

## Memokath 044 Stent for the Treatment of Recurrent Bulbar Urethral Strictures

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### ABSTRACT

**Introduction:** Urethral strictures are first described as causing bladder outlet obstruction in ancient literature dating back to the Greek and Egyptian period. The management of urethral stricture remains a challenge to all urologists, especially for those failing to respond to repeated dilatation or optical urethrotomy, and for strictures recurring after urethroplasty. So the idea is to use stents for preventing stricture recurrence based on mechanical interference, and to prevent the scarring process that ends in contraction.

**Objective:** In this study, we tried to assess the efficacy and safety of the Memokath 044 temporary stent in the treatment of recurrent bulbar urethral strictures.

**Patients and Methods:** Between April 2010 and May 2011, 16 patients presented with bladder outlet obstruction (BOO) due to recurrent bulbar urethral strictures. All underwent Memokath 044 stenting. The stents were inserted endoscopically under local or saddle-block anesthesia. Patients were followed up with Qmax, post-void residual urine (PVR), sexual function, and quality of life (QoL) scores at 2 weeks, 1 month, 3 months, 6 months, and 12 months, post-insertion.

**Results:** All the stents were successfully inserted. The operative time ranged from 20 to 40 minutes ( $30 \pm 6.45$ ) with no intraoperative complications. All patients achieved spontaneous voiding after insertion. The mean Qmax, PVR, and QoL scores significantly improved after the procedure and continued to improve throughout the follow-up period. There were minimal postoperative complications; transient and treated conservatively. Stent migration took place in 6.25% of cases with easy endoscopic repositioning. Obstruction of the stent lumen occurred in 6.25%, which mandated stent removal.

**Conclusion:** The Memokath 044 stent is straightforward to insert and to remove, it can relieve the symptoms of BOO due to recurrent bulbar urethral strictures in surgically risky patients, maintaining urethral patency without affecting sexual intimacy and thereby improving the quality of life.

**KEYWORDS:** Uerthral stricture, Memokath 044, stent, bladder outlet obstruction

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### ACRONYMS AND ABBREVIATIONS

<b>Qmax:</b> Maximum flow rate	<b>UTI:</b> Urinary tract infection
<b>PVR:</b> Post-void residual urine	<b>QoL:</b> Quality of life
<b>BOO:</b> Bladder outlet obstruction	
<b>VIU:</b> Visual internal urethrotomy	
<b>AUR:</b> Acute urinary retention	
<b>BPH:</b> Benign prostatic hyperplasia	

## INTRODUCTION

Urethral strictures are first described in ancient literature dating back to the Greek and Egyptian period. Currently, it is relatively common, with most strictures acquired from infection and trauma, but iatrogenic causes that result in strictures anywhere in the urethra are probably the most common causes [1].

The management of urethral strictures remains a challenge to all urologists. This is especially true for those failing to respond to repeated dilatation or optical urethrotomy, and for strictures recurring after urethroplasty [2]. There is great variation in recurrence rates reported after urethral dilatations and urethrotomies with a 50 to 60% success rate in short strictures without spongiofibrosis. In longer strictures with spongiofibrosis, the recurrence rate is about 80% because of scarring contraction, so the idea is to use the stents for preventing recurrence based on mechanical interference to prevent the scarring process that ends in contraction [3].

Two different stents have been studied: either permanently implanted or those temporarily left indwelling and then removed. Permanent stents have higher migration rates, and resulting hyperplastic tissue growth can cause recurrent obstruction. The deployed permanent wall stent is 30% shorter than its constructed length, and concerns about fertility and the potential long-term risk of malignant transformation need to be considered. In an effort to circumvent these difficulties, the Memokath stents have been investigated (Engineers & Doctors A/S [now Pnn Medical SA], Hornbaek, Denmark) [4]. In 1988, Milroy implanted the first stent in the urinary tract for the treatment of urethral stricture [5].

Memokath was first introduced as the second-generation stent for the treatment of upper and lower urinary tract obstruction in 1993. It is used for the treatment of benign and malignant ureteric strictures (Memokath 051), bladder outlet obstruction due to BPH (Memokath 028), and recurrent urethral stricture (Memokath 044 and Memokath 045). It is a thermo-expandable stent made from a nickel and titanium alloy that has a "shape memory" feature. It softens at < 10° C and regains its original shape when heated to 50° C. The alloy exists in 2 distinct crystalline forms: martensite and austenite. The former will, after a plastic deformation, return to its original shape when heated, within limits. This process occurs as a result of a specific type of phase change known as martensitic transformation. This process is complex and the transition temperature depends on the alloy mix, deformation, type, and the direction of applied stresses [6].

## AIM OF THE WORK

The aim of this work is to assess the use of the Memokath 044 in the treatment of recurrent bulbar urethral strictures.

## MATERIALS AND METHODS

This study included 16 patients that presented with symptoms of bladder outlet obstruction (BOO) due to recurrent bulbar urethral strictures between April 2010 and May 2011 in the Urology Department of Benha University Hospital. All patients had previously undergone many dilatations, internal urethrotomies, and/or urethroplasty.

Inclusion criteria included recurrent bulbar urethral stricture that was 50 mm in length on urethrography and the presence of 10 mm of healthy urethral tissue from both ends of the stricture.

Exclusion criteria included the presence of < 10 mm of visibly healthy urethral tissue at both ends of the stricture; strictures of the meatus, prostatic, or membranous urethra; patients with bulbar urethral strictures that extended into the prostatic or membranous urethra, any urethral stricture associated with or suspected to be urethral carcinoma, or strictures due to urethral distraction injuries; the inability to enlarge the urethral stricture to 26 F; the presence of any other urologic implant, including stents, penile prosthesis, or artificial sphincters; uncontrolled bleeding disorders; or active urinary tract infection.

All patients were subjected preoperatively to a full history, including personal history; a history of present illnesses, including the QoL assessment; and a past history, including trauma, genital infections, previous indwelling catheters, and previous urologic interventions.

Complete general and urological examinations included urine analysis with culture and sensitivity tests, pelviabdominal US to measure PVR, urethral US (sonourethrography retrograde and voiding cystourethrogram) (Figure 1), uroflowmetry to establish the Qmax, and the voided urine volume.

## THE MEMOKATH

### *Memokath 044 Urethral Stent*

It is available in lengths from 30 to 70 mm in intervals of 10 mm. It expands from 24 to 44 F. At its proximal end it forms a cone that fixes it to the urethra and prevents its migration (Figure 2). It is a thermo-expandable stent made from a nickel and

Figure 1. Cystourethrogram of the bulbar urethral stricture.  
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Figure 2. The Memokath 044.  
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titanium alloy that has a “shape memory” feature. It softens at < 10° C and regains its original shape when heated at 50° C.

### The Technique of Insertion

According to the American Society of Anesthesiologists (ASA), the physical states of patients were assessed by anesthetists. Two patients were ASA grade 2, 9 were grade 3, and 5 patients with grade 4 (Table 1).

The techniques of insertion and removal were performed according to the method described by Engineers & Doctors A/S [now Pnn Medical SA], Hornbaek, Denmark (the manufacturers of Memokath).

Outlined below are the steps we followed:

1. Pre-procedural antibiotic was administered orally or intravenously.
2. Nine patients received local anesthesia augmented with analgesia along with saddle block in 7 patients who couldn't tolerate local anesthesia.
3. After the patient had been prepped and draped appropriately, urethrocytostcopy was performed to assess the location of the targeted urethral stricture and the

Table 1. ASA physical status grading system (source: ASA website).

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ASA Grade	Description	No. Patients
1	normally healthy patient	0
2	patient with mild systemic disease	2
3	patient with severe systemic illness	9
4	patient with severe systemic illness that is a threat to life	5
5	morbid patient who is not expected to survive without surgery	0
6	a declared brain-dead patient	0

4. The targeted urethral stricture was treated by either dilatations in 10 patients or internal urethrotomy in 6 patients to a minimal diameter of 26 F.
5. After treating the stricture and confirming hemostasis, we

Figure 3. The distal end of the stent checked by the cystoscope.

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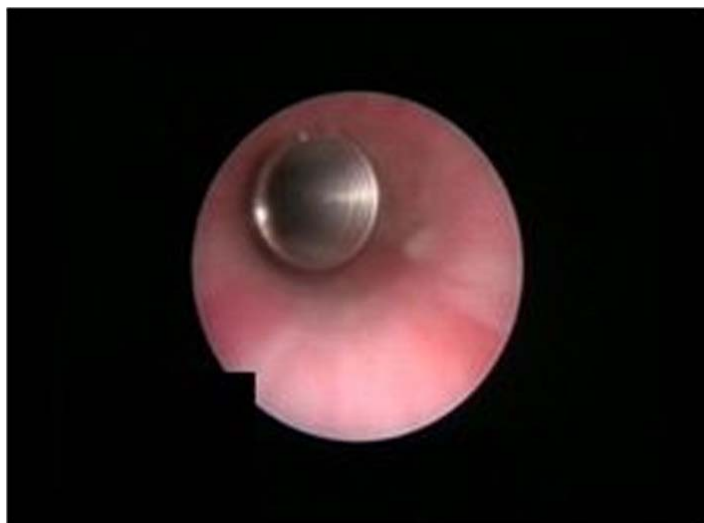


Figure 4. Assessment of the stent after insertion. a) Plain X-ray. b) Cystourethrogram with free passage of the dye.

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selected an appropriate length of Memokath 044 stent based on the estimated stricture length plus 2.0 cm to allow for a 10 mm overlap at either end of the treated segment.

6. We removed the 3 retaining straps from the transport shell using the supplied suture cutter, working from the most distal end of the product toward the hub end of it. The transport shells were removed from the stent/delivery system and the mandrel was pushed out of the delivery system by inserting the cystoscope lens into the hub of the delivery system. We aligned the lens with the black tip of the delivery system.
7. The locking collar was gently rotated clockwise at the base of the insertion sheath. A soft rubber ring inside the collar will compress and create a watertight junction between the sheath and the scope lens. We connected sterile water or saline at a temperature  $\leq 35^{\circ}\text{C}$  to the stopcock and mounted the light source.
8. The stent was placed on its introducing sheath, mounted onto the cystoscope so that the tip of the cystoscope was clear of the stent by 2 to 3 mm, and the cystoscope was advanced until the tip passed about 1 cm approximately to the proximal end of the stricture. After, 50 ml of hot water ( $50^{\circ}\text{C}$ ) was flushed through the cystoscope, expanding the proximal 4 to 6 mm into a cone shape (44 F), which locked the stent into position.
9. The stent released from the sheath when the scope lens

was withdrawn from the black connector at the tip of the stent.

10. We steadied the outer sheath. Under direct vision, we gently retracted the joined inner sheath and cystoscope lens from the outer sheath until the black connector at the tip of the introducer was outside the stent. We then observed that the stent had been released (Figure 3).

Patient follow-up included uroflowmetry to measure Qmax, PVR, sexual function during the Memokath indwelling, postoperative complications, a check of stent position (Figure 4a and Figure 4b), QoL, and the ease and the time of stent removal. Repositioning of the stent can be accomplished easily by flushing the stent with cold saline at  $< 10^{\circ}\text{C}$ , pushing it by the cystoscope sheath to its correct position under vision, and then irrigating the stent with warm saline at  $50^{\circ}\text{C}$  to get full expansion.

#### *The Technique of Memokath Removal*

After a patient was properly prepped and draped, diagnostic urethroscopy was done to check the distal end of the Memokath. The stent was irrigated with the cold saline  $< 10^{\circ}\text{C}$  to become soft. Grasping the tip the Memokath with forceps, we pulled it distally and it released, turn-by-turn, linearly (Figure 5, Figure 6).

A paired t-test was used to compare between pre- and postoperative parameters; p values  $< 0.05$  were considered statistically significant.

Figure 5. Memokath after extraction.

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Figure 6. The impact of the rings of the stent on the urethra.

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Table 2. The demographic distribution of the baseline Qmax, QoL, and PVR.

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Parameter Frequency	Qmax (ml/s)	QoL	PVR (ml)
Mean	4.87	5.12	80.71
SD ±	2.41	0.64	10.96
Min	0	4	70
Max	8	6	100

## RESULTS

Sixteen patients presented with symptoms of bladder outlet obstruction due to recurrent bulbar urethral stricture with only 1 patient presenting with acute urinary retention (AUR) and indwelling suprapubic catheter. The mean age of the patients at time of the stent insertion was  $62.5 \pm 24.74$  (45 to 80) years. All previously had urethrotomy or urethral dilatation or urethroplasty. The length of the stricture measured during insertion ranged from 2 to 5 cm ( $3.31 \pm 0.99$ ). The patient was assessed preoperatively with the Qmax, QoL, and PVR (Table 2).

Before Memokath insertion, the strictures were treated by dilatation in 10 patients (62.5%) and by VIU in 6 patients (37.5%). All the stents were inserted successfully as a day-case intervention. The operative time ranged between 20 to 40 minutes ( $30 \pm 6.45$ ) with no obvious intraoperative complications. Spontaneous voiding was achieved in all patients immediately after stent insertion. All patients were followed-up using Qmax, PVR, and QoL score at 2 weeks, 1 month, 3 months, 6 months, and 12 months, post-insertion.

Postoperative complications included mild perineal discomfort in 4 cases (25%), UTI in 4 cases (25%), bleeding via the urethra and mild penile pain in 3 cases (18.75%), urinary retention in 2 cases (12.5%), distal migration of the stent in 1 case (6.25%) that could be repositioned easily to the correct position under vision, and marked encrustation with obstructed lumen that needed removal of the stent in 1 case (6.25%). Removal was uneventful and done under sedation and local anesthesia and took about 15 minutes to accomplish. Statistical analysis demonstrated that improvements in the Qmax, PVR, and QoL scores were statistically significant throughout the follow-up period, with the p values  $< 0.05$  (Table 3).

Table 3. Demographic distribution of the mean, SD  $\pm$ , and p values of the Qmax, QoL, and PVR preoperatively and at 2 weeks, 1 month, 3 months, 6 months, and 12 months postoperatively.

<http://dx.doi.org/10.3834/uj.1944-5784.2012.08.02t3>

	Prep	Postoperative				
		2 weeks	1 month	3 months	6 months	12 months
Qmax	4.87 $\pm$ 2.41	19.5 $\pm$ 3.25 < 0.05	21 $\pm$ 2 < 0.05	20.5 $\pm$ 0.92 < 0.05	19.5 $\pm$ 1.41 < 0.05	19.7 $\pm$ 1.32 < 0.05
QoL	5.12 $\pm$ 0.64	1.25 $\pm$ 0.46 < 0.05	1.25 $\pm$ 0.64 < 0.05	1.37 $\pm$ 0.51 < 0.05	1.14 $\pm$ 0.37 < 0.05	1.25 $\pm$ 0.22 < 0.05
PVR	80.7 $\pm$ 10.9	18.57 $\pm$ 13.75 < 0.05	19.28 $\pm$ 14.26 < 0.05	16.42 $\pm$ 7.48 < 0.05	15 $\pm$ 8.94 < 0.05	15 $\pm$ 6.82 < 0.05

## DISCUSSION

The management of urethral stricture remains a challenge to all urologists; this is especially true for those who fail to respond to repeated dilatations, optical urethrotomy, and urethroplasty [2]. The most common complication of internal urethrotomy is the incidence of stricture recurrence. A report published by Pansadoro and Emilioi [7] shows curative success rates of 30 to 35% and another by Santucci and McAninch [8] showing success rates of 20%. Because of these dismal success rates, several techniques have been proposed to oppose the process of wound contraction and to prevent stricture recurrence is the use of urethral stents [9].

The placement of stents has been used for the treatment of obstruction in different parts of the body to treat coronary, femoral, and renal artery stenosis; vena caval obstruction; bronchial obstruction; tracheal stenosis; and lacrimal duct obstruction. In 1980, Fabian first described the use of stents in urology when he suggested their usefulness in the treatment of outlet obstruction secondary to enlargement of the prostate and, after that, the use of stents was advocated in the treatment of urethral stricture [9].

Memokath was first introduced as second-generation stents for the treatment of upper and lower urinary tract obstruction. In 1993, this was a thermo-expandable stent made from a nickel and titanium alloy that has a "shape memory" feature [6]. This alloy is present in two crystalline forms: martensitic and austenitic. The more rigid austenite form holds the memorized shape of the Memokath at body temperature and higher. The martensite form is softer and pliable. A transition to this form takes place when the alloy is cooled to 10°C. This structural change is a result of a coordinated movement of large blocks of atoms with a change in the temperature and is known

as reversible martensitic transformation [10]. In this study, Memokath stents were inserted in 16 patients with recurrent bulbar urethral strictures after dilatations, visual internal urethrotomies (VIU), or urethroplasty aiming to assess their efficacy and safety. The ages of these patients ranged from 45 to 80 years (62.5  $\pm$  24.74). The etiology of the strictures was idiopathic in 37.5%, iatrogenic in 25%, traumatic in 25%, and infective in 12.5% of cases. The length of the stricture ranged from 2 to 5 cm. All patients were assessed preoperatively with the Qmax, QoL, and the PVR. The Qmax ranged from 0.0 to 8 ml/sec, the QoL ranged from 4 to 6, and the PVR from 70 to 100 ml.

The 16 Memokath 044 stents were inserted successfully under local anesthesia or saddle block after urethral dilatation in 10 patients (62.5%) and after VIU in 6 patients (37.5%). The operative time ranged from 20 to 40 minutes (30  $\pm$  6.45) without intraoperative complications.

All patients were followed up with the Qmax, PVR, and QoL scores at 2 weeks, 1 month, 3 months, 6 months, and 12 months, postoperatively. The mean Qmax improved from 4.87 to 19.5, 21, 20.5, 19.5, and 19.7 ml/sec, respectively. Our results agreed with that of Milory and his colleagues who reported on long-term results of 50 patients with recurrent urethral strictures after stenting. The flow rate was 19.7 ml/s, and 93% of patients were satisfied with the stent [11]. Also, our results are compatible with that of Tammela et al. who verified at least 4 times better results of uroflowmetry than before insertion. They removed the stents after 12 months, and in all patients they found complete recanalization without any dysuric problems [12]. Riedasch and colleagues found that after removal of the stents, a non-inflammatory, multilayer urothelium had covered the former strictures area circumferentially and the patients showed ongoing normal width and smooth lining of the neourethra in the expanded Memokath stented area [13]. Moreover, Yachia

et al. added that, unlike the permanent stents, the experience with the Memokath stents showed that they can be used in posttraumatic and in post-urethroplasty strictures where skin was used because they did not infiltrate by tissue, and they did not have to cut through the skin patch to imbed the stents [14].

In Egypt, the stent alone costs about 7 000 LE (1 156 USD), which could limit its widespread use; however, in the study of Jordan and van der Burght, they concluded that the Memokath 044 stent is a cost-effective alternative to repeated dilatation/urethrotomy [16].

There were minimal postoperative complications in the form of mild penile and perineal pain and discomfort, UTI, and urethral bleeding, all usually mild, transient, and treated conservatively, as in the study of Jordan and Van Der Burght who noted that penile pain had no untoward effects on the patient's sexual life, nor did it affect the urodynamic parameters, as in our study [16].

Stent migration has been a significant drawback, particularly in the non-expandable spiral stents accounting for 10 to 38% [15]. While Memokath stents are associated with lower migration rates ranging from 0 to 13% according to Perry et al. [6], which is consistent with our results. Since distal migration of the stent took place in 1 case (6.25%) 3 months post-insertion, and easily repositioned endoscopically, this low rate of migration can be explained by the soft structure and the conic shape of the posterior part of the stent, which did not aid in the proximal migration of the stent or lesions with external sphincter irritation [16]. Also, these results confirmed with those of Nita et al. who reported stent migration in 9% of cases [17] as well as with a study by Hamid and colleagues who found that the stent migration rate was very low and it was easy to correct [18].

Secondary obstruction by conventional stents was explained by the ingrowth of scar tissue known as "transmesh ingrowth" of connective tissue under the stimulus of locally released fibroblast growth factor [13]. In our study, 1 stent was removed (6.3%) due to obstructive occlusion of the stent lumen, consistent with the results of Jordan and van der Burght who reported obstructive occlusion in 4.8% of cases of Memokath stents [16]. Due to the spiraled construction of a self-expanding nitinole, they seem theoretically less prone to this complication if the secondary ingrowth of connective tissue is avoided by continually expanding the urethrotomized scarred area until a new urothelial lining has been furnished from the proximal and distal stent openings as stated by Darshan et al. [19]. Our results also agreed with those of Pannek et al. who noted zero

intraoperative complications in their study and did not find significant encrustation, and they postulated that this finding may be because of the stent observation period (13 months). Even in the subset of patients who had a stent for longer periods, they did not encounter encrustation [20]. However, removal was easy, taking about 15 minutes by flushing the stent with cool water  $\leq 10^{\circ}\text{C}$ , which alters the spiral so it becomes soft and pliable in order to facilitate transurethral removal such as that done in the study by Neil et al. in which removal took an average of 11 minutes. They added that urethral stenting offers an alternative to minimally invasive procedures to relieve the symptoms of BOO in high surgical risk patients and is an alternative to open urethroplasty in selected populations [10].

In conclusion, the stent was straightforward to insert and to remove, the side effects were favorable and could relieve the symptoms of BOO due to urethral strictures in high surgical risk patients, maintaining urethral patency without interference with a patient's sexual life and thereby improving QoL. However, we recommend further studies with a larger scale of patients and for longer follow-up periods to assess the long-term efficacy and safety as well as the cost-effectiveness of the Memokath stents in the treatment of recurrent bulbar urethral strictures.

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