Pseudo-malfunction of the Coloplast Titan Inflatable Penile Prosthesis One-Touch Release Pump

Bruce B. Garber, Jacob L. Khurgin, Doron S. Stember, and Paul E. Perito

OBJECTIVE To define and describe a type of pseudo-malfunction of the Coloplast Titan Inflatable Penile Prosthesis (IPP) One-Touch Release (OTR) pump (Coloplast Corp, Minneapolis, MN).

MATERIALS AND METHODS We retrospectively reviewed a consecutive series of 550 patients with refractory organic erectile dysfunction who were implanted with a Coloplast Titan IPP with the OTR pump during a period of approximately 4 years.

RESULTS All patients were implanted using standard techniques through an infrapubic or penoscrotal approach. Twenty-nine patients (5.3%) complained that their IPP would not inflate and that the pump bulb felt "hard." Examination revealed that their IPP was working normally; however, the inflate/deflate valve disc had become stuck in the deflate position. Very firm pressure had to be applied to the pump bulb to move the valve disc into the inflate position. Once this was accomplished, the device inflated and deflated normally. Another 14 patients (2.5%) reported this phenomenon to us but were able to apply enough pressure on the pump bulb to rectify it.

CONCLUSION The inflate/deflate valve disc in the Coloplast Titan OTR pump can occasionally become stuck in the deflate position (7.8% of patients in our experience). Patients may be unable to inflate the device and return for evaluation. In all cases we have encountered, firm pressure on the pump bulb caused the valve to shift into the inflate position, and the device worked properly thereafter. Patients and implanting urologists should be aware of this issue and of the way in which it can be rectified. UROLOGY 84: 857–859, 2014. © 2014 Elsevier Inc.

The use of inflatable penile prostheses (IPPs) for the treatment of organic erectile dysfunction refractory to medical therapy is a well-established procedure among urologists practicing in the field of sexual medicine. In 1973, Scott et al[1] introduced the inflatable prosthesis in a case series of 5 patients. This IPP was composed of silicone and was placed intracorporeally. A separate pumping mechanism was used for inflating and for deflating the cylinders.

IPPs have undergone a tremendous evolution since their introduction to become the technologically advanced prosthetic devices of today.[2] In addition to changes in materials and construction, the pump mechanism has been modernized. In 2008, Coloplast (Minneapolis, MN) introduced the One-Touch Release (OTR) pump to its Titan series (Fig. 1). This pump allowed a single firm squeeze on the release valve to allow complete deflation of the device. A statistically significant reduction in patient teaching visits has been documented with the OTR pump compared with the prior Genesis pump.[3]

A prospective study by Ohl et al[4] in 2012 reported the overall 12-month patient satisfaction rate was 90% with the Coloplast Titan with OTR pump. Ease of deflation was improved compared with historical data.[4] A Danish study revealed that 1 of 33 patients (3%) with an OTR pump implant had to undergo revision surgery for a deflation problem.[5] An 85% overall satisfaction rate was noted. We have recently identified a type of pseudo-malfunction of the OTR pump that has not been previously reported.[6] Patients reported that their pump bulb felt "hard" and they could not inflate the device. In this study we define and describe this phenomenon.

MATERIALS AND METHODS

We retrospectively reviewed a consecutive series of 550 patients with refractory organic erectile dysfunction who were implanted with a Coloplast Titan IPP with OTR pump, during a period of approximately 4 years, by a single surgeon. All patients were

Financial Disclosure: *Bruce B. Garber and Paul E. Perito are paid consultants to Coloplast and American Medical Systems. The remaining authors declare that they have no relevant financial interests.*

From the Department of Urology, Hahnemann University Hospital, Drexel University College of Medicine, Philadelphia, PA; the Department of Urology, Einstein Medical Center, Philadelphia, PA; the Department of Urology, Mount Sinai Beth Israel, New York, NY; and the Department of Urology, Coral Gables Hospital, Coral Gables, FL

Reprint requests: Jacob L. Khurgin, D.O., Einstein Medical Center, 5501 Old York Rd, Klein 500, Philadelphia, PA 19141. E-mail: jacobkhurgin@gmail.com

Submitted: March 24, 2014, accepted (with revisions): June 6, 2014

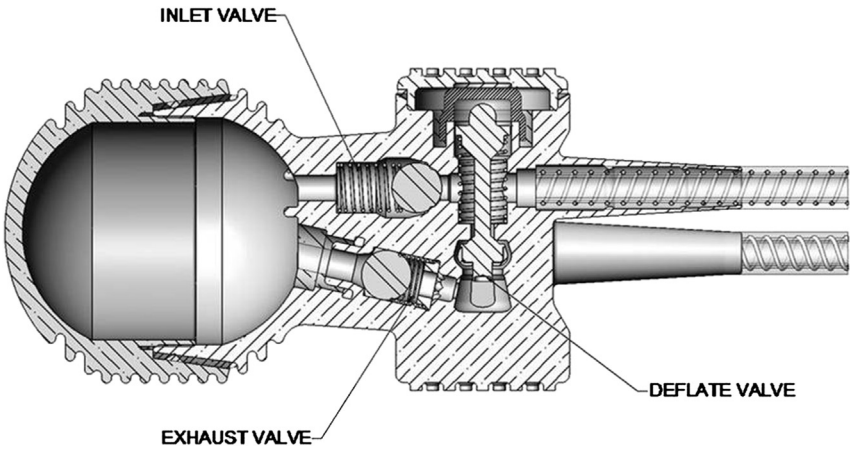

Figure 1. Schematic of Coloplast Titan One-Touch Release pump, showing inflate/deflate valve disc. Titan® is a registered trademark of Coloplast A/S. © Coloplast Corp. REPRINTED WITH PERMISSION-ALL RIGHTS RESERVED.

implanted using standard techniques through an infrapubic or penoscrotal approach. Patients were discharged home the same day as their procedure and returned to the office on postoperative day 1 for removal of their closed suction drain and Foley catheter. Patients were instructed not to operate the pump until their 6-week postoperative visit. Follow-up visits were scheduled at 2 weeks, 6 weeks, 3 months, 6 months, and as needed thereafter. Medical records were retrospectively reviewed, and the incidence of this type of pump issue was tabulated.

RESULTS

Of the 550 patients reviewed, 29 (5.3%) returned with the complaint that their IPP would not inflate, indicating that their pump bulb felt "hard." An examination of these patients revealed that their IPP was working normally; however, the inflate/deflate valve disc had become stuck in the deflate position. Very firm pressure had to be applied to the pump bulb to move the valve disc into the inflate position. Once this had been accomplished, the device inflated and deflated normally, without the resistance felt previously. An additional 14 patients (2.5%) reported this phenomenon to us but were able to apply enough pressure on the pump bulb on their own to rectify it (Table 1). No predictive factors that might have contributed to the development of pump pseudo-malfunction were identified. The timing of the pseudo-malfunction was variable, presenting early or late. Several patients reported recurrent episodes.

Table 1. Summary of patients with One-Touch Release pump pseudo-malfunction

	No. (%) (n = 550)
Patients with One-Touch Release pumps	
Patients with pseudo-malfunction	43 (7.8)
Pseudo-malfunction rectified by	
Physician	29 (67.4)
Patient	14 (32.6)
Pseudo-malfunction rectified nonoperatively	43 (100)

COMMENT

With decreasing rates of IPP infection, mechanical malfunction issues are becoming increasingly relevant to the longevity of these devices. In a series of more than 200 revision surgeries by Henry et al,[7] 65% of the revisions were performed because of mechanical failure. One large series that used a variety of implants found the overall survival of IPPs was about 96% at 5 years and 60% at 15 years for primary implantations.[8] These authors reported a nearly 2-to-1 likelihood of failure from mechanical reasons than from infectious ones at 10 years, noting a 10-year revision-free survival for all reasons of 68.5%, whereas freedom from mechanical breakage at 10 years was 79.4%. Most mechanical failures of the Coloplast Titan IPP are related to silicone tubing fractures near the strain reliefs adjacent to the pump.[9,10]

The Coloplast OTR pump was introduced in 2008 and designed so that one firm squeeze on the release valve allows complete deflation of the device. Patient teaching was reduced compared with the Genesis pump, and no difference in perceived ease of implantation by the surgeons was reported.[3] We are unaware of reports before this one describing pseudo-malfunction with the OTR pump, with an inability to inflate properly.[6] Pseudo-malfunction occurred in 43 patients (7.8%) in our series of 550. Of these patients, 67.4% were unable to solve this problem on their own and required another postoperative teaching visit, whereas 32.6% were able to rectify the pseudo-malfunction themselves by applying sufficient pressure to the inflate bulb. All patients (100%) were managed nonoperatively. Some patients reported recurrent episodes of this problem; however, once the valve issue was explained to them, they were able to self-correct it.

Patients with an OTR pump should be informed that approximately 8% might develop pseudo-malfunction in the postoperative period. The mechanism underlying this problem and the way to rectify it should be explained. In our series, nearly one-third were able to rectify this mechanical difficulty without any preceding information provided and were thus able to avoid a visit to their implanting urologist. Providing patients with proper

education and realistic postoperative expectations after IPP placement can decrease anxiety and improve patient satisfaction. The manufacturer has been made aware of our findings. Hopefully, this pseudo-malfunction issue can be corrected in future iterations of the Coloplast OTR pump, thus improving the overall performance of this implant.

Limitations of our study include its retrospective nature and the subjective nature of the malfunction being addressed. We hope that this report will inform implanting urologists about this issue so that it can be managed expeditiously.

CONCLUSION

The inflate/deflate valve disc in the Coloplast Titan OTR pump can occasionally get stuck in the deflate position, which occurred in 7.8% of patients in the current series. Patients may notice an inability to inflate the device and may return for evaluation. In all cases we have encountered, firm pressure on the pump bulb caused the valve to shift into the inflate position, and the device worked properly thereafter. Patients should be informed of this issue and of the way in which it can be rectified.

References

1. Scott FB, Bradley WE, Timm GW. Management of erectile impotence. Use of implantable inflatable prosthesis. *Urology*. 1973;2:80-82.
2. Trost L, Hellstrom WJ. History, contemporary outcomes, and future of penile prostheses: a review of the literature. *Sex Med Rev*. 2013;1:150-163.
3. Shaw T, Garber BB. Coloplast Titan® inflatable penile prosthesis with one-touch release pump: review of 100 cases and comparison with genesis pump. *J Sex Med*. 2011;8:310-314.
4. Ohl DA, Brock G, Ralph D, et al. 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.
5. Lindeborg L, Fode M, Fahrenkrug L, Sønksen J. Satisfaction and complications with the Titan® one-touch release penile implant. *Scand J Urol*. 2014;48:105-109.
6. Khurgin JL, Garber BB. Pseudo-malfunction of Coloplast Titan inflatable penile prosthesis with OTR pump [abstract]. Presented at: 19th Annual Fall Scientific Meeting of SMSNA. Nov 21-24, 2013; New Orleans, LA. Session XI - Moderated Posters - Poster Session IV - Implant Part I, Abstract 68. Available at: http://www.smsna.org/V1/showabstract.php?pid=150. Accessed March 6, 2014.
7. Henry GD, Donatucci CF, Conners W, et al. An outcomes analysis of over 200 revision surgeries for penile prosthesis implantation: a multicenter study. *J Sex Med*. 2012;9:309-315.
8. Wilson SK, Delk JR, Salem EA, Cleves MA. Long-term survival of inflatable penile prostheses: single surgical group experience with 2,384 first-time implants spanning two decades. *J Sex Med*. 2007;4(4 Pt 1):1074-1079.
9. Garber BB. Inflatable penile prosthesis: site-specific malfunction analysis. *Int J Impot Res*. 2003;15:22-25.
10. Wilson SK, Cleves MA, Delk JR Jr. Comparison of mechanical reliability of original and enhanced Mentor Alpha 1 penile prosthesis. *J Urol*. 1999;162:715-718.