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# SAFETY AND EFFECTIVENESS OF A NEW SALINE FILLED TESTICULAR PROSTHESIS

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ABSTRACT

Purpose: Testicular prostheses have been used for 50 years to replace missing or removed testes. In 1995 the manufacture of the silicone gel filled testis prosthesis in the United States was discontinued because of concern about the safety profiles of other implants. We assessed the safety and effectiveness of a new, saline filled implant for testicular replacement.

Materials and Methods: This open label, multicenter, prospective, case controlled clinical trial was done at 18 American tertiary referral centers. Adult and pediatric male patients missing 1 or 2 testes and without evidence of active malignancy or rheumatological disease were enrolled. All patients underwent formal rheumatological and urological evaluation prior to and after prosthesis placement. Main outcome measures were prosthesis safety assessed by adverse events and effectiveness assessed by changes in testis dimension. Secondary outcome measures were quality of life assessments with 3 validated instruments. All patients were followed a minimum of 1 year in this 5-year study.

Results: Postoperative adverse events observed in 19% of 149 patients included device related discomfort or pain in 3%, scrotal edema in 1.3%, infection in 1.3%, extrusion in 2.6%, deflation in 0.7% and pulmonary emboli in 0.7%. No patient reported rheumatological symptoms at 1 year. Testis dimensions were significantly increased in patients missing a testis at baseline ($p < 0.001$). Subjective assessment of testicular appearance was significantly improved ($p < 0.001$) and scores were stable or significantly improved in 2 of 3 quality of life instruments.

Conclusions: At short-term followup a new, saline filled testis prosthesis appears safe and well tolerated. Importantly validated self-esteem measures also suggest improvement in quality of life after prosthesis placement.

KEY WORDS: testis, prostheses and implants, self concept, orchiectomy, silicones

Testicular loss occurs for various reasons in adults and children. Loss following orchiectomy for cancer, torsion or agenesis was thought to be associated with psychological distress in children and adults in anecdotal reports.[1,2] Therefore, prosthetic devices have been developed to restore the normal appearance of the scrotum and hopefully restore quality of life.

Multiple materials have been used for testicular prosthesis. The first testicular prosthetic device was implanted in 1939 by Bowers using the metal alloy vitalium.[3] Subsequently in an effort to develop a more cosmetically acceptable prosthetic various materials have been used, including glass spheres, polymerized methyl methacrylate, methacrylate and polyurethane foam. A dramatic improvement in device consistency was achieved by Lattimer et al in 1973 with a silicone gel filled, silicone rubber prosthesis.[4] Used widely until 1995, manufacture of this device was discontinued because of emerging concerns over the association of silicone implants with connective tissue disease.[5–7] Subsequently multispecialty expert panels in the United States (Institute of Medicine and the National Science Panel) and United Kingdom failed to find evidence indicating any causal linkage. In fact, gel filled implants are still currently used in the United Kingdom.[8] These events spurred the development of even more sophisticated and well designed devices for testicular prostheses.

This open label, multicenter, prospective study focused on the safety profile of implanting a new, saline filled testicular prosthesis in children and adults. We also assessed whether prosthetic placement was associated with signs and symptoms of connective tissue disorders. Perhaps most importantly the impact of testicular prosthetic placement on quality of life was measured using validated psychological instruments.

## MATERIALS AND METHODS

*Testis prosthesis device.* The prosthesis under study was Food and Drug Administration approved as an investigational device and implanted under institutional review board approval at each study center. The prosthesis consists of a silicone composite shell 0.035 inches thick filled with injectable grade (United States Pharmacopoeia) normal saline to achieve the desired consistency (see figure). The prosthesis is manufactured in 3 sizes, namely small—8 to 9, medium—9 to 11 and large—15 to 16 ml. At the upper pole of the device the silicone shell is thicker to prevent leakage after needle penetration (27 gauge) during device filling. At the lower pole there is a recessed suture tab that allows the device to be fixed in place during placement.

*Patient criteria.* A total of 149 adult and pediatric patients from 18 institutions were accrued into the study during the 1-year period 1998 to 1999. The study inclusion criterion was loss of a testicle from birth or following orchiectomy. Patients were excluded from study due to connective tissue disease, intrascrotal infection or scrotal malignancy, uncontrolled di-

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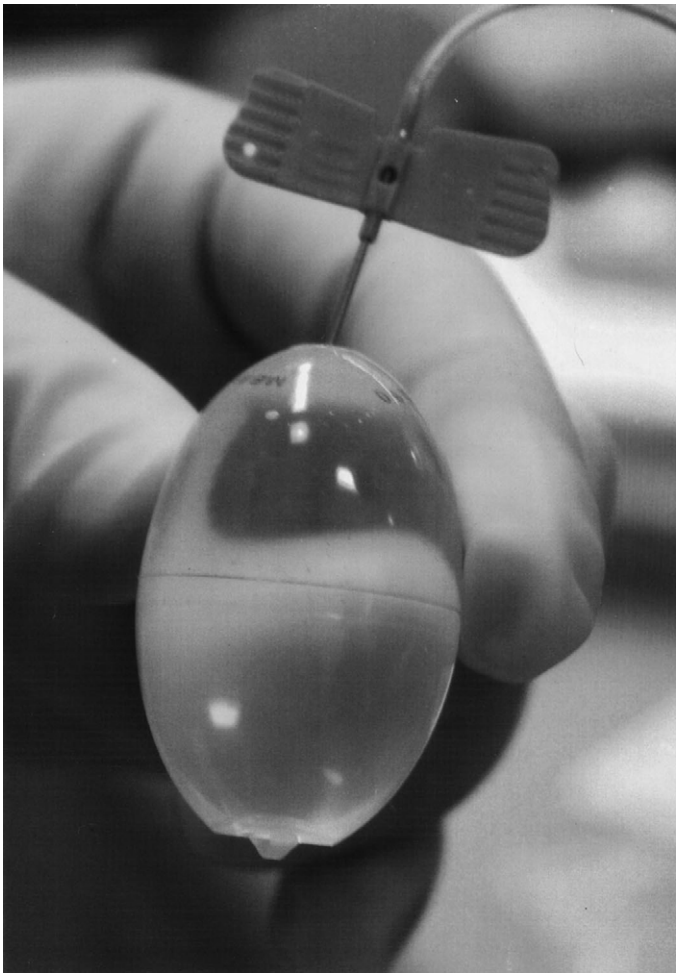

Testicular prosthesis is filled with saline through self-sealing port at device apex. Note suture tab at device base.

abetes, any previous testicular prosthetic placement, silicone implants elsewhere in the body or psychiatric disease. Enrolled patients composed 2 cohorts, namely those missing a testicle(s) at study baseline and those who had 2 testicles at study enrollment. Patients were followed a minimum of 1 year after surgical prosthesis placement.

*Patient assessment.* Preoperatively all patients underwent a thorough review of the medical history and a complete physical examination to determine surgical candidacy. This included a questionnaire and evaluation for rheumatological disease in an assessment performed by study investigators after formal training in rheumatological history and physical examination. In addition, patients older than 13 years completed 3 validated psychological questionnaires, namely the Rosenberg Self-Esteem Scale and the Body Esteem Scale (Physical Attractiveness Sub-scale) to assess self-esteem and body image, and the Body Exposure in Sexual Activities Questionnaire (BESAQ) to assess sexual quality of life. The Body Esteem scale is a 35 item scale with 5 response categories (strong negative feelings, moderate negative feelings, no feeling 1 way or another, moderate positive feelings and strong positive feelings) that measures subjects feelings toward themselves. The Rosenberg Self-Esteem scale is a 10-item scale that also measures subject overall feelings toward themselves using the 4 response categories 1—strongly agree, 2—agree, 3—disagree and 4—strongly disagree.

Postoperatively all assessments, including psychological and rheumatological questionnaires, were repeated at 1 year and annually thereafter following prosthesis placement. Postoperative evaluation was done 3 months, 1 year and annually thereafter after prosthesis placement. The primary outcome assessments were objective measurement of testicle size by the surgeon who performed implantation using a Prader orchidometer (ASSI Instruments, Westbury, New York) and subjective assessment of appearance using the 5 point scale, 1—missing, 2—very abnormal, 3—somewhat abnormal, 4—almost normal and 5—normal. Secondary outcome measures were the results of the 3 validated psychological and 1 rheumatological questionnaires. Medical and surgical complications were also assessed at each time point.

*Surgical technique.* All prostheses were placed surgically on an outpatient basis. Prior to placement all patients received perioperative intravenous antibiotics (surgeon choice) and thorough skin preparation with an iodine or chlorhexideine based scrub. Prostheses were placed via scrotal or inguinal incisions based on surgeon preference. Scrotal incisions were made in the midline scrotal raphe or in a rugal skin fold with the site of entry distant from the final resting position of the prosthesis. After the incision a scrotal pouch was created with blunt dissection and meticulous hemostasis was achieved within the scrotal wall. The dartos fascia in the most dependent posterior portion of the inner scrotal wall was lightly grasped with an Allis clamp and with the help of an index finger pushing in from outside the scrotum was everted to visualize this area. Although it was a matter of surgeon choice, most commonly a nonabsorbable stitch (2-zero braided polyester) was used to fix the dartos fascia to the prosthesis through the suture tab and help maintain its dependent position. The scrotal skin was then inspected for evidence of suture perforation or dimpling. The prosthetic device was bathed in antibiotic solution and filled through the self-sealing injection port with United States Pharmacopoeia grade normal saline (0.9%) with displacement of all air until the softest possible fluid consistency was achieved without dimpling of the prosthetic wall (see figure). After prosthesis placement into the scrotal pouch it was examined for suitability and dependent lie. The scrotal or abdominal wall was closed in multiple nonoverlapping layers with absorbable suture after copious antibiotic irrigation. Drains were contraindicated in this procedure. Postoperatively patients were discharged home on several days of oral antibiotics and reexamined within 3 months of surgery.

*Statistical methods.* Primary and secondary outcomes were collected from all enrolled patients and entered into a database. Measured outcomes were device safety and effectiveness. Device safety was assessed by 95% CI analysis and Cox regression modeling was applied for covariate analysis of risk factors. Effectiveness was measured by paired t test analysis of changes in testis dimension and ANOVA analysis of stability in dimensions. Variables in self-esteem scales were assessed by stepwise, repeated measures ANOVA analysis with $<0.05$ considered significant. Statistical analyses were performed with SAS, version 8 (SAS Institute, Cary, North Carolina).

## RESULTS

Overall 149 patients had a total of 176 testicular prostheses inserted, including 27 with bilateral implants. Of all patients 76 were adults (18 years or older) and 73 were children (0 to 17 years old). Mean age was 31.3 years in adult patients and 12.8 years in pediatric patients. The majority of subjects were white (91.3%) and most adults (67%) were single with at least some college education (80%). Adult patients had been without a testicle a median of 1.9 years and pediatric patients had been without one median of 9.1 years. The majority of prostheses (64%) were placed after orchiectomy for suspected malignancy (table 1). Other reasons for device placement were testis agenesis, and prior orchiectomy for torsion and trauma (table 1). Another indication for device placement in pediatric patients was treatment of inter-

TABLE 1. *Pathological condition leading to prosthesis placement*

| Pathological Condition | No. Adult | No. Pediatric | Total No. |
|---|---|---|---|
| Orchiectomy | 66 | 47 | 113 |
| Agenesis | 11 | 32 | 43 |
| Torsion | 4 | 11 | 15 |
| Trauma | 4 | 1 | 5 |

sex disorders. A minimum 1-year followup was required in each patient.

*Device safety.* Adverse events were defined as events occurring at or after surgical placement of the device that were deemed related to the device or the placement procedure. They were classified as major or minor complications based on whether reoperation was (major) or was not (minor) required for relief (table 2). Major complications were device extrusion in 3 patients (2%) and device migration in 1 (0.7%). The reoperation rate was 3 of 149 cases (2%) in the study. Minor complications managed nonoperatively were discomfort or pain in 9% of cases, allergies or sinusitis in 5%, scrotal edema in 3%, and hematoma, numbness, keloid and mild migration in 1% each (table 2). Importantly 14.5% of adverse events were deemed device related by investigators, including those in 3 patients (2%) with pain or discomfort. The remainder of reported adverse events were deemed procedure or nonprocedure related. The Kaplan-Meier survival estimate of experiencing discomfort/pain within 1 year of device placement was 6.7%. Cox regression analysis did not identify any statistically significant risk factors related to adverse events (ie smoking or age).

In general adults had a higher rate of adverse events compared to pediatric patients but this difference did not achieve statistical significance. By physical examination and detailed rheumatological questionnaire no patient had connective tissue disease within 1 year of device placement.

*Device effectiveness.* The primary outcome measure of effectiveness was the investigator assessment of prosthetic testicle size and the subjective assessment of appearance (tables 3 and 4). Testicular implant size remained stable when measured at 3-month intervals (data not shown). Not unexpectedly clinician assessment of appearance increased significantly from a baseline median value of 1 (missing) to a value of 4 (almost normal) in adults and children (table 4). Secondary outcome measures were the Body Esteem Scale, the Rosenberg Self-Esteem Scale and BESAQ (tables 5 and 6). Highly statistically significant increases were observed when baseline and post-placement assessments were compared in the BESAQ and in the physical attractiveness subscale of the Body Esteem Scale ($p < 0.001$).

When adult and pediatric patients were analyzed together, statistically significance increases were not achieved at 12 months on the Rosenberg Self-Esteem Scale. However, when the pediatric cohort was analyzed separately, statistically significant increases were seen on the Rosenberg Self-Esteem Scale 1 year after prosthesis placement. Thus, using several validated scales this prospective study showed quantifiable increases in several parameters of well-being in prosthesis recipients, including improved self-satisfaction and self-esteem, physical attractiveness, and behaviors and feelings during sexual activity in appropriate age groups.

TABLE 2. *Major and minor complications*

| Type | No. (%) |
|---|---|
| Major: | |
| Extrusion | 3 (2) |
| Migration | 1 (0.07) |
| Minor: | |
| Discomfort/pain | 13 (9) |
| Allergies/sinusitis | 8 (5) |
| Scrotal edema | 3 (2) |
| Displacement | 2 (1) |
| Hematoma | 2 (1) |
| Keloid | 2 (1) |
| Numbness | 2 (1) |

TABLE 3. *Testicle size assessment*

| Visit | No. Pts | Size (ml) | | |
|---|---|---|---|---|
| | | Mean | Median | SD |
| Adult: | | | | |
| Baseline | 52 | 0 | 0 | 0 |
| 12 Mos | 38 | 22.7 | 24 | 4.4 |
| Pediatric: | | | | |
| Baseline | 62 | 0 | 0 | 0 |
| 12 Mos | 50 | 21.5 | 23 | 4.9 |
| Orchiectomy at prosthesis placement: | | | | |
| Adult baseline | 22 | 13.5 | 12 | 12.5 |
| Adult 12 mos | 21 | 24.5 | 25 | 5.1 |
| Pediatric baseline | 9 | 1.3 | 1 | 0.9 |
| Pediatric 12 mos | 9 | 20.2 | 24 | 6.8 |

TABLE 4. *Subjective testicular appearance assessment*

| Visit | No. Pts | Score | | |
|---|---|---|---|---|
| | | Mean* | Median* | SD |
| Adult: | | | | |
| Baseline | 76 | 1.5 | 1 | 0.9 |
| 6 Mos | 65 | 3.3 | 4 | 1.2 |
| 12 Mos | 62 | 3.4 | 4 | 1.1 |
| Pediatric: | | | | |
| Baseline | 73 | 1.2 | 1 | 0.7 |
| 6 Mos | 64 | 3.6 | 4 | 0.8 |
| 12 Mos | 60 | 3.8 | 4 | 0.6 |

Adult and pediatric $p < 0.001$ vs baseline.
* Range 1 to 5.

TABLE 5. *Changes in body esteem and Rosenberg self-esteem scales*

| Visit | No. Pts | Mean Score ± SD | p Value Change |
|---|---|---|---|
| Body: | | | |
| Baseline | 130 | 40.2 ± 7.8 | |
| Mo 6 | 112 | 42.1 ± 7.7 | 0.009* |
| Mo 12 | 103 | 43.3 ± 7.4 | <0.001* |
| Rosenberg: | | | |
| Baseline | 130 | 34.4 ± 4.5 | |
| Mo 6 | 116 | 35.1 ± 3.8 | 0.045† |
| Mo 12 | 104 | 35.5 ± 4.7 | 0.396† |

* Vs baseline.
† Vs last assessment.

TABLE 6. *BESAQ in adults*

| Visit | No. Pts | Mean Score ± SD | Median |
|---|---|---|---|
| Baseline | 75 | 39.5 ± 18.6 | 37 |
| Mo 6 | 63 | 25.6 ± 18.2 | 25 |
| Mo 12 | 58 | 25.9 ± 20.8 | 27 |

Change vs baseline $p < 0.001$.

## DISCUSSION

Admittedly the effectiveness of a testicular prosthesis is difficult to assess accurately. Evidence for this includes the fact that there are no prospective studies in the literature that address this issue. Despite this fact there are small, retrospective studies of the issue of patient satisfaction, sexual functioning and body image.[9–11] In general these studies show increases in satisfaction, sexual functioning and body image after prosthesis placement but by design (lack of preoperative baseline assessments) they are unable to account for patient bias. Although it seems intuitive that testicular loss would result in decreased self-esteem and decreased emotional well-being, this has also not been formally studied and reported in the literature. To our knowledge this study is the first to apply well validated psychological instruments in a prospective manner to assess the impact of testicular gain

on psychological well-being in a large cohort of patients. Indeed, the results confirm that significant increases in several measures of well-being and quality of life are possible with testis prosthesis placement. Interestingly such data are readily available in cases of breast implant surgery following mastectomy, of which the outcome has been prospectively studied with various psychological instruments.[12, 13]

Several retrospective studies have examined complications rates following the placement of various testicular prostheses.[14, 15] From these studies it is clear that the incidence of wound dehiscence and prosthesis extrusion is 3% to 8% following device placement. In the current study the extrusion rate of 2% compares favorably with that in these reports. On close analysis all episodes of extrusion in this series were found in pediatric patients who were missing testicles at baseline and who also had a scrotal incision for prosthesis placement. Thus, in patients with a paucity of distensible scrotal skin it may be prudent to use a suprapubic or inguinal approach to prevent pressure necrosis and extrusion.

Prior studies indicate postoperative pain in 1% to 5% of implanted patients.[10, 14] Our series suggests that 9% of patients experience postoperative discomfort or pain. However, the detailed formal pain tool used in this study included minor levels of discomfort and also early postoperative pain. Such detail may not have been applied to pain assessments in prior studies. In addition, only 2% of patients were deemed to have pain that was actually device related. As such, this discrepancy in pain findings may reflect a true physiological observation or it may simply be an artifact of more intensive sampling. Short-term rheumatological assessment also showed that the current prosthesis is not associated with connective tissue disease. Obviously further followup is needed and planned to confirm these observations and monitor the long-term safety of this device.

## CONCLUSIONS

This study demonstrates that the saline filled testicular prosthesis can be implanted with few complications and with a low or absent risk of rheumatological disease. Importantly, in addition to its cosmetic value, testicular prosthesis placement results in an improved sense of well-being in an understudied population of males with unilateral or bilateral anorchia.

Mentor Corp. provided testis prostheses, assisted with the study and reviewed the manuscript.

## APPENDIX: TESTICULAR PROSTHESIS STUDY GROUP

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