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Presentation Title: COMPARISON OF THE VERSATILITY AND EFFICACY OF NGAGE

AND NOVEL DAKOTA BASKETS IN STONE CAPTURE AND RELEASE

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Introduction and Objective

The objective of this study was to compare the efficacy and versatility of a novel open-faced basket, Dakota™ (Boston Scientific, Marlborough, MA, USA), with the contemporary open-faced basket, NGage™ (Cook Medical, Bloomington, IN, USA).

Methods

A total of 60 devices (30 from each manufacturer, 15 8mm and 15 11mm open basket diameter) were evaluated through a simulated endoscopic 3.6F working channel. Each basket was tested for its ability to capture and release simulated stone models of progressive diameter to demonstrate efficacy. Stones started at 1mm, and increased sequentially by 1mm to a maximum size manageable by the basket to demonstrate basket versatility. For each trial, a new basket was passed through the working channel and opened to capture the stone against gravity. Inability to capture was defined by the basket failing to grasp the stone. Each stone captured was raised 3 inches above the capture site and the basket was opened to passively release the stone with gravity assistance. If the stone failed to disengage, the basket handle was shaken in attempt to disengage the stone. If these two maneuvers were unsuccessful in releasing the stone from the Dakota, then the "Sure Release" feature was utilized in an attempt to passively release the stone with gravity assistance. Manual release was defined by inability to release after these maneuvers.

Results

Both 8mm basket types captured each stone size up to 8mm (Table 1). However, Dakota was able to release 7-8mm stones more effectively compared to NGage (p<0.0001). For stones that were not disengaged with either passive release or shaking, the Sure Release mechanism of Dakota permitted stone release in all instances. NGage required manual release in 13 cases compared to none with Dakota. Similar findings were seen with the 11mm basket trial with stone sizes up to 10mm. In addition, Dakota was more effective in capturing 11mm stones (100% vs. 0%) (p<0.0001); however, the Sure Release mechanism was required for release of each 11mm capture.

Conclusion

Both baskets demonstrated comparable efficacy in stone capture. Dakota™ showed improved efficacy in the release of stones >7mm. The Dakota demonstrated greater versatility when compared to the NGage™ in demonstrating a greater range of stone sizes successfully captured and released. The 11mm Dakota specifically demonstrated the ability to entrap 11mm stones more effectively than the 11mm NGage Basket.

Table 1. Basket Data

8mm Devices (N=15)	7mm stone		8mm stone		9mm 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
Release stone by gravity	100% (15/15)	13% (2/15)	7% (1/15)	0% (0/15)	0% (0/3)	NA
Retained stone release by shaking device	NR	100% (13/13)	86% (12/14)	13% (2/15)	33% (1/3)	NA
Retained stone manually removed	NR	NR	NR	87% (13/15)	66% (2/3)	NA

11mm Devices (N=15)	9mm stone		10mm stone		11mm 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
Release stone by gravity	100% (15/15)	67% (10/15)	100% (15/15)	7% (1/15)	0% (0/15)	NA
Retained stone release by shaking device	NR	100% (5/5)	NR	100% (14/14)	100% (15/15)	NA
Retained stone manually removed	NR	NR	NR	NR	NR	NA

Bench Test results may not necessarily be indicative of clinical performance.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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