ARE ALL DEVICES USED TO CORRECT URINARY INCONTINENCE BY TENSION-FREE MESH THE SAME?

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ABSTRACT

ARE ALL DEVICES USED TO CORRECT URINARY INCONTINENCE BY TENSION-FREE MESH THE SAME?

Since 1996, when Ulmsten described the TVT (Tension-free Vaginal Tape) procedure for correcting urinary stress incontinence, numerous variations have been described and a large number of devices have been put on the market, all attempting to reproduce the original technique. However, the results do not depend on the surgical technique alone but also on two other basic factors:

1. Properties and type of mesh used.
2. System and route used to insert it.

The properties of the mesh used are probably just as important as the surgical technique, if not more important. The data from TVT cannot be extrapolated to other meshes. Before assertions of that nature can be made, further random studies comparing the different techniques would be needed. The route of insertion is also extremely important in the results obtained.

In this paper we review the characteristics of meshes and their properties as well as the different approaches in terms of route and positioning. We also analyse the influence of each of these factors on the surgical results. Finally, we review the principal devices on the market, the properties of the mesh and the system used to implant each one.

KEY WORDS: TVT. Female urinary stress incontinence. Incontinence surgery. Mesh characteristics.

RESUMEN

¿SON IGUALES TODOS LOS SISTEMAS EMPLEADOS PARA CORREGIR LA INCONTINENCIA URINARIA MEDIANTE MALLAS LIBRES DE TENSIÓN?

Desde the año 1996 in que Ulmsten describe the técnica of the TVT (Tension-free vaginal tape) para la corrección de la Incontinencia Urinaria de Esfuerzo (UIE), han sido numerosas las variantes descritas y los dispositivos existentes en el mercado que tratan of reproducir la técnica original. Sin embargo, los resultados no van a depender exclusivamente de la técnica quirúrgica sino también de otros dos factores fundamentales que son:

1. Características y tipo de malla utilizada.
2. Sistema y vía de implantación de la misma.

Las características de la malla empleada possiblemente sean tan importantes o más que la propia técnica quirúrgica. No es posible extrapolar los datos relativos al TVT para otros dispositivos. Sería necesario realizar estudios randomizados en los que se comparen las diferentes técnicas para poder hacer afirmaciones semejantes. La vía de implantación tiene también una gran importancia en los resultados obtenidos.

En el presente trabajo se hace una revisión de las características de las mallas y sus propiedades así como de las diferentes vías de abordaje y colocación de las mismas. Se analiza también la influencia de cada uno de estos factores sobre los resultados quirúrgicos. Finalmente se repasan los principales dispositivos existentes en el mercado, las propiedades de la malla y del sistema de implantación de cada uno de ellos.

PALABRAS CLAVE: TVT. Incontinencia urinaria de esfuerzo femenina. Cirugía de la incontinencia. Características de las mallas.

1. GENERAL DESCRIPTION OF MESHES

1.1. Physical characteristics of meshes

1.1.1. Material used in manufacture: Meshes can be classified by the material they are made from, as follows:

- Biological meshes: which, according to their origin, can be:
  - Autologous: biological material obtained from the patient (aponeurosis of recti; tensor fascia lata; vaginal mucosa). The use of this type of implant causes increased morbidity and often gives unsatisfactory results[1]. At present its use is very limited and is becoming increasingly more restricted.
  - Allografts: biological material obtained from other people (duramater, fascia lata). This type of material presents a small risk of transmitting diseases caused by prions, as well as HIV infections, lentiviruses, etc.[1]. On the other hand, allografts can maintain enough residual antigenicity to produce an immune response that destroys them. Recently surgeons have begun to use acellular allografts which have a much lower risk of developing an immune response.
  - Xenografts: biological material obtained from animals (small intestine and dermis from pigs, bovine pericardium). With this type of implant, immunological rejection can be even greater than with allografts. The transmission of diseases caused by prions is also possible.
- Synthetic mesh: polypropylene (Prolene, Marlex, Atrium), polyglycol acid (Dexon), polyglactin 910 (Vicryl), PTFE (Gore-tex, Teflon), polyethylene (Mersilene), etc.

1.1.2. Structure of the material: this refers to the monofilament or multifilament character of the individual strands of the mesh (Figs. 1 and 2).

- Monofilament type: polypropylene (usually).
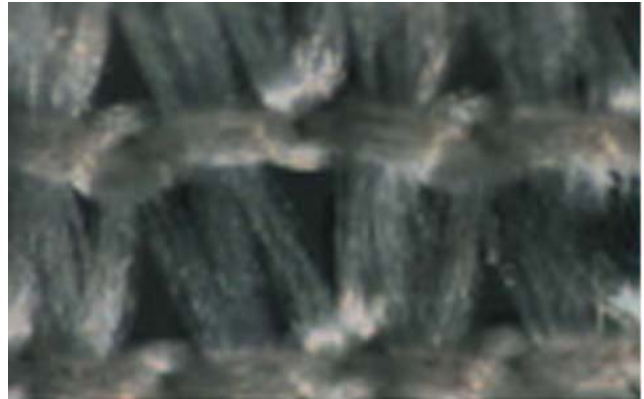- Multifilament types: PTFE, polyethylene, polyglycol acid , polyglactin 910.
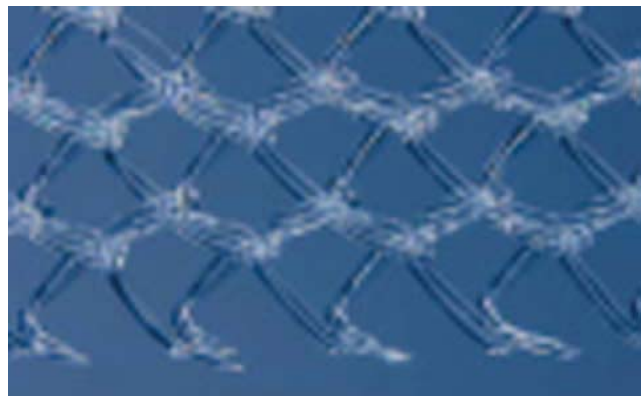

FIGURE 1. Multifilament mesh.

FIGURE 2. Monofilament mesh.

1.1.3. Pore size: the size of the pores of each filament making up the mesh is one of the most important factors to be considered. Experimental studies have shown that pore size influences important aspects such as[1]:

- Resistance to infection.
- Flexibility of the prosthesis.
- Infiltration by fibroblasts: scar formation, integration in surrounding tissue, formation of seromas.
- Mechanical anchorage of the mesh.
- Angiogenesis.

Meshes are classified by pore size in 3 groups[2]:

- Macroporous: the pores of the filaments have a minor diameter of more than 75 µm.
- Microporous: when the pores are <10 µm.
- Submicroscopic pores: when the pore size is <1 µm.

From the point of view of the structure and porosity of the material, meshes are classified in four major groups (Amid classification)[2]:

- Type I (totally macroporous): macro-porous monofilament meshes.
  - TVT
  - SPARC
  - Gynemesh
- Type II (totally microporous):
  - Goretex meshes
- Type III (macroporous meshes with microporous elements): macroporous meshes that have micoporous elements in their structure (e.g. multifilaments).
  - IVS
  - Mycromesh
- Type IV (meshes with submicroscopic pores).

1.1.4. Weave structure: three main groups can be distinguished based on weave structure:
- Knitted meshes: the filaments are interlaced and knotted together.
- Woven meshes: the filaments are interlaced in two directions, as when produced in a loom. Generally these meshes are very closely woven and have a high density of material.
- Thermocoagulated meshes: when the weave is obtained by fusing the filaments with heat.

1.1.5. Density of the material (porosity): density refers to the quantity of material per unit of area. Density depends on the diameter of the threads that form the mesh and how close together they are. Porosity is expressed as a percentage (proportion of area of interstices to total area). This property will influence the inflammatory response as well as the probability of seromas forming or erosion occurring. It has been shown that the intensity of infiltration of macrophages and the thickness of the fibrous capsule formed depend directly on the density of the mesh[3] [4]. Meshes can be classified by porosity as[4]:
- High density: very closely woven meshes with hardly any spaces between the interwoven filaments.
- Low density: meshes with large spaces between the filaments.
- Intermediate density.

1.2. Mechanical properties of meshes

1.2.1. Resistance: the resistance of the mesh refers to its capacity to withstand tension without breaking (Fig. 3). Generally this property is over-designed in most materials on the market, and is therefore a factor of little influence.

Apart from the resistance of the mesh itself, account must be taken of its long-term resistance after being implanted in the patient[5]. This property depends on two essential factors:
- The material it is made from: absorbable or non absorbable[6]. It has been proven that the use of reabsorbable meshes does not guarantee the long term durability of the repair as the percentage of relapses are higher[6].
- Integration of the mesh with the surrounding tissue: the greater the integration of the interlacing with fibrous tissue, the greater the resistance of the device as a whole. Conversely, in the case of poor integration or encapsulation, it will be less resistant. The final resistance will depend basically on the degree to which mature type I collagen fibres are laid down.

1.2.2. Elasticity: this is understood as the capacity for elongation without rupture and then recovery to the initial length. It is recommended that a mesh should have good elasticity, especially in the initial stages, for small traction forces (which are the ones it will support physiologically).
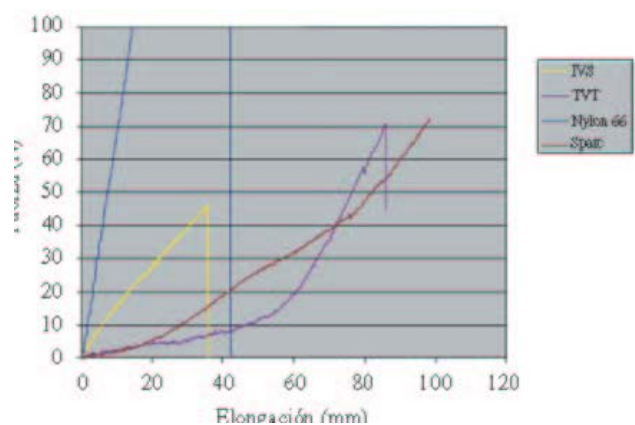

FIGURE 3

Y axis = Force (N)
X axis = Elongation (mm)

The importance of this property was not fully accepted until recently. But in the last few years its relevance has been established, especially in pelvic floor surgery. Lack of elasticity of the scar results in greater vaginal rigidity and may cause discomfort during coitus, limit the distensibility of the bladder, produce symptoms of irritation during urination, etc.[4].

Elasticity depends not only on the properties of the mesh (porosity, density, the material from which it is made, its weave structure) but also on its interaction with the host (resulting fibrous scar tissue, integration with it, etc)[8]. It has been noted that, with a low density mesh, the collagen fibre bundles adopt a distribution parallel to the filament interlacing. This more even collagen arrangement gives the scar greater elasticity[9].

The elasticity of natural tissues for a tensile stress of 16N varies between 10 and 35%[8]. This elasticity must be the target for the implanted materials. Polypropylene meshes adapt best to this behaviour[10].

1.2.3. Malleability, ductility: is the capacity of the mesh to adapt to the surface on which it is placed, adjusting to the shape and irregularities of this surface.

1.3. Behaviour of meshes once implanted

1.3.1. Absorption capacity of the material. According to the behaviour of the material, in terms of its capacity to be reabsorbed, meshes can be classified in:
- Absorbable: made with material that is digested by the receiving organism. Derived from polyglycol acid (Vicryl, Dexon).
- Non absorbable: polypropylene (Prolene); ePTFE; polyester; composites.
- Partially absorbable: made from a blend of materials (absorbable and non absorbable), e.g. polypropylene and polyglycol acid (Vypro II).

1.3.2. Resistance to infection: a fundamental factor to be considered, it depends on the following characteristics:
- Filament pore size: the size of a macrophage is about 16-20 μm, leucocytes 9-15 μm and bacteria measure around 1 μm. Macrophages and leucocytes are incapable of attacking bacteria harboured in pores less than 10 μm in diameter. This factor has a significant influence, as many studies have shown[11]. The published incidence of infection for Amid type II / III meshes varies between 9.6-50% while it is 0% for type I meshes. Infection of the implant in type I meshes can be managed by antibiotic treatment and by draining the wound. Conversely, with type II or III meshes, the mesh must be removed[12].
- Apart from the pore size, the space between the filaments in multifilament meshes can be less than 10 μm. That is why this type of mesh is not included in Amid subtype I (totally macroporous)[13].
- Growth rate of fibrous and vascular tissue. The rapid vascularisation of the scar and the increase in adherence to the surrounding tissues, reducing the gaps, are decisive factors helping to lower the risk of infection[12]. The capacity for angiogenesis and collagen formation depends on how specific molecules of the extracellular matrix and growth factors with an angiogenic capacity, interact with the material forming the mesh. This interaction is especially favourable in type I macroporous meshes[14].

1.3.3. Well tolerated, biocompatible, inert: a biocompatible material is one that causes a favourable reaction when implanted in a living person. It should not induce an inflammatory, allergic or carcinogenic response. The tolerance and biocompatibility of meshes depend on two basic factors:

the material from which they are made[11,15] and its density; the greater the density (more closely woven mesh) the lower its biocompatibility. It has been shown that the lower the density of a mesh, the lower the inflammatory response induced[9] (fewer phenomena of apoptosis and cell proliferation; increase in the expression of cytoprotector factor HSP70[16]). For a mesh to be biocompatible it must not induce:

- an inflammatory reaction: an excessive inflammatory response increases the risk of seromas forming. Another factor that facilitates the accumulation of a seroma is the existence of gaps between the mesh and the surrounding tissue. These gaps are produced when the mesh integrates slowly or poorly with the surrounding tissue and this depends, as we have seen, on the size of the pores and the density of the material[12,15].
- an allergic reaction: an allergic reaction will cause rejection and extrusion of the prosthesis[11].
- tumour growth.

1.3.4. Adherence to the surrounding tissue: the adherence of the mesh to the surrounding tissue depends on two basic factors:

- Initially it depends on the "velcro effect" of the mesh, that is, the structure of the braiding and filaments making up the mesh. This property is important for keeping it in position while it becomes integrated with the surrounding tissue.
- Subsequently, adherence depends on the integration of fibrous tissue in the mesh itself.

1.3.5. Minimum retraction: mesh retraction is due to the fibrous scar tissue that it induces. In all cases there will be some retraction, estimated at between 10-20%[11]. For this reason the mesh must always be left tension-free and sufficiently loose; the less the integration of the lattice with fibrous tissue, the greater the retraction of the scar.

2. GENERAL DESCRIPTION OF INSERTION ROUTE

2.1. Retropubic route

This is the route initially described for the insertion of TVT in 1997. Previously it had been used extensively for the surgical correction of SUI, numerous procedures having been described using needles to pass the tensioning sutures from the vaginal cavity to the abdominal wall. In this surgical approach, the needles are passed through the paraurethral ligaments, the endopelvic fascia, Retzius' space and the abdominal wall. The insertion needles must be passed through these structures as close as possible to the bones of the pelvis. Two methods are described, depending on how the needles are inserted: the lower route (from vagina to abdominal wall) and the upper route (from abdominal wall to vagina). The main disadvantages of the retropubic route are:

- Bladder perforation: an event that occurs relatively frequently and makes an inter-operative endoscopy essential. It is estimated that this bladder injury is produced in around 6% of patients[17]. Perforation is especially frequent in previously operated or very thin women. A perforation, if noted and corrected, barely alters the prognosis or morbidity of the procedure.
- Vascular lesion: vascular lesion is also relatively frequent, especially lesion of the prevesical veins in Retzius' space. With an ultrasound scan or post-surgical blood count (haematocrit and haemoglobin) it is possible to find a high percentage of patients in whom quite a large haemorrhage has occurred in this space. Some authors even quote this percentage as up to 15% of cases[18], although only 0.8% of cases will suffer clinical consequences from it[19,20]. The possibilities of bleeding increase when retropubic vein anastomosis occurs. This can be found in up to 1/3 of women.

To reduce the possibilities of bleeding in this venous plexus, it is recommended that the exit holes of the needles should be made about 3-4 cm from the midline and that the bladder should be left filled with about 300 cc of serum for 60-90 minutes after the operation. A full bladder will have a compressive effect on these veins and will prevent excessive bleeding. Much less frequent is the lesion of larger calibre vessels, generally ileac vessels. Some 20 cases of ileac vessel lesion are described in the literature[21].

- Lesion of intestinal loops: this is a very rare complication but one with serious clinical consequences. It usually occurs when the exit point of the needles is high up in the abdomen[22,23].

There are two basic methods for implanting meshes in a retropubic position:

2.1.1. Lower (from vagina to abdomen): when the needles are inserted from the vaginal cavity to the abdominal wall. Recently a lower retropubic method has been described[24], the intention being to avoid the risk of bladder perforation and bleeding in Retzius' space by passing the needles in front of the pubic bone, through the subcutaneous cell tissue. With this method, the mesh seems to be less well secured and there are more post-operative problems. The long-term results with this method are not yet known.

2.1.2. Upper (from abdomen to vagina): when the needles are passed from the abdominal wall to the vagina. The advantage of this form of insertion is that accidental lesion of large vessels or intestinal loops is more difficult, but some problems do occur:

- A larger vaginal incision and a larger paraurethral dissection are necessary.
- In obese patients it is difficult to position the needles correctly.
- The mesh tends to be placed in a position closer to the neck of the bladder, which results in an increase in post-operative dysuria[25].

2.2. Transobturator route

The transobturator route is intended to avoid accidental perforation of the bladder and therefore the need for an intra-operative endoscopy[26,27]. The needles are passed from the inner face of the thigh to the paraurethral vaginal region through the obturator foramen and the puborectal muscles[26]. Two different methods have been described: from the thigh to the vagina ("out-in" method) and in the opposite direction ("in-out"). This type of correction reproduces the natural anatomical suspension of the urethra. The incidence of post-operative dysuria also seems to be lower than with the retropubic route[26]. However, as some studies have shown, there is a slight probability of injury to the bladder, therefore it is recommended that a cystoscopy should always be carried out, especially in "out-in" procedures[28]. The use of an "in-out" access, i.e. from the urethra outwards, practically eliminates the possibility of bladder injury (making an intra-operative endoscopy unnecessary) and allows a smaller paraurethral dissection to be made.

Results for the correction of SUI after 12 months appear to be similar to those obtained with the retropubic route[29]. However, to evaluate the effectiveness and long-term results of this new approach, well designed future studies comparing both methods over a period of time will be necessary.

3. USE OF TENSION-FREE SYSTEMS TO CORRECT SUI

At present there are a large number of options on the market for the surgical correction of SUI using tension-free mesh systems (Table 1). However, not all current products are the same and the choice of one or other must be made on soundly based criteria. There follows a brief description of each one, with comments on their main features and properties.

3.1. TVT (Gynecare) (Fig. 4)

This mesh is the most widely used and therefore must be regarded as the benchmark

	TVT	SPARC/MONARC	IVS	URATAPE / OBTAPE	URETEX
			TABLE 1		
Manufacturer	Gynecare	AMS	Tyco	Porges - Mentor	Bard - Sofradin
Composition	Polypropylene	Polypropylene + Absorbable suture (PGA)	Polypropylene	Polypropylene	Polypropylene
Filament structure	Monofilament	Monofilament	Multifilament	Monofilament	Monofilament
Mesh structure	Knitted	Knitted	Knitted	Thermocoagulated	Knitted
Mesh geometry	Quadrilateral	Quadrilateral	Triangular	Square	Quadrilateral (Diagonals: 1' x 2'4 mm)
Porosity (hole Area / total Area	60%	46%	10%	13%	64%
Pore size	> 75 μm	> 75 μm	< 10 μm	< 10 μm	> 75 μm
Amid type	Type I	Type I	Type III	Type II	Type I
Weight (g/m^2)	95	120	84.2	98	87
Thickness (mm)	0.65	0.69	0.38	0.55	0.63
Breaking point	84 N	50 N		50 N	76 N
Elasticity (% elongation with 15 N)	92%	44%	12%	8%	54%
Dimensions	1.1 x 45 cm	1.1 x 35 cm	0.6 x 40 cm	2 x 60 cm	1.1 x 45 cm
Implantation route	Abdominal: retropubic transobturator	Abdominal: Transobturator	Retropubic	transobturator	Abdominal: retropubic

against which to compare the rest. Its basic characteristics are as follows:

- Made from Amid type I monofilament polypropylene (Prolene). From the experimental data published, poly-propylene appears to be the most appropriate material for tension-free meshes used to correct SUI[2,12].
- Knitted.
- Low density, it has a porosity of 60%.
- Optimum elasticity: the mesh has a very good elongation capacity, especially for tensions up to 10 N. With this tension an elongation of 40 mm is obtained. Breaking point is reached at a force of more than 70 N.
- Plastic sheath for the mesh during insertion.
- Metal insertion system for inserting it

- from vagina to abdomen. There is also a device for inserting the mesh by the transobturator "in-out" route (TVT-O) or by the retropubic route from abdomen to vagina.

The TVT system has been used since 1996, when it was described by Ulmsten[30], with extensive experience existing throughout the world. Since then, more than 500,000 devices have been implanted. Recent studies published have reported the experience and results with TVT after 7 years of the surgery. Innumerable studies have also been published by European and American groups, etc. showing their results in correcting SUI with this type of suburethral tape. This state of affairs is of enormous importance and one of the most important considerations when selecting the device to use.
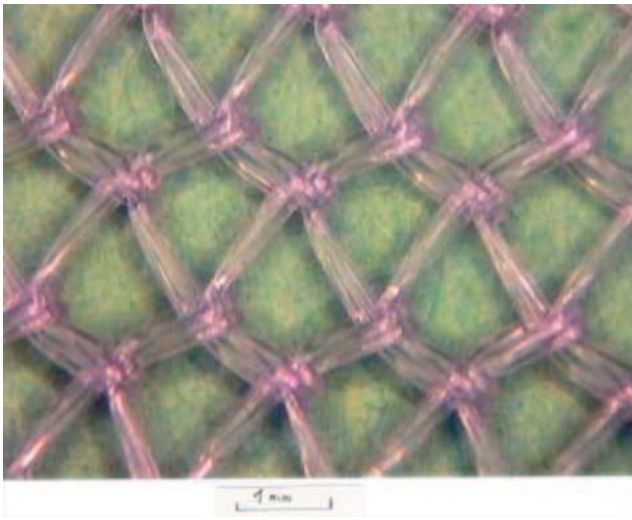
FIGURE 4. TVT Mesh.

FIGURE 5. Sparc system Mesh.

Much less experience has been gained with the other meshes and there are no published series with a sufficient number of patients and follow-up time to allow comparison of the results with TVT[31,32]. We do not believe that it is possible to extrapolate the results obtained with TVT to any other tension-free system. As has been established, the differences in the characteristics of the mesh or the system of implantation make such an extrapolation meaningless. The results for each individual system must be analysed without assuming that the efficacy achieved with one will be obtained with another.

3.2. SPARC / MONARC (AMS) (Fig. 5)

The mesh used by the SPARC / MONARC system is the one most resembling that of TVT. In its present form, it is also made from knitted monofilament polypropylene of low density (46%), protected by a plastic sheath to facilitate insertion. The elasticity of the mesh is good although not as favourable as TVT, as can be seen in Figure 3 which shows that, to obtain an elongation of 40 mm, a force of at least 20 N must be applied (double that required with TVT). One of the improvements provided by this device is that it has a suture of absorbable material (PGA) which allows the implant to be pulled if it has been placed with excessive tension.
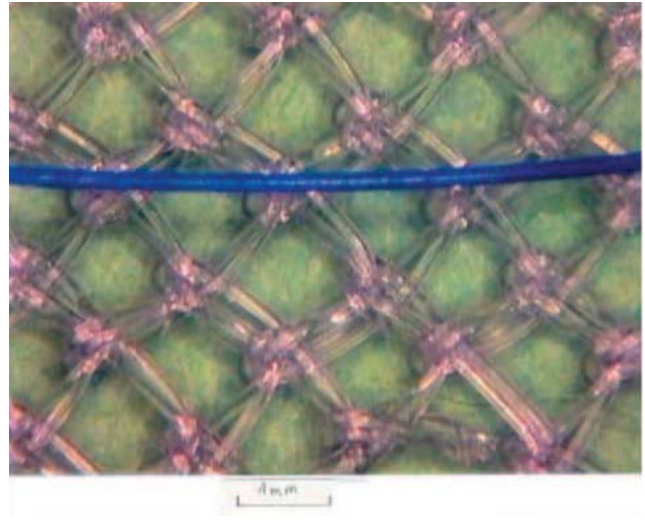
The primary differences from Gynecare mesh lie in the insertion system. In this case the mesh is placed by inserters that pass from the abdomen to the vagina (SPARC) or by the transobturator "out-in" route (MONARC). The disadvantage of this insertion system is that the mesh cannot be released from its attachment to the needle so that, if the need arises (inadvertent perforation of the bladder, etc.), a new device must be used.

3.3. IVS (Tyco) (Fig. 6)

This is a knitted multifilament polypropylene mesh (Amid Type III), with a high density of material (10%). The "velcro effect" is practically nil therefore it is unnecessary to have a protective plastic sheath, and indeed it does not have one. The mesh is implanted by a retropubic method.
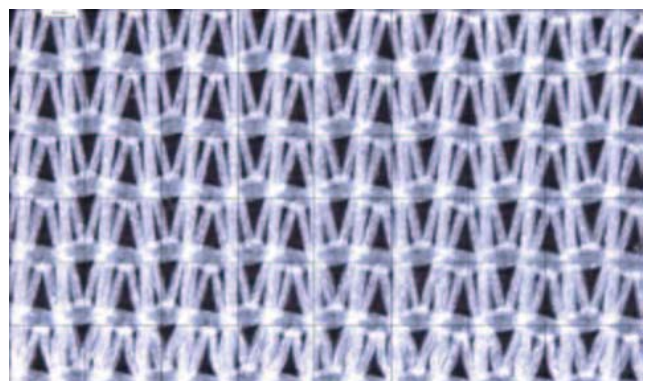

FIGURE 6. IVS Mesh.

3.4. URATAPE / OBTAPE (Porges) (Fig. 7)

Porges mesh was made initially from two components: the ends were of thermo-coagulated monofilament polypropylene and the middle, on which the urethra is supported, was silicon. This middle part was characterised by its high density and microporous properties, but it has been dropped recently. The uratape system is inserted by the retropubic route and the obtape system by the transobturator route.

3.5. URETEX (Bard) (Fig. 8)

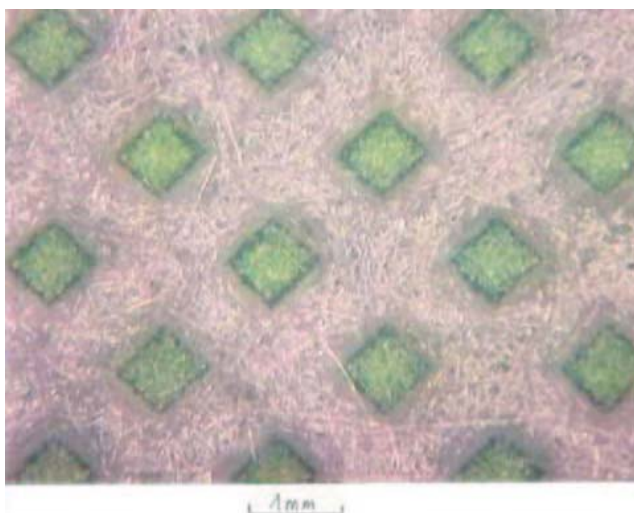This is a knitted monofilament polypropylene mesh of low density (64%) for insertion by the retropubic route.

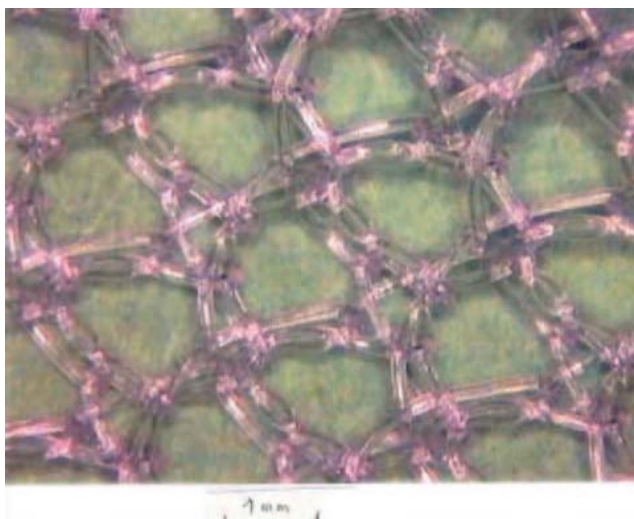

FIGURE 7. Uratape/Obtape Mesh.

FIGURE 8. Uretex Mesh.

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