Multi-Institutional Prospective Randomized Control Trial of Novel Intracorporeal Lithotripters:
ShockPulse-SE vs Trilogy Trial

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Abstract

Introduction: Currently, there are multiple intracorporeal lithotripters available for use in percutaneous nephrolithotomy (PCNL). This study aimed to evaluate the efficiency of two novel lithotripters: Trilogy and ShockPulse-SE.

Materials and Methods: This is a prospective multi-institutional randomized trial comparing outcomes of PCNL using two novel lithotripters between February 2019 and June 2020. The study assessed objective measures of stone clearance time, stone clearance rate, device malfunction, stone-free rates, and complications. Device assessment was provided through immediate postoperative survey by primary surgeons.

Results: There were 100 standard PCNLs completed using either a Trilogy or ShockPulse-SE lithotrite. Using quantitative Stone Analysis Software to estimate stone volume, the mean stone volume was calculated at 4.18 ± 4.79 and 3.86 ± 3.43 cm³ for the Trilogy and ShockPulse-SE groups, respectively. Stone clearance rates were found to be 1.22 ± 1.67 and 0.77 ± 0.68 cm³/min for Trilogy vs ShockPulse-SE (p = 0.0542). When comparing Trilogy to ShockPulse-SE in a multivariate analysis, total operative room time (104.4 ± 48.2 minutes vs 121.1 ± 59.2 minutes p = 0.126), rates of secondary procedures (17.65% vs 40.81%, p = 0.005), and device malfunctions (1.96% vs 34.69%, p < 0.001) were less, respectively. There was no difference in final stone-free rates between devices.

Conclusion: Both the Trilogy and ShockPulse-SE lithotripters are highly efficient at removing large renal stones. In this study, we noted differences between the two devices including fewer device malfunctions when Trilogy device was utilized. Clinical Trial ID number: NCT03959683

Keywords: nephrolithiasis, percutaneous nephrolithotomy, lithotripter

Introduction

Intracorporeal lithotripters are essential equipment for the success of percutaneous nephrolithotomy (PCNL),1 which is the recommended monotherapy for the management of stones ≥2 cm and lower pole stones >1 cm, that PCNL be the preferred monotherapy because of the highest stone-free rates (SFRs).1,2 A variety of lithotripters have been developed that use ballistic, ultrasonic, and laser energy to fragment stones.3-5 The ShockPulse-SE (Olympus, Center Valley, PA, USA) lithotripter has been widely adopted since its introduction in the United States in 2017. ShockPulse-SE has a unique ultrasonic generator that produces a ballistic force (300 Hz) and in inanimate studies, Carlos and
colleagues demonstrated superior stone clearance compared with the LUS-2™ (Olympus), Cyber-Wand™ (Olympus), and LithoClast™ (Nyon, Switzerland) devices.6

In 2018, EMS and Boston Scientific codeveloped and launched a dual-energy (ultrasonic/ballistic 12 Hz) single-probe lithotripter named Trilogy. Multiple bench6 and limited surgical evaluations2–9 have been published demonstrating exceptional lithotripsy potential; however, a comparison with currently utilized lithotrities has not yet been performed. The purpose of this article is to compare Trilogy with the ShockPulse-SE system in a prospective randomized multicenter clinical trial.

In prior studies,3,4,10 the primary metric for lithotripsy efficiency has been stone clearance rate (mm²/min). Quantifying stone burden is clinical beneficial for surgical planning and from a research perspective to compare the most efficient modes of stone clearance. In collaboration with the Mayo Clinic–Rochester, MN we incorporate a novel software adjunct to objectively quantify total stone burden (cm³) and stone characteristics (HU) on a noncontrasted CT.11 This is the first comparative trial, to our knowledge, to use this type of program to measure the stone volume to calculate clearance rates (cm³/min) between two lithotriters. We hypothesize that both the Trilogy and ShockPulse-SE lithotripter will demonstrate superior stone clearance rates compared with previous lithotriters and that for larger harder stones, Trilogy will preserve clearance rates compared with the other lithotriters.

Materials and Methods

After institutional review board approval at all institutions (IRB: 1807352316), we performed a prospective multi-institutional randomized control trial comparing two novel lithotriters: Swiss LithoClast® Trilogy (EMS—Nyon and Boston Scientific Marlborough, MA, USA) and ShockPulse-SE (Olympus). After consent was obtained to undergo PCNL and the surgeon identified a patient as an appropriate candidate for the trial based on stone size and inclusion or exclusion criteria, the patient was enrolled and randomized to a lithotripter by a dedicated clinical research assistant in a 1:1 ratio with either the Trilogy or ShockPulse-SE lithotripter established by our biostatistician using RedCap.

We included patients >18 years with stones ≥20 mm in diameter based on standard preoperative CT imaging or >15 mm in a lower pole stone. Stone size was established by measuring greatest diameter of contiguous stone material in the axial series by the primary surgeon and confirmed to be accurate based on the radiographic read. Stone surface area (SA) (mm²) was measured by the surgeon. Preoperative stone characteristics, including stone volume (cm³), HU, and number of stones, were objectively recorded using quantitative Stone Analysis Software (qSAS) developed by the CT Clinical Innovation Center (Rochester, MN, USA).10

Patient demographics, medical and stone history, peroperative findings, and postoperative outcomes were prospectively recorded in an encrypted RedCap database. Patients were excluded if they were pregnant, had an untreated urinary tract infection, were anticipated to need a multiaccess PCNL, or had prior shockwave lithotripsy within 3 months of anticipated PCNL. Percutaneous renal access was obtained by the urologist unless the patient had an indwelling nephrostomy tube. The decision for location of percutaneous accesses and patient positioning was at the surgeon’s discretion.

All procedures were performed by seven surgeons at three high-volume tertiary stone institutions where ShockPulse-SE was the institutional lithotripter of choice for >24 months. Before enrolling in the study, each surgeon was required to have performed at least 10 PCNLs with both lithotriters to ensure proficiency with each device. Permitted access sheaths ranged from 24 to 30F to accommodate the 11.7/9.5-F × 350–440 mm Trilogy, 11.3/9.9-F × 396 mm ShockPulse-SE probes and 24-F rigid nephroscopes. All intraoperative data were entered through an immediate postoperative RedCap survey completed by the operating surgeon. The survey recorded total lithotripsy time, any device malfunctions, and a device assessment, including overall surgeon satisfaction using a 10-point Likert scale.

Stone clearance times were recorded by research personnel with a stopwatch starting from the moment the lithotripter was first activated on the target stone until the stone was removed and the surgeon switched to flexible nephroscopy. In the event lithotripsy was restarted after inspection of the collecting system by flexible nephroscopy; timing resumed. Total operative room (OR) time was calculated using only unilateral percutaneous procedures without pre-existing renal access and was established from the time of intubation to the surgery stop time designated before extubation.

All patients received a postoperative CT scan of the abdomen and pelvis to evaluate for residual stone burden and any injury to surrounding structures. The management of residual stone fragments was left to surgeon preference. Secondary procedures for stone removal were recorded along with postoperative outcomes, including complications using the Clavien–Dindo scale and were classified as immediate postoperative or delayed (90-day) complications. The risk of postoperative infectious complications was assessed using the quick Sequential Organ Failure Assessment (qSOFA) scoring system because of a recent Endourology Disease Group Excellence (EDGE) publication demonstrating a high prediction for infection-related complications after PCNL.12

Clinic follow-up appointments at 6–12 weeks provided SFRs through kidney, ureter, and bladder radiograph, and ultrasound and delayed complications. Postoperative stone analyses were designated as hard (Brushite and calcium oxalate monohydrate) or soft (hydroxyapatite, struvite, calcium oxalate dihydrate, and uric acid) based on the >50% stone composition. Statistical analysis was performed by a biostatistician from the department of statistics at Indiana University. Student’s t-test with a power of 90% and a significance level of alpha = 0.05 was used to perform a power analysis. The primary outcome of interest was the clearance rate of the targeted stone burden. Preliminary in vitro data showed a reduction of ~50% in the mean lithotripter clearance time of a 1 cm³ BegoStone for the Trilogy lithotrite compared with the ShockPulse-SE. Given the increased variability of use in vivo and across subjects, a more conservative difference was considered for sample size estimation. Assuming a 25% improvement in clearance rate that results in an effect size of 0.7, a sample size of 44 subjects in each group is required. To account for the possibility of unevaluable data a total of 100 patients were enrolled to quantify differences in lithotripsy potential by each lithotripter. A multivariate analysis for the impact stone volume, number, hardness, and type of lithotripter had on clearance time, operative time, and secondary procedures was performed.
Results

Between February 2019 and June 2020, 100 patients with a target kidney stone ≥1.5 cm underwent PCNL using either Trilogy (n = 51) or ShockPulse-SE (n = 49). Men represented 39.2% vs 32.5% (p = 0.678) for each group, respectively. There was no difference in mean age at treatment 59.6 ± 14.8 years vs 60.4 ± 16.2 years, and body mass index 33.4 ± 12.3 kg/m² vs 32.5 ± 10.1 kg/m² for Trilogy vs ShockPulse-SE, respectively (p ≥ 0.5). There were no differences with laterality of the procedure between groups. The mean volume of the target stone was 4.18 ± 4.79 cm³ vs 3.86 ± 3.43 cm³ (p = 0.713) for Trilogy vs ShockPulse-SE. SA (mm²) and HU were similar between groups and are reported in Table 1.

Table 2 summarizes perioperative outcomes, including change in hemoglobin (−1.52 ± 1.6 vs −1.59 ± 3.26, p = 0.407) and transfusion rate (1.96 vs 4.08%, p = 0.613), for Trilogy and ShockPulse-SE. Stone clearance rates were calculated with both SA (101.3 ± 92.5 mm²/min vs 83.7 ± 69.3 mm²/min, p = 0.292) and volume (1.22 ± 1.67 cm³/min vs 0.77 ± 0.68 cm³/min, p = 0.054) for Trilogy and ShockPulse-SE, respectively. On a multivariate analysis of clearance time (minutes; Table 4) accounting for stone size, number, hardness, and lithotripter type, Trilogy was found to have a significant reducing effect (−0.450 [−0.110 to −0.788]; 95% confidence interval; CI, p = 0.021). Similarly, total OR time was shorter (104.4 ± 48.2 minutes vs 121.1 ± 59.2 minutes, p = 0.126) and with significant effect on multivariate analysis (−36.03 [−6.64 to −65.41]; 95% CI, p = 0.017) assessing for the same variables as aforementioned.

Eleven percent of the cases were completed as an outpatient procedure. Of those admitted, the majority of those discharged were within 24 hours of the primary PCNL (68.6% vs 59.2%, p = 0.243). Mean length of stay was 1.29 ± 1.47 vs 1.27 ± 1.18 (p = 0.931) with residual stone fragments on CT >4 mm (16.6% vs 24.5%; p = 0.302) being the most common reason for prolonged hospitalization in the Trilogy and ShockPulse-SE groups, respectively. Postoperative complications were rare (7.84% [4] vs 4.08% [2]; p = 0.678 Trilogy and ShockPulse-SE) with one Clavien–Dindo IIIb for a hemorrhotax requiring an anesthetic for an Interventional Radiology-placed chest tube for 48 hours, and one IVa for respiratory insufficiency requiring reintubation and a 72-hour Intensive Care Unit stay. Complications from the time of discharge to 90 days postop were also rare but did include four (4%) grade IIIa events, including two additional anesthetics to place retrograde stents for a premature dislodged nephrostomy tube and for a persistent urine leak. The remaining two complications included a delayed gastrointestinal bleed and pyelonephritis requiring readmission. Patient follow-up rates (63.3% vs 66.7%, p = 0.832) and the breakdown of stone types were similar, including stone hardness, and are reported in Table 2. Final SFRs were calculated using postoperative CT, effective stone clearance after secondary stone procedure, and follow-up imaging at 6 weeks, and were estimated at 90.2% and 89.8% for Trilogy vs ShockPulse-SE (p = 0.758), respectively. Device assessment and surgeon satisfaction are reported in Table 3. There was a higher number of device malfunctions in the ShockPulse-SE group (17) 34.69% compared with the Trilogy group (1) 1.96%, which was statistically significant (p ≤ 0.001). There was no difference in overall surgeon satisfaction between devices.

Discussion

The Trilogy and ShockPulse-SE lithotripters represent major technologic advances that improve the efficiency and safe removal of complex calculi from the collecting system. To date there is limited clinical data on both systems and no head-to-head comparison. This is the first prospective randomized trial to provide clinical data on patient outcomes, surgeon experience, and benefits afforded by either device. The primary endpoint was stone clearance rates. Previous publications on earlier lithotripters suggest a range of stone clearance rates (mm²/min), including 16.8–75.9 (LUS-II), 25.9 (StoneBreaker), 31.1–61.9 (Cyberwand), and 51.9 (UreTron).3–5 Interestingly, ShockPulse-SE has no published data on in vivo stone clearance rates, but has been shown in bench models to outperform the aforementioned lithotripters.14 In our study, we found clearance rates of 101.3 ± 92.5 mm²/min for Trilogy and 83.7 ± 69.3 for ShockPulse-SE (p = 0.292); both being far superior to prior studied lithotripters. A recent publication suggested that clearance rates based on stone volume are more representative of stone lithotripsy potential.6 Using qSAS to calculate stone volume, we demonstrated clearance rates of 1.22 ± 1.67 and 0.77 ± 0.68 cm³/min (p = 0.054) for Trilogy vs ShockPulse-SE.
## Table 2. Outcomes

|                     | Trilogy (N = 51) | ShockPulse (N = 49) | p     |
|---------------------|-----------------|---------------------|-------|
| **Outpatient vs admitted (% OP)** | 13.7% (7)       | 8.2% (4)            | 0.526 |
| **Was this patient on anticoagulation (% yes)** | 11.8% (6)       | 18.4% (9)           | 0.410 |
| **Was it discontinued? (% yes)** | 100%            | 100%                |       |
| **Positive preoperative urine culture? (%)** | 49.0% (25)      | 55.1% (27)          | 0.556 |
| **Preoperative hemoglobin (g/dL)** | 12.9 ± 2.0      | 13 ± 2.1            | 0.801 |
| **Preoperative creatinine (mg/mL)** | 1.0 ± 0.4       | 1.0 ± 0.46          | 0.739 |
| **ASA score**       | 2.7 ± 0.5       | 2.7 ± 0.6           | 0.802 |
| **Was this patient’s GU anatomy normal? (% yes)** | 80.4% (41)      | 79.6% (40)          | 1.000 |
| **Study side access location (% LP)** | 38.3% (20)      | 53.2% (25)          | 0.210 |
| **Duration of case (minutes from induction of anesthesia to end of anesthesia)** | 104.4 ± 48.2    | 121.1 ± 59.2        | 0.126 |
| **Was the case aborted? (% yes)** | 1.9% (1)        | 2.0% (1)            | 1.000 |
| **Clearance time of targeted stone (minutes)** | 5.8 ± 6.3       | 6.7 ± 6.2           | 0.481 |
| **Clearance rate SA (mm²/min)** | 101.3 ± 92.5    | 83.7 ± 69.3         | 0.292 |
| **Clearance rate volume (cm³/min)** | 1.22 ± 1.67     | 0.77 ± 0.68         | 0.054 |
| **Average hospital LOS (days)** | 1.3 ± 1.5       | 1.3 ± 1.2           | 0.931 |
| **LOS traversed >1 midnight (% no)** | 31.4% (16)      | 40.8% (20)          | 0.302 |
| **Residual stone (%)** | 50.0% (8)       | 75.0% (15)          |       |
| **Sepsis (%)**      | 6.3% (1)        | 5.0% (1)            |       |
| **Bleeding (%)**    | 6.3% (1)        | 10.0% (2)           |       |
| **Respiratory (%)** | 6.3% (1)        | 5.0% (1)            |       |
| **Organ complication (%)** | 6.3% (1)      | 5.0% (1)            |       |
| **Debilitation (%)** | 12.5% (2)       | —                   |       |
| **Placement (%)**   | 18.8% (3)       | —                   |       |
| **Postoperative hemoglobin (g/dL)** | 11.3 ± 1.9     | 11.4 ± 2.1          | 0.981 |
| **Change in hemoglobin (g/dL)** | −1.5 ± 1.6     | −1.6 ± 3.3          | 0.111 |
| **Postoperative creatinine (mg/mL)** | 1.2 ± 0.5       | 1.2 ± 0.6           | 0.635 |
| **Postoperative WBC** | 11.2 ± 3.8     | 12.2 ± 4.2          | 0.227 |
| **Did the patient spike a fever overnight? (% yes)** | 1.9% (1)        | —                   |       |
| **Postoperative qSofa 1** | 90.0% (45)     | 77.6% (38)          |       |
| **Postoperative qSofa 2** | 10.0% (5)       | 16.3% (8)           |       |
| **Postoperative qSofa 3** | 0               | 2.1% (1)            |       |
| **Postoperative qSofa 4** | 0               | 0                   | 0.242 |
| **Transfusions**    | 2.0% (1)        | 4.1% (2)            | 0.614 |
| **Postoperative CT stone free? (% yes)** | 56.0% (28)      | 42.9% (21)          | 0.105 |
| **<2 mm (%)**       | 18.0% (9)       | 18.4% (9)           | 0.978 |
| **2–3 mm (%)**      | 8.0% (4)        | 10.2% (5)           | 0.779 |
| **4–10 mm (%)**     | 12% (6)         | 22.4% (11)          | 0.056 |
| **>10 mm (%)**      | 6.0% (3)        | 6.1% (3)            | 0.824 |
| **Postoperative hospital-associated complications** | 9.8% (5)       | 10.2% (5)           | 0.678 |
| **I**               | 40.0% (2)       | 80.0% (4)           |       |
| **II**              | 40.0% (2)       | 0% (0)              |       |
| **IIa**             | 20.0% (1)       | 0% (0)              |       |
| **Iva**             | 0%              | 20.0% (1)           |       |
| **Secondary procedure performed for residual stone fragment(s)** | 17.7% (9)     | 34.7% (17)          | 0.005 |
| **Stone culture positive (%)** | 45.6% (23)      | 44.2% (21)          | 1.000 |
| **Stone free? (% yes)** | 90.2% (46)     | 89.8% (44)          | 0.758 |
| **Outpatient follow-up imaging?** | —               | 52.9% (27)          | 0.167 |
| **US and KUB**      | 52.0% (27)      | 32.6% (21)          |       |
| **US**              | 27.5% (14)      | 14.3% (7)           |       |
| **CT**              | 32.0% (16)      | 42.9% (21)          |       |
| **None**            | 21.6% (11)      | 28.6% (14)          |       |
| **Did patient come to clinic for follow-up? (% yes)** | 63.3% (32)     | 66.7% (33)          | 0.832 |
| **Stone free? (% yes)** | 90.2% (46)     | 89.8% (44)          | 0.758 |

(continued)
Despite the overall satisfaction with the device? 8.7 ± 0.9 8.4 ± 1.8 0.340

Secondary procedures performed was found to be statistically significant with a p < 0.05 on t-test.
Trilogy has a bulky handpiece, but this finding is not supported in the surgeon satisfaction evaluation. The novel software such as qSAS in future comparative stone studies has the potential to standardize sizing variability. We acknowledge the paucity of data on the validity of the software and understand that our conclusions about stone clearance, as a function of stone volume, would become unsupported if qSAS were to be discredited. Finally, there are concerns over any potential bias given the disclosures of all participating surgeons; however, all surgeons are familiar with ShockPulse-SE and sought to provide objective efficiency, and outcomes data for two available lithotripters using novel stone volume analysis software.

### Table 4. Multivariate Analysis

| Effect               | Estimate | Standard error | p      |
|----------------------|----------|----------------|--------|
| Clearance time (minutes) |          |                |        |
| Lithotripter (Trilogy) | -0.4489  | 0.1705         | 0.010  |
| Stone volume         | 0.09709  | 0.02079        | <0.001 |
| Stone number         | 0.03103  | 0.044          | 0.483  |
| Hard stone           | 0.3006   | 0.1733         | 0.087  |

| Effect               | Operative time (minutes) | p      |
|----------------------|--------------------------|--------|
| Lithotripter (Trilogy) | -36.0259                | 0.017  |
| Stone volume         | 2.4557                   | 0.185  |
| Stone number         | 3.0301                   | 0.437  |
| Hard stone           | 16.5143                  | 0.275  |

| Effect               | Odds ratio | 95% CI     | p     |
|----------------------|------------|------------|-------|
| Secondary procedures | 0.256      | 0.094      | 0.694 | 0.007 |
| Lithotripter (Trilogy)| 1.105      | 0.987      | 1.237 | 0.082 |
| Stone volume         | 1.021      | 0.801      | 1.301 | 0.868 |
| Stone number         | 1.192      | 0.445      | 3.197 | 0.727 |
| Hard stone           | -0.1289    | -0.79      | 0.54  | 0.704 |
| Anticoagulated patient| -0.1289   | -0.79      | 0.54  | 0.704 |

Secondary procedures performed was found to be statistically significant with a $p<0.05$ on $t$-test.

FIG. 1. Graphical representation of stone volume (cm$^3$) and clearance time (minutes) partitioned by lithotripter type.
In conclusion, both the Trilogy and ShockPulse-SE lithotripters are highly efficient at removing large renal stones. In this study, we noted differences between the two devices, including fewer device malfunctions, when Trilogy device was utilized. The efficiency, safety, and reliability of Trilogy optimizes stone clearance rates and OR times for large renal stones. In addition, software, such as qSAS, should be utilized for future comparative studies on stone clearance rates, as it provides a more accurate measurement of the amount of stone material in the collecting system.

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Author Disclosure Statement
Dr. Amy Krambeck is a consultant for Boston Scientific Corporation, Lumenis, and Sonomotion. Dr. Mitchell Humphreys is a consultant for Boston Scientific Corporation and AURIS. Dr. Bodo Knudsen is a consultant for Boston Scientific Corporation, Olympus Surgical, and Becton Dickinson and Company. Dr. Marcelino Rivera and Dr. Tim Large are consultants for Boston Scientific Corporation.

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Abbreviations Used
BMI = body mass index
CT = computed tomography
HU = Hounsfield unit
KUB = kidney, ureter, and bladder radiograph
LOS = length of stay
OR = operating room
PCNL = percutaneous nephrolithotomy
qSAS = quantitative Stone Analysis Software
qSOFA = quick Sequential Organ Failure Assessment
SA = surface area
SFR = stone-free rate