1. Introduction:
Form and size of the penis affect male self-image and self-confidence 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 penis extensor.
The collected baseline data included the measurement of length and circumference of the penis both in flaccid and 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.

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.

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

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.

<table>
<thead>
<tr>
<th>Penile size</th>
<th>Length of flaccid (cm)</th>
<th>Perimeter of flaccid (cm)</th>
<th>Length of erect (cm)</th>
<th>Perimeter of erect (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>7.1±1.5</td>
<td>6.3±1.3</td>
<td>9.3±2.3</td>
<td>8.1±1.7</td>
</tr>
<tr>
<td>After three-month</td>
<td>9.2±2.0*</td>
<td>8.1±1.2*</td>
<td>12.3±1.9*</td>
<td>10.0±1.9*</td>
</tr>
</tbody>
</table>

*compared with base line, P<0.05.
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 its 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 penile 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.