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Periurethral Injection of Self-Detachable Silicon Microballoons for Female Urinary Incontinence: Surgical Technique and Long-term Results

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ABSTRACT

INTRODUCTION: Periurethral injections of absorbable and nonabsorbable materials have been proposed as treatment options for urinary incontinence due to intrinsic sphincter deficiency (ISD). Periurethral microballoon implantation has emerged more recently, but there are few reports regarding its efficacy and safety. The purpose of the present study was to describe the surgical technique and long-term follow-up results of periurethral microballoon implantation.

METHODS: A total of 11 female patients with urinary incontinence due to ISD were prospectively evaluated and treated with periurethral microballoon implantation. All patients were evaluated with a physical exam, urodynamic study, and 1-hour pad test both preoperatively and at follow-up assessments. The preoperative and final number of urine loss episodes, urodynamic assessment measures, and pad test results were compared statistically.

RESULTS: The mean operative time was 31 minutes (range, 20-47 minutes). The mean follow-up was 18 months (range, 9-60 months). Postoperatively, 3 patients (27.3%) were continent, 5 patients (45.4%) were improved, and 3 patients (27.3%) were incontinent. Both Valsalva leak point pressure and pad test weight values decreased significantly after surgery ($P < .001$). There were no significant presurgery and postsurgery differences for the number of urine loss episodes, detrusor pressure at maximum flow, maximum flow, maximum cystometric capacity, or postvoid residual volume ($P > .05$). Complications included *de novo* detrusor hyperactivity in 1 patient and microballoon extrusion in 5 patients (2 in the first year). Early extrusions appeared due to superficial injection of the balloon. Later extrusions may be attributed to the balloon's oval shape, because it offers no mechanical adherence to surrounding tissues.

CONCLUSION: Periurethral microballoon injection should not be used as an alternative treatment for female urinary incontinence because of a high number of extrusions and other reported complications.

KEYWORDS: Urinary incontinence; Treatment; Periurethral injection; Microballoon

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Abbreviations and Acronyms
ISI = intrinsic sphincter insufficiency
VLPP = Valsalva leak point pressure

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original study

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INTRODUCTION

Female urinary incontinence can occur as a consequence of urethral hypermobility or intrinsic sphincter insufficiency (ISI) of the urethral sphincteric mechanism. The former may be a consequence of pelvic floor alterations that disrupt the physiologic balance between abdominal pressure and the complex bladder and urethra, causing urinary incontinence. Urethral sphincter function can be compromised after pelvic surgical interventions, trauma, myelodisplasia, hypoestrogenism, pelvic irradiation, or other causes. In the presence of sphincter dysfunction, urethral resistance is exceedingly low and urinary leakage may occur with minimal physical effort.

Suburethral slings are the primary therapeutic choice when hypermobility is associated with urinary incontinence. The slings simultaneously correct both bladder and ureter pathophysiologic pathways. Periurethral injections are most suitable for patients with pure ISD, no detrusor dysfunction, adequate bladder capacity, and no anatomic abnormality (eg, hypermobility).

Periurethral injections were developed to be a minimally invasive approach that could be achieved on an outpatient basis. It was hypothesized that they would provide success rates comparable to the previously proven techniques. Several different materials have been used as bulking agents, such as polytetrafluoroethylene (Teflon), autologous fatty tissue, and purified bovine collagen. However, these injection materials present several drawbacks such as elevated costs, allergic reactions, particle migration, and material reabsorption that may lead to incontinence recurrence [1,2]. In addition, medium-term follow-up (mean 49 months) of women treated with polytetrafluoroethylene (PTFE) injection is discouraging. The reported success rate is only 38%, and local effects that include fibrosis in the urethra and bladder granuloma balls were found in 15% of the patients [3].

Self-detachable silicon balloons were first described in 1992 for the treatment of vesicourethral reflux [4]. More recently, it has been suggested that the balloons can be used as periurethral implants for treatment of urinary incontinence [5]. However, there are few reports about their safety and efficacy, particularly over a long-term period. Therefore, the purpose of the present study was to describe the surgical technique and follow-up results of periurethral microballoon implantation for the treatment of female urinary incontinence.

METHODS

Participants

The participants were 11 female patients with a diagnosis of urinary incontinence due to ISI. A diagnosis of ISI was made when the Valsalva leak point pressure (VLPP) was < 90 cm H_2O. Patients were excluded from the study if they had: (1) detrusor involuntary contractions during the filling phase, or (2) infravesical obstruction.

The means and standard deviations for age, weight, height, body mass index, and pregnancy history are contained in Table 1a. Relevant surgical and medical history and characteristics of patient incontinence are contained in Table 1b. The mean age was 47.9 years (range, 18-73 years). Six patients had a history of surgical intervention to treat urinary incontinence. Eight patients had a first degree cystocele. No other pelvic organ prolapses were identified.

Table 1a. Patient Means and Standard Deviations (SD) for Age, Weight, Height, Body Mass Index, and Pregnancy History (N = 11). doi: 10.3834/uij.1944-5784.2010.04.11t1a

Characteristic	Mean	SD
Age (years)	47.9	13.3
Weight (Kg)	63.36	8.9
Height (m)	1.54	7.0
Body mass index (Kg/m^2)	26.73	4.2
Parity (n)	4.45	3.1
Deliveries (n)	4	2.44
Abortions (n)	0.45	0.93
C-section (n)	0.72	0.81

Table 1b. Characteristics of Patient Incontinence and Relevant Surgical and Medical History (N = 11). doi: 10.3834/uij.1944-5784.2010.04.11t1b

Characteristic	n	% N
Enuresis	6	54.5
Urgency	3	27.3
Daily use of pads	7	63.6
Nocturia	7	63.6
Previous vaginal surgery	5	45.5
Previous abdominal surgery	3	27.3
Previous sling	1	9.1
Cystocele Grade I	8	72.7
Rectocele Grade I/II	4	36.3
Perineal rupture	5	45.4

The study was approved by the Institutional Ethics Committee. All patients provided informed consent to participate. The study was conducted between January 2003 and January 2008.

Evaluation

Patients were evaluated with a physical examination, urodynamic study, and 1-hour pad test. The urodynamic study was performed according to International Continence Society (ICS) recommendations. The 1-hour pad test was adapted from the technique originally described by Sutherst and colleagues [4].

Patients were assessed preoperatively. After surgery, the tests were repeated monthly for 6 months and every 3 months thereafter. The urodynamic study and pad test were repeated at 6-month intervals.

Surgical Technique

All patients underwent periurethral silicon microballoon implantation. The balloons are commercially available in 2 different sizes, with 0.2 mL and 0.9 mL volumes. Each balloon used in the present study had a 0.9 mL volume. When fully inflated, the 0.9 mL balloon reaches 8.5 mm x 21 mm. Inflation is maintained by a microvalve. Filling material is a solution of hydrosoluble gel with 40-90% water, in which poly-N-vinyl pyrrolidinone microparticles are immersed. These particles are large enough to prevent migration of the solution through the surrounding silicon cast.

The insertion device is 10 cm long. It is composed of a rigid polycarbonate sheath and a steel trocar for vaginal wall perforation (Figure 1). After the exact point of the balloon placement is determined, the trocar is withdrawn and replaced by the insertion of an open catheter with a balloon at its tip. A Luer-lock system at the proximal edge of the sheath allows its retraction. The balloon is then exposed at the distal end so that it can be inflated with gel (Figure 2).

Surgery can be performed either under local anesthesia with intravenous sedation or a spinal block. The patient is kept in a lithotomy position and prepared in a manner similar to any other vaginal surgery. An Allis clamp is used to hold the vaginal wall laterally to the urethral meatus. This position prevents excessive urethral mobilization during puncture, which may lead to balloon misplacement.

Punctures are generally undertaken at 3:00, 9:00, and 12:00 hour sites. Under endoscopic surveillance, the sheath and trocar complex is introduced into the vaginal wall and slid until it reaches the middle third of the urethra. The trocar is then replaced by the conjunct catheter and balloon. The balloon is then filled for maximal possible urethral coaptation. Best results are seen when balloon delivery occurs precisely into the urethral muscle envelope. Eventually, ideal coaptation requires a fourth puncture at the 6 o'clock site. A 14 Fr Foley catheter is left in place at the end of the procedure until the patient has spinal block recovery.

Figure 1. Microballoon Implantation Set.
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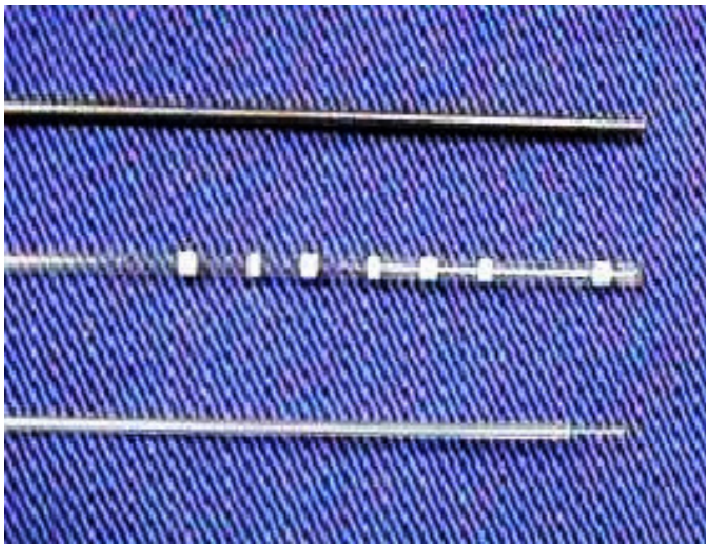

Figure 2. Silicon Microballoon.
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Data Analysis

The mean operative time, number of procedures, intraoperative complications, continence status at the final follow-up evaluation, and number of microballoon extrusions were recorded and summarized.

The variables of urine loss episodes per day, detrusor pressure at maximum flow, maximum flow, VLPP, maximum cystometric capacity, postvoid residual volume, and the results of the pad test were compiled. The mean pretest values were compared with the final posttest using the Student *t* test. Statistical significance was defined as $P < .05$.

RESULTS

The mean operative time was 31 minutes (range, 20-47 minutes). Each patient underwent a median of 1.36 procedures (range, 1-3 procedures). No intraoperative complications occurred. All patients were discharged in the first postoperative day.

The mean follow-up period was 18 months (range, 9-60 months). At the end of the follow-up period, 3 patients (27.3%) were continent, 5 patients (45.4%) were improved, and 3 patients (27.3%) were incontinent, according to Stamey criteria.

The results of the presurgical and final follow-up evaluations are contained in Table 2. The mean VLPP was significantly increased from 46.8 cm H_2O before surgery to 112.3 cm H_2O at the final evaluation ($P < .001$). The mean pad test weight was significantly decreased from 88.25 grams before surgery to 32.63 grams at the final evaluation ($P < .001$). There were no significant differences between the presurgical and final follow-up evaluations for the number of urine loss episodes, detrusor pressure at maximum flow, maximum flow, maximum cystometric capacity, or postvoid residual volume ($P > .05$).

One patient presented with detrusor *de novo* hyperactivity and was successfully treated with anticholinergics. None of the patients had infectious complications.

Five patients presented with microballoon extrusion (2 cases in the first year). Clinically, extrusion manifested as recurrent urinary tract infections and what was described by the patients as a *vaginal bump* sensation. These patients had their implants removed but were able to maintain their continence abilities.

DISCUSSION

The minimally invasive aspect of microballoon injection therapy makes it a very attractive alternative to other procedures used to treat female urinary incontinence. Several injection materials have been proposed. Sequential periurethral lipoinjection was proposed by Palma and colleagues [5], but multiple procedures are required because of its absorbable properties. Additionally, significant complications have been described [6].

Both absorbable and nonabsorbable products must be injected precisely inside the urethral muscle envelope. An advantage of silicon microballoons is that the surgeon can be certain that the fluid is injected into a fixed and restrained spot around the urethra. In the same way, the surgeon can be sure about the volume delivered at each point of periurethral space. Previous studies have shown that balloons are not biodegradable, show acceptable biocompatibility, and do not permit fluid extravasation [7,8].

Another advantage of silicon microballoons over other injectable devices is that balloons can be disinflated through a simple direct puncture with a syringe, when necessary. The hydrogel is promptly reabsorbed by the human organism and the remaining silicon cast is as small as approximately 2 mm.

Table 2. Means and Standard Deviations (SD) for the Number of Urine Loss Episodes and Results of the Urodynamic Assessments and Pad Tests at the Presurgical and Final Follow-up Evaluations; Probability of Significant Differences (N = 11). doi: 10.3834/uij.1944-5784.2010.04.12f3

Outcome Variable	Before Surgery		Final Follow-up		*P*
	Mean	SD	Mean	SD	
Urine loss episodes per day (n)	3.18	2	1.36	1	.095
Detrusor pressure at maximum flow (cm H_2O)	13.27	7.6	14.87	20.2	.811
Maximum flow (mL/s)	23.18	10.38	18.75	6.9	.309
Valsalva leak point pressure (cm H_2O)	46.81	12.32	112.3	25.75	**.001**
Maximum cystometric capacity (mL)	368.63	112.19	312.87	43.12	.201
Postvoid residual volume (mL)	30.45	26.18	48.37	78.55	.486
Pad test weight (grams)	88.25	29.2	32.63	24.46	**.0002**

Balloons can also be tracked with a transvaginal ultrasound examination during the postoperative period [9].

The surgical technique for microballoon placement is a bit more difficult when compared with other periurethral injection procedures, because the trocar used in the former procedure is thicker and there is greater risk for urethral perforation. The risk for balloon extrusion is also higher, especially when it is inserted too close to the urethral wall or inflated too quickly.

Mazouni and colleagues [10] reported that 45 incontinent patients were successfully treated with periurethral microballoon implantation. The patients had a median gain of 10 cmH_2O in urethral closure pressure. However, short follow-up times and high failure rates (35%) make their conclusion uncertain.

The patients in the present study had a significant gain in VLPP. However, 5 of the 11 patients presented with balloon extrusion, with 2 occurring in the first year. The latter 2 extrusions were apparently the result of superficial injection of the balloon. The remaining extrusions may be attributed to the balloon's oval shape, because it offers no mechanical adherence to surrounding tissues.

CONCLUSION

Considering the high extrusion rates observed in the present study and previously reported complications, the authors do not recommend the silicon periurethral microballoon injection as a treatment option for female urinary incontinence.

Conflict of Interest: none declared

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