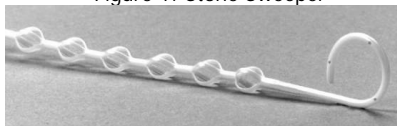

Ureteral Stone Sweeper[®]: Clinical Study

Summary and Update (as presented at AUA, April 2004)

A radially expanding stent, Stone Sweeper[®] was designed to produce enhanced dilatation of the ureter allowing for more flow and a larger passageway for stone migration. In addition, expanding baskets allow for direct capture of small stones/fragments (2-5mm) to facilitate stone removal. 62 patients aged 24-94 years old were implanted with the Stone Sweeper for duration of 3-49 days, with an average of 13 days. Fifty of those patients had a stone burden at the time of Sweeper placement. The Sweepers were inserted and extracted safely in all patients. No encrustation was reported. Anecdotal reports of significant dilatation were reported. In 46/50 patients (92%), stones were caught in baskets (20) or passed with the Sweeper in place (26).

Figure 1: Stone Sweeper



The Journal of **UROLOGY**

444 THE JOURNAL OF UROLOGY

Vol. 171, No. 4, Supplement, Tuesday, May 11, 2004

HUMAN RESULTS OF URETERAL STONE EXTRACTION WITH THE STONE SWEEPER

*David M Albala, Durham, NC; Thomas Rickner, Toccoa, GA;
David M Hoenig, Bronx, NY; Mitchell Bamberger, Worcester, MA*

INTRODUCTION AND OBJECTIVE: In this report we investigate a radially expanding stent with baskets along the length of the stent designed to produce dilatation of the ureter for capture and removal of small ureteral stones.

METHODS: Forty-seven patients ranging in age from 24-94 years old, had the Ureteral Stone Sweeper placed, with thirty-nine placed alongside stone fragments in eight different medical centers. The fragments ranged from 4 to 50 mm pre-treatment, and the number of fragments/stones ranged from 1 to more than 5. In the eight that were placed without a stone, they were placed alongside tumors or after stones were removed. The locations of the stones varied from kidney to distal ureter. The Sweeper is inserted in the closed position similar to a standard ureteral stent, but then gently opens 15-17 baskets designed to capture up to 5mm fragments. The Sweeper was left in place 3-49 days, with an average of 11 days.

RESULTS: The device was inserted and extracted safely in all patients. Pain was rated and averaged a 2.4 on an equivalent 1-10 scale. There was no technical difficulty with stent removal, and no adverse events. There was no encrustation reported. In patients with a stone, there was 87% success rate removing the stone with Sweeper in place.

CONCLUSIONS: The Ureteral Stone Sweeper has been used safely in 47 patients. The device removed ureteral stones in its baskets as well as let stones pass. The degree of ureteral dilatation that is produced by the stent remains to be quantified. The Stone Sweeper represents a new stone removal and dilation tool worthy of further clinical study.

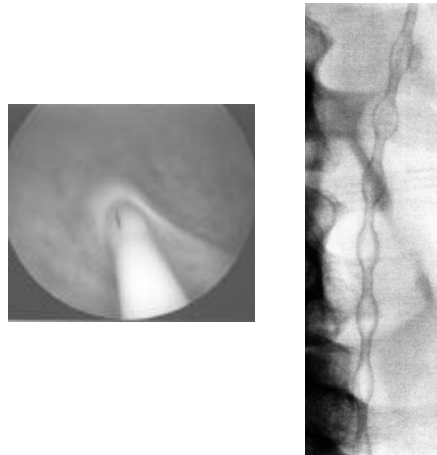
Materials and Methods

Polyurethane ureteral stents were slit to open 15-17 four-strand baskets along the length. The baskets passively dilate the ureter over time and can open to 21F, able to capture 5mm stones in size or less. 62 patients received the Stone Sweeper safely at 16 medical centers, with 50 of the placements occurring in the presence of stones. The first 15 patients were implanted with a 5F Fossa Stone Sweeper with a 7F Teflon sheath to close down the baskets. The next 47 patients received a 6.5F sheathless Fossa Stone Sweeper. The size of the baskets in both groups was the same.

The patients aged 24-94 years old, 46% male, had fragments that ranged from 1 to 20 mm pre-treatment, and the number of fragments/stones ranged from 1 to more than 5. The locations of the stones varied from kidney to lower ureter. The Sweeper was inserted in the closed configuration similar to a standard ureteral stent and left in place 3-49 days, with an average of 13 days.

An image was typically taken pre-treatment. The device was used five times with no other treatment, ten times pre-ESWL, one time post-ESWL only, four times post intracorporeal lithotripsy (IL) and pre-ESWL, 29 times post IL only and one time post-percutaneous procedure antegrade. In 12 patients, the device was used as a ureteral stent after stones were removed or for other indications.

Figure 2: Cystoscopy and fluoroscopy at time of insertion



Results

The device was inserted and extracted safely in all patients. In 46 of 50 (92%) of stone patients, stones passed or were caught in the baskets. Of the first 15 patients treated with the 5F Sweeper 13/15 were stone free following treatment. In 2 patients stones were caught in the baskets, and in 11 the stones passed. In the second group of 35 patients with the 6.5F device 33/35 were stone free following treatment. In 18 patients stones were caught in the baskets, and in 15 patients stones passed. The two treatment failures in this group consisted of patients with stones retained in the kidney. In all patients the ureters were cleared of stones.

Patient/clinician assessments were conducted on the 6.5F device, ease of insertion was rated by the inserting urologist as a 1.2 on a 1-5 scale, with 1 being excellent. The patients pain experience rated an average score of 3.3 (assessed by physician) estimated on the standard pain scale between 1-10 with 10 being the most severe. All stents were removed without complication. In two of 50 patients, patient pain required anesthesia for removal.

Radiographs following insertion show baskets in a partially open state (Figure 2).

Ureteral dilation was not quantified in this study because devices were typically removed in the office; however in the several cases where KUB were obtained prior to removal, significant radial expansion of the baskets was observed.

The longest indwelling time was 49 days with an average of 13 days. None of the stents exhibited any encrustation on removal.

Sequence of Procedures	n=	Patients in Which Stones Were not Completely Cleared	Mean Size of Largest Stone Fragment in Each Patient at Time of Stent Removal (mm)
Stent alone	5	1	6
Pre-ESWL	10	0	13
Post-ESWL	1	0	13
Post-IL/Pre-ESWL	4	2	16
Post-IL	29	1	8
Post Percutaneous-NL	1	0	20

Conclusion

The Ureteral Stone Sweeper has been used safely in 62 patients, 50 of these were in the presence of ureteral stones. The device directly removed ureteral stones by catching them in the baskets as well as by dilating the ureters and allowing stones to pass. The degree of ureteral dilatation that is produced by the stent remains to be quantified. We anticipate the Stone Sweeper will play a major role in the clinical management of ureteral stones and represents a novel stent configuration and tool to provide gentle dilation of the ureter.