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Non-invasive methods of penile lengthening: fact or fiction?

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Penile size is a matter of great interest among men who are affected by 'short penis syndrome' or just believe themselves to have a small penis, even though the dimensions of the organ fall within the normal range. Surgical procedures of 'lengthening phalloplasty' lack standardized indications and carry a high risk of complications. Several non-invasive methods of penile lengthening have been described, such as vacuum devices, penile traction devices and penoscrotal rings; even 'physical exercises' have been popularized through the media. Most of these techniques, however, are not supported by any scientific evidence. We briefly analyse the efficacy and scientific background of such non-surgical methods of penile lengthening. It seems that penile extenders represent the only evidence-based technique of penile elongation. Results achieved do not seem to be inferior to surgery, making these traction devices an ideal first-line treatment option for patients seeking a penile lengthening procedure.

What's known on the subject? and What does the study add?

Penile lengthening methods remain a controversial issue. Surgical procedures of "lengthening phalloplasty" are characterized by poorly defined indications and an unacceptably high rate of complications, as recently outlined by a literature review, while non-surgical techniques are largely popularized by the media but often lack scientific evidence. In the literature we found only ten articles/abstracts of studies pertaining to the topic of our review.

With our review, we aimed to explore whether non-surgical methods of penile lengthening may have some scientific background. We focused specifically on penile extenders, which among conservative methods are those whose efficacy is supported by some scientific evidence. It seems that penile traction devices should be proposed as the first-line treatment option for patients seeking a penile lengthening procedure.

KEYWORDS

penile lengthening, micropenis, small penis, dysmorphophobia, penile extenders, Peyronie

INTRODUCTION

Penile size continues to represent a matter of great concern among men and an increasing number of patients seek urological advice for the so-called 'short penis', wondering if there is the possibility of having their penis enlarged. Notably, penile length is normal in most of these men who tend to overestimate normal phallic dimensions [1]. Furthermore, surgical procedures of 'lengthening phalloplasty' remain a controversial issue, being characterized by poorly defined indications and an unacceptably high rate of complications as recently outlined by a literature review [2]. In this brief overview we aim to explore whether non-surgical methods of penile lengthening, largely popularized through the media, may have some scientific background.

MATERIALS AND METHODS

A literature search was conducted and focused on non-invasive methods of penile lengthening. The PubMed, Ovid, Embase and Cochrane-Central Register of Controlled Trials databases were searched, using various combinations of the following free text: 'short penis', 'penile lengthening', 'Peyronie', 'extenders', 'micropenis', 'therapy', 'dysmorphophobia'. Identified articles were examined by the authors (M.O. and P.G.), and the most relevant articles were selected according to their levels of evidence, as defined by the Oxford Centre for Evidence-based Medicine [3]. In addition, abstracts presented at the 2008–2009 annual meetings of the EAU and the AUA were screened to identify relevant studies.

RESULTS

Among the 154 reports matching our search terms, only 10 articles/abstracts of studies were found to pertain to the topic of the review. These clinical data were limited to case series (level of evidence 4 according to the Oxford Centre for Evidence-based Medicine [3]) with none being a review article. Ten dealt with general concepts related to short penis, of which four were used to define the terms of the disease. The remaining reports addressed the role of surgery for penile enlargement ($N = 5$), including a comprehensive review [2] which was kept for comparison with the results of conservative methods.

NORMAL PENILE SIZE AND CONDITIONS OF SHORT PENIS

What is a normal penile size is a knotty question which some studies have tried to answer. Penile length has to be measured along the dorsal side of the penis, from the pubo-penile skin junction to the meatus, while the circumference is measured at the mid-shaft. According to Wessells *et al.* [4], normal penile dimensions should be considered to be any length within 2 SDs of the mean, that is >4 cm for the flaccid state and >7.5 cm for the stretched state.

Ponchietti *et al.* [5] confirmed these findings, concluding that >4 and >7 cm, respectively for the flaccid and stretched states, represent the normal range, bearing in mind that these measurements have to be interpreted in the light of other variables, such as body mass index.

The main problem with patients who complain of 'short penis' and who request surgical correction is that they often overestimate 'normal' penile length [1]. They suffer from so-called 'dysmorphophobia', a condition consisting of an imaginary flaw in the physical appearance [6], in this case a false perception of inadequacy of the penis even though its dimensions fall within the normal range [7]. Dysmorphophobia can be an aesthetic issue, if the altered perception concerns the penis in its flaccid state, or functional, during erection [8]. In both cases, the psychological aspect should be the main concern and a multidisciplinary approach, comprising urological, psychosexual and psychological assessment, is advised [9]. A nomogram was developed to show to the patients how they compared with other men [5]. This tool was found to be very useful to reassure these patients: in a study by Mondaini *et al.* [1], 70% of their sample felt reassured after being educated about the normal variation in penile size and was no longer interested in undergoing a surgical procedure for penile enlargement.

Penile shortening is a phenomenon associated with several medical and surgical conditions, such as prostate cancer treated with radical prostatectomy, Peyronie's disease and congenital abnormalities. A significant reduction in penile length was recorded 3 months after radical retropubic prostatectomy [10], although the aetiology is not clear. A statistically significant decrease in penile length was also found in men treated with hormonal suppression plus radiation [11]. One of the most common causes of penile shortening is represented by Peyronie's disease, an acquired penile deformity of the erect penis, caused by fibrous plaque. Both the natural history of the disease and the scarring process after surgical repair can cause a decrease in penile length [12]. Short penis can also be congenital, as a result of embryonic or developmental defects. Lastly, sometimes the shortness of the penis is the result of the so-called 'hidden penis' [13], a condition caused by obesity, aging with an overlying fold of abdominal fat and skin, and a shortage of penile skin from chronic inflammation or an aggressive circumcision.

NON-INVASIVE METHODS OF PENILE LENGTHENING: A NEW PERSPECTIVE

VACUUM DEVICE

Vacuum devices are used as a treatment for erectile dysfunction. A recent study assessed the long-term effect of repeated vacuum treatment for penile elongation and concluded that there was no significant physical change after 6 months of therapy. Vacuum treatment of the penis was not found to be effective for penile elongation, although it provided some sort of psychological satisfaction for some men [14].

PENILE EXTENDERS

Recently, great attention has been given to penile extenders, non-surgical devices that generate progressive mechanical traction to the penis. Although there are only a few well-conducted studies to assess their efficacy, it seems that these devices can produce an effective and durable lengthening of the penis, in both the flaccid and the stretched states [7]. In 2002, a small study by Colpi *et al.* [15] began to unveil the efficacy of penis-stretching physiotherapy in the 'small penis' treatment, showing a stretched penis augmentation of +1.8 cm (range +0.5 to +3.1 cm) after 4 months of use of a penis-stretcher device called Andropenis (Andromedical, S.L., Madrid, Spain) for at least 6 h/day. A recent prospective study [7] showed that, after 6 months of daily use of the same extender device for ≥4 h/day, there was a significant gain in length, of 2.3 and 1.7 cm for the flaccid and stretched penis, respectively, but no significant change in penile girth was detected. These findings were confirmed by another prospective study conducted by Nikoobakht *et al.* [16], who found a statistically significant increase in length, both for the flaccid and for the stretched state, after 3 months of use of the Golden Erect extender device (Ronas Tajhiz Teb, Tehran, Iran). This study also failed to show any significant change in penile girth, although it suggested the possibility of glans penis enhancement. Treatment with penile extenders is generally reported to be well-tolerated, although longer daily use would probably reduce patients' compliance [6,16], and the patients seem to be happy with the outcome [6]. In conclusion, penile extenders appear to be an effective treatment for patients who complain of 'short penis'. The application of such devices can be recommended in all patients regardless of the penile length, because of the low risk of complications [16].

After promising results in the treatment of short penis, penile extenders have also been used in an attempt to correct the defect associated with Peyronie's disease. The first-line therapy of this disease is usually represented by conservative medical treatment, although there is little evidence that this is effective; alternatively, the surgical option must be considered once the disease has been stabilized [17]. In 2008, a non-controlled pilot study by Aberne and Levine [18] showed a trend toward improvement with intralesional verapamil injections plus penile traction therapy compared with injections alone. Another pilot study [19] suggested prolonged daily external penile traction therapy as a new approach for the non-surgical treatment of Peyronie's disease, with the rationale that chronic traction can cause soft tissue cellular proliferation, and eventually reduce penile curvature. This study actually showed curvature was reduced by 10–45° after 6 months of use of the FastSize Penile extender (FastSize LLC, CA, USA). Stretched flaccid penile length increased 0.5–2.0 cm and erect girth 0.5–1.0 cm. These results, however, were only partially confirmed by a prospective study by Gontero *et al.* [17]. After 6 months of treatment with Andropenis, penile curvature improved only minimally, from an average of 31° to 27°, although a reasonable level of patient satisfaction was obtained: this was probably because of the increased mean stretched (1.3 cm) and flaccid (0.83 cm) penile lengths. The authors, however, explained that the particular selection of patients (stabilized disease, penile curvature <50°, no severe erectile dysfunction) may have led to underestimation of the potential efficacy of the treatment [17].

PENOSCROTAL RINGS

Other devices include penoscrotal rings that, in association with phosphodiesterase-5 inhibitors, might help to augment penile size and maintain erections in men suffering from anxiety [20]. To our knowledge, however, the efficacy of these devices has been described in only two case reports.

TABLE 1 Comparison between surgical and conservative methods of penile lengthening

Reference, year	Type of method	*N*	Mean age (years)	Mean follow-up (months)	Type of disease	Size gain			Side effects
						Flaccid (cm)	Stretched/Erect (cm)	Girth/Diameter (cm)	
Surgical									
Austoni *et al.* [23] 2002	Dissection of suspensory ligament	18	24–47	9	Penile hypoplasia, dysmorphophobia	–	1.5–2.5	–	None serious
Spyropoulos *et al.* [8] 2005	Dissection of suspensory ligament	11	28	–	Penile dysmorphophobia	1.6 (1–2.3) (flaccid stretched)	–	–	None serious
Li *et al.* [24] 2006	Dissection of suspensory ligament	42	39	16	Penile dysmorphophobia, Peyronie's disease, micropenis, penile carcinoma, trauma	1.3 ± 0.9 (flaccid stretched)	–	–	Postoperative wound infection ($n = 4$), wound breakdown ($n = 1$)
Panfilov [25] 2006	Dissection of suspensory ligament	31	33.8	12	Not reported	2.42	–	–	None serious
Perovic and Djordjevic [26] 2000	Penile disassembly with autologous cartilage transplantation	19	29.4	3.3	Erect penis length of 6–10 cm	2–4	–	–	Moderate dorsal penile curvature ($n = 5$)
NON-SURGICAL									
Aghamir *et al.* [14] 2005	Vacuum device	37	24 (18–35)	8	Stretched penis length of <10 cm	–	0.3	–	Penis haematoma ($n = 1$), glans numbness ($n = 1$)
Colpi *et al.* [15] 2002	Penile extender (Andropenis®)	9	26–43	4	Small penis	–	1.8 (0.5–3.1)	–	None reported
Gontero *et al.* [7] 2008	Penile extender (Andropenis®)	15	45.7	6	Penile dysmorphophobia, hypoplastic penis, short penis due to penile surgery	2.3	1.7	0.03	Penile bruising ($n = 1$), temporary penile discoloration ($n = 1$), pain ($n = 1$)
Levine *et al.* [19] 2008	Penile extender (FastSize®)	10	56.4	6	Peyronie's disease	0.5–2 (flaccid stretched)	–	0.5–1	None reported
Gontero *et al.* [17] 2009	Penile extender (Andropenis®)	15	53.33	12	Peyronie's disease	0.83	1.3	No difference	Penile bruising ($n = 2$), itching ($n = 1$)
Nikoobakht *et al.* [16] 2009	Penile extender (Golden Erect®)	23	26.5	3	Short penis	1.7	1.7	No difference	None reported

BOTULINUM TOXIN

A recent study by Shaeer *et al.* [21] proposed injection of botulinum toxin as an alternative to surgery and penile extenders for alleviating penile retraction in patients suffering from short penis as a result of hyperactive retraction reflex. This preliminary report showed that botulinum toxin may have a potential effect in temporarily decreasing penile retractions, as well as improving flaccid length.

PENILE LENGTHENING EXERCISES

In recent years, there have been many advertisements for non-invasive procedures that should increase penile size, taking advantage of the concerns of men with small penises. This is the case for 'penile lengthening exercises', a technique that in spite of the lack of any scientific evidence claims to represent an effective method to permanently stimulate penile lengthening by up to 3 inches (7.5 cm). Although this technique is not supported by any evidence, it is given great attention by patients, attracted by the idea of a non-invasive, low-cost method of having their penis enlarged. By way of example, if we search Google for the combination 'penile lengthening exercise', we can find up to 41 800 results!

DO CONSERVATIVE METHODS PRODUCE PENILE GIRTH ENLARGEMENT?

Several surgical techniques have been perfected to obtain penile girth enlargement. Among conservative methods, it has been claimed that penile extenders can increase penile circumference by 0.6–1 cm/month [22]. It is not clear why these devices should be effective in enhancing penile girth; it has been hypothesized that chronic traction causes soft tissue cellular proliferation with tissue growth in a multiplanar fashion [19]. These findings, however, were not confirmed by a study by Gontero *et al.* [7], who found only negligible changes in penile girth after 6 months of traction therapy. Nikoobakht *et al.* [16] did not find significant changes in proximal penile circumference, either, although a significant difference was found in glans penile circumference. It is interesting, however, that no girth decrease was reported with traction therapy, as one would have instinctively thought.

ARE CONSERVATIVE METHODS LESS EFFECTIVE THAN SURGERY?

No comparative studies have been conducted so far between surgical and conservative methods of penile lengthening. Reviewing the recent literature, however, it would seem that among non-invasive techniques penile extenders represent an effective and durable method of penile lengthening, capable of elongating the penis by an average of 1.5–2.5 cm, with minimal side effects. We should keep in mind, though, that published data on penile extenders are still limited to non-controlled case series. Further comparative studies should be performed to gain more evidence. Table 1 [7,8,14–17,19,23–26] shows the results of the main studies conducted on the techniques of penile lengthening.

CONCLUSIONS

Despite demonstration of a normal-sized penis, a certain proportion of patients still request some sort of procedure to enlarge their 'under-estimated' penis [1]. Surgery, however, is characterized by a high risk of complications and unwanted outcomes, apart from the lack of consensus on indications and surgical techniques used [2]. All those things considered, a non-surgical approach should be attempted for those patients who persist in requesting treatment. Cognitive behavioural therapy can be useful in building confidence for those suffering from dysmorphophobia [6]. As for non-invasive physical treatments, various procedures have been attempted – vacuum devices, penile extenders, penoscrotal rings and botulinum toxin. Among these conservative methods of penile lengthening, penile traction devices are the technique for which the efficacy is supported by some scientific evidence. This is mainly generated by pilot studies with a prospective non-comparative design and further studies are needed. While the penis can effectively be elongated by an average of 1.5–2.5 cm based on the underlying condition, there is no evidence that the girth can be increased by applying traction forces. Taking into account that surgical methods are not supported by a better scientific background nor have they shown better results, penile traction devices should be proposed as a first-line treatment option for patients seeking a penile lengthening procedure. The same consideration may apply to Peyronie's disease where surgical correction of curvature carries a high risk of patient dissatisfaction because of additional penile shortening. The current evidence suggests that selected cases may benefit from a conservative approach with penile traction devices.

In conclusion, level 4 evidence (according to the Oxford Centre for Evidence-based Medicine) suggests that penile extenders are effective minimally invasive methods of penile lengthening, although further studies, preferably comparative, should be performed to gain more scientific evidence.

CONFLICT OF INTEREST

None declared.

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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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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

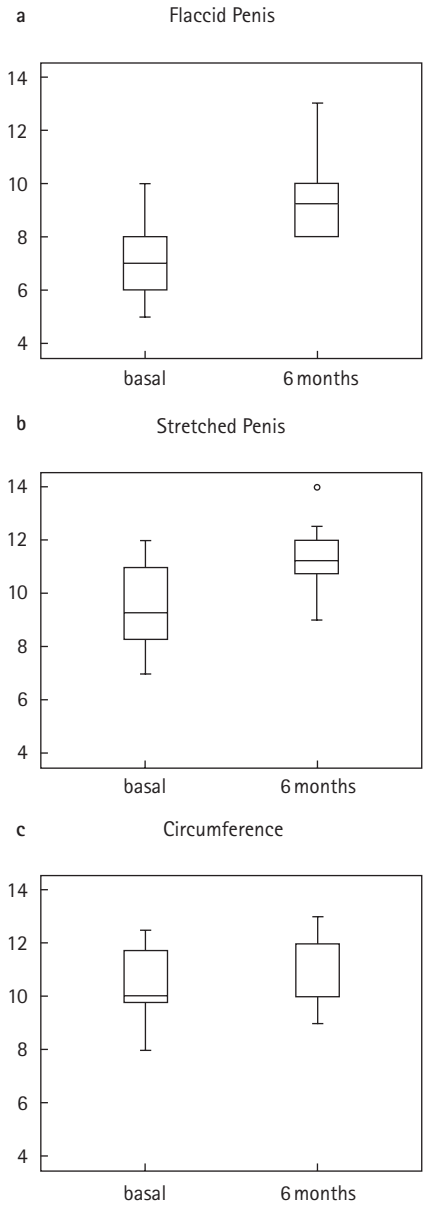
Variable	Mean (SD) or *n* (%)
Age, years	45.7 (11.1)
Penile dimensions, cm	
Flaccid	7.15 (1.43)
Stretched	9.62 (1.56)
Circumference	10.4 (1.34)
Aetiology of short penis	
Dysmorphophobic	12 (57)
After penile surgery	8 (38)
Hypoplastic penis	1 (5)
IIEF EF domain score	
Normal (26–30)	9 (43)
Mild ED (17–25)	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.



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}).

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 (–)

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.