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Device	Retreatment rate	90 day stone free rate	Post ESWL complication rate	Remarks
Dornier HM3	~ 6.0%	~ 79.0%	Post lithotripsy: 3.8%*	<ul style="list-style-type: none"> Note: FDA approval is for renal stones only. No approval for ureteral stones.
TRT lithogold380	Single treatment according to protocol	95%	Colic: - Steinstrasse: - Urinary obstruction: 5%*) Nausea/ vomiting: 5%*) Sepsis: - Other: 5%*)	<ul style="list-style-type: none"> FDA clearance K062081; November 2, 2006 Clinical data taken from the confirmatory study with 20 subjects *) The LithoGold study is a confirmatory study, and therefore is not powered to definitively determine the adverse event rates. Nonetheless, it appears that the adverse event rates for the LithoGold are within the incidence rates reported in the literature.
Storz Modulith	24.0%	74.0%	Colic: 21.8 % Gross Hematuria: 1.9 % Infection: 2.2 % Steinstrasse: 0.3 % Urinary Obstruction: 1.9 % Other: 2.0 %	<ul style="list-style-type: none"> IDE results reported Feb 17, 1995. Butterworth, Univ. of Tennessee, Univ. of Arkansas, Univ. of Mississippi
HMT LithoTron	4.1%	86.1%	Colic: 4.6 % Steinstrasse: 3.3 % Urinary Obstruction: 2.6 % Nausea / Vomiting: 4.0 % Sepsis: 0.6 % Other: 3.3 %	<ul style="list-style-type: none"> Report on Final 215 patients within FDA IDE protocol, May 1997
Dornier Doli U30	32.0%	85.9%	Colic: 16.1 %	<ul style="list-style-type: none"> As reported by Schmidt, Volz and



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			Perineal Hematoma: 0.6 % Other: 1.3 %	Eisenberger in J Endourol (Journal of endourology) 1995, Vol. 9; page 363-366 <ul style="list-style-type: none">Note: FDA approval is for renal stones only. No approval for ureteral stones.
Donier Compact S	19.0%	62.0%	Colic: 39.0 % Steinstrasse: 4.0 % Urinary Obstruction: 1.1 % Nausea / Vomiting: 14.0 %	<ul style="list-style-type: none">FDA study - Univ. of California - J. of Urology, Sep 1995Note: FDA approval is for renal stones only. No approval for ureteral stones
MFL 5000	23.7% Chaussy 12.0% Senge	72.0% Chaussy 64.0% Senge	Colic: 7.0 % Analgesics: 4.5 % Steinstrasse: 4.5 % Urinary Obstruction: 3.0 % Other: 2.0 %	<ul style="list-style-type: none">As reported by Prof Chaussy & Senge to the FDA (PMA # P 840008), 1989
Medstone	8.0%	72.0%	Un known	<ul style="list-style-type: none">Historical Data
Siemens Lithostar Multiline	36.0%	87.0%	Colic: N/A Hematoma: N/A Urinary Obstruction: 6.7 % Sepsis: 2.0 %	<ul style="list-style-type: none">As reported by Thuroff and Chaussy in 1995, Journal of endourology, Vol. 9



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* Teichman et al., "In vitro comparison of shock wave lithotripsy machines", J Urol. (October 2000); 164(4): pp. 1,259–1,264

HISTORICAL DATA: No actual published data could be uncovered. The listed values are based upon discussions and comments with various physicians. N/A: not announced.

ABSTRACTS

Schmidt, A.; Volz, C.; Eisenberger, F.
J Endourol (Journal of endourology) 1995, Vol. 9; page 363-366

Abstract:

Since August 1993, the Dornier Lithotripter U 30 has been used at the Department of Urology of the Katharine hospital in Stuttgart. The machine consists of an endourologic table with an X-ray unit mounted on a C-arm and an electromagnetic shockwave source equipped with an inline ultrasound scanner and oblique shockwave coupling with a water cushion. Stone location can be performed with fluoroscopy or simultaneous ultrasound scanning. Until December 1994, 1092 stones had been treated, requiring 1533 sessions: 497 stones (45.5%) were situated in a calix, 426 (39%) in the renal pelvis, 130 (11.9%) in the upper ureter, and 39 (3.6%) in the distal ureter. Auxiliary measures were necessary before SWL in 245 patients (16%): double-J stent placement in 184 patients (12%), percutaneous lithotripsy in 43 patients (2.8%), and percutaneous nephrostomy in 15 patients (1%). The mean number of shockwaves was 3018, ranging from 250 to 3750. The time needed for positioning ranged from 1 to 10 minutes (mean 3 minutes). The mean treatment time was 30.5 minutes (range 10-50 minutes). There were 26 treatments (1.7%) performed without analgesic medication. In 1359 cases (88.6%), analgesics were utilized, and in 108 cases (7.0%), a sedative was added. In 40 patients (2.6%), general anaesthesia was necessary. Complete stone disintegration was achieved in 94%. Auxiliary measures after SWL were ureteroscopy in 8.4% and percutaneous nephrostomy in 1.3%. Perirenal hematomas were found in 10 patients (0.6%). Colic pain necessitating analgesic medication was reported by 247 patients (16.1%). Body temperature above 38 degrees C occurred after 20 treatments (1.3%). At 3 months' follow-up, 110 patients of 128 patients (85.9%) were stone free. The Dornier Lithotripter U 30 has proven highly effective for SWL of renal and ureteral stones, radiolucent and radiopaque, and can be used as a full endourologic work-station.



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Thuroff, S.; Chaussy, C. G.

First clinical experience and in situ treatment of ureteric stones using Lithostar Multiline lithotripter

J Endourol (Journal of endourology) 1995, Vol. 9, page 367-370

Abstract:

This article reviews the first experience using the Siemens Lithostar Multiline lithotripter in 372 consecutive treatments of ureteric and kidney stones. The disintegration rate was 97.7%, and a stone-free rate of 87% was achieved at the end of 3 months. Auxillary procedures were required in only 11% of the patients. No medication was required for pain management in 60.4% of the patients. The results were especially impressive in the management of ureteric stones, with a success rate of 91%, these patients being stone free after 1 week using the new booster technique. Analysis of the data indicates that the Siemens Lithostar Multiline is a safe, effective, and economically sound device to treat patients with ureteric and renal stones.