MT02 (24 months)

Second generation of temporary implantable nitinol device (iTind) in men with LUTS: 2 year results of the MT02 study.

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Objective

To report medium-term functional results of a novel minimally-invasive treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH) with the second generation of the temporary implantable nitinol device (iTind; Medi-Tate Ltd®, Israel). Further, the study aimed to identify preoperative baseline parameters predicting response to iTind treatment.

Methods

This multicenter, single-arm, prospective study evaluated the feasibility and safety of the second-generation temporary implantable nitinol device (iTIND) in 81 patients.

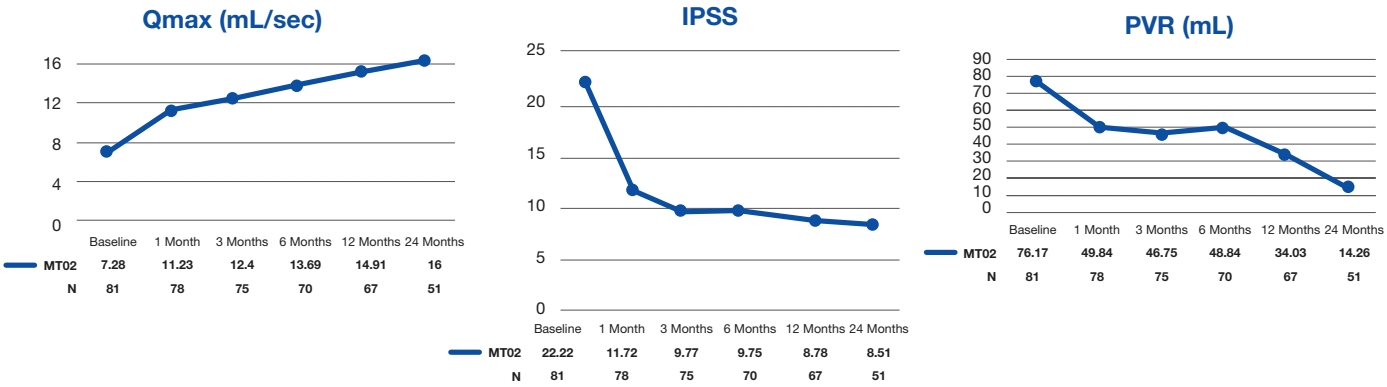
Inclusion Criteria:
· IPSS ≥ 10
· Qmax < 12 mL/s
· Prostate volume < 75 mL

Exclusion Criteria:
· PVR > 250 mL
· Obstructive median lobe
· Previous prostate surgery
· Confounding bladder or sphincter dysfunction
· Active urinary tract infection
· Unable to interrupt antithrombotic or antiplatelet treatment

A wash-out period of 1 month for alpha-blockers and 6 months for 5-ARIs was mandatory to avoid confounders. The iTind was implanted within the bladder neck and the prostatic urethra under light sedation, using a rigid cystoscope. The device was removed 5-7 days later in an outpatient setting. Demographics, perioperative results, complications (according to the Clavien-Dindo system), functional results and quality of life (QoL) were evaluated. Follow-up assessments were conducted at 1, 3, 6, 12 and 24 months postoperatively.

Results

Of the 81 patients initially enrolled in this study, follow-up included 67 men at 1 year and 51 men at 2 years. For the 51 men included in the present analysis, the median age was 65 years and median prostate volume was 37 mL (range 16–65 mL). Baseline values for IPSS and QoL were 20.51 ± 4.58 and 3.96 ± 0.87. Qmax and PVR were 7.62 ± 2.25 mL/s and 65.84 ± 38.46, respectively. No intraoperative complications were observed, and the average pain level recorded on the visual analogue scale (VAS) was 3.2 ± 1.6. A significant reduction in symptoms and improvement in urinary flow was observed ($p < 0.0001$) at all assessment points: At 24 month follow-up, IPSS and QoL improved to 8.51 ± 5.51 and 1.76 ± 1.32, respectively; and Qmax increased to 16.00 ± 7.43 mL/s. None of the patients who were previously sexually active reported a deterioration in sexual or ejaculatory functions according to two yes/no questions over the follow-up period. Excluding the patients lost at follow-up, five patients underwent surgery between 12 and 24 months. Upon investigation, it was discovered that four of the five patients requiring surgery had median lobes and were protocol deviators. A failure analysis was carried out for all 81 patients in order to identify baseline parameters that could predict treatment failure. 58.33% ($p < 0.0001$) of patients in the failure group (7 out of 12) had median lobes. No other preoperative variables (age, prostate volume, IPSS score, Qmax, PVR, and PSA) were found to predict response to iTind treatment.



Adverse Events

Complication	%	Treatment
Hematuria	12.3%	Self-resolving
Urgency	11.1%	Self-resolving
Pain	9.9%	Oral analgesic
Dysuria	7.4%	Self-resolving
Urinary retention (immediately post-procedure)	9.9%	- Empty bladder with 12F catheter through device struts - Patient discharged without catheter

Conclusion

iTind treatment for LUTS secondary to BPH showed marked and durable reduction in symptoms and improvement of functional parameters and quality of life at 24 months follow-up. It was found that median lobe may predict failure of iTind treatment. According to the yes/no questions, ejaculatory and sexual functions do not seem to be affected following treatment, however, this finding must be supported with further studies using standardized measures.

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