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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Study Type – Therapy (case series)
Level of Evidence   4

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 effect size of >0.8. Eligible patients were counselled how to use the penile extender for at least 4 h/day for 6 months. Penile dimensions were measured at baseline and after 1, 3, 6 and 12 months (end of study). The erectile function (EF) domain of the International Index of EF was administered at baseline and at the end of the study. 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.

KEYWORDS

penile extender, penile dysmorphophobia, penile size, short penis

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 dysmorphophobia', 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.

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 corporoplasty 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 (t_0) 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 (t_1), 3 (t_3), 6 (t_6) and 12 months (t_{12}) (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).
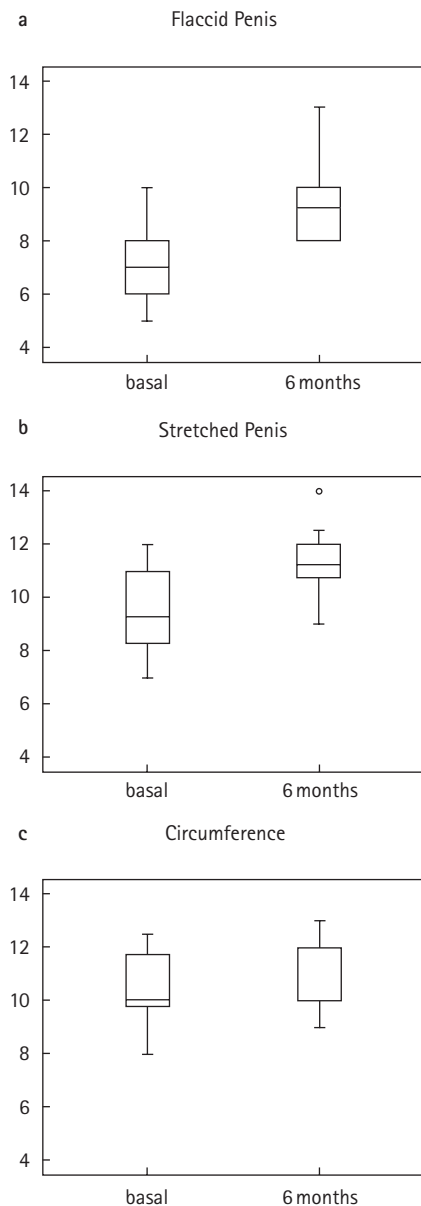
TABLE 1 *The baseline characteristics of the 21 patients*

Variable	Mean (SD) or *n* (%)
Age, years	45.7 (11.1)
Penile dimensions, cm	
Flaccid	7.15 (1.43)
Stretched	9.62 (1.56)
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)

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. 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. At the end of treatment (6 months), there was a significant overall

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.

a — Flaccid Penis

b — Stretched Penis

c — Circumference

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_3, 3 months; t_6, 6 months; t_{12}, 12 months) and corresponding 95% CI

Interval	Mean (95% CI) change, cm
Stretched penis	
t_0–t_1	0.94 (0.62–1.26)
t_1–t_3	0.44 (0.05–0.82)
t_3–t_6	0.38 (0.02–0.73)
t_6–t_{12}	0.06 (−0.10–0.23
Flaccid penis	
t_0–t_1	1.13 (0.72–0.53)
t_1–t_3	0.71 (0.42–1.00)
t_3–t_6	0.41 (0.14–0.69)
t_6–t_{12}	−0.09 (−0.24–0.05)
Circumference	
t_0–t_1	0.13 (0.01–0.24)
t_1–t_3	0.16 (0–0.32)
t_3–t_6	−0.09 (−0.24–0.05)
t_6–t_{12}	0.0 (−)

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. The gain in length was maximal at t_0–t_1 and slowed in t_1–t_3 and t_3–t_6. The mean (SD) gains in flaccid and stretched penile length were 2.05 (1.32) and 1.30 (0.75) cm in dysmorphophobic 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. 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 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 Wessells 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

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, 0–3)
Q4: your sexual life?	2.3 (0.94, 0–3)
Q5: overall result achieved?	2.8 (1.5, 0–4)

Scores are rated as described in Patients and methods.

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 except 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.

CONFLICT OF INTEREST

None declared.

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Abbreviations: **IIEF**, International Index of Erectile Function; **ED**, erectile dysfunction.