

**Final report on the investigation and clinical evaluation of the
LMA STONEBREAKER™.**

This study was carried out on behalf of LMA International NV, HO Jersey, Channel Islands in accordance with standards applicable to the investigating centres.

Objectives:

To evaluate the following properties in the STONEBREAKER™, a new intracorporeal pneumatic lithotripsy device:

- a) Ease of use
- b) Efficacy
- c) Retropulsion
- d) Safety
- e) Satisfaction score.

Subjects:

102 patients with calculus disease of the urinary tract who warranted intracorporeal lithotripsy were treated with the STONEBREAKER™.

Time Frame:

The investigation commenced on 30th May 2005 and ended on 15th December 2005.

Results:

All stones fragmented satisfactorily with minimal retropulsion and no obvious evidence of urothelial tissue trauma.

Conclusions:

The STONEBREAKER™ is a safe, robust and effective intracorporeal lithotripsy device.

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Signature:

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REPORT ON STONEBREAKER™

The STONEBREAKER™ is a novel device invented by the engineers who made the successful Lithoclast™ pneumatic intracorporeal lithotripter. This mono-component hand-held intracorporeal lithotripter is powered by replaceable carbon dioxide cartridges. As a result, this 'second generation' device is much more compact and ergonomic as compared to the Lithoclast™. It also has the advantage of being much more powerful, generating a contact pressure of 29 bar; this enables better pneumatic fragmentation and removal of stones during percutaneous nephrostolithotomy (PCNL), ureteroscopic stone fragmentation (USF) and vesical lithotripsy (VL).

Risk analysis:

The device is an intracorporeal lithotripter, and would be used in the setting where the benefits and precision of controlled stone fragmentation would be of greater benefit than extracorporeal lithotripsy. The device is pneumatically driven; similar devices, such as the Swiss Lithoclast have been used intracorporeally for the last 15 years or so¹⁻³. The devices are broadly similar with regard to clinical, technical and biological parameters; the principles of operation and materials used in the manufacture of the device used to effect stone disintegration are also consonant.

Investigation parameters

The investigation comprised two stages:

1. Animal lab studies
2. Clinical studies

1. Animal lab studies:

Materials and methods:

Multiple gypsum artificial stones (mean length 12.0 +/- 0.5 mm; mean diameter 7.5 +/- 0.1 mm) were placed in the lower porcine ureter of a 48 kg male anaesthetized domestic pig. A 7.2 F Storz semirigid ureteroscope (Karl Storz , Germany) was used for USF using the 1 mm probe attached to the STONEBREAKER™ . The times required for complete stone fragmentation were assessed, and macroscopic evaluation of the ureter was documented. This segment of ureter was harvested and histological examination of the lower ureter to document any evidence of perforation and or tissue reaction was carried out immediately after the experiment. A similar segment of the virgin contralateral ureter was used as a control.

Results:

The Stonebreaker™ achieved complete stone fragmentation of the artificial stones following 5 shocks in each case. Histological examination showed no evidence of significant tissue reaction or perforation.

2. Clinical studies:

On the basis of these results, a decision was taken to evaluate the functional and safety parameters of the STONEBREAKER™ in a human cohort.

Four centres participated in the evaluation trials:

- All India Institute of Medical Sciences, New Delhi, India
- Vedanayagam Hospital, Coimbatore, India
- Mamata Hospital, Mumbai, India
- King George Hospital, Lucknow, India

Local ethical considerations were acted upon as appropriate by the local investigating authorities

The clinical investigation plan was to evaluate the efficacy, safety and satisfaction following uses of the device with a single end-point i.e. intracorporeal fragmentation of the stone to render the patient stone free. The STONEBREAKER™ comes with a number of probes of varying widths; the probe most appropriate for the stone to be dealt with was utilised during the investigation. No modifications of the device were either necessary or performed during the investigation.

Exclusion criteria:

- fulminant urosepsis
- small stones unsuitable for lithotripsy.

Sample size:

102 patients (87 male)

Results:

Clinical centre	Surgeon	URS*	VL**	PCNL***	Total
Bombay	Dr PP Rao	8	1	12	21
Delhi	Prof NP Gupta	9	3	21	33
Lucknow	Prof Dalela	1	0	3	4
Coimbatore	Dr Kandasamy	31	1	12	44
Total		49	5	48	102

Key

* : ureterorenoscopy

** : vesical lithotripsy

*** : percutaneous nephrostolithotomy

Duration of follow up:

All patients were followed up with a plain x-ray to confirm that they were indeed stone free prior to discharge from hospital

All investigations and clinical investigators adhered rigidly to the protocol and no breaches of protocol were identifiable.

Adverse events:

There were no adverse events directly attributable to the device.

Investigation variables:

6 different clinicians used the device.

Clinical evaluation initiation date

October 2, 2005

Clinical evaluation completion date

December 15, 2005

Conclusions

The device is a successor to the Swiss Lithoclast™ and uses the same energy source i.e. compressed CO₂.

This device appears to be much more robust and effective than other currently available pneumatic intracorporeal lithotripsy devices since the number of shocks required is minimal to achieve good fragmentation and render the patient stone free. This parameter is important, bearing in mind that prolonged intracorporeal lithotripsy can result in diminution of vision during the procedure and this could have implications on successful outcome as well as the potential to cause tissue trauma.

The STONEBREAKER™ performed very well with no evidence of tissue trauma or failure to fragment a stone during the study itself; therefore there is a very high benefit to risk ratio.

References:

1. Wadhwa SN, Hemal AK, Sharma RK. Intracorporeal lithotripsy with the Swiss lithoclast. Br J Urol. 1994 Dec;74(6):699-702
2. Denstedt JD, Eberwein PM, Singh RR. The Swiss Lithoclast: a new device for intracorporeal lithotripsy. J Urol. 1992 Sep;148(3 Pt 2):1088-90
3. Schulze H, Haupt G, Piergiovanni M, Wisard M, von Niederhausern W, Senge T. The Swiss Lithoclast: a new device for endoscopic stone disintegration. J Urol. 1993 Jan;149(1):15-8.