



MEMOKATH™ CLINICAL STUDIES

MEMOKATH™044 – A REMOVABLE STENT FOR TREATMENT OF RECURRENT BULBAR URETHRAL STRICTURES RESULTS OF THE NORTH AMERICAN STUDY GROUP'S MULTI-CENTRE TRIAL

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Introduction & Objectives: Urethral stricture disease involves scarring of the anterior urethra resulting in a limitation in the lumen of the urethra. The long-term success rate of dilations and/or urethrotomies is low and the average patient needs repeated treatment several times yearly. The study compared the urethral patency rates in patients with dilation or internal urethrotomy and then randomized to either a short-term foley catheter diversion versus placement of a Memokath™ 044 stent – a densely coiled thermo-expandable nitinol, shape memory stent.

Material & Methods: The study was a US, phase III, randomized, multi-centre controlled investigation - 92 patients treated with either dilation or internal urethrotomy and randomized either to placement of a Memokath™ 044 stent (N=63) or one week foley drainage (N=29). The primary endpoint was urethral patency defined as the ability to pass a calibrated 16 French flexible cystoscope through the region of the treated stricture. Standard urodynamic parameters and adverse events were followed. Stents were left in place for up to 12 months.

Results: The Memokath™ patients remained patent 3.5 times longer than the control group (292D vs. 84D (median), $p < 0.001$). Qmax, Qavg, IPSS, and QoL scores were improved. 24/29 control patients developed recurrent strictures.

Stenting was offered as an option for these control patients, and 22/24 possible candidates accepted. Memokath™ stent was usually inserted in an out-patient setting without difficulty. The stent was successfully removed in 100 percent of patients, using local anesthetic, without difficulty. The most frequent side-effects in the stent patients were urinary tract infections, hematuria, and penile pain—all usually mild and transient. Penile pain had no untoward effects on the patient's sexual function. Clinically significant stent relocations were observed in 14 patients (22%). Minimal or partial occlusions (encrustation or tissue hyperplasia at the end of the stent) were observed, but did not affect urodynamic parameters significantly. Obstructive occlusion was observed in three patients.

Conclusions: Memokath™ 044 was shown to maintain urethral patency significantly longer than dilation or urethrotomy by themselves. Thus, the average patient will experience fewer urethrotomies and dilations and thereby improved QoL. The side-effect profile was favorable. The stent was straightforward to insert and was removed without difficulty- even after long-term placement-. Memokath™ 044 is a cost-effective alternative to repeated dilation/urethrotomy. Durability effect on the stricture was not assessed in this study.

A NOVEL THERMO-EXPANDABLE URETERAL METAL STENT FOR THE MINIMAL INVASIVE MANAGEMENT OF URETERAL STRICTURES.

Athanasios G. Papatsoris, M.D.,M.Sc., and Noor Buchholz, M.D. Journal of Endourology, Vol.24, number 3, March 2010.

Purpose: To assess the safety, efficacy, and cost of the novel long-term indwelling thermo-expandable Memokath™ ureteral stent for the management of malignant and benign ureteral strictures.

Materials and methods: A prospective study of patients with ureteral strictures who underwent insertion of a Memokath stent from April 2004 to March 2009.

73 patients (34 men), ages 23 to 84 years (mean 57.7) with 86 ureteral strictures (13 bilateral) were treated with the Memokath™ 051. The causes of the strictures were benign in 55 cases and malignant in 31 cases. Follow-up included radiography, renal ultrasonography, and renography if needed after 2 weeks, 3 months, and then every 6 months.

Results: Memokath™ could be inserted in all patients as planned. The mean operative time was 23 minutes (range 17-52 min) while the mean hospital stay was 1.5 days (range 1-5 d). The average indwelling time of an individual Memokath™ was 11.2 months (range 1-39 mos). After a mean follow-up period of 17.1 months (range 1-55m), there were 68 stents in situ.

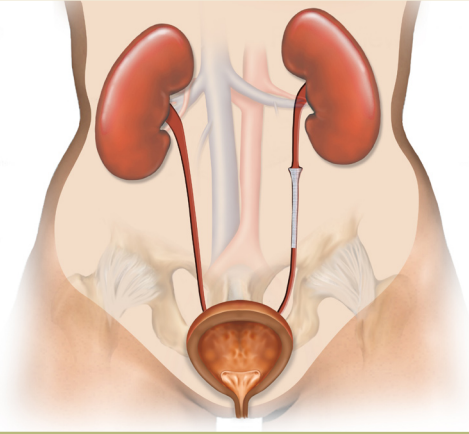
In 12 cases, spontaneous resolution of the ureteral stricture was revealed after a mean indwelling time of 9 months. Six cases were treatment failures.

In 15 cases, because of late complications, a Memokath™ exchange took place after a mean period of 18 months. A total of 26 complications were revealed after the insertion of 102 Memokath™. These included six cases of urinary tract infections; 15 Memokath™ manipulations were needed because of stent dislodgement, and 5 Memokath™ was removed because of encrustation and blockage. In the long term, the overall costs for the Memokath™ treatment and follow-up were considerably less than with the conventional Double-J stent.

Conclusions: The Memokath™ 051 ureteral ,is an attractive long term and cost effective minimally invasive management option for both benign and malignant ureteral strictures. It bears no risk for bladder irritation, reflux and flank pain, in contrast to conventional JJ stent. Also there is no need for frequent replacement, such as with the JJ stent, resulting in improvement of quality of life.

MEMOKATH™ 051 URETER

- **Covers simply the stricture***
 - No need for frequent replacement
 - No foreign material in bladder or kidney
- **Improve Quality of Life**
 - Avoid flank pain
 - Fewer hospital visits
- **Cost – Effective**
 - Decrease bed days



*Assessing the Impact of Ureteral Stent Design on Patient Comfort

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(The comfort Study Team) From the Methodist Hospital Institute for Kidney Stone Disease (JEL, AEK), Indianapolis, Indiana, Division of Urology, Duke University (GMP), Durham, North Carolina and Hudson Valley Urology Center (ERG), Poughkeepsie, New York

Conclusion: Although it was not statistically significant, patients stented with the short loop tail had lower questionnaire pain scores on day 4 after placement and lower pain medication use on day 1 after placement, when pain peaked in all stent groups, suggesting that ureteral stent comfort, *especially pain, may be improved by less material in situ*. The Ureteral Stent Symptoms Questionnaire may be better suited for long term comparisons in stented vs nonstented patients, rather than in this short-term ureteral stent trial.

COMPARISON OF STENT-RELATED SYMPTOMS BETWEEN CONVENTIONAL DOUBLE-J STENTS AND A NEW-GENERATION THERMOEXPANDABLE SEGMENTAL METALLIC STENT: A VALIDATED-QUESTIONNAIRE-BASED STUDY

Maan,Z.; Patel,D.; Moraitis,K.; El-Husseiny,T.; Papatsoris,A.G.; Buchholz,N.P.; Masood,J.
Journal of Urology , Volume 181, June 2009.

Introduction: Double-J stents revolutionized the minimally invasive management of ureteral strictures, but have significant morbidity. We compare stent-related symptoms and quality of life between a conventional Double-J stent and a novel thermo expandable metal segmental ureteral stent (Memokath™) in patients with ureteral strictures.

Materials and methods: Seventy patients with a conventional Double-J stent or a Memokath™ for ureteral strictures were mailed the validated ureteral stent symptom questionnaire (USSQ) four weeks after stent placement. USSQ is a multidimensional measure that evaluates stent-related morbidity in six sections: urinary symptoms, body pain, general health, work performance, sexual matters, and additional problems. Statistical analysis compared the differences in these parameters between the two groups.

Results: Forty-one patients (58.5%) responded, 23 with a Double-J stent and 18 with a Memokath™ .

A subgroup of 10 patients had both a Double-J and a Memokath™ stent. Nearly 70% of patients with Double-J stents experienced urine frequency ≤ 2 hours versus 47% with Memokath™. About 31.8% of patients with Double-J stents were extremely bothered by urinary symptoms versus 5.6% with Memokath™. About 66.7% of patients with Double-J stents had a negative view toward living with their current urinary symptoms versus 35.3% with Memokath™.

Discussion: The ureteral stent symptom questionnaire revealed that pain, urinary symptoms index, and general health were statistically better in the Memokath™ group. The Memokath™ group significantly outperformed the Double-J stent group in terms of the light and heavy activity. In terms of future stent insertion, patients preferred the Memokath™. There were improvements in general health and other quality-of-life parameters, and there was a tendency in favor of the Memokath™.

TREATING BLADDER-OUTFLOW OBSTRUCTION WITH THERMO-EXPANDABLE PROSTATE METAL STENTS.

Papatsoris AG, El-Husseiny T, Sawada Y, Takahashi T, Nagaoka A, Maan Z, Moraitis K, Masood J, Junaid I, Buchholz N. Expert Rev Med Devices. Volume 6, number 4, July 2009

Introduction: Bladder-outflow obstruction (BOO) is a common age-related clinical entity due to a variety of benign and malignant diseases of the prostate. Surgical treatment is not suitable for high-risk elderly patients who seek minimally invasive management. The review presents the prostatic thermo-expandable metal stent Memokath™028 for treating bladder-outflow obstruction.

Content of the review: The publication includes the design characteristics of Memokath™028, the performance assessment in comparison with alternative devices, the limitations, authors' personal clinical experience, literature review and expert commentary.

Several studies are included in this review as well as the authors own clinical experience, which was conducted in a retrospective manner;

In total 127 patients with a mean age of 82 years (range 64-97years) with BOO due to BBH (84%) or prostate carcinoma (16%).

Local anesthesia and flexible cystoscopy was used in 80% of patients as day-case procedures. Prior to Memokath™ insertion, 80% of patients had an indwelling bladder catheter for chronic urinary retention. Most patients were high medical risk patients being American Society Anesthesiologist Score (ASA) 3 – 68%, ASA 2- 27% and ASA 1 – 5%. Patient with lower ASA score underwent Memokath™ 028 insertion because they requested this procedure despite the option of undergoing standard TURP or laser prostatectomy. The patients wished to have an intervention under local anesthesia in order to be able to work the following day. Anticoagulation medication was not discontinued. Follow up consisted of flow rate and measurement of the residual urine. If required. Removal and/or exchange of the Memokath™ were easily and quickly performed in all cases (mean operation time 11 minutes).

The mean follow up duration was 6 years. During the follow up the mean maximum flow rate increased by 7 ml/s (mean preoperative 7.6ml/s;

postoperative 14, 6 ml/s). Mean residual urine volume decreased by 126 ml, (mean preoperative: 147ml; postoperative: 21ml)

The mean International Prostate Symptom Score (IPSS) decreased by 13 points (from 25 to 12 points), and the Quality of Life index by 3, 1 points (from 5.1 to 2points)

The mean single Memokath™ indwelling time was 1 year, with a maximum of 4 years.

41% of the stents needed to be removed and/or exchanged due to encrustation (15%), migration (10%), penile pain (6%), BOO symptoms (5%), urinary incontinence (<3%), recurrent urinary tract infections (<3%) or urethral stricture (<3%).

Expert commentary: According to all relevant studies, it appears that use of the prostatic Memokath™028 is safe and efficient, particularly in high risk patients. Its closed, tight –spiral structure prevents urothelial in-growth and, thus, it facilitates its easy removal whenever required. This is a great advantage in comparison with previously used metal stents, which allowed tissue in-growth and made stent removal very traumatic and painful. Other metal stents do not have this property of softening and easy removal because of metallurgical differences.

The Memokath™028 does not interfere with normal bladder function and is not prone to tissue in-growth. It shows a low rate of encrustation. Removal and /or exchange of the Memokath™028 are easy, quick and uncomplicated. Most patients outlive the Memokath™028 and do not need regular catheter changes, thereby resulting in a significant improvement in their quality of life.

The cost- effectiveness of the Memokath™028 needs to be assessed since it is a relatively costly device. The initial price of the Memokath™ is outweighed by the benefits of avoidance of catheter changes and complications associated with indwelling catheters, not to mention the gaining of social and quality of life, which cannot be valued in monetary terms.

ADVANTAGES OF MEMOKATH™

Memokath™ 028 Prostate

- Minimal invasive compared to TURP
- Local

Memokath™ 044 Urethra

- Urethral patency significantly longer than dilation or uretrotomy
- A cost-effective alternative to repeated dilation/urethrotomy

Memokath™ Overall

- Reversible
- Daycase treatment
- Improves Quality of Life

Memokath™ 045 Urethra

- Minimal invasive compared to sphincterotomy
- Local

Memokath™ 051 Ureter

- Covers only the stricture
- Cost-effective
- No need for frequent replacement

STATEMENTS FROM STUDIES

- There is no need for frequent replacement, such as with the JJ stent, resulting in improvement of quality of life.¹
- The Memokath™ group significantly outperformed the Double-J stent group.²
- It appears that use of the prostatic Memokath™028 is safe and efficient, particularly in high risk patients. Its closed, tight –spiral structure prevents urothelial in-growth and, thus, it facilitates its easy removal whenever required.³
- Memokath™ is not only an alternative treatment option to sphincterotomy, but it is a safe and successful second-line treatment after sphincterotomy failure.⁴

Sources:

- 1) A novel thermo-expandable uretral metal stent for the minimal invasive management of ureteral strictures. Athanasios G. Papatsoris, M.D., M. Sc., and Noor Buchholz, M.D. *Journal of Endourology*, Vol.24, number 3, March 2010.
- 2) Comparison of stent-related symptoms between conventional double j stents and a new generation thermoexpandable segmental metallic stent: A validated-questionnaire-based study. Maan,Z.; Patel,D.; Moraitis,K.; El-Husseiny,T.; Papatsoris,A.G.; Buchholz,N.P.; Masood,J.; *Journal of Endourology* , Volume 24, number 4, April 2010.
- 3) Treating bladder-outflow obstruction with thermo-expandable prostate metal stents. Papatsoris AG, El-Husseiny T, Sawada Y, Takahashi T, Nagaoka A, Maan Z, Moraitis K, Masood J, Junaid I, Buchholz N. *Expert Rev Med Devices*. Volume 6, number 4, July 2009
- 4) Clinical Usefulness of the Memokath™ Stent as a Second-Line Procedure After Sphincterotomy Failure. Juergen Pannek, M.D., Konrad Göckling, M.D., and Ulf Bersch, M.D. *Journal of Endourology*, voloume 25, number 2, February 2011

CONTACT

- If you wish to learn more about the Memokath™ stent, please contact Pnn Medical A/S or your local distributor.

- Memokath™ is distributed in the following countries:

Australia	Philippines
Austria	Poland
Denmark (Direct Sale)	Portugal
Egypt	Romania
France	Russia
Germany (Direct sale)	Saudi Arabia
Greece	Singapore
Holland	South Africa
Hong Kong	South Korea
Indonesia	Switzerland (Direct Sale)
Ireland	Spain
Japan	Sweden (Direct Sale)
Lebanon	Thailand
Malaysia	Turkey
New Zealand	UAE
Norway (Direct Sale)	UK

China & India will soon be registered.

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MEMOKATH™ OVERVIEW

