

Effects on Penile Size with Penile Extensor by Traction Force

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1. INTRODUCTION:

The penile size and form affect males' self-image and self-confidence. Penile curvature and Peyronie's disease are usually deformities in clinical work, which also influence erectile function and lead to erectile dysfunction. Surgery and medicines to change penile size could not make males satisfied. Penile extensor produced in Spain (Andromedical) could tract the penis and make it larger. We applied the device to treat 30 cases in clinical trial from Jun 30 to Sept 30, 2005. And the efficacy and safety about the extensor were studied.

2. CLINICAL DATA AND METHODS

2.1 Study design

The clinic trial was prospective and self-control to follow up the penile size and form through using the penile extensor. The base line data were collected which included penile length and circumference in flaccid and erect state, and subjects' psychology state were also evaluated. During this period, the subjects were taught to master how to put on the extensor over 9 h daily. During the 1st month, the periodicity of the medical controls were weekly. During the 2nd and 3rd month, visits were followed every two weeks. According to GCP, the trial was going through.

2.2 Subjects

2.2.1 Indications

The subjects' age was between 16-70 years old, whose penis could be lengthened without surgery. Their penile curvature could be treated without surgery. Their penis needed postoperative treatment after penis-reconstructing surgery, penis-lengthening surgery, associated with any form of penile surgery requiring control of postoperative scar retraction. All patients signed informed consent to certify that he has been informed correctly about how to use the device.

2.2.2 Contraindications

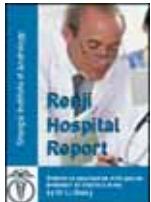
The device should not be used until any penile wounds, lacerations or infected zones have completely healed. And it should not be used by patients with penile tumor, chronic disorders affecting blood circulation, oxygenation and regeneration of tissues (advanced or uncontrolled diabetes, liver cirrhosis, advanced respiratory failure). The subjects suffered from priapism, uncontrolled psychology disorders, diabetes, heart diseases and hand disorders not to use the device.

2.3 Efficacy evaluation

They should use the device over 9 hours daily. According to the medical protocol, lengths are 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 at the mentioned angle, without pressing upon the area. The perimeters or circumferences in turn should be measured midway along the length of the penis. Measurements should first be made in the flaccid state and then erect induced by sexual stimulation. The values should be registered on the treatment evaluation sheet. If the penile length and perimeter of subjects increased over 1 cm in flaccid and erect state in three months, the treatment was thought as efficacy. If not, it would be not effective.

2.4 Safety evaluation

In every visits, the penile discomfort, pain, foreskin edema should be paid attention to. The Penile Extensor should not be used: In the presence of pain, numbness or paleness of the glans. In such situations the device should be removed immediately. During physiological activities such as defecation, micturition, sports, sexual intercourse or any other potentially hazardous physical activities involving the risk of falls. Following excess consumption of alcohol, analgesics or euphorizing agents.



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2.5 Statistics

SAS (Statistical Analysis System software) had been applied to compare different data on penile length and perimeter between base line and the third month. The means and standard deviations were calculated. The differences between two means were evaluated using t-test. If $P < 0.05$, the difference is statistically significant.

3. RESULTS

30 males were recruited and applied penile extensor to tract penis. Their ages was 16-40 years old in whom 26 males wanted to make penis larger and 4 cases were applied to tract penis after penile curvature surgery. 23 males had finished the clinical trial, while 7 cases were out. 6 cases were out because they did not like to put on over 9 hours daily after 1-2 month treatment. One case was out because of penile discomfort. In trial, no case was discovered being penile pain, ulcer, foreskin edema. No case reported erectile dysfunction and urination dysfunction. 23 cases were effective after three-month treatment and the effective rate was 100%.

Tab 1 Penile size in different state before and after three-month treatment

Penile size	Length of flaccid (cm)	Perimeter of flaccid (cm)	Length of erect (cm)	Perimeter of erect (cm)
Base line	7.1-1.5	6.3±1.3	9.3±2.3	8.1±1.7
After three-month	9.2±2.0*	8.1±1.2*	12.3-1.9*	10.0±1.9*

*compared with base line, $P < 0.05$.

4. Discussion

The penile size and form is important male sexual characteristics which affects male self-confidence and self-evaluation. Though penile size does not directly influence the female sexual orgasm?some male pay too much to their penile size. If they thought their penis were not enough large, they did not

make love with female and even take part in swimming in public. Now, no standard surgery to length the penis and no medicine to control the penile size. The principle of traction is commonly used in plastic surgery in tissue expansion procedures, where skin is generated for use in skin grafts to cover cutaneous defects, burns or bald zones. It is also used in bone distraction for lengthening 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, such as the neck in the Paduang tribe in Burma ("giraffe-women"), or the lips or ears in African or Amazon tribes - with the fitting of prostheses or weights to achieve the desired lengthening.

The Extensor produces 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 gives rise to an adaptive reaction on the part of the penis tissue structures, with an increase in cell multiplication of the vesicular vessels, urethra, corpus cavernosum and spongy tissue; 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 have invented the penile extensor to tract penis, which had been used in Europe, Japan and North American. We used the device to tract the penis in 30 cases. 23 of 30 cases have finished the clinical trial after three-month treatment and the effective rate was 100%. 4 cases who applied to tract penis after penile curvature surgery were also effective. In the clinical trial, 7 cases were out. 6 cases were out because they did not like to put on over 9 hours daily after 1-2 month treatment. One case was out because of penile discomfort. After penile traction, penile length had increased, 2.1 cm in flaccid and 2.0 cm in erect state. The penile perimeter also increased, 1.8 cm in flaccid and 1.9 cm in erect. The effect of traction was related to the time to put on. There was no effect if subjects could not insist on using. In the first week during clinic trial, penile discomfort appeared. But the discomfort disappeared step by step. During trial, there were no adverse effect appeared. In the future, many men would apply the device to tract their penis.

4. CONCLUSION

Penile extensor can tract the penis and make it larger in length and perimeter. And it was safe and no adverse effects .