

MT01 (12 months)

Temporary implantable nitinol device (TIND): a novel, minimally invasive treatment for relief of lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH): feasibility, safety and functional results at 1 year of follow-up.

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Objective

To report the first clinical experience with a temporary implantable nitinol device (TIND; Medi-Tate®) for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

Patients and Methods

This single-arm, prospective study evaluated the feasibility and safety of TIND implantation in 32 patients presenting with LUTS secondary to BPH.

Inclusion Criteria:

- Age > 50 years
- IPSS \geq 10
- Qmax \leq 12 mL/s
- Prostate Volume < 60 mL

Exclusion Criteria:

- Prior prostate surgery
- Prostate cancer
- Urethral stricture
- Bladder stones
- Obstructing median lobe
- Haemostatic disorder
- Neurological conditions that could potentially affect voiding function

The TIND was implanted within the bladder neck and the prostatic urethra under light sedation, using a rigid cystoscope. The device was removed 5 days later in an outpatient setting. Demographics, perioperative results, complications (according to the Clavien system), functional results and quality of life (QoL) were evaluated. Follow-up assessments were made at 3 and 6 weeks, and 3, 6 and 12 months postoperatively.

Results

All implantations were successful, with no intraoperative complications recorded. All but one of the devices (96%) were removed 5 days after implantation in an outpatient setting. Four complications (12.5%) were recorded, including urinary retention (one, 3.1%), transient incontinence due to device displacement (one, 3.1%), prostatic abscess (one, 3.1%) and urinary tract infection (one, 3.1%). Multiple regression analysis failed to identify any independent prognostic factor for complications. There were statistically significant differences in IPSS, QoL score and Qmax at every post-operative follow-up time point.

Mean patient age: 69.4 years old

Mean prostate volume: 29.5mL

Overview

	Pre operative	12 month follow-up
Qmax	7.6 mL/s	12 mL/s
IPSS	19	9
QoL	3	1

At 12 month follow-up, no patients required medical therapy or surgical procedures for BPH.

Conclusion:

TIND implantation is a feasible and safe minimally invasive option for the treatment of BPH-related LUTS. The functional results are encouraging and the treatment significantly improved patient QoL. Further studies are required to assess durability of TIND results and to optimize the indications of such a procedure.

Manufactured by Medi-Tate Ltd., 17 Hauman Street, Hadera, 3850169 Israel.
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