Penile extender should be regarded as a minimally invasive and effective treatment options to elongate the shaft in patients seeking treatment for short penis. Paolo Gontero, Massimiliano Di Marco, Gianluca Giubilei, Giovanni Pappagallo, Andrea Zitella, Alessandro Tizzani, Nicola Mondaini.
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1. Introduction:

The penile extender, a non-surgical device that employs progressive mechanical traction to the penis, has been claimed to produce significant improvement in penile length and circumference both in the flaccid and the erect state. Little scientific evidence, based to our knowledge exclusively on abstracts presented to international conferences, supports the potential clinical utility of the penile extender (Colpi GM, 2001; Moncada I, 2005).

In the current study we assessed a marketed brand of penile extender, the **Andropenis**® device, in a phase II single arm study that was powered to detect significant changes in penile size.

2. Material and methods:

2.1.- Patients eligibility:

Patients complaining of "small penis" and highly motivated to receive effective treatment were considered eligible for the study. Patients seeking exclusively a circumference augmentation were excluded.

For study entry, a psychosexual counselling was required to select those for whom the treatment was deemed beneficial from the psychological point of view. Penile shortening following corporoplasty for curvature of the shaft was an inclusion criteria provided a minimum of 6 months from surgery had elapsed with no residual curvature.

An hypoplastic penis was defined by any flaccid and stretched length equal or below 4 and 7.5 cm respectively, the lower cut-off of the normal reference value (Ponchietti et al, 2001). Any size above constituted a penile dysmorphophobia, a condition where a patient with a normal sized penis is dissatisfied with its dimensions in the flaccid and/or the erect state (Austoni E, 2002). Patients complaining of shortening following penile surgery were considered as a separate subgroup.

2.2.- Study endpoints:

Changes in flaccid and stretched penile length and circumference over baseline after 6 months of treatment and durability of the response at 1 year after treatment discontinuation were considered the primary study end point. These were defined also taking into account the "efficacy data" suggested by the patient's information sheet provided by the Company (Andromedical, Madrid, Spain; Gomez EA, 2001).

Treatment tolerability, patient's compliance and satisfaction as well as changes in the IIEF erectile function domain (EF) scores at last follow up over baseline constituted secondary end points.

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2.3.- Device description and treatment schedule:

The **Andropenis**® 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 2 dynamic metallic rods originate 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 gr during the 1st month, 900 gr during 2nd month, up to 1200 gr during 5th y 6th month were provided following the manufacturer's leaflet.

Patients were requested to wear the device preferably for 6 hours (and no less than 4 hours) daily and consecutively for an optimal duration time of 6 months according to the manufacturer suggestions.

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 Kleinfelter syndrome.

* Two obese patients complained of hidden penis
** IIEF EF domain = erectile function domain of the IIEF
*** ED = erectile dysfunction Baseline patients characteristics (N=21)

Variable	Categorization	Value
Mean age (SD)	–	45.7 (11.1)
Mean values (in cm) of penile measurents (SD)	Flaccid Stretched Circumference	7.15 (1.43) 9.62 (1.56) 10.4 (1.34)
Etiology of short penis N (%)	Dysmorphophobic Post penile surgery Hypoplastic penis	12 8 1 (previous penile surgery)
IIEF EF domain score **N (%)	Normal (26-30) Mild ED*** (17-25) Moderate ED*** (11-16) Severe D*** (1-10)	9 9 1 2

Mean change for stretched and flaccid penile length and circumference at different time intervals (t_0 = baseline, t_1 = one month of treatment, t_3 = 3 months, t_6 = 6 months, = 12 months), and corresponding 95%. Confidence interval (95% CI).

Time interval	Mean change (cm)	95% CI	
Stretched penis			
$t_0 - t_1$	0.94	.62	1.26
$t_1 - t_3$	.44	.0	.82
$t_3 - t_6$	.38	.02	.73
$t_6 - t_{12}$	0.06	-.1	.23
Flaccid penis			
$t_0 - t_1$	1.13	.72	1.53
$t_1 - t_3$	.71	.42	1.00
$t_3 - t_6$	.41	.14	.69
$t_6 - t_{12}$	−.09	-.24	.05
Circumference			
$t_0 - t_1$	0.13	.01	.24
$t_1 - t_3$	0.16	.0	.32
$t_3 - t_6$	−0.09	-.24	.05
$t_6 - t_{12}$	0.00	-	-

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Mean scores of the 12 months satisfaction questionnaire (N = 17)

Question: after treatment...	Mean score	Min score	Max score	SD
Q 1: How would you rate your flaccid penile length?*	3.31	1	4	1.2
Q 2: How would you rate your penile length during erection?*	3.37	1	4	1.2
Q 2b: How would you rate your penile girth?*				
Q 3: How would you rate the overall result achieved?**	3.8	1	5	1.5
Q 5: How would you rate your sexual life?*	3.3	1	4	0.94

*Q1, Q2, Q2b, Q5 scores: 1=reduced, 2=unchanged, 3=mild improvement, 4=significant improvement.
**Q3 scores: 1=no result, 2=very mild, 3=acceptable, 4=good, 5=optimal.

Figures 1 and 2 show the changes which occurred in the flaccid and stretched penile length respectively during the different time intervals. At the end of treatment (6 months), a significant overall mean gain in length of 2.3 cm and of 1.7 cm for the flaccid (Wilcoxon Z test: -3.532; p<.00) and stretched (Wilcoxon Z test: -3.541; p<.00) penile length respectively was observed. As shown in figure 3, there were no remarkable changes (although statistically significant: Z -2.121; P=.034) in penile girth at all times during treatment.

FIGURE 1: Flaccid Penis
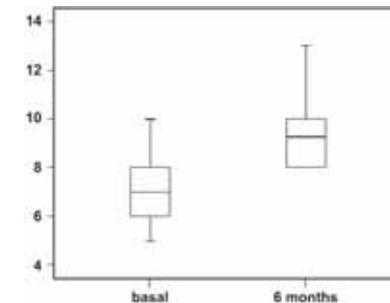
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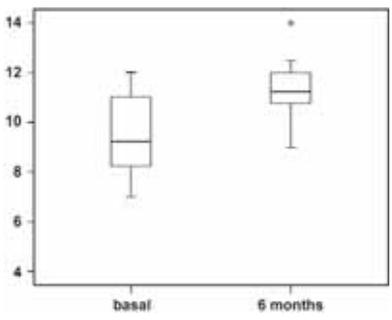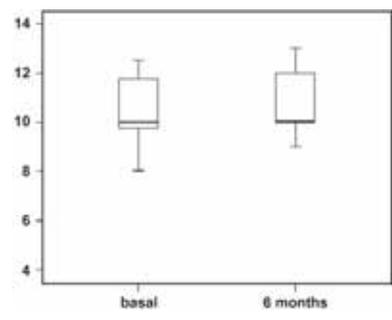
FIGURE 2: Stretched Penis

FIGURE 2: Stretched Penis

3. Conclusions:

The penile extender device provides an acceptable, minimally invasive tool able to produce effective and durable lengthening of the penis both in the flaccid and in the stretched state. No measurable changes in the penile girth are to be expected. If these results are confirmed, it should be proposed as first line treatment option for patients seeking a penile lengthening procedure.