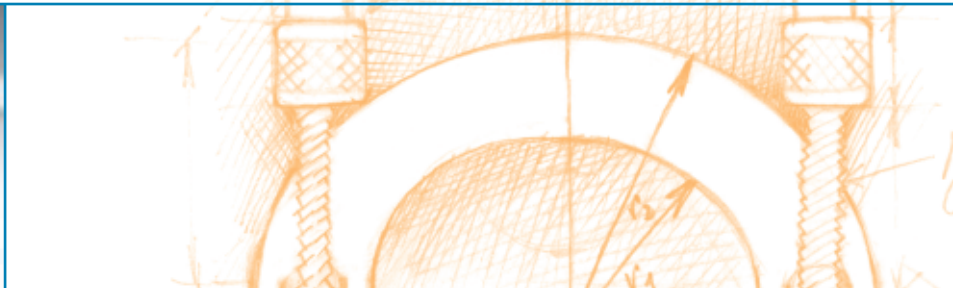
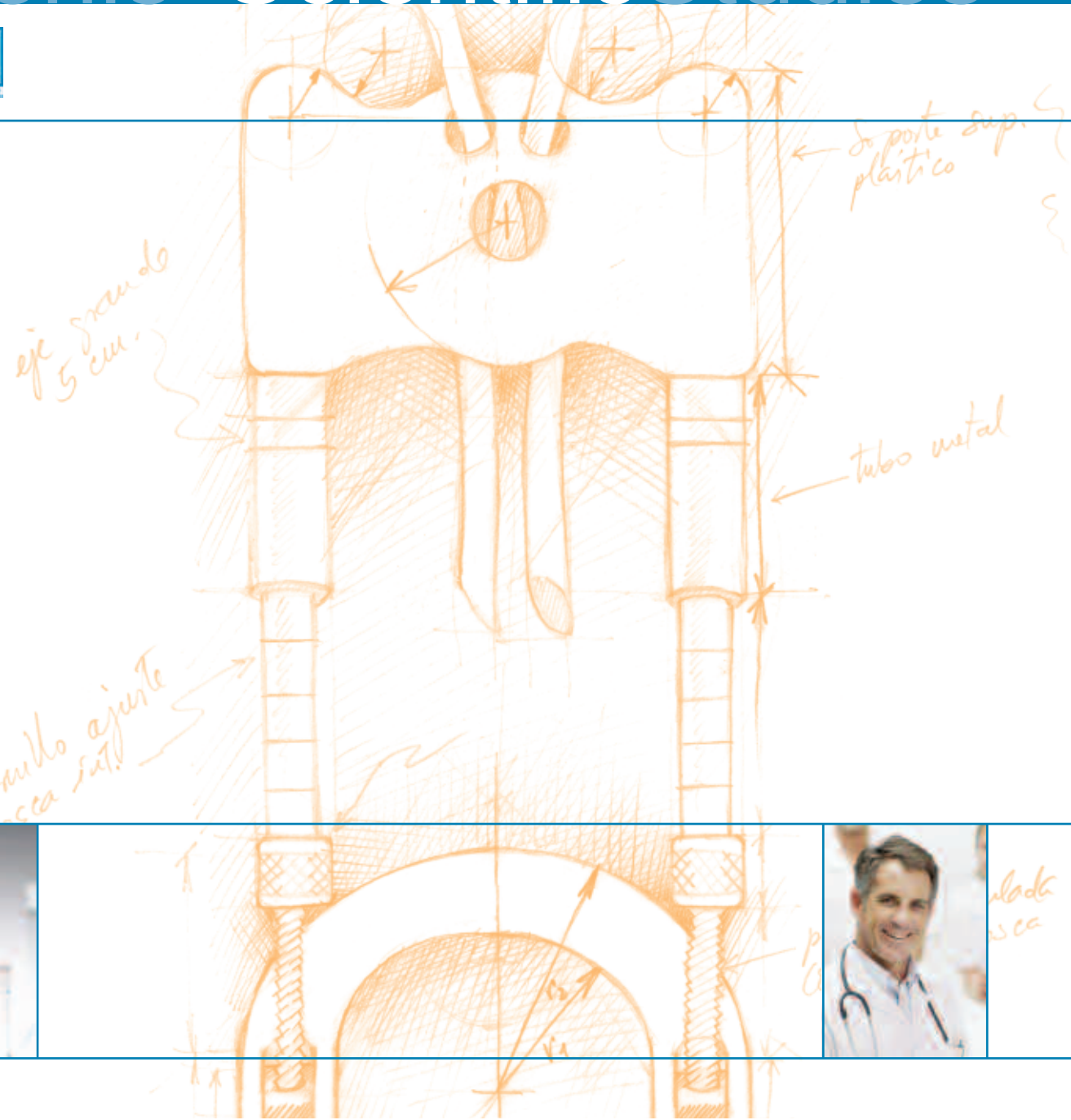


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Peyronie's disease



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



Can an External Penis Stretcher Reduce Peyronie's Penile Curvature?



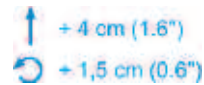
Treatment with penile retraction in evolutive peyronie's disease with external penis-stretching



Peyronie's Disease. Latest treatment options



Conservative treatment in a case of in-duratio penis plastica



Penile enlargement



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



Enlargement of penis in patients with hypogonadism complex approach to the clinical practice



Penile enlargement without surgery with Andropenis®



Effects on penile size with penile extensor by traction force



Efficacy of the daily penis-stretching technique to elongate the "small penis"



Urological Post-surgery



Management of penile shortening after peyronie's disease surgery



Management of penile shortening after peyronie's disease surgery



Post-surgical use of Andropenis® following the plaque removal and its substitution with autologous venous patch in the penis shaft curvatures provoked by peyronie's disease.



Long Term Results in Augmentation Phalloplasty through a 2-cm Incision: Technique, Anatomical Description in a Human Cadaver and Satisfaction Assessment



Penis enlargement: ventral and dorsal combined technique



Treatment of penis hypoplasia as a consequence of epispadia surgery through penis extensor



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ABSTRACT

Introduction. Pilot experiences have suggested that tension forces exerted by a penile extender may reduce penile curvature as a result of Peyronie's disease.

Aim. To test this hypothesis in a Phase II study using a commonly marketed brand of penile extender.

Methods. Peyronie's disease patients with a curvature not exceeding 50° with mild or no erectile dysfunction (ED) were eligible. Fifteen patients were required to test the efficacy of the device assuming an effect size of ≥ 0.8 , consistent with an "important" reduction in penile curvature. Changes in penile length over baseline and erectile function (EF) domain scores of the International Index of Erectile Function (IIEF) constituted secondary end points.

Main Outcome Measures. Patients were counselled on the use of the penile extender for at least 5 hours per day for 6 months. Photographic pictures of the erect penis and measurements were carried out at baseline, at 1, 3, 6, and 12 months (end of study). The IIEF-EF domain scores were administered at baseline and at the end of study. Treatment satisfaction was assessed at end of study using a nonvalidated institutional 5-item questionnaire.

Results. Penile curvature decreased from an average of 31° to 27° 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, res-

pectively 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."

Conclusions. In our study, 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°, and no severe ED may have led to outcomes underestimating the potential efficacy of the treatment.

Introduction

Peyronie's disease can be defined as an acquired penile deformity of the erect penis, which is caused by a fibrous plaque. Men with Peyronie's disease may present with a combination of complaints, including penile curvature, painful erections, erectile dysfunction (ED), and penile shortening leading to significant detrimental psychological effects [1-4]. A conservative medical treatment is usually advocated as the first-line therapy, particularly in the early inflammatory phase, although there is little evidence that this is effective [5]. If such management proves unsuccessful, a more invasive surgical approach may be contemplated once the disease has been stabilized, usually after 1 year from onset [1]. The long-term results of surgery are not devoid of complications, particularly following graft procedures, with ED and penile shortening being not un-

sual complaints [6,7]. It has been claimed that the penile extender, a nonsurgical device that employs progressive mechanical traction to the penis, produces a significant improvement in penile length [8,9]. Two preliminary pilot experiences have suggested that the tension forces exerted by a penile extender could also reduce penile curvature as a result of Peyronie's disease [10,11]. The combination of these effects may provide an intriguing treatment option in selected Peyronie's disease patients. We tested this hypothesis in a Phase II study designed to assess whether a penile extender produces significant improvement in penile curvature as a result of Peyronie's disease.

Material and methods

Patient eligibility

Patients with a penile curvature as a result of Peyronie's disease were considered eligible for the study if they met the following inclusion criteria: (i) a penile curvature not exceeding 50°, sustained by fibrous plaques detectable through genital palpation or ultrasound (US); (ii) a history of the disease lasting at least 12 months; and (iii) no penile pain in the flaccid state. Previous medical treatment did not contraindicate study participation. The exclusion criteria were a history of major psychiatric disorder, reduced manual dexterity that might prevent the correct use of the device, previous penile surgery, or severe ED based on the erectile function (EF) domain scores of the International Index of Erectile Function (IIEF).

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End points and sample size statistics

Changes in penile curvature during erection compared with the baseline after 6 months of treatment and durability of the response 6 months after treatment discontinuation were considered the primary study end points. Given the objective difficulty of estimating the standard deviation of baseline penile curvature, calculation of the sample size was based on the "effect size" [12]. Effect-size is a standardized, scale-free measure of the relative size of the effect of an intervention. It is particularly useful for quantifying effects measured on unfamiliar or arbitrary scales and for comparing the relative sizes of effects from different studies. Cohen [12] defined the effect size "d" as the difference between the means, $M1-M2$, divided by standard deviation, s , of either group. By convention, the subtraction, $M1-M2$, is performed so that the difference is positive if it is in the direction of improvement or in the predicted direction, and negative if in the direction of deterioration or opposite to the predicted direction. Thus, effect size quantifies the size of the difference between groups, and may therefore be said to be a true measure of the significance of the difference. Effect sizes were defined as "small, $d = 0.2$," "medium, $d = 0.5$," and "large, $d = 0.8$ ". Effect sizes can also be interpreted in terms of the percent of non-overlap of the experimental group's values with those of the control group: a d of 0.8 indicates a non-overlap of 47.4% in the two distributions; a d of 0.5 indicates a 33% non-overlap; and a d of 0.2 a 14.7% non-overlap. It was assumed that with 15 evaluable patients, the finding of a "relevant" reduction in penile curvature, defined by an effect size ≥ 0.8 , would have a statistical power of 80% and a probability of a false negative result of less than 5% (2-sided). Changes in flac-

cid and stretched penile length, plaque size, treatment tolerability, patient compliance and satisfaction, as well as changes in the IIEF-EF domain scores at last follow-up compared with the baseline measurements constituted secondary end points.

Baseline investigations

Baseline patients' assessment included full medical and sexual history, and physical examination. The EF domain scores of the IIEF were administered at baseline and at the end of the study (6 months after treatment discontinuation). Patients scoring severe abnormal values (IIEF-EF ≤ 10) were excluded [13]. A penile US was required for study entry in order to record the size of plaques (determined as the product of length and width in mm^2) and the location and sonographic appearance (calcified, hypoechoic, hyperechoic) of the plaques. Fibrous nodules undetectable sonographically were measured manually using a caliper. The same measurement method was used in each patient for the posttreatment determination of the plaque size. The degree of curvature was documented using photographic pictures taken by the clinician from three angles (frontal, lateral, and dorsal) during an in-office intracavernous injection test with 20 mcg alprostadil or, for patients refusing the injection, by self-photographs during an at-home full erection. The former was strictly required for patients scoring abnormal IIEF-EF domain scores. The magnitude of curvature on photographs was determined by placing a goniometer in the angle formed by the intersection of two drawn segments running parallel to each of the two bended portions of the shafts. Following pharmacological erection, the center of the goniometer was placed over the point of maximum curvature and

the limbs were positioned along the shaft, proximal to and distal to this point. Posttreatment curvature was determined in each patient using the same method they had chosen at baseline. Penile measurements (t_0) were obtained employing the standard technique validated by Wessells et al. [14]. Using a taper ruler to the nearest 0.5 cm, the penis was initially measured in the flaccid state and then while applying tension to maximally stretch it, from the pubopenile skin junction to the meatus. The circumference was measured at midshaft. Inter-operator agreement was assessed by performing a set of measurements on a small sample of young volunteers ($N = 8$) with individual variability always falling below 0.5 cm.

Device description and treatment schedule

After signing the informed consent form, patients were taught how to use a common brand of penile extender, the Andropenis® (Andromedical, Madrid, Spain), a device designed to exert a continuous and gradually increasing traction force on the penis. The device consists of a plastic ring, where the penis is introduced, and from where two dynamic metallic rods originate the traction. In the upper part there is a plastic support where a silicone band holds the glans in place. Detailed instructions on how to increase the traction force from 600 g during the first month, 900 g during the second month, up to 1200 g during the fifth and sixth months were provided following the manufacturer's leaflet. Briefly, the traction is rendered a dynamic process by means of the rigid rods combined with the action of "compression springs" (springs that react by exerting a traction when compressed). As the tissues are stretching throughout

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months of treatment, more and more elongations of the two metal rods of Andropenis® combined with the action of the "compression springs" are needed to achieve the needed traction forces [15]. In cases of concomitant untreated ED, patients were advised to postpone the use of erectile aids until the end of study. Sexual activity was not interdicted at any time during the study. It was suggested that patients wear the device for up to 9 hours/day and it was explained that, based on the available evidence [10,16,17], the magnitude of both the straightening and the elongating effect would be proportional to the traction time. The minimum daily use for testing treatment efficacy was assumed to be 5 hours and this was the minimum requirement for entry into the study.

Follow up visits

Follow-up visits were scheduled at 1 (t1), 3 (t3), 6 (t6), and 12 months (t12) (end of study, after a washout period of 6 months) to record side effects, treatment compliance, calculations of curvature using fresh photographs, and to carry out genital examinations and take penile measurements. At the end of the study, the EF domain scores of the IIEF and a satisfaction questionnaire were administered. The latter consists of a set of five questions designed by the investigators that ask patients to assess subjective improvements in penile curvature (Q1) on a 0–4 scale (0 = worsening, 1 = unchanged, 2 = mild improvement, 3 = significant improvement, 4 = complete resolution), as well as to assess flaccid penile length (Q2), erect penile length (Q3), and overall results (Q4) on a 0–3 scale (0 = no change/worsening, 3 = optimal result). Lastly, Q5 addresses overall results on a 0–4 scale (0 = no result, 1 = very mild, 2 = ac-

ceptable, 3 = good, 4 = optimal results). Plaque size was also calculated at the end of study using a caliper or a penile US. The study protocol was granted Ethical Committee approval in February 2005.

Results

Out of a set of 40 patients referring with a complaint of penile curvature between February 2005 and May 2006, 19 met the inclusion criteria and entered the study. Reasons for exclusion were congenital curvature (N = 2), concomitant penile pain (N = 6), disease history lasting less than 12 months (N = 6), a curvature exceeding 50° (N = 4), and refusal to undergo the proposed treatment (N = 3). Baseline characteristics of the sample for age, disease features, EF domain scores of the IIEF, and penile measurements are listed in Table 1. None of the eligible patients was taking ED therapy at study entry.

Table 1 Baseline patient characteristics (N = 19)

Variable	Categorization	Value
Mean age (SD)	—	53.89 (7.48)
Mean disease duration (months) (SD)	—	36 (3.5)
Previous medical treatment (N (%))	None Oral agents Intralesional therapy Surgical therapy	5 (26) 3 (16) 4 (21) 3 (16)
Mean plaque size (mm) (SD) (method of determination: US; N = 13; caliper; N = 6)	—	3.4 (0.8)
Plaque position at US (N (%))	Cebral Proximal Midshaft Distal	7 (37) 2 (11) 4 (21) 6 (32)
Plaque location (N (%))	Proximal Midshaft Distal	3 (16) 10 (53) 6 (31)
Mean curvature degree (SD) (method of determination: intracavernous injection; N = 12; at-home photographs; N = 7)	—	31 (11.58)
Curvature location (N (%))	Cebral Ventral Lateral (left or right) Proximal Distal	9 (47) 3 (16) 9 (47) 3 (16) 3 (16)
Mean values (mm) of penile measurements (SD)	Circumference Flaccid (25–30) MaxED (17–25) MaxED (17–19) Stretched ED (7–10)	9 (4) 13.66 (0.8) 13.88 (0.4) 13.88 (0.4) 13.88 (0.4)

US = ultrasonography; IIEF = International Index of Erectile Function; SD = standard deviation; ED = erectile dysfunction.

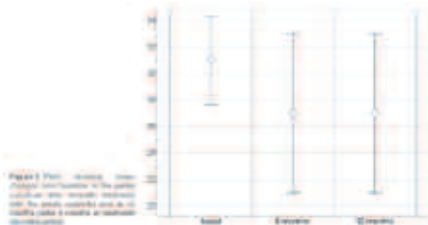
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One patient discontinued treatment with the penile stretcher after a few days because of discomfort caused by the device and three patients did not attend the scheduled follow-up visits and were lost to follow-up. Data on the 6-month treatment period and follow-up were available for all 15 remaining patients. Median time of daily use of the device was 5.5 hours (minimum–maximum: 3–6 hours) at 1 month, 5 hours (minimum–maximum: 3–6 hours) at 3 months, and 5 hours (minimum–maximum: 2–8 hours) at 6 months, respectively ($P = 0.191$; Greenhouse–Gasser corrected, repeated measure analysis of variance). Penile curvature decreased from a mean baseline value of 31° (SD 1.55) to 27° (SD 2.79) after 6 months of treatment ($P = 0.059$) (Figure 1).



The degree of curvature worsened ($+10^\circ$) in one patient, remained unchanged in eight, and decreased in six (-20° in 2/6, -10° in 2/6, and -5° in 2/6). Curvature values remained unchanged in each patient after the 6 months wash-out period. Figures 2 and 3 report the box plots related to the changes in the flaccid and stretched penile length, respectively at 6 months. After 6 months of treatment with the penile extender, a significant (Wilcoxon $Z = -2.852$, $P = 0.004$ and Wilcoxon $Z = -3.068$, $P = 0.002$) and overall mean gain of 1.3 and of 0.83 cm for the flaccid and stretched penile length, respectively was observed.

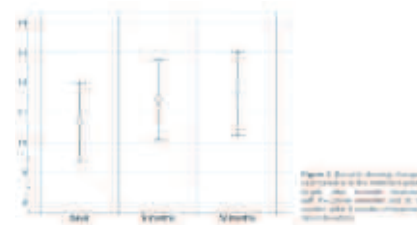
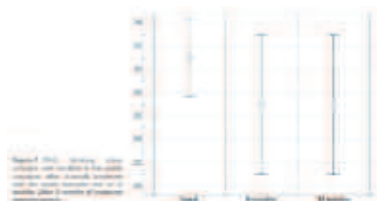


Table 2 reports the changes which occurred across all time intervals in penile curvature and length. The gain in length was maximal in the t_0 – t_1 time interval and showed progressive declines in t_1 – t_3 and t_3 – t_6 intervals. Curvature degrees and penile length remained stable at 12 months (t_6 – t_{12}). Changes in penile girth were negligible and not significant (mean value of 9.86 cm at baseline and of 9.96 cm at 6 months). Plaque size did not show significant changes during the study period (1.35 cm vs. 1.30 cm, $P = 0.4$). No patient requested treatment for ED during the study period. IIEF-EF domain scores showed only marginal improvements, from a mean baseline value of 23.8 (SD 4.07) to 24.7 (SD 4.11) at 12 months ($P = 0.23$). Specifically, 6 months after treatment, the IIEF-EF domain score normalized in three out of six patients with mild ED at baseline, while two patients with normal pretreatment EF scored IIEF-EF values consistent with mild ED.

Table 2. Mean changes in penile curvature and length, stretched and flaccid penile length, at different time intervals and corresponding 95% confidence intervals (95% CI).

Parameter	n	Mean change	95% CI
Penile curvature	Baseline	31.0	29.5–32.5
	1 month	28.5	27.0–30.0
	3 months	27.5	26.0–29.0
	6 months	27.0	25.5–28.5
Stretched penile length	Baseline	10.23	10.14–10.32
	1 month	10.36	10.27–10.45
	3 months	10.31	10.22–10.40
	6 months	10.36	10.27–10.45
Flaccid penile length	Baseline	9.86	9.77–9.95
	1 month	10.19	10.10–10.28
	3 months	10.14	10.05–10.23
	6 months	10.19	10.10–10.28

Mean patient satisfaction scores for the 5-item questionnaire are reported in Table 3. The treatment was generally well tolerated, with only three patients reporting bruising ($N = 2$) or itching ($N = 1$).

Table 3. Mean scores of the 5-item satisfaction questionnaire (N = 15).

Questionnaire item	1st month	3rd month	6th month	SD
Q1: How would you rate your penis curvature?	1.5	1.5	1.5	0.58
Q2: How would you rate your flaccid penile length?	1.5	1.5	1.5	0.58
Q3: How would you rate your stretched penile length?	1.5	1.5	1.5	0.58
Q4: How would you rate your overall satisfaction?	1.5	1.5	1.5	0.58
Q5: How would you rate the overall sexual satisfaction?	1.5	1.5	1.5	0.58

Discussion

Several treatment options, including oral compounds, intraleisional and topical agents, have been proposed for the treatment of Peyronie's disease but the evidence that any of these may be effective remains weak, such that observation alone is considered a viable option [7,18,19]. The lack of precise data on the pathogenesis of Peyronie's disease is probably one key element that prevents the development of appropriate treatment strategies for this disease. Some data suggest that the currently available nonsurgical options may have a window of opportunity in the acute phase of the disease. Once the disease has stabilized, typically after 12–18 months, it is unlikely that any medical treatment will produce a beneficial effect [20]. At this stage, surgery may be contemplated as the last remaining option to restore successful sexual intercourse [7]. All the currently available surgical techniques are essentially unable to provide a curative effect of the disease; rather, they aim to palliate its side effects by restoring a straight shape to the curved penis. Strict selection criteria (i.e., highly motivated patients with severe curvature impairing sexual intercourse) are mandatory as tunical lengthening surgical procedures carry a significant risk of complications leading to a high patient dissatisfaction rate. On the other side, tunical shortening procedures such as the Nesbit corporoplasty, in spite of the low morbidity, may result in a significant loss of penile length [21]. We selected a study population of patients

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with clinically stable Peyronie's disease and a mild to moderate degree of curvature (not exceeding 50°) and no severe ED as defined by the EF domain scores of the IIEF [11]. No specific treatment is currently available for this disease subgroup as surgery may probably turn out to be an overtreatment while non-surgical options are unlikely to be effective once the disease is stabilized [22]. Notably, the majority of our patients had previously failed medical treatment. Based on the preliminary evidence reported by Scroppo et al. [10] of a 50% reduction in the curvature of the shaft after the application of progressive mechanical traction forces on the penis over a 6-month period, these patients may be ideal candidates for a trial with a penile extender device. In our series, the mean curvature of the shaft decreased by 4° (13% of the baseline value) following a 6-month treatment period using the same brand of penile extender.

Albeit of borderline significance, the magnitude of improvement did not meet the expected "effect size" necessary to state that the treatment was effective. Interestingly enough, these results were comparable with the average absolute improvement in penile curvature (13.5%) reported in a recent meta-analysis on intracavernosal injection therapy, one of the most popular treatment modalities for Peyronie's disease [5]. Measurable reductions in curvature ranging from 5° up to 20° were recorded in 6 out of 15 (40%) evaluable patients, the remaining patients having stable (8/15) or progressive (1/15) disease. Although spontaneous im-

provement in the degree of bending has been reported [2,23], this is less likely to occur when the disease is stabilized, as in our series. Of note, no changes in penile curvature were detected after 6 months of treatment wash out. If it seems reasonable to state that the treatment proved effective in some patients, the small sample size did not allow us to identify predictors of response. In a subgroup of our patients refusing an in-office intracavernous injection, the curvature was calculated based on at-home photographs, a methodology that has been recently found to underestimate the degree of penile bending as compared with trimix intracavernous injection[24]. This may have led to inaccurate measurements, given the inability of the investigator to assess the rigidity of the erection. It may be speculated that the shorter daily use of the device in our study in comparison with the study of Scroppo et al. [10] might account for the lower degree of curvature reduction.

The mean time of daily use of the device in our study tended to be close to the minimum required for study entry. It is likely that a more strict protocol requiring a minimum of 8 or 9 hours of daily use would greatly reduce patients' compliance [10,17]. Our results were overall lower than that reported in a recent pilot study where an average 33% curvature reduction was recorded [11]. Differences in selection criteria, device properties, and treatment schedule may account for these discrepancies in outcomes and represent limitations of the current study. For instance, the requirement of a "clinically" stable disease for study entry

may have led to select a subgroup of patients with a disease less amenable to plastic changes following the application of traction forces as opposed to a Peyronie's plaque in the acute phase. The reason for these strict inclusion criteria was to minimize the possibility of self-improvement of the curvature that could more likely occur during the acute disease phase. Also, by restricting the limit of penile bending to 50°, we may have reduced the chances to obtain an effect of significant magnitude. Baseline mean curvature in our study was 31° as compared with 51° in the study by Levine et al. [11]. With these inclusion criteria, we aimed to minimize the risk of study dropout from patients with a severe curvature that could have been less compliant to a 1 year duration trial.

Variations in plaque size constituted a secondary study end point. The lack of significant posttreatment changes in the current study is likely to be clinically irrelevant and it does not affect the potential efficacy of the device as no correlation between the extent of the plaque and the severity of curvature has been demonstrated so far. Besides, it is possible that the two different methods employed in the current study to obtain plaque size (US or caliper) may not be equally accurate. Whether the application of the device in the acute disease phase may reduce the plaque size remains to be proven. The application of a penile extender in the current study caused only minimal and self-resolving side effects, leading to discontinuation of treatment in only one case. Mean baseline IIEF-EF domain

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scores were consistent with mild ED as we deliberately excluded patients with severe ED that may be less amenable for conservative treatment of Peyronie's disease. Sexual dysfunction is a common complication in the presence of fibrous penile plaques with both psychological and organic factors contributing to its pathogenesis [22]. Currently, there is no evidence that any medical treatment may have beneficial effects on the sexual function of Peyronie's disease patients [5]. An average 5-point improvement of the IIEF-EF domain scores has been recently reported in a pilot experience on a penile traction device [11]. Posttreatment IIEF-EF domain scores in our study showed marginal, non significant changes compared with baseline scores. It is possible that the lower degree of baseline sexual dysfunction in our series as opposed to the one of the Levine et al. study [11] (mean IIEF-EF domain score of 23.8 vs. 18.3) may account for the lower degree of improvement. Notably, our finding corroborates the safety profile of the penile traction device as opposed to the detrimental effect on sexual function sometimes reported following graft surgery [6]. The Andropenis® produced an effective and durable (over the 6-month off treatment period) lengthening of the penis both in the flaccid and the stretched state.

The elongating effect was of a lower magnitude than that observed in our previous study where Dysmorphophobic and postsurgery short penises underwent the same treatment protocol [9]. A reduction in penile elasticity as a consequence of the re-

duced content in elastin within the fibrous plaques could explain why Peyronie's disease patients are less susceptible to the elongating effects of the penile extender [25]. Even though baseline penile size in our patients falls within the normal range based on the criteria outlined by Wessells et al. [14], penile lengthening was probably the most notable clinical finding of the current study. Penile shortening, a bothersome symptom of Peyronie's disease, cannot be addressed as an end point by any medical treatment. Restoration of penile lengthening would involve a complete reversal of the fibrotic process, a finding that has never been proved to occur with any specific treatment modality in Peyronie's disease.

Besides, it is usually significantly worsened by surgery, no matter which procedure is employed, leading to a high dissatisfaction rate [7]. From this perspective, the penile extender could play an essential role as part of a multimodal treatment strategy. In the absence of validated instruments to assess the patients' perception of the efficacy of the device, we designed a specific posttreatment 5-item questionnaire. Average scores for the two questions about the flaccid and stretched penile length were consistent with "acceptable results," meaning that patient self-judgment of the gain in both the flaccid and the erect penile length somehow substantiated the objective changes we recorded through measurements. While improvement in sexual function and penile curvature were rated as intermediate between "no changes" and "acceptable," the overall results were surpri-

singly assessed by the patients as "acceptable." Our satisfaction assessment is limited by the absence of a comparative pre- and posttreatment analysis, and lack of validation. Notwithstanding these limitations, it hints at favorable acceptance of the device that warrants further study to explore the clinical utility of this noninvasive treatment modality in Peyronie's disease.

Conclusions

In our study population, the penile extender produced an improvement in penile curvature of clinical interest when compared with that achieved with other commonly used treatment modalities such as intralesional injections. Overall, the reduction of curvature was not of great clinical relevancy. However, results were achieved in a selected population with stable disease, a condition where the existing treatment options are less likely to be effective. Significant lengthening of the penis both in the flaccid and in the stretched state was also recorded, albeit of lower magnitude than that obtained in studies on short penis. The device caused negligible side effects. Overall results were self-reported as "acceptable," making this minimally invasive treatment modality a potential new treatment option in selected Peyronie's disease patients.



Can an External Penis Stretcher Reduce Peyronie's Penile Curvature?

International Journal of Impotence Research (volume 13, sup. 4, Oct-2001) and presented at the 4th annual European Society for Sexual and Impotence Research (ESSIR) Conference (Rome, Oct. 2001). Scropo FI., Mancini M., Maggi M.*, Colpi GM. Andrology Service, Ospedale San Paolo, Milano (Italy). * Andrology Unit, Dip. Fisiopat. Clin., Università di Firenze, Firenze (Italy).

1. Introduction & Objectives:

Peyronie's fibrotic lesions frequently affect the dorsal tunica albuginea and the septum of the penis. Subsequently they can lead to plaque development, penile deformity and pain during erection. Duplex sonographic scanning may allow an objective evaluation of the fibrosis, assessing the thickening of the tunica albuginea and penile plaques. The aim of this study is to investigate the efficacy of mechanical penile stretching (PS) to reduce plaque thickness and penile deformity during erection.

2. Materials & Methods:

Eight patients (age 58.5 ± 5.3 yrs.) affected by Peyronie's disease, apparently unmodified at least for the latest 3 months and causing penile curvature during erection (PEC), were trained to use a mechanical penis stretcher. None of them complained about erectile dysfunction according to IIEF test, and penile pain.

After intracavernous injection of PgE1 5-15 mg to obtain full erection (assessed by both Digital Inflection Rigidometry and palpation), cross scanning of tunica albuginea by duplex sonography, photographs of the erect penis according to Kelami's projections, and penile diameters and length measurements were performed before and after daily home PS application (at least four hours/day) for 3 to 6 months.

Individual follow-up examinations were scheduled after 3 and 6 months. At the present time, all patients have concluded the 3-month follow-up, and two of them the 6-month one.

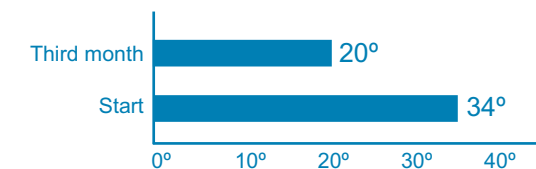
3. Results:

The tunica highest thickness resulted 1.8 ± 0.6 mm before and 1.6 ± 0.3 mm after PS (n.s.). The septum latero-lateral maximum thickness was 2.2 ± 0.7 mm before and 1.8 ± 0.8 mm after PS (n.s.). Penile length, dorsally measured from penopubic angle to meatus, was 100.5 ± 27.3 mm before and 104.6 ± 22.2 mm after PS (n.s.).

Photographs showed that PEC decreased from $34.1 \pm 4.9^\circ$ before to $20.0 \pm 12.2^\circ$ after PS ($p \leftarrow 0.05$). The treatment was

well tolerated (no severe complication and no drop out occurred).

CORRECTION OF CURVATURE CAUSED BY PEYRONE'S DISEASE USING THE **Andropenis**[®]



4. Conclusions:

These results suggest a promising use of PS in selected Peyronie's patients affected by penile curvature without erectile dysfunction.

Treatment with penile retraction in evolutive Peyronie's disease with external penis-stretching

5th Congress of the European Society for Sexual and Impotence Research (ESSIR). Hamburg, Germany. December 1-4, 2002. Scientific study published in the International Journal of Impotence Research (volume 14, suppl. 4, Dic-2002). Colpi G.M., Martini P., Scropo F.I., Mancini M., Nerva F. Andrology Service, San Paolo Hospital – University of Milan, Milan, Italy.

1. Objectives:

One of the major complaints of Peyronie's disease is penile retraction. The aim of this study was to verify the efficacy of the mechanical penile stretching in evolutive Peyronie's disease.

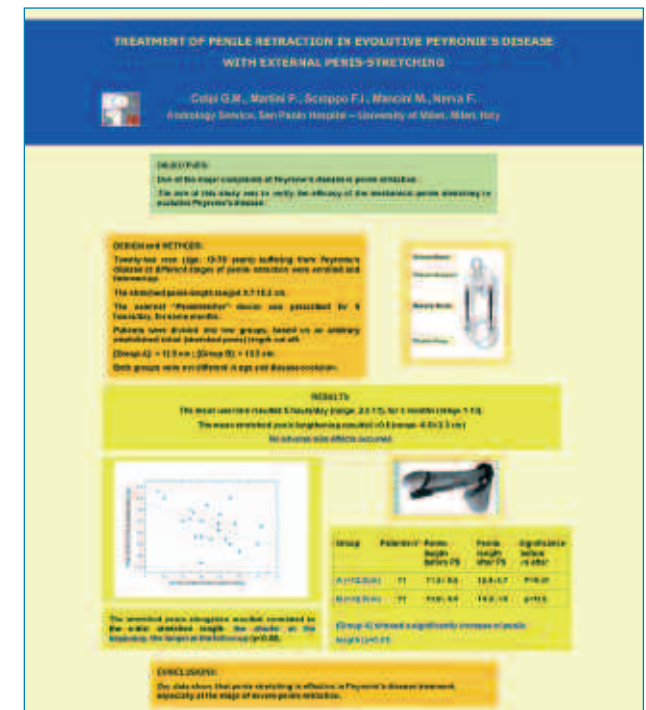
Twenty-two men (age: 18-78 years) suffering from Peyronie's disease at different stages of penile retraction were enrolled and followed-up. The stretched penis length ranged 9.7-15.2 cm. The "Penistretcher" device was prescribed for 6 hours/day, for some months.

2. Results:

The mean use resulted 5 hours/day (range: 2.5-11), for 3 months (range 1-13). No adverse side effects occurred. The stretched penis elongation (average +0.8; range 0.8/+2.3 cm) results correlated only versus the initial stretched length: the shorter at the beginning, the longer at the follow-up ($p < 0.05$).

3. Conclusions:

Our data show that penis stretching is effective in Peyronie's disease treatment, especially at the stage of severe penile retraction.





1. Introduction:

Until recently, there has been little option for men who suffer from Peyronie's disease. Wendy Hurn considers this innovative device as a method to change the way these men have been treated until now with remarkable results.

In clinical practice, we observe a considerable number of men with penile curvature due to Peyronie's plaques. Peyronie's disease is a condition in which a plaque, or hard lump, builds on the penis in form of a fibrotic scar that develops within the tunica albuginea of the corpora cavernosa and may cause a curvature of the erect penis.

There is a variety of opinions, but a recent study seems to put the percentage rate of his incidence as high as 3,2%. However, it is difficult to estimate the exact number of men suffering from this disease, since many of them do not seek a doctor because they feel embarrassed or ashamed.

This area of scarring, or plaque, typically develops on the dorsal surface of the penis (dorsum), although it may also develop on the ventral side or on the lateral side of the penis. It may progress to calcification in approximately 30 % of the patients and that indicates that the scar is mature.

Peyronie's plaques can cause embarrassment and discomfort or even pain to the partner during sexual intercourse. If not treated, the disease may be a cause of serious erectile dysfunction and even produce a breakdown in the relationship.

2. Treatment options:

Initially, the first line of treatment was to "watch and wait" in order to find out if the curvature resolved itself and, in case it became worse, to give the patient a high dose of vitamin E daily. A vitamin E treatment is normally a long-term treatment of usually almost a year and may not produce any positive results.

In recent years, this treatment has been considered unsafe because of its side effects on blood pressure, leading in some cases to stroke and cardiac events. A recent Heart Outcomes Prevention Evaluation (HOPE) Study suggests such a conclusion, while many other studies continue to emphasize the overall benefits of vitamin E for the cardiovascular system. There are surgical options available, such as the Nesbit's procedure (placation procedure) or the Lue procedure (venous graft); however, given the existence of side effects and risks, this may not always be the most appropriate way.

The innovative **Andropenis®** traction device represents an alternative method to surgery and demonstrated very positive results.

The device is placed by the patient himself after being carefully instructed about how to use it effectively. The device is small, robust and discreet and shall be worn during daytime. It cannot be worn during sleep due to nocturnal tumescence. It takes just a few moments to apply and should be worn for a period of time gradually building up to approximately 6-8 hours a day to produce the optimum effect.

It works by gently stretching the penis and elongating the plaque, which in turn breaks it down. If worn as instructed, the first results should be recognized within 3-4 weeks, while full results will show up after approximately 3-6 months.

Peyronie's disease - latest treatment options

Wendy Hurn, Urology Specialist Practitioner

Bristol Royal Infirmary UK



Currently there are 25 patients receiving therapy with the **Andropenis**® at the Bristol Royal Infirmary's Andrology clinic, one of several busy clinics which Urology Department is offering to men suffering from Peyronie's disease both conventional surgical procedures and penile prosthetics.

The patients show different degrees of deviation; most of them having been submitted to daily treatment with the penile extender for three months or more and wearing the device during the waking hours. There has been a marked decrease of about 30-45% in degree of angulation, with a sensible reduction of discomfort and the possibility to resume sexual intercourse in most cases. The patients continue wearing the device and the evolution will be checked after six months of treatment. Two case studies will be described.

Case study 1

Patient C is a 51-year-old man who three years back developed an area of fibrosis on the dorsal part of his penis. Having unsuccessfully tried vitamin E treatment, he did not wish to undergo surgery. His marriage broke up due to his incapability to perform penetrative sexual intercourse for over a year.

He underwent medical examination at the Clinic and an injection of Alprostadil revealed a penile deviation of approximately 70° with a fibrotic thickening that could be easily identified.

A daily application of the **Andropenis**® device was prescribed and the patient used it as instructed. C underwent a check-up after three months and the fibrotic plaque had lengthened and decreased in width, while the penis itself had lengthened approximately 1.2 cms.

The patient reported that the curvature had decreased approximately 20°. He underwent an examination again after six months and improvements were confirmed with a further increase in length of 1.52 cms, plus a decrease in the size of the plaque. An Alprostadil injection revealed a 25-30° curvature without discomfort or difficulty in penetration. He will continue wearing the device for a further two months and then underwent a new review.

Case study 2

Patient F is a 62-year-old man who three years back suffered a radical prostatectomy for carcinoma of the prostate gland. He suffered no long-term consequences but noticed that his penis had retracted and showed a curvature of 45° during erection.

The use of the **Andropenis**® was prescribed for a period of 4 months, with the advice to wear it for at least 4 hours a day. Initially, the penis length was 5.5 cms and a 3 mm fibrotic area showed up on the dorsal surface of the penis.

After 4 month the review evidenced that the penis now measured 6.86 cms and that the plaque had reduced in size about 2 mm.

The patient reported a correction of 50% of the penis deviation and confirmed to be extremely pleased with the results. He continues wearing the device until his next review.

3. Conclusion:

The election of the treatment method of the Peyronie's disease will be discussed between patient and specialist. For those patients who cannot or don't want to choose the surgical option, the **Andropenis**® represents a real alternative.

It gives the patients autonomy and allows them to take some control over the situation, while getting positive results. As patient and doctor discuss the possible treatment options, it is extremely important to exhaustively inform the patient that the treatment with the **Andropenis**® has to be considered an overall effective and viable treatment, and the physicians themselves will appreciate the potential benefits of this device after seeing the positive effects that their patients can achieve by using it.

Conservative treatment in a case of induratio penis plastica

XXI National Congress of the SIA Regional Sections (Italian Andrology Society) Trieste, Italy, September 23rd-26th, 2004.

G. Piediferro, F.I. Scroppo, F. Castiglioni, R. Benaglia e G.M. Colpi. Departmental Unit of Andrology – San Paolo Hospital – Polo Universitario, Milan, Italy

1. Case report:

Male aged 52, suffering from ischemic cardiopathy, who two years back underwent an angioplastic stent procedure. He takes beta blockers and nitro derivatives with a satisfactory control of the cardiovascular pathology. Three months ago, a left lateral curvature of 30° appeared along the retrocoronal sulcus of the erected penis, with moderate pain during coitus.

2. Clinical data and diagnostic analysis:

The clinical examination detects an I.P.P. nodule, similar to a grain of corn, between septum and left cavernous body at the middle/distal third of the shaft. The length of the stretched penis is 15.2 cms.

A dynamic duplex sonographic scanning of the penis in full erection shows a left lateral curvature of approximately 30 degrees at middle/distal third of the shaft, at a level with a not calcificated septal nodule of 7 x 7 x 6 mm.

3. Treatment:

24 intracavernous injections of Verapamil 5 mg were prescribed over a 4-month period. Following this, the application of traction through a penis stretching device for between 4 and 6 hours a day over a period 6 month.

4. Results

The treatment with the prescribed stretching device over 6 month allows a progressive and complete stretching of the shaft. The objective assessment after treatment end shows that the septal nodule is no more palpable, it results a penis elongation of 0.8 cms, while the stretched penis reaches a length of 16,0 cms, and the duplex sonographic scanning is no more able to distinguish the septal nodule. The follow-up after 2 years confirms a stabilization of the situation.

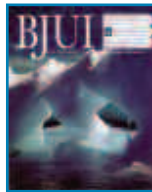
5. Discussion and Conclusions:

The excellent results achieved through the combined pharmacological and physiotherapeutic treatment of Peyronie's disease within his active phase would deserve a multicentric study.



Penile enlargement

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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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Enlargement of penis in patients with hypogonadism complex approach to the clinical practice

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Penile enlargement without surgery

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Effects on penile size with penile extensor by traction force

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Efficacy of the daily penis-stretching technique to elongate the "small penis"

↑ + 4 cm (1.6")
↻ + 1,5 cm (0.6")



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

Paolo Gontero, Massimiliano Di Marco, Gianluca Giubilei, Riccardo Bartoletti, Giovanni Pappagallo, Alessandro Tizzani and Nicola Mondaini.
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BJU International, Year 2009, Volume 103, Issue 6, pages 793-797, March 2009

ABSTRACT

OBJECTIVE

To assess a commonly marketed brand of penile extender, the Andro-Penis® (Andromedical, Madrid, Spain), widely used devices which aim to increase penile size, in a phase II single-arm study powered to detect significant changes in penile size, as despite their widespread use, there is little scientific evidence to support their potential clinical utility in the treatment of patients with inadequate penile dimensions.

PATIENTS AND METHODS

Fifteen patients were required to test the efficacy of the device, assuming an effectsize of ± 0.8 . Eligible patients were counseled 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. Treatment satisfaction was assessed using an institutional unvalidated five-item questionnaire.

RESULTS

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. Treatment satisfaction scores were consistent with acceptable to good improvement in all items, except for penile girth, where the score was either 'no change' or 'mild improvement'.

CONCLUSIONS

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.

1. Introduction

In recent years penile size has become a matter of great debate, with an increasing number of patients seeking urological advice for a so-called 'short penis'. In a clinical setting, the definition of 'short penis' is more often attributed to a condition termed 'penile dysmorphism', i.e. the perception of inadequacy of the penis even though the true dimensions of the organ fall within the normal range [1,2]. A 'clinically relevant' short penis, definable as any length of < 4 cm for the flaccid penis and < 7 cm for the stretched penis [3,4], is quite unusual in men seeking medical treatment for inadequate penile size [5]. Several augmentation phalloplasty procedures have been proposed with the aim of elongating the shaft or enlarging the penile girth [2,6] but at present the drawbacks of these techniques are a lack of standardization,

the potential risk of complications [7], and a high rate of patient dissatisfaction [8].

Given these premises, methods to increase penile dimensions which are less invasive than surgery would be preferable. It has been claimed that the penile extender, a nonsurgical device that used progressive mechanical traction to the penis, produces a significant improvement in penile length and circumference, both in the flaccid and the erect state. Little scientific evidence and no peer-reviewed clinical study supports the potential clinical utility of the penile extender in the treatment of patients complaining of inadequate penile size [9,10]. In the present study we assessed a commonly marketed penile extender in a phase II single-arm study that was powered to detect significant changes in penile size.

2. Patients and methods

Patients complaining of 'small penis' and highly motivated to receive effective treatment were considered eligible for the study. Patients seeking exclusively an augmentation of circumference were excluded. For study entry, psychosexual counselling was required to select those for whom the treatment was deemed beneficial from a psychological perspective. A history of major psychiatric disorder, anatomical penile deformity or reduced manual dexterity that might prevent the correct use of the device were exclusion criteria. Penile shortening after corporo-



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plasty for curvature of the shaft was an inclusion criterion, provided ≥ 6 months had elapsed since surgery, with no residual curvature. A hypoplastic penis was defined as any flaccid and stretched length of ≤ 4 and 7 cm, respectively, the lower threshold of the normal reference value [3]. Any size above these led to the definition of penile dysmorphophobia, a condition where a patient with a normal-sized penis is dissatisfied with its dimensions in the flaccid and/or erect state [1]. Changes in flaccid and stretched penile length and circumference over baseline after 6 months of treatment and durability of the response after 1 year, i.e. after an additional 6 months without treatment, were considered the primary study endpoint. Treatment tolerability, patient compliance and satisfaction, and changes in the International Index of Erectile Function (IIEF) EF domain scores after 12 months constituted secondary endpoints.

The baseline patient assessment included a full medical and sexual history, physical examination and psychosexual counselling. The EF domain of the IIEF was scored at baseline and at the end of the study (after 12 months). Patients scoring abnormal values (IIEF EF < 25) [11] were offered a diagnostic evaluation, including sexual hormone profile and appropriate treatment where needed. Penile measurements before treatment (t0) were obtained by two physicians using the standard technique validated by Wessells et al. [4]. Using a tape ruler to the nearest 0.5 cm, the penis was initially measured in the flaccid state and then while applying tension

to maximally stretch it, from the pubopenile skin junction to the meatus. The circumference was measured at the mid-shaft. Inter-operator agreement was assessed by making a set of measurements on a small sample of eight young volunteers; the individual variability was always < 0.5 cm. Patients were instructed in the use of the penile extender, the Andro-Penis® (Andromedical, Madrid, Spain), a device designed to exert a continuous and gradually increasing traction force on the penis.

The device consists of a plastic ring, where the penis is introduced, with two dynamic metallic rods which produce the traction. In the superior part there is a plastic support where a silicone band holds the glans in place. Detailed instructions on how to increase the traction force from 600 g during the first month, 900 g during the second, up to 1200 g during the fifth and sixth months, were provided, following the manufacturer's instructions. Patients were requested to wear the device preferably for 6 h (and at least 4 h) daily, and for an optimum duration of 6 months, according to the manufacturer's suggestions [12]. Patients were asked to sign an informed consent before study entry. They were told that, according to the scant published data available [9,10], the use of the penile stretcher following the suggested protocol might elongate the shaft by at least as much as surgery, and that a gain in circumference, of lower magnitude, was also to be expected. It was further specified that the treatment was safe but that any

adverse reaction must be immediately reported to the investigators. The devices were provided free of charge to patients by the Andromedical. The protocol was granted institutional Ethical Committee Approval in January 2005.

Follow-up visits were scheduled at 1 (t1), 3 (t3), 6 (t6) and 12 months (t12) (end of study, after a 'wash-out' period of 6 months) to record side-effects, treatment compliance and carry out a genital examination and penile measurements. At the end of the study the EF IIEF and an unvalidated satisfaction questionnaire were completed. The latter consisted of a set of five questions designed by the investigators asking about subjective improvements in flaccid penile length (Q1), erect penile length (Q2), circumference (Q3), overall penile size (Q4) on a 0–3 scale (0, worsening; 3, significant improvement) and sexual life (Q5) on a 0–4 scale (0, no result; 4, optimal result). Given the objective difficulty of estimating the SD of baseline penile measurements in a series of patients with presumed 'short penis', the sample size was based on the 'effect size' method [13]. Thus 15 evaluable patients were required for the study to have 80% statistical power of detecting an 'important' change in penile dimensions (defined by an effect size = 0.8), with an α error of $< 5\%$ (two-sided Wilcoxon test).



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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 BJU International, Year 2009, Volume 103, Issue 6, pages 793-797, March 2009

3. Results

Of 30 patients referred with a complaint of 'short penis' between March 2005 and April 2006, 21 were eligible and entered the study. Reasons for exclusion from the protocol were refusal of the patient to comply with the proposed treatment (five) and ineligibility resulting during psychosexual counselling (four). The baseline characteristics of the sample for age, aetiology of the disease, EF domain of the IIEF and penile measurements are listed in Table 1.

TABLE 1 The baseline characteristics of the 21 patients

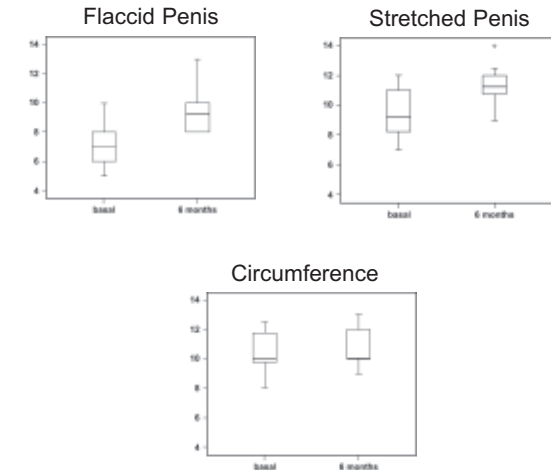
Variable	Mean (SD) or n (%)
Age, years	45.7 (11.1)
Penile dimensions, cm	
Flaccid	7.15 (1.43)
Stretched	9.62 (1.50)
Circumference	10.4 (1.34)
Aetiology of short penis	
Dysmorphophobic	12 (57)
After penile surgery	8 (38)
Hypoplastic penis	1 (5)
IIEF EF domain score	
Normal (26-30)	9 (43)
Mild ED (17-25)	9 (43)
Moderate ED (11-16)	1 (5)
Severe ED (1-10)	2 (10)

Only one patient could be categorized as having a hypoplastic penis. None of the patients scoring abnormal IIEF EF domain values (12/21) agreed to undergo specific assessments, as they related their sexual dysfunction to the inadequate penile size.

Four patients discontinued treatment, three at 3 months (one for achieving satisfactory results, one for lack of efficacy and one for inability to comply with the protocol), and one at 1 month for side-effects (pain and penile bruising). One patient did not attend the visit after 6 months and was lost to follow up.

All patients were included in the intention-to-treat analysis, but only the 16 completing the 6-month treatment period were evaluable for the primary endpoint. The median time of daily use of the device was 5 h at 1 month, 5 h at 3 months and 4 h at 6 months, respectively (chi-square, $P = 0.104$). Figure 1a,b shows the changes after 6 months in the flaccid and stretched penile length, respectively.

FIG. 1. Box plots showing changes over baseline at 6 months in (a) flaccid penile length; (b) stretched penile length; and (c) in penile circumference.



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At the end of treatment (6 months), there was a significant overall mean mean gain in length of 2.3 cm and of 1.7 cm for the flaccid and stretched (Wilcoxon Z-test, both $P < 0.001$) penile length, respectively. The changes which occurred across all intervals for the whole group are reported in Table 2.

TABLE 2 Mean changes in stretched and flaccid penile length and circumference at different intervals: t_0 , baseline; t_1 , 1 month of treatment; t_2 , 3 months; t_3 , 6 months; t_4 , 12 months; and corresponding 95% CI

Interval	Mean (95% CI) change, cm
Stretched penis	
t_1-t_0	0.94 (0.62-1.26)
t_2-t_0	0.44 (0.08-0.82)
t_3-t_0	0.38 (0.02-0.75)
t_4-t_0	0.09 (-0.10-0.23)
Flaccid penis	
t_1-t_0	1.13 (0.72-0.53)
t_2-t_0	0.71 (0.42-1.00)
t_3-t_0	0.41 (0.14-0.68)
t_4-t_0	-0.09 (-0.24-0.05)
Circumference	
t_1-t_0	0.33 (0.01-0.24)
t_2-t_0	0.18 (0-0.22)
t_3-t_0	-0.09 (-0.24-0.05)
t_4-t_0	0.0 (-)

The gain in length was maximal at t_0-t_1 and slowed in t_1-t_2 and t_3-t_4 . The mean (SD) gains in flaccid and stretched penile length were 2.05 (1.32) and 1.30 (0.75) cm in dysmorphic and 2.58 (1.02) and 2.50 (0.89) cm in penises shortened by surgery. Changes in penile girth at 6 months, albeit statistically significant ($P = 0.034$), were negligible (+0.03 cm) (Fig. 1c; Table 2). There were no significant changes in any of the penile measurements after the 6-month off-treatment period (t_6-t_{12}).

IIEF EF domain scores improved from a mean baseline value of 19.9 (8.77) to 27.1 (1.4) at 12 months (Wilcoxon Z-test, $P = 0.007$). Specifically, after the 6-month period off-treatment, the IIEF EF domain scores normalized in five of six patients with mild erectile dysfunction (ED) at baseline, in one with moderate ED at baseline and in both men with severe ED at baseline, and it was unchanged in one of six with mild ED. None of the nine patients with normal EF before treatment had abnormal IIEF EF domain values at 1 year.

The mean patient satisfaction scores, measured using the five-item questionnaire, are reported in Table 3.

TABLE 3 The mean scores of the satisfaction questionnaire administered after 12 months (17 patients)

Question	Mean (SD) range score
After treatment, how would you rate your:	
Q1: flaccid penile length?	2.31 (1.2, 0-3)
Q2: penile length during erection?	2.37 (1.2, 0-3)
Q3: penile girth?	1.1 (0.4, 0-2)
Q4: your sexual life?	2.3 (0.94, 0-3)
Q5: overall result achieved?	2.8 (1.5, 0-4)

Score one worst as described in Patients and Methods.

The treatment was generally well tolerated; one case of penile bruising and one of temporary penile discoloration changes were recorded, while one patient withdrew from the study because of pain.

DISCUSSION

The present study shows effective elongation of the penis after 6 months of treatment with a penile extender, and suggests that the results are maintained after an additional 6 months with no treatment. The magnitude of the elongating effect (1.7 and 2.3 cm for the stretched and the flaccid length, respectively) was less than the 3.3 cm gain in erect state achieved in a market study [12], where the Andropenis was prescribed for 10 h daily for 6 months, but was still impressive when compared with the modest results of penile lengthening surgery. In a recent prospective study [2] the mean gain was 1.6 cm



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in penile length, documented in 11 patients receiving the standard Z-plasty suprapubic skin incision, together with suprapubic lipectomy and incision of the suspensory ligament of the penis. In another series of 42 patients operated with the same technique, mean increases in penile length of 1.1 (1.2) cm were not statistically significant [8]. Moderately better elongating effects of 2–3 cm have been reported with an experimental technique that involves a major surgical approach, with penile disassembly and the interposition of rib cartilage between the glans and the corpora cavernosa [14].

The notable risk of morbidity with all the above procedures needs to be added to the conflicting results of surgery. Wessells et al. [7] reported 12 cases of major complications, including wound infections, scar deformities and sexual dysfunction, that were referred at their centre over a 1-year period. They concluded that the lack of well-designed, prospective trials should lead clinicians to regard penile-lengthening procedures as still experimental. The application of a penile extender in the current study caused only minimal and self-resolving side-effects, leading to discontinuation of treatment in only one patient. This favourable safety profile further supports its use as a feasible conservative and hence first-line treatment option in men seeking penile lengthening.

This statement is particularly true when considering that the vast majority of patients complaining of 'short penis' have a penile size falling within the normal reference values [5], making the role of treatment more a cosmetic issue than a functional goal. In the present series all but one of the eligible patients had normal penile dimensions according to the definition of We sells et al. [4], and the American Guidelines strongly discourage the use of surgery for such cases [4]. Based on previous experience, the penile extender provokes a linear and time dependent gain in length of ≈ 0.5 cm per month, according to the manufacturer's leaflet [12].

By contrast, we documented a maximum elongating effect after the first month that progressively decreased in the subsequent intervals. It is possible that the shorter daily use of the device in the present study compared with other studies [12] might explain these discrepancies. Notably, the mean time of daily use of the device in the present study tended to be close to the minimum required for study entry.

It is likely that the prescription of longer daily use would greatly reduce patients' compliance to the treatment. The gain in length was maintained after 6 months off-treatment, suggesting that the traction forces do indeed produce a permanent elongating effect.

The possibility of an effective elongation of body structures after applying prolonged and progressive tension forces holds its rationale both in anecdotal photographs of the Polynesian technique of elongating the penis using a heavy tube [15], and in the well-documented generation of new tissue after applying skin expanders in plastic surgery [16].

It is less clear why the device should also be effective in increasing penile girth, as suggested by the 0.6–1 cm / month gain in circumference in the manufacturer's study [12]. In the present study we failed to detect clinically relevant changes in penile circumference and this was confirmed by the patients themselves, who reported their penile girth as unchanged after treatment. The device is therefore not appropriate for patients requesting exclusively an increase in the girth of their penis.

A notable finding of the current study was the significant improvement in the IIEF EF domain score after treatment, by contrast with the potential risk of ED inherent in any additive penile surgery [7]. As any change in the stretched penile length can be translated to the penis in the erect state [7], it is likely that the increased penile size might account for the improved sexual performance and/or satisfaction detected by the IIEF questionnaire. In the absence of validated instruments to assess the patient's perception of the efficacy of the device, we designed a specific five-item questionnaire. The mean reported scores were consistent with mild to good improvement in all items ex-



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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BJU International, Year 2009, Volume 103, Issue 6, pages 793-797, March 2009

cept for penile girth, where the score was consistent with no changes.

Our assessment of patient satisfaction is limited by the absence of a comparative analysis before and after treatment, and lack of validation. Notwithstanding these limitations, the questionnaire used suggests a favourable acceptance of the device on the part of the patients, which is in stark contrast with the high dissatisfaction rates reported by patients who have had surgery [1,8].

In conclusion, the penile extender device provides an acceptable, minimally invasive method that can produce an effective and durable lengthening of the penis, both in the flaccid and in the stretched state. There were no measurable changes in penile girth. If these results are confirmed, use of the device should be proposed as a first-line treatment option for patients seeking a penile lengthening procedure.

Enlargement of penis in patients with hypogonadism complex approach to the clinical practice

M.M. Sokolschik, R.Y. Petrovich, S.V. Gagarina, Ya.A. Vaziev, I.V. Sadakova
Moscow, Russia

1. Objective:

Despite of the known expression that the «main thing is not the size but the skill», the majority of men wish to enlarge their penises at least by a couple of centimeters, irrespective of the initial size. Such aspiration is quite justified, and it can be hardly called a whim first of all because it is more likely subconscious, vested by nature, and expressed more strongly, the more a man feels himself a male or a leader in the society. Meantime an insufficient length of penis causes a restraint in communication with women for a man, loss of interests, as well as a general uncertainty and complexes. In such a way, the size of the penis becomes one of determinatives of realization of the man as a person, as well as an important parameter directly influencing the quality of life.

Besides the social importance, the size of penis is also a reflection of the general health of the man, in particular the state of endocrine system. The fact is that the length of penis depends on a level of sexual hormones (first of all testosterone and its derivatives) during the puberty when the most intensive growth of external genitals is observed.

Now about 20 congenital diseases are known associated with hypogonadism and micropenis. And their prevalence is high enough and is nearly 1 in 500 newborn boys.

2. Design and method:

In our clinical practice we used complex approach for penis enlargement in patients with hypogonadism, which included hormonal therapy and extender **Andropenis**[®] (Andromedical, Spain).

All the patients were treated with testosterone undecanoate (NEBIDO) intramuscular injections (hormonal replacement therapy) within 1 year. The treatment was held under the control of blood serum testosterone level.

With the majority of patients we could not start extender use simultaneously with hormone therapy because of insufficient penis length and impossibility to fix the extender. So we used only testosterone therapy and when physiological penis enlargement was achieved we applied extenders for our patients.

Extender **Andropenis**[®] is a medical devise using the principle of traction. The use of the extender results in a constant mechanical influence on corpora cavernosa (stretching) that leads to growth of tissues and increase of tunica albuginea elasticity.

As a rule, the elongation occurs within the terms from 4 to 8 months.

3. Results:

From 2005 to 2007 50 patients with hypogonadism addressed to the clinic for the penis enlargement. The causes of hypogonadism were Kallmann syndrome, anorchism, cryptorchism, previous traumas, inflammatory diseases of testicles in the anamnesis and Klinefelter syndrome.

The age of patients was within the limits of 16-54 years. The sizes of penises were within the limits of 2-4 cm (3.5 cm in average) in flaccid condition, 5-9 cm (6.5 cm in average) within erection.

We examined all patients after they reached the stable result of penis enlargement after 1 year of hormone replacement therapy. All patients demonstrated the normal level of testosterone, development of the secondary sexual characters and enlargement of penis up to 4 cm in average during erection. Thus, the average size of penis was 6.5 cm in the flaccid condition and 10.5 cm during erection.

Enlargement of penis in patients with hypogonadism complex approach to the clinical practice

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Moscow, Russia

For 6 months 44 people used **Andropenis**[®] extender and continued hormonal therapy. In half a year we estimated the result: augmentation of the sizes of penis by 2.5 cm in average during erection referring to the stable result reached after hormonal therapy.

In such a way, the total augmentation of penis length after carrying out of hormone replacement therapy and use of **Andropenis**[®] extender was 6.5 cm in average during erection in patients with hypogonadism and micropenis.

3. Conclusion:

After penis enlargement many patients with hypogonadism had an improvement of the social and professional functioning level that reflected in the expansion of social contacts range on the basis of a rising self-rating.

The results received after use of conservative penis enlargement allow us to judge the efficiency of hormone replacement therapy in combination with the **Andropenis**[®] extender.

In our opinion patients with hypogonadism show best results when they use extender after the physiological growth of penis as a result of long-acting injections of testosterone undecanoate (NEBIDO).





Penile enlargement without surgery

Scientific Research presented in the First Virtual Sexology and Hispanoamerican Sexual Education Congress (February-2001).
Dr. Eduardo A. Gómez de Diego, 1998, Andrology Service, Biomedical-Estetica Clinic, Madrid (Spain).

1. Introduction:

When human tissues are submitted to a force of traction, they react by increasing in size.

The principle of traction is applied in modern medicine to stimulate the generation of new tissue to cover burn wounds or areas of hair loss (placing a tissular expander underneath the normal skin) or to generate bone lengthening.

In other cultures this principle is applied to lengthen different parts of the body, like the neck of the Giraffe Women of the Paduang tribe in Birmania, or to produce a lengthening of the lips in certain African tribes, by using pieces of wood to create traction. In India, they hang stones on the penis as a form of penitence, with the result being an enlargement of the organ.

The external penis stretcher device design is based on the principle of external traction.

It is able to exert a gradual traction force of 600 to 1200 grams.

The device consists of a plastic ring into which the penis is introduced and from where 2 dynamic metal rods originate the traction. In the upper part there is a plastic support where a silicone band holds the glans in place.

Based on our clinical experience the traction device yields the following results:

- An increase in the length of the penis in erection and flaccidity.
- An increase in the girth of the penis in erection and flaccidity.

These results will be analyzed statistically to be verified and quantified. See next.

2. Materials and methods:

Number of patients: 37 men, 22 to 60 years of age. These men came from different cities in Spain. The patients enrolled in the study were healthy men with normal erection capabilities who never underwent penile surgery. Patients suffering from penile curvatures or other diseases were excluded from the study.

Traction device: The external penis stretcher device (from Biomedical-Estetica, now Andromedical®).

Traction Force: 600 gr during the 1st month, 900 gr during the 2nd month, 1100 gr during the 3th and 4th month, and 1200 gr during 5th y 6th month.

Application period: 10 hours a day, every day of the month over a period of 3-6 months.

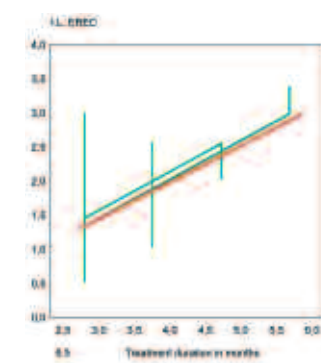
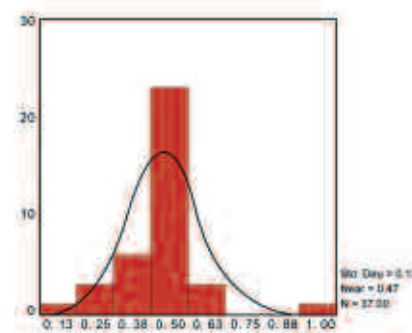
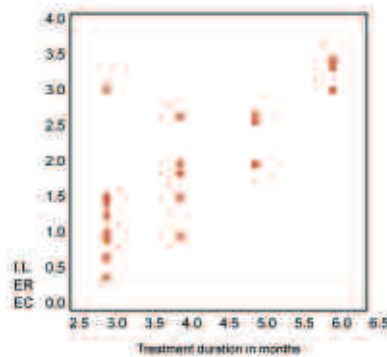
3. Results:

3.1.- Increase in length in erection:

The increase in the length of the penis in erection is proportional to the amount of time the device is worn. Such growth is linear, as it can be observed in the chart. This translates into the following: the longer the time of use, the more length is obtained. The lineal correlation coefficient between time of use and increase in length in erection is 0.760 ($p=0.000$).

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The average length increase of the penis in erection after a month of use is 0.4726 cm. The standard deviation is 0.1329 cm. The 95% confidence interval is [0.4283 ; 0.5169]; that indicates a minimal gain in the population of 0.4283 cm/month.

Regression line is:

$$DL \text{ errec} = - 0.327 + 0.562 \times t$$

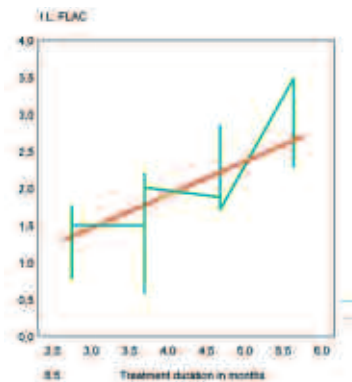
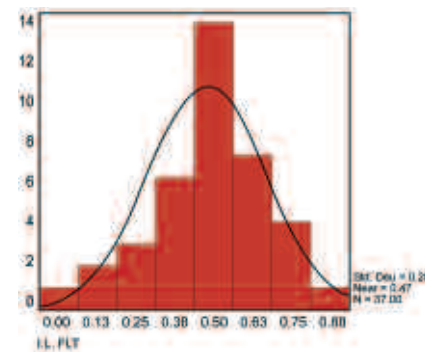
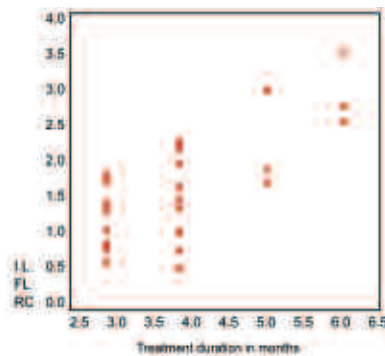
This calculation will allow us to estimate the increase in length of the penis in erection, based on the months of use of the device. There is a variance of 57.7% in the increment in length, which is explained by the variance in the duration of treatment ($R^2=0.577$). The other 42.3% of variance is due to other differences which are innate to each individual and don't depend on the duration of treatment.

3.2.- Increment in length in the flaccid state :

The increment in length in the flaccid state is not related to the time of use of the device. Said increment is linear as the graph shows. The longer the device is worn, the greater the increase in length. The coefficient of the linear correlation between the time of use and the increment in length in the flaccid state is 0.725 ($p=0.000$).

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The average monthly increment in length of the penis in the flaccid state is 0.4834 cm and the typical deviation is 0.1983 cm. The 95% confidence interval is [0.4173; 0.5495] and indicates a minimum increase in the population of 0.4173 cm/month.

Regression line is:

$$DL \text{ flac} = - 1.300 + 0.840 \times t$$

This calculation allows us to estimate the length increment of the penis in the flaccid state based on the months of use of the device. There is a variance of 52.5% in the increment of length, that can be explained on the base of the variation of the treatment duration ($R^2=0.525$). The remaining 47.5% is due to other differences which are innate to the individual and not to be associated with the duration of the treatment.

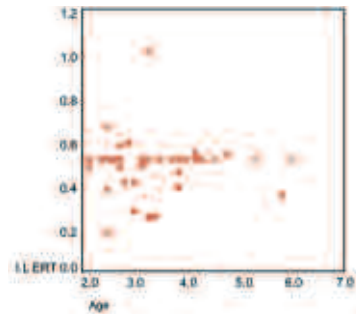
3.3.- Variability:

The variability in the length increase of the penis in erection state is different from that of the penis in flaccid state; the difference in variation is significant ($p=0.003$) and indicates a greater dispersion of the length increase during flaccidity than in erection.



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3.4.- The length increment doesn't depend on the age:

As a very interesting result, the study shows that the length increment doesn't depend on the age of the patient, since the linear correlation coefficient is not significant ($r=0.008$, $p=0.961$). In other words, the patient's age doesn't affect the length increment.

3.5.- Circumference increment in erection:

In erection, the average increment of the circumference was 0.8405 cm and the typical deviation $s=0.5382$. The average growth of the initial circumference was 7.1743%. The confidence interval of 95% of the studied population was 0.6111;1.0200; that shows a minimal growth increment of 0.6111 cm.

3.6.- Circumference increment in flaccid state:

The average increment of the circumference in flaccid state was 0.8405 cm and the typical deviation $s=0.6057$. The average percentage of growth was 9.0741%. The 95% confidence interval of the studied population was 0.6386;1.0425, what shows a minimal perimeter growth increase of 0.6386 cm.

3.7.- Length increase in erection state depending on use:

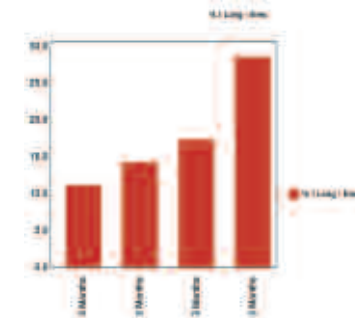
Dividing the studied population in four subgroups, depending on the amount of time they used the Andropenis®, we obtain the following results:

After three month:

The average length increment in erect state was 1.4118, obtaining an average growth of 10.5580% compared to the initial length. The 95% confidence interval of the studied population was 1.1522;1.6713, which shows an average minimum growth of 1.1522 cm in three months.

After four month:

The average length increment in erected state was 1.8462, obtaining an average growth of 14.1113% compared to the initial length. The 95% confidence interval of the studied population was 1.5809;2.1114, which shows an average minimum growth of 1.5809 cm in four months.



After five month:

The average length increment in erected state was 2.2750, obtaining an average growth of 16.6303% compared to the initial length. The 95% confidence interval of the studied population was 1.7656;2.784, which shows an average minimum growth of 1.7656 cm in five months.

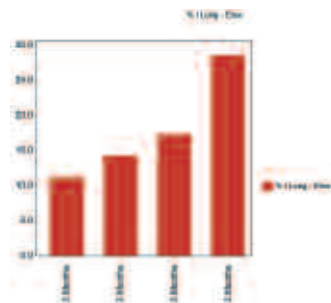
Penile enlargement without surgery

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Dr. Eduardo A. Gómez de Diego, 1998, Andrology Service, Biomedical-Estetica Clinic, Madrid (Spain).

After six month:

The average length increment in erected state was 3.3333, obtaining an average growth of 27.5% compared to the initial length. The 95% confidence interval of the studied population was 2.8162;3.8504, which shows an average minimum growth of 2.8162 cm in six months.

The samples corresponding to a time of use of five and six months are very small, consequently they show small intervals and are less reliable.



3.8.- Distribution:

Although the variables that we considered in the population are not normal, the average samples have normal distribution since the amount of the sample is greater than 20.

3.9.- Abbreviations:

Inc-Long-Erec	Length increment in erected state
DL erect	Change in length increment in erected state
I.L.ERT	Length increment in erection
I.L.FLAC	Length increment in flaccid state
DL flac	Change in length increment in flaccid state
I.L.FLT	Length increment in flaccid state as a function of the time variable
Inc-Long-Erec	Length increment in erected state
% I Long-Erec	Length increment percentage in erected state

4. Conclusions:

The use of the external penis stretcher device (from Biomedical-Estetica, now Andromedical®) will increase the length of the penis, both in erect and flaccid state.

The increase in length, both in erection and flaccidity, is directly proportional to the time of use.

The increase in length both in erection and flaccidity does not depend on the natural size of the patient's penis.

The average length growth of the penis in cm/month in 95% of the patients lay between 0.4283 and 0.5163 in erection and between 0.4173 and 0.5495 in flaccidity.

The variances in the length of the penis in erection are more uniform than those in flaccidity, which tend to be more disparate.

The variance of the length of the penis in erection is not related to the age of the patient.

The use of the penile traction device will increase the circumference of the penis, both in erection and flaccidity.

The average circumference growth in cm/month in 95% of the patients was between 0.6111 and 1.0200 in erection, and between 0.6386 and 1.0425 in flaccidity. The duration of treatments was of 3-6 months.



1. Introduction:

Form and size of the penis affect male self-image and selfconfidence worldwide. Penis curvature and Peyronie's disease are usually considered deformities in clinical work, since they also influence the erectile function and lead to erectile dysfunction. Undergoing surgery or taking pills to increase the size of the penis didn't satisfy men adequately.

On the contrary, the penis extensor that is produced in Spain (Andropenis®) is able to lengthen the penis by applying a gentle traction on it without any contraindications.

We used the device to treat 30 cases in clinical trial from June 30 to September 30, 2005, in order to study the efficacy and safety of the penis extensor.

2. Clinical data and methods:

2.1.- Study design:

The clinical trial was conducted to determine potential modifications in penis size and form through the application of the penile extensor.

The collected baseline data included the measurement of length and circumference of the penis both in flaccid and in erect state, as well as the evaluation of the psychological state of the subject. During the trial, the subject was instructed how to put on the extender and advised to wear it over 9 hours a day. During the first month the check-ups were performed once a week. During the second and third month the checkups were performed every two weeks. The trial was conducted according to GCP (Good Clinical Praxis).

2.2.- Subjects:

2.2.1.- Indications:

The subjects were between 16-70 years old; their penis could be lengthened without surgery.

Their penis curvature could be treated without surgery. They all needed postoperative treatment after penis reconstruction surgery or penis lengthening surgery, in general penile surgery requiring a control of the postoperative scar retraction.

All patients signed informed consent to certify that they had been correctly informed about how to use the device.

2.2.2.- Contraindications:

The device should not be applied until any penile wounds, lacerations or infected zones had completely healed. And it should not be used by patients with penile tumor, chronic disorders affecting the blood circulation, or the oxygenation and regeneration of tissues (advanced or uncontrolled diabetes, liver cirrhosis, advanced respiratory failure). Similarly, the use of the device was contraindicated for subjects suffering from priapism, uncontrolled psychology disorders, diabetes, heart diseases and hand disorders.

2.3.- Efficacy evaluation:

The patients were advised to use the device for over 9 hours daily. According to the medical protocol, the length had to be measured on the dorsal surface of the penis, from the pubic penile angle to the tip of the glans. Point zero of the measuring tape should be placed on the mentioned angle, without pressing upon the area.

Effects on Penile Size with Penile Extensor by Traction Force

(Report of 30 cases) Z Lee, XB Zhu, YD Liu, WJ Ye, YX Wang. Shanghai Institute of Andrology, Renji Hospital Affiliated to Medical. College, Shanghai Jiaotong University (Shanghai, China, 2001)

The perimeter or circumference in turn should be measured midway along the length of the penis. Measurements should first be made in flaccid state and then in erect state induced by sexual stimulation. The values should be registered on the treatment evaluation sheet. If the penile length and perimeter of the penis increased over 1 cms both in flaccid and in erected state within three months, the treatment had to be considered effective. If not, it had to be considered not effective.

2.4.- Safety evaluation:

Every review should especially register any penile discomfort, pain, foreskin edema etc. This being the case, the Penis Extender should not be used: In presence of pain, numbness or paleness of the glans the device should be removed immediately, as well as during physiological activities such as defecation, micturition, sports, sexual intercourse or during any other potentially hazardous physical activities involving the risk of falls. The same applies to excessive consumption of alcohol, analgesics or euphorizing agents.

3. Results:

30 males were recruited for the study with the aim to investigate the effects of a penis extensor in order to lengthen the penis. They were between 16 and 40 years old and among them 26 wanted to achieve a larger penis, whilst the remaining 4 were treated to extend the penis after being submitted to penile curvature surgery. 23 of the patients completed the clinical trial, whilst 7 broke it off. In the latter case, 6 of them, after 1-2 month of treatment, did not complete the therapy because of their refusal to wear the device over 9 hours a day. One patient broke off therapy complaining of penile discomfort. During the trial, there was no case of penile pain, ulcer or foreskin edema registered. None of the patients reported erectile dysfunction or urination dysfunction. In 23 patients the effectiveness of the device was demonstrated after a three-month treatment and the effectiveness rate was 100%.

Table 1 Penile size in different penis state before and after three month of treatment:

Penile size	Length of flaccid (cm)	Perimeter of flaccid (cm)	Length of erect (cm)	Perimeter of erect (cm)
Base line	7.1±1.5	6.3±1.3	9.3±2.3	8.1±1.7
After three-month	9.2±2.0*	8.1±1.2*	12.3±1.9*	10.0±1.9*

*compared with base line, P<0.05.

4. Discussion

Form and size of the penis are important sexual characteristics and affect men's self-confidence and self-evaluation. Though the size of the penis doesn't directly influence the female orgasm, there are many men who give an enormous importance to the size of their penis. That is so true, that the thought that their penis isn't large enough makes them avoid making love to a woman and even swimming in public. No standard surgery and no pills or medicines are able to lengthen the penis definitively.

The principle of traction is commonly used in plastic surgery to generate the expansion of human tissues, in order to use the new skin in skin implantations or to cover cutaneous defects, burns or bald zones. It is also used in bone distraction in order to lengthen the diaphysis of long limb bones and phalangeal bones.

In ancient cultures the same principle has been used to lengthen different parts of the body – as for example the neck in the Paduang tribe in Burma ("giraffe-women"), or the lips or ears in African or Amazon tribes - through the fitting of prostheses or weights to achieve the desired lengthening.

Effects on Penile Size with Penile Extensor by Traction Force

(Report of 30 cases) Z Lee, XB Zhu, YD Liu, WJ Ye, YX Wang. Shanghai Institute of Andrology, Renji Hospital Affiliated to Medical College, Shanghai Jiaotong University (Shanghai, China, 2001)



The extensor applies a traction force of 600 to 1500 grams to the penis for continued periods of time. The force vector is aligned with the principal axis of the penis.

Such traction provokes an adaptive reaction on the affected part of the penis tissue structures, with an increase in cell multiplication of the vesicular vessels, urethra, corpus cavernosum and spongy tissue and of the skin, Buck's fascia and dartos muscle, etc.

The latest studies suggest that traction can induce an increase in the number of cellular mitoses as a result of cell flattening.

Andromedical® in Spain has invented the penis extensor **Andropenis®**, which is used in Europe, Japan and North America.

We prescribed the penis extender device in 30 cases. In 23 of them the patients concluded the clinical trial after a three-month treatment and the effectiveness rate was 100%. In 4 further cases, in which the penis extender had been applied to stretch the penis after surgery for penile curvature the device demonstrated his effectiveness.

In 7 cases the patients didn't conclude the therapy. During clinical trial, 6 patients, after 1-2 month of treatment, did not complete the therapy because of their refusal to wear the device over 9 hours a day.

One patient broke off therapy complaining of penile discomfort. After penis traction therapy, the length of the penis showed an increase of 2.1 cms in flaccid state and 2.0 cms in erected state. The perimeter of the penis as well showed an increase of 1.8 cms in flaccid state and 1.9 cms in erected state. The efficacy of the applied traction force was directly related to the time of use of the traction device.

No efficacy could be demonstrated in those subjects, who ceased the continuous use. In the first week of the clinic trial, some patients felt a light penile discomfort. But the discomfort disappeared gradually.

During clinical trial no adverse effect was registered. In the future, there will be a lot of men using the device in order to elongate their penis.

5. Conclusion:

The penis extender has the capability to stretch the penis and produce an increase in its length and width.

It has been demonstrated to be safe and free of adverse side effects.

Efficacy of the daily penis-stretching technique to elongate the “Small Penis”

5th Congress of the European Society for Sexual and Impotence Research (ESSIR). Hamburg, Germany. December 1-4, 2002. Scientific study published in the International Journal of Impotence Research (volume 14, suppl. 4, Dic-2002). Colpi G.M., Martini P., Scropo F.I., Mancini M., Castiglioni F. Andrology Service, San Paolo Hospital – University of Milan, Milan, Italy.

1. Objectives:

The main surgical demand for penis enlargement comes from men whose penis size is within the standard limits but isn't considered satisfactory by the subject (“small penis”).

The aim of this study was to verify the efficacy of mechanical penis stretching physiotherapy in order to produce a penis enlargement.

2. Design and methods:

Nine healthy men suffering from “small penis” were enrolled (range age: 26-43 years). The initial stretched penis length was 12.0 cm (range 8.1-15.4). The **Andropenis®** was prescribed for at least 6 hours a day, over a period of at least 4 months.

3. Results:

In all subjects the enlargement of the penis was directly related to the time of use of the device. After 4 months the augmentation of the stretched penile length was +1.8 cm (range +0.5-+3.1 cm).

The daily average use was 6½ hours (range 3-9 hours). No side effects were registered.

4. Conclusions:

The data show the efficacy of the daily penis-stretching technique to elongate the “small penis”.



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Management of penile shortening after peyronie's disease surgery

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Post-surgical use of Andropenis® following the plaque removal and its substitution with autologous venous patch in the penis shaft curvatures provoked by peyronie's disease.

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Long Term Results in Augmentation Phalloplasty through a 2-cm Incision: Technique, Anatomical Description in a Human Cadaver and Satisfaction Assessment

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Treatment of penis hypoplasia as a consequence of epispadia surgery through penis extensor



Management of penile shortening after Peyronie's disease surgery

European Society of Andrological Urology (ESAU) and European Society for Genito-Urinary Reconstructive Surgeons (ESGURS) are full members of the EAU Section Office. Thursday, 25 October 2007. Dr Moncada, Madrid (ES).
10th Congress of the European Society for Sexual Medicine (ESSM). Dr. Moncada, 25 - 28 November, 2007. Lisboa Congress Center, Lisbon, Portugal.



1. Introduction and Objective:

Loss of penile length is a common complaint of patients undergoing surgical correction of penile curvature for Peyronie's (PD) disease. Penile extenders have been developed to increase penile length by regular application on the penis based on their tissue expansion properties.

We assessed the value, in terms of increasing penile length, of the application of a penile extender (**Andropenis**[®]) in men who have undergone tunica albuginea plication or grafting for PD.

We have also studied the impact of this treatment on the health related quality of life (HRQoL).

2. Methods:

40 men, aged between 54-64 (mean 58 y.o.), undergoing PD surgery constituted the study population; 12 patients were submitted to a grafting procedure while the rest (n=28) underwent a plication technique. 20 consecutive patients were treated with a penile extender device (**Andropenis**[®]) while the previous 20 served as a control group.

The extender was applied when the circumcision had healed (2 to 3 weeks after surgery) with a traction force of 900 to 1200 gr 8 to 12 hours daily during at least 4 months.

Parameters studied were penile length before, after surgery and after the continued use of the device. HEQoL using the SF-36 questionnaire was also assessed to compare both groups of patients.

3. Results:

Penile shortening after surgery ranged from 0.5 cm to 4 cm. Shortening was slightly less relevant in patients undergoing a grafting procedure but this difference was not statistically significant.

Treatment with the device produced a length increase ranging from 1 to 3 cm, this increase was proportional to the number of hours per month the patient was using the extender.

There were significant differences in several of the SF-36 parameters in the patients under the device when compared to those not using the extender ($p < 0.001$).

Four patients had to reduce the time of application of the extender because of moderate pain in the circumcision wound; no other side effects were reported.



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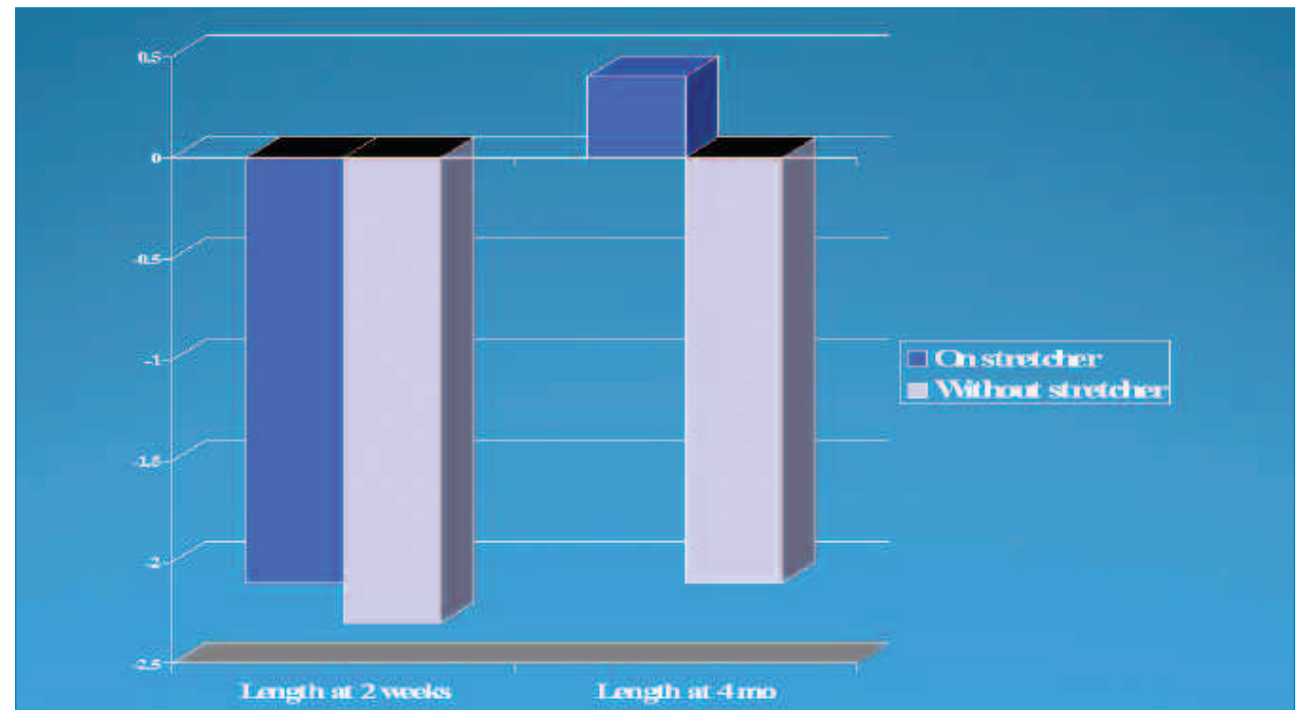
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4. Conclusions:

Our study suggests that the use of a continuous penile stretching device (**Andropenis**[®]) is an effective and safe approach to maximize penile length in patients undergoing PD surgery.

Its use produces an improvement in QoI parameters when compared to a control group.



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11th World Congress of the International Society for Sexual and Impotence Research. Oct 17th-21st, 2004. Buenos Aires, Argentina. 7th Congress of the European Society for Sexual Medicine. December 5-8, 2004. London, UK. Moncada, I.; Jara, José; Martínez-Salamanca, J.I.; Cabello, R.; Hernández, C. Urology Unit. Hospital Gregorio Marañón, Madrid. Spain.

1. Objective:

The aim of the study was to evaluate the effects of a daily application of a penile extender device over 8–12 hours, in order to increase the length of the penis in patients who had undergone penile surgery for Peyronie's disease. A secondary aim was to determine the health related quality of life (HRQOL) outcome in patients using this device.

2. Design and methods:

30 men aged 54–64 years (mean age 58) underwent penile surgery for PD. The surgical technique applied in eight of the patients was the incision of the fibrous plaque and grafting, while the others underwent plication of the albuginea (Essed technique). After the surgery, 15 of the 30 patients were treated with a penis extender (**Andropenis**) daily, over a 4-month period.

Length and girth of the penis were measured before and after surgery as well as after the use of the extender. HRQOL was also determined using the SF-36 survey to compare both groups of patients.

3. Results:

Sustained treatment over a period of 4 months with the penile stretching device provided an increase in length of 1 to 4 cms and an increase in girth of 0,5 to 1,5 cm. Comparing the results of the SF-36 survey, a significant difference could be observed between both groups ($p < 0.001$).

The use of the device was generally well tolerated, only 2 patients had moderate penile pain. No further complications were recorded.

4. Conclusion:

The use of a penile extender device over 8 to 12 hours daily is an effective and safe way to minimize loss of penile length in patients operated for PD. Its use provides a significant improvement in HRQOL outcomes compared to the control group.

Management of penile shortening after Peyronie's disease surgery
 Ignacio Moncada, José José Jara, José Martínez-Salamanca, J. I. Cabello, R. Hernández, C. Urology Unit. Hospital Gregorio Marañón, Madrid.

ABSTRACT
 The aim of the study was to evaluate the effects of a daily application of a penile extender device over 8–12 hours, in order to increase the length of the penis in patients who had undergone penile surgery for Peyronie's disease. A secondary aim was to determine the health related quality of life (HRQOL) outcome in patients using this device.

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CONCLUSION
 The use of a penile extender device over 8 to 12 hours daily is an effective and safe way to minimize loss of penile length in patients operated for PD. Its use provides a significant improvement in HRQOL outcomes compared to the control group.

INTRODUCTION
 Peyronie's disease (PD) is a chronic condition characterized by the development of fibrous plaques in the tunica albuginea of the penis, leading to penile shortening and curvature.

DESIGN
 This study was a prospective, randomized, controlled trial comparing the use of a penile extender device with a control group.

MATERIALS & METHODS
 Thirty men aged 54–64 years (mean age 58) underwent penile surgery for PD. The surgical technique applied in eight of the patients was the incision of the fibrous plaque and grafting, while the others underwent plication of the albuginea (Essed technique). After the surgery, 15 of the 30 patients were treated with a penis extender (Andropenis) daily, over a 4-month period.

RESULTS
 Sustained treatment over a period of 4 months with the penile stretching device provided an increase in length of 1 to 4 cms and an increase in girth of 0,5 to 1,5 cm. Comparing the results of the SF-36 survey, a significant difference could be observed between both groups ($p < 0.001$).

CONCLUSION
 The use of a penile extender device over 8 to 12 hours daily is an effective and safe way to minimize loss of penile length in patients operated for PD. Its use provides a significant improvement in HRQOL outcomes compared to the control group.

LOCALIZATION
 The study was conducted at the Urology Unit of the Hospital Gregorio Marañón, Madrid, Spain.

Post-surgical use of the Andropenis® following the plaque removal and its substitution with autologous venous patch in the penis shaft curvatures provoked by Peyronie's disease.

20th Italian Society of Andrology Conference, Capri (Italy), Oct. 03 and ESSIR Conference, Istanbul (Turkey), Nov. 2003. Diego Pozza, Claudio Barteri, Antonio Aversa, Carlotta Pozza, Francesco Barrese. Studio di Andrologia e di Chirurgia Andrologica, Nuova Villa Claudia, Roma, Italy.

1. Introduction and objectives:

The attempt at finding the most suitable material to substitute the albuginous membrane in Peyronie's disease has not been clearly defined, yet. Autologous and eterologous materials often show the tendency to thicken and scar that can undo the corrective effects of surgery. Several vascular rehabilitation methods have been put forward to avoid such phenomena. In our tests, we used a penile extender, the **Andropenis**®, to reduce the secondary retraction.

2. Materials and methods:

Five patients (52 to 72 years of age) with satisfactory erections, both spontaneous and with the use of Sildenafil or PGE1, suffering from a shaft curvature on the dorsal side of more than 45° (so much as to impede penetration) have undergone the removal of the dorsal fibrous plaque and the covering of the albuginous space with an autologous part of the saphena.

From day 7 after surgery, patients have started a vascular "rehabilitation" therapy with Sildenafil 25 mg in the evening on alternate days for 20 days.

Moreover, from day 10 patients have started using the **Andropenis**® for an average of 2 hours a day in the morning, 2 in the afternoon and 2 in the evening.

These results have been compared with those of 5 patients of similar characteristics, who have undergone the same surgery and have been treated with the same rehabilitation therapy (Sildenafil) without applying the penile extender.

3. Results:

At least three months after the surgery, those five patients that followed the treatment with Sildenafil and used the extender have shown no reduction in size nor curvature of the penis shaft and an adequate penetrative activity.

Among the remaining five patients, we have registered two cases of progressive shaft curvature that does not allow penetration, and venous patch retraction in one case, which favours a new curvature. Although the latter case does allow penetration, it has not been accepted aesthetically nor psychologically by the patient, thus causing dissatisfaction.

4. Conclusions:

The removal of fibrous plaques from the cavernous bodies albuginea and its substitution with autologous veins represent quite a codified procedure today.

The added use of FosfoEsosolomerase inhibitors to increase the cavernous microcirculation and the use of mechanical penile extenders can easily avoid the cavernous patch retraction and guarantee increased surgical results.

**Long Term Results in Augmentation Phalloplasty through a 2-cm Incision: Technique, Anatomical Description in a Human Cadaver and Satisfaction Assessment**

Department of Urology, Iaso General Hospital; Department of Anatomy, Athens Medical School, Athens University; The Second Urological Department, Sismanoglion Hospital, Athens University; dAndrology Institute of Athens, Athens University, Athens, Greece

Vassilis D. Protopogroua, Sofia Anagnostopouloub, John M. Varkarakisc, Dionissis Venierato, Kostas G. Konstantinidisd, Athanassios N. Kostakopouloua

1. Objective:

An increase in the length of the penis is feasible with techniques that either divide the penis' ligaments (fundiform and triangle) or use grafts to increase the size of the corpora. Girth enhancement can be done with fat autoinjection or with dermal grafts. We present our technique together with an anatomical description in a human cadaver.

2. Patients and Methods

Forty patients underwent augmentation phalloplasty. To increase the length of the penis the ligament was divided through a small 2-cm incision at the base of the penis. Girth enhancement was achieved through fat autoinjection with fat taken from the inner thighs. The dissection of the ligament was also demonstrated in a human cadaver to allow for more explicit presentation of the anatomy of the area. A questionnaire was used to assess the patients' satisfaction. Results: Before operation all patients had a normal penis with a length 9.5 ± 2.2 cm (8.1–13.5 cm) in the flaccid state and 11.8 ± 1.9 cm (10.9–17.2 cm) in the erect state.

The mean circumference was 9.9 ± 2.3 cm (7.6– 11.8 cm). The increase in length 12 months post-operatively was 3.5 ± 1.3 cm (2.3–5.1 cm) in the flaccid state, 1.8 ± 1.4 cm (1.4–3.2 cm) in the erect state and 3.5 ± 1.4 cm (2.1–5.2 cm) in girth. There was a statistically significant difference ($p < 0.005$) between pre-operative and post-operative status. The overall satisfaction rate was 67.5%, and 57.5% of the patients stated that the surgical outcome met their pre-operative expectations.

3. Conclusion

Penile lengthening is technically possible provided that some basic principles are followed. Psychological disturbance though, might be present and such patients might not be pleased even after a successful operation.

Introduction

The size of the penis is considered to be an important factor for male self-esteem. Although the 'normal' size of the penis varies [1], men are often not capable of evaluating the proportion of their genitalia and have a tendency of underestimating the size of their phallus [2], a psychological disorder called dysmorphophobia. Sex education has been found very effective in the treatment of men complaining of a short penis [3], but still some men look for a surgical treatment of their 'problem'. Several techniques of augmentation phalloplasty have been described [4–11]. Total phalloplasty with additional placement of a penile implant for rigidity is also feasible and can be used either in transsexual operations or after penile agenesis or amputation [12–15]. We present our results of augmentation phalloplasty performed through a 2-cm incision as well as an anatomical description in a human cadaver.



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Table 1. Satisfaction rates 12 months following the operation

	YES	NO
Do you consider the increase of your penis significant?	31 (77.5%)	9 (22.5%)
Does it satisfy the image you had in mind pre-operatively, regarding the result of the operation?	23 (57.5%)	17 (42.5%)
Did you notice any change in the quality of your erections?	0	40 (100%)
Overall, are you pleased with the result of the operation?	27 (67.5%)	13 (32.5%)

Patients and Methods

From February to July 2005, we performed augmentation phalloplasty in 40 patients. The mean age of the patients was 28.3 years (range 22–45 years) and all of them had normal erectile function assessed with Rigiscan and Doppler. Penis measurements were done by the same doctor in a standardized way with the patient lying on the examination bed, at the same room temperature and reasonably relaxed. The length was measured from the base of the penis (over the pubic bone) to the tip of the glans and girth was measured in the mid-shaft of the penis. The erect penis was measured after intracorporeal injection of prostaglandin. Of course, variations might occur and therefore every effort was made to maintain the same conditions for all patients.

Since there was no medical indication in any of the cases (micropenis, buried penis, etc.), the operation was considered as esthetic surgery. In pre-operative counseling, the details of the operation, the possible complications and the expected results were discussed with the patients to clear up any possible illusions the patients might have about the outcome of the operation. The postoperative result was measured 12 months after the operation. In the fourth post-operative week the patient was instructed to use the Andro-Penis® (penis-extender, Andromedical ©, Spain), 30 min daily for 6 weeks and then for another 6 weeks with increasing force in order to avoid contraction of the penis. Paired t test was used for statistical analysis.

A simple 4-question questionnaire (table 1) was also used 12 months post-operatively to assess the satisfaction rate of the patients regarding the outcome of the operation.

Operative Technique: Lengthening of the Penis

The lengthening of the penis was done by dividing the suspensory ligaments (both midline and lateral branches: fundiform and triangle). While the patient was sedated, the area over the base of the penis and the pubic bone was injected with a solution made of 30 ml 2% xylocaine and 30 ml saline. A 2-cm incision was performed at the base of the penis and superficial veins were ligated.



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The suspensory ligament was identified and palpated with the index finger of the left hand while at the same time it was dissected with scissors near the pubic bone. Since the size of the incision did not allow clear vision at the time of the dissection, the index finger was used as a guide and as well for protection of the penis. The assistant put some traction of the penis so that the ligaments could be easily identified. Sharp or blunt dissection was used as necessary.

The inferior part of the pubic bone was used as a landmark for the end of the dissection. Then, the pubic adipose tissues on either side were approximated to each other to fill the gap between the penis and the pubic bone and the incision was sutured. No filler or any kind of silicon material was used.

In selected patients (fat patients or after their demand, if that was feasible), fat over the pubic bone was removed with liposuction to enhance the result of the operation.

Operative Technique: Girth Enhancement of the Penis

Girth enhancement was done with autologous fat transfer by liposuction and injection of the fat into the penis. Through a small incision in the inguinal area, liposuction was performed. The harvested fat was cleared from the abundant saline and from the fibers, and then it was injected in the shaft of the penis through a small incision at both sides of its base starting from the corona and then pulling the needle back towards the base. Finally both incisions were sutured and tight underwear that compressed the thighs was put on the patients. The patients were discharged from the hospital the same day.

Anatomy of a Human Cadaver

An anatomical study was also performed in a human cadaver at the Department of Anatomy of Athens University. After removal of the skin and fat from the area between the symphysis and the penis, the fundiform ligament can be identified as a continuation of the linea alba. As one dissects deeper, this ligament continues as the ligament of the penis. The dissection of these ligaments mobilizes the penis allowing it to be pulled out once you apply a slight traction. The further the ligament is divided the more the penis is freed. In a deeper plane, the ligament is divided into left and right branches which attach each crus to the pubic rami (fig. 1). The inferior border of the pubic arch, which is the limit where one should stop dissecting, lays deeper, behind this separation. At this stage the penis can be pulled out or in fact placed in a lower position (fig. 2). By stopping the dissection at this stage, we do not risk creating a 'loose' penis even if in reality we are dealing with a penis that is now hanging a little bit lower than it used to be. It is important to note that, during the dissection one does not meet any vessel and so the risk of bleeding is minimal.



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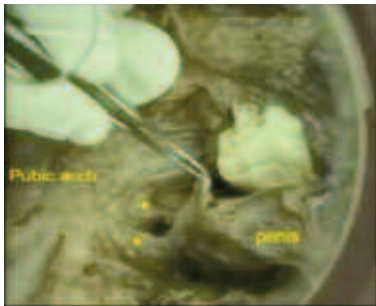


Fig. 1. The ligament after having been dissected and the 2 branches of the ligaments (marked with *) that attach the crura to the pubic rami.

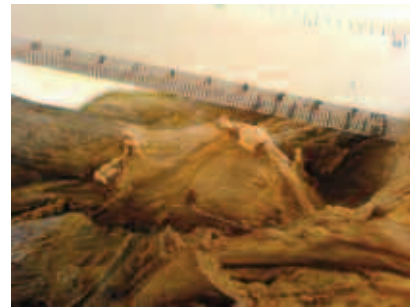


Fig. 2. The new position of the penis moved away from the pubic bone.

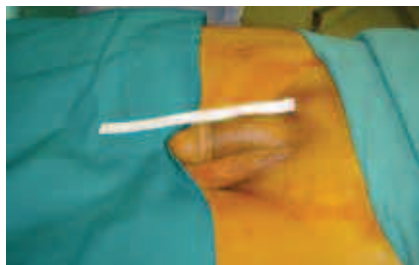


Fig. 3. Pre-operative measurement of the penis.



Fig. 4. Post-operative outcome of the penis.

Results

The duration of the operation was 66 min (55–80 min) and all patients were discharged the same day. The mean flaccid length pre-operatively was 9.5 ± 2.2 cm and the erect length was 11.8 ± 1.9 cm. Twelve months postoperatively the measurements of the penis were: mean increase in the flaccid length of the penis was 3.5 ± 1.3 cm (2.3–5.1 cm) while the increase in the erect penis was 1.8 ± 1.4 cm (1.4–3.2 cm). The increase in the circumference was 3.5 ± 1.4 cm (2.1–5.2 cm) (table 2). The preoperative and immediate post-operative appearance of the penis is shown in figure 3, 4. The difference in all the measurements post-operatively was statistically significant ($p < 0.005$) compared with the pre-operative status.

There were no significant complications noted except in one patient who developed a small hematoma in the area of the incision that did not need any additional treatment and healed on its own.

According to the questionnaire, 31 (77.5%) patients considered the increase of their penis significant and 23 (57.5%) stated that it fulfilled their expectations. Overall, 27 (67.5%) patients were pleased with the operation (table 2). There were no cases of erectile dysfunction.

	Pre-operative	Post-operative increase	p
Flaccid length, cm	9.5 ± 2.2 (8.1–13.5)	3.5 ± 1.3 (2.3–5.1)	0.0022
Erect length, cm	11.8 ± 1.9 (10.9–17.2)	1.8 ± 1.4 (1.4–3.2)	0.0035
Circumference, cm	9.9 ± 2.3 (7.6–11.8)	3.5 ± 1.4 (2.1–5.2)	0.0012



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Discussion

The penis, which most of the times remains hidden underneath our clothes, is considered important to men and we also presume that women have a special interest in this part of a man's body. But, are the penis and specifically, the size of the penis really that important to women? In a recent study, 375 sexually active women were asked about this [16]. Less than one-fourth (21%) stated 'size does matter'. Probably, the best way to interpret this result is that sex does matter and size might play a role but definitely is not the cornerstone of lovemaking or of a healthy relationship. Nevertheless, the demand for a bigger penis is something that men still seek help for from an andrologist or a plastic surgeon.

In our cadaver anatomical description, the dissection of the ligament moved the penis 3 cm from its original position (fig. 2). Individual anatomical differences might offer different results but as we demonstrated in the cadaver, the dissection of the ligament can definitely offer immediate positive post-operative results. The main problem is the long-term results. During healing, contraction is possible which decreases the apparent length of the penis. Since the division of the ligament does not change

the total length of the corpora bodies, the lengthened penis is actually a penis pulled out from its original position. This is the reason why the gain in the flaccid state might decrease or even disappear in the erect state, when the erect penis proximate the pubic bone towards its original position. Real increase in the length of the penis is not possible unless the corpora bodies are dissected and grafts are used or if the disassembly technique with the additional use of various tissues, like cartilage is used [6, 8].

What are the advantages of our technique? Although surgical expertise is of paramount importance in these operations we believe that our small 2-cm incision not only offers better cosmetic results but minimizes scarring and penis retraction. Also, for the same reason, in the fourth post-operative week our patients start to apply tension to their penis with the Andro-Penis®, 30 min daily for 6 weeks and then for another 6 weeks with increasing force. We believe that our technique minimizes scarring and the use of the Andro-Penis® further contributes to the avoidance of retraction. The success rates following lengthening procedures either after dissection of the ligament or by using different techniques (disassembly technique or grafts) vary from a length gain of 1–5 cm in

the flaccid state [5, 8, 10], and 1.5–3 cm when erect [4, 6]. Our patients at 12 months post-operatively have minimal scarring and the gain in the length of the penis is significant (3.5 cm in the flaccid state and 1.8 cm when erect), which compare favorably with results reported in the literature. We must point out that the best results come from the fact that liposuction from the area over the pubic bone was performed together with the release of the ligament.

Penis' ligaments are considered to contribute to the stability of the penis and possibly to the upwards orientation during erection. Extensive release of the ligaments might cause the penis to lose its stability and perhaps lose upwards orientation, making intercourse problematic and needing manual assistance for penetration. If the landmarks we mentioned are followed, such a problem will not appear and none of our patients complained for such a side effect

Girth gain is usually between 1.1–2.1 cm regarding diameter [4, 9] and 2.0–3.0 cm regarding circumference [5]. In general, fat injection is a faster procedure, but up to 90% of the injected fat can be absorbed during the first year with a 50% absorption rate being more common



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[17, 18]. Top-ups can be performed at later stages and this is a relatively easy procedure. A dermal graft needs hospital stay, and is relatively more difficult but more stable [5] while saphenous venous grafting is technically a significantly more challenging operation [4]. In our patients at 12 months post-operatively and after fat absorption, the mean increase in the circumference was 3.5 cm which is in accordance with the results reported by others [5].

There were no complications in our patients although several complications have been reported by others such as cosmetic deformities and disappointment from the result of the operation [5, 6, 8–11, 17–19]. Irregular residual fat nodules, skin deformity and scarring, as well as scrotalization are the most severe complications while penile retraction and shortening of the penis are probably the complete failure of a lengthening procedure.

Over half of the patients (57.5%) stated that the postoperative result is what they had in mind before the operation.

This further contributes to the idea that many men who seek penis lengthening operations do not have logical expectations and a lot of the patients kept on dreaming for a 'megapenis'. Nevertheless, probably due to our ex-

tensive pre-operational counseling, the majority of our patients (77.5%) consider the increase in the size of their penis significant, giving an overall satisfaction rate of 67.5%. This further supports the need for careful and extensive pre-operative counseling to clear up any illusions the patients might have about the post-operative results. All patients maintain their erectile capacity intact.

Our study has its limitations because different techniques were used (ligaments' dissection and penis stretching) together with suprapubic fat removal in selected patients and one can not actually extract results from each technique independently, nevertheless we believe that we have described a complete unified method for penis augmentation together with interesting anatomical details. Lengthening of the penis is possible but limitations do exist and pre-operative counseling of the patient is mandatory. We must still consider these operations to be experimental and they should be carried out by a skilled surgeon after having the nature of the operation explained in details to the patient.

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1. The Koro syndrome:

Small penis syndrome that provokes psychological disorders affecting one's personality and social behaviour, although it is not to be considered as a psychiatric disease.

2. The Changing Rooms syndrome:

The problem arises because of the look of one's own penis in the state of flaccidity. Two thirds of men accept the way their penis looks. The rest prefer hiding it, although they report no problem in their sexual intercourses.

Such set of symptoms is worsened by the following factors: the way or angle to look at one's own penis, malicious remarks or jokes of one's friends or partner, the spread of pornography.

3. Penis enlargement; the combined technique:

The average penis size, taken from the pubis to the glans in the state of flaccidity and under traction, varies between 10 and 14 cms. The size of the majority of people is normal, as is their erectile function.

This is not just another plastic surgery technique.

We are called upon to ask ourselves whether results can be positive, what are the best techniques, whether the quality of the sexual intercourse is satisfactory and what can the side effects be. Ethics of results: completely satisfactory results cannot be reached, and the patient cannot have all his expectations fulfilled.

4. Non-invasive procedures:

Vacuum pump (totally inefficient). **Andropenis**[®]: mechanism of continuous traction that gives a real enlargement.

5. Surgical procedure:

First surgery: Dr. Long, 1984.

Various techniques exist, though they all include the following:

- Snipping of the suspensory ligament
- Separation of the fundiform ligaments
- Suprapubic liposuction (in some cases)

6. Surgical technique:

- Balanopreputial incision
- Penis denudation to the base of the shaft
- Snipping and ligation of the superficial dorsal vein
- Snipping of the suspensory ligament
- Snipping of the fundiform ligaments

A constant traction of the penis shaft during surgery is advisable to ease the ligaments snipping, establish the actual elongation and precisely carry out the lateral ligation of the albuginea to the straight abdominal terminal membrane, impeding thus the penile retraction.

A rigorous hemostasy is necessary. Total bandaging in the first 10 days is advisable. The **Andropenis**[®] is to be worn 3 to 4 weeks after surgery for no less than 2 months.

7. Postsurgical Recovery:

Antiinflammatory drugs for 10 days. Antibiotic every 8 hours for 5 days. Keep the bandaging for 10 days. Local cold applications in the first hours after surgery.

8. Main complications:

Bruising, penile retraction, oedema, loss of sensitivity, psychogenic erectile dysfunctions.

9. Our experience:

25 patients with unique or combined technique. Average gain in length: 5cm. No complication. High degree of satisfaction of the patients.

Treatment of penis hypoplasia as a consequence of epispadia surgery through penis extensor

XXI National Congress of the SIA Regional Sections (Italian Andrology Society) Trieste, Italy, September 23rd-26th, 2004.
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1. Case report:

Man aged 25 who had undergone multiple epispadia operations and Mitrofanoff's continent cutaneous appendicovesicostomy procedure. He urinates every 3 hours through an intermittent catheter. Rare episodes of urinary infection. He seeks medical advice because of penis hypoplasia that causes coital difficulty.

2. Objective examination:

At clinical examination, the stretched penis length is 7,8 cms, with a girth of 9.8 cms measured on the middle third of the shaft, while the length in erected state is 8 cms.

3. Treatment:

The advised treatment is the application of a penis extensor, that the patient shall undergo after signing informed consent about the unpredictability of its outcomes, further advising him an 8 hours daily use for a period of 8 month.


The patient's compliance leads to a daily use of the device of 4-6 hours over 8 month.

4. Results:

The follow-up after 3 months showed that the stretched penis measured 9.5 cms, after 6 months 10.0 cms and after 8 months 10,2 cms, with an unmodified girth of 9.8 cms. No adverse side effects were recorded during treatment, except a temporary delayed ejaculation that couldn't be reliably proved to be related to the treatment.

5. Discussion:

A penis-stretching device seems to be a valid method to lengthen the penis in patients with antecedent penis surgery.



TRATTAMENTO DI IPOPLASIA PENISINA IN ESITI CHIRURGICI PER EPISPADIA MEDIANTE ESTENSIONE PENISINO

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CASE REPORT
 Uomo di 25 anni. Patti di gliacci interventi per epispadia, portatore di apparato vesicostomiale continentale tipo Mitrofanoff. Urina mediante catetere intermittente. Infezioni urinarie ricorrenti ogni 3 ore. Rari episodi di calcolosi urinaria. Soffre per ipoplasia penesina limitatamente all'atto di coito.

ESAME OGGETTIVO
 Alla visita, il pene "steso" misura 7,8 cm, con una circonferenza di 9,8 cm misurata al 1/3 medio dell'asta, mentre in erezione la lunghezza è di 8 cm.

INDICAZIONI
 Il paziente è interessato con estensore penesino, previa firma di consenso informato sulla sua prevedibilità nei risultati, anche nel caso di utilizzo quotidiano dello strumento per 8 ore al giorno per un periodo di 8 mesi.
 La compliance del paziente consente un uso quotidiano dello strumento di 4-6 ore al giorno per 8 mesi.

RISULTATI
 Al follow-up a 3 mesi, il pene steso misura 9,5 cm, a 6 mesi 10,0 cm ed a 8 mesi 10,2 cm, con una circonferenza invariata di 9,8 cm. Non segnalati eventi avversi durante il trattamento, ad eccezione di un'epididimite non trattata, per la quale venne applicato il classico effetto del trattamento.

DISCUSSIONE E CONCLUSIONI
 L'estensore penesino sembra costituire un valido metodo per allungare il pene in pazienti con ipoplasia chirurgica dell'organo.



Treatment options for “hydiopathic short penis”: what is the evidence?

7th Congress of the European Society for Sexual Medicine (ESSM). London, UK. December 5-8, 2004. Paolo Gontero, Nicola Mondaini*, Bruno Frea. Department of Urology, University of Piemonte Orientale, Italy. *Department of Urology, University of Florence, Italy.

1. Introduction:

Penile size is becoming a healthcare problem given the increasing number of patients seeking urological advice for a so-called “short penis”. Aim of the present study was to review the level of evidence in literature for any treatment option to elongate the penis.

2. Materials and methods:

The study was conducted through a medline search for the last 20 years on surgical and non surgical treatment modalities for penile lengthening. Peer reviewed abstracts were also included. We focused on the term “lengthening phalloplasty”, that summarises a small group of surgical procedures aimed to elongate the shaft mainly in the flaccid state. Other search terms included non invasive methods like “penile stretchers”.

3. Results:

Based on the currently available literature it appears that the most common techniques to lengthen the penis (section of the penile suspensory ligament, the infrapubic liposuction and a V-Y or Z plasty) provide only rudimentary results and a high patient dissatisfaction rate.

On the other hand, literature reports mainly the disastrous results of pericavernosal apposition of autographs.

In a recent technique of augmentation phalloplasty bilateral saphena grafts have been employed to increase the corpora cavernosa girth thus providing a “true” penile enlargement during erection.

Interestingly, a number of peer reviewed abstracts agree that the so-called “penile stretchers” may significantly improve penile length with an extremely low complication rate.

4. Conclusions:

Penile additive surgery remains a controversial issue, dominated more by opinions than a scientific background. In our opinion, a more open view should be directed in the field of conservative methods of penile lengthening.

Theoretically, there is no reason to believe that a penile stretcher may be less successful than surgery in elongating the suspensory ligament. Additionally, the use of non-invasive options gives the opportunity of widening considerably the indications for a treatment that, in the majority of cases, is merely cosmetic.



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Penis enlargement: Patient classification based on a psychological study



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Penis enlargement: Patient classification based on a psychological study

Fernando Molina-Campuzano, clinic psychologist, Madrid-Spain. When a patient decides to obtain information regarding penile enlargement, many psychological aspects have to be taken into consideration: reasons for their request, motivating factors, and expectations are of extreme importance for the management of each case.

1. Psychological aspects:

In each treatment, psychological factors play an important role during the consultation, treatment development and evaluation, and post treatment evaluation.

2. The physician:

The expectations of the patient seeking information on penile enlargement should be determined. The patient is expecting to find a doctor who can explain the process in full detail in a professional and confidential fashion.

3. The patient:

By listening to the patient carefully, the physician can appreciate his goals and expectations. One should not generalize with different patients, since there are different reasons and personality traits involved in the patient's objectives for using the **Andropenis®**. One would want to carefully evaluate those personality traits that involve insecurity, role improvement, and relationship improvement.

As long as we identify the patient's objectives and remind him of his goals, the physician will help maintain the patient's interest, achieving more effective compliance during the treatment period.

4. Patient classification according to motivating factors:

Type I:

Primary Objectives: Size.

Secondary Objectives: To reinforce self-confidence in sexual relationships, to achieve increased desirability, to avoid rejection and solitude, to be part of the winners circle, and to improve pleasure given to their sexual partner.

A prototype patient is a 40 year old individual who, for the first time in his life, is confronted with erectile dysfunction. He perceives a decreased length of his penis or diminished virility. In this case, by explaining that tissue growth and neo-vascularisation caused by the treatment improves not only the quality of erections but also the length of the penis and a sense of virility, the patient's objective(s) will be achieved.

Important emotional changes, which affect the patient, are readily observable. Sometimes, however, there may be a change in the partner's attitude, which may present an entirely new set of issues for the patient. Attempts to help the patient identify these can be helpful, especially if rejection is an issue.

This patient is likely to avoid intimacy, and has an absence of emotional or sexual relationships. They may constantly seek superficial interactions, in some degree, to compensate for personal frustrations, which may have originated in their youth (L. Festinger 1975).

We need to transmit confidence to the patient, with the reassurance that his penis will grow and that the quality of his erection will also improve. When they perceive a penis of a larger dimension, the patient's self esteem should also improve. The patient will think of himself as a better lover and feel more proud of his sexual attributes. As a response to the phallic myth, he will likely see an increased sexual desire in his partner, which can enhance foreplay and improve positive expectations from intercourse.

The patient will receive all this information as a feedback. Increased confidence and self esteem will make his sexual approach calm and relaxed, thus automatically helping to activate the parasympathic nervous system—a key factor in erection.

Type II:

Primary Objective: Obtain a penis of normal or average dimensions.

Secondary Objective: Eliminate insecurity, complexes, solitude and rejection.



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Penis enlargement: Patient classification based on a psychological study

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We are talking about a patient with a smaller than average penis, or a small penis that creates an inferiority complex in the patient. Some of these individuals avoid situations in which their nudity will be exposed (dressing rooms, beaches, sexual encounters, etc.). They present obsessive thoughts on their nudity, which are focused on the size of their penis. Such individuals, during their consultation, express feelings of being observed and perhaps of being made fun of due to the small size of their penis. This individual wants to make sure that the growth will be both in erection (to satisfy their own needs as well as those of their partners) and in flaccidity (since they feel observed and criticized by others).

At the beginning, these patients may not seem to expect results from the treatment, but due to their high personal motivation, and after being provided with the proper scientific information, they usually decide to begin the treatment. They have the highest treatment compliance index and tend to use the device for more than 10 hours a day.

Even though they are very enthusiastic with the treatment, if they do not see results on a short term (1-2 months), they question the treatment's efficacy. In such instances, it is recommended to instruct the patient that the first month is an adaptation period, and to continue the treatment 11 hrs a day for the first month and a half to accelerate growth. Important emotional changes, which affect the patient, are re-

dily observable. Sometimes, however, there may be a change in the partner's attitude, which may present an entirely new set of issues for the patient. Attempts to help the patient identify these can be helpful, especially if rejection is an issue.

During treatment, these individuals require a parental-like guidance and continuous support from the physician.

Type III:

Primary Objective: Obtain a penis of large dimensions.

Secondary Objective: They usually possess narcissistic traits with the goals being to elicit sexual desire from their partners and admiration by others. They believe that with a larger penis, they will belong to the elite group of winners.

Some of the patients encounter difficulties in establishing significant personal relationships and base their communication on sexual assets, which make them feel comfortable and more secure. We are talking about in 4 categories:

A - Males in a stable relationship: those who want to obtain a larger penis to improve their relationship and to introduce new forms of play that will gratify both individuals. They seek a change in their routine. They tend to have financial means to seek treatment.

B - Males without a stable relationship: those who have multiple sexual partners. They find gratification in such relationships. They are very proud of their physique, of their appearance, and of their large penis ("Teoría Psicoanalítica de las neurosis", Fenichel, 0-1987).

C - Sportsman: those who invest a lot of time and money in their physique and traits and who are narcissistic. They frequent places where they can exhibit themselves (nudist beaches, swimming pools, dressing rooms, etc...) since they feel very comfortable and know how to elicit admiration by others.

D - Homosexuals: these men often place a lot of importance on their penis size. There is generally less of a need to be convinced about the efficacy of the treatment, but when these patients obtain 1 or 2 cm of growth, they often abandon the program prematurely. Compliance is encouraged.



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