Reconstructive Urology

Survival From Revision Surgery for New Rigicon Infla10 Three-piece Inflatable Penile Prosthesis Is Comparable to Preceding Devices

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OBJECTIVE To report the incidence of the reoperation surgeries of nearly all the Rigicon Infla10 implants performed since device introduction in 1/2019. Inflatable penile prosthesis has some of the highest survival from revision surgery of any medical device implanted in humans [1]. We expand on previous Rigicon Infla10 research, adding more patients and increasing follow-up duration [2].

MATERIALS AND METHODS 535 patients had Rigicon Infla10 devices implanted from 1/2019 to 8/2022. 103 surgeons from 26 centers in 15 countries participated in the study. Patient information forms were analyzed from virtually all implantations. Explantation or revision surgery for mechanical failure, infection, other medical reasons, and patient dissatisfaction were cataloged. SPSS 25.0 (IBM) was used for the statistical analysis of Kaplan Meier survival statistics.

RESULTS Mean follow-up was 24.2 months (7-43 months). Mean patient age was 56 years. Reoperation was necessary for 3.5% of subjects. Revision for mechanical failure occurred in 2.24% (12/535). The rate of explant for patient dissatisfaction was 0.56% (3/535). Revision for component out of place was 0.37% (2/535) with an infection rate and unsuccessful Peyronie's correction being 0.19% (1/535). Survival from requiring another corrective surgery at 1, 2, and 3 years was 96.4%, 95.0%, and 94.0%, respectively. These initial survival rates compare favorably to devices currently available, which have been repeatedly enhanced to improve reliability.

CONCLUSION In its first 2-3 years of availability, The Rigicon Infla10 inflatable penile prosthesis shows freedom from revision comparable to existing enhanced devices that have been on the market for decades. UROLOGY xx: xxx–xxx, xxxx. Published by Elsevier Inc.

Erectile dysfunction (ED) is defined as the inability to achieve and/or maintain an adequate penile erection for sexual intercourse.[1] The worldwide prevalence of ED between the ages of 40-70 is estimated to be over 40%.[2] Arteriosclerotic cardiovascular disease, prostate and other pelvic surgery, diabetes mellitus, and Peyronie's disease are the common etiologies for the development of ED.[1,2] When conservative treatment fails, penile prosthesis implantation is a highly effective treatment option. Penile prostheses are classified as inflatable and malleable.[3] Inflatable penile prostheses (IPP), available since 1973, offer patients with ED the opportunity to have excellent erectile rigidity and concealment when flaccid.[4]

IPP are the most preferred penile prosthesis types in the United States (US) today. Their advantage over malleable prostheses is control of erection and flaccidity, better cosmetic appearance and more concealability.[3] The Infla10 is a new three-piece inflatable penile prosthesis launched in 2019 by Rigicon (Ronkonkoma, NY). The Infla10 is currently undergoing clinical investigation for Pre-Market Approval (PMA) for Food and Drug Administration (FDA) clearance in the US but is already available in many countries outside the US. One of the most important concerns for patients and physicians is the safety of a new device. Safety is defined as the risk of

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revision or removal of prosthesis for malfunction, infection, other medical reasons, or patient dissatisfaction. This is a continuation of a study previously published with more patients and longer follow-up.[5] Our current study expanded on these results with many more patients and longer follow-up of this recently introduced IPP. Furthermore, it evaluated the need for reoperation for virtually all Rigicon IPP implants performed since its introduction in January 2019.

METHODS: PATIENT COLLECTION

Between January 2019 and August 2022, 535 patients with ED underwent implantation with Rigicon Infla10 three-piece IPP by 112 physicians from 30 centers in 15 countries (Table 1). All participating implanters were among the most prolific and experienced IPP surgeons in their respective countries. A patient information form (PIF) including demographic information was completed at time of original implantation and whenever any reoperation was necessary. The PIF's were expunged of any information regarding patient's identity prior to analysis. Only the surgeon's name and the patient's hospital number remained on the PIF. Retrospective PIF analysis was deemed exempt from ethical institution review board approval as has been the case for many seminal prosthetic urology papers.[6-8]

A Kaplan-Meier survival analysis of freedom from reoperation for any reason was done to determine the endpoints of reoperation for the Rigicon Infla10 IPP. Statistical analysis was completed using the SPSS 25.0 program (IBM, Armonk, NY).

RESULTS

Rigicon Infla10 prostheses with three different cylinder types were used to treat ED in this study. Frequency of usage of the different models was 64.6% Infla10 X (girth expansion), 34.7% Infla10 AX (length and girth expansion), and 0.7% Infla10 Narrow Body (2 cm narrower base, smaller width expansion). The mean follow-up of 535 patients was 24.2 months with a range of 7-43. The mean patient age was 56 years.

Table 1. The distribution of countries where Rigicon prostheses are implanted.

Country	Frequency	Percent
Australia	5	0.94
Colombia	9	1.68
Dominican Rep.	19	3.55
Greece	3	0.56
Germany	25	4.67
France	16	2.99
Spain	17	3.17
Qatar	8	1.50
Italy	2	0.37
India	7	1.32
Romania	3	0.56
Jordan	13	2.43
Turkey	373	69.72
Ukraine	20	3.74
United Kingdom	15	2.80
Total	535	100

Table 2. Demographic data–etiology of erectile dysfunction.

Organic	226	42%
Diabetes mellitus	182	34%
Post prostatectomy/Pelvic surgery	64	12%
Peyronie's disease	30	6%
Vascular insufficiency	16	3%
Spinal cord trauma	3	0.6%
Priapism	1	0.19%
Other	13	2.21%

The most often selected etiology of ED in this study from PIF forms was organic (Table 2). Unfortunately, the initial PIF supplied by the manufacturer allowed the person completing the form to check "organic" instead of selecting a more precise organic etiology (prostate surgery, ASCVD, diabetes, spinal trauma etc). The PIF was corrected after the original study detected the error.[5] Penoscrotal incision was utilized in 90.7% of operations. Infrapubic incision was performed on 3.6% of patients. The subcoronal technique was used in one patient (0.3%). A combination of surgical incisions was used to implant 5.5% of patients.

Reoperation was necessary in 19 (3.55%) patients. Mechanical failure with fluid leak and return of impotence occurred in 12 subjects (2.24%). Most of these patients had single-affected component replacement rather than complete device exchange. There were 3 (0.56%) patients who were dissatisfied with their result and requested removal. Cylinder malposition occurred in 2 patients—1 was impending erosion of the cylinder tip and the other was a cylinder crossover.[9] One patient (0.19%) had insufficient Peyronie's Disease curvature correction requiring reoperation, and another single patient (0.19%) had a device infection requiring removal (Table 3). Kaplan Meier statistical analysis of the Rigicon Infla10 showed that survival of the device from requiring another corrective surgery was 96.4%, 95.0%, and 94%, and at 1, 2, and 3 years, respectively (Fig. 1). These are very similar to statistics calculated when the number of subjects in the study was smaller and follow-up shorter.[5]

COMMENTS

The goals of penile prosthesis surgery include restoring erectile function while reducing risks of complications to

Table 3. Reason for prosthesis revision/removal—total 3.55%.

Fluid loss (mechanical failure)	12	2.24%
Patient dissatisfaction	3	0.56%
Component out of place	2	0.37%
Peyronie's failed correction	1	0.19%
Infection	1	0.19%
Total	19	3.55%

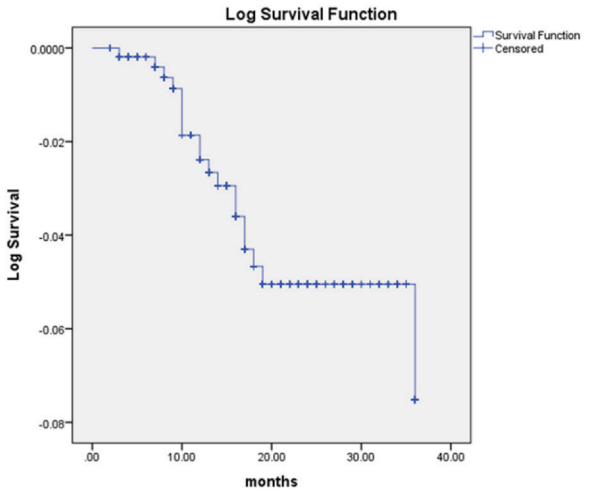

Figure 1. Survival analysis for 36 months. (Color version available online.)

provide high patient satisfaction. The surgical fit of the implanted prosthesis, its ability to mimic a physiological erection, and its ease of use play an important role in the satisfaction of couples.[10] Just as important to patient and partner satisfaction is the safety of the device from reoperation for any reason. The aim of the present study was to validate durability from revision surgery for Rigicon Infla10 IPPs placed since introduction to the market in January 2019 and specifically to add more patients and longer follow-up duration than our original study.[5] Our findings are very similar to the statistics from our initial study and indicate excellent Infla10 freedom from need of revision.

Mechanical failure is always a problem in all medical devices implanted into humans. Historically, IPP's have been marketed for 50 years.[4] Initially the inflatable implant was plagued with a high failure rate and patients were distressed by the return of their impotence and the necessity of reoperation.[3,10] In 2012, a large single surgeon series showed IPP reliability had improved to be the best in class among all devices placed in humans.[11] In other words, AMS and Mentor IPP's were least likely to require revision surgery when compared to hips, knees, breasts, lenses, and so on.[11] Our present study indicates that the first IPP prostheses available from a new manufacturer in decades, have an overall survival from revision for any cause of 96.5% at 2 years.

The survival from mechanical failure (n = 12) was 97.76%. All devices that failed in our series were returned to the manufacturer. Thorough examination of failed devices indicated that the most common site of fluid leakage on the Infla10 was the reservoir tubing (n = 9). The manufacturer has since implemented device reinforcements to diminish this issue. The other three causes of mechanical failure were pinpoint cylinder leakage gradually appearing in the first 14 months. These incidents were thought to be attributable to iatrogenic needle sticks with eventual fluid loss due to device cycling.

Revision rates for competitors IPPs based on PIF studies in the literature are similar to our findings. PIF studies are useful for assessing device durability and longevity but also prompt manufacturers to address repetitive device failures of the same type. The revision rate for mechanical failure of the AMS700 IPP (Boston Scientific, Marlborough, MA) is 3.3% (96.7% survival); the reoperation rate for mechanical reason of an enhanced Mentor (now Coloplast, Humlebaek, Denmark) Titan was 1.3% (98.7% survival).[6,7] That result was reported after the manufacturer enhanced the Mentor Alpha 1 (now called Coloplast Titan) to diminish tubing breakage at the pump junction and prior to enhancement, the failure rate was 5.5%.[8]

The Infla10 mechanical failure rate is acceptable when compared to other three-piece penile prostheses available in the US and the current survival from reoperation with more patients and longer follow-up is even better than previously (3.5% vs 4.4%). These results indicate Rigicon Infla10 IPP is safe in terms of mechanical durability. Nevertheless, it should be noted that the maximum follow-up of our study is less than 4 years while the larger PIF studies for AMS (now Boston) and Mentor (now Coloplast) number 36 and 14 years, respectively. This might cause the safety from revision to be overestimated for the Rigicon device. The manufacturer plans to update these data periodically, particularly after the device is available in the US. The PMA investigation for FDA clearance currently going on will also add patient satisfaction data for the Infla10 not available on PIF studies.

Device infection is the most dreaded complication in penile prosthesis surgery. The two competitive devices have infection retardant coatings applied: AMS has the antibiotics of Rifampin and Minocycline (InhibiZone) applied at the factory and Coloplast has a hydrophilic coating which when dipped in an aqueous solution absorbs whatever antimicrobials were added to the solution.[12] The Infla10 has a similar hydrophilic coating on all external surfaces which allows the surgeon to select whatever antimicrobials are appropriate for their patient population. Following implantation, the absorbed antimicrobials elute into the implant spaces to help prevent infection. In addition, the coating promotes easier device implantation because it makes the implant surface lubricious when moistened.

In this study, Infla10's infection rate was found to be very low with only one infection in 535 patients with follow-up times ranging from 7 to 43 months. Infection rates of IPP have been reported in the literature as low as 0.46%.[13] Most penile implant device infections occur within the first 12 months.[12] Because our study includes patients only 7 months from surgery, infections may have not yet clinically appeared. There is also the possibility that the infected patient presented to a different hospital and the surgeon removing the device was not as vigilant in PIF compliance as the original surgeon would have been. Regardless, even if a few more

infections become evident, the infection rate of the Infla10 three-piece IPP with 103 different implanting surgeons is well within expectations.

Our study is limited by the inherent challenges related to PIF data, which are dependent on accurate recording and logging of information. PIF data are not comprehensive and lack granularity regarding individual patients. Complications may not have been completely or accurately reported via the PIF system. Additionally, as we have noted above, our follow-up duration is far shorter than that of previous studies of other IPPs. With that said, thus far the Rigicon Infla10 exhibits comparable device durability in this expanded series of patients.

CONCLUSION

This second study with more patients and longer time of follow-up validates the early positive findings for durability from revision reoperation for any reason for the new Rigicon Infla10 three-piece inflatable penile prosthesis. Analysis of the first 535 patients implanted with the Rigicon Infla10 shows safety data for survival from mechanical failure, device infection, other medical problems, and patient dissatisfaction to be consistent with results for established competitor devices.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: SW: International Medical Device, Rigicon, Uramix. HM: None. BK: None. GT: Rigicon. CL: Coloplast. MR: None. AC: None. MH: None. MG: Coloplast.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.urology.2023.06.031.

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Editorial Comment

We applaud the authors for their expansion and longer follow-up for this important new product that hopefully will be a valuable addition to the armamentarium in managing refractory erectile dysfunction. Patient satisfaction and device durability represent a major concern for patients and urologists.

In the United States (US), two existing three-piece inflatable penile prosthesis (IPP) products have been used for decades to manage erectile dysfunction; these are the Coloplast Titan series (Coloplast, Minneapolis, MN) and the American Medical Systems (AMS) 700 (AMS, Minnetonka, MN, a subsidiary of Boston Scientific). Both have had durable reported outcomes extending to >15 years and have been shown to have high patient satisfaction rates and very few shortcomings.[1] This sets a high bar for Rigicon (Ronkonkoma, NY) as it makes its way into the market with those two reputable and established competitors.

In general, prosthesis infections occur in 2%-3% of first-time implants. Most infections will be manifest at 3 months, although the vast majority will occur in the first year[2] and various risk factors and prevention strategies have been described.[3,4] In the current cohort of 535 implants, there was only one infection reported, although the shortest follow-up time was 7 months. In terms of revision rates, in a prior publication, Wilson et al[1] reported a cohort of over 2000 first-time IPPs, and

the 5, 10, and 15-year revision-free survival rates were 79%, 69%, and 60%, respectively. In the current cohort, for the Infla10, the authors report an encouraging 3-year survival rate from needing another surgery of 94%. Only time and consistent follow-up of patients with this new device will reveal if it is better, worse, or comparable to its competitors in terms of need for revision.

The surgeons for the cohort were comprised of experienced implanters from 15 different countries, which makes it more generalizable; however, about 70% were from a single country (Turkey). More granular data pertaining to number of implanters from each country and their level of experience may provide additional insight. A limitation of this study is that it is difficult to track patient outcomes with deidentified data from the patient information form and the reoperation rates may be underreported. How often did surgeons actually fill out the patient information form for repeat surgery related to the IPP? At least with a list of identifying data, attempts could be made to individually contact patients to determine if they had additional surgeries, either at the same or different facility, and queried as to satisfaction with the device.

Surgeons for the most part are creatures of habit and if the Infla10 is approved by the Food and Drug Administration in the US, it can be challenging to sway the implanters toward a newer product, away from something that is already working well. Marketing, favorable cost, and good longitudinal data may encourage hospitals, patients, and physicians to adopt this new implant. More importantly, the device will need to prove that it's not just "noninferior" to its long well-known competitors.

Declaration of Competing Interest

None Declared.

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