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Endoscopic clearance lithotripsy devices bench comparison of stone elimination capacity and drilling speed

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Abstract

Introduction & Objectives

Several endoscopic stone fragmentation and clearance lithotripsy systems are currently available:

The Swiss LithoClast Master (EMS Switzerland) offers stand-alone ultrasonic lithotripsy and ultrasonic / pneumatic combination lithotripsy with 2 coaxially mounted probes to transmit ultrasonic vibration and impact generated compression waves. The Shockpulse SE (Olympus Germany) transmits ultrasonic vibration and an ultrasonically generated shock through the same hollow probe. The latest development is the Swiss LithoClast Trilogy (EMS Switzerland) employing an ultrasonic lithotripter an electromagnetic impactor to deliver ultrasonic vibration and ballistic impact compression waves though the same hollow probe (single probe / dual energy lithotripter). The objective of this study was to compare stone elimination and drilling speed of this 3 devices in an in-vitro setting.

Methods

10 stone phantom fragmentation and clearance tests were performed under direct view in an underwater hemi-sphere by 5 different operators (totally 50 test runs per device).

1cm³ cube shaped BegoStone phantoms (BegoStone-to-water ratio: 15:3) were used for clearance testing. The average stone removal time per operator and per device was recorded.

For the drilling speed test, a free-hand set-up was used. BegoStones of 15mm size were positioned on one side of an underwater balance and lithotripter probes in direct contact with the phantoms were vertically mounted. A weight of 450g was placed on the other side of the balance to assure a constant contact pressure. The drilling time until breakthrough or the achieved drilling depth after 1 minute if no breakthrough occurred was measured and the resulting drilling speed was calculated. Statistical analysis was performed with ANOVA.

Results:

The Swiss LithoClast Trilogy was clearing the stone phantoms significantly faster than all other devices ($p < 0.001$). The LitoClast Master ultrasound (us) only was similar in clearance time to the ShockPulse SE.

A significant difference ($p < 0.004$) was found between LithoClast Master used in combination mode vs. ultrasound stand alone:

Trilogy: 26,7 seconds, ShockPulse: 37 seconds, LithoClast Master ultrasound (us) only: 37,7 seconds LithoClast Master combined (us +pn): 48,2 seconds.

A similar pattern was seen for the drilling speed, where the LithoClast Trilogy outperformed all other lithotripters ($p<0.05$):

Trilogy: 0.65 mm/sec, ShockPulse: 0.46 mm/sec, LithoClast Master combined: 0.47 mm/sec and LithoClast Master US only: 0.18 mm/sec.

Conclusions

The Swiss LithoClast Trilogy was significantly faster than all other devices in clearing stone phantoms as well as in drilling speed comparison.

Since the other devices use comparable probe sizes and lumen, it seems that the clearance and drilling speed advantage of the LithoClast Trilogy is based on the better performance of the electromagnetic impactor.

Further clinical testing is needed to ascertain safety and efficacy in patients.

Methods

Fragmentation and Clearance Testing:

Bego stone phantoms were produced at the Munich university LIFE center (Bego:Water ratio: 15:3, size: 1cm³, tensile strength: 7MPa). Stones were placed in a hemispherical silicone support inside a water container (Picture 1).

The largest available lithotripter probes were used for the testing to compare maximum clearance capability. All lithotripters were operated using a peristaltic pump set to 40% suction which corresponded to a suction flow of 300 ml / min through the different lithotripter probes and hand pieces. Fragments were collected in a stone fragment separator placed downstream the hand piece before the peristaltic pump connection.

The lithotripter probes were hand guided under direct view. An irrigation sheath with proximal silicone seal was used for supporting guidance of the lithotripter probe. The irrigation port of the sheath was connected to the water return pipe (outlet of the peristaltic pump) to form a closed water circuit.

Cleaning of probe and hand piece after each test run was performed to avoid gradual build-up of obstruction by fragments which could impair the clearance results. For Lithotripter specification see Table 1 and Picture 2. Ten repetitions of the test per lithotripter configuration were performed by 5 different experimenters.

Time until complete fragmentation and evacuation of the stone phantom was recorded.

Statistical analysis was performed with ANOVA

Drilling Speed Testing:

For the drilling speed test, a free-hand set-up was used. BegoStones of 15mm size were positioned on one side of an underwater balance and lithotripter probes in direct contact with the phantoms were vertically mounted. A weight of 450g was placed on the other side of the balance to assure a constant contact pressure. (Pictures 3 and 4). The drilling time until breakthrough or the achieved drilling depth after 1 minute if no breakthrough occurred was measured and the resulting drilling speed was calculated.

Statistical analysis was performed with ANOVA.

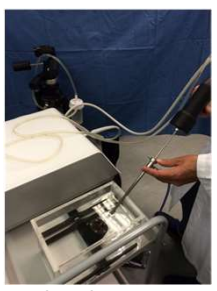
Fragmentation / Clearance and Drilling Speed Testing: Device Settings:

- Swiss LithoClast Trilogy: ultrasonic output: 100%, shockwave output: 70%,12 Hz, suction setting: 40% (300 ml/min), single probe: (⦸ 3.9 mm)
- Olympus ShockPulse SE: High power, suction setting: 40% (300 ml/min), single probe: (⦸ 3.76 mm)
- Swiss LithoClast Master: ultrasonic output: 100%, pneumatic output: 100%, 12 Hz, suction setting: 40% (300 ml/min).
- Swiss LithoClast Master operated in 2 configurations:
  1. Standard ultrasonic lithotripsy: single probe (⦸ 3.8 mm)
  2. Ultrasonic and pneumatic simultaneous combination lithotripsy: dual probe (⦸ 3.8 mm / ⦸1 mm)

EMS LithoClast Trilogy®	Olympus ShockPulse SE®	EMS LithoClast Master®
– single probe/dual energy lithotripsy – probe: (⦸ 3.9 mm) ➢ ultrasonic vibration + electromagnetic impact	– single probe/dual action lithotripsy – probe: (⦸ 3.76 mm) ➢ ultrasonic vibration / shock wave generation	– dual probe simultaneous dual energy lithotripsy – probes: (⦸ 3.8 / ⦸1 mm) – combination hand piece ➢ ultrasonic vibration + pneumatic impact

Tab.1: Lithotripsy devices: Specifications

Pic.2: Set-up: Lithotripsy device armamentarium



Pic.1: Set-up: Stones placed in a hemispherical silicone support inside a water container

Pic. 3: Set-up: Drilling Speed Test

Pic. 4: Set-up: Stones placed in an under-water balance with a 450g weight placed on the other side

Results

Fragmentation and Clearance Testing (Fig. 1)

– The LithoClast Trilogy was significantly faster than all other devices ($p < 0.001$)
– The LithoClast Master combined (us + pn) was by trend slower than all other devices
– The ShockPulse SE was similar to the LithoClast Master ultrasound (us) only

Drilling Speed Testing (Fig. 2)

– The LithoClast Trilogy was significantly faster than all other devices ($p < 0.05$)
– LithoClast Master ultrasound only (us) was significantly slower than all other devices ($p < 0.05$)
– The ShockPulse SE was similar to the LithoClast Master combined (us+ pn)

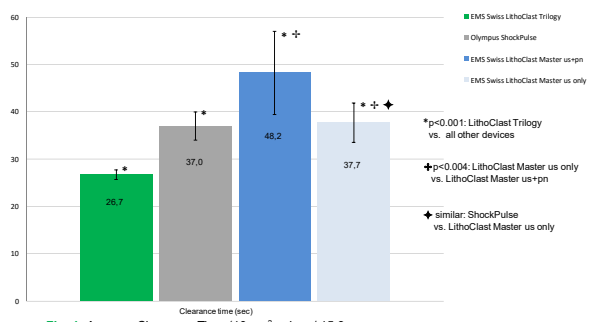


Fig. 1: Average Clearance Time (10mm³ cubes / 15:3 ratio)

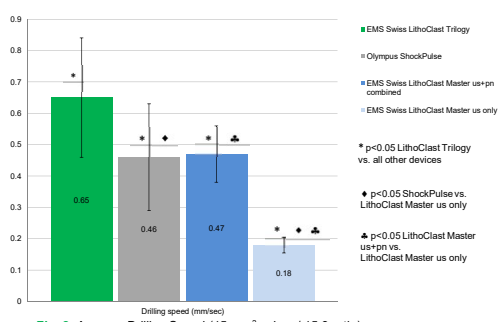


Fig. 2: Average Drilling Speed (15 mm³ cubes / 15:3 ratio)

Conclusions

- ➢ The Swiss LithoClast Trilogy cleared stones faster than all other devices
- ➢ This difference was significant ($p < 0.001$) and independent of test persons
- ➢ The same applied for the drilling speed comparison ($p < 0.05$)
- ➢ There is evidence that the very small standard deviation of Trilogy clearance compared to the relatively large standard deviations of the other devices might show that the Trilogy performs in a more reproducible and stable manner than the other devices.
- ➢ As the Swiss LithoClast Trilogy was always used as first tool per test sequence this could confirm the ease of use and the short learning curve for operating this new device.