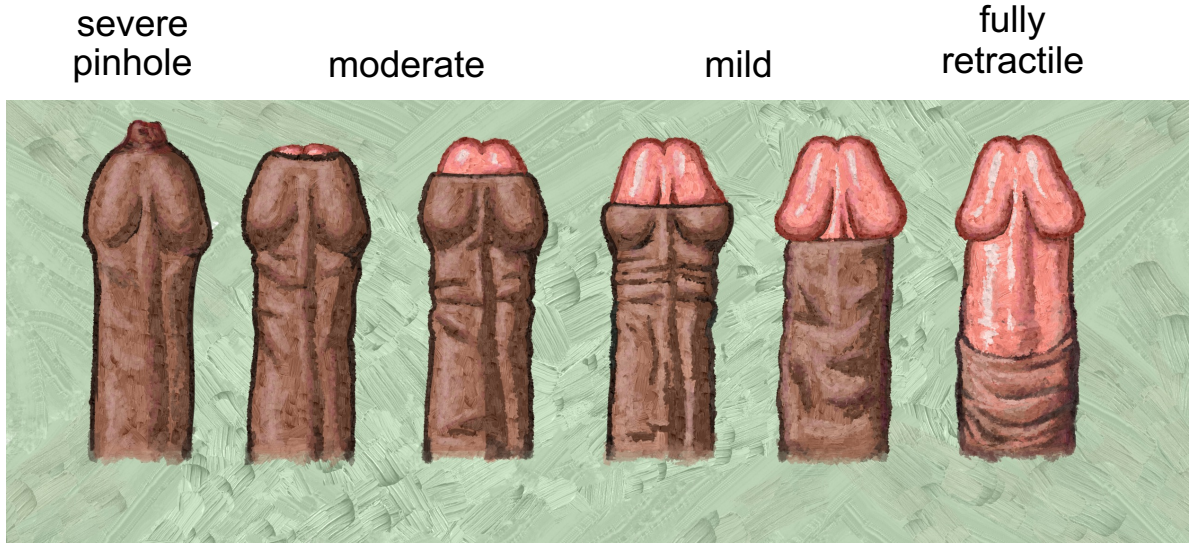
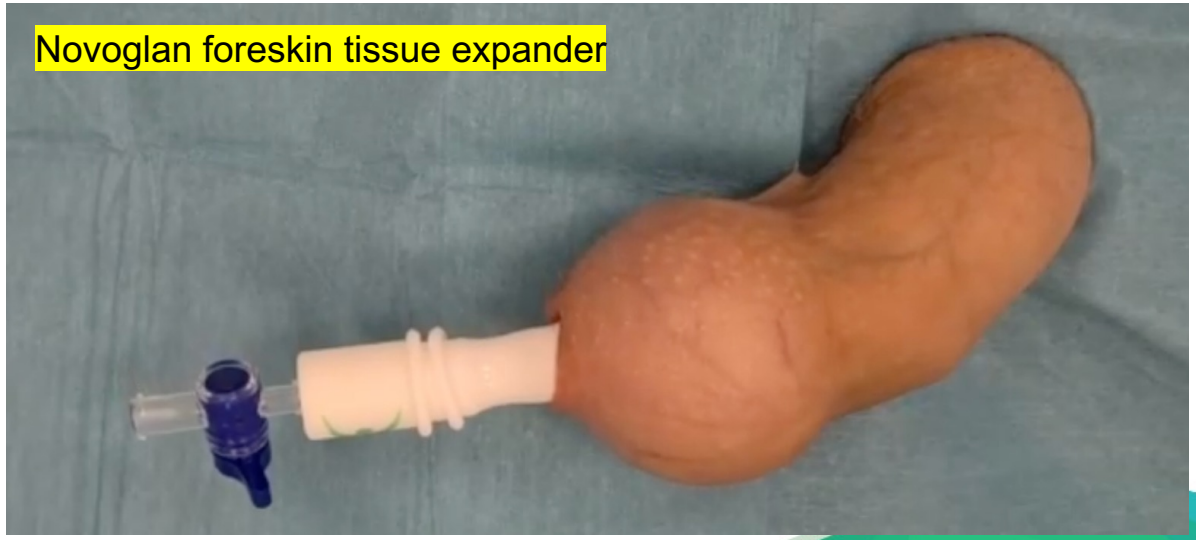
AUSTIN UROLOGY

Introduction Phimosis

- Ranges from mild (partial retraction) to severe (pinhole phimosis).
- In Australia, ~ 30% of men referred to urology clinics for phimosis review are diagnosed as uncomplicated that have **not** responded to topical steroids
- Often face long wait-times for non-urgent circumcision in public hospitals
- Published clinical research has established the Novoglan Non-Surgical Phimosis Treatment Kit as a viable alternative for all grades of uncomplicated Phimosis.





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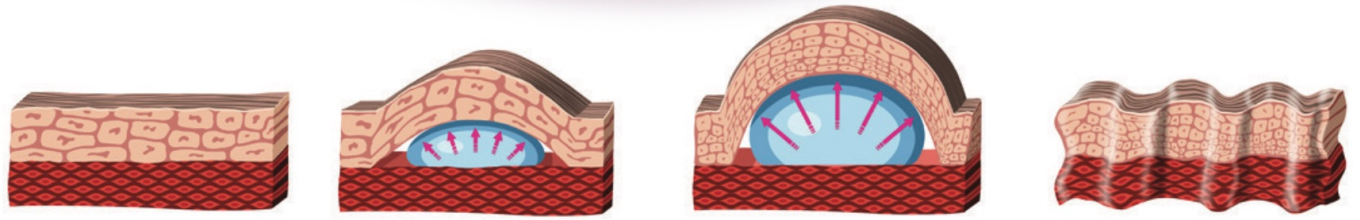
Methodology

- comparative review conducted of:
  - independent multi-site clinical trial with selected patients
  - post-marketing surveillance studies into the Novoglan Non-Surgical foreskin tissue expander medical device
- evaluation of treatment:
  - Efficacy
  - Safety
  - Tolerability QoL

Novoglan foreskin tissue expander



tightness before stretching -> gentle stretching stimulates tight junctions -> 30 mins daily stretching for 6 weeks -> expanded foreskin tissue

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Results

Post-marketing study:

93.5% reported successful treatment outcomes

91.8% finding the device easy to use

85.3% reported positive impacts on mental wellbeing and sexual health.

12.7 % reported mild to moderate pain on initial use

Clinical trial:

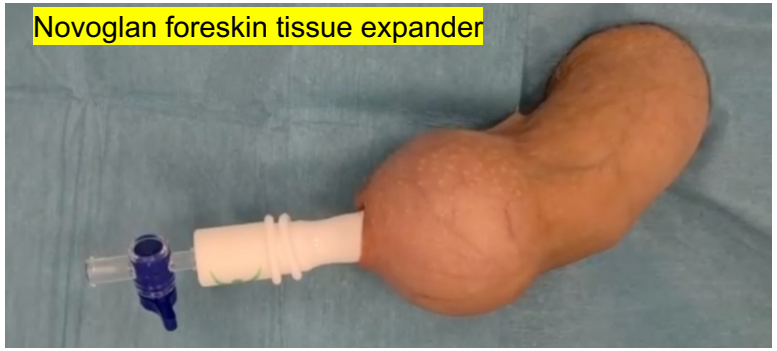
90% of participants showed improvement in foreskin retraction

95% experiencing reduced level of anxiety & over 60% patients reported reduced pain/discomfort during sex

95% satisfaction associated with sex and enhanced mental health post treatment.

15% reported minor side effects that resolved during ongoing treatment

Conclusion



- The findings supports the reliability of both studies.
- The Novoglan device demonstrates high efficacy and patient satisfaction in treating uncomplicated phimosis, without surgery and with minimal side effects.

At early diagnosis, General Practitioners:

- can offer patients an effective at-home non-surgical first-line treatment option
- may reduce need for circumcision, alleviating pressure on public hospital waiting lists
- should consider the Novoglan device when, upon visual clinical examination, the patient has approximately >80% healthy foreskin tissue, necessary for effective tissue expansion.
- Complications presented as moderate to severe scarring, BXO plaques, or suspicious lesions should be referred to a urologist

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

E. Chung[1], D. Polikarpov[2], H. Mazure[3], A. James[4], H. Doosti[5], D. Campbell[6], D. Gillatt[7]

[1]Princess Alexandra Hospital, Brisbane, Australia
[2]Wagga Base Hospital, Wagga Wagga, Australia
[3]HGM Consultants, Sydney, Australia
[4]Platigo Solutions Pty Ltd, Sydney, Australia
[5]Macquarie University, Sydney, Australia
[6]Minomic International Ltd., Sydney, Australia
[7]Macquarie University Hospital, Sydney, Australia

Aim:
Conventional definitive treatment for adult phimosis is circumcision. Novoglan device is a potential non-surgical alternative through the application of custom-moulded balloons for gradual skin remodelling and prepuce dilation. Initial results of the NOVOGLAN-01 open-label clinical trial demonstrated promising outcomes. This follow-up abstract presents the two-year results, aimed at establishing long-term efficacy, safety, and tolerability.

Methods:
A prospective, open-label trial was conducted on the first 20 adult patients with phimosis at Macquarie University Hospital and Princess Alexandra Hospital. Following eligibility screening, patients underwent Novoglan treatment involving twice-daily 10-minute applications for 4-8 weeks. Efficacy was measured by the degree of phimosis before and after treatment, with follow-ups at 6-8 weeks and two years. Each patient served as their own control. Safety and tolerability were assessed using questionnaires.

Results:
Two-year follow-up data revealed that 19 of the first 20 patients (95%) maintained successful outcomes with full normal retraction. Among these 19 patients, 100% reported no new symptoms and did not require further intervention or circumcision. The statistical analysis supports that these results are likely attributable to the Novoglan treatment rather than chance, given the consistent improvement across individual cases and sustained efficacy over two years.

Conclusions:
The NOVOGLAN-01 trial's two-year follow-up data underscore the long-term efficacy and safety of Novoglan for treating adult phimosis. Each patient serving as their own control further strengthens the validity of these results. The high success rate, absence of new symptoms, and lack of need for further surgical intervention highlight the potential of Novoglan as a viable non-surgical alternative to circumcision.

References:

Trial registration:
The NOVOGLAN-01 study is registered with the Australia and New Zealand Clinical Trial Registry under reference ACTRN 1262 10009 24853, dated 15 July 2021.

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

Authors:
Dmitry Polikarpov, Eric Chung, Hubert Mazure, Andrew James, Hassan Doosti, Douglas Campbell, David Gillatt

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.

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

Authors:
Eric Chung, Dmitry Polikarpov, Hubert Mazure, Andrew James, Hassan Doosti, Douglas Campbell, David Gillatt

---

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:

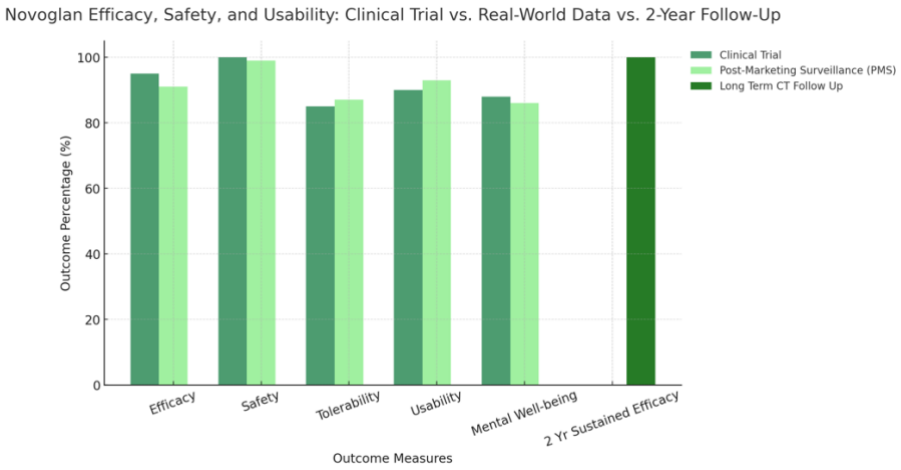
Short-Term (6–8 weeks):

- 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.

Resultados Psicológicos y Satisfacción Sexual en Hombres con Fimosis Tras el Tratamiento con Novoglan: Perspectivas Comparativas de Ensayo Clínico, Vigilancia Postcomercialización y Seguimiento a Largo Plazo

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

[1]Princess Alexandra Hospital, Brisbane, QLD, Australia
[2]Royal Prince Alfred Hospital, Sydney, NSW, Australia
[3]HGM Consultants, Sydney, NSW, Australia
[4]Platigo Solutions Pty Ltd, Roseville, NSW, Australia
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[6]Minomic International Ltd., Sydney, NSW, Australia
[7]Macquarie University Hospital, Sydney, NSW, Australia

Antecedentes

La fimosis en hombres adultos suele asociarse con actividad sexual dolorosa, reducción de la satisfacción sexual y ansiedad. Aunque la circuncisión se ofrece comúnmente, un número significativo de pacientes prefiere alternativas que preserven el prepucio. Novoglan, un expansor tisular no quirúrgico del prepucio, ofrece esta opción. Este estudio compara los resultados psicológicos, de salud sexual y de resolución de la fimosis en cohortes clínicas, de vigilancia postcomercialización y de seguimiento a largo plazo.

Métodos

Se evaluaron tres conjuntos de datos:
1. Ensayo clínico (n=20) – Estudio prospectivo y multicéntrico; los pacientes utilizaron Novoglan durante 6 a 8 semanas con evaluación urológica y cuestionarios psicosexuales.
2. Vigilancia postcomercialización (n=811) – Encuestas del mundo real evaluando el éxito del tratamiento, facilidad de uso, seguridad e impacto psicológico.
3. Seguimiento a dos años (n=20) – Participantes del ensayo clínico revaluados para comprobar eficacia a largo plazo y recurrencia.

Resultados

Resolución de la fimosis:
- El 95% de los pacientes del ensayo clínico lograron la retracción completa del prepucio.
- El 91% de los encuestados en la vigilancia postcomercialización reportaron éxito en el tratamiento.
- El 95% mantuvo la retracción completa dos años después, sin recurrencia ni cirugía.

Resultados sexuales y psicológicos:
- El 95% informó dolor durante las relaciones sexuales al inicio; tras el tratamiento, el 80% reportó dolor leve o ausencia de dolor.

- El malestar psicológico disminuyó del 100% al 15% en la cohorte del ensayo clínico.
- El 76.2% de los encuestados en PMS reportaron mejora en su bienestar mental.

Satisfacción del paciente y seguridad:
- El 88.8% expresó satisfacción con el tratamiento; el 81.8% volvería a usar Novoglan.
- No se reportaron eventos adversos graves en ninguno de los conjuntos de datos.

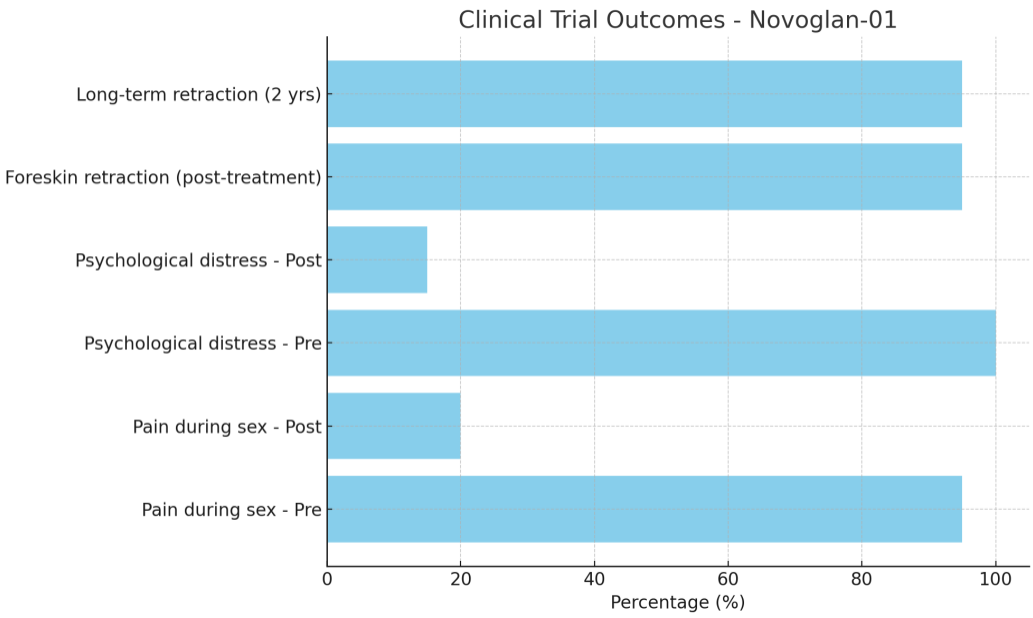

Figura 1. Resultados del ensayo clínico – Novoglan-01

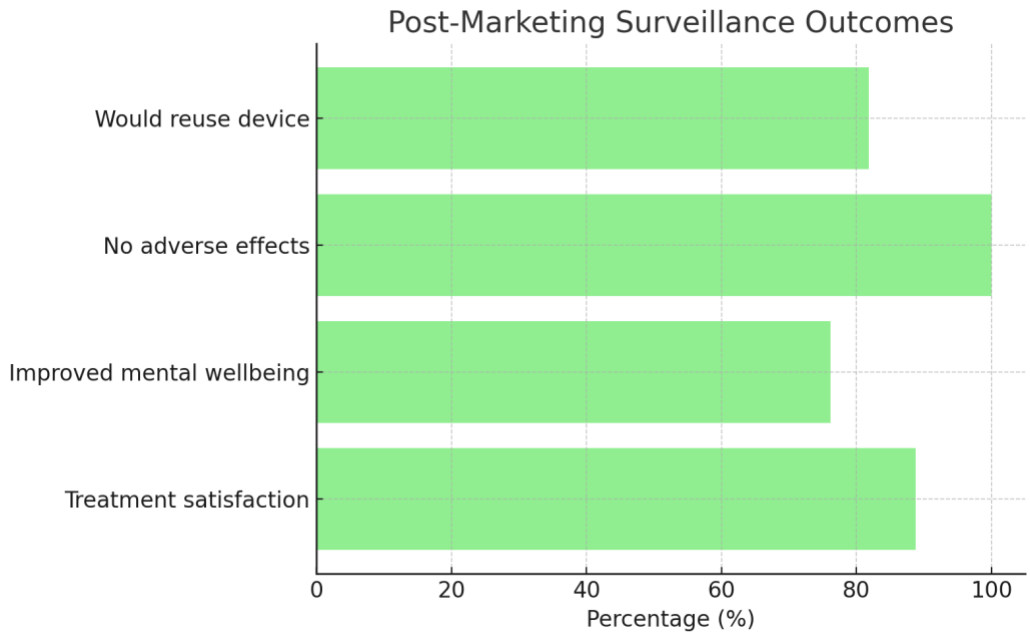

Figura 2. Resultados de la vigilancia post-comercialización – Novoglan-01

Conclusiones

Novoglan es una alternativa segura, eficaz y conservadora a la circuncisión para hombres adultos con fimosis. Proporciona una resolución constante de la fimosis (91–95%), alivia el malestar sexual y mejora la salud psicológica. El seguimiento a largo plazo confirma su durabilidad y la satisfacción del paciente, validando a Novoglan como una opción terapéutica no quirúrgica sólida.

Aprobación Ética

Aprobado por:
- Comité de Ética en Investigación Humana de la Universidad Macquarie (Ref: 520193 3799 8816, 11 de junio de 2019)
- Comité de Ética en Investigación del Metro Sur de Queensland Health (Ref: HREC/2020/QMS/66682, 17 de noviembre de 2020)

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

Dr Dmitry Polikarpov1, Prof Eric Chung 2, Dr Hubert Mazure 3, Mr Andrew James 4, Prof David Gillatt 5

1 Northern Beaches Hospital, Frenchs Forest, Australia, 2 Princess Alexandra Hospital, Woolloongabba, Australia, 3 HGM Consultants, Winston Hills, Australia, 4 Platigo Solutions Pty Ltd, Roseville, Australia, 5 Macquarie University Hospital, Macquarie University, Australia

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.

(386) Rethinking Phimosis Management: Conservative and Surgical Alternatives to Circumcision

M George; J Gibson; A Khan; V Modgil; I Pearce; T Stasinou

Manchester University NHS Foundation Trust

Bolton NHS Foundation Trust

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Published: 09 December 2025

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Abstract

Introduction

Phimosis is a common urological condition characterised by the partial or complete inability to retract the foreskin, which can cause genital pain and sexual dysfunction. The condition may be classified according to its severity and underlying aetiology, both of which guide clinical decision-making. Whilst circumcision remains the conventional surgical treatment, it is a radical intervention associated with inherent risks.

These include not only surgical complications but also a notable risk of medico-legal litigation, compounded by the procedure's perceived simplicity and the subjective nature of cosmetic outcomes, resulting in an average claim of approximately $175,000 in the United States of America. Furthermore, cultural and religious beliefs often influence patients' attitudes toward circumcision.

In recent years, there has been a shift towards less restrictive therapies that preserve the prepuce, with advances in surgical innovation having expanded the range of treatment options for phimosis. As these novel approaches gain traction, it is essential that urologists maintain a comprehensive understanding of their indications, benefits and limitations to ensure informed, high-quality patient counselling.

Objective

This narrative review provides a contemporary overview of prepuce-preserving treatment options for phimosis, encompassing non-operative approaches and surgical techniques.

Methods

A structured literature search was conducted using key search terms capturing both the condition (e.g. "phimosis", "non-retractile foreskin") and its management (e.g. "treatment", "topical corticosteroids", "preputioplasty"). Identified articles underwent manual review prior to inclusion.

Results

A wide variety of alternatives to circumcision are available in the treatment of phimosis, encompassing non-operative and operative techniques. A key first-line non-operative strategy employs gentle daily foreskin retraction combined with topical corticosteroid therapy, which has demonstrated high efficacy and minimal adverse effects; however, recurrence rates of up to 18% provide rationale for alterative options in those wishing to avoid surgery.

As such, novel therapies such as platelet-rich plasma injections and medical-grade dilatation devices have been proposed. Platelet-rich plasma therapy has demonstrated promise in early studies.

Dilatation devices such as Novoglan and Phimostop offer graded dilation of the phimotic ring via an inflatable balloon or silicone tuboid inserted beneath the prepuce, respectively; these devices allow for self-administered, community-based treatment and have shown encouraging outcomes, including high patient satisfaction and ease of use. For patients with phimosis that is refractory or not amenable to conservative therapy, preputioplasty serves as a viable surgical option.

Unlike circumcision, preputioplasty encompasses a variety of techniques aimed at preserving the cosmetic and protective functions of the foreskin. Dilatation devices and preputioplasty are contra-indicated in cases associated

with balanitis xerotica obliterans due to the risk of iatrogenic trauma and impaired wound healing respectively.

Effective phimosis management requires an individualised approach that considers patient preferences, clinical severity and the individual's ability and/or willingness to comply with treatment. Patient information materials serve as valuable resources capable of supporting individuals in determining their treatment preferences and actively participating in informed, shared decision-making.

Conclusions

A growing array of prepuce-preserving alternatives to circumcision, including dilatation devices and evolving surgical techniques, are reshaping the management of phimosis. Promoting awareness of these options among clinicians and patients is essential to promoting patient-centred care.

Disclosure

No

The Use of NovoglanTM Device in Reducing Psychosexual Burden in Patients Suffering From Phimosis and Awaiting Circumcision in a Public Hospital

#050

Chung, E1

1 - AndroUrology Centre

Introduction:

Phimosis, whether congenital or acquired, affects a significant proportion of adult males and can cause urinary and sexual dysfunction. While topical corticosteroids may be effective in a subset of patients, many patients experience persistence or progression of their phimosis, necessitating surgery. Circumcision, although effective, is associated with potential complications including meatal stenosis, altered penile sensitivity, sexual dysfunction and suboptimal cosmetic outcomes. Many males are keen to avoid circumcision due to possible adverse outcomes and to be able to preserve their foreskin for sexual satisfaction and avoid psychological distress related to being circumcised.

Objective:

This prospective study evaluates the positive psychosexual impact of the use of the NovoglanTM device in patients currently on the surgical waitlist for circumcision.

Methods:

A single-arm, open-label prospective trial was conducted at the Princess Alexandra Hospital (Brisbane, Australia), enrolling 24 adult males with persistent phimosis unresponsive to standard conservative therapy and who were currently on the circumcision waitlist. Ethics approval was obtained (HREC: PR/2023/QMS/66682). Participants were offered an 8-week trial of the NovoglanTM device while awaiting surgery. Baseline and post-treatment assessments included phimosis grading, psychosexual symptom burden, and quality of life metrics across domains such as pain, sexual function, daily activities, and psychological well-being.

Results:

Of the 24 enrolled participants, 20 completed the study, while 4 withdrew due to personal reasons. The mean age of participants was 36.3 ± 13.7 years. Balanitis xerotica obliterans (BXO) was clinically diagnosed in 70% of cases. Following 8 weeks of NovoglanTM use, 75% of participants reported improvement in foreskin retractability, and all patients reported improvement in psychosexual domains and quality-of-life scores. Notably, 20% of patients avoided circumcision altogether and reported significant psychological relief and better sexual satisfaction.

Conclusions:

In a cohort of patients with refractory phimosis, the NovoglanTM device demonstrated clinically meaningful improvements in psychosexual symptoms and quality of life. Importantly, it enabled a subset of patients to avoid circumcision, highlighting its potential role as an effective therapy in addressing the long waitlist times for circumcision in the public health settings, where surgical resources are limited and importantly, patients can keep their foreskin and alleviate psychosexual distress associated with circumcision and/or phimosis.

Disclosure:

Yes, this is sponsored by industry/sponsor: Novoglan device

Clarification:

Industry funding only - investigator initiated and executed study

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Of the 24 enrolled participants, 20 completed the study, while 4 withdrew due to personal reasons. The mean age of participants was 36.3 ± 13.7 years. Balanitis xerotica obliterans (BXO) was clinically diagnosed in 70% of cases. Following 8 weeks of NovoglanTM use, 75% of participants reported improvement in foreskin retractability, and all patients reported improvement in psychosexual domains and quality-of-life scores. Notably, 20% of patients avoided circumcision altogether and reported significant psychological relief and better sexual satisfaction.

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Disclosure:

Yes, this is sponsored by industry/sponsor: Novoglan device

Clarification:

Industry funding only - investigator initiated and executed study

Novoglan device use in public hospitals: enhancing outcomes and avoiding circumcision in phimosis

Dr Zhong Li Titus Lim, Dr Handoo Rhee
Princess Alexandra Hospital, Woolloongabba, Australia

Introduction:

Phimosis, whether congenital or acquired, affects a significant proportion of adult males in Australia. While topical agents with manual manipulation remain common strategies, a subset of patients experience persistent or progressive disease necessitating surgical intervention. Circumcision is effective, although associated with potential long-term complications including meatal stenosis, altered penile sensitivity and suboptimal cosmetic outcomes. Consequently, there is growing interest in non-surgical alternatives. This prospective study evaluates the clinical utility of the Novoglan device in patients referred for circumcision following failed conservative management.

Methods:

A single-arm, open-label prospective trial was conducted at the Princess Alexandra Hospital (Brisbane, Australia), enrolling 24 adult males with persistent phimosis unresponsive to standard conservative therapies. Ethics approval was obtained (HREC: PR/2023/QMS/66682). Participants were offered an 8-week trial of the Novoglan device whilst awaiting circumcision. Baseline and post-treatment assessments included phimosis grading, symptom burden, and quality of life metrics across domains such as pain, sexual function, daily activities, and psychological well-being.

Results:

Of the 24 enrolled participants, 20 completed the study, with 4 withdrawing due to personal reasons. The mean age of participants was 36.3 ± 13.7 years. Comorbidities included diabetes mellitus (n = 6, 30%) and genital psoriasis (n = 2, 10%). Balanitis xerotica obliterans (BXO) was clinically diagnosed in 70% of cases. Following 8 weeks of Novoglan use, 75% of participants reported improvement in foreskin retractability and symptom relief. Quality of life scores improved across all measured domains. Notably, 20% of patients avoided circumcision altogether, and 80% indicated they would recommend the device to others.

Conclusion:

In a cohort of patients with refractory phimosis, including those with suspected BXO, the Novoglan device demonstrated clinically meaningful improvements in symptoms and quality of life. Importantly, it enabled a subset of patients to avoid circumcision, highlighting its potential role as a salvage therapy in public health settings where surgical resources are limited or patient preference favours conservative management.

Novoglan Tissue Expander as a Non-Invasive Alternative: Comparative Outcomes from Australian and UK Prospective Studies

Primary Authors: Zhong Li Titus Lim, Prabhat Narayan, Nadine Hall, Paul Hadway, Shafi Wardak, Bob Yang, Eric Chung, Handoo Rhee

Introduction
Adult phimosis is typically treated with circumcision following unsuccessful topical therapy; however, surgery entails risks such as altered penile sensitivity, cosmetic dissatisfaction, and psychological distress. Non-surgical options that keep the foreskin, like the Novoglan tissue expansion device, may help with these problems by making it easier for patients to retract the foreskin without surgery. This abstract contrasts the outcomes of two prospective cohorts in Australia and the UK, examining the efficacy of Novoglan in clinical settings, its effectiveness in preventing circumcision, and its psychological benefits for patients.

Methods
Data were synthesised from two single-arm prospective studies of adult males with symptomatic phimosis refractory to standard medical therapies. The first study involving an Australian cohort comprised 24 patients on a public hospital circumcision waitlist, including those with suspected balanitis xerotica obliterans, who used Novoglan for 8 weeks. The second study involved the UK cohort, which included ten patients with mild to moderate phimosis, excluding balanitis xerotica obliterans (BXO), who used the device for 30 minutes per day for six weeks after receiving structured training. Outcomes included about 80% of patients reporting improved foreskin retractability (Kikiros Phimosis Score) and 50% of patients reporting treatment satisfaction and deciding against circumcision; 100% of patients rated the device as "easy to use”. No serious adverse effects, bothersome pain, or bleeding were recorded.

Results
In the Australian cohort, 20 of 24 patients who were on the waitlist for surgery completed treatment, with 75% reporting improved foreskin retractability and symptom relief; quality of life improved across physical, sexual and psychological domains, and 20% took their names off the circumcision waitlist. In the UK cohort, the mean Kikiros Phimosis Score significantly improved, 80% reported subjectively better retraction, all patients described reduced pain and anxiety during sexual activity, and 50% elected not to proceed with circumcision. Across both settings, the device was well tolerated and rated easy to use, and no serious adverse events were reported.

Conclusions

Across two independent cohorts, the Novoglan device provided consistent, clinically significant improvements in adult phimosis and reduced psychological burden. The findings from two different studies showed that 20% of waitlist patients in the first cohort chose to avoid circumcision, while 80% of patients reported improved foreskin retractability in the second cohort. These findings support the incorporation of Novoglan as a conservative, foreskin-preserving option within phimosis management pathways in both public and specialist urology practice.

Novoglan device for non-surgical treatment of phimosis – updated outcomes from the NOVOGLAN-01 clinical trial

Authors: Dr Dmitry Polikarpov[1], Prof Eric Chung[2], Dr Hubert Mazure[3], Mr Andrew James[4], Prof David Gillatt[5]

Institutions: Northern Beaches Hospital, Frenchs Forest, Australia; 2Princess Alexandra Hospital, Woolloongabba, Australia; 3HGM Consultants, Winston Hills, Australia; 4Platigo Solutions Pty Ltd, Roseville, Australia; 5Macquarie University Hospital, Macquarie University, Australia

Introduction & Objectives: Phimosis can cause significant physical and psychosocial burden. The mainstay of phimosis treatment is circumcision, 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 (grades 1-4) achieving full retraction (grades 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 a slight level and 73% reporting no discomfort. Impact on usual activities fell from 9% to 2%, with no cases above the 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.

First UK outcomes of a Novel, Non-Surgical Alternative for Adult Phimosis: Safety, Efficacy, and Tolerability of the Novoglan™ Device.

Authors: Prabhat Narayan, Nadine Hall, Paul Hadway, Shafi Wardak, Bob Yang

Institution: Royal Berkshire Hospital, Reading, UK

Introduction

Circumcision remains the definitive treatment for adult phimosis following the failure of topical corticosteroid therapy. However, this surgical approach is associated with potential morbidity, particularly regarding the impact on sexual function in younger men. The Novoglan™ device is a novel, conservative treatment utilising a custom-moulded balloon for gradual preputial dilation and skin remodelling, offering a potential foreskin-sparing alternative. This study aimed to evaluate the safety, efficacy, and tolerability of the Novoglan™ device in the treatment of adult phimosis.

Methods

10 adult patients with symptomatic phimosis who had failed prior medical therapies were identified. Patients clinically with balanitis xerotica obliterans were excluded. Following initial consultation and training, participants were instructed to use the device independently at home for 30 minutes daily over a six-week period. The primary outcome was change in foreskin retractability, objectively measured using the Kikiros Phimosis Score.

Results

The mean patient age was 31.7 years (range 18-59). The mean pre-treatment Kikiros Phimosis Score was 2.33 +/- 1.41. Foreskin retractibility significantly improved to 1.44 +/- 1.13 post-treatment (mean difference: 0.89 +/- 1.05; $p = 0.035$). Subjectively, 80% of patients reported improved foreskin retraction at the six-week follow-up, and all reported reduced pain and anxiety during sexual intercourse. The device was universally rated as easy to use (100%). Importantly, 50% of patients were satisfied with the outcome and had decided against proceeding with a circumcision. No serious adverse events were recorded; specifically, there were no reports of bothersome pain or bleeding.

Conclusion

The first UK analysis demonstrates that the Novoglan™ device is a safe, effective, and well-tolerated non-surgical option for the treatment of adult phimosis. It shows strong potential as a conservative, foreskin-preserving alternative for patients with mild to moderate phimosis who wish to avoid the morbidity associated with circumcision.