

ORIGINAL RESEARCH—SURGERY

Prospective Evaluation of Patient Satisfaction, and Surgeon and Patient Trainer Assessment of the Coloplast Titan One Touch Release Three-Piece Inflatable Penile Prosthesis

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ABSTRACT

Introduction. A single-armed, prospective, multicenter international study evaluated the redesigned Coloplast Titan One Touch Release (OTR) pump inflatable penile prosthesis. The OTR pump has a unique release valve that permits deflation of the implant with one squeeze of opposing touch pads.

Aims. To assess the impact of a new penile prosthesis design, the Titan OTR, on patient ease of operation. Furthermore, to assess patient satisfaction, surgeon acceptance, and the ease with which patients were trained in device operation in the clinic setting.

Methods. A total of 113 eligible patients from eight centers were recruited from men presenting with erectile dysfunction without prior prosthetic implantation. The subjects had a mean age of 61 years, and had a number of comorbidities, including diabetes (31.9%), hypertension (34.5%), and Peyronie's disease (23.9%). All underwent implantation of the study device.

Main Outcome Measures. Questionnaires were used to capture patient satisfaction as well as physician feedback on ease of implantation and patient education. A paired analysis was completed for patient satisfaction at 6 (N = 96) and 12 (N = 90) months.

Results. Overall satisfaction with the device was 90.6% and 90.0% at 6 and 12 months, respectively. The primary end point, ease of deflation, was seen in 70.8% and 73.3% at these two time points, with the 12-month value statistically better than historical controls. Physicians overwhelmingly reported straightforward/simple intraoperative product preparation (97.3%) and equivalent or easier training compared with their previous pump of choice (96.4%). Adverse events for all subjects (N = 113) included removal of the device in four cases (3.5%) for infection and one case for chronic pain (0.8%).

Conclusions. The Titan OTR represents an advance in penile prosthetic technology that is well accepted by patients and physicians. The study design allowed for realistic evaluation of the new technology aimed at enhancing clinical outcomes. **Ohi DA, Brock G, Ralph D, Bogache W, Jones L, Munarriz R, Levine L, and Ritenour C. Prospective evaluation of patient satisfaction, and surgeon and patient trainer assessment of the Coloplast Titan One Touch Release three-piece inflatable penile prosthesis. J Sex Med 2012;9:2467–2474.**

Key Words. Erectile Dysfunction; Three-Piece Inflatable Penile Prosthesis; Patient Satisfaction; Surgical Treatment

Introduction

Erectile dysfunction (ED) is a prevalent condition. The Massachusetts Male Aging Study estimated that 52% of men aged 40–70 suffered from some degree of erectile impairment [1]. In a large survey of men of all ages in the United States, Laumann et al. found that the incidence of clinically significant ED was 7% in men aged 18–29 and rose to 18% in men aged 50–59, trailing premature ejaculation, which was the most common sexual dysfunction seen in the survey [2]. ED has many causes, including vascular inflow disease, veno-occlusive dysfunction, neuropathy, and psychogenic issues.

Medical management of ED was vastly improved with the introduction of the type 5 phosphodiesterase inhibitors in 1998 [3]. However, efficacy rates with these agents only range from 60% to 70% at best, and poorer results are seen in men with diabetic neuropathy and those who have undergone radical prostatectomy [4]. In many men, other treatments, including intraurethral alprostadil, penile injection therapy, and vacuum constriction devices, are needed [5]. All these treatments have advantages and disadvantages. Furthermore, patient acceptance of those medical treatments varies widely.

Since the introduction of the inflatable penile prosthesis (IPP) by Scott et al. in the 1970s [6], there have been multiple modifications in device design. Device failures during the early experience were numerous, and most of the device modifications have been successful efforts directed toward increasing the mechanical reliability of the implants [7,8]. The most recent revision of the device described in the current paper is aimed to improve the ease of inflation and deflation of the device.

Aims

The purpose of this study was to determine the impact of a new penile prosthesis design, the Coloplast Titan One Touch Release (OTR; Coloplast Corporation, Minneapolis, MN, USA), on patient ease of operation. Furthermore, we sought to determine patient satisfaction, surgeon acceptance, and the ease with which patients were trained in device operation in the clinic setting.

Methods

A total of 113 eligible patients dispersed over eight sites underwent implantation of the Titan OTR

IPP from November 2007 to April 2009 in this prospective, non-randomized, international multi-center clinical trial. Surgical technique was determined by the individual surgeon and did not vary from typical implantation procedures. The study is prospective in nature, therefore limiting selection bias via adherence to predefined inclusion and exclusion criteria. Eligibility criteria included men at least 18 years of age willing to undergo implantation of a device to treat ED. Patients with compromised immune systems, active genitourinary infection, and severe coagulopathies were among those excluded from the study. Those who had previous devices implanted for ED were also excluded. All protocols received institutional review board approval, and all patients signed informed consent documents to participate in the study.

The Titan OTR prosthesis is a three-piece implant that involves cylinders placed in the corpora cavernosa of the penis, a pump placed in the scrotum, and a reservoir placed in the abdominal cavity of the patient (Figure 1). The entire device has a hydrophilic coating that rapidly absorbs aqueous solutions when soaked, and the cylinders and reservoir are manufactured from silicone and Bioflex (Coloplast Corporation). The hydraulic OTR pump transfers fluid between the cylinders and reservoir to allow for rigidity (inflation) and flaccidity (deflation) of the penis as appropriate.

The OTR pump has a unique release valve that permits deflation of the implant with one squeeze of the opposing touch pads (Figure 2). The size of the new pump is similar to the previous model. When the deflate mechanism is activated, the valve only allows fluid to be transferred from the



Figure 1 Titan One Touch Release three-piece penile prosthesis



Figure 2 One Touch Release pump

cylinders to the reservoir. After activation, the pump is locked in the deflate function, preventing the need for continuous pressure to allow the flow toward the reservoir. The OTR pump's predecessor required constant pressure to be held on the deflation pads during the deflation process, and the need for constant pressure was a consistent complaint of patients. The cost difference between the OTR pump and its predecessor is approximately US \$200.

Subjects and implanting surgeons completed baseline questionnaires, and data were collected by questionnaire at 6 weeks, 3 months, 6 months, and 12 months after implantation. Data were compiled, and standard statistical analyses were performed using SAS version 9.1 or above (SAS Institute, Cary, NC, USA) or another validated statistical software package.

Main Outcome Measures

The primary end point of the study was to assess the satisfaction with ease of deflation of the OTR pump at 6 months by subject questionnaire. Retrospective data from three comparator trials were used to create a weighted average of 64% for patient satisfaction with pump deflation as a threshold with which to compare the current study [9–11]. The primary end point is a binomial proportion of participants completely or mostly satisfied with deflation performance, similar to the criteria for satisfaction reported in the comparator studies. The end point was constructed as a one-sided test with a 0.05 alpha level and was analyzed by comparing the lower bound of the two-sided 90% confidence interval with the performance goal of 64%.

Assuming a true (expected) rate of satisfaction of 76%, an alpha level of 0.05 and a one-sided hypothesis test, this design provides 80% power to achieve the study objective with a total enrollment of 92 participants. Allowing for 20% participant attrition (participant lost to follow-up, participant death, visits outside the follow-up window), 115 participants needed to be enrolled to reach the minimum sample size of 92.

Secondary end points included overall satisfaction measures of the patient, implanting surgeon, and trainer. These were reported with standard statistical descriptions. For continuous variables, means, standard deviations, and confidence intervals were reported while categorical variables were summarized with frequency distributions. Adverse event data were reported and tabulated from all sites. Events were reported as procedure or device-related and classified based on severity.

Results

Patient Population

One hundred twenty-four patients signed consent forms for the study, but 9 were not implanted due to medical reasons, withdrawal of consent or lack of device availability, and 2 were excluded from analysis after it was determined they did not actually meet inclusion/exclusion criteria at baseline. The 113 patients included in the study were recruited from eight sites, including six in the United States, one in Canada, and one in the United Kingdom. Median enrollment per site was 13.5 patients, and no site was permitted to implant more than 25 patients. At 6 and 12 months there were 96 and 90 subjects available for analysis, respectively.

The patient population baseline characteristics are shown in Table 1. The primary cause of ED was vascular disease and/or diabetes in more than half the group. Of note, 34.5% of the patients had abnormal curvature of the penis, with 23.9% reported as having evidence of Peyronie's disease. Prior ED treatments were given in all the subjects. These included oral medications (97.3%), penile injection therapy (63.7%), vacuum device (31%), intraurethral suppository (19.5%), and testosterone administration (5.3%).

Surgical Data

All patients received preoperative and postoperative antibiotic prophylaxis. Furthermore, all devices were soaked in antibiotic-containing

Table 1 Demographics and baseline characteristics

Characteristic	N	mean \pm SD or % (n/N)	Range
Age (years)	113	61.0 \pm 9.1	(34.5, 81.2)
BMI (kg/m ²)	113	29.4 \pm 5.0	(18.4, 45.9)
Primary indications (not mutually exclusive)			
Vascular disease	113	34.5% (39/113)	
Diabetes mellitus	113	31.9% (36/113)	
Post-cancer treatment	113	26.5% (30/113)	
Pelvic surgery	113	8.8% (10/113)	
Neurogenic	113	4.4% (5/113)	
Psychological causes	113	4.4% (5/113)	
Pelvic trauma	113	4.4% (5/113)	
Iatrogenic	113	0.9% (1/113)	
Other	113	31.9% (36/113)	
Peyronie's disease	113	23.9% (27/113)	
Curvature abnormal	113	34.5% (39/113)	
Stretched penile length (cm)	106	11.9 \pm 2.5	(6.0, 19.0)
Single sexual partner	113	63.7% (72/113)	

SD = standard deviation; BMI = body mass index

solution prior to implantation. The choice of antibiotic solution was based on individual surgeon preference. The data on individual surgeon preference were not recorded. A penoscrotal approach was used in 98% of cases, and operative time averaged 61.5 \pm 22.6 minutes. Average cylinder length was 15.9 \pm 2.0 cm, and reservoir volume 74 \pm 11 mL. The average length of rear tip extenders was 1.9 cm, and in 16 subjects, no rear tip extenders were utilized. The pump was placed in the midline in 95% of cases, dartos pouch in 78%, and 65% were surgically secured in place to prevent migration. Devices were universally filled with normal saline, and a surgical drain was placed in 47% of cases.

Surgeon's Assessment of New Device

Surgeons were asked to answer three questions regarding the intraoperative experience with the device. In 97.3% of the cases, the surgeon agreed that the implant preparation was straightforward. The surgeons felt that in 89.4% of the cases, the OTR pump was easier to prepare than their previous pump of choice. It was determined that the patient's scrotum was easily able to accommodate the pump placement 97.4% of the time. In all of the above queries, if a positive response was not given, the response was neutral. In no case was a negative impression of the device reported.

Trainer's Assessment of the Device Activation Session

At the 6-week follow-up appointment, patients were trained in the operation of the device. The person administering the training session, who was usually a clinic nurse, was asked to fill out a

questionnaire regarding their impression of the session. The results are shown in Table 2. As one can see, the trainers felt that the vast majority of men found the device somewhat/very/extremely easy to find the inflation and deflation mechanism and to operate the device. Ninety-nine point one percent of subjects reported to the trainer that they liked the pump. The practitioners felt that 97.2% of subjects found the operation of the device easy to learn, and in comparison with prior device training experience, the subject training with the OTR pump was easier than previous pumps 99.1% of the time.

Primary End Point Assessment

The primary end point in the study was patient ease of deflation at 6 months, at which time 70.8% found the ease of deflation to be satisfactory or somewhat satisfactory. When compared with historical controls, as described earlier (64% from pooled studies), the increase in satisfaction demonstrated a trend for improved satisfaction, but did not reach statistical significance (lower 95% confidence limit 62.7%, $P = 0.082$). When analyzing this end point at 12 months, the satisfaction rate rose to 73.3%, and this value was statistically significant to the 64% seen in historical controls (lower 95% confidence limit 65%, $P = 0.033$).

It is also important to point out that many subjects were neutral on ease of deflation at 6 and 12 months. The numbers of men who were neutral or satisfied with ease of deflation at the two time points were 83.3% and 80.1%, respectively, with a minority reporting dissatisfaction (16.7% and 19.9%, respectively).

Table 2 Clinician/trainer 6-week questionnaire

Characteristic	N	% (n/N)
It was easy for the subject to find the inflation bulb?		
Not at all	108	0.0 (0/108)
A little	108	0.9 (1/108)
Somewhat	108	4.6 (5/108)
Very	108	13.9 (15/108)
Extremely	108	80.6 (87/108)
It was easy for the subject to find the deflation touch pads?		
Not at all	108	1.9 (2/108)
A little	108	3.7 (4/108)
Somewhat	108	9.3 (10/108)
Very	108	26.9 (29/108)
Extremely	108	58.3 (63/108)
It was easy for the subject to inflate the device?		
Not at all	108	1.9 (2/108)
A little	108	0.9 (1/108)
Somewhat	108	4.6 (5/108)
Very	108	17.6 (19/108)
Extremely	108	75.0 (81/108)
It was easy for the subject to compress the deflation touch pads?		
Not at all	108	2.8 (3/108)
A little	108	1.9 (2/108)
Somewhat	108	10.2 (11/108)
Very	108	25.9 (28/108)
Extremely	108	59.3 (64/180)
Subject training with OTR pump was easier than with previous pump?		
Not at all	108	1.9 (2/108)
A little	108	1.9 (2/108)
Somewhat	108	16.7 (18/108)
Very	108	16.7 (18/108)
Extremely	108	63.0 (68/108)
The OTR pump was easy to use at 1st cycling?		
Not at all	108	1.9 (2/108)
A little	108	5.6 (6/108)
Somewhat	108	8.3 (9/108)
Very	108	21.3 (23/108)
Extremely	108	63.0 (68/180)
The subject likes the OTR pump?		
Not at all	108	0.9 (1/108)
A little	108	3.7 (4/108)
Somewhat	108	13.0 (14/108)
Very	108	20.4 (22/108)
Extremely	108	62.0 (67/108)
How easy was it for the subject to learn?		
Not at all	107	2.8 (3/107)
A little	107	8.4 (9/107)
Somewhat	107	7.5 (8/107)
Very	107	29.9 (32/107)
Extremely	107	51.4 (55/107)

OTR = One Touch Release

Secondary End Point Assessment

Table 3 shows patient satisfaction with various aspects of the device at 6 and 12 months. As one can see, satisfaction rates in all parameters exceeded 68.9%, with a large proportion of other responses remaining neutral. The lowest rates were seen with ease of deflation, as discussed in the previous section, and length when inflated, a commonly stated disappointment with all penile implant patients. At 6 and 12 months, 90.6%/90%

of patients were satisfied with the overall function of the device. At 12 months, 86.7% stated they would proceed with the operation again, and 94.5% were either neutral or positive when asked the question. Eighty-seven point eight percent would recommend the device to other men with ED, with 95.6% remaining at least neutral.

Adverse Events

Table 4 shows the total reported adverse events during the study. The serious adverse events are shown in Table 5. Overall, there were 41 adverse events in 30 patients (26.5% of patients experienced at least one adverse event).

Autoinflation was the most common problem seen at the early follow-up visits (14/113, 12.4%).

Table 3 Subject satisfaction at 6 and 12 months

Question	6 months		12 months	
	N	% (n/N)	N	% (n/N)
Overall function				
Satisfactory and somewhat satisfactory	96	90.6 (87/96)	90	90 (81/90)
Neither	96	2.1 (2/96)	90	1.1 (1/90)
Soft enough to conceal when deflated				
Satisfactory and somewhat satisfactory	96	76 (73/96)	90	82.2 (74/90)
Neither	96	9.4 (9/96)	90	9.9 (8/90)
Ease of locating the deflation touch pads				
Satisfactory and somewhat satisfactory	96	78.2 (75/96)	89	77.6 (69/89)
Neither	96	9.4 (9/96)	89	10.1 (9/89)
Ease of inflation				
Satisfactory and somewhat satisfactory	95	85.3 (81/95)	88	86.4 (76/88)
Neither	95	7.4 (7/95)	88	6.8 (6/88)
Ease of deflation				
Satisfactory and somewhat satisfactory	96	70.8 (68/96)	90	73.3 (66/90)
Neither	96	12.5 (12/96)	90	6.8 (6/90)
Hardness of erection when inflated				
Satisfactory and somewhat satisfactory	94	91.5 (86/94)	89	93.2 (83/89)
Neither	94	4.3 (4/94)	89	2.3 (2/89)
Width when inflated				
Satisfactory and somewhat satisfactory	94	86.1 (81/94)	89	79.8 (71/89)
Neither	94	5.3 (5/94)	89	10.1 (9/89)
Length when inflated				
Satisfactory and somewhat satisfactory	95	61.1 (58/95)	90	68.9 (62/90)
Neither	95	9.5 (9/95)	90	7.8 (7/90)
Would you recommend this penile implant device to men with the same erectile difficulty that you had?				
Yes and probably	96	86.5 (83/96)	90	87.8 (79/90)
Don't know	96	5.2 (5/96)	90	7.8 (7/90)
If you had the decision to make again, would you undergo this penile implant procedure again?				
Yes and probably	96	83.3 (80/96)	90	86.7 (78/90)
Don't know	96	9.4 (9/96)	90	7.8 (7/90)

Table 4 Total adverse events (AEs)

Adverse event	Number of AEs	Subjects with AE % (n/N)
Auto deflation	2	1.8 (2/113)
Auto inflation	14	12.4 (14/113)
Cylinder extrusion	1	0.9 (1/113)
Cylinder tips asymmetrical	1	0.9 (1/113)
Delayed wound healing	2	1.8 (2/113)
Device malfunction	2	1.8 (2/113)
Discomfort	5	4.4 (5/113)
Fever	1	0.9 (1/113)
Hematoma	4	3.5 (4/113)
Infection	4	3.5 (4/113)
Reservoir herniation	1	0.9 (1/113)
Pain—chronic	1	0.9 (1/113)
Penile edema	1	0.9 (1/113)
SST deformity	2	1.8 (2/113)
Total	41	26.5 (30/113)

SST = supersonic transport

However, 10 patients reporting autoinflation early on spontaneously resolved during the course of the study, leaving the final autoinflation rate of 3.5%. Many other complications were minor and also resolved spontaneously.

Infection occurred in four devices and all of these devices were explanted. Two infections occurred at a single center and the other two occurred at two different centers. Therefore, we could not determine that infection was site-related. The small number of patients with infection did not allow any analysis of comorbidities that would put patients at risk for infection.

One patient with intractable chronic pain also had his device removed. Seven revision surgeries were performed, with successful resolution of the problem. Revisions were performed for device malfunction (2), discomfort (2), reservoir herniation (1), and scrotal hematoma (2). The investigators classified the two device malfunctions as device-related adverse events and the other revisions as procedure-related.

Discussion

IPPs are well-recognized treatments for ED. Previous studies have demonstrated high rates of

Table 5 Severe adverse events (SAEs)

SAE type	Number of SAEs	Patients with SAE % (n/N)
Severe		
Cylinder extrusion	1	0.9 (1/113)
Device malfunction	2	1.8 (2/113)
Hematoma	2	1.8 (2/113)
Infection	4	3.5 (4/113)
Pain—chronic	1	0.9 (1/113)
Total severe	10	7.1 (8/113)

patient satisfaction [7,10–12], although few studies have captured prospective data. The current study provides significant information on satisfaction captured throughout the first year after surgical implantation of the Titan OTR IPP. It offers unique data based on specific collection from invested parties including surgeons, trainers, partners, and patients.

While oral medications for ED have revolutionized the treatment paradigm, these therapies do not work for all patients. Likewise, other treatments, while highly effective for some, also do not provide correction of dysfunction for all [12,13]. Penile prostheses are reliable, effective devices that provide an alternative for men who wish to undergo surgical treatment of ED. However, understanding the issues related to satisfaction and managing patient expectations are critical for the implanting surgeon to recognize. Patients who have IPP surgery but are unable to operate the device afterward are particularly frustrated. Therefore, constant assessment and modification of existing devices is important to provide the best options for patients.

The Titan OTR IPP was conceived as a safe, effective device that is easier for patients to use. While the basic design of the cylinders and reservoir is well established as an effective product, the IPP pump is the part of the device that requires the most patient interaction and control. Creating a pump that allows for easy cylinder inflation and deflation is an important goal. The touch pads of the OTR pump allow for a single-squeeze mechanism that is improved over the continuous manual pressure required for deflation of previous devices.

Improved ease of operation of the OTR pump was verified in a study of practitioners who perform penile prosthesis training in the clinic setting. In this study, an *in vitro* scrotal model with different pump designs was used to ask these individuals their opinions of pump designs. The OTR pump was found to be easier to operate over other pump designs, and the differences were statistically significant [14].

Prosthetic surgeons are generally interested in decreasing operative time. More efficient use of resources is accomplished by this and some believe that decreasing operative time may lead to improved outcomes. Factors that make device preparation easier can decrease operative time. In this study, implanting surgeons reported that device preparation was straightforward/simple 97% of the time. In 89% of the cases, the physician

stated the pre-implant preparation was easier than other IPP pumps. These data reflect overall satisfaction with intraoperative device handling.

Likewise, postoperative training for IPP patients can require significant amounts of time. For Titan OTR study patients, training was completed around 6 weeks after implantation. The study represents one of the first to capture prospective data from those training the patient. With this pump design, the trainers reported that the process was easier than with previous IPP pumps in 96% of cases. The importance of ease of patient education for device use cannot be understated, as this will translate to less time required by the office staff, fewer remedial training sessions, and less frustration for patients. Indeed, Shaw and Garber demonstrated a statistically significant decrease in the number of training sessions required with the OTR pump, as compared with its predecessor [15].

Perhaps the most important measure of success after IPP implantation is that of patient satisfaction with use. Traditionally, IPP patient satisfaction rates have been around 90% [16], and the current study again shows >90% overall patient satisfaction at 6 and 12 months. Satisfaction regarding deflation with the OTR device in particular compares well with previous studies with 70.8% and 73.3% responding positively to this question at 6 and 12 months, respectively. At 12 months, the patient satisfaction with ease of deflation was statistically better than historical controls. One could argue that this is not clinically significant, because the difference between the ease of deflation and historical controls is modest. However, any improvement in the satisfaction of the patient undergoing implant surgery is an advance in prosthetic surgery.

It is possible that satisfaction rates may be affected by the type of disease present. For example, prior studies have suggested a lower rate of ED treatment satisfaction in men with Peyronie's disease. At the time of this writing, analysis by disease state has not yet been completed but is planned. Other factors that have recently been shown to affect postoperative satisfaction include reasonable preoperative expectations [17] and favorable female sexual function [18].

The adverse events identified in this study are well recognized in patients undergoing penile prosthetic surgery. In particular, early autoinflation was identified in 12.4%, but most of these cases resolved spontaneously with no further intervention needed such that the autoinflation

rate was 3.5% at the end of the study. This is similar to the rate of 4.3% identified in a previous study [19].

The number of infections in this study is higher than typically reported to implant company databases. Since report forms submitted to the implant companies are voluntary and incomplete, it is likely that underreporting of complications to such databases occurs. This study collected data prospectively and was complete. Nevertheless, the infection rate of 3.4% is higher than reported in recent publications, and may reflect the effects of a small number of patients presently included. More investigations are in order to assure that this infection rate does not represent the true infection rate of this device. Since the materials are unchanged from the previous devices, the authors believe that the high infection rate seen here will not be seen in future studies. Standardized antibiotic coating of the hydrophilic surface of the Titan device may help. Dhabuwala's group has suggested that rifampin and gentamicin may be the ideal choice of antibiotic solution [20].

This study represents one of the few prospective studies assessing penile implants. There are, however, several limitations of the trial. Due to staggered regulatory and Institutional Review Board (IRB) approvals of the protocol, several centers started surgical implantations earlier and entered higher subject numbers into the study. The comparison used for primary end point assessment relied on historical data. Furthermore, the comparator trials assessed satisfaction data that were collected at much later time intervals after surgery. If, for example, there is a progressive improvement over time in patient acceptance, the 64% cut point in ease of deflation may be too high when comparing with 6- and 12-month data. Indeed, in the current study there was an improvement in primary end point data between the 6- and 12-month marks.

Finally, it is important to recognize that there was no "head-to-head" comparisons in this trial, only historical controls from the literature. Ideally, a head-to-head comparison with two current devices would be interesting. Furthermore, identical questionnaires were not used in this and prior studies, possibly confounding the comparison. Also, the number of centers utilized in this study was few, and if extended to more cooperating centers in future studies, a stronger data set could be generated in future studies. An ideal comparator study would be a prospective, randomized large multicenter study comparing two different devices under the same conditions.

Conclusions

In this prospective study, the Coloplast Titan OTR performed well in all measures of patient and clinician satisfaction. The device was felt by the implanters to be easier to prepare than the previous standard pump. The patient trainers found that it was easier to train patients in the operation of the device than previous devices, and this may lead to decreased training time and limitation of remedial training sessions. Finally, there was high satisfaction in all aspects of the device and higher satisfaction rates in the primary end point (ease of deflation) when compared with pooled historical controls at 12 months.

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Statement of Authorship

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