

# A New Automatically Fixating Stone Basket (2.5 F) Prototype with a Nitinol Spring for Accurate Ureteroscopic Stone Size Measurement

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## ABSTRACT

**Introduction:** Intraoperative assessment of stone size is crucial for the successful and safe extraction of stones. The first automatically fixating measuring stone basket prototype showed a mismatch between the steel spring and the nitinol basket; therefore, to improve this prototype, the steel spring was replaced with a nitinol spring and a modified scale was implemented on the basket handle for accurate intraoperative stone size measurement.

**Methods:** The proposed tipped basket was composed of nitinol. A standard handle with a spring-supported self-closing mechanism (2.5 F, Urotech<sup>®</sup>) was used, and a modified nonlinear millimeter scale was established on the handle. The grasping force was provided by the new nitinol spring mechanism in the handgrip. Various colors associated with the stone size were applied on the scale.

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**Results:** The material difference between the basket and the spring was eliminated. The measuring scale ranged from 2 mm (green) through 5 mm (yellow) to 8 mm (red), and the scale was nonlinear because of the nonlinear relationship between the diameter of the stone and the distance marked on the scale.

**Conclusion:** The proposed automatically fixating stone basket with a nitinol spring has the potential to improve the safety and effectiveness of endourological stone retrieval. Further validation of this new scale and basket should follow.

**Keywords:** Endourology; Nitinol; Stone basket; Stone measurement; Ureteroscopy

## INTRODUCTION

Ureteroscopy (URS) is currently the first-choice therapy for ureteral stones and is the recommended therapy option for kidney stones smaller than 2 cm [1]. The growing prevalence of kidney stone disease worldwide and the favorable characteristics of URS (i.e., low invasiveness, high stone-free rates, and relatively low risk of intra- and postoperative complications) predict that there will be a growing demand for URS in the future [2, 3].

Low-dose noncontrast computer tomography (CT) is the gold standard for the diagnosis of acute flank pain and therefore for the

preoperative planning of endourological treatment [4]; however, in certain settings, the accuracy of CT-based preoperative stone size assessment, especially regarding ureteral stones, may be inaccurate [5]. Moreover, Patel et al. revealed that the CT-based estimation of stone diameter for larger stones ( $\geq 4$  mm) may be less precise than intraoperative visual assessment by the surgeon [6]. Thus, additional reliable stone size assessment during URS would be helpful for making decisions about whether to perform direct stone extraction or laser lithotripsy for larger stone fragments.

Current literature regarding the unique concept of a stone size measuring basket is scarce.

Our research group previously introduced a nonlinear millimeter scale coupled with various self-closing nitinol stone baskets (2.5, 3.0, and 4.0 F) to enhance intraoperative stone size measurements [7]. The nonlinear millimeter basket scale was compared in vitro with the visual estimation of two surgeons, and manual stone measurement was used as the reference method. The 2.5-F nitinol basket was the most accurate for measuring larger stones ( $> 6$  mm) with sensitivity of 56% and specificity of 84%, while the 4.0-F basket was the most accurate for smaller stones ( $< 3$  mm); however, the study showed that the visual ureteroscopic estimation was superior to the basket measurement [8]. The basket system could have been inferior to visual assessment as a result of a mismatch between the steel spring and the nitinol basket, which may have influenced the measurement accuracy depicted on the scale. The different material-specific relationships of steel and nitinol regarding their stress and strain could explain this phenomenon. Initially steel is not flexible and shows increasing stress during engaging the stone, whereas nitinol shows more strain and less stress. Even less stress is present during the reverse action [9].

Therefore, to resolve the described mismatch and to improve the measurement accuracy, a new basket prototype, especially for ureteral and renal pelvic stones, has been proposed in which the steel spring has been replaced with a nitinol spring.

## METHODS

The tipped automatically fixating stone basket was composed of nitinol to provide maximal safety to the surrounding urothelial tissue and best possible performance. The steel spring was replaced with a suitable nitinol spring as a part of the stone-fixating mechanism. The slider on the front side of the handle opens the basket and enables the stone to be grasped (Fig. 1).

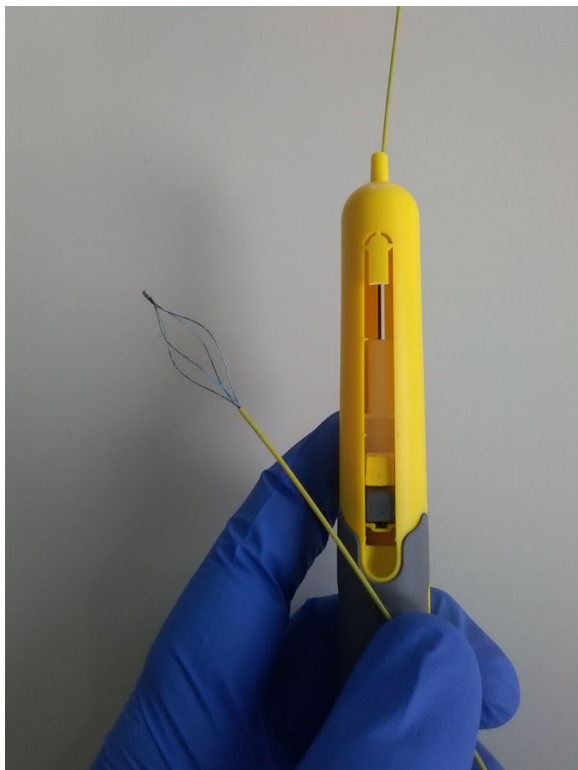
A standard handle (Urotech<sup>®</sup>) connected to a 2.5-F basket was described previously [7, 8] and was used in this prototype. It was developed in cooperation with Prof. S. Lahme (Pforzheim, Germany). The handle has two unique design elements: firstly, it has a mentioned spring mechanism that enables automatic stone fixation in the basket; secondly, it is equipped with a dis- and reconnectable handle so that the



**Fig. 1** A handle with a new colored millimeter scale and slider

ureteroscope can be fully removed while the retrieval basket with the grasped stone remains in place. The handle can be reconnected again if needed. The handle should be opened on the back side to disconnect the basket (Fig. 2), as this maneuver enables a switch to be made between different URS devices without the need to disengage the stone.

A modified nonlinear millimeter scale was established on the handle. The scale was standardized by grasping standardized (DIN “Deutsche Industrie Norm” ISO 281) screws with the basket. Various colors on the millimeter scale were applied, and the color change from green to yellow was based on the study by Abdelrahim et al. They showed that stones greater than 5 mm in width are associated with a statistically significant higher incidence of intraoperative complications [10]. The color change from yellow to red was a proposal by the author and should be further investigated.



**Fig. 2** The opened back of the handle demonstrates the slider in an opened-basket position. The nitinol spring is in the proximal gray part of the handle

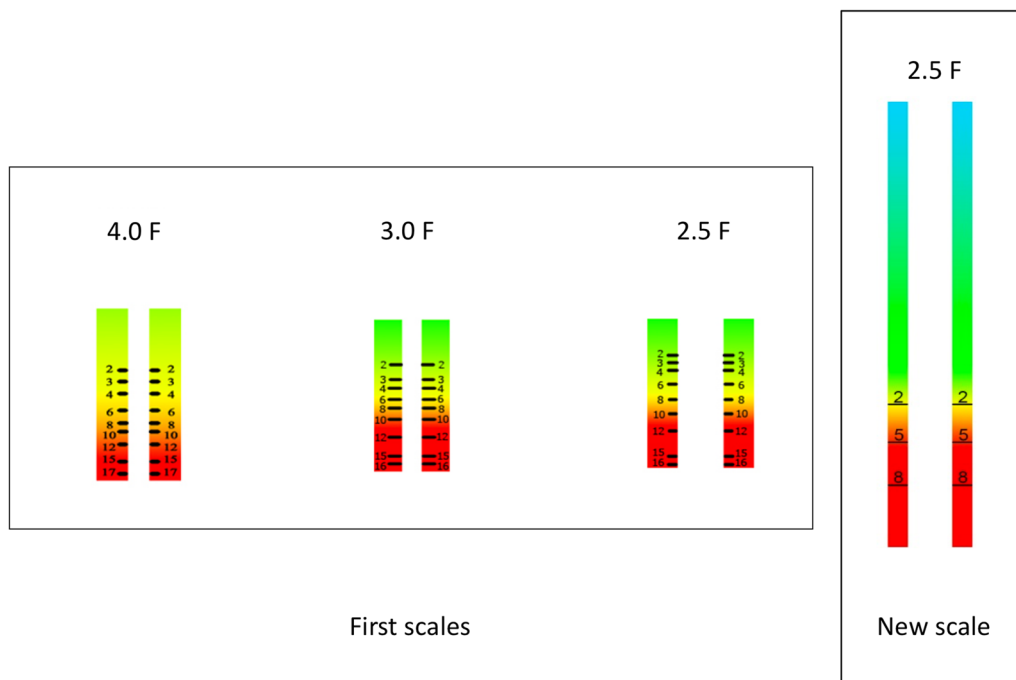
Extreme caution should be applied during manipulation of the stones situated in the red area because of their size. The development of the presented prototype did not contain any studies with human participants or animals performed by any of the authors.

## RESULTS

Figure 1 depicts the front side of the final prototype. The measuring scale ranges from 2 mm (green) through 5 mm (yellow) to 8 mm (red), and the scale is nonlinear because of the nonlinear relationship between the diameter of the stone and the distance marked on the scale. The newly proposed prototype managed to eliminate the material difference between the basket and the spring, which was present in the first prototype [7]. Furthermore, the layout of the scale was improved to make it more comprehensible in comparison with previous scales (Fig. 3).

## DISCUSSION

In URS, as in every other surgical procedure, patient safety is the main goal for the surgeon. Despite the many improvements over the years (e.g., invention of ureteral access sheaths, dilators, safety wires, and especially laser lithotripsy), there is still a need to improve endourological safety, as ureteral injury (of any severity) still occurs in up to 30% of URS cases [11]. Stone diameters greater than 5 mm, a patient history of URS, a dilated proximal ureter, stone location above the ischial spines, and the involvement of a junior urologist are all factors that are known to be associated with a significantly higher incidence of intraoperative complications [10]. The results of our previous study were in line with those of Patel et al. [6] and confirmed that endourologists are able to assess residual stone fragment size accurately enough to make intraoperative decisions about direct extraction or further laser lithotripsy. Conversely, we also showed that it was feasible to measure the stone with the described basket handle scale [8], which could be especially



**Fig. 3** Evolution of the measuring scale—current nonlinear version ranges from 2 mm (green) through 5 mm (yellow) to 8 mm (red)

suitable for junior endourologists; however, improvements regarding the accuracy of this new method were required and a possible solution is provided in the current study. It has been already shown that the visual stone size estimation is biased by multiple factors, such as the color of the stone and the experience of the surgeon [8]. Interestingly, a slight tendency to underestimate the size of large stones (> 6 mm) was observed [8]; therefore, the measurement of these stone sizes could be enhanced with the proposed basket prototype.

It is already known that intraoperative visual stone assessment and measurements using regular preoperative diagnostic tools (i.e., CT and ultrasound) are biased [12–14]. Other experimental methods such as ultrasound strain sonography have not yet gained clinical application [15]. In our opinion, the modified measuring basket prototype reported here could attempt to level these discrepancies and objectify stone size measurements in the future.

Ludwig et al. recently proposed another approach to improve the intraoperative stone measurement accuracy that was based on

additional measuring software calibrated in accordance with the distance of the basket tip in the visual field of the ureteroscope [16]. Future comparison between the “hardware” basket concept and the proposed URS software would be surely interesting to assess their influences on intraoperative outcomes and patients’ safety.

## CONCLUSIONS

The proposed automatically fixating stone basket with a nitinol spring has the potential to improve the safety and effectiveness of endourological stone retrieval; however, further validation of the proposed prototype regarding measurement accuracy, durability of the device, and patient safety is required.

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**Compliance with Ethics Guidelines.** This article does not contain any studies with human participants or animals performed by any of the authors.

**Data Availability.** The manuscript has no associated data.

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