ARTICLE

Short-term revision rate of Rigicon Testi10™ testicular prosthesis in adolescents and adults: a retrospective chart review

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Testicular prosthesis implantation is a valuable solution for the physical, cosmetic, and psychological challenges associated with testicular loss which may affect males of any age. We evaluated the safety and reliability of the new Rigicon Testi10™ testicular prosthesis in adults and adolescents by performing an IRB-approved retrospective study of data drawn from Patient Information Forms (PIFs). A total of 427 patients (382 adults and 45 adolescents) had at least one testicular prosthesis implanted. Only one adult patient required revision surgery due to rupture of the Rigicon Testi10 ™ saline-filled prosthesis. A 40-year-old patient was found to have a leaking prosthesis approximately one week postoperatively, which was suspected to be due to inadvertently punctured by the surgeon during the sterile saline filling process. There were no post-implantation revisions required for adolescent patients. According to our results, Kaplan–Meier calculation of survival from removal or revision was 99.8% for all patients at 54 months (99.7% for adults and 100% for adolescents). The complication rates among patients in this study are lower than those reported in previous published studies. Our study underscores the generally safe nature of testicular prosthesis implantation, as well as the very rare incidence of revision surgery for this new device.

IJIR: Your Sexual Medicine Journal; https://doi.org/10.1038/s41443-024-00893-8

INTRODUCTION

Testicular absence can result from various causes, including congenital testicular agenesis [1], undescended or atrophic testis [2, 3], and removal due to tumors [4], torsion [5], infection or trauma [6, 7]. The absence of one or both testicles can result in male physical and psychological concerns which can be effectively addressed through testicular prosthesis implantation [8, 9]. This is particularly important during childhood and adolescence, where ensuring safe testicular prosthesis placement involves selecting the appropriate prosthesis size, using the correct surgical approach, and providing adequate post-operative care [10–13]. A favorable cosmetic result significantly contributes to the psychosocial development of young boys and adolescents during puberty [14–18].

Dr. Ralph Bowers is credited with the first implantation of a testicular prosthesis in 1939 [19]. This initial implant was made of a non-ferrous alloy called vitallium, which consisted of chromium, cobalt, and molybdenum, and the introduction of this device prompted further experimentation with materials such as lucite, glass, and gels [20–22]. Subsequent prosthetic efforts attempted to approximate the appearance and feel of natural testicles. In the 1960s, Prentiss et al. introduced solid silicone prosthetic testes, which were deemed to be significantly firmer than testes [23]. Lattimer et al. later developed gel-filled silicone testicular implants, similar to gel-filled breast implants, resulting in more natural results [24]. Gel-filled silicone breast implants eventually sparked great public controversy in the United States, which led to a halt in the production of similarly constructed testicular prostheses in 1995 [24–26].

Current global manufacturers of testicular implants include GC Aesthetics (Dublin, Ireland), Aart (Carson City, NV, USA), Coloplast (Minneapolis, MN, USA), Osteotec (Christchurch, New Zealand), Sebbin (Boissy-l'Aillerie, France), Uromed (Oststeinbek, Germany), and Promedon (Córdoba, Argentina). The available implants on the market are made of silicone and are filled with either gel, solid elastomer, or saline solution. In the United States, the only FDA-approved testicular implant for adults and children is the Coloplast Torosa™ which is a saline-filled implant [16].

The newest testicular prosthesis in the worldwide market is the Rigicon Testi10™ testicular prosthesis (Ronkonkoma, NY, USA). This device is not currently FDA approved for use in the United States but has been used in over 30 countries worldwide since its introduction in 2019. The Testi10™ has three different models: solid silicone (Testi10™ Firm), a saline model filled during manufacture (Testi10™ Saline-Filled), and an empty saline model (Testi10™ Saline). The former two devices come ready to be implanted. The latter model is supplied empty and injected with saline during surgery. The Rigicon Testi10™ is crafted from

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Received: 12 January 2024 Revised: 19 March 2024 Accepted: 10 April 2024
Published online: 07 May 2024

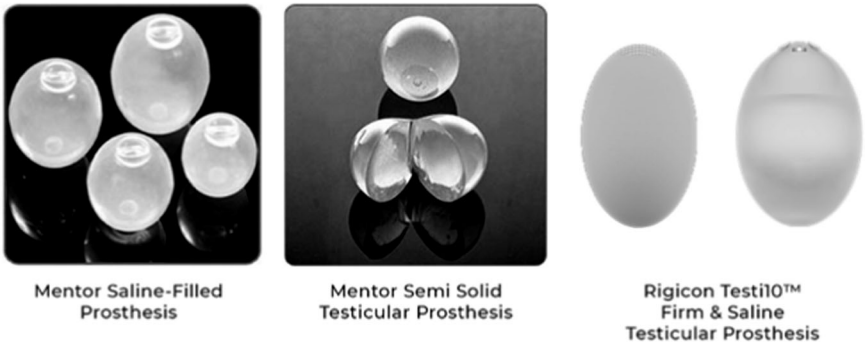

Fig. 1 Testicular prostheses.

medical-grade silicone elastomer and is equipped with a mesh tab to facilitate securing of the artificial testicle within the scrotal region. The saline-filled testicular prosthesis is initially manufactured without saline filling and is filled with sterile saline during the surgical procedure. The saline testicular prosthesis comes prefilled with saline during its manufacturing process. Various testicular prostheses are shown in Fig. 1.

We investigated the safety of all three models of Testi10TM testicular prosthesis implantation using Patient Information Forms (PIFs) completed by physicians and staff at the time of surgery.

MATERIAL AND METHODS

Study design and patient selection

Between February 2019 and August 2023, a total of 427 male patients (382 adult and 45 adolescent) underwent Rigicon Testi10^{TM} testicular prosthesis implantation by a total of 132 physicians from 45 centers in 26 countries (110 physicians from 25 centers in 11 countries for adults and 22 physicians from 20 centers in 15 countries for adolescents). IRB approval for this study was obtained from the Istanbul Medipol University Ethics Committee (approval number: 2023–425). All patients had 1 or 2 missing testicles and showed no signs of active malignancy or active rheumatologic disease. Individual patient consent, aside from standard surgical consent forms, was not needed as this was a retrospective study. The choice of incision, either inguinal or scrotal, was made based on physician judgement and patient-specific factors.

Patient data were obtained via PIFs that were completed by the surgeon or staff during the implantation process. Hospital and patient PIFs are shown in Figs. 2 and 3. All patient identifiers were meticulously redacted prior to analysis, leaving only the hospital number and the surgeon's name. The information derived from the analyzed PIFs included patient characteristics (such as age, height, weight, and the cause of testicular loss), surgery date, testicular model and size, surgical incision site, and any reasons for reoperation.

Statistical analysis

Patient demographic analysis and Kaplan–Meier survival calculations were performed using SPSS 22.0 software (IBM, Armonk, New York). The average standard deviation values for the cases were documented as Kaplan–Meier survival rates at the 54-month mark after operation.

RESULTS

The total number of cases in the study cohort was 427. The demographic data and the etiology of testicular loss for the study cohort are presented in Table 1. The mean age of the participants was 22.02 ± 7.31 years (range 7–54). The average follow-up period for the study was 19.53 ± 15.12 months (range 1–54). Overall, the top three most common causes of testicular loss were tumor (36.30%), torsion (14.75%), and orchitis (8.67%).

For adults, the etiology of testicular loss was attributed to tumors in 38.48% of the total cases. After unknown etiology (23.3%), testicular torsion was the second most common cause, representing 13.61% of the cases. Other causes included orchitis (9.16%), atrophy (4.45%), ectopic (4.19%), agenesis (3.4%), Gender Affirming Surgery (2.1%), trauma (1.31%). Table 2 details the characteristics of testicular prostheses used for adult patients. The most commonly implanted model was the Testi10^{TM} Saline-Filled (75.13%), followed by Testi10^{TM} Saline (23.56%) and then Testi10^{TM} Firm (1.31%). In terms of testicular prothesis size, the Medium size was most common ($n = 172$) and Extra-Small was least common ($n = 7$), with all available sizes shown in Fig. 4.

For adolescents, testicular loss was due to torsion in 24.44% of cases, followed by tumors (17.78%) and atrophy (8.89%). Other causes included ectopia (6.67%), orchitis (4.44%), and agenesis (2.22%). In 35.56% of cases, the cause of testicular loss was not identified on the PIF form. Table 2 shows the models and sizes of implanted testicular prostheses in the adolescent cohort. The majority of implanted devices were Testi10^{TM} Saline-Filled (75.56%), followed by Testi10^{TM} Saline (20%) and then Testi10^{TM} Firm (4.44%). The most commonly implanted size was Large (31.11%) while the least common size was Small (8.89%).

The overall complication rate was 0.23% ($n = 1/427$). The only complication occurred intraoperatively for an adult patient where a saline testicular prosthesis ruptured during filling. Initially, the saline-filled testicular prosthesis, manufactured empty, is filled with sterile saline during the surgical operation. During this process, surgeons must exercise caution to avoid puncturing the prosthesis from the inside. However, in this specific case, it was noted that the prosthesis was inadvertently punctured by the surgeon during the filling process. There were no complications in the adolescent cohort. The Kaplan–Meier calculation of survival from removal or revision was 99.8% for all patients at 54 months (99.7% for adults and 100% for adolescents) (Fig. 5).

DISCUSSION

Congenital or acquired loss of one or both testicles can negatively influence the physical and emotional health of affected individuals. Testicular prosthesis implantation has stood the test of time as a valuable solution to effectively address these issues [27, 28]. We evaluated the safety and of Testi10^{TM} Testicular Prosthesis implantation in 427 patients and found this device to have high safety and an extremely low complication rate despite being implanted by multiple physicians in many different countries outside the US.

The most common indications for testicular prosthesis insertion were tumors and testicular torsion. We presume that the large, reported percentage of unknown etiologies (23.3% for adults and 35.56% for adolescents) is attributable to a different surgeon implanting the prosthesis from the original testicle removal surgeon. Previous publications have shown that the complication rate varies depending on the indication for testicular prosthesis. Hayon et al. found that implants for patients who underwent orchiectomy for testicular tumors had the lowest overall complication rate at 11% [16]. Marshall's review of 2500 patients

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PATIENT INFORMATION (MAY USE PATIENT STICKER/LABEL)	PATIENT NAME (LAST) ..... (FIRST) ..... (MIDDLE) .....

SOCIAL SECURITY NO. (U.S. ONLY)	MONTH DAY YEAR DATE OF BIRTH / /	PLACE OF BIRTH

ADDRESS
CITY, STATE, POSTAL CODE, COUNTRY
.....

TELEPHONE NUMBER
.....

INSURANCE CARRIER
.....

HOSPITAL NAME, ADDRESS, TELEPHONE NUMBER	MONTH DAY YEAR DATE OF SURGERY / /

IMPLANTING SURGEON (LAST) (FIRST) (MIDDLE)

ETIOLOGY

☐ Ectopic testicle	☐ Testicular atrophy	☐ Transsexual surgery
☐ Genitourinary cancer / Metastatic prostate cancer	☐ Testicular agenesis (unilateral or bilateral congenital	☐ Others (Please indicate in comments)
☐ Testicular bulk/tumour	☐ Orchitis	
☐ Testicular torsion	☐ Trauma, disease or other	

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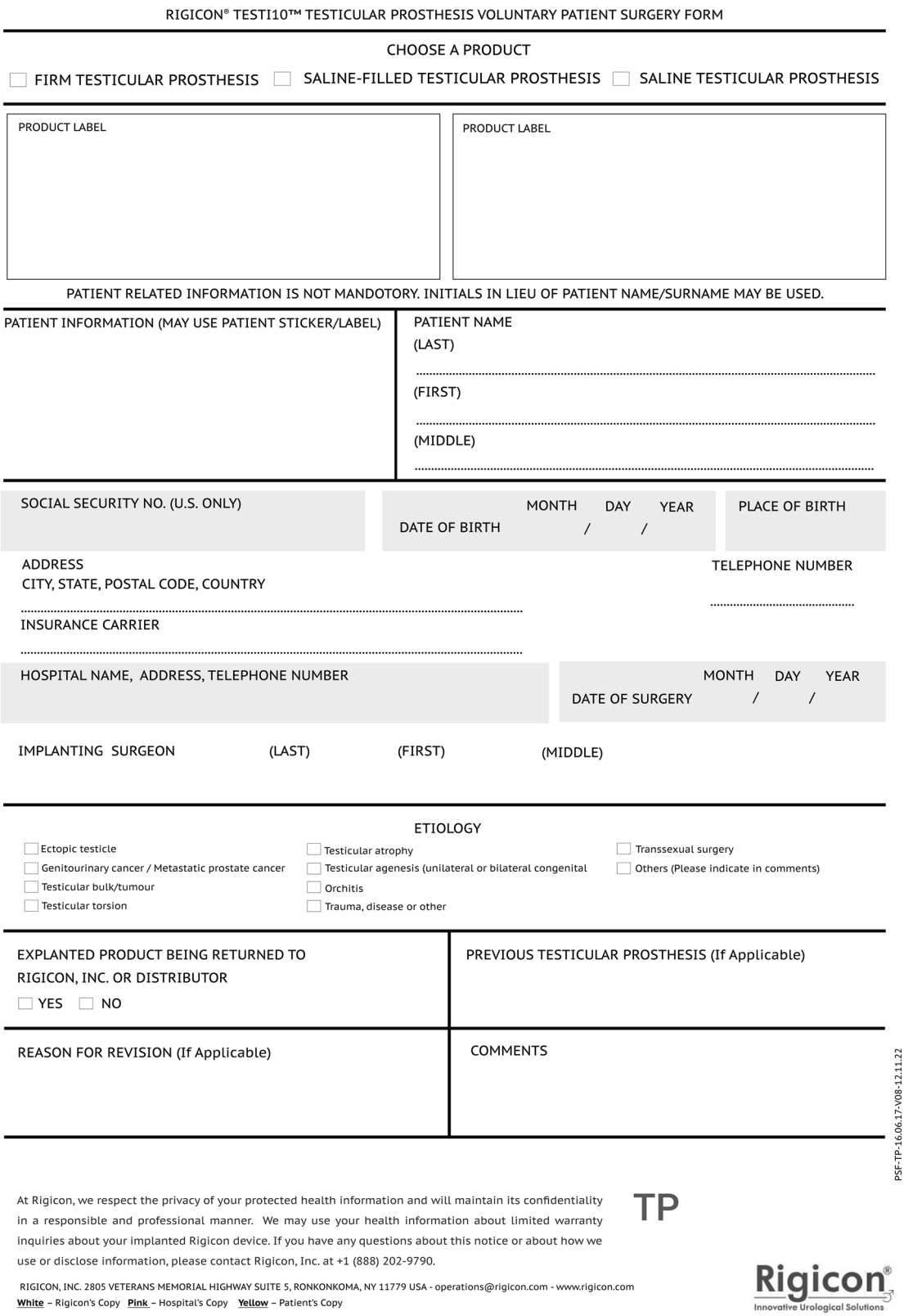
Fig. 2 Hospital PIF.

showed that implants performed for epididymitis/orchitis had the highest overall complication rate at 31% [6]. Postoperatively, Marshall reported a 22% risk of transient scrotal contraction, an 11% risk of persistent scrotal contraction, an 8% risk of wound dehiscence/prosthetic extrusion, a 3% risk of infection, and a 3% risk of postoperative pain in that series. Our results exhibited a lower complication rate compared to other studies. Our only complication stemmed from a surgical error; the implanting surgeon overfilled the device which resulted in intraoperative rupture.



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PATIENT NAME
(LAST)
.....
(FIRST)
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(MIDDLE)
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SOCIAL SECURITY NO. (U.S. ONLY)

DATE OF BIRTH MONTH / DAY / YEAR

PLACE OF BIRTH

ADDRESS
CITY, STATE, POSTAL CODE, COUNTRY
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TELEPHONE NUMBER
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INSURANCE CARRIER
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☐ Ectopic testicle
☐ Genitourinary cancer / Metastatic prostate cancer
☐ Testicular bulk/tumour
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☐ Testicular atrophy
☐ Testicular agenesis (unilateral or bilateral congenital
☐ Orchitis
☐ Trauma, disease or other
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Fig. 3 Patient PIF.

The literature on post-operative complications in boys who undergo testicular implant surgery is notably limited. Kogan highlighted the potential dangers of prosthesis rupture leading to silicone leakage in a study analyzing silicone gel models of testicles [17]. Given the potential risk, Rigicon elected not to market a silicone gel-filled testicular prosthesis. Peycelon et al. identified other complications, including prosthesis migration, extrusion, and wound infections [10]. Turek and Master raised concerns about the risk of pulmonary embolism with silicone gel [13]. Mohammed et al. emphasized the importance of

Table 1. Number of patients, follow-up, etiology of testicular loss.

	All patients ($n = 427$)		Adults ($n = 382$)		Adolescents ($n = 45$)	
Demographic age and follow-up period						
	Mean ± SD	**Range**	**Mean ± SD**	**Range**	**Mean ± SD**	**Range**
Age (years)	22.02 ± 7.31	7–54	31.01 ± 10.47	18–54	13.02 ± 4.14	7–17
Follow-up (months)	19.53 ± 15.12	1–54	17.17 ± 13.39	1–54	21.88 ± 16.84	1–54
Etiology of testicular loss						
	n	**%**	***n***	**%**	***n***	**%**
Tumor	155	36.30	147	38.48	8	17.78
Torsion	63	14.75	52	13.61	11	24.44
Orchitis	37	8.67	35	9.16	2	4.44
Atrophy	21	4.92	17	4.45	4	8.89
Ectopic	19	4.45	16	4.19	3	6.67
Agenesis	14	3.28	13	3.40	1	2.22
Gender affirming surgery	8	1.87	8	2.1	0	0
Trauma	5	1.17	5	1.31	0	0
Unknown	105	24.59	89	23.30	16	35.56

Table 2. Models and sizes of testicular prosthesis.

	All patients ($n = 427$)		Adults ($n = 382$)		Adolescents ($n = 45$)	
Model of testicular prosthesis						
	n	**%**	***n***	**%**	***n***	**%**
Testi10^{TM} saline-filled	321	75.18	287	75.13	34	75.56
Testi saline	99	23.19	90	23.56	9	20
Testi firm	7	1.64	5	1.31	2	4.44
Size of testicular prosthesis						
XS	15	3.51	7	1.83	8	17.78
S	32	7.49	28	7.33	4	8.89
M	184	43.09	172	45.03	12	26.66
L	157	36.77	143	37.43	14	31.11
XL	56	13.11	49	12.83	7	15.56

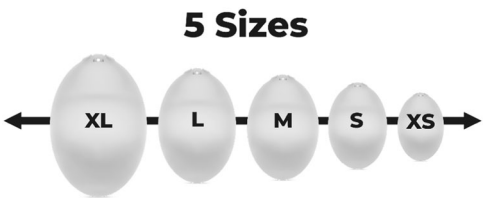

Fig. 4 Size options for the Testi10^{TM} testicular prosthesis.

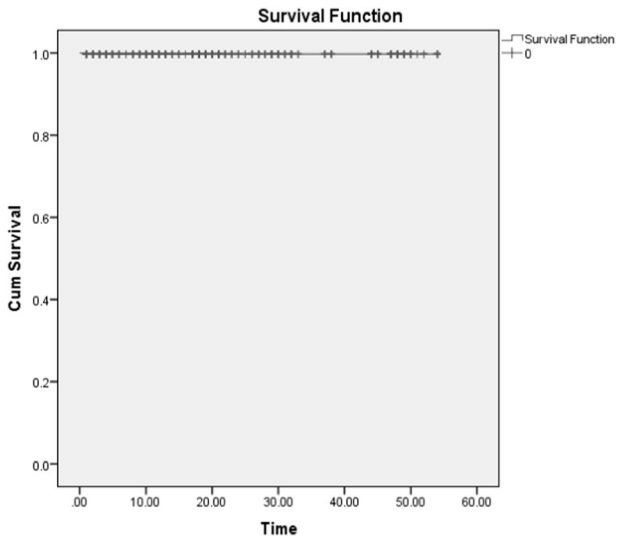

Fig. 5 Kaplan–Meier survival analysis for 54 months for all patients.

comprehensive follow-up care for these patients [18]. Henderson et al., as well as Pidutti and Morales, both conducted investigations into the immunological-systemic responses to silicone implants [26, 29]. For both groups of researchers, their findings lacked definitive evidence of any potential influence of associated immune disorders. Genest et al. observed that the presence of a testicular prosthesis, like any foreign object, triggered a local tissue response, resulting in the formation of a two-layered capsule composed of collagen fibers containing silicone particles [30]. A 2018 multi-institutional study has shown that early complications, such as wound infections, delayed wound healing, and skin necrosis, were noted in 15% of boys, while late complications, including prosthesis displacement, partial exposure, and prolapse, were observed in 8% of boys [31]. To date we have not experienced any of these adverse events. Our study is limited by our reliance on safety data gathered from PIFs. These are completed at the time of surgery by the surgeon, the operating room staff, or the company representative present at surgery. PIF form data can miss reoperation information, particularly if the revising surgeon is not the original implanter. Revision surgery by a different surgeon at a remote hospital may have led to the unintentional exclusion of surgery on some implanted patients from our cohort. However, concerns about such variances are somewhat alleviated by the fact that examination of removed medical devices by pathology is required at all implanting hospitals prior to the device being returned to the manufacturer. This return of the explanted device gives a back-up check when compared to the PIF log of implanted patients.

PIF data is commonly used for prosthetic urology research for a variety of reasons. Because of the rarity of testicular prostheses,

like other prosthetic urology procedures, and the need for substantial outcome data from a high number of small volume surgeons, PIF data have become a trusted source for significant studies in prosthetic urology, as evidenced the penile prosthesis literature [32–35]. Testicular implants are a distinctly uncommon surgery and assessment of safety from revision would not be possible using an individual physician's experience. With regard to accuracy of PIF's, physicians and staff are stimulated to accurately fill out PIFs during the initial surgery because these forms activate the device warranty. Similarly, PIF completion during revision surgery is also motivational because it justifies a "no charge" status for the substitute implant. Thus, over the 50 years of prosthetic urology, PIF data are among the most useful tools for assessing device safety and reliability [32–35].

In summary, our research underscores the early safety in adult and adolescent patients of all Rigicon Testi10™ Testicular Prostheses available since 2019. The very low rate of device complications signifies the early safety from revision surgery for any reason. The comparison literature on post-operative complications in patients undergoing testicular implant surgery is limited, and our findings still need verification with longer follow-up than 2 years. Nevertheless, our study is encouraging for safe adoption of this new product in a highly competitive field. Rigicon's Testi10™ comes in a more extensive range of available sizes and models than competing devices, which allows patients and surgeons to make tailored choices to aid in achieving desired esthetic outcomes.

CONCLUSIONS

Insertion of a Rigicon Testi10™ testicular prosthesis appears to be a safe procedure for the treatment of testicular loss in these early follow-up data. The overall complication rate is very low in this series and is also comparable to other reported studies. Larger studies and prospective investigations are warranted to further validate our findings and to assess the long-term outcomes of Testi10™ Testicular Prosthesis implantation.

DATA AVAILABILITY

The data generated during this study can be found within the published article or can be made available from the corresponding author on reasonable request.

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AUTHOR CONTRIBUTIONS

All authors have made substantial contributions to this work. All authors (BLA, DK, SKW, OK, RSP, CMV, ND, MSG) were involved in the acquisition, analysis, and interpretation of data for the work, with final statistical analyses performed by OK. SKW, BLA, OK & MSG all contributed to drafting the manuscript and revised it critically for important intellectual content including final approval of the version to be published. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

COMPETING INTERESTS

DK is a paid employee of Rigicon responsible for PIF data assemblage. SW is a consultant for Rigicon. All other authors have nothing to disclose related to this article.

ADDITIONAL INFORMATION

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