# **The Clinical Case for ESWL**



A Summary of Peer-Reviewed Articles

October 2017 - Issue #1



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### **Editorial**

Dear Doctor,

Extracorporeal Shock Wave Lithotripsy (ESWL) has been the cornerstone of non-invasive kidney stone management for over four decades. As the Medical Officer of Dornier MedTech, I would like to take this opportunity to introduce to you the first issue of "The Clinical Case for ESWL". It is a collection of summaries of some very interesting and important peer-reviewed articles published on ESWL.

As the innovators of ESWL technology, we at Dornier MedTech continuously strive to improve and enhance the efficacy and safety of our ESWL devices. These studies utilized Dornier Delta I and Delta II devices, and continuing this rich tradition, it gives me immense pleasure to introduce to you the latest Dornier Delta® III lithotripter.

The Dornier Delta<sup>®</sup> III offers even more powerful imaging for improved stone visualization, greater penetration depth to treat more stones in more patients, and greater efficiency with time saving features. This semi-integrated lithotripter has everything you need to best manage your patients' stones, and perhaps our most important feature, Opticouple<sup>®</sup> technology—Optical Coupling Control (OCC) which significantly improves stone free rates and lowers retreatment rates.

> It is only prudent that we have a look at some of the important recent evidence published on ESWL, especially with Dornier devices. We have made a sincere attempt to present the most relevant information in a concise and lucid manner with figures where appropriate. I am sure you will find this compendium very useful for your clinical practice.

> > Happy reading!

Yours sincerely,

Dr. Dipen Jagatiya M.B.B.S, M.P.H

Medical Officer Dornier MedTech



This clinical summary reviews the following article from the International Journal of Urology.



International Journal of Urology (2008) 15, 210-215

Outpatient basis extracorporeal shock wave lithotripsy for ureter stones: Efficacy of the third generation lithotripter as the first line treatment

Akiko Murota-Kawano, Kazuhiro Ohya and Hideaki Sekine

### ESWL - A First Line Treatment for All Ureteric Stones?

#### Background

Extracorporeal shock wave lithotripsy (ESWL) is commonly used for the treatment of ureteral stones. Newer Lithotripters are less invasive and are less likely to require anesthesia.

#### Objective

This study presented the outcomes with Dornier Compact Delta Lithotripter in treating ureteral stones from a single center in Japan.

#### **Methods**

A total of 401 cases from December 2001 for which follow up data was available were included in this study.

#### **Treatment Protocol**

Almost all patients (98%) received outpatient treatment. Appropriate analgesia was used and patients were treated in the supine position. The treatment head was positioned under the table for proximal ureteric stones and over the table for mid-distal ureteric stones. Although the intended number of total shocks for each patient was 3000 per session, it was stopped earlier if fluoroscopy showed sufficient fragmentation. The shocks were administered at the rate of 60 shocks per minute. The treatment was started with the lowest intensity and gradually increased to the recommended level ( $\geq$ 16 mJ/shot). About 200 shots were administered at each level. After treatment, patients were categorized as stone free, success (residual fragments  $\leq$ 4 mm) or failure (residual fragments >4 mm).

#### Results

- The median age of patients was 50 years (range 3-92 years).
- The stone free rate was 94.5% (n=379) from 401 cases.
- Stone length (p=0.004), stone location (p=0.04) and sex (p=0.05) significantly predicted stone free rate in univariate analysis. However on multivariate analysis, stone free rate was significantly predicted by stone length only (p=0.01).
- The stone free rate was similar for larger (≥10mm) and smaller (<10mm) stones in the mid-distal ureter (97.1% vs. 97.7%; p=ns)
- Treatment sessions are described below (Table 1):

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Average number of sessions	1.3 (Range 1-5)
Average treatment time	49 minutes per session
Average number of shock waves	3013
Retreatment rate	15.7%
Stone free rate	
1 session	81.3%
2 sessions	91.8%
3 sessions	93.5%

Table 1. Description of shock wave treament

- There was significant difference in the number of treatment sessions required between smaller stones and larger stones on univariate analysis (1.13 vs. 1.30; p=0.006) Outcomes after a single session
- A total of 331 patients received treatment for only one session. Only 1 patient did not have satisfactory results. (Figure 1)



Figure 1. Treatment outcomes in patients who received a single session of ESWL only

- Among stone free patients, patients with smaller stones were more likely to be stone free after a single session as compared to larger stones. (90.1% vs. 77.5%; p=0.0008). There was no difference on the basis of stone location.
- Overall, 22 patients did not achieve stone free status even after multiple sessions. Of these, 18 patients were deemed success as the residual fragments were ≤4mm.
- Only one patient developed subcapsular renal hematoma (major complication) associated with severe flank pain which resolved with conservative treatment.

#### Conclusion

In patients with ureteric stones, including mid-distal stones, treatment with a third generation lithotripter is associated with a high stone free rate and small number of treatment sessions. This non-invasive procedure can be the first line treatment of all ureteric stones.

#### **Reference:**

Murota-Kawano A et al. (2008). *Outpatient basis extracorporeal shock wave lithotripsy for ureter stones: Efficacy of the third generation lithotripter as the first line treatment.* Int J Urol. 2008 Mar;15(3):210-5. doi: 10.1111/j.1442-2042.2007.01970.x.

The full article can be accessed after purchase by <u>clicking this link:</u>



This clinical summary reviews the following article from the International Journal of Urology.



International Journal of Urology (2013) 20, 214-219

# Extracorporeal shock wave lithotripsy for distal ureteral calculi: Improved efficacy using a low frequency

Francisco Jose Anglada-Curado, Pablo Campos-Hernández, Julia Carrasco-Valiente, et al.

### Lower Frequency Improves Outcomes with ESWL in Distal Ureteral Calculi

#### Background

Literature suggests that lithotripsy with lower frequency may be associated with favorable outcomes. Clinical trials with low frequency lithotripsy have focused on kidney and proximal ureteric stones.

#### Objective

To study the impact of two different shock wave frequencies on the fragmentation of distal ureteral calculi.

#### **Methods**

This was a prospective study involving patients with distal ureteric calculi randomized into two treatment groups (based on shock wave frequency), at 80 (High Frequency Group) and 60 shock waves per minute (Low Frequency Group). Only stones between the longitudinal diameter of 0.5 cm and 1 cm were included to reduce the impact of size. However, patients were divided into two groups according to stone size: stone size up to 0.7 cm and stone size between >7 mm and  $\leq$ 1 cm. Cystine, radiolucent or tenuously calcified stones were excluded.

#### **Treatment Protocol**

A Dornier Compact Delta lithotripter was used. Patients were radiologically monitored every 100 shock waves and the shock wave intensity was scaled-up according to patient tolerance. All patients reached the maximum wave intensity of 70 mJ and majority (95%) of them achieved it before reaching 1000 shock waves. Treatment was stopped at 3000 shock waves or if there was evidence of stone fragmentation on monitoring. If non-fragmented calculus was seen on x-ray at one week, a repeat session was performed at the same frequency with a maximum of three sessions.

#### **Primary Outcome**

The total number or dose of shock waves applied.



#### Secondary Outcomes

- The number of sessions received
- Time to the elimination of the calculus
- The rate of resolution
- Pain perception by visual analog scale from 0 to 5

#### Results

A total of 150 patients, 72 in the HFG group and 78 in the LFG group, recruited between September, 2007 and September, 2009 were included in the final analysis. There was a significantly higher number of stones with size 0.7 cm or more in the HFG group as compared to the LFG group (64.3% vs. 40%; P 0.004). The investigators adjusted for this difference in their analysis.

#### Number of shock waves and sessions

The total mean number of shock waves was significantly higher in the HFG group as compared to the LFG group ( $5752\pm3121$  vs.  $2980\pm1211$ ; p<0.001). The number of sessions required was lower with the LFG group ( $1.14\pm0.41$  vs.  $1.56\pm0.75$ ; p<0.001). Both remained significant even after adjusting for difference in stone size distribution. (Figure 1)



Figure 1. Total mean number of shock waves and lithotripsy sessions for HFG and LFG groups

#### Time to elimination

Days to elimination was significantly lower with the LFG group as compared to the HFG group (7.15±4.78 vs. 17.68±12.48;p<0.001); even after adjustment for stone size (0.006) (Figure 2)





#### **Rate of resolution**

Rate of resolution was 100% in LFG group which was significantly better than HFG group (92.9%)(p=0.02). This difference was not significant for calculi >0.7 cm.

#### Pain perception and complications

Pain perception was similar between the two groups (p=0.46). Minor complications like fever and renal colic occurred in 5 patients in the HFG group and renal colic occurred in 3 patients in the LFG group.

#### Conclusion

For treatment of distal ureteric stones, lithotripsy at a rate of 60 shocks per minute is associated with better outcomes as compared to 80 shocks per minute.

#### Reference

Anglada-Curado FJ et al. (2013) Extracorporeal shock wave lithotripsy for distal ureteral calculi: Improved efficacy using low frequency. Int J Urol. 2013 Feb;20(2):214-9. doi: 10.1111/j.1442-2042.2012.03133.x. Epub 2012 Sep 12

The full article can be accessed after purchase by <u>clicking this link:</u>



This clinical summary reviews the following article from the International Journal of Urology.



### Shock Wave Lithotripsy - The Reliable Option

#### Introduction

Shock wave lithotripsy (SWL) is a safe and effective method of treating urolithiasis.

#### Objective

This study described the experience of treating more than 5,000 patients over 25 years using shock wave lithotripsy at a single center. The authors assessed the impact of various treatment optimizing strategies by evaluating annual SWL treatment rate, patient demographics, stone and treatment data, re-treatment (repeat SWL), auxiliary procedures, complications and stone-free rate (SFR) during an arbitrary four phases of development since the introduction of SWL.

#### Methods

The patients were divided into four groups; A (treatment period 1989-1994), B (treatment period 1995-2000), C (treatment period 2001-2006) and D (treatment period 2007-2013) which included 1561, 1741, 1039 and 676 patients respectively. Patients in groups A and B were treated using Sonolith 3000 and patients in groups C and D were treated using Dornier Compact Delta lithotripter. Optimization was done by frequent re-localization, restricting maximum number of shocks and utilizing booster therapy in group B and Hounsfield unit estimation, power ramping and improved coupling in group D.

#### Results

A total of 5,017 patients were included in the final analysis.

#### Stone Location and Stone Free Rate

The stone free rate was 81.3% (n=4079). The number of patients by stone location and stone free rate by stone location are shown in the graph below (Figure 1). The stone free rate according to stone size was 80.5% (n=99), 82.8% (n=1671), 81.0% (n=2021) and 75.4% (n=288) for sizes <0.5 cm, 0.6-1.0 cm, 1.1-2.0 cm and 2.0 cm respectively.





Figure 1. Stone location and SFR for each location

#### **Dornier Compact Delta vs. Sonolith 3000**

Stone free rate was significantly better (p<0.001) with Dornier Compact Delta (84.72%) as compared to Sonolith 3000 (79.53%). There was a progressive improvement in stone free rate from group A to group D (p<0.001) (Figure 2).



Figure 2. Stone free rate in each group

Fewer patients treated with Dornier Compact Delta needed multiple sittings/repeat SWL as compared to Sonolith 3000. (13.6% vs. 40.6%; p<0.001) (Figure 3)



Figure 3. Number of sittings of SWL required by the patients

#### **Other Outcomes**

There was also a statistically significant sequential decline in the total number of shocks required (A, 2153; B, 1817; C, 1528; and D, 1486; p<0.001) and the complication rates (A, 8.0%; B, 6.4%; C, 4.9%; D, 1.6%; p<0.001). About six percent patients (n=298) developed any complications. The efficiency quotient (EQ) improved over the duration of the study (A, 50.41; B, 58.94; C, 68.78; and D, 77.06; p< 0.001). A total of 4.62% (n=232) patients required an auxiliary procedure after SWL and their rate was similar across all groups (p=0.62).

#### Conclusion

Modern lithotripters combined with intelligent treatment strategies have made SWL a highly safe and effective method for treating urolithiasis in properly selected patients.

#### Reference

Jagtap J et al (2014) Evolution of shockwave lithotripsy (SWL) technique: a 25-year single centre experience of >5000 patients. BJU Int. 2014;114:748-53. doi: 10.1111/bju.12808. Epub 2014 Aug 11.

The full article can be accessed after purchase by clicking this link:

This clinical summary reviews the following article from the Hinyokika Kiyo. Acta Urologica Japonica.



### Anesthesia & ESWL: Performance with a third generation lithotripter

#### Background

Newer lithotripters require a lesser degree of anesthesia or no anesthesia and they are also more mobile as compared to the Dornier HM3 lithotripter, the world's first commercially available lithotripter. However, they may not be as effective as the Dornier HM3 lithotripter.

#### Objective

To study the effectiveness of a third generation lithotripter, Dornier Compact Delta, in treating renal and ureteral stones under anesthesia.

#### Methods

A total of 502 patients with symptomatic renal and ureteral stones were treated from January 1, 2003 to December 31, 2005. All patients were treated using the Dornier Compact Delta lithotripter by a single surgeon who recorded all preoperative, intraoperative and postoperative data to avoid inter-operator variability. Treatment success was defined as residual stone fragments less than 4 mm on radiography. Postoperative follow up was conducted at 1 and 3 months to determine success. Stones were classified by location and size using the Japanese Urological Association criteria.

#### **Treatment Protocol**

Patients were treated in the supine position. Seventy percent of patients were given general anesthesia using midazolam. Remaining patients received epidural anesthesia with or without intravenous analgesia. Shock waves were applied at a mean intensity of 5 and an average 3,471 shocks were applied. Patients with treatment failure were treated with repeat extracorporeal shock wave lithotripsy (ESWL) or alternative procedures.



#### Results

There were 334 male and 168 female patients. About 37% of stones were located in the kidney and 63% stones were located in the ureters. A total of 61.8% (310) patients had stones <1 cm, 29.7% (149) had stones from 1 to 2 cm and the remaining 8.6% (43) had stones larger than 2 cm. A total of 459 (91.4%) patients completed the 1 and 3 month follow up. Treatment success rate was 95.9%; 83.9% (385) were stone free and 12% (55) had residual fragments smaller than 4 mm.

#### **Fragmentation by Stone Location**

Treatment success by stone location is shown in figure 1 below. Stones smaller than 2 cm had a greater success rate.



Figure 1: Fragmentation by Stone Location; Stone location: R1, renal calyceal diverticulum; R2, renal pelvis; R3, ureteropelvic junction; U1, upper ureter; U2, middle ureter; U3, lower ureter

#### **Fragmentation by Stone Size**

Treatment success by stone size is shown in figure 2 below. Treatment of ureteral stones had a better success rate irrespective of stone size.



Figure 2: Fragmentation by Stone Size; Stone size: DS2, ≤4 mm; DS3, 4 mm< ≤10 mm; DS4, 10 mm< ≤20mm; DS5, 20 mm< ≤30 mm; DS6, ≥30 mm

The efficiency quotient (EQ), based on stone free rate, retreatment rate and auxiliary procedures, of Dornier Compact Delta in this study was 0.65 which was similar to the EQ of 0.67 of Dornier HM3 published previously.

#### Conclusion

This third generation lithotripter was found to be effective in treating renal and ureteral stones. Treatment efficacy can be improved by performing lithotripsy under anesthesia.

#### Reference

Kurihara K, Kamiyama Y, Saito K, Yasuda M, Ide H, Muto S, Okada H, Horie S. (2007). Anesthesia for extracorporeal shockwave lithotripsy: Teikyo University Hospital experience using the third generation lithotripter. Hinyokika Kiyo. 2007;53(8):545-9

The full article can be accessed after purchase by <u>clicking this link:</u>

Dornier MedTech

This clinical summary reviews the following article from the journal Urolithiasis



### Newer advances - Optical coupling control for ESWL

#### Background

Modern Lithotripters use gel or oil to couple the cushion of the treatment head with the skin of the patient. Any air which gets trapped at the coupling interface can affect the quality of stone fragmentation by interfering with the transmission of shock waves to the patient. The therapy heads of latest Dornier devices come fixed with a video camera and a LED light – Opticouple imaging technology which helps to detect air bubbles and imperfect coupling.

#### Objective

To compare the outcomes of optical coupling control (OCC) with blind coupling during treatment of renal stones with extracorporeal shock wave lithotripsy (ESWL)

#### **Methods**

A total of 336 patients with upper urinary tract stones were randomized into an optical coupling control (OCC; Group A – 169 patients) and a blind coupling (Group B – 167 patients) group between January 2014 and February 2015. A Dornier Compact Delta II UIMS was used. The same urologist performed all the procedures. The shock waves were delivered at 70 shocks per minute and the power was gradually increased to 100%. In the OCC group, air pockets were removed under visual control from the video camera by gently swiping, repeatedly if needed, a hand between the patient and the inflated water cushion. It is preferable to apply the ultrasound gel from a large container instead of a squeeze bottle to avoid air bubbles. Stone free rates at 3 months were measured.

#### Results

The stone characteristics were similar between the two groups (p=ns). The overall stone free rates at 3 months were significantly higher in Group A for both kidney stones (78.2% vs 62.8%; p=0.027) and ureteral stones (81.7% vs 67.9%; p=0.042). The treatment results were also stratified by stone location and they were significantly better in Group A for all stone locations (p<0.05) (Figure 1, 2 and 3).





Figure 1: Stone free percentage by location







Figure 3: Ancillary procedure percentage by stone location

Group A also needed significantly lesser mean number of shocks ( $1900\pm363$  vs  $2400\pm320$ ; p=0.013), lesser treatment time (p=0.021) and lesser energy levels ( $1.6\pm0.8$  vs  $2.3\pm1.2$ ; p=0.036) compared to Group B. Mean fluoroscopy time was less with Group A but not statistically significant ( $1.5\pm0.7$  vs  $1.8\pm0.8$ ; p=0.067).

#### Conclusion

The new Opticouple coupling control technique is associated with significantly better outcomes. It improved the efficiency of shock wave transmission and reduced energy loss leading to optimization of treatment outcomes.

#### **Reference:**

Lv JL. (2016). A new optical coupling control technique and application in SWL. Urolithiasis. 2016; 44(6):539-544. https://doi.org/10.1007/s00240-016-0874-9.

The full article can be accessed after purchase by <u>clicking this link:</u>





