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

Materials and Methods

Veno-Oclusion 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).

The Loverband® device is distributed by Bliss Products, LLC., 5775 SW 72 Street, Miami, Fl 33143. Ph.: (888) 954-7774 USA Toll Free. Email: contactus@theloverband.com

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.
Introducing Venous Leak Pressure Decrease Factor $C_{VL}$:

$$P_f = (P_c - P_f) C_{VL}$$  \hspace{1cm} (9)$$

$$C_{VL} = \left(\frac{\sin \theta}{\sin \phi}\right) \left(\frac{K_f}{K_t}\right) \leq 1.0$$  \hspace{1cm} (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 $\theta$ & $\phi$ and the stiffness ratio between the DF and TA. If $C_{VL}$ equals 1.0 ($\theta = \phi = 45^\circ$ 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):

$$Q = u_1 A_1 = u_2 A_2$$  \hspace{1cm} (12)$$

$$\Delta P = P_1 - P_2 = \rho/2 \left(u_2^2 - u_1^2\right)$$  \hspace{1cm} (13)$$
The Bernoulli pressure and flow equation:

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

Where \( \rho \) is the density of the blood fluid.

From (14) left, for flow into the corpora cavernosa and letting \( \Delta P \) at a lower occlusion equal \( \Delta P \) at a higher occlusion, the Inflow/Outflow Rate Decrease Factor \( I_{OR} \) is:

\[ I_{OR} = \frac{Q_1 \text{ @ Higher Occlusion}}{Q_1 \text{ @ Lower Occlusion}} \]  

\[ I_{OR} = \sqrt{\frac{(A_1/A_2)^2 - 1)}@ Lower Occlusion}{(A_1/A_2)^2 - 1)}@ Higher Occlusion} \leq 1.0 \]  

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

\[ C_{OP} = \frac{\Delta P \text{ @ Higher Occlusion}}{\Delta P \text{ @ Lower Occlusion}} \]  

\[ C_{OP} = \frac{(A_1/A_2)^2 - 1)}@ Higher Occlusion}{(A_1/A_2)^2 - 1)}@ Lower Occlusion} \geq 1.0 \]  

The relationship between the Inflow/Outflow Rate Decrease Factor \( I_{OR} \) and the Occlusion/Pressure Increase Factor \( C_{OP} \) is defined by:

\[ C_{OP} = \left( \frac{1}{I_{OR}^2} \right) \]  

**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):

\[ ME_T = EPE + KE \]  

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:

\[ W = \Delta EPE + \Delta KE \]  

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:

\[ KE = \frac{D}{2} v_2^2 = \frac{\Delta P}{(1 - (A_2/A_1)^2)} \]  

From the Work-Energy Theorem, the net work done is transformed into KE by the net forces \( F_s - F_c > 0 \) 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 \( F_s = F_c \). At this point, peak cavernosal pressure \( P_c \) 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:

\[ P_c = \Delta P \]
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:

$$C_{OP} = \frac{P_s (A_1/A_2)^{EL_{t}}}{P_c} \quad (28)$$

Where $(A_1/A_2)^{EL_{t}}$ is the highest occlusion ratio corresponding to the elastic limit of the TA (EL$_t$) and peak cavernosal pressure $P_{cp}$.

$$EL_{t} = \left(\frac{F_s}{F_c}\right) EL_4 >= EL_4 \quad (29)$$

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

$$\left(\frac{1}{I_{OR}}\right) = \frac{P_s (A_1/A_2)^{EL_{t}}}{P_c} \quad (30)$$

From the strain-elasticity behavior of collagen fibrils$^2$:

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

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 $C_{OP}$:

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

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

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

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

The contact pressure deficiency $\Delta P_t (%)$ recovered by The Loverband® device is:

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

### 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](image-url)

**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 $Q_s$ at 91.5 % occlusion = 0.4 ml/min (2.5 min/ml) with systolic pressure $P_d = 120$ mmHg.

Diastolic flow $Q_d$ of 25 ml/min is obtained using 87.3 percent occlusion, cavernosal pressure $P_c = 0.01$ mmHg, flow 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. Diastolic flow will be reversed increasingly until the systolic flow reaches a low continuous flow to maintain the erection at peak cavernosal pressure.

Flow Rate Vs. Cavernosal Pressure

![Flow Rate Vs. Cavernosal Pressure graph]

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 $\Delta l = 1.85$ inches.

From Hooke’s Law ($F = K \Delta l$), using the band’s spring constant $K = 0.625$, the tension in the band $T = F = 0.625 \times 1.85 = 1.156$ 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 $t_{eb} = 0.20$ inches is: $P_L = (1.35 \text{ Lbs/in}/0.20 \text{ in})/(0.0193 \text{ Lbs/in}^2 \text{ mmHg}) = 350$ 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 $\Delta P_t$ (35):

$$C_{OP} = 1,411 / 905 = 1.56$$
$$C_{VL} = 1 / 1.56 = 0.64$$
$$P_L = 1,411 \times (0.5 - [(0.64)^2 / (1+0.64)]) = 353$$
$$\Delta P_t = 350 \text{ max} / (0.5 \times 1,411) = 50\% \ P_t \text{ recovery}$$

**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 $K_t = K$ and $\theta = \phi = 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.

**References**