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A Guide to Peyronie's Disease, Current Research and Emerging Treatments

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“A Guide to Peyronie’s Disease, Current Research and Emerging Treatments”

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Contents

Acknowledgements:

The number of Peyronie's Disease cases reported in the United States has recently undergone a dramatic increase. This is either because men are now more willing to discuss the issue with their physicians than in the past, or, for some as yet unknown reason, there is actually an increase in the incidence of the disease. Most likely, both factors account for the fact that ten percent of men in the US suspected of having the disease. The disease is one that has not attracted the attention of mainstream researchers in the past, or that of pharmaceutical companies or medical device manufacturers. For this reason the author (and doubtless those men afflicted with Peyronie's Disease who read this guide) thanks the organizations, companies and experts who have taken on the challenge of finding a treatment for the disease, and who have made this guide possible. The Association of Peyronie's Disease Advocates has established itself as the single most reliable source of information on management and treatment news of the disease. Marti KcKown, one of the leading lights within the APDA, has been especially helpful in providing insight and guidance on the gathering of data for the guide. FS PhysioMed, the medical marketing division of FastSize LLC, is to be applauded for its financial support for the production of the guide and the cost of printing hard copies for distribution. Larry Levine, of Urology Specialists SC of Chicago, should also be given special mention for the frequent assistance rendered to the author during the writing of the text.

The following experts were also consulted on the contents of this guide and were kind enough to offer observations and advice:

Wayne Hellstrom, M.D., F.A.C.S., Professor of Urology, Chief of Andrology (male infertility and sexual dysfunction) at Tulane University School of Medicine in New Orleans.

Steven Lamm, M.D., known to millions as the doctor on ABC-TV's The View, hardness is a practicing internist and faculty member at New York University School of Medicine

Laurence A Levine M.D., FACS, Professor of Urology, Rush University, Chicago, Illinois

Ronald W. Lewis, M.D., is Chief of Urology at the Medical College of Georgia and a world-renowned expert on sexual dysfunction.

John Mulhall, MD., is associate professor in the Department of Urology, Weill Medical College of Cornell University, New York Presbyterian Hospital, New York, New York and the director of the Sexual Medicine Program.

Mariano Rosselló M.D., is an internationally known expert on erectile function and a key scientist behind Dr. Steven Lamm's bestseller "The Hardness Factor." Dr. Rosselló is based in Spain where he manages a thriving sexual medicine practice.

Introduction:

There has been much public comment about how the introduction of oral drugs for the treatment of erectile dysfunction (ED) in the 1990s finally began an open dialog between the ED afflicted patient and his physician. One result has been increasing recognition of the fact that ED is far more prevalent than was originally thought.

The same phenomena appear to be the cause of a rise in reported cases of Peyronie's Disease. Initially this was a condition that, it was thought, affected perhaps 3% of the male American population. Today, it is believed that it afflicts up to 10%[i] of the adult male population.

Until recently, there remains no standard of care treatment for the disease. The purpose of this book is to help you understand the disease – and to provide you with information on promising new treatments being developed by leading researchers.

Peyronie's: A Brief History:

Background: In 1587, Guilio Cesare Aranzi formally described Peyronie's Disease in his book *Tumores praeter naturam.* He called the disease "a rare affection of the genitals in people with excessive sexual intercourse: a little penile tumor palpable like a bean in the flaccid penis causing a deformity similar to a ram horn during erection."

Figure 1: Francois de la Peyronie.

The disease was not given its current name until 1743, when Francois Gigot de la Peyronie (Figure 1) described the cases of 3 men with fibrous thickening of the penile shaft, painful erections, and penile curvature (Figure 2).

Figure 2: Typical Peyronie's Disease

Peyronie's Disease is associated with ED in more than 50% of patients whose experience ranges from minimal to complete dysfunction, however, experts now recognize ED as only one factor associated with the disease that is not always present.

Description of Peyronie's Disease

Peyronie's Disease is a condition characterized by the development of fibrous nodules or lumps within a tough sheath of tissue beneath the skin of the penis. This sheath is called the *tunica albuginea* (Figure 3).

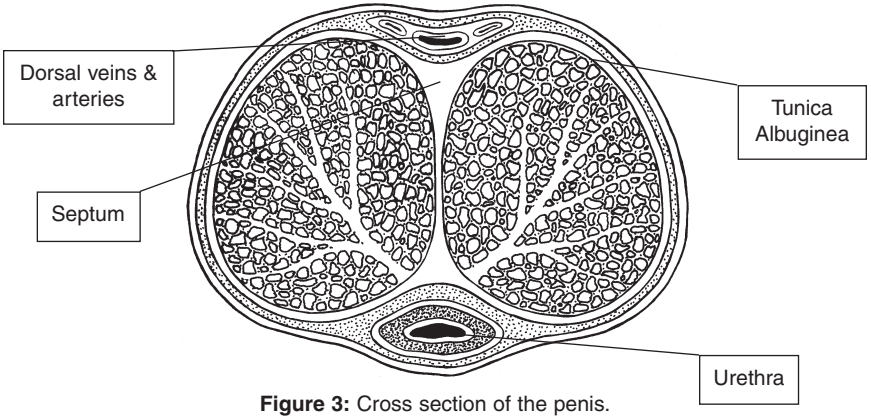

Figure 3: Cross section of the penis.

Two chambers inside the penile shaft called the *corpora cavernosa,* are filled with spongy vascular tissue that fills with blood during the erection process. The fibrous lumps within the *tunica albuginea* prevent one or both of these chambers from expanding properly (Figure 4), causing the penis to bend to the left, right or upwards (the most common) or

downwards. The plaque itself is benign, and non-cancerous. In some cases, the plaque develops on both top and bottom, leading to indentation and shortening of the penis.

There is often some degree of pain associated with the early development of the disease. This often resolves itself. In a small percentage (less than10%) of patients with the milder form of the disease, the condition may resolve itself without causing significant pain or a permanent bend. Extreme curvatures (120°+ have been recorded) may be painful during erection and attempts at penetrative sex, and can make intercourse difficult or impossible depending upon the degree of curvature.

When the pain, bending, and emotional stress of Peyronie's Disease are severe enough to prevent intercourse, it usually results in sexual problems that disrupt a couple's physical and emotional relationship and lead to lowered self-esteem in the male.

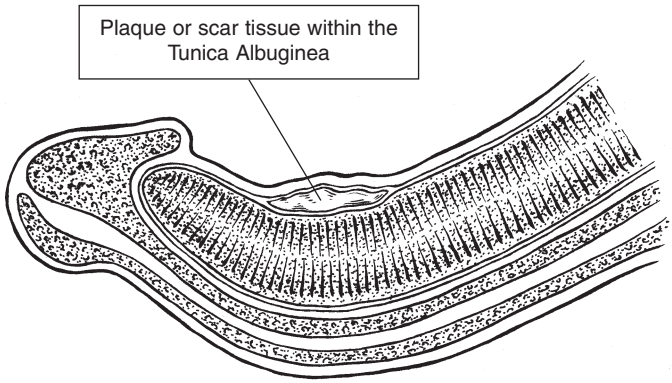

Figure 4: Cross section showing plaque at curvature site.

Who Gets Peyronie's Disease?

Peyronie's Disease is most common between ages 40 and 70 but no age is exempt and even teenagers can be affected. The exact cause of the disease is not known. The fibrous lumps can occur spontaneously, but it has been noted that scarring can follow sex or even a relatively mild blow to the flaccid (soft) penis, causing the lumps to form in susceptible men.

Early studies found Peyronie's Disease occurring in 1%-3% of men. Today it is known that this figure is closer to 10%. Although the disease occurs mostly in middle-aged men, younger and older men can acquire it.

Up to 30% of people with Peyronie's Disease develop fibrosis (hardened tissue) in other elastic tissues of the body, such as on the hand or foot. A common example is a condition known as Dupuytren's contracture of the hand. Dupuytren's contracture is an abnormal thickening of the sheath of tissue in the palm of the hand surrounding the flexor tendons of the fingers. The scarring of this sheath to the tendons restricts finger mobility and can cause them to curl. It is more common in men than in women. In some cases, men who are related by blood tend to develop Peyronie's Disease, which suggests that genetic factors might make a man vulnerable to the disease. Men with Peyronie's Disease usually seek medical attention because of painful erections and difficulty with intercourse. Since the cause of the disease and its development are not well understood, many doctors still treat the disease empirically; that is, they prescribe treatments that have not been proven to help but have been used in the past. The goal of therapy is to keep the patient sexually active with a more functional erection.

Course of the Disease

Many researchers believe the plaque of Peyronie's Disease develops following trauma (hitting or bending). The two vascular chambers of the penis (corpus cavernosa) are surrounded and separated by a thick fibrous sheath called the tunica albuginea. The separation is an extension of the sheath called the septum and it attaches at the top and bottom of the sheath.

If the penis is abnormally bumped or bent, tissues in the area where the septum attaches to the elastic fibers of the surrounding sheath may stretch beyond their limit. This may result in injury of the lining of the erectile chamber and rupture of small blood vessels. As a result of aging, diminished elasticity near the point of attachment of the septum might increase the chances of this type of injury.

While trauma might explain acute cases of Peyronie's Disease, it does not explain why most cases develop with no apparent traumatic event. It also does not explain why some cases disappear quickly. Some researchers theorize that Peyronie's Disease may be an autoimmune disorder. This is a condition in which tissues of the body are attacked by the body's own immune system which appears to mistake the tissues for foreign or invasive cells, such as those that cause infection, for example. This may be a possible explanation for the formation of the plaque.

Historically a number of drugs have been listed as causing Peyronie's Disease as a **possible** side effect. Most of these drugs belong to a class of blood pressure and heart medications called beta-blockers. Another drug that may cause Peyronie's Disease is Phenytoin, an anti-seizure medicine. There is no firm scientific evidence to support the claim, however, that any of these drugs are responsible for Peyronie's Disease.

Past Treatments

A number of treatments for Peyronie's Disease have been attempted in the past – from oral vitamin E regimens to application of drugs in topical form such as a Verapamil cream. Topical Verapamil is administered by massaging it into the skin above the plaque. This has been found to transmit too low a dose of the drug into the plaque to be effective. Radiation has also been attempted, all with little success.

New Treatments:

In recent years new treatment protocols have emerged and success rates with some of the treatments (in terms of reduced deformity) ranging from 40 to 70% have been reported.

Verapamil

Verapamil is FDA approved for the treatment of irregular heartbeats (arrhythmias) and high blood pressure. It relaxes blood vessels so the heart does not have to pump as hard. It has since been discovered that when injected into tissue such as fibrotic plaque, Verapamil blocks the production of collagen by the cells that make scar tissue in the plaque. There is now a growing body of research and direct clinical experience that shows that Verapamil is one of the most promising drug treatments available for the disease when injected directly into the plaque.

Collagenase

Some researchers have experimented with the direct injection of Collagenase into the fibrotic plaque.[ii-iii] These trials did not report significant changes in curvatures and noted that the drug appeared to work best in the least severe cases of the disease. Large-scale FDA clinical trials with Collagenase are forthcoming.

Interferon

In the body, Interferon governs immune and inflammation response and is generally used to treat neurological and viral disorders. Interferon is also

active against tumors. The drug is still considered experimental in terms of Peyronie's treatment, but researchers may soon report that it has produced significant improvement in the treatment of Peyronie's using interferon alfa-2b (Intron-A).[IV]

Mechanical Traction

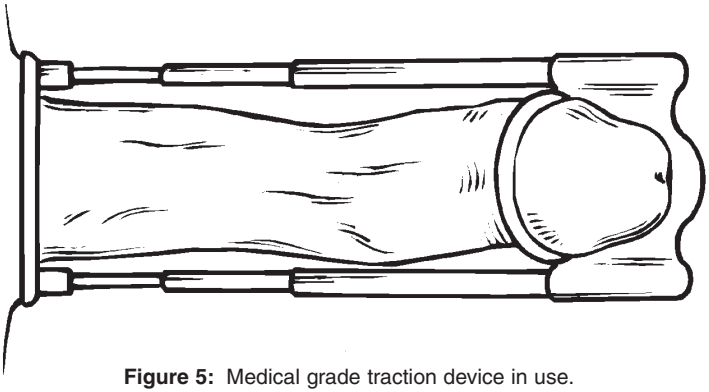

Figure 5: Medical grade traction device in use.

Mechanical traction involves devices designed to pull and stretch penile tissue (Figure 5). First developed in Europe in the 1990's, the devices were initially designed for non-surgical lengthening of the penis.[v] It was soon noticed that this same action appeared to stretch the plaque and reduce the severity of the curvature. This has led to increase use of mechanical traction therapy in Europe for the treatment of Peyronie's Disease. The device works by allowing the patient to stretch the flaccid penis for several hours a day. The level of traction can be adjusted by adding metal sections to the length of the splint. Over time, the stretching action appears to either elongate the plaque, or cause remodeling of the tissue. Only one US Company manufactures the device for medical distribution in the Americas, fsPhysioMed LLC, and a clinical trial have been completed in the US on this device.

The results confirmed the efficacy of mechanical traction. All of the patients in the trial received some measure of improvement of their curvatures, ranging from 10 to 45 degrees of the original curve. They also gained girth and length, up to an increase in length of 2.5cm in one case. This is an important side-effect of value to patients who have suffered a decrease in penile length with the disease.

Another important aspect of the treatment regimen was that medical supervision over the six month length of the traction program had a significant effect on patient compliance and success rates. During the trial, subjects wore the Extender device for a minimum of two to four hours a day, some even longer. Weekly contact with the subject ensured continued motivation and compliance with the treatment regimen. The result was the high level of success reported at the end of the trial.

Low Pressure Traction

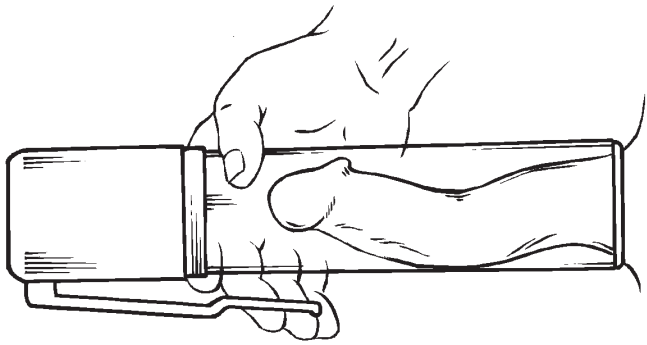

Figure 6: Medical grade vacuum device in use

Low-pressure traction is intended to use the same principle as mechanical traction (Figure 6), but the stretching force is provided by the straightening action that occurs when the flaccid penis is made artificially erect inside a plastic cylinder in which a partial vacuum is created. Some success has been reported with the system with reduction of curvature.[VI] This experience includes the use of injected Verapamil in combination with the vacuum therapy. No trials on this method have been conducted and clinical experience indicates that Verapamil injections alone are equally as effective as the combination treatment.

Iontophoresis

Iontophoresis is the process by which drugs, usually dexamethasone and lidocaine, are introduced into a joint or small body part via electrical current.[vii] It is non-invasive, painless and it eliminates potential side effects and adverse reactions that can occur with medications delivered orally or by injection. The same process has been employed to transfer Verapamil into Peyronie's plaque tissues,[viii-ix]

Surgery

Because the course of Peyronie's Disease is different in each patient and some patients (less than 10%) experience improvement without treatment, medical experts have suggested a 9 to 12 month wait or longer before attempting to correct it surgically. Peyronie's Disease has been treated with the most rapid and reliable success by surgery. The most common surgical methods are shortening the convex side of the penis by removal or pinching of tissue from the side of the penis opposite the plaque, which cancels out the bending effect. The second method involves expanding the restricting plaque by cutting part of it out. This is followed by placement of a graft, The first method may cause some shortening of the erect penis. The second method can involve partial loss of erectile function, especially rigidity.

Most types of surgery produce positive results. However as a result of possible side affects associated with surgery (for example, shortening of the penis), most doctors prefer to perform surgery only on men with curvature that significantly compromises sexual intercourse. Also on men who are consistently psychologically disturbed by the curvature or its appearance, or who have partners who suffer discomfort from the curvature. (1-National Kidney and Urological Diseases Information Clearinghouse-NKUDIC)

Implants

For those men who have poor quality erections and Peyronie's Disease, implantation of a device that increases rigidity of the penis is recommended (Figure 7). In some cases, an implant alone will straighten the penis adequately. In other cases, implantation is combined with a technique of tissue modeling, incisions, and grafting or plication (pinching or folding the skin).

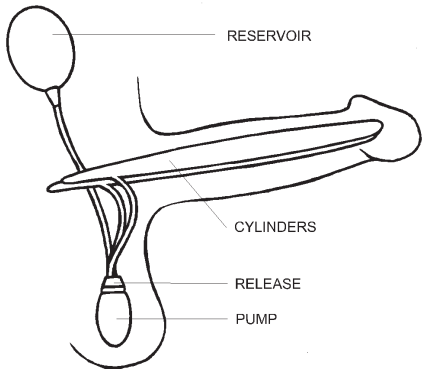

Figure 7: Typical implant device

Radiation
Radiation therapy, in which high-energy x-rays are aimed at the plaque or scar tissue, has also been used in the past. Like some of the chemical treatments, radiation appears to reduce pain (possibly due to damage to peripheral nerves), but it has appears to have no effect on the plaque and there is significant risk of subsequent erectile dysfunction.

Topical Applications
A number of topical agents, such as Verapamil and vitamin E cream and gels are aggressively marketed on the Internet as cures for Peyronie's Disease. These claims are not supported by published clinical trials and are discounted by the medical profession.

Herbal Remedies
Like topical agents, herbal remedies are also aggressively marketed on the Internet as cures for Peyronie's Disease. These claims are also not supported by published clinical trials and are discounted by the medical profession.

Resources:
The Association for Peyronie's Disease Advocates (has links to commercial companies and products mentioned above): **www.peyroniesassociation.org**

The Sexual Medicine Society of North America at
www.sexhealthmatters.org.

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