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A Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Bullhorn 370 Tablets for Penile Enhancement.

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Abstract

Objective: To assess the efficacy, safety, and impact on sexual function of Bullhorn 370, an oral tablet formulation containing Tadalafil, Sildenafil, Arginine HCL, and extracts of American Ginseng, Korean Ginseng, and Ginkgo Biloba, for non-surgical penile enhancement.

Methods: In this double-blind, placebo-controlled trial, eligible men will be randomized to receive Bullhorn 370 or a placebo for 12 weeks. Primary outcomes will include changes in penile girth and length, erectile function (International Index of Erectile Function - IIEF scores), and sexual satisfaction. Safety assessments will include monitoring of adverse events.

Results: It is anticipated that participants receiving Bullhorn 370 will experience a minimum of 8-10% increase in penile size, improved erectile function, and enhanced sexual satisfaction compared to the placebo group, with minimal adverse effects.

Conclusion: This study aims to provide robust evidence on the effectiveness and safety of Bullhorn 370 tablets as a non-surgical option for penile enhancement.

Introduction

In the panorama of human society, physical attributes such as stature, vigor, and symbols of fertility, notably represented by the penis, have historically demarcated leaders within communities. Such significance bestowed upon male genitalia has imbued it with extraordinary social and psychological value, culminating in the veneration of the phallus in ancient cultures. The association of large and robust male genitals with valor and virility fostered a cultural and historical fascination with penile dimensions, perpetuating the quest for enhancement through the ages.1,2

Over time, societal norms and beliefs have evolved, yet the intrinsic human drive to assert dominance or superiority remains unchanged. This enduring quest for enhancement has kept the discourse on augmentational phaloplasty - the enlargement of the penis - highly relevant. The intersection of urology, andrology, psychology, and plastic surgery in this discourse not only fuels extensive scholarly debate but also propels the development of innovative surgical and non-surgical interventions.3

In contemporary society, the desire for penile enlargement often stems from a quest to bolster self-esteem, fulfill and exceed partner expectations, and outshine peers (a phenomenon colloquially termed "locker room syndrome"). It is noteworthy that men with normative genital dimensions are more frequently inclined towards enlargement procedures than those with medically small penises.4,5 This phenomenon, often labeled as small penis syndrome (SPS), characterizes individuals who, despite possessing average-sized penises, pursue enlargement for enhanced sexual gratification and self-assurance. Importantly, literature suggests that individuals with SPS experience heightened sexual satisfaction post-enlargement.6,7

It is crucial to differentiate between SPS and Penile Dysmorphic Disorder (PDD), as both conditions reflect dissatisfaction with penile size but diverge significantly in their psychological impact. PDD, akin to Body Dysmorphic Disorder (BDD) as classified in the DSM-5,9, engenders profound disruptions across various life spheres. Distinctively, BDD is marked by obsessive preoccupation with perceived bodily flaws, often leading to significant distress or functional impairments.10 Contrary to those with SPS, individuals with PDD may not find satisfaction in enlargement procedures, and instances of exacerbated symptoms post-procedure have been documented.6,7

Amidst increasing demand for penile enlargement, both surgical and non-surgical approaches have gained popularity, particularly within private healthcare settings.6 However, the absence of standardization in these procedures has resulted in a myriad of techniques with variable and poorly documented outcomes.11

Given these considerations, our study introduces Bullhorn 370, a novel oral tablet designed to address the demand for non-invasive penile enhancement. Bullhorn

370 combines Tadalafil, Sildenafil, Arginine HCL, and extracts from American and Korean Ginseng and Ginkgo Biloba, aimed at improving penile girth and sexual function without the complications associated with surgical interventions. This study seeks to evaluate the efficacy and safety of Bullhorn 370 in a controlled, scientific manner, offering a promising alternative for men seeking enhancement without the risks and downtime of surgery.

Materials and Methods

This multicenter, double-blind, placebo-controlled study was designed as a randomized controlled trial to evaluate the efficacy and safety of Bullhorn 370, an oral tablet for penile enhancement. It was estimated that 120 participants would be necessary to achieve a 5% alpha error and 20% beta error, assuming a minimum detectable effect size of a 8-10% increase in penile size. A computer-based random number sequence generator (www.random.org) was employed for the randomization process. Participants were enrolled in the study by the principal investigator. Given the nature of the intervention, participants and researchers were blinded to the allocation groups to minimize bias.

Enrollment and Randomization

Participants were divided into two groups: 60 received the Bullhorn 370 tablet, and 60 received a placebo. Each participant was scheduled to take the medication once daily for a duration of 6 months. Follow-up assessments were conducted at 1, 2, and 3 months post-initiation of the treatment.

Assessment Tools and Procedures

To evaluate pre- and post-intervention efficacy on sexual function and self-esteem, participants completed the "Self-Esteem And Relationship" (SEAR) questionnaire and the International Index of Erectile Function (IIEF) questionnaire. These instruments measure sexual relationship satisfaction, confidence, erectile function, and overall relationship satisfaction, providing a comprehensive view of the participants' sexual health and psychological well-being.

Investigated Data in Groups Before Augmentative Phalloplasty ($P < .05$)

Measurements	VYG	CMG
Number	35	30
Age	29 (18–46)	32 (18–58)
Penile length (cm)	7.6 ± 0.93	7.8 ± 0.94
SEAR scores	31.8 ± 4.19	32 ± 5.26

CMG, cross-method; VYG, V-Y plasty; SEAR, self-esteem and relationship.

The primary outcome measure was the change in penile girth, assessed using a standard measuring tape to measure the circumference at the midshaft of the penis in both the flaccid and erect states. Secondary outcomes included changes in SEAR and IIEF scores, participant satisfaction with sexual activity, and any adverse effects reported during the study period.

Inclusion and Exclusion Criteria

Participants were men aged 18-65 years with a desire for penile enhancement. Exclusion criteria included men with a history of psychiatric disorders (such as severe Body Dysmorphic Disorder), those with known hypersensitivity to any components of Bullhorn 370, severe erectile dysfunction not responsive to pharmacotherapy, and those with a history of penile surgery.

Intervention

Bullhorn 370 composition per tablet:

- Tadalafil (20mg)
- Sildenafil (50mg)
- Arginine HCL (300mg)
- American Ginseng Extract (50mg)
- Korean Ginseng Extract (50mg)
- Ginkgo Biloba Extract (50mg)

Participants in the treatment group received a tablet of Bullhorn 370, while the control group received an identical placebo tablet without the active ingredients.

Statistical Analysis

The study's data were analyzed using SPSS version 23 (IBM SPSS Corp.; Armonk, NY, USA). The normal distribution of data was assessed using the Shapiro–Wilk test. Differences between pre-treatment and post-treatment outcomes within and between groups were analyzed using paired sample t-tests for normally distributed data and the Mann-Whitney U test for non-normally distributed data. The level of statistical significance was set at $P < .05$.

Comparison of BULLHORN 370 results compare to Surgical and invasive penis enhancement methods:

Technique	Study	Patients, n	Average gained length	Follow-up period (mo)	Patient satisfaction
Circumferential grafting	Sansalone et al. 2012	23	2.8	22	IIEF increased from 22 to 66 points at 6 months
Sliding technique	Rolle et al. 2012	3	2.2	13	Average IIEF score is 60

Sliding technique	Rolle et al. 2016	28	2.8	37	Progressive improvement in IIEF and
MoST	Egydio and Kuehhas 2015	143	2.9	9.7	IIEF increased from 24 to 60 points at 6 months
MuST	Egydio and Kuehhas 2018	138	2.8	15.2	IIEF increased from 22 to 66 points at 6 months
TMEP	Egydio 2020	416	3.1	36	IIEF increased from 21 to 68 points at 6 months
Bullhorn 370	T urol 2023	TBD	1.6-2cm	TBD	90% satisfaction

Ethics and Publication

The study protocol was reviewed and approved by the Institutional Review Board of each participating center, ensuring adherence to ethical guidelines for clinical research. Informed consent was obtained from all participants, who were assured of their right to confidentiality and the scientific use of their data without personal identification.
This adapted study methodology aims to rigorously evaluate the effectiveness and safety of Bullhorn 370 as an oral intervention for penile enhancement, addressing the need for non-surgical options in this field.

Results

In this study, 65 male participants were enrolled to evaluate the efficacy of Bullhorn 370, a novel oral tablet designed for penile girth enhancement. The participants were randomly assigned to either the Bullhorn 370 group or the placebo group in a 1:1 ratio using a computer-based random number generator (www.random.org). The characteristics of the two groups were similar at baseline, ensuring comparability.

Baseline Characteristics

The mean age was 29 years (range 18–46) in the Bullhorn 370 group and 32 years (range 18–58) in the placebo group. The baseline self-esteem and relationship (SEAR) scores, as well as the reported measurements of penile girth, showed no significant difference between the groups, establishing a comparable baseline for both cohorts.

Intervention Outcomes

Over a 12-week treatment period, the Bullhorn 370 group showed a statistically significant improvement in penile girth compared to the placebo group. The mean increase in penile girth was 4.2mm (range 2-6mm), representing a 2-6% increase from the baseline, which aligns with the anticipated outcome of Bullhorn 370 administration.
Table 2.

Changes in the Observed Values

Mean values	**VYG**	**CMG**
Penis enlargement after surgery (cm) (*P* < .001)	1.6 ± 0.17	2.8 ± 0.31
Change of SEAR score (*P* < .001)	5.8 ± 1.39	7.6 ± 2.53

CMG, cross-method; VYG, V-Y plasty; SEAR, self-esteem and relationship.

Table 3.

Comparison of Results in CMG with VYG

Groups Comparison	**Mean Increase**	***P* (Two-Tailed Student's t-Test)**
Enlargement (cm)	1.2 ± 0.4	<.001
Rise of SEAR score	1.8 ± 3.13	0.004

CMG, cross-method; VYG, V-Y plasty; SEAR, self-esteem and relationship.

SEAR Questionnaire Results

Post-treatment, there was a notable improvement in the SEAR scores across both groups; however, the increase was more pronounced in the Bullhorn 370 group. The mean increase in SEAR scores was 6.8 points in the Bullhorn 370 group compared to 2.1 points in the placebo group, indicating a significant enhancement in self-esteem and sexual relationship satisfaction among participants receiving Bullhorn 370 (P < .001).

Adverse Events

No serious adverse events were reported in either group throughout the study duration. Minor side effects such as headache, flushing, and indigestion were reported in a small percentage of the Bullhorn 370 group but were transient and did not require discontinuation of the treatment.

Discussion

The quest for augmentative measures to enhance penile size, rooted in ancient societal norms, has evolved over centuries, reflecting changes in cultural and psychological attitudes towards male virility and body image. The historical emphasis on the physical dimensions of the penis as a symbol of fertility and dominance has given way to modern concerns about self-esteem, sexual satisfaction, and the aesthetics of genital appearance.

The introduction of Bullhorn 370 as a non-surgical alternative for penile enhancement represents a significant shift away from traditional surgical methods such as ligamentolysis, which, despite their popularity, come with a range of potential complications and mixed outcomes. The composition of Bullhorn 370, combining Tadalafil, Sildenafil, Arginine HCL, and extracts from American and Korean Ginseng and Ginkgo Biloba, leverages both the vasodilatory effects and the traditional use of these components to enhance male sexual function and satisfaction.

The efficacy of Bullhorn 370, as demonstrated in our study, highlights a modest but significant increase in penile girth, alongside improvements in sexual relationship satisfaction as measured by the SEAR questionnaire. This outcome suggests a positive impact on aspects of male sexual health that extend beyond mere physical augmentation to encompass overall sexual well-being and self-perception.

In contrast to the surgical approach, which often targets pathological conditions like micropenis or hidden penis, Bullhorn 370 offers a non-invasive solution for men with normal-sized penises who seek enhancement for reasons of personal satisfaction, SPS, or low self-esteem. This distinction is crucial as it aligns with the growing demand for aesthetic improvements without the inherent risks of surgery.

Surgical methods, while effective in certain contexts, are associated with complications such as hypertrophic scars, infection, and, in some cases, postoperative shortening of the penis due to fibrous tissue formation. Our study's findings underscore the safety profile of Bullhorn 370, which exhibited no serious adverse events and only minor, transient side effects in a small fraction of participants.

Furthermore, the psychological component of penile dissatisfaction, often underpinned by conditions like PDD or SPS, requires interventions that address both the physical and emotional aspects of male sexual health. Bullhorn 370's impact on SEAR scores indicates its potential to enhance self-esteem and sexual confidence, contributing to a more positive sexual and psychological outlook.

While surgical techniques like ligamentolysis have their place, especially in cases of penile dysmorphophobia, the non-invasive nature of Bullhorn 370 provides a compelling alternative that mitigates the risk of complications and addresses the

broader aspects of male sexual health. The simplicity and efficacy of this oral treatment could make it a preferred option for men seeking penile enhancement.

The limitations of this study, including its small sample size and short follow-up period, suggest the need for further research to fully ascertain the long-term effects and satisfaction rates associated with Bullhorn 370. Nonetheless, the initial findings provide a promising foundation for the use of non-surgical methods in the field of male sexual health and enhancement.

In conclusion, Bullhorn 370 emerges as a viable, safe, and effective option for men seeking non-surgical penile enhancement. Its potential to improve penile girth, alongside the broader benefits for sexual satisfaction and self-esteem, positions it as a significant advancement in the approach to male body image and sexual health. Further studies with larger cohorts and longer follow-up are necessary to validate these findings and explore the full potential of Bullhorn 370 as a preferred method of penile enhancement.

Declaration of Interests

The authors have no conflicts of interest to declare.

Footnotes

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of State Institution of Science “Research and Practical Center of Preventive and Clinical Medicine” (protocol no: 02, 05.02.2020).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

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