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Initial Clinical Experience with Swiss LithoClast Trilogy during Percutaneous Nephrolithotomy

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Abbreviations:

PCNL = Percutaneous Nephrolithotomy

URS = Ureteroscopic Retrograde Stone Removal

Abstract

Introduction and Objective:

Current, available lithotrites have clinical stone clearance rates averaging 24-32 mm^2/min. The objective of this study was to critically evaluate the initial experience with the Swiss LithoClast® Trilogy lithotrite during percutaneous nephrolithotomy (PCNL).

Methods:

We prospectively enrolled patients with a minimum of 15 mm of stone in axial diameter at three locations (Indiana University, University of California Davis, and University of California San Diego) scheduled to undergo PCNL for nephrolithiasis over a 60-day trial period. We assessed objective measures of stone clearance time, stone clearance rate, device malfunction, stone-free rate, and complications. Each surgeon also evaluated subjective parameters from each case related to use of Trilogy on a 1-10 scale (10 = Extremely Effective), and compared it to their usual lithotrite on a 1-5 scale (5 = much better).

Results:

We included 43 patients and had 7 bilateral (16.3%) cases, for a total of 50 renal units. One case was a mini-PCNL. Two cases experienced device malfunctions requiring troubleshooting but no transition to another lithotrite. The mean stone clearance rate was 68.9 mm^2/minute. The stone-free rate on post-operative imaging was 67.6% (25 of 37 patients with available imaging). The lowest subjective rating was the ergonomics score of 6.7, and the highest subjective rating was the ease of managing settings score of 9.2. The surgeon impressions of ultrasound (7.3), ballistic (8.1), combination of ultrasound and ballistic (8.7), and suction (8.4) were high. One patient experienced an intraoperative renal pelvis perforation, one patient required a blood transfusion, one patient had a pneumothorax requiring chest tube placement, and one patient had a renal artery pseudoaneurysm requiring endovascular embolization.

Conclusions:

This multi-institutional study evaluated a new and efficient combination lithotrite that was perceived by surgeons to be highly satisfactory, with an excellent safety and durability profile.

Introduction:

Percutaneous nephrolithotomy (PCNL) is the preferred treatment for renal stones > 20 mm in diameter[1], and has been widely adopted since its original description in 1976[2,3]. The tools used for stone fragmentation and extraction have continued to improve since that time, with the energy sources for commonly-available lithotrites categorized as ultrasonic, kinetic, combination, laser, or electrohydraulic[4]. Each type of lithotrite has its own strengths and weaknesses, with no general consensus as to the single best modality for stone breakage at the present time[5–8].

Modern lithotrites available for PCNL aspire for maximal efficiency in both stone breakage and stone removal for all potential types of stone types encountered. Several available models typically incorporate ultrasonic energy bolstered either by another energy source such as pneumatic or mechanical energy. Depending on the method of calculation, stone clearance rates for modern lithotrites can range from 24-76mm^2/min, with substantial variability in clearance rate for the same device depending on the study[6–8]. One of the newest lithotrites on the market is the LithoClast® Trilogy (Electro Medical Systems S.A., Nyon, Switzerland). This single-probe device delivers both ultrasonic and electromagnetic ballistic energy, as well as suction capability, under surgeon control via a single foot pedal. Laboratory studies have suggested that Trilogy offers faster stone clearance than other ultrasonic and combination ultrasonic devices[9]. The objective of this study was to critically evaluate the initial experience with the Swiss LithoClast® Trilogy lithotrite during PCNL.

Methods:

Study Overview

After institutional review board approval, we performed a prospective trial evaluating the Swiss LithoClast® Trilogy lithotrite in human patients at three institutions (Indiana University, IRB #1807352316; University of California San Diego, IRB #190883; University of California Davis, IRB #1304925). The number of patients included at each site is presented in Table 1. Each site obtained IRB approval, and data for all institutions was stored and analyzed at Indiana University using a secure web database REDCap server[10].

Patient Enrollment

Enrollment occurred at the time of the initial clinic consultation. We enrolled patients at least 18 years of age who were able to provide informed consent. Patients were included if they had a total stone diameter of 15 mm measured in any single plane (axial, coronal, or sagittal) and were planning for surgical management of their stone disease using PCNL. Patients with bilateral stone disease were included, and individuals requiring bilateral PCNL had both sides treated with the Trilogy device. Patients undergoing contralateral ureteroscopic retrograde stone removal (URS) were also included.

PCNL Technique

Percutaneous renal access was obtained by the urologist at each site unless the patient had an indwelling nephrostomy tube placed prior to surgery for urgent decompression. The urologist was allowed to obtain new and multiple access sites if deemed necessary for successful case complication.

When the urologist obtained percutaneous renal access, either fluoroscopic or ultrasound-assisted fluoroscopic renal puncture was utilized. Percutaneous renal access was maintained using either a 30F nephrostomy sheath for standard PCNL or a 17.5F sheath for mini-PCNL.

Cases for standard PCNL were performed using 3.9 mm x 350 mm and 3.9 x 440 mm probes. Mini-PCNL was performed using 1.5 mm x 440 mm probes. Figure 1 contains representative intra-operative images of the Trilogy hand piece, generator, and foot pedal.

Stone Size Measurements

The stone surface area was calculated with two-dimensional axial imaging. The total stone length and width was determined by the principal investigator at each site, and the stone surface area was then calculated in millimeters squared mm^2 using the formula for surface area of a an ellipse ($\pi \times r_1^2 \times r_2^2$).

Outcomes Assessed

The Trilogy device allows variability in ultrasound energy (0-100% scale), presence or absence of electromagnetic ballistic energy (0-100% scale), ballistic rate (1-12 Hz), and suction intensity (1-100 scale, 100 = the highest). The settings used for the majority of each case were recorded for analysis, although the surgeon could change settings during each case to find the optimal settings for the target stones.

Each surgeon evaluated the following subjective parameters from each case related to use of the lithotrite on a 1-10 scale (10 being Extremely Effective): ergonomics, ultrasound effectiveness, ballistic effectiveness, combination ultrasound and ballistic effectiveness, suction effectiveness, ease of set up prior to procedure, ease of troubleshooting, and ease of settings management. Further, all surgeons compared Trilogy to their usual lithotrite on a 1-5 scale (1 = much worse, 3 = the same, and 5 = much better). Stone clearance time, stone clearance rate, device malfunction, stone-free rate, and complications were collected. At each site, stone clearance time was recorded with a stopwatch only during the times of pedal activation of the Trilogy. Stone free assessment (defined as no stones seen) was determined with a CT scan, KUB, or ultrasound either on postoperative day 1 or at follow up outpatient visit (1-8 weeks postoperatively).

Results:

We included all 43 patients who were initially enrolled, and did not have to exclude any patients. Patient inclusion by location is described in Table 1, with 7 (16.3%) bilateral cases for a total of 50 renal units. One case was successfully completed as a mini-PCNL, and one mini-PCNL was converted to standard PCNL. The mean highest ultrasound setting was 92%, mean highest ballistic frequency was 6 Hz, and mean highest suction was 55%. Thirty-nine patients had cases completed with manufacturer-suggested ballistic energy of 80%, and four cases utilized variable ballistic energy levels throughout each case.

Two cases experienced device malfunctions through which the team was able to troubleshoot, and no case required transition to another lithotrite. One malfunction was a breakage of a 1.5 mm diameter probe during mini-PCNL, and the case was ultimately transitioned to a standard PCNL with a 3.9 mm diameter probe. The second malfunction

was clogging of the suction tubing, which was able to be unclogged by the surgical team and did not require any new suction tubing or other device parts.

The mean stone clearance rate was 68.9 mm^2/minute. Of the 37 patients with postoperative imaging available for review, the stone-free rate was 67.6% (n=25). The lowest subjective rating was the ergonomics score of 6.7, and the highest subjective rating was the ease of managing settings score of 9.2. Importantly, the surgeon impressions of ultrasound (7.3), ballistic (8.1), combination of ultrasound and ballistic (8.7), and suction (8.4) were high. The question that asked surgeons to compare Trilogy to their contemporary lithotrite demonstrated average score 3.6 on a 5-point scale, with 3 representing “the same” and 4 representing “slightly better.”

One patient experienced an intraoperative renal pelvis perforation, one patient required a blood transfusion, one patient had a pneumothorax requiring chest tube placement, and one patient had a renal artery pseudoaneurysm requiring endovascular embolization; the latter three complications were attributed to the percutaneous renal access, and not to the Trilogy device. The renal pelvis perforation likely occurred during the balloon dilation portion of the percutaneous access and was recognized upon the initial insertion of the nephroscope, and did specifically appear to be related to difficulty handling the Trilogy device or other difficulty with the nephroscope. Fortunately the case was successfully completed and this perforation was managed with nephroureteral stent placement for two weeks, after which time an antegrade nephrostogram revealed no leak so the nephroureteral stent was removed without further complications.

Discussion:

We completed a multi-institutional *in vivo* assessment of the EMS Swiss LithoClast® Trilogy lithotrite. This study included both objective and subjective device assessments to provide a thorough evaluation of device performance and surgeon experience.

The most notable finding of this study is the rapid stone clearance rate of 68.9 mm^2/minute by this device. Previously, the Olympus LUS-II appeared to have a faster stone clearance rate of 75.9 mm^2/minute when compared to Cyberwand (61.9 mm^2/minute)[6] in a multi-centered, randomized trial. Interestingly, this stone clearance rate is substantially

higher than previously-reported clearance rates for the LUS-II at 16.8 mm^2/minute in a much older study from 2003[11]. Given the time difference, this may represent advances overall in PCNL, which could both directly and indirectly impact stone clearance. York et al[8] more recently reported the stone clearance rates of three commonly-utilized lithotrites in a multi-center, randomized-controlled trial comparing the EMS LithoClast® Select, Olympus Cyberwand, and StoneBreaker (paired with the Olympus LUS-II). In this study, the adjusted clearance rates were 28.5, 31.1, and 25.9 mm^2/minute, respectively, for each device. Although the stone surface area was smaller in our present study (surface areas were 408-628 mm^2), this may suggest a faster rate of stone clearance with Trilogy over these other devices. However, it should be noted that the stone clearance time in that study included time spent removing stones using means other than the lithotrite, which may at least in part explain the much slower clearance times. Interestingly, Sabnis et al[12] recently reported a remarkably rapid stone clearance rate of 230 mm^2/min with Trilogy in 31 human patients, which included both standard and mini-PCNL. It is unclear exactly how the stone clearance time was calculated, but this would suggest a very efficient rate of stone clearance.

Another single-probe ultrasonic device (UreTron) touts a 51.9 mm^2/minute stone clearance rate in human studies[7]. This study used the same technique as that of our present study for calculating stone clearance time, such that clearance time was recoded with a stopwatch while from the moment of lithotrite activation during rigid nephroscopy until the time when the surgeon transitioned from rigid to flexible nephroscopy. While efficient, the rate of the UreTron was still less than what we observed of Trilogy in the present study.

Benchtop testing of Trilogy has also demonstrated similarly efficient stone clearance. Carlos et al[9] evaluated three EMS lithotrites (Trilogy, Select-US, and Select-USP) and the Olympus ShockPulse in a lab environment using a Begostone model. Trilogy was twice as fast in clearance testing compared to ShockPulse and the other devices, which was statistically significant. However, the Trilogy device did not independently outperform other lithotrites during the drill testing phase of the study. The ShockPulse device is currently being compared to Trilogy in a formal trial setting (clincaltrials.gov identifier:

NCT03959683)[13], and this data will certainly be of value given the higher reported stone clearance rate than some of the other devices mentioned above. However, the historic data for the ShockPulse is still not as rapid as Trilogy in this current study. Taken together, these data suggest that Trilogy offers comparatively efficient stone clearance in practice.

While Trilogy objectively appears to fragment efficiently, the surgeon assessments give a mixed picture of efficacy. Assessments of ultrasound, ballistics, combination, and suction effectiveness ranged from 7.3 to 8.7 out of a 10-point scale, suggesting that surgeons generally felt the device performed effectively. However, the question comparing Trilogy to the surgeon's current lithotrite suggested surgeons felt Trilogy was perceived between "the same" and "slightly better" than their current lithotrite. As reviewed above, Trilogy appears to efficiently fragment and remove stone better than other available devices, but other lithotrites of the modern era still offer reasonably efficient stone fragmentation. Another piece of data not to be ignored is the surgeon assessment of ergonomics, which averaged 6.7 out of 10. This metric was the lowest rating of all variables assessed. The Trilogy handpiece has a bulkier, heavier frame than other devices, weighing 1200 grams, which may at least partially explain the overall impression.

A key element to the surgeon's experience and to efficient surgical care is the reliability of a given technology. In the previous comparisons mentioned above evaluating CyberWand, LUS-II, UreTron, StoneBreaker, and LithoClast®, reported malfunction rates ranged from 9-32%, with most falling between 11-17%[6–8]. In the present study, we observed only 2 device malfunctions out of 43 (4.7%). While device malfunctions mentioned in both the present and prior studies may not cause early termination of a case and can easily be overcome, they still disrupt the workflow, add additional time to an operative case, and can cause frustration among the surgical team.

In addition to reliability, device safety is vitally important. Fortunately this device appears to be reasonably safe both in benchtop and clinical settings. A recent study by Khoder et al[14] compared bladder urothelial damage incurred by three lithotrites: Storz Calculson, Swiss LithoClast® Vario, and Trilogy. They observed no difference in urothelial damage when evaluating the histologic epithelial changes, leukocyte infiltration, vascular

congestion, and edema 7 days postoperatively in a porcine model. Clinically, Sabnis et al[12] observed no device-related complications in their trial of 31 patients using Trilogy. Taken with our data in which we observed minimal tissue damage with the device, this device appears to have a favorable safety profile.

This study does have limitations. Although it is prospective in design and historical comparisons to other devices are available, this was not a randomized or otherwise directly comparative trial. Fortunately, historical data comparing currently-available devices has been published relatively recently and contains high quality data with similar outcome parameters, making the comparison more valid. As stated above, there is an ongoing multi-institutional, randomized clinical trial (clincaltrials.gov identifier: NCT03959683) comparing Trilogy to the Olympus ShockPulse-SE at the time of this manuscript writing[13], to which one of the sites in this present study is actively contributing additional patients. This study also includes all patients with any stone type who met inclusion criteria, and does not more finely specify if patients with certain stone types or other patient variances may have differences in outcomes. Differing outcomes may be seen in hard stones, matrix-containing stones, or a large burden of stone sediment.

Conclusions:

This multi-institutional study evaluated a new and efficient combination lithotrite that was perceived by surgeons to be highly satisfactory, with an excellent safety and durability profile.

Disclosures:

RL Sur is a speaker for Boston Scientific, a speaker for Cook medical, on the advisory board for Retrophin, a speaker for Karl Storz, and the chief medical officer for Kalera Medical.

NE Canvasser is a consultant for Boston Scientific, a consultant for BD Medical, and a consultant for Cook medical.

AE Krambeck is a consultant for Boston Scientific.

No other authors have anything to disclose.

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Table 1. Principal investigator and number of patients at each study location.			
Location	Principal Investigator	Number (%) of Patients	Number of Bilateral Cases
Indiana University	Amy E. Krambeck	25 (58.1)	4
University of California San Diego	Roger L. Sur	14 (32.6)	2
University of California Davis	Noah Canvasser	4 (9.3)	1

Table2. Patient demographics and perioperative outcomes for the initial Swiss LithoClast® Trilogy Experience (n = 43 patients and 50 renal units).	
Mean (SD) Age in Years on Date of Surgery	59 (18)
Mean (SD) BMI	32.3 (10.8)
Mean (SD) ASA Score	2.8 (0.8)
Female Sex, n (%)	22 (51.2)
Left Sided Only, n (%)	25 (58.1)
Bilateral PNL, n (%)	7 (16.3)
Mean (SD) Maximal Stone Diameter in Millimeters	22 (12)
Mean (SD) Stone Surface Area in Millimeters^2	345 (387)
Mean (SD) Stone Hounsfield Units	780 (362)
Mean (SD) Stone Clearance Time in Minutes	9.3 (10.1)
Mean (SD) Stone Clearance Rate in Millimeters^2/Minute	68.9 (108.4)
Mean (SD) Highest Ultrasound Setting	92 (15)
Mean (SD) Highest Ballistic Frequency in Hz	6 (3)
Mean (SD) Highest Suction Setting	55 (11)
Mean (SD) Ergonomics Impression Score (1-10, 10 = Extremely Comfortable)	6.7 (1.4)
Mean (SD) Impression of Ultrasound Effectiveness (1-10, 10 = Extremely Effective)	7.3 (1.7)
Mean (SD) Impression of Ballistic Effectiveness (1-10, 10 = Extremely Effective)	8.1 (1.4)
Mean (SD) Impression of Combination Effectiveness (1-10, 10 = Extremely Effective)	8.7 (1.2)
Mean (SD) Impression of Suction Effectiveness (1-10, 10 = Extremely Effective)	8.4 (1.0)
Mean (SD) Overall Impression of Trilogy Relative to Usual Lithotriptor (1-5, 1 = much worse, 2 = slightly worse, 3 = the same, 4 = slightly better, 5 = much better)	3.6 (1.0)
Device Malfunctions, n (% of patients)	

Handpiece	0
Probe	1 (2.3)
Suction	1 (2.3)
Other	0
Need to Use Another Lithotrite, n	0
Mean (SD) Impression of Ease of Set Up before Procedure (1-10, 10 = Extremely Easy)	8.3 (1.4)
Mean (SD) Impression of Ease of Troubleshooting (1-10, 10 = Extremely Easy)	8.6 (1.1)
Mean (SD) Impression of Ease of Managing Settings (1-10, 10 = Extremely Easy)	9.2 (0.7)
Patients with No Stones Present on Postoperative Imaging, n (%)	25/37 (67.6)
Complications, n (%)	
Renal Pelvis Perforation	1 (2.3)
Blood Transfusion	1 (2.3)
Pneumothorax Requiring Chest Tube Placement	1 (2.3)
Renal Artery Pseudoaneurysm	1 (2.3)

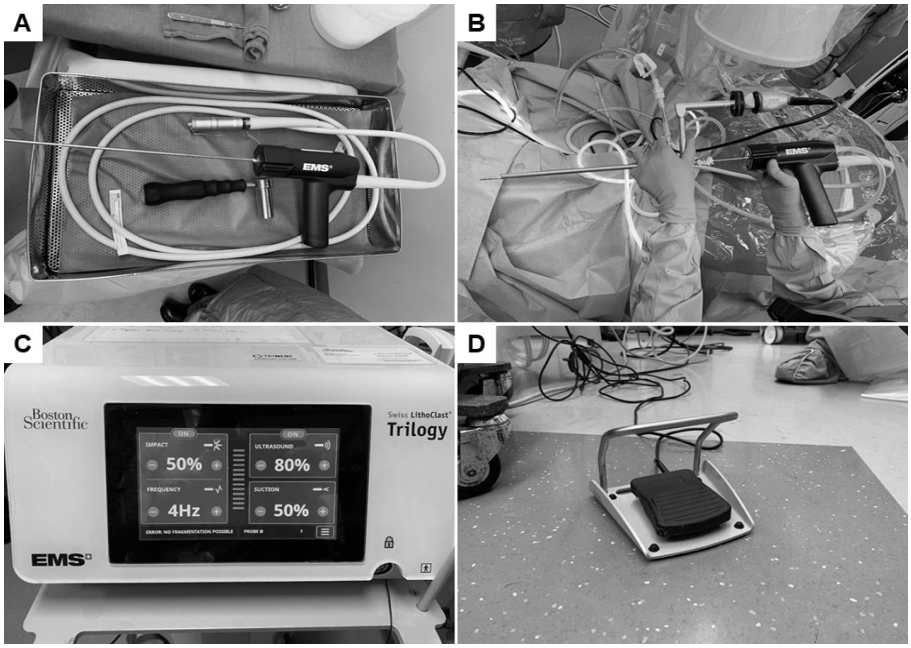

Figure 1. Photographs of the Swiss LithoClast® Trilogy (**A**) handpiece with wrench below and attached 3.9 mm x 440 mm probe, (**B**) inserted through a nephroscope, (**C**) generator with touch-screen display, and (**D**) foot pedal.