

Introduction

Dysfunction of the pelvic floor musculature is a significant etiologic factor in the development of urinary incontinence (UI) [1]. Pelvic floor muscle exercises (PFME) are a mainstay in the conservative management armamentarium for the three main types of UI - stress urinary incontinence (SUI), urge urinary incontinence (UUI) and mixed urinary incontinence (MUI). At least 30% of incontinent women are unable to effectively contract their pelvic floor muscles [2]. Biofeedback (BF) and electrical stimulation (ES) are often used to assist patients in identifying and properly contracting their pelvic floor muscles, as well as providing direct stimulation of muscle contraction and pudendal nerve inhibition [3]. These adjunctive modalities are typically available only through a physical therapy program that requires multiple visits with a therapist.

Rationale/Purpose of the Study

A new product for the conservative management of urinary incontinence has been developed that combines home PFME, BF and ES. InTone™ (InControl Medical, LLC) is a non-implanted device that is inserted into the vagina and provides both BF and ES to facilitate pelvic floor muscle training (PFMT). The purpose of the present study is to assess the efficacy and usability of InTone in treating UI in women.

Methods

- IRB-approved, prospective, single institution pilot study
- Eligibility: Women aged 18 to 70 years with SUI, UUI or MUI with ≥ 1 incontinent episode/day on bladder diary and $\geq 10g$ of leakage on 24 hr pad weight testing
- Exclusions: incontinence <6 months duration, pregnancy or delivery within 6 weeks, vaginal or pelvic surgery within previous 6 months, pelvic organ prolapse greater than stage 2 (POP-Q), active UTI or history of recurrent UTIs (more than 3 in a year), recurrent vaginitis (bacterial/fungal), pelvic pain/painful bladder syndrome, underlying neurologic/neuromuscular disorder, or inadequate vaginal caliber
- Patients on stable dosing of overactive bladder medication were allowed to continue

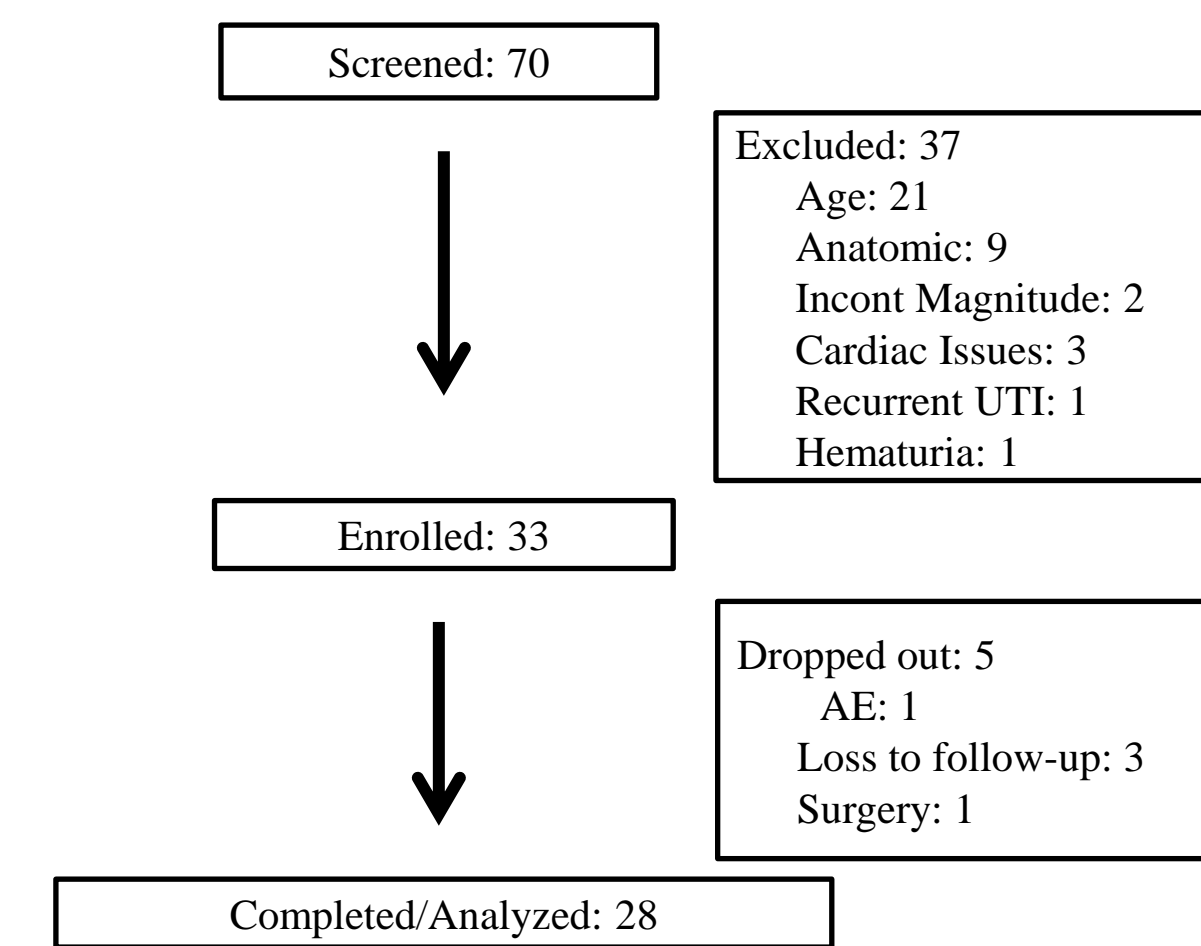
InTone device

- Class II non-implanted electrical continence device (InControl Medical)
- Applies ES to the pelvic floor musculature and surrounding structures as well as biofeedback for re-education purposes
- Has hand pump built into the handle of the probe that inflates the probe to provide a secure fit and allow for direct contact between the stimulating electrodes and the vaginal wall
- An Intone session is 12 minutes in duration: 7 minutes of biofeedback-assisted pelvic muscle contractions and 5 minutes of ES.
- Patients instructed to use InTone 5-6 days a week



Outcome Evaluation

- All patients completed symptom scores (UDI-6, IIQ-7), 48 hour bladder diaries, 24 hr pad weight tests (PWT) at baseline and monthly for 12 weeks
- 1^o outcome measure: improvement in 24 hr pad weight testing at 12 weeks
- Additional measures: improvement in symptom questionnaires (UDI6, IIQ7), pad use/day, incontinence episodes /day, device safety (adverse effects) and device usability (percent of expected use via device log and the System Usability Scale, a 10 point Likert index providing a global view of the patient's assessment of usability – a score greater than 68 is considered above average [4])
- The changes from baseline to month 3 were compared for the entire group of patients (primary outcome) using Chi-square and Wilcoxon Rank-Sum tests where appropriate. In addition, we secondarily compared results between patients with predominantly SUI (pure SUI and stress predominant MUI) and predominantly UUI (pure UUI and urge predominant MUI).



Baseline Demographics (28 completers)

Variable	Total N=28 (%)	Predom SUI N=21 (%)	Predom UUI N=7 (%)	P (SUI vs UUI)
Age*	50.0 (35.0-69.0)	47.0 (35.0-66.0)	64.0 (54.0-69.0)	<0.001 [^]
BMI*	27.6 (18.0-42.3)	27.8 (18.0-39.1)	27.4 (23.3-42.3)	0.987 [^]
Parity*	2.0 (0-9)	2.0 (0-4)	2.0 (0-9)	0.753 [^]
Vaginal delivery*	2.0 (0-8)	2.0 (0-4)	2.0 (0-8)	0.699 [^]
Post-menopausal*	14 (50.0)	8 (38.1)	6 (85.7)	0.077 [^]
Hormone replacement therapy	8 (28.6)	4(20.0)	4(57.1)	0.145 [^]
Hysterectomy	8 (28.6)	6 (28.6)	2 (28.6)	1.00 [^]
Use of OAB med	5 (17.9)	2 (9.5)	3 (42.9)	0.082 [^]
Prior pelvic floor therapy	23 (88.5)	18 (94.7)	5 (71.4)	0.167 [^]
Prior incontinence surgery	5 (17.9)	2 (9.5)	3 (42.9)	0.082 [^]

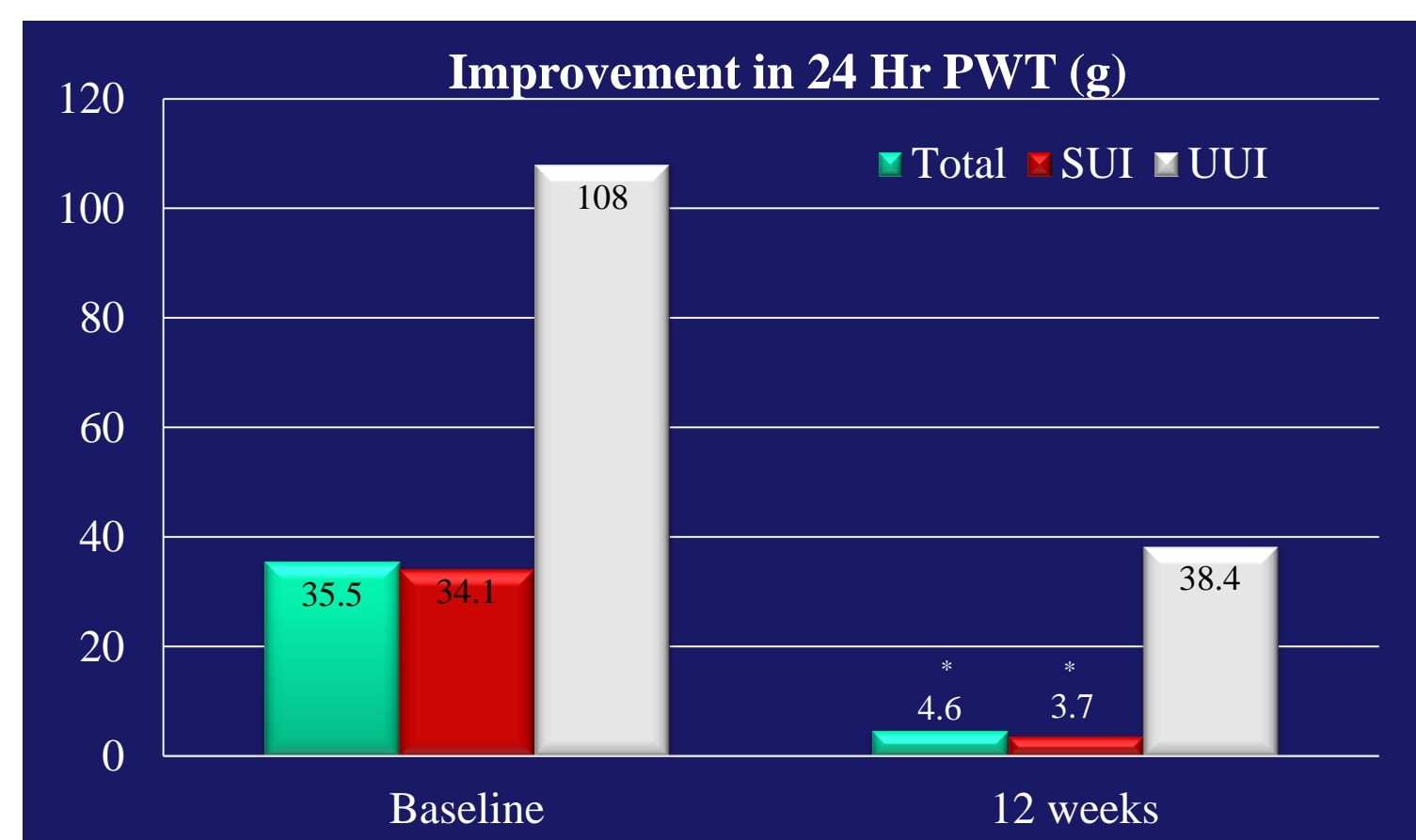
*Presented as median (range)

[^]Wilcoxon rank-sum test used for continuous variables

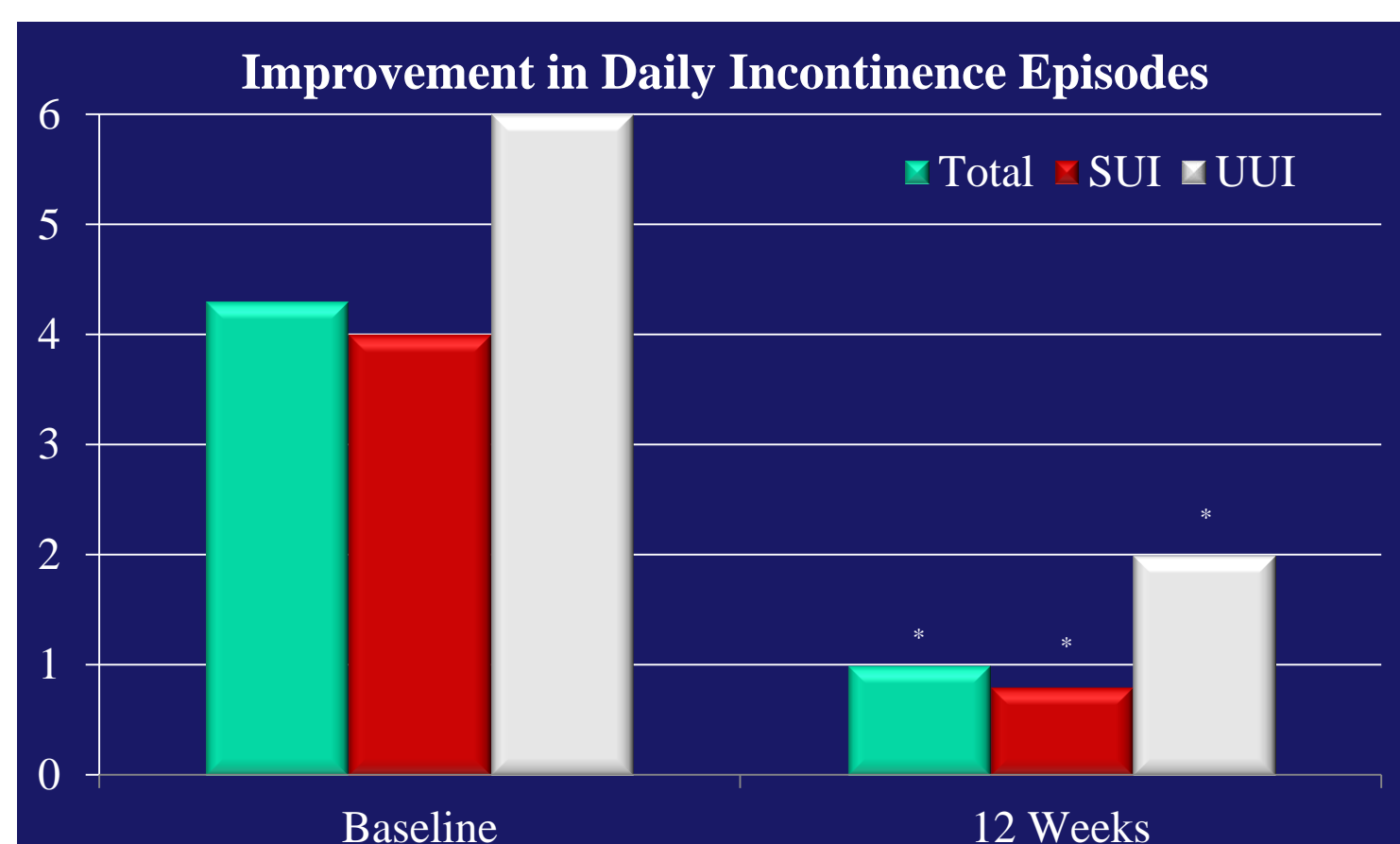
[^]Chi-square test used for categorical variables

Predom SUI = pure SUI + stress predominant MUI

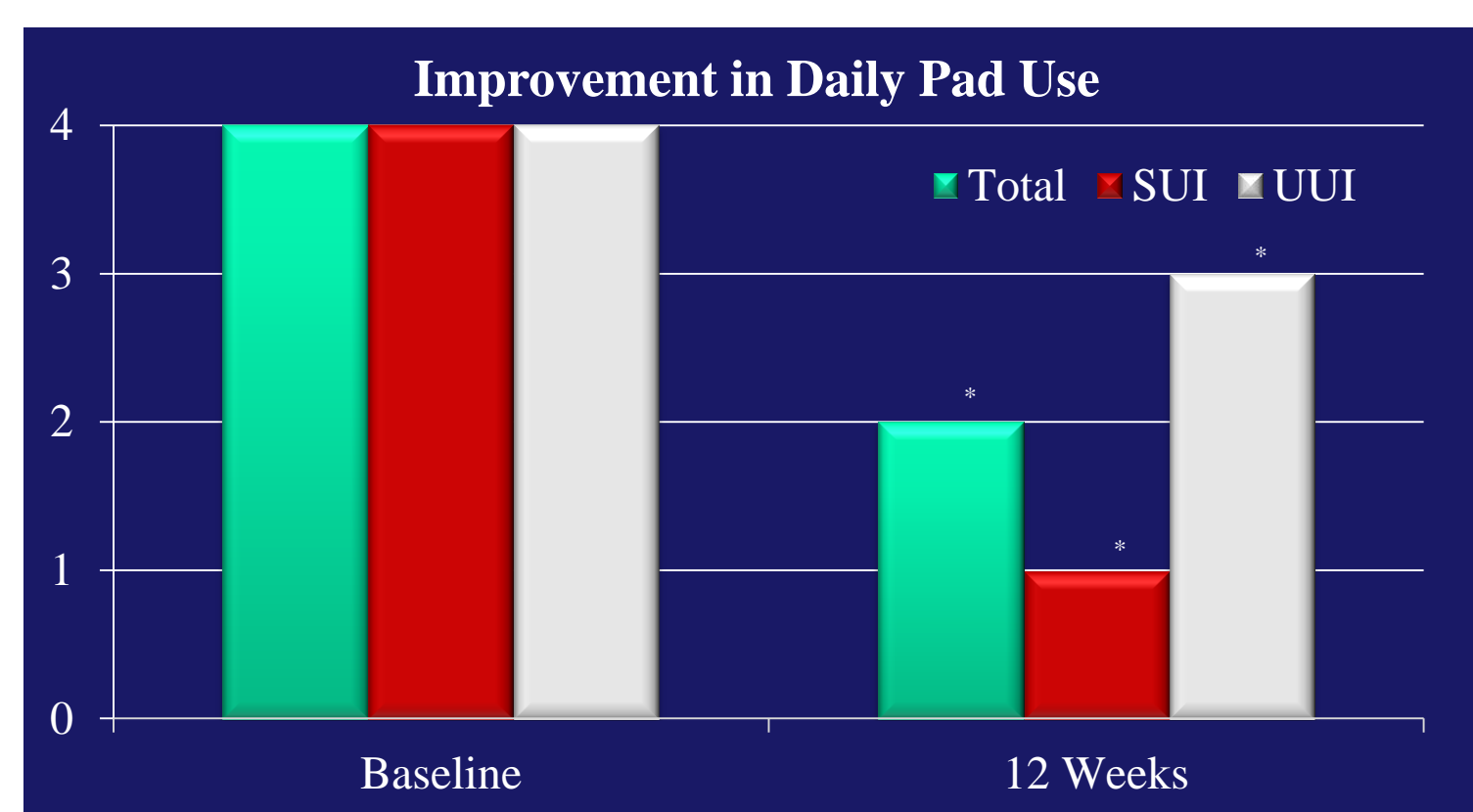
Predom UUI = pure UUI + urge predominant MUI



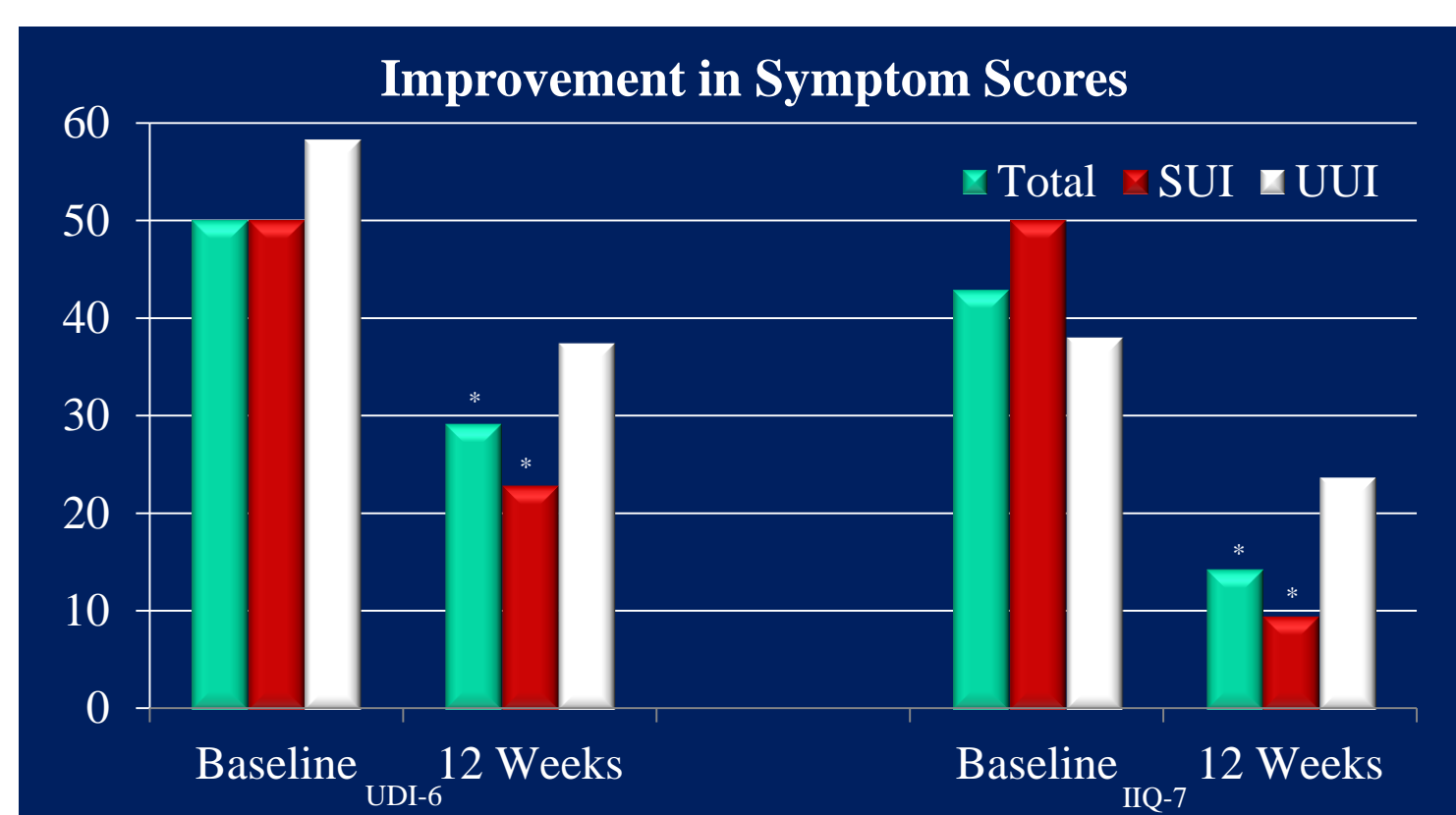
* P<0.05 vs Baseline
68% of patients had >50% reduction in PWT
No signif difference between SUI and UUI



* P<0.05 vs Baseline
No signif difference between SUI and UUI



* P<0.05 vs Baseline
68% of patients had >50% reduction in pad use
No signif difference between SUI and UUI



* P<0.05 vs Baseline
12 week UDI-6 significantly (P<0.05) different between SUI and UUI patients

Median Percent Change/Improvement from Baseline to 12 Weeks

Variable	Entire Group N=28	Predom SUI N=21	Predom UUI N=7	P (SUI vs UUI)
PWT	90*	90*	60 [^]	0.091
Pad Use	60*	60*	50 [#]	0.230
IED	80*	90*	30 [#]	0.137
UDI 6	40*	40*	0 [^]	0.001
IIQ 7	60*	60*	50 [^]	0.100

* P<0.001

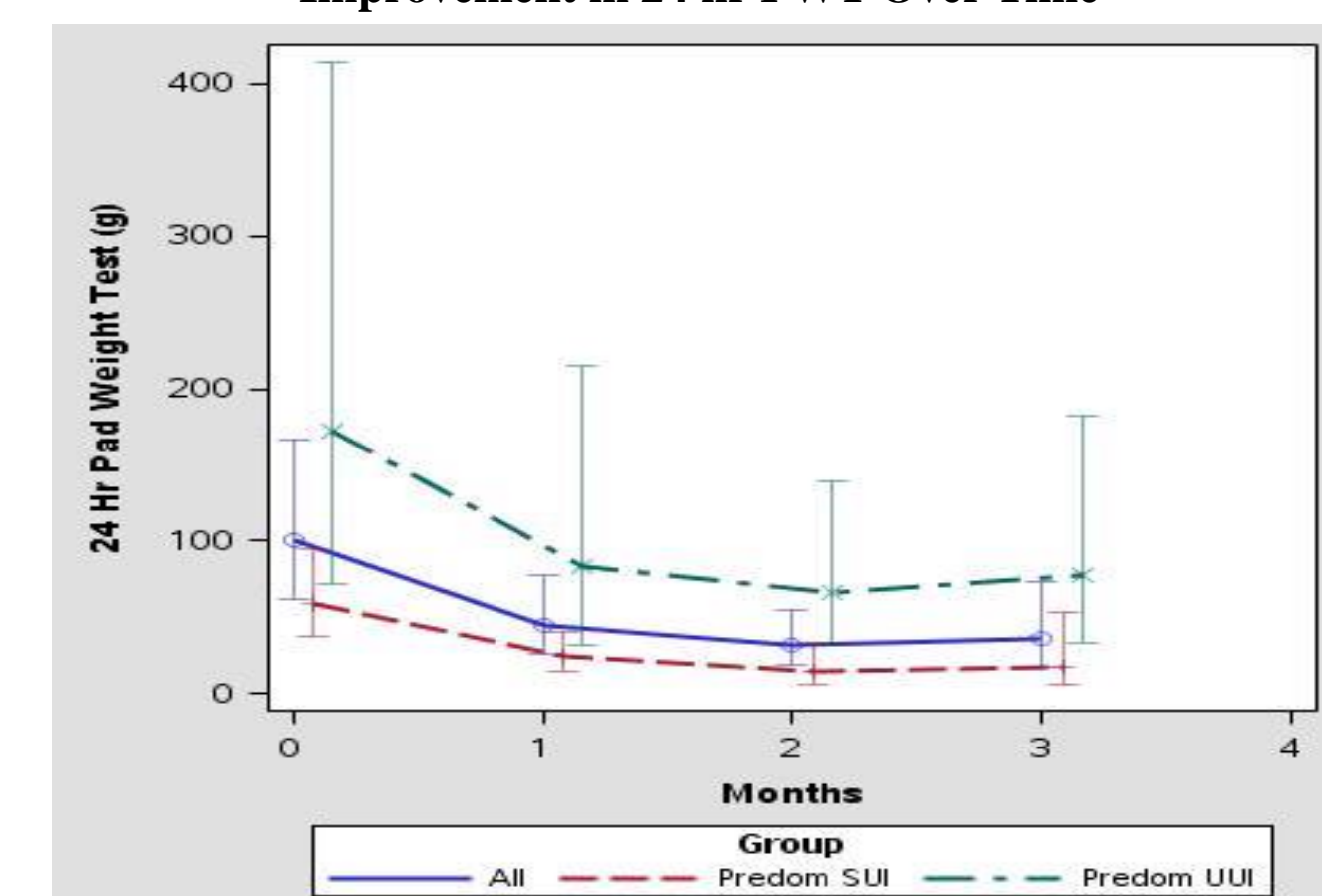
[#] P<0.05

[^] Not statistically significant (P>0.05)

PWT= 24 Hr pad weight test

IED= Incontinence episodes per day

Improvement in 24 hr PWT Over Time



To plot PWT improvement over time, a generalized linear model with generalized estimating equations (GEE) was used to generate least square mean estimates of pad weights. A log-link function was used because pad weights were not normally distributed.

Device Usability

- Device usability was considered very good with a median SUS score of 86.3 (range 22.5 - 100.0). There was no significant difference between SUI and UUI patients.
- Median percent of expected use of InTone was 107% (range 30-140%) indicating excellent compliance with device usage (based on minimum expected use of 5 days/week).

Adverse Events

- Infections occurred in 9 patients:
 - 5 had UTI
 - 4 had vaginitis (1 Gardnerella, 4 Candida)
 - One of the Candida infections occurred in a patient who received antibiotic treatment for Gardnerella.
- Most infections occurred within the first month of use and appeared to resolve with additional patient instruction regarding proper cleaning procedures. One patient withdrew due to infection.
- Device issues in 6 patients:
 - 4 had depleted batteries
 - 2 had "electrical shocking" sensations
- No patient withdrew because of device electrical issues.

Appendix: System Usability Scale [4]

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

Conclusions

- InTone combines the advantages of a physical therapist (verbal cues, use of BF and ES) without the need for frequent office visits.
- Our trial demonstrated that women who used InTone, particularly for SUI, experienced significant reductions in urinary incontinence and improvements in objective symptom scores.
- UUI patients using InTone did not respond as well as SUI patients although they did have significant reduction in pad usage and incontinence frequency. The lack of a statistically significant difference in these outcomes between SUI and UUI patients needs to be interpreted cautiously since the UUI patients were few and comparing SUI and UUI patients was not a primary goal of this trial.
- Our pilot trial provides positive preliminary data on InTone that justifies future randomized trials.

References

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- Bo K (2003) Pelvic floor muscle strength and response to pelvic floor muscle training for stress urinary incontinence. NeuroUrol Urodyn 22(7):654-658
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