



STUDIO URO-ANDROLOGICO

INDICAZIONI E LIMITI DEI DISPOSITIVI ESTERNI IN ANDROLOGIA

L. Gallo

Studio Uro-Andrologico Gallo
Napoli



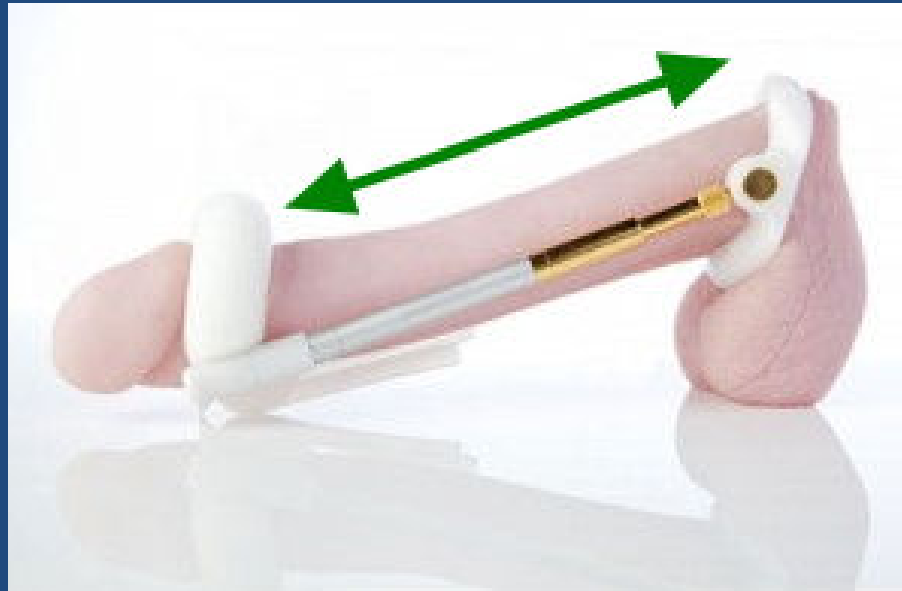
Presidente Aldo Maffucci

Convegno Annuale Update in Urologia



NAPOLI - Castel dell'Ovo
14 maggio 2016

- Plastic support ring, a silicone band, and two dynamic rods
- The PTT works by holding the penis in a cradle and subjecting it to gentle and progressive traction forces that can be achieved by the addition of small metal extensions to the dynamic rods and cradle frame every few weeks
- There are several commercially available penile stretching or traction devices



Estensore: indicazioni terapeutiche

Peyronie

- monoterapia
- terapia multimodale
- associato alla chirurgia

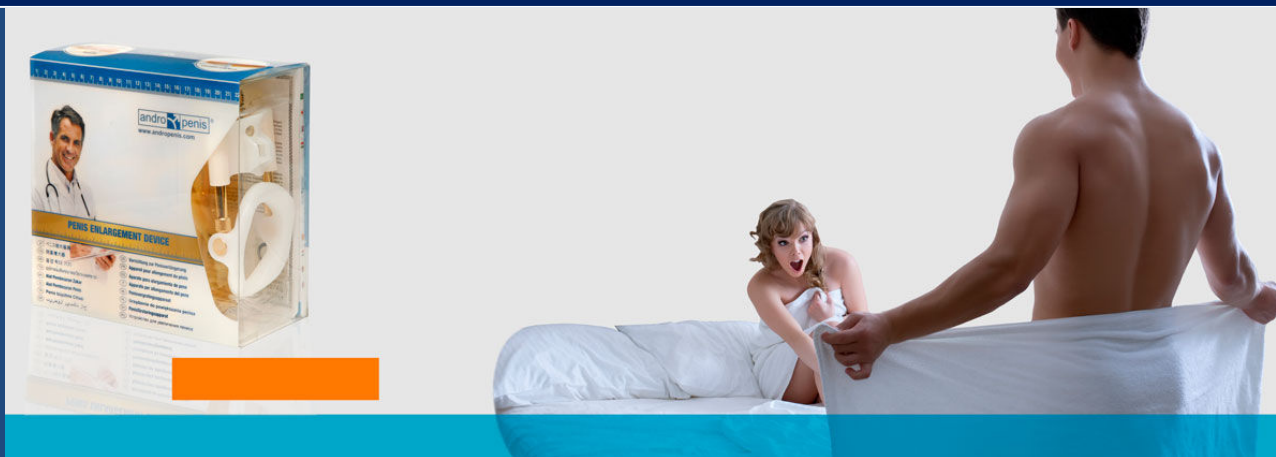
Pene corto

- monoterapia
- associato alla chirurgia



PENILE TRACTION THERAPY: BIOLOGIC MECHANISMS

- Placing tissues under tension has been used in a number of fields including orthopedics, maxillofacial and plastic surgery
- Mechanical stress modulates cell function through a process called mechanotransduction by activating multiple signal transduction pathways via the internal cytoskeleton and extracellular matrix
- On a histologic level, tension has been demonstrated to induce an increased production of metalloproteinases, as well as a change in the orientation of the collagen fibres parallel to the traction forces when applied to Dupuytren's contracture tissue
- On a genetic level, mechanical shear stress has been shown to cause an upregulation of antifibrotic genes
- Mechanotransduction, or gradual expansion of tissue by traction, results in formation of new connective tissue by cellular proliferation

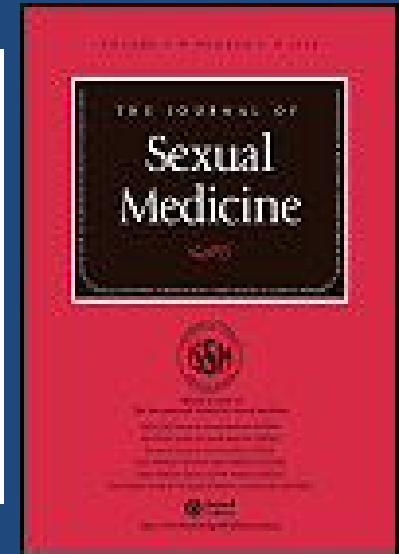


ORIGINAL RESEARCH—PEYRONIE'S DISEASE

Penile Traction Therapy for Treatment of Peyronie's Disease: A Single-Center Pilot Study

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- Ten men with PD completed this noncontrolled pilot study of traction therapy using the FastSize Penile Extender
- Nearly all (90%) had failed prior medical therapy. Traction was applied as the only treatment for 2-8 hours/day for 6 months
- Objective measures demonstrated reduced curvature in all men from 10-45 degrees
- Average reduction for the group was 33% (51-34 degrees)
- SPL increased 0.5-2.0 cm and erect girth increased 0.5-1.0 cm with correction of hinge effect in four out of four men
- International Index of Erectile Function-erectile function domain increased from 18.3-23.6 for the group
- There were no adverse events including skin changes, ulcerations, hypoesthesia or diminished rigidity.
- Prolonged daily external penile traction therapy is a new approach for the nonsurgical treatment of PD

ORIGINAL RESEARCH—PEYRONIE'S DISEASE

Use of Penile Extender Device in the Treatment of Penile Curvature as a Result of Peyronie's Disease. Results of a Phase II Prospective Study

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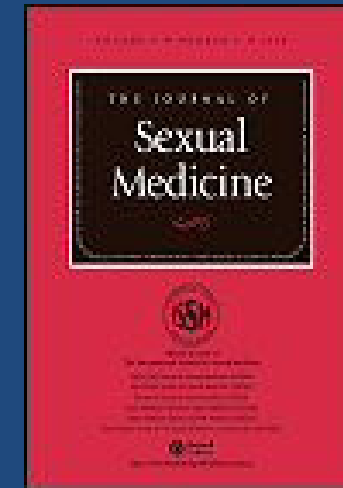
- Peyronie's disease patients with a curvature not exceeding 50 degrees with mild or no erectile dysfunction (ED) were eligible.
- Patients were counselled on the use of the penile extender for at least 5 hours per day for 6 months
- Penile curvature decreased from an average of 31 degrees to 27 degrees at 6 months without reaching the effect size ($P = 0.056$)
- Mean stretched and flaccid penile length increased by 1.3 and 0.83 cm, respectively at 6 months
- Results were maintained at 12 months
- Overall treatment results were subjectively scored as acceptable in spite of curvature improvements, which varied from "no change" to "mild improvement."
- The use of a penile extender device provided only minimal improvements in penile curvature but a reasonable level of patient satisfaction, probably attributable to increased penile length.
- The selection of patients with a stabilized disease, a penile curvature not exceeding 50 degrees, and no severe ED may have led to outcomes underestimating the potential efficacy of the treatment.

ORIGINAL RESEARCH—PEYRONIE'S DISEASE

Acute Phase Peyronie's Disease Management with Traction Device: A Nonrandomized Prospective Controlled Trial with Ultrasound Correlation

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- A total of 55 patients underwent PTT for 6 months and were compared with 41 patients with AP of PD who did not receive active treatment ("no intervention group" [NIG]).
- The mean curvature decreased from 33° at baseline to 15° at 6 months and 13° at 9 months with a mean decrease 20° ($P < 0.05$) in the PTT group
- VAS score for pain decreased from 5.5 to 2.5 after 6 months ($P < 0.05$); EF and erection hardness also improved significantly
- The percentage of patients who were not able to achieve penetration decreased from 62% to 20%
- In the NIG, deformity increased significantly, stretched flaccid penile length decreased, VAS score for pain increased, and EF and erection hardness worsened
- PTT was associated with the disappearance of sonographic plaques in 48% of patients
- Furthermore, the need for surgery was reduced in 40% of patients who would otherwise have been candidates for surgery and simplified the complexity of the surgical procedure (from grafting to plication) in one out of every three patients
- PTT seems an effective treatment for the AP of PD in terms of pain reduction, penile curvature decrease, and improvement in sexual function.

ORIGINAL RESEARCH—PEYRONIE'S DISEASE

Combination of Penile Traction, Intralesional Verapamil, and Oral Therapies for Peyronie's Disease

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- To assess the benefit of penile traction therapy (PTT) when added to intralesional verapamil injections (IVI) combined with oral L-arginine 1g bid and pentoxifylline 400 mg tid in men with PD
- 74 men with PD completed 12 IVI; Patients electing to add PTT were advised to wear the device for 2-8 hours daily, and no longer than 2 hours per session
- 39 patients in the PTT group (I) vs. 35 patients in group (II) completed the protocol
- Responders had a mean EPC improvement of 26.9 degrees in group I vs. 20.9 in group II
- Multivariate analysis revealed that duration of PTT use significantly predicts length gain (0.38 cm gain for every additional hour per day of PTT use, $p = 0.007$)
- There was a trend toward measured curvature improvement, and a significant gain in SPL in men using the combination therapy protocol
- Length improvement is related to duration of use of the traction device [corrected].

The Effect of Duration of Penile Traction Therapy in Patients Undergoing Intralesional Injection Therapy for Peyronie's Disease

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- A retrospective review of patients who underwent interferon α -2b therapy between 2001 and 2012 was performed
- A total of 112 patients underwent a median of 12 interferon α -2b injections
- Daily use of penile traction therapy was reported by 31% of patients
- Overall, the use of penile traction therapy did not effect change in penile circumference, change in curvature or change in stretched penile length
- Men who used penile traction therapy 3 or more hours per day gained significantly greater stretched penile length compared to those who did not use penile traction therapy
- Routine penile traction therapy during intralesional injection with interferon α -2b for Peyronie's disease may result in a small but subjectively meaningful improvement in stretched penile length, without affecting curvature, if used for at least 3 hours a day

- The aim of this study was to study patient outcomes with penile length change and patient satisfaction after surgery following tunica albuginea plication (TAP) and partial plaque excision and grafting (PEG) with or without postoperative TT.
- Retrospective analysis was performed from our cohort of Peyronie's reconstructive surgery between 2007 and 2010.
- SPL was measured dorsally from pubis to corona and recorded at the initial office visit and then compared to most recent postoperative visit.
- Traction therapy was initiated for >2 hours a day for 3 months typically starting 3-4 weeks postoperatively.
- Mean length change seen in TAP (TT+) was 0.85 cm (0.25-1.75) vs. -0.53 cm (-1.75 to 0.5) in TAP (TT-) ($P < 0.001$). The mean length change seen in PEG (TT+) was 1.48 cm (0-6) vs. PEG (TT-) 0.24 cm (-1 to 2.5 cm) ($P < 0.001$).
- Sixty-one percent of surveys were returned; 85% lost length prior to the initial office evaluation, with an average of -2.5 cm lost. Importantly, in those who used traction, there was no perceived length loss, 58% reported a mean erect length gain of 1.1 cm. However, only 54% of all patients were satisfied with their current erect length.
- Loss of length in men with PD remains a serious concern. It appears that postoperative TT can result in length preservation, and in many, a measured and perceived length gain following correction of the curvature.

Rybak J, Papagiannopoulos D, Levine L. A retrospective comparative study of traction therapy vs. no traction following tunica albuginea plication or partial excision and grafting for Peyronie's disease: measured lengths and patient perceptions. J Sex Med. 2012 Sep;9(9):2396-403



A pilot phase-II prospective study to test the 'efficacy' and tolerability of a penile-extender device in the treatment of 'short penis'

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Accepted for publication 9 July 2008

- Fifteen patients were required to test the efficacy of the device
- Eligible patients were counselled how to use the penile extender for at least 4 h/day for 6 months
- Penile dimensions were measured at baseline and after 1, 3, 6 and 12 months (end of study)
- The erectile function (EF) domain of the International Index of EF was administered at baseline and at the end of the study
- After 6 months the mean gain in length was significant, meeting the goals of the effect size, at 2.3 and 1.7 cm for the flaccid and stretched penis, respectively
- No significant changes in penile girth were detected
- The EF domain scores improved significantly at the end of study
- Penile extenders should be regarded as a minimally invasive and effective treatment option to elongate the penile shaft in patients seeking treatment for a short penis.

Effect of Penile-Extender Device in Increasing Penile Size in Men with Shortened Penis: Preliminary Results

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- The aim of this study was to assess the efficacy of a penile-extender in increasing penile size on subjects complaining about "short penis"
- After measuring the penile length in flaccid and stretched forms and penile circumference, patients were instructed to wear Golden Erect(®) , 4-6 hours per day during the first 2 weeks and then 9 hours per day until the end of the third month;The subjects were also trained how to increase the force of the device during determined intervals
- Twenty-three cases entered the study; The mean flaccid penile length increased from 8.8 cm to 10.1 and 10.5 , respectively, in the first and third months of follow-up, which was statistically significant ($P < 0.05$)
- Mean stretched penile length also significantly increased from 11.5 cm to, respectively, 12.4 cm and 13.2 cm during the first and second follow-up ($P < 0.05$)
- No significant difference was found regarding proximal penile girth
- Our findings supported the efficacy of the device in increasing penile length.

Applying Extender Devices in Patients with Penile Dysmorphophobia: Assessment of Tolerability, Efficacy, and Impact on Erectile Function

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- 163 men presented to our institution complaining of small penile length and/or girth
- All patients received structured psychosexual counseling
- Fifty-four patients were willing to use the AndroPenis penile extender after counseling
- Patients with major psychiatric disorders were excluded from enrollment
- The patients were instructed to wear the device between 4 and 6 hours per day for 6 months
- At 6-month follow-up, a mean gain of 1.7, 1.3 and 1.2 cm was noted for the flaccid, stretched, and erected penile lengths, respectively (all P values < 0.001)
- Patient satisfaction survey revealed modest satisfaction
- From 13 patients with mild baseline erectile dysfunction, nine patients reported normal erectile function after 9 months.
- Penile extender as a minimally invasive technique is safe and provides modest benefits and patient satisfaction.

Traction Therapy for Men with Shortened Penis Prior to Penile Prosthesis Implantation: A Pilot Study

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- Loss of penile length after penile prosthesis implantation is one of the most common complaints. There is no recognized reliable technique to gain length once the device is placed.
- Ten men with drug refractory erectile dysfunction and a complaint of a shorter penis as a result of radical prostatectomy in four, prior prosthesis explantation in four, and Peyronie's disease in two were entered into this trial
- External penile traction was applied for 2-4 hours daily for 2-4 months prior to prosthesis surgery.
- Daily average device use was 2-4 hours and for up to 4 months
- No man had measured or perceived length loss after inflatable penile prosthesis placement
- Seventy percent had measured erect length gain compared with baseline pre-traction SPL up to 1.5 cm. There were no adverse events.
- External traction therapy appears to result in a preservation of penile length, as no man had measured or perceived length loss following prosthesis placement, but in fact, a small length gain was noted in 70% of the subjects with no adverse events.
- The protocol is tedious and requires compliance to be effective
- External traction therapy prior to inflatable penile prosthesis placement appears to preserve and possibly result in increased post-prosthesis implant erect length.



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Guidelines on Penile Curvature

K. Hatzimouratidis (Chair), I. Eardley, F. Giuliano,
I. Moncada, A. Salonia

Penile traction devices and vacuum devices may reduce penile deformity and increase penile length.

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