Development of a Quantitative Model in Erection Mechanics and The Loverband® Therapeutic Device for the Treatment of Veno-Occlusive Dysfunction (VOD)

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Abstract

Erectile Dysfunction (ED) is a medical problem affecting millions of adult men worldwide. The majority of cases are of Vasculogenic origin with a high incidence (over 85%) resulting from the inability of the penis to hold blood under high pressure during sexual activity. Peak cavernosal pressure in the order of twelve times systolic blood pressure is sustained by the occlusion of the venular plexus between the Tunica Albuginea (TA) and the Deep Fascia (DF) when these collagen structured fibroelastic layers are of equal stiffness. Variations in the stiffness of the TA and DF with the expanded penis cross-sectional shape lead to deficient veno-occlusions or Veno-Occlusive Dysfunction (VOD). A quantitative model in erection mechanics has been developed with support from existing clinical observations to determine these findings and to assist in the design and manufacture of The Loverband® device.

Keywords: Biomechanics, Physiological Systems, Erection Mechanics, Venous Leak, Impotence

Introduction

Mechanical forces play an important role in achieving and sustaining a penile erection. During erection, volume and expansion cause the occlusion of veins throughout the penis in order to maintain a high erection pressure equilibrium under a low continuous flow rate. Sustainability of the high corpora cavernosa pressure by the occlusion of the sub-tunical venules, involves the occlusion of the out-of-tunica venular plexus by the expanded Tunica Albuginea and Deep "Buck's" Fascia closure mechanism.

In Vasculogenic Erectile Dysfunction cavernosal pressure and rigidity are deficient due to inadequate inflow rates (Arteriogenic ED) and/or incomplete veno-occlusions (Venogenic ED). Deficiencies in the erectile occlusion system, at the present time, can only be treated by deep dorsal vein surgery with limited effectiveness. Consequently, a new external device and method to improve veno-occlusions has been developed.

The Loverband® device recovers up to 60% deficiency of the out-of-tunica closure mechanism by the controlled application of pressure at the penis dorsal base without adversely affecting blood circulation of the penis. The applied pressure temporarily desensitizes the dorsal nerves and reduces hypersensitivity of the glans penis. Ejaculatory latency time is delayed in cases with Primary Premature Ejaculation without affecting the sensation of ejaculation.[5]

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Materials and Methods

Veno-Occlusion Mechanics is combined with a Converging Venous Outflow method using mechanical engineering principles for the occlusion analysis of the out-of-tunica venular plexus and the development of the quantitative model.

Converging Venous Outflow represents occlusion of the dorsal veins at the penis base and their relationship to the occlusion of the remaining venular plexus as pressure increases within the corpora cavernosa.

The Loverband® device is an adjustable soft elastic band made of latex-free/hypoallergenic medical grade rubber. Installation and method of use are illustrated schematically (Fig. 1).

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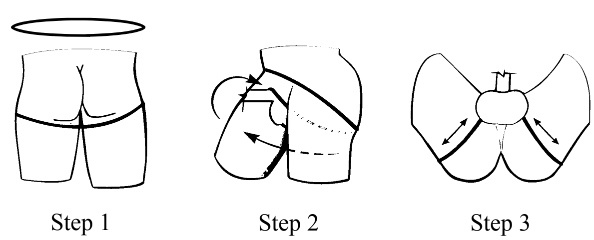

Figure 1 The Loverband® installation diagrams and how to use instructions. Step 1 - Wear around the waist below the buttocks; Step 2 - Pull the back of the band from under the scrotum, between the legs, and place over the penis base when erect; Step 3 - Stretch to adjust pressure and comfort.

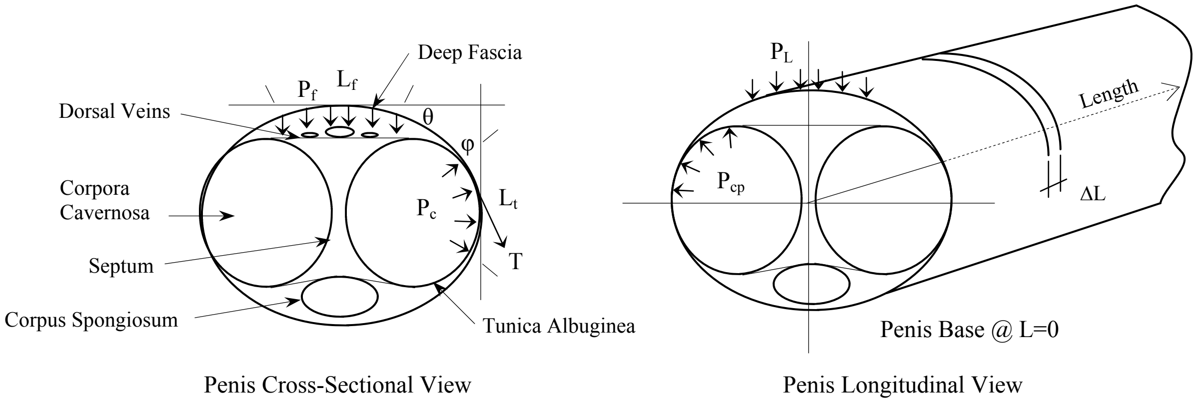

Figure 2 Schematic diagram of the penis showing the variables in Veno-Occlusion Mechanics. P_c is the cavernosal pressure, P_{cp} is peak cavernosal pressure, P_f is the contact pressure exerted by the DF on the out-of-tunica venular plexus against the TA, P_L is the external restoring pressure exerted by The Loverband® device, L_t is the effective length of the TA, L_f is the effective length of the DF, θ & φ are the angles of curvature with respect to the horizontal and vertical axes respectively, T is the tangential tension force from the stretched TA and DF, ΔL is the change in location for every cross-section along the penis length up to the glans penis.

Quantitative Model

Veno-Occlusion Mechanics

From Hooke's Law (linear elasticity or nonlinear with the existence of an elastic potential for linearity) and equilibrium:

$$\epsilon_f = \epsilon_t \tag{1}$$

$$p = E\,\epsilon \tag{2}$$

Where subscript f stands for Deep Fascia and t for Tunica Albuginea, ϵ is strain, p is stress and E is Young's Modulus.

From equilibrium of forces $T_f = T_t$, the strain equation (1) and Hooke's Law (2):

$$T_f \sin\theta = P_f L_f / 2 \tag{3}$$

$$T_t \sin\varphi = (P_c - P_f)\, L_t / 2 \tag{4}$$

$$\frac{P_f L_f}{2\, A_f \sin\theta\, E_f} = \frac{(P_c - P_f)\, L_t}{2\, A_t \sin\varphi\, E_t} \tag{5}$$

Solving for the contact pressure exerted by the Deep Fascia P_f , and using effective thickness t_e per unit length to replace area A:

$$P_f = (P_c - P_f)\left(\frac{\sin\theta}{\sin\varphi}\right)\left(\frac{L_t}{L_f}\right)\left(\frac{t_{ef}}{t_{et}}\right)\left(\frac{E_f}{E_t}\right) \tag{6}$$

Substituting for stiffness $K = AE/L$ (7)

$$P_f = (P_c - P_f)\left(\frac{\sin\theta}{\sin\varphi}\right)\left(\frac{K_f}{K_t}\right) \tag{8}$$

Introducing Venous Leak Pressure Decrease Factor C_{VL}:

$$P_f = (P_c - P_f)\, C_{VL} \tag{9}$$

$$P_f = P_c\left(\frac{C_{VL}}{1 + C_{VL}}\right) \tag{10}$$

$$C_{VL} = \left(\frac{\sin\theta}{\sin\varphi}\right)\left(\frac{K_f}{K_t}\right) <= 1.0 \tag{11}$$

Venous Leak Pressure Decrease Factor C_{VL} is dependent on the cross-sectional shape of the penis when expanded beyond tumescence by the ratio of the sin function of the angles of curvature θ & φ and the stiffness ratio between the DF and TA. If C_{VL} equals 1.0 ($\theta = \varphi = 45°$ and $K_f = K_t$), the erectile occlusion system is most efficient and there is no dysfunction due to occlusion.

Converging Venous Outflow

From Bernoulli and the Continuity Principles (steady continuous flow, non-viscous incompressible fluid):

$$Q = \upsilon_1 A_1 = \upsilon_2 A_2 \tag{12}$$

$$\Delta P = P_1 - P_2 = \rho/2\,(\upsilon_2^2 - \upsilon_1^2) \tag{13}$$

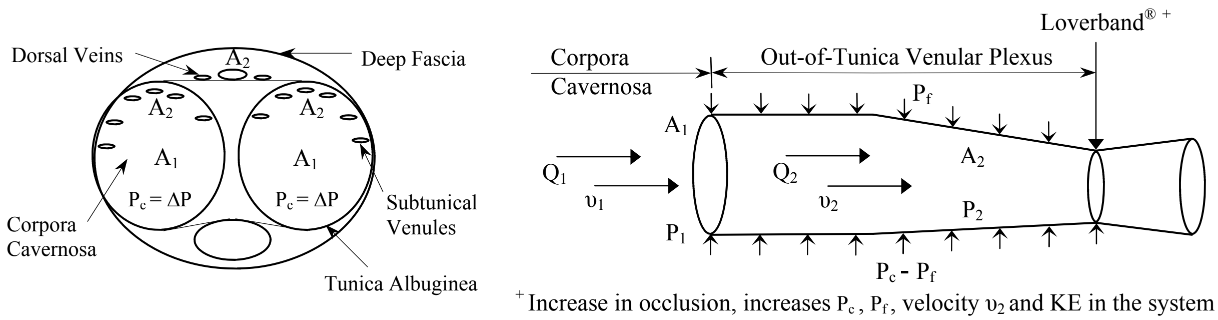

Figure 3 Schematic diagram of the penis showing the variables in the Converging Venous Outflow method. Q is the volumetric flow rate, Q_1 into the corpora cavernosa and Q_2 thru the venules and veins, υ is the velocity of the blood fluid, A_1 is the net sinusoidal area, A_2 is the net venules and veins area, (A_1/A_2) is the occlusion ratio, (A_2/A_1) is the flow resistance ratio, ΔP is the differential pressure from occlusion. The out-of-tunica venular plexus includes the deep dorsal and lateral para-arterial veins with their corresponding circumflex veins.

The Bernoulli pressure and flow equation: (14)

$$Q = A_1\sqrt{\frac{2\,\Delta P}{\rho\,((A_1/A_2)^2 - 1)}} = A_2\sqrt{\frac{2\,\Delta P}{\rho\,(1 - (A_2/A_1)^2)}}$$

Where ρ is the density of the blood fluid.

From (14) left, for flow into the corpora cavernosa and letting ΔP at a lower occlusion equal ΔP at a higher occlusion, the Inflow/Outflow Rate Decrease Factor IO_R is:

$$IO_R = \frac{Q_{1\ @\ \text{Higher Occlusion}}}{Q_{1\ @\ \text{Lower Occlusion}}} \quad (15)$$

$$IO_R = \sqrt{\frac{((A_1/A_2)^2 - 1)_{@\ \text{Lower Occlusion}}}{((A_1/A_2)^2 - 1)_{@\ \text{Higher Occlusion}}}} <= 1.0 \quad (16)$$

From (14) left, for pressure inside the corpora cavernosa and letting Q_1 at a lower occlusion equal Q_1 at a higher occlusion, the Occlusion/Pressure Increase Factor C_{OP} is:

$$C_{OP} = \frac{\Delta P_{\ @\ \text{Higher Occlusion}}}{\Delta P_{\ @\ \text{Lower Occlusion}}} \quad (17)$$

$$C_{OP} = \frac{((A_1/A_2)^2 - 1)_{@\ \text{Higher Occlusion}}}{((A_1/A_2)^2 - 1)_{@\ \text{Lower Occlusion}}} >= 1.0 \quad (18)$$

The relationship between the Inflow/Outflow Rate Decrease Factor IO_R and the Occlusion/Pressure Increase Factor C_{OP} is defined by:

$$C_{OP} = \left(\frac{1}{IO_R^{\,2}}\right) \quad (19)$$

Work, Energy and Cavernosal Pressure

From the Law of Conservation of Energy, the total mechanical energy (ME_T) in the erectile system consist of elastic potential energy (EPE) and kinetic energy (KE):

$$ME_T = EPE + KE \quad (20)$$

The work done (W) by the force of blood (systolic force F_s) filling the corpora cavernosa increases the EPE as it is stored within the stretched TA and DF (elastic force F_e). The EPE from the expansion of the TA and DF is transformed into KE as blood flows out of the corpora cavernosa thru the venules and veins (cavernosal force F_c) during occlusion:

$$W = \Delta EPE + \Delta KE \quad (21)$$

With linear elastic behavior, there is no loss of mechanical energy. In this case, any loss of EPE is gained as KE and vice versa.

From (12) and (14) right, the kinetic energy is:

$$KE = \frac{\rho}{2}\,\upsilon_2^{\,2} = \frac{\Delta P}{(1 - (A_2/A_1)^2)} \quad (22)$$

From the Work-Energy Theorem, the net work done is transformed into KE by the net forces $F_s - F_e > 0$ and $F_s - F_c > 0$. If the net forces are nonzero, then the blood fluid will accelerate in the direction of the unbalanced force F_c.

As occlusion and pressure increase, the systolic and cavernosal forces will increase until they equal each other $F_s = F_c$ at the elastic limit of the TA, where $F_s = F_e$. At this point, peak cavernosal pressure P_{cp} is reached, the net work equals zero and $\Delta KE = 0$.

Using (20) and releasing the EPE, $ME_T = KE$, then from KE (22) the relationship between pressure and occlusion used in this model and cavernosal pressure is:

$$P_c = \Delta P \quad (23)$$

The systolic/diastolic forces F_s / F_d are defined as the systolic/diastolic pressures P_s / P_d exerted on the net sinusoidal area A_1:

$$F_s = P_s A_1 \quad (24)$$

$$F_d = P_d A_1 \quad (25)$$

The cavernosal force F_c is defined as the cavernosal pressure P_c exerted on the net venules and veins area A_2:

$$F_c = P_c A_2 \quad (26)$$

Veno-Occlusion Mechanics, Converging Venous Outflow, Work, Energy and Cavernosal Pressure Combined

From net work = 0, $\Delta KE = 0$, $F_s = F_c$ and using (24), (26):

$$P_s A_1 = P_c A_2 \quad (27)$$

From the net force $F_s - F_c > 0$, and letting the cavernosal pressure P_c increase by C_{OP} (18) until $F_s = F_c$ (27), the occlusion/cavernosal pressure relationship is:

$$C_{OP} = \frac{P_s (A_1/A_2)_{ELt}}{P_c} \quad (28)$$

Where $(A_1/A_2)_{ELt}$ is the highest occlusion ratio corresponding to the elastic limit of the TA (EL_t) and peak cavernosal pressure P_{cp}.

$$EL_f = \left(\frac{E_f}{E_t}\right) EL_t >= EL_t \quad (29)$$

From (15), (19) and (28) the flow/cavernosal pressure relationship is:

$$\left(\frac{1}{IO_R}\right) = \sqrt{\frac{P_s (A_1/A_2)_{ELt}}{P_c}} \quad (30)$$

From the strain-elasticity behavior of collagen fibrils[2]:

$$(A_1/A_2)_{@ \% \text{ Occlusion}} = \frac{1}{1 - \left(\frac{\% \text{ Occlusion}}{100}\right)} \quad (31)$$

From Veno-Occlusion Mechanics (10), Converging Venous Outflow (19) and (28), the Venous Leak Pressure Decrease Factor C_{VL} is expanded as the inverse of the Occlusion/Pressure Increase Factor C_{OP}:

$$C_{VL} = \left(\frac{1}{C_{OP}}\right) = IO_R^2 <= 1.0 \quad (32)$$

From (10), (17), (32) and $C_{VL} = 1.0$ @ P_{cp}, The Loverband® device restoring pressure P_L is:

$$P_L = \Delta P_f = \frac{P_{cp}}{2} - P_c C_{OP} \left(\frac{C_{VL}^2}{1 + C_{VL}}\right) \quad (33)$$

$$P_L = P_{cp} \left(0.5 - \frac{C_{VL}^2}{1 + C_{VL}}\right) <= 350 \text{ mmHg} \quad (34)$$

The contact pressure deficiency ΔP_f (%) recovered by The Loverband® device is:

$$\Delta P_f \ (\%) = \left(\frac{P_L}{0.5 \ P_{cp}}\right) \text{x } 100 <= 60\% \quad (35)$$

Results

The relationship between occlusion and cavernosal pressure (28) is illustrated graphically (Fig. 4).

Peak cavernosal average pressure[1] of 1,411 mmHg is obtained by setting the highest occlusion at 91.5 percent with $C_{OP} = 1.0$ and systolic pressure $P_s = 120$ mmHg.

Diastolic flow reversal occurs when the net force $F_d - F_c = 0$ and F_c continues to increase until $F_s - F_c = 0$. At the point of flow reversal, cavernosal pressure is 632 mmHg obtained at 87.3 percent occlusion with $P_{cp} = 1{,}411$ mmHg.

High cavernosal pressures are reached at high occlusions after the stiffened TA begins to resist tissue expansion at large elongations.[2]

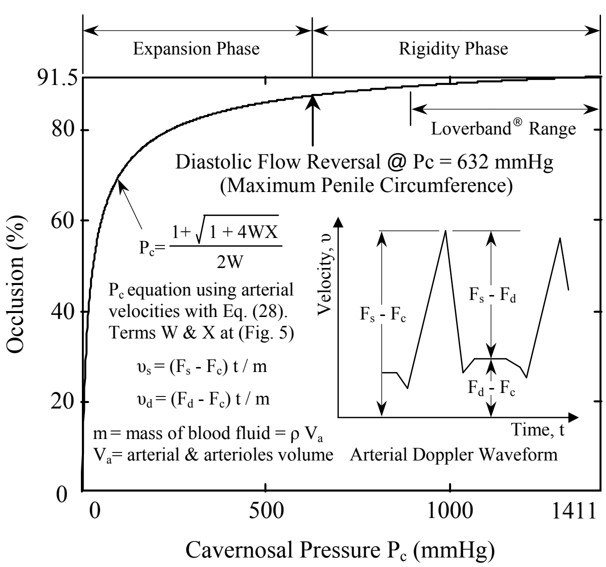

Figure 4 Relationship between occlusion and cavernosal pressure for a normal erection during continuous flow. At high occlusions, small percentage changes in occlusion represent large changes in cavernosal pressure.

The relationship between flow and cavernosal pressure (30) is illustrated graphically (Fig. 5).

Systolic flow Q_s of 150 ml/min to induce the erection is obtained using 91.5 percent occlusion, cavernosal pressure P_c = 0.01 mmHg, flow to maintain Q_l at 91.5 % occlusion = 0.4 ml/min (2.5 min/ml) with systolic pressure P_s = 120 mmHg.

Diastolic flow Q_d of 25 ml/min is obtained using 87.3 percent occlusion, cavernosal pressure P_c = 0.01 mmHg, flow Q_l at 87.3 % occlusion = 0.1 ml/ min (10 min/ml) with diastolic pressure P_d = 80 mmHg.

Systolic and diastolic flows will decline considerably approaching low values before high cavernosal pressures are reached.[3]

Diastolic flow will be reversed increasingly[4] until the systolic flow reaches a low continuous flow to maintain the erection at peak cavernosal pressure.

Flow Rate Vs. Cavernosal Pressure

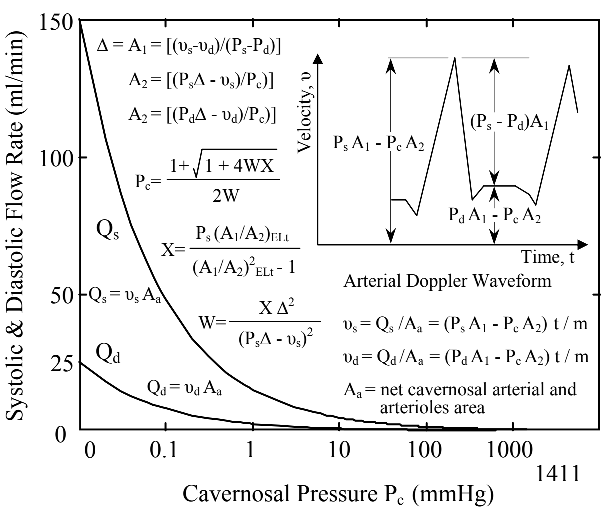

Figure 5 Relationship between flow and cavernosal pressure for a normal erection during continuous flow. Cavernosal pressure is plotted on a logarithmic scale for clarity of the flow lines.

The Loverband® device maximum effective stretch over the penis dorsal base is Δl = 1.85 inches.

From Hooke's Law ($F = K \Delta l$), using the band's spring constant K = 0.625, the tension in the band T = F = 0.625 x 1.85 = 1.156 Lbs.

From Laplace's Law ($T = P r$), using an average effective radius r = 0.855 inches, the pressure exerted by the band P_L = 1.156/0.855 = 1.35 Lbs/in.

The Loverband® device maximum effective pressure using the band's thickness t_e = 0.20 inches is: P_L = (1.35 Lbs/in/0.20 in)/(0.0193 Lbs/in^2 mmHg) = 350 mmHg.

The external pressure P_L required to bring a deficient erection from P_c = 905 mmHg to a peak pressure P_{cp} = 1,411 mmHg is computed using C_{OP} (17), C_{VL} (32), P_L (34) and ΔP_f (35):

C_{OP} = 1,411 / 905 = 1.56

C_{VL} = 1 / 1.56 = 0.64

P_L = 1,411 x {0.5 - [(0.64)^2 / (1+0.64)]} = 353

ΔP_f = 350 max / (0.5 x 1,411) = 50% P_f recovery

Discussion

Veno-Occlusive Dysfunction can result from variations in the stiffness of the TA and DF, the expanded penis cross-sectional shape, and the contraction inability of the perineal muscles to regulate occlusion.

The quantitative model which has been presented provides a novel solution to the understanding of the erectile mechanism leading to the development of a biomedical engineered device for the treatment of VOD and Primary Premature Ejaculation. The Loverband® device is effective in VOD cases with satisfactory arterial flows where deficient rigidity or glanular insufficiency exist.

The relevant findings of this study are that the occlusion mechanism of penile erection is dependent on the transfer of pressure between the TA and DF and the expanded penis cross-sectional shape (optimally achieved with $K_f = K_t$ and $\theta = \varphi = 45°$); the Converging Venous Outflow method from Bernoulli's pressure and flow principle correlates occlusion of the dorsal veins with the remaining venular plexus and the corpora cavernosa; and peak cavernosal pressure is reached at the elastic limit of the TA.

Further work is aimed at determining the stiffness of the TA and DF at varying cavernosal pressures up to P_{cp}.

Conflict of Interest

The author is the patent owner for The Loverband® method and declares a conflict of interest.

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