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SAFETY AND EFFICACY OF INFLATABLE PENILE PROSTHESES IN PEOPLE WITH SPINAL CORD INJURY/DYSFUNCTION: A HOLISTIC TERTIARY REFERRAL CENTER WORKFLOW

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List of abbreviations

AD	Autonomic Dysreflexia
AIS	American Spinal Injury Association (ASIA) Impairment Scale
AUC	Area Under the Curve
BTX-A	Onabotulinum Toxin A
CCI	Charlson Comorbidity Index
CI	Confidence Interval
CIU	Chronic Idiopathic Urticaria
DO	Detrusor Overactivity
ED	Erectile Dysfunction
EHS	Erection Hardness Score
IC	Intermittent catheterization
ICI	Intracavernosal Injections
ICIQ-UI SF	International Consultation on Incontinence Questionnaire-UI Short Form
IIEF-5	International Index of Erectile Function-5
IM	Intramuscular
IPP	Inflatable Penile Prosthesis
IQR	Interquartile Range
IUC	Indwelling Urinary Catheter
IV	Intravenous

MENTOR Tool	Monitoring Efficacy of NBD Treatment On Response Tool
MRA	Muscarinic Receptor Antagonist
NBD	Neurogenic Bowel Dysfunction
NLI	Neurological Level of Injury
NLUTD	Neurogenic Lower Urinary Tract Dysfunction
NR	Not Reported
OT	Operative Time
OSAS	Obstructive Sleep Apnea Syndrome
PDE5I	Phosphodiesterase type 5 inhibitor
PEG	Polyethylene Glycol
POD	Post-operative Day
PP	Penile Prosthesis
PROM	Patient-Reported Outcome Measures
QoL	Quality of Life
QoLSPP	Quality of Life and Sexuality with Penile Prosthesis
RARP	Robot-Assisted Radical Prostatectomy
ROC	Receiver Operating Characteristic
SCI/D	Spinal Cord Injury/Dysfunction
SCI/D-RAPPS	Spinal Cord Injury/Dysfunction – Referral Appropriateness Penile Prosthesis Score
SEP	Sexual Encounter Profile
SF-Qualiveen	Short Form - Qualiveen
TAI	Trans-Anal Irrigation

UI	Urinary Incontinence
UTI	Urinary Tract Infection
VED	Vacuum Erection Device
VTE	Venous Thromboembolism
VUR	Vesicoureteral Reflux

1. Abstract

1.1 Introduction

ED is common after SCI/D and often coexists with NLUTD, NBD, spasticity, AD risk and high vulnerability to pressure injuries. PP implantation in SCI/D has historically been regarded as “high risk,” mainly because of increased infection, erosion/extrusion, revision and explant rates reported in older series. This study approaches IPP surgery in SCI/D as a workflow-dependent intervention, where outcomes are influenced by all steps in a Spinal Unit: pre-operative optimization, surgical technique and post-operative management.

1.2 Aim of the study

The primary objective of the study was to assess the safety of contemporary IPP implantation in selected men with SCI/D managed within a structured multidisciplinary workflow by a tertiary referral Spinal Unit. Secondary objectives included: to assess functional efficacy of IPPs; to quantify patient satisfaction and likelihood of recommending the procedure; to evaluate impact on bladder and bowel management, and IC; to evaluate referral appropriateness in a large screened cohort and develop a referral appropriateness PP score (SCI/D-RAPPS) to use in routine clinical practice; to collect and summarize all the precautions adopted in a practical risk mitigation plan for other surgeons who are approaching IPP surgery in SCI/D.

1.3 Materials and methods

After the approval by the Institutional Review Board, a prospective, longitudinal, single-center study was initiated in an Italian tertiary referral Spinal Unit setting. The initial enrollment period was from Feb 2023 to Jan 2024 with a 12-month-long follow-up period ending in Jan 2025. Due to reduced enrollment for strict selection process, the study was extended with a new enrollment period from Jun 2024 to May 2025, with follow-up period prolonged up to May 2026. Two linked samples were analyzed: (1) a consecutive cohort of 263 men with SCI/D evaluated for IPP during the enrollment period by our center, considered to develop the SCI/D-RAPPS; (2) the subgroup that underwent three-piece IPP implantation (n = 12) with standardized pre, peri and post-operative data collection within a follow-up of 12 months. To reduce the risk of complications, all factors that may influence surgical outcomes were evaluated and optimized in people addressed to IPP surgery, including bladder and bowel management, IC technique, spasticity management, skin integrity and UTI risk. In the first cohort, multivariate logistic regression with internal bootstrap was used to develop a model to predict appropriateness for IPP evaluation according to different patient characteristics. In the second sample, PROMs were collected for bladder evaluation (e.g., SF-Qualiveen, ICIQ-UI SF, ease of IC insertion), bowel function (e.g., NBD score, MENTOR tool) and patient experience (QoLSPP and 10-point Likert scales for evaluating satisfaction and recommendation).

1.4 Results

Among 263 evaluated men with SCI/D, 61/263 (23.2%) referrals were classified as appropriate and 202/263 (76.8%) as inappropriate.

In multivariate analysis, referral appropriateness was associated with younger age (OR 0.97 per year), lower comorbidity burden (CCI ≥ 3: OR 0.26), lower UTI burden (OR 0.26), stable partner status (OR 2.52) and an appropriate psychological profile (OR 10.71). Model performance showed Nagelkerke's $R^2 = 0.298$, apparent AUC = 0.801 and corrected AUC = 0.751 after bootstrap validation (B = 1, 000). Using p ≥ 0.30, sensitivity and specificity were 0.705 and 0.738, respectively. A SCI/D-RAPPS software application probability calculator was developed to use this score in routine clinical practice.

Twelve out of 61 (19.7%) patients underwent three-piece IPP implantation, while the others refused after adequate counselling and/or presented clinical issues to solve before IPP. The median admission-to-discharge LOS was 4 days (IQR 4-8), with one markedly prolonged admission (23 days) due to a sacral pressure injury after a prolonged waiting time before entering the operating room because of organizational issues.

After a median follow-up of 16 months (IQR 14-20), explantation was performed in 1 out of 12 cases (8.3%) at 6 months because the scrotal surgical wound persistently failed to heal.

Across 12-month follow-up, bladder-related PROMs (SF-Qualiveen and ICIQ-UI SF) and bowel function (NBD score) remained stable overall. IC management showed an improvement in perceived ease of catheterization, significantly advancing (p = 0.006) from median 7 (pre) to 9 (post). Satisfaction and recommendation scores remained high and stable (p > 0.05) over time; at 12 months, medians for satisfaction and recommendation were 9 and 10, respectively. The QoLSPP total and domains scores

remained high and stable throughout 12 months ($p > 0.05$) with a median total score of 67/80 at 12 months.

The study collected all the precautions adopted and summarized the adopted pathway into a replicable plan to reduce the risks that other surgeons may need to manage in this population.

1.5 Discussion

In people with SCI/D, IPP implantation should be regarded as the result of a complex selection and optimization pathway. Our referral analysis showed that most patients assessed did not meet appropriateness criteria, indicating that early triage tools such as SCI/D-RAPPS could help limit unnecessary evaluations and focus specialists on those most likely to benefit.

Among implanted patients, satisfaction was high and remained stable over time, while bladder and bowel PROMs did not worsen. This suggests that, in carefully selected patients managed within a specific setting, three-piece IPP can provide effective sexual rehabilitation without compromising other pelvic functions. The improvement observed in IC ease is particularly relevant in SCI/D, where the catheterization technique often has a major impact on independence.

As for complications, a patient with a high comorbidity burden required explantation because of persistent scrotal wound dehiscence. Although the patient remained afebrile and repeated swabs were negative, the clinical course raised suspicion of an underlying chronic infection. Other possible contributing factors were also considered, including an altered inflammatory or immune response in the setting of chronic idiopathic

urticaria, mechanical factors related to obesity in paraplegia with pump prominence and scrotal friction possibly altering wound healing.

Overall, these observations support the need for a precise strategy to reduce the risks that covers pre-operative optimization, intra-operative measures and structured post-operative follow-up.

1.6 Conclusions

In a specialized Spinal Unit, the use of a structured pre-, intra- and post-operative pathway was associated with low complication rate, high patient satisfaction, stable bladder and bowel PROMs and easier IC insertion after IPP implantation in carefully selected men with SCI/D. These findings underscore the value of a multidisciplinary approach. The high rate of inappropriate referrals among screened patients also suggests that SCI/D-RAPPS may be a useful referral-support tool to improve patient selection. In addition, the proposed risk-mitigation plan may help surgeons address the specific technical and clinical challenges of IPP surgery in people with SCI.

2. Introduction

Sexual health is a central component of overall well-being and is consistently prioritized by people living with spinal cord injury/dysfunction (SCI/D).[1] Indeed, what clinicians label as "secondary" outcomes are often "primary" to people with SCI/D: a systematic review of priorities reported by patients after SCI consistently identified bowel, bladder and sexual function among the domains most valued by individuals living with SCI.[2]

The altered genital sensation, ED, impaired ejaculation, altered orgasm and psychosexual distress contribute to a reduced QoL for many men after SCI.[3,4] Despite increasing attention to this frail population, the management of ED in SCI/D remains unevenly offered across health systems all over the world and is rarely discussed with patients in case of need.

IPPs represent a reliable on demand solution for medically refractory ED in the general population. Over the years, in SCI/D the procedure has been considered as "high-risk" for several reasons. General practitioners and urologists may discourage SCI/D candidates due to increased risk of infection, erosion/extrusion or mechanical failure. Therefore, men who could benefit from IPP implantation may never take advantage of this solution.

A tertiary referral Spinal Unit can reduce modifiable drivers of complications through multidisciplinary assessment of different issues, including bladder management (e.g., catheterization technique, upper urinary tract safety), bowel management (constipation prevention, predictable evacuation), spasticity control, skin protection, hand function adaptations by occupational therapists and structured follow-up. [5–7]

While it is true that penetrative intercourse is not strictly required to experience pleasure or orgasm, this statement can be misapplied in clinical counselling when it is used to minimize patient goals. In our clinical experience, many men with SCI/D describe penetrative capacity as a "need for normality": it is essential for self-image and continuity with their pre-injury sexual life. For these people, the opportunity to regain valid penetration is a meaningful psychosocial outcome that should be approached with respect and appropriate discussion about possible risks.

2.1 Male sexual dysfunctions in SCI/D

After SCI/D, male sexuality is shaped by disruption of somatosensory afferents, spinal reflex circuits and supraspinal autonomic pathways, producing variable impairment in (1) genital sensation, (2) erection, (3) ejaculation and (4) orgasm.[4]

Genital sensory disturbance is common and clinically consequential: in a questionnaire-based cohort of 199 men with SCI, only 42.9% reported retained genital sensation and, among those reporting orgasm, 72.8% had preserved genital sensation, highlighting the tight link between sensory preservation and sexual experience.[8]

Penile erection may be reflexogenic (genital stimulation via an intact S2-S4 reflex arc), psychogenic (erotic thoughts/visual/olfactory stimuli via supraspinal input and sympathetic pathways, broadly T10-L2) or spontaneous/nocturnal; therefore, lesion level and completeness strongly influence which mechanisms are preserved (e.g., suprasacral injuries may preserve reflexogenic erections while limiting psychogenic erections, whereas sacral/conus or cauda equina involvement can compromise reflexogenic capacity).[9–11] Regarding erectile outcomes, many men recover some erectile function over time (often cited as about 80% regaining some degree of erectile

function by 2 years). Erections that are valid for sexual intercourse without any pharmacologic aid are less frequent; indeed, a large randomized trial highlighted that only 25% of men with SCI have erections adequate for intercourse without treatment.[12] Contemporary standards for autonomic characterization after SCI (ISAFSCI) emphasize that sexual function is tightly linked to the integrity of these autonomic and sensory pathways and should be documented together with motor/sensory classification.[13]

Ejaculatory dysfunction is even more prevalent: reviews consistently report that up to 95% of men with SCI experience ejaculatory dysfunctions (anejaculation and/or retrograde ejaculation), meaning most cannot ejaculate during intercourse without assisted techniques.[3]

Finally, orgasm may be preserved, diminished, delayed or qualitatively altered and it does not reliably correlate with ejaculation: a population-based rehabilitation cohort reported orgasm after injury in 65% of men (most described as "weaker orgasms"), while broader reviews commonly cite orgasmic ability in approximately half of men with SCI, highlighting that orgasm and ejaculation should be assessed as distinct outcomes.[14] Incomplete lesions are generally associated with higher orgasmic capacity than complete injuries and autonomic responses (e.g., cardiovascular changes) may contribute to orgasmic experience and/or AD-related symptoms in susceptible individuals.[15,16]

These mechanisms highlight why counselling after SCI/D should explicitly consider "erection that is valid for intercourse" and should address fertility, ejaculation and orgasm as distinct therapeutic targets.

2.2 Treatment of ED in SCI/D

In men with SCI/D, ED is typically managed with a stepwise strategy tailored to neurological level, preserved reflexogenic/psychogenic pathways and patient/partner preferences.[17] Contemporary reviews emphasize that many patients retain some erectile capacity but only a minority report erection that is valid for intercourse without any treatment; therefore, a structured escalation from oral therapy to invasive options remains clinically appropriate.[18]

Oral PDE5-Is are commonly used as first-line therapy in SCI-related ED.[19] According to a multicenter, randomized, double-blind, placebo-controlled, parallel-group study in clinical practices in Europe, tadalafil (10-20 mg) significantly improved erectile function versus placebo and was well tolerated in traumatic SCI. In particular, the tadalafil group compared with the placebo group was significantly greater ($p < 0.001$) in mean per-patient percentage of successful penetration attempts (SEP question 2; 75.4% vs 41.1%) and intercourse attempts (SEP question 3; 47.6% vs 16.8%).[12] In men who respond inadequately, up-titration of vardenafil from 10 to 20 mg improved significantly erectile outcomes in an SCI cohort with valid tolerability.[20] In prospective multicenter experience, 88.2% of patients and 85.3% of their partners reported improved erection with sildenafil, while no serious adverse events were observed.[21]

When oral therapy is ineffective or contraindicated, ICI therapy with vasoactive agents remains a highly effective second-line option, although penile pain, bruising, priapism and risk of corporal fibrosis can limit long-term adherence.[22]

VEDs represent a non-pharmacological alternative and can be effective for intercourse in many couples, but acceptance is variable due to reduced spontaneity, device-related discomfort or local adverse effects.[23] VEDs are endorsed in the 5th International

Consultation on Sexual Medicine as an evidence-based therapy across ED etiologies, including difficult-to-treat cohorts such as SCI, although long-term abandonment is common. In this context, patient selection and coaching are crucial.[24]

In people who (1) are not suitable for different pharmacotherapies or prefer a definitive therapy and (2) do not respond to pharmacological therapies, PP implantation provides a definitive solution in selected neurologically impaired patients, though it requires careful counseling regarding complications (e.g., infection, erosion, mechanical failure) and, for inflatable systems, adequate manual dexterity.[7] Uniquely in SCI, PPs may also confer functional benefits for urinary management by improving penile handling during IC and/or positioning of urinary condoms through the placement of malleable cylinders.[25] Historically, this was the main indication for this population. In parallel, PP surgery consensus recommendations stress that patient and partner expectations, manual dexterity, device handling training and realistic discussion of risks are central to durable satisfaction.[26] Patient-reported outcome research using the QoLSPP instrument consistently demonstrates high satisfaction across functional, relational, social and personal domains after prosthesis implantation, supporting the use of validated tools in clinical follow-up and research.[27]

Other options have more limited evidence in SCI, including intraurethral alprostadil (with modest effectiveness and potential blood pressure effects requiring monitoring) and sublingual apomorphine, which has shown relatively low response rates and frequent side effects in SCI populations.[28,29]

Current guidelines suggest that each patient with ED should be informed about all available treatments for ED.[5,30] After adequate counseling, focused on pros and cons

of each treatment modality, the patient and doctor should decide how to proceed with the diagnostic-therapeutic care pathway.

The present study considers IPPs as the final step in a pathway that is often prematurely interrupted by altered risk perceptions. Our hypothesis is that a meaningful proportion of complications historically attributed to SCI are amplified by modifiable factors (suboptimal catheterization routines, uncontrolled bowel dysfunction, inadequate skin protection and fragmented follow-up) rather than by neurologic injury per se.[6,31]

Alongside pharmacological escalation, sexual rehabilitation in SCI must consider modifiable cardiometabolic factors, AD triggers, spasticity, pain, fatigue and psychosocial determinants of intimacy. A recent narrative review emphasized that structured lifestyle interventions (physical activity adapted to lesion level, weight management, smoking cessation and sleep improvement) can complement pharmacotherapy, while careful medication review may reduce iatrogenic sexual side effects.[24,32]

Long-term data on PDE5Is support their sustained efficacy and acceptable safety profiles in men with SCI, although adherence can be limited by logistics and expectations. In a 10-year follow-up experience, sildenafil maintained clinically meaningful benefit for a substantial proportion of responders, reinforcing the value of longitudinal counseling and periodic reassessment of treatment goals.[33,34]

Importantly, sexual function in SCI extends beyond penetrative intercourse. ED and infertility are frequent and often under-discussed. Sexual identity and relational wellbeing may be affected by altered sensation, body image and caregiver dependence. A contemporary state-of-the-art review highlighted the need for early integrated

counseling on fertility options, ejaculatory retrieval techniques and couple-centered interventions.[35,36]

At the same time, a purely device-centric approach to sexual rehabilitation is insufficient. Neurologic examination combined with reflex testing, as described through the ISAFSCI, helps clinicians anticipate psychogenic and reflex erection potential, ejaculation and orgasmic capacity; this framework can support shared decision-making and realistic goal setting.[33]

Finally, psychosocial determinants cannot be ignored. In an observational study of men with traumatic SCI, factors such as a fixed partner, masturbation and ejaculation were protective in multivariable models, while erectile and orgasmic dysfunction and infrequent intercourse predicted worse satisfaction: these results reinforced the need for integrated counseling and partner-inclusive care alongside any medical intervention.[36]

2.2.1 Penile prostheses

PP implantation is a definitive surgical therapy for ED when conservative options fail or are unsuitable, with the goal of restoring reliable penetrative rigidity while maintaining comfort, concealability and long-term device safety. Modern implants are broadly categorized into malleable (semirigid) and hydraulic (inflatable) systems. Across both categories, published outcomes consistently show high satisfaction, typically in the 80-90% range and durable function, although revisions still occur in roughly 15% of patients by 5 years and 30% by 10 years, reflecting the reality of long-term implanted devices.[37]

Malleable PPs (Fig. 2.1) are the simplest option: two bendable rods are inserted into the corpora cavernosa and remain firm at baseline, with the penis positioned manually upward for intercourse and downward for concealment.[38] Because there is no pump or reservoir, malleable implants are valued for mechanical simplicity and may represent a valid solution for men with limited manual dexterity; moreover, mechanical breakage of malleable devices is described as exceedingly rare.[37] Contemporary malleable implants typically share a silicone outer jacket, while stiffness and memory are determined by the internal core design. Core materials included nitinol (nickel-titanium alloy), braided silver wire and braided stainless-steel wire: each aiming to balance axial rigidity for penetration with controlled bendability for concealment and comfort.[39] According to a large series by Jorissen et al. (2019), the patient and partner satisfaction rates, after one year since surgery, were 83.2 and 85.4%, respectively.[40]

IPPs (Fig. 2.2) are engineered to better reproduce natural physiology by providing both a rigid erection and a more natural-looking flaccid state. The most widely used configuration is the three-piece IPP, consisting of two intracavernosal cylinders connected via tubing to a scrotal pump and an abdominal reservoir; squeezing the pump transfers fluid into the cylinders to create rigidity, while deflation restores a softer resting state. Devices differ in how the cylinders expand (Fig. 2.3): some are optimized mainly for girth expansion, while others are designed for girth plus length expansion; in some cases, length-expanding design may increase length up to 25% under certain conditions.[39] Materials and engineering choices vary by manufacturer and model, including cylinder bodies using polyurethane (Bioflex) versus multi-layer reinforced silicone constructions and functional innovations such as lockout mechanisms to reduce unintended auto-inflation and reservoir designs (Fig. 2.4)

intended to improve concealment and ease alternative placement when needed. In a series with mean follow-up of 59 months, 92% of men were using their three-piece implant (average 1.7 times/week), 98% rated erections excellent or satisfactory and 83% of partners reported excellent or satisfactory outcomes.[41] As for longer-term reliability data, ten-year Kaplan-Meier estimates of overall and mechanical survival were 74.9% (95% CI 69.2-81.1) and 81.3% (95% CI 75.7-87.3), respectively.[42]

One of the most consequential modern developments, relevant to both malleable and inflatable implants, has been infection prevention. Overall implant infection incidence is reported in literature as approximately 1-3%.[43] Device-level strategies include antibiotic impregnation (e.g., rifampin-minocycline) and hydrophilic coatings that bind antibiotic "dip" solutions; together, these manufacturer modifications are reported to have cut infection rates in half.[44,45] Surgical technique adds further protection: e.g., the "no-touch technique" (excluding skin contact with the implant and field) achieved an infection rate of 0.46% in >1500 cases.[46]

Figure 2.1 Commercially available malleable PP devices: (a) Coloplast Genesis prosthesis; (b) Boston scientific Tactra prosthesis; (c) Rigi10® prosthesis; (d) Promedon TUBE malleable prosthesis; (e) Zephyr ZSI 100 prosthesis; (f) Zephyr ZSI 100 FTM prosthesis; (g) Shah prosthesis.

Source: Chung, Eric & Wang, Juan. (2023). State-of-art review of current malleable penile prosthesis devices in the commercial market. Therapeutic Advances in Urology. 15. 10.1177/17562872231179008.

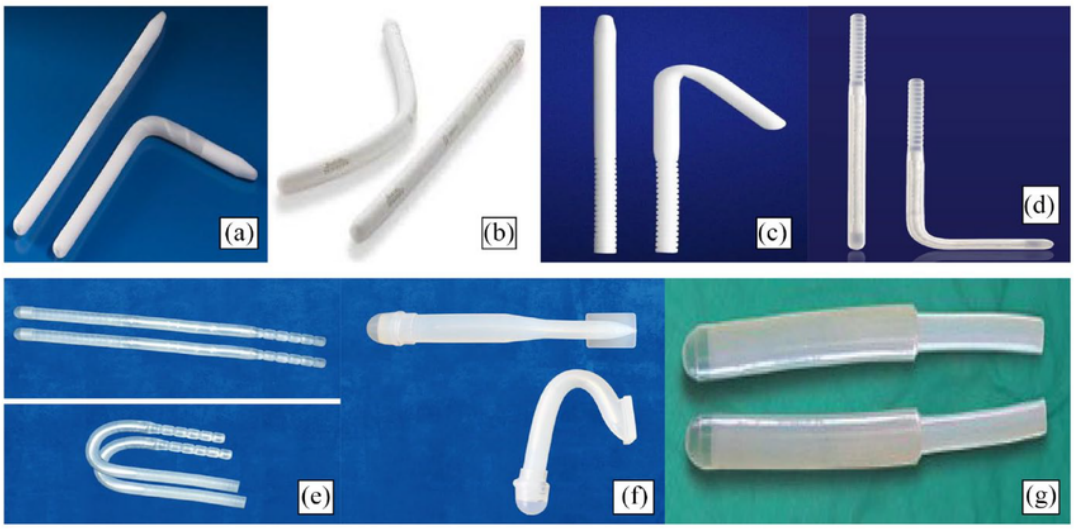


Figure 2.2 The image depicts an IPP in its two functional states. On the left side (Flaccid), the device is shown during rest (the penis is soft): the fluid reservoir is positioned in the abdomen and is connected by tubing to the scrotal pump and the paired cylinders within the penis. On the right side (Erect), the prosthesis is shown after activation: by pressing the pump in the scrotum, the fluid is transferred from the reservoir into the penile cylinders, which then become rigid and produce an erection. The connecting tubes are visible in both panels to show how the three components work together.

Source: Bruce Blaus. Penile Implant. Wikimedia Commons. 2015. Available at: https://commons.wikimedia.org/wiki/File:Penile_Implant.png. License: CC BY-SA. Accessed on Jan 31st, 2026.

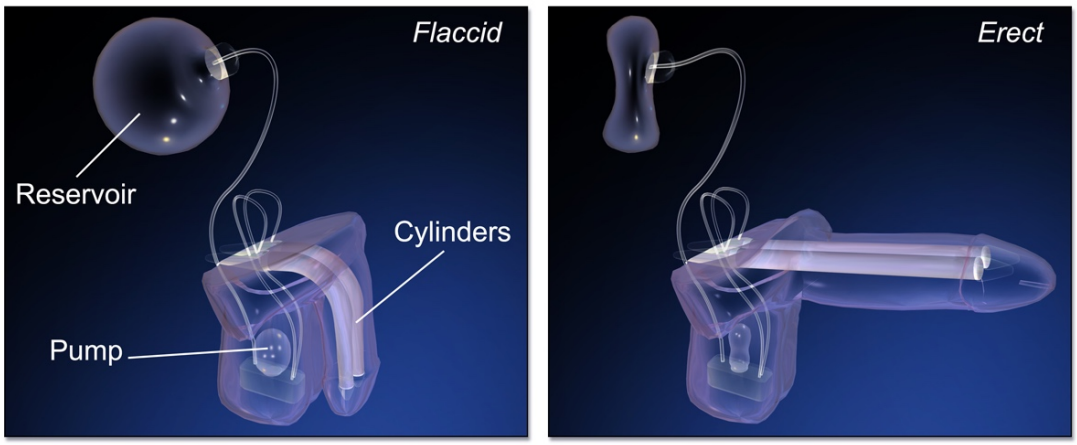


Figure 2.3 The image compares four inflatable penile implant cylinders: Ambicor (21 cm), Titan (20 cm), AMS 700 (21 cm) and ZSI 475 (22 cm). Differences in shape and length are clearly shown. The lower panels measure approximate cylinder diameters with a different caliber: 14 mm (Ambicor), 16 mm (Titan), 17 mm (AMS 700) and 20 mm (ZSI 475).

Source: Hovhannes Karapetyan. Comparison of cylinders of inflatable penile implants. Wikimedia Commons. 2020. Available at: https://commons.wikimedia.org/wiki/File:Comparison_of_penile_implants.jpg. License: CC BY-SA. Accessed on Jan 31st, 2026.

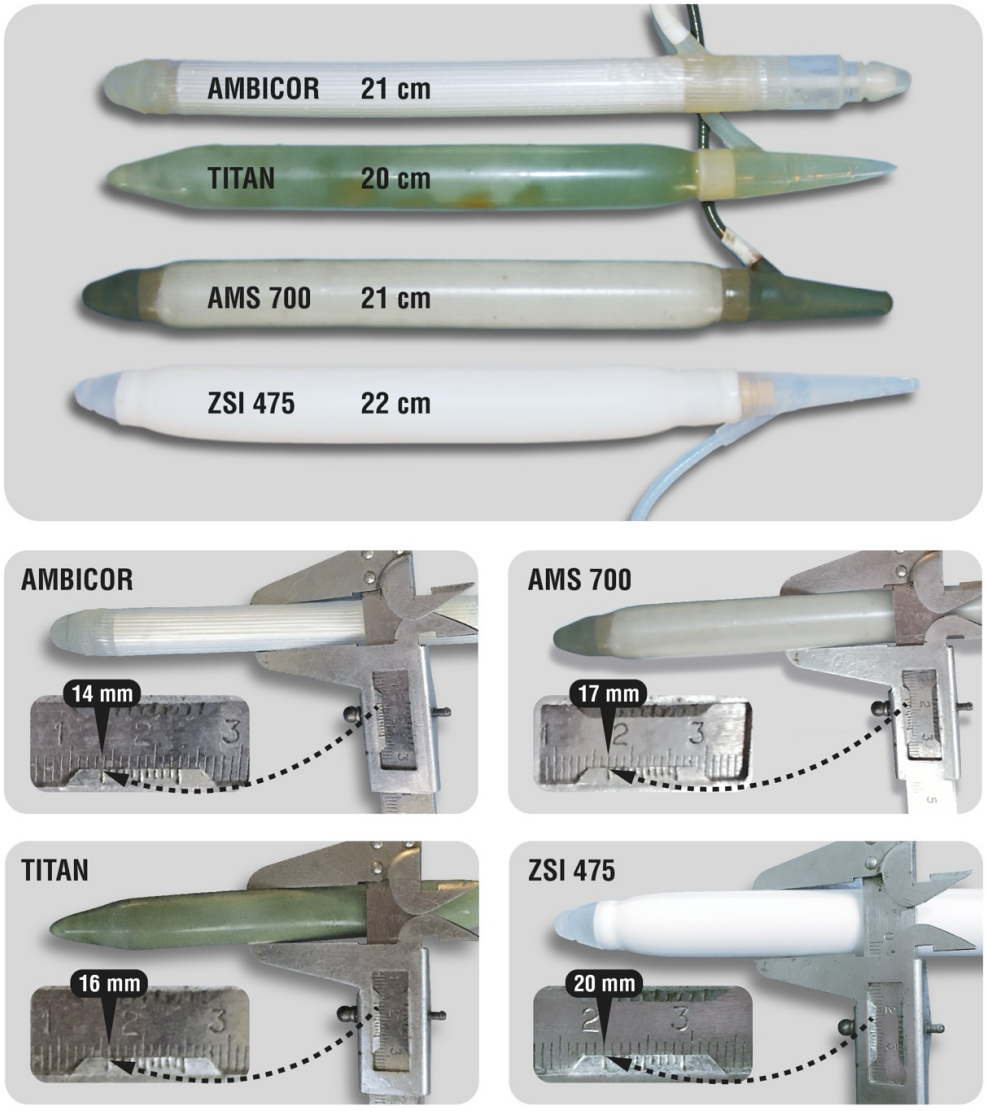
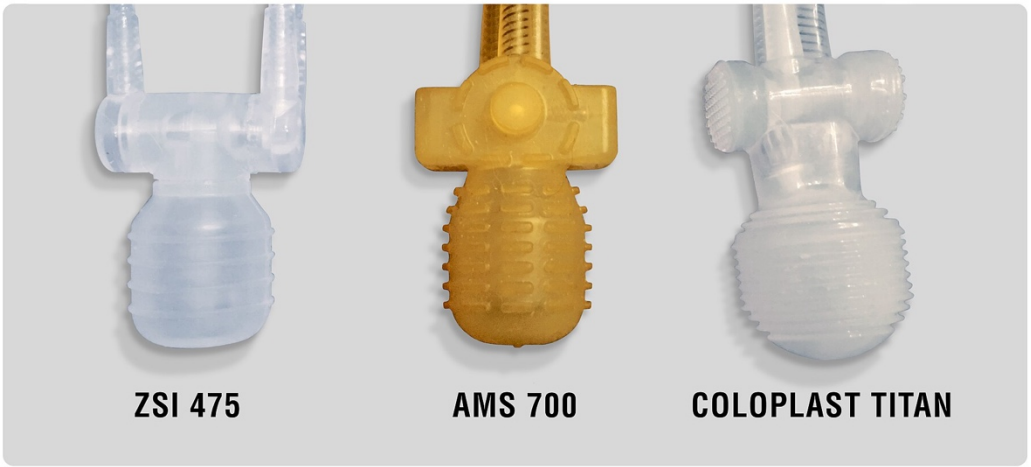


Figure 2.4 The image shows three inflatable penile implant pumps placed side by side for comparison:

- On the left side, the ZSI 475 pump is transparent, with a rounded bulb at the bottom and a more angular upper portion where the tubing connects;
- In the center, the AMS 700 pump has an amber color, a clearly visible circular central element and a ribbed squeeze bulb that improves grip;
- On the right side, the COLOPLAST TITAN pump is also translucent, with a larger rounded lower bulb and textured lateral pads on the upper part, features that appear designed to make handling easier.

Source: Hovhannes Karapetyan. Comparison of penile implant pump designs. Wikimedia Commons. 2020. Available at: https://commons.wikimedia.org/wiki/File:Penile_implant_pump_design_comparison.jpg. License: CC BY-SA. Accessed on Jan 31st, 2026.



2.3 Studies regarding PP implantation in SCI/D

Despite a long history of prosthetic surgery in ED, the scientific evidence about men with SCI/D is characterized by retrospective case series and heterogeneous mixed cohorts. Early reports often used semirigid devices, often for dual goals (sexual intercourse and facilitation of urinary management) and were marked by relatively high rates of erosion and infection. These initial outcomes contributed to a durable perception of SCI as a high-risk population for PP implantation. Contemporary series suggest that complication profiles improve substantially when patient selection and peri-operative infection prevention are optimized.[6]

Through a PubMed search on 31 January 2026 using the keywords “penile prosthesis” and “spinal cord injury” (including relevant synonyms and combinations), the studies considering the implant of PPs in people with SCI/D were analyzed and reported in Tables 2.1-2.5.[47–59] Tables 2.1 and 2.2 described the characteristics, demographics and SCI-specific clinical features of included studies. Table 2.3 focused on intraoperative data. Table 2.4 reported post-operative complications. Table 2.5 summarized functional outcomes, including patient satisfaction, sexual function and urinary management outcomes when available.

A detailed critical assessment of these studies is provided in the Discussion.

The overall complication rate appeared increased compared to general population. Several mechanisms had been proposed over the years: reduced tissue trophism, impaired sensation leading to delayed detection of pressure-related injury, recurrent UTIs, increased exposure to healthcare environments with presence of resistant organisms and difficulties with hygiene and catheterization.

Table 2.1 Study characteristics and demographics of the studies considering PP in people with SCI/D.

Study (author, year)	Country	Study period	Design	Follow-up (months)	SCI sample (n)	Control group (n)	Main focus
Golji, 1979	USA	1974-1976	Retrospective	3-27	25	NR	SCI; ED and/or urinary management
Light & Scott, 1981	USA	1976-1980	Retrospective	3-48	18	NR	SCI; inflatable PP for ED
Rossier & Bushra, 1984	USA	7 years	Retrospective	12-84	36	NR	SCI; ED and/or urinary management
Green & Sloan, 1986	USA	5 years	Retrospective	NR	40	NR	SCI; ED (counseling + surgery)
Iwatsubo et al, 1986	Japan	5 years	Retrospective	19 (6-46)	37	NR	SCI; ED and/or urinary management
Collins & Hackler, 1988	USA	1975-1987	Retrospective	41 (6-132)	63	NR	SCI; ED (complications)
Perkash et al, 1992	USA	PPs placed in the past 14 years	Retrospective	85 (12-168)	79	NR	Condom catheter retention; urinary management in SCI
Kimoto & Iwatsubo, 1994	Japan	10 years	Retrospective	48 (12-120)	82	NR	Neuropathic bladder + sexual dysfunction after SCI
Choi et al, 1994	Korea	1983-1993	Retrospective	34	48	247	ED; SCI subgroup
Montague & Lakin, 1994	USA	1987-1992	Retrospective	32 (6-60)	12	35	Neurogenic ED; SCI subgroup
Wilson et al, 1995	USA	1986-1993	Retrospective	NR	66	757	IPP infections; SCI subgroup
Zermann et al, 2006	Germany	1980-1996	Retrospective	86 (max 204)	245	NR	ED and/or urinary management; long-term follow-up
Kim et al, 2008	Korea	1990-2004	Retrospective	11.7 (3-17)	48	NR	SCI; malleable PP; long-term follow-up
Falcone et al, 2023	Italy	2014-2021	Retrospective, multicentric	83 (IQR 67-99.5)	23 (overall 33)	NR	Neurologic ED; SCI subgroup outcomes

Table 2.2 Participant characteristics, SCI features, indications and PPs types of the studies considering PP in people with SCI/D.

Study (author, year)	Age, years	SCI characteristics	Indications
Golji, 1979	25-60	Cervical 36%; Thoracic 56%; Lumbar 4%; Cauda equina 4%; Complete 68%	ED 68%; urinary 8%; both 24%
Light & Scott, 1981	22-36	Cervical 16.7%; Thoracic 61.1%; Lumbar 22.2%	ED 100%
Rossier & Bushra, 1984	38.5 (21-58)	Paraplegia 77.8%; Tetraplegia 22.2%	ED 47.2%; urinary 30.6%; both 22.2%
Green & Sloan, 1986	33 (21-60)	Paraplegia 70%; Tetraplegia 30%	ED 100%
Iwatsubo et al, 1986	42 (21-63)	Paraplegia 62.2%; Tetraplegia 27.0%; Walking 10.8%	ED and/or urinary 100%
Collins & Hackler, 1988	NR	NR	ED 100%
Perkash et al, 1992	41.9 (20-74)	Tetraplegia 48%; Paraplegia 47%; Cauda equina 5%; Complete 77%	Urinary management (condom catheter loss due to small retractile penis); sexual function secondary
Kimoto & Iwatsubo, 1994	NR	Paraplegia 39.0%; Tetraplegia 35.4%; Walking 25.6%	ED 12.2%; urinary 62.2%; both 25.6%
Choi et al, 1994	NR	NR	ED 100% (SCI subgroup)
Montague & Lakin, 1994	NR	NR	Neurogenic ED 100%
Wilson et al, 1995	NR	NR	ED
Zermann et al, 2006	40.8 (16-75)	Paraplegia 188; Tetraplegia 57	Urinary management only 134; ED only 60; both 51 (overall cohort)
Kim et al, 2008	58.9 (39-74)	Cervical 18.8%; Thoracic 43.8%; Lumbar 37.5%; Complete 14.6%	ED 52.1%; ED + urinary management 47.9%
Falcone et al, 2023	49 (IQR 41-55) (overall)	Cervical 4.3%; Thoracic 13.0%; Lumbar 82.7%; Complete 8.7%	Refractory neurogenic ED

Table 2.3 Intraoperative data of the studies considering PP in people with SCI/D.

Study (author, year)	**Implant types**	**Approach**	**Peri-operative prophylaxis (as reported)**
Golji, 1979	Semi-rigid (Small-Carrion) 100%	Perineal (92%) or dorsal penile (8%)	IV gentamicin
Light & Scott, 1981	IPP 100%	NR	NR
Rossier & Bushra, 1984	Semi-rigid	Perineal (61.1%) or dorsal (38.9%)	NR
Green & Sloan, 1986	Malleable 85%; IPP 10 %; Self-contained inflatable Hydroflex 5%	Subcoronal (semi-rigid); pubic (IPP)	NR
Iwatsubo et al, 1986	Semi-rigid 100%	Dorsal-base	NR
Collins & Hackler, 1988	Semi-rigid 84.1%; IPP 15.9%	Penile base dorsal/inferior to symphysis pubis (semi-rigid); low suprapubic symphyseal (inflatable)	IV aminoglycoside + cephalosporin
Perkash et al, 1992	Semirigid: Small-Carrion 49%; Flexirod hinged 45%; other 5%	Infrapubic midline 93.7%; Perineal 6.3%	Preop urine cultures and targeted antibiotics to sterilize urine
Kimoto & Iwatsubo, 1994	Semi-rigid 93%; Self-contained inflatable 7%	Infrapubic	IV cephalosporin + IM gentamicin
Choi et al, 1994	Mixed malleable/self-contained/2-piece/3-piece	Infrapubic or penoscrotal	IV aminoglycoside + cephalosporin
Montague & Lakin, 1994	Mixed malleable/self-contained/3-piece	NR	NR
Wilson et al, 1995	Different IPP types	Infrapubic or penoscrotal	IV vancomycin + gentamicin
Zermann et al, 2006	Jonas semirigid 50.2%; Self-contained inflatable (Dynaflex/Hydroflex) 38.6%; 3-piece inflatable (AMS 700) 11.3%	Infrapubic	1980-1988: 1st-gen cephalosporin from 3 days preop to 5 days postop; after 1988: single-dose preop 3rd-gen cephalosporin; chlorhexidine whole-body disinfection
Kim et al, 2008	Malleable 100%	Penoscrotal	IV cephalosporin + gentamicin
Falcone et al, 2023	Inflatable 91.3%; Malleable 8.7%	Penoscrotal 90.9%; Infrapubic 9.1%	NR

Table 2.4 Complications of the studies considering PP in people with SCI/D.

Study (author, year)	Infection	Erosion/ perforation	Mechanical issues	Revision/ reimplantation	Explantation/ removal
Golji, 1979	16.0%	8.0%	NR	8.0%	8.0%
Light & Scott, 1981	5.6%	11.1%	44.5%	44.4%	16.7%
Rossier & Bushra, 1984	11.1%	11.1%	NR	11.1%	5.6%
Green & Sloan, 1986	8.3%	11.1%	NR	NR	8.3%
Iwatsubo et al, 1986	5.4%	5.4%	NR	Revision due to migration 2.7%	2.7%
Collins & Hackler, 1988	7.9%	17.5% (all semi-rigid)	8.0%	15.9%	NR
Perkash et al, 1992	1.3%	NR	NR	NR	7.6%
Kimoto & Iwatsubo, 1994	10.0%	3.7%	NR	9.8%	14.6%
Choi et al, 1994	2.1%	2.1%	0%	NR	2.1%
Montague & Lakin, 1994	0%	8.3%	NR	NR	8.3%
Wilson et al, 1995	9.1%	NR	NR	NR	NR
Zermann et al, 2006	5.0%	8.7% (malleable, 18.1%; self-contained IPP 2.4%; IPP 0%)	13.0%	43 (semirigid 33.7%; self-contained 15.5%; IPP 7.1%)	7.7%
Kim et al, 2008	8.3%	4.2%	0%	NR	4.2%
Falcone et al, 2023	3.0% (overall)	NR	0%	NR	3.0% (overall)

Table 2.5 Functional outcomes of the studies considering PP in people with SCI/D.

Study (author, year)	Patient satisfaction	Sexual function / intercourse	Urinary management outcomes
Golji, 1979	90% wished they had PP sooner	NR	NR
Light & Scott, 1981	92.9%	NR	NR
Rossier & Bushra, 1984	Up to 90.9% for urinary management	Satisfactory sexual intercourse 36.0%	Improved urinary condom use 90.9%
Green & Sloan, 1986	81.6%	Satisfactory sexual intercourse 86.1%	NR
Iwatsubo et al, 1986	Up to 86.5% for urinary management	Improved sexual intercourse 40.5%; unchanged sexual intercourse 48.7%	Improved urinary management 86.5%
Collins & Hackler, 1988	Functioning PP 82.5%	NR	NR
Perkash et al, 1992	Rated shaft excellent for condom drainage 79% All cases reported improved hygiene, easier and faster condom application, increased mobility and reduced fear of UI	68% used implant for intercourse and reported partner satisfaction	Condom loss accidents: 81% none; 19% still lost; indwelling catheters removed except in one case; 2/3 suprapubic catheters successfully managed
Kimoto & Iwatsubo, 1994	Up to 92.8% for urinary management	Satisfactory sexual intercourse 64.0%	Satisfied with urinary management 92.8%
Choi et al, 1994	NR	NR	NR
Montague & Lakin, 1994	Functioning PP 91.5%	NR	NR
Wilson et al, 1995	NR	NR	NR
Zermann et al, 2006	Satisfied with treatment 82.6%; partners satisfied 67.4%	Intercourse possible 83.7%	Urinary management problems solved in 90.3%
Kim et al, 2008	79.2%	NR	Improved catheter or urinary condom use 91.3%
Falcone et al, 2023	84.8% fully satisfied; overall satisfied 90.7% (overall)	IIEF-5 median improved 8 to 22; SEP-2 yes 97%; SEP-3 yes 87.9%	NR

These studies were often presented without careful adjustment for confounding variables. Many cohorts mixed malleable and early-generation inflatable devices, included implants for stress UI rather than ED alone and were performed in patients with severe comorbidities.

From a methodological perspective, this is a classic setup for high complication rates: selection bias (only the most complex SCI/D cases received PPs), era effects (pre-coated devices) and heterogeneous peri-operative management. Therefore, a modern and protocolized evaluation is needed.[6,7]

Moreover, epidemiologic context is changing: in a population-based Italian study of SCI, patients were predominantly male with a rising mean age and a high proportion of incomplete lesions, reflecting the contemporary shift toward patients with preserved sensitivity that may help to reduce the risk of erosion/extrusion, but also older, medically complex cohorts who may also carry higher baseline infection risk due to comorbidities and more challenging bladder and bowel management needs.[60,61]

2.4 Penile prosthesis outcomes in SCI/D

In SCI/D, the risk is highly sensitive to modifiable factors that sit outside the operative field: bladder pressure control, IC technique, bowel routine, skin integrity, spasticity triggers and the availability of trained caregivers.[62] These factors determine the probability of post-operative events that can secondarily contaminate the device (e.g., catheter-associated UTIs, wound contamination during bowel accidents, pressure-related tissue injuries). The approach presented in this study highlights IPP implantation as the final step of a complex pathway.

In NLUTD, inadequate detrusor pressure control and urgency UI can undermine hygiene, increase UTI risk and complicate peri-operative management. When IC + MRAs are inadequate to afford an appropriate urinary continence and valid bladder pressure control with risk of upper urinary tract damage, intradetrusor injections of BTX-A may be offered. In case of IPP surgical planning, these injections should be performed in the months preceding the IPP implantation to optimize bladder storage and continence during the first crucial period after the IPP placement.

Because intradetrusor BTX-A effects wane over time, some people may require repeat injections at approximately 9-10 months during follow-up. These procedures could be conducted without major issues but demanded a prosthesis-aware cystoscopy approach: i.e., gentle urethral access, minimal instrument torque, careful visualization and controlled needle manipulation to avoid iatrogenic urethral injury that could be associated with different PP complications.

After IPP implant, novel IC training may be necessary to check whether the maneuver is performed in a clean and linear way. Otherwise, people may try and change the device or adopt new precautions to complete the procedure. All these evaluations should be performed under the supervision of an experienced nurse in IC.

NBD influences urological outcomes through the bladder-bowel axis and through hygiene stability that is crucial for prosthetic surgery. In some candidates, TAI was started, re-initiated or substantially revised prior to surgery to achieve predictable evacuation and reduce unplanned bowel accidents.[63] This pre-operative plan should be considered part of the entire process: fewer bowel accidents translate into a lower probability of perineal contamination during early wound healing.

Bladder and bowel management in individuals with SCI/D is a broad and highly specialized topic that falls beyond the scope of this book. A comprehensive discussion of acute and long-term assessment and treatment strategies is reported in two book chapters written by our center, Rapidi et al. (2022) and Sampogna et al. (2025).[64,65]

In most centers, PP surgery is performed in general urology units where the surgeon is not responsible for chronic neurogenic bladder or bowel care. In contrast, within a Spinal Unit the surgeon is embedded in a multidisciplinary network and is often directly responsible for urinary and bowel management plans.

This approach focuses to optimize modifiable risks and represents our contribution to fill the gap in the literature regarding the safety of PPs in this population. Indeed, the literature is still controversial about PP outcomes in people with SCI/D reporting contradictory results. Therefore, this study evaluates the role of a precise workflow to implant safely PPs in people with SCI/D and that can be replicated in other specialized units.[66–71]

3. Aims of the study

The aim of the study was to evaluate the safety and efficacy of modern three-piece IPP implantation in carefully selected men with SCI/D treated within a multidisciplinary workflow at a tertiary referral Spinal Unit.

The primary objective of the study was to evaluate the safety and describe complications within a predefined follow-up.

Secondary objectives included:

- To assess functional efficacy of IPPs;
- To quantify patient satisfaction and likelihood of recommending the procedure;
- To evaluate the impact of IPPs on bladder and bowel management through well-structured and validated international questionnaires, in particular on the ability to perform IC;
- To identify parameters associated with referral appropriateness for PP surgery among consecutive patients assessed over a two-year period in the Neuro-Urology outpatient clinic at our center and build a referral appropriateness PP score, called SCI/D-RAPPS;
- To develop and formalize a risk-mitigation plan for surgeons interested in implanting IPPs in SCI/D candidates.

4. Materials and methods

This study was designed as interventional, prospective, longitudinal, monocentric and aimed at improving clinical practice.

4.1 Study protocol

The study was performed by the Service of Neuro-Urology, inside the Spinal Unit, at the Niguarda Hospital in Milan, Italy. This Service is a tertiary referral center for NLUTD, NBD and neurogenic ED in people with SCI/D with an extensive clinical and research activity. Each year, the Center performs approximately 400 inpatient admissions for neurourological surgery, 80 rehabilitation admissions for acute-phase spinal cord injury, 1,500 neurourology outpatient visits, 500 urodynamic studies and 350 andrology consultations. As part of the andrology service, specific procedures are also provided, including training in ICIs, penile vibratory stimulation and penile color Doppler ultrasonography.

Over the years, our center has developed specific expertise in SCI/D to deliver patient-tailored solutions for clinical management, comprehensive rehabilitation programs and adaptation of aids (e.g., patient-specific wheelchairs and, in general, devices).

After obtaining the approval by the Institutional Review Board (code: 5-16012023), patients meeting specific requirements started being evaluated for IPP surgery during outpatient office visits for this study.

The study duration considered the following dates:

- Starting enrolling date: February 1st, 2023
- Closing enrolling date: January 31st, 2024

- Closing follow-up date: January 31st, 2025

The inclusion criteria of the study were the following ones:

- History of SCI/D;
- Age ≥ 18 years;
- Men with ED not responding to other therapies or unwilling/unable to follow other therapies;
- Consent and compliance with all aspects of the study protocol and with providing requested data during follow-up.

The exclusion criteria of the study were the following ones:

- No history of SCI/D;
- Age < 18 years;
- Penile erections valid for penetration with or without any other therapies than IPPs;
- Patient documented sensitivity to IPP materials;
- Unwillingness to undergo any further surgery for device revision;
- No consent and compliance with all aspects of the study protocol and with providing requested data during follow-up.

A subject could be discontinued from the study at any time if the subject or the investigators felt that it was not in the subject's best interest to continue.

Possible reasons for study treatment discontinuation were: screening failure; subject withdrawal of consent; subject is not compliant with study procedures; adverse event that in the opinion of the investigators would be in the best interest of the subject to discontinue study participation; protocol violation requiring discontinuation; lost to follow-up; request by the Niguarda Hospital for early termination of study; subject

death; difficulties with enrollment due to patients' unwillingness and/or specialists' contraindications.

Because inclusion criteria were intentionally stringent, recruitment was slower than expected. Since only five patients proceeded to IPP surgery during the initial study period, a formal amendment by the Institutional Review Board (4885_SA_02.04.2024_N) extended the recruitment window from Jun 1st, 2024, to May 31st, 2025, and the follow-up period was extended up to May 31st, 2026.

The study protocol specified standardized baseline evaluation, explicit eligibility criteria, structured follow-up visits and the use of validated PROMs. Key instruments included IIEF-5, SF-Qualiveen, ICIQ-UI SF, MENTOR tool and QoLSPP.[27,72–74]

A distinctive methodological feature was an optimization step before surgery. Patients were referred to surgery only after bladder and bowel management were improved. This process was structured through clinical criteria (limitation of incontinence episodes undermining hygiene, absence of recurrent UTIs or accessory gland infections, non-traumatic IC) and objective tools (SF-Qualiveen for UI; MENTOR green/yellow-light for bowel management).

Beyond bladder-bowel readiness, candidates underwent a structured comorbidity evaluation aimed at reducing avoidable complications. This included active screening and management of conditions that could destabilize wound healing or increase complication risk (e.g., untreated pressure injuries, severe spasticity, uncontrolled UI, unresolved urological malignancy work-up, active thromboembolic risk or any situation likely to require early re-interventions).

Psychological profile played a pivotal role in addressing people to IPP surgery. In SCI/D patients undergoing IPP surgery, an "appropriate psychological profile" was

defined by mental stability, the capacity to provide informed consent, realistic expectations and demonstrated adherence to hygiene, IC, bowel routine, device cycling and follow-up care. The psychological profile was not appropriate when there was active uncontrolled psychiatric illness, significant cognitive impairment, substance misuse, unrealistic expectations or a pattern of poor adherence, as these factors increased the risk of complications and dissatisfaction.

When the above-mentioned issues were identified, they were treated and stabilized first. This stepwise strategy was central to patient safety and partly explains the slow recruitment and high screening-to-enrolment funnel.

This design choice served two roles. First, it was an ethical safety measure: the highest-risk modifiable conditions were corrected before implanting a foreign body (IPP). Second, it was a scientific strategy: it reduced heterogeneity and confounding, yielding a cleaner estimate of outcomes under best practice conditions.

A substantial proportion of referred patients could not be enrolled because clinically relevant concomitant problems required prioritization and stabilization (e.g., pressure injuries, severe incontinence, recurrent UTIs or complex pelvic surgical history). This highlights that refractory ED is necessary but not a sufficient indication for safe implantation in SCI/D; indeed, the patient should be globally evaluated.

4.2 Pre-operative work-up

Pre-operative evaluation included several assessments.

Each patient underwent comprehensive andrological evaluation (genital exam; exclusion of phimosis, severe Peyronie’s disease requiring alternative surgery or

malignancy); baseline erectile function (IIEF-5); and EHS.[75,76] Penile duplex ultrasound was performed selectively to characterize vascular status.

Definition of optimal bladder management required stable IC without significant difficulties, absence of macrohematuria and absence of recurrent or febrile UTIs. A 3-day bladder diary and kidney-ureter-bladder ultrasound were completed in all patients. Videourodynamics was always performed to exclude urodynamic risk factors that could affect outcomes or increase infection risk (e.g., uncontrolled high-pressure storage, VUR).

All patients were assessed by a gastroenterologist with expertise in NBD.[77] The MENTOR tool and included NBD score were used to guide decision-making and allowed surgery only in patients categorized as green or yellow.[74] Bowel diaries for 7 days supported assessment of valid bowel programs.[78]

In case of need, patients were addressed to physical medicine and rehabilitation doctors to perform counseling for the evaluation of rehabilitation programs (e.g., to improve hand function for IPP activation or spasticity management).

Similarly, occupational therapists with expertise in SCI/D were involved for the pre- and post-operative counseling to optimize the devices in use (e.g., development of wheelchair cushions to reduce the pressure at the level of external genitalia reducing the risk of IPP extrusion).

Most people with SCI/D were followed by a psychologist/psychiatrist to cope with disease-related issues. When this support lacked, a psychiatrist collaborating with the study center was involved to manage psychological issues negatively impacting sex life and, in general, QoL.

When patients reported problems with IC technique, they were addressed to nurses with a long-lasting experience in the management of SCI/D for coaching and choice of new devices.

4.3 Peri-operative management

The peri-operative strategy was designed to reduce infection risk, acknowledging the significant consequences of prosthesis infection. Three pillars were emphasized:

1. Microbiology-informed extended prophylaxis: Urine culture and rectal swab were obtained pre-operatively. Antimicrobial therapy was tailored according to local resistance patterns in collaboration with infectious disease specialists. Probiotics were administered for a month.
2. Environmental control: Procedures were performed in dedicated clean operating theatres, avoiding trauma theatres with high bacterial load. Intra-operative traffic was minimized and non-essential door openings were restricted.
3. Patient optimization: Bowel emptying was confirmed the day before surgery (abdominal radiography in case of doubt). Bladder routines were stabilized and IC technique reinforced. Nutritional supplements were administered to improve skin recovery in malnourished patients.

Extended prophylaxis was standardized as follows: gentamicin weight-adjusted dosing plus cefazolin 2 g three times daily, administered the day before surgery, the day of surgery and the day after surgery, with adjunctive caspofungin (70 mg on the operative day and 50 mg on the first post-operative day) based on local fungal infection data and contemporary prosthesis infection literature; also implant components were soaked in

a solution containing vancomycin, gentamicin and caspofungin prior to insertion.[66,71,79–83]

The minimum LOS was 3 days to complete antimicrobial therapy. However, our hospital organization allowed flexible extension up to 7-10 days for selected individuals who lacked caregiver support or reported organizational barriers at home to conclude the first week after surgery in a safe way. This flexibility was adopted to improve patient safety, particularly in people with limited caregiver support.

During admission, nursing staff were explicitly briefed on strict hygiene measures and, where feasible, single rooms were preferred. Because catheter-related infections can seed prosthetic infection, aseptic catheter handling and careful perineal hygiene were treated as part of the prevention plan.

An IUC was maintained for at least 7 days to reduce urethral microtrauma and early post-operative urethral lesions. Prolonged catheterization beyond this window was avoided due to increased infection risk. Catheter removal was scheduled based on patient availability for follow-up, highlighting the role of disability-related logistics.[84]

Pressure injury prevention was particularly critical around the peri-operative period, when patients might spend prolonged time supine during transport, pre-operative waiting and recovery. In SCI/D, reduced sensation could delay detection and exacerbate tissue damage. Therefore, pressure-relief surfaces were mandatory: during transfers and peri-operative waiting, patients were maintained on open-cell polyurethane foam supports and post-operatively high-risk patients were managed on air-fluidized therapy beds when needed.[85]

AD is a potentially life-threatening complication in individuals with lesions at or above T6 and can be triggered by bladder or bowel distension, surgical pain and skin

irritation. Peri-operative strategy included proactive pain control, careful bladder drainage, avoidance of noxious stimuli and education of all involved personnel (surgeons, anesthesiologists, nurses) on AD management.

If a surgeon does not consider the needs of people with SCI/D, the risk for surgical complications is significantly high. Therefore, the peculiarities of people with SCI/D should always be addressed when performing surgery in this population, as largely discussed in a book chapter collecting the experience by our center, Sampogna et al. (2023).[62]

4.4 Surgical technique

All implants were contemporary three-piece IPPs inserted via the penoscrotal approach.[86] To reduce contamination, a strict sterile field protocol was used and staff access to the operating room was limited during critical steps of device handling.

The surgical field was prepared with a 10-minute scrub using chlorhexidine. A 16-Fr silicone Foley urethral catheter was inserted and the balloon inflated with 10 mL within the bladder. A transverse penoscrotal incision of approximately 3 cm was performed and the corpora cavernosa were exposed with careful preservation of the urethra (Fig. 4.1). Bilateral corporotomies were then created via longitudinal cold-knife incisions, followed by progressive distal and proximal dilation using Brooks dilators. The corporal spaces were measured and a three-piece IPP was selected: in this study, the Coloplast Titan model. The cylinder length was selected according to the measured corporal length.[87] The corporotomies were closed with horizontal mattress sutures using 2-0 polyglactin and correct device cycling (activation and deactivation) was verified. After bladder drainage, the reservoir was placed in the space of Retzius,

using the right pubic tubercle as an anatomical landmark and lateralizing the right spermatic cord. Reservoir placement could also be ectopic or high submuscular: these approaches were appropriate when the retropubic space was hostile or unsafe, including after prior pelvic surgery.

Then, the pump was positioned within the scrotal pouch after blunt dilation performed with a Killian nasal speculum. All tubing connections were completed and tested, confirming watertight integrity through repeated activation and deactivation. Meticulous hemostasis was prioritized to reduce hematoma formation, a known mediator of infection risk. [88,89] Layered wound closure was performed with interrupted 2-0 polyglactin sutures, ensuring deep placement of the prosthetic components and the skin was closed with interrupted Donati vertical mattress sutures using 3-0 polyglactin. A compressive dressing, the so-called "mummy wrap", was applied around the penis and scrotum with multiple overlapping layers so that the area was "wrapped" in a uniform way (hence the term "mummy") to provide gentle and distributed compression to reduce post-operative edema and bruising, limit hematoma/seroma formation, protect the tissues, support the scrotal contents and the implanted pump. At the end of the surgery, the prosthesis was partially inflated (about 50%) and the IUC was left.

4.4.1 Device choice

The device implanted was the Coloplast Titan Touch™. It is a three-piece IPP, a self-contained hydraulic system intended for the surgical treatment of ED. Once implanted, it is completely internal (Fig 4.2) and allows the patient to voluntarily control penile rigidity and flaccidity by transferring sterile isotonic saline between a reservoir

(implanted in the space of Retzius or the abdominal wall) and two Bioflex® cylinders (standard or narrow) placed in the corpora cavernosa, using a scrotal pump. Key design features include a Lock-Out™ valve in the reservoir designed to minimize auto-inflation and the HydroVANTAGE™ hydrophilic coating over all components (including extenders, connectors and reservoir), which can absorb an antibiotic solution selected by the surgeon and release it post-operatively to help reduce infection risk. Additional elements supporting anatomical fit and implantation include Bioflex® cylinder material, 0-degree proximal tubing angulation to facilitate insertion and a shaped distal tip. The Titan Touch Narrow Base variant is specifically designed for patients with narrow corpora cavernosa.

4.4.2 Anesthesiologic considerations

Most patients underwent general anesthesia according to standard institutional practice. However, one medically complex patient (Case #12) with obesity, OSAS treated with nocturnal CPAP and absent sensation below the inter-mammillary line underwent a sedation-based strategy.[90] After standard monitoring, 1 mg midazolam was administered, followed by infusion (0.7 µg/kg/h during preparation, titrated up to 1.0 µg/kg/h) and ketamine boluses (10 mg increments to 30 mg total) to achieve sleep while maintaining spontaneous breathing.[91] CPAP was applied at the patient's home settings with supplemental low-flow oxygen. Hemodynamics remained stable without bradycardia and no neurovegetative reflexes were observed.

4.5 Follow-up

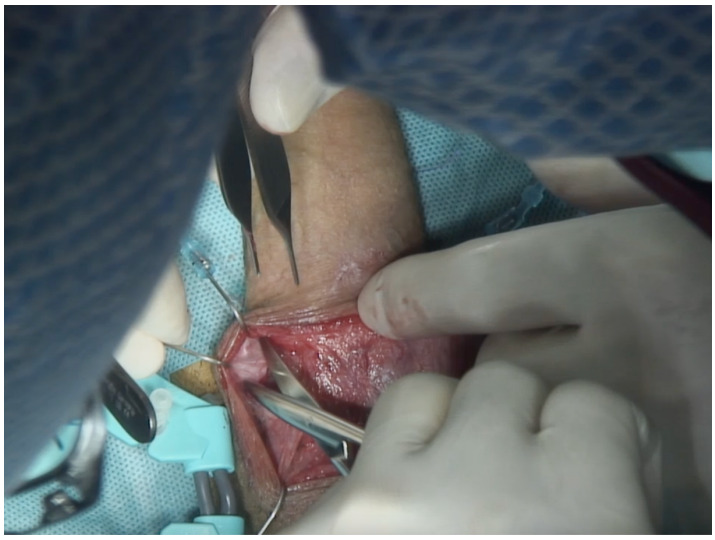
After surgery, patients attended the follow-up visits at 14 days, 1 month, 3 months, 6 months, 9 months and 12 months. During each follow-up visit the investigators evaluated the following features:

- Physical examination to recognize early IPP-related complications (e.g., infection, erosion, extrusion) or perineal/anal problems or pressure injuries;
- Adverse events and/or complications following surgery;
- Current medications and/or novel comorbidities diagnosed since the last visit;
- Specific questionnaires assessing QoL and all autonomic pelvic functions (SF-Qualiveen, ICIQ-UI SF, NBD score and MENTOR tool);
- The ease of catheter insertion was estimated pre-operatively and after one month since surgery on a 10-point Likert scale;
- QoLSPP scores, starting at the 3-month visit to allow patients sufficient time to use the device in real-life conditions following activation and training because of the complex and complete score evaluation;[27,92]
- Subjective evaluations based on a 10-point Likert scale assessing patient satisfaction and recommendation of this treatment to other people, since the visit after 4 weeks when the patient could activate and use the IPP.

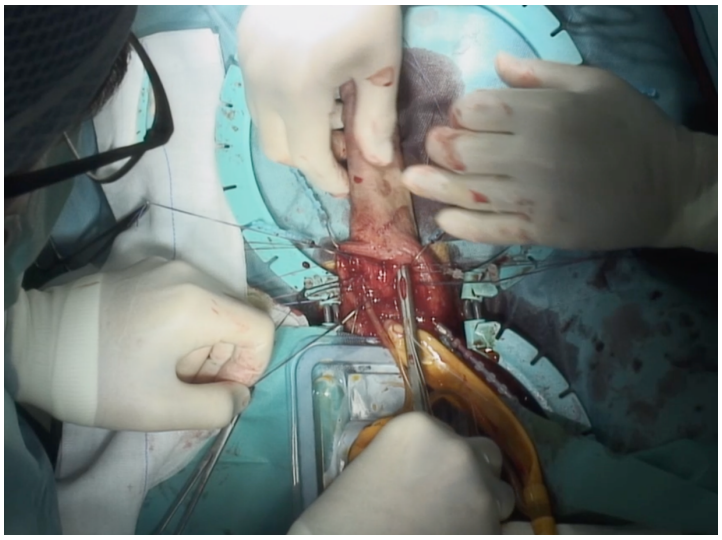
On January 31st, 2026, all patients, who had completed the predefined 12-month-long follow-up, were contacted by phone for updating about possible complications.

Figure 4.1 Intraoperative photographs demonstrating the key steps of IPP placement. A) After transverse penoscrotal incision, corpora cavernosa are exposed with careful preservation of the urethra. B) Corporotomies are performed to access the corpora cavernosa, followed by sequential dilation of the corporal bodies through Brooks dilators. After appropriate cylinder length measurement, the paired inflatable cylinders are inserted into the corpora cavernosa using a Furlow inserter. C) The reservoir is positioned in the retropubic space and the pump is placed within the scrotum through the same scrotal incision.

A)



B)



C)

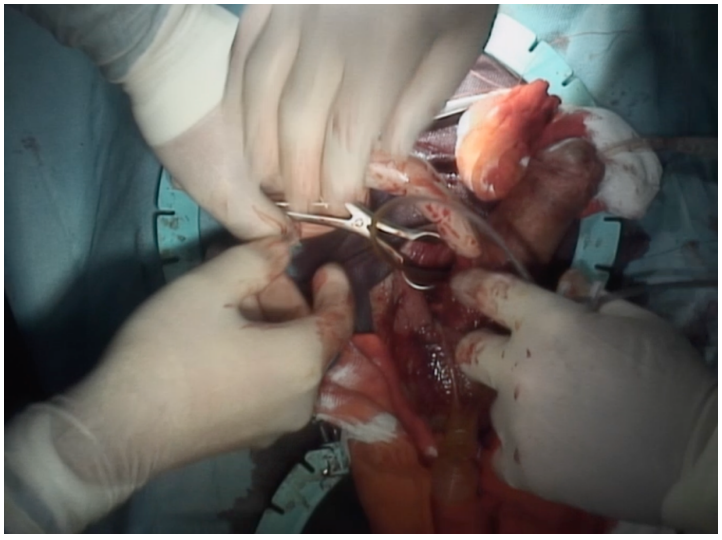


Figure 4.2 The final image shows the post-operative appearance of penis and scrotum with the device in situ, illustrating appropriate positioning and cosmetic outcome.

4.6 Data collection

Two linked samples were analyzed: (1) a consecutive cohort of men with SCI/D evaluated for IPP during the two-year enrollment period by our center, used to quantify referral appropriateness and develop the SCI/D-RAPPS; (2) the subgroup that underwent three-piece IPP implantation with standardized peri-operative data collection and scheduled follow-up through 12 months.

As for people referred for IPPs, different variables were analyzed: age; time since SCI; SCI severity as reported by Biering-Sørensen et al., 2017 (Group 1: C1-C4 AIS A-C; Group 2 = C5-C6 AIS A-C; Group 3 = T1-S5 AIS A-C; Group 4 = AIS D); CCI ≥ 3; safe urodynamics (DO with filling > 400 ml, reduced bladder compliance and absence of VUR); UTI burden (febrile or recurrent UTIs); MENTOR Tool result (green, yellow or red); stable partner; history of pressure ulcers; severe spasticity (Modified Ashworth Scale [MAS] ≥ 3); appropriate psychological profile (in case of doubt our psychology/psychiatry team was consulted).[93,94]

As for the subgroup addressed to IPP surgery, pre-, intra- and post-operative data were collected prospectively. In particular, the variables collected were:

- Demographics and general health status: sex, age at the procedure, etiology of SCI/D, NLI, time since SCI/D, BMI, smoking status (assessed as a dichotomic variable considering the widely accepted definition of "current smoker", who is an adult who has smoked 100 cigarettes in his or her lifetime and who currently smokes cigarettes), comorbidities, presence and degree of spasticity involving muscles near the IPP localization, history of previous pressure ulcers, manual dexterity to manage IPP autonomously, marital status;

- Pre-procedural evaluation: bladder management (use of ICs, medicines, periodical infiltration of BTX-A), previous urological surgery, NBD routine, use of TAI and ED-related PROMs like EHS and IIEF-5;
- Peri-procedural data: surgical approach, reservoir placement, length of implanted cylinders, Wilson's maneuver to correct penile curvature, OT, intra-operative complications, admission-to-discharge LOS and post-operative LOS
- Follow-up evaluations at 14 days, 1 month, 3 months, 6 months, 9 months and 12 months: recording of adverse events and/or complications following surgery; current medications and/or novel comorbidities diagnosed since the last visit; SF-Qualiveen and ICIQ-UI SF; NBD score and MENTOR tool; QoLSPP; subjective evaluations based on a 10-point Likert scale assessing patient satisfaction and suggestion of this treatment to other people.

Data collection was carried out progressively following patients through each step. The required data were retrieved for each patient from his interview and documentation, which was available in electronic health records and paper-based medical records. The data were digitally entered by the investigators for each patient in a specified database accessed only by a predefined hospital computer through a password, known only by the principal investigator and the data manager.

Data collection followed the principles outlined in the Declaration of Helsinki. Data processing followed principles and rules outlined in the General Data Protection Regulation (GDPR).

4.7 Statistical analysis

The statistical analysis was conducted on two different samples: 1) SCI/D population evaluated for PP implant consecutively at our Neuro-Urology outpatient clinic during the two-year enrollment period of the study; 2) people undergoing IPP surgery.

The primary outcome was referral appropriateness for PP surgery, coded as a binary endpoint (1 = appropriate referral; 0 = inappropriate referral). Predictors were prespecified a priori and reflected infos that are routinely available at the time of referral. These included age, SCI severity group (1-4), time since SCI, comorbidity burden captured by the CCI and clinical factors potentially relevant to surgical candidacy and peri-operative risk such as urodynamic safety, UTI burden and the presence of a MENTOR tool red flag. In addition, variables describing the psychosocial and functional context were included, namely stable partner status, history of pressure ulcers, severe spasticity and psychological profile appropriateness. For model development, we fitted a multivariable logistic regression including all prespecified predictors simultaneously (full model), in order to preserve clinical completeness and avoid exclusion of potentially important referral determinants. SCI severity group was modeled as a categorical variable.

Model performance was assessed primarily in terms of discrimination, quantified by the AUC. To address potential over-optimism inherent to fitting and evaluating a model in the same dataset, we performed internal validation using bootstrap resampling (B = 1000) and derived a corrected ROC curve and AUC. Overall model fit was summarized using Nagelkerke's R^2, providing an interpretable measure of explained variation for logistic regression.

Since the intended use of SCI/D-RAPPS was referral support, we adopted a probability threshold of 0.30 to classify a referral as positive. This cut-off was chosen to prioritize sensitivity, reflecting the clinical preference to minimize missed appropriate candidates (false negatives), while accepting a relatively higher number of false-positive referrals that can subsequently be filtered during specialist evaluation.

Finally, to facilitate routine use of the SCI/D-RAPPS model in everyday practice, we translated the final regression equation into a dedicated Excel-based calculator, allowing clinicians to rapidly compute the predicted probability of referral appropriateness at the point of care.

This prediction model study was reported in accordance with the TRIPOD (Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis) statement.

As for the population addressed to IPP surgery, descriptive analysis was performed: whole numbers and proportions were used to describe categorical variables (e.g., SCI etiology, NLI, comorbidities, smoking status), reporting medians with IQRs and ranges.

Dealing with functional data variations over time, the Wilcoxon signed-rank test was used to compare two paired measurements within the same subjects (e.g., pre- vs post-intervention) and the Friedman test to compare three or more repeated measures within the same subjects across multiple time points or conditions.

The statistical analysis was performed with the collaboration of a statistical expert working by the Larice Lab, IRCCS Fondazione Don Carlo Gnocchi and the Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy.

The medical record collection and statistical analysis were conducted using Microsoft Excel (Microsoft Corporation, Redmond, WA), SPSS Statistics Version 30.0 (Armonk, NY) and R software package 4.5.2 (Institute for Statistics and Mathematics, Vienna, Austria; www.r-project.org).

The significance level was defined as $P < 0.05$.

Data were treated and presented in an aggregate manner impeding any patient recognition in accordance with current data processing principles.

5. Results

In this section, findings were reported across six sections: enrollment evaluations and SCI/D-RAPPS development (Section 5.1); baseline characteristics of the implanted cohort, peri-operative outcomes and post-operative complications (Sections 5.2-5.4); longitudinal PROMs (Section 5.5); risk mitigation plan development (Section 5.6).

5.1 Referral to IPP surgery

The enrollment process followed a strict pathway according to the principles reported in the previous section. A total of 263 patients were evaluated for IPP surgery as depicted in Fig. 5.1, where the study flow diagram according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement is reported.[95] A total of 263 individuals were included in the analysis. Overall, 61 patients (23.2%) were classified as having an appropriate referral for PP surgery, while 202 (76.8%) were classified as inappropriate. Descriptive characteristics stratified by outcome are reported in Table 5.1. In the full multivariable logistic regression model (Table 5.2), all prespecified predictors were entered simultaneously, with SCI severity group treated as a categorical variable (reference: group 1). The model showed moderate-to-good overall fit, with a Nagelkerke's R^2 of 0.298, indicating a meaningful proportion of explained variation for a clinical referral tool. With respect to discrimination, the model achieved an apparent (standard) ROC AUC of 0.801. After internal validation using bootstrap resampling (B = 1000), the optimism-corrected AUC was 0.751, suggesting expected reduction in performance when generalizing to new samples (Fig. 5.2).

Figure 5.1 The study flow diagram of the study according to the STROBE statement.

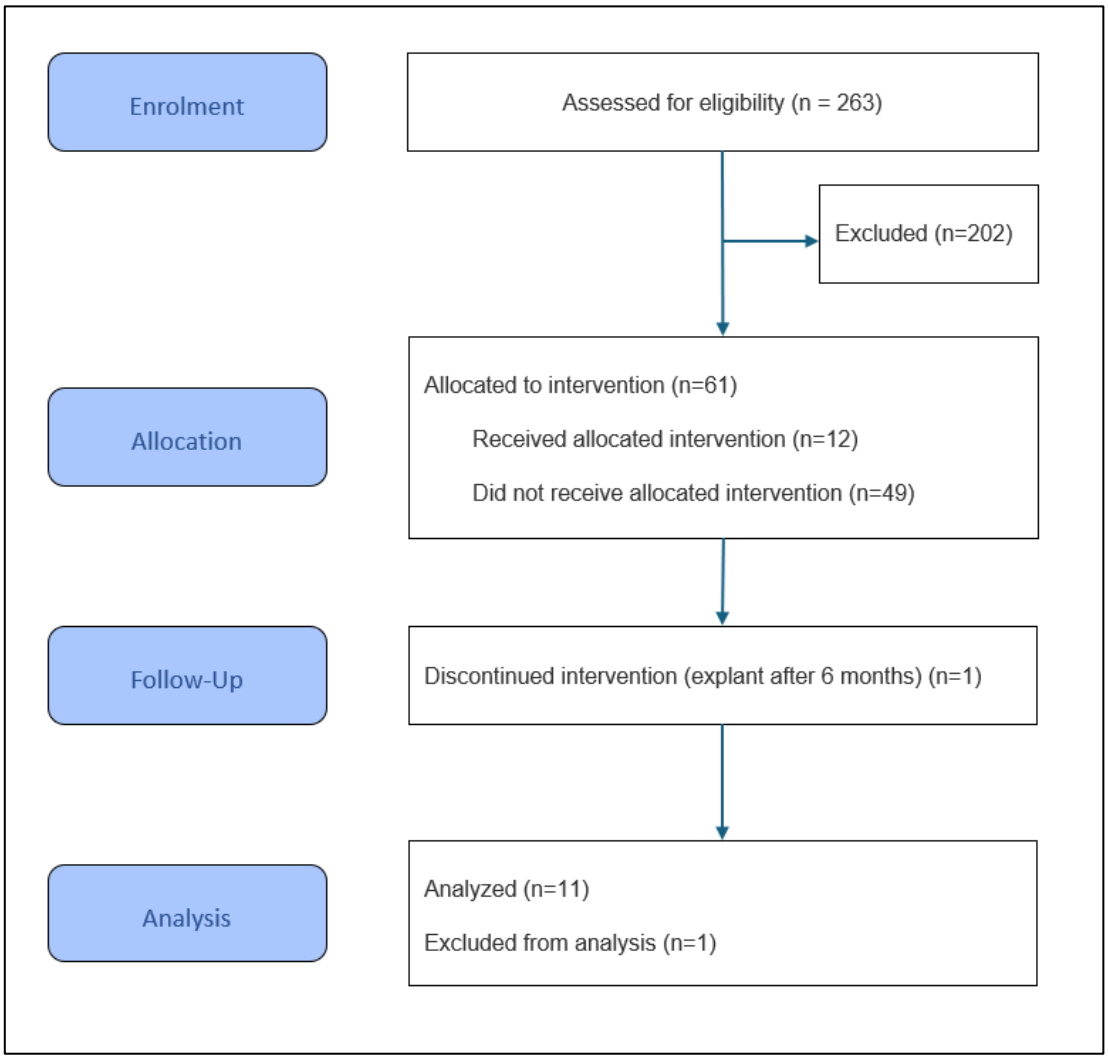


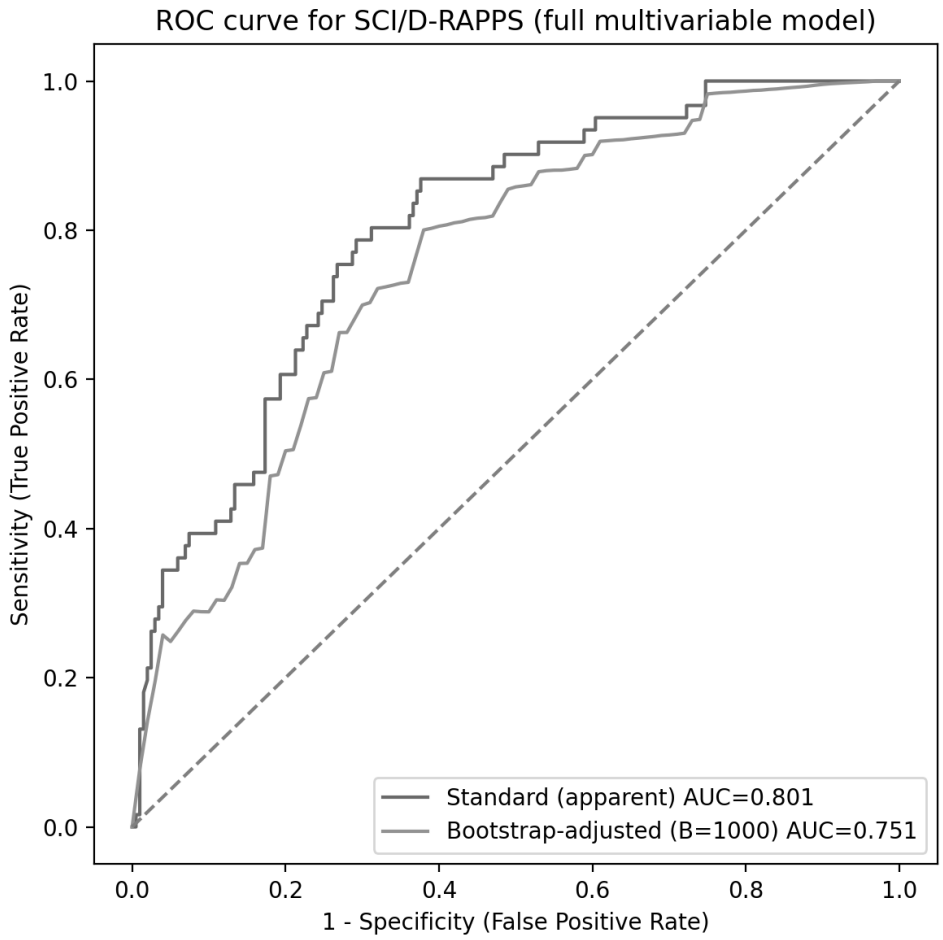
Table 5.1 Descriptive characteristics of patients considered for IPP referral.

Variable	Overall (n=263)	Appropriate (n=61)	Inappropriate (n=202)
Age (years)	50.1 (SD 17.1)	45.0 (SD 16.9)	51.6 (SD 16.8)
Time since SCI (years)	10.9 (SD 7.4)	12.1 (SD 7.3)	10.5 (SD 7.4)
Tetraplegia C1-C4 AIS A-C	29 (11.0%)	2 (3.3%)	27 (13.4%)
Tetraplegia C5-C6 AIS A-C	56 (21.3%)	13 (21.3%)	43 (21.3%)
Paraplegia T1-S5 AIS A-C	120 (45.6%)	27 (44.3%)	93 (46.0%)
AIS D	58 (22.1%)	19 (31.1%)	39 (19.3%)
CCI ≥ 3	38 (14.4%)	3 (4.9%)	35 (17.3%)
Safe urodynamics	75 (28.5%)	18 (29.5%)	57 (28.2%)
UTI burden	61 (23.2%)	5 (8.2%)	56 (27.7%)
MENTOR tool = red	48 (18.3%)	8 (13.1%)	40 (19.8%)
Stable partner	143 (54.4%)	42 (68.9%)	101 (50.0%)
History of pressure ulcers	38 (14.4%)	6 (9.8%)	32 (15.8%)
Severe spasticity	33 (12.5%)	5 (8.2%)	28 (13.9%)
Appropriate psychological profile	219 (83.3%)	60 (98.4%)	159 (78.7%)

Table 5.2 Univariate and multivariable logistic regression analyses of people considered for IPP referral.

Variable	Univariate OR (95% CI)	Univariate p value	Multivariate OR (95% CI)	Multivariate p value
Age (per year)	0.98 (0.96-0.99)	0.008	0.97 (0.95-0.99)	0.004
SCI severity group 2 vs 1	4.08 (0.85-19.51)	0.078	3.10 (0.57-16.87)	0.191
SCI severity group 3 vs 1	3.92 (0.88-17.55)	0.074	3.55 (0.69-18.20)	0.129
SCI severity group 4 vs 1	6.58 (1.41-30.60)	0.016	4.98 (0.92-26.82)	0.062
Time since SCI (per year)	1.03 (0.99-1.07)	0.150	1.05 (1.00-1.10)	0.052
CCI ≥3 (yes vs no)	0.25 (0.07-0.83)	0.024	0.26 (0.07-0.95)	0.042
Safe urodynamics (yes vs no)	1.06 (0.57-2.00)	0.845	1.13 (0.55-2.33)	0.735
UTI burden (yes vs no)	0.23 (0.09-0.61)	0.003	0.26 (0.09-0.75)	0.013
MENTOR Tool = red (yes vs no)	0.61 (0.27-1.39)	0.239	0.56 (0.22-1.44)	0.231
Stable partner (yes vs no)	2.21 (1.20-4.06)	0.011	2.52 (1.27-5.03)	0.008
History of pressure ulcers (yes vs no)	0.58 (0.23-1.46)	0.247	0.65 (0.22-1.88)	0.425
Severe spasticity (yes vs no)	0.55 (0.20-1.51)	0.247	0.54 (0.17-1.68)	0.285
Appropriate psychological profile (yes vs no)	16.23 (2.19-120.47)	0.006	10.71 (1.37-83.48)	0.024

Figure 5.2 ROC curves for the SCI/D-RAPPS model showing the standard performance in the development sample and the bootstrap optimism-corrected performance (B = 1000 resamples).



The SCI/D-RAPPS equation was reported.

Linear predictor (LP) = -3.6768 + 1.1310·I(severity=2) + 1.2661·I(severity=3) + 1.6055·I(severity=4) + -0.0313·Age + 0.0457·Time_since_SCI + -1.3479·CCI≥3 + 0.1246·Urodynamics_safety + -1.3357·UTI_burden + -0.5742·MENTOR_red + 0.9260·Stable_partner + -0.4343·Pressure_ulcers_history + -0.6214·Severe_spasticity + 2.3711·Psych_appropriate

Predicted probability: p = 1 / (1 + exp(−LP)).

Using the prespecified referral threshold of 0.30, the model prioritized sensitivity as intended for a screening/referral context. At this cut-off, sensitivity was 0.705 and specificity was 0.738. The positive predictive value (PPV) was 0.448, while the negative predictive value (NPV) was 0.892. In absolute terms, this threshold yielded 43 true positives, 53 false positives, 18 false negatives and 149 true negatives in the present dataset. These operating characteristics are consistent with a referral-oriented strategy in which the tool is designed to reduce missed appropriate candidates (false negatives), accepting a higher number of referrals that may later be deemed inappropriate during specialist assessment. An accompanying software application calculator with MS Excel implemented the final equation for point-of-care probability estimation (Fig 5.3).

Figure 5.3 Screenshot of the SCI/D-RAPPS Excel probability calculator. The upper panel lists the required input variables with definitions and coding. The lower panel reports the model outputs.

SCI/D-RAPPS

Input	Value	Definition
Age (years)	35	Continuous
SCI severity group (1-4)	3	1=Tetraplegia C1-C4 AIS A-C, 2=Tetraplegia C5-C8 AIS A-C, 3=Paraplegia T1-S5 AIS A-C, 4=AIS D
Time since SCI (years)	10	Continuous
CCI ≥3	0	0=No, 1=Yes
Urodynamics safety	1	0=No, 1=Yes
UTI burden	0	0=No, 1=Yes
MENTOR tool = red	0	0=No, 1=Yes
Stable partner	1	0=No, 1=Yes
History of pressure ulcers	0	0=No, 1=Yes
Severe spasticity	0	0=No, 1=Yes
Psychological profile = appropriate	1	0=No, 1=Yes

Model outputs		
Linear predictor (LP)	0,374	
Predicted probability	0,593	
Referral decision (threshold 0.30)	Refer	

Some patients were addressed to IPP after an initial exclusion, because they presented:

- Right trochanteric pressure ulcer, right ischiorectal fossa abscess extending to the right perineal and scrotal regions and to the right posterior compartment, with cutaneous fistulization. The patient required long-period antibiotic therapy, periodical outpatient wound care visits and complex reconstructive surgery.
- Prostatic cancer requiring RARP. The diagnosis was performed during pre-operative exams, highlighting increased PSA. Subsequently, the prostate biopsy confirmed prostate cancer and the patient was addressed to Retzius-sparing RARP with a bilateral nerve-sparing approach without lymphadenectomy. The histological examination revealed acinar prostatic adenocarcinoma, Gleason Score 3+4, TNM staging pT2a pNx.
- Infiltration of BTX-A into the detrusor wall one month before IPP surgery to maximize the benefits for DO and UI control.
- Physiatrist visit to treat significant thigh spasticity that could alter the activation/deactivation of the IPP besides increasing the risk of scrotal pressure ulcer.

All the evaluated people with spina bifida were excluded from the study, since they presented different issues that could be associated with intra- and/or post-operative complications.[96] People with spina bifida often walk with thigh scissoring, which increases the risk of erosion/extrusion of the scrotal pump. Their skin is frequently non-eutrophic and thin, further predisposing to device erosion/extrusion, also because they often have more severe UI than individuals with acquired spinal cord injury, as they more commonly experience stress UI in addition to urgency UI.

Recruitment barriers were mainly due to the following causes: the need to meet strict eligibility criteria; frequent discouragement by external clinicians based on historical complication rates; patient reluctance driven by risk narratives rather than contemporary evidence. These findings suggest that tertiary referral pathways should support also accurate counseling and risk communication.

For all these reasons, after the first year of enrollment, only 5 patients were addressed to IPP implant. Other ones were correcting problems encountered during initial evaluations (e.g., pressure ulcer) to reduce the risk of complications. Therefore, another year of enrollment was done, addressing other seven cases to IPP surgery.

5.2 Characteristics of patients undergoing IPPs

Twelve out of 61 (19.7%) patients underwent three-piece IPP implantation, while the others refused after adequate counseling and/or presented clinical issues to solve before IPP and reduce the risk (e.g., optimal bladder and bowel management, spasticity evaluation, pressure ulcer check, wheelchair control).

Baseline characteristics are reported in Table 5.3. The median age was 41.6 years (IQR 32.5-53.0; range 25-59). Most patients (66.7%) suffered from traumatic SCI, while had spinal cord ischemia (n=1), multiple myeloma compressing spinal cord (n=1), MS characterized by multiple and widespread spinal cord lesions (n=1) and spinal epidural abscess (n=1), probably due to therapy for treating Coronavirus Disease 2019 (COVID-19), a singular case reported in Sampogna et al. (2020).[97] Another case suffered from both neurofibromatosis type 1 compressing spinal cord and a pelvic malignant peripheral nerve sheath tumor (MPNST) with rhabdomyoblastic differentiation (so-called, malignant triton tumor), which was treated with neoadjuvant

chemo-radiotherapy and subsequently managed surgically with en bloc resection of the rectum, coccyx and most sacrum. No tetraplegic people underwent IPP surgery. Indeed, most of them (58.3%) were affected by complete paraplegia. The median length time since SCI was 14.5 years (IQR 7-22.5). The median BMI was 22.6. One third patients were current smokers. As for comorbidities, we observed the following diseases in different patients: favism (n=1), hypertension (n=1), multiple myeloma and psoriasis. Case #12 reported the following diseases: obesity, fatty liver disease, CIU, OSAS, previous VTE, prostate cancer requiring RARP. Most patients (66.7%) reported mild spasticity, controlled by medicines and some of them (33.3%) had a previous history of pressure ulcers. All of them presented an adequate manual dexterity to activate/deactivate IPP. Patients were married and single in 58.3 and 41.7%, respectively.

In Table 5.4 we reported the evaluation of the pelvic autonomic functions.

All patients performed ICs, associated with MRA in 75% cases, that were not sufficient to treat DO in 3 cases, that were addressed years ago to augmentation cystoplasty (n=1) and periodical infiltration of BTX-A into the detrusor wall (n=2). In this way there was a safe videourodynamics evaluation.

The bowel management was based on the use PEG (n=6), digital anorectal stimulation (1), clysma with < 150 ml (n=4) and TAI (n=4). One patient underwent ileostomy (n=1) for pelvic tumor.

All patients were non-responder to PDE5i and ICI with median EHS and IIEF-5 equal to 2 and 5, respectively. All cases had neither significant penile curvature nor Peyronie's disease.

Table 5.3 Baseline characteristics of considered patient population (n=12).

Variables	Values
Age, median (IQR, range) Years	41.6 (32.5-53.0; 25-59)
SCI/D Etiology	
- **Trauma**	7 (58.3%)
- **Vascular**	1 (8.3%)
- **Tumor**	2 (16.7%)
- **MS**	1 (8.3%)
- **Infection**	1 (8.3%)
NLI	
- **T1-S5 AIS A**	7 (58.3%)
- **T1-S5 AIS B-C**	4 (33.3%)
- **L1 AIS D**	1 (8.3%)
Length of SCI/D, median (IQR, range) Years	14.5 (7-22.5; 2-26)
BMI, median (IQR, range) Kg/m^2	22.6 (19.7-25.7; 14.8-31.6)
Current smoker	4 (33.3%)
Comorbidities	
- **Favism**	1 (8.3%)
- **Hypertension**	1 (8.3%)
- **Multiple myeloma**	1 (8.3%)
- **Psoriasis**	1 (8.3%)
- **Fatty liver disease**	1 (8.3%)
- **CIU**	1 (8.3%)
- **Previous VTE**	1 (8.3%)
- **OSAS**	1 (8.3%)
- **Prostate cancer requiring RARP**	1 (8.3%)
Spasticity	
- **None**	4 (33.3%)
- **Mild**	8 (66.7%)
Previous pressure ulcers	4 (33.3%)
Adequate manual dexterity	12 (100%)
Marital status	
- **Single / Married**	5 (41.7%) / 7 (58.3%)

Table 5.4 Evaluation of bladder, bowel and sexual management of patients enrolled.

Variables	Values
Bladder management	
- **IC**	12 (100%)
- **MRA**	9 (75%)
- **Augmentation cystoplasty**	1 (8.3%)
- **BTX-A injections into the detrusor wall**	2 (16.7%)
Videourodynamics	
- **DO with filling > 400 ml**	5 (41.7%)
- **Absence of VUR and reduced compliance**	12 (100%)
Bowel management	
- **PEG**	6 (50%)
- **Digital anorectal stimulation**	1 (8.3%)
- **Clysma, < 150 mL**	4 (33.4%)
- **TAI**	4 (33.4%)
- **Ileostomy**	1 (8.3%)
IIEF-5, median (IQR, range)	5 (4.25-8; 0-11)
EHS	2 (2-2; 1-2)
Penile curvature ≥ 30°	None
Peyronie's Disease	None

5.3 Peri-operative data and hospital stay

All cases were admitted to hospital the day before the surgery to start antimicrobial extended prophylaxis that continued through POD 1.

Median post-operative LOS was 3 days (IQR 3-7) as reported in Table 5.5. In selected patients, admission was extended up to 7 days until IUC removal to facilitate bladder and bowel management at home when caregiver support was absent or logistics were challenging. Operating theatre standards included use of dedicated clean rooms, avoidance of trauma theatres and minimization of intra-operative traffic.

Table 5.5 Intra-operative data concerning the surgical procedures of the patients enrolled int the study.

Variables	Values
Penoscrotal approach	12 (100%)
OT, median (IQR, range) min	115 (104-135; 90-150)
Reservoir placement - **Retropubic** - **Lateral ectopic**	 10 (83.3%) 2 (16.7%)
Length of cylinders cm - **Right** - **Left** - **Asymmetry (≤ 1 cm)**	 19 (17-20; 17-21) 19 (17-19.5; 16-21) 4 (33.3%)
Wilson's Maneuver	None
Intra-operative complications	None
Admission-to-discharge LOS	4 (4-8; 4-23)
Post-operative LOS	3 (3-7; 3-22)

5.4 Key adverse events

After a median follow-up of 16 months (IQR: 14-20 months; range: 12-24 months), one out of 12 (8.3%) patient underwent an attempted salvage procedure for persistent wound dehiscence and ultimately required IPP explantation at 6 months.

One case in this series developed a sacral pressure injury after an unusually prolonged waiting time before entering the operating room due to organizational issues. This event increased length of stay from the typical 3 days to 22 days. This case emphasized the importance of maintaining SCI/D patients on appropriate pressure-relief surfaces during transport, pre-op waiting and intra-operative positioning.

The twelfth patient experienced several issues. To start with, he experienced a suspected allergic reaction to cefazolin pre-operatively, prompting a switch to

vancomycin, that was discontinued on post-operative day 1 due to diarrhea as a precaution. He was discharged on the 3rd POD. At 14 days, the patient presented with scrotal wound dehiscence localized over the pump button region. A partial salvage procedure was performed following immediate extensive washout principles of Mulcahy-type protocol, without placing any semirigid IPP and administering IV antibiotic coverage, including Dalbavancin 1,500 mg.[69] Wound healing was challenging and multiple advanced dressings were trialed, including dialkylcarbamoyl chloride coated antimicrobial dressing systems, hydrofiber dressings with ionic silver and chelators, polyabsorbent fiber dressings containing silver and enzyme-based antimicrobial hydrogels. Photobiomodulation was used as an adjunct as well.

After a period of closure, the wound slowly reopened at a separate point over the pump region. The patient was never critically ill with neither fever nor increased spasticity. Explantation was recommended given the risk of occult chronic infection, erosion or biofilm-driven persistence, but the patient initially refused after counseling. A final attempt at wound closure was made with one-week strict bed rest; the wound remained closed at early follow-up, but it reopened and, considering recurrence and risk profile, explantation was performed 6 months after implantation.

After explantation, the hospital stay was complicated by hyperpyrexia on POD 1, prompting escalation from vancomycin/gentamicin to ertapenem for 7 days. Linezolid was initiated but stopped after 3 days due to suspected allergy. The patient, with chronic idiopathic urticaria, developed multiple allergic-type reactions managed with cetirizine. Multiple wound swabs (including intra-operative samples) remained negative.

5.5 Functional outcomes and patient experience

The functional outcomes were collected for all patients except for case #12, as he was never able to complete a full functional evaluation due to surgical wound complications.

Bladder-related QoL remained stable overall: SF-Qualiveen (Table 5.6 and Fig. 5.4), both total and domain scores (Bother with limitations, Fears, Feelings and Frequency), together with ICIQ-UI (Table 5.7 and Fig. 5.5) did not show significant change over time on Friedman testing.

Importantly, patients reported easier IC after implantation (Table 5.8 and Fig. 5.6: the IC ease-of-insertion score improved from median 7 (pre) to 9 (post) (Wilcoxon p=0.006).

NBD score remained stable (Friedman p=0.499) as reported in Table 5.9 and Fig. 5.7. MENTOR Tool remained always “green” or “yellow” during post-operative period, so that no patients required significant change in bowel management.

IPP activation occurred after 4 weeks with structured training for safe pump handling. After surgery, among evaluable patients (n=11), all reported ability to have penetrative intercourse without significant limitations in contrast to pre-operative condition.

Median satisfaction (Table 5.10 and Fig. 5.8) remained high across time points (median 9/10 from 4 weeks to 12 months; Friedman p=0.698) and recommendation scores (Table 5.11 and Fig. 5.9) were similarly high (median 9-10/10; Friedman p=0.817).

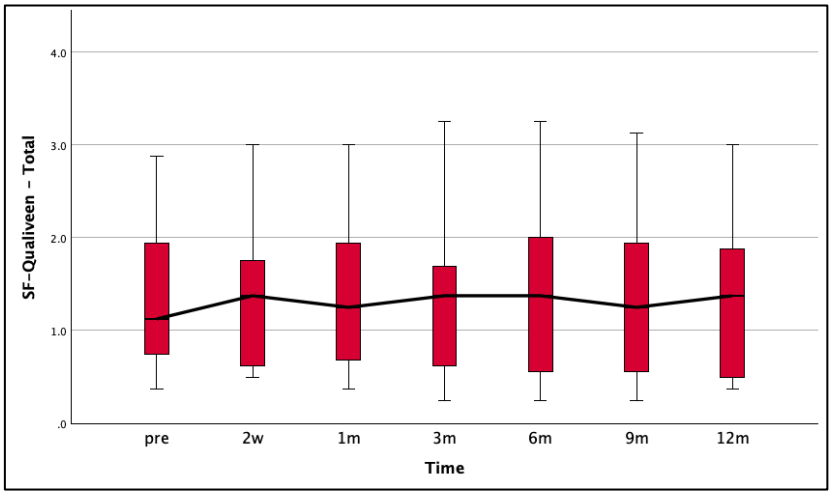
QoLSPP (available from 3 months onward) remained stable through 12 months for the total score and all domains (Functional, Relational, Social, Personal) as reported in Table 5.12 and Fig. 5.10.

Table 5.6 Longitudinal patient-reported outcomes estimating urinary through the SF-Qualiveen total and domain scores.

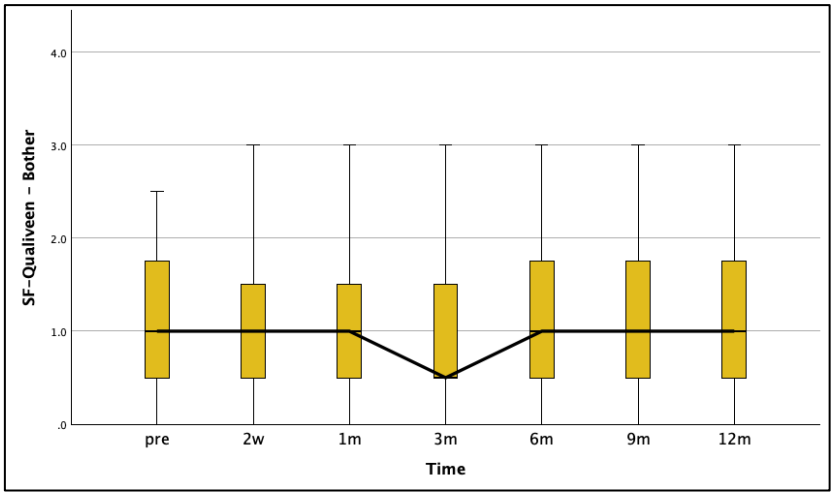
Item	**Pre-Op** Median (IQR)	**2 weeks** Median (IQR)	**1 month** Median (IQR)	**3 months** Median (IQR)	**6 months** Median (IQR)	**9 months** Median (IQR)	**12 months** Median (IQR)	**p value**
SF-Qualiveen – Total (0-4)	1.12 (0.75-1.94)	1.38 (0.62-1.75)	1.25 (0.69-1.94)	1.38 (0.62-1.69)	1.38 (0.56-2)	1.25 (0.56-1.94)	1.38 (0.5-1.88)	0.988
SF-Qualiveen – Bother domain (0-4)	1 (0.5-1.75)	1 (0.5-1.5)	1 (0.5-1.5)	0.5 (0.5-1.5)	1 (0.5-1.75)	1 (0.5-1.75)	1 (0.5-1.75)	0.642
SF-Qualiveen – Fears domain (0-4)	1 (0.5-2)	1.5 (0.75-2)	1 (0.5-2.25)	1 (0.75-2)	1 (0.5-2)	1 (0.75-1.5)	1.5 (0.75-1.5)	0.885
SF-Qualiveen – Feelings domain (0-4)	1 (0.25-1.5)	0.5 (0.5-2)	1 (0.25-2)	0.5 (0.5-2)	1.5 (0.25-1.5)	1.5 (0.5-2)	1 (0.5-2)	0.749
SF-Qualiveen – Frequency domain (0-4)	2.5 (1.5-3)	2 (1.25-2.75)	2 (1.25-2.75)	2 (1-3)	2 (1-3)	2 (1-3)	2 (1-2.75)	0.302

Figure 5.4 Box-and-whisker plots of SF-Qualiveen scores from pre-intervention to post-intervention follow-up. The figure displays the distribution of the SF-Qualiveen Total score (A) and domain scores, Bother with limitations (B), Fears (C), Feelings (D) and Frequency of limitations (E), assessed before the intervention and at follow-up visits up to 12 months. Boxes represent the IQR, the horizontal line within each box indicates the median and whiskers denote the spread of the data (outliers shown where applicable). A connected line overlays the boxplots to highlight changes in the median score over time.

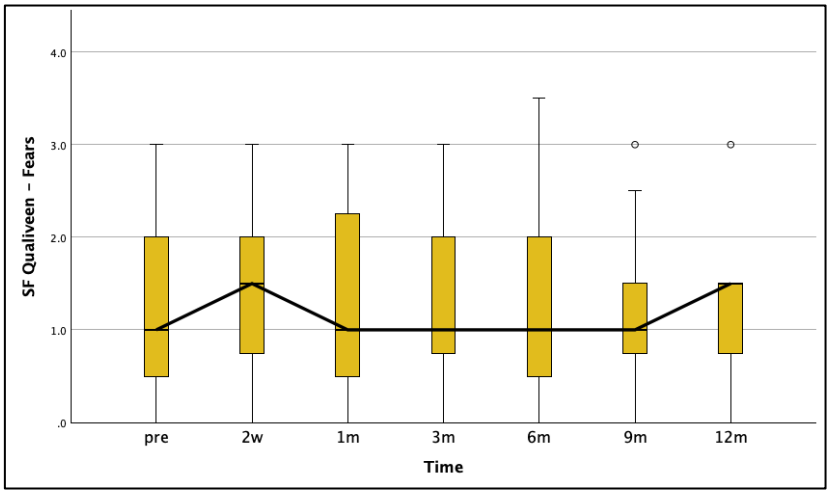
A. SQ-Qualiveen – Total



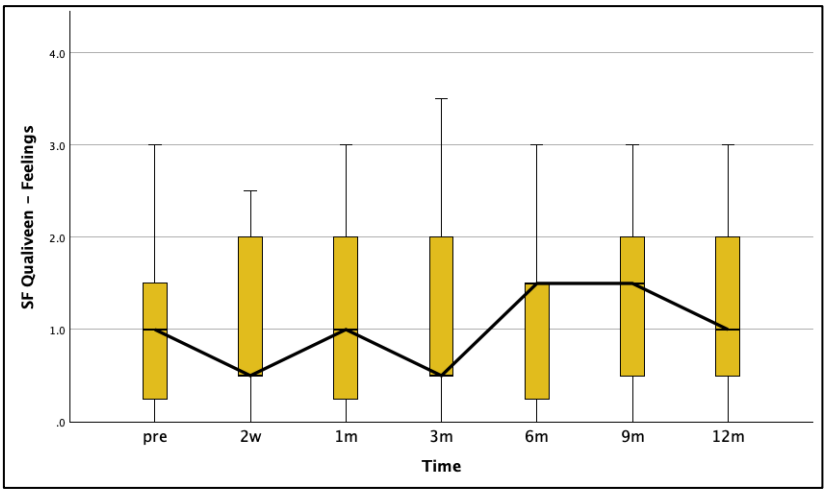
B. SQ-Qualiveen – Bother with limitations



C. SQ-Qualiveen – Fears



D. SQ-Qualiveen – Feelings



E. SQ-Qualiveen – Frequency of limitations

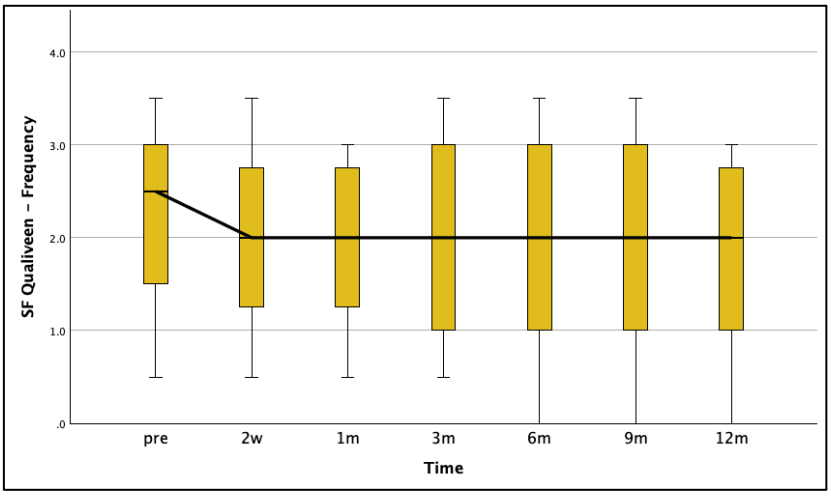


Table 5.7 Longitudinal patient-reported outcomes estimating UI through the ICIQ-UI SF.

Item	Pre-Op Median (IQR)	2 weeks Median (IQR)	1 month Median (IQR)	3 months Median (IQR)	6 months Median (IQR)	9 months Median (IQR)	12 months Median (IQR)	p value
ICIQ-UI SF (0-21)	6 (1-7)	6 (2-8.5)	3 (2-5.75)	4 (2-9)	4 (1.5-9.5)	6 (2-8.5)	5 (2-7)	0.392

Figure 5.5 Box-and-whisker plots showing the distribution of ICIQ-UI SF scores at each follow-up time point from pre-operative situation to month #12. The central line within each box indicates the median and the box represents the IQR. The whiskers show the spread of the data. A connected median line is overlaid to highlight changes in the median ICIQ-UI SF score across time.

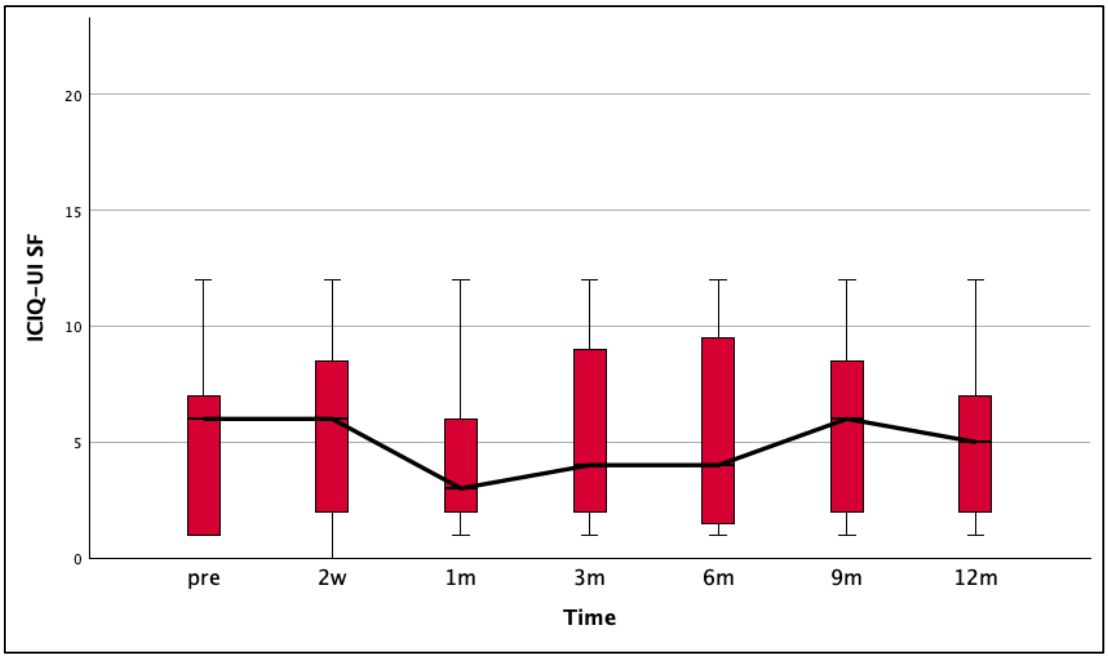


Table 5.8 Catheter insertion ease score pre and post IPP surgery.

Item	Pre-IPP Median (IQR)	Post-IPP Median (IQR)	p value
Catheter Insertion Ease Score (1-10)	7 (7-7.5)	9 (8.5-10)	0.006

Figure 5.6 Box-and-whisker plot of catheter insertion ease score: pre vs post IPP surgery

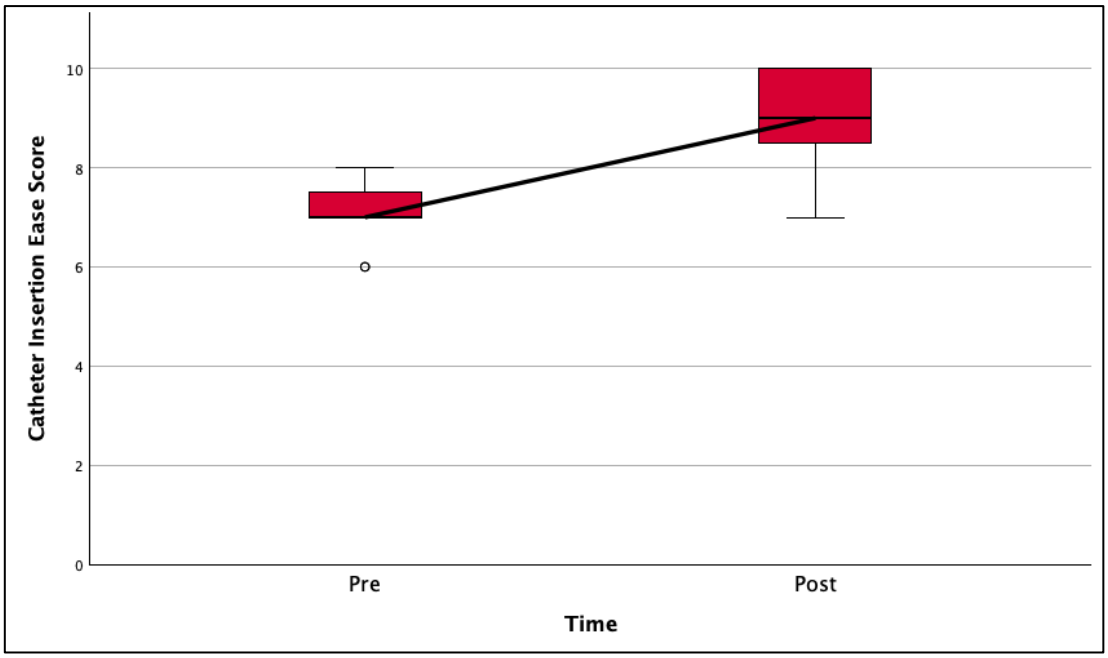


Table 5.9 Longitudinal patient-reported outcomes estimating bowel dysfunction through the NBD scores.

Item	Pre-Op Median (IQR)	2 weeks Median (IQR)	1 month Median (IQR)	3 months Median (IQR)	6 months Median (IQR)	9 months Median (IQR)	12 months Median (IQR)	p value
NBD score (0-47)	12 (10.5-13.5)	13 (10.5-15.5)	12 (9.5-13.5)	13 (11.5-15)	13 (10-15)	12 (10.5-15)	13 (11-15)	0.499

Figure 5.7 Box-and-whisker plots showing the distribution of NBD scores at each follow-up time point from pre-operative situation to month #12. The central line within each box indicates the median and the box represents the IQR; the whiskers show the spread of the data. A connected median line is overlaid to highlight changes in the median NBD score across time.

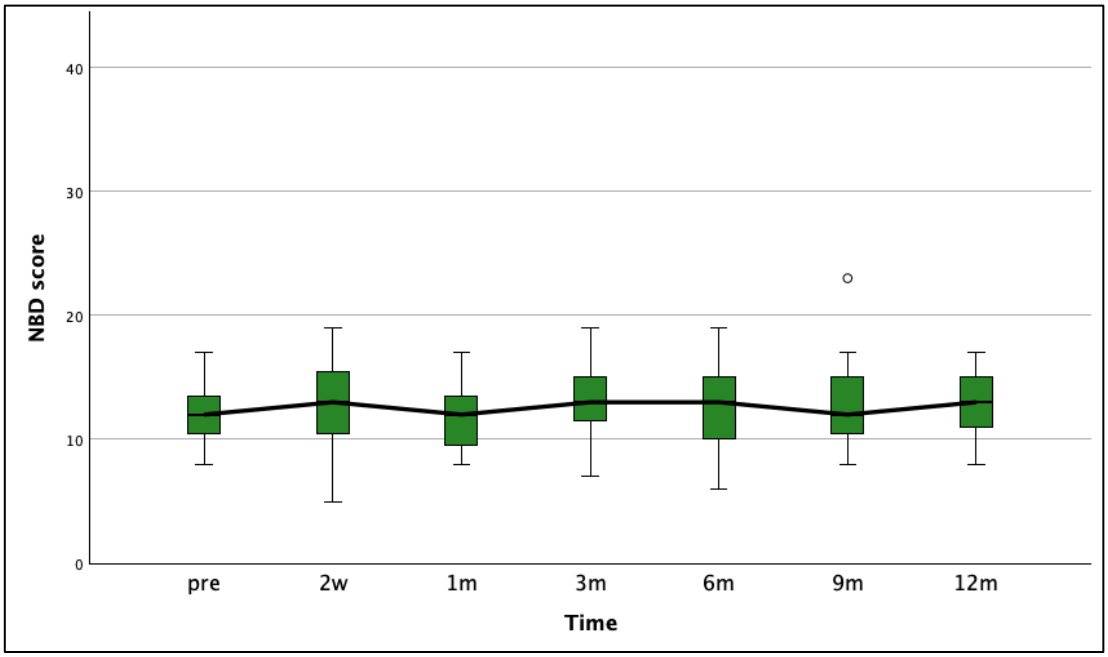


Table 5.10 Longitudinal patient-reported outcomes estimating patients' satisfaction according to Likert scale.

Item	1 month Median (IQR)	3 months Median (IQR)	6 months Median (IQR)	9 months Median (IQR)	12 months Median (IQR)	P value
Satisfaction (1-10)	9 (9-10)	9 (8-9.5)	9 (9-10)	9 (8.5-10)	9 (8.5-10)	0.698

Figure 5.8 Box-and-whisker plots showing the distribution of satisfaction scores at each follow-up time point (1, 3, 6, 9 and 12 months). The central line within each box indicates the median and the box represents the IQR; the whiskers show the spread of the data. A connected median line is overlaid to highlight changes in the median satisfaction score across time.

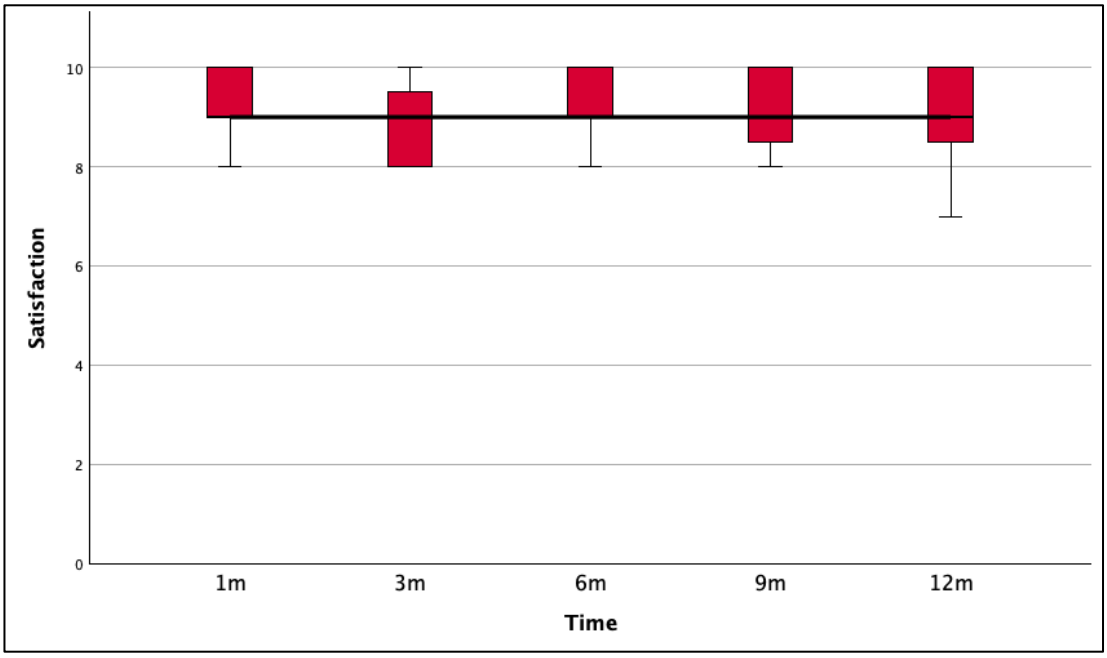


Table 5.11 Longitudinal patient-reported outcomes estimating patients' recommendation according to Likert scale.

Item	1 month Median (IQR)	3 months Median (IQR)	6 months Median (IQR)	9 months Median (IQR)	12 months Median (IQR)	P value
Recommendation (1-10)	9 (8.5-10)	9 (9-10)	10 (9-10)	9 (8.5-10)	10 (9-10)	0.817

Figure 5.9 Box-and-whisker plots showing the distribution of recommendation scores at each follow-up time point (1, 3, 6, 9 and 12 months). The central line within each box indicates the median and the box represents the IQR; the whiskers show the spread of the data. A connected median line is overlaid to highlight changes in the median recommendation score across time.

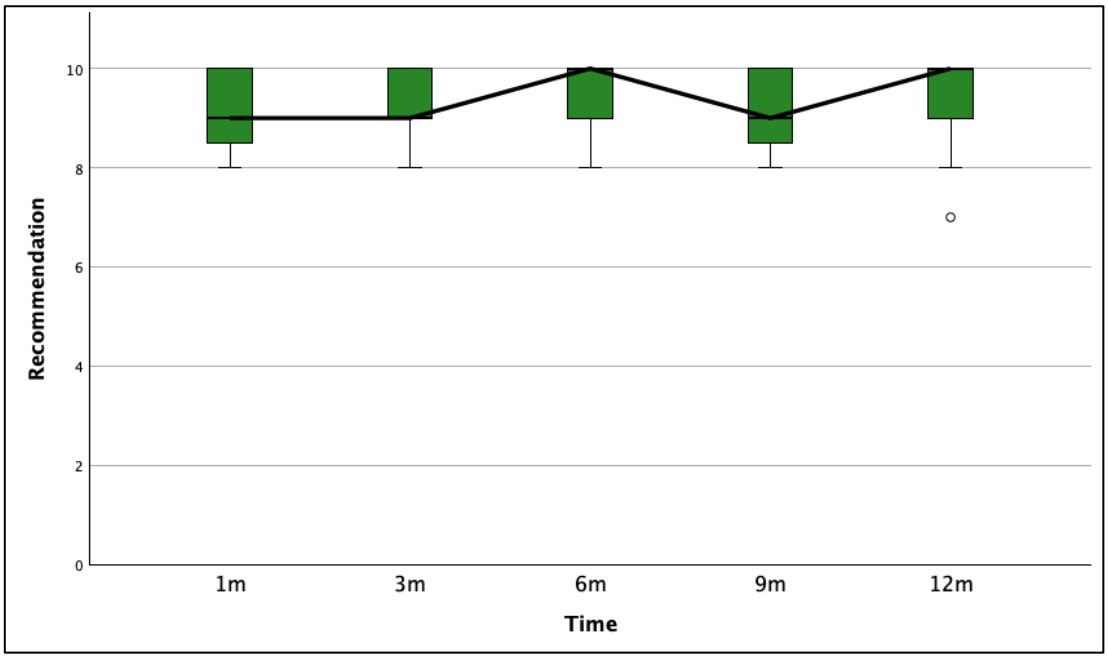
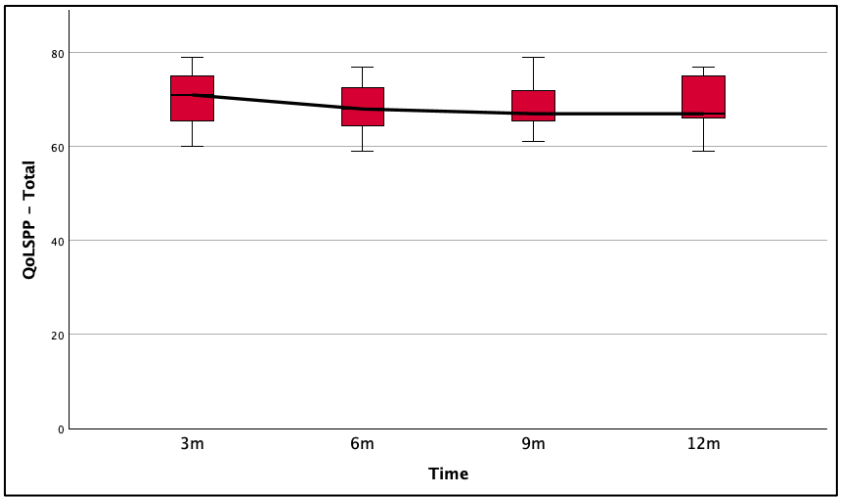


Table 5.12 Longitudinal patient-reported outcomes estimating the QoLSPP total and domain scores through the follow-up period.

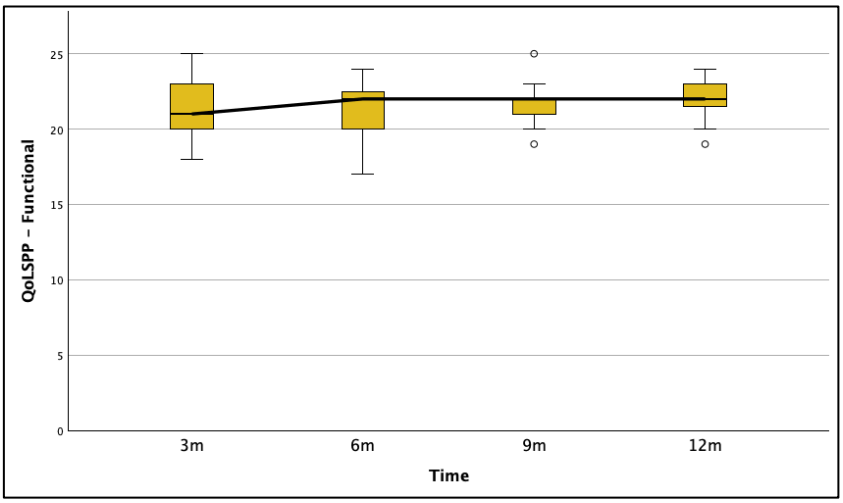
Item	**3 months** Median (IQR)	**6 months** Median (IQR)	**9 months** Median (IQR)	**12 months** Median (IQR)	**P value**
QoLSPP Total (0-80)	71 (65.5-75)	68 (64.5-72.5)	67 (65.5-72)	67 (66-75)	0.359
QoLSPP Functional Domain (0-25)	21 (20-23)	22 (20-22.5)	22 (21-22)	22 (21.5-23)	0.782
QoLSPP Relational Domain (0-20)	18 (16-20)	17 (16-18)	17 (16-18.5)	16 (16-19)	0.630
QoLSPP Social Domain (0-15)	13 (11.5-14.5)	12 (11.5-14)	12 (12-14.5)	12 (12-14.5)	0.967
QoLSPP Personal Domain (0-20)	18 (16-20)	17 (16-20)	17 (16-20)	17 (16-19.5)	0.592

Figure 5.10 Box-and-whisker plots of QoLSPP scores from pre-intervention to post-intervention follow-up. The figure displays the distribution of the QoLSPP Total score (A) and domain/subscale scores: Functional (B), Personal (C), Relational (D) and Social (E). Boxes represent the IQR, the horizontal line within each box indicates the median and whiskers denote the spread of the data (outliers shown where applicable). A connected line overlays the boxplots to highlight changes in the median score over time.

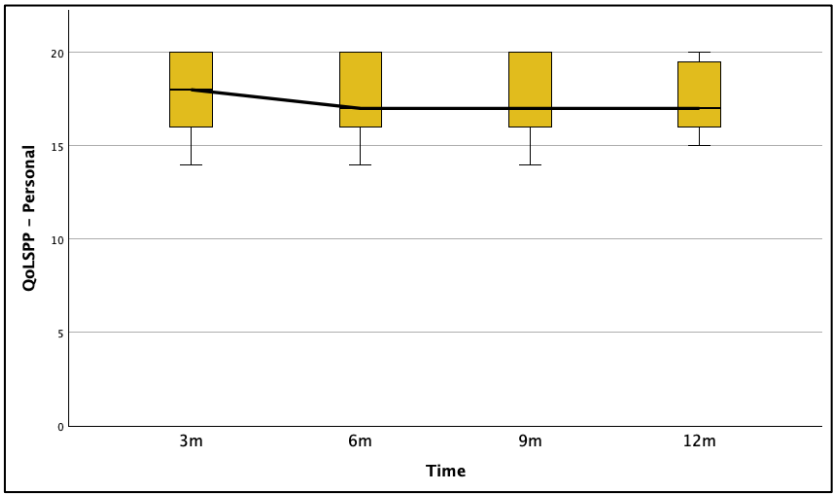
A. QoLSPP – Total



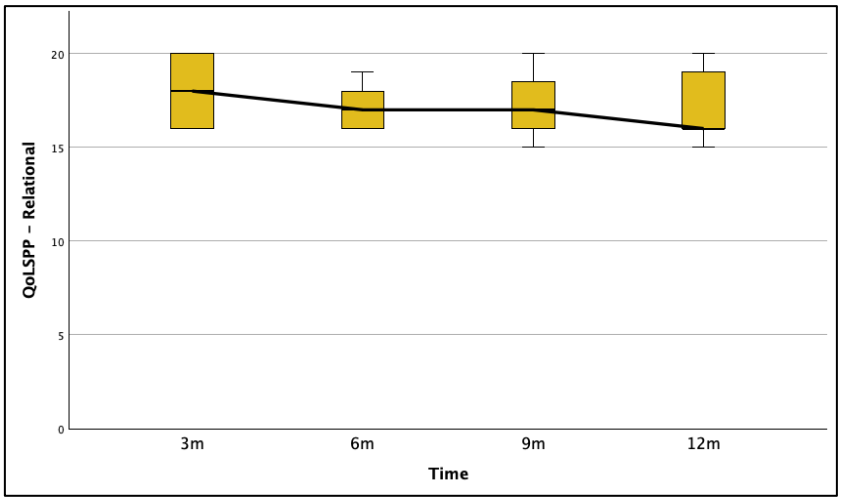
B. QoLSPP – Functional



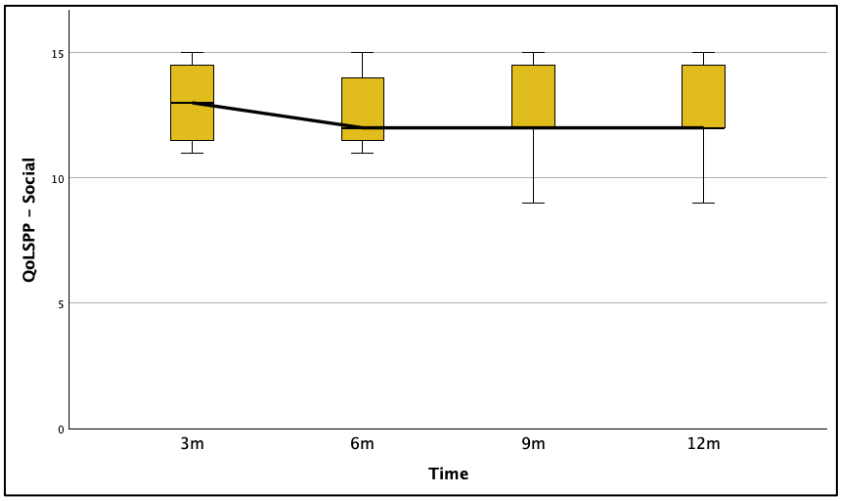
C. QoLSPP – Personal



D. QoLSPP – Relational



E. QoLSPP – Social



5.6 Risk mitigation plan

The study workflow was translated into a pragmatic decision tool for urologists interested in IPP surgery in people with SCI/D. The workflow was designed to prevent the main complications in the frail population represented by people with SCI/D: infection, erosion/extrusion, pressure injury, AD and functional non-use. In Appendix there is a table summarizing all the following issues to adopt in routine clinical practice.

5.6.1 Pre-operative evaluation

- Goal alignment between patient and surgeon: confirm ED refractory to conservative therapies; clarify priorities (penetration, intimacy, possible alterations of bladder and bowel management even if IPP usually facilitates catheterization, body image).
- SCI phenotyping: neurological level, AIS grade, residual genital sensation, history of autonomic dysreflexia, spasticity triggers, hand function assessment.
- Bladder: appropriate bladder management according to recent guidelines; treat symptomatic bacteriuria; address possible NLUTD complications; ensure urodynamic safety (avoid uncontrolled high-pressure storage and/or VUR); screen for pelvic cancer to reduce the risk of a new pelvic surgery with possible reservoir infection.
- Bowel: MENTOR tool should be green-light; bowel diary shows predictable evacuation; treat constipation; consider TAI when needed; confirm bowel emptying pre-op when in doubt.

- Skin/pressure plan: seating assessment; ensure appropriate cushions; plan peri-op pressure-relief surfaces for transport, reduce the waiting time for patient transfers or positioning and early post-op.
- Microbiology and antibiotics: urine culture + rectal swab; involve infectious disease specialist; plan extended prophylaxis (including antifungal when local epidemiology warrants); plan device immersion in the antimicrobial solution selected with the support from infectious disease specialists.
- Spasticity: optimize antispastic regimen; ensure peri-op pain control.
- Autonomic dysreflexia: educate staff on recognizing and treating AD signs and/or symptoms; avoid triggers (e.g., bladder and/or bowel distension).
- Rehab and usability: occupational therapy plan for pump manipulation; partner/caregiver training if appropriate; evaluation of posture and wheelchair to reduce the risks of pressure at the level of the scrotal pump.
- Consent: discuss legacy risk narratives but explain modern pathway; explicitly counsel about salvage and explantation scenarios; inform about penile length reduction.

5.6.2 Intra-operative measures

- Use dedicated clean theatres; avoid trauma theatres; minimize room traffic.
- Strict sterile field; limit device exposure time; consider “no-touch” concepts.
- Meticulous hemostasis to reduce hematoma risk.
- Gentle urethral manipulation; maintain urethral catheter for ≥7 days post-op to protect early healing, after one week remove it as soon as possible to reduce the risk of infections according to patients’ clinical conditions.

- Document device model, sizes, reservoir placement and any deviations.

5.6.3 Post-operative and follow-up

- Aseptic catheter care; plan catheter removal at 7-10 days (trade-off: urethral protection vs infection risk).
- Maintain stable bowel routine; prevent constipation; coordinate nursing education and caregiver planning.
- Pressure injury prevention: use open-cell polyurethane foam during transfers/waiting; consider air-fluidized beds for high-risk cases; document positioning schedules.
- Early warning triggers: fever, scrotal swelling, wound separation, new catheterization difficulty, skin changes should be evaluated immediately.
- Activation training after 4 weeks; support from occupational therapists for pump manipulation in case of need; structured PROM collection.

6. Discussion

This thesis evaluates contemporary three-piece IPP implantation in men with SCI/D managed within a dedicated Spinal Unit pathway and contextualizes these outcomes within a broader analysis of referral appropriateness. The Discussion is structured around different themes: how the study results aligns with the existing literature; why outcomes in SCI/D should be interpreted as pathway-dependent; practical implications; limitations; future directions; overall impact.

6.1 Context with the current literature

Compared to the literature, the demographic characteristics of the patients attending our Neuro-Urology outpatient clinic were similar to multicenter prospective observational study described by Franceschini et al (2020).[61] Indeed, a high percentage of people with tetraplegia, incomplete SCI/D and of middle age was considered.

Only a small percentage (23.2%) was addressed to IPP surgery highlighting the strict enrollment protocol. Most candidates did not proceed to implantation due to refusal after counseling and/or unresolved clinical issues requiring optimization before IPP surgery.[98]

The description of IPPs implantation in individuals with SCI/D, together with the risk-mitigation workflow outlined in the study, was deemed worthy of inclusion in the Springer's book "The One Hundred Most Challenging Surgical Procedures," currently in preparation. This recognition reflects both the delicacy of implanting such a device in a clinically frail patient population and the innovative nature of the approach described, which offers a structured pathway to reduce complications and improve surgical safety in this complex setting.[99] Indeed, the study complication rate remained

probably low largely because of strict patient-selection criteria. Compared with the studies reported in the Section 2.3, the considered cohort consisted of paraplegic patients, who had few comorbidities, excellent manual dexterity and often incomplete lesions (AIS B-D). Unfortunately, key aspects related to bladder and bowel management were not detailed in earlier reports, making meaningful comparisons challenging.

In the considered literature, reported safety outcomes varied widely, including infection (0-16%), erosion/perforation (2.1-11.1%) and mechanical failure (0-44.5%), while explantation (2.1-16.7%) and revision/reimplantation (2.7-44.4%) were inconsistently reported across series. Despite this, PROMs were generally favorable: 79.2-92.9% of men were satisfied with their prosthesis and 36-86.1% reported satisfactory sexual intercourse. Additional SCI-focused cohorts further support a meaningful benefit for urinary management: in a 79-patient SCI series aimed at maintaining external condom catheter drainage, 81% cases reported no condom loss accidents after implant.[59] Finally, large neurologic cohorts with substantial SCI representation corroborate long-term effectiveness: in Zermann et al., urinary management problems were resolved in 90.3% and sexual intercourse was possible in 83.7% with infection and perforation rates varied according to device type.[7] Contemporary registry data in neurologic patients by Falcone et al. highlights high satisfaction with modern practice patterns (predominantly IPPs), with an overall satisfaction of 90.7% and device infection requiring explantation in 3%.[58]

6.2 Interpretation of the major findings

6.2.1 The referral-to-implant pathway

A key contribution of this work is that, among a large and heterogeneous group of men assessed for IPP, only a minority ultimately proceeded to implantation. This was due to patient preference and, more commonly, the need for additional evaluation, improvement of other functions (e.g., bladder, bowel) and/or other treatments before prosthetic surgery was considered as appropriate. In this context, selection was a core component of risk reduction in SCI/D.[100]

This finding has practical consequences. It helps explain why many historical series were associated with high complication rates. If referral pathways are poorly filtered, the implanted population can become associated with increased risks (e.g., recurrent UTI, uncontrolled bowel dysfunction, active skin fragility, severe comorbidity burden).[101] This study argues for structured triage and standardized prehabilitation as essential prerequisites for safe prosthetic surgery in SCI/D.

6.2.2 Specialized care

Within the implanted cohort, patient experience was consistently positive. Satisfaction and willingness to recommend remained high over follow-up, while bladder and bowel PROMs were overall stable after surgery. Importantly, many patients reported easier IC after implantation; an outcome that is highly relevant in SCI/D, where day-to-day autonomy often depends on catheterization feasibility. Together, these findings support the concept that IPP implantation can deliver meaningful benefit without systematically altering bladder or bowel management.

The surgical technique may be tailored according to patients' needs. For example, reservoir placement should be tailored: ectopic/high submuscular techniques are appropriate when the retropubic space is hostile or unsafe, including after prior pelvic surgery. In two patients who underwent extensive pelvic surgery, an ectopic reservoir strategy was adopted supporting the broader thesis that technical customization is not a deviation from standard care, but a cornerstone of safe prosthesis surgery in complex patients.[89] Indeed, prior pelvic surgery can obliterate the normal space of Retzius and increase the risk of bladder or vascular injury during retropubic reservoir placement.

A meta-analysis by Tienforti considering 18 studies, providing information on 1079 implantation procedures, determined a pooled PP infection rate of 8.0% (95% CI: 5.0-11.0%), with significant heterogeneity ($I^2 = 67.0\%$).[102] The heterogeneity is crucial to understand the previous considerations on PP surgery in SCI/D. Actually, this population is significantly varied and according to patient-specific characteristics the risk may be increased versus decreased. The infection rate was higher for IPPs than for malleable PPs (16.4% vs 8.9%, $p = 0.027$), but semirigid cylinders could be associated with increased risk of erosions/extrusions for constant gland pressure and urethral trauma in people without sensitivity and performing ICs.

6.3 Factors affecting outcomes

6.3.1 The role of a Spinal Unit

This study supports a reframing of IPP implantation in SCI/D from "discouraged" to "specialized but feasible" when delivered through a defined workflow that reduces the risks.[103] Therefore, the contribution is the development of a replicable pathway that treats risk as modifiable through an optimization plan, protocolized infection-prevention practices and structured post-implant follow-up integrated with rehabilitation and nursing expertise.

Historically, many cohorts included older device generations, variable antimicrobial approaches and a high prevalence of complex indications.[104] In addition, neurogenic patients face distinct mechanisms of harm: reduced genital sensation and mobility (leading to unrecognized pressure or friction), catheter-related urethral trauma, higher baseline colonization burden, greater comorbidity and prior pelvic surgery. These features demand a setting where the pathway can be managed in the appropriate way: a tertiary Spinal Unit rather than a generic surgical environment is the ideal one.

6.3.2 The bladder-bowel axis

The bladder-bowel axis is a practical target for infection prevention. Constipation and unpredictable evacuation can worsen urinary emptying and IC conditions, increase perineal contamination and promote urinary colonization and symptomatic UTI episodes. Because prosthesis infection is typically mediated by contamination followed by biofilm formation, recurrent UTIs and unstable bowel management become downstream threats to implant survival. In this cohort, bowel stabilization was therefore treated as a prerequisite and the overall stability of urinary and bowel

PROMs over follow-up is consistent with the hypothesis that enforcing pre-operative stability reduces post-operative destabilization.

6.3.3 Bladder management and intradetrusor BTX-A

A distinctive element of this study is the research for optimal bladder management as a peri-prosthetic strategy. In selected patients, intradetrusor BTX-A was used before implantation to stabilize storage pressures, reduce leakage and improve catheterization conditions to reduce contamination risk and catheter-associated microtrauma. Because toxin effects are time-limited, repeated injections were performed in two cases during follow-up requiring procedural discipline to avoid urethral trauma in a vulnerable population. Performing these interventions within the same specialized team improves safety.

6.3.4 Bowel management and transanal irrigation

Many prosthetic series do not report bowel management. In SCI/D, this omission can obscure an important mediator of early wound vulnerability and infection risk. In this cohort, initiating or revising TAI pre-operatively was used as a deliberate stabilizing intervention to reduce accidents and protect early wound healing. Bowel stability is reasonably linked to implant safety and is central to pathway reproducibility. In our study, MENTOR tool was an easy-to-use tool to monitor the treatment of NBD through the final result according to a “traffic light” (green/yellow/red) to determine any need for treatment changes.[74]

6.4 Beyond the operative field

6.4.1 Operating-room logistics

In prosthetic surgery, small differences in environmental control may translate into meaningful differences in contamination risk. Beyond IV antimicrobial choice, complication prevention measures in prosthetic urology consistently emphasize: meticulous hair removal and skin preparation; minimizing operating-room traffic; strict glove/gown changes after draping; “no-touch” handling of implant components; antibiotic dip protocols for device soaking; early recognition of wound complications with consideration of salvage when appropriate.[84,105] This matters in SCI/D because of multiple vulnerabilities, like colonization burden, catheter dependence, reduced sensation and tissue fragility.

6.4.2 Pressure-injury prevention

The pressure injury observed in the cohort illustrates a central principle. Prolonged waiting times, transfers and positioning can generate clinically consequential pressure lesions that prolong hospitalization and intensify care. This supports a practical recommendation: pressure-relief surfaces and protocols should be mandatory across the peri-operative journey (transport, holding areas, theatre positioning and recovery) and waiting time should be explicitly addressed as a safety variable.[85]

6.4.3 Safe discharge

The median LOS was compatible with a streamlined pathway, but selective extension was sometimes ethically and clinically justified. In SCI/D, discharge readiness includes stable bowel routine, safe catheter management, caregiver availability and

pressure-relief capacity at home. Extending admission until IUC removal and wound closure are completed can reduce the transfer of risk from hospital to home.

6.4.4 The catheter trade-off

Catheter management in SCI/D requires explicit trade-offs. A period of IUC can protect healing tissues and reduce early urethral trauma before resuming IC, but prolonged indwelling catheter exposure increases bacteriuria and UTI risk. This study considers catheter management as a balance between healing and catheter-related risk. Moreover, it highlights the role of post-implant IC reassessment (e.g., catheter type and size, lubrication, hand positioning) as an important step in reducing urethral microtrauma and secondary infection.

6.4.5 Antimicrobial strategy

The antimicrobial plan in this cohort was intentionally aggressive, designed in collaboration with infectious disease specialists to account for local resistance patterns and the catastrophic consequences of device infection. Adjunctive antifungal coverage was included to address the emerging recognition of fungal prosthesis infections in selected contexts and device soaking operationalized a multi-layered barrier approach.[79,80] At the same time, antibiotic stewardship remains essential. The goal should be maximal risk reduction with minimal unnecessary exposure: prophylaxis should be periodically re-evaluated against institutional epidemiology and outcomes.[106] This study proposes a dynamic approach: extended prophylaxis should be protocolized but not static, incorporating surveillance data, colonization patterns and prospective outcome monitoring.

6.5 Case #12: complication mechanisms

Case #12 carried a substantial comorbidity burden with a CCI of 6: obesity, fatty liver disease, OSAS, CIU, prior VTE, prostate cancer treated with RARP besides SCI. All these conditions underscored severe baseline vulnerability. In such a phenotype, adverse outcomes may emerge despite stringent pre-operative selection because multiple interacting domains (metabolic/inflammatory status, tissue perfusion, mechanical stress) converge to destabilize wound integrity around prosthesis.

Following international consensus practice to reassess UI at ≥12 months after prostatectomy, the patient was re-evaluated approximately one year later. The urodynamic testing demonstrated mild-moderate UI. During counseling, it was explicitly discussed that reservoir placement could potentially precipitate or unmask UI episodes and that additional continence procedures might become necessary; despite this, the patient confirmed to proceed.

Given the patient's markedly high-risk profile, a thorough pre-operative counseling process was undertaken. Nevertheless, he remained strongly motivated to proceed and explicitly accepted the associated risks. As for pre-operative testing, it was reassuring, including safe VUD, MENTOR tool = green/yellow, no serious spasticity, no sitting problems.

However, the clinical course was characterized by several issues: suspected peri-operative beta-lactam allergy requiring antibiotic modification, early scrotal wound dehiscence over the pump region, an attempted salvage strategy, recurrent wound breakdown despite advanced wound care and eventual explantation at approximately six months. This trajectory is clinically important because repeated superficial compromise overlying device components represents a recognized warning pattern in

prosthetic surgery. Even in the absence of systemic toxicity, persistent or recurrent breakdown increases the likelihood of erosion and progression to overt infection justifying definitive explantation to prevent device-related complications.

Repeated negative cultures reduced the probability of infection. Standard superficial swabs may fail to detect low-grade biofilm-associated infection, particularly when antibiotics have been administered, as sampling is non-deep, organisms require prolonged incubation or bacterial burden is within the fibrous capsule. Contemporary device-infection literature emphasizes that delayed presentations may be driven by less virulent skin flora (e.g., coagulase-negative staphylococci) within biofilm, where organisms are protected from immune clearance and may be intermittently shed, producing negative cultures.[67,84,105] In this context, Mulcahy-style salvage can transiently control the process in up to 93%; however, recurrent tissue compromise around the prosthesis should prompt early reassessment and definitive removal when durable soft-tissue coverage cannot be maintained.[70]

In parallel, Case #12 plausibly reflects an exaggerated or dysregulated host response. True hypersensitivity to implant materials is considered uncommon, but it is reported and the patient's history of CIU increases biological plausibility for an inflammatory environment that could impair local wound stability. Importantly, this does not imply a systemic "allergy to the implant"; rather, it raises the possibility that local inflammatory reactivity, potentially compounded by peri-operative antibiotic intolerance and subsequent antimicrobial changes, may have contributed to delayed dehiscence and recurrent superficial breakdown in the absence of clear microbiological confirmation. From a diagnostic standpoint, the literature cautions against reassurance

from negative cultures; clinicians should integrate timing, local tissue behavior, response to interventions and objective inflammatory markers into their reasoning.

Notably, anticoagulation may have acted as an enabling factor for wound failure. While apixaban is not typically described as directly impairing wound healing biology, anticoagulation increases the risk of post-operative bleeding. This can stress incision lines, reduce local perfusion and create a permissive microenvironment for bacterial colonization. In a patient with obesity (increasing pressure over the pump region) and a history of VTE (often necessitating anticoagulation), even subclinical micro-bleeding can contribute to iterative tissue breakdown.

Future work could reduce diagnostic ambiguity by applying enhanced microbiological and pathological methods in similar cases, including deep tissue sampling, prolonged incubation protocols, sonication of explanted components to disrupt biofilm and histopathological assessment to distinguish infection-provoked inflammation from hypersensitivity-pattern inflammation. Overall, Case #12 highlights that in patients with severe comorbidity, recurrent wound compromise over prosthetic material should be treated as a high-risk signal and definitive explantation may be the most defensible strategy even when routine cultures remain negative.

Finally, it is notable that serious infectious complications have been described in this patient in other clinical contexts, including a singular report of spinal epidural abscess associated with therapies used for Coronavirus Disease 2019 (COVID-19).[97] While not directly linked to the present prosthetic course, such observations reinforce a broader principle relevant to high-comorbidity patients: immunomodulatory exposures, antibiotic variations and systemic inflammatory states may increase susceptibility to indolent infection

6.6 Implications for referral appropriateness

Slow recruitment and discouragement by external clinicians reflect an important gap: historical complication rates can function as barriers to care and may prevent specialist assessment in candidates who could benefit from modern practice. The high proportion of inappropriate referrals and pathway drop-out further supports the need for structured triage and consistent counseling between community care and tertiary centers.

SCI/D-RAPPS is best interpreted as a referral-support tool. Its value lies in improving referral quality, prioritizing evaluations and aligning expectations early, so that tertiary resources are concentrated on candidates most likely to benefit from a straight pathway for IPP implant.

Although non-penetrative sexuality can be satisfying, many men articulate penetrative intercourse as a core personal goal linked to "normality" and relationship identity.[107] Recognizing this need aligns shared decision-making with what patients actually value.

As for counseling, in a multicenter series of 253 patients undergoing PP surgery from Italy and Germany, outside the SCI population, overall satisfaction was high, but mechanical failures (9%) and erosions (6.5%) remained clinically relevant, underscoring the importance of expectation management and long-term follow-up.[108] International recommendations also stress that pre-operative counseling should explicitly address device handling, realistic penile length expectations and the need for periodic inflation (cycling) to preserve tissue compliance and reduce functional decline over time.[84]

6.7 Limitations of the study

This work should be interpreted considering several limitations. First, the cohort is small and derived from a single, highly specialized Spinal Unit. Although this is precisely the environment in which bladder, bowel, skin integrity, spasticity and caregiver needs can be properly evaluated and managed, the external validity of this workflow cannot be assumed for centers lacking comparable neuro-urology, rehabilitation, nursing and other specialist support. Second, the study design is observational and lacks a comparator group. Therefore, causal statements about the effect of the pre-surgical optimization plan or the antimicrobial protocol cannot be made. Third, the strict eligibility criteria, while ethically necessary in a frail population, introduce selection effects that may underestimate complication rates seen in less controlled real-world practice and simultaneously limit insight into how to safely expand eligibility. Fourth, follow-up duration remains relatively limited for mechanical survival analyses. Indeed, cycling adherence and long-term component failure require multi-year observation. Fifth, several endpoints are patient-reported and susceptible to reporting bias, particularly in a setting where extensive counseling and close clinical relationships may influence responses. Finally, the antimicrobial strategy is grounded in local epidemiology and contemporary infection literature, but it may not generalize across resistance settings. The reproducibility will require context-specific stewardship rather than simple protocol replication.

6.8 Future directions

Future research should move beyond simply asking whether IPP surgery is safe in SCI/D and focus on which pre-, intra-, and post-operative measures may affect the clinical outcomes. A multicenter prospective registry considering neurologic population could quantify how baseline sexual reflex potential, bladder regimen, bowel regimen, spasticity, caregiver support and prior pelvic surgery interact with device outcomes and satisfaction. In parallel, microbiology-focused work should address why some patients manifest recurrent wound problems with negative cultures. This should be performed through standardized sampling, extended culture protocols, molecular diagnostics, systematic reporting of antimicrobial exposures and adverse reactions. Randomized trials are unlikely to be feasible at the single-center level, but comparative-effectiveness studies (e.g., optimized approach versus usual care; standard prophylaxis versus extended and stewardship-structured regimen) may be achievable through collaborative networks. Finally, health-economic analyses and patient-partner qualitative studies are mandatory to investigate relationship outcomes and autonomy in self-care routines.[2,33]

6.9 Impact of the study

The principal impact of this study is a conceptual shift: PP implantation in SCI/D should be considered as the result of a structured optimization pathway, and not as a standalone surgical procedure. Systematic evidence indicates that bowel, bladder and sexual function consistently emerge among the most valued recovery domains for people living with SCI. Therefore, the treatment of sexual dysfunctions is still insufficiently addressed in rehabilitation programs compared to the patient needs. Within this approach, the Niguarda workflow provides a practical aid for surgeons dealing with this population. Indeed, this study outlines a replicable model for safer implementation and more reasonable access by documenting high patient satisfaction, overall stability of bladder/bowel PROMs and practical benefits for IC, besides describing accurately complications and the referral appropriateness. If validated across centers, this model could improve referral pathways and expand access to a therapy that many patients describe as restoring a sense of normality and intimate identity.[2]

7. Conclusions

This prospective single-center work suggests that contemporary three-piece IPP implantation can provide high patient-reported benefit in selected men with SCI/D when delivered within a dedicated Spinal Unit. With this approach, the risk is treated as modifiable through a structured pre-operative optimization, protocolized infection prevention, rehabilitation program and standardized follow-up. Bladder and bowel PROMs remained stable overall highlighting that IPP does not affect the bladder and bowel management. Interestingly, many patients reported easier IC insertion**.** Satisfaction and willingness to recommend were consistently high.

Complications in SCI/D may arise from issues beyond the operative field. A pressure-related event underscored the importance of peri-operative control and pressure-injury prevention, while one explantation highlighted ongoing diagnostic uncertainty in non-healing wounds among highly comorbid patients.

The large proportion of inappropriate referrals and drop-out along the pathway supports SCI/D-RAPPS as a referral-support tool to improve triage and to focus tertiary resources on candidates most likely to benefit from IPPs. At last, this study proposes a replicable risk mitigation plan integrating many challenges of people with SCI (e.g., bladder and bowel management, spasticity control, prevention of pressure ulcers, AD recognition) that could help surgeons to deal with IPP surgery in people with SCI/D to reduce the risks and improve the outcomes.

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9. Appendix

9.1 The PROSTHESIS-SCI/D Workflow

The holistic workflow described in the study for PP implantation in people with SCI/D was condensed in several points to help surgeons address potential challenges and guide patients toward a safe and efficient PP implantation.

P	Priorities (goal alignment: penetration/intimacy/IC/body image)
R	Risk phenotype of SCI (NLI, AIS, sensation, AD history, spasticity, hand function)
O	Organisms (urine culture, rectal swab, antibiotic and antifungal therapy for patients and devices)
S	Skin & seating (pressure plan: cushions, transfers or positioning, post-op surfaces; consider nutritional supplement to increase skin repair)
T	urinary Tract (IC strategy, treat symptomatic bacteriuria, exclude possible NLUTD complications, videourodynamics)
H	bowel Habits (MENTOR tool, diary, constipation, TAI training, pre-op emptying, probiotics)
E	Education (modern workflow, salvage and explantation scenarios, staff AD recognition and management)
S	Spasticity (optimize medications, pain control, avoid triggers, reduce pressure at the scrotal level)
I	Intra-operative discipline (clean theatre, no-touch mindset, hemostasis, gentle urethra, document peculiarities)
S	Surveillance (catheter positioning for at least 7 days, IPP activation after 4 weeks, PROMs, strict follow-up to evaluate and treat promptly red flags)
SCI/D	Spinal Cord Injury/Dysfunction