Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

Dr. S Bandi Mackay Urology
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

Traction applied to penile tissue causing cellular multiplication and reproduction.

Contraindications: Patients with uncontrolled diabetes, genital herpes, sexually transmitted diseases, urethritis and acute cystitis, acute prostatitis, abdominal hernia, dermatitis, testicular cancer, lymphatic cancer, lymphoma, paraplegics and quadriplegics.

Dr. S Bandi Mackay Urology
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

Study Design

Inclusion criteria
Age between 40 and 70 years
Peyronie’s disease reported for more than one year, with an ultrasonographically demonstrated fibrotic plaque (stabilized disease)
Patients with ED, defined by IIEF ED domain score <21

Dr. S Bandi Mackay Urology
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

Study Design

Exclusion criteria:
Severe CVD, which according to the Princeton criteria is included in the recommendations to patients to refrain sexual intercourse.

*Presence of bleeding disorder and/or use of anticoagulants*

*Concurrent use of nitrates or recent myocardial infarction.*

Dr. S Bandi Mackay Urology
Methodology

- Subjects studied 5 times - baseline, months 1, 2, 3 and at the end of the study (month 6).
- At first visit, we assessed sexual and medical history, physical examination, baseline blood pressure and heart rate, penile duplex ultrasonography, and a photograph of the erect penis. All patients completed the IIEF-5 score and had an educational course on the use of the extender.
- At visits 1, 2 and 3 months, all patients completed the IIEF-5 score and had a physical exam.
- Education followed regarding technical questions. The procedure of visit 1 was repeated at the end of the study at 6 months.
- Prior the study each subject signed a written consent form, approved by an Ethics committee.
**Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial**

<table>
<thead>
<tr>
<th>Question</th>
<th>Very low</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
<th>Very high</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do you rate your confidence that you could get an keep an erection?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When you had erections with sexual stimulation, how often were your erections hard enough for penetration?</td>
<td>Never or almost never</td>
<td>A few times</td>
<td>Sometimes</td>
<td>Most times</td>
<td>Almost always or always</td>
</tr>
<tr>
<td>During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?</td>
<td>Never or almost never</td>
<td>A few times</td>
<td>Sometimes</td>
<td>Most times</td>
<td>Almost always or always</td>
</tr>
<tr>
<td>During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?</td>
<td>Extremely difficult</td>
<td>Very difficult</td>
<td>Difficult</td>
<td>Slightly difficult</td>
<td>Not difficult</td>
</tr>
<tr>
<td>When you attempted sexual intercourse, how often was it satisfactory for you?</td>
<td>Never or almost never</td>
<td>A few times</td>
<td>Sometimes</td>
<td>Most times</td>
<td>Almost always or always</td>
</tr>
</tbody>
</table>
COMPONENTS (fig. 1): 1 plastic base ring, 2 metal axis, 3 Threaded bar, 4 threaded adjustable rod, 5 metal rod, 6 screw, 7 spring, 8 screw to secure the spring, 9 large 4cm rod (1.6”), 10 medium 2 cm rod (0.8”), 11 small 0.5 cm rod (0.2”), 12 smallest rod, 0.3 cm (0.1”), 13 upper plastic support, 14 silicone band, 15 protective cushion (andro-top).
The treatment consists of 2 periods:

An **adaptation period**, lasting 15 days.

An **evolution period**, consisting of 3 separate phases:

**Initial evolution phase** (1st and 2nd month), **Intermediate phase** (3rd and 4th month) and **Final evolution phase**, which begins in the 5th month.

Any deviation from the treatment program could alter the results achieved.
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

DEVICE SIZE

<table>
<thead>
<tr>
<th>Adaptation period</th>
<th>Daily duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>First 5 days Initial size</td>
<td>3 hours</td>
</tr>
<tr>
<td>Day 6 - 10 Add a small 0.5cm rod (piece 11).</td>
<td>6 hours</td>
</tr>
<tr>
<td>Day 11 - 15 Add a small 0.5cm rod (piece 11).</td>
<td>6-8 hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evolution period</th>
<th>Daily duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st and 2nd month Add a small 0.5cm rod (piece 11) every 7 days</td>
<td>6-9 hours</td>
</tr>
<tr>
<td>3rd and 4th month Add a small 0.5cm rod (piece 11) every 10 days</td>
<td>6-9 hours</td>
</tr>
<tr>
<td>From the 5th month Add a small 0.5cm rod (piece 11) every 15 days</td>
<td>6-9 hours</td>
</tr>
</tbody>
</table>

Note: for your own comfort, from the 5th month onward, it is possible to first add a 0.3 cm rod (piece 12) and a few days later change it for a 0.5cm rod (piece 11) to make the traction more progressive.

It is recommended locating the device in the upwards position one day, one side the following day and the other side the next day. Every 2 hours the device needs to be removed for a few minutes to allow the tissues to relax. After the 5th month, this rest period should be observed every 1.5 hours.

Dr. S Bandi Mackay Urology
Do not use **Andropenis®**: 

while sleeping  
while partaking in strenuous physical activity or sport  
while under the effects of recreational drugs or alcohol  
if you have an ulcer, sexual transmitted disease or wound in the genital area  

**Maintain strict hygiene standards whilst using the device.**  

**Remove the device to urinate or defecate.**  

If you have an erection whilst using the device, do not worry: it will simply feel a little tighter.  

If you see white areas on the glans, do not worry: These are areas of oedema or fluid retention possibly due to the loop being too tight. Massage the area and they will disappear.  

If you develop white spots on your glans, it is necessary to see a doctor, since you may have developed a fungal infection. Personal hygiene is very important. Keep the device clean.  

**IMPORTANT: The use of medication for stimulating hair growth or make your hair stronger, medication to treat depression, sleeping pills, sedatives and tranquillizers can significantly diminish the effectiveness of Andropenis®.**
Andropenis® is based on the principle of traction which results in the expansion of human tissue by gradual stretching, and then allowing the body to remodel itself naturally.

It has been widely used in cosmetic surgery to repair and cover skin defects such as burns and large wound areas; and in orthopaedic surgery to enlarge the diaphysis of bones and phalanges (Bryant’s traction, Buck’s traction in hip fractures, Dunlop’s traction in humeral fractures and Russell’s traction). In ancient cultures the principle of traction was also applied to enlarge different parts of the body, like the neck of the Giraffe women of the Paduang tribe in Burma, or the lips and ears of other African and Amazonian tribes.
Aims of study

To provide:

1) New data on the proposed novel treatment of patients with Peyronie’s disease.
2) Data on the necessity of using the extender in this specific patient population by urologists.
3) Essential data on the market-potential in this group of patients.
4) To establish any working or practical problems with the device with continuous long term usage.
5) Insight into any problems or side effects in patients with continuous usage.

Dr. S Bandi Mackay Urology
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

### RESULTS

<table>
<thead>
<tr>
<th>Ages</th>
<th>Numbers</th>
<th>LEr4 minus LEr0</th>
<th>LFl4 minus LFl0</th>
<th>PEr4 minus PEr0</th>
<th>PFl4 minus PFl0</th>
</tr>
</thead>
<tbody>
<tr>
<td>40-49</td>
<td>3</td>
<td>3.10cms</td>
<td>3.30cms</td>
<td>5.97cms(+d 1.90cms)</td>
<td>5.07cms(+d 1.60cms)</td>
</tr>
<tr>
<td>50-59</td>
<td>9</td>
<td>2.88cms</td>
<td>2.84cms</td>
<td>5.02cms(+d 1.60cms)</td>
<td>5.26cms(+d 1.67cms)</td>
</tr>
<tr>
<td>60-69</td>
<td>8</td>
<td>2.65cms</td>
<td>2.625cms</td>
<td>3.03cms(+d 0.96cms)</td>
<td>3.83cms(+d 1.22cms)</td>
</tr>
</tbody>
</table>

L measurements  tabled as length in cms from base to tip of penis
P measurements tabled as perimeter in cms at base of penis
D measurements using PI value of 3.14159

Dr. S Bandi Mackay Urology
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

40-49 AGE GROUP

MONTHS 0, 1, 2, 3 AND 6

DEGREES

PATIENT 20
PATIENT 9
PATIENT 6

Dr. S Bandi Mackay Urology
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

50-59 AGE GROUP

MONTHS 0, 1, 2, 3, AND 6

DEGREES

PATIENT 17
PATIENT 16
PATIENT 15
PATIENT 14
PATIENT 12
PATIENT 10
PATIENT 7
PATIENT 5
PATIENT 3

Dr. S Bandi Mackay Urology
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

AGE GROUP 60-69

MONTHS 0, 1, 2, 3 AND 6

DEGREES

PATIENT 19
PATIENT 18
PATIENT 13
PATIENT 11
PATIENT 8
PATIENT 4
PATIENT 2
PATIENT 1
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

United Colours of Bend a ton……..

Dr. S Bandi Mackay Urology
Penile Lengthening After The Application Of Andro-Penis Penile Extender In Patients With Peyronie’s Disease: 6 Month Trial

CONCLUSIONS 1

• The maximum increase in length was noted in the 40-49 age group with 3.1cm increase in the erect state and 3.3cms in the flaccid state at 6 months.

• The maximum increase in girth was noted in the 40-49 age group with 5.97cms(+d 1.90cms) increase in the erect state and in the 50-59 age group with 5.26cms(+d 1.67cms) increase in the flaccid state at 6 months.

• The greatest improvement in penile deviation was achieved in Patient 8 aged 61 with a 40 degree improvement with 9 hour usage daily in the Evolution period over 6 months.

• The greatest impediment to recruitment was the period of usage per day which resulted in only 3 patients recruited in the 40-49 age group who were all stay at home dads.
CONCLUSIONS 2

• Some patients developed a rash from frequent use and there were some issues with the silicone bands snapping after a few months but the new wider silicone bands (Androcomfort) seems to have addressed this problem.

• The Andropenis Gold device is available in Australia at a cost of Aus $249.95 online from www.andropenis.com.au and the Andropenis Gold Premium with 6 Androcomfort bands extra for $324.95.

• A new study using the device post operatively in patients undergoing radical prostatectomy for prostate cancer as part of penile rehabilitation to prevent loss of penile length is commencing shortly in Greenslopes Hospital.

Dr. S Bandi Mackay Urology