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Comparison of Stone Fragmentation Characteristics of the 9 Fr and 1.9 Fr Next-Generation Electrohydraulic Lithotripters and Current Lithotripsy Modalities

Shaopeng Zhang[1], Robert Qi[2*], Russell Terry[2], Patrick Whelan[2], Glenn Preminger[2], Michael Lipkin[2], Pei Zhong[1,2]

[1]Department of Mechanical Engineering and Material Science, Duke University, Durham, North Carolina, USA

[2]Division of Urologic Surgery, Duke University Medical Center, Durham, North Carolina, USA

[*]**Corresponding author:** Robert Qi, Division of Urologic Surgery, Duke University Medical Center, Durham, North Carolina, USA

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Introduction

Electrohydraulic Lithotripsy (EHL) was invented in 1955 and was one of the first intracorporeal methods available to treat kidney stones [1]. The EHL probe's working component consists of a pair of concentric electrodes maintained at different voltages and separated by an insulating layer. When a charge is applied, an electric spark is created and generates a plasma channel that vaporizes the water around the EHL probe tip. This rapidly expanding plasma channel produces a hydraulic shock wave that leads to formation of a cavitation bubble. The expansion and subsequent collapse and rebound of the cavitation bubble generates additional shock waves [2]. Shock waves from the explosive expansion of the plasma, the collapse of the cavitation bubble, and from the rebound of the cavitation bubble all contribute to stone fragmentation.

In the United States, Intracorporeal EHL (IEHL) was used to treat kidney and ureteral stones in the 1980s and 1990s [3]. Studies from that time reported successful fragmentation of up to 94% of stones to less than 2 mm fragments, and successful treatment of up to 99% of patients [4,5]. The thin IEHL probes were well-suited for the endoscopes at the time [6]. However, there were concerns for the safety of IEHL. The shockwave was considered to propagate outward and damage surrounding urothelial tissue [7,8], potentially risking ureteral perforation and concomitant premature termination of the procedure by the urologist. For this concern of safety, IEHL fell out of favor as a treatment for ureteral stones compared with other contemporary modalities such as Holmium: Yttrium Aluminum Garnet (Ho: YAG) Laser Lithotripsy (LL) and extracorporeal shockwave lithotripsy which had better safety profiles.

Since that time, there has been continued refinements of IEHL technology. Improvements in probe design, power output consistency, and navigation interface have been made to enhance the reliability of the AUTOLITH® Uro-Touch IEHL® System by NTI™ (Northgate Technologies Inc, Elgin, IL). The Uro-Touch system can be connected to either a 9 French (Fr) probe for use in the bladder or a 1.9 Fr probe for use in the ureter and kidney. In this study, we report the efficacy of the updated Uro-Touch IEHL® system using both a 9 Fr probe to simulate fragmenting bladder stones and a 1.9 Fr probe to simulate fragmenting ureteral and renal stones *in vitro* as compared with other commonly-used devices for lithotripsy.

Materials and Methods

9 Fr Probe Testing

To simulate bladder stone treatments, the Uro-Touch IEHL® 9 Fr probe was compared with the Swiss LithoClast Master 9.9 Fr probe (Electro-Medical Systems, Switzerland), which is a mechanical lithotrite device that combines pneumatic and ultrasonic ablation modalities to fragment stones using a hollow, rigid probe, which has suction capability for simultaneous evacuation of smaller fragments [9]. Testing was conducted under direct vision without use of a nephron scope. Uro-Touch IEHL® with 9 Fr probe was set at 30 Hertz (Hz) at about 5000 volts (V) either at medium or high output setting and compared to LithoClast Master with ultrasound mode at 60% duty time at 100% power and pneumatic mode at 4 Hz at 100% power. These specific settings were chosen based on the manufacturers' published recommendations. One 6x6 mm cylindrical hard BegoStone phantom (15:3 powder: water by weight) was tested inside a rubber bladder model for 30 seconds per trial for 6 trials. Likewise, one 6x6 mm cylindrical soft BegoStone phantom (15:6 powder: water by weight) was tested inside the same rubber bladder for 30 seconds per trial for 6 trials.

1.9 Fr Probe Testing

To simulate ureteral and renal stone fragmentation, the Uro-Touch IEHL® 1.9 Fr probe was compared with a 272 µm Ho:YAG laser (Quanta Systems, Italy). Both Uro-Touch IEHL® probe and laser fibers were inserted through a PU3022A single-use ureteroscope (Pusen, China) with water irrigation of 50 mL per minute. A 7.5 mm diameter silicone tube attached to a closed 250 mL fluid reservoir was used to simulate the ureter and kidney, and the phantom was placed inside the lumen of the silicone tubing at the initiation of each trial. Soft BegoStone phantoms were ablated using the medium setting of the Uro-Touch IEHL® and 30 Hz or laser settings of 0.5 Joules (J), 20 Hz, long pulse. Hard BegoStone phantoms were ablated using the high setting of the Uro-Touch IEHL® and 30 Hz or laser settings of 1 J, 10 Hz, short pulse. Trials were conducted on 6x6 mm cylindrical hard or soft BegoStone phantoms, and one stone phantom was tested per trial. Total treatment time per trial was 120 seconds, and each trial was repeated 6 times. The Uro-Touch IEHL® 1.9 Fr probe was changed once per trial according to the manufacturer-recommended lifetime of an individual probe (approximately 1100 shocks); the 10 to 15 seconds required for exchanging probes was excluded from the measured treatment time.

For both sets of testing, the stone phantoms were soaked in saline solution for two hours before the experiments. The acoustic and mechanical properties of BegoStone phantoms have been characterized in previous studies and found to be comparable to human kidney stones of various compositions [10]. The dry weights of the original BegoStone before and resident fragments post treatment following sequential sieving were measured to determine the treatment outcomes. Fragmentation efficiency was determined by measuring the percentage by dry-weight of all fragments < 3 mm, all fragments < 2 mm, and the Largest Remaining Single Fragment (LRSF). Mean fragment dry-weights for each device were compared using t-tests with significance at $p < 0.05$.

Results

9 Fr IEHL Probe vs LithoClast® Master

For hard BegoStone phantoms, the Uro-Touch IEHL® 9 Fr probe produced a larger proportion of sub-3 mm fragments (68% vs 15%, $p < 0.01$) and sub-2 mm fragments (42% vs 15%, $p < 0.01$) compared to the LithoClast Master after 30 seconds (Figure 1). The LRSF was smaller for the Uro-Touch IEHL® 9 Fr than for the LithoClast Master (24% vs 82%, $p < 0.01$). The EHL probe did not require exchange during the 30 second trials. For soft BegoStone phantoms, the Uro-Touch IEHL® 9 Fr probe again produced a larger proportion of sub-3 mm fragments (100% vs 54%, $p < 0.01$) and sub-2 mm fragments (93% vs 38%, $p < 0.01$) compared to the LithoClast Master after 30 seconds (Figure 2). The LRSF was smaller for the Uro-Touch IEHL® 9 Fr than for the LithoClast Master (3% vs 34%, $p < 0.01$).

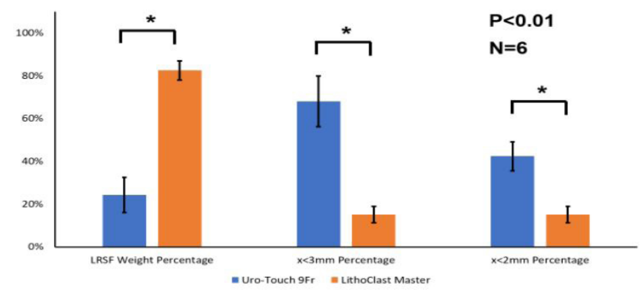

Figure 1: Hard BegoStone Fragmentation Percent Result of Uro-Touch 9 Fr & LithoClast Master.

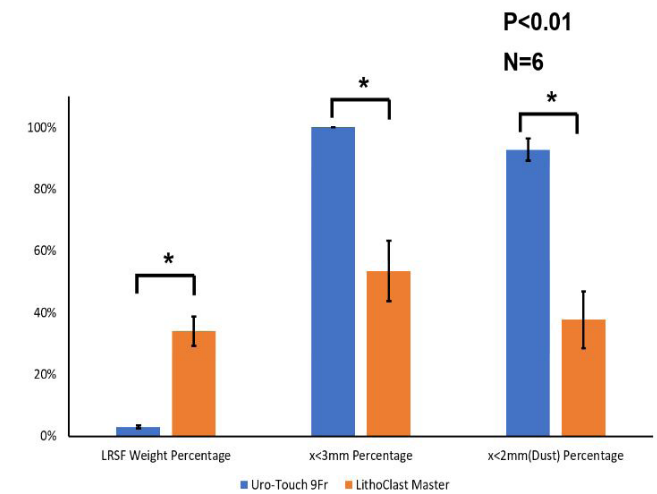

Figure 2: Soft BegoStone Fragmentation Percent Result of Uro-Touch 9 Fr & LithoClast Master.

1.9 Fr IEHL Probe vs 272µm Ho:YAG laser

For hard BegoStone phantoms, the Uro-Touch IEHL® 1.9 Fr probe produced a smaller proportion of sub-3 mm fragments (1% vs 43%, $p < 0.01$) and sub-2 mm fragments (1% vs 43%, $p < 0.01$) compared to the Ho:YAG laser after 120 seconds of treatment time (Figure 3). The LRSF was larger for the Uro-Touch IEHL® 1.9 Fr than for the Ho:YAG laser (99% vs 31%, $p < 0.01$). EHL probes were changed once per 120-second trial. For soft BegoStone phantoms, the Uro-Touch IEHL® 1.9 Fr probe produced a larger proportion of sub-3 mm fragments (90% vs 32%, $p < 0.01$) and sub-2 mm fragments (60% vs 26%, $p < 0.01$) compared to the Ho:YAG laser after 120 seconds of treatment time (Figure 4). The LRSF was smaller for the Uro-Touch IEHL® 1.9 Fr than for the Ho:YAG laser (14% vs 36%, $p < 0.01$). EHL probes were changed once per 120-second trial.

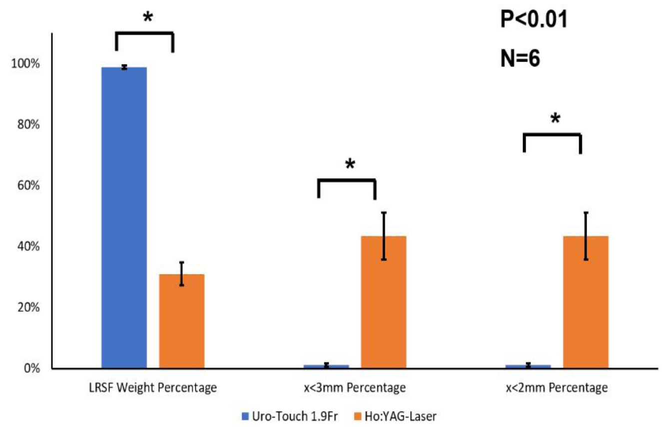

Figure 3: Hard BegoStone Fragmentation Percent Result of Uro-Touch 1.9 Fr & Ho: YAG Laser.

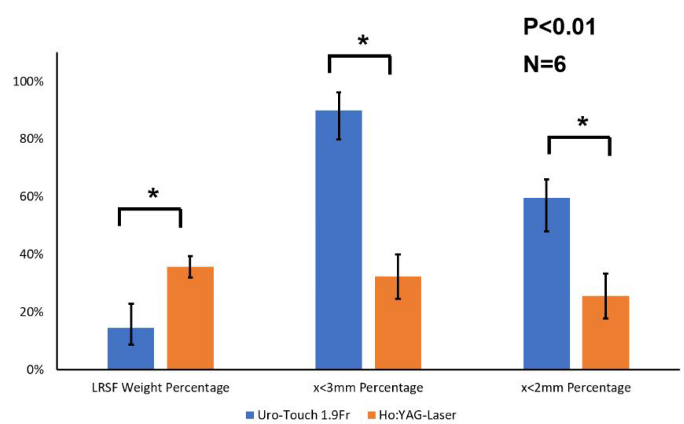

Figure 4: Soft BegoStone Fragmentation Percent Result of Uro-Touch 1.9 Fr & Ho: YAG Laser.

Discussion

In this study, we observed that the AUTOLITH® Uro-Touch IEHL® System 9 Fr probe is effective in fragmenting both hard and soft BegoStone phantoms when compared to the LithoClast® Master in a bladder stone model. We also observed that the Uro-Touch IEHL® 1.9 Fr probe is effective in fragmenting soft BegoStone phantoms—but not hard phantoms-when compared to the Ho:YAG laser in a ureteral stone model. The manufacturer of the AUTOLITH® Uro-Touch IEHL® System states that several technical improvements have been incorporated into this latest generation IEHL device. The probe tip was redesigned to increase its strength and reliability, while the manufacturing process was updated to improve conductor stability and decrease the likelihood of premature probe degradation. These changes were made to reduce the necessity of frequent probe replacement which can be costly and time-consuming. Updates were also made to the electrical system to provide a higher and more consistent voltage output to the probe. The IEHL frequency was fixed at 30 Hz which has been shown to be the most effective against mobile, non-impacted stones [11]. Finally, the navigation interface was modernized from a multitude of knobs and dials to a simplified touch screen format. Our experience using the device for this testing was generally reflective of these changes. We found the frequency of required probe replacement to be acceptably lower compared to prior device iterations, the device demonstrated acceptable efficacy for the majority of testing applications, and the interface was user-friendly and comparable to other modern lithotripsy devices. The safety profile of IEHL was a concern when the technology was first introduced, since off-target shockwaves had the potential to cause acute urothelial abrasion [8], bleeding, edema [12], and perforation [13]. In case of perforation, the urologist is forced to place a stent and abort the procedure for the safety reasons. These acute risks also confer longer term risks of ureteral stricture formation, and in the aggregate, they represented a major limiting factor to more widespread adoption of IEHL technology. In light of these concerns with the prior-generation equipment, safety testing of the newly-redesigned probes needs to be performed prior to widespread adoption, and such testing is on-going at present.

Previous studies comparing the stone ablation efficacy of IEHL with LL were conducted in the 1990s. Teichman et al reported a retrospective series of patients who underwent ureteroscopy for mostly calcium oxalate monohydrate stones. The authors observed that patients who underwent 1.9 Fr IEHL stone ablation (50–100 V, 20 Hz) had faster operative times and equivalent 3-month stone-free rate (SFR) compared with patients who underwent Ho:YAG LL (365 μm laser fiber, from 0.6 J/5 Hz to 1.5 J/10 Hz) for stones smaller than 15 mm. For ureteral stones 15 mm or greater, however, Ho:YAG had superior operative times and 3-month SFR [14]. In a subsequent study, the same group performed an *in vitro* comparison of Ho:YAG LL, pulsed dye LL, IEHL, and LithoClast® against weight-matched samples of human kidney stones of varying compositions. The Ho:YAG laser was observed to create smaller fragments than all other modalities, including IEHL, for all tested stone types [15].

Our study found that the new generation IEHL device offers efficient fragmentation of hard and soft stone phantoms with the larger 9 Fr probe and against soft stones with the smaller 1.9 Fr probes. Interestingly, the new generation of 1.9 Fr IEHL was observed to be more effective in fragmenting soft phantoms (with stiffness comparable to uric acid stones) than the Ho:YAG laser, but it was relatively ineffective against hard phantoms (with stiffness comparable to calcium oxalate monohydrate stones). Meanwhile, the 9 Fr probe was highly effective in fragmenting both phantom types. These findings are consistent with those of the Teichman group, who also observed relative decrease in IEHL ablation efficiency as the stone size to probe size ratio increased [14]. The efficacy discrepancy between 9 Fr and 1.9 Fr probe fragmentation of hard phantoms could be explained by differences in cavitation bubble size and subsequently decreased acoustic transient pressure generation by the smaller probe tip. It is known that the mechanism of IEHL involves spark generation which produces a hydraulic shock wave that first causes direct mechanical damage to the stone, and then secondly creates a cavitation bubble which then collapses and thereby produces a delayed second pressure pulse which also damages the stone [13]. In this framework, if there exists a mechanical energetic threshold which must be surpassed in order to achieve stone ablation, then it may be the case that the larger probe produces hydraulic shock waves and cavitation bubble collapse which are sufficiently energetic to surmount such a threshold in both hard and soft phantoms, whereas the smaller probe only produces enough force to ablate the soft stones. Moreover, since the mechanism of the Ho: YAG laser is considered to be predominantly thermal ablation and less dependent on mechanical damage, our findings of grossly comparable fragmentation efficiency between hard and soft phantoms with the laser herein make sense.

Limitations to our study include the *in vitro* nature of the testing. 6x6 mm phantoms were used in our bladder model, and while bladder stones typically grow larger than before requiring treatment, this phantom size nonetheless seemed to allow for adequate testing of the devices. The probes in the bladder model were used under direct vision to perform the ablation testing, whereas in clinical use they would be placed through the working channel of a cystoscope. We also had the advantage of using optimized device settings for this benchtop evaluation which were able to be held constant for the duration of testing, whereas settings in clinical use may more variable and dependent on many different patient-specific factors. The time required for Uro-Touch IEHL® probe exchanges (about 10 to 15 seconds per probe exchange) was excluded from our tests as we compared the direct functional efficacy, although in reality this time would contribute to overall procedural time. Moreover, based on our observed decrease in efficacy when using smaller probes against hard stones, it is possible that the number of required probe changes could limit the utilization of Uro-Touch IEHL® and potentially make clinical adoption prohibitive. Finally, since this was a purely benchtop evaluation, the underlying concern of safety with the device was not assessed and cannot be reasonably commented upon. Safety testing remains ongoing and results pending.

Conclusion

The new generation AUTOLITH® Uro-Touch IEHL® device demonstrates good efficacy *in vitro* against hard and soft BegoStone phantoms in a bladder model using a 9 Fr probe when compared to the LithoClast® Master mechanical lithotrite. The Uro-Touch also demonstrates good efficacy against soft phantoms, but not hard phantoms, in a ureteral model with a 1.9 Fr probe when compared to Ho:YAG laser. While these data are encouraging, it will be imperative to assess the results of ongoing safety testing prior to adopting the system for routine clinical use.

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