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SHAFAER WIDTH AND GIRTH: The Use of Injectable Fillers for Penile Enhancement

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PROTOCOL

BACKGROUND

Juvederm Voluma XC is an established volume enhancer for mid-face and cheeks. Several off-label areas such as chin, jawline and nose enhancement are also standard uses. Juvederm Vollure XC is an established dermal filler for facial wrinkles and folds. Several off-label areas are commonly treated such as tear troughs and temples. Both Juvederm Voluma XC and Juvederm Vollure XC have an excellent safety profile, bio- compatibility and longevity. Patients and practitioners are constantly expanding uses for both products. Juvederm Voluma XC injected in the penile shaft and Juvederm Vollure XC injected in the glans for penile enhancement are excellent expanded uses for these products. The injections achieve an increased width and girth of the penis shaft with Voluma XC and increased size and improved shape of the glans penis with Juvederm Vollure XC. This new treatment area fills a need for an expanding population in cosmetic surgery: male patients. Our center has already treated several patients with Juvederm Voluma XC and Juvederm Vollure XC with cannula technique for penile enhancement. Our experience has shown that this procedure has a very high satisfaction rate and a very low complication rate similar to on-label treatment with both products. This study is intended to determine the safety of the procedure, objectively measure the effectiveness of the procedure, determine the subjective measures of patient and partner satisfaction, and third party perception. This data will contribute to the medical community knowledge base and add evidence for the safety and effectiveness of performing this procedure on their patients.

HYPOTHESIS:

Men who undergo penile enhancement with Juvéderm Voluma XC and Juvéderm Vollure XC will see increased girth and width of their penis that will last at least one year with a complication profile consistent with current FDA approved uses of the products.

OBJECTIVES:

1. Determine the effectiveness of Juvéderm Voluma XC and Juvederm Vollure XC in enhancing penile length and girth. This will be done by quantitatively assessing patient measured changes to length and girth.
2. Evaluate the safety and potential side effects of complications of penile enhancement with aforementioned Juvéderm filler products.
3. Determine how long treatment with Juvéderm products produces a measurable difference in penile size and appearance. This will be done by evaluating patients at multiple visits over the course of a year.
4. Understand the impact of penile enhancement on self perception of patients and their partners in their personal lives.
5. Evaluate how third parties perceive penile enhancement.

STUDY DESCRIPTION:

This is a prospective, single-arm, single-center study to evaluate the efficacy and safety of Juvederm Voluma XC and Juvederm Vollure XC in penis enhancement. Approval will be obtained through a commercial Institutional Review Board prior to commencing the study. A total of 20 subjects will be recruited by advertisement within our current patient base as well as our local community. Each individual will undergo penile enhancement as detailed below.

Study subjects will be evaluated at their initial visit, as well as the 2, 6, 12 weeks, and 1 year following their initial treatment for measurements and photographs. Subjects will be offered a second treatment at the 2 week appointment. Individuals who have contour deformities will be treated with a second treatment at 2 weeks.

The size and shape of the penile shaft and glans will be measured in each individual in the supine position in the flaccid and erect state at each visit. Measurements will be determined utilizing a calculation based on circumference, width and length resulting in surface area as well as girth for both the penile shaft and glans. Digital photographs obtained as before and after views will be submitted for blinded evaluation by a secondary investigator. 3D VECTRA images will be obtained before and at the first follow-up visit for volumetric comparison.

Patients and partners will respond to surveys at each visit. The survey will assess for satisfaction with current penis size and appearance, potential side effects of treatment, compliance with the study protocol, and their self perception.

Photographs taken during the study will also be used to create a survey which will be administered to 1000 individuals via a crowd-sourcing technology. The survey will be designed to assess if the public can perceive a difference in appearance of the penises before and after treatment, as well as how their perception of the patient's may change following treatment.

SUBJECTS

A total of 20 healthy males aged 21 to 65 years of age who are seeking enhancement of their penile width and girth will be enrolled in our study. Exclusion criteria include any patient with a history of psychological or psychiatric illness, congenital or acquired penile malformation, previous plastic surgery or non-invasive treatments of their penis, chronic disease, vascular disorder, urological disorder, myocardial infarction, hypertension, cerebrovascular accident or coagulopathy. Patients with a history of allergic reactions to hyaluronic acid derivatives will also be excluded from the study.

Individuals with penises measured less than 6 cm in length in the flaccid, non-stretched position will be excluded due to small size, and those with penises greater than 12.5 cm in length in the flaccid, non-stretched position will also be excluded. Individuals with uncircumcised penises will also be excluded.

INDICATION FOR USE:

Enlargement of width and girth of the male penis in the flaccid state.

INJECTION MATERIAL

Juvederm Voluma XC and Juvederm Vollure XC, both hyaluronic acid gel dermal fillers, will be used for this study. Both products are FDA approved and indicated for subcutaneous injection in the cheek for age-related volume deficit in the mid face (Juvederm Voluma XC) and for the treatment of moderate to severe wrinkles and folds (Juvederm Vollure XC). This study will examine the off-label use of both products injected into the subcutaneous layer of the penis.

INJECTION METHOD

Injections will be performed by Dr. David Shafer under sterile technique in an office- based setting under local anesthesia (2% lidocaine with 1:100,000 epinephrine). After ten minutes of topical anesthesia (compounded 23% lidocaine, 7% tetracaine, and 0.5% phenylephrine), the patient will be placed in the supine position and a dorsal nerve block will be performed followed by cannula insertion at the 10 o'clock and 2 o'clock positions on the penis.

The penis will then be induced into the erect state with a 2.5 microgram intracavernous injection of Alprostadil. If the patient is unable to be induced into the erect state with this dose than an additional 2.5mcg will be given. If erection still cannot be achieved then the patient will be excluded from the study. Pre-injection erect state photographs will be taken at this time. Following the photographs, Juvéderm will be injected in the erect state. The cannula (*SoftFil® 25g XL micro-cannula*) will be carefully inserted into the areolar tissue located between the deep penile (Buck) fascia and the superficial Dartos fascia. With this technique, the deep dorsal vein and paired dorsal arteries and branches of the dorsal nerves, contained within the deep penile (Buck) fascia, are protected. Juvederm Voluma XC 1 cc syringes will then be used to inject the product along the penile shaft. The cannula will be positioned longitudinally and injections performed in a "fanning" technique to smoothly deposit product circumferentially around the penis.

Depending on the patient's anatomy, a pre-determined amount of Juvederm Voluma XC (5, 10 or 15 cc) will be injected. The glans penis will then be injected with Juvederm Vollure XC (1-3 cc) with sharp needle (*TSK laboratory 30 g x 25mm*) into the subcutaneous tissue with fanning technique. Following the completion of the injections and post-injection photographs, triple antibiotic ointment (*Water-Jel Technologies, LLC*) will be applied and the penis bandaged (*Surgitube® 1"*) dressing.

The patient will then be returned to the flaccid state with an intracavernous injection of 100 mcg of phenylephrine. Should the patient not return to the flaccid state within 5 minutes of injection, an additional 100 mcg of phenylephrine will be given. Re-evaluation will be done every 5 minutes and an additional 100 mcg of phenylephrine will be given until a total of 500 mcg of phenylephrine is achieved. If a patient is still in the erect state after the maximum dose of phenylephrine is given, he will be monitored until a total of 4 hours have passed from initial injection of the alprostadil. If he remains in the erect state following this time period, he will be directed to the emergency room for emergent urological evaluation.

The patient will be given MethylPrednisolone Tablets Dose Pack to help with post-injection swelling. Patients will be instructed to keep their dressing on for the remainder of the day and to avoid sexual intercourse for three days following treatment. Patients are also instructed to massage their penises a

minimum of 15 minutes a day. All patients will be asked to use condoms for at least three months following their final injections.

Each patient will return in 4 weeks after the primary treatment for another treatment to reach full correction. The same technique will be used for maximum of 35 syringes per patient.

PATIENT/PARTNER SURVEY

Patients and their partners will answer surveys at the initial visit, and each follow up visit (2, 6, 12 weeks). Satisfaction of treatment and self-perception will be graded on a 5 point scale. The satisfaction (G0-G4) grading system will determine G0 indicating dissatisfaction; G1, neither satisfied and dissatisfied; G2, somewhat satisfied; G3, moderately satisfied; and G4, very satisfied. The self-perception (SP0-SP4) grading system SP0 indicating smaller; SP1, no change, SP2 somewhat larger; SP3, moderately larger; SP4, much larger.

The survey portion that assesses potential side effects and functional changes in the penis will ask participants about:

- ability to achieve erection
- ability to maintain erection
- penile sensation loss
- changes in time for ejaculation
- penile stiffness
- bruising/discomfort

The survey portion that assesses the patient's and partner's satisfaction with appearance will ask use a five point likert scale to assess for patient confidence and perceived appearance of their penis. There will also be a "free text" portion of the survey that asks survey takers why they are interested in penile enhancement.

Patients will also be asked questions regarding their compliance with study protocol including:

- total time dressing remained on penis following each treatment
- amount of time spent massaging penis daily
- time elapsed between treatment and intercourse
- completion of steroid taper

SURVEY PORTION CROWDSOURCING

A survey will be created using before injection and after injection photos of the patients from 6 weeks post-treatment. This survey will be made using Qualtrics and administered to 400 individuals via crowdsourcing on the Amazon Turk platform. Eligible survey takers will be over the age of 18, living within the United States, and without any diagnoses of Autism, Schizophrenia, or Bipolar Disorder. The survey takers must consent to see graphic photographs. Demographic information will be collected from survey takers, specifically their age, sexual orientation, gender, and race/ethnicity.

Survey takers will view before and after photos of all 20 patient's penises in a random order. They will be asked to grade the penis on a seven point Likert scale on several characteristics including perceived size and masculinity. Survey takers will be paid \$0.25 to take the survey. We anticipate the survey will take them approximately 45 minutes.

MAIN OUTCOME MEASURES

The primary endpoints are increased width, girth and surface area of the penile shaft and glans penis as determinants of overall penis size. The study also aims to identify the duration of time subjects experience increased width, girth and surface area of the penis. Secondary endpoints are perceived high levels of satisfaction and increased size in the patient and partner surveys. Crowdsourc survey secondary endpoints include improved girth and length.

GOALS OF STUDY

The first goal of this study is to achieve on average a 20% increase in width, girth and surface area of the penile shaft and glans penis across subjects. The effects of treatment are anticipated to last for a minimum of at least one year for each subject.

A second goal of the study is to achieve an average of G2 (somewhat satisfied) and SP2 (somewhat larger) in the patient and partner survey components

CASE REPORT FORMS

Please see attached documents.

ANALYSIS OF PROTOCOL

This section will be completed by an IRB once submitted.

STUDY OVERSIGHT

This study will be overseen by the Advarra Independent Review Board.

IRB REVIEW AND ETHICS

The study will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and the following:

United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

Investigators and clinical study site staff who are responsible for the conduct, management, or oversight of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form. All changes to the protocol or consent that are approved by the IRB will be submitted to the FDA for approval prior to advancement of the study. These changes will be submitted with a red-line strike through copy of the original document, a clean copy of the modified documents, as well as a table specifying the nature of the changes and where each change occurred.

WITHDRAWAL OF SUBJECTS:

Patients may be withdrawn from the study for the following reasons:

- failure to follow instructions
- failure to show up for study visits
- if it is not in the patient's best interest to continue the study
- the study is stopped

If a patient chooses to withdraw the data already collected from them will continue to be used, however no new data will be collected.

PATIENT INCENTIVES/COMPENSATION:

Patients will not be paid for their participation in this study, however they will be offered gift cards for \$200 and \$250 worth of skin care services at Dr. David Shafer's plastic surgery office following return for follow-up visits at the 3 month and 1 year visits.

DATA STORAGE AND SAFETY PLAN:

Records of patient visits will be maintained at Dr. David Shafer's plastic surgery office in a HIPAA compliant password protected charting system. All individuals who have access to patient charts are HIPAA trained and certified.

To assure safety of patient personal information, data will be de-identified as follows: Each patient will be assigned a unique number as their identifier. When patients and their partners answer survey questions using Qualtrics, they will enter their unique identifier into each survey they answer.

After the study is complete, the de-identified data and photographs will kept for an unconditional amount of time, in storage at Dr. David Shafer's plastic surgery office and may be used in other future studies and future analysis. Permission to maintain data at Dr. David Shafer's office will be included in the informed consent.

CONFIDENTIALITY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), regulatory agencies or pharmaceutical company supplying study product may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at Dr. David Shafer's office for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, stored in the Qualtrics database. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by Dr. David Shafer's research staff will be secured and password protected. At the end of the study, all study databases will remain de-identified and archived at the Dr. David Shafer's office.

STUDY TIMELINE

The anticipated time to enroll subjects will be approximately two weeks. Once enrolled subjects will undergo treatment at the initial visit and touch-ups at 4- 2 weeks. Subjects will then follow up at 6 weeks, 3 months, and 12 months from their initial treatment date. Data collection will take place at each visit.

Photographs of the patients will be used from the 6 week visit to create a survey that will be administered on the Amazon Turk crowdsourcing platform. We anticipate that it will take no more than 2 weeks to gather the desired 1000 survey responses.

Visit	Description of Visit
Initial Visit	Initial Treatment Measurements Taken Photographs Taken

2 weeks	Contour Correcting Treatment Patient and Partner Survey Measurements Taken Photographs Taken Adverse Events Record/Monitor
6 weeks	Patient and Partner Survey Measurements Taken Photographs Taken Adverse Event Record/Monitor
3 months	Patient and Partner Survey Measurements Taken Photographs Taken Adverse Event Record/Monitor Patient Compensation \$200
12 months	Patient and Partner Survey Measurements Taken Photographs Taken Adverse Event Record/Monitor Patient Compensation \$250

STATISTICAL ANALYSES

Statistical analysis will be performed by and in consultation with a subcontracted statistician for this study.

CONSENT PROCESS:

Each patient will receive a consent form with details regarding what is expected of them in the study as well as the risks, benefits, and options they have regarding participation in the study. One of the physicians will discuss study details with the patients and answer any questions they have prior to asking them to sign the consent forms.

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