Original Article

In vitro head-to-head comparison of the durability, versatility and efficacy of the NGage and novel Dakota stone retrieval baskets

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Contributions: (I) Conception and design: JE Abbott, RL Sur; (II) Administrative support: None; (III) Provision of study materials or patients: None; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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Background: To compare head to head two end-engaging nitinol stone retrieval devices available to urologists, in terms of durability, versatility and efficacy.

Methods: For durability testing, 30 NGage and Dakota baskets were cycled 20 times between grasping and releasing synthetic stone models and evaluated for damage or device failure. For versatility and efficacy testing, baskets were assessed in their ability to capture and release stone models from 1 to 11 mm. Each stone was raised above the capture site and the basket was opened to passively release the stone. If the stone did not release, the basket handle was shaken and the OpenSure feature employed if needed. Manual release was used as a last resort.

Results: Durability—the Cook NGage demonstrated a statistically significant increased rate of visible device breakdown (P=0.0046) in 8 of 30 (26.7%) devices *vs.* 0 of 30 Dakota devices, with mean damage at 13.5 cycles. Versatility and efficacy—both 8 mm baskets successfully captured stones from 1–8 mm. The Dakota more effectively released 7–8 mm stones (P<0.0001). NGage required manual release of 8 mm stones in 13 cases compared to none with Dakota. For 11 mm baskets, the Dakota released all stones up to 10 mm with simple opening, while the NGage released 10 of 15 (67%) of 9 mm stones and 1 of 15 (7%) of 10 mm stones by simple opening. For 11 mm stones, the Dakota captured 100% whereas NGage could not capture any.

Conclusions: Both baskets showed similar durability characteristics. The Dakota basket more effectively captured and released stones over 7 mm, as compared to the NGage basket. The OpenSure aspect conferred an advantage in handling and release of larger stones. These *in vitro* results demonstrate potential versatility, durability and efficacy of the Dakota basket.

Keywords: Kidney stone; stone basket; tipless; nitinol; durability

Submitted Sep 22, 2017. Accepted for publication Nov 23, 2017.
doi: 10.21037/tau.2017.11.30
View this article at: http://dx.doi.org/10.21037/tau.2017.11.30

Introduction

Technological advances in ureteroscopy have led to smaller scopes with increased deflection and hence easier ability to access the lower pole and difficult renal calyceal anatomy. Many different stone baskets are commercially available that differ in size, wire material, stiffness, opening dynamics, and ability to capture or disengage a stone (1-3). Traditionally, stainless steel tipped baskets were used for removing ureteral stones due to their increased radial strength and rigidity. The introduction of tipless devices using the hydrophilic material nitinol has increased the efficacy and safety profile of baskets when manipulating and extracting stones. These baskets can be opened adjacent to tissue surfaces such as renal calyces, enabling better targeting of

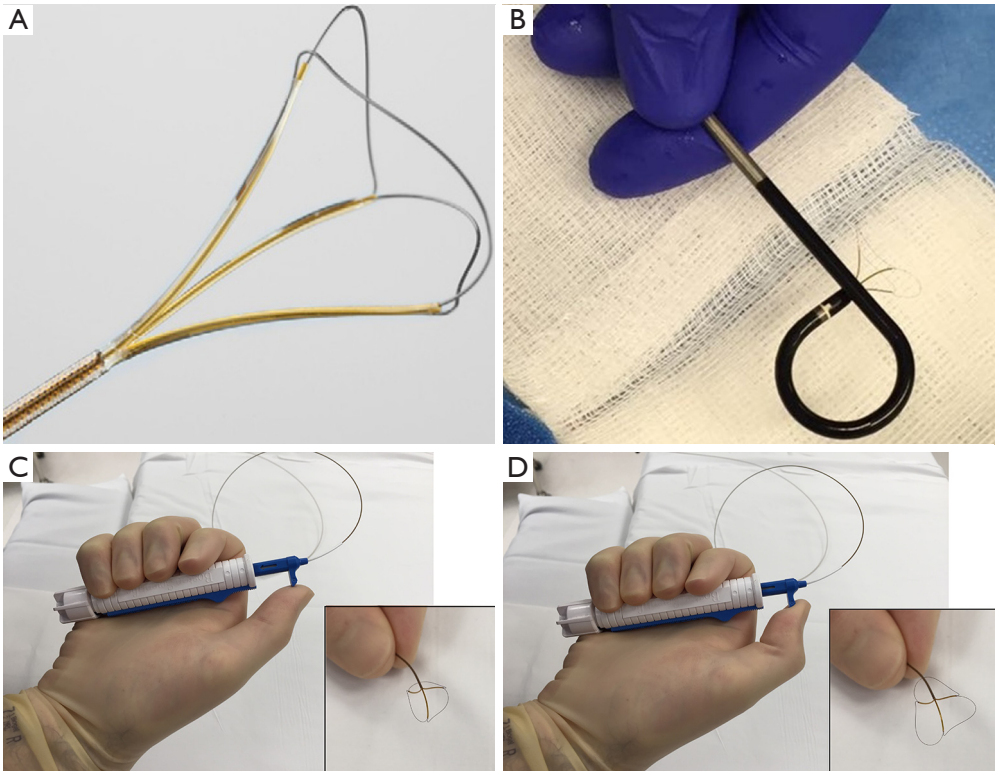

Figure 1 The two commercially available end-engaging Nitinol stone retrieval devices, NGage™ (Cook Urological Inc., Bloomington, IN, USA) and Dakota™ (Boston Scientific, Natick, MA, USA), hold stones like a basket but engage and release like a grasper. (A) Closeup of the NGage in open position; (B) opening of the Dakota at full deflection of the ureteroscope; (C,D) Dakota with OpenSure™ handle in normal open basket position (C) and with handle engaged in full open position (D).

stones in small spaces. The tipless design reduces trauma to the ureter and renal papilla when negotiating difficult anatomy or impacted stones (4). Finally, smaller diameter nitinol baskets are less rigid than other basket materials and allow for greater scope deflection and better irrigation flow during flexible ureteroscopy (5,6).

End-engaging baskets add an additional element of performance and control to stone removal procedures. These devices hold stones like a typical basket but engage and release stones like a grasper in a head-on fashion, thereby enabling a more precise grasping of stones and an easier release of large stones as well as the ability to disengage a stone within the ureter or kidney when necessary, such as when relocating a large stone from the lower pole to a more accessible mid-pole location (7,8). Thus, the dual design better allows capturing, repositioning, extracting and releasing stones.

Despite the large number of different baskets commercially available, there are currently only two end-engaging Nitinol stone retrieval devices available, the NGage™ nitinol stone extractor (Cook Urological Inc., Bloomington, IN, USA) and the Dakota™ nitinol stone retrieval device with OpenSure™ Handle (Boston Scientific, Natick, MA, USA). We sought to compare bench top characteristics of these two baskets with regards to durability as well as versatility and efficacy.

Methods

Devices

The NGage basket is available in either 1.7 or 2.2 Fr and with either 8 or 11 mm opening diameters (*Figure 1A*). It is flexible and kink resistant and is reported to have a 50% greater retention strength than traditional graspers. It also has an improved ability to release simulated stone fragments as compared to standard nitinol baskets (9,10).

The Dakota basket is 1.9 Fr and with either 8 or 11 mm opening diameters. It is flexible and reportedly opens and

Figure 2 Durability, versatility and efficacy testing. (A) The basket was passed through a simulated endoscopic working channel and cycled in grasping and releasing synthetic stones; (B) red arrows depict areas of visible basket breakdown in baskets inspected after repetitive use; (C) stone model showing 1 and 9 mm synthetic model stones.

closes at full deflection of an ureteroscope (*Figure 1B*). This basket is designed to grasp stones as small as 1 mm. The OpenSure™ Handle confers a safety mechanism for entrapped stones that cannot be released by traditional opening of the basket—specifically, it enlarges by 50% and 39% in diameter for 8 or 11 mm baskets, respectively (*Figure 1C,D*). This enlargement potentially allows the release of entrapped stones.

Durability testing

For durability testing, NGage 1.7 Fr, 11 mm diameter (n=30) and Dakota 1.9 Fr, 11 mm diameter (n=30) baskets were evaluated. Durability of each of the baskets was assessed by passing the basket through a simulated endoscopic 3.6 Fr working channel and cycling repetitively 20 times in grasping and releasing an 8 mm diameter synthetic stone model (0.6788 g) (*Figure 2A*). Of note, the Dakota OpenSure™ feature was not implemented in the cycles. Each basket was then tested on its ability to grasp a 1 mm synthetic stone model. Durability failure was defined as the inability to grasp a 1 mm synthetic stone model (0.3439 g).

A secondary outcome included visual inspection: each device was physically examined by eye for damage and warping after each cycle. Damage was defined as any grossly visible breakdown in the integrity of the basket working elements (*Figure 2B*).

Versatility and efficacy testing

For versatility and efficacy testing, we studied the ability of the baskets to capture and release stones. NGage 1.7 Fr, 8 mm (n=15) and 11 mm (n=15) diameter and Dakota 1.9 Fr, 8 mm (n=15) and 11 mm (n=15) diameter baskets were evaluated. Each basket was tested in its ability to capture and release simulated stone models of progressive diameter starting at 1 mm and increasing incrementally by 1 mm up to 8 or 11 mm (*Figure 2C*) depending on basket size—i.e., the 8 and 11 mm baskets were tested up to 8 or 11 mm, respectively. Each basket was passed through the simulated endoscopic 3.6 Fr working channel and opened to capture the stone against gravity (*Figure 2A*). Each stone was raised 3 inches above the capture site and the basket was opened to passively release the stone with gravity assistance. Inability to capture was defined as a basket's failing to grasp the stone 3 inches above the capture site. If the stone failed to disengage, the basket handle was gently shaken in attempt to disengage the stone. If these two maneuvers were unsuccessful in releasing from the Dakota, the OpenSure™ feature was then employed to passively release the stone with gravity assistance. NGage basket does not have this feature and therefore this maneuver could not be performed for NGage. If the above techniques failed to release the stone, manual release was performed by physical grasping of the stone with fingers to remove it from the basket.

Statistics

Inferential statistics were performed using the chi-square test for categorical variables with type I error $\alpha = 0.05$. All analyses were performed using SAS version 14.1 (SAS Institute, Cary, NC, USA).

Results

Durability testing

No durability failures (primary outcome), defined as inability to grasp a 1 mm stone model, were observed with the two basket types after 20 repetitive cycles. Visible breakdown (secondary outcome) was observed

Table 1 Efficacy testing: ability of 8 mm baskets to capture and release various stones

8 mm devices (N=15)	7 mm stone		8 mm stone		9 mm stone	
	Dakota	NGage	Dakota	NGage	Dakota	NGage
Capture & elevate stone	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	20% (3/15)	Would not capture
Released stone by gravity	100% (15/15)	13% (2/15)	7% (1/15)	0% (0/15)	0% (0/3)	NA
Retained stone; released by shaking device	NR	100% (13/13)	86% (12/14)	13% (2/15)	33% (1/3)	NA
Retained stone; released using OpenSure™	NR	NA	NR	NA	NR	NA
Retained stone; manually removed	NR	NR	NR	87% (13/15)	67% (2/3)	NA

NA, not applicable; NR, not required.

in 8 of 30 NGage devices [mean 13.5 cycles (range, 7–18 cycles)] (*Figure 2B*) compared to no visible breakdowns in all 30 Dakota devices (P=0.0046). NGage specifically demonstrated splitting of the end effector tube and kinking at the strain relief site.

Versatility and efficacy testing

Both 8 mm basket types successfully captured each stone model size up to 8 mm. The Dakota was able to release 7–8 mm stones more effectively compared to the NGage (P<0.0001): for 7 mm stones, the Dakota released all stones after simple opening of the basket, whereas 13 of 15 stones (87%) required shaking to release them from the NGage. For 8 mm stones, 13 of 15 stones (87%) were released from Dakota after simple opening or shaking, whereas 2 of 15 stones (13%) were released after shaking from the NGage. For stones that were not disengaged with either passive release or shaking (n=2), the OpenSure mechanism of Dakota permitted stone release in all instances with no need for manual removal of the stone. NGage required manual release in 13 cases compared to none with Dakota (*Table 1*).

Both 11 mm basket types successfully captured each stone model size up to 10 mm. The Dakota released 9–10mm stones more effectively than the NGage (P<0.0001): for 9 mm stones, the Dakota released all stones after simple opening of the basket, whereas 5 of 15 stones (33%) required shaking to release them from the NGage (P=0.0143). For 10 mm stones, all stones were released after simple opening of the Dakota, whereas 14 of 15 stones (93%) required shaking to release them from the NGage (P<0.0001). Only the Dakota released all stones after simple opening of the basket. In addition, the 11 mm Dakota basket was significantly more effective in capturing 11 mm stones (100% *vs.* 0%) (P<0.0001), but the OpenSure mechanism was required for release of each 11 mm captured stone (*Table 2*).

Discussion

As the incidence of kidney stone disease continues to rise with almost 10% of the United States population being affected (11), the adoption of ureteroscopy for surgical management also has increased. Advances in technology have led to the development of smaller, increased fidelity flexible scopes as well as an armament of endourological tools for fracturing and extracting the stones. Manipulation and/or retrieval of the stone are arguably one of the most important steps and can directly influence procedure time, effectiveness and safety of the operation. For these reasons, innovations in basket design are ongoing.

Many different stone baskets are commercially available, all of which offer advantages in stone retrieval in certain settings. The introduction of tipless devices using the hydrophilic material nitinol has increased the efficacy and safety profile of baskets. These baskets can be opened adjacent to delicate tissue surfaces such as renal calyces. Furthermore, smaller diameter baskets that are more flexible enable better scope deflection and irrigation flow during flexible ureteroscopy (5,6).

End-engaging or open tip baskets offer several advantages over traditional baskets. Their open end allows for targeted head-on capture of a stone. This is advantageous when a

Table 2 Efficacy testing: ability of 11 mm baskets to capture and release various stones

11 mm devices (N=15)	9 mm stone		10 mm stone		11 mm stone	
	Dakota	NGage	Dakota	NGage	Dakota	NGage
Capture & elevate stone	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	Would not capture
Released stone by gravity	100% (15/15)	67% (10/15)	100% (15/15)	7% (1/15)	0% (0/15)	NA
Retained stone; released by shaking device	NR	100% (5/5)	NR	100% (14/14)	100% (15/15)	NA
Retained stone; released using OpenSure™	NR	NA	NR	NA	NR	NA
Retained stone; manually removed	NR	NR	NR	NR	NR	NA

NA, not applicable; NR, not required.

stone is attached to a papilla or impacted against urothelial tissue. For stones trapped in small calyces or tortuous anatomical locations, the end on grasping ability may be more direct and in line with the scope visualization then trying to manipulate a tipless basket adjacent to the stone in order to capture it from the side of the basket (12). When opening, the tipless basket may be pushed out of the small calyx or off the wall, effectively moving further away from the stone. In contrast, the end-engaging basket tip remains in position during opening. Stones may be grasped and directly removed or transposed to another more accessible region of the kidney. Finally, if the stone is too large to be extracted through a narrow infundibulum, tight ureter, or ureteral access sheath, the open tip potentially permits easier release than a tipless basket.

Our objective was to perform a head to head comparison of the two end-engaging baskets commercially available. In this *in vitro* bench study, we focused on functional parameters that are of importance to performing efficient and efficacious stone surgery: basket durability as well as capture and release performance. There were no differences in durability (defined by ability to capture a 1 mm synthetic stone) after cycling the baskets 20 times. However, we did notice a finding of unknown clinical significance: specifically, 26% of NGage baskets broke down on visible inspection, whereas we did not see this phenomenon with the Dakota baskets. This integrity issue may or may not have clinical significance, though situations exist where it may affect surgical outcomes. For example, treatment of large stones results in increased fragments, and basket failure translates into either lower stone free rates or additional costs due to extra basket use.

Both baskets demonstrated equal ability to capture stones of various sizes as small as 1 mm, but the Dakota was more versatile and efficacious in releasing stones. The 8 mm Dakota baskets were able to easily release all 7 mm stones with simple opening of the basket whereas the NGage required shaking to release the stones. The Dakota released 87% of 8 mm stones with shaking or simple opening, whereas the NGage required manual removal of the stones from the basket 87% of the time. The OpenSure mechanism permitted easy stone release for the remainder of stones for Dakota, eliminating the need for manual manipulation of the basket. This aspect of Dakota may confer a safety margin in cases where the stone is entrapped in the basket. Although entrapped baskets can be treated by disassembling or cutting the basket, a basket that can obviate this step appears to be a favorable device iteration.

The Dakota showed better versatility in the larger 11 mm basket size as well. All stones up to 10 mm were easily removed by simple opening of the Dakota basket, while the 11 mm NGage required additional maneuvers to release the 9–10 mm stones in over 63% of cases. The Dakota was able to capture and release 11 mm stones using the OpenSure mechanism, where NGage was not able to capture them at all. This capture and release aspect may be particularly important during translocation of renal stones from the lower pole calyx to another calyx. Furthermore, when attempting to extract a stone that is too large to fit in the ureteral sheath or pass through a narrowed ureteral segment, the ability to release a stone may reduce the risk of injury to the ureter and time spent manipulating the stone.

In today's financially contracting health care environment, there is a shift towards more cost effective surgeries with improved outcomes and safety profiles. The goal of stone surgery is to render patients stone free

efficiently with maximum cost containment. Urologists traditionally may consider different baskets for different scenarios based on stone size and location, leading to increased costs to maintain a supply of several baskets. Identifying baskets that permit urologists to improve these outcomes will become increasingly important. It will be interesting and important to determine if the Dakota bears out in clinical performance some of the bench top characteristics we uncovered in this study. Given that this study is only a bench-top trial it is possible that clinical findings may or may not match these *in vitro* findings. However, the ability to enlarge the basket (OpenSure) conceivably adds a layer of safety and improved capture/release aspect to the current market of stone baskets.

Notwithstanding the above limitation, the unique features of this novel end-engaging basket merit clinical investigation. Furthermore, the testing was done with industry standardized bench top testing. This study provides a foundation for further *in vivo* studies to assess the Dakota's clinical performance. We are currently conducting a user survey to gain information regarding clinical function from the perspective of the practicing urologist.

Conclusions

In a head to head comparison with the NGage in *in vitro* testing, the Dakota end-engaging nitinol tipless basket demonstrated similar durability characteristics. There appeared to be differences in capture and release between the two types of baskets, as Dakota demonstrated greater versatility in releasing the larger stones. In conjunction with its proprietary OpenSure aspect, the Dakota basket potentially confers an improved iteration in the end-engaging basket arena that both clinical practice and trials should evaluate.

Acknowledgements

None.

Footnote

Conflicts of Interest: SK Bechis is a Consultant to Boston Scientific; JE Abbott is a speaker for and Consultant to Boston Scientific; RL Sur is a speaker for Cook Medical, speaker for and Consultant to Boston Scientific.

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Cite this article as: Bechis SK, Abbott JE, Sur RL. *In vitro* head-to-head comparison of the durability, versatility and efficacy of the NGage and novel Dakota stone retrieval baskets. Transl Androl Urol 2017;6(6):1144-1149. doi: 10.21037/tau.2017.11.30

URO-537009-AA APR 2018