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# Objective and Subjective Changes in Patients with Peyronie's Disease after Management with Shockwave Therapy

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## ABSTRACT

***Background and Purpose*: Very few reports have been published on the management of Peyronie's disease by shockwave therapy. Existing publications on this topic are based on subjective improvement described by the patients themselves. Our aim was to determine objectively the effect of shockwave therapy on the signs and symptoms caused by Peyronie's disease.**

***Patients and Methods*: To date, 65 patients (age 58.4 ± 8.7 years) have been enrolled in a therapeutic pilot study. The disease duration was 33.7 ± 42.9 months. Inclusion criteria were palpable plaque together with deviation, pain (visual pain scale), or loss of distal rigidity. Clinical examination (prior to first therapy and 1, 6, and 18 months after last shockwave delivery) included palpation and sonography of the plaque (mean surface size 2.2 ± 1.1 $cm^2$), measurement of deviation, assessment of pain and distal loss of rigidity (artificial erection induced by intracavernosal injection of 5 $\mu$g of alprostadil [Caverject]). Shockwaves (1000 impulses at 12 kV per square centimeter of plaque) were delivered to the nonerect penis once a week for a period of 5 weeks with the Minilith; Storz Medical.**

***Results*: Eighteen months ($N = 35$) after the last shockwave session, the deviation angle had decreased from 59.3° ± 38.1° to 49.3° ± 32.5° ($N = 24$; $P = 0.1496$). Pain during erection disappeared in 15 of 17 patients and was reduced in 1 other patient ($P < 0.0001$). There was no effect on distal rigidity in any patient. Six patients achieved satisfactory sexual intercourse (vaginal penetration) before and 15 patients after shockwave therapy. The adverse effects were small skin hematomas in 90% of patients and initial transient macrohematuria in 30%.**

***Conclusion*: Our study demonstrates objective and subjective changes in patients with Peyronie's disease after shockwave therapy. Artificial erection served as a control to assess improvement of the deviation angle.**

## INTRODUCTION

PEYRONIE'S DISEASE is characterized by a lesion in the tunica albuginea of the corpora cavernosa. During erection, this lesion causes functional shortening and curvature of the involved aspect of the corporeal body. In general, this lesion has been defined as plaque.[1] There is a prevalence of Peyronie's disease of approximately 1% in white men.[2] Although reports have been published on the incidence in younger patients, this disease clearly predominates in patients between 45 and 60 years of age. Despite the currently high number of conservative treatment options available, none of these deals with the underlying cause of Peyronie's disease. Reports have been made on several oral drugs and various pharmacologic agents that were injected directly into the plaque. Radiation, diathermy, and ultrasound have also been described as physical treatment options.[3–7]

In 1989, Bellorofonte and colleagues[8] reported good subjective results following shockwave treatment for Peyronie's disease. Six years later, Butz disclosed excellent results after shockwave treatment in 12 patients.[9,10] Meanwhile, further published articles have reported subjective good results after shockwave treatment.[11,12] All of the above-mentioned studies recruited inhomogeneous patient groups and evaluated only the subjective (symptom) change. We attempted to assess the objective long-term changes in patients with Peyronie's disease

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Table 1. Inclusion and Exclusion Criteria for Shockwave Therapy

| *Inclusion criteria* | *Exclusion criteria* |
|---|---|
| Peyronie's disease in the stable phase | Peyronie's disease in the active phase |
| Palpable plaque | Patient age <18 years |
| Deviation and/or painful erection and/or loss of distal rigidity | Blood clotting disorders |
| 4 weeks elapsed since failed medical therapy | Aspirin intake <3 days before treatment |

after treatment with extracorporeal shockwaves. In contrast to Lebret and colleagues,[13] who claimed that shockwave treatment was ineffective during the acute phase of Peyronie's disease, our patient group was treated during the stable phase of the disease.

## PATIENTS AND METHODS

### *Selection of patients and documentation of symptoms*

Since 1998, a total of 65 patients with a mean age of 58.4 ± 8.7 years have been recruited from our outpatient unit. Inclusion and exclusion criteria are given in Table 1. The stable phase of the disease was defined by the presence of Peyronie's disease over at least 6 months and unchanged symptoms during additional 3 months as well as painless palpation of the plaque in the nonerect penis. The duration of the disease averaged 33.7 ± 42.9 months. Prior to treatment, the size of the plaque was assessed by ultrasonography as having a mean surface of 2.2 ± 1.1 $cm^2$. Artificial erection was initiated to establish standardized objective evaluation (intracavernosal injection of 5 $\mu$g of alprostadil [Caverject]). Pain experienced during erection was measured with the aid of a visual analog pain scale. A urologist measured the angle of penile curvature with an orthopedic protractor and assessed the loss of distal penile rigidity by palpation. Additionally, all patients provided information on the ability to achieve sexual intercourse (vaginal penetration).

### *Statistical methods*

For the statistical analyses of the deviation angles, the sign test was used. A decrease in deviation angle was considered as an improvement and was given the value +1. If the deviation angles remained the same, there was no improvement in the patient, and the value −1 was given. If the deviation angle before treatment was zero, no improvement was possible, and a 0 was given. These zero values were not considered using the sign test. For the statistical analyses of the pain, the Wilcoxon signed-rank test was used.

### *Treatment*

All patients underwent one treatment session per week over a period of 5 weeks. A dose of 1000 impulses was applied per square centimeter of plaque at an energy density of 0.07 to 0.17 $mJ/mm^2$ with the Minilith SL 1 (Storz Medical, Kreutzlingen,

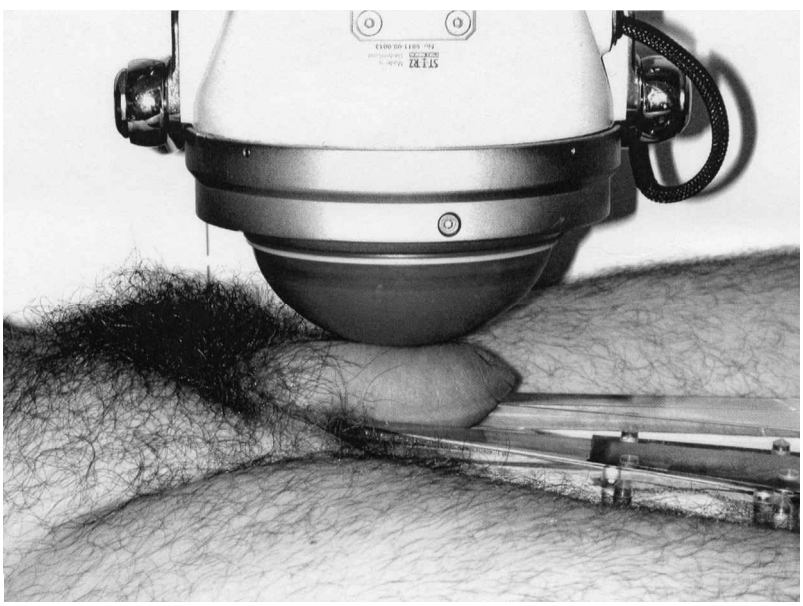

**FIG. 1.** Treatment setting. Penis is fixed on acrylic table while shockwaves are delivered to plaque through dorsal surface of penis.

TABLE 2. OBJECTIVE CHANGES AFTER SHOCKWAVE THERAPY (35 PATIENTS WITH 18-MONTH FOLLOW-UP)

| | *Before SWT* | | *1 month* | | *6 months* | | *18 months* | |
|---|---|---|---|---|---|---|---|---|
| | *N* | *Mean ± SD* | *N* | *Mean ± SD* | *N* | *Mean ± SD* | *N* | *Mean ± SD* |
| Deviation | 24 | 59.3 ± 38.1 | 17 | 50.4 ± 28.3 | 19 | 44.8 ± 30.1 | 19 | 49.3 ± 32.5 |
| Pain | 17 | 7.1 ± 2.9 | 1 | 1.2 ± 1.3 | 2 | 2.1 ± 1.3 | 2 | 2.0 ± 1.1 |
| Intercourse possible | 6 | | 15 | | 16 | | 16 | |
| Loss of distal rigidity | 5 | | 4 | | 5 | | 5 | |

Switzerland). No sedation or anesthesia was administered. During treatment, the penis was fixed on an acrylic table positioned between the legs of the patient (Fig. 1). Each treatment session began at an energy level of 0.07 mJ/mm$^2$. This was evaluated to 0.17 mJ/mm$^2$ during the first 200 impulses. The plaques were localized in the nonerect penis with an inline ultrasound scanner. The surface of the plaque was scanned during treatment. After 1, 6, and 18 months, the penis was reevaluated during artificial erection.

## RESULTS

The adverse effects were slight pain during treatment as well as petichial skin bleeding in 90% of patients and initial transient macrohematuria in 30%. There was no progressive or new plaque formation in any patient after treatment. Of the 65 patients, 35 were followed for at least 18 months. Six of the remaining 30 patients underwent surgical correction during the course of the study (Schroeder-Essed procedure). The rest were treated within the last 12 months without follow-up.

There was no change in the plaque size or loss of distal rigidity in the 35 patients followed for 18 months. No difference was detected in the response of calcified and noncalcified plaques. Pain during erection disappeared in 15 of 17 patients and was reduced in another. The Wilcoxon signed rank test showed a highly significant reduction in pain after treatment ($P < 0.0001$). There was a trend for the deviation angle to decrease. However, in the sign test, no significant change could be observed ($P = 0.1496$). Ten patients who were incapable of intercourse before treatment achieved sexual intercourse after treatment (vaginal penetration). It must be noted that, in contrast to the other patients, the penile deviation in this latter group was moderate. The overall results were stable after follow-up (Table 2).

## DISCUSSION

Previously disclosed results on the management of Peyronie's disease with shockwave treatment were all gained from inhomogeneous patient groups and specified subjective criteria.[8–11,13–16] Accordingly, statements from these studies concerning the treatment outcome of patients with Peyronie's disease are restricted. We carefully selected our candidates, although the majority of patients were reluctant to participate in a study with a sham treatment group. Only patients in the stable phase of the disease were enrolled. A standardized treatment protocol was followed, and the patients were objectively examined and subjectively evaluated before treatment and 1, 6, and 18 months after treatment. Artificial erection served as a control to assess improvement of the deviation angle. With our standardized specifications, we expected to reduce the estimated placebo effect of 50% to a minimum. The "lysis" of plaques after shockwave treatment, as described by Butz,[9,10] was not observed by us or any other group. This was possibly an incidental event. In our study, and in contrast to results published by Baumann,[11] Mirone,[16] and Abdel-Salam[14] and their associates, sexual intercourse (vaginal penetration) was achieved by only 25% of the men. Moreover, in contrast to previous studies, the loss of distal rigidity was not improved by shockwave treatment. In accordance with Mirone and associates[16] and Lebret and colleagues,[13] in our study, it was possible to relieve the pain experienced during erection by shockwave therapy. We were able to show a highly significant reduction in pain after treatment ($P < 0.0001$). In contrast, shockwave delivery did not decrease the angle of deviation to a statistically significant extent. However, this does not mean that there was no improvement in the patients' condition as judged by a medically relevant change in the deviation angle. Furthermore, a larger patient population (100 or more) could influence the $P$ value of the results of the reduction of the deviation angle. The results of our precise and objective evaluation during artificial erection were superior to the subjective quantification described in other studies. Conclusively, our objective and standardized quantification of the deviation angle and pain experienced during erection in men with Peyronie's disease, both before and after shockwave treatment, only partly confirms the results gained in earlier subjective studies. In our study, the loss of distal rigidity was not improved by shockwave treatment.

## CONCLUSION

Shockwave therapy is a useful alternative option to relieve painful erections and in part the penile deviation in men with Peyronie's disease who have pain during erection, moderate penile deviation, or both.

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## EDITORIAL COMMENT

This study evaluates the effects of shockwave therapy for Peyronie's disease. Thirty-five men in the stable phase of the condition underwent preoperative testing to assess penile deviation, pain, and loss of distal rigidity during an erection created with intracavernosal injection and ability to achieve vaginal penetration. Following five weekly shockwave therapy sessions (1000 impulses/cm$^2$ of plaque at 0.17 mJ/mm$^2$ with the Minilith SL1), all men were reassessed at 1, 6, and 18 months. The authors found pain to be significantly decreased 1 month postprocedure, and this effect sustained at 6 and 18 months. There was no change in the penile deviation or the loss of distal rigidity. Seventeen percent of the patients (6/35) were able to achieve vaginal penetration preoperatively compared with approximately 40% (15/35) 1 month after the procedure. Skin hematomas were seen in 90% of patients and gross hematuria in 30%.

The strength of this study lies in the authors' attempts to quantitatively measure changes in penile curvature and pain during an artificial erection before and after treatment. Unfortunately, these quantitative instruments are not necessarily "objective," as stated in the title. Although the penile plaque is not always evidenced by ultrasound imaging, it would have been interesting to report any radiographic postoperative changes in the plaques that were documented preoperatively.

From this study, it appears that the benefit of shockwave therapy for Peyronie's disease may be a decrease in pain during an erection, which translated into a higher percentage of men being able to achieve vaginal penetration. However, because only 50% (17/35) of the patients initially presented with pain, one could argue that the other 50% of the men would not gain any benefit from the procedure. Even the ability of the procedure to improve pain with erection is in question, as a natural history study of Peyronie's disease in 97 patients followed for up to 8 years[1] suggests that pain resolves spontaneously in 94% of men. Without a control arm, there is no way to know if the improvement in pain following therapy is a real effect. This technique awaits a randomized, crossover study.


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