European Review for Medical and Pharmacological Sciences 2023; 27: 1367-1373

Use of the Deniz™ rigid stone basket for treating ureteral calculi

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Abstract. – OBJECTIVE: Advancements in ureteroscope and stone basket design have introduced ureteroscopy to the forefront of surgical stone management. However, different issues, such as stone migration and ureteral injury, remain a challenge among urologists. The Deniz™ rigid stone basket is a patented product (patent number: TR 2016 00421 Y) manufactured in Turkey. Herein, we report our initial experience with the Deniz™ rigid stone basket for managing urinary calculi and compare the use of this device with other methods to optimize ureteroscopic stone management.

PATIENTS AND METHODS: Fifty patients undergoing ureteroscopic laser lithotripsy for urinary calculi were retrospectively evaluated by two surgeons. The Deniz™ rigid stone basket was utilized to prevent retrograde ureteral stone migration or to facilitate fragmentation and extraction of ureteral calculi.

RESULTS: In total, 29 men and 21 women, with a mean age of 46.5 (range: 21-69) years, were treated for upper (n = 30), medium (n = 7), and lower (n = 13) ureter calculi. The mean stone diameter was 13.08 (range: 7-22) mm; the mean operative time, 46 (range: 20-80) min; the mean energy utilization, 2.98 (range: 1.5-3.5) kJ; and the mean laser frequency, 6.96 (range: 6-12) hz. None of the patients developed complications, and 46 (92%) patients who underwent ureteroscopic laser lithotripsy using the Deniz™ rigid stone basket were declared stone-free. Four patients had residual stones measuring < 3 mm on post-operative imaging.

CONCLUSIONS: The Deniz™ rigid stone basket is safe and effective for preventing stone migration and facilitating ureteroscopic laser lithotripsy procedure and stone extraction.

Key Words:
Rigid stone basket, Ureteral calculi, Laser lithotripsy, ESWL, Renal stone.

Introduction

Urolithiasis is defined as the formation of calculi in the urinary tract. Due to changing life conditions nowadays, the incidence of urolithiasis is increasing every day. Thus, it is becoming a common pathology. The lifetime risks are 13% in men and 7% in all people worldwide. The peak incidence of urolithiasis is observed at ages 30-40 years. Approximately 75% of people present with this condition once in their lifetime, and 25% experience stone recurrence[1]. Muslumanoglu et al[2] performed an epidemiological study on 2,468 individuals aged 18-75 years. Results showed that 11.1% had a history of urinary stone disease diagnosed by a physician, and 52 (2.1%) had at least one lifetime episode of colic pain. The male-to-female ratio was 1:1[2].

Extracorporeal shock wave lithotripsy is a popular method for eradicating urinary tract stones. Meanwhile, shock wave lithotripsy (SWL) is commonly used as the first-line therapy. Some studies[2,3] have shown concerns over the long-term safety of SWL and its decreased efficacy in managing proximal and middle ureteral calculi. Further, semirigid or flexible ureterorenoscopes have become a widely used method for stones that cannot be broken with extracorporeal SWL and laser or pneumatic lithotripsy with the developing technology[3]. Advancements in ureteroscopy and stone basket design have introduced ureteroscopy to the forefront of surgical stone management. However, different issues, such as stone migration and ureteral injury, remain a challenge among urologists. Stone migration, which occurs in 5-40% of ureteroscopic procedures, continue to persist even among the most experienced urologists. The failure rates of ureteroscopic lithotripsy for proximal ureteral stones are as high as 25%[4,5]. Stone migration or other issues may contribute to increased operative time and decreased stone-free rates, which require secondary procedures and lead to increased morbidity and healthcare costs[1,6,7,8].

The use of ureteroscopy has spread rapidly worldwide because it can be easily learned and is used frequently. The complication rate varies from 9 to 25%. However, Clavien-Dindo grade

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1-2 complications were the most common. Ureteral perforation (< 1%), ureteral stricture (< 1%), and major complications, such as ureteral avulsion (< 0.1%), are still observed occasionally[9]. Ureteral stones account for 20% of all urinary system stones. With technological advancements in the design of ureteroscopic instruments, increased treatment success rates and decreased major complication rates have been observed lately[8,9]. Currently, ureteroscopy is the first choice of treatment for stones in all localizations of the ureter. Excellent outcomes were obtained with the use of flexible ureteroscopes and laser probes[8].

The Deniz™ rigid stone basket is a patented product (patent number: TR 2016 00421 Y) manufactured in Turkey. The device is designed to capture calculi and facilitate simultaneous laser or pneumatic. lithotripsy in situ. Herein, we report our initial experience with the Deniz™ rigid stone basket for managing urinary calculi[10]. These are the preliminary results that should be published on a new patented product, and no similar device of this type exists in previous literature. Therefore, a comparison study has not been conducted. The current research aimed to evaluate the efficiency, reliability, and working principle of the new device and its outcomes.

Patients and Methods

This retrospective study evaluated 50 patients who underwent ureteroscopic holmium. Yttrium-aluminum-garnet laser lithotripsy for urinary calculi was performed at two institutions by two surgeons. The study was approved by the institutional Ethics Committee (T.C Yalova University Ethics Committee, 27.07.2021, protocol number: 2021/88), and all procedures were performed in accordance with the principles of the Declaration of Helsinki. The consent form for the surgery was filled and signed by the patients. Due to the retrospective nature of the research, the need for a written informed form was waived. This study was limited to 50 patients to be the first trials of Deniz rigid basket and to determine and follow-up its long-term results.

Inclusion and Exclusion Criteria

Inclusion criteria: Stones measuring 7-25 mm.

Exclusion criteria: Stones measuring < 7 mm; stones measuring > 25 mm; stones that fully occlude the ureter and do not allow the basket to work; ureteral stricture.

Participants who had positive culture result before surgery have been treated and included in the study after negative culture result.

Ureterorenoscopy was performed with the Deniz™ rigid stone basket on patients with fifty ureteral stones by two different urology specialists between 2019 and 2021. In all procedures, a 7-Fr semi rigid uretrerenoscope (viewing angles of 6° and 5-Fr working channels) and a holmium oil laser (Ho-YAG) were used to break up the stones.

Data on demographic and operative characteristics and stone size were evaluated retrospectively. The stone clearance rates were assessed based on the surgeon's discretion via kidney, ureter, and bladder radiography or computed tomography (CT) scan. All patients underwent kidney, ureter, and bladder radiography and/or non-contrast-enhanced CT scan. After diagnosis, all patients were informed of the treatment options.

Endoscopic procedures were completed under spinal anesthesia using a 7-Fr semi rigid (5-F working channel) ureteroscope. Cystoscopy with retrograde pyelography was routinely performed, and a guidewire was passed to the level of the renal pelvis. During contrast installation, caution was taken to avoid high pressures to prevent inadvertently propelling ureteral stones into the renal pelvis. Continuous irrigation was used, as necessary, to provide adequate visibility. The Deniz™ rigid stone basket was utilized to prevent migration of proximal ureteral calculi and to stabilize stones during laser lithotripsy in the ureter.

A Ho-YAG laser was used in all cases (200-m fiber), with settings of 6-10 Hz and 0.5-3.5 kJ. After laser lithotripsy, stones were extracted with the Deniz™ rigid stone basket. Meanwhile, insignificant fragments that could not be basketed were allowed to pass spontaneously. Ureteral stents were routinely left in place and were removed in an outpatient setting. Patients with embedded stones were excluded because there was not enough passage to keep the basket inside the stone and to prevent ureteral trauma. The ureter was dilated with a balloon dilator under fluoroscopy in case of ureteral strictures. Double J stent implantation was conducted under fluoroscopy in patients without ureteral stricture, and the procedure was delayed after 3 weeks. As there was not any comparative arm in the study, statistical analysis was not performed.

Device

The overall length of the Deniz™ rigid stone basket is 60 cm, and its 10-15-cm long handle is


a


b

Figure 1. a-b, Handle of the Deniz™ rigid stone basket.

made of light alloy metal. The other end is a new type of basket made of semi rigid 3- or 4-Fr metal pipe, which is 40-45 cm long, passing through the ureteroscope working channel, with holes that allow liquid passage. Inside, there is a 1.9-Fr four-wire nitinol basket placed to hold and grasp stones (Figure 1a-b).

The handle has a side screw system that allows the basket to be locked after taking the stone into it and a side entry that allows laser or pneumatic probe tips to be sent inside. In addition, there is a hidden screw system on the head that allows the device to be separated and disassembled from the basket inside during the process in case there are issues with the metal handle part (Figures 2, 3 a-b and 4). Further, it works with a spring system, which allows the nitinol basket at the far end to be opened to the maximum or to the desired amount. Hence, the nitinol basket can be opened according to stone size.

If the basket is opened for the ureter, the metal handle allows easy movement around the stone without damaging the ureter. The smallest hand movement of the doctor performing the surgery can be transmitted to the basket wires in the proximal and distal handle, and basket manipulation can be conducted precisely without errors. After the stone is placed in the basket, the basket can be closed and locked regardless of stone size. Hence, the stone cannot escape into the upper urinary system.

The stone for the basket is broken either with 200-micron laser fiber or a 2.3-Fr pneumatic probe right in the middle of the stone. Only holmium laser was utilized in this study, and a 2.3-Fr pneumotic probe was used. Laser fiber or pneumatic probes come out of the stone exactly in the middle of the basket, not from the side. Further, it can prevent the stone from moving up during the breaking process or damaging the ureter.

Due to its metal structure, the Deniz™ rigid stone basket can be sterilized via gas sterilization or steam autoclaving and is cost effective as it can be used repeatedly. In case of laser or pneumatic power sources damage or nitinol wire breakage, only the inner nitinol wire part can be replaced.

Results

This study evaluated 50 patients (29 men, 21 women), with a mean age of 46.5 (range: 21-69) years. The number of outpatient ureteroscopic procedures with Ho-YAG laser lithotripsy using the Deniz™ rigid stone basket were 30 for upper, 7 for middle, and 13 for lower ureter calculi. All surgeries were performed by two different urologists with the same semi rigid ureteroscope and Deniz™ rigid stone basket. The mean stone diameter was 13.08 (range: 7-22) mm; the mean operative time was 46 (range: 20-80) min; the mean energy utilization 2.98 (range: 1.5-3.5) kJ; and the mean laser frequency 6.96 (range: 6-12) Hz (Table I).

The stones did not go up, and all were taken into the Deniz™ rigid stone basket and broken with the laser. Stone pieces were taken out with the basket. Thereafter, a 4.7-Fr double J stent was placed in all patients.

In this study, 46 (92%) patients were declared stone-free, and four patients with upper ureteral

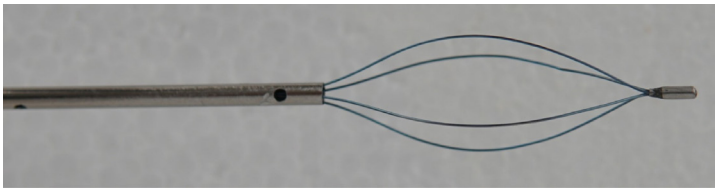

Figure 2. Nitinol end part of the Deniz™ rigid stone basket.

Table I. Demographic characteristics of patients.

Characteristics (N = 50)	Mean (min-max) or N (%)
Age (years)	46.5 (21-69)
Sex	
Male	29 (58%)
Female	21 (42%)
Location of the stone in the ureter	
Upper	30 (60%)
Middle	7 (14%)
Lower	13 (26%)
Stone diameter (mm)	13.08 (7-22)
Operative time (minute)	46 (20-80)
Energy utilization (kJ)	2.98 (1.5-3.5)
Laser frequency (Hz)	6.96 (6-12)

stones and stones with a diameter of 18-22 mm had residual stones on post-operative imaging. In one patient, stone fragments measuring < 4 mm escaped into the upper urinary system due to stone breakage. No additional treatment was provided, and the patient was followed-up.

The Deniz™ rigid stone basket was used in all cases. Due to its metal structure, it was sterilized via gas sterilization or steam autoclaving. In five cases, only the inner nitinol basket part was replaced because the nitinol wires were cut by the laser.

No major or minor intraoperative complications occurred while using the Deniz™ rigid stone basket. None of the patients required hospital readmission or ureteral stent replacement. In addition, no long-term complications, such as stricture and obstruction, were observed.

Discussion

SWL is the most minimally invasive type of treatment. However, ureterorenoscopy (URS) may be a more effective treatment in some settings[11,12]. Lam and et al[13] have reported that the initial stone-free rates were 100% for proximal ureteral

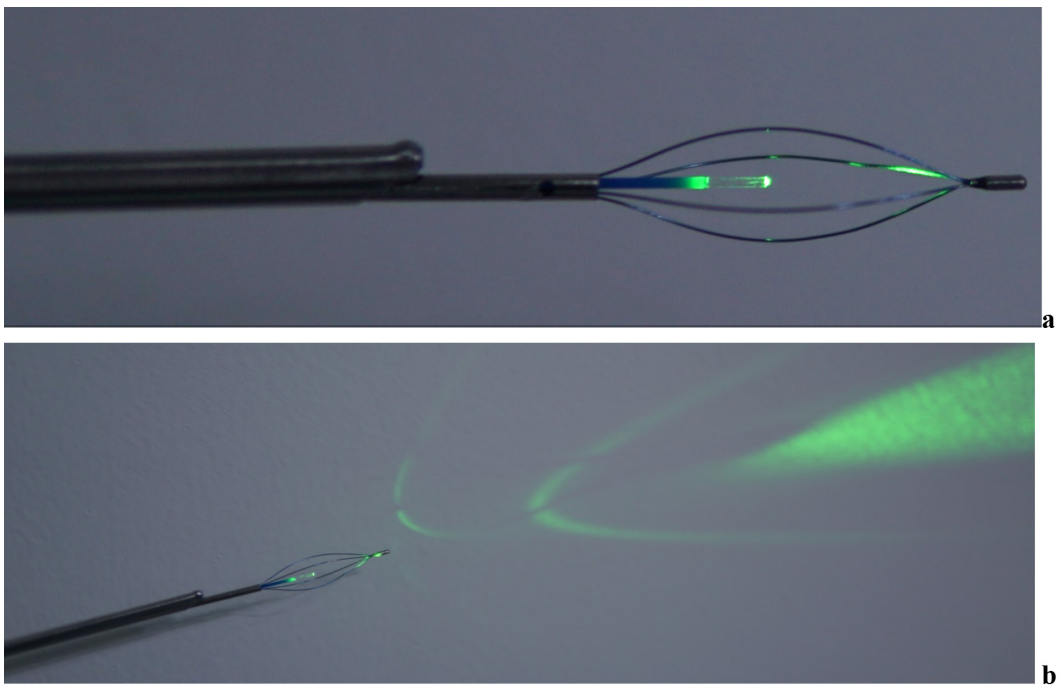

Figure 3. **a-b**, Output image of the Deniz™ rigid stone basket laser probe.

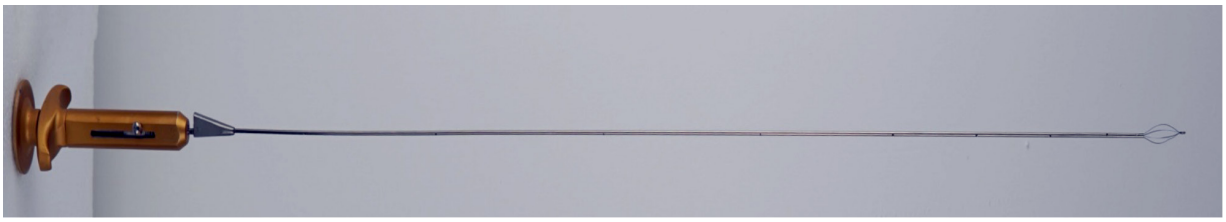

Figure 4. Deniz™ rigid stone basket.

stones measuring < 1 cm and 80% for SWL. For stones measuring > 1 cm, URS had higher success rates than SWL (93% *vs.* 50%, $p = 0.04$). Similarly, Wu et al[6] reported that the initial stone-free rates were 92.3% for URS and 61.0% for SWL ($p = 0.003$) for the management of proximal ureteral stones measuring > 1 cm, despite the larger mean stone size in the ureteroscopy cohort ($p = 0.0009$).

SWL had several limitations. Hence, positioning URS is an acceptable method and often preferred for managing ureteral calculi. Despite the high success rate of URS, inherent challenges, such as proximal migration of urinary stones, may complicate this procedure. In recent years, several innovative devices have been developed to address these issues. However, none of them did not have any inherent disadvantages[6,14].

Desai et al[10] reported the initial clinical study using the Stone Cone. Stone migration was not reported. However, more than half of participants had distal or midureteral stones, which are less likely to migrate into the kidney compared with proximal stones. The success rate (defined as no residual fragments larger than 3 mm) was 100%. However, 12% of patients had residual stones measuring < 3 mm on post procedure fluoroscopy. Six minor complications (n = 5, ureteral abrasions and n = 1, submucosal cone wire placement) were observed. No major complications were reported[5,10].

Maislos et al[15] reported that the success rate of the Stone Cone with semi rigid ureteroscopy for treating 19 patients with proximal ureteral stones was 100%. No stone migration or complications occurred. The Stone Cone was specifically used as a backstop, but not for stone removal. The Stone Cone is safe and effective for managing proximal ureteral calculi as its design allows residual fragments smaller than 3 mm to act as a nidus for future stone formation or infection. However, it plays no role in the management of ureteral calculi and often requires additional endoscopic steps to free up the working channel for laser fiber passage[5,12,20,21].

The escape nitinol retrieval basket, a new product, has been introduced. However, the number of publications about this device is extremely low. Only Stuart et al[17] conducted a study on other products used in 23 patients in 2008. Results showed that it is extremely difficult to move the distal end of the plastic manage and basket and to interfere with the stone without causing ureter damage.

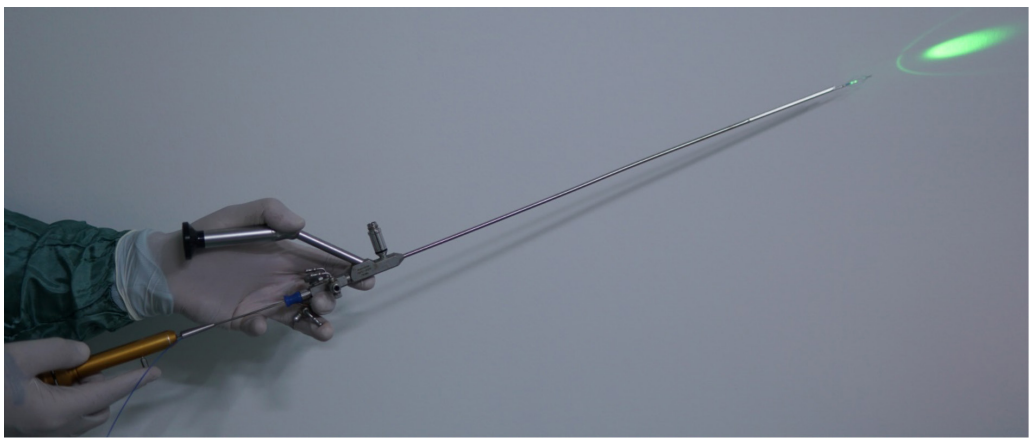

Figure 5. Use of the Deniz™ rigid stone basket and holmium laser inside the URS.

Simultaneously, it can only be used once and is expensive[7,18].

The Deniz™ Rigid Stone Basket, launched in September 2019, is among the most recent advancements in stone basket technology for assisting with URS and stone clearance. This basket offers unique benefits compared with other devices. These are the preliminary results on a novel patented product that should be published, and no similar device of this type exists in previous literature. Therefore, a comparison study has not been conducted. The current research aimed to promote the efficiency, reliability, and working principle of the new device and its outcomes.

The whole Deniz™ rigid stone basket is made of metal. It is extremely safe and easy to take the stone in the ureter into the nitinol basket wires, as the smallest movements of the surgeon proximally are completely transmitted to the nitinol wires distally. Second, the Deniz™ rigid stone basket acts as a barrier against proximal ureteral stone migration by engaging the stone within the basket wires. Unlike other designs, it allows pinpoint laser or pneumatic lithotripsy during complete basket stabilization of ureteral calculi. Stone rotation within the basket is easily performed to facilitate efficient stone fragmentation. The distinct basket design enables the basket to expand as much as the surgeon needs in the ureter, based on stone size and without damaging the ureteral mucosal walls. The inability to disengage large calculi that may be affected within the ureter is one of the paramount concerns with stone basketing. The hyperextension capability of the Deniz™ rigid stone basket can prevent disengagement challenges. The Deniz™ rigid stone basket comprises a metal structure, and it can be used repeatedly with proper sterilization and is economical. In addition, in some cases, the nitinol wires are damaged or broken, replacing the inner part alone is sufficient.

The current research confirmed that the use of the Deniz™ rigid stone basket for large urinary calculi (mean size: 13.08 mm) in high-risk situations, such as migration and residual calculi, resulted in reasonable stone clearance rates. The operative times were within the expected range for URS of large stones[5,6,12,13]. The strength of the study is that it showed that the stones were removed via URS without damaging the ureter and the stones could not escape to the upper urinary system. Nevertheless, future studies with a higher number of patients should be conducted to confirm our results.

Conclusions

The Deniz™ rigid stone basket is an effective and safe device that can be used to assist ureteroscopic lithotripsy in managing ureteral calculi. This tool may prevent ureteral stone migration, stabilize ureteral calculi during laser lithotripsy, and relocate stones to more optimal locations for effective fragmentation and retrieval. However, future studies with a higher number of patients should be conducted to further evaluate the use of the Deniz™ rigid stone basket.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Funding

There is no specific funding related to this research.

Ethics Approval

The study was approved by the institutional Ethics Committee (T.C Yalova University Ethics Committee, 27.07.2021, protocol number: 2021/88), and all procedures were performed in accordance with the principles of the Declaration of Helsinki.

Informed Consent

The consent form for the surgery was filled and signed by the patients. Due to the retrospective nature of the research, the need for a written informed form was waived.

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