

MODULITH® SLX
MODULITH® SLK

Papers held at Congresses 1993 - 2003

ACCEPTED ABSTRACTS 1993 - 2003

English / German / Spanish

	Page
First Experience with the Modified Modulith SLX Using In-line Fluoroscopic Localization ESWL (Dr. K.U. Köhrmann, Mannheim, Germany)	5
New In-Line Fluoroscopic Localisation for ESWL; First Clinical Experience Using the Modulith SLX (Dr. K.U. Köhrmann, Mannheim, Germany)	6
Experimental Basics for the "Low Energy Principle" for ESWL of Kidney Stones (Dr. K.U. Köhrmann, Mannheim, Germany)	7
First Results with the New MODULITH SLX Lithothiptor (Dr. A. Wolf, Bamberg, Germany)	9
Tratamiento de la litiasis uretral con STORZ MODULITH SLX (Dr. E. Basigaluz, Montevideo, Uruguay)	10
Primeros 200 pacientes litiasicos tratados con STORZ MODULITH SLX en América (Dr. M. Villar, Montevideo, Uruguay)	11
ESWL eines Harnleitersteines in der 3. Schwangerschaftswoche (Dr. A. Wolf, Bamberg, Germany)	12
Stone treatment in renal transplant by SWL (Dr. E. Montanari, Milano, Italy)	13
Urological application of the MODULITH SLK (Dr. P.M. Braun, Mannheim, Germany)	14
Low-dose lithotripsy on electromagnetic shock wave sources: Outcome in 68 out of 1443 ESWL-treatments (Dr. A. Weber, Mannheim, Germany)	18

Are auxiliary measures necessary in therapy of urolithiasis in children ? (Dr. P.M. Braun, Mannheim, Germany)	20
S.W.L. in patients treated with antiaggregant or anticoagulant drugs (Dr. G. Zanetti, Milano, Italy)	21
One decade experience with ESWL using the electromagnetic shock wave source MODULITH SL 20 and MODULITH SLX (Dr. A. Weber, Mannheim, Germany)	22
Clinical evaluation of an interactive navigation system for integration of fluoroscopic and ultrasound imaging of the MODULITH SLK lithotripter (Dr. K.-U. Köhrmann, Mannheim, Germany)	23
Outcomes of shock wave lithotripsy utilizing a STORZ MODULITH SLX: Results in the first 200 patients (Dr. M.E. Moran, Albany, USA)	24
Outcomes of shock wave lithotripsy comparing a modified access algorithm for managing acute vs. elective stone cases (Dr. M.E. Moran, Albany, USA)	25
Pain control by local subcutaneous block augmented by parenteral analgesia utilizing the STORZ MODULITH SLX (Dr. M.E. Moran, Albany, USA)	26
MODULITH SLK – a new lithotripter for interdisciplinary use: First clinical data (Dr. K.U. Köhrmann, Mannheim, Germany)	27
MODULITH SLX – clinical results and experience of 10 years (Dr. Braun, Mannheim, Germany)	28
Long-time experience with the MODULITH SLX – a multifunctional workstation (Dr. Wolf, Bamberg, Germany)	29
In vitro shock wave lithotripsy comparison (Dr. Joel, San Antonio, USA)	30
Interactive Navigation System for Shock Wave Applications (Dr. Ing. U. Hagelauer)	31

A Multivariate Analysis of Risk Factors Associated With Subcapsular Hematoma Following Electromagnetic Shockwave Lithotripsy (N. Dhar, C.S. Ng, A.J. Yost, S.B. Strem)	32
Primary ESWL for Ureteric Stones Avoids Intervention and Injury (M.A. Hanna, J.D. Olsburgh, C. Hudd, J.W.A. Ramsay)	33

Update: October 2003/ok
K:/PE/Abstract-Literaturverzeichnisse/SLX_SLK_10_2003

11th World Congress on Endourology and ESWL
20. - 23.10.1993, Florence, Italy

FIRST EXPERIENCE WITH THE MODIFIED MODULITH SLX USING IN-LINE FLUOROSCOPIC LOCALIZATION

K.U. Köhrmann, *O. Wess, J. Rassweiler, P. Alken
Department of Urology, Klinikum Mannheim, Mannheim, Germany
*STORZ MEDICAL AG, Kreuzlingen, Switzerland

After establishing of the MODULITH SL 20 with its high disintegrative efficacy using coaxial X-ray localization system in a virtual focus, this lithotripter was modified for realtime in-line fluoroscopy.

First localization of the stone is performed using the free movable C-arm. Thereafter the shock wave source, fixed on a swing arm, ist brought to the treatment position. The stone position in the focus can be controlled after coupling of the water cushion and during shock wave application passing the electromagnetic cylinder in the sagital position and in the diagonal direction.

The first 53 patients (66 stones with diameter > 1 cm in 33 %, 52 % ureteral stones, 18 % multiple stones) were treated by an average number of 3918 shock waves at 17 kV (Ø 39 minutes) under analgosedation. In 24 % of cases auxiliary measures were performed before ESWL, in 8 % thereafter. Sufficient disintegration at discharge was achieved in 93 %. In addition to this high success rate the in sute fluoroscopy of the focal position ensured easy handling and a short learning period for this modified lithotripter.

In conclusion the modification of real time in-line fluoroscopic localization leads at least to the good results of the MODULITH SL 20 and simplifies the procedure.

5th European Urolithiasis Symposium
21. - 23.04.1994, Manchester, England

NEW IN-LINE FLUOROSCOPIC LOCALISATION FOR ESWL: FIRST CLINICAL EXPERIENCE USING THE MODULITH SLX

K.U. Köhrmann, I. Hügner-Zimmermann, J. Rassweiler, P. Alken
Department of Urology, Klinikum Mannheim, Mannheim, Germany

In the development of lithotripters there is a trend towards fluoroscopy as the essential stone localization system. But the techniques of the X-ray systems for ESWL have normally disadvantages. In some the information on the stone position is lost by the low contrast of blown up pictures during focusing. In others, stone position is changed during coupling of the shock wave source requiring new adjustment of the stone within the focus.

With the free mobile C-arm of the new MODULITH SLX (STORZ MEDICAL AG), the stone is first localized in the focal point by large-scale fluoroscopy. The highly efficient shock wave source (electromagnetic cylinder with paraboloid reflector), attached to a swing arm, then moves automatically to the treatment position. The focusing image becomes the central part of the initial large scale image. Coupling the shock wave source will - if at all - only change the vertical position of the stone within the focal zone. The following data were evaluated with the first patients:

No. of patients	140
Multiple stones	20 %
Ureteral stones	56 %
Auxiliary measures before ESWL	25 %
∅ shock wave number	3770

89th Annual Meeting of the American Urological Association
15. - 19.05.1994, San Francisco, USA

EXPERIMENTAL BASICS FOR THE „LOW ENERGY PRINCIPLE“ FOR ESWL OF KIDNEY STONES

K.U. Köhrmann, S. Kuppeck, N. Schreck, J. Rassweiler, P. Alken
Department of Urology, Klinikum Mannheim, Mannheim, Germany

The dosis of applied shock waves (SW dosis) for ESWL is defined by the energy level (generator voltage, kV) and the number of impulses (SW number). Stone disintegration and kidney trauma correlate with both factors. However, the optimal combination of both parameters, for achievement of a high fragmentation rate with minimal renal trauma is unknown.

Disintegration was performed using an artificial stone (dental cement, glas microsphere, 1.0 ± 0.01 g) in a wire net. Shock waves were applied until all fragments had passed through the mesh. The shock wave number necessary for disintegration was evaluated for low (12 kV), medium (16 kV) and maximal (20 kV) energy levels using the electromagnetic lithotripter Modulith SLX.

Renal trauma was investigated using the isolated, perfused kidney model. Kidney from slaughtered pigs were flushed by Tyrode solution. During shock wave application BaSO₄ suspension was perfused. The roundish area of petechial dye paravasation, representing the extent of vascular lesion, was quantified after documentation on mammographic film. Furthermore the lesion was evaluated by histomorphology. Kidneys (n - 24) were exposed to the identical SW number and kV as in the stone model.

(continued)

The following are the SW numbers necessary for stone disintegration as well as angiographic kidney trauma:

Energy level	SW number for complete stone disintegration	Size of renal trauma
12 kV	870 SW	Ø 4,1 mm
16 kV	179 SW	Ø 10,6 mm
20 kV	85 SW	Ø 12.0 mm

Histological findings showed gap-like defects that worsened with increase of the applied energy level.

The model of the isolated, perfused kidney using slaughtered pig kidney has proved to be ideal to evaluate the dose dependency of the shock wave induced renal lesion

This study shows that a low energy level combined with a high number of shock waves leads to a sufficient stone disintegration with the lowest risk of renal trauma. This finding should be respected in the clinical ESWL although high energy levels will be necessary in special situations like cystine, ureteral or diverticular stones.

6th European Symposium on Urolithiasis
08. - 10.06.1995, Stockholm, Sweden

FIRST RESULTS WITH THE NEW MODULITH SLX LITHOTRIPTER

A. Wolf, P. May

Department of Urology, Klinikum Bamberg, Bamberg, Germany

The MODULITH SLX (STORZ MEDICAL AG) is a further development of the third generation SL 20 with an electromagnetically energy source, in-line fluoroscopy and optionally ultrasound.

From 6/94 to 12/94 106 consecutive patients were treated. In 6 patients several stones were treated in one session. Intravenous sedation and analgesia was performed in all patients. Energy level 6 was used for the kidney and level 8 for the ureter (max. 9). A shock wave (SW) frequency of 120/minute could be used in all except for 3 patients. Follow-up was conducted for up to 3 months to determine stone free rate and success rate (≤ 3 mm).

	pelvis	calices	ureter
pat. no.	39	36	31
size (mm)	12,5	8,9	7,2
SW	2892	3032	3600
success 1. day %	84,6	75	83,8
success 3 months %	92,3	94,4	87

7 patients needed further treatment (6 ESWL, 1 perc. Nephrolitholapaxie). One hematoma was treated conservatively.

Conclusion:

The MODULITH SLX is an effective uncomplicated machine with an above average success rate.

Congreso Argentino de urología

TRATAMIENTO DE LA LITIASIS URETRAL CON STORZ MODULITH SLX

M. Villar, J. Nallem, E. Basigaluz, N. Fierro, G. Labella
Sanatoria Americano, F.E.M.I., Montevideo, Uruguay

Objetivo

Demonstrar que el nuevo modelo SLX de STORZ es un litotritor válido para el tratamiento de la litiasis urinaria.

Material y metodos

Se utilizó el STORZ MODULITH SLX primer equipo instalado en América. Se analizan las características del mismo; y diferencia con otros modelos.
Se evalúan los 200 primeros pacientes tratados con este equipo.

Resultados

Se analizan los resultados del tratameinto en las distintas localizaciones, tamaño y población.

Conclusiones

Se concluye que el bajo índice de retratamiento, escaso uso de procedimientos auxiliares y de complicaciones hacen de este equipo una opción válida en el tratamiento de la litiasis urinaria por ESWL.

Congreso Argentino de urología

PRIMEROS 200 PACIENTES LITIASICOS TRATADOS CON STORZ MODULITH SLX EN AMERICA

E. Basigaluz, N. Fierro, G. Labella, J. Nallem, M. Villar
Sanatoria Americano, F.E.M.I., Montevideo, Uruguay

Objetivo

Demonstrar la eficiencia del MODULITH SLX en el tratamiento de la litiasis uretral.

Material y metodos

Se analizan las primeras 50 litiasis uretrales tratadas en América con MODULITH SLX, durante el período marzo-septiembre de 1996.

Resultados

Más del 50 % de los cálculos fueron resueltos en una a dos sesiones.

Conclusiones

La facilidad de localización y control del cálculo, el bajo índice de retratamientos y el escaso uso de procedimientos auxiliares, hacen del STORZ MODULITH SLX una opción válida para el tratamiento de litiasis uretral con litotricia extracorpórea por ondas de choque.

XXIII. gemeinsame Tagung der österreichischen Gesellschaft für Urologie und der bayrischen Urologenvereinigung
01.-03.05.1997, Baden bei Wien, Austria

ESWL EINES HARNLEITERSTEINES IN DER 3. SCHWANGERSCHAFTSWOCHE

A. Wolf, P. May

Department of Urology, Klinikum Bamberg, Bamberg, Germany

Eine 29-jährige Patientin wurde uns im April 1996 aufgrund ausgeprägter linksseitiger kolikartiger Flankenschmerzen zugewiesen. Das Ausscheidungsurogramm zeigte die typischen Zeichen eines prävesikalen okkludierenden Harnleitersteins. Die Abflussbehinderung wurde mit einem JJ-Ureterenkatheter überbrückt. Dabei wurde das Konkrement auf Höhe LWK 3 verlagert. Dies erfolgte nach der üblichen Aufklärung, die anhand eines Formulars dokumentiert wurde und auch die Frage nach einer möglichen Schwangerschaft beinhaltete. Ein routinemässiger Grav-Index war negativ.

Das Konkrement wurde mit 6500 Impulsen der zweithöchsten Energiestufe mit dem MODULITH SLX desintegriert. Bei der Behandlung wurde 1,3 Minuten durchleuchtet. Folgende Medikamente wurden während der gesamten Behandlung verabreicht: Buscopan, Novalgin, Paspertin, Kepinol, Sab simplex, Tranxilium, Dormicum und Rapifen.

Nach der überraschenden Feststellung einer Schwangerschaft wurde die Patientin in der 12. SSW genetisch beraten und zu der Fortführung der Schwangerschaft ermuntert. Die verabreichten Medikamente stehen nicht im Verdacht, bei kurzfristiger Anwendung in der Frühschwangerschaft teratogen oder embryotoxisch zu wirken. Die gesamte Strahlenbelastung des Embryos wurde auf max. 8 mSv berechnet. Ab 100 mSv ist ein Beratungsgespräch mit der Patientin indiziert. Zudem sind die ersten 20 Tage als relativ unempfindlich gegen äussere Einflüsse anzusehen. Der Focus-Embryo-Abstand von mind. 15 cm liess eine Schädigung des entstehenden Kindes als sehr unwahrscheinlich erscheinen. Ausserdem besteht vor der Zeit der Organdifferenzierung das „Alles-oder-Nichts-Gesetz“.

Am 5. Januar 1997 wurde nach unauffälliger Schwangerschaft ein gesundes Mädchen geboren. Dieser Bericht soll natürlich nicht zur wissenschaftlichen Wiederholung animieren, sondern dieses seltene Ereignis dokumentieren.

15th World Congress on Endourology and ESWL
31.08.-03.09.1997, Edinburgh, UK

STONE TREATMENT IN RENAL TRANSPLANT BY SWL

E. Montanari, A. Guarneri, G. Zanetti, A. Trinchieri
Institute of Urology, IRCCS Ospedale Maggiore, Milan, Italy

Introduction

Urolithiasis in transplanted kidney is a rare event. In the early reports surgical treatment of stones in renal transplants was discouraged. Afterwards pyelolithotomy and percutaneous nephrolithotomy have been described. SWL provides an alternative non-invasive method to treat renal calculi in the transplanted kidney.

Methods

Between 1991 and 1996 nine cases with renal or ureteral stones in a transplanted kidney were treated with SWL. The SWL was performed on a Dornier MPL 9000 or a MODULITH SLX STORZ lithotripter under analgosedation in a prone position with ultrasonic targeting. Out of 9 stones 6 were radiopaque and 3 were radiolucent. The stones were calyceal in 6 cases, pyelic in one case and in other 2 cases in the ureter.

In patients with ureteral stones a nephrostomy was placed before treatment: moreover in one case an ureteral stent was placed with mixed antero-retrograde access. The stone diameter ranged 8 to 23 mm.

Results

With MPL 9000 Dornier lithotripter the shock wave number ranged 1000 to 2800 with kilovoltage between 16 and 18. With MODULITH SLX STORZ lithotripter the shock wave number ranged 1300 to 2000 with kilovoltage between 16 to 18.

The patients tolerated the procedure well and no complications were observed.

At discharge 5 patients were radiographically free of stone fragments, while 2 were discharged with residual stone fragments. One patient required ureterolithotomy for the failure of SWL.

Before the treatment serum creatinine was lower than 1.8mg/dl in 6 cases, more than 1.8 mg/dl in 3. At discharge we observed no change in serum creatinine levels.

Conclusion

SWL appears to be a successful method to treat renal calculi in transplanted kidneys, although intense monitoring after treatment is necessary since transplant patients may be more susceptible to complications of shock waves.

16th World Congress on Endourology and ESWL
03.-06.09.1998, New York, USA

UROLOGICAL APPLICATION OF THE MODULITH SLK

P.M. Braun, K.U. Köhrmann, M.S. Michel, E.H. Marlinghaus*
Department of Urology, University Hospital Mannheim, University of
Heidelberg, Germany

* STORZ MEDICAL AG, Kreuzlingen, Switzerland

Abstract

A lithotripter for interdisciplinary use is tested clinically. It combines the large focal depth and aperture of the machines designed for urological use with the flexibility of the orthopaedic lithotripter. The data show that the efficacy of the MODULITH SLK is as high as the efficacy of the MODULITH SL 10/SLX using ultrasound localization.

Introduction

Beside urolithiasis a number of indications for the therapeutic application of shock waves are on the increase, e.g. Peyronie's disease¹, salivary tract stones², pseudarthrosis³, tendinosis calcarea⁴, and tennis elbow⁵. For lithotripsy in the urinary tract, the focal depth of a lithotripter has to be large in order to reach the stones especially for obese patients. For anaesthesia-free treatment, the coupling area to the patient must be large to keep the energy flux density low at the skin. These design features result in a powerful but relatively big therapy head (MODULITH SL 10/SLX).

For the other applications a shorter focal depth is sufficient, so a smaller therapy head was designed for the MINILITH SL 1. Due to the different applications (around the body), a flexible articulated arm carrying the light-weight therapy head is mandatory.

For interdisciplinary use in all the applications, the MODULITH SLK was designed. It combines a powerful deep-focus therapy head with the flexible arm of the MINILITH SL 1.

This study tests the hypothesis, that the clinical efficacy of the SLK is as high as that of the MODULITH SL 10/SLX⁶ for all stones detectable with ultrasound. Data on treatment results with X-ray localization will be published later⁷.

Materials and Method

Shock wave generator: The therapy heads of the different STORZ lithotripters are shown in figure 1. The basic components are the electromagnetic cylindrical coil, the metallic membrane and the parabolic focusing reflector. A high voltage storage capacitor is discharged by a switch to the coil. The electrical current in the coil induces a strong eddy current in the membrane, resulting in a displacement of the membrane. Thus, a cylindrical pressure pulse in the surrounding water is generated, which diverges to the parabolic reflector. Here it is focused to the target. In contrast to the opinion of others⁸ the complete surface of the paraboloid is used. Since the travel time of the pressure pulse from all parts of the membrane to the geometric focus of the reflector is exactly identical (linear approximation), the wave is focused without any temporal stretching. On its way to the focus, the pressure pulse steepens to a rise time of well below 50 ns as measured by PVDF-needle and fiber optic laser hydrophons in degassed water.

Characteristic data of the machines are given in table one. The nominal power level of the SLK ranges from 1 to 70. By adjusting the high voltage setting, the energy flux density in the focus of the SLK in level 10 to 70 is matched to level 1 to 7 of the MODULITH SLX. Levels 1 to 9 cover the lower part of the energy flux density range of the MINILITH SL 1. Figure 2 shows the lateral pressure distribution in the focus of the SLK.

Table 1: Characteristic data of the STORZ machines

		SL 1	SLK	SL 10/SLX
Reflector diameter	mm	144	175	300
Focal distance	mm	50	140	165
Aperture angle		84°	64°	84.5°
Peak positive pressure	MPa	70	80 *	100 *
Peak positive pressure	MPa	(92)	(-)	(150)
Peak negative pressure	MPa	(19)	(-)	(19)
Focal extend (x, y)	mm	2.5	3 ... 5	6
Focal extend (z)	mm	25 ... 40	35 ... 55	28
Energy flux density	mJ/mm ²	0.5	0.6 *	1.0 *
Energy in the - 6 dB-focus (E _{P+})	mJ	(3.36)	-	(11.7)
Energy in the 5 MPa-focus (E _{P+})	mJ	(15.7)	22.5	(100)
Energy in the 5 mm focal area (E _{P+})	mJ	(6.6)	-	(25)
Total energy in the 5 MPa-focus	mJ	(74)	-	(160)

* Risettime limit of needle hydrophon exceeded

(...) Measured by fiber optic laser hydrophon

P₊ = Positive part of pressure signal

The in vitro stone disintegration of artificial stones (cubes of plaster of Paris) demonstrated a comparable disintegrative efficacy of both machines in level 10 to 70 and 1 to 7, resp.

For target localization, an ultrasound transducer (3.5 MHz, annular array) is mounted in-line in the coil. It can be rotated manually and adjusted coaxially by a motor to give contact to the patient skin for better image quality. As an option, a C-arm for X-ray localization can be attached.

The shock wave head is mounted on an articulated arm with five degrees of freedom for manual movement. The arm is fixed by five brakes acting simultaneously. In the fixed state, fine adjustment of the focus positioning is possible in two axes. Due to this very flexible design, an optimal entrance window for both ultrasound localization and shock wave transmission can be found.

Patient data

No. of patients	50
No. of stones	54
Stone location	
Calix	27/54 (50.0%)
Pelvis	11/54 (20.3%)
Upper ureter	10/54 (18.5%)
Prevesical ureter	6/54 (11.1%)
Stone size	Ø 11 mm (range from 6 to 22 mm)

Treatment parameters

Treatment period	May to August 1998
Localization system	in-line ultrasound
SW-number	4000 for kidney and upper ureteric stones 6000 for prevesical ureteric stones
Energy level	Ø 50 (range from level 10 to 70)
Treatment duration	Ø 45 min.
Analgo-sedation	Piritramid 0.1 mg/kg, Midazolam 1-3 mg
Follow up	6 weeks (range from 2 to 12 weeks)

ESWL-Results

Disintegration rate (fragments < 4 mm)	43/54 (79.6%)
Re-ESWL	10/54 (18.5%)
Auxiliary measures before ESWL	5/50 (10.0%)
Auxiliary measures after ESWL	4/50 (8.0%)
adjuvant (stent, PCN)	3/50 (6.0%)
curative (URS)	1/50 (2.0%)

Complications

Colics	9/50 (18.0%)
Fever > 38°C	2/50 (4.0%)
Subcapsular hematoma	1/50 (2.0%)

Discussion

Due to the increasing application of shock waves for new therapies on the one hand and cost pressure on the other hand, the design of a new generation of lithotripters is necessary. The MODULITH SLK allows interdisciplinary use at reduced cost.

The first prototype of the MODULITH SLK is used in our clinic routinely. All patients whose stone(s) could be localized by in-line ultrasound were treated with the SLK. All stones that could be visualized by an external handheld ultrasound probe ($\approx 80\%$ of all patients) could be localized by the in-line ultrasound as well and treated.

Conclusion

The data presented in this study show that the efficacy of the MODULITH SLK is as high as the efficacy of the MODULITH SL 10/SLX using ultrasound localization.

Given the option of attaching a fluoroscopic C-arm, the outlook for the SLK as an interdisciplinary lithotripter is promising especially in urological applications.

Literature

- 1 Bellorofonte C., Ruoppolo M., Tura M. et al.: Possibility of using the piezoelectric lithotripter in the treatment of severe cavernous fibrosis; *Arch. Ital. Urol. Nefrol. Androl.* 1989, 61/4, pp. 417 - 422
- 2 Kater W., Meyer W.W., Wehrmann T.: Efficacy, risks and limits of extracorporeal shock wave lithotripsy for salivary gland stones; *Journal of Endourology*, 1994, 8, pp. 21 - 24
- 3 Valchanou V.D., Michailov P.: High energy shock waves in the treatment of delayed and nonunion of fractures; *Int. Orthop.*, 1991, 15, pp. 181 - 184
- 4 von Hasselbach Ch.: Therapy-resistant insertion tendinosis. Indication for extracorporeal shock wave therapy or surgery; in: Siebert W., Buch M. (Eds.): *Extracorporeal shock waves in orthopaedics*, Springer, Berlin 1997, pp. 201 - 212
- 5 Russo S., Gigliotti S., De Durante C. et al.: Results with extracorporeal shock wave therapy in bone and soft tissue pathologies; in: Siebert W., Buch M. (Eds.): *Extracorporeal shock waves in orthopaedics*, Springer, Berlin 1997, pp. 149 - 155
- 6 Rassweiler J., Henkel T.O., Joyce A.D. et al.: Extracorporeal shock wave lithotripsy of ureteric stones with the MODULITH SL 20; *British Journal of Urology*, 1992, 70, pp. 594 - 599
- 7 Hagelauer U.: to be published
- 8 Ueberle F.: Shock wave technology; in: Siebert W., Buch M. (Eds.): *Extracorporeal shock waves in orthopaedics*, Springer, Berlin 1997, pp. 59 - 87

16th World Congress on Endourology and ESWL
03.-06.09.1998, New York, USA

LOW-DOSE LITHOTRIPSY ON ELECTRO- MAGNETIC SHOCK WAVE SOURCES: OUTCOME IN 68 OUT OF 1443 ESWL-TREATMENTS

A. Weber, J. Wannemacher, M.S. Michel, P.M. Braun, K.U. Köhrmann, P. Alken
Department of Urology, University Hospital Mannheim, University of
Heidelberg, Germany

With respect to concomitant morbidity of the patients and occasionally high individual pain sensitivity extracorporeal shock wave lithotripsy (ESWL) will not be performed with the accepted maximal energy dosage (including energy level and number of shock waves). With the technical prerequisites of electromagnetic shock wave sources (MODULITH SLX/STORZ MEDICAL AG and Lithostar Plus/Siemens) it seems questionable whether the maximal possible energy level of the generator is always required for successful fragmentation.

In order to analyse the success rate of low-dose ESWL-concept the data of 68 out of 1443 ESWL-treatments were available with regard to age, gender, lithotripter, number of shock waves (SW), energy level, stone localisation, degree of fragmentation and anesthetic efforts.

Age ranged from 10 to 87 years (av. 49 yrs.), including 3 children. 38 female and 30 male patients underwent ESWL. 37 patients were treated on the MODULITH SLX and 31 on the Lithostar Plus overhead module. On the MODULITH SLX the number of SW ranged from 2000 to 4500. On the Lithostar 1000 to 4000 SW were applied. On both electromagnetic sources the energy level did not exceed medium energy level (level 5). For comparative reasons only 3 localisations were distinguished: kidney, upper ureter, lower ureter. Stone size ranged from 5 to 18 mm and from 4 to 16 mm respectively. In 72% of the cases disintegration was noted after the first treatment. Detailed results are shown in the following table:

Total N = 68	kidney	upper ureter	lower ureter	no success	partial success	compl. success
SLX	32	3	2	11	21	5
Lithostar	27	3	1	8	20	3
Σ	59	6	3	19	41	8

In this retrospective serie the reasons for the low-dose concept were early desintegration, cardiovascular adverse effects and pain. No adult patient required ITN, whereas children up to the age of 16 routinely receive an ITN undergoing ESWL. The majority of patients received analgosedation, a few needed topical EMLA-cream and NSAID's only.

Electromagnetic lithotripters offer the technical prerequisites for a low-dose ESWL-concept in selected cases. Re-treatment rate is higher in comparison to standard regimen. Wether optimal tuning of energy range, number of shock waves (SW) and frequency of SW-application could be beneficial in terms of fragmentation and pain sensation remains to be studied.

16th World Congress on Endourology and ESWL
03.-06.09.1998, New York, USA

ARE AUXILIARY MEASURES NECESSARY IN THERAPY OF UROLITHIASIS IN CHILDREN ?

P.M. Braun, A. Weber, M.S. Michel, M. Spahn, K.U. Köhrmann, A. Krautschick, P. Alken

Department of Urology, University Hospital Mannheim, University of Heidelberg, Germany

Since the introduction of extracorporeal shock wave lithotripsy (ESWL) in the 1980's this method became first line treatment for urolithiasis in adults as well as in children. Besides supportive medical treatment auxiliary measures are required for optimized urological outcome of the procedure. In comparison to adults auxiliary measures are rare in children, but can not always be avoided. Subject of this retrospective study is to analyze necessity and succes of auxiliary measures in children treated for urolithiasis.

From 1990 to 1997, n=44 children, 24 female and 18 male patients, in the age from 8 months to 17 years, have been treated for urolithiasis. 38 children received ESWL. ESWL was performed with the Lithostar Plus overhead module and the STORZ MEDICAL MODULITH SLX (localisation by in-line ultrasound). Adjuvante auxiliary measures got 9 children: 15 children presented with upper urinary tract obstruction. 9 out of 15 had fever > 38° C and analgesiaresistant loin pain which lead to pigtail insertion (n=6; age 14 - 17 years) or percutaneous drainage (n=3; age 3 - 5 years). Curative auxiliary measures: 3 children underwent ureterorenoscopy (URS) for distal ureteric stones, 1 child had percutaneous nephrolitholapaxy (PCNL) secondary to homozygous cystinuria, 1 child needed section alta and open nephrolithotomy was performed in 1 case.

After ESWL 17/38 (44,7%) children were discharged with clinical insignificant residual fragments (CIRF), 11 residual fragments were smaller than 3 mm, 6 children left hospital with residuals smaller than 5 mm. 5 out of 38 (13,7%) children needed retreatment by ESWL due to recurrent stones secondary to metabolic disorders (primary oxalosis n=1; homozygous cystinuria n=1), anatomic abnormality of renal pelvis and the collecting system (n=1) or recurrent urinary tract infections (UTI) (n=2). After curative auxiliary measures all children were stonefree.

Curative and adjuvante auxiliary measures prior to treatment are generally not required in children. The exception for adjuvante auxiliary measures are complicated upper urinary tract obstructions and/or persistant pain due to obstruction.

16th World Congress on Endourology and ESWL
03.-06.09.1998, New York, USA

SWL IN PATIENTS TREATED WITH ANTI- AGGREGANT OR ANTICOAGULANT DRUGS

G. Zanetti, E. Montanari, I.K. Goumas, A. Trinchieri, F. Rovera, A. Federici, E. Pisani
Institute of Urology, IRCCS Ospedale Maggiore, Milan, Italy

Introduction

Post SLW haemorrhagic complications are well known. Large perirenal haematomas are described following SWL in patients previously treated with antiplatelet drugs. The aim of this paper is to define how to perform a safe SWL in anticoagulated patients and when and how drugs should be given up.

Patients and methods

Between Jan. 1996 and Dec. 1997, 388 patients underwent electromagnetic shock wave lithotripsy (STORZ MEDICAL AG, MODULITH SLX). Out of them nine patients treated either with antiplatelets or anticoagulant drugs had a renal stone. Out of this subgroup, five patients were taking aspirin because of a previous myocardial infarction, one patient aspirin and one other warfarin because of a previous aortocoronary by-pass, one patient ticlopidin because of previous transitory ischemic attack and the last patient aspirin because of atrial fibrillation. The patients underwent SWL in the morning between 9 and 10 a.m. The high thrombotic risk patients (aortocoronary by-pass, atrial fibrillation, cerebrovascular disease) gave up the chronic antiaggregant/anticoagulant therapy and unfractionated heparin 5000 U.I.t.i.d. (8 a.m. - 4 p.m. - 12 p.m.) were given. On the treatment day the 8 a.m. administration was suspended. The low thrombotic risk patients (previous myocardial infarction) discontinued antiplatelet therapy 10 days before SWL. The treatment voltage ranged between 15 and 18 kV and shock wave number between 1200 - 3500. In the short-term follow-up (1 - 3 - 7 days post-op.) all the patients underwent kidney ultrasonography, X-ray plain abdominal film, blood sample for haemoglobin. On the third post-op. day perop. antiaggregant or anticoagulant therapy was restored.

Results

Neither perirenal haematoma nor haemoglobin drops were observed during the follow-up period. Seven patients were stone free at 1 month follow-up.

Conclusion

In our experience SLW is a safe and efficacious treatment in patients with chronic anticoagulant or antiaggregant treatment. Obviously thrombotic prophylaxis has to be tailored looking at thrombotic and bleeding risk and a careful follow-up is strongly indicated.

4th Asian Congress in Urology
17.-20.09.1998, Singapore

ONE DECADE EXPERIENCE WITH ESWL USING THE ELECTROMAGNETIC SHOCK WAVE MODULITH SL20 AND SLX

A. Weber, K.U. Köhrmann, M.S. Michel, P.M. Braun, P. Alken
Department of Urology, University Hospital, Mannheim, Germany

Extracorporeal shock wave lithotripsy (ESWL) was introduced over one decade ago as an authentic modern miracle for the treatment of urinary stone disease. It has developed first choice for nearly all kinds of urinary tract calculi. In Mannheim since 1989 ESWL is performed on the MODULITH SL 20 and the MODULITH SLX.

From 9/1989 to 1/1996 1302 patients with nearly 1600 calculi underwent lithotripsy. Gaining experience with early evolutions of the generator we developed an ESWL-standard regimen. The scheme defines the amount of shock waves, and the energy level according stone localisation. Monitoring, as well as pain management is standardized. Post-ESWL routine care includes ultrasound and plain X-ray.

In 60% of the cases the stones were localized within the kidney. Stone size larger than 1 cm occurred in 35% of the cases. In 74% primary ESWL was performed. Average number of shock waves was 3400 at an energy level of 16.5 kV. Overall rate of auxiliary measures was 26%, the vast majority was needed in ureteric stones (22%). In Mannheim the 4 of 5 patients with ureteric stones receive an in situ ESWL. Auxiliary measures could be reduced by the concept of re-ESWL (27%) to 13%. Only 7% curative auxiliary means were necessary.

After a follow up of 4 months 82% of the patients were stone free and 5% presented with significant residual fragments. In 80% auxiliary measures finally resulted in a stone free situation. Complications due to ESWL were rare, i.e. 1.5% perirenal hematoma and 2.6% fever. Septical complications were not observed. Our results match with the AUA Guideline Panel basing on „articles with acceptable outcome data“.

In conclusion the electromagnetic shock wave generator MODULITH by STORZ MEDICAL AG achieved excellent results even with the early evolutions of SL 20 and SLX. It was possible to maintain the concept of in situ ESWL and reducing the necessity for auxiliary measures. ESWL remains first line treatment for the vast majority of urinary stones.

XIVth Congress of the European Association of Urology
07.-11.04.1999, Stockholm, Sweden

CLINICAL EVALUATION OF AN INTERACTIVE NAVIGATION SYSTEM FOR THE INTEGRATION OF FLUOROSCOPIC AND ULTRASOUND IMAGING OF THE MODULITH SLK LITHOTRIPTER

K.U. Köhrmann, U. Hagelauer*, P.M. Braun, M.S. Michel, A. Weber, P. Alken
Department of Urology, University Hospital, Mannheim, Germany
*STORZ MEDICAL AG, Kreuzlingen, Switzerland

Introduction and objectives

Combined localisation using fluoroscopy and inline ultrasound is the preferred imaging modality for interdisciplinary and flexible use of a lithotripter. In most lithotripters this combined use is limited due to technical circumstances. The aim of this study was to evaluate an interactive navigation system for positioning of the therapy head and to demonstrate faster and more flexible use of both imaging modalities.

Material and methods

The lithotripter MODULITH SLK is equipped with a shock wave source mounted on a 6 degrees of freedom articulated arm. An inline 5 MHz ultrasound is integrated in this source. A conventional C-arc is used for stone localisation (a.p. and 30°) and the stone is positioned in the isocenter. An electrooptical system comprising a stereo camera and three light emitting infrared diodes (Lithotrack system) is used to detect the position of the therapy head. The data is transmitted into a computer system and a graphical virtual reality display is calculated in real time, allowing the user to interactively position the stone in the focal area.

Results

Pretreatment controls with cross hair marked artificial plaster stones were performed to verify that the accuracy of the Lithotrack system was smaller than focal dimensions. Verification of X-ray based positioning with integrated ultrasound on patients also proved congruence of both imaging modalities. First clinical applications to kidney and ureter stones showed satisfactory stone free rates.

Conclusions

The flexible adaption of a C-arc using the Lithotrack system enabled localisation and shock wave application to different parts of the urinary tract with the patient in prone and supine position. Any available C-arc can be used for this localisation system. The Lithotrack system also seems ideal for orthopaedic indications (pseudarthrosis, tendinitis calcarea).

17th World Congress on Endourology and SWL
02.-05.09.1999, Rhodes, Greece

OUTCOMES OF SHOCK WAVE LITHOTRIPSY UTILIZING A STORZ MODULITH SLX: RESULTS IN THE FIRST 200 PATIENTS

M.E. Moran, V.L. Wilbur, P.J. Desai, C.J. Calvano, M.D. White
St. Peter's Kidney Stone Center, Albany NY, USA

Introduction

The STORZ MEDICAL MODULITH SLX is a 4th generation, multifunctional lithotripsy unit with an electromagnetic shock wave generator. This study represents the results of the first 200 patients treated with this device.

Materials and methods

The first 200 patients treated with this lithotripter were available for follow-up at a mean follow-up of 10 months (range 3 to 17). Patients were stone free if no fragments could be identified on a post-operative abdominal X-ray, they had non-significant fragments if they were less than 2 mm in size. An efficiency quotient was calculated in the standard fashion. There were 12 urologists performing SWL in this series.

Results

42% of the patients treated were women (58% male), 36.5% were right sided, 59% left, and 4.5% had bilateral treated stones. Stone size ranged from 4 to 22 mm in diameter, and were lower caliceal in 33% (66), UPJ 16.5% (33), ureteral in 11.5% (23), and staghorn in 1% (2). The efficiency quotient for all 12 urologists in this series is 0.65 (range 1.0 to 0.2). 72% patients are stone free and 13% have small residual fragments (75% of these in the lower pole).

Conclusions

The STORZ MODULITH SLX lithotripter is more powerful than an unmodified Dornier HM-3 with varying power output. Our outcomes are still early with a mean follow-up of 10 months. 72% are stone free with an EQ of 0.65 with multiple urologists utilizing this device.

17th World Congress on Endourology and SWL
02.-05.09.1999, Rhodos, Greece

OUTCOMES OF SHOCK WAVE LITHOTRIPSY COMPARING A MODIFIED ACCESS ALGORITHM FOR MANAGING ACUTE VS. ELECTIVE STONE CASES

M.E. Moran, V.L. Wilbur, P.J. Desai, C.J. Calvano, M.D. White
St. Peter's Kidney Stone Center, Albany NY, USA

Introduction

It is widely appreciated that the primary conditions effecting the outcome of lithotripsy include stone size, location, composition, and degree of hydronephrosis. Utilizing a STORZ MEDICAL MODULITH SLX lithotripter patients were stratified by their urgency in a simple 1-4 scale (1=immediate, 2=urgent, 3=soon, 4=elective). Outcomes were then compared between groups to see if the urgency of performing lithotripsy effected outcomes.

Materials and Methods

200 consecutive shock wave lithotripsy patients were evaluated. Follow-up ranged from 17 months to 3 months (mean 10 months). Stone free status is defined as no fragments identified, minimal stone burden refers to those particles less than 2 mm, efficiency quotients were calculated. Each category by urgency was then compared by Chi Square analysis for statistical significance.

Results

The stone free rate was not effected by the urgency of performing the shock wave lithotripsy. Urgent cases did have slightly higher rate of cystoscopy and stenting, but the stone free rate at the mean follow-up of 10 months was not different.

Conclusions

The ability to access an open community lithotripter by urgency was evaluated in a prospective fashion. Most urgent cases were associated with more patient discomfort, but not necessarily more hydronephrosis. It is not surprising that the degree of urgency did not effect the stone free rate or rate of auxiliary measures.

17th World Congress on Endourology and SWL
02.-05.09.1999, Rhodos, Greece

PAIN CONTROL BY LOCAL SUBCUTANEOUS BLOCK AUGMENTED BY PARENTERAL ANALGESIA UTILIZING THE STORZ MODULITH SLX

M.E. Moran, V.L. Wilbur, A.R. Parekh, P.J. Desai, C.J. Calvano, M.D. White
St. Peter's Kidney Stone Center, Albany NY, USA

Introduction

During the first 200 cases of shock wave lithotripsy utilizing a STORZ MEDICAL MODULITH SLX device pain control was evaluated prospectively. Attempts at local subcutaneous block using bupivacaine HCl and intravenous sedation was instituted in all patients not electing to have a general anesthetic. Patients were asked to subjectively rate their discomfort during the procedure and asked to compare this procedure to any previous treatments (if any using an analogue visual pain scale).

Materials and Methods

Prospective tabulation of the outcomes and questionnaires of all patients treated on an open stone center's lithotripter were evaluated for pain control and patient comfort for the first 200 patients. Statistical comparison was accomplished utilizing Chi Square analysis.

Results

Power settings varied from level 1 to level 9 (highest) with 51% of the patients being treated level 9. Utilizing the linear pain scale, the average pain level with a local block was 1.01 (range 0 to 10, median 1). Numbers of shock waves varied from 825 to 3600. Patients did receive intravenous analgesics and neuroleptic drugs. Fentanyl averaged less than 100 mg per patient and Versed averaged less than 2 mg per patient.

Conclusion

Pain control utilizing a STORZ MEDICAL MODULITH SLX lithotripter was substantially improved with a local subcutaneous block. Our average pain scale was reduced to 1/10 with the first 200 patients in this series. Most patients were cognitive and interactive throughout the shock wave lithotripsy procedure.

17th World Congress on Endourology and SWL
02.-05.09.1999, Rhodos, Greece

MODULITH SLK – A NEW LITHOTRIPTOR FOR INTERDISCIPLINARY USE: FIRST CLINICAL DATA

K.U. Köhrmann, M.S. Michel, P.M. Braun, A. Musial, A. Weber, P. Alken, M.
Marlinghaus*

Department of Urology, University Hospital, Mannheim, Germany

*STORZ MEDICAL AG, Kreuzlingen, Switzerland

Introduction and Objectives

For interdisciplinary use (salivatory tract stones, pseudarthrosis, Peyronie's Disease) the MODULITH SLK was designed. It combines the powerful deep focus therapy head of the SLX with the flexible arm of the MINILITH SL1. This paper presents the results about the first urological application.

Methods

The shock wave source of the MODULITH SLK is based on the STORZ MODULITH geometry. Cylindrical coil emitting acoustic waves which are focussed by a paraboloid reflector (diameter 175 mm) in the depth of 138 mm. The focal pressure reaches 75 MPa (needle hydrophone, Imotech) within the focal size of 50 x 3 mm (-6 dB). In clinical application stone localisation is made by an integrated inline ultrasound unit. Between May 1998 and October 1998 we treated 74 patients (82 stones) with the MODULITH SLK. The localisation system was inline ultrasound and the number of shock waves ranged from 4000 SW for kidney stones and 6000 SW for prevesical ureter stones. The average energy level was 50 (range level 10-70). All patients were treated in analgosedation (Piritramid 0.1 mg/kg; Midazolam 1-3 mg).

Results

Desintegration rate (fragments < 4 mm) 66/82 (80.5%); Re-ESWL 15/74 (20.3%); auxiliary measures before ESWL 14/74 (14.9%); auxiliary measures after 8/74 (10.9%); adjuvant (stent, PCN) 6/74 (8.1%) curative (URS) 2/74 (2.7%); complications: colics 11/74 (14.9%), fever > 38.8° C 5/74 (6.8%), subcapsular hematoma 2/74 (2.7%).

Conclusion

Due to the increasing application of shock waves for new therapies on the one hand and cost pressure on the other hand, the design of a new generation of lithotripters is necessary. The MODULITH SLK allows interdisciplinary use at reduced cost. The data presented in this study indicate that the efficacy of the MODULITH SLK is as high as the efficacy of the MODULITH SLX using ultrasound localisation.

Urolithiasis 2000
13.-17.02.2000, Kapstadt, South Africa

MODULITH SLX – CLINICAL RESULTS AND EXPERIENCE OF 10 YEARS

P.M. Braun, K.U. Köhrmann, A. Weber, M.S. Michel, P. Alken
Department of Urology, University Hospital, Mannheim, Germany

Objectives

The lithotripter has been used in our urology unit since 1989. We present the clinical results and experience of 10 years.

Material and Methods

The MODULITH SLX features a unique source design characterised by an electromagnetic cylinder and a paraboloid reflector. The source has the widest aperture of 300 mm diameter, a focal distance of 165 mm, peak pressures up to 100 MPa (1000 bar) and energy flux density values up to 1 mJ/mm² (measured by PVDF needle hydrophon). Thus, a high fragmentation efficiency is associated with very low pain sensation at skin level. The source design enables inline ultrasound as well as inline X-ray localisation for ease of patient positioning and simultaneous treatment surveillance.

To date, we have treated 2445 patients between the age of 8 and 87 years, 72% renal calculi and 28% ureteric calculi. The mean stone size for renal calculi was 9.8 mm (2-42 mm), for ureteric stones 2.2 mm (1.1-3 mm). Treatment was performed without or low analgosedation.

Results

Auxiliary measures: preoperative	15%
Auxiliary measures: postoperative	14%
Average number of shock waves	3200
Complication: minor colics	10%
Complication: major renal haematoma	2%
Stone free rate after ESWT	87%
Stone free rate (patients left hospital)	98%

Retreatment rate with ESWL ranged from 6 to 15% and depended on stone size and stone localisation.

Conclusion

The MODULITH SLX has proven to be one of the most effective lithotripters yet requiring no or low analgesia. It is fast, easy to use and gives excellent results also for in situ treatment of ureteric stones. It can be considered as the most advanced modern lithotripter designs offering additionally multifunctional uro-applications.

Urolithiasis 2000
13.-17.02.2000, Kapstadt, South Africa

LONG TIME EXPERIENCE WITH THE MODULITH SLX – A MULTIFUNCTIONAL WORKSTATION

A. Wolf, H. Schorn, P. May
Department of Urology, Klinikum Bamberg, Germany

Due to the financial restraints in the health care system there is a growing economical need for multiple use of costly devices and hospital facilities. The newest generation of Extracorporeal Shock Wave Lithotripsy (ESWL) machines includes not only stone treatment features but also enables multifunctional use of the device.

Since 1994 we use the MODULITH SLX (STORZ MEDICAL AG, Switzerland). The electromagnetic cylinder source is combined with in-line fluoroscopy and (optional) ultrasound. Focus size is 6x6x28 mm. Pressure can be adjusted from 10 to 100 MPa. Maximum energy flux density (ED₊, measured by PVDF needle hydrophone) is 1,06 mJ/mm².

From 6/94 to 12/98 1238 consecutive patients were treated. A JJ-stent was inserted in 46,9%. Intravenous sedation and analgesia was used in all patients except 3. Energy level 6 was used for kidney stones and level 9 (max.) in the ureter. The shock wave repetition frequency was, generally, 120 per minute. The follow-up period was 3 months to determine stone free rate and success rate (□ 3 mm). Success rate was 91,4% in 756 kidney stone patients and 87,1% in 482 patients with ureteric stones. Further treatments were performed in a total of 117 patients (9,5%). 93 patients (7,5%) underwent re-ESWL, 18 (1,5%) URS, and 6 (0,5%) PNL. Out of 8 haematomas (0,6%) 7 were treated conservatively and one by drainage.

With the introduction of a hospital information system (KIS) and digitalisation of our 3 urologic X-ray places the MODULITH SLX is now used as a multifunctional working place (retrograde and percutaneous procedures). The optional data interface allows to retrieve relevant data for treatment documentation.

The MODULITH SLX is an effective, reliable and easy to use high energy machine which can be used as a multifunctional working place.

95th Meeting of the American Urological Association (AUA)
29.04.-02.05., Atlanta, USA

IN VITRO SHOCK WAVE LITHOTRIPSY COMPARISON

M. Joel, H. Teichman, A.L. Portis, P.J. Parker, W.L. Bub, R.C. Endicott, B. Denes, M.S. Pearle, R.V. Clayman
San Antonio, St. Louis, Dallas, USA

Objectives

We test the hypothesis that shock wave lithotripsy machines (SWL) differ in ability to fragment calculi.

Methods

Human urinary calculi composed of calcium hydrogen phosphate dihydrate (CHPD), calcium oxalate monohydrate (COM), cystine (CYS), and magnesium ammonium phosphate hexahydrate (MAPH) were randomly distributed among 7 different SWL machines. SWL was done at each machine's suggested kV for 500 shocks, 2000 shocks, and FDA treatment limits for shocks. There were 5 calculi per composition-machine-shock number cohort. After SWL, stone fragments were sorted by size and compared with analysis of variance.

Results

There were no statistical differences across cohorts for pre-SWL stone mass ($p < 0.9$) or fragment mass recovery yield ($p < 0.6$). The mean differences (mean \pm standard deviation, % of total recovered stone mass) in fragments < 2 mm after FDA treatment limits were:

Machine	CHPD	COM	CYS	MAPH
Dornier HM3 (unmodified)	0 \pm 1	0 \pm 1	1 \pm 2	0 \pm 1
STORZ MODULITH SLX	0 \pm 0	0 \pm 0	0 \pm 0	0 \pm 0
Siemens Lithostar C	0 \pm 0	0 \pm 0	1 \pm 3	1 \pm 1
Medstone STS-T	10 \pm 15	0 \pm 0	10 \pm 21	0 \pm 0
HealthTronics Lithotron	3 \pm 2	0 \pm 1	14 \pm 18	3 \pm 4
Dornier Doli	29 \pm 20	4 \pm 5	3 \pm 4	0 \pm 0
Medispec Econolith	18 \pm 33	9 \pm 14	9 \pm 18	0 \pm 0
p value	0.04	0.15	0.44	0.05

Conclusions

SWL machines vary in ability to fragment stones. All machines are satisfactory for fragile compositions (MAPH). The HM3, MODULITH, and Lithostar C fragmented durile stones best.

INTERACTIVE NAVIGATION SYSTEM FOR SHOCK WAVE APPLICATIONS

U. Hagelauer, DR.-ING. , S. Russo, M.D. , S. Gigliotti, M.D. , C. de Durante, M.D. ,
E.M. Corrado, M.D.

Department of Orthopedic Surgery, Hand Surgery and Microsurgery, Federico II
University, Naples University Medical School, Italy (S.R., S.G, C.de D., E.M.C.),
and Storz Medical AG, Kreuzlingen, Switzerland (U.H.)

The latest generation of shock wave lithotripters, with therapy heads mounted on articulated arms, have found widespread application in the treatment of orthopedic diseases. Currently, integration of an ultrasound probe in the therapy head is the dominant modality for positioning the shock wave focus on the treatment area. For orthopedic applications, however, X-ray imaging is often preferred. This article describes a new method to locate the therapy head of a Lithotripter.

In the first step, the surgeon positions the tissue to be treated at the isocenter of a C-arc. This is achieved using AP and 30-degree lateral projections, with corresponding horizontal and vertical movements of the patient under fluoroscopic guidance. These movements register the anatomic location in the coordinate system of the C-arc.

In the second step, the therapy head is navigated to align the shock wave focus with the isocenter. Position data are reported from an optical tracker mounted on the X-Ray system, which tracks an array of infrared LEDs on the therapy head. The accuracy of the tracking system was determined on a test bench, and was calculated to be 1.55 mm (RMS) for an angular movement of ± 15 degrees around a calibrated position. Free-hand navigation and precise alignment are performed with a single virtual reality display. The display is calculated by a computer system in real time, and uses graphical symbols to represent the shock wave path and isocenter. In an interactive process, the physician observes the display while navigating the therapy head towards the isocenter.

Precise alignment is achieved by displaying an enlarged view of the intersecting graphical symbols. Results from the first test on 100 patients demonstrate the feasibility of this approach in a clinical environment.

21st WORLD CONGRESS on ENDOUROLOGY and SWL
19th Basic Research Symposium, September 21-24, 2003
Montréal, Canada

Moderated Poster Session 5 / Shock Wave Lithotripsy

MP05.17

A MULTIVARIATE ANALYSIS OF RISK FACTORS ASSOCIATED WITH SUBCAPSULAR HEMATOMA FOLLOWING ELECTROMAGNETIC SHOCKWAVE LITHOTRIPSY

N. Dhar, C.S. Ng, A.J. Yost, S.B. Stroom

Glickman Urological Institute, Cleveland Clinic Foundation, Cleveland, OH, USA

Objective Subcapsular or perirenal hematoma is the most commonly-experienced adverse effect directly attributable to extracorporeal shockwave lithotripsy (ESWL). We evaluate the frequency of and risk factors for subcapsular hematoma following high-power electromagnetic SWL using the Storz Modulith SLX lithotripter.

Methods Using an IRB-approved protocol, 483 consecutive renal units were prospectively evaluated with abdominal radiograph and renal ultrasound one month following ESWL by one surgeon using the electromagnetic Storz Modulith SLX lithotripter. A multivariate analysis of potential risk factors, including stone burden and location, number and intensity of shockwaves, and perioperative blood pressure, was performed.

Results Of 483 renal units, 13 (2.7%) were found to have a subcapsular hematoma, which was comparable to the reported incidence with electrohydraulic lithotripsy. By multivariate analysis, no factor was associated with an increased risk of subcapsular hematoma. More specifically, blood pressure at the time of ESWL was not associated with increased risk of subcapsular hematoma in our series.

Conclusion The incidence of subcapsular hematoma following electromagnetic SWL in our series is similar to that of electrohydraulic SWL. However, contrary to prior reports, blood pressure at time of treatment was not associated with an increased risk of subcapsular hematoma.

21st WORLD CONGRESS on ENDOUROLOGY and SWL
19th Basic Research Symposium, September 21-24, 2003
Montréal, Canada

Moderated Poster Session 31 / Shock Wave Lithotripsy

MP31.26

PRIMARY ESWL FOR URETERIC STONES AVOIDS INTERVENTION AND INJURY

M.A. Hanna, J.D. Olsburgh, C. Hudd, J.W.A. Ramsay
Department of Urology, Charing Cross Hospital, London, UK

Objectives The aim of this study was to determine the number of interventions that were necessary following 185 consecutive treatments (primary ESWL) for ureteric stones.

Methods A retrospective analysis of 185 consecutive patients with ureteric stones was performed, over a period of 3 years from October 1999. Patients were referred from 9 urology units and treated within 15 days from referral date on a Storz Modulith SLX-MX. Mean duration of treatment was 35 minutes with average 3500 shocks. Patients required 1.4 sessions per stone. 156 of the patients were male, 29 female. Ages ranged from 20-83 years. Treated as outpatients, using rectal diclofenac as a routine analgesic. Average stone size was 6x7mm, 105 left and 80 right. There were 112 Upper, 21 Middle and 52 Lower ureter.

Results 179 [97%] were stone free. 2 had ureteric stent for steinstrasse, however they were stone free after removal of the stent, 4 patients needed ureteroscopy.

Conclusion The review of the literature suggests that ureteroscopy may be the preferred treatment for calculi in the lower third of the ureter. These results suggest that all patients should be offered primary ESWL.