

## Treatment of Peyronie's Disease by Extracorporeal Shockwave Therapy: Evaluation of Our Preliminary Results

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### ABSTRACT

**Background:** Peyronie's disease is an idiopathic disorder of the penis that produces erectile dysfunction. It affects mainly the tunica albuginea. We describe our preliminary results with extracorporeal shockwave therapy (ESWT) as a new noninvasive modality for the treatment of Peyronie's disease.

**Patients and Methods:** In this study, 24 patients aged 36 to 67 years were treated with ESWT on the Lithostar overhead-module (Siemens). All our patients had unsuccessful medical treatment before ESWT. The average plaque was 7 × 15 mm. The number of shockwaves ranged from 15,000 to 25,000 (18–21 kV) delivered in four to ten sessions. Most patients needed local anesthesia before therapy.

**Results:** Four patients (17%) showed marked improvement and complete remission of the penile deviation. Six patients (25%) showed partial remission with painless erections after treatment. Four patients had painless erections after treatment but still had some penile deviation. In 10 patients (41%), ESWT failed, necessitating subsequent penile surgery.

**Conclusions:** Our preliminary results with a response rate of 59% with ESWT for Peyronie's disease, including a 17% complete remission rate, is encouraging. However, further multicenter studies will have to prove if ESWT is a real therapeutic option for this disease.

### INTRODUCTION

PEYRONIE'S DISEASE is a connective tissue disorder that affects the tunica albuginea of the corpora cavernosa of the penis. The disease is not uncommon: approximately 10% of all men with erectile dysfunction have Peyronie's disease. It appears that severely deforming or disabling contracture of the tunica albuginea attributable to Peyronie's disease is rare, but minor inflammation and post-inflammatory fibrosis affecting the tunica are relatively common.<sup>1</sup> Lindsay and associates<sup>2</sup> found that the incidence of Peyronie's disease in a population-based study in Rochester, Minnesota, was 26 per 100,000 men with a prevalence of 389 per 100,000. The exact etiology of Peyronie's disease has not been established. However, it has been suggested that it may be a disorder of wound healing.<sup>3</sup> Several authors suggest that patients with Peyronie's disease may have a genetic predisposition because of its association with Dupuytren's contracture and HLA-B7 antigens. Others suggest

an autosomal-dominant mode of transmission in some families.<sup>4,5</sup> Also, several studies suggest the possibility of an autoimmune etiology of this disease.<sup>6</sup> Trauma to the penis (whether erect or nonerect) is a strongly suggestive etiologic factor. Acute or even minimal repetitive trauma to the erect penis during normal sexual intercourse may induce Peyronie's disease. Patients with partial erectile dysfunction may be even more prone to Peyronie's disease because of the increased mechanical stress associated with the buckling that occurs while attempting sexual intercourse with a partially erect penis.<sup>7</sup> The classical triad of symptoms for patients with Peyronie's disease are pain, abnormal penile curvature during erection, and as a result, to difficult sexual intercourse. On examination, there is palpable calcific plaque in the corpora cavernosa.<sup>8</sup>

Although there are multiple modalities for the treatment of Peyronie's disease, which range from simple medical measures to surgical intervention, there is no well-established treatment for this disease. Oral agents such as vitamin E, potassium para-

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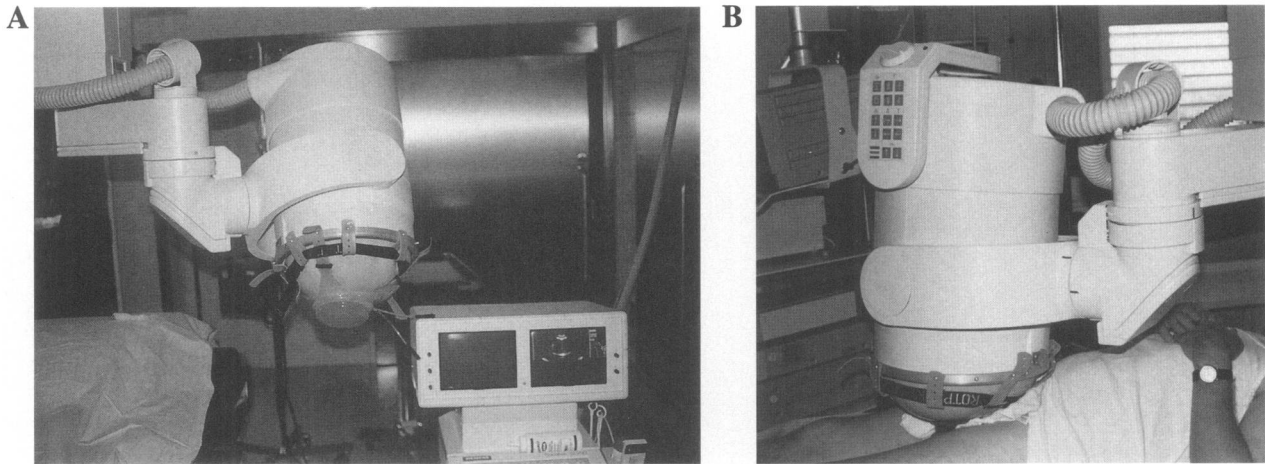


FIG. 1. (A) Siemens Lithostar overhead module for shockwave therapy. (B) Arrangement for treatment.

aminobenzoate, oral tamoxifen, or procarbazine have been used. Intralesional injection of steroids in the form of hydrocortisone, cortisone, dexamethasone; parathyroid hormone; collagenase; or a calcium-channel blocker such as verapamil has been described, but most of these agents have been compromised mainly because of the inadequate follow-up and the inconclusive results.

Because extracorporeal shockwave therapy (ESWT) is a new and very efficient approach to calcifications of connective tissues in orthopedics,<sup>9</sup> we evaluated our preliminary results with ESWT as a minimally invasive modality for Peyronie's disease. The use of ultrasonic waves as a mode of energy transfer has been reported since 1971 as a treatment option for Peyronie's disease.<sup>10</sup> The mode of action of ESWT in Peyronie's disease is not well known. It seems that it destroys the calcific plaque and then improves the elasticity of the penis.<sup>11</sup> Our purpose in this study was to determine whether lysis of the calcific plaque by ESWT would improve the quality of life of our patients by reducing the pain and curvature during penile erection.

## PATIENTS AND METHODS

### *Patient Population and Pretreatment Assessment*

This study was done from January 1997 to September 1998 on 24 patients found to have Peyronie's disease by history and clinical examination. Their mean age was 55.2 years (range 36–67 years), and they had suffered from Peyronie's disease for a mean of 25.8 months (range 6 months–20 years). All our patients had undergone previous nonsurgical treatment in the form of potassium para-aminobenzoate (19 patients), vitamin E (4 patients), cortisone injection (4 patients), radiation therapy (3 patients), and ultrasonic therapy (2 patients). Some patients had received many forms of therapy, but all of these treatment modalities failed. We estimated the original plaque size by multiplying the ultrasonically determined length and width. The mean plaque size was  $15 \times 7$  mm (range  $4 \times 3$  mm to  $15 \times 30$  mm). The angle of penile deviation was measured by comparing a Polaroid picture of the erect penis before and after every ESWT session. The angle of deviation in our patients ranged from  $30^\circ$  to  $80^\circ$ .

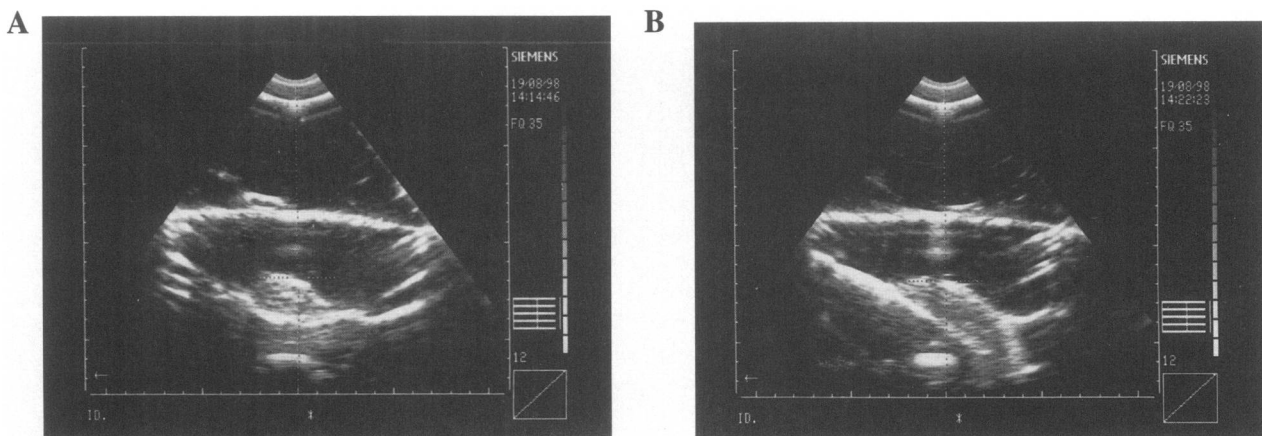
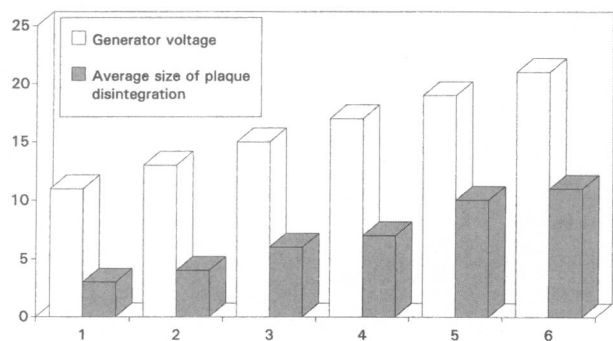


FIG. 2. Ultrasonic localization of calcific plaque. (A) Cross-section. (B) Longitudinal section.



**FIG. 3.** Extent of plaque destruction in relation to generator voltage.

### Technique

We performed ESWT using the Lithostar overhead module from Siemens (Fig. 1). The patient lies in the supine position. Ultrasonic localization of the plaque was done with a coupling device especially designed for SWL in children (Fig. 2).

In the first four cases, we started our treatment without using local anesthesia, but we found that with local anesthesia, we could increase the generator voltage of the shockwaves, which proved to be important for disintegration of the plaque (the extent of calcific plaque disintegration is directly proportional to the energy of the shockwaves) (Fig. 3). We used local anesthesia in the form of 10 mL of Xylonest 1% as penile innervation blockade in all of the following patients. The number of shockwaves ranged from 5000 to 43,000 given over multiple sessions (average 4000/session). The mean number of shockwaves for patients not previously manipulated with local anesthesia was 17,500. The mean number of shockwaves for patients previously manipulated with local anesthesia was 26,000. Also, we increased the shockwave power to 21 kV, but without local anesthesia, we used a power of not more than 15 to 17 kV. The mean number of ESWT sessions was 5 (range 3–10).

Sexual activity was not permitted in the first 24 hours after ESWT.

### Follow-Up

The length of follow-up of our patients ranged from 3 to 9 months and was done only in the responders. Patients in whom ESWT failed were submitted to surgical intervention. Follow-up was done once monthly in the first 3 months and then every 3 months for 1 year. We did our follow-up by patient interview and examination as follows:

### Evaluation of pain during erection:

- No pain
- Improvement but still with some pain
- No change
- Pain became worse after therapy;
- Ultrasonographic evaluation of the plaque size;
- Evaluation of the angle of penile deviation by comparison of Polaroid pictures of the fully erect penis before and after ESWT.

## RESULTS

Table 1 summarizes the response of our patients. Four patients (17%) reported complete remission of all signs and symptoms and could practice a normal sexual life. Ten patients (42%) had painless erection with a reduced angle of deviation. The size of the calcific plaque decreased in all responders, and the average amount of plaque disintegration correlated with the generator voltage of the shockwaves (Table 2; see Fig. 3). The improvement of the penile angle in all responders with restoration of a straight penis in four patients indicates that the main effect of ESWT is lysis of the calcific plaque. In turn, this change improves the angle of penile deviation and the elasticity of the penis.

The only complication was intolerable pain during therapy in two patients, which necessitated stopping the session. After we began using local anesthesia, we found that there is no pain during therapy, regardless of the energy power used. Most patients developed minimal penile ecchymosis after ESWT, which improved spontaneously without medication within 2 to 3 days.

## DISCUSSION

The first experimental results on the effect of shockwaves on bony and connective tissues were reported in 1988 by Graff et al.<sup>12</sup> Their work stimulated further experiments that eventually led to significant clinical applications in orthopedics.<sup>13–15</sup> Peyronie's disease, in many cases, cannot be corrected by conservative or surgical methods. A targeted application of shockwaves promises relief in some cases. The goal is to reduce the pain and the kink (bend) of the erect penis.<sup>16</sup>

The first application of ESWT in Peyronie's disease was reported in 1995 by Butz at the 13th World Congress on Endourology & SWL.<sup>17</sup> In his study of 12 patients, he found that in 8 patients, penile deviation was abolished almost completely, and in 3 patients, deviation improved. Eleven patients had pain-

**TABLE 1. RESULTS OF ESWT FOR PEYRONIE'S DISEASE (%)**

Symptom/Sign	Complete Remission	Better	Stable	Worse
Pain	14 (59)	3 (13)	7 (29)	0
Penile deviation	4 (17)	10 (42)	10 (42)	0
Ability of intercourse & overall condition	4 (17)	10 (42)	7 (29)	3 (13)

TABLE 2. CORRELATION BETWEEN EXTENT OF CALCIFIC PLAQUE DISINTEGRATION AND GENERATOR VOLTAGE

Generator Voltage (lcV)	Average Size of Plaque Destroyed (mm)
11	3
13	4
15	6
17	7
19	10
21	11

less erections after therapy, and treatment failure was observed in only one patient. Plaque disappeared completely in six patients.

We find that conservative management of Peyronie's disease is always advisable in the first 6 months to allow the pathology of the disease to stabilize. Our preliminary results with the use of ESWT as a minimally invasive treatment option showed improvement of the clinical symptoms in 59% of our patients. We found that ESWT results in rapid reduction of pain, decrease of the angle of penile curvature, and improvement of sexual function. Our results are similar to those of Butz,<sup>17</sup> Giannone and associates,<sup>11</sup> and Baumann and Tauber<sup>18,19</sup> in separate studies. Those groups of investigators showed that after ESWT, more than 60% of patients had marked improvement of their symptoms, considerable straightening of the penis, and easier and more satisfactory sexual intercourse. To date, there are no reported complications of ESWT.

From our results, we found that the ideal candidates for ESWT are those patients with:

- Painful erection;
- Failed previous medical treatment;
- Mild to moderate degree of penile curvature (angle of deviation <50°);
- Plaque <20 × 10 mm in diameter.

Patients with no response to ESWT after 6 sessions should be considered nonresponders. Surgical intervention (i.e., corporoplasty) is the treatment of choice.

We think that the use of local anesthesia in every ESWT session is very important to reduce the pain. This in turn allows the use of higher shockwave energies, which is important to increase the efficacy of ESWT.

## CONCLUSION

Our results are encouraging, especially for patients in whom conservative treatment fails. Because of the noninvasive characteristics of shockwaves and the good objective and subjective results, shockwave therapy is obviously a new alternative or complementary treatment modality. It has also been requested by patients. However, a multicenter randomized study is necessary for further evaluation of the effectiveness of this

new, minimally invasive modality for the treatment of Peyronie's disease.

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