







# Long-term penile prosthesis couple's satisfaction: A systematic review and meta-analysis

Giovanni Corona<sup>1</sup>  | Daniele Santi<sup>2</sup>  | Andrea Cocci<sup>3</sup>  | Walter Vena<sup>4,5</sup> |  
 Alessandro Pizzocaro<sup>6</sup> | Linda Vignozzi<sup>7</sup> | Andrea M. Isidori<sup>8</sup>  |  
 Rosario Pivonello<sup>9,10</sup>  | Andrea Salonia<sup>11,12</sup>  | Suks Minhas<sup>13</sup> | Carlo Bettocchi<sup>14</sup> |  
 Yacov Reisman<sup>15</sup> | Mario Maggi<sup>16</sup>

<sup>1</sup>Endocrinology Unit, Azienda AUSL Bologna, Ospedale Maggiore, Bologna, Italy

<sup>2</sup>Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Unit of Endocrinology, Department of Medical Specialties, Azienda Ospedaliero-Universitaria of Modena, Modena, Italy

<sup>3</sup>Department of Urology, University of Florence, Florence, Italy

<sup>4</sup>Endocrinology, Humanitas Gavazzeni-Castelli, Bergamo, Italy

<sup>5</sup>Department of Biomedical Sciences, Humanitas University, Milan, Italy

<sup>6</sup>Unit of Endocrinology, Diabetology and Medical Andrology, IRCSS, Humanitas Research Hospital, Rozzano, Milan, Italy

<sup>7</sup>Andrology, Women's Endocrinology and Gender Incongruence Unit, Mario Serio "Department of Experimental and Clinical Biomedical Sciences, University of Florence, Florence, Italy

<sup>8</sup>Department of Experimental Medicine, "Sapienza" University of Rome, Policlinico Umberto I Hospital, Rome, Italy

<sup>9</sup>Dipartimento di Medicina Clinica e Chirurgia, Sezione di Endocrinologia, Diabetologia, Andrologia e Nutrizione, Unità di Andrologia e Medicina della Riproduzione, Sessualità e Affermazione di Genere, Università Federico II di Napoli, Naples, Italy

<sup>10</sup>Staff of UNESCO Chair for Health Education and Sustainable Development, Federico II University, Naples, Italy

<sup>11</sup>Division of Experimental Oncology/Unit of Urology, URI, IRCCS Ospedale San Raffaele, Milan, Italy

<sup>12</sup>University Vita-Salute San Raffaele, Milan, Italy

<sup>13</sup>Department of Urology, Imperial College NHS Healthcare, London, UK

<sup>14</sup>Andrology and Male Genitalia Reconstructive Surgery Unit, University of Foggia, Foggia, Italy

<sup>15</sup>Sexual Medicine, Flare-Health, Amsterdam, the Netherlands

<sup>16</sup>Endocrinology Unit, Mario Serio" Department of Experimental and Clinical Biomedical Sciences, University of Florence, Florence, Italy

## Correspondence

Dr. Giovanni Corona, Endocrinology Unit, Azienda AUSL Bologna Maggiore Hospital, Largo Nigrisoli, 2-40133 Bologna, Italy.  
 Email: [jocorona@libero.it](mailto:jocorona@libero.it)

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## Abstract

**Context:** Data supporting successful and satisfactory penile prosthesis (PP) implantation outcomes are mainly based on subjective, rather than objective, analysis.

**Objective:** To systematically review and objectively analyze, all available data related to patient and partner PP satisfaction.

**Evidence acquisition:** An extensive search was performed, including the following key-words: ("penile prosthesis" and "satisfaction"). The search, which accrued data from January 1, 1969, up to July 31, 2023, was restricted to English-language articles including human participants.

**Evidence synthesis:** Out of 663 retrieved articles, 83 were considered including, 12,132 subjects with a mean age and mean follow-up of 58.6 [range 20; 77.1] years and

47.6 [range 6; 374] months, respectively. Overall, a high patient satisfaction rate was observed 83[80; 86]%. The satisfaction rate increased in subjects with three-piece PP and in those with a higher rate of cardiovascular or neurological diseases and was independent of the patient's age. Partner's satisfaction rate was lower when compared to that observed in men and it increased according to the use of inflatable devices and the presence of patient Peyronie's disease. The long-term complication rate was limited ranging from 3% for erosion to 4.6% when mechanical failure was considered.

**Conclusions:** Patient and partner satisfaction is excellent and increases with time. The number of complications is limited and is strongly associated with the presence of diabetes mellitus.

**Patient summary:** We found a high couple satisfaction score that was higher when reported by males compared to females. Patient satisfaction increased with time, and it was independent of age.

#### KEYWORDS

erectile dysfunction, penile prosthesis, Peyronie's diseases, satisfaction

## 1 | INTRODUCTION

According to available guidelines, penile prosthesis (PP) implantation represents the 3rd line therapy for patients with erectile dysfunction (ED) who do not respond to the conventional therapy or present contraindications for the available medical therapy.<sup>1,2</sup> Neophallus creation due to penile malformation in subjects with disorders of the sexual development or in the transgender population along with severe penile curvature due to Peyronie's disease (PD) represent other possible indications.<sup>3,4</sup>

The current available PPs include inflatable (IPP, two- and three-piece) and semi-rigid devices (malleable, mechanical, and soft flexible). Although IPPs are usually preferred by patients due to the development of a more "natural" and physiological erection, semi-rigid devices can still represent a valid option, especially in subjects with limited manual dexterity.<sup>2,5</sup> When eligible patients are adequately preoperatively selected, PP is usually associated with a high satisfaction rate in either patients or partners, with limited short-term and long-term complications.<sup>4-7</sup> Despite the aforementioned considerations, PPs still remain an underutilized option, accounting for less than 5% of patients with refractory ED.<sup>4</sup> Data derived from long-term prospective studies showed that the mean duration of ED symptoms before surgical intervention ranges from 3–6 years.<sup>8</sup> This could reflect the lack of objective data to adequately identify and redirect patients for whom less-invasive ED treatment options are likely to fail. On the other hand, the high long-term post-surgical satisfaction rate in both partners and the available data supporting the patient's willingness to recommend similar treatments to relatives or friends can suggest a lack of sufficient information and knowledge of the possible advantages and limitations

related to the PPs approach to ED subjects. Hence, the correct identification of the most suitable candidates for the surgical approach represents a crucial step. Although several systematic reviews have identified and discussed the most important determinants supporting successful and satisfactory PP implantation outcomes,<sup>4-7,9</sup> the available results are mainly based on subjective, rather than objective, analysis.

The aim of this study is to systematically review and objectively analyze, through a meta-analytic approach, all available data related to patient and partner PP satisfaction rates in order to correctly identify possible determinants and limitations.

## 2 | METHODS

This meta-analysis was performed in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guideline and Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines (Supporting information files 1 and 2).

The following PECO criteria were used<sup>10</sup>: **population**: general male population  $\geq 18$  year old; **exposure**: patients with ED from heterosexual couples undergoing PP implantation; **comparison**: prospective or retrospective analysis from baseline; **outcomes**: patients and partner long-term satisfaction, patient sexual function improvement from baseline and long-term complications.

The protocol of this study (CRD420223455010) was published on the website of the University of York (Centre for Reviews and Dissemination, <https://www.crd.york.ac.uk/PROSPERO/#recordDetails> CRD420223455010).

## 2.1 | Search strategy

An extensive Medline, Embase, and Cochrane search was performed, including the following keywords: (“penile prosthesis”[MeSH Terms] OR (“penile”[All Fields] AND “prosthesis”[All Fields]) OR “penile prosthesis”[All Fields]) AND (“personal satisfaction”[MeSH Terms] OR (“personal”[All Fields] AND “satisfaction”[All Fields]) OR “personal satisfaction”[All Fields] OR “satisfaction”[All Fields] OR “satisfactions”[All Fields] OR “satisfaction s”[All Fields]). The search, which accrued data from January 1, 1969, up to July 31, 2023, was restricted to English-language articles including human participants. The identification of relevant studies was performed independently by five of the authors (DS, AC, WV, AP, and GC), and conflicts were resolved by a consensus discussion among all authors. We did not employ search software but hand-searched the bibliographies of retrieved papers for additional references. The main source of information was derived from published articles.

## 2.2 | Study selection

All prospective and retrospective observational trials reporting data on PP patient and partner satisfaction were included, independent of the specific question used to assess the topic. When possible, data derived from PP re-implantation were excluded from the analysis. Case reports were excluded. Similarly, studies on PP not reporting patient or partner satisfaction were excluded from the analysis. In addition, only studies evaluating PP outcomes related to ED in heterosexual couples were considered (Figure S1). Data derived from phalloplasty reconstructive surgery or from ED in homosexual couples were excluded from the analysis. In particular, data on homosexual couples were not considered due to the limited number of available studies and to avoid possible bias in the evaluation of patient and partner satisfaction.

## 2.3 | Outcome and quality assessment

The principal outcome measure was the assessment of patient satisfaction with PPs. Secondary outcomes included overall partner's satisfaction as well as patient's and partner satisfaction according to the different types of PPs. Sexual function improvement after PP using the International Index of Erectile Function (IIEF) was also investigated whenever possible. In addition, when available, long-term adverse events related to PP surgery were also assessed, along with their possible determinants. The quality of the trials and risk of bias were determined using the ROBINS-E tool for observational studies (Table S1).<sup>11</sup>

## 2.4 | Statistical analysis

Heterogeneity was assessed using  $I^2$  statistics. Even when low heterogeneity was detected, a random-effect model was applied because

the validity of heterogeneity tests can be limited with a small number of component studies. We used funnel plots and the Begg-adjusted rank correlation test to estimate possible publication or disclosure bias.<sup>12</sup> However, undetected biases may still be present because these tests have low statistical power when the number of trials is small. Meta-regression analyses were performed whenever indicated. All data were calculated using Comprehensive Meta-analysis Version 2, Biostat (Englewood, NJ, USA). Multivariate analysis was performed on SPSS (Statistical Package for the Social Sciences; Chicago, IL, USA) for Windows 25.1.

## 3 | RESULTS

### 3.1 | Descriptive statistics

Out of 663 retrieved articles, 83 were included in the study (Table 1; see also Appendix A and Figure S1).

Overall, 12,132 subjects were included with a mean age and mean follow-up of 58.6 [range 20; 77.1] years and 47.6 [range 6; 374] months, respectively. Among the included studies, 32 prospectively evaluated the patient's outcomes, whereas 51 reported a retrospective analysis (Table 1). In addition, when the type of PP was considered, 11 and 46 studies reported data only on malleable or inflatable PP, respectively. Furthermore, seven authors compared different approaches, and 19 studies showed data derived from a mixed population of patients treated with either malleable or inflatable PP (Table 1).

### 3.2 | Patient outcomes

Completed data related to patient satisfaction were available for 9,429 subjects. The Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) was the most used validated questionnaire, whereas a lower number of studies applied IIEF, or quality of life and sexuality with penile prosthesis (QoLSP). Finally, many authors utilized a non-validated questionnaire (Table 1).

The  $I^2$  in trials assessing patient satisfaction was 90.27 ( $p < 0.0001$ ). A funnel plot and Begg adjusted rank correlation test (Kendall's  $\tau$ : 0.17;  $p = 0.03$ ) suggested publication bias (Figure S2A).

Overall, a high patient satisfaction rate (> 80%) was observed (Figure 1). In addition, when patient satisfaction was investigated according to the type of PP, a higher rate was detected when inflatable devices were compared to malleable ones ( $Q = 9.03$ ;  $p = 0.003$ , see also Figures 1 and S3A–C). Duval and Tweedie's “trim and fill” revealed a non-significant difference in PP satisfaction rate for all studies (satisfaction rate = 78[74; 82]%) or when only inflatable PPs were considered (satisfaction rate = 88[84; 91]%; see also Figure S2B).

The patient satisfaction rate did not differ when prospective studies were compared to retrospective analyses (81[76;85]%; vs. 85[81;88]%;  $Q = 1.74$ ;  $p = 0.19$ ), and when studies using the EDITS questionnaire were compared to the rest of the sample (83[78;87]%; vs. 84[80;87]%;  $Q = 0.038$ ;  $p = 0.845$ ). Similar results were observed

**TABLE 1** Characteristics of studies included in the meta-analysis.

Author	Study design	Patients N	Partners N	Duration (months)	Age (years)	Prosthesis type	DM (%)	Pelvic surgery or trauma (%)	CVD (%)	PD (%)	HPT (%)	Spinal cord injury (%)	Questionnaires used for satisfaction outcome/erectile function
Beutler et al., 1986	R	43		40.8	58.8	2	10.8	4.4	9.5	13.6		3.7	Other
Beutler et al., 1986*	R	14		37.2	65.5	1	0	11	1.5	3		3	Other
Dorflinger et al., 1986	R	57		11	57	1	25	20	21	2			Other
Krauss et al., 1989	P	19	19	12	59.9	1							Other
Fein, 1994	P	122	122	31.7	63	2							Other
Garber et al., 1994	R	50	48	15	59	2	36	6	20	4			Other
Burns Cox et al., 1997	R	172	103		54	3	38.9		48.3	19.2			Other
Dubocq et al., 1997	R	43		40	67	3		0					Other
Goldstein et al., 1997	R	234		21.3	64	2	12		57				Other
Kabalin et al., 1997	R	62		50	63.5	2							Other
Holloway et al., 1997	R	145	145	62	58	3	27.6	13.1	13.1		27.6	0.7	Other
Tefilli et al., 1998	P	35		12	64	2							Other
Kupeli et al., 1999	R	67	71		55	3	20	6	6	8	16		Other
Chang et al., 2000	P	82		60	60	3	12.7	0.6	63.5	6.6		2.7	Other
Montorsi et al., 2000	P	200	120	59	55	2		44	44	28			Other
Levine et al., 2001	R	131	91	43.4	56.8	2		19	62	15			EDITS
Ferguson et al., 2003	P	94		68.4	63	1							Other
Manning et al., 2003	R	32	29	29	56	2	63	19			37.5		Other
Mulhall et al., 2003	P	96		52	56	2	39	12			36		EDITS/IIIEF-EFD
Rajpurkar et al., 2003	P	32		19.5	55.7	2	10.6	38.7	9.4		55.3	1.2	EDITS
Usta et al., 2003	R	61	52	21.9		2	26.2			100	11.5		Other
Salama, 2004	R	50	38	84	42	1	36	22	14		24		Other
Austoni et al., 2005	P	114	36	13	63	1				100			Other
Brinkman et al., 2005	R	199				2							Other
Jensen et al., 2005	P	39	39	35		2							Other
Minervini et al., 2005	P	447		50	52	3	27.3	16.6	25.7	11.6		2.9	Other
Ransawh et al., 2005	P	51		60.9	63.9	2		100					EDITS

(Continues)

TABLE 1 (Continued)

Author	Study design	Patients N	Partners N	Duration (months)	Age (years)	Prosthesis type	DM (%)	Pelvic surgery or trauma (%)	CVD (%)	PD (%)	HPT (%)	Spinal cord injury (%)	Questionnaires used for satisfaction outcome/erectile function
Akin-Olugbade et al., 2006	P	114			59	2		12.3		15.8			EDITS/IIEF-EFD
Borges et al., 2006	R	303				2				10			Other
Zermann et al., 2006	R	245	43	374		3						100	Other
Deveci et al., 2007	P	56			62	2	50	28.5		0	36		EDITS/IIEF-EFD
Lux et al., 2007	R	146		38	58.7	2	13	17	56	11		1	EDITS
Wilson et al., 2007	R	2384		180		2							Other
Grasso et al., 2008	R	12	12	72		1	0	0	0	100			Other
Kim et al., 2008	R	48		140.4	58.9	1		0				100	Other
Mancini et al., 2008	P	31		32	66	2							Other
Natali et al., 2008	R	200	115	60	58.9	3	41	38	11	10			EDITS
Al-Najar et al., 2009	R	18		93	74.5	2		38.9					EDITS
Cortés-González et al., 2009	R	45			60	1	25.6	25.3	19.4	10.4			Other
Cortés-González et al., 2009*	R*	20			60	2	25	25.3	19.4	10.4			Other
Knoll et al., 2009	P	69	66	6	60.1	2	18	24	15	11			Other
Salem et al., 2009	P	775	775	36		2							Other
Bae et al., 2010	R	69		68.2	56.5	2	37.5		62.9	32.7	37.5		IIEF-EFD
Bae et al., 2010*	R*	52		68.2	56.5	1	37.5		62.9	32.7	37.5		IIEF-EFD
Bettocchi et al., 2010	R	80	80	33.6	62.9	2	17.9	2.5	12.5	2.5			Other
Kramer et al., 2010	P	21				2							Other
Levine et al., 2010	R	90		49	57	2	30			100	50		EDITS
Paranhos et al., 2010	R	139	139	40	63	3	45.3	29.5	21.5	6.5	64	3.6	Other
Zhu et al., 2010	R	25	25	28.8	31.5	3			18.1				Other/IIEF-5
Menard et al., 2011	P	87		37.6	63.2	3		100					IIEF/IIEF-ERD
Menard et al., 2011*	P*	123		35.6	59.3	3			100				IIEF/IIEF-EFD
Moskovic et al., 2011	R	45	32	26.4	67.4	3							Other
Sansalone et al., 2012	P	23	35	22	53	2				100			EDITS

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TABLE 1 (Continued)

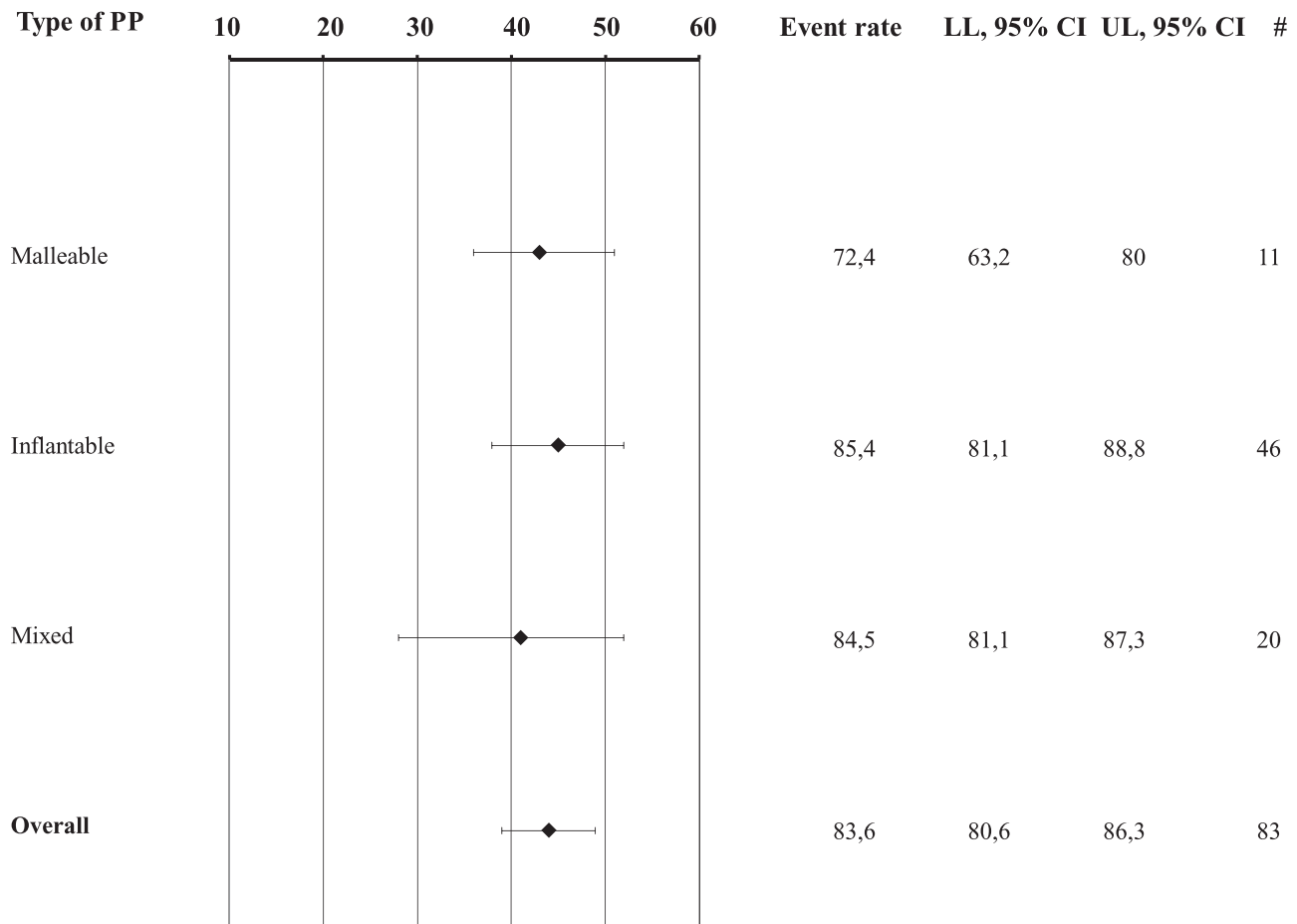
Author	Study design	Patients N	Partners N	Duration (months)	Age (years)	Prosthesis type	DM (%)	Pelvic surgery or trauma (%)	CVD (%)	PD (%)	HPT (%)	Spinal cord injury (%)	Questionnaires used for satisfaction outcome/erectile function
Villarreal et al., 2012	R	56		18	74.3	2							Other
Djordjevic et al., 2013	R	62		35		3			100				IIEF/IIEF-EFD
Megas et al., 2013	P	24		24		2	0	100	0		28		IIEF/IIEF-EFD
Song et al., 2013	R	224	201	68.3	35.9	3	4	11.6	57.6	4		0.9	Other/IIEF-5
Vakalopoulos et al., 2013	P	90	69	45.8	56.4	2	17.4	40.6	2.9	8.7			EDITS/IIEF-5
Chung et al., 2014	R	30		38.8	77.1	2							EDITS
Kılıçarslan et al., 2014	P	23		24		1							EDITS
Kılıçarslan et al., 2014*	P*	23		24		2							EDITS
Lindeborg et al., 2014	P	33		16	61	2	30.3	15.2	24.2	9		3.3	EDITS
Bozkurt et al., 2015	R	118	118	34	63	2		37.2	44.1	10.2		4.2	EDITS/IIEF-EFD
Bozkurt et al., 2015*	R*	139	139	52	59	1		40.1	51.1	9.4		2.2	EDITS/IIEF-EFD
Carvalho et al., 2015	R	47		38.3	63.13	3	14.9	25.5			25.5	2.1	EDITS
Lledó-García et al., 2015	R	110	93		57.56	2	25.3		40	10		38.6	Other
Ji et al., 2015	R	74		105.5	57	2	21.6		20.3	8.1			Other
Kucuk et al., 2016	R	22	22		56.2	3		73					EDITS/IIEF-5
Young et al., 2016	R	9		50	19.7	2							EDITS
Pryor et al., 2016	P	40		24	66.2	2	30	10	32.5				Other
Akdemir et al., 2017	R	46	46	12	63.6	3	10.9	6.5	30.4	6.5			EDITS/IIEF-EFD
Otero et al., 2017	R	248	207		57.77476	2	27.1	27.5			18.1		EDITS
Pillay et al., 2017	R	71	43	30.1	63	3		100					EDITS
Andrienne et al., 2018	R	96	56	62.7	60.96	2	4.6	21	43.7	3.72			EDITS
Grande et al., 2018	P	42	42	37.8	63.6	2	19	41					EDITS

(Continues)

TABLE 1 (Continued)

Author	Study design	Patients N	Partners N	Duration (months)	Age (years)	Prosthesis type	DM (%)	Pelvic surgery or trauma (%)	CVD (%)	PD (%)	HPT (%)	Spinal cord injury (%)	Questionnaires used for satisfaction outcome/erectile function
Habous et al., 2018	P	902	773	28.5	56.6	3	75			34	33		Other
Mondaini et al., 2018	R	10	10	32.2	61	2		100					Other
Awwad et al., 2019	P	50	50			1							Other
Chierigo et al., 2019	R	51		206	51	2		7.8	39	29			QoLSPP
Jorissen et al., 2019	R	126	95	39.9	58.3	2	10.3	23	70.6	25.4			Other
Carlos et al., 2020	R	75		37.8		2	28						QoLSPP
Di Pierro et al., 2021	R	20	20	37	64	2	25	35					EDITS
Palmisano et al., 2021	R	6		78	33	1							Other
ElGharably et al., 2022	P	31		6	59	1			32.3				EDITS/IIEF-EFD
ElGharably et al., 2022*	P*	30		6	52.5	1			23.3				EDITS/IIEF-EFD
La Croce et al., 2022	P	285		12	60	3		39		21			QoLSPP
Luna et al., 2022	R	322		6		2	32.6	1.6	83.9	14.6			EDITS
Palasi et al., 2022	P	102		6	67	2			57				EDITS
Palmisano et al., 2022	R	549	162	14.6	60.6	3	40.8	23.3	18	18.2	59.6		Other
Shaeer et al., 2023	P	35			58.8	0							Other

Abbreviations: R, retrospective study; P, prospective trials; DM, diabetes mellitus; CVD, cardiovascular disease; PD, Peyronie's disease; HPT, hypertension; EDITS, erectile dysfunction inventory of treatment satisfaction; IIEF, international index of erectile function; QoLSPP, quality of life and sexuality with penile prosthesis. Type of implanted prosthesis: malleable = 1; inflatable = 2; mixed groups = 3; \*same study cohort, different group. Quantitative variables are expressed as mean. See also Appendix A.



**FIGURE 1** Patient satisfaction rate on penile prosthesis (PP) according to the type of device implanted. LL, Lower level; UP, upper level; CI, confidence interval.

when all studies using validated questionnaires were compared to the rest of the sample (84[80;88]% vs. 83[79;87]%;  $Q = 0.206$ ;  $p = 0.650$ ).

Meta-regression analysis showed that the overall patient satisfaction rate was independent of age ( $S = -0.001[-0.011;0.010]$ ;  $p = 0.847$ ;  $I = 1.407[0.771;2.043]$ ;  $p < 0.0001$ ; Figure S4A) and increased in subjects with three-piece PP and in those with a higher rate of cardiovascular (CV) or neurological diseases (Figure 2A–C). Similarly, the patient satisfaction rate increased as a function of study follow-up ( $S = 0.006[0.005;0.007]$ ;  $p < 0.0001$ ;  $I = 1.250[1.162;1.338]$ ;  $p < 0.0001$ ) and the number of the patients included in the study ( $S = 0.0009[0.0008;0.0010]$ ,  $p < 0.0001$ ;  $I = 1.1553[1.0811;1.2294]$ ;  $p < 0.0001$ ). Conversely, a lower patient satisfaction rate was observed in subjects with a previous history of spinal cord injury (SCI; Figure 2D). Finally, no difference in the patient satisfaction rate according to the presence of diabetes mellitus, pelvic surgery or trauma, PD, or arterial hypertension was observed (Figure S4B–E). Similar data were observed when only subjects with inflatable PP were considered (not shown). Investigation of the role played by other clinical parameters or associated morbidities was not possible due to the limited number of available data.

### 3.3 | Partner outcomes

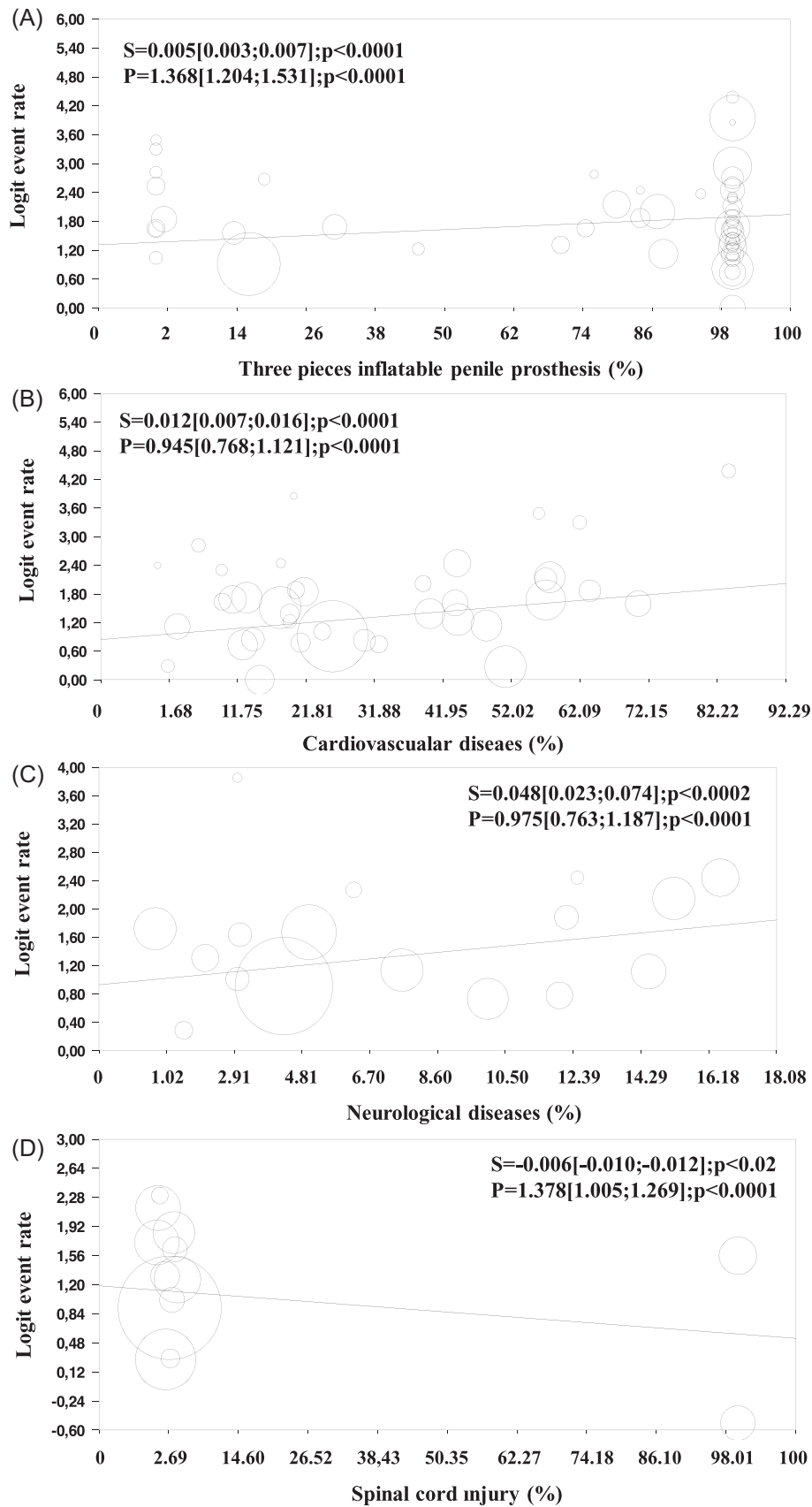
Data related to partner satisfaction were available in 39 studies, including 4,381 women (Table 1).

The  $I^2$  in trials assessing partner satisfaction rate was 90.24 ( $p < 0.0001$ ). A funnel plot and Begg-adjusted rank correlation test (Kendall's  $\tau$ : 0.14;  $p = 0.22$ ) suggested no publication bias.

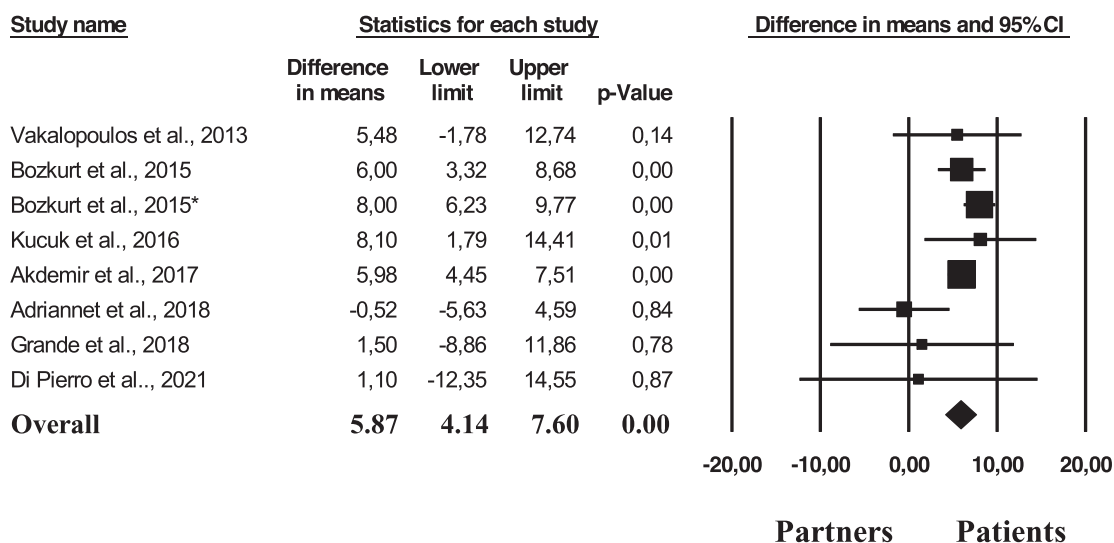
When the whole population was considered, a trend toward a lower satisfaction rate in partners when compared to that observed in patients was observed (76[74;77]%). This was confirmed in those trials which simultaneously reported EDITS data for both partners (Figure 3). Interestingly, the difference in EDITS score was confirmed when older (published before 2018) studies were considered 6.72[5.69;7.76], but not when more recently published papers were analyzed 0.00[−4.43;4.34]. The former, enrolled older subjects ( $62.1 \pm 1.4$  vs.  $59.9 \pm 2.8$  years;  $p < 0.0001$ ) with longer follow-up ( $52.8 \pm 12.3$  vs.  $40.5 \pm 12.7$  months;  $p < 0.0001$ ) when compared to the latter.

Similar to what was observed in men, a higher satisfaction rate in female partners was detected when inflatable PPs were compared to malleable ones (81[72;88]% vs. 68[55;78]%;  $Q = 3.53$ ,





**FIGURE 2** Impact of amount of three pieces inflatable penile prosthesis (A), cardiovascular disease (B), neurological diseases (C), and spinal cord injury (D) on overall patient penile prosthesis satisfaction.



**FIGURE 3** Weighted mean differences (with 95% CI) in Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) score between patients and partners as derived from studies included in the analysis. UL, Upper levels; LL, low levels; CI, confidence interval.

$p = 0.06$ ). In addition, meta-regression analysis showed that partner satisfaction increased as a function of PD and declined according to patient age (Figure 4A,B). The effect of female age on partner and patient satisfaction was not possible due to the limited available data.

### 3.4 | Patient sexual function

Data on IIEF were available in 14 studies, including 1,263 patients (Table 1). In particular, the erectile function was assessed by IIEF5 and IIEF-EFD in 4 and 10 studies, respectively. The  $I^2$  in trials assessing the overall erectile function was 99.08 ( $p < 0.0001$ ). A funnel plot and Begg-adjusted rank correlation test (Kendall's  $\tau$ : 0.48;  $p = 0.005$ ) suggested publication bias. PP implantation resulted in a significant improvement of the erectile function which was confirmed when the data were restricted to only those studies using the IIEF-EFD score (standardized mean 5.73[4.51;6.95] and 6.52[5.03;8.01] for overall erectile function and IIEF-EFD, respectively; see also Figure S5A,B). The data on the overall erectile function were confirmed after applying Duval and Tweedie's "trim and fill" test (effect size = 7.32[4.76;9.88]).

Similar to what was observed for the erectile function, PP implantation significantly increased all the other IIEF domains (Figure S5C-G).

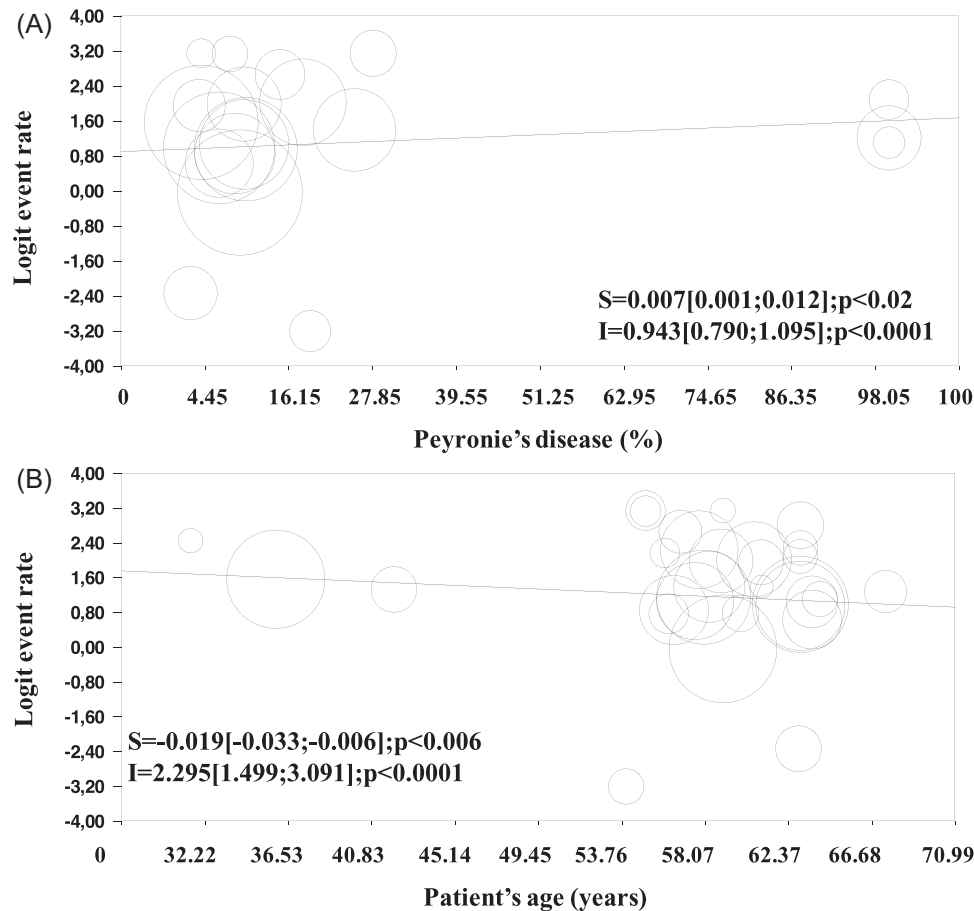
### 3.5 | Long-term complications

Overall, 46 studies reported data on long-term complications (Table S2). Among them, the erosion rate was reported in 25 trials, whereas the incidence of infection, mechanical failure, and pain was declared

in 46, 37, and 21 studies, respectively (Table S2). The  $I^2$  in trials assessing the overall erectile function was 65.77 ( $p < 0.0001$ ). A funnel plot and Begg-adjusted rank correlation test (Kendall's  $\tau$ : 0.38;  $p = 0.69$ ) suggested no publication bias. The mean long-term complication rate ranged from 3% for erosion to 4.6% when mechanical failure was considered (Figure S6 A-D). The infection rate ranged from 2.9% to 4.5% and was tightly related to the prevalence of diabetes among the included studies ( $S = 0.008[0.001;0.015]$ ;  $p < 0.02$ , and  $I = -3.256[-3.569;-2.942]$ ,  $p < 0.0001$ ). No difference in the infection rate between malleable and inflatable PP was detected (4.8[3.2;7.2%] vs. 3.0[2.1;4.4%] for malleable and inflatable, respectively;  $Q = 2.748$ ,  $p = 0.097$ ). The presence of any PP complication was inversely related to patient's satisfaction after alternative multivariate linear regression analyses, weighting each study for the number of subjects enrolled, and adjusting for trial duration and patient's age (see Table S3; all  $p < 0.0001$ ).

## 4 | DISCUSSION

Our study confirms that PPs represent a suitable therapeutic option for more severe ED subjects. We also confirm the high couple satisfaction rate, with patients reporting higher outcomes when compared to their female partners. When the specific determinants were analyzed, patient satisfaction was independent of age, whereas it declined in older couples when partner opinion was considered. CV and neurological diseases represented the morbidities associated with better PP outcomes when patients were considered. Conversely, the presence of a history of SCI was characterized by a lower patient satisfaction rate. When female counterparts were investigated, PD was the only factor



**FIGURE 4** Impact of amount of patient Peyronie's disease (A) and patient's age (B), on overall patient penile prosthesis satisfaction.

significantly related to better post-surgical satisfaction. The presence of long-term surgical complications was limited and in line with what was previously reported.<sup>13,14</sup>

The higher patient satisfaction rate observed with IPP and with three-piece devices is not surprising and well-known.<sup>9,15</sup> Usually, these types of devices can guarantee a relatively more natural penile rigidity allowing a rapid return to penile flaccidity after sexual intercourse.<sup>4,6,9</sup> Accordingly, the placement of semirigid has progressively declined during last the 15 years. Another very interesting finding derived from this study is the direct correlation between patient satisfaction and the duration of follow-up. Some studies have shown that patient satisfaction usually increases in the first year reaching a plateau stage thereafter.<sup>16,17</sup> It can be speculated that long-lasting experience with the devices can help to overcome possible initial difficulties in their management, allowing them to reach a better couple sexual intimacy and to cope with potential initial negative feelings and dissatisfactions. The latter observation is particularly noteworthy considering the data derived from a recent meta-analysis showing that the IPP device survival rate ranges from 93.3% at 1 year to 52.9% at 20 years.<sup>18</sup>

The different outcomes in the PP-satisfaction rate related to the role played by aging observed in patients and partners are very interesting and deserve further discussion. A large body of evidence has clearly documented that a high number of elderly men and women

remain sexually active despite an age-dependent increase in sexual dysfunctions.<sup>19–22</sup> The same studies have also clarified that men self-reported more frequent sexual activity and a more positive and permissive attitude toward sex when compared to women. This discordant behavior can result in potentially negative consequences for couple well-being, such as chronic tension, impairment of other aspects of the couple's life, or even extramarital affairs.<sup>22–25</sup> In addition, it should be recognized that female partners of men with ED often report a higher frequency of sexual dysfunction and an impaired sexual activity satisfaction, tightly related to the onset of their partner's erectile difficulties.<sup>26,27</sup> All these factors can be used to clarify the differences observed in male and female PP satisfaction as well as possible age-related divergences. Similarly, possible differences in the population characteristics can explain, at least partially, the lower differences between patient and partner's PP satisfaction observed in more recently published surveys. On the other hand, the improvement of surgical techniques and the quality of the implanted devices represent other possible reasons for supporting the latter results. Accordingly, despite what is observed in this study in women, several trials have shown excellent results in male PP satisfaction rates even in patients older than 70 years.<sup>28–30</sup>

The higher male PP satisfaction rate according to CV diseases (CVD) is not surprising. In the latter population, the concomitant use

of nitrates might represent a possible contraindication for a conservative therapy favoring the use of PP.<sup>1,2</sup> On the other hand, specific studies have shown a PP higher satisfaction rate in subjects with vasculogenic ED when compared to those with radical prostatectomy (RP) related ED.<sup>31-33</sup> RP is frequently associated with subjective penile length loss as well as the loss of ejaculation function. Both conditions can have a tremendous impact on patient wellbeing<sup>34,35</sup> and they can contribute to the observed higher satisfaction rate in patients who have progressively lost their erectile function due to chronic damage to the vascular endothelium. Similar considerations can be drawn for the higher satisfaction rate observed in subjects with neurological diseases. In addition, in the latter condition, the lower efficacy of the traditional medical therapy for ED can represent another source of explanation.<sup>1,2</sup> However, when the role of PP in subjects with SCI was investigated, a lower satisfaction rate was observed. Some studies have shown that PP implantation in people with SCI can represent a suitable option not only to improve the erectile function but also to manage bladder dysfunction through the positioning of the urinal condom.<sup>36,37</sup> A recent meta-analysis<sup>14</sup> indicated that PP in subjects with SCI is associated with a relatively higher infection rate (up to 11%), which can explain the lower satisfaction rate observed in this study. The use of PP implantation is frequently required in the setting of PD, particularly when associated with a preoperative ED. Despite the overall good results related to the correction of the penile curvature, several complaints, such as decreased penile dimensions and sensitivity as well as persistent penile deviation particularly in the presence of complex pre-operative deviation, can limit the satisfaction rate after IPP placement.<sup>5,9,17</sup> The higher satisfaction rate observed in females according to the presence of male PD can reflect the improvement of the sexual function after PP implantation. Accordingly, a worse sexual function has been reported in women of subjects with PD.<sup>38</sup>

The analysis of the specific determinants of PP long-term complications is behind the aim of this study and has been revised elsewhere.<sup>14,39</sup> Our data showed that the long-term complications are limited, in line with what is reported in the current literature.<sup>40</sup> Interestingly, as previously reported,<sup>39</sup> the PP infection rate was closely related to the presence of diabetes mellitus (DM) as well as to the lowest stratification rate after the adjustment for confounders. The association between DM and a higher risk of infection is well known due to its association with leukocyte dysfunction and microangiopathy. The latter point is crucial considering the large prevalence of ED among diabetic patients.<sup>41</sup> Some evidence has demonstrated that pre-operative glycometabolic control represents a crucial factor in predicting DM-related infection after PP surgery. In particular, by applying ROC curve analysis in a consecutive series of 902 diabetic subjects Habous et al.<sup>42</sup> recently showed that a mean Hb1Ac higher than 8.5% predicted infection with a sensitivity and specificity of 80% and 65%, respectively. However, it should be recognized that more recent data including 932 diabetic patients undergoing primary PP implantation from 18 high-volume PP implantation surgeons have shown that Hb1Ac and blood glucose levels were not predictive for higher post-operative infection.<sup>43</sup> However, the same study showed that a history

of DM-related complications was a significant predictor of a higher revision rate.<sup>43</sup>

Several limitations should be considered. Systematic reviews and meta-analyses have been considered as a particularly useful tool to address questions for which multiple data sources are conflicting, or when there is a variety of reports with low statistical power, since pooling data can improve statistical power providing more convincing results. However, it should be recognized that most data included in the present meta-analysis are derived from subjective evaluation of satisfaction and not from validated questionnaires representing a possible source of bias. In addition, combining data of flawed evidence does not remove biases. Furthermore, the concept of satisfactory surgery is quite conflicting and can be strongly different between patients and surgeons. The ideal tool for investigating satisfaction after PP implantation should be specifically evaluated and validated in this population. However, the vast majority of the available self-reported tools were designed to evaluate patient satisfaction derived from the oral ED therapy,<sup>44,45</sup> whereas only the treatment satisfaction scale was validated for partners' outcomes.<sup>46</sup> At present, only "Quality of Life and Sexuality with Penile Prosthesis"<sup>47</sup> and the Satisfaction Survey for Inflatable Penile Implant (SSIFI)<sup>48</sup> received sufficient validation in subjects with PP. The latter, in particular, is nowadays considered the current frontrunner for PPs.<sup>48</sup> However, none of the available studies used SSIFI since its validation is relative recent.<sup>48</sup> The lack of a sufficiently validated instrument can result in heterogeneity in satisfaction report and publication bias. Accordingly, the vast majority of the studies included in the present meta-analysis did not apply a validated instrument to assess patient and partner satisfaction, resulting in high heterogeneity. In addition, the satisfaction rate increased according to the number of patients included in the study, confirming the greater likelihood of publishing their results in high-volume centers, usually characterized by better outcomes. However, the differences in patient satisfaction were negligible when those studies using validated tools were compared to the rest of the sample. Similarly, the application of Duval and Tweedie's "trim and fill" showed a non-significant difference in the PP patient satisfaction rate. Finally, no data on patient and partner expectations were available. Furthermore, to avoid possible bias in the evaluation of patient and partner satisfaction we restricted our analysis on heterosexual couples and data derived from phalloplasty reconstructive surgery or from ED in homosexual couples were excluded from the analysis. Therefore, more research in the field is needed. Finally, since not included among the main research outcomes, data related to the long-term complication rates should be considered with cautions. Accordingly, important studies might have been missed.

In conclusion, our data showed that PP represents a very good therapeutic option for patients with ED. Patient and partner satisfaction is excellent and can improve with time. The number of complications is limited and strongly associated with the presence of DM. Pre-operative patient selection appears to be a crucial step in order to avoid false and unrealistic post-operative expectations. The association between poor PP outcomes and DM can stimulate patients to promote healthier behaviors in order to improve glycometabolic control.

## AUTHOR CONTRIBUTIONS

Andrea Cocci, Walter Vena, Alessandro Pizzocaro, performed the research. Giovanni Corona, Daniele Santi, Carlo Bettocchi and Mario Maggi analyzed the data and wrote the paper. Linda Vignozzi, Yacov Reisman, and Andrea M. Isidori drew the figures. Suks Minhas, Andrea Salonia, and Rosario Pivonello prepared the tables and all the authors revised and approved the final manuscript.

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## CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

## ORCID

Giovanni Corona  <https://orcid.org/0000-0002-9894-2885>

Daniele Santi  <https://orcid.org/0000-0001-6607-7105>

Andrea Cocci  <https://orcid.org/0000-0003-0138-6294>

Andrea M. Isidori  <https://orcid.org/0000-0002-9037-5417>

Rosario Pivonello  <https://orcid.org/0000-0002-9632-1348>

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

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## SUPPORTING INFORMATION

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

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