



Which patient may benefit the most from penile prosthesis implantation?

Giovanni La Croce¹ | Nicolò Schifano² | Edoardo Pescatori³ | Enrico Caraceni⁴ | Fulvio Colombo⁵ | Carlo Bettocchi⁶ | Maurizio Carrino⁷ | Antonio Vitarelli⁶ | Diego Pozza⁸  | Stefano Fiordelise⁹ | Francesco Varvello¹⁰ | Matteo Paradiso¹¹ | Mauro Silvani¹² | Nicola Mondaini¹³ | Alessandro Natali¹⁴ | Marco Falcone¹⁵ | Carlo Ceruti¹⁵ | Andrea Salonia¹⁶  | Gabriele Antonini¹⁷ | Tommaso Cai¹⁸  | Alessandro Palmieri¹⁹ | Federico Dehò² | Paolo Capogrosso² 

¹Department of Urology, ASST Papa Giovanni XXIII, Bergamo, Italy

²Department of Urology, Circolo & Fondazione Macchi Hospital, University of Insubria, Varese, Italy

³Andrology Service, Hesperia Hospital, Modena, Italy

⁴Department of Urology, Area Vasta 3 Asur Marche, Civitanova Marche, Italy

⁵Andrology Unit, Sant'Orsola University Hospital, University of Bologna, Italy

⁶Department of Urology, University of Bari, Bari, Italy

⁷Department of Urology, AORN Antonio Cardarelli, Naples, Italy

⁸Studio di Andrologia e di Chirurgia Andrologica, Rome, Italy

⁹Andrology Unit, ASL di Piacenza, Piacenza, Italy

¹⁰Department of Urology, S. Lazzaro Hospital, Alba, Italy

¹¹Department of Urology, Ospedale Cardinal Massaia, Asti, Italy

¹²Department of Urology, Ospedale di Biella, Biella, Italy

¹³Department of Urology, Villa Donatello Hospital, Florence, Italy

¹⁴Department of Urology, Careggi Hospital, University of Florence, Florence, Italy

¹⁵Urology Clinic, Città della Salute e della Scienza, University of Turin, Turin, Italy

¹⁶Division of Experimental Oncology, Unit of Urology, URI, IRCCS Ospedale San Raffaele, Università Vita-Salute San Raffaele, Milan, Italy

¹⁷Antonini Urology, Rome, Italy

¹⁸Department of Urology, Santa Chiara Regional Hospital, Trento, Italy

¹⁹Department of Neurosciences, Reproductive Sciences, Odontostomatology, University of Naples Federico II, Naples, Italy

Correspondence

Paolo Capogrosso, Department of Urology, Circolo & Fondazione Macchi Hospital, University of Insubria, Viale Borri 57, 20181 Varese, Italy.
Email: paolo.capogrosso@asst-settelaghi.it

Funding information

Boston Scientific and Coloplast Inc.

Abstract

Background: Penile prosthesis implantation has been associated with overall good functional outcomes. Of relevance, some patients reported higher level of satisfaction and quality of life.

Aim: We investigated the profile of the patients who may benefit the most from penile prosthesis implantation.

Giovanni La Croce and Nicolò Schifano contributed equally to this work.

© 2022 American Society of Andrology and European Academy of Andrology.

Materials and methods: Data from a national multi-institutional registry of penile prostheses including patients treated from 2014 to 2017 in Italy (Italian Nationwide Systematic Inventarization of Surgical Treatment for Erectile Dysfunction) were analyzed. All data have been prospectively recorded by 45 surgeons on a dedicated website (www.registro.andrologiaitaliana.it) and revised by a single data manager. Patients' baseline characteristics were recorded. In order to simultaneously evaluate perceived penile prosthesis function and quality of life, all patients were re-assessed at 1-year follow-up using the validated questionnaire Quality of Life and Sexuality with Penile Prosthesis. High quality of life after surgery was defined as a score higher than the 75th percentile in each of the subdomains of the Quality of Life and Sexuality with Penile Prosthesis questionnaire. Logistic regression analysis tested the association between clinical characteristics and high quality of life after penile prosthesis implantation.

Results: Follow-up data were available for 285 patients (median age 60 years; interquartile range: 56–67) who underwent penile prosthesis implantation. Erectile dysfunction etiology was organic in 40% (114), pelvic surgery/radiotherapy in 39% (111), and Peyronie's disease in 21% (60) of the cases. Patients showed good overall Quality of Life and Sexuality with Penile Prosthesis scores at 1-year follow-up for functional (22/25), personal (13/15), relational (17/20), and social (13/15) domains. Overall, 27.0% (77) of patients achieved scores consistent with the high quality of life definition. These patients did not differ in terms of median age (60 vs. 62), type of prosthesis (inflatable penile prostheses: 95% in both of the cases), and post-operative complications (10% vs. 14%) than those with lower quality of life score (all $p > 0.1$). At logistic regression analysis, erectile dysfunction etiology was the only factor independently associated with high quality of life at 1 year after surgery ($p = 0.02$). Patients treated for Peyronie's disease (odds ratio: 2.62; $p = 0.01$; 95% confidence interval: 1.20–5.74) were more likely to report better outcomes after accounting for age, post-operative complications, and surgical volume.

Conclusion: Penile prosthesis implantation is associated with an overall good quality of life. The subset of patients affected by erectile dysfunction secondary to Peyronie's disease seemed to benefit the most from penile prosthesis implantation in terms of functional outcomes, relationship with their partners and the outside world, and perceived self-image. The systematic use of validated questionnaires specifically addressed at evaluating quality of life and satisfaction after penile prosthesis implantation should be further implemented in future studies to better define the predictors of optimal satisfaction after penile prosthesis implantation.

KEYWORDS

erectile dysfunction, penile prosthesis implantation, Peyronie's disease, questionnaire, sexual satisfaction

1 | INTRODUCTION

Penile prosthesis implantation (PPI) is a well-established treatment for the management of patients affected by erectile dysfunction (ED) refractory to other options and in selected patients with Peyronie's

disease, such as those with complex curvatures and any concomitant degree of ED.^{1,2}

Inflatable penile prostheses (IPPs) optimally reproduce a physiological erection and are considered the gold standard treatment option in those patients who are not responsive to the other lines of

treatment or when these options are poorly tolerated or contraindicated. Overall, IPPs have been associated with excellent functional outcomes that have been proved to be durable also in the very-long-term follow-up studies.³⁻⁶ Semirigid devices are also associated with high levels of patients' satisfaction, although some possible issues of concealability and suboptimal mimicry of a physiological erection may explain why these devices seem to be associated with worse satisfaction outcomes versus their inflatable counterparts.⁷ High levels of sexual satisfaction, with an associated positive impact on the quality of life (QoL) of the patients being treated, has been documented in more than 90% of patients undergoing IPP implantation,^{5,8-10} even though the methods/questionnaires used to assess sexual satisfaction and QoL after PPI were highly heterogeneous in the available studies. Indeed, the recent improvements in materials and surgical techniques allowed reaching optimal and durable levels of patients' satisfaction while reducing the risk of perioperative morbidity.³ PPI is not devoid of potentially devastating complications and surgical revision could be required over time for a range of reasons, including mechanical failure.⁸ In this context, an accurate selection of the candidate, a thorough patients' counseling, intraoperative and perioperative optimization are all essential to set realistically and meet the patients' expectations.

Although several studies have confirmed high levels of patients' satisfaction, few studies were specifically addressed to identify which patients would take more advantage from PPI.

Therefore, in this study, the clinical profile of those patients who may benefit the most from PPI was investigated using data from a national multicenter prospective registry.

2 | MATERIALS AND METHODS

Data of patients who underwent PPI from December 2014 to November 2017 and prospectively recorded in the Italian Nationwide Systematic Inventarization of Surgical Treatment for ED (INSIST-ED) registry were analyzed here.

The INSIST-ED is a prospective database of penile prostheses (all brands) open to all surgeons implanting penile prostheses in Italy. INSIST-ED study details have been previously reported.¹¹

Data are filed and consultable at www.registro.andrologiaitaliana.it (username: demo@registrosia.it; password: RegSia2015_demo) in a demonstration version of the INSIST-ED registry.

Forty-six surgeons from 30 different hospitals collaborated to the project. Data are available for both virgin cases and revision surgeries and include patients' baseline characteristics, device type, and surgical technique. Intraoperative early (within 1 month from surgery) and late (within 1 year) post-operative complications are recorded. Functional outcomes and patient' satisfaction are assessed with the Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaire administered at the 1 year from surgery follow-up assessment. The QoLSPP questionnaire comprises four domains including questions dealing with prosthesis function (functional domain), relationship with partner (relational domain), relation to the outside world (social

domain), and self-image (personal domain). Each domain displays a different number of items (from 3 to 5) and answers are based on a six-point (0-5) Likert scale, where higher values represent higher satisfaction levels.¹²

All data included in the registry have been checked and revised by a single data manager to guarantee completeness and accurateness of data.

The registry is approved by the Società Italiana di Andrologia Ethical Committee and the study has been conducted in accordance with the Declaration of Helsinki. All patients signed an informed consent agreeing to share their anonymous information for future studies.

2.1 | Statistical analysis

The aim of our study was to investigate patients pre-operative characteristics associated with higher levels of QoL after PPI.

Considering the lack of standardized cut-off points to define patients' satisfaction degree for the QoLSPP total and domain scores, higher QoL levels (hQoL) after PPI were defined when a score higher than the 75th percentile (considering the entire cohort of patients included in the registry with available follow-up) in each of the sub-domains of the QoLSPP was reached. Descriptive statistics were used to compare baseline characteristics of the patients with and without hQoL at 1-year follow-up. Post-operative adverse events were classified according to the Clavien-Dindo classification of surgical complications.¹³

Logistic regression analysis was applied to test the possible predictors of hQoL after PPI; thus including age, ED etiology, surgical approach, type of prosthesis, and center experience (this being defined based on the number of procedures performed by each center during the study period).

Complete 1-year follow-up data were available for 285 patients (285/1465; 19%) of the total number of patients with at least 1-year follow-up duration from recruitment. In order to mitigate the possible selection bias being associated with the possibility that a number of patients may have been missed over the follow-up because of poor satisfaction, a sensitivity analysis was performed to compare the baseline characteristics of the patients with and without complete follow-up data.

Statistical analyses were performed using STATA 15.0 (StataCorp, College Station, TX, USA) with a two-sided statistical significance at $p < 0.05$.

3 | RESULTS

Complete follow-up data were available for 285 patients with a median age of 62 years (interquartile range: 56-67). Overall, the most common etiology of ED was organic in 40% (114) followed by pelvic surgery/radiotherapy in 39% (111) and Peyronie's disease in 21% (60). In all patients receiving a PPI for Peyronie's disease, the penile

TABLE 1 Descriptive statistics of the entire cohort (N = 285)

Age (years), median (IQR)	60 (56, 67)
Type of prosthesis, no. (%)	
Semirigid	16 (5.7%)
Bi-component	20 (7%)
Tri-component	249 (87%)
Surgical approach, no. (%)	
Penoscrotal	219 (77%)
Subcoronal	6 (2%)
Longitudinal corporotomy	4 (1.2%)
Infrapubic	56 (20%)
Center surgical volume ^a , median (IQR)	105 (54, 494)
ED etiology, no. (%)	
Organic	114 (40%)
Post-surgery/radiotherapy	111 (39%)
Peyronie's disease	60 (21%)

Abbreviations: ED, erectile dysfunction; IQR, interquartile range.

^aNumber of penile prosthesis implantation (PPI) procedures during the study period.

curvature was managed with manual modeling only. Most patients received an IPP (94%), while only the remaining 6% of patients received a semirigid penile prosthesis. Among the IPPs being implanted, the preferred device was the tri-component device (87% out of the total number of procedures), while a bi-component IPP was placed in the remaining 7% of the cases. The most common surgical approach was the penoscrotal one (77%). Median surgical volume per center (i.e., median number of PPI procedures in the study period) was 105 procedures (Table 1).

Surgical complications were reported in 11% (31 patients) (Table 2), the vast majority of which (7.9%, 22 cases) were classified as Clavien-Dindo 1 adverse events, with conservatively managed penoscrotal hematoma being the most frequently reported complication.

Overall, 27% (77 cases) of the patients reported hQoL after surgery according to the QoLSPP total score (QoLSPP > 71) (Table 3). Patients reporting hQoL at 1 year did not differ in terms of median age (62 years vs. 60 years, respectively, in the hQoL subset vs. the remaining), type of prosthesis (IPP implanted in 95% in both the hQoL subset vs. the non-hQoL subset), center surgical volume (105 vs. 71 procedures, respectively, in the hQoL subset vs. the remaining), and post-operative complications (14% vs. 10% in the hQoL subset vs. the remaining) (all $p > 0.1$) (Table 4). Conversely, hQoL scores were reported more frequently ($p = 0.02$) by those patients with pelvic surgery/radiotherapy-related ED (45% vs. 37% in the hQoL subset vs. the remaining) and Peyronie's disease (27% vs. 18% in the hQoL subset vs. the remaining). Organic etiology ED patients were less likely to reach QoLSPP scores consistent with hQoL (27% vs. 46% in the hQoL subset vs. the remaining).

At the logistic regression analysis (Table 5), ED etiology was found to be the only factor being independently associated with hQoL at

TABLE 2 Complications occurred in the whole cohort

Post-operative complications	No. (%)
Overall number of complications	31 (11%)
Pain	4 (1.1%)
Wound infection	5 (1.8%)
Penoscrotal hematoma	10 (3.4%)
Fever	2 (0.7%)
Myocardial infarction	1 (0.4%)
Local allergic rash	1 (0.4%)
Urinary retention	1 (0.4%)
Displacement of the reservoir	2 (0.8%)
Cylinder extrusion	1 (0.4%)
Scrotal erosion	2 (0.8%)
Urethral lesion	1 (0.4%)
Glans necrosis	1 (0.4%)
Clavien-Dindo 1	22 (7.9%)
Clavien-Dindo 2	4 (1.1%)
Clavien-Dindo 3	5 (1.9%)

TABLE 3 Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) scores in the whole cohort at the 1-year post-treatment follow-up

QoLSPP domains	Scores
Functional domain score (IQR)	22/25 (19, 24)
Personal domain score (IQR)	13/15 (12, 15)
Relational domain score (IQR)	17/20 (15, 19)
Social domain score (IQR)	13/15 (12, 15)
Total score (IQR)	66/75 (58, 71)

Abbreviation: IQR, interquartile range.

1 year after surgery ($p < 0.01$) after accounting for age, center experience, complications, and type of implant (IPP vs. malleable). More in detail, those patients receiving a PPI because of Peyronie's disease (odds ratio: 2.62; 95% confidence interval: 1.20–5.74) were more likely to report better outcomes at 1 year after surgery (Figure 1).

The sensitivity analysis did not show significant differences between patients with and without complete follow-up data in terms of age, ED etiology, and type of prosthesis. Conversely, those patients with complete follow-up data significantly differed from the complete follow-up group in terms of surgical approach being adopted ($p = 0.002$), and in terms of center surgical volume ($p = 0.0005$) (Table S1).

4 | DISCUSSION

We investigated the profile of patients who benefited the most from PPI in terms of QoL improvement using data from a multicenter

TABLE 4 Odds of reporting high quality of life (hQoL) after accounting for patient-related features and surgical-related features

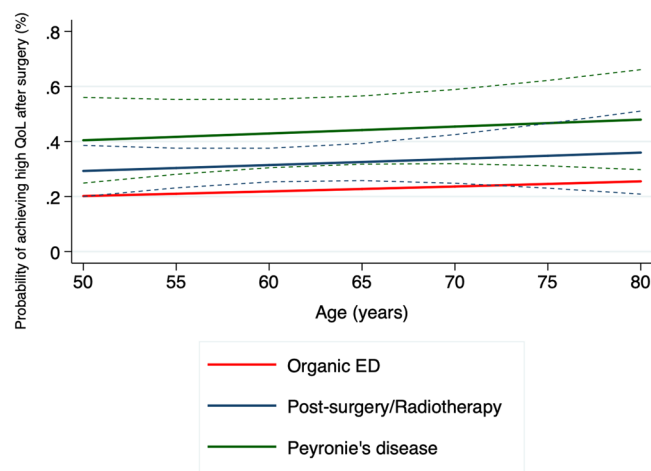
	Patients not reaching scores consistent with the hQoL definition	Patients reaching scores consistent with the hQoL definition	p-Value
Age	60.0 (55.0, 66.0)	62.0 (57.0, 67.0)	0.2
Center volume, median (IQR)	71.0 (54.0, 494.0)	105.0 (44.0, 494.0)	0.7
Etiology			0.024
Organic, no. (%)	96 (46%)	21 (27%)	
Pelvic surgery or RT, no. (%)	77 (37%)	35 (45%)	
Peyronie's disease, no. (%)	35 (18%)	21 (27%)	
Post-operative complications, no. (%)	20 (10%)	11 (14%)	0.3
IPPs, no. (%)	198 (95%)	73 (95%)	0.9

Abbreviations: IPP, inflatable penile prosthesis; IQR, interquartile range; RT, radiotherapy.

TABLE 5 Logistic regression model predicting high quality of life (QoL) after penile prosthesis implantation (PPI)

	OR	95% CI	p-Value
Age	1.01	0.98, 1.04	0.6
Center surgical volume	1.00	1.00, 1.00	1
ED etiology			
Organic versus post-surgery/radiotherapy	1.94	0.98, 3.83	0.057
Organic versus Peyronie's disease	2.62	1.20, 5.74	0.01
Type of prosthesis (semirigid vs. IPP)	1.37	0.38, 4.94	0.6
Post-operative complications	1.48	0.64, 3.38	0.4

Abbreviations: ED, erectile dysfunction; IPP, inflatable penile prosthesis; OR, odds ratio; 95% CI, 95% confidence interval.

**FIGURE 1** Adjusted probability of achieving high quality of life (QoL) after penile prosthesis implantation (PPI) according to age and erectile dysfunction (ED) etiology

national prospective registry. Our data showed that those patients undergoing a PPI for ED associated with Peyronie's disease were three times more likely to report high QoL and satisfaction at 1 year after treatment than those undergoing surgery for other causes and regard-

less of age, type of implanted device, surgical approach, and center surgical volume.

Penile prostheses are aimed to restore a normal erectile function reproducing an erection which is as similar as possible to a physiological one in those patients suffering from ED and/or Peyronie's disease where other treatment options are not viable. Achieving high levels of QoL and sexual satisfaction is crucial in this context, and should be regarded as one of the primary goals of this surgery, along with ensuring its safety. However, the sexual satisfaction and QoL after PPI has to be considered as a complex outcome, which is dependent upon several different factors in addition to the mere restoration of a normal erectile function.^{10,14,15} The evaluation of the satisfaction after PPI should therefore be based on the use of adequate tools/validated questionnaires specifically designed to evaluate sexual satisfaction in this very specific context. The vast majority of the previous studies dealing with this issue have not used validated questionnaire to assess sexual satisfaction or QoL.^{9,16-18} Montorsi et al.¹⁸ assessed the mechanical reliability of American Medical Systems three-piece IPPs and their impact on patient-partner satisfaction in 200 consecutive patients in Europe, finding satisfaction rates exceeding 90%. However, the questions being used to evaluate the post-operative satisfaction were not described in detail in the paper, and some possible determinants of QoL after the PPI were not explored, raising possible concerns regarding the comparability of their findings with other studies. Conversely, Brinkman et al.¹⁷ introduced the first attempt of a systematic approach in evaluating satisfaction after PPI. They surveyed 330 patients undergoing virgin three-piece IPP surgeries performed at a single institution, documenting high levels of satisfaction with the use of the implants. Although it lacked of validation, their questionnaire comprised seven sections of questions covering a number of important possible determinants of the patients' satisfaction, including satisfaction of the partner, impacts of the surgery on the quality of the relationship, and patients' satisfaction with the education about the prosthesis being provided by the surgical team. A number of studies assessed post-operative satisfaction after PPI using validated questionnaires, which were however designed to assess the clinical response to medical management of ED other than specifically addressed to evaluate satisfaction after PPI, such as the Erectile Dysfunction Inventory of Treatment

Satisfaction (EDITS) or the International Index of Erectile Function (IIEF).¹⁹⁻²¹ A long-term satisfaction rate of 97% at the 60-month follow-up was reported by Natali et al.²² using the EDITS score.

Similarly, Vitarelli et al.²³ reported high satisfaction rates after two-piece PPI at a mean follow-up of 27.6 months according to the EDITS and the IIEF questionnaires scores.

In our study, we reported the functional and QoL outcomes of patients treated with PPI using the QoLSPP, a tool specifically created to assess satisfaction in this subset of patients. The QoLSPP was developed by Caraceni and Utizi¹² to investigate a number of different aspects pertinent with the sexual satisfaction and QoL after PPI, thus including questions relating to the impact of the treatment on the relationship with the partner and some other questions addressed to investigate on functional aspects, such as the easiness of use of the device itself. Since PPI is a one-way/non-reversible procedure aimed at QoL improvement, an accurate pre-operative selection of those candidates who could take the more advantage from this treatment appears of outmost importance. Our findings confirmed that overall QoL and satisfaction scores after PPI were high, although the best outcomes were achieved by patients implanted for ED secondary to Peyronie's disease. Penile morphometric changes represent one of the main factors, which typically may have a strong impact on the satisfaction levels after every PPI surgery.^{24,25} Discussing this issue in the pre-operative setting becomes particularly important in those patients having ED secondary to Peyronie's disease. Indeed, these patients almost invariably experience post-operative penile shrinkage because of the natural history of the disease and because of the changes introduced intraoperatively, and especially so when plication or grafting are needed in addition to the PPI to correct complex deformities.²⁶ Moreover, the risk of detrimental outcomes is reported to be higher in those patients undergoing PPI in the context of Peyronie's disease when grafting is needed, with an expected impact on the satisfaction levels. Interestingly enough, according to existing literature it appears that those patients undergoing PPI for Peyronie's disease presented with worse satisfaction versus other etiologies, and this is speculated to be secondary to the morphometric changes that frequently these patients experience. This may appear in contrast with our findings. Firstly, we could speculate that in our series the application of a dedicated tool assessing more specifically the satisfaction with the device itself and its efficacy may have led to more reliable findings versus those studies using non-validated questionnaires or questionnaires being developed for different purposes. Secondly, those patients with Peyronie's disease undergoing PPI may have presented with higher post-operative QoL and satisfaction scores in those cases when this difficult category of patients, who usually are young and present with very poor pre-operative sexual fitness after the onset of the disease, were successfully rehabilitated to satisfactory levels of sexual functioning.²⁷ In support of this apparently paradoxical finding, a number of studies have documented that the higher satisfaction scores for the surgical treatment of Peyronie's disease are achieved when a PPI (alone or concomitant with other straightening procedures) is performed,²⁸ versus the mere adoption of plication or grafting strategies. Thirdly, in the present series all of the Peyronie's disease patients were managed with

manual modeling only during PPI and additional grafting or plication was not needed to correct their curvatures. The adoption of manual modeling only as a straightening strategy may have introduced less penile size loss in these patients, and a more favorable complication profile versus possible grafting or plication. We could speculate that this issue has contributed to the high satisfaction levels after PPI documented in this subset of patients. Surprisingly, the type of implanted device was not associated here with the odds of obtaining very high QoL outcomes, while the existing literature to this respect has clearly shown significantly better outcomes for those patients receiving an IPP—either bi-component or tri-component—versus those patients receiving a semirigid rod.^{2,3,7,29,30} It can be speculated that a thorough and expert pre-operative counseling setting realistic expectations could help to achieve optimal satisfaction even when a malleable device is the only viable option, provided that the downsides of this type of prosthesis, such as limited concealability or perception of unnatural erection, are extensively discussed with the candidate pre-operatively. In support of this, better scores were observed for those patients undergoing PPI in high volume centers, thus confirming previous findings based on the INSIST-ED registry.¹¹ A number of additional factors may explain why the ED etiology seemed to predict better optimal satisfaction levels versus the type of prosthesis. In fact, a malleable prosthesis is capable of providing better satisfaction levels in certain categories of patients, including those with poor manual dexterity and those with partially buried penis (i.e., obese patients), who may struggle to action an inflatable device.³⁰ Moreover, one could argue that the inferior costs being associated with the malleable devices may have exerted an indirect effect on the perception of satisfaction among the malleable device receivers,³⁰ in a country where IPPs are not reimbursed. Although better pre-operative counseling, better cosmetic results, and overall lower risk of complications are expected to be provided in high volume centers, the surgical volume did not predict hQoL as reliably as the ED etiology in this analysis.

Our study is not devoid of limitations. First, complete follow-up data were not available for the totality of the patients. This may have introduced levels of selection bias, as the less satisfied patients may have been less inclined to attend to the scheduled follow-up visits at 1 year versus the satisfied patients. To mitigate this issue, a sensitivity analysis has been introduced, showing no significant differences in terms of age, ED etiology, and surgical approach between patients with and without complete follow-up data. Finally, we acknowledge that a number of baseline patient-related features such as body mass index and comorbidities which could influence the risk of complications which in turn likely impact on the satisfaction levels were not made available here. Finally, the hQoL definition which was here adopted is not validated, and should be considered arbitrary.

This study does present however with a number of strengths. First, the data are filed in a multicentric database, which collects data coming from different centers throughout Italy, providing a representative national figure of the outcomes of this surgery in the country. Second, all of the data have been checked and revised by a single data manager to guarantee completeness and accurateness of the data, and the whole cohort underwent the same standardized follow-up schedule. Finally,

the use of a validated questionnaire specifically addressed to assess satisfaction after PPI was here used.

5 | CONCLUSIONS

Penile prosthesis implantation is associated with overall excellent post-operative satisfaction scores and quality of life. Patients affected by erectile dysfunction secondary to Peyronie's disease appear to benefit the most from penile prosthesis implantation in terms of functional outcomes, relationship with their partners and the outside world, and perceived self-image. Objective assessment of the satisfaction outcomes after penile prosthesis implantation using validated questionnaires specifically designed to evaluate quality of life in this context should be systematically implemented in future studies. These data could be useful to guide the clinicians in identifying and adequately counsel in the pre-operative setting those patients who may benefit the most from penile prosthesis implantation.

AUTHOR CONTRIBUTIONS

Paolo Capogrosso designed the study and led the statistical analysis. Edoardo Pescatori, Enrico Caraceni, Fulvio Colombo, Carlo Bettocchi, Maurizio Carrino, Antonio Vitarelli, Diego Pozza, Stefano Fiordelise, Francesco Varvello, Matteo Paradiso, Mauro Silvani, Nicola Mondaini, Alessandro Natali, Carlo Ceruti, Andrea Salonia, Gabriele Antonini, Tommaso Cai, Alessandro Palmieri, and Federico Dehò took care of the patients and contributed to the data collection. Giovanni La Croce, Nicolò Schifano, and Paolo Capogrosso drafted the report.

ACKNOWLEDGMENT

We thank all active members of the INSIST-ED project: Antonino Laganà, Antonio Avolio, Antonio Corvasce, Antonio Barbieri, Marco Bitelli, Francesco Boezio, Carlo Negro, Sandro Ciampalini, Enrico Conti, Giuseppe Dachille, Patrizio Vicini, Fabrizio Palumbo, Alessandro Francescheli, Francesco De Luca, Giorgio Franco, Nicola Ghidini, Giovanni Alei, Giulio Garaffa, Emilio Italiano, Giuseppe La Pera, Paolo Liguori, Massimiliano Timpano, Massimiliano Capone, Massimo Polito, Matteo Matera, Aldo Tamai, Piero Letizia, Giuseppe Ludovico, Giovanni Grimaldi, Alessandro Izzo, Giuseppe Cardo, Francesco Paolo Maselli, Francesco Montorsi. This research was partially supported by an unrestricted educational grant from Boston Scientific and Coloplast Inc.

CONFLICT OF INTEREST

The authors declare they have no conflicts of interest.

ORCID

Diego Pozza <https://orcid.org/0000-0002-5931-3226>

Andrea Salonia <https://orcid.org/0000-0002-0595-7165>

Tommaso Cai <https://orcid.org/0000-0002-7234-3526>

Paolo Capogrosso <https://orcid.org/0000-0003-2347-9504>

REFERENCES

- Hatzimouratidis K, Salonia A, Adaikan G, et al. Pharmacotherapy for erectile dysfunction: recommendations from the fourth International Consultation for Sexual Medicine (ICSM 2015). *J Sex Med.* 2016;13(4):465-488. <https://doi.org/10.1016/j.jsxm.2016.01.016>
- Levine LA, Becher EF, Bella AJ, et al. Penile prosthesis surgery: current recommendations from the international consultation on sexual medicine. *J Sex Med.* 2016;13(4):489-518. <https://doi.org/10.1016/j.jsxm.2016.01.017>
- Wilson SK, Delk JR, Salem EA, Cleves MA. Long-term survival of inflatable penile prostheses: single surgical group experience with 2,384 first-time implants spanning two decades. *J Sex Med.* 2007;4(4 Pt 1):1074-1079. <https://doi.org/10.1111/j.1743-6109.2007.00540.x>
- Trost L, Wanzek P, Bailey G. A practical overview of considerations for penile prosthesis placement. *Nat Rev Urol.* 2016;13(1):33-46. <https://doi.org/10.1038/nrurol.2015.270>
- Bettocchi C, Palumbo F, Spilotros M, et al. Patient and partner satisfaction after AMS inflatable penile prosthesis implant. *J Sex Med.* 2010;7(1 Pt 1):304-309. <https://doi.org/10.1111/j.1743-6109.2009.01499.x>
- Chung E. Penile prosthesis implant: scientific advances and technological innovations over the last four decades. *Transl Androl Urol.* 2017;6(1):37-45. <https://doi.org/10.21037/tau.2016.12.06>
- Bayrak O, Erturhan S, Seckiner I, Ozturk M, Sen H, Erbagci A. Comparison of the patient's satisfaction underwent penile prosthesis; Malleable versus Ambicor: single center experience. *Arch Ital Urol Androl.* 2020;92(1):25-29. <https://doi.org/10.4081/aiua.2020.1.25>
- Chierigo F, Capogrosso P, Dehò F, et al. Long-term follow-up after penile prosthesis implantation—survival and quality of life outcomes. *J Sex Med.* 2019;16(11):1827-1833. <https://doi.org/10.1016/j.jsxm.2019.08.001>
- Akakpo W, Pineda MA, Burnett AL. Critical analysis of satisfaction assessment after penile prosthesis surgery. *Sex Med Rev.* 2017;5(2):244-251. <https://doi.org/10.1016/j.sxmr.2017.01.001>
- Habous M, Tal R, Tealab A, et al. Predictors of satisfaction in men after penile implant surgery. *J Sex Med.* 2018;15(8):1180-1186. <https://doi.org/10.1016/j.jsxm.2018.05.011>
- Capogrosso P, Pescatori E, Caraceni E, et al. Satisfaction rate at 1-year follow-up in patients treated with penile implants: data from the multi-centre prospective registry INSIST-ED. *BJU Int.* 2019;123(2):360-366. <https://doi.org/10.1111/bju.14462>
- Caraceni E, Utizi L. A questionnaire for the evaluation of quality of life after penile prosthesis implant: quality of life and sexuality with penile prosthesis (QoLSPP): to what extent does the implant affect the patient's life? *J Sex Med.* 2014;11(4):1005-1012. <https://doi.org/10.1111/jsm.12453>
- Mitropoulos D, Artibani W, Biyani CS, Bjerggaard Jensen J, Roupêt M, Truss M. Validation of the Clavien-Dindo grading system in urology by the European Association of Urology Guidelines ad hoc panel. *Eur Urol Focus.* 2018;4(4):608-613. <https://doi.org/10.1016/j.euf.2017.02.014>
- Ji YS, Ko YH, Song PH, Moon KH. Long-term survival and patient satisfaction with inflatable penile prosthesis for the treatment of erectile dysfunction. *Korean J Urol.* 2015;56(6):461-465. <https://doi.org/10.4111/kju.2015.56.6.461>
- Kane RL, Maciejewski M, Finch M. The relationship of patient satisfaction with care and clinical outcomes. *Med Care.* 1997;35(7):714-730. <https://doi.org/10.1097/00005650-199707000-00005>
- Bernal RM, Henry GD. Contemporary patient satisfaction rates for three-piece inflatable penile prostheses. *Adv Urol.* 2012;2012:707321. <https://doi.org/10.1155/2012/707321>
- Brinkman MJ, Henry GD, Wilson SK, et al. A survey of patients with inflatable penile prostheses for satisfaction. *J Urol.* 2005;174(1):253-257. <https://doi.org/10.1097/01.ju.0000161608.21337.8d>
- Montorsi F, Rigatti P, Carmignani G, et al. AMS three-piece inflatable implants for erectile dysfunction: a long-term multi-institutional study

- in 200 consecutive patients. *Eur Urol.* 2000;37(1):50-55. <https://doi.org/10.1159/000020099>
19. Pillay B, Moon D, Love C, et al. Quality of life, psychological functioning, and treatment satisfaction of men who have undergone penile prosthesis surgery following robot-assisted radical prostatectomy. *J Sex Med.* 2017;14(12):1612-1620. <https://doi.org/10.1016/j.jsxm.2017.10.001>
 20. Althof SE, Corty EW, Levine SB, et al. EDITS: development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. *Urology.* 1999;53(4):793-799. [https://doi.org/10.1016/S0090-4295\(98\)00582-2](https://doi.org/10.1016/S0090-4295(98)00582-2)
 21. Rosen RC, Riley A, Wagner G, Osterloh IH, Kirkpatrick J, Mishra A. The international index of erectile function (IIEF): a multidimensional scale for assessment of erectile dysfunction. *Urology.* 1997;49(6):822-830. [https://doi.org/10.1016/S0090-4295\(97\)00238-0](https://doi.org/10.1016/S0090-4295(97)00238-0)
 22. Natali A, Olianias R, Fisch M. Penile implantation in Europe: successes and complications with 253 implants in Italy and Germany. *J Sex Med.* 2008;5(6):1503-1512. <https://doi.org/10.1111/j.1743-6109.2008.00819.x>
 23. Vitarelli A, Divenuto L, Fortunato F, et al. Long term patient satisfaction and quality of life with AMS700CX inflatable penile prosthesis. *Arch Ital Urol Androl.* 2013;85(3):133-137. <https://doi.org/10.4081/aiua.2013.3.133>
 24. Akin-Olugbade O, Parker M, Guhring P, Mulhall J. Determinants of patient satisfaction following penile prosthesis surgery. *J Sex Med.* 2006;3(4):743-748. <https://doi.org/10.1111/j.1743-6109.2006.00278.x>
 25. Schifano N, Cakir OO, Castiglione F, Montorsi F, Garaffa G. Multi-disciplinary approach and management of patients who seek medical advice for penile size concerns: a narrative review. *Int J Impot Res.* 2022;34(5):434-451. <https://doi.org/10.1038/s41443-021-00444-5>
 26. Levine LA, Benson J, Hoover C. Inflatable penile prosthesis placement in men with Peyronie's disease and drug-resistant erectile dysfunction: a single-center study. *J Sex Med.* 2010;7(11):3775-3783. <https://doi.org/10.1111/j.1743-6109.2010.01971.x>
 27. Gamidov S, Shatylo T, Gasanov N, Scherbakov D, Li K, Sukhikh G. Long-term outcomes of surgery for Peyronie's disease: focus on patient satisfaction. *Int J Impot Res.* 2021;33(3):332-338. <https://doi.org/10.1038/s41443-020-0297-6>
 28. Khera M, Bella A, Karpman E, et al. Penile prosthesis implantation in patients with Peyronie's disease: results of the PROPPER study demonstrates a decrease in patient-reported depression. *J Sex Med.* 2018;15(5):786-788. <https://doi.org/10.1016/j.jsxm.2018.02.024>
 29. Minervini A, Ralph DJ, Pryor JP. Outcome of penile prosthesis implantation for treating erectile dysfunction: experience with 504 procedures. *BJU Int.* 2006;97(1):129-133. <https://doi.org/10.1111/j.1464-410X.2005.05907.x>
 30. Eardley I. Malleable vs inflatable implant? Which one to choose. *J Sex Med.* 2017;14(8):975-976. <https://doi.org/10.1016/j.jsxm.2017.05.015>

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: La Croce G, Schifano N, Pescatori E, et al. Which patient may benefit the most from penile prosthesis implantation? *Andrology.* 2022;1-8. <https://doi.org/10.1111/andr.13294>