# **Peyronie's Disease**

Papers held at Congresses 1995 - 2001

## ACCEPTED ABSTRACTS 1995 - 2001

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Update: Juni 2001/ok ok/Abstract-Literaturverzeichnisse/IPP\_Juni 2001 13th World Congress on Endourology and ESWL 26.11.-01.12.1995, Jerusalem, Israel

### TREATMENT OF PEYRONIE'S DISEASE (PD) BY EXTRACORPOREAL SHOCK WAVES (ESW)

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There are a variety of treatment modalities with unpredictable results. Presumably shock waves can loosen the fibrous thickening (plaque) of the corpora. Basing on a new technical shock wave device we initiated a study with ESW-therapy in patients with PD.

### Methods

12 patients (27-63 yrs. age) with severe penile deviation and painful erection entered the study. Therapy was performed with a miniaturized lithotripter "MINILITH" (STORZ MEDICAL AG). The plaques were targeted by an inline ultrasound device (7,5 MHz). All patients were treated twice or more with maximum dose of 3.500 SW per application.

#### Results

The mean follow up was 21 weeks. In 8 patients deviation was abolished almost completely, in 3 patients deviation improved. 11 patients had a painless erection. Treatment failure was observed in 1 case. Smaller plaques disappeared in 6 patients. There was no significant difference between ultrasound patterns of plaques before and after therapy. Severe side effects were not observed. Minimal initial bleeding from the urethra occured in 4 patients.

#### Conclusion

ESW seem to alter the structure and elasticity of plaques with good morphological and functional results. For final evaluation of ESW treatment of PD more patients and longer follow up are necessary.

XI. National Congress of the Italian Andrological Society 16.-18.10.1997, Roma, Italy

### PEYRONIE'S DISEASE: COMBINING INVASIVE AND NON-INVASIVE TREATMENT METHODS – OUR EXPERIENCE

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In 1994, we started medical treatment of patients suffering from Peyronie's disease by injecting verapamil into the stabilised plaque. Initially, verapamil was injected into the plaque itself (52 patients) and subsequently into the perilesional regions (21 patients). For a period of six months, 10 mg of verapamil were injected every two weeks. During the last six months, we have been using a MINILITH SL1 which allows the type of plaque we are dealing with here to be treated by means of shock waves. Hence, we decided to prove the effectiveness of a therapeutic combination of shock waves and verapamil (perilesional injection) by carrying out this type of treatment on 36 patients suffering from stabilized Peyronie's disease (with almost completely calcified plaque with a maximum length of 25 mm). All patients were first subjected to three treatment sessions by means of the MINILITH SL1, each session lasting 20 minutes and with a weekly interval between the individual sessions. Each patient was then given a total of 12 verapamil injections (10 mg), that is one injection every two weeks for a period of six months.

The ultrasound image taken after completion of the therapy proved that the plaque had diminished in seven out of 36 patients. The treatment was well tolerated by all patients, and only eleven petechiae were found on some of our patients after extracorporeal shock wave therapy. Patients suffering from penile angulation at the beginning of our study experienced a reduction in the curving of the penis. On the other hand, patients who had suffered from penile pain, which is one of the symptoms of Peyronie's disease, reported that the sensation of pain had soon disappeared.

We have thus come to the conclusion that the combination of the two treatment methods outlined above can be drawn upon to stabilise Peyronie's disease without the patients having to undergo surgery.

## THE USE OF SHOCK WAVES IN THE TREATMENT OF PEYRONIE'S DISEASE

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### Objectives

The increasing experience gathered in the field of extracorporeal lithotripsy and the technological progress in this sector have led to the recent introduction of a lithotripter of compact design (MINILITH SL1 manufactured by STORZ) which has already proved its worth in orthopaedic applications and in the treatment of stones in the salivary glands. The use of this apparatus in the extracorporeal shock wave therapy (ESWT) of Peyronie's disease was originally suggested by M. Butz.

Since November 1996, we have been using the MINILITH SL1 in order to study the effectiveness of this system and the indications it is suitable for and examine the patients' tolerance to this type of therapy.

### Methodology

The study was carried out on 45 patients aged between 36 and 69 (average age 56.2) whose anamnesis was established and who were subjected both to an objective examination and a dynamic ultrasound examination of the penis. A photograph of the penis was taken after a pharmacologically induced erection. The onset of the disease could be dated back to a minimum of three up to a maximum of 48 months before the beginning of the therapy. 15 patients reported that they felt pain during erection. 41 patients exhibited penile angulation during erection. The dynamic ultrasound images revealed calcified plaque in the case of 13 patients and fibrotic plaque in the case of 32 patients.

During each treatment session, 2000 to 4000 shock waves were targeted on the plaque which the ultrasound image had shown to be the biggest. The energy density varied between 0.07 mJ/mm<sup>2</sup> and 0.17 mJ/mm<sup>2</sup>. The intention was to subject each patient to at least three treatment sessions. The use of anaesthetics and analgesics proved unnecessary. Energy level 4 (0.11 mJ/mm<sup>2</sup>) was well tolerated by 33 patients, whereas 12 patients reported that they had felt pain when the energy level was increased above level 3 (0.07 mJ/mm<sup>2</sup>). All three treatment sessions were performed on a total of 42 out of the initial 45 patients. Only one patient had to interrupt treatment because of severe pain during the therapy. The other two patients had to give up due to business commitments. The dynamic ultrasound examination carried out before the start of the therapy revealed that 12 patients exhibited calcified plaque, whereas the other 30 patients showed signs of fibrotic thickening in the region at issue.

After conclusion of the third treatment session, all 42 patients completed a questionnaire answering questions on the subjective results of the extracorporeal shock wave therapy, i.e. reduction in the sensation of pain, modification of the penile angulation and consistency of the plaque examined by the patients by palpation.

### (continued)

At the end of the therapy, the patients were again subjected to a dynamic ultrasound examination of their penis.

All patients who had experienced a subjective improvement as a result of the therapy were subjected to additional treatment sessions, whereas the "non responders" were referred to alternative treatment methods.

### Results

The results are based on the 42 patients that completed the first series of three treatments. No significant complications occurred. Only three patients exhibited minor damage to the penile cutis in the form of petechiae, which, however, suddenly disappeared within 24 hours. 35 out of 42 patients (83.3 %) reported a subjective improvement in the sense that the disease "had come to a halt" as well as "softer" plaque.

As regards the sensation of pain (felt by 15 patients), seven patients (40 %) reported a complete remission of the symptom. 14 patients out of 41 (33 %) experienced a reduced penile angulation during erection. The ultrasound examination carried out before the therapy revealed calcified plaque in only seven of the 35 patients that reported a subjective improvement, whereas all other 28 patients exhibited fibrosis. Seven patients out of 42 (16.6 %) experienced no subjective improvement of their disease and consequently interrupted extracorporeal shock wave therapy. The ultrasound examination carried out before the therapy revealed calcified penile plaque in five out of these seven patients, which, incidentally, was the only pathologic characteristic the "non responders" had in common.

The dynamic ultrasound examination carried out after the third treatment session revealed that the size of the plaque had diminished in 12 cases, whereas 19 patients merely exhibited a modified pathogenicity. The ultrasound image of the remaining 11 patients revealed no modification at all.

The 35 patients who had responded to the first three treatments were subjected to an additional examination after six treatment sessions. 14 out of the 28 patients whose ultrasound image had not revealed any calcified plaque reported a further remission of the symptoms. Five out of the seven patients with calcified plaque (70 %) experienced a further improvement of their condition, whereas the disease had at least stabilized in the remaining two cases.

### Conclusion

Against the background of the results detailed above, it can be said that extracorporeal shock wave therapy presents itself as a new treatment method with a promising future.

ESWT has proved to be free from complications, reproducible and easy to perform. As regards the effectiveness of the treatment it can be said that patients not exhibiting calcified plaque seem to respond better to the treatment and that in most cases a first remission of the symptoms occurs after only a few treatment sessions.

When treatment is continued, about 50 % of the patients experience a further abatement in the severity of the symptoms. Patients exhibiting calcified plaque seem to require a higher number of treatment sessions.

XIIIth Congress of the European Association of Urology (EAU) 21. – 25.03.1998, Barcelona, Spain

### EXTRACORPOREAL SHOCK WAVES TREATMENT (ESWT) IN LA PEYRONIE DISEASE (P.D.): A NEW THERAPY ?

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### Introduction & Objectives

The etiology of P.D. is unknown; neither current conservative nor operative treatment can cure the painful angulation of the erected penis due to fibrous plaques within the tunica albuginea of the penis. M. Butz (1995) and L. Orestano et al. (1996) published their results applying a new miniaturized extracorporeal shock wave device often destroying the plaques and improving the elasticity of the fibrous plaques. Therefore we performed ESWT to verify these first results.

#### Material & Methods

From April to August 1997, 43 patients (age 31 - 70, mean 55.9), with a clinical onset of the disease from 2 to 60 months (mean 24 months) were treated. Prior to ESWT, all the patients underwent a penile dynamic ultrasound, 30/43 pz. had photodocumentation of a physiological erection. 3/43 suffered from Dupuytren disease; 33/43 received medical therapy and/or physical-injective treatment with Ergotein or Verapamil before ESWT. 13/43 pz. complained painful erection, 41/43 angulation of the penis (19 pz. with  $\ge 40^{\circ}$ , 13 pz. 20° - 40°, 9 pz. 10° - 20°). 23/43 had difficult penetration, 16/43 erectile disfunction. Concerning the dimension of the plaques: 18 pz. had plaques  $\geq$  3 cm, 23 pz. 1 – 3 cm, 2 pz.  $\leq$  1 cm; 31/43 presented calcified plaques at ultrasound (7 completed, 24 partial, fibrotic in 12). 33 pz. had one plaque, 9 pz. two, 1 pz. 3. We utilized the STORZ MINILITH SL1 lithotripter with a 7.5 MHz in-line ultrasound scanner, rotable through 360°, with a focal depth from 0.5 to 4 cm, 120 shock waves per minute. All the patients underwent 6 treatments and for each one from 3000 to 4000 shock waves were administered on the plaque responsible for the recurvatum (energy 0.07 mJ/mm<sup>2</sup> - 0.11 mJ/mm<sup>2</sup>). Neither anaesthesia nor analgesia were needed.

### Results

After 6 treatments all the patients were re-evaluated with clinical examination, auto-evaluation questionnaire and photodocumentation. 32/43 pz. (74,5 %) had subjective results, such as improvement of elasticity of the plaque with easier and more satisfactory intercourse, even for the partner; and objective improvement, with plaque and recurvatum reduction from 10 to 50 %. A complete remission of P.D. in 4/32 pz. (12,5 %) with a recurvatum from  $20^\circ$  -  $40^\circ$  there was obtained. Pain disappeared in 13/13 pz. (100 %). We observed 11/43 nonresponder patients (25,5 %): 5/19 (26 %) with a recurvatum >  $40^\circ$ , 2/13 pz. (15,3 %) between  $20^\circ$  -  $40^\circ$ , 3/9 pz. (33,3 %) between  $10^\circ$  -  $20^\circ$ . The ecogenicity of plaques varied only in the fibrotic or partially calcified ones (36/43 pz., 80,6 %).

### Conclusion

ESWT seems to improve both pain and chronicized angulation of the erectile penis. A most effective response is observed in fibrous and partially calcified plaques. There is a positive correlation between the size of the plaques and the timing of the treatments. ESWT was easily performed without any major complications. A longer follow-up is needed to evaluate the evolution of the fragmented plaques. 93<sup>rd</sup> Annual Meeting of the American Urological Association (AUA) 30.05. – 04.06.1998, San Diego, USA

### TREATMENT OF PEYRONIE'S DISEASE (PD) BY EXTRACORPOREAL SHOCK WAVES (ESW)

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#### Introduction and Objectives

Conservative therapeutical methods of PD suffer from a lack of validation with regard to effectiveness. Theoretically, application of ESW to fibrotic plaque could change its structure and elasticity. We initiated an ESW-study of PD with an miniaturized lithotriptor.

### Methods

From June, 1995 until October, 1997, 52 men aged 24 to 74 years (mean 55.1 yrs.) with disabling curvature of the penis entered the study. Shock waves were applied with a miniaturized lithotriptor (MINILITH SL1, STORZ MEDICAL AG). The plaques were identified with an inline ultrasound scanner (7.5 MHz). 3000 shock waves were applied per treatment (1 to 7 treatments). The mean follow up is 9 months.

#### Results

1. Penile angulation was abolished in 3 and improved in 18 cases (p=.007).

2. 10 patients out of 21 regained capability of sexual intercourse (p=.038).

3. 15 patients out of 18 were cured from painful erections (p=.019).

As to erectile dysfunction a tendency of improvement was observed. Patient's benefit from ESWT was independent of the size, localisation or calcification of the induration. Moderate side effects of ESWT were skin hematoma (75 %) and short urethral bleeding (5.7 %). The overall success rate of ESWT was qualified as good respectively satisfying by 53.8 % of the patients.

### Conclusions

Relief of the main symptoms (penile curvature and pain) is statistically significant. So far the success rate of ESWT seems to be superior to other conservative methods of treatment. ESWT represents a non invasive procedure which can be applied on an outpatient basis. Serious side effects were not observed. Extended follow up is warranted for evaluation of effectiveness of ESW of PD.

Source of Funding None.

93<sup>rd</sup> Annual Meeting of the American Urological Association (AUA) 30.05. – 04.06.1998, San Diego, USA

### SHOCK WAVES IN LA PEYRONIE'S DISEASE: THE PRELIMINARY REPORT

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### Introduction

A small-sized lithotriptor was appleid for the local shock wave treatment (ESWT) of La Peyronie's disease, with the aim of verifying ist therapeutic efficacy.

### Materials and Method

70 pts. aged 36 – 72 years (av.age: 54 yrs.) all referred for La Peyronie's disease lasting for a period of time varying from 3 to 52 months were enrolled in the protocol. 31 pts. complained for painful erection and 56 pts. reported bending of the penis during erection. We used an apparatus (MINILITH SL1, STORZ MEDICAL AG), equipped with a jointed arm which made it extremely easy to manouvre. Each treatment session called from a minimum of 2000 to a maximum of 4000 shock waves, targeting the largest plaque revealed by the ultrasonic scan. The emission frequency was 120 shocks per minute in all cases. The protocol called for at least three treatment sessions for each patient. The pre-treatment dynamic ultrasonic scans of the penis revealed cacific plaques in 25 pts., while in 42 cases plaques with a fibrous pattern were shown up.

### Results

67 out of 70 pts. completed the cycle of a 3 treatment sessions, and the results were therefore evaluated on the basis of this number. On completion of the 3<sup>rd</sup> treatment session, 51 pts. (76 %) reported subjecitve improvement described as "stoppage in the progression and/or partial regression of the disease" on self examination. Pain disappeared in 25 out of 31 pts. concerned (80 %). In 22 cases out of 56 (39 %), a reduction in the degree of bending of the penis during erection was reported. In the group of 16 pts. who felt no subjecitve improvement, the pre-treatment ultrasonic scan had showed calcific plaques. The 51 pts. who reported subjective improvement underwent a further cycle of 3 treatment sessions. Of the 42 pts. in whom the disease had non-calcific characteristic, 18 (42 %) reported further regression of their symptoms and in 24 (58 %) the result was stabilized. Of the 9 pts. with calcific plaqes, 6 reported further improvement, 3 reported stabilization of the pathological profile.

#### Conclusions

Shock wave therapy seems to be free of complications, easy to implement and repeatable. Initial regression of the symptoms occurs in must cases after a limited number of applications. Non-calcific plaques appear to respond faster than the calcific ones.

Source of Funding None

39. Tagung der Südwestdeutschen Gesellschaft für Urologie 21.-23.05.1998, Mannheim, Germany

### EXTRAKORPORALE STOSSWELLENTHERAPIE (ESWT) BEI INDURATIO PENIS PLASTICA

M. Butz, H.-M. Teichert Nürnberg, Germany

Einleitung:

Eine Vielzahl nicht standardisierter Behandlungsmethoden wird bei IPP weitestgehend erfolglos angewandt. Die positiven Erfahrungen mit der ESWT bei orthopädischen Schmerzzuständen waren Anlass, die ESWT bei IPP zur Besserung bzw. Heilung der Symptome Schmerz und Deviation zu versuchen.

### Methodik:

Von 6/1995 bis 10/1997 wurden 52 Männer (Durchschnittsalter 55,1 Jahre) mit dem Lithotripter MINILITH SL1 (STORZ MEDICAL AG) mit durchschnittlich 3 Sitzungen (1-7 Sitzungen) je 3000 Impulse ohne Anästhesie bzw. Analgesie behandelt. Die Plaques wurden mit einem Inline-Ultraschall-Scanner (7,5 MHz) geortet. Das mittlere Follow up betrug 6 Monate.

Ergebnisse und Schlussfolgerung:

- 1. Von 21 Patienten mit Schmerzsymptomatik waren 15 schmerzfrei (p=0,05).
- 2. Die Deviation wurde bei 3 Patienten beseitigt und bei 18 Patienten signifikant gebessert (p=0,005).
- 3. 10 von 21 Patienten konnten wieder Geschlechtsverkehr ausüben.
- 4. Von 11 Patienten mit erektiler Dysfunktion beobachteten 8 eine Besserung (p=0,01).

Grösse, Anzahl, Lokalisation und Kalzifizierung der Plaques korrelierten nicht mit dem Behandlungsergebnis. Als Nebenwirkungen der ESWT wurden bei 75 % kleine Hauthämatome und bei 5,7 % eine passagere, minimale urethrale Blutung registriert. 53,8 % der Patienten beurteilten das Behandlungsergebnis abschliessend als gut bis zufriedenstellend. Die vorläufigen positiven Erfahrungen mit der ESWT bei IPP rechtfertigen die Evaluierung der Behandlungsergebnisse durch eine kontrollierte Studie.

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

### SHOCK WAVES IN LA PEYRONIE'S DISEASE: TWO-YEARS EXPERIENCE

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### Introduction and Objectives

The application of a small-sized lithotriptor for the shock wave treatment (ESWT) of La Peyronie's disease (PD) was originally suggested by M. Butz in 1996. In November 1996 we started to use this method with the aim of checking its tolerability and effectiveness.

### Materials and Methods

From November 96 to April 98 we treated 90 patients with PD, aged between 34 and 74. The protocol called for at least three weekly treatment sessions for each patient. Each treatment session called for the patient to receive 3000 shock waves, targeting the largest plaque revealed by ultrasonic scan. The emission frequency was 1200 strokes per minute in all cases. All patients underwent a physical examination, a dynamic ultrasonography (dUS) and a photograph of the penis after drug-induced erection. 34 patients reported painful erections and 72 showed curvature of the penis during erection. The pre-treatment dUS revealed plaque with calcific features in 32 patients, while for 54 the images were compatible with fibrotic thickening. We used a device produced by STORZ MEDICAL AG, called MINILITH SL 1. This machine was originally employed for orthopaedic use. No anaesthesia or analgesia was required. 4 patients withdrew from the study. The results have been therefore compiled on 86 patients. At the end of the 3<sup>rd</sup> treatment, the patients filled in a questionnaire to provide a subjective evaluation, and they also underwent a physical examination and a dynamic ultrasound of the penis. Starting from April 98 we have been treating our patients with higher levels of energy. We have been giving the patients at least four treatment sessions for each cycle. We treated 23 patients according to this new protocal.

### Results

At the end of the 3<sup>rd</sup> treatment session, 62 patients out of 86 (72%) reported a subjective improvement described as "stoppage in the progression and/or partial regression of the disease" with a feeling of a smaller size of the plaque on self examination. Pain disappeared in 32 out of 34 patients concerned (94%). In 31 cases out of 72 patients (43%) a reduction in the degree of curvature was reported. When we checked the results with photographs and ultrasound it was possible to recognise a reduction of penile curvature in 18 out of 72 cases (25%) and to note that in 23 out of 86 cases (27%) a change had come about in the echogenicity of the loaded plaque.

We were unable to note any significant complication. In 9 patients slight alteration occurred on the skin of the penis, which disappeared sponateously within 72 hours. A slight bleeding from the urethra was observed in one patient, and it stopped within 12 hours. The patients who had reported subjective improvement in their questionnaire received a further cycle of 4 treatment sessions. Of the 47 patients in whom the disease had fibrous characteristics 17 (36%) reported a further regression of their symptoms and in 30 (64%) the results had stabilised. In the group of 15 patients with calcific plaqes, 11 (73%) reported further improvement while 4 (27%) reported stabilisation of the pathological profile. Concerning the 23 patients treated by the new protocol we observed 48% of subjective improvement (11 pts.).

### Discussion

The shock wave's biological effects are mainly purely mechanical interaction and transient cavitation processes. In the case of ESWT, the physical reaction is created by differences in pressure which are generated in the fluid which the shock wave passes through. The fluid blast following the shock wave and the compression and tensile stress may explain part of the SW mechanical effects. Lesions are created inside the tissues being treated, and the extent of these lesions is proportional both to the number of the impulses and to their energy. The structureal modifications which came about in the PD plaque due to application of the shock waves are still being investigated by means of histological and ultrastructural studies at our institute. We are comparing samples of albugineous and sub-albugineous tissues taken from patients with PD who have not undergone shock wave treatment with other samples from patients who have been treated with ESWT.

### Conclusions

ESWT seems to be a new option with encouraging prospects. It is free of complications, easy to implement and repeatable without any negative long-term side effects. Fibrotic plaque appears to respond better, and initial regression of the symptoms occurs in most cases after a limited number of applications. Calcific plaque seems to require a higher number of treatments.

94<sup>th</sup> Annual Meeting of the American Urological Association (AUA) 01.-06.05.1999, Dallas, USA

### LA PEYRONIE'S DISEASE (IPP) AND EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT): OUR EXPERIENCE

E. Gianneo, R. Nespoli, G. Conti, G. Comeri Hospital St. Anna, Como, Italy

From April 1997 to July 1998, 153 patients (age 31-76) with La Peyronie's Disease were treated. 50/153 patients complained painful erection, 151/153 angulation of the penis ( $57 \ge 40^\circ$ ,  $67 \ 20-40^\circ$ ,  $27 \le 20^\circ$ ). 95/153 had difficult penetration, 74/153 erectile disfunction. 55 patients had plaques  $\ge 3$  cm, 86 from 1 to 3 cm,  $12 \le 1$  cm; at ultrasonography 35 patients presented calcified, 101 partial calcified and 17 fibrous plaques. 127 patients had one plaque, 30 patients two, 6 patients three. We utilized the STORZ MINILITH SL 1 lithotripter with a 7.5 MHz in-line ultrasound scanner. All the patients underwent 6 to 8 treatments. 3000 to 4000 shock waves with an energy of 3 - 4 (0.07 - 0.11 mJ/mm<sup>2</sup>) were applied in the middle or at the edge of the plaque.

After treatment all patients were re-evaluated with clinical examination, self-evaluation questionnaire and photodocumentation. 103/153 (67.3%) had good subjective results, such as improvement of elasticity of the plaque with easier and more satisfactory intercourse, even for the partner. Objectively we observed: plaque reduction in 82/153 (53.5%), disappearance in 14/153 (9.1%); recurvatum disappeared in 13/151 patients (8.6%), lowered about 50% in 22/151 patients (14.5%) and about 20% in 67/151 patients (44.3%). Out of 50/153 patients complaining pain, 48/50 (96%) had complete remission. The erectile function improved in 46/74 patients (62.1%). We observed 51/153 nonresponder patients (33.3%): 21/51 (41.1%) with a recurvatum  $\ge 40^\circ$ , 21/51 (41.1%) between 20-40°m 9/51 (17.6%)  $\le 20^\circ$ . We had one bleeding from urethra, one hematoma and the onset of 6 new recurvatum during therapy.

In our experience ESWT cures pain, improves elasticity of the plaque but in a less degreee the angulation of the erectile penis. It is more effective in fibrous and partially calcified plaques. It gives better results in unique plaque, less than 3 cm, located in the middle of the penis. There are no statistically significant differences between patients treated with medical or physical treatment before or during ESWT and patients treated with ESWT alone. It is a non-invasive method, which can be repeated several times, without any major complications. A 6-12-15 months follow-up shows a stability of the obtained results.

94<sup>th</sup> Annual Meeting of the American Urological Association (AUA) 01.-06.05.1999, Dallas, USA

### SHOCK WAVE THERAPY FOR THE TREATMENT OF PEYRONIE'S DISEASE: FIRST CLINICAL INVESTIGATION FOR THE OBJECTIVE DETERMINATION OF DEVIATION IMPROVEMENT BY MEANS OF ARTIFICIAL ERECTION

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### Introduction and objectives:

The literature contains few studies dealing with shock wave therapy of Peyronie's Disease. These studies are based on the subjective symptom improvement described by the patients. Despite the fact that the placebo effect of instrumental therapy forms is about 50%, the deviation improvement of these patients can not be assessed. Thus, some conflicts still exist as to precisely what the objective improvement in terms of deviation angle is. The aim of this study was the objective determination of shock wave effects on the symptoms caused by Peyronie's Disease.

#### Materials and methods:

Up to now, 25 patients (age:  $54.4 \pm 8.9$  years) were enrolled into a therapeutic pilot study. The disease duration was  $30.9 \pm 46.0$  months. Inclusion criteria were: palpable plaque with one of the following symptoms: deviation, pain (visual pain scale), loss of distal rigidity. Clinical examination (prior to first therapy and 1 month after last shock wave application) included: palpation and sonography of the plaque (size), measurement of deviation, pain and distal loss of rigidity (artificial erection, Caverject 5  $\mu$ g). 1000 shock waves (12 kV) per plaque were applied onto the non-erected penis once a week for a period of five weeks (MINILITH SL 1, STORZ MEDICAL).

### Results:

One month after the last shock wave therapy session the deviation angle was decreased from  $57.6 \pm 33.2^{\circ}$  to  $47.2 \pm 29.6^{\circ}$  (n = 19). Erection pain was eliminated in 14 out of 15 cases and reduced in 1 out of 15 cases. Distal rigidity was in none of the cases influenced. Six patients were capable of sexual intercourse before and 11 patients after shock wave therapy. Plaque size was partially reduced in 5 cases and not reduced in 13 cases. One patient stopped the treatment after the second session and dropped out of the study. Other significant side effects than small skin hematoms (90%) or transistent macrohematurias (30%) were not observed.

### Conclusion:

This study demonstrates the objective symptom changes of patients with Peyronie's Disease who underwent shock wave therapy. In contrast to other studies no significant improvement of deviation angle was observed using artificial erection as control parameter. Artificial erection seems to be an objective parameter to evaluate the deviation improvement under standardised conditions. In order to determine the factual significance of this treatment option it seems to be essential to continue with studies based on this concept. Furthermore, experimental studies are necessary to explore the histopathological mechanism of shock wave interaction in fibrotic tissue.

22<sup>nd</sup> Congress of the Scandinavian Association of Urology 10.-11.06.1999, Reykjavic, Iceland

### TREATMENT WITH EXTRACORPOREAL SHOCK WAVES FOR PEYRONIE'S DISEASE (INDURATIO PENIS PLASTICA, IPP) - EXPERIENCE WITH 72 PATIENTS

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#### Introduction and objectives:

So far, neither conservative nor surgical methods have led to satisfactory results in the treatment of IPP. The fibrous and/or calcaneous depositions in the penile fascia lead to painful erection, penis deviation and often to impotentia coeundi. First reports on the local application of extracorporeal shock waves (ESW) describe this method as promising in the treatment of IPP.

### Patients and methods:

Between 4/97 and 12/98 we treated 72 patients with ESW locally applied by a special lithotripter MINILITH SL 1 manufactured by STORZ MEDICAL AG. Per sitting maximally 3000 shock waves were applied to the plaques with 7.5 MHz in-line ultrasound guidance. Depending on the size of the plaques, treatment had to be repeated one to six times (average 3.1). Simultaneous administration of analgesia was required in no patient.

#### Results:

On the basis of parameter scores such as pain, penis deviation and ability to have intercourse the effect of the therapy was assessed by patients and physicians from six weeks to one year. We observed a success rate of 70% in pain, 42% in penis deviation and 35% in the ability to have intercourse. We saw no complications, except some minor petechial haemorhage on the skin of the penis.

#### Conlusions:

The good early results of this new therapy give us reason to hope that the local application of ESW to fibrous/calcaneous plaques in IPP can become an effective method or treatment. In the context of our study larger number of patients have to be included and further experience gathered, especially in respect to long-term results.

Annual Meeting of the British Association of Urological Surgeons (BAUS) 21.-25.06.1999, Glasgow, Scottland

## AN EVALUATION OF A NEW TREATMENT OF PEYRONIE'S DISEASE USING ESWL

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### Introduction:

Peyronie's Disease is a common cause of erectile dysfunction, sometimes requiring surgical correction. We report the efficacy and safety of a new minimally invasive technique using shock waves generated by a MINILITH SL 1 lithotripter (STORZ MEDICAL AG).

Patients and methods:

19 patients (mean age 54 years, range 33-63) whose onset of disease was > 12 months earlier. All the patients described the presence of an angualtion of their penis during erection: eight patients experienced pain during intercourse and all patients had one or more palpable plaques. The patients were assessed using the International Index of Erectile Function, Sexual Functions and a Pain Score questionnaire. The angulation, plaque size and location were observed and photographed. All the patients received three treatments during which a maximum of 3000 shock waves per plaque at a maximum power level of 5 - 6 were administered. The plaques were measured, using ultrasonography, during treatment.

### Results:

The results are based on the patient's subjective improvement and objective evidence from photographs, plaque size on ultrasonography, measurement of angulation and questionnaire scores. One or more variables improved in 18 patients (95%): in 15 (74%) there was an improvement in angulation. There were no major complications and no treatment was discontinued because of pain: all patients complied with the treatment.

### Conclusion:

This treatment is safe, 'patient-friendly', easy to administer and effective. Further evaluation and longer follow-up is necessary.

55. Jahresversammlung der Schweizerischen Gesellschaft für Urologie 02.-04.09.1999, Fribourg, Switzerland

### EXTRAKORPORALE STOSSWELLEN-LITHOTRIPSIE BEI DER INDURATIO PENIS PLASTICA

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### Ziel

Bisher wurde die induratio penis plastica (IPP9 therapeutisch meist erfolglos medikamentös oder mittels einem operativen Verfahren angegangen. In jüngster Zeit wurden auch Therapien mit extrakorporalen Stosswellen beschrieben, welche als minimal invasive Methode gute Resultate erzielten. Seit Juli 1998 standen uns zur Evaluation dieser Therapiemodalität zwei Geräte zur Verfügung. Von der Firma Dornier der Epos Ultra und von der Firma STORZ der MINILITH SL1. Ziel dieser Untersuchung war es, die Effektivität dieser Behandlung zu überprüfen.

### Methode

Von Juli 1998 bis Februar 1999 wurden 18 Patienten mit einem mittleren Alter von 52,9 Jahren (42-72 Jahre) behandelt. Bis zum September 1998 erfolgte die Behandlung mit dem Epos Ultra, einem Gerät mit angekoppeltem Ultraschall zur Ortung, ab September 1998 mit dem MINILITH SL1, mit einem inline Ultraschall. Es wurden 3 – 10 Stosswellentherapien appliziert. Die ersten 5 Sitzungen in der Regel mit einem Intervall von 1 Woche. Nach 5 Sitzungen erfolgte eine Zwischenanalyse. Je nachdem erfolgte eine zweite Serie von weiteren 5 Sitzungen. Es wurden ohne Analgesie 3000 Stosswellen mit einer Energie bis unter die Toleranzgrenze appliziert. Bei den ersten Behandlungen wurde eine künstliche Erektion mit Prostaglandin E1 intrakavernös provoziert. Die Patienten hatten alle eine schmerzhafte Deviation bei Erregung respektive schmerzbedingt (auch Sexualpartnerin) keinen Geschlechtsverkehr mehr. die Krankheit bestand seit 1 Monat bis 11 Jahre.

#### Resultate

Nach der ersten Behandlungsserie (3-6 Sitzungen) hatten 12 der 18 Patienten eine deutliche Besserung bezüglich der Erektionsschmerzen respektive der Geschlechtsverkehrstauglichkeit. 10 von 13 Patienten (76%) mit schmerzhafter Erektion berichten über eine komplette Schmerzfreiheit, 2 über eine deutliche Besserung. Bei 1 Patient persistierte der Schmerz. 9 Patienten (8 davon wegen der Deviation) hatten nach der Therapie wieder ein ungestörtes Sexualleben. Eine Verschlechterung der Situation wurde nicht beschrieben. 4 Wochen nach der Therapie zeigten 3 Patienten ein völliges Verschwinden der IPP (Deviation, Plaque). Bei 3 weiteren Patienten nahm die Deviation zwischen 10°-30° ab. Nebenwirkungen ausser kleinen Hautläsionen mit geringen Hämatomausbildungen traten nicht auf.

### Schlussfolgerung

Die extrakorporale Stosswellentherapie als minimal invasive Methode scheint eine gute Therapiemodalität zu sein. Gute Resultate werden bezüglich der Schmerzlinderung erreicht, der Erfolg bezüglich der Deviation ist subjektiv besser als die Messungen. Die Effektivität beider Geräte ist identisch, das Handling mit der inline Sonographie ist einfacher. Bayerisch-Österreichischer Urologenkongress 05. 2001 Graz, Österreich

### IST DIE BEHANDLUNG DER INDURATIO PENIS PLASTICA MITTELS EXTRAKORPORALER STOSSWELLENTHERAPIE OBSOLET? BREMER ERGEBNISSE AN 81 PATIENTEN MIT IPP

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Die Ätiologie und Pathogenese der IPP sind noch immer nicht hinreichend erforscht. Allgemein wird von einer pathologischen Wundheilung der penilen Tunica albuginea nach vorangegangenem Mikrotrauma bei diesen Pat. ausgegangen. Medikamentöse Therapieansätze haben sich weitgehend als unwirksam erwiesen. Die Ergebnisse der ESWT werden in letzter Zeit zunehmend kontrvers diskutiert.

- Methode: In unserer Klinik wurden von 1997 bis jetzt insgesamt 81 Patienten in Alter von 19 bis 72 Jahren mit einer IPP durch ESWT (Minilith SL1 der Firma Storz) behandelt. Die Mehrzahl der Patienten war zuvor erfolglos medikamentös behandelt worden. Die Plaquegrösse lag zwischen 3 x 5 und maximal 20 x 50 mm. In 5 – 10 Sitzungen in einem Zeitraum von 5 – 10 Wochen wurden insgesamt zwischen 15.000 und 30.000 Stosswellen bei einer Energieflussdichte zwischen 0,03 und 0,25 MJ/mm<sup>2</sup> pro Patient appliziert. Die Beobachtungszeit nach ESWT lag bei bis zu 3 Jahren.
- **Ergebnisse:** Zuvor schmerzhafte Erektionen waren nach der Behandlung zu 98 % nicht mehr schmerzhaft, die Deviation bei 46 % der Patienten deutlich rückläufig oder verschwunden. Ein zuvor zum Teil zusätzlich bestehender distaler Rigiditätsverlust war bei lediglich 28 % der Patienten rückläufig. Bei 38 % blieb die ESWT bezüglich der Deviation ohne Effekt. 16 % der Patienten verzeichneten einen leichten bis mässigen Rückgang der Deviation. Patienten mit kleineren und nicht verkalkten Plaques profitierten von der Behandlung eher, als Pat. mit grossen, verkalkten Plaques, welche zum Teil schon seit Jahren bestanden. Lediglich 7 % der Patienten zu unterziehen.
- Schlussfolgerung: Die ESWT ist ein minimal invasives und risikoarmes Verfahren mit befriedigenden Ergebnissen und bat nach unseren derzeitigen Erfahrungen einen festen Platz in der Behandlung der IPP. Vor allem, da sich bislang keine zufriedenstellende medikamentöse Therapieansätze ausmachen lassen und als Alternative mit Erfolgsaussicht den Patienten z. Zt. nur eine operative Intervention angeboten werden kann.

Zum besseren Verständnis dieser Erkrankung sind unseres Erachtens noch weitere Grundlagenforschungen und prospekziv randomisierte Multicenterstudien erforderlich