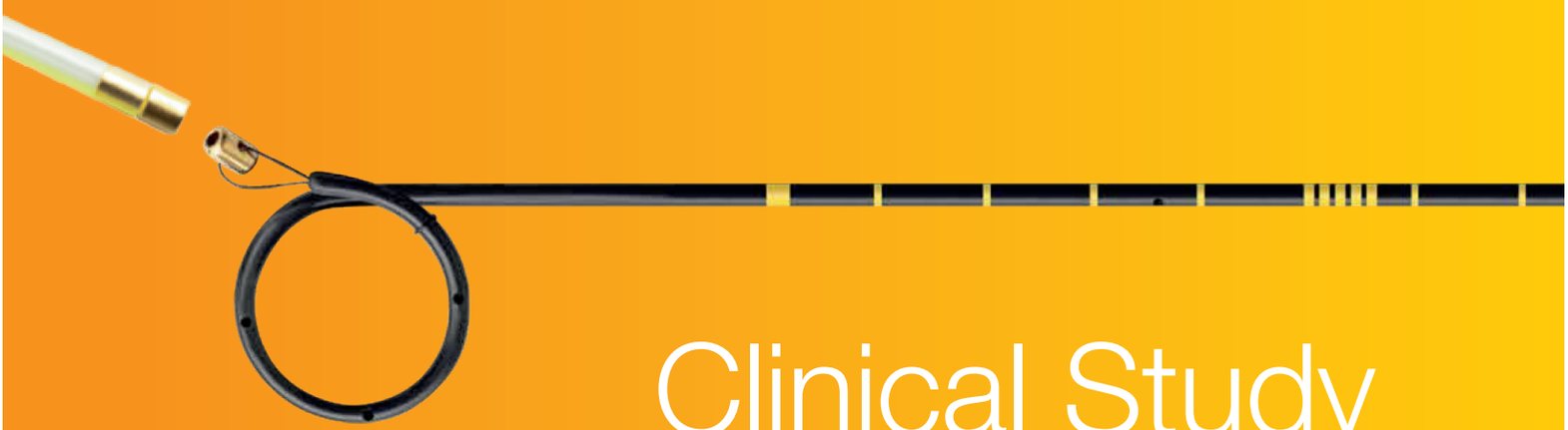
UROTECH®
A MEDI-GLOBE COMPANY

Magnetic Black-Star®



Clinical Study Booklet

Your Partner in Endourology

Magnetic Black-Star® – The easiest way to remove stents

The insertion of an ureteral stent is a recognized standard for a variety of indications. In common practice, the ureteral stent is inserted using the Seldinger technique and removed with a cystoscopy. This is time and labor intensive.

Take advantage of a smarter solution:

Quick, comfortable and resource sparing removal with the Magnetic Black-Star®.

Recently, the new Magnetic Black-Star® XS has been developed to solve the challenges posed by ureteral stent insertion in children. The magnet at the pigtail-end on the bladder side has been reduced in size to facilitate cystoscopic insertion also with pediatric cystoscopes.

Magnetic Black-Star® is also unique in the clinical evidence generated with more than 15 clinical publications, abstracts and reports, and still inspires users for new studies and publications on their experience. In this clinical study booklet we highlight some reports where the unique features of the Magnetic Black-Star® showed important advantages during stent removal process in different patient populations.

> **“The Magnetic Black-Star® offers an ideal solution as an ureteral stent for patients with a planned short indwelling time, as it can be removed quickly and easily without cystoscopy.”**
>
> *Dr. M.-C. Rassweiler-Seyfried,*
> *University of Mannheim, Germany.*

Systematic Review

"The "ins and outs" of the magnetic ureteral stent: A novel innovation in Endourology"

Damodarana V, Elsa B, Daras E , Kataka T, Gulamali S , Ntakana S, Perera M , Adam A. Current Urology. 2022.

"The efficiency of magnetic ureteral stents allows for **convenient stent removal in an out-patient setting**, thus shortening patient waiting times. In addition, there are **cost benefits** as the cost for the procedure and equipment used were much lower compared to the traditional double-J stent method: this is attributed to the **negation of admission for inpatient removal**."

"Other advantages to be considered regarding patient experience include the duration of stent indwelling time, as well as the extraction time. It was found that magnetic stents had a **shorter stent duration** than the traditional double-J stents. This can be extended to reduce opportunities for infections and other complications. Many factors allow for easier and more efficient extraction of these stents, such as extraction being an easier and less invasive procedure to perform, primarily because it can be performed in an outpatient capacity, as it does not require anaesthesia to perform in the majority of cases. As such, extraction times were also shorter, translating to a **shorter period of discomfort for the patient and a decreased risk of nosocomial infection**."

"Within the recent COVID-19 setting, the advantages of magnetic ureteral stents are attractive in mitigating the potential spread. Reducing the need for inpatient removal and hospital stay not only reduces potential risk but also reduces added costs with regard to staff and theater segregation, personal protective equipment, mandatory testing, and sanitization. Furthermore, the decreased need for inpatient removal allows for **better allocation of hospital resources during the pandemic**."

A systematic review of magnetic versus conventional ureteric stents for short term ureteric stenting.

Lyons L, Kinnear N, Hennessey D. Irish Journal of Medical Science. 2022.

"In this review, we analysed all studies comparing magnetic vs. conventional ureteral stents. We noted that **magnetic stents are associated with less pain and discomfort at the time of removal** when compared to cystoscopic removal of conventional ureteral stents."

"Two studies found magnetic ureteral stents were found to be viable options for ureteral stenting for kidney transplant procedures to avoid post-operative complications."

"All the six studies reported that **the removal of magnetic stents was more cost-effective** than conventional ureteral stents. This is most likely due to the inclusion of sterilisation costs required per cystoscopically removed conventional ureteral stents. The amount saved per stent removal procedure was approximately equivalent, ranging from €100 to €203. This mechanism of ureteral stenting reduces cost but can also **reduce resources being utilised for stent removal**, with a nurse run clinic able to perform magnetic stent removals."

General

"**Removal** … was **easy, almost painless** for the patients and nearly 100 % successful. The Magnetic Black-Star® is a practicable and, with regard to cystoscopic DJ removal, **cost-effective alternative** in everyday clinical practice."

Blasl-Kling F et al. 2016

"Can be removed **easily** and with a **high accuracy** rate. The **removal was faster** and **less costly** than the standard DJ. This magnet retrieval system is a feasible and simpler alternative to the cystoscopic retrieval of ureteral stents."

Farouk A et al. 2019

"[Magnetic Black-Star® stents] are associated with **less pain** during removal. The outpatient-based removal is also **faster** and more **convenient**, resulting in **significant cost savings** and supporting the more widespread use of magnetic stents."

O'Kelly JA et al. 2020

Kidney

"[Magnetic Black-Star®] appeared to be **safe and cost-effective**. Advocate its **routine implementation** in kidney transplantation because of an **easy** and **comfortable extraction** in the outpatient setting **even by non-dedicated staff**, without detrimental impact on the rates of urological complications and urinary tract infections."

Capocasale E et al. 2019

"Using Magnetic Black-Star® is a **feasible option** for living donation AB0-identical kidney transplant recipients."

Pohlmann PF et al. 2019

Pediatric

"[Magnetic Black-Star® stents] represent a **safe** and **equally effective alternative** to standard stents, especially in pediatric patients."

Mitchell A et al. 2020

"It is a **safe** and **effective** strategy that obviates the need for additional general anesthesia in children. The **easy** and **less time-consuming removal** of the MBS **benefits both the patient and the hospital** and validates its clinical use."

Chalhoub M et al. 2021

Removal

"**Nurse-led removal** of magnetic stents is **safe** and **well tolerated by patients**, and enables expedient stent removal. It also provides **a significant cost benefit** and frees up valuable endoscopic resources."

O'Connell L et al. 2018

"Removal of the **magnetic DJ is less painful, faster and cheaper** compared to the standard DJ and could be **performed by trained urologic nurses**."

Rassweiler MC et al. 2017

Pain

"[Magnetic Black-Star®] is a **safe option** associated with **less pain**, particularly for male patients requiring short-term ureteric stenting. Removal of the ureteral stent using a catheter is less painful than cystoscopic standard extraction and **can even be performed by non-medical staff**."

Sevcenco S et al. 2018

"It **does not increase symptomatology** or **medical complications** when compared to the standard DJ. Removal does not require the use of cystoscopy and can be performed in an outpatient setting in an **easy, less painful and faster way**."

Diranzo-Garcia M et al. 2021

The “ins and outs” of the magnetic ureteral stent: A novel innovation in Endourology.

Damodarana V, Elsa B, Daras E , Kataka T, Gulamali S , Ntakana S, Perera M , Adam A. Current Urology. 2022.

Background & Aim:

Ureteral stents play a major role in maintaining ureteral patency. The novel, innovative, magnetic double-J ureteral stent (Magnetic Black-Star ®, Urotech) is made of polyurethane and has a cylindrical magnet attached to the distal stent coil. This new Magnetic-End Double-J Ureteral Stent (MEDJUS) facilitates outpatient removal using a magnetic stent removal device. This systematic review was conducted to critically appraise the published efficacy, cost-saving aspects, pain response, symptomatology and general outcomes related to MEDJUS.

Design & Methods:

An electronic database search (PubMed, EMBASE, Cochrane Library, Scopus, and Web of Science) was performed at the end of the year 2020 using the following terms: “MEDJUS,” “ureteric,” “stent,” “double-J,” “Urotech,” and “Black-Star” and the final analysis only included paediatric, clinical comparative, nonclinical comparative, and cost evaluation/comparison studies.

9 studies were included for appraisal: 3 retrospective studies, 3 randomized control trials, 2 prospective studies, and 1 case–control study, for a total combination of 685 patients. The total number of MEDJUS procedures used was 498 (73%) compared to the 187 (27%) traditional double-J stent method.

As regards to the endpoints, pain response and tolerance of the patients (using the Ureteral Stent Symptom Questionnaire – USSQ), costs, complications and suitability for paediatric patients were assessed.

Results:

The average pain score for the MEDJUS (stent in situ) was 2.46, compared with 2.94 for the traditional double-J stents. Similarly, the average pain score for stent removal was lower within the MEDJUS group compared with the traditional double-J stent group: 2.78 and 4.03, respectively. It was found that MEDJUS had a shorter stent duration than the traditional double-J stents. This can be extended to reduce opportunities for infections and other complications. Moreover, extraction times were shorter, translating to a shorter period of discomfort for the patient and a decreased risk of nosocomial infection.

The most common complication found in four studies was sporadic infection. The total reported MEDJUS-related UTI incidence was 7 cases in this review (7/498, 1.4%). No significant differences in stent irritation were found in the cohort of patients carrying and indwelling stents for 4 weeks.

All 5 studies including a cost analysis reported a cost benefit per case with MEDJUS use compared to traditional double-J stent use (across 4 different countries, 3 studies being European, 1 African and 1 North American). This is attributed to the negation of admission for inpatient removal, despite the initial higher cost of MEDJUS compared to the traditional double-J cost.

UROTECH®
A MEDI-GLOBE COMPANY

Conclusion:

Ureteric stenting is a common and important urological procedure, of which many innovations and advances have been made. It still presents some challenges because of the invasive nature of the procedure. Nevertheless, the popularity and availability of new stenting modalities such as magnetic ureteric stenting spreads significantly. Based on this review, MEDJUS aims to provide cost and pain benefits compared to the traditional double-J stent method.

A systematic review of magnetic versus conventional ureteric stents for short term ureteric stenting.

Lyons L, Kinnear N, Hennessey D. Irish Journal of Medical Science. 2022.

Background & Aim:

Ureteral stents play an essential role in urology. However, patients can suffer a range of stent-related symptoms (frequency, urgency, haematuria, incomplete emptying as well as flank and suprapubic pain) with stents in situ and during removal. In contrast to standard double-J stents, new magnetic stents may be rapidly removed without any flexible cystoscopy.

The primary aim of this systematic review was to compare the morbidity associated with magnetic versus conventional ureteral stents both in situ and at stent removal. The secondary aim was the cost-effectiveness of each stent type.

Design & Methods:

Data from 30 male patients aged 24 to 82 years (meSearches were performed using medical databases (Pubmed, Embase, Scopus and Cochrane) and following search terms: “ureteric stent”, “magnetic”, “pain”. Inclusion criteria were determined utilising the PICOS method. Eligible studies included only patients with ureteral stents (P), presented groups with magnetic (I) and conventional stents (C), assessed pain or cost (O) and were comparative in nature (S).

Six studies were eligible for inclusion comprising 1 randomised control trial, 3 observational case–control studies and 2 cohort studies. Total number of included patients was 457.

The primary outcomes were patients reported morbidity. The secondary outcome was the cost analysis. Because of non-homogeneous studies methodologies, this study only focused on a quantitative analysis of the data.

Results:

Rassweiler et al. published in 2017 a randomised control trial to assess the impact of magnetic ureteral stents on patient’s quality of life and discomfort during the removal: the VAS scores showed the magnetic ureteral stent with a mean of 3 versus 5 for the conventional stent. Magnetic ureteral stents were removed in a shorter time frame of 9.55 min compared to the flexible cystoscopy for conventional ureteral stents (21.35 min).

Sevcenco et al. and O’Kelly et al. published both observational case–control studies in 2017 and 2019, to compare magnetic with conventional stents regarding morbidity, pain on removal, complications and cost effectiveness: O’Kelly found no significant difference between magnetic and conventional ureteral stents USSQ scores (14.3 vs. 15.3, $p=0.32$) whereas Sevcenco et al. reported a significant difference between the two types of stents for indwelling pain, using a VAS (2.17 vs. 5.88; $p<0.001$).

The secondary outcome of this review was to assess the cost-effectiveness of using magnetic vs. conventional ureteral stents. All six studies showed a reduction in cost using magnetic ureteral stents. This is most likely due to the inclusion of sterilisation costs required per cystoscopically removed conventional ureteral stents. The cost per patient was calculated by O’Kelly et al. and Sevcenco et al. studies, showing a saving per patient €203.

Two studies found magnetic ureteral stents were found to be viable options for kidney transplant procedures to avoid post-operative complications, even though this finding was not an aim of this review.

UROTECH®
A MEDI-GLOBE COMPANY

Conclusion:

Magnetic ureteral stents are associated with less pain and discomfort at the time of removal when compared to cystoscopic removal of conventional ureteral stents. In addition, they are associated with a considerable cost saving when considering the same comparison.

DJ Catheter Removal After Stone Therapy: What Are Advantages of the Magnetic DJ Catheter?

Blasl-Kling F, Wiesend F, Madeo J, Humke U. UroForum. 2016;12: 38-40.

Background & Aim:

DJ stent placement after successful ureterorenoscopic stone therapy previously required a cystoscopy to remove the DJ stent, which can be traumatic and painful, especially for men. The study investigated whether the new magnetic DJ stent Magnetic Black-Star® (MBS; Urotech) could be suitable as a cost-effective alternative to post-stenting that is well tolerated by male patients.

Design & Methods:

Data from 30 male patients aged 24 to 82 years (median 48.3 years) who were treated in the clinic for stone disease were collected. All 30 patients received an MBS as post-stenting after successful unilateral ureterorenoscopic stone extraction. The MBS was removed on an outpatient basis 6-14 days later. The MBS has a small magnet at its distal end in the urinary bladder and is removed using a special retrieval device with a magnetic tip that is inserted via the urethra. The two magnets connect, and the DJ can be pulled out.

To objectify the tolerability of the MBS, patients were asked about their symptoms before removal of the MBS using the International Prostate Symptom Score (IPSS) and the Visual Analog Scale (VAS). In addition, the costs of MBS removal were compared with cystoscopic DJ removal with and without analgosedation, considering operating time at 5.93 €/min and anesthesia time at 2.99 € /min (costs for staff, medical and non-medical infrastructure included). The average required time of surgery and anesthesia resulted from the analysis of 60 patient data (30 cystoscopic DJ removals with analgosedation, 30 without).

Results:

Removal of the MBS was successful, easy and almost painless in 29 of 30 patients, while one patient required cystoscopic removal due to an enlarged endovesical prostate middle lobe that prevented the magnetic connection. The median IPSS value of the patients with an MBS was 9.3 (range 2-19) and the median VAS pain score 2.2 (range 1-6).

Conventional DJs used in the clinic cost around €20, while an MBS with retrieval device costs €80. However, median operating time for cystoscopic DJ removal with analgosedation (12.7 min) or without (14.0 min) and median anesthesia time (21.4 min) increased the total costs of cystoscopic removal, whereas removal of the MBS did not cause any additional costs. Thus, the overall costs of MBS removal (€80) were considerably lower than cystoscopic removal with analgosedation (€159.31) or without (€103.20) **(Figure 1)**.

Conclusion:

Removal of the MBS using the associated retrieval device was easy, almost painless for the patients and nearly 100 % successful in this study. Therefore, the MBS is a practicable and, with regard to cystoscopic DJ removal, cost-effective alternative in everyday clinical practice.

UROTECH®
A MEDI-GLOBE COMPANY

Damodarana V et al. 2022

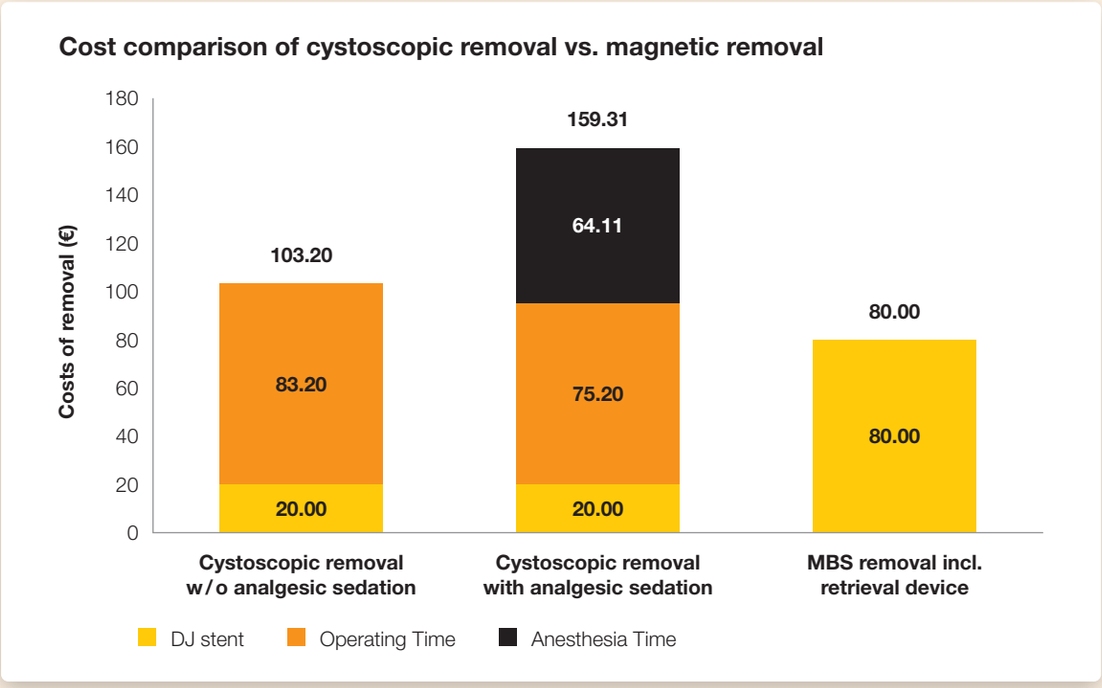
Lyons L et al. 2022

Blasl-Kling F et al. 2016

Farouk A et al. 2019

O'Kelly JA et al. 2020

Figure 1



Cost comparison of MBS removal with DJ stent removal using cystoscopy with and without analgosedation.

Can Magnitip Double-J Stent Serve as a Substitute for a Standard Double-J Stent?

Farouk A, Tawfick A, Hasan M, Abuftira AA, Maged WA. Turk J Urol. 2019; 45: 437-443.

Background & Aim:

Indwelling ureteral stents have significant adverse effects such as discomfort, infection, migration, and encrustation, known as 'stent syndrome', which can lead to considerable morbidity. Further, many patients require general anesthesia or sedation for removal, which is expensive, time-consuming, and carries an anesthetic risk for the patient. Using magnets could allow removing stents without cystoscopy or general anesthesia. The study evaluated the morbidity, the accuracy of stent removal and the costs of a magnetic DJ (Magnetic Black-Star®; Urotech) and compared it with a standard DJ.

Design & Methods:

50 patients with a ureteral stone were randomly assigned to receive ureteroscopic treatment and A) a magnetic DJ (n = 25) or B) a standard DJ (n = 25). All stents were removed after 2 weeks: in group A) by introducing a magnetic retrieval device into the bladder and removing the magnetic DJ after connection of the magnets, in group B) by flexible cystoscopy under local anesthesia. On the day of removal, post-operative morbidity using the ureteral stent symptom questionnaire (USSQ) and discomfort during removal using a visual analogue scale (VAS) were assessed. In addition, total costs in Egyptian Lira (E. L.) were calculated by considering hospital bills.

Results:

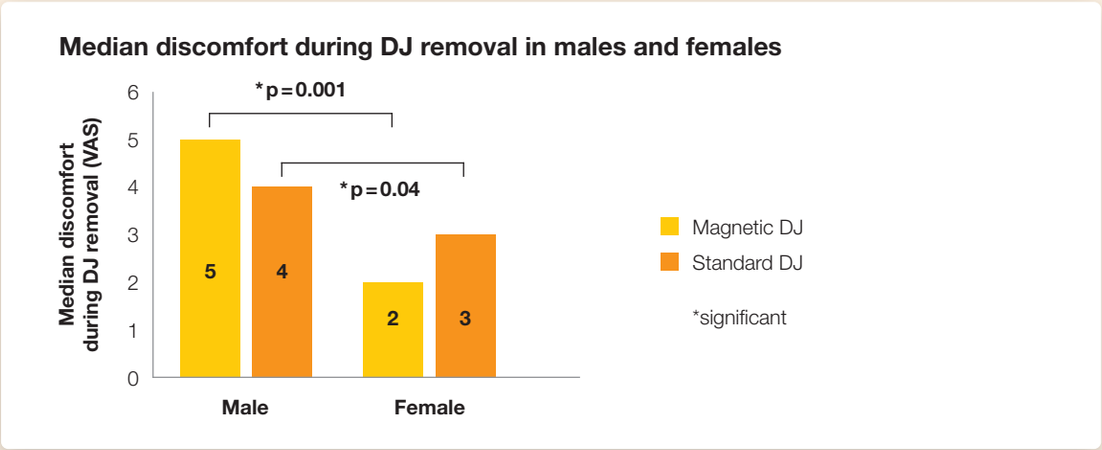
Overall, post-operative morbidity was higher with a magnetic DJ than with a standard DJ. However, differences between the two groups were statistically significant ($p < 0.05$) only for urinary symptoms, pain, work performance, and the total USSQ score, whereas the differences were not statistically significant for general health, sexual matters, and additional problems. Differences between both groups regarding application, accuracy of retrieval, and discomfort during removal were not significant, but discomfort during removal was in both groups significantly higher in males than in females **(Figure 1)**.

Although the mean costs of DJ placement were significantly higher ($p = 0.001$) for the magnetic DJ due to the costs of the stent, the total costs of placement and removal were due to the simpler and faster removal significantly lower for the magnetic DJ (E. L. 8444 ± 784) than for the standard DJ (E. L. 9600 ± 1457; $p = 0.001$) **(Figure 2)**.

Conclusion:

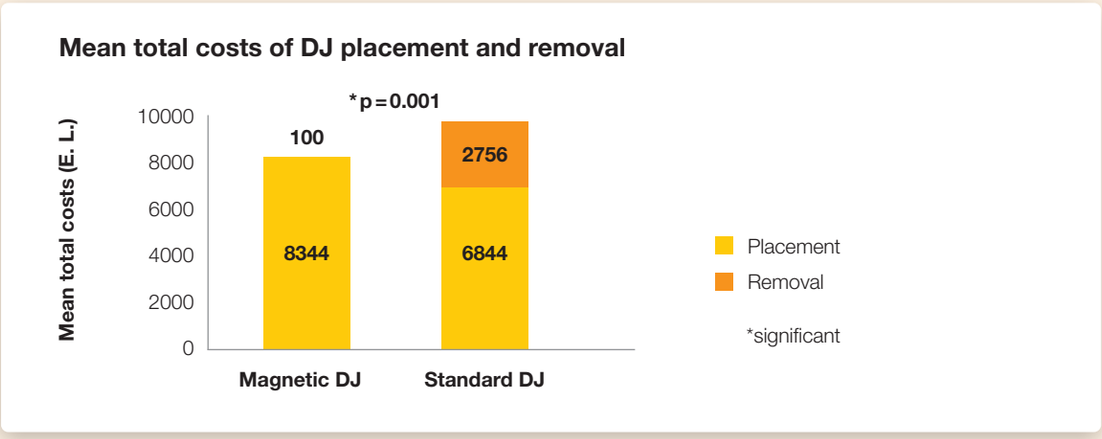
The magnetic DJ can be removed easily and with a high accuracy rate. The morbidity caused by the magnetic DJ was found to be higher, but its removal was faster and less costly than the standard DJ. The magnetic DJ is a feasible and simpler alternative to standard DJs and particularly suitable for outpatient removal.

Figure 1



Median discomfort during DJ removal in males and females as assessed by a VAS. DJ, Double-J stent; VAS, visual analogue scale.

Figure 2



Mean total costs of DJ placement and removal. DJ, Double-J stent; E. L., Egyptian Lira.

Ureteric Stenting with Magnetic Retrieval: an Alternative to Traditional Methods

O'Kelly JA, Haroon UM, Rauf AJ, Breen KJ, McGuire BB, Cheema IA, McLornan L, Forde JC. Ir J Med Sci. 2020; 189: 289-293.

Background & Aim:

Ureteric stents are frequently placed following endo-urological procedures and cause significant morbidity. Standard ureteric stents are removed by flexible cystoscopy, which can be unpleasant for patients and requires additional resources. A newly designed magnetic stent (Magnetic Black-Star®; Urotech) allows removal in an outpatient setting. The study compared the magnetic stent with standard ureteric stents with regard to morbidity, pain during removal, and cost-effectiveness.

Design & Methods:

The study was carried out across two sites. On site A, 50 consecutive patients received a magnetic stent that was removed by a magnetic retrieval device. At the time of stent removal, the patients completed the Ureteric Stent Symptom Questionnaire (USSQ) and a Visual Analogue Scale (VAS). On site B, 50 patients who received a standard stent (soft polyurethane) that was removed by flexible cystoscopy were identified retrospectively and completed questionnaires by post. Cost analysis was performed by contacting the finance department at each site to determine the costs of each stent and the costs of removal.

Results:

The analysis included 100 questionnaires (magnetic stent n = 50; standard stent n = 50). Median duration of stenting was significantly shorter in the magnetic stent group (5.5 vs. 21.5 days, $p < 0.001$). While complication rates were similar in both groups, pain during stent removal was significantly less with magnetic retrieval (mean VAS score 2.9 vs. 3.9, $p < 0.05$).

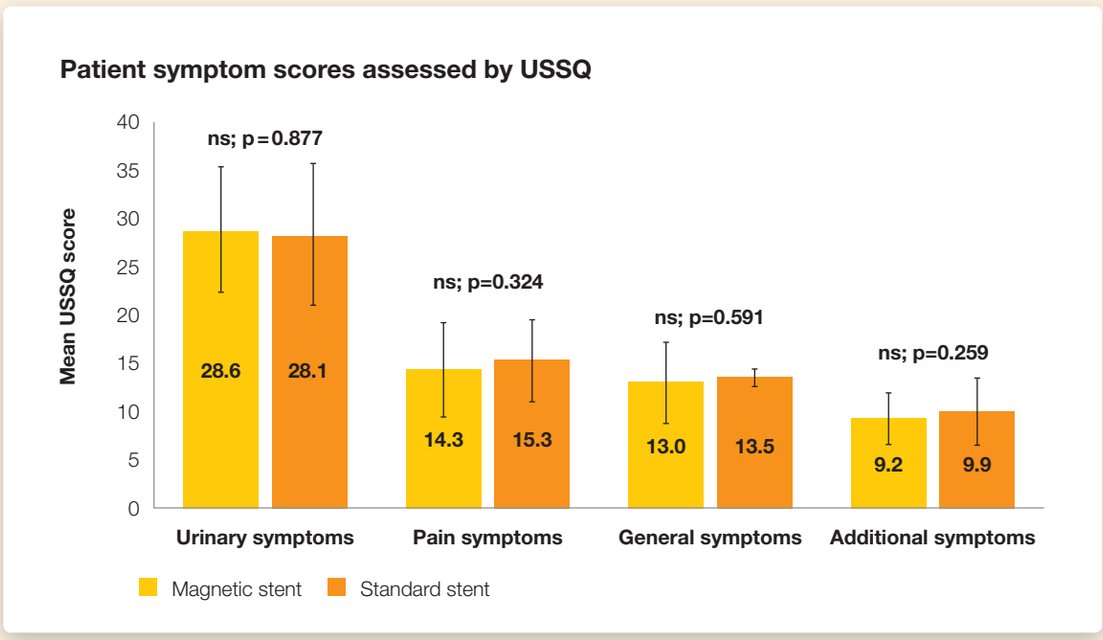
There were no significant differences in stent morbidity between both groups as assessed by the USSQ **(Figure 1)**.

Cost analysis demonstrated a total cost saving of €10,150 (€203 per patient) when using a magnetic stent with magnetic retrieval device **(Figure 2)**.

Conclusion:

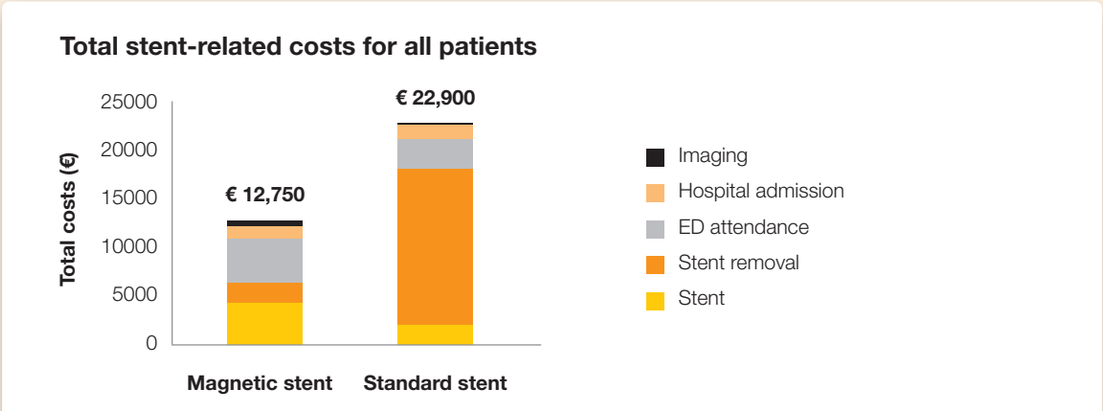
Magnetic stents cause similar morbidity when compared with standard stents removed by flexible cystoscopy, but they are associated with less pain during removal. The outpatient-based removal is also faster and more convenient, resulting in significant cost savings and supporting the more widespread use of magnetic stents.

Figure 1



Results of the USSQ (mean and standard deviation) in patients with magnetic stent and standard stent. ns, not significant; USSQ, Ureteric Stent Symptom Questionnaire.

Figure 2



Cost analysis including stent, stent removal procedure (cost of hospital attendance and removal by urology nurse in magnetic stent group; flexible cystoscopy and removal in day theatre in standard stent group), and complications. ED, emergency department. ED attendance: €450 per patient; hospital admission: €350 per patient; magnetic stent/removal: € 90/40 per patient; standard stent/removal: €40/325 per patient.

Implementing a Ureteric Magnetic Stent in the Kidney Transplant Setting: Report of 100 Consecutive Cases

Capocasale E, Cremaschi E, Dalla Valle R, Ferretti S, Pellegrino C, Iaria M, Puliatti C. Transplantation. 2019; 103: 2654-2656.

Background & Aim:

Kidney transplantation is the treatment of choice for end-stage kidney disease. The Double-J (DJ) stent has been used to prevent urological complications, but it requires cystoscopic extraction. The novel stent Magnetic Black-Star® (MBS; Urotech) provided with a customized retrieval device has been developed to spare cystoscopy. The study evaluated the use of the MBS in 100 consecutive kidney transplant patients.

Design & Methods:

The retrospective analysis included 100 consecutive kidney transplant patients who received the MBS to protect Lich-Gregoir ureteroneocystotomy. The MBS was removed 4 weeks after kidney transplantation using either a 9 Fr (n = 61) or a 15 Fr (n = 39) retrieval device. After connection of the magnets from stent and retrieval device, the device was pulled back with the stent attached. A basic ultrasonography was used in 78 cases to ease the detection of the magnetic tip and to guide the retrieval device. No imaging was used in 22 cases. At the end of the removal procedure, each patient was interviewed according to the Visual Analogue Scale (VAS) for pain. Patients were followed up for 3 months.

Results:

Intraoperative MBS insertion was straightforward in all cases. Its extraction was carried out in the outpatient setting in 93 patients and as a bedside procedure in 7 hospitalized patients.

Extraction time was < 30 sec in 45 of 61 patients (73.8 %) using the 9 Fr retrieval device and in 38 of 39 patients (97.4 %) using the 15 Fr retrieval device. In 15 patients, MBS removal took 30-180 sec, and only 2 cases required cystoscopic removal **(Figure 1)**.

Regarding the VAS, 93 patients reported a pain grade defined as discomfort and 7 as distress. No pain medication use after the extraction and no post-procedural hematuria were observed.

During follow-up, 2 patients had urological complications (1 with urinary leak during stent indwelling, 1 with anastomotic stenosis). Only 9 patients reported indwelling stent-related symptoms, which did not require any treatment, and 8 urinary tract infections were observed within 60 days after kidney transplantation.

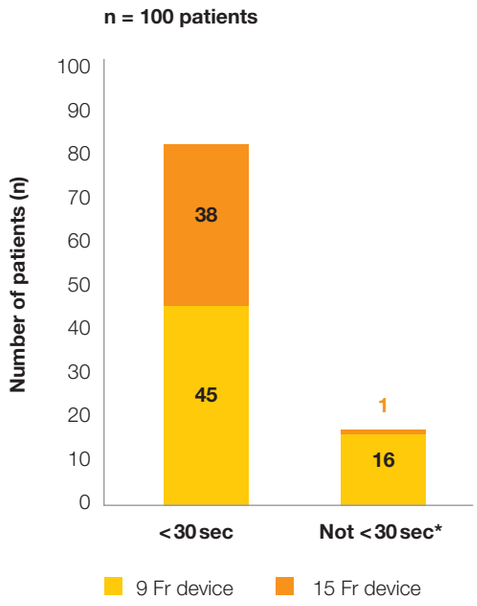
Conclusion:

The MBS appeared to be safe and cost-effective. The authors advocate its routine implementation in kidney transplantation because of an easy and comfortable extraction in the outpatient setting even by non-dedicated staff, without detrimental impact on the rates of urological complications and urinary tract infections.

UROTECH®
A MEDI-GLOBE COMPANY

Figure 1

Patients with extraction time <30 sec or not



*Extraction time not <30 sec	Number of patients (n)
Removal 30-180 sec	15
Cystoscopic removal required	2

Number of patients with extraction time <30 sec or not, differentiated by size of retrieval device (9 Fr vs. 15 Fr). Removal in patients not achieving an extraction time <30 sec required 30-180 sec or cystoscopy (see table; not differentiated by size of retrieval device).

Magnetic Ureteral Stents are Feasible in Kidney Transplant Recipients: a Single-Center Experience

Pohlmann PF, Kunzelmann M, Wilhelm K, Miernik A, Gratzke C, Jud A, Pisarski P, Jänigen B. Int J Organ Transplant Med. 2019; 10: 162-166.

Background & Aim:

Insertion of ureteral stents is a common procedure in kidney transplantation. The stent is usually removed by cystoscopy, which is associated with fears and pain for patients and costs for the health care system. Magnetic ureteral stents that can be removed without additional cystoscopy may be an alternative to conventional stents. The study assessed the functional efficacy and feasibility of a magnetic double J (DJ) stent (Magnetic Black-Star®; Urotech) in kidney transplant recipients.

Design & Methods:

The study included 7 cases of exclusively AB0-identical living donations who received magnetic DJ stents. The stents were removed by transplant surgeons in an Intermediate Care Unit routinely 10-12 days after transplantation, but remained for 6-8 weeks in some recipients due to medical reasons. By using a magnetic retrieval device, the stents were removed after connecting with the device. In order to determine quality of life and pain, the patients filled out the Ureteral Stent Symptoms Questionnaire (USSQ) around day 5 after transplantation and completed a pain questionnaire including a Visual Analogue Scale (VAS) after stent removal. The total removal time was recorded and the cost reduction was calculated.

Results:

The stents were removed after a mean period of 30.0 (± 221.1) days after transplantation. Removal of the magnetic DJ was successful in all patients. The mean duration of stent removal was 3.4 (± 1.6) min. Six of seven USSQs were collected. Mean pain with the indwelling stents was 2.67 (± 2.51). Mean pain during magnetic removal using the VAS was 2.6 (± 1.1) **(Table 1)**.

In addition, using the magnetic DJ stent was associated with a cost reduction of € 130 per case.

Conclusion:

Using magnetic ureteral stents is a feasible option for living donation AB0-identical kidney transplant recipients.

Table 1

Patient characteristics	
Sex, n **female** **male**	 4 3
Age, years (mean ± SD)	48.7 ±12.4
BMI, kg/m² (mean ± SD)	24.2 ± 4.2
Procedure- and stent-related details	
Duration of stent indwelling, days (mean ± SD)	30.0 ± 221.1
Pain with indwelling stent according to USSQ (mean ± SD)	2.67 ± 2.51
Succesful removal, n	7
Pain during removal according to VAS (mean ± SD)	2.6 ± 1.1

Patient characteristics as well as procedure- and stent-related details. BMI, body mass index; SD, standard deviation; USSQ, Ureteral Stent Symptoms Questionnaire; VAS, Visual Analogue Scale.

Use of a Magnetic Double J Stent in Pediatric Patients: A Case-Control Study at Two Canadian Pediatric Centers

Mitchell A , Bolduc S, Moore K, Cook A, Fermin C, Weber B. J Pediatr Surg. 2020; 55: 486-489.

Background & Aim:

Ureteral stents with magnetic tips (Magnetic Black-Star®; Urotech) were recently approved for use in Canada. Traditionally, pediatric stent insertion and removal are performed under general anesthesia (GA). However, due to associated risks, it is suggested that any anesthetic in children should be minimized, and multiple exposures should be avoided. The use of magnetic stents obviates the need for GA as they can be removed easily with or without fluoroscopy. Magnetic stents have three main benefits in pediatric patients: cost savings, decreased operation room time and reduced GA exposure. The study created the first published evidence of the use of these magnetic stents in pediatric patients.

Design & Methods:

The case-control study included a total number of 80 pediatric patients undergoing ureteroscopy, ureteric re-implantation, or pyeloplasty at two Canadian centers. While 40 patients received a magnetic double J stent (n = 24 with fluoroscopy-guided removal due to surgeon preference at one site; n = 16 without fluoroscopy at the other site), 40 control patients received regular double J stents that were removed under GA. Data on demographics, side, surgical indication, stent size, duration of indwelling, side effects and complications, and concomitant use of other medications were collected. The amount of radiation for fluoroscopy-guided removal as well as the time in the operation room for standard cystoscopic removal were also recorded.

Results:

The mean age of patients with magnetic stent / fluoroscopy, magnetic stent / no fluoroscopy, and standard stent was 4.6 (± 3.6), 6.2 (± 1.0), and 5.0 (± 4.6) years, respectively **(Table 1)**.

The mean duration of stent indwelling in patients with magnetic stent / fluoroscopy, magnetic stent / no fluoroscopy, and standard stent was 44.1 (± 8.6), 24.9 (± 2.0) and 48.8 (± 17.6) days, respectively. While none of the patients with fluoroscopy-guided retrieval required a second pass with the retrieval device to 'catch' the magnetic stent, 38 % of patients with magnetic removal without fluoroscopy did. However, retrieval was still successfully completed in all but one case, in whom cystoscopic removal under GA was necessary **(Table 1)**. Fluoroscopy is not required for retrieval and, if used, the mean radiation exposure was only 0.93 mGy (less than 1 abdominal x-ray).

Complication rates in patients with magnetic stents (1 urinary tract infection) were not statistically different from the control group. For the control group, the mean operation room (OR) time for cystoscopic removal under GA was 29.2 (± 8.4) min, adding up to a total of 20 hours in the 12-month index period. Less OR time (30 min per case saved) corresponds in a cohort of 40 patients to 2.5 days or 14 to 17 cases who could be treated with a magnetic stent instead.

Conclusion:

Magnetic stents represent a safe and equally effective alternative to standard stents, especially in pediatric patients. If, in the worst case, the removal of the magnetic stent with the retrieval device fails, conventional cystoscopic removal can still be performed.

Table 1

Stent and removal procedure	Patients (N)	Patient age (years; mean ± SD)	Duration of stent indwelling (days; mean ± SD)	Successful retrieval (%)
Magnetic stent, fluoroscopy-guided removal	24	4.6 ± 3.6	44.1 ± 8.6	100
Magnetic stent, removal without fluoroscopy	16	6.2 ± 1.0	24.9 ± 2.0	94*
Standard stent, cystoscopic removal (control)	40	5.0 ± 4.6	48.8 ± 17.6	100

Patient demographics, duration of stent indwelling, and retrieval rates for pediatric patients who underwent magnetic or standard stent use. SD, standard deviation.

** 1 patient with cystoscopic removal*

Feasibility and Safety of Magnetic-End Double-J Ureteral Stent Insertion and Removal in Children

Chalhoub M, Kohaut J, Vinit N, Botto N, Aigrain Y, Héloury Y, Lottmann H, Blanc T. World J Urol. 2021; 39: 1649-1655.

Background & Aim:

One of the drawbacks of a standard Double-J ureteral stent (DJUS) is the need for surgical removal. Apart from the increased cost, repeated exposure to general anesthesia (GA) is a concern in children. Alternative techniques have been described, none of which could be incorporated into routine practice. Stents with a distal magnetic end have only recently gained acceptance. The study evaluated the feasibility and safety of insertion and removal of the magnetic-end DJUS Magnetic Black-Star® (MBS; Urotech) in a pediatric population.

Design & Methods:

The retrospective analysis included 100 children who received the MBS surgically under GA in an antegrade procedure (n = 47), by a retrograde route (n = 10), and during open surgery (n = 43), followed by routine abdominal plain X-ray after pyeloplasty. The surgeons had no prior experience with the MBS. In case of insertion failure, a standard DJUS was placed. Magnetic removal took place in the outpatient clinic by means of a magnetic removal device, whereas non-magnetic removal was performed cystoscopically under GA. In the last 55 patients, age-adapted pediatric pain scales were used and the duration of stent removal documented.

Results:

Stent insertion was successful in 84 of the 100 patients, including all open surgery cases, all retrograde cystoscopy insertion attempts and 31 of the 47 cases with an antegrade approach **(Figure 1A)**. Antegrade insertion failed in 16 cases, 11 of which occurred in the early study period when there was still little experience with the MBS. In 83 of the 84 cases (one kidney transplant failed and required kidney removal within 24 hours) with successfully placed MBS, magnetic removal was attempted and completed without complications in 81 patients **(Figure 1B)** after a mean of 35 days.

In two kidney transplant cases, non-surgical removal failed because the magnetic end was inside a bladder diverticulum, preventing the connection with the magnetic removal device.

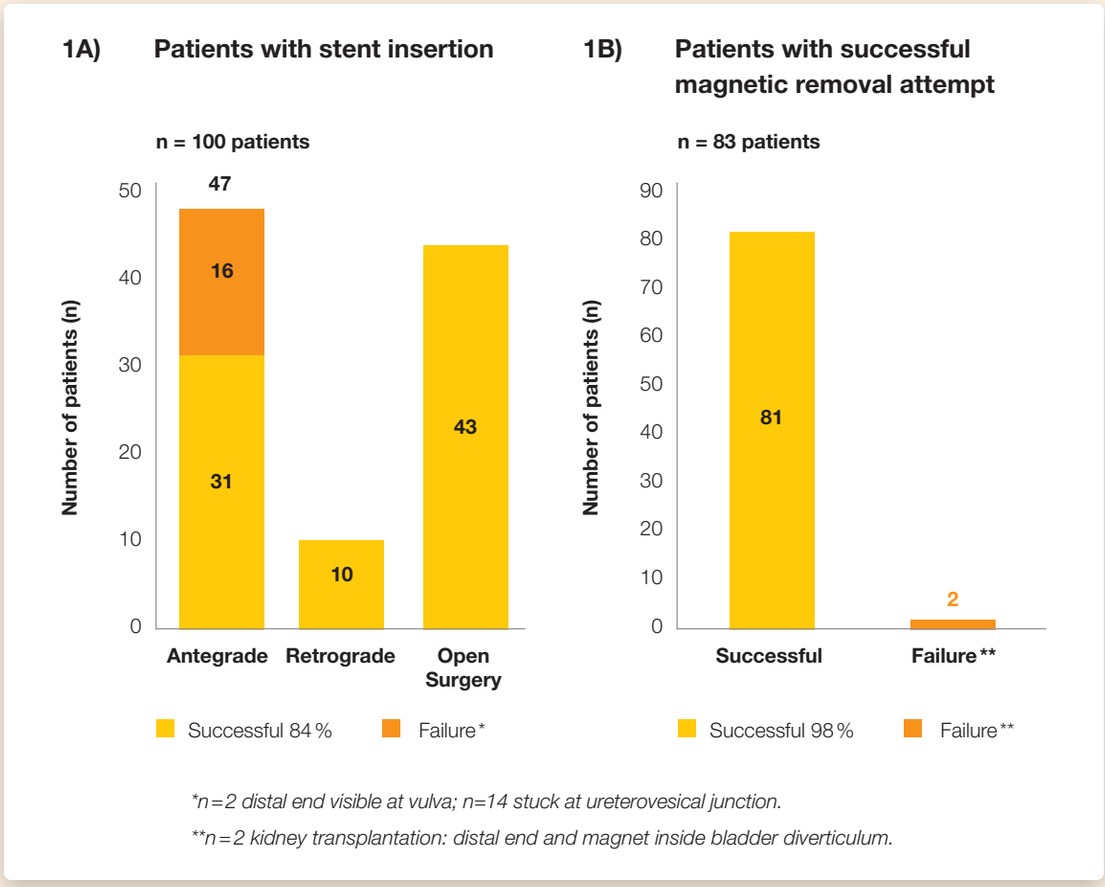
The mean pain score was 3/10 (range 0-7); 40 % did not report any pain during removal. The mean duration of stent removal was 4 min (range 1-25), with two-thirds of the procedures lasting ≤ 2 min.

In one child, the MBS had to be removed after 5 days because of major urinary symptoms and pain. Five children (four girls and one boys) were treated for febrile urinary tract infection with oral antibiotics.

Conclusion:

The use of the MBS is a safe and effective strategy that obviates the need for additional GA in children. Insertion is similar to that of standard DJUS, but there is a learning curve with pyeloplasty, especially for antegrade insertion. The easy and less time-consuming removal of the MBS benefits both the patient and the hospital and validates its clinical use.

Figure 1



**n = 2 distal end visible at vulva; n=14 stuck at ureterovesical junction.*

***n = 2 kidney transplantation: distal end and magnet inside bladder diverticulum.*

Patients with stent insertion (A) and patients with successfully inserted stent and magnetic removal attempt (B).

Magnetic Stent Removal in a Nurse-Led Clinic; a Nine Month Experience

O'Connell L, Broe M, Rooney D, Elhag S, Cheema I, McGuire B. James Connolly Memorial Hospital Blanchardstown, Dublin; 2018.

Background & Aim:

Ureteric stents are frequently inserted after endourological procedures. However, subsequent endoscopic stent removal requires a second procedure, mostly flexible cystoscopy. The use of magnetic stents that are removed with a magnetic retrieval device (Magnetic Black-Star®; Urotech) offers an alternative which obviates the need for cystoscopy. The study assessed treatment outcomes, patient experiences, and cost savings for this novel method in a nurse-led clinic.

Design & Methods:

A retrospective analysis of all patients undergoing magnetic stent insertion and subsequent removal over a nine-month period was performed. Patients were followed up with a prospective validated Ureteral Stent Symptoms Questionnaire (USSQ) and a satisfaction form. A cost analysis was done by the finance department.

Results:

In total, 59 patients received magnetic stents following ureteroscopy performed for ureteral or kidney stones. The median duration of indwelling was 5.8 days (range 1-11). The overall complication rate was low (6.7 %), including urosepsis, urinary tract infection, acute urinary retention and a ureteral stent aborted in one patient via the urethra. Based on the USSQ, < 10 % experienced significant functional impairments due to the ureteral stent. Only 30 % of patients felt affected by significant urinary tract symptoms, and only 25 % reported significant pain that restricted them in their everyday activities **(Figure 1A)**. In addition, stent symptoms resulted only in minimal days of employment lost (mean 0.75 days).

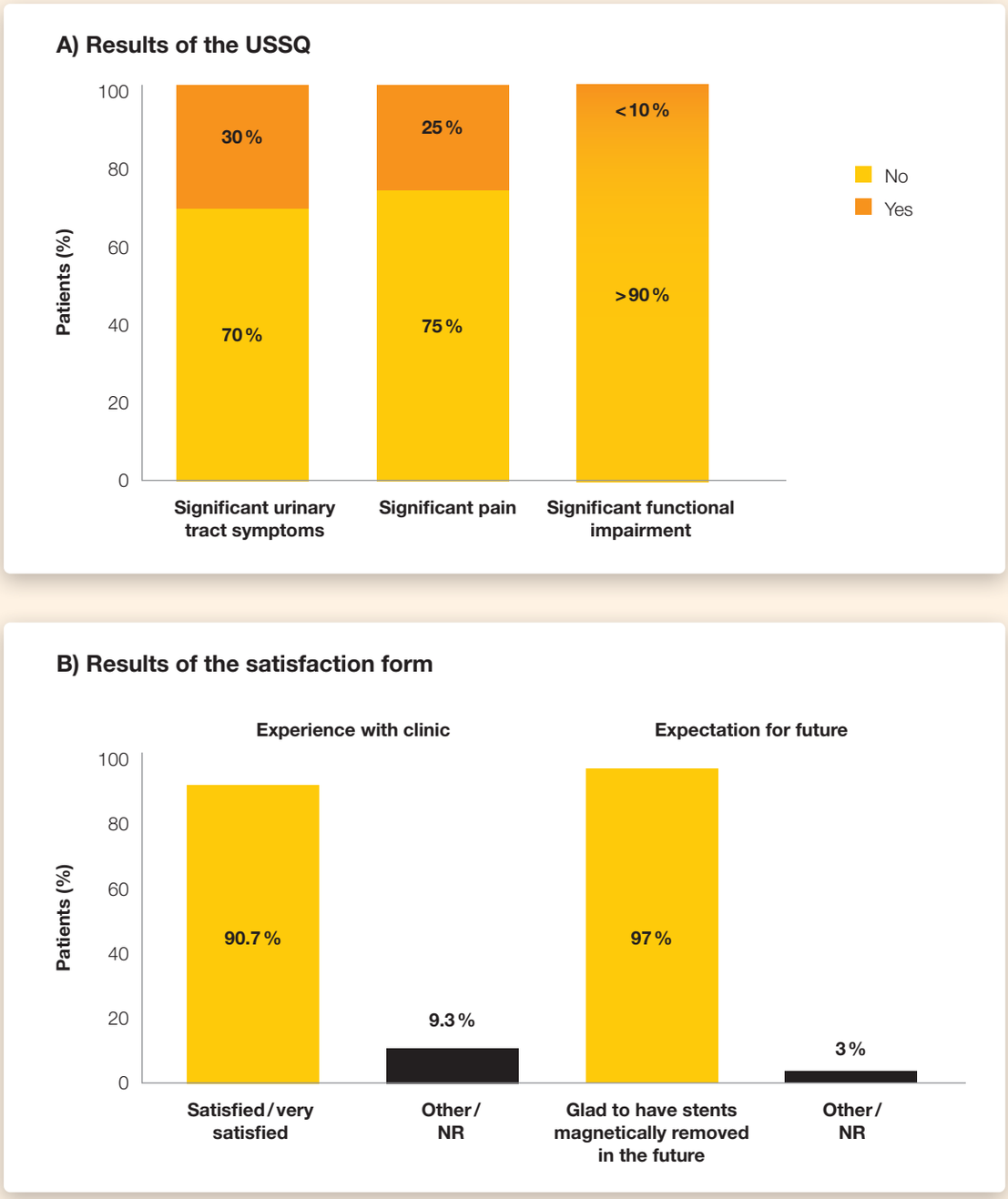
All removals performed by the nurses were successful. In addition, 90.7 % of the patients reported to be satisfied / very satisfied with their experience in the clinic, and 97 % were glad to have their stents removed by this method in the future **(Figure 1B)**.

The mean cost savings per procedure were €200 - 810. This resulted in cost savings totaling €47,790 within nine months.

Conclusion:

Nurse-led removal of magnetic stents is safe and well tolerated by patients, and enables expedient stent removal. It also provides a significant cost benefit and frees up valuable endoscopic resources.

Figure 1



Results of the USSQ (A) and the satisfaction form (B). Response rate for the USSQ was 74.6 %. NR, not rated; USSQ, Ureteral Stent Symptoms Questionnaire.

Magnetic Ureteral Stent Removal Without Cystoscopy: A Randomized Controlled Trial

Rassweiler MC, Michel MS, Ritter M, Honeck P. J Endourol. 2017;31: 762-766.

Background & Aim:

Ureteral stenting is a standard procedure in urology when drainage of the upper urinary tract is needed. Cystoscopic removal of Double-J stents (DJ) causes unpleasant side effects and negatively impacts the patient's quality of life (QoL). The study evaluated a new magnetic DJ and compared it with a standard cystoscopic DJ in terms of QoL during indwelling and discomfort during removal.

Design & Methods:

The magnetic DJ (Black-Star®, Urotech) is a standard polyurethane ureteral stent with a small magnetic cube fixed through a string on the loop of the distal part of the stent. For removal, a catheter-like retrieval instrument with a magnetic tip is inserted, the two magnets connect, and the DJ can be removed with the retrieval instrument. The magnetic DJ was initially tested in 20 cases (part I) and then evaluated in 40 prospectively randomized consecutive cases who required DJ placement after ureterorenoscopy (part II; n = 20 magnetic DJ, n = 20 standard DJ). QoL was assessed by the ureteral stent symptom questionnaire (USSQ), consisting of six sections with a total of 48 questions about voiding symptoms, pain, general health, job performance, sexual health, and additional problems. A visual analogue scale (VAS) documented pain during DJ removal 7 to 14 days after insertion.

Results:

In part I, 13 of 16 patients with returned USSQ and VAS did not complain of pain associated with the magnetic DJ, while 7 of 16 reported urgency to urinate. The mean pain VAS score during DJ removal was 2 (range 0-8). In part II, patients with magnetic DJs had less pain during indwelling (mean USSQ score 3, range 0-9) compared to patients with standard DJs (mean USSQ score 5, range 0-8; p = 0.156) and significantly less pain during removal [mean VAS score 3 (range 0-6) vs. 4 (range 1-8); p = 0.019] **(Figure 1)**.

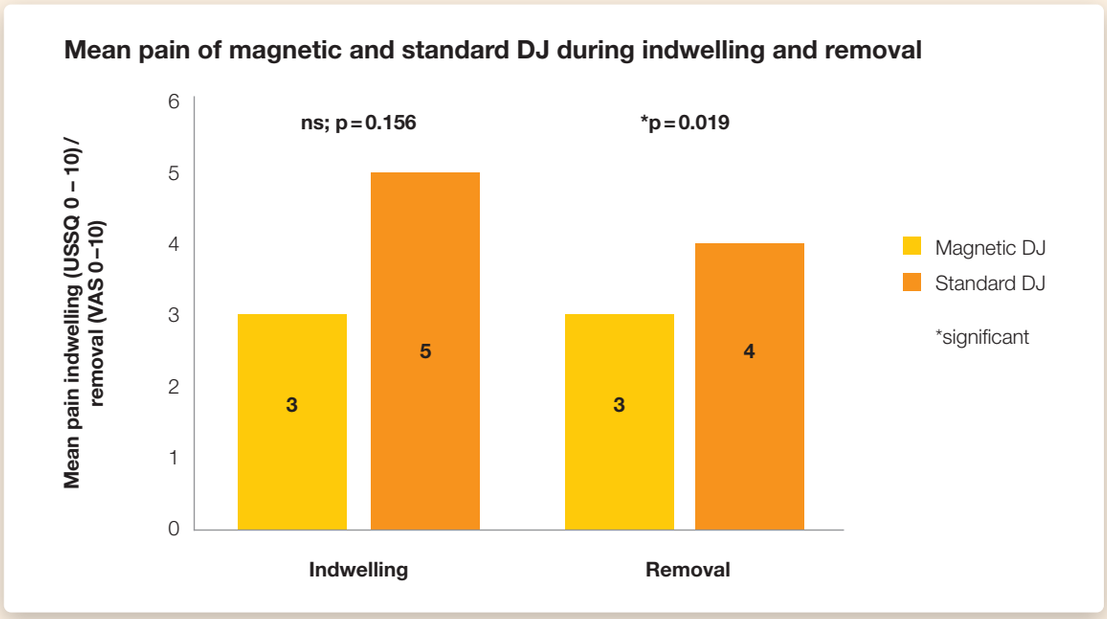
With the magnetic DJ, maximal pain was located in the lower abdomen and / or around the bladder in 48 %, whereas the standard DJ caused flank pain in 54 % of patients. The difference in pain locations was significant (p = 0.038). The mean time for DJ removal including preparation and cleaning was 9.55 min for the magnetic DJ and 21.35 min for the standard DJ **(Figure 2)**.

Cost analysis showed a cost reduction of € 101.41 when using the magnetic DJ (€ 193.75 for standard DJ vs. € 92.34 for magnetic DJ), which was due to the fact that no urologist, no operating theater, no cystoscopy and no sterilization were necessary.

Conclusion:

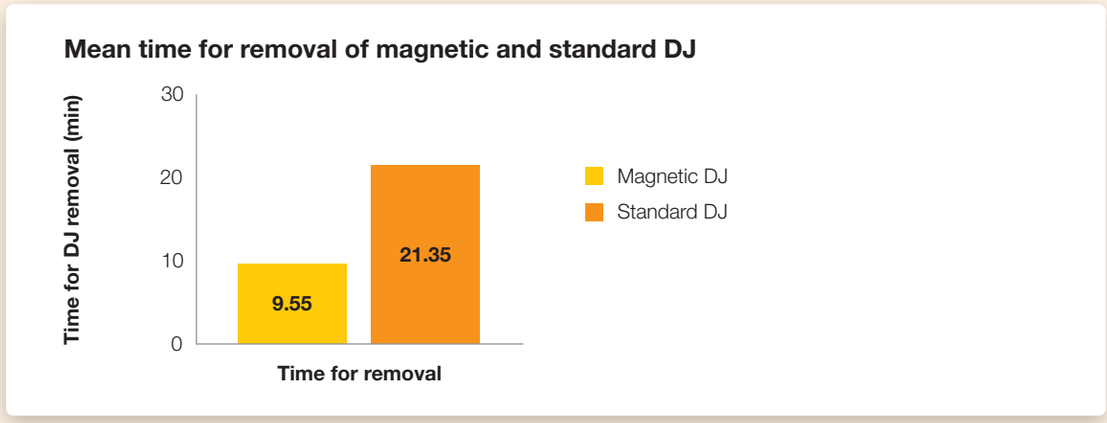
Discomfort caused by the indwelling magnetic DJ is comparable with that of the standard DJ. However, removal of the magnetic DJ is less painful and faster compared to the standard DJ and could be performed by trained urologic nurses.

Figure 1



Mean pain of magnetic and standard DJ during indwelling and removal. DJ, Double-J stent; ns, not significant; USSQ, ureteral stent symptom questionnaire; VAS, visual analogue scale. Differences for indwelling and removal: p = 0.156 (ns) and p = 0.019

Figure 2



Mean time for removal of magnetic and standard DJ in minutes. DJ, Double-J stent.

Evaluation of Pain Perception Associated with Use of the Magnetic-End Ureteric Double-J Stent for Short-Term Ureteric Stenting

Sevcenco S, Eredics K, Lusuardi L, Klingler HC. World J Urol. 2018; 36: 475-479.

Background & Aim:

Ureteral stents are used for adequate drainage of the upper urinary tract. Particularly after an endoscopic stone extraction, short-term stents are placed, which are removed on an outpatient basis using flexible cystoscopy. However, removing the stent can be associated with complications, especially in men. A significant proportion of younger male patients therefore wish for removal local, if not general, anesthesia, which increases costs and effort. The study investigates morbidity, complication rate and pain perception in connection with the use of a novel magnetic tip Double-J (DJ) stent, which was developed for atraumatic removal as part of a simple catheterization.

Design & Methods:

The study prospectively enrolled 151 consecutive male patients who underwent semirigid ureterorenoscopy (URS) for stone removal and received the magnetic tip DJ stent Magnetic Black-Star® (MBS, Urotech; n = 118) or a conventional DJ stent (control; n = 33). Stent length was based on the patient's height and ranged from 24 to 28 cm. Magnetic stents were removed under local anesthesia one week following URS. Both the MBS and its extraction catheter have a magnet attached to their tips, which allows extraction after magnetic connection. In the control group, stents remained significantly longer and were removed by flexible cystoscopy. In addition to the male group with short-term stents, the long-term effect of the MBS was investigated in 12 female patients who had undergone laparoscopic pyeloplasty (LPP) and received an MBS for 4 weeks. In all patient groups, medical history, prior urine culture result, renal ultrasonogram, and visual analog scale (VAS) scores regarding 1) stent irritation and 2) pain during removal were documented at follow-up.

Results:

Stent-related irritation during indwelling was slightly higher in patients with a magnetic stent than in those with a regular stent (mean VAS score 2.42 ± 0.79 vs. 2.15 ± 1.23; $p < 0.001$) **(Figure 1)**. However, no significant differences in stent irritations were found in the subgroup of patients who had a magnetic stent for 4 weeks after LPP ($p = 0.20$).

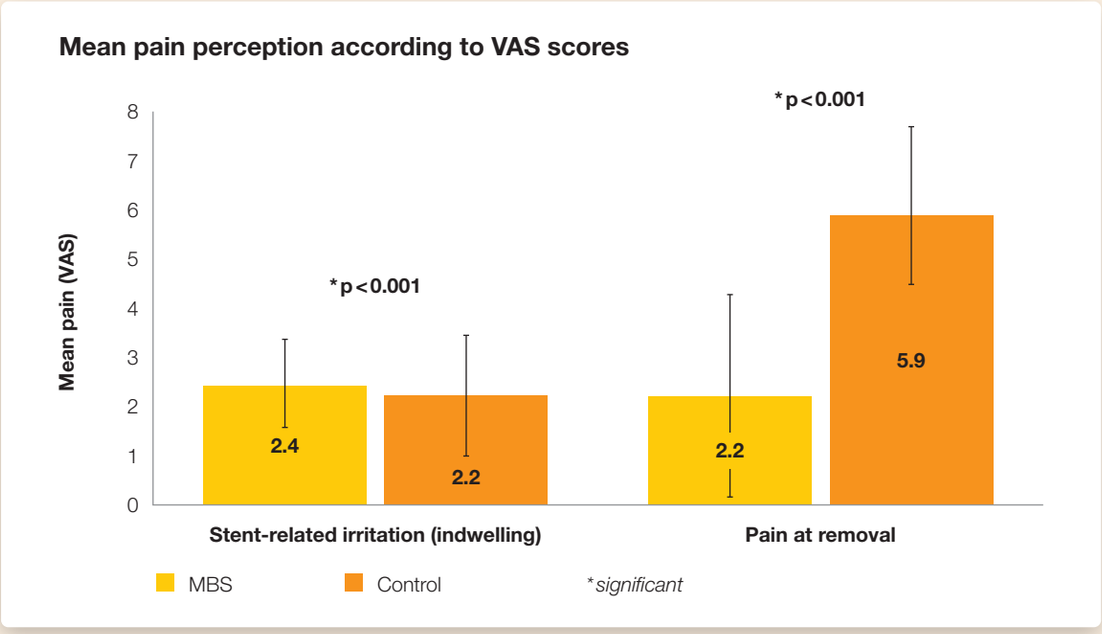
In contrast to stent-related irritation, patients with a magnetic stent experienced significantly less pain during removal than those with a regular stent (mean VAS score 2.17 ± 1.89 vs. 5.88 ± 1.45; $p < 0.001$) **(Figure 1)**.

The stent length correlated with both stent irritation ($p = 0.05$) and with pain during removal ($p < 0.001$).

Conclusion:

The magnetic-end ureteric DJ stent is a safe option associated with less pain, particularly for male patients requiring short-term ureteric stenting. Removal of the ureteral stent using a catheter is less painful than cystoscopic standard extraction and can even be performed by non-medical staff.

Figure 1



Mean pain perception during indwelling and at removal according to VAS scores. Error bars indicate standard deviations. MBS group includes URS and LPP patients. MBS, Magnetic Black-Star®; VAS, visual analogue scale.

Magnetic Double-J Stent: Evaluation of Tolerance and Impact on Quality of Life Compared to Traditional Double-J Stent

Diranzo-Garcia M, Pardo-Duarte P, Álvarez-Barrera A, Juan-Escudero JU, Beltrán-Puig M, Monzó-Cataluña A, Rechi-Sierra K, Sánchez-Ballester F, Garcia-Ibáñez J, López-Alcina E. Actas Urol Esp (Engl Ed). 2021; S0210-4806(21)00007-3.

Background & Aim:

The placement of a ureteral stent is one of the most widely performed procedures in urology. Side effects and the need of cystoscopy for removal can negatively impact the patients' quality of life. Thus, attempts have been made to develop the ideal Double-J (DJ) stent that allows removal without the need for cystoscopy, such as magnetic stents. The study compared symptoms and impact on quality of life of patients with two types of ureteral stents: a standard DJ vs. a magnetic DJ (Magnetic Black-Star®; Urotech). In addition, tolerability, difficulty of removal, and complications were assessed.

Design & Methods:

The prospective, randomized study included 46 patients undergoing ureterorenoscopy for lithiasis with DJ stent placement (standard DJ n = 23; magnetic DJ n = 23). Stents were removed within less than 4 weeks: standard stents in the urology exam room by flexible cystoscopy (urologist plus specialist nurse); magnetic stents in the outpatient department by sterile bladder catheterization with a magnetic retrieval device (urologist only). The operative time was recorded. Patients completed the Ureteral Stent Symptom Questionnaire (USSQ) for symptoms during indwelling and scored the pain at removal using a visual analogue scale (VAS). Urologists answered a VAS to assess the perceived technical difficulty during removal. Medical records were reviewed to assess visits to the emergency room or primary care center for complications related to the ureteral stent and/or its removal.

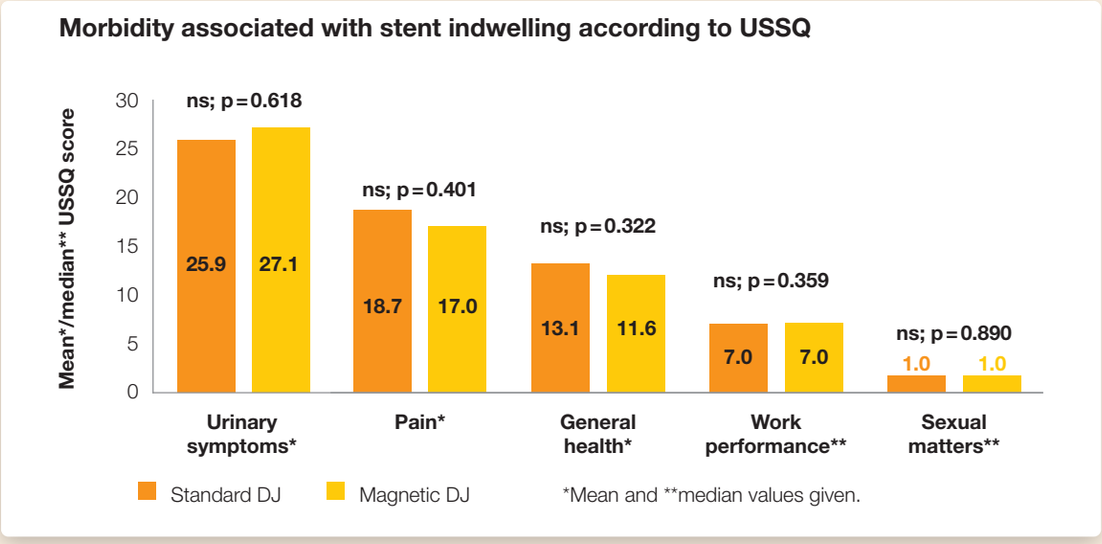
Results:

Both groups were homogeneous in terms of age, sex, and stone location. The USSQ did not show statistically significant differences between the standard and the magnetic DJ in any domain: urinary symptoms ($p = 0.618$), pain ($p = 0.401$), general health ($p = 0.322$), work performance ($p = 0.359$), and sexual matters ($p = 0.890$) **(Figure 1)**. Removal of the magnetic DJ (98 % success rate) was associated with less technical difficulties (mean VAS 1.6 vs. 3; $p < 0.001$) and less pain (mean VAS 1.5 vs. 4; $p = 0.001$) **(Figure 2)**. It was also faster than cystoscopic removal (11.7 min vs. 22.2 min; $p < 0.001$) **(Figure 3)**. Rates of stent-related complications were not significantly different. Magnetic stents saved the center about €70 per procedure.

Conclusion:

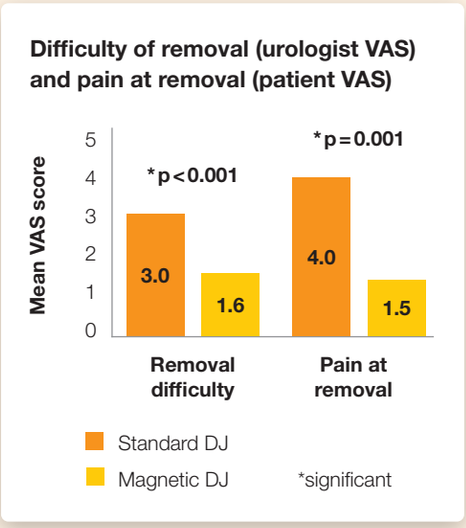
The magnetic DJ does not increase symptomatology or medical complications when compared to the standard DJ. Removal does not require the use of cystoscopy and can be performed in an outpatient setting in an easy, less painful and faster way. In addition, if magnetic removal fails, it can easily be removed endoscopically.

Figure 1



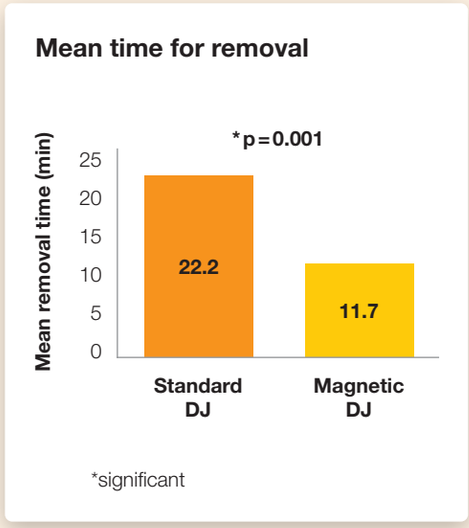
USSQ results of patients with standard and magnetic DJ. ns, not significant; USSQ, Ureteral Stent Symptoms Questionnaire.

Figure 2



Mean VAS results of urologists (difficulty of removal) and patients (pain at removal). VAS, visual analogue scale.

Figure 3



Mean time for removal of standard vs. magnetic DJs.

Statement Prof. Dr. Hans Christoph Klingler

Chief Urologist, Wiener Gesundheitsverbund Klinik Ottakring, Vienna, Austria:

“At our clinic, we are very pleased to use the Magnetic Black-Star® – in particular after an uncomplicated URS after stone therapy (standard here) or as a stent after laparoscopic pyeloplasty. What we particularly like about it is that the stent is extremely easy to remove. The effort is much less, as it can be done on **any** examination bench or in bed. It is also easy to transfer the procedure to the general practitioner ordinations. Complaints due to stent removal - the difference in favour of the Magnetic Black-Star® is striking (see also our own publication). Overall, the costs are lower due to the omission of cystoscopy.**”**

Statement Dr. Marie-Claire Rassweiler-Seyfried

Senior Urologist, University Hospital Mannheim / Germany:

“The Black-Star® offers an ideal solution as an ureteral stent for patients with a planned short indwelling time, as it can be removed quickly and easily without cystoscopy. Especially in women, but also in men without a pronounced middle lobe, the ureteral stent can be removed easily by trained nursing staff.**”**

Statement Dr. Maurizio Iaria

Division of General Surgery, Transplant Surgery Unit Parma University Hospital / Italy

“I started using the Magnetic Black-Star® ureteric stent in April 2015 and, since then, I never stopped. I could not find any drawback and my transplant patients are so glad and truly amazed once they realize it is already out literally in seconds with such negligible discomfort.**”**

Urotech GmbH

Medi-Globe-Straße 1–5
D-83101 Rohrdorf OT Achenmühle
Tel.: +49 (0) 8032 973-210
Fax: +49 (0) 8032 973-211
Email: info@urotech.com
www.urotech.com