OBJECTIVE

The following summarizes the initial clinical results of the Econolith™ EM1000. Clinical data was collected from two medical institutions overseas. The purpose of this information is to evaluate the prevalence of several anatomical locations of urinary stones, patients' demographics, overall and specific effectiveness, and most importantly the incidence of adverse events when using the Econolith™ EM1000.

METHOD

A total of 25 patients were treated with the EM1000 between September 2005 and July 2006. Data was received from two medical centers in Israel: Urology Dept. in Hillel-Yafe Medical Center – Hadera, Israel and Urology Dept. in Haemek Medical Center – Afula, Israel. Both medical centers contributed raw patient data for overall analysis

Patient Distribution

Of 25 patients treated, 20 were treated at the Urological Dept. in Hillel-Yafe Medical Center – Hadera, Israel, and 5 were treated in Haemek Medical Center – Afula, Israel. The treatment distributions among the medical centers are as follows:

Diagram 1 - Patients' Distribution According to Medical Centers

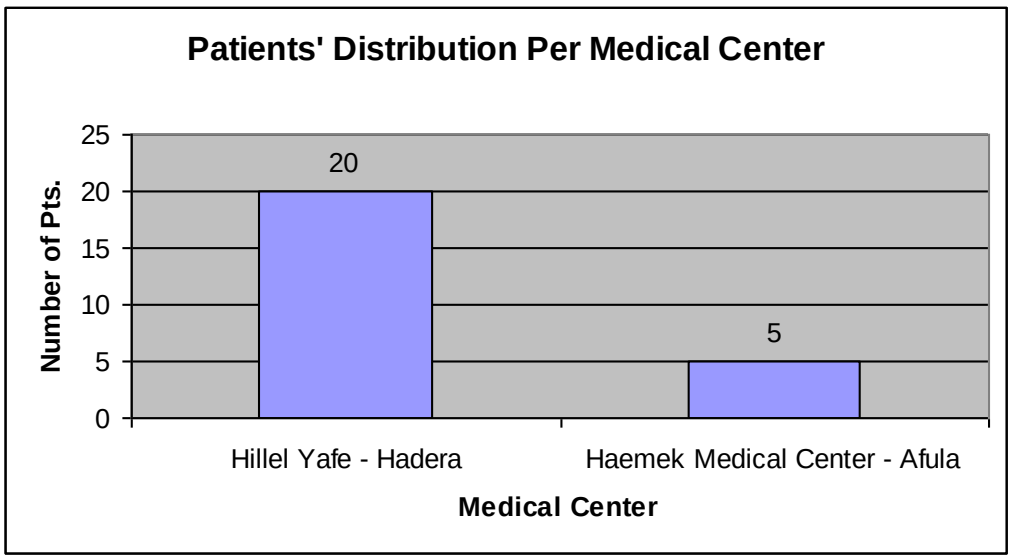


Table 1 - Number of Patients per Medical Center

Site Number	Medical Center	Country	Number of Patients
1	Hillel-Yafe Medical Center – Hadera	Israel	20
2	Haemek Medical Center – Afula	Israel	5

Demographics

Age

The average age of the patients amongst the two medical centers was 54.04 years of age (n=25).

Gender

The gender distribution made up of 48% male and 52% female. Out of 25 patients to whom gender data were available, 12 were male and 13 were female.

Anatomical Location of the Stones

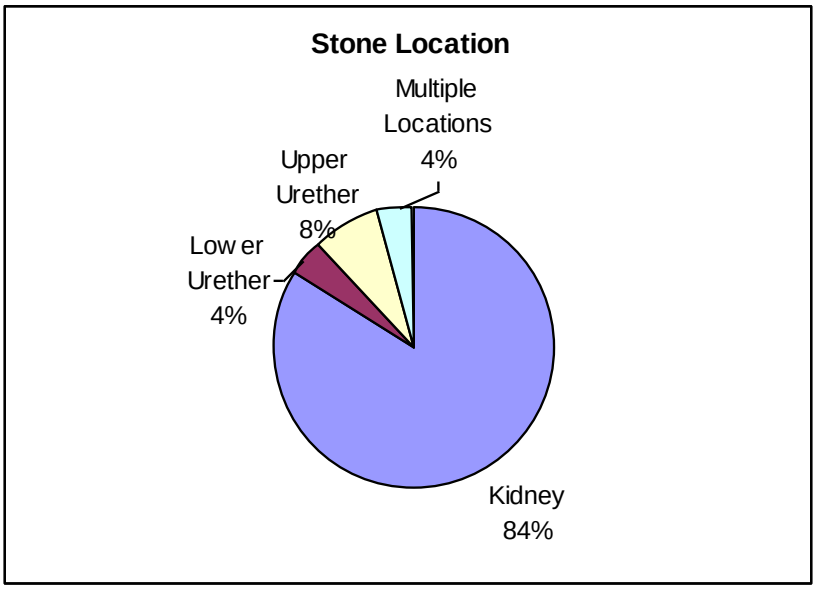
Stones treated by the EM1000 were situated in different anatomical locations all of which were gathered in a single location category of renal:
- Upper Calyx
- Middle Calyx
- Lower Pole Calyx
- Pelvis

Other stone groups were located in the ureter, divided into the following:
- Upper ureter
- Middle ureter
- Lower ureter

Patient Distribution According to Anatomical Location of Stones

Of 25 total patients treated, 21 had stones in a renal location, 2 had a stone in the ureter, 1 had a stone in the lower ureter and 1 in multiple locations. Diagram 2 represents patient distribution according to the anatomical location of the urinary stones.

Diagram 2 - Patient's Distribution according to the Stone's Anatomical Location

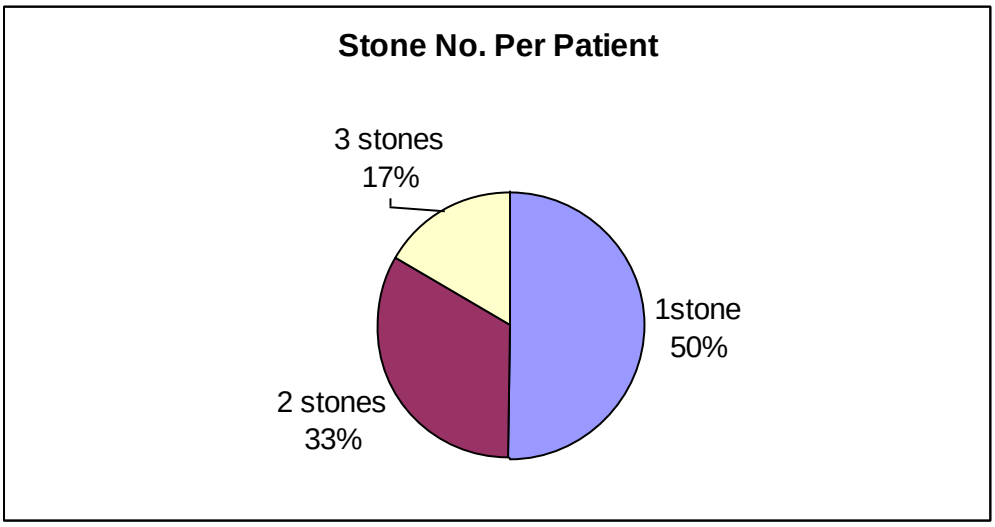


According to Diagram 2, most of the treated stones (84%) were located in the kidney, (n=21), followed by 8% in the upper ureter and 4% in the lower ureter as well as 4% in multiple locations.

Number of Stones per Patient

The average number of stones per patient was 1.24 (n=25). The maximal number of stones per patient was 3, and the minimum number of stones per patient was 1. Diagram 3 below represents patients' distribution according to the number of stones.

Diagram 3 - Patient's Distribution according to the Number of Stones



According to Diagram 3, 50% of the patients had 1 stone, 33% of the patients had 2 stones and 17% of the patients had three stones.

Stone Size

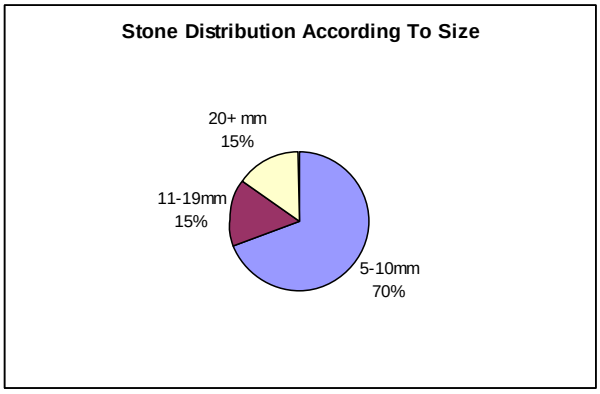
The size of stones ranged between 5 mm and 40 mm. The average stone size was 11.2 (n=28). Stone size was categorized into three groups: Group A: 5-10mm, Group B: 11-19mm and Group C: 20+mm. The following numbers detailed in Table 2 were found:

Table 2 – Stone Size

S.N.	GROUP	STONE'S SIZE (mm)	NUMBER OF STONES
1	Group A	5-10	18
2	Group B	11-19	4
3	Group C	20+	4

According to Diagram 4 below, 70% of the stones were 5-10 mm in size, 15% of the stones were 11-19mm in size and 15% were 20mm in size and over.

Diagram 4 – Stone Distribution



Data Collection

Data was collected from two medical centers due to the cooperation of the attending physicians. Standard data collection forms were prepared to ease and regulate data collection. The forms were filled by the physicians and sent for analysis to Medispec Ltd.

Treatment Parameters and Procedures

Treatment parameters were divided into:

- Shock wave intensity (Energy Level),
- Shock wave frequency (number of shock waves per minute),
- Total number of shock waves per treatment session, and
- Number of treatment sessions per patient

Shock Wave Intensity: Average shock wave intensity (energy level) was 20kV (n=25).

Frequency: Average frequency level was 100.8 shocks per minute (n=25)

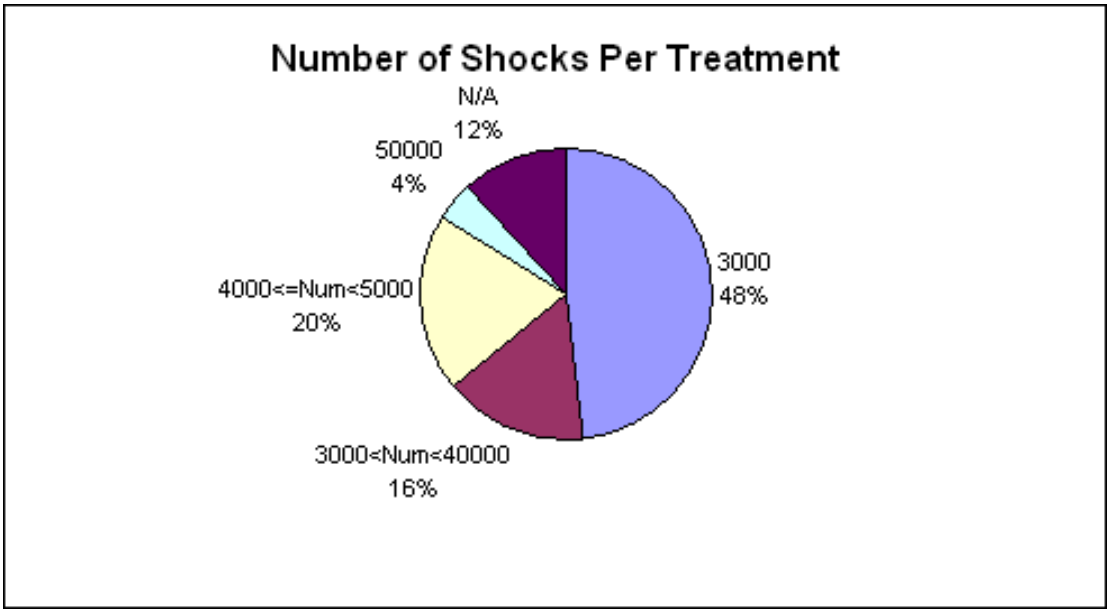
Total Number of Shock Waves per Treatment: Average number of shocks per treatment was 3418.18 (n=22)

Patient distribution according to the number of shocks administered per treatment was as follows:

No. of Shocks	**No. of Patients**
3000	10
3000 - 40000	4
4000 - 5000	5
50000	1

Diagram 5 demonstrates the patients' distribution according to the number of shocks per treatment session.

Diagram 5 - Patient Distribution According to the Number of Shocks per Treatment



In Diagram 5, 48% of the patients were treated with 3000 shocks per treatment, 20% of the of the patients received between 4000 to 5000 shocks, 16% received between 3000 to 4000 shocks, 4% received 5000 per treatment and 12% of the patients had missing results.

Number of Treatment Sessions: Average number of treatment sessions per patient was 1.04.

Number of Patients with Reoccurring Treatments: The number of patients with recurrent treatments was 1.

RESULTS

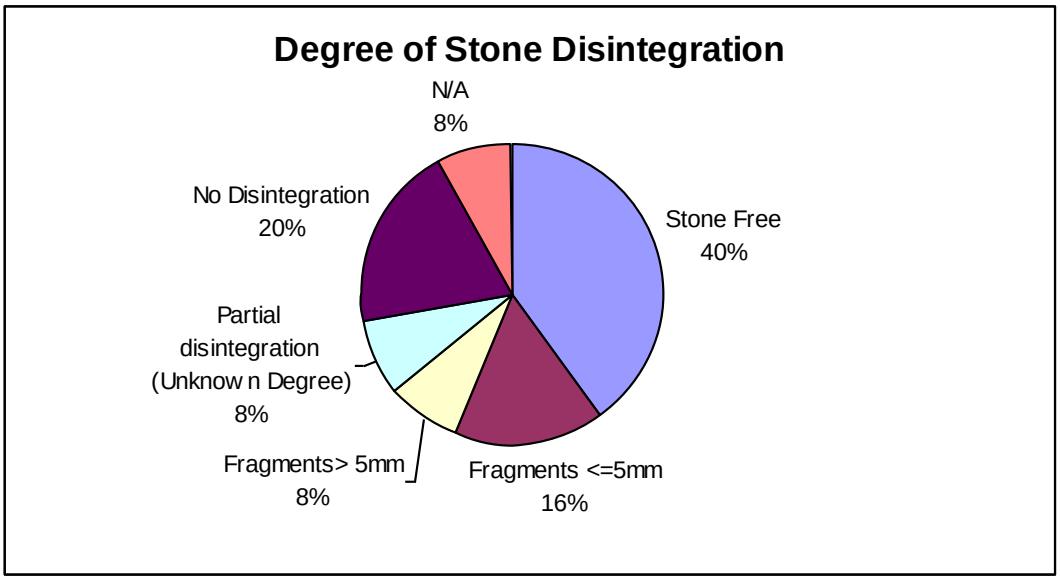
Anesthesia

Out of 25 patients treated (22 having available data), 21 treatments (95.45%) were performed under general anesthesia and one treatment (4.54%) under regional anesthesia.

Overall Success Rates

Out of 25 patients, 10 (40%) patients showed complete disintegration of the stone, and 32% have shown partial disintegration of the stone. Of the second category 4 (16%) shown stone fragments which were less than 5mm in size and 2(8%) have shown fragments which were 5mm in size and larger. Additional 2(8%) patients have shown a certain degree of fragmentation which could not be determined from the data submitted and 5 (20%) of the patients had no stone disintegration. Diagram 6 demonstrates the patient distribution according to the degree of stone's disintegration.

Diagram 6 - Patient's Distribution according to Stone Fragmentation.



Since stone fragments less than 5mm in diameter are secreted spontaneously from the urinary tract, we tend to address this patient category as successful treatment. Thus, 14 (56%) of the treatment were considered as successful. If we consider success as any degree of disintegration then 72% are considered successful.

Diagram 7 - Patient's Distribution according to Stone Fragmentation.

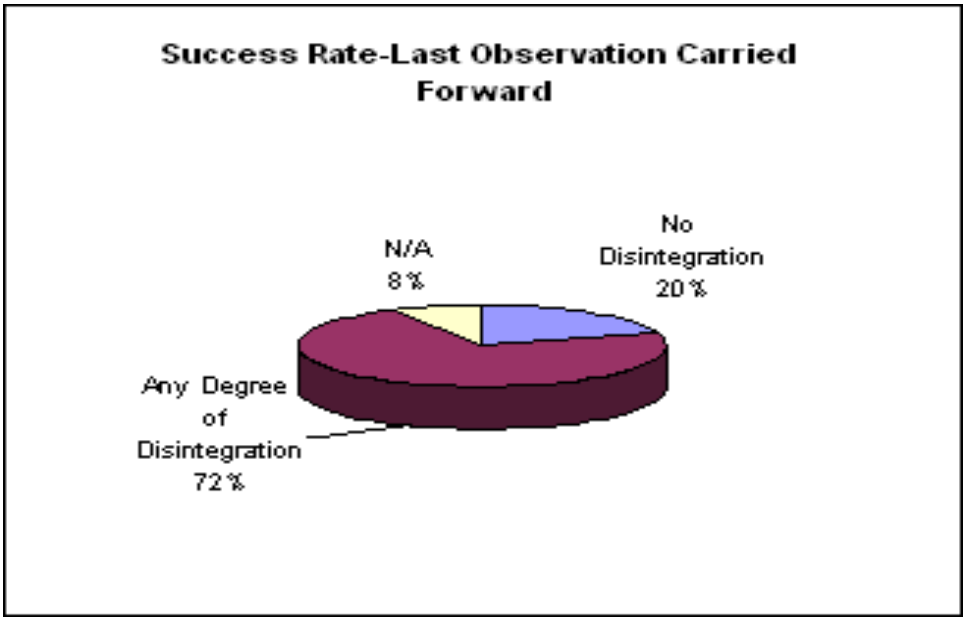
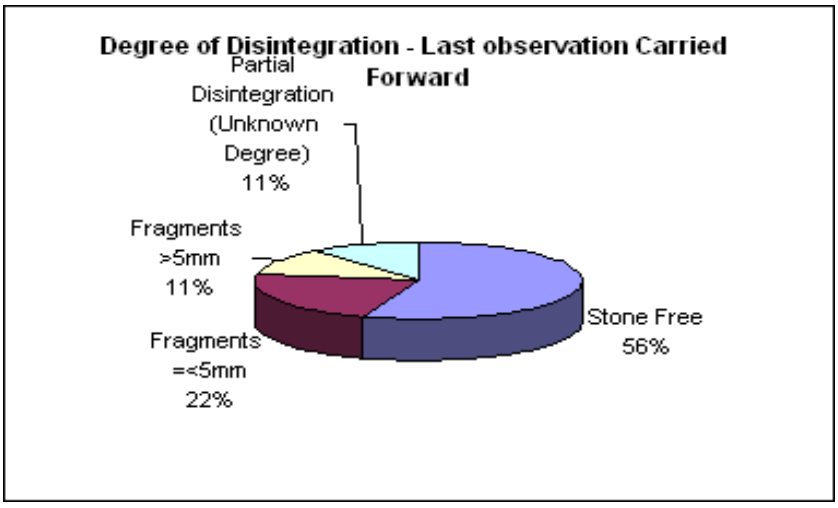


Diagram 8 - Patient's Distribution according to Degree of Stone Fragmentation.



Success Rates per Medical Center

Table 4 demonstrates the degree of success for each participating medical center. Overall success equals the sum of complete disintegration + partial disintegration with fragments smaller than 5mm.

Table 4 – Success Rates per Medical Center

MEDICAL CENTER	(N)	Success				No Success			
		Complete Disintegration		Partial Disintegration (fragments<5mm)		Partial Disintegration (fragments≥5mm)		No Disintegration	
		n	%	n	%	n	%	n	%
1	20	9	45	4	20	2	10	3	15
2	5	1	20	Undetermined	-	Undetermined	-	2	40

In the table above 10 (40%) of the stones have undergone complete disintegration, 4 (16%) of the stones were broken to less than 5mm, thus could be further excreted in the urine, 2 (8%) were disintegrated to fragments of 5mm and over – a size which has to undergo re-treatment, since it is too large a stone to be excreted spontaneously, 2 (8%) of the stones have undergone partial disintegration to an uncertain degree, and 5 (25%) have not disintegrated at all. Diagram 6 demonstrates the degree of stone disintegration.

Re-treatment Rate

Out of 25 treatments, 2 treatments (8%) were performed on the same patient. Nevertheless, it is unclear whether it was re-treatment of the stone fragment of the previous treatment, or whether it was a treatment of a new stone formed after an eight month interval.

Safety Report

Out of 25 treatments, 2 (8%) presented adverse reactions. The adverse reactions evident were steinstrasse. One of the patients has undergone uretheroscopy. The other patient's further outcome is currently unclear to us. Two patients have undergone ESWL treatment with stent insertion. In one patient, treatment was combined with PCN. The other patient was scheduled for PCNL treatment due to the non-success of the pre-ESWL treatment.

Functionality

The treating physicians have shown satisfaction of the device. It's been reported as functional, easy to operate, user friendly and physically adequate. The instructions for use were clear, and moreover, all treatments were performed in the presence of a highly trained and qualified Applications technician. No technical malfunctions of the device were reported.

CONCULUSION

According to the data presented in this document we conclude that the Econolith^{TM} EM1000 is both safe and effective in the treatment of urinary tract stones.