Throughout history penile size has been a matter of great debate among men. In recent years this topic has become a healthcare problem, given the increasing number of patients seeking urological advice for a so called ‘short penis’.

New developments in penile enlargement surgery have generated great interest; no exact data are available about the number of men who apply for these surgical procedures. We only know that in the United States it is estimated that 10,000 men have undergone elective penile lengthening or girth enhancement from 1990 to 1997.

Although there are several techniques for successfully enhancing penile girth, a genuine increase in length cannot be achieved with any present surgical method. Yet, penile deformities are common with this type of surgery leading to the general opinion that a more open view should be directed at conservative methods of penile lengthening. The use of non-invasive options gives the opportunity of widening considerably the indications for a treatment that, in many cases, is merely cosmetic.

With this letter, I’d like to present my personal experience with the AndroPenis device. I will comment on the efficacy and safety of this device in a very selected group of patients, patients with objective penile shortening due to iatrogenic causes.

AndroPenis is a traction device used to enlarge the penis composed of a plastic ring connected to two dynamic metal rods, a plastic support and a silicone band that holds the glans penis in place. The device applies a traction force of 600 to 1500 grams on the penis for continued periods of time. Such traction creates an adaptative reaction of the penile tissue structural components, with an increase in cellular multiplication, which translates in an increase in the total penis length both in erection and flaccidity. The principle of traction is used in plastic surgery for tissue expansion. The regeneration of new tissue is used to cover skin defects, burns, and areas of hair loss. It is also used in orthopaedic surgery to enlarge long bones and phalanges.

My personal experience is based in two clinical circumstances in which a clinically significant penile shortening is present:

1) following the removal of an inflatable penile prosthesis (IPP) after infection: in these cases corporal scarring and fibrosis are usually significant, resulting in a dramatic loss of penile length. This makes subsequent re-implantation extremely difficult and when is possible the final size of the penis do not allow a normal sexual intercourse. Shortening of the penis in these cases is very difficult to manage; only the use of vacuum devices has been reported to have some success in lengthening the penis. We have evaluated the value, in terms of increasing the length of the penis, of 12-hour daily application of a penile extender device post-explantation in 16 men and were compared to a group of patients who underwent IPP re-implantation without the use of the penile stretcher. All 16 men used the device for 4 months before re-implantation surgery. Corporal measurements in the patients treated with the extender, decreased from 0.5-2 cm at re-implantation. In the patients not treated with the penile extender, corporal length decreased from 3.5-5 cm. The treatment was well tolerated; only 2 patients had to decrease the number of hours of use due to mild pain. No other complications were recorded. In my experience the

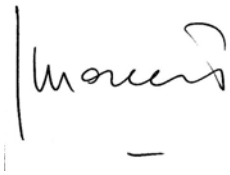
use of the penile extender device on a 8 to 12-hour daily regimen immediately post-explantation of an infected penile prosthesis, appears to minimize loss of penile length, facilitating re-implantation.

b) Penile shortening is also one of the commonest complications of Peyronie's disease surgery. Plicature of the albuginea and ellipse resection techniques cause penile shortening by definition, whereas grafting allows for the preservation of penile length at the cost of a high post-operative erectile dysfunction rate of about 30%. I assessed the value, in terms of increasing the length of the penis, of 8 to 12-hour daily application of a penile extender device after penile surgery for Peyronie's disease (PD). 34 men, ages 54-64 years (mean: 58), underwent penile surgery for PD. In nine patients the surgical technique was incision of the fibrous plaque and grafting, while the rest 25 underwent plication of the albuginea (Essed technique) All patients were treated with a penile extender (Andro-penis device) daily (8 to12 hours of continuous stretching ranging from 900 to 1200 gr.) over a 4-month period. Length of the penis was measured before and after surgery and subsequently after the use of the penile extender. Penile shortening ranged from 0,5 to 4 cm after surgery for PD. Sustained treatment for 4 months with the penile stretching device provided an increase from 1 to 4 cms. The use of the device was very well tolerated, 3 patients had to decrease the number of hours of use due to mild penile pain. No other complications were recorded. In conclusion, the use of a penile extender device on an 8 to 12-hour daily regimen is an effective and safe way to minimize loss of penile length in patients operated for PD.

The objectives of this two clinical studies were (i) to evaluate the potential of the device to cause complications that necessitate surgical or medical intervention (e.g., erosion of the skin, erectile difficulties, orgasmic difficulties, prolonged or intractable pain, patient dissatisfaction, urinary disturbances, etc.); and (ii) to assess the ability of the device to provide increased length of the penis. Both endpoints were successfully accomplished, a highly safe profile was observed together with a proven efficacy of the device. 50 patients were enrolled in both studies, using appropriate inclusion/exclusion criteria, and evaluated the effects of repeated device use.

Each patient was adequately screened using standard methods as having measured penile length prior to use the device. Furthermore, each subject had completed an appropriate sexual function questionnaire, for later comparison to the post-treatment results for evaluation of device performance. Prior to device use, the subjects were provided with detailed patient labelling. We recorded appropriate data during the study, such as: proper placement of the device, number of hours and days of use, and assessment of device function/anatomical outcome. We also, followed-up he patients after the studies to physically assess for the incidence of any complications, as well as the anatomical placement of the prosthesis in the patients who were secondarily implanted. Lastly, at the end of the follow-up period, each patient was questioned regarding his level of satisfaction with the various qualities of the device (i.e., concealability, ease of use, length in flaccidity, length in erection). This clinical experience was conducted in accordance with the provisions of the IDE regulations regarding the protection of human research subjects (commonly referred to as the "Declarations of Helsinki"), and the data are applicable to the U.S. population and medical practice.

In my opinion, this device represents a technology that provides a clinically meaningful advantage over existing technology leading to a clinical improvement in the management of a very common condition such as post-operative penile shortening which may have a profound effect on quality of life and sexuality. The availability of this device is in the best interest of patients. That is, the device provides a specific health benefit, and meets the need of a well-defined patient population.



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