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Development and Validation of the Satisfaction Survey for Inflatable Penile Implant (SSIPI)

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Abstract

Background: No validated English language patient-reported outcome (PRO) currently exists that assesses satisfaction with inflatable penile prosthesis (IPP). Satisfaction data have been largely based primarily on surgeon assessment of patients or using questionnaires that have not been designed for this purpose.

Aim: To develop an English-language validated PRO that assesses patient satisfaction after IPP surgery.

Methods: Initially, a literature review and discussions with experts defined domains important to IPP satisfaction (pain, appearance, function, overall satisfaction). The initial 35-item Satisfaction Survey for Inflatable Penile Implant (SSIPI) was developed. Cognitive interviews were then performed with IPP patients (n=12) to gain feedback on the SSIPI domains and items. These data were used to modify SSIPI with the addition of two questions for a final item number of 37. Patients from 4 centers, who were between 6 months and 5 years after IPP, were administered the questionnaire through RedCap. Reliability statistics and content analysis were used to winnow questions to yield the final 16-item version of the SSIPI. Internal consistency was assessed via Cronbach's alpha and item-total correlation. Test-retest reliability was assessed via intraclass correlation coefficients using baseline and 2-week data. For convergent validity, the Erectile

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Dysfunction Inventory of Treatment Satisfaction (EDITS) and the Self-Esteem and Relationship (SEAR) questionnaire were used. For discriminant validity, the International Prostate Symptom Score (IPSS) was used. Confirmatory factor analysis was used to assess the factor structure of the SSIPI.

Outcomes: Internal consistency, test-retest reliability, convergent and discriminant validity, and confirmatory factor analysis were assessed.

Results: 118 men were surveyed. Mean age was 66.8±9.5 years. The 16-item SSIPI showed high internal consistency with an overall Cronbach's Alpha of 0.97 (domains 0.85–0.89). Item-total correlations for individual items to subscales ranged from 0.60–0.91. The overall test-retest reliability was 0.94 (domains 0.87–0.93). EDITS and SEAR had correlations of 0.84 overall (domains 0.57–0.79) and 0.47 overall (domains 0.34–0.44), respectively. IPSS (discriminant validity) had correlations of −0.29 overall (domains −0.17 to −0.31).

Clinical Implications: SSIPI is the first English-language validated IPP satisfaction PRO. This will enable clinicians to collect satisfaction data in a standardized way.

Strengths and Limitations: As strengths we have used a rigorous psychometric process and have no industry sponsorship. Limitations include small numbers of specific subpopulations.

Conclusions: The SSIPI has demonstrated robust psychometric properties.

INTRODUCTION

Inflatable penile prosthesis (IPP) surgery is a well-recognized treatment for medication-refractory erectile dysfunction (ED). Utilization data can be gleaned from the Medicare public use files, which is a random sampling of 5% of the Medicare database. Medicare is the primary insurance for 97% of the ≥ 65-year-old population in the United States.[1] In this database, excluding patients <65 years-old and patients covered by private insurance carriers, from 2001–2010 there were 53,180 men who had a penile prosthesis placed, of these, 92.2% were inflatable.[1] These data demonstrates the high number of patients in the US who undergo penile implant surgery.

Given the frequency of penile implant surgery, it is surprising that no validated English language patient-reported outcome (PRO) assessing penile implant satisfaction currently exists. Most satisfaction data in the literature are based primarily on surgeon assessment of patients or using questionnaires not validated for implants. For example, several studies have used English-validated questionnaires designed for assessing erectile dysfunction (ED) such as the International Inventory of Erectile Function (IIEF)[2] or the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS)[3] which assesses ED treatment satisfaction. These tools were never designed to assess satisfaction with an IPP and thus, do not address key aspects such as device function, concealability and naturalness.

Cayn et al (2019) used a modified EDITS to assess patient and partner satisfaction in >500 men with an IPP. Results showed an overall high satisfaction rate with 90.9% of 3-piece IPP patients being 'very satisfied' and 85% of men responded that the IPP 'completely' met their expectations.[4] While these results are promising, further questions reveal only 67% of men thought the IPP was 'very easy' to use and only 71% were 'very likely' to continue to use

their IPP.[4] The adapted questionnaire was limited and could not ascertain why the implant was not easy to use in these men or why they might not continue using it. Thus, more data is clearly needed to address specific IPP concerns.

While Caraceni et al. (2014) developed an implant satisfaction questionnaire, it is validated in Italian only[5] and is therefore, of limited utility in English speaking patients. The lack of linguistic validation results in awkward English phrasing such as asking if the implant makes the patient feel 'lively and witty'[5] which further limits its usefulness in English. Furthermore, this questionnaire does not have questions specific to the IPP, such as pump placement or ease of use. Given that the vast majority of penile implants in the US are inflatable,[6] there is a clear need for an English-validated IPP satisfaction PRO.

The purpose of this study was to develop and validate a new PRO to measure patient satisfaction after penile implant surgery, the Satisfaction Survey for Inflatable Penile Implant (SSIPI). We hypothesized the SSIPI would demonstrate sound psychometric properties meeting acceptable criteria for measurement development, reliability and validity.

METHODS

Questionnaire Development:

Initially, we conducted a thorough literature review and held discussions with six experts with extensive clinical experience in the field of penile implant surgery to define areas considered to be important for assessing patient satisfaction. The literature review and discussions outlined four important conceptual areas to assess: pain, appearance, function and overall satisfaction. The study team developed questions to assess these key topics with an emphasis on both patient satisfaction and expectations. Response items were based on PROMIS-approved verbiage.[7] Each question was scored on 1–5 point Likert scale with a higher score denoting a more positive response. The draft in the developmental stage of the process consisted of 35 questions.

Patient Cognitive Interviews:

After approval by the institutional review board (#X17–029), cognitive interviews were conducted at the study's primary institution to gain patients' feedback on the four themes assessed, the wording of the questions, the response time, the response format, and the length of the questionnaire. Patients were eligible for inclusion if they were between 6 months and 5 years after primary implantation of an IPP (patients undergoing repeat surgery were excluded). Cognitive interviews were performed with 12 patients until saturation of themes was reached. These interviews were conducted over the phone by a single urologist evaluator. The data were used to modify the survey and the version to be validated was created containing 37 questions (Appendix 1).

Questionnaire Validation:

Patients from 4 centers were administered the questionnaire through the electronic system RedCap.[8, 9] These men were all between 6 months and 5 years after initial IPP placement. Patients were not excluded based on surgical complications, relationship status, sexual

orientation or comorbidities. The surgeons of these men have a combined 52 years of experience between them (range 6–25 years). Both American Medical Systems (Boston Scientific) and Coloplast implants were used. Patients received a letter explaining the project and asking for their participation. The RedCap questionnaire was then sent to them via email. If men did not respond within 1 week, they received automated weekly reminders, for a total of 3 emails. The Redcap questions included a demographics questionnaire, the 37-item SSIPI and questionnaires for convergent and discriminant validity. For convergent validity, we used the EDITS[3], the Self-Esteem and Relationship (SEAR) questionnaire[10], and the erectile function domain (EFD) of the IIEF[2]. We excluded patients from the EFD analysis if they were not sexually active. We expected a strong correlation (≥ 0.6) between the SSIPI and EDITS, and a moderate to high correlation (≥ 0.4) between the SSIPI and the SEAR, and between the SSIPI and EFD. For discriminate validity, we used the International Prostate Symptom Score (IPSS)[11], and expected a low to moderate (≤ 0.4) negative correlation between the SSIPI and the IPSS. In order to assess test-retest reliability, the SSIPI was automatically resent 2 weeks after the initial questionnaire completion.

Item Winnowing:

We were initially overly inclusive of items in the draft measure, planning to winnow the number of questions following initial reliability statistics. We used Cronbach's alpha (internal consistency) and item-total correlations from the validation data of the 37 questions. We used these data and reviewed the content of each question to determine which questions could be removed. The final version contained 16 items (see Results section below).

Statistics:

Descriptive statistics were used for patient demographics. Psychometric analysis was then performed. Reliability was assessed via Cronbach's alpha, item-total correlations (Pearson correlation coefficient, items correlated with their subscale), and test-retest reliability. Test-retest reliability was assessed via intraclass correlation coefficients using baseline and 2-week data. For the final 16-item measure, we used values of at least 0.70 to indicate acceptable Cronbach's alpha and intraclass correlations coefficient values. We used values of ≥0.40 to indicate acceptable item-total correlations. Convergent and discriminant validity was assessed using Pearson correlation coefficients. Convergent validity was assessed with correlations of ≥0.40 and divergent validity was assessed with correlations <0.40.

We analyzed the item structure with confirmatory factor analysis (CFA). We used a CFA since we developed a-priori subscales based on literature and expert feedback, and presented these for feedback through patient cognitive interviews. The CFA used oblique factors, maximum likelihood estimation, and used the items as continuous variables. We used the fit indices of comparative-fit index (CFI), Tucker-Lewis index (TLI), and root means square error of approximation (RMSEA) to determine the appropriateness of the tested model. For acceptable fit, we used CFI > 0.90, TLI >0.90, and RMSEA < 0.01, and assessed the overall fit to be acceptable if at least two of these criteria were met.[12, 13] We used item-total correlations to assess factor loading, with the criteria stated above to indicate sufficient correlation.

RESULTS

Patients:

Data from 118 men were analyzed. See Table 1 for demographics. Self-reported time since IPP implantation was a mean of 25.2±17.4 months. 94.9% of men were still using their implant. These men endorsed using the implant a mean of 27.5±28.6 times within the 6 months preceding the questionnaire, equivalent to approximately once per week. Comorbidities included: hypertension 50%, hyperlipidemia 30.5%, diabetes 17.8%, obstructive sleep apnea 15.3%, Peyronie's disease 15.3%, coronary artery disease 9.3% and prior stroke 3.4%.

Cognitive Interviews:

The cognitive interviews demonstrated additional questions, beyond those suggested by experts, related to penile sensation changes and implant concealability in the flaccid state. Two questions were added to SSIPI to reflect these areas of concern, bringing the total to 37 questions. Multiple patients also remarked on the absence of partner satisfaction questions. However, given that we plan to ultimately develop a partner satisfaction questionnaire and were concerned about the validity of patient reported partner issues, these questions were not added to the current instrument. Additionally, many patients dismissed the issue of postoperative pain and a few admitted to a lack of any pre-operative expectations and thus had difficulty in answering questions on whether their expectations had been met. We elected to keep these questions for the validation phase to assess if this held true for a larger patient population.

Winnowing:

The 37-item draft measure was used in this validation study. To winnow questions, we assessed the Cronbach's alpha of the subscales and the item-total correlations. The Cronbach's alphas were all high (≥0.90), which indicated that there were a number of redundant questions in each subscale. We then assessed the individual item-total correlations of the subscales. These ranged from 0.39–0.91. We used these data, along with content analysis to winnow questions. In the content analysis, we removed the expectation questions, as the cognitive interviewing indicated patients had difficulty answering these questions.

Furthermore, the satisfaction questions had similar item-total correlations to the analogous expectation questions (range 0–0.13 difference, mean difference of 0.06). This process yielded a final version of SSIPI with 16 questions and 4 domains of overall satisfaction, appearance, pain, and function (Appendix 2). The validation statistics below are presented for this final 16-item version of the SSIPI.

Reliability:

Table 2 contains the item-total correlations for the 16-item version. For individual item-total correlations, correlations ranged from 0.60–0.91, demonstrating high consistency within domains. The SSIPI showed a Cronbach's Alpha (Table 3) of 0.97 for SSIPI total scale (SSIPI domains 0.85–0.89). The overall test-retest reliability was good with an intraclass correlation of 0.73 for the SSIPI total scale (SSIPI domains 0.68–0.73). Of note, a single

patient (#90) scored vastly differently on his SSIPI re-test and when excluding him the test-retest intraclass coefficients were much higher, overall 0.94 and 0.87–0.93 for the domains (Table 4). We assume that this patient had some change in his health or his implant function between these 2 surveys. However, given the de-identified nature of this study, we cannot confirm this.

Confirmatory Factor Analysis:

The final version demonstrated a good fit, as CFI and RMSEA met the defined criteria. The TLI fit criteria fell below the acceptable range (Table 5). The item-total correlations all demonstrated good factor loading for each question in the designated domain. The fit indices showed improved fit for the 16-item version compared to the initial 37-item questionnaire. While these results met our defined criteria for acceptable fit (two out of three fit indexes acceptable, item-total correlation >0.40), we did review four questions for removal which had the lowest item-total correlations, all in the appearance domain, to possibly improve the TFI fit index. These questions related to length, girth, concealability, and pump location. On review, the study team felt these were all important questions to retain, with little overlap, and all had item-total correlations (0.57–0.62) well above the 0.40 acceptable criteria.

Validity:

With regards to convergent validity, EDITS had a strong correlation of 0.83 with SSIPI total scores and all domain scores (SSIPI domains 0.57–0.79), all $p<0.01$ (Table 6). As expected, the correlations among the SEAR and SSIPI were moderate to strong, yet not as high as compared to the correlations among the EDITS and SSIPI. SEAR total scores had a correlation of 0.47 with the SSIPI total scores (SSIPI domains 0.34–0.44), all $p<0.01$. Discriminant validity was also as predicted, the correlation between the IPSS total scores and SSIPI total scores was −0.29 (domains −0.17 – −0.31), $p<0.02$ for all except appearance $p=0.09$. For the IIEF-EFD, we excluded from the analysis men who answered a ‘0’ on any question, meaning that they were not currently sexually active. Unexpectedly, the correlation between the EFD and SIPPI total score was 0.10 (SSIPI domains 0.03– 0.14), all $p>0.18$. The distribution of the EFD scores was also not expected, with approximately 28% indicating severe ED (EFD ≤10), 33% indicating mild or moderate ED, and only 39% indicating no ED (EFD ≥ 26). Since 95% of the men were using their implant on average 4 times a month, the study team expected the vast majority of men to have a score on the EFD ≥26. Additionally, the EFD did not perform as expected compared to the EDITS. Based on previous research, we expected to find a strong correlation ($r\geq 0.70$) between the EFD and EDITS.[14] However, the correlation between the EFD and EDITS was low and non-significant in the sample ($r=0.11$, $p=0.31$). We hypothesize that most men completed the EFD considering their erectile function prior to the implant, which would not provide an appropriate barometer for satisfaction with the implant.

IPP Satisfaction:

Results of the final 16-item version of SSIPI revealed high patient IPP satisfaction with a total score of 4.15±0.9 (score range 1–5). The results for subscales showed an overall satisfaction score of 4.15±1.0, pain subscale of 4.56±0.9, appearance subscale of 3.72±1.0 and function subscale of 4.16±1.0 (Table 7).

DISCUSSION

The first IPP was described in 1973[15] and has become an increasingly popular treatment option for ED since then. Of an estimated 53,180 men undergoing penile implants in the US covered by the Medicare system, over a 9-year period, over 92% of them were IPPs.[1] The preference for IPP over malleable penile prosthesis (MPP) is seen in many other countries worldwide however, their utilization is restricted due to cost. In a series of almost 7,000 penile implants in France, 79% were IPP.[16] Similarly, a penile implant registry in Italy demonstrated that 88% of implants were inflatable.[17] This predominance of IPPs is not universal. In the United Kingdom, only 62% of implants are inflatable.[18] This is even more pronounced in Saudi Arabia, where the majority of implants are MPP and only 30% IPP.[19] Given the higher prevalence of IPPs in the US and many English-language countries abroad, we opted to focus the initial questionnaire development on the inflatable version of the penile implant.

There is a clear need for a consistent method of assessing patient satisfaction after penile implant surgery. Chouhan et al in 2020 evaluated the most heavily cited articles from 2009–2019 assessing penile implant outcomes. They found that there was no high-quality evidence on outcomes. Such studies have suffered from two major limitations, either they failed to state what method was used to assess patient satisfaction or no standardized assessment whatsoever was utilized.[20] A similar study performed a PubMed search from 2006–2016 and evaluated 48 articles assessing patient satisfaction after penile implant. Only 43.8% of studies used a validated questionnaire such as IIEF or EDITS. While validated for ED patients, these questionnaires are suboptimal for implant patients as both were designed to assess functional and satisfaction outcomes in response to PDE5 inhibitors. The remainder of the studies evaluated used proprietary, non-validated questionnaires to assess satisfaction.[21] This underscores the pressing need for a standardized assessment of patient satisfaction after penile implant surgery.

While there is one penile implant satisfaction questionnaire, the Quality of Life and Sexuality with Penile Prosthesis (QoLSSP), it is not validated in English.[5] This questionnaire does not contain question specific to IPPs, further limiting its application in much of the penile implant world. To date, this questionnaire has not been subjected to English linguistic validation. There are issues specific to an IPP, such as ease of use, pain with inflation and satisfaction with pump placement that are not addressed in the existing implant questionnaire. Additionally, this questionnaire did not address key topics such as the naturalness of the erection, its concealability in the flaccid state, length, girth, or pain, all of which are felt to be important to gauging patient satisfaction. Therefore, we felt there was a need to create a new PRO instrument to address these concerns. Furthermore, the QoLSSP contained many questions that we felt were multifactorial and not specific to an implant, such as sexual frequency, orgasm, contentment, well-being and sexual desire. There was concern that too many external factors influence these outcomes and we wanted an instrument that focused solely on the penile implant.

Historically, satisfaction has been defined through a surgeon’s interpretation of what patients say in response to some satisfaction question at a variable time-point after the operation.

As is the case in other areas of urological surgery, the surgeon being the interviewer is fraught with issues pertaining to being able to obtain accurate data. This introduces the issue of patient social desirability, where patients might feel pressured into telling the surgeon what they believe the surgeon wishes to hear. Furthermore, given that much of the data acquired on penile implant satisfaction has been acquired by high-volume implanters whose livelihoods depend on performing implants regularly, the validity and veracity of the satisfaction data that has been reported to date could be called into question. Of note, despite approaching both major penile implant manufacturers neither deemed this project of a sufficiently high priority to offer funding, and thus, this project was funded by a seed grant from the Sexual Medicine Society of North America.

With regards to timing of questionnaire administration, we limited the inclusion criteria to men between 6 months and 5 years post-IPP for multiple reasons. 6 months was chosen as we thought this was far enough post-operatively so that acute post-op pain would not be a factor. This is an established time point to assess implant satisfaction in prior studies.[22, 23] Serial assessment with IIEF and EDITS at 3, 6, and 12 months post-op showed improvement in EDITS and IIEF-EFD between 3 and 6 months[23] so we did not want to include a time point sooner than 6 months. Furthermore, 6 months would allow for men to recover after the operation and begin using their implant and we deemed this would be enough experience for most men to obtain an accurate impression of their device. 5 years was chosen as an endpoint as we felt that this was early enough that most men would still be using their implant and any device breakdown or malfunction would be unlikely to have occurred and impact upon patient satisfaction outcomes. We believed that this would reduce recall bias by excluding men who were too far out from their operation.

In terms of the questionnaires for convergent and discriminant validity, this was complicated by the lack of an English-validated penile implant questionnaire to use for convergent validity. We opted not to use the QoLSSP as it is only validated in Italian.[5] The EDITS questionnaire was used for convergent validity as it is designed to assess satisfaction with ED treatment, albeit PDE5 inhibitors.[3] Similarly, the SEAR questionnaire addresses multifactorial domains such as confidence, self-esteem, and the overall relationship which we thought would have some correlation with implant satisfaction. We hypothesized lower correlation with the IIEF-EFD but were surprised to see such a low correlation even when excluding men who were not sexually active. However, while it was thought to be implied, we didn’t explicitly ask them to answer questions based on their IPP, which might explain the weak correlation. Furthermore, the EFD domain of the IIEF assess only function (5/6 questions) and a single question on confidence. The multidimensionality of the SSIPI might explain the low correlation.

Additionally, prior data has also shown lower than expected IIEF scores in men post-IPP. A group of 180 men given the IIEF-5 at 12 months post-op only scored an average of 20.6 ± 2.7[24] which is consistent with mild ED.[25] This emphasizes the fact that the IIEF is not a useful tool for assessment of implant satisfaction.

For divergent validity, we included the IPSS as this is a questionnaire commonly given to urologic patients in this age group and expected a negative correlation between urinary symptoms and penile implant satisfaction.

Given the lack of an English-validated implant satisfaction questionnaire, it is difficult to compare our data to others'. Capogrosso et al 2019 administered the QoLSSP to 122 Italian IPP patients 1-year post-op. Out of a total score of 75 (higher score denoting high satisfaction), the median for IPP patients was 68 (IQR 63, 72).[26] These results are promising and demonstrate high patient satisfaction. While not a linguistic validation study, Carlos et al (2020) did administer the English translation of this questionnaire to 90 English-speaking implant patients (which is clearly scientifically flawed) at a mean duration of 3.15 years post-operatively. 84% of men had a positive response (as defined as an average score of ≥ 3 on a 5-point grading scale).[27]

SSIPI has 4 subdomains: overall satisfaction, pain, appearance and function. We established these subdomains based on expert opinion of what is important with IPP satisfaction. The overall satisfaction subdomain focuses on patients' confidence in their sexual ability, sexual and overall satisfaction, and whether they regret pursuing IPP insertion. Pain assesses for discomfort following implant surgery. The appearance subdomain interrogates conceability, naturalness of erection and length/girth. Lastly, the function subdomain includes questions on ease of use and ability to utilize the scrotal pump.

The clinical implications of this study are obvious. As the first English-validated penile implant satisfaction questionnaire, SSIPI will allow us to objectively and consistently assess patient satisfaction. This will ultimately allow us to better counsel pre-operative patients, as we will have high-quality patient satisfaction data. It will further allow us to identify the relative importance of implant function, appearance and pain in satisfaction outcomes and with studies of ethnic and sexual orientation sub-populations eventually allow us to compare satisfaction outcomes across groups.

Strengths of this study include that we have used a rigorous psychometric process, including the use of expert opinion, patient cognitive interviews, and multi-center validation. We utilized Redcap to administer the questionnaires, which increased patient compliance and reduced any potential bias that may come from a member of the treatment team administering questionnaires. Additionally, the study was devoid of any industry sponsorship and the potential optics of this. Limitations include small numbers of specific subpopulations, such as gay men or men with PD. We did not assess their pre-operative erectile function which may have impacted their post-operative satisfaction. We did not include any questions on reservoirs. However, in our clinical experience (and in the expert opinion and patient interviews) this is not a common issue and thus we excluded this. Additionally, we did not address partner satisfaction, as patient-reported partner satisfaction measurement is problematic. Lastly, while the IIEF is a validated questionnaire, the IIEF-EFD has not been validated as an independent measure, as the IIEF was only formally validated for men on phosphodiesterase inhibitors and has not been validated for IPPs. For future research, an additional step in the validation process would include investigating known group differences, responsiveness to change, and minimal important difference

(MID). If the measure continues to perform well on all validation metrics, the final step would be translating the measure into other languages.

CONCLUSION

The SSIPI has demonstrated robust internal consistency, test-retest reliability, and expected convergent and discriminant validities. Patients demonstrate a high satisfaction with IPPs. Thematic analysis resulted in exclusion of redundant questions, rendering a final survey of 16 items.

Source of Funding:

SMSNA grant awarded to author Phil Vu Bach.

Appendix 1: Original 37-Item SSIPI

Overall Satisfaction
When you attempted sexual intercourse with the penile implant, to what degree did it meet your expectations?
When you attempted sexual intercourse using the penile implant, how often was it satisfactory for you?
How satisfied have you been with your overall sex life with your penile implant?
Overall, how satisfied have you been with the penile implant?
How confident have you been about your ability to engage in sexual activity with the penile implant?
Do you feel more sexually desirable since your implant surgery?
If you were to talk to another man considering the operation, how likely would you be to recommend the implant?
If you could do it over again, how likely would you be to have a penile implant placed again?
Have you experienced any regret about having a penile implant placed?
Pain
How often do you have pain or discomfort when the implant is activated/inflated?
How severe is the pain or discomfort when the implant is activated/inflated?
How bothered are you by the pain or discomfort when the implant is activated/inflated?
When the implant is inflated, how often does the pain or discomfort limit your ability to use the implant?
Appearance
How satisfied are you with the naturalness of your erection with the penile implant when activated/inflated?
To what degree has the naturalness of your erection with the penile implant activated/inflated met your expectations?
How satisfied are you with the length of your penis with the penile implant activated/inflated?
To what degree does the length of your penis with the penile implant activated/inflated meet your expectations?
How satisfied are you with the girth/width of your erection with the penile implant when activated/inflated?
To what degree has the girth/width of your erection with the penile implant activated/inflated met your expectations?
To what degree has the swelling of the head of your penis with the penile implant activated/inflated met your expectations?
How satisfied are you with the naturalness of your penis when the penile implant is inactivated/deflated?
To what degree has the naturalness of your penis when the penile implant is inactivated/deflated met your expectations?
How satisfied are you with your ability to conceal the implant in its inactivated/deflated state?

To what degree has your ability to conceal the implant in its inactivated/deflated state met your expectations?
How satisfied are you with the location of the pump in your scrotum?
To what degree has the location of the pump in your scrotum met your expectations?
To what extent are you bothered by the tubing in your scrotum?
Function
To what degree are you satisfied with your penile sensitivity?
How did your penile sensitivity meet your expectations?
To what degree does the hardness/rigidity of your erection with the penile implant activated/inflated meet your expectations?
When the penile implant is activated/inflated, how often has it worked properly?
How often have you had difficulty using the pump in your scrotum to inflate or deflate the device?
How often did the penile implant provide an erection suitable for sexual intercourse?
How satisfied are you with the ease of use of your penile implant?
To what degree has the ease of use of your penile implant met your expectations?
How satisfied are you with the spontaneity of the erection with the penile implant?
To what degree does the spontaneity of the erection with the penile implant meet your expectations?

Appendix 2: Satisfaction Survey for Inflatable Penile Implant

Please complete these questions based on your experiences with your inflatable penile implant.

1. When you attempted sexual intercourse using the penile implant, how often was it satisfactory for you?				
Almost never/never 1	A few times (much less than half the time) 2	Sometimes (about half of the time) 3	Most times (much more than half of the time) 4	Almost always/ always 5
2. Overall, how satisfied have you been with the penile implant?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5
3. How confident have you been about your ability to engage in sexual activity with the penile implant?				
Not at all confident 1	Somewhat unconfident 2	Neither confident nor unconfident 3	Somewhat confident 4	Very confident 5
4. Have you experienced any regret about having a penile implant placed?				
Very much 1	Quite a bit 2	Somewhat 3	A little bit 4	Not at all 5
5. How bothered are you by the pain or discomfort when the implant is activated/inflated?				
Very much 1	Quite a bit 2	Somewhat 3	A little bit 4	Not at all 5
6. When the implant is inflated, how often does the pain or discomfort limit your ability to use the implant?				
Almost always/ always 1	Most times (much more than half of the time) 2	Sometimes (about half of the time) 3	A few times (much less than half the time) 4	Almost never/ never 5

7. How satisfied are you with the naturalness of your erection with the penile implant when activated/inflated?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5
8. How satisfied are you with the length of your penis with the penile implant activated/inflated?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5
9. How satisfied are you with the girth/width of your erection with the penile implant when activated/inflated?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5
10. How satisfied are you with the naturalness of your penis when the penile implant is inactivated/deflated?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5
11. How satisfied are you with your ability to conceal the implant in its inactivated/deflated state?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5
12. How satisfied are you with the location of the pump in your scrotum?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5
13. **How often have you had difficulty using the pump in your scrotum to inflate or deflate the device?**				
Almost always/ always 1	Most times (much more than half of the time) 2	Sometimes (about half of the time) 3	A few times (much less than half the time) 4	Almost never/ never 5
14. How often did the penile implant provide an erection suitable for sexual intercourse?				
Almost never/never 1	A few times (much less than half the time) 2	Sometimes (about half of the time) 3	Most times (much more than half of the time) 4	Almost always/ always 5
15. How satisfied are you with the ease of use of your penile implant?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5
16. How satisfied are you with the spontaneity of the erection with the penile implant?				
Very dissatisfied 1	Somewhat dissatisfied 2	Neither satisfied nor dissatisfied 3	Somewhat satisfied 4	Very satisfied 5

Total Score:

Subdomains:

Overall satisfaction: 1–4

Pain: 5–6

Appearance: 7–12

Function: 13–16

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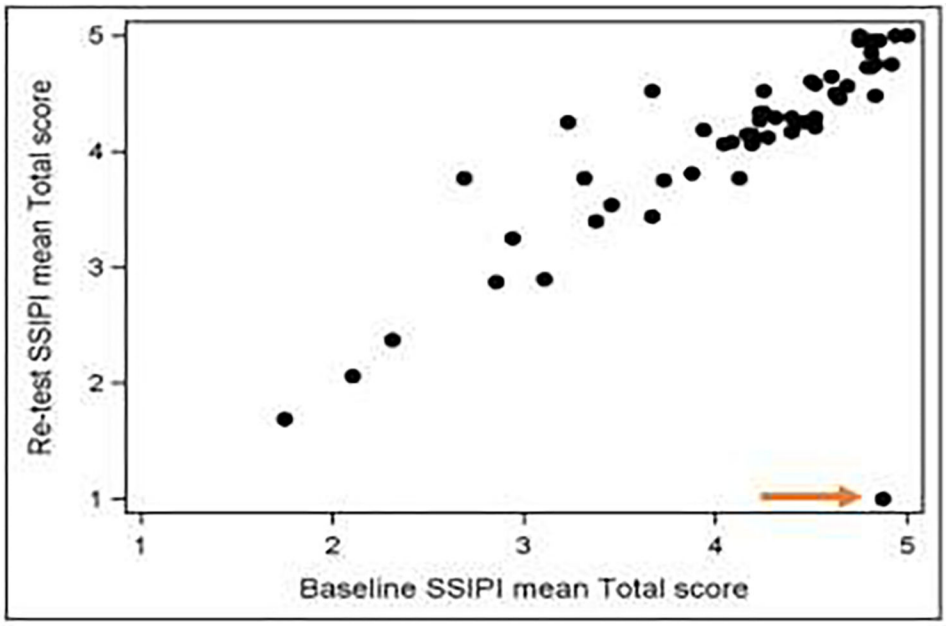

Figure 1.
Test retest reliability. Arrow denotes patient #90.

Table 1:

Patient Demographics (N=118)

Age (years)	66.8±9.5
Race (%)	
White	78
Black	11.9
Hispanic	9.3
Other	0.9
Relationship status (%)	
Single	6.8
Divorced	7.6
Widowed	5.1
Married	73.7
Unmarried partner	6.8
Mean relationship duration (months)	32.8 (15.6)
Mean partner age (years)	62.3 (10.5)
Mean time since implant (months)	25.2 (17.4)
Still using implant? (% Yes)	94.9
# times using implant in past 6 months	27.5 (28.6)
Sexual orientation (%)	
Straight	94.9
Gay	5.1
Cancer(%)	
Prostate	32.2
Bladder	6.8
Colorectal	3.4
Other	11
None	51.7

Comorbidities (%)	
Hypertension	50
Hyperlipidemia	30.5
Diabetes	17.8
Obstructive Sleep Apnea	15.3
Peyronie's Disease	15.3
Anxiety	11.9
Coronary Artery Disease	9.3
Depression	8.5
Stroke	3.4

Table 2:

Item to Total Correlations for SSIPI Subscales

Overall Satisfaction	
When you attempted sexual intercourse using the penile implant, how often was it satisfactory for you?	0.82
Overall, how satisfied have you been with the penile implant?	0.89
How confident have you been about your ability to engage in sexual activity with the penile implant?	0.73
Have you experienced any regret about having a penile implant placed?	0.74
Pain	
How bothered are you by the pain or discomfort when the implant is activated/inflated?	0.91
When the implant is inflated, how often does the pain or discomfort limit your ability to use the implant?	0.80
Appearance	
How satisfied are you with the naturalness of your erection with the penile implant when activated/inflated?	0.76
How satisfied are you with the length of your penis with the penile implant activated/inflated?	0.68
How satisfied are you with the girth/width of your erection with the penile implant when activated/inflated?	0.62
How satisfied are you with the naturalness of your penis when the penile implant is inactivated/deflated?	0.73
How satisfied are you with your ability to conceal the implant in its inactivated/deflated state?	0.60
How satisfied are you with the location of the pump in your scrotum?	0.65
Function	
How often have you had difficulty using the pump in your scrotum to inflate or deflate the device?	0.63
How often did the penile implant provide an erection suitable for sexual intercourse?	0.75
How satisfied are you with the ease of use of your penile implant?	0.75
How satisfied are you with the spontaneity of the erection with the penile implant?	0.79

Table 3:

Cronbach's Alpha Internal Consistency Statistics

Subscale	# items	Cronbach's Alpha
Overall satisfaction	4	0.89
Pain	2	0.87
Appearance	6	0.85
Function	4	0.87
Total score	16	0.97

Table 4:

Test-Retest Reliability

	Intraclass Correlation Coefficient
Overall satisfaction	0.93
Pain	0.87
Appearance	0.89
Function	0.90
Total	0.94

Table 5:

Confirmatory Factor Analysis

	Comparative Fit Index	Tucker-Lewis Index	Root Mean Square Error of Approximation
Original (37 items)	0.75	0.65	0.12
Final Version (16 items)	0.92	0.86	0.10

Table 6:

Convergent and Discriminant Validity [correlation (p-value)]

	Overall satisfaction	Pain	Appearance	Function	Total Score
Convergent Validity					
EDITS	0.79 (<.001)	0.57 (<.001)	0.71 (<.001)	0.78 (<.001)	0.84 (<.001)
SEAR Sexual Relationship	0.44 (<.001)	0.42 (<.001)	0.29 (.003)	0.41 (<.001)	0.45 (<.001)
SEAR Self Esteem	0.34 (<.001)	0.27 (0.006)	0.35 (<.001)	0.35 (<.001)	0.38 (<.001)
SEAR Overall Relationship	0.40 (<.001)	0.33 (<.001)	0.32 (<.001)	0.47 (<.001)	0.44 (<.001)
SEAR Total	0.44 (<.001)	0.40 (<.001)	0.34 (<.001)	0.44 (<.001)	0.47 (<.001)
Discriminant Validity					
IPSS	−0.22 (0.025)	−0.30 (0.002)	−0.17 (0.095)	−0.31 (.001)	−0.29 (0.003)

Table 7:

Preliminary SSIPI Results

	Mean (SD)
Overall satisfaction	4.15 (1.0)
Pain	4.56 (0.9)
Appearance	3.72 (1.0)
Function	4.16 (1.0)
Total	4.15 (0.9)