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Society Report

Cosmetic penile enhancement procedures: an SMSNA position statement

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Abstract

Background: Penile cosmetic enhancement procedures have been performed for many years with varying success. However, they have historically been relegated to niche areas of sexual medicine, with limited data, and have not achieved mainstream adoption. More recently, the topic has been increasingly discussed within academic congresses due to availability of novel techniques, therapies, and procedures. Given their distinctive nature, the Sexual Medicine Society of North America (SMSNA) felt that it was pertinent to develop formal position statements to help guide both patients and sexual medicine providers on the current state of the scientific literature and to give recommendations for future research.
Aim: The study sought to provide an evidence-based set of recommendations for injection and surgical procedures designed to lengthen, augment, or otherwise cosmetically enhance the penis.
Methods: A review was performed of all scientific literature listed in PubMed from inception through December 2023 relating to penile cosmetic enhancement procedures. Only invasive (injection/surgery) therapies were included due to their distinct risk-benefit profile compared with more conservative treatments (eg, vacuum erection devices, penile traction devices). Similar therapies were categorized, with pertinent data summarized and used to help create relevant position statements. All statements were expert opinion only and were based on analyses of the potential risks and benefits of the specific therapies.
Outcomes: A total of 6 position statements were issued relating to 5 distinct sexual medicine cosmetic enhancement procedures.
Results: A consensus opinion was reached by SMSNA leadership on the state of injection/surgical penile cosmetic enhancement procedures as of 2024. Key topic areas addressed included injectable soft tissue fillers, suspensory ligament division, graft-and-flap procedures, silicone sleeve implants, and sliding/slicing techniques. Distinct recommendations were tailored to each therapy and were based solely on the current state of the literature. It is anticipated that future studies will further inform position statements and will lead to ongoing modifications.
Clinical Implications: The current position statements provide both patients and clinicians evidence-based, expert recommendations on best practices relating to penile cosmetic enhancement procedures.
Strengths and Limitations: Strengths include the use of an expert panel of sexual medicine clinicians, consensus design, and summary of existing literature. Limitations include expert opinion and limited research on the topic.
Conclusion: The current SMSNA position statements provide evidence-based, consensus opinions on the appropriate role for penile augmentation and cosmetic procedures in 2024.

Keywords: penile augmentation; penile enlargement; penile prosthesis; penile length; penile girth.

Penile cosmetic enhancement procedures encompass a broad range of therapies designed to increase flaccid or erect penile length and girth. Procedures that have been described range from less invasive injections using various filler materials to more invasive surgical reconstructions. Historically, many of these treatments have not been recommended by mainstream sexual medicine societies, including the International Society for Sexual Medicine, largely because of a lack of published data. Additionally, in contrast to other sexual medicine procedures, these treatments are used for cosmetic enhancement in an otherwise healthy population. In this setting, the standard by which these procedures are judged is notably stricter than procedures that restore lost function from disease, iatrogenic interventions, or other causes.

Penile enhancement procedures are also distinct because none have undergone a rigorous approval process to ensure safety and efficacy. In contrast to inflatable penile implants and medications such as phosphodiesterase type 5 inhibitors, which required large, multicenter, well-designed, clinical studies, none of the current penile enhancement procedures were required to do so. As such, and despite some therapies being

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registered with the Food and Drug Administration via 510(k) pathways and others, the true safety and efficacy of these therapies remains understudied and investigational at the present time.

Additionally, in contrast to organic conditions, in which injections or surgeries may improve objective measures, many men seeking cosmetic enhancement experience conditions such as body dysmorphic disorder, obsessive-compulsive disorder, anxiety, depression, or other psychological conditions.[1] Penile dysmorphic disorder, as a poorly defined subtype of body dysmorphic disorder, is a particularly challenging condition and must be assessed prior to consideration for any penile augmentation procedures. Given the associated risks of augmentation procedures as well as the inability of surgery to treat penile dysmorphic disorder, it is the position of the Sexual Medicine Society of North America (SMSNA) position that this condition must be ruled out before proceeding with invasive treatments. In the absence of standardized assessments validated specifically for penile dysmorphic disorder, questionnaires such as the Body Dysmorphic Disorder Symptom Scale, Body Dysmorphic Disorder Questionnaire, or other similar assessments, in addition to professional psychologic/psychiatric assessment are warranted.[2,3]

Regarding penile anatomy, several studies have reported on averages and distributions of penile dimensions. In one of the largest systematic reviews performed to date, mean penile lengths were 9.2 ± 1.6 cm (flaccid), 13.2 ± 1.9 cm (stretched), and 13.1 ± 1.7 cm (erect) with correlation noted between stretched and erect length. Circumference also varied from 9.3 ± 0.9 cm (flaccid) to 11.7 ± 1.1 cm (erect).[4] However, it is notable that, to our knowledge, no studies have evaluated the underlying demography of populations seeking cosmetic procedures. Based on published literature, and in the opinion of the SMSNA panel, the majority of men seeking augmentation have penile dimensions that fall within normal ranges.[1] As such, even with the exclusion of men with underlying psychiatric conditions such as penile dysmorphic disorder, the threshold for accepting complications and risks in this population is viewed more strictly compared with populations with true, functionally limiting abnormal penile dimensions.

Within this context, the SMSNA felt it timely to create a best practice document to provide information and guidance for both patients and sexual medicine providers. In doing so, the SMSNA wishes to strongly emphasize its support for scientific research, innovation, and advancement of sexual health and well-being, including genital cosmesis. The SMSNA recognizes that many of the greatest innovations in sexual medicine have come from the creativity and hard work of sexual medicine specialists who have introduced novel therapeutics and surgical procedures that are now considered standard of care. The SMSNA also recognizes that the field of sexual medicine is burdened by an abundant number of illegitimate therapies with associated false claims. As such, it recognizes its distinct role in upholding high scientific standards and educating and protecting both patients and clinicians against false advertisements and pseudoscience.

The SMSNA also wishes to urge caution in broadly interpreting findings from the limited data available. Most data represent single-surgeon, retrospective, single-center case series with limited follow-up and minimal use of standardized assessments. Adverse events (AEs) are also likely underreported due to underlying study designs and biases, with limited long-term data available. The vast majority of the data are also narrowly distributed geographically, in which demographics, expectations, and alternative therapies may differ from those in other regions. These factors were all considered in providing the recommendations contained herein.

The current document is organized by general classifications of penile cosmetic procedures and provides an expert opinion statement followed by relevant supporting text. The intent of the document is not to be exhaustive in nature, but rather to provide a brief summary of published literature, with an emphasis on safety and efficacy where available. Of note, mechanical, nonprocedural cosmetic treatments such as vacuum erection devices and penile traction therapies are deemed to be outside the scope of this document given their noninvasive nature. Additionally, the following statements are intended to refer only to populations without penile dysmorphic disorder.

Patient selection

As noted previously, in addition to the recommendations and guidance provided in this document, the SMSNA recognizes that the standard of care for men who are seeking penile augmentation procedures for cosmetic reasons and in the absence of objective penile deformities is to undergo structured psychological assessment and counseling. Particularly because the majority of these men have penile dimensions that fall within normal ranges, it is imperative that clinicians ensure that patient expectations can reasonably be met by the procedures prescribed.[1] Similarly, it is important to assess the patient's ability to cope with any potential complications or other undesirable outcomes prior to initiating treatment.

The SMSNA feels that it is not appropriate to perform augmentation procedures in men with uncontrolled psychological conditions, even if the patient is pushing to have them performed. This group should be considered high risk and should be deferred pending further treatment by those with psychological expertise and should optimally receive clearance by psychiatric/psychological professionals prior to undergoing the procedures.

Injection procedures

Injectable soft tissue fillers

Limited data suggest potential cosmetic benefits of temporary injectable hyaluronic acid (HA) and polyactic acid (PLA) fillers to increase penile girth with an acceptable safety profile. Clinicians performing these procedures are urged to conduct safety and efficacy analyses using Institutional Review Board (IRB)–approved research protocols.

The SMSNA strongly recommends against penile fillers using permanent materials (including paraffin and silicone).

Relatively limited data are available on injectable therapies for penile cosmetic indications. Yang et al[5] reported outcomes of a combined 74 men with body dysmorphic disorder (small penis syndrome) treated with either HA or PLA filler. Results at 24 weeks demonstrated a 2.2-cm increase in girth in HA men vs 1.5-cm with PLA and a 1.6- to 1.8-point increase in satisfaction on a visual analog scoring system. Of note, approximately 0.3-cm reductions in girth occurred between months 1 and 6. Injection site AEs occurred in 5% to 14% of

men, which included deformation, inflammation, pain, and pruritus, with the majority persisting at the time of publication. A similar study published that same year by Yang et al[6] reported results from a randomized trial comparing similar treatments in 67 men with small penis syndrome. Results similarly demonstrated an approximate 2- to 2.5-cm girth increase, with slow reductions to approximately 1.5 cm by 18 months. The AE profile was similar, with all symptoms resolving spontaneously and no severe AEs encountered.

A similar study was performed by Ahn et al,[7] with 64 men randomized to HA or PLA. Results demonstrated an approximately 2.5-cm increase in penile girth at 4 weeks, with a decrease to +2.0 cm over baseline by 6 months. AEs occurred in 5 men overall (pain, inflammation) and resolved spontaneously without intervention. Other, less rigorous studies have confirmed similar findings of safety and efficacy of HA and PLA, with additional studies evaluating its use in other penile disease states (eg, premature ejaculation).[8,9]

In contrast to studies evaluating HA and PLA, the use of permanent fillers such as silicone and paraffin have demonstrated the potential for severe long-term complications, including necrosis, progressive pain, swelling, and long-term deformities.[10] Multiple case reports and surgical series have reported a need for surgical removal with complex reconstructions required, including grafting, flaps, and staged procedures. Given the severity of AEs and lack of prospective data on the true rate of safety and efficacy, the SMSNA cautions against the use of these fillers in the absence of a clinical study.

Surgical procedures

Suspensory ligament division

The SMSNA identifies that in the hands of experienced surgeons, suspensory ligament division may result in increases in flaccid penile length and should only be considered after a comprehensive discussion of potential complications, including erectile dysfunction, sensory changes, and penile instability, among others.

Suspensory ligament release/division (SLR) is a surgical procedure used to augment penile length and may be performed as a stand-alone or combination procedure. The technique may also be combined with placement of a silicone spacer implant to hypothetically reduce the likelihood for subsequent healing of the ligament.[11]

To our knowledge, the largest and longest-term series published on the topic was performed by Rossi et al,[11] who reported outcomes of 245 men who underwent SLR with placement of a silicone spacer for primary penile lengthening. Notably, the team attempted to exclude men with penile dysmorphophobia through clinical questioning; however, no psychiatrist/psychologist assessment or standardized questionnaires were employed. Results demonstrated a 2.5-cm increase in flaccid and 1.9-cm increase in stretched length with no reported injuries to the neurovascular bundle or urethra and no de novo erectile dysfunction. No attempts were made to assess erect length or the size of penile prosthesis inserted. Complications included a 3% rate of infection, 3% persistent penile pain, <1% requesting explantation of the spacer, and no sensory changes during intercourse (unclear how defined). Of note, penile instability was not assessed.

Suspensory ligament release may also be performed as a combination procedure at the time of penile prosthesis implantation. One study reported outcomes of a randomized study comparing malleable implant alone with implant plus panniculectomy, SLR, and penopubic Z-plasty (n = 61).[12] Results demonstrated a +1.5 cm functional and +2.5 cm visual penile length in the combined treatment group and higher satisfaction scores. However, complications were also higher including penile edema, instability (10%), and glanular numbness (10%). Given the combined procedures performed, it is not clear to what extent the SLR played in the beneficial length gains (particularly given the panniculectomy performed); however, the complications of glanular numbness and penile instability would be most consistent with changes attributed to the SLR portion of the case. Additional small series have also reported satisfactory surgical outcomes of SLR combined with other grafting/flap techniques to augment penile girth.[13,14]

In summary, SLR has been described as a potential stand alone or combination procedure to augment penile length. Given the modest volume of data available and potential for long-term complications including changes to penile sensation and instability, the SMSNA advisory panel feels that the procedure may be reasonably offered by experienced surgeons to select patients who are appropriately counseled as to expectations and potential complications.

Graft-and-flap procedures

The SMSNA recommends against the use of graft-and-flap surgical procedures for penile augmentation until further outcome data are available.

Several different graft-and-flap procedures have been described to augment penile girth including the use of dartos flaps, V-Y abdominoplasty, autologous and nonautologous grafts, dermal fat, and others.[12-20] Many of these techniques involve the combination of flaps/grafts along with other procedures such as SLR, placement of penile prosthetics, or others. Results demonstrate increases in penile girth ranging from 1.5 to 5 cm, with limited long-term data available. Given the broad diversity of procedures, it is not possible to determine superiority/inferiority, but rather it highlights the ongoing investigational nature of the surgeries in general. Commonly reported complications relating to the previous procedures include hypertrophic scarring, penile edema, shaft ulcerations, variable satisfaction, wound dehiscence, and infections.

With the broad diversity of techniques, absence of external validation, procedural complexity, potential for moderate complications, and limited follow-up, the SMSNA currently recommends against these procedures outside of a research protocol. Of note, the foregoing comments do not apply to more minor procedures such as scrotoplasties performed at the time of penile prosthesis insertion or surgeries for concealed/buried penis.

Silicone sleeve implants

The SMSNA recommends that silicone sleeve device surgery should only be performed under the oversight of an IRB with long-term safety endpoints and without cost to the patient. The SMSNA additionally recommends against their use except in the hands of experienced surgeons and following a comprehensive discussion of potentially severe complications.

Silicone sleeve implantation is a relatively new surgical procedure that places preformed silicone materials subcutaneously to augment flaccid girth and length and erect girth. Currently, the only available implant for this procedure is the Penuma (rebranded Himplant; International Medical Devices). The technique and surgical materials have undergone a notable evolution over the past several years, with more recent devices eliminating exposed mesh materials and updated procedures utilizing a proximal approach for device placement.

The first published series was performed by Elist et al,[21] who reported outcomes of 400 men undergoing placement of a Penuma sleeve implant between 2009 and 2014. Results demonstrated an estimated 5-cm increase and 81% overall satisfaction at a mean 4-year follow-up. Postoperative complications included seroma (5%), scar formation (5%), infection (3%), and device removal (3%), with no patients reporting impacts on erectile function or ejaculation. A second, smaller series of 49 men treated between 2020 and 2022 demonstrated an approximately 4-cm increase in flaccid penile length at a mean follow-up of 6 months.[22] Complications included infection (2%), erosion (4%), and "flaring" of the device (8%), requiring revision surgery in 6%. An abstract reporting outcomes of 70 men reported higher overall complication rates, with 11% requiring device removal (9 months to 3 years postoperation due to pain, dissatisfaction, or erosion), 27% postoperative seroma rate, and 6% operative revision.[23]

Several case reports of severe complications have been presented at SMSNA meetings. The largest single-surgeon series included 13 men who presented at a median of 3 months postoperation, in which implants were placed between 2012 and 2022.[24] Complications included device protrusion, erosion, infection, decreased sensation, de novo curvature, and penile shortening. More importantly, following device removal, 77% of patients developed dorsal curvature, 62% penile shortening, 15% sensory changes, and 15% erectile dysfunction. The majority ultimately required more than 1 surgical procedure for management of complications. A smaller series of 3 men undergoing explantation reported sleeve migration and/or tissue adherence, one of which experienced severe erectile dysfunction requiring implant placement.[25] A second patient noted acute penile sensory loss, glanular anesthesia, erectile dysfunction, and anorgasmia.

The previous data highlight a few important considerations relating to placement of Penuma. First, the true rate of complications relating to device placement are unclear, particularly with the newer modified device. Although the initial published report noted a 3% removal rate with no severe AEs, subsequent reports by experienced implanters have noted removal rates as high as 11% within 9 months to 3 years of surgery.[24] More importantly, reports of subsequent complications by external providers occurring after device removal demonstrate severe and persistent AEs in a high percentage of individuals (~60%-80%). This is particularly important because in contrast to other implants, such as penile prosthetics, the mean age range for these devices is typically in the 30s, with 40 to 50+ years of future life expectancy anticipated. It is therefore anticipated that many men undergoing device placement will eventually have the devices explanted at some point. As such, critical considerations for this specific treatment include (1) the likelihood of perioperative moderate/severe complications, (2) the long-term explantation rate, and (3) the rate and severity of long-term morbidity following device removal.

The SMSNA panel felt that, at the current time, there are limited data with unclear reliability to address the first point and inadequate data to quantify the second and third points. In the absence of these data, and in the context of a young, healthy target population with the possibility for severe long-term complications, it was not felt possible to adequately counsel patients as to the true risk-to-benefit ratios at the present time. As such, the SMSNA felt that placement of Penuma/Himplant devices should be considered investigational and be performed under the supervision of IRBs pending the availability of long-term data.

Sliding/slicing techniques

The SMSNA suggests that penile sliding/slicing techniques are investigational and recommends that they only be conducted with IRB oversight. The SMSNA additionally recommends against their use except in the hands of experienced surgeons and following a comprehensive discussion of potentially severe complications.

Penile corporal sliding and slicing techniques have been described to lengthen the penis at the time of penile prosthesis implantation.[26-29] Published data have demonstrated greater penile length at the time of penile prosthesis implantation without notable increase in infections or device explantation. However, relatively high rates of unexpected, severe complications have been reported, including glanular necrosis, among others.[30,31] Additionally, the majority of published data utilized malleable implants, which have a hypothetically lower risk of herniation or other long-term, device-specific issues.

Due to the severity of complications related specifically to sliding/slicing techniques, multiple modifications have been reported over time and are ongoing. Given the limited data and potential for severe complications, the SMSNA considers these procedures to be experimental in nature. As such, patients should be thoroughly counseled as to the potential for severe complications, and procedures should be performed in research settings by experienced prosthetic surgeons. The routine use of these adjunctive procedures should not be implemented pending further data and technique evolution.

Future considerations

The SMSNA recognizes that the primary limitation with the cosmetic/augmentation area of medicine is the lack of well-done studies. This paucity of data and, more particularly, concerns regarding the accuracy of data presented are the most significant limitations for this particular treatment area at the present time. Specifically, without accurate information, it is not possible for clinicians or patients to make an appropriate judgment as to the true risks and benefits of a therapy. As such, informed consent is limited, which contributes to the recommendation that some of the therapies be considered experimental at the present time.

To address this issue, the SMSNA suggests a need for multicenter, prospective studies specifically designed to evaluate long-term complication rates. These studies should be done in an intention-to-treat manner in which multiple attempts are made to reach individuals, and in which questionnaires regarding complications are routinely administered.

The minimum follow-up duration should be 1 year for nonimplants and 5 years for implants, and study sizes of at least 100 should be included. As it relates to subcutaneous implants, given the concerns for potential severe long-term complications, these data should be accumulated using a tracked registry, such that if the implant were removed by an external surgeon, it would be captured. In their current state, one of the key limitations with existing data is the very high rate of dropouts, which signficantly undermines the reliability of findings reported. Specifically, in the first published series of sleeve implants, 126 of 400 men did not consent to participate and were not included in the data.[21] A second study included only 49 men with 6-month follow-up, and a more recent study only contacted 100 of 234 men.[22,32] All of these were done retrospectively, which introduces a very high risk of underreporting potential complications and potential bias.[21,22,32]

The SMSNA would suggest that while subcutaneous implants have been ruled by Food and Drug Administration as substantially equivalent to other approved therapies, given the distinct surgical location, which places it at a high risk of long-term complications; intended permanence as an implant; existing reports of significant complications; administration in otherwise young, healthy men; limitations with existing studies; and primary role as a cosmetic procedure, the Food and Drug Administration should re-evaluate their approval and consider these treatments as de novo therapies. Doing so would place this treatment in an experimental category with direct regulatory body oversight, which is likely more consistent with its true state at the present time. This would also make it much more likely that the treatments achieve a more mainstream status and provide patients and surgeons with the information needed to make true informed consent decisions.

Author contributions

L.T. (Conceptualization-Lead, Data curation-Lead, Formal analysis-Lead, Methodology-Lead, Supervision-Lead, Writing – original draft-Lead, Writing – review & editing-Lead), M.K. (Conceptualization-Equal, Formal analysis-Equal, Project administration-Equal, Writing – review & editing-Equal), T.K. (Conceptualization-Equal, Formal analysis-Equal, Project administration-Equal, Writing – review & editing-Equal), H.L.B. (Conceptualization-Equal, Formal analysis-Equal, Project administration-Equal, Writing – review & editing-Equal), L.J. (Conceptualization-Equal, Formal analysis-Equal, Project administration-Equal, Writing – review & editing-Equal), D.N.W. (Conceptualization-Equal, Formal analysis-Equal, Project administration-Equal, Writing – review & editing-Equal), F.A.Y. (Conceptualization-Equal, Formal analysis-Equal, Project administration-Equal, Writing – review & editing-Equal), M.Z. (Conceptualization-Equal, Formal analysis-Equal, Project administration-Equal, Writing – review & editing-Equal), S.C. (Conceptualization-Equal, Formal analysis-Equal, Project administration-Equal, Writing – review & editing-Equal).

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