Jes-Extender®

INDEX to MEDICAL DOSSIER

1 · DESCRIPTION (1/4)

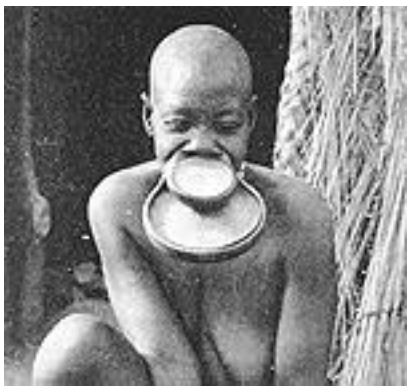
The JES Extender® is a medical device that uses the principle of traction to treat penile hypoplasia and to correct penile curvature.

It has been developed by Danamedic Aps. (Denmark).

In assessing the potential of this method various different concepts were evaluated:

A. ***Observation and analysis of African tribal practices***, where elongation of different body parts are a traditional ritual. For hundreds of years lips, necks, penises, ear lobes and noses have been elongated by methods of long-term traction.



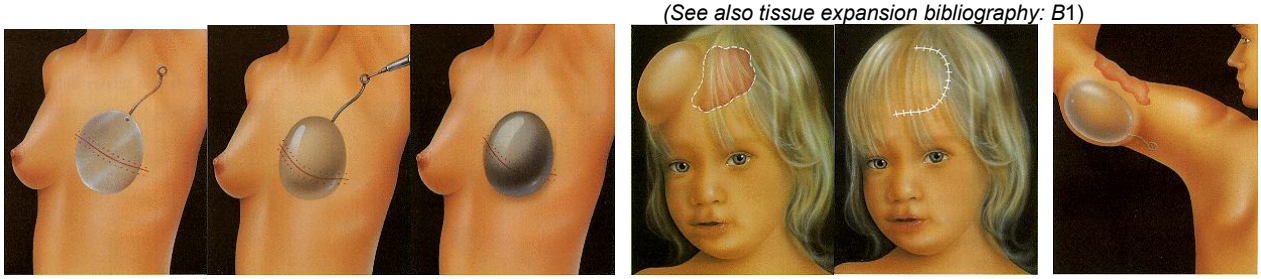



B. ***Medical and scientific antecedents*** of different uses of traction have been extensively described and published in scientific journals and are now becoming accepted as feasible by the medical community. The effective use of traction is based in the capability of tissue components to respond when different stimuli are applied. Such stimuli include continuous traction that promotes an increase in the total number of cells due to cellular proliferation of skin and other tissue components.

B1. ***Tissue expansion:*** Tissue expanders are used in reconstructive plastic surgery, permitting reconstruction of wide areas of tissue-cover defects of most body areas, including:

1 Breast reconstruction after mastectomy
2 Abdominal wall reconstruction after trauma, infection or surgical procedures.
3 Head and neck reconstruction (facial, nose, ear, scalp, brow)

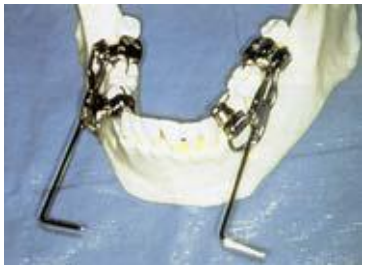
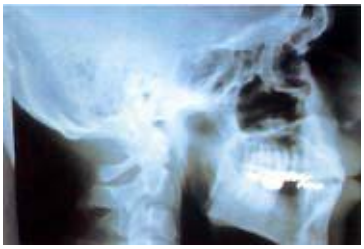
(See also tissue expansion bibliography: B1)



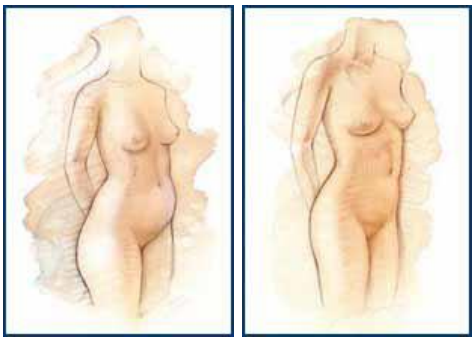
1 · DESCRIPTION (2/4)

B2. ***Tissue Extension:*** (With and without interruption of cortical bone). Tissue extending devices have been used to elongate arms, fingers and legs in Orthopedic Surgery since Ilizavov described this technique in 1969. Small tissue extension devices are also widely used in cranio-maxillary-facial surgery to treat mandibular and maxillary distortion or asymmetry as well as for craniosynostosis and facial adjustments.

(See also tissue extension bibliography)


B3. ***Liposuction:*** This surgical technique first described by Illouz (1982) and later modified by Gasparotti (1990) has demonstrated the enormous elastic capability of the skin, after large lipodystrophic volumes have been aspirated from subcutaneous layers of abdomen, legs, neck etc.



B4. ***Other surgical techniques*** where final result depends on tissue reaction, including:

1 Reduction mammoplasty with vertical scar described by Lejour.

2 Non-excisional eyelid adjustment surgery using CO2 or Erbium laser resurfacing.

1 · DESCRIPTION (3/4)

The JES Extender® consists of:

1. One plastic base ring, with depression for the urethra. This must be positioned around the base of the penis and with the depression located immediately below the urethra.

2. One distal support of surgical quality plastic and silicone which secures the glans [penis head] while not impairing its blood supply.

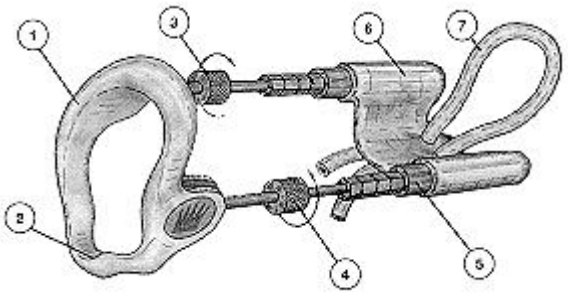
3. Two metallic side bars (axes). These rigidly maintain the selected distance between the base ring and the distal support, and can be altered in length by rotational adjustments.
   A spring security system permits continuous traction.

Using the device a variable degree of traction is thus produced and transmitted with its force vector acting directly along the penile axis. This origin and direction of the vector permits maximum tissue stimulation and substantially lower complications potential. (Other devices, such as weight-applying implements, have a force vector outside the penile axis so that traction is not transmitted continuously along the penile axis. More distal areas will thus be subject to greater traction, possibly impairing blood supply to the glans, and also interfering with other forces such as gravity, inertia and centrifugal force, that can cause potential complications).

• ***Penis elongation*** capability depends on total time of usage, and may differ between patients. To obtain maximum results, **the JES Extender®** must be used for at least 8 to 10 hours daily and over a minimum period of three months.

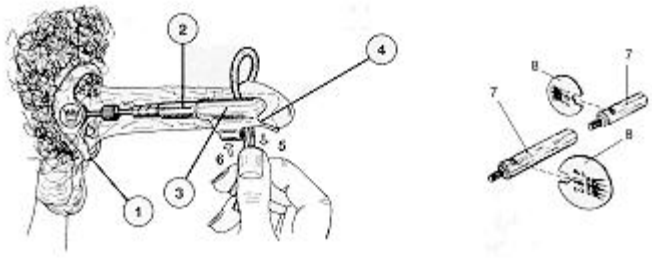
• To treat ***Penile curvature*** a longer period is required, usually up to about 6 months, also wearing the device for 8 to 10 hours daily.

1 · DESCRIPTION (4/4)



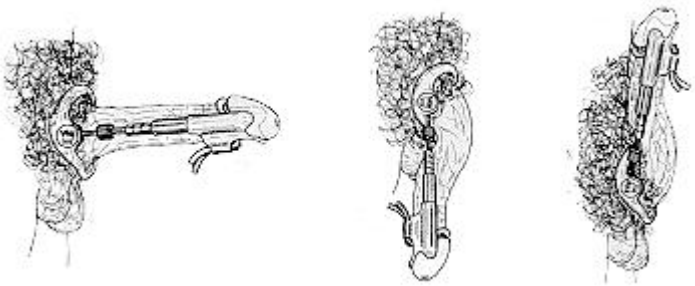
The JES Extender®

1 – Anillo basal
2 – Depresión para la uretra
3 – Eje roscado sentido horario
4 – Eje roscado sentido antihorario
5 – Sistema dinamométrico
6 – Soporte distal
7 – Tubo de silicona



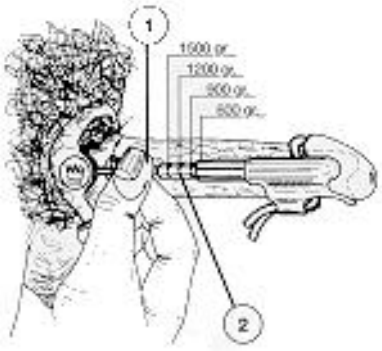
Ajdjustement

1 – Anillo basal
2 – Ejes metálicos
3 – Soporte distal
4 – Orificios del soporte distal
5 – Extremo del tubo de silicona
6 – Canales de sujección
7 – Piezas de metal adicionales
8 – Llaves de utillaje



Possibilities for Use

1 – Posición para uso sin ropa
2 – Posición Inferior
3 – Posición Superior



Instructions of Adjust

1 – Ejes roscados
2 – Indicadores dinamométricos

Fuerza:
1500 g
1200 g
900 g
600 g

2 · ACTION AND PROPERTIES

Action

The mechanism of action of **The JES Extender®** relies upon the application of traction with the force vector directed along the same penile axis over an extended period of time.

This continuous traction stimulates adaptation of all penis tissue components and an increase in cellular multiplicity.
The number of cells of vascular vessels, urethra, corpus cavernosum and spongiosum, cutaneous cover, muscle and fasciae are all subject to proliferation.

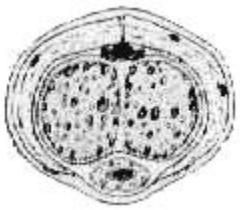


Diagram: Penis cross-section

(Latest studies indicate that traction can cause an increase in cellular division (mitosis) due to local suppression of an inhibitor of cellular multiplication.
At the present time numerous studies have been initiated to evaluate this concept.)

Effectivity

Permanent and definitive effects obtained:

1. Microscopic:
   - An increase in the total number of cells.

2. Macroscopic:
   - An increase in the overall length of the penis.
   - Adjustment of penile curvatures (if present).
   - No change in penis shaft diameter. (Remains undiminished).
   - Erectile and orgasmic capacities are not affected.
   - Elongation obtained is (indefinitely) permanent.

(See Appendix 5: Clinical studies)

The JES Extender® is 100 % effective:

• All users who have followed the Instruction Manual have obtained an increase in penis length. Length gained ranged from 1.5 cm. to 5 cm. after 4 months.

• All users that have followed the Instruction Manual have undergone improvement of existing penile curvature. Improvement degree has ranged from 50% to 90% correction (straightening).

• All patients who have used **the Jes-Extender®** as post-operative therapy following surgical lengthening of the penis obtained a more rapid increase of penis length. This is possibly due to traction also stimulating tissues that are in the initial phases of scarring. By combining surgical intervention with **the JES.Extender®**, the maximum effect was obtained, with a lengthening that varied from 4 cm. to 11cm.

(These results are most impressive since no other method (surgical or mechanical) can offer equivalent results in respect of lengthening and curvature correction).

3 · INDICATIONS

The use of **The JES Extender®** is indicated in:

1. **Treatment of clinical/objective congenitally subnormal penis size.**
   (Functional)

2. **Treatment of subjective congenitally subnormal penis size.**
   (Aesthetic)

3. **Treatment of acquired decrease in penis size.**
   (Shortening due to scar retraction or other connective tissue disorders and pathologies such as Peyronie's disease, etc.)

4. **Treatment of abnormal penile curvature.**
   (Bending of the penis)

5. **Post-surgical therapy after penile lengthening surgery**
   (To enhance effects of Suspensory Ligament Release Surgery).

6. **Post-surgical therapy following any penile surgery with high risk of post-operative scar retraction:**
   · Skin grafts, dermal fat grafts, flaps and pedicles.
   · Hypospadias and epispadias.
   · Surgical correction of curvature.

   (Active penis extension methods during the post-operative scarring period reduce the incidence of subsequent deformities and improve overall results.)

The JES Extender® has been proven in clinical studies conducted since May, 1994 for Danamedic Aps., and is now widely accepted by Urologists and Plastic Surgeons as:

- A non-surgical medical method of correcting penile curvature
- A non-surgical medical method of penis elongation
- A post-surgical therapy for preventing scar contraction

4 · NORMS OF CORRECT USE (1/2)

How to use **The JES Extender®**

The JES Extender® can be used:

A. As a non-surgical method:

- To increase penis length
- To correct abnormal penile curvature

B. As an adjuvant post-operative treatment:

- To enhance the effects of penis-lengthening surgery.
- To reduce post-operative scar formation and retraction during the healing period.

It is imperative that the user follows the *Instruction Manual* that comes with each **Jes-Extender®**. The manual explains, in simple terms, how to assemble, position, adjust, disassemble, and maintain the device.
To begin treatment the user must be able to mount and disassemble **The Jes-Extender®** by himself.

Supervising doctors must facilitate progress by supplying all additional information the patient requires.

A demonstration video **The JES Extender®** is available. (10 min)

The Technical Department of SURGEST MEDICAL (Tel: +34 3 589 53 50) is available for questions concerning the Jes-Extender®, during office hours.

4 · NORMS OF CORRECT USE (2/2)

DESCRIPTION (fig.1)

The Jes-Extender® consists of a plastic base ring with a depression for the urethra. The ring is positioned around the base of the penis. Two metallic axes, one rotatable clockwise the other anti-clockwise, are fixed to the base ring. Within both metallic axes, spring systems regulate the degree of stretch. The distal ends of the axes are coupled to the penis support cradle upon which the head of the penis is retained by means of a tube of surgical quality silicone. Therapy with **The Jes-Extender®** requires consistent use for an initial period that may vary from one to two weeks. Both the degree of traction and the period of use are increased steadily, beginning with periods of 2 to 6 hours (divided into periods each of 30 to 60 minutes) and at a traction of 600 gr. Therapy sessions increase progressively, eventually to attain 8-10 hours daily at a traction of 900 to 1200g. Used in this way **The Jes-Extender®** will gradually modify the penis tissues.

MOUNTING (fig.2)

The Jes-Extender® is positioned by locating the ring around the base of the penis with both axes parallel with the shaft of the penis, one on each side, and the head of the penis resting on top of the plastic support. The silicone tube is looped over and around the penis head, ideally in the sulcus (groove) between it and the shaft. The ends of the tube, passing through the existing holes in the plastic support, should be adjusted (by pulling through, one way or the other) such that the snugly fitting loop maintains the head of the penis in position. In men who have not been circumcised, the tube should be located immediately behind the base of the glans with the foreskin, in its drawn-forward position, protecting the glans. (Fig. 3): Additional metal pieces can be coupled, by means of the use of the mounting keys, in order to increase the length of the axes.

ADJUSTMENT (fig.4)

When the device is correctly positioned and the penis comfortably fixed, the force of traction can be easily regulated from 600g. up to 1500g. merely by rotating the two axis bars. The degree of traction is shown by the measurements appearing on the axes. These are, respectively, at 600g., 900g., 1200g. and 1500g. The recommended starting traction is about 900-1200g, but can vary with each individual. Warning signs of too great a degree of traction, - discomfort, pain, loss of colour, and shrinkage of the head of the penis, should not be experienced when the device is being properly used.
The degree of traction is directly proportional to the length of the axis bars. The greater their length the greater will be the traction.
It is important to use the foam protector in cases of marked sensitivity in the balano-preputial sulcus (groove) behind the glans.

The Jes-Extender® should be washed daily with water and bland soap. A solution of Clorexidin (5%) can be used for disinfection. Alternate use of the two silicone tubes is recommended as, in order best to maintain penis position, they should be totally dry.

5 · MEDICAL FOLLOW-UP PROTOCOL (1/4)

Medical supervision of:
- Penis lengthening without surgery
- Penis curvature correction without surgery
- Post-surgical treatment in penile lengthening and other surgery.

1st CONSULTATION:

How does the patient request penis lengthening?

Patients frequently enquire, sometimes jokingly, what facilities are available for increasing penis size. Social criteria commonly surround such enquiries with shyness and reticence. Men therefore tend to hope that the doctor will understand their concern, and are grateful when information is provided in a serious, professional, easy to understand manner and in total confidence. A good doctor-patient relationship is beneficial in all medical treatment.

Why does the patient request penis lengthening?

There are many possible reasons, but patients whose wishes are suspected of originating from pathological alterations of personality (dysmorphophobia) or unrealistic expectations should be rejected as unsuitable. Aesthetic/plastic surgeons usually have considerable expertise in this kind of patient evaluation.

Many different factors such as cultural stereotypes of masculinity, feminism, publicity, media pressure and environmental concerns etc. may influence the picture. These and other factors may have produced a subjective but distorted valuation of ideal penis size.

Why does the patient request correction of penile curvature?

When functional problems are present and significant, correction of abnormal curvature may be felt necessary.
In patients without functional problems, marked penile curvature can cause psychological problems due to increased insecurity in sexual relationships and a poor self-image.
In patients with a small degree of curvature surgical correction may not always be indicated due to potential risks and potential post-surgical penile shortening. Non-surgical correction may then enable patients to obtain successful results while avoiding these potential risks.

5 - MEDICAL FOLLOW-UP PROTOCOL (2/4)

TREATMENT OPTIONS

Surgical Penile Lengthening

Surgical procedures for penile lengthening have been suitably developed only over the past two decades. Plastic Surgeons and Urologists described how to perform Suspensory Ligament Surgical Release for penile elongation in cases of micropenis long before this, but it was only at the end of 80's that the technique became widespread. Largely this was due to patient pressure from the increasing number of male patients seeking aesthetic penile enhancement.
Surgeons performing this kind of operation require detailed knowledge of the anatomy of the genitourinary region, experienced surgical skills, and must treat all tissues with extreme care.

The major and more frequent potential risks in these procedures follow the sequence:

HemorrageZHematomaZInfectionZTissue (scar) retraction.

So-called 'commercial surgeons' of inadequate training and who obtained their patients from promotional advertising in newspapers and magazines found, in this kind of surgery, a fast way to obtain economic benefits. However, the consequences swiftly included substantial numbers of complications, dissatisfied patients and corresponding claims and law suits.
Penis lengthening surgery was therefore regarded as 'experimental' by orthodox scientific and surgical publications and was viewed with suspicion in most medical/surgical circles.

At the present time, the most recent advances in Urology and Plastic Surgery permit appropriately trained surgeons to offer predictably good results with wide security margins to patients requesting penile lengthening.
The best results are obtained due to many and varied factors including extreme care with hemostasis, pre- and peri-operative antibiotic prophylaxis, the use of aspirated drainage, post-operative immobilization, minimum use of permanent sutures (foreign body reaction) and the use of 'minimally invasive techniques.'

With minimally invasive surgery [MIS] (without extensive dissection, undermining etc.) via short incisions and using fiber-optic endoscopic techniques good results can be achieved because the penile release obtained by surgical section of the suspensory ligament is maximally converted into subsequent penile length increase by using a **post-surgical penis traction device: The Jes-Extender®**, thus avoiding scar tissue retraction during healing in the post-operative period.

This principle has been widely acknowledged in Orthopaedic Surgery since Ilizarov first described his technique for lengthening bones in arms and legs by applying a traction device that sustained the elongation of all tissue components.
(See Appendix 3: Tissue distraction bibliography)

Today, penis-lengthening surgery performed by fully trained specialists is a valid and secure treatment option for patients requesting penis enhancement. When MIS techniques are employed in combination with post-operative use of **The Jes-Extender®**, overall results are conspicuously improved while potential risks are reduced.
(See Appendix 4: Penile surgery bibliography)

5 · MEDICAL FOLLOW-UP PROTOCOL (3/4)

TREATMENT OPTIONS

Y Non-Surgical Penile Lengthening

The JES Extender®, was first developed by Dr. Jörn Ege Siana to control and minimise tissue retraction during post-operative healing following penis surgery.
Later he began clinical trials on the use of **The JES Extender®** in healthy patients that had not received surgery in order to assess the value of traction as a technique for non-surgical penile lengthening. The conclusions were that continuous traction succeeded in inducing permanent penis lengthening without secondary adverse effects.
(See Appendix 5: Clinical studies)
For patients requesting non-surgical lengthening the following protocol is recommended:

NON-SURGICAL PENILE LENGTHENING MEDICAL PROTOCOL

• ***Detailed Clinical Evaluation***, including:
- · Vascular data and history (local and general)
- · Dermatological data and history (local and general).

• ***Measurement:*** There are various techniques for penis measurement. It is important that measurements are always made by the same person, using the same techniques and with the same implements; measurements of the same penis made by different person can vary considerably.
It is recommended that the patient himself, once properly taught, should take and record his own measurements.
Measurements should be made using flexible, tailor-type metric ribbon. Use of metallic metric ribbons or rigid metric rules is not recommended.

Three measurements are recommended:

a. In the flaccid state without traction: the end (0 cm.) of the metric ribbon is positioned at the point where the dorsal aspect of the penis meets the anterior abdominal wall (Point x), using slight pressure against the pubic bone area. (Exactly the same technique of positioning is used in all successive measurements). The total length of the penis from this point to the tip of the glans is measured, carefully ensuring that there is no traction on either the penis or the measuring ribbon.

b. In the flaccid state with traction: the penis is extended by pulling with the fingers gripping the balano-preputial sulcus. Traction needs to be firm but painless. (The same traction is used in all successive measurements).

c. In the erect state: as in (a.) above, the zero end of the ribbon is located at Point x and the total distance to the tip of the penis measured while the penis is erect. (This measurement should be made by the patient at home and should be recorded on forms provided).

• ***Assembly Test***: The doctor must demonstrate to the patient how **The Jes-Extender®** should be assembled and positioned. The doctor should follow the detailed 'Instruction Manual' that is supplied with **The Jes-Extender®**, and should ensure that the patient can manage both procedures by himself.

• ***Adjusting Test:*** once assembled, **The Jes-Extender®** can be adjusted. Marks on the metallic axes indicate in stages the degree of traction being applied.
During the first two weeks it is recommended that a traction force of 600g is used to start then progressively increased to reach 1200 g. During this period the patient will become familiar with:

· The maximum traction that can be applied (sensitivity may vary from patient to patient).

· Unsuitable fixing methods due to incorrect adjustment, insecure glans fixation, excessive traction, badly positioned device (see ‘Instruction Manual’, Positions 1, 2 and 3), excessive humidity or inadequate drying of the silicone band after cleaning.

MEDICAL FOLLOW-UP TIMING:

First month (weekly):	First assessment:	First Week
	Second assessment:	Second Week
	Third assessment:	Third Week
	Fourth assessment:	Fourth Week
Second month (bi-weekly):	Fifth assessment	Sixth week (Measurement)
	Sixth assessment	Eighth week "
Third month (bi-weekly):	Seventh assessment	Tenth week "
	Eighth assessment	Twelfth week "
Fourth month and on (monthly):	Ninth assessment	Sixteenth week "
	Tenth assessment	Twentieth week "

Follow-up consultations:

Follow-up consultations have the following main objectives:

· To verify that **The JES Extender®** is being used appropriately (without any pain, and using the correct traction).

· To control the lengthening process, obtaining data about length progression in each patient. (Recording measurements is recommended during each consultation after the first month of treatment).

· To offer continuous support to patients and to deal with any questions arising.

Inicio del Tratamiento

A los 6 meses

5 · MEDICAL FOLLOW-UP PROTOCOL (3/4)

TREATMENT OPTIONS

Non-surgical penis curvature correction

The Jes-Extender®, first developed by Danamedic Aps. as a means to control tissue retraction during post-surgical healing, was also tested and found to yield good results in non-surgical penis lengthening.

The use of **The Jes-Extender®** in patients presenting with penis curvature began after these studies. Results were also spectacular, with curvature improvement being observed in between 50% and 90% of all patients studied. This means that patients can anticipate improvement of curvature, in some cases up to 90%, without the need for any surgical procedure and while avoiding all such potential complications as post-operative retraction.

The required period of use of **The JES Extender®** is longer in curvature correction than in simple lengthening. 6 to 8 months for 8 hours daily comprises the minimum treatment period recommended.

It is also recommended closely to follow the protocols described above concerning

- **NON-SURGICAL PENIS LENGTHENING MEDICAL PROTOCOL**
- **MEDICAL FOLLOW-UP TIMING**

and adapting them to the requirements of curvature correction.

(See Appendix 5: Clinical studies)

6 · CONTRA-INDICATIONS AND PRECAUTIONS

The following contra-indications and precautions must be observed:

The JES Extender® should not be used:

· During physiological activities of defecation and micturition, sporting activities, sexual intercourse or any potentially dangerous or strenuous physical activity.

· After consumption of alcohol or ingestion of painkillers or euphoriants.

· During activities in areas where the potential risk of falling exists; the user should take extreme care when climbing stairs, walking on slippery surfaces etc.

· While using or being in the vicinity of machinery, motorized vehicles, bicycles, cooking or manipulating hot objects.

· If, during use, pain or pallor or discoloration of the glans of the penis is experienced, the use of the device should be immediately discontinued.

· In the presence of trauma, pain, skin lacerations or infected areas in or on the penis, **The Jes-Extender®** should not be used until complete resolution of the lesions has been achieved.

· In chronic diseases that could impair blood circulation, oxygenation and regeneration of tissues (advanced diabetes, cirrhosis, respiratory insufficiency etc.).

It is strongly recommended that in any case of doubt skilled medical advice should be sought.

7 · MAINTENANCE AND CLEANING

El **Jes-Extender®** debe ser lavado diariamente con agua y jabón neutro. Una solución de Clorexidina al 5% puede ser usada para su desinfección. Se recomienda alternar la utilización de los dos tubos de silicona, ya que para asegurar la fijación deben estar totalmente secos.

8 · MATERIALS USED

- Silicone Band Type: WMQ, USP 21-4, PA/HP/exp3/(82)57/1984.
- Plastic Material: POM (Hostaform), C 2521 G.
- Metallic Material: CuZnS9Pb3 - W.no.2.0401.
- Stain Steel Springs:: Din 17224 - W. no .4310.
- Foam: Brand PUR.
- Plastic bags: without PVC.
- Wood: Mahogany
- Recycled Paper (Instruction Manual)

9 · PRESENTATION

The JES Extender® is supplied and shipped protected in a suitable packing.
Manufacture of the packaging uses only recycled materials.

The box contains: 1 complete **JES Extender®**
1 complete Instruction Manual (in Spanish and English)
4 (four) additional metallic, lengthening pieces for the axes
1 extra silicone band
1 protective foam
2 (two) adjusting keys
1 certificate of warranty

10 · WARRANTY AND CLASSIFICATION

WARRANTY:

The Jes-Extender® is covered by warranty for a period of 12 months under the following conditions:

The warranty covers claims, which result from defects in material or workmanship. If a defect is discovered **The Jes-Extender®** must be returned to ***Surgest Medical*** together with the completed warranty card.

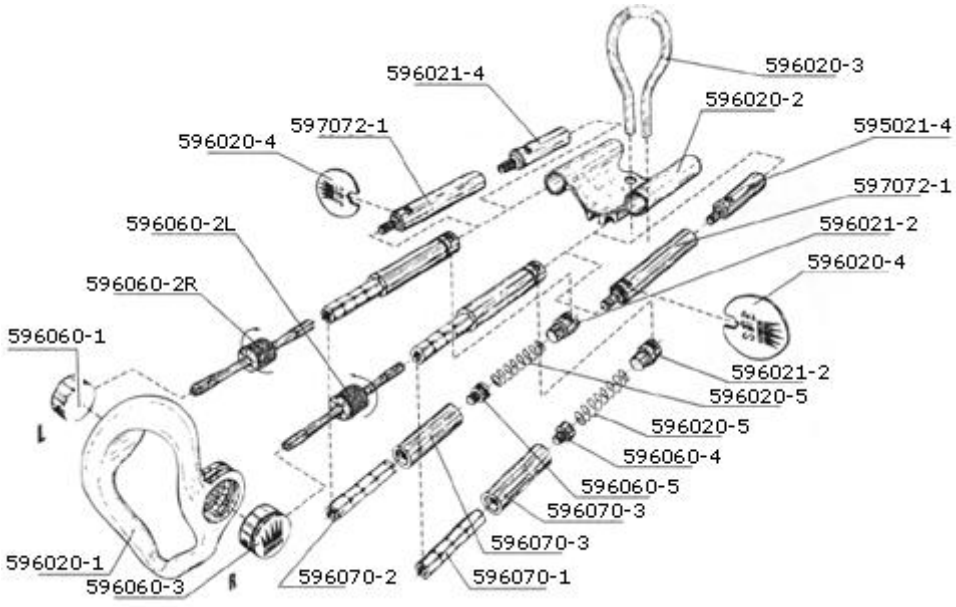
CLASSIFICATION AND CE MARK:

The JES Extender® has been classified as a Medical Device Class I (one) by Health Authorities of the European Community.

The JES Extender® has obtained the CE MARK number 0503, and can be sold freely in the CE (European Community).

CE

10/A · DESPIECE



13 · REFERENCIAS BIBLIOGRÁFICAS

Annex 5: Clinical Studies and CE [European Union] Certification

CERTIFICATION

Documentation of: The Official Journal of the European Communities Nº. L 169/32
Council directive concerning medical devices and Gazette A 1994 Annex 135

Regulations concerning medical equipment

The present CE-Certification concerns the Jes-Extender, a traction device for penile lengthening.

The device is produced by EFA Production APS, Managing Director Bent Andreasen.

The Jes-Extender is distributed in Denmark and throughout the world by MBS Trading APS

Gazette A., 1994, Annex 135 Regulations concerning medical equipment,
CHAPTER 1

FIELD OF APPLICATION AND DEFINITIONS

The Jes-Extender falls within the scope of Regulations concerning medical equipment, cf 1,2 - schedule 1C, any device produced for human application with a view to anatomical changes

Gazzete A 1994, Annex 135 Regulations concerning medical equipment
SECTION 2

MARKETING, USAGE AND REGISTRATION

Provided that the Jes-Extender is applied, maintained and used correctly and in accordance with the specifications of section 2 it constitutes no health hazard or safety risk for patients, users or any third parties involved.

The manual is written in Danish, of section 2,2 and in the native language of those countries where it is marketed.

EFA Production APS undertakes to provide both the manual and the packaging (brown mahogany box, containing the constituent parts of the Jes-Extender) with a conspicuous, indelible and easily readable CE-certification label, of Section 3,2.
The particular design of the Jes-Extender precludes labelling of the device proper.

EU DIRECTIVE - SUPPLEMENT IX - CLASSIFICATION CRITERIA

Definitions in accordance with section 1.4 - Active medical devices

The Jes-Extender in a device for penile lengthening by means of traction.
Traction of the penis does not rely on any electrical source of energy but merely the body's own energy and gravity.

The effect of the JES Extender does not depend on any significant transmission of energy from the medical device to the penis but penile lengthening is obtained solely by constant static traction. Hence the JES Extender must be considered a non-active medical device.

The JES Extender is therefore a Class I device and an EC Declaration of Conformity will be drawn up and signed by EFA Production APS.

EU-DIRECTIVE - SUPPLEMENT VII, SUBSECTION 3 - EU DECLARATION OF CONFORMITY

GENERAL DESCRIPTION OF THE DEVICE

The JES Extender utilises the principle of traction for tissue expansion.
The device consists of a basal, anatomically shaped plastic ring and a distal plastic-silicone support, connected by two adjustable metal bars. The basal plastic ring is fastened around the root of the penis and the plastic- silicone support is attached at the head of the penis.
Modifiable traction of the penis is transmitted via the two adjustable metal bars connecting the basal ring and the distal support. (Please refer to illustrations and descriptions in the JES Extender manual).

DESIGN DRAWINGS

The original design drawings are kept by Bent Andersen, EFA Production APS.

For further information please refer to the JES Extender manual, Supplement 1.
The design drawings will constitute Supplement 2 of the total material submitted for CE certification.

RISK ANALYSIS

The following hazards have been taken into consideration:

a) The basal ring: To ensure a diameter, which will not constitute a risk at erection by blocking afferent and efferent vessels. An inner diameter of 42 mm. is considered optimal by a study reporting on a device for traction of the urethra to correct scarring caused by previous mutilating cystoscopy. (Early examinations of the bladder were carried out by the introduction of thick tubes for possible visualization of the wall and the contents of the bladder and subsequent disruption of bladder stones via the tubes).
Lesions of the urethral wall caused by the tube led to scarring and contractions (Ref. 1).
In two patients with exceptionally large penises, both when flaccid and during erection, the basal ring, provided with a specially designed recess for the urethra, proved able to permit unhampered erection.
Ref. 1: Emerson CH. Vorrichtung zum Strecken der Harnröhre.
Kaiserliches Patentamt, Patentschrift nr. 166168
Klasse 30d, 29 märz 1904.

b) The distal plastic-silicone support; to design a support, which might be fastened near the penis head without compromising the blood supply and thus damaging the tissue through lack of oxygen. The illustrations of the JES Extender manual show that between the two holes in the bowl-shaped support, through which the tubes are passed, is an uncovered triangular area that permits unimpeded blood supply.

c) The two adjustable connecting bars; To ensure function of the basal ring via the two connective bars which might facilitate attainment of the desired angle of the penis during erection without inadvertently blocking blood vessels with the basal ring.

d) The employment of exclusively non-reactive POM (Hostaform). The connective metal bars are made of Nitin coated brass. Nitin is an intermetallic alloy of nickel and tin, derived by electrolytic precipitation.
Despite the fact that clinical trials have proven that nickel allergics do not react to the coating, which contains 35 per cent of nickel, such patients are recommended to use silver- or gold-coated devices.

TESTINGS - CLINICAL DATA

No proper unbiased, randomised, double blind trials have been carried out, but treatment with the Jes-Extender has been widely used at the Scandinavian Clinic of Surgery.
No actual study reports have been drawn up, but as the device has been used for treatment individual data have been recorded.
Initially the device was tested on 22 patients, consisting of three different categories:

a) 10 patients who had not undergone surgical penis lengthening in the previous 3 months
b) 10 patients who had undergone surgical penis lengthening within the previous 3 months
c) Two patients who started treatment with the device 2 weeks after surgery.

Clinical data are recorded on appropriate pages.

EU DIRECTIVE - SUPPLEMENT VII, SUBSECTION 4 - EU DECLARATION OF CONFORMITY

The producer, EFA Production APS and the main distributor, MBS Trading APS are in close co-operation.

As of now there have been no reports concerning malfunctioning on deterioration of the Jes-Extender, neither have any injuries been reported.

This product is the first of its kind and no technical or medical considerations related to the various features of the device have led the producer to withdraw any similar device from the market.

EU DIRECTIVE - SUPPLEMENT X - CLINICAL EVALUATION

1. General provisions
1.1. Provided that it is used for its proper purposes the device is guaranteed to comply with the requirements concerning characteristics and performance stipulated in Supplement I, subsections 1 and 3

On the condition that the device is used correctly and in accordance with the provided manual the design and the process of manufacture safeguard against any deterioration of the patient's clinical condition and any hazard to either his or any third party's health or safety.
All decisions concerning the design have been reached after carefully weighing risk factors against possible advantages and strict safety and health precautionary measures.
Testing of the device has not revealed any injuries, or any short-term or long-term adverse effects.
The device possesses the yielding capacity stated by the manufacturer and after three months of at least 12 hours correct daily usage all 22 patients had obtained a measurable lengthening of the penis.

1.1.1. A survey of relevant scientific literature, describing the purpose and the mechanism of similar devices.

(Parts of the following are intended for later publication and will be submitted to a Medical Journal. The text is structured as a medical report).

INTRODUCTION

No proper unbiased, randomised double blind study has been performed.
The Jes-Extender is a medical device, categorized a Class I device.
Over a 2-year period, from January 1st to January 1st 1996 more than 400 patients have undergone surgical penis lengthening and thickening at the Scandinavian Clinic of Plastic Surgery. Also, on the basis of African reports on penis lengthening achieved by attaching weights, such as stones, to the penis, and on the fact that traction has led to expansion of lip tissue in Plate-lipped Negroes and ear tissue in Masai Warriors and women, experiments involving penis traction have been performed at the clinic during the same period.
Initially two patients had lead weights, in the shape of 'cartridge belts', weighing from 600 to 1.000 gram, attached to the penis.
Whenever possible the weights were worn for more then six hours a day and after a period of 4-6 months the patients had obtained an average lengthening of approximately 0.5 cm per month.
Following the same principle patients in the USA have had 2-pound weights suspended from their penises attached to silicone tubes fastened around the corona glandis. This device was marketed under the name of the PLD or the PLD Hangman. A similar device, marketed under the name of the PUD or the PUD Tugger, consisted of a steel cylinder, which was fastened around the glans (also used for circumcision) and to which various weights were attached. A German patient, who was treated at the clinic, informed the staff of the clinic that he had ordered a PLD Hangman, as he wanted to attempt traction treatment after undergoing penis surgery.
The American manufacturer delivered a traction device with weights, weighing a total of 3 kilos.

In 1940 Emarson, a German physician, began studies on the lengthening of urethral contractions, caused by the formation of scar tissue following mutilating cystoscopies (Ref. 1).

In 1912 The German manufacturer Lother patented a similar device in Norway (Ref. 3). Only references published by the respective patent agencies are currently available (Ref.1 and 3).
In contrast to the previously mentioned devices, which apply traction by means of weights fastened around the glans, the two latter devices operate on the shaft of the penis.

Ref. 1 Emarson CH. Vorrichtuny zym Strecken der Harnröhre.
Kaiserliches Patentamt, Patenschrift nr 166168 Klasse 30 d, 29 märz 1904.

Ref. 3 Lother M. Apparat til strekning af urinror. Norsk Patent nr. 23227, 13. August 1912.

2. Clinical Testing

2.1 Purpose

To obtain penile lengthening without previous surgical lengthening and further to improve the results achieved by surgery a device was required which was painless and more effective than earlier designs and which, when used correctly, would not damage tissues.

To serve this purpose a new traction device was designed whose vector was shifted from its earlier position immediately below the glans to a proximal position so that the force of traction was

exerted on the shaft of the penis. New features were the anatomically correct plastic base ring provided with a recess for the urethra which was to be positioned around the root of the penis, and the optimal distal part for the fastening of the glans by means of a silicone tube, passed through two holes in a bowl-shaped plastic support. Another novelty was the construction of two adjustable metal bars, whose purpose was to apply traction to the penis. The bars were fitted with 2 small manual screws for varying adjustment and the force was regulated by means of built in cylinders with springs activated by pistons attached to the two screws. (Please refer to the construction diagrams).
In yet another innovation the two metal bars were hinged to the basal ring thus permitting the penis to assume any angular position.

2.2 Ethical considerations

Subsequent testing was performed in accordance with the Helsinki Declaration, adopted in 1964 at the 18th session of the World Medical Assembly in Helsinki, Finland, and last revised in 1989 at the 41st session of the Assembly in Hong Kong.

2.3 Methods

Prototypes of **The Jes-Extender*** traction device were tested over a 12-month period at the Scandinavian Clinic of Surgery on 22 male patients ranging from 23 to 45 years of age. A traction force of 1.000 gram was applied to the penis daily for at least 12 hours.

The patients were not randomised but divided consecutively into three different groups:

a) 10 patients who had not undergone surgical penis lengthening

b) 10 patients who had undergone surgical penis lengthening three months prior to the application of the traction device

c) Two patients who had undergone surgical penis lengthening two weeks prior to the application of the traction device.

Data are based on self-reported measurements. Previous studies indicate that patients who have paid for their treatment are not likely to over-estimate the results but expect to get their money's worth.
Furthermore, the patients were sceptical at the outset and such patients tend to complain of insufficient effect rather than overestimate the results (Ref.2) (This paragraph is intended for inclusion in the Discussion section of a future publication).

RESULTS

All patients from no.1 up to and including no.11 were treated without previous operation, patients no.12 up to and including no.20 were treated with traction three months after surgical lengthening and nos.21 and 22 were treated with traction two weeks after surgical lengthening.

The 10 patients who were treated with traction without previous surgical lengthening achieved an average lengthening of the penis at erection of 2.8 cm (range 1.5 - 5.0cm) after using the device for at least 12 hours a day over a period of 16.4 weeks (range 8 - 24 weeks).

Those patients who had undergone surgical penile lengthening three months prior to application of the device achieved an average lengthening of 4.5 cm (range 3.0 - 5.5 cm) after using **The Jes-Extender*** for an average period of 16.0 weeks (range 16 - 16 weeks)
However, if **The Jes-Extender*** is applied only two weeks after surgery an average lengthening of 9.5 cm (range 8.0 - 11 cm) is achieved after using the device for an average of 20 weeks (range

16 - 24 weeks).
During the period of testing 4 patients had minor epidermal abrasions at the site of the corona, but no other injuries were reported. The abrasions occurred during fastening of the device and were caused by the somewhat rugged exterior of the prototype. When used correctly the ultimate design does not cause abrasions or epidermolysis.

Owing to pain in the head of the penis two patients who had previously undergone surgical lengthening started out gently by using the device for only 30 - 45 minutes per day and then gradually increased the time-span to two hours per day over a period of two weeks. After two months they were able to use the device continuously for approximately 12 hours.
The remaining patients started out by using the device for a minimum of two successive hours and then after 1 - 2 weeks gradually increasing the time-span to approximately 12 consecutive hours.

RESPONSIBLE HEAD OF PROJECT

The undersigned, Jorn Ege Siana, M.D., Specialist in General and Plastic Surgery, has developed and tested **The Jes-Extender*** as described above.
The manufacture of the device is of high quality and it has been tested meticulously on patients. When used correctly the device has yielded satisfactory results and apart from minor lesions of the skin, caused by inappropriate fixation of the prototypes, no injuries to the penis have been reported.
These problems have now been solved by fastening the corona glandis with a soft silicone tube, which is gentle to the skin and by using an anatomically correct plastic support for the head of the penis.

Copenhagen, December 21st 1995 Jorn Ege Siana, M.D. Specialist in Plastic Surgery

Annex 6:

PENILE - EXTERNAL TRACTION DEVICE - TREATMENT PROTOCOL

DATA retrieval

1. PERSONAL DATA

Name: .....
Surname: .....
Age: .....
Civil Status: .....
Occupation: .....
Address: .....
Telephone: .....

2. REASON FOR CONSULTATION

Start Date: ..... / ..... / .....
Penis Elongation ☐ Penile Curvature ☐ Other ☐

3. PATHOLOGICAL HISTORY

Genitourinary Congenital Malformations ☐
Penile Trauma ☐
Urethral Catheterisation ☐
Diabetes ☐ H.T.A. ☐ Vascular Pathology ☐
Dermatological Pathology ☐ Other ☐
Specify:

Surgical History:

Abdominal surgery ☐ Genitourinary Surgery ☐
Other ☐
Specify:

Toxic habits:

Tobacco ☐ Alcohol ☐ Other ☐ Pharmaceutical ☐

Allergies:

To Medication ☐ To Metals ☐ Other ☐
Specify:

4. SEXUAL PROFILE

Sexual Disposition: Heterosexual ☐ Homosexual ☐ Bisexual ☐
Sexual Habits: Coital ☐ Masturbatory ☐ Other ☐

Erectile Function: Normal ☐ Erectile dysfunction ☐

Sex drive: Normal ☐ Altered ☐

Hypogonadism ☐ Andropause ☐

Ejaculation: Normal ☐ Early ☐

Premature ☐ Retarded ☐

Retrograde ☐ No-ejaculation ☐

5.- PHYSICAL EXAMINATION:

General Examination: Normal ☐ Abnormal ☐

Virilization: Normal ☐ Hypoandrogenism ☐

Gynecomasty: Absent ☐ Present ☐

Tañer Stage ☐ Fat Layer ☐

Genitourinary Examination

Penis: Normal ☐ Phimosis ☐

Orthotopic ☐ Plaques ☐

Hypospadias ☐ Dermal Alterations ☐ Epispadias ☐

Chord ☐

Glans Abnormalities ☐ Sensitivity Abnormality ☐

Pain ☐

Scrotum: Normal ☐ Palmate ☐

Hypoplasic ☐ Aplasic ☐

Testicles; epididymus and v.deferens:

Inguinal Exploration:

Other Symptoms:

Dupuytren's Syndrome ☐ Presence of Cheloids ☐

Right Hand ☐ Gallizia triad ☐

Left Hand ☐ Fibrous Dystrophy Simple ☐

6. PENIS MORPHOMETRY

Flaccid State Measurements:

Length:..... Circumference: .....

Diameter: .....

Penis Sensitivity :

Normal ☐ Altered ☐

Presence of plastic indurations:

- Consistency: ☐ Cartilaginous ☐ Fibrous ☐ Calcified
- Localization: ☐ Corpus Cavernosum ☐ Septum ☐ Dorsal ☐ Ventral ☐ Lateral left ☐ Lateral right ☐ Coronal ☐ Base ☐ Axis
- Number: ☐ Unique ☐ Multiple ☐☐
- Size: ☐ < 1.5 ☐ 1.5-3 ☐ > 3
- Pain: ☐ Absent ☐ When erected ☐ Continuous
- Penetration: ☐ Possible ☐ Difficult ☐ Impossible
- Dispareunia: ☐ Absent ☐ Occasional ☐ Continuous
- Shortening: ☐ Absent ☐ Present ☐☐
- Erectile Dysfunction ☐ Absent ☐ Occasional ☐ Continuous

Intracavernous Injection of PGE1:

Doses: ☐☐ Latency Time: ☐☐

T.A. basal: ☐☐☐ - ☐☐☐

Tumescence 10': ☐☐☐ Rigidity 10': ☐☐☐

Tumescence 20': ☐☐☐ Rigidity 20': ☐☐☐

Erection Status Measurements:

Length: ..... Circumference: .....

Diameter: .....

Angle of Erection: ☐ < 90º ☐ > 90º

Curvature Angle Determination:

☐ < 30º ☐ 30º-45º ☐ 45º-60º ☐ > 60º

Other Explorations:

☐ Penile arterial-venous Doppler ☐ Penile Ecography

☐ Penile Radiography Simple ☐ Topography Axial Helicoidally

☐ Cavernosography

RESULTS:

7. DIAGNOSTIC ORIENTATION:

☐ Normal Penis ☐ Penile Torsion

☐ Peyronie's disease ☐ Cavernous Aplasia

- ☐ Kelâmi Syndrome
- ☐ Congenital Curvature
- ☐ Chord
- ☐ Hypospadias
- ☐ Epispadias
- ☐ Short Urethra
- ☐ Phimosis
- ☐ Cavernous Hypoplasia
  - ☐ Cavernous Hyperplasia
  - ☐ Penile Hypoplasia
  - ☐ Micropenis
- ☐ Buried Penis
  - ☐ Palmate Penis
  - ☐ Penile Trauma

8. <u>PROPOSED TREATMENT</u>

- ☐ Lengthening by External Traction
- ☐ Curvature Correction by External Traction
- ☐ Surgical Lengthening
- ☐ Surgical Curvature Correction
- ☐ Surgical Lengthening + External Traction
- ☐ Surgical Curvature Correction + External Traction

<u>Endoscopic Plastic Surgery for Penile Enhancement</u>

Authors: Dr. Bayard Olle Fischer Santos,
Dr. Marco Aurelio Faria Correa, Dr. Nelson Heller

ALARGAMIENTO POR ENDOSCOPIA Y AUMENTO CON INJERTO GRASO
ENDOSCOPIC LENGTHENING AND GIRTH AUGMENTATION WITH FAT GRAFTS

SUMMARY
It is possible by surgical means to enhance the length and girth of the penis. Currently there are a number of techniques in use. Generally these techniques require wide incisions. The development of a special video-endoscope to work in the subcutaneous tissue through minimal incisions, allowed the authors to accomplish penis enhancement with this technique. The purpose of this paper is to document our experiences beginning on January 28, 1997 with the video-endoscopic enhancement phalloplasty procedure.

INTRODUCTION
For over a decade, penis enhancement surgery has been winning followers all over the world. One of the first publications on penis lengthening for treatment of congenital deformities was that of Johnston (1-2), in the United States in 1974. In China, a country also considered a pioneer in the field, the surgeon Dr. Long Daochao (3) developed the technique of penis lengthening. This technique was introduced into the United States in Miami in 1991, by the urologist Harold Reed (4). Starting in 1992 it spread throughout the country, and from there to the rest of the world. Currently, it is included in the list of techniques that comprise aesthetic surgery. In Brazil, one of the authors of this paper presented its use in penis liposculpture (5) in 1993.

We verified that, as far back as the most distant periods of human history (6) the size of penis has been important psychologically and has been undeniably linked to masculine self-esteem and self -image. This

can be observed in the oldest art expressions, depicted in drawings, paintings and sculptures from the most primitive civilisations. (7) It seems to us that independent of the culture or of the peoples' socio-economic or religious situation, this concept has overcome all borders, throughout the ages, and brought along a symbolism of power, manliness and dominance, and definitely persists in modern man. The studies published in our field show that the patients that seek penile enhancement are ordinary men: executives, husbands, and family heads that have penises that function normally even if they are anatomically small, often hidden within the pubic fat. Some may even have a penis that is actually average or normal sized. These patients' main complaints are related to traumatic situations from their childhood or teenage years or to embarrassing moments that occurred when they used a public bathroom, a sauna or a gym dressing room (athletes). There are even cases of body builders with penises of disproportionate size when compared to their muscular bodies. Thus, they refer to the size of their sexual organ as a genuine anatomical anomaly that directly affects their self-image and self esteem and consequently interferes with their romantic, social and professional relationships.

15 · REFERENCIAS BIBLIOGRAFICAS · Anexo 8/E: TRABAJOS CIENTÍFICOS *(2/6)*

MATERIAL AND METHODS

It was understood that penis enhancement is a process that consists of surgery and physiotherapy to avoid scar tissue retraction and beyond that, additional gain. (8) There was post-operative use of a weight device (9) and the use of the Jes-Extender (10) beginning 20 days later. The duration of Jes-Extender treatment was to be determined by the development of each case. The patients' selection for videoendoscopic surgery followed the same approach as conventional surgery (11- 1 2), which are as follows:

a) AESTHETICS

We have observed that the great majority of the patients that seek this type of surgery have penises that are within the range of what is considered of medium size. In spite of efforts by doctors to explain to the patient that his penis is normal from a functional perspective this does not give them emotional relief. In general, they are more interested in a surgical solution that will give them a visible aesthetic result than in psychological treatment, which many of them consider ineffective. We have found in our practice that the best candidates for this surgical procedure are those that are mature and socially balanced, those that are genuinely deformed or have a penis of a disproportionate size, and that are not unbalanced and do not have strong neuroses resulting from these problems. The more real and evident the deformity, the more realistic and honest our clarifications and commitments to our patients and the greater their satisfaction.

b) FUNCTIONAL

The indication of functional reasons occurs when the penis is of an inadequate size for normal intercourse, according to the norms established at the Ist Annual Scientific World Congress of the American Academy of Phalloplasty Surgeons held on 11 - 13 October, 1996 in Aspen, Colorado. Which are as follows:

I - length of less than 10cm when in a state of erection
II - circumference of less than 9cm when in a state of erection
III - post-prostheses penis that presents poor residual erection
IV - penile deformity that affects size such as: micropenis, hypospadias, epispadias, post traumatic, fibroses, etc.

The videoendoscopic procedure was used on 14 patients beginning on 28 January, 1997 with ages varying between 27 and 62, with an average age of 36.3. The aesthetic indication was the most frequent, comprising 10 cases. The surgical procedure for the increase of the length of the penis consists of the sectioning of the suspensory and fundiform ligaments that fasten the dorsum of the penis to the inferior part of the pubic bone, (figure 1) allowing the part of the penis hidden below the bone to emerge, increasing the external portion of the penis, as per the conventional technique (9-13-14).

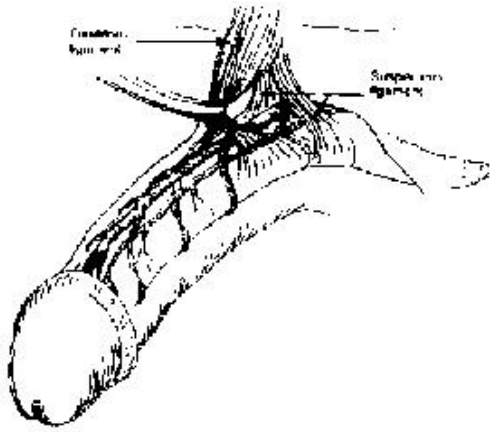


Figure 1: Anatomical scheme of suspensory and fundiform ligaments

The difference here is that the section of the ligaments is done by videoendoscope, while the traditional techniques use incisions in M and VY, which leave unpleasant scars and involve a more aggressive manipulation of the tissues. We accomplished the whole procedure by means of a small 3cm incision (figure 2), hidden in the pubic hair area. Through this incision, and with the aid of video surgery, we identified and sectioned the ligament that fastens the penile dorsum to the pubic bone, allowing the intrapelvic part of the penis to emerge thereby increasing the length of the pendular portion of the organ by an average of 2.5 to 3.Ocm. This technique is different from the videolaparoscopic and other endoscopic procedures because it does not need a liquid or gas chamber and permits direct visualization inside the tissues. This device was developed by a Brazilian doctor and is used quite frequently in plastic surgery of the subcutaneous tissue in mammoplasty, abdominoplasty and others with minimal scars (16-17).

The increase in girth is accomplished by a fat graft to the subcutaneous tissues of the organ. The fat used in this procedure is removed preferably from the pubic mound, crotch area or from the lower abdomen, by liposculpture in these areas and improving the projection and look of the penis, following the techniques previously described (4-5-9-13-14).

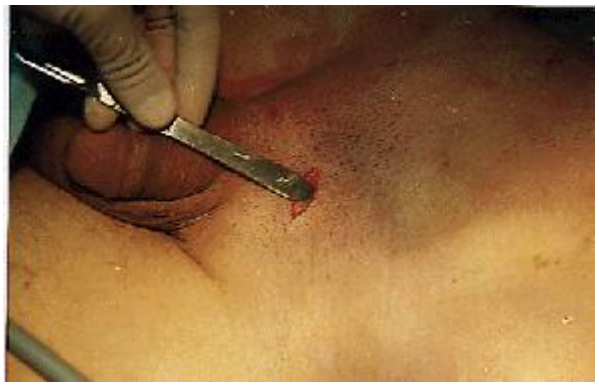


Figure 2: Small incision

The use of physiotherapy with weights for traction began on the first day and continued for 20 days after the surgery (figure 3).

Figure 3: the weight device

Then we switched to **the JES Extender** to avoid scar retraction (figure 4).

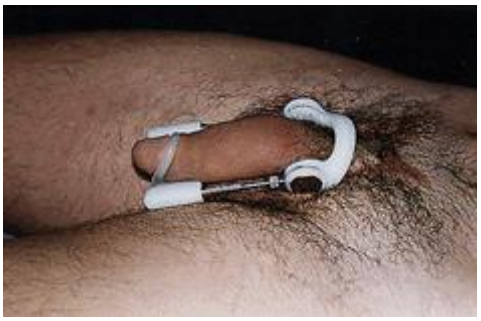


Figure 4: The JES Extender

Liposuction was carried out in the pubic area, the lower abdomen and the crotch area to make the organ even more visible and projected. To have a proportional increase in diameter, we had improved the girth previously by means of a graft with the liposuctioned fat. The anaesthesia used was raquidiana with 5% lidocane and all patients were treated as outpatients, leaving the clinic 4 hours after the procedure began.

RESULTS

A follow up visit 6 months after the surgery showed a gain in length that varied from 1.5cm to 6.2cm, with an average of 3.9. As far as the diameter is concerned, the gain was 1.9cm to 3.4cm, with an average of 2.5cm. The increases in length and in girth are similar to those in previous studies (13-15) which document the conventional technique, without a significant statistical difference in the results (figures 5 - 6 - 7).

Figure 5: Before surgery

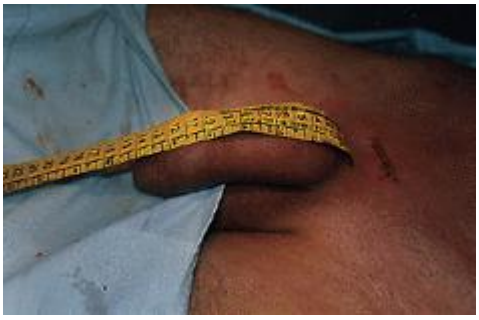


Figure 6: After surgery

Figure 7: four months after surgery

DISCUSSION

Undesirable sequelae after surgery will surely be fewer as this technique addresses the issues in a more delicate manner, and because optical advantages, being 40 times greater than an unassisted human eye, enhance technical conditions during surgery. The need for further surgery to correct asymmetry of the fat infusion should be equivalent to the conventional technique that is 15 to 20% according to previous studies (9-15). However, scar hypertrophy resulting from a misalignment of the tension lines in the VY and M techniques does not occur with minimum incision size and videoendoscopy as there is no misalignment in skin tension lines.

Moreover, we emphasize that the skin in this area has a significantly elastic quality that is not in any way a limiting factor in penis enhancement. Also, the surgery does not interfere with organ function. Possible complications are as follows: partial absorption of the fat grafts, small nodules in the transplanted fat, haematoma and infection (15). Twenty per cent of the patients underwent additional procedures of fat graft and/or nodule removal. Most patients commenced sexual activity 8 days after the surgery. Despite not being statistically significant, in absolute values the gain in length of these current results is greater. We understand this to be a result of the surgical expertise and mainly to the application of continuous traction provided by the Jes-Extender (8). This new technique was presented last February at the 8th Andrology Congress held on 5-7 March, Spanish Association in Seville, Spain and at the 2nd World Congress of Phalloplastic Surgeons (American Academy) held on 17 - 18 October, 1997 in Aspen, USA.

The innovations presented in our proposals were very well received by the scientific community, where those present look forward to making this a standard technique internationally.

CONCLUSION

Videoendoscopic technique for penile enhancement presents advantages in relation to the conventional technique, not as far as the gains accomplished but rather as being less aggressive and mainly, in its ability to eliminate the most frequent post-operative complaint - scar hypertrophy.

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1st International Interdisciplinary Symposium on Genitourinary Reconstructive Surgery in Congenital Malformations, Transsexuals and Impotence Sitges (Barcelona - Spain) April, 6th, 7th and 8th, 1998	SURGICAL PENILE ENLARGEMENT (Elongation and thickening) Author: Jørn Ege Siana, MD, Scandinavian Clinic of Plastic Surgery, Copenhagen

Surgical Penile Enlargement (Elongation and thickening)
Author: Jørn Ege Siana, MD

1. - INTRODUCTION

The need for surgical penile enlargement has increased since 1994 when Hennie Roos from South Africa was the first to describe his method. In the Scandinavian Clinic of Plastic Surgery in Copenhagen the first procedure for penis enlargement was introduced September 1994. Initially traditional methods were used subsequently developing into the endoscopic technique practised today.

2. - MATERIAL AND METHODS

2.1.Period: September 1993 to March 1998 (54 months)
2.2.Number: 1355 patients operated from December 1993 to March 1998 (54 months)
2.3.Age: 16-73 years (average 30 years)
2.4.Technique:
2.4.1. Incisions: 817 patients: X-Y, elipsis-Y or V-Y (70-140 mm)
538 Patients: endoscopic technique with horizontal - vertical (10-20 mm)
2.4.2. Dissection of the suspensorium and transverse perineal ligaments
2.4.3. Interposition of adipose swing-flap: a) Y-incisions - from mons pubis
b) endoscopic technique - from funiculus
2.4.4. Closure of the scarpas fascia over the interposited tissue

3. - RESULTS:

3.1. Y-incision: Number of one year controls: 268 of 817 patients (32,8%)

	Length Increase (Flaccid)	Circumference Increase (Flaccid)	Length Increase (Erection)
Mean (cm)	4,7	2,8	2,3
Range (cm)	(0 - 9,0)	(0,5 - 9,0)	(0 - 6,0)

3.2. Endoscopic techniques: Number of one year controls: 144 of 538 patients (26,8%)

	Length Increase (Flaccid)	Circumference Increase (Flaccid)	Length Increase (Erection)
Mean (cm)	4,3	2,9	2,6
Range (cm)	(0 - 7,0)	(0,5 - 6,0)	(0 -5,0)

4. - CONCLUSIONS

Even though non-optimal the surgical results are acceptable
There is no significant difference in results according to surgical techniques
Y-incisions give unsatisfactory scars and scrotalisation of the penis
Endoscopy-assisted surgery with incisions less than 2 cm gives natural appearance
Y-incisions have to be selected for obese patients with an excess of skin on mons pubis
Additional post-operative treatment has to be developed to avoid scar contractions and to create more desirable elongation results for the patients

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NON-SURGICAL PENILE ELONGATION USING TISSUE EXPANSION WITH JES
Tractive Elongation of the Penis by Means of Stretching

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Non-Surgical Penile Elongation using Tissue Extension with the JES Extender
Tractive Elongation of the Penis by Means of Stretching
Author: Jørn Ege Siana, MD, Scandinavian Clinic of Plastic Surgery, Copenhagen

1. - INTRODUCTION
Based on the evidence of human tissue response to stretching a traction device for non-invasive penile lengthening has been designed: The Jes-Extender.

TRACTION DEVICE - THE JES EXTENDER
- Basic ring, fastened proximally around the root of the penis, abutting on the symphysis.
- Two adjustable metal bars hinged to the ring, connecting it to the silicon-support, fastened around the corona glandis at the distal end of the penis.
- By gradually increasing the tractive force on the two metal bars a stretching force is exerted on the corporae, which equals a tractive force of a 600-1500 g weight attached to the penis.

2. - MATERIAL AND METHODS
2.1. Number of patients: 10 patients ranging from 23-47 years
2.2. Patient selection: 2.2.1. Inclusion: normal erectile capacity and no penile surgery
2.2.2. Exclusion: chronically diseases
2.3. Traction force: 0- 2 weeks - 900-1000 g
2-24 weeks - 1000-1200 g

2.4. Treatment period: 12 hours daily 7 days a week 8 to 24 weeks
2.5. Follow up: every 2 weeks

3. - RESULTS - Results in Erection

	Weeks	Length before	Length after	Difference	Length %
Mean (cm)	14,8	12,0	14,8	2,8	24
Range (cm)	(8 - 24)	(9,5 - 15,0)	12,5 - 18,5)	(1,5 - 5,0)	(10 - 42)

4. - CONCLUSIONS
- Preliminary study
- All patients achieved penile lengthening after traction with the JES Extender
- Lengthening per week was 1,9 mm
- No complications
- Medical indications a) non-invasive: hypoplasic penis, Peyronie's disease

b) postoperative: hypospadias / epispadias, penile lengthening procedures

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LENGTHENING WITH THE JES EXTENDER
Combination of surgical lengthening and postoperative penile traction with The JES Extender
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Lengthening with the JES EXTENDER
Combination of surgical lengthening and postoperative penile traction with The JES Extender
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1. - INTRODUCTION

Depending on surgical techniques used penis elongation surgery creates acceptable results. Follow-up shows however, that retraction of the penis occurs because of wound healing contraction. Post-operative treatment is necessary to avoid scar contraction and to yield greater length to the penis.

2. - MATERIAL AND METHODS

2.1. Number of patients: 10 patients ranging from 18-43 years.
2.2. Patient selection: Inclusion: normal erectile capacity after penile surgery
Exclusion: disadvantage in using traction after surgery
2.3. Traction: 0-2 weeks - 900-1000 g
2-20 weeks - 1000-1200 g
2.4. Treatment period: 8-12 hours daily 7 days a week 8-20 weeks
2.5. Follow up: every 2 months

3. - RESULTS - Results in Erection

	Length before surgery	Length after surgery	Difference	Length after traction	Difference	Difference after combination
Mean (cm)	12,0	14,3	2,3	17,5	3,4	5,7
Range (cm)	(10 - 13,5)	(11 - 17)	(1,5 - 4)	(15 - 19,5)	(2 - 4,5)	(4 - 8,5)

Weeks	Mean: 10,7 weeks Range: 8 - 20 weeks

4. - CONCLUSIONS

- Preliminary study
- All patients avoided scar contractions and achieved more length to the penis after surgery
- Lengthening per week was 3,2 mm
- Traction gives better results in combination with surgery (traction alone: 1,9 mm / week)

- The combination of surgery and traction gives better results (mean 5,7 cm) compared to surgery alone (mean 2,3 cm)

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TRACTION WITH THE JES EXTENDER IN PEYRONIE'S DISEASE AND HYPOSPADIAS

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Traction with the JES EXTENDER in Peyronie's Disease and Hypospadias
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1. - INTRODUCTION

Non-invasive penile elongation has been achieved by traction using the Jes-Extender. Patients with **Peyronie's disease** may benefit from using traction before surgical correction is planned. After penile surgery for elongation traction has been found indicated to avoid scar contraction and to give more length to penis. Patients with hereditary deformities such as **micropenis and hypospadias / epispadias** may also benefit from traction after surgery.

2. - MATERIAL AND METHODS

2.1. Number of patients: 2 patients with Peyronie's disease (without surgical correction)
4 patients with hypospadias (after surgical correction)
2.2. Traction: 0 - 2 weeks: 900 - 1000 g
2 - 20 weeks: 1000 - 1200 g
2.3. Treatment period: 8-12 hours daily. 7 days a week. 2-7 month

3. - RESULTS (Results in erection)

3.1. Peyronies disease

Patient	Before traction Deformity degree	After traction Deformity degree	Months of treatment
01	45º	20º	6
02	30º	15º	6

3.2. Hypospadias

Patient	Length before surgery	Length after surgery (pre-traction)	Length after traction	Months of treatment
03	8 cm	9, 5 cm	11 cm	4 months
04	7 cm	8 cm	10 cm	4 months
05	7 cm	10 cm	13, 5 cm	7 months
06	10 cm	12 cm	13 cm	2 months

4. - CONCLUSIONS

The JES Extender can be a medical (non-surgical) indication for treatment with penile traction in:
- Patients with Peyronie's disease before surgical correction is planned
- Hypospadias patients treated with elongation surgical procedures after initial corrections.