

SOMACorrect for Peyronie's Disease Management.

SOMACorrect Peyronie's Correction Therapy (Type 1 Medical Device, European Health Certification - CE) is the revolutionary NEW treatment regimen for men with the penile curvature associated with Peyronie's disease. Side-effect free, SOMACorrect (Peyronie's Disease Management) was developed over a number of years by a Urological Consultant (USA) who has treated Erectile Dysfunction (ED) for more than 30 years. The treatment involves placing the penis in one of the 3 appropriate 'sized to fit (Stf)' adapted circumferential cylinders (5 cylinder sizes available in total) and using vacuum therapy pressure to forcibly induce a series of 'straight' erections over a 20 minute

period daily for up to 26 weeks as standard (up to 52 weeks maximum), with the effect of gradually reducing the impact of the plaque area on the overall angle of curvature and improve penile health in general. With additional UK based studies underway, early unpublished anecdotal reports, such as those by Dr. DiLoreto of the Michigan Institute of Urology, suggest significant response rates, in excess of 60% and up to 80%, are being achieved. Clinical Studies conducted by the Urology Department of Antwerp University Hospital found that for 75% of the patients, the angle of curvature had reduced by at least 50% after 6 months of regular vacuum therapy plaque stretching. For 58% the plaque had disappeared completely.[5]

SOMACorrect vs Penimaster PRO

	Assist with erectile dysfunction?	Curvature at base of Penis?	hour-glass deformity?	Improves penile girth?	Improves penile length?	Time per day	Can be used discretely	Moduc Operandi	Plaque calcified?
SOMACorrect	yes	if cylinder tilted away from side of curvature ?	yes	Normalises Girth	Normalises length	20 minutes	no	Manipulation of plaque	?
PeniMaster PRO	no	yes	no	Minimal	Exceeds normal penile length (up to 4 cms)	2-4 hours	Yes (with belt system)	Manipulation of plaque and tissue expansion	yes

SOMACorrect™

Peyronie's Correction Therapy



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	SOMACorrect (10080)		
	2015		

Size to Fit (STF)

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SOMACorrect™

Peyronie's Correction Therapy

Peyronie's disease (PD), a benign condition of uncertain cause, is characterized by the formation of fibrous tissue plaques often palpable as a hard lump, within the tunica albuginea on the penis usually causing a penile deformity and a subsequent degree of erectile dysfunction (41-55%)[1]. (First fully described by Francois Gigot de la Peyronie)[2]. A plaque on the top of the shaft (most common) causes the penis to bend upward; a plaque on the underside causes it to bend downward. In some cases, the plaque develops on both top and bottom, leading to indentation and shortening of the penis. At times, pain, bending, and emotional distress prohibit sexual intercourse.

The incidence of Peyronie's disease is 3.2% [1] of whom about two thirds are aged 40-60 years. The common suspected causal factors include sexual trauma in those with a genetic predisposition to aberrant wound healing, or part of a generalised connective tissue, auto-immune or arterial disease. The



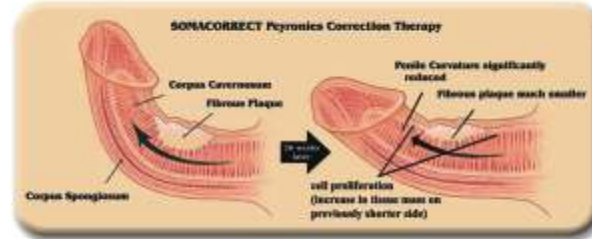
Mechanisms of Action?

Regular stretching and straightening may burst an element of the collagen fibres that make up the scar tissue (plaque area) and help to (A) 'RESHAPE' the plaque thereby reducing its contractile impact (degree of Mechanical Distortion) and the degree of penile curvature. It is theorised that regular SOMACorrect may cause (B) PARTIAL FRAGMENTATION of the plaque itself (particularly when diffuse in nature) with some element of plaque (C) SURFACE REABSORPTION and an (D) INCREASE IN VASCULARIZATION of plaque tissue. This remains as yet unproven, but are likely mechanisms of action for those patients who do respond with recorded plaque size reduction. Recent research into the aetiology of PD implies an imbalance between profibrotic and antifibrotic substances. [9]

Over-expression of TGF-beta1 has been shown to induce penile plaques in the rat model. [10] TGF-beta1 has also been shown to be over-expressed in PD plaques as compared with patients without evidence of PD. [11] Another group of profibrotic proteins includes fibrin and plasminogen activator inhibitor-1 (PAI-1). Like TGF-beta1, fibrin has been shown to induce plaque formation in an animal model; levels of PAI-1 are elevated in these plaques. [12] Vacuum Therapy use is clinically well recognised for producing "a significant increase in the penile-brachial pressure index following regular use" [13] with a multitude of clinical studies establishing the link between regular vacuum therapy application and penile neovascularization [14,15].

Run Wang has demonstrated that mean Oxygen saturation of corporeal blood immediately after vacuum-therapy induced erection was predominantly arterial in nature and therefore

initial theory of repeated minor sexual trauma is currently still the most likely cause. This is supported by the finding of fibrin within the plaques but not in control tunica, indicating microvascular injury [3]. Penile pain may be persistent in the inflammatory stage of the disease but is usually not severe but may interfere with sexual function, although spontaneous improvement usually occurs as the inflammation settles within 3-6 months[4]. After 18-24 months, plaque angulation and calcification tend to predominate. Spontaneous resolution of the condition is thought to occur in up to 15% of cases.



oxygen enriched. It is also known that an increase in corporal Oxygen tension is associated with a rapid increase in unstimulated PGE2 (Phosphodiesterase 2) followed by a suppression of TGF-Beta 1 induced collagen synthesis. [16,17]. This is one possible mechanism of action by which regular penile vacuum therapy induced penile oxygenation could suppress excessive penile fibrosis in patients with Peyronie's Disease. Also, studies show that nitric oxide, by acting as a scavenger for reactive oxygen free radicals, may exert a protective effect via inducible nitric oxide synthase (iNOS) activity. Peyronie's plaques have a reduced iNOS, an increased reactive oxygen free radical content and consequently more fibrosis than control tunica [18]. Hence (E) EARLY TREATMENT OF ASSOCIATED ERECTILE DYSFUNCTION (ED) in relevant patients may be of benefit. Certainly mechanical tissue expansion principles of action with subsequent stimulated (F) CELL (TISSUE) PROLIFERATION may also apply with regular SOMACorrect application [19-21], increasing tissue mass on the interior curved side of the penis: FORCE + TIME = GROWTH / tissue expansion: sustained mechanical stress inducing increased biosynthetic activity of the shorter side as it is subject greater traction). A high degree of calcification may reduce the pliability and scope for revascularization of plaque tissue - therefore vacuum therapy application is particularly indicated during the active phase of Peyronie's disease and certainly pre-calcification if possible, although response rates may be influenced by plaque location / shape / size / patient's potential for stimulated cell proliferation and compliance in procedural use. In some cases, a vacuum induced erection captured with an erection maintenance ring is 'artificially' less curved in light of the extra-corporeal filling effect so long as the ring is held in place.



Clinical References

[1] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

[2] Gigot de la Peyronie F. (1785) *Recherches sur la Maladie de la Peyronie*. Paris: Chez la Citoyenne Debilly.

[3] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

[4] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

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[9] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

[10] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

[11] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

[12] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

[13] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

[14] Hatzichristou D, Soteriou S, Vardi A, et al. (2005) The prevalence of Peyronie's disease: a systematic review. *Sexual Medicine Reviews* 33(2): 10-18.

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Size to Fit (STF)

	Effective Length (mm)	Internal Aperture - minus insert (mm)
A	203.2	37
B	203.2	44
C	203.2	56
Xi	203.2	63
X.L.	274.9	63

Pilot / Published Studies:

(SOMACorrect) Vacuum Therapy for Peyronie's Deformity: An Effective Alternative to Surgery

Norfolk & Norwich University Hospitals NHS Foundation Trust
Norwich UK. Presented ESSM December 2011, Milan, Italy
Key Finding: Average: 47% curvature reduction for 80% of users. Vacuum Therapy is an effective and viable alternative to surgery in select group of patients (with preference for non-surgical therapy).

A SINGLE CENTRE EXPERIENCE OF VACUUM DEVICES IN THE TREATMENT OF PEYRONIES DISEASE

Frances Burge, Savvas Omorphos, Alvaro Bazo.
Nottingham University Hospitals NHS Trust.
Published - Abstracts / International Journal of Surgery
8 (2010) 501-578

Key Finding: 17 patients were identified. The median age was 59 yrs and median length of treatment was 10 months (range 1-24). A subjective improvement in degree of curvature and size of plaque was noted in 71% and 65% respectively. Erectile dysfunction reduced from 53% to 6% following treatment. The inability to have penetrative intercourse was reduced from 47% to 12%.

Conclusion: Our experience appears to support the growing body of evidence that there is a role for V.T. in the treatment of Peyronies disease

Vacuum Therapy as Treatment for Penile Curvatures
- Benny Verheyden, MD, Andrology Unit, Dept. Urology, Antwerp University Hospital, Belgium.

Key Finding: Measured reduction of Curvature was in 9/12 patients at least 50% with a mean of 70% (89%-34%).

A Single Centre Experience of a Non-invasive Combination Treatment for Patients with Peyronie's Disease
(Shawket Alkhalay, Jai Seth, George John and Matthew Fletcher)
Dept Urology, The Royal Sussex County Hospital, Brighton.

Key Finding: More than 80% of the patients who used the pump noted some improvement in their penile curvature which is probably due to the stretching and traction effect.



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