

The iTind Temporarily Implanted Nitinol Device for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Multicenter, Randomized, Controlled Trial (MT03)

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Objective and Indication

To compare results of treatment with iTind vs. sham treatment in lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH)

Design

Multicenter, randomized, controlled trial (RCT): iTind vs. sham treatment (randomized 2:1)

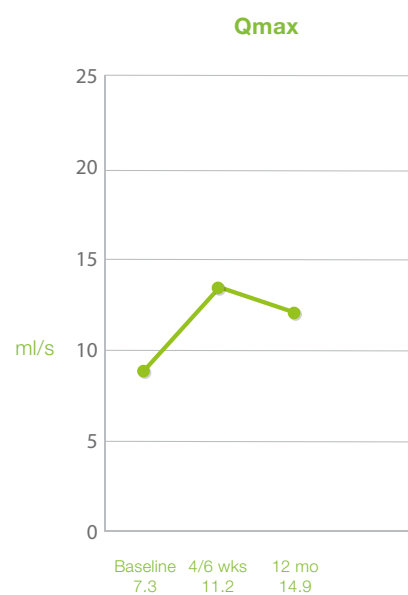
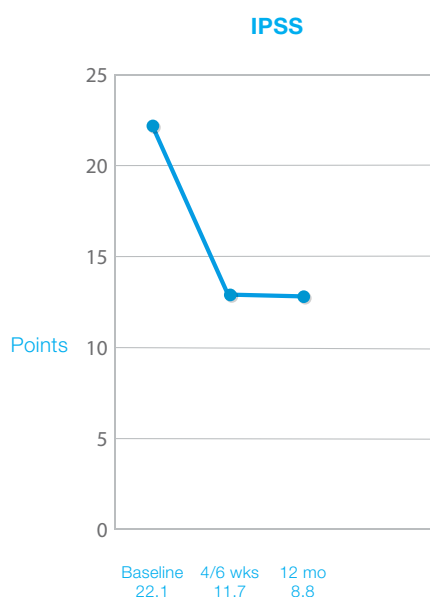
Assessment at baseline, 1.5, 3, and 12 months postoperatively: IPSS, PFR (Qmax), residual urine, QoL, and IIEF

Subjects

175 men 50 years or older (mean age 61.1 years); (118 iTind vs. 57 sham)

Results

- At 3 months, 78.6% of iTind patients had a reduction of ≥ 3 points in IPSS, vs. 60% in the sham group
- At 12 months, iTind patients showed a significant decrease in IPSS (-9.25 points), a significant increase in PFR (+3.52ml/s) and a significant reduction in QoL (-1.9 points)
- No patient experienced de novo ejaculatory or erectile dysfunction. AEs, which were typically mild and transient, occurred in 38.1% of iTind patients and 17.5% of sham patients (most were Clavien-Dindo grade I or II).



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Key Findings

- Second-generation iTind proved to provide a significant, rapid and durable improvement in LUTS
- iTind is effective and safe, especially in terms of preservation of sexual function

Conclusion

iTind provides significant, rapid and durable improvement in LUTS due to BPH and preserves sexual function over a follow-up period of 12 months.

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Urinary and sexual function after treatment with temporary implantable nitinol device (iTind) in men with LUTS: 6-month interim results of the MT-06-study

World J Urol. 2021;39(6):2037-2042. doi:10.1007/s00345-020-03418-2

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Objective and Indication

Evaluation of functional outcome and preservation of urinary continence and sexual function in men treated with iTind for LUTS due to BPH

Design

Prospective, single arm, multicenter, international clinical study. Interim report: Assessment of post-operative VAS, complications (Clavien Dindo-Grading System), preservation of urinary continence and erectile and ejaculatory function (according to ISI, MSHQ-EjD and SHIM), and post-operative IPSS, QoL, Qmax and PVR at 1, 3, and 6 months follow up.

Subjects

- 70 men with symptomatic benign prostatic obstruction (BPO) and IPSS ≥ 10 , Qmax < 12 ml/s, prostate volume < 120 ml
- Patients did not wash out BPH medication before iTind treatment

Results

- 70 patients with a median age of 62.31 years and a mean prostate volume of 37.68 ml (15–80 ml) were enrolled
- No intraoperative complications were observed, average post-operative VAS score was 3.24 ± 2.56
- Return to daily life after an average of 4.3 days post iTind retrieval
- All patients showed preserved sexual function and urinary continence according to ISI, SHIM and MSHQ-EjD
- IPSS, QoL and Qmax improved significantly ($p < 0.0001$) vs. baseline levels



Urinary and sexual function after treatment with temporary implantable nitinol device (iTind) in men with LUTS: 6-month interim results of the MT-06-study

Key Findings

- iTind treatment preserves sexual function and urinary continence, offers a rapid return to daily life, and provides a significant improvement of symptoms and urinary flow up until 6-months post-surgery

Conclusion

Minimal invasive treatment with iTind is well-tolerated, preserves sexual function and urinary continence, offers rapid recovery/return to daily life and provides significant improvements in LUTS and urinary flow at 6-month follow-up.

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3-Year results following treatment with the second generation of the temporary implantable nitinol device in men with LUTS secondary to benign prostatic obstruction

Prostatic Dis. 2021;24(2):349-357. doi:10.1038/s41391-020-00281-5

Daniele Amparore, Cristian Fiori, Massimo Valerio, Claude Schulman, Ioannis Giannakis, Sabrina De Cillis, Gregor Kadner, Francesco Porpiglia

Objective and Indication

To follow up on the 3-year results of patients treated with iTind for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

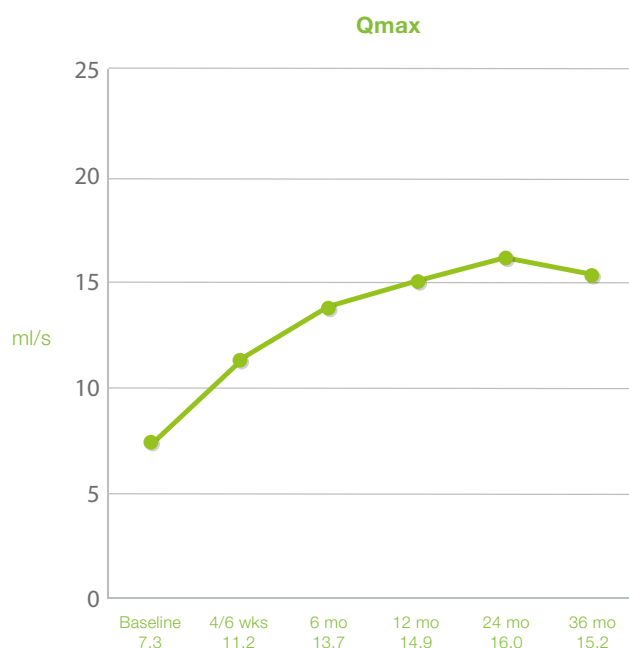
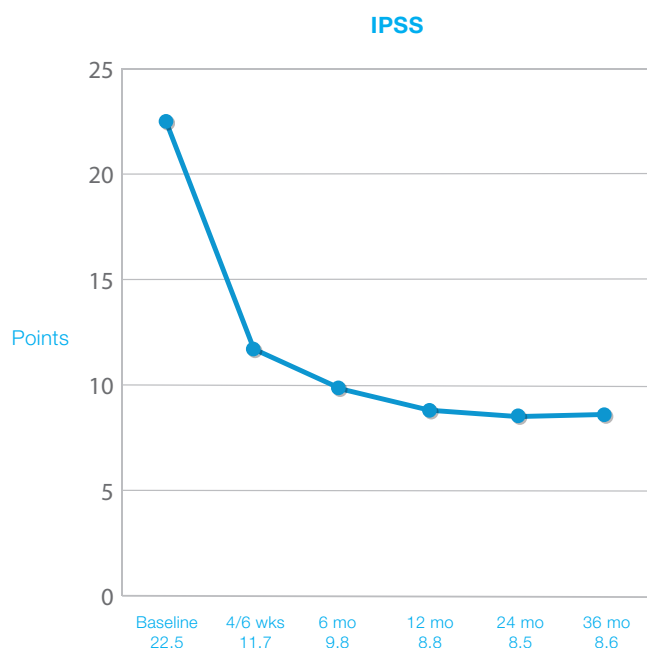
Design

Prospective, single arm, multicenter, international clinical study. Assessment at baseline, 1, 3, 6 months, 1, 2 and 3 years postoperatively: OR-time, pain, postoperative complications, functional results (IPSS, Qmax, PVR, QoL), sexual and ejaculatory function (two yes/no questions) were assessed.

Subjects

81 men with symptomatic benign prostatic obstruction (BPO) and IPSS ≥ 10 , Qmax < 12 ml/s, prostate volume < 75 ml.

Results



3-Year results following treatment with the second generation of the temporary implantable nitinol device in men with LUTS secondary to benign prostatic obstruction

- 50 patients were available for the 3 year follow up analysis
- iTind efficacy was stable through 36 months, resulting in significantly improved functional values: IPSS (8.55+6.38; -58.2%), QoL (1.76+1.32; -55.6%), Qmax (15.2+6.59ml/s; +114.7%) and PVR (9.38+17.4ml; -85.4%)
- Using an Intent to Treat Analysis (ITT) all 3 -year results remained significantly improved vs. baseline
- No late post-op complications were observed from 12-36 months follow-up, sexual function remained stable (no report of sexual or ejaculatory dysfunction) and no alternative treatments were performed between 2 and 3-years of follow-up
- iTind provided significant and durable improvement in symptoms and functional parameters over 3 years
- There were no late post-operative complications, sexual dysfunction or additional treatment failures from 24 to 36 months

Conclusion

iTind treatment. provides a significant and durable improvement in lower urinary tract symptoms, functional parameters and quality of life over 3 years of follow-up.

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