

Focal Shock Wave Therapy and Its Efficacy on Treatment of Peyronie's Disease in a Sample of Iraqi Patients

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Abstract: Erectile dysfunction & painful erections may be linked to Peyronie's disease, an acquired injury in the tunica albuginea represented by the growth of a fibrous tissue plaque. The purpose of this study was to evaluate the safety, efficacy, and satisfaction of patients with Peyronie's disease after receiving focused shock wave treatment. Thirty patients having Peyronie's disease participated in an open-label, single-arm, prospective trial following giving their informed permission. The International Erectile Function Index-5 score, patient demographics, lesion hardness and penile curvature modifications, and overall satisfaction rate were all noted. The Peyronie's plaque is treated with 3000 focused shock waves over the course of 20 minutes, once a week for six weeks. Thirty patients in all, with an average age of fifty, were enrolled in the research over the course of a year. After 33 years, dorsal site curvatures as well as fibrous plaque were the most prevalent. Around two-thirds stated having penile curvature for less than a year, with the majority having greater degrees (30°–60°), and around one-third reported feeling penile discomfort during an erection. When using focused shock wave treatment. After six weeks of follow-up, the majority of patients who had focused shock wave therapy showed significant improvements in their sexual function, as well as alterations to their penile curvature, plaque size, and discomfort, with identical results at the three-month mark. Focal shock wave therapy seems to be extremely safe, highly effective in reducing pain along with penile curvature, preserving penile length, and linked to the highest patient satisfaction rate in these short-term studies in a carefully chosen group of people with Peyronie's disease characteristics.

Keywords: Peyronie's disease, focal shock wave therapy, oral therapies, and erectile function.

INTRODUCTION

Because Francois Gigot de la Peyronie, a surgeon serving King Louis 15th of France, was the first to diagnose and provide treatment for Peyronie's illness in a report published in 1743 [Herati, A. S., & Pastuszak, A. W. 2016], the condition was named after him. However, this anomaly of the penis was last documented by Guilielmus de Saliceto during the thirteenth centuries along with Gabriele Falloppio of the fifteenth century. Peyronie's disease, often referred to as Morbus Peyronies, Induration Penis plastic (IPP), or Nodus Penis, was an acquired injury of the tunica albuginea that is characterized by the development of fibrous plaque and may be linked to painful erections and erectile dysfunction (ED). [El-Sakka, A. I. 2021; Goldstein, I. *et al.*, 2020]

Although the underlying pathophysiology of Peyronie's disease is unknown, it is generally accepted that it is an abnormal wound healing disorder caused by repeated microinjury to the erect penis, which in genetically susceptible individuals results in fibrous plaque within the bilayer for tunica albuginea [Hayat, S. *et al.*, 2023]. When the penis is erect, this plaque, an inelastic fibrotic scar, causes penile curvature on the other side [Chaussy, C. H. *et al.*, 1980]. The two primary stages of Peyronie's disease are the inflammatory (acute) as well as stable (chronic) stages. A patient often reports a recent beginning

of penile discomfort and curvature (less than six months) during the inflammatory phase in Peyronie's disease. [Hayashi, D. *et al.*, 2012]

The entire symptom in the active stage is penile or glanular discomfort or pain for the flaccid as well as erected penis [Becker, M. *et al.*, 2014]. A previous history of penile injuries during sexual activity may be linked to the start of symptoms [Hazan-Molina, H. *et al.*, 2015]. Penile hardness could or could may not be present in the patient. Pain and increasing deformity can also cause distress [Olsen, A. B. *et al.*, 2015; Mirone, V. *et al.*, 1999; Palmieri, A. *et al.*, 2009]. According to patient or physician accounts, the chronic phase patient's symptoms have not changed clinically for at least three months [Hauck, E. W. *et al.*, 2000; Poulakis, V. *et al.*, 2006].

PATIENTS & METHODS

Study Design.

The safety, satisfaction, and efficiency of focal shock wave treatment (FSWT) caused by a specially designed shock wave generator in a private clinic setting were evaluated in an open-label single-arm prospective trial for people with Peyronie's disease.

Study Population.

Each patient completed a permission form upon being fully briefed about FSWT and possibilities for conservative medical therapy.

Data Collection.

The IIEF-5, VAS score before and after FSWT, and the designed questionnaire based on an interview were used to gather data. Penile curvature (based on a digital snapshot of the erect penis) and clinical examination (subjective evaluation of the hardness of the plaque) were performed. According to Rosen *et al.*, the International Index in Erectile Function (IIEF-5) abridged version was used to assess erectile function: absent ED (a score of 22 to 25), mild ED (a score of between 17 and 21), mild to moderate ED (a score of twelve to sixteen), moderate ED (a score of 8–11), as well as severe ED (score: 5–7).

The visual analog scale (VAS), which ranges from 0 for no discomfort to 10 for severe pain, was used to measure painful erections. The results were calculated at baseline, six weeks, and three months after the FSWT trial was finished. A specialized probe connected to a small device with a concentrated shockwave generator (Duolith SD1 extreme Storz Medical) was utilized to administer shockwaves. Focused shock waves (F-SW), which have a short pulse length as well as are concentrated on areas a few millimeters within diameter, enable pulse waves be delivered to a tightly localized area, throughout deeper tissue layers.

Procedure.

The FSWT occurred out in a secure setting utilizing Duolith SD1 ultra without the addition of either systemic or local analgesics. Before

completing an informed approval form, patients were given details about the FSWT's mechanics and process. After locating and marking the plaque location, the patient was placed in the lithotomy position, with the penis completely extended and held on a special stand. The focused shock wave probe (F-SW) was then held. The focused shock wave hand piece (C) and the extracorporeal shock wave treatment equipment (A, B).

Statistical Analysis.

The FSWT was carried out in a private environment utilizing Duolith SD1 ultra without the use of systemic or local analgesics. Before signing an informed permission form, patients were instructed about the FSWT's mechanics and process. After locating and marking the plaque location, the patient was placed in the lithotomy position, with the penis completely extended and held on a special stand. The focused shock wave probe (F-SW) was then held. The focused shock wave hand piece (C) and the extracorporeal shock wave treatment equipment (A, B). The SPSS program for Windows version 24 was employed for the statistical analysis. The paired t-test was utilized to compare the means for a variable prior to and following FSWT.

RESULTS

Thirty patients in all consented to participate in the trial over the course of a year. 23 patients (76.7%) reported having penile curvature and/or deformity for less than a year (mean, 9.93 months; range, 5–17 months), and the average age is 50.33 years (range, 30–69 years). Just three patients (10%) reported having had penile injuries in the past. Twenty-four patients (80%) had undergone and failed prior medical treatment.

Table 1. Baseline characteristics of the studied group (N = 30).

Variable		No.	%
Age (year)	30 - 39	2	6.7
	40 - 49	11	36.7
	50 - 59	14	46.7
	60 - 69	3	10.0
Side of curvature	Ventral	2	6.7
	Dorsal	16	53.3
	Right	4	13.3
	Left	8	26.7
History of penile trauma	Yes	3	10.0
	No	27	90.0
Duration of disease	≤ 12 months	23	76.7
	> 12 months	7	23.3
Failed medical therapy	Yes	24	80.0
	Medication not used	6	20.0

Characteristic of plaque	Fibrous	21	70.0
	Calcified	9	30.0

The degree of curvature was significantly reduced after FSWT, where the mean degree of curvature was (39.7 ± 14.7) before and became (29 ± 15.6) after FSWT (P < 0.001). additionally, the comparison of patients according to different categories of degree of curvature was also statistically significant that the proportion of patients with a degree of < 30 increased significantly after FSWT from 20% to 43.3%, while the proportion of patients with larger degrees

30-60 reduced from 70% to 56.7% and none of the patients had a degree of 60–90 after FSWT, (P=0.001). Nonetheless, the curvature post FSWT was improved in 22 (73.3%); improvement in penile curvature (15 degrees and more) observed in 14 patients (46.7%) with the range of improvement varying between 5 to 25 degrees), unchanged in 6 (20%) and unfortunately, worsened (5 and 15 degrees) in 2 patients (6.7%).

Table 2. Pre and post FSWT degree of penile curvature of the studied group (N = 30).

Degree of penile curvature	Pre FSWT		Post FSWT		P. value
	No.	%	No.	%	
< 30°	6	20.0	13	43.3	0.001 <i>sig</i>
30°-60°	21	70.0	17	56.7	
60°-90°	3	10.0	0	0.0	
Total	30	100.0	30	100.0	
mean (SD*)	39.7 (14.7)		29.0 (15.6)		< 0.001 <i>sig</i>

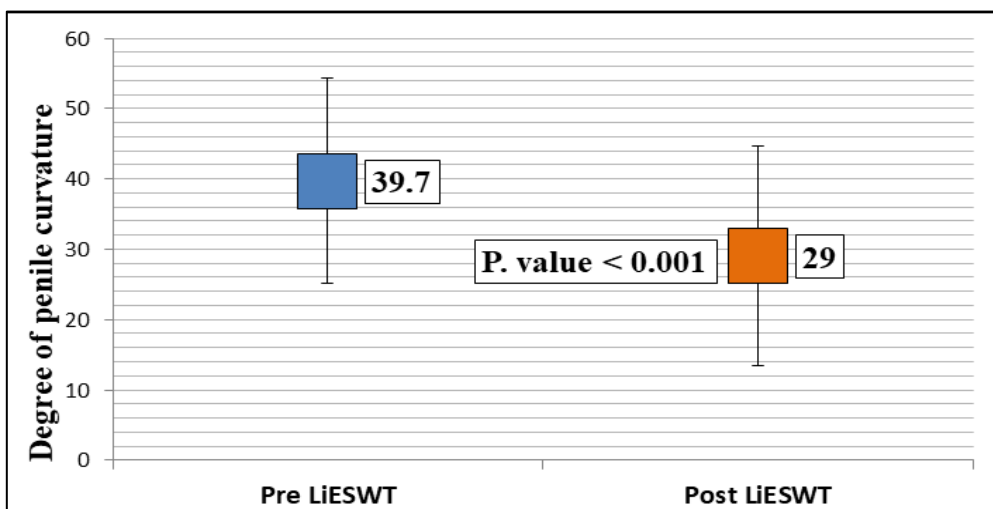


Figure 1. Comparison of pre- and post-FSWT mean Degree of penile curvature (N=30).

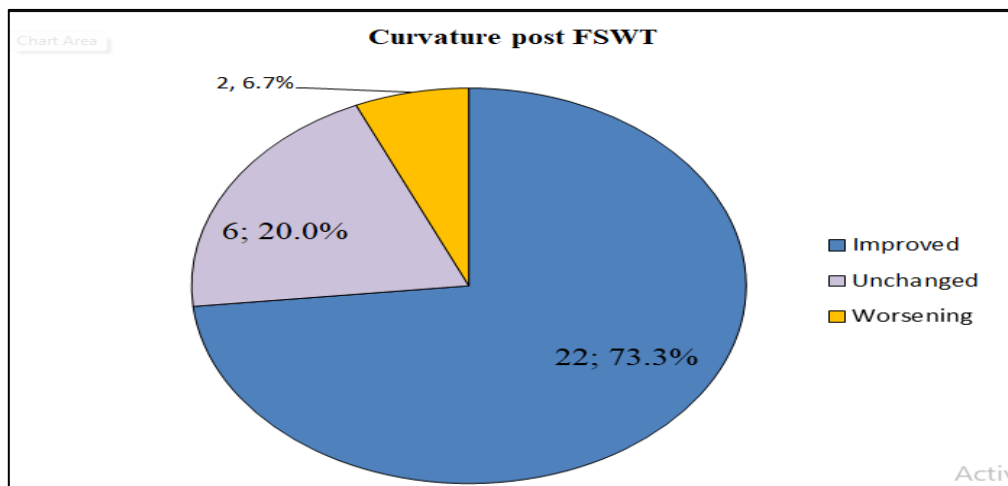


Figure 2. Change in penile curvature post FSWT (N=30).

The size of the penile plaque was significantly reduced after FSWT ($P < 0.05$). The comparison was statistically significant, showing that post-FSWT, a large proportion of patients became with smaller size plaques, where the proportion of patients with size $< 2 \times 2$ cm² increased by 30%

from 43.3% before to 73.3% after FSWT. half of the patients had relatively no change in plaque size by 2cm² (Stabilization), while 12 (40%) patients get decreased in plaque size to less than 2 cm², and only 3 (10%) patient get increased of size more than 2 cm².

Table 3. Pre and post FSWT Size of penile plaque (by US) of the studied group (N = 30).

Size of penile plaque (cm ²)	Pre FSWT		Post FSWT		P. value
	No.	%	No.	%	
$< 2 \times 2$	13	43.3	22	73.3	0.017 <i>sig</i>
$> 2 \times 2$	17	56.7	8	26.7	
Total	30	100.0	30	100.0	

Table 4. Changes in the size of penile plaque (cm²) post FSWT (by US) of the studied group (N = 30).

Changes in the size of penile plaque (cm ²) post FSWT	No.	%	
Increased \ get worse ($> 2\text{cm}^2$)	3	10%	
Decreased \ get better ($< 2\text{cm}^2$)	12	40%	
The same size \ stable	($< 2\text{cm}^2$)	10	33.3%
	($> 2\text{cm}^2$)	5	16.6%

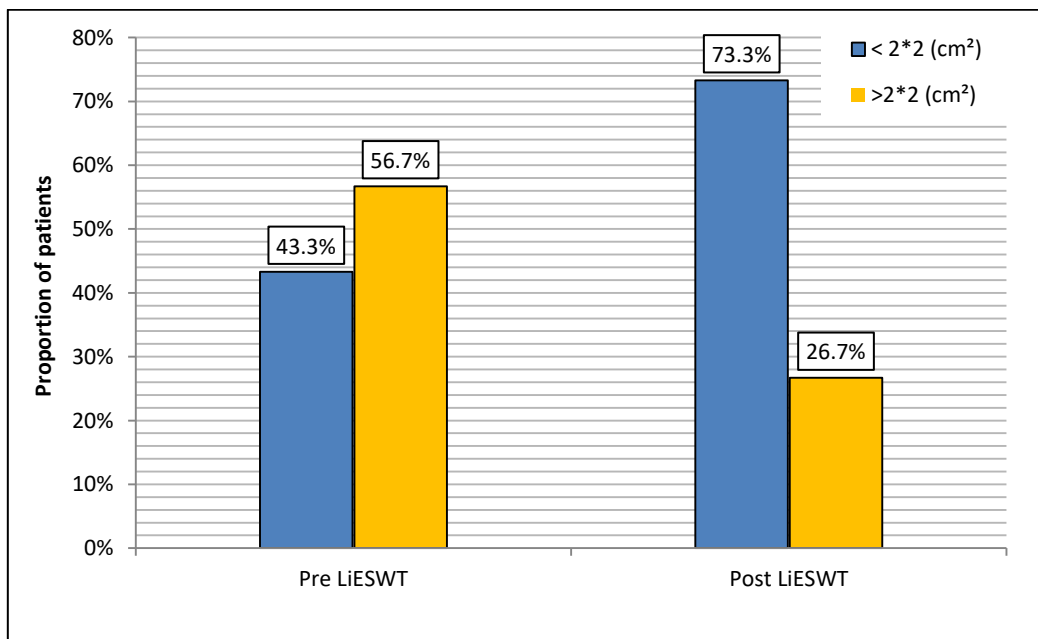


Figure 3. Proportional distribution of pre- and post- FSWT Size of penile plaque (N =30).

Table 5. Pre and post FSWT Penile pain during erection of the studied group (N = 30).

Penile pain during erection	Pre FSWT		Post FSWT		P. value
	No.	%	No.	%	
Yes (VAS ≥ 3)	11	36.7	2	6.7	0.001 <i>sig</i>
No (VAS ≤ 2)	19	63.3	28	93.3	
Total	30	100.0	30	100.0	

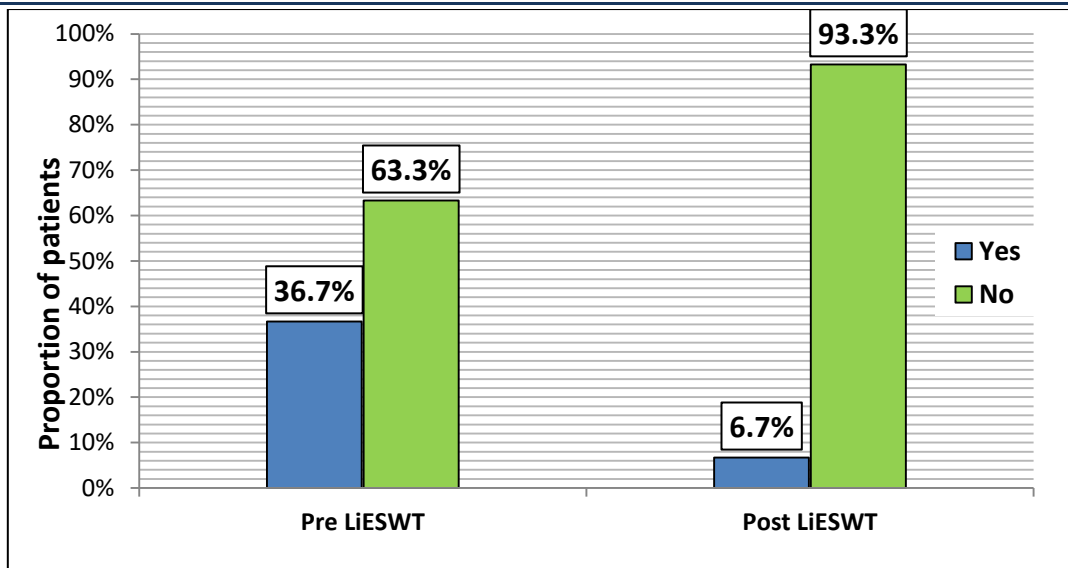


Figure 4. Proportional distribution of pre- and post- FSWT Penile pain during erection (N =30)

The percentage of individuals who experienced penile pain throughout an erection decreased statistically significantly after FSWT, from 36.7% to 6.7%

($P < 0.05$). The VAS score also significantly decreased after FSWT ($P < 0.05$), as well as none of the participants reported a score of 4.

Table 6. Pre and post FSWT patients’ VAS score (N = 30).

VAS score	Pre FSWT		Post FSWT		P. value
	No.	%	No.	%	
1	5	16.7	6	20.0	0.028
2	14	46.7	21	70.0	
3	6	20.0	3	10.0	
4	5	16.7	0	0.0	
Total	30	100.0	30	100.0	

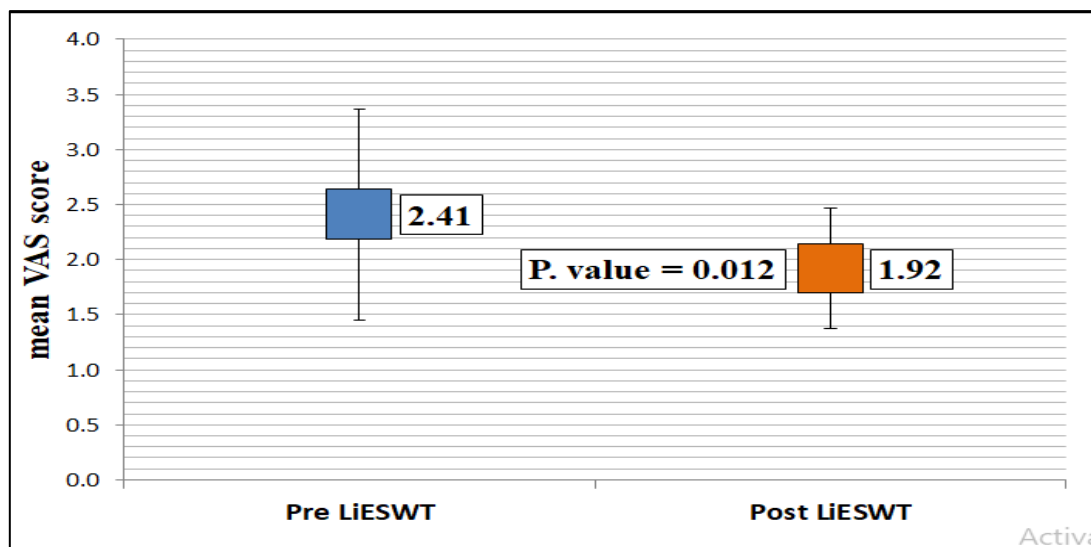


Figure 5. Comparison of pre- and post-FSWT mean VAS score of the patients (N = 30).

Table 7. Pre and post FSWT IIEF-5 score of the studied group (N = 30).

IIEF-5 score	Pre FSWT		Post FSWT		P. value
	No.	%	No.	%	
> 17	17	56.7	27	90.0	0.009 sig
< 17	13	43.3	3	10.0	
Total	30	100.0	30	100.0	

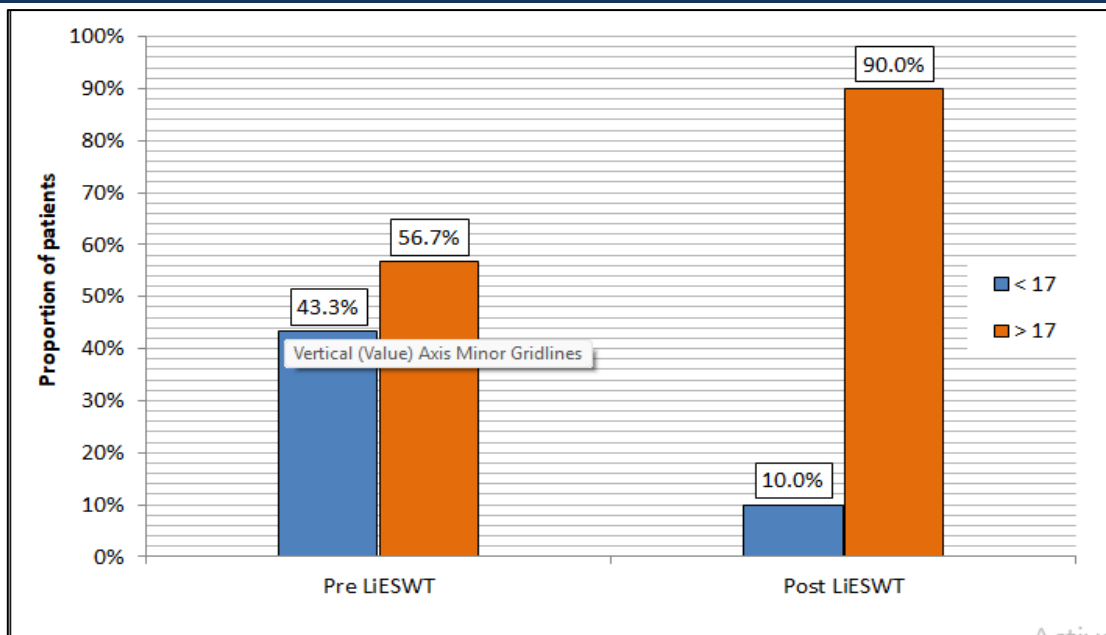


Figure 6. Proportional distribution of pre- and post- FSWT IIEF-5 score (N =30).

There were no dropouts in this study, and every patient finished the FSWT regimen. On the pain visual analog scale, the majority of patients (80.0%) had a score of less than 2 out of 10, and none of them reported persistent pain lasting over

four hours. There was no evidence of urethral hemorrhage, dysuria, or petechial bruises. Eighty percent of patients were happy and gave their overall satisfaction a rating of one to three out of five.

Table 8. Response and experiences of patients towards FSWT (N = 30).

Variable	No.	%	
Pain with FSWT	None	24	80.0
	< 4 hours	6	20.0
Psychological status	Improved	26	86.7
	Not improved	4	13.3
Satisfaction rate	1 - 3	24	80.0
	4 - 5	6	20.0
Future recommendation	Yes	23	76.7
	May be	5	16.7
	No	2	6.7

A statistically significant correlation was discovered between the patient's satisfaction rate as well as penile pain during erection following FSWT (P=0.044) after additional analysis was done to evaluate the relationship between each

degree of curvature, along with penile pain during erection. Nevertheless, there was no statistically significant association (P > 0.05) between the degree of penile curvature following FSWT and the patient's satisfaction rate.

Table 9. Correlation of post-FSWT patients' satisfaction rate with post-FSWT penile pain during erection and degree of penile curvature (N = 30).

		Patient satisfaction rate				Total	P.value
		1 - 3	4 - 5				
Penile pain during erection post FSWT	Yes	0	00.0%	2	33.3%	2	0.044
	No	24	100.0%	4	66.7%		
	Total	24	100.0%	6	100.0%		
Degree of penile curvature post FSWT	< 30°	12	92.3%	1	7.7%	13	0.31
	30°-60°	12	70.6%	5	29.4		
	60°-90°	0	00.0%	0	00.0%		
	Total	24	100.0%	6	100.0%	30	

DISCUSSION

The average age in the current study was 50.33 years, and the majority of patients (46.7%) were adult males between the ages of 50 and 59. The average age proved 55 years, and a significant portion of patients (43%) were between the ages of 50 and 59. Additionally, a Canadian study [Chitale, S. *et al.*, 2010] found that the mean age at disease presentation had been 53.5 years. Therefore, it appears that middle-aged males are susceptible to Peyronie's disease [Moher, D. *et al.*, 2010]. In this study, 76.7% of participants had penile curvature for less than a year (mean, 9.93 months). Penile curvature or a deformity lasting more than six months (mean, 12.8 months). This corresponds to the period of time during which the illness moves from an acute phase to a stable phase. The development of plaques indicates that the disease's acute inflammatory stage has ended [Hatzichristodoulou, G. *et al.*, 2013; Mortensen, J. *et al.*, 2021]. Only during the chronic stage of the illness has the FSWT been implemented. Fibrous plaques were the most prevalent kind in color penile Doppler (70.0%) compared to calcified plaques (30%), which were more prevalent compared to fibrous plaques (30%).

The dorsum of the penis (53.3%) was the most often occurring side of the curvature, followed by the left lateral side (26.7%). This is consistent with Byström and Palmieri A's findings. Although the IIEF-5 score has never been officially validated for use in this disease state, it is commonly used to assess sexual function among men with Peyronie's disease. The improvement of sexual function ranges from 12% to 80%, according to a published meta-analysis [Wang, H. J. *et al.*, 2017]. In the present study, the number of patients having mild to moderate ED decreased from 43.3% before to FSWT to 10% following FSWT, and the IIEF-5 score increased considerably following FSWT. We postulated that improved erectile function may be related to the improvement in penile curvature with better sexual penetration and possibly underlying neovascularization brought on by FSWT. Following FSWT, the majority (90%) had a VAS score of 2 out of 10 or below, and the VAS score was considerably lower ($P < 0.05$). At the end of FSWT, the size of penile plaque decreased by 2 cm² in 40% of patients, and the percentage of patients with less than 2*2 cm² rose by 30%, from 43.3% prior to 73.3% following FSWT on penile US performed at 6 weeks post-therapy. These findings are consistent with [Hauck, E. W. *et al.*, 2004; Fu, M. *et al.*, 2011].

It should be noted, though, that our measurement of plaque size is two-dimensional because plaque measurement is frequently insufficient and/or impractical due to a number of factors, including operator dependence, plaque configuration, along with the absence of appropriate ultrasound software [Cai, H. Y. *et al.*, 2015]. It should also be noted that because there is no control group in our trial, we are unable to directly compare the effectiveness of FSWT with the normal development as well as regression of Peyronie's disease. The ability of FSWT to promote angiogenesis is the fundamental mechanism that encourages its usage [Hatzimouratidis, K. *et al.*, 2012; Fischer, S. *et al.*, 2015]. FSWT, which was first created for therapeutic lithotripsy, has been effectively used to treat soft tissue inflammation with low energy density (0.03 mJ/mm²). It was expected that FSWT would increase nitric oxide synthesis in cells since nitric oxide plays a significant role in inflammation [Fojecki, G. L. *et al.*, 2017].

However, because plaque measurement is often unreliable and/or impractical due to various factors, such as operator dependence, plaque configuration, and the use of appropriate ultrasound software [Cai, H. Y. *et al.*, 2015], it should be mentioned that we are able to directly compare the efficacy of FSWT with the typical development and/or regression for Peyronie's disease due to the lack of a control group in our experiment. The electromagnetic shock wave can have a constant energy density for 1.25 mJ/mm² to a penetration depth of 65 mm.

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CONCLUSION

FSWT, as a minimally invasive treatment option, is suitable in people with Peyronie and who have tried the conventional therapies (medical interventions) but have not succeeded and do not wish to undergo surgery. FSWT seems to be non-hazardous and highly effective to diminish penile pain and curvature in a well-selected patient population with the characteristics of Peyronie

disease. These short-term studies also have the highest level of patient satisfaction associated with it.

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