

Coloplast Titan Inflatable Penile Prosthesis with One-Touch Release Pump: Review of 100 Cases and Comparison with Genesis Pump

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ABSTRACT

Introduction. In 2008 Coloplast Corporation modified their Titan inflatable penile prosthesis (IPP) with a new One-Touch Release (OTR) pump, in an attempt to facilitate device deflation. There is currently little published data concerning this new pump.

Aim. The aim of this pilot study was to assess initial patient and physician experience with the Titan OTR pump.

Methods. Retrospective chart review was used to assess the functionality and surgeon experience with 100 consecutive patients implanted with a Titan OTR pump, compared with 100 prior consecutive patients implanted with a Titan Genesis pump.

Main Outcome Measures. The ease of implantation of the OTR pump, the number of required postoperative inflate/deflate teaching visits, and OTR pump functionality were assessed and compared with that of the prior Genesis pump.

Results. The mean length of follow-up in the Genesis group (N = 100) was 20.8 months, and mean length of follow-up in the OTR group (N = 100) was 8.4 months. There was one device infection in each group. The average number of postoperative teaching sessions needed to teach the patient how to operate the device was 1.87 in the Genesis group, and 1.19 in the OTR group ($P < 0.001$). The range of teaching visits was 1–5 in the Genesis group, and 1–3 in the OTR group ($P < 0.001$). No pump malfunctions were seen in either group. Subjectively, the OTR pump was just as easy to implant as the Genesis pump. In addition, the OTR pump was subjectively easier for the surgeon and the patient to deflate, and just as easy to inflate, compared with the Genesis pump.

Conclusions. This pilot study revealed that the OTR pump functioned as specified by the manufacturer. With short-term follow-up, no pump malfunctions were detected. The OTR pump was associated with a statistically significant reduction in the number of postoperative teaching sessions required for the patient to properly operate the device. It was subjectively just as easy to implant and inflate, and easier to deflate, compared with the Genesis pump. Shaw T, and Garber BB. Coloplast Titan inflatable penile prosthesis with one-touch release pump: Review of 100 cases and comparison with genesis pump. *J Sex Med* **,**,**_**.

Key Words. Inflatable Penile Prosthesis; One-Touch Release Pump; Genesis Pump; Coloplast Titan Penile Implant

Introduction

Prior to the 1970s, erectile dysfunction (ED) was widely believed to be a psychological illness, and there were few treatment options available. Scott [1] is credited with the first implantation of an inflatable penile prosthesis (IPP) in 1973, thus establishing the foundation for modern penile prosthetic surgery. Pharmaco-

logical advancements in the management of ED soon followed, with the discovery of erectogenic medications that act on penile cavernous or arterial smooth muscle. Intracavernous injection of papaverine for the treatment of ED became available in 1982 [2], and oral phosphodiesterase type 5 (PDE5) inhibitors received United States Food and Drug Administration approval in 1998 [3].

Despite the advancements in medical therapy for erectile dysfunction, surgical therapy still provides exceptional satisfaction rates compared with all of the available modalities of treatment [4]. Setting realistic expectations with the patient prior to surgery and providing an accurate description of the procedure further enhances patient satisfaction after implant surgery [5]. The most common indication for a penile prosthesis is refractory organic ED. Other common indications for prosthetic surgery include post-prostatectomy ED, penile trauma, priapism, and Peyronie's disease. Current research indicates that despite the widespread use of PDE5 inhibitors, the number of patients requiring or requesting a penile prosthesis will likely remain stable or even increase, especially at centers specializing in ED treatment and penile implant surgery [6].

Since the advent of penile prosthetic surgery, many product enhancements have been developed in an attempt to lower the rates of IPP mechanical failure and prosthetic infection, and to improve

the ease of device inflation and deflation [7,8]. American Medical Systems (AMS) recently developed and released a Momentary Squeeze pump for their 700 series IPP, to facilitate device deflation [9]. This publication reports our initial experience with the new Coloplast Titan One-Touch Release (OTR) pump that became commercially available in the United States in September of 2008. Titan OTR pumps are now available as separate units or pre-connected to prosthesis cylinders. The OTR pump was developed in an attempt to make device deflation easier for the patient. Although not well documented in the published literature, the authors have noted that patients implanted with a Genesis pump not infrequently had difficulty deflating the device, because of the firm continuous pressure that must be applied to the Genesis release bars. The new OTR pump allows cylinder deflation with one firm squeeze to the release pads (Figure 1). The purpose of this study was to clinically evaluate the OTR pump, and to compare it with the prior Genesis pump.

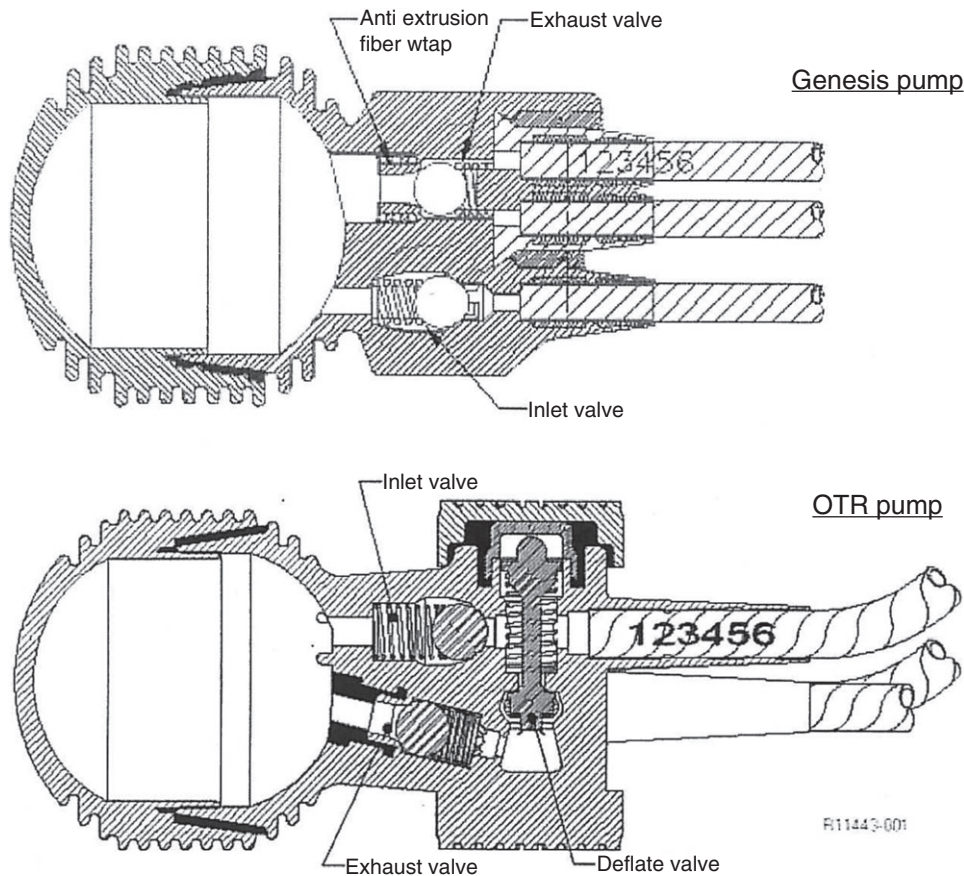


Figure 1 Schematic of Coloplast Genesis pump compared with One-Touch Release (OTR) pump.

Materials and Methods

The design of the study was a retrospective review of 100 consecutive patients implanted with a Titan IPP containing a Genesis pump, compared with 100 consecutive patients implanted with a Titan IPP containing an OTR pump. All patients were asked to inflate and deflate a corresponding sample device pre-operatively, to assure that they had sufficient intelligence and dexterity to operate an inflatable implant. One hundred percent of the patients were available for follow-up analysis; they all returned to learn how to operate their device. Implantation was via a scrotal, infrapubic, or combined approach, depending on body habitus and prior surgical history. All of the procedures were done as an outpatient by a single high-volume (>2000 cases) implanting urologist. All patients received intravenous vancomycin and gentamicin preoperatively, and each IPP was soaked in a rifampin and gentamicin (1 mg of each per mL) antibiotic irrigation solution. Our standard technique involves presoaking the IPP in antibiotic solution and this practice is corroborated by a recent article by Dhabuwala [10] who has shown that soaking the Titan Coloplast implant in a rifampin (10 mg/mL) plus gentamicin (1 mg/mL) solution produces a zone of inhibition greater than that produced by the AMS Inhibizone-coated prosthesis for both *Staphylococcus epidermidis* and *Escherichia coli*. All patients were discharged on the day of surgery with a Foley catheter and a closed suction drain, both of which were removed in the office on postoperative day one.

The number of postoperative teaching visits required for the patient to demonstrate they could properly inflate and deflate their device was used as a surrogate for ease of use of the device. A teaching visit for the purpose of this study was defined as a teaching session between the surgeon and the patient whereby inflation and deflation of the pump was demonstrated and reviewed. Patients were instructed concerning the operation of their implant by showing them and allowing them to inflate and deflate a sample device, and then asking them to operate their own device. They were also given a pump diagram to study. Patient partners were not included in the teaching sessions. Differences between the two study groups in the number of teaching visits required for proper usage of the IPP were tested for statistical significance using both a parametric Student's *t*-test and a nonparametric Mann-Whitney test. Statistical significance for this study was set a *P* value of less than 0.001. Postoperative phone

Table 1 Results of One-Touch Release (OTR) pump compared with Genesis pump

| | Genesis pump (N = 100) | OTR pump (N = 100) |
|--|---------------------------|-----------------------|
| Mean length of follow-up (months) | 20.8 | 8.4 |
| % Follow-up | 100 | 100 |
| Number of inflatable penile prosthesis infections | 1 | 1 |
| Average number of postop teaching visits (<i>P</i> < 0.001) | 1.87 | 1.19 |
| Range of teaching visits (<i>P</i> < 0.001) | 1–5 | 1–3 |
| Number of pump malfunctions | 0 | 0 |

calls concerning difficulties with device operation were handled by a follow-up office visit, and were thus counted as a required teaching visit. Other objective data included assessment of IPP malfunction and infection rates. Subjective data included an assessment by the primary surgeon regarding the ease of surgical implantation of the Genesis and OTR pumps, as well as the ease of inflation and deflation by the surgeon and patient during subsequent office visits. A questionnaire was not used because there is no validated questionnaire to assess these parameters.

Results

The mean follow-up time, percentage follow-up, number of IPP infections, average number of teaching visits, range of teaching visits, and number of pump malfunctions for both the Genesis and OTR groups are listed in Table 1. The OTR pump resulted in a statistically significant reduction in the number of required postop inflate/deflate patient teaching sessions. There were no instances of pump malfunction in either group. Each group had a single prosthetic infection that was treated with explantation. Subjectively, we felt the OTR pump was just as easy to surgically implant as the Genesis pump, was easier for the surgeon and patient to deflate, and equally easy to inflate.

Discussion

The major modification incorporated into the OTR pump design involves the deflation mechanism. The OTR pump is equipped with release pads instead of release bars. One firm squeeze of these pads causes the deflate valve to shift into the open position, establishing a pathway for fluid from the cylinders to return to the reservoir

without having to pass through the pump bulb. In contrast, deflating an IPP equipped with a Genesis pump requires firm, continuous pressure on the release bars, which allows fluid from the cylinders to pass through the pump bulb and then back to the reservoir (Figure 1). We believe that the Genesis pump was more difficult to deflate than the OTR pump because of the continuous, firm pressure than had to be applied to the two small release bars. Patients often indicated that this was uncomfortable, and this discomfort sometimes caused them to discontinue deflation efforts prematurely. In contrast, the OTR pump only requires one short, firm squeeze to initiate deflation. Patients seemed to find this procedure less uncomfortable.

In this study, the number of teaching visits required for successful usage of the OTR pump was used as a proxy for overall ease of device use. Our study revealed a statistically significant decrease in the number of postoperative teaching visits required for patients to learn how to inflate and deflate their IPP pump. Currently, only one other published manuscript describes the OTR pump. Quallich et al. [11] reported that a small sample of urologic practitioners found the OTR pump easier to inflate and deflate, compared with the AMS MS and Tactile pumps. They did not, however, compare the OTR pump to the Genesis pump. Short term follow-up in our series also revealed no instances of OTR or Genesis pump malfunction.

Conclusions

This pilot study reveals that the Coloplast Titan IPP equipped with an OTR pump functioned as specified by the manufacturer. Compressing the pump bulb transfers fluid to the cylinders, allowing device inflation. One firm squeeze on the release pads opens the release valve, allowing cylinder deflation. With an average of 8.4 months of follow-up, we found no instances of pump malfunction, and a statistically significant reduction in the number of required postoperative teaching visits. We also subjectively felt that the OTR pump was just as easy to implant as a Genesis pump, and made deflation easier and less uncomfortable for patients, compared with the Genesis pump. Limitations of the present study include the fact that it is retrospective, with short follow-up, relatively small numbers of patients, and no validated way to define ease of device use. However, our review suggests a clinical advantage

of the OTR pump over the Genesis pump, in terms of a decrease in the number of postoperative teaching visits necessary for patients to learn how to properly operate their IPP pump. Other manufacturers [8] have addressed this issue, and have likewise modified their pump to facilitate IPP deflation.

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Conflicts of Interest: Dr. Garber has served as a consultant to Coloplast Corporation, and to American Medical Systems, Inc.

Statement of Authorship

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(a) Conception and Design

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Category 2

(a) Drafting the Article

Tavis Shaw

(b) Revising It for Intellectual Content

Tavis Shaw; Bruce B. Garber

Category 3

(a) Final Approval of the Completed Article

Bruce B. Garber

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