The introduction of mid-urethral slings: an evaluation of literature

Cornelis R. C. Hogewoning[1*]
Lieke Gietelink[1*]
Rob C. M. Pelger[1]
Cornelis J. A. Hogewoning[2]
Milou D. Bekker[1]
Henk W. Elzevier[1]

** Both authors attributed equally to the manuscript*

1. Department of Urology, Leiden University Medical Center
2. Department of Obstetrics and Gynecology, Albert Schweitzer Medical Center

(International Urogynecology Journal & Pelvic Floor Dysfunction (2015 Feb);26(2):229–234)

2

Introduction

Over the last two decades, synthetic mid-urethral slings (MUS) have changed urogynecological surgery for stress urinary incontinence (SUI) in women. The tension-free vaginal tape (TVT; Women's Health & Urology, Ethicon, Johnson & Johnson) was introduced by Ulmsten et al. in 1996 (1). With a reported 16-year success rate of 70–90% and a low risk of complications, the technique has proven to be effective and safe over the years (2;3). The principle of the TVT is based on restoring the anatomy and function of the mid-urethra, resulting in the restoration of the patients' continence using minor surgery. The TVT therefore became the cornerstone of surgical treatment for SUI.

Soon after the introduction of the TVT other MUS devices started reaching the market. Over the last decade, numerous MUS devices have been introduced, and although these products claimed to have sufficient similarity to the gold standard TVT, nowhere near all the devices were able to achieve comparable results (2–5). So far, more than 2 million women worldwide have had surgery using MUS. With an ageing population and the increasing availability of healthcare worldwide, this number is sure to increase over the coming years.

In order to provide optimal care for patients, new pharmaceutical products are introduced after extensive, strictly reviewed, and standardized research to ensure safety and efficacy. It is only after intensive evaluation that a new product receives its Food and Drug Administration (FDA) clearance or Conformité Européenne (CE) mark and can be launched for commercial use. In the sling industry, however, companies can introduce a new device without comparative studies. That this method of introduction is far from optimal and can even result in unsafe situations for patients is illustrated by the Mentor ObTape™, which was introduced in 2003 and caused vaginal erosion and obturator abscesses in an unacceptably large proportion of patients (4).

Over the past few years a global discussion has flared up about the regulation of the introduction of new medical devices, such as slings, onto the market. This worldwide problem had already been recognized and extensively analysed in an "editorial" in 2011 by Abrams et al. in the journal European Urology (6). Although this paper very clearly described the problems with the introduction of vaginal slings and proposed well-grounded recommendations, so far, no action has been undertaken by the official bodies responsible.

The first part of this study provides an overview of the degree and reliability of evidence used by the manufacturers before the introduction of MUS onto the commercial market by reviewing pre-introduction data. The second part presents minimum standards for marketed slings by evaluating recent suggestions regarding the introduction of urogynecological meshes devised in an IUGA round-the-table session (7;8).

Materials and methods

The aim was to review and evaluate the research on MUS that was conducted before the launch of a particular sling onto the commercial market. A search for literature was conducted using PubMed and commercial internet search engines (Google ™, Yahoo™) to attempt to identify most types of MUS introduced by the industry over the last decade. Slings were listed and a literature search was performed using MESH terms: "stress urinary incontinence," "mid urethral sling," and brand and/or company name of the sling to identify any pre-launch data. "Related articles" were used to expand the search. Moreover, manufacturers were contacted by email, mail, and phone to provide data used before the introduction of the sling onto the commercial market. Requested data included articles published in either peer-reviewed or non peer-reviewed journals, online data, manuscripts, presentations, brochures, personal communications, and unpublished research. Companies received multiple reminders by mail, by email, and by phone. At the end of the established 6-month deadline, all data received were structured and divided into multiple categories. In the discussion an "experts round the table" discussion by urogynecologists, specializing in SUI, was used to obtain expert views. The design of this study does not include medical research involving human subjects; therefore, no approval of the Medical Ethics Committee was needed.

Results

Forty-one sling devices introduced between 1996 and 2012 were identified (Table 1). Of these 41 slings, 10 were described in a total of 20 studies with sample sizes varying from 10 to 368. The studies included comprised a total of 1,633 patients. Two randomized controlled trials were identified, one of which was published (9); all other studies were non-randomized case series. A total of 6 studies were conducted in a multicenter setting. Thirteen of the studies described were published in peer reviewed journals; the other studies were either unpublished or not publicly available (Tables 2, 3) (1;9-19). Two studies were orally presented at an international conference. The number of articles per sling varied from one to four (Tables 2, 3).

Table 1 Type and manufacturer of MUS

Sling	Technique	Year of approval by FDA/CE	Manufacturer	Company Headquarters
Monarc	Trans-obturator	2002	AMS	Minnetonka Minnesota, USA
Sparc	Retropubic	2004	AMS	"
Miniarc	Single incision (TO)	2007	AMS	"
Uretex	Trans-obturator	2004	Bard	Murray Hill, New Jersey, USA
Pelvilace	Trans-obturator	2004	Bard	"
Align	Retropubic	2010	Bard	"
Ajust	Single incision (TO)	2012	Bard	"
Lynx	Retropubic	2004	Boston Scientific	Natick, Massachusetts, USA
Protegen^	Urethropexy	1996	Boston Scientific	"
Prefyx	Prepubic	2007	Boston Scientific	"
Advantage	Retropubic	2007	Boston Scientific	"
Solyx	Single incision (TO)	2008	Boston Scientific	"
Obtryx	Trans-obturator	2012	Boston Scientific	"
Retropubic I-stop	Retropubic	2005	CL Medical	Winchester , Massachusetts, USA
Trans-obturator I-stop	Trans-obturator	2006	CL Medical	"
Aris	Trans-obturator	2005	Coloplast	Humlebæk, Danmark, EU
Supris	Retropubic	2011	Coloplast	"
T-sling	Trans-obturator	2012	Coloplast	"
Minitape*	Single incision (TO)	2008	Mpathy Medical	-
Omnisure*	Trans-obturator	2009	Mpathy Medical	-
Obtape**^	Trans-obturator	2003	Mentor Medical	-
Sabre**	Trans-obturator	2003	Mentor Medical	-
Uratape**^	Trans-obturator	‡ 2000	Mentor Medical	-
Biodesign Surgisis	Retropubic	2002	Cook Medical	Bloomingdale, Indiana, USA
Intramesh Lift	RP/TO	‡‡ 2012	Cousin Biotech	Wervicq-Sud, France, EU
IVS	Retropubic	2001	Covidien/Tyco	Dublin, Ireland, EU
EmeraldPlus	Single incision	‡‡ 2006	Gallini	Mantova, Italy, EU
T-sling	RP/TO	2002	Herniamesh	Chivasso, Italy, EU
TVT	Retropubic	1996	Johnson & Johnson	New Brunswick, New Jersey, USA
TVT-Obturator	Trans-obturator	2003	Johnson & Johnson	"

Table 1(continued) Type and manufacturer of MUS

Sling	Technique	Year of approval by FDA/CE	Manufacturer	Company Headquarters
TVT-Secur^^	Single incision (TO, RP)	2005	Johnson & Johnson	"
TVT-Abbrevo	Trans-obturator	2010	Johnson & Johnson	"
Remeex	Retropubic	2004	Neomedic	Terrassa, Barcelona, Spain, EU
Needleless TOT	Single incision (TO)	2006	Neomedic	"
Safyre	RP/TO	2002	Promedon	Cordoba, Argentina
Ophira	Single incision (TO)	2012	Promedon	"
Minisling	Single incision (TO)	2007	Prosurg	San Jose, California, USA
Serasis	RP/TO	‡‡ 2007	Serag Wiessner	Naila, Germany, EU
Swing-band	Trans-obturator	‡‡ 2006	Texhitec	St. Pons de Thomières, France, EU
Just Swing	Single incision (TO)	‡‡ 2009	Texhitec	"
TFS	Single incision (TO)	2005	TFS Surgical	Allenby Gardens, Australia

TO: transobturator, RP: Retropubic
^ Withdrawn from market due to high complication rate
^^ Withdrawn from market
* Previously produced by Mpathy Medical, acquired by Coloplast in 2010
** Previously produced by Urology division of Mentor Medical, acquired by Coloplast in 2006
‡ Introduced on European market only, withdrawn due to disappointing results
‡‡ Introduced on European market only

Cure rates found ranged from 78 to 92%. Three studies did not mention any success rates. Reported follow-up ranged from 1 to 36 months, with a mean of 11 months. Complication rates showed a large variation throughout the studies (0-22.1%). These complications included bladder injuries, urinary retention, vaginal erosion, vaginal abscesses, voiding difficulties, and de novo urge incontinence. None of the articles used expressed negative opinions or made any objection about the particular product and its introduction onto the commercial market.

Table 2 Companies and response

Company	Number of slings†	Response*	Data received^	Number of slings with data^^	Data in peer reviewed journal
AMS	3	Yes	Yes	1	YES
BARD	4	Yes	No	0	-
Boston scientific	6	Yes	No	0	-
CL medical	2	No	No	0	-
Coloplast**	8	Yes	Yes	1	NO
Cook Medical	1	Yes	No	0	-
Cousin Biotech	1	Yes	Yes	1	YES
Covidien	1	No	No	0	-
Gallini	1	No	No	0	-
Herniamesh	1	No	No	0	-
J&J	4	Yes	Yes	3	YES
Neomedic	2	Yes	Yes	2	YES
Promedon/ pelvitec	2	Yes	Yes	2	YES
Prosurg	1	No	No	0	-
Serag Wiessner	1	No	No	0	-
Texhitec	2	Yes	No	0	-
TFS Surgical	1	No	No	0	-

† Included in this research

* Response received by either mail, phone or email.

** Including tapes by Mpathy Medical, acquired by Coloplast in 2010, and Mentor Medical, Urology division acquired by Coloplast in 2006

^ Data included articles , papers published in either peer-reviewed or non peer reviewed journals, presentations, brochures, and unpublished research. Answer YES/NO

^^ Number of slings by the different companies examined in this paper

The results of one animal study and two cadaver studies were presented. The animal study included 9 rabbits and showed the tissue response up to 3 months after mesh implantation (study by BIOMATECH, October 2004 on the ARIS sling by Coloplast, unpublished). The cadaver studies primarily looked at the trans-obturator technique and both studies included 10 cadavers (12;16).

Table 3 Data on slings

Company	Sling	Nr. of studies	Patients included	Study design	Animal/ cadaver study	Published in peer reviewed journal*
AMS	SPARC	1 [9]	104	Case series	No	Yes (1)
Coloplast	Aris	2	368	Case series	Animal	No
Cousin biotech	LIFT	2	165	1. RCT 2. Case series	No	Yes (1)**
J&J	TVT	2 [1,16]	256	Case series	No	Yes (2)
J&J	TVT-O	3 [8, 14, 17]	170	Case series	Cadaver	Yes (3)
J&J	TVT-Abbrevo	2 [7,10]	185	1. RCT 2. Case series	Cadaver	Yes (2)
Neomedic	Remeex	4 [15]	69	Case series	No	Yes (1)
Neomedic	Needleless TO	1	56	Case series	No	No
Promedon	Safyre	2 [12,13]	240	Case series	No	Yes (2)
Promedon	Ophira	1 [11]	20	Case series	No	Yes (1)

* Published in a peer reviewed journal: YES/NO (number of publications)
** Published in the Austrian specialist journal ***'Geburtshilfe und Frauenheilkunde'***, volume 67, September 2006, not found on PubMed but available online.

The 41 MUS identified were produced by a total of 19 different companies, two of which have been acquired by a third company in the past decade (Table 1). Seven companies never responded to recurrent emails, phone calls or other means of attempted contact. Information was received on 10 MUS; leaving the remaining 31 slings (76%) without comparative pre-launch data.

Discussion

After its introduction in 1996, multiple companies modified or attempted to recreate the original TVT in order to claim a spot in the growing MUS market. Over the years, dozens of new slings, with multiple new techniques and different materials, have been introduced, but not all of these MUS achieved satisfactory results compared with the gold standard TVT.
A new medical product is cleared for sale after making assertions to the FDA of "substantial equivalence" under Section 510(k) of the Food, Drug, and Cosmetic Act. The FDA states on its website that substantial equivalence is established with regard to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility,

standards, and other characteristics, as applicable. In short, this act states that any new device should be at least as safe and effective as comparable devices already marketed. In the European Union, a CE mark notification is obtained by approval from an independent notified body and a declaration of conformity. When seeking approval by an independent notified body this is usually done by site audits and assessment of technical documentation. A declaration of conformity is a statement by the manufacturer that the product meets the requirements of the European directive. If the device is permitted, the company receives a clearance to market by the FDA or, in Europe, the CE mark. As most devices are relatively comparable with existing slings, permission is generally granted without major obstacles. The new implant should then participate in a post-clearance surveillance to validate its rightful niche in the market.

Regarding the MUS that were described in this study, results show a lack of adequate pre-launch data as well as a defect in the accessibility of follow-up data. This was further illustrated by the fact that only 13 studies were actually published in peer-reviewed journals (Tables 2, 3). Eleven out of 17 companies (65%) did or could not provide any information, which makes validating any statement or conclusion difficult. The high percentage of nonresponses after multiple reminders enhances the supposition that these companies may not have the requested data at their disposal or were not willing to cooperate in sharing information. This study is aware of the difficult, grey area that this suggestion may lead to. However, realizing that sling surgery is so frequently performed and that it has such a great impact on quality of life, data should always be easily accessible (20).

In the process of identifying slings for this study the authors at some point had to limit the research. Inevitably, some slings and companies were not mentioned in the paper. To include all slings introduced onto the commercial market over the past few years would of course be the ultimate goal, but proved to be impossible. This limitation had nothing to do with either inclusion criteria or study restriction, but rather the identification of the many individual slings. Moreover, the aim of this project was not to include all slings up to the present day, but to place emphasis on the lack of pre-launch data in general.

This paper illustrates that company databases are often poorly maintained, not validated, highly variable, and may sometimes be non-existent. Keeping this in mind, the concept of "informed consent" is put into a different perspective altogether. How can one clarify whether a newly introduced sling is both safe and effective, without reliable information being provided to both patients and physicians? With the increase in sling surgery worldwide and new products being developed each year, this is a serious and potentially dangerous issue. Furthermore, physicians worldwide should be more reserved when using new marketed devices. Even though it is legal for a physician to implant a new medical device such as MUS, clinicians and their professional organisa-

tions should only choose those devices that have adequate clinical data to support their efficacy and safety.
A parallel to this dilemma can be found in the use of mesh material in vaginal prolapse surgery. An International Urogynecological Association (IUGA) round table conference in 2012 resulted in a paper addressing similar issues (7;8). The paper states that a standard, before the launch and marketing of a new mesh, should be demanded and guarded by the FDA. The group suggested the following four steps to be taken before the introduction of a new surgical device to achieve this:

1. Comprehensive and exact data on the physical properties of the product.
2. Data on the biological properties of the product following implantation from high-quality animal studies.
3. Anatomical studies on cadavers.
4. A well-constructed and documented cohort study

These four obligatory points should then be followed by compulsory registration of the first 1,000 consecutive patients. The registration should not be liable to any bias and therefore not sponsored by companies involved. Furthermore, the first patients should be operated on by a selected group of specialists who are known experts in this area. As mentioned in the introduction, this matter was also discussed in detail by Abrams et al. in 2011, and similar recommendations were suggested (6).
Finally, we propose that in the future full disclosure of data for either FDA clearance or CE notification should be mandatory for all manufacturers of slings in order to ensure complete openness. These submissions should then be analysed by the surgical committee and published in order to encourage clinicians to judge the scientific merit on which the CE mark or FDA clearance was awarded. The combination of these guidelines should ultimately ensure that in the near future all new slings fulfil their obligations of being both safe for patients and likely to produce a significant improvement in incontinence and quality of life.

Conclusion

Often, no reliable pre-launch data is available or presentable to scientifically prove the performance of new MUS. The FDA and European authorities should undertake immediate action by introducing strict rules, comparable with the suggestions made for meshes in vaginal prolapse surgery, before the launch of new MUS.

Addendum

On 29 April 2014 the FDA released the following press announcement:
The U.S. Food and Drug Administration today issued two proposed orders to address the health risks associated with surgical mesh used for transvaginal repair of pelvic organ prolapse (POP). If finalized, the orders would reclassify surgical mesh for transvaginal POP from a moderate-risk device (class II) to a high-risk device (class III) and require manufacturers to submit a premarket approval (PMA) application for the agency to evaluate safety and effectiveness. Although these two proposals do not include the MUS addressed in this study, the surgical mesh used for transvaginal POP repair is essentially the same material (polypropylene mesh) that is used for most MUS. These recent developments only further amplify our call for immediate action by the FDA and European authorities.

Reference list

1. Ulmsten U, Henriksson L, Johnson P, Varhos G (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 7:81–85
2. Novara G, Ficarra V, Boscolo-Berto R, Secco S, Cavalleri S, Artibani W (2007) Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness. Eur Urol 52:663–678
3. Ogah J, Cody DJ, Rogerson L (2011) Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in wom- en: a short version Cochrane review. Neurourol Urodyn 30:284–291
4. Deval B, Ferchaux J, Berry R, Gambino S, Ciofu C, Rafii A, Haab F (2006) Objective and subjective cure rates aftertrans-obturator tape (OBTAPE) treatment of female urinary incontinence. Eur Urol 49: 373–377
5. Hogewoning CR, Ruhe IM, Bekker MD, Hogewoning CJ, Putter H, DeRuiter MC, Pelger RC, Elzevier HW (2012) The MiniArc sling for female stress urinary incontinence: clinical results after1-year fol- low-up. Int Urogynecol J 23:589–595
6. Abrams P, Chapple CR, Drake M, El-Neil S, Ludgate S, Smith AR (2011) Synthetic vaginal tapes for stress incontinence: proposals for improved regulation of new devices in Europe. Eur Urol 60:1207– 1211
7. Davila GW (2012) Optimizing safety and appropriateness of graft use in pelvic reconstructive surgery: introduction to the 2nd IUGA Grafts Roundtable. Int Urogynecol J 23(Suppl 1):S3–S6
8. Slack M, Ostergard D, Cervigni M, Deprest J (2012) A standardized description of graft-containing meshes and recommended steps be- fore the introduction of medical devices for prolapse surgery. Consensus of the 2nd IUGA Grafts Roundtable: optimizing safety and appropriateness of graft use in transvaginal pelvic reconstructive surgery. Int Urogynecol J 23 [Suppl 1]:S15–S26
9. De Leval J, Thomas A, Waltregny D (2011) The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial. Int Urogynecol J 22:145–156
10. De Leval J (2003) Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape in- side-out. Eur Urol 44:724–730
11. Deval B, Levardon M, Samain E, Rafii A, Cortesse A, Amarenco G, Ciofu C, Haab F (2003) A French multicenter clinical trial of SPARC for stress urinary incontinence. Eur Urol 44:254–258
12. Hinoul P, Bonnet P, Krofta L, Waltregny D, de Leval J (2011) An anatomic comparison of the original versus a modified inside-outtransobturator procedure. Int Urogynecol J 22:997–1004
13. Palma P, Riccetto C, Reges R, Fraga R, Miyaoka R, Hermann V, Marcondes T (2008) Arcus to arcus microsling: technique and pre- liminary results. Int Urogynecol J Pelvic Floor Dysfunct 19:1133– 1136
14. Palma PC, Riccetto CL, Dambros M, Thiel M, De FR, Tamanini JT, Herrmann V, Netto NR Jr, Grossi O, Zangone M, Paladini M, Retto H, Colaco J, Castro DD (2004) SAFYRE. A new concept for adjust- able minimally invasive sling for female urinary stress incontinence. Actas Urol Esp 28:749–755
15. Palma PC, Dambros M, Riccetto CZ, Thiel M, Netto NR Jr (2005) The Ibero-American experience with a re-adjustableminimally inva- sive sling. BJU Int 95:341–345
16. Rogers RM, Lucente VR, Raders J L. Anatomic considerations for the TVT-Obturator approach for the correction of female stress urinary incontinence. 2004; 2004.

17. Sousa-Escandon A, Lema GJ, Rodriguez Gomez JI, Rios TL, Uribarri GC, Marques-Queimadelos A (2003) Externally readjustable device to regulate sling tension in stress urinary incontinence: preliminary results. J Endourol 17:515–521

18. Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, Olsson I (1998) A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 9:210–213

19. Waltregny D, Reul O, Mathantu B, Gaspar Y, Bonnet P, de Leval J (2006) Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: interim results of a prospective study after a 1-year minimum followup. J Urol 175:2191–2195

20. Labrie J, Fischer K, van der Vaart CH (2012) Health-related quality of life. The effect of pelvic floor muscle training and midurethral sling surgery: a systematic review. Int Urogynecol J 23:1155–1162

Erratum to: The introduction of mid-urethral slings: an evaluation of literature

Cornelis R. C. Hogewoning[1]
Lieke Gietelink[1]
Rob C. M. Pelger[1]
Cornelis J. A. Hogewoning[2]
Milou D. Bekker[1]
Henk W. Elzevier[1]

1. Department of Urology, Leiden University Medical Center
2. Department of Obstetrics and Gynecology, Albert Schweitzer Medical Center

(International Urogynecology Journal & Pelvic Floor Dysfunction (2015 Sep);26(9):1403–1404)

2

Erratum

The idea for this study originated in 2012 and aimed to check the availability of company databases on mid-urethral slings. Due to the lack of response and data provided by the involved companies, we decided to perform an additional literature search via PubMed to identify available pre-launch data. In this secondary search the FDA or EU date of approval (whichever was earlier) was used as introduction date. The final results of this search were sent to every company involved for verification. Since the publication of our paper however, relevant information has become available on two slings of which we stated that no pre-launch data was available; the TFS and the I-Stop.

The TFS is produced by TFS Surgical (Allenby Gardens, Australia) and received its FDA approval in May 2005 based on a 510 k declaration of substantial equivalence. Following the publication of our article, information was received that the TFS was in fact under review for 5 years (2004–2009) and not commercialized on the date that the FDA approval suggested. During this period the TFS was deliberately withheld from the from the commercial market and multiple studies were conducted and published in various peer-reviewed magazines (1-5).

The second sling, the I-Stop by CL-medical (Sainte-Foy-lès-Lyon, France), was CE-approved during the last quarter of 2002 after a pre-launch case series of 50 patients (not published). Upon approval, the tape had a targeted launch with a limited number of surgeons willing to participate in the clinical evaluation of the sling. The clinical evaluation was then presented as a poster at the National Congress of the French Association of Urology (AFU) in November 2003 and published as an article in the French magazine 'Endomag' in June 2004 (both not available on Pubmed). The first paper available on Pubmed was published in September 2004 in the journal European Urology (6).

Summarizing, the I-Stop was commercially available on the European market from the last quarter of 2002 to November 2003, without any available pre-launch data. However, during this first year the company did restrict the export of the sling to a limited number of specialists.

With this relevant new data available, table 3 of our article is incomplete. Although we feel that companies should provide an insight into their databases upon request, we realize that by stating a systematic review was performed, we, and not the companies involved, are ultimately responsible for data collection. We therefore apologize for these errors and any issues arising from them. Nonetheless, the conclusion of our article remains unchanged: mid-urethral slings are most often introduced without any scientifically proven basis or pre-launch research.

Reference list

1. Petros PE, Richardson PA (2005) Midurethral Tissue Fixation System sling – a 'micromethod' for cure of stress inconti- nence– preliminary report. Aust N Z J Obstet Gynaecol 45: 372–375
2. Petros PE, Richardson PA (2005) Tissue Fixation System posterior sling for repair of uterine/vault prolapse – a preliminary report. Aust N Z J Obstet Gynaecol 45:376–379
3. Petros PE, Richardson PA (2008) Midurethral tissue fixation system (TFS) sling for cure of stress incontinence–3 year results. Int Urogynecol J Pelvic Floor Dysfunct 19:869–871
4. Petros PE, Richardson PA (2009) The TFS mini-sling for uterine/ vault prolapse repair: a three-year follow-up review. Aust N Z J Obstet Gynaecol 49:439–440
5. Petros PE, Richardson PA, Goeschen K, Abendstein B (2006) The Tissue Fixation System provides a new structural method for cystocoele repair: a preliminary report. Aust N Z J Obstet Gynaecol 46:474–478
6. Krauth JS, Rasoamiaramanana H, Barletta H, Barrier PY, Grisard- Anaf M, Lienhart J, Mermet J, Vautherin R, Frobert JL (2005) Sub- urethral tape treatment of female urinary incontinence–morbidity assessment of the trans-obturator route and a new tape (I- STOP): a multi-centre experiment involving 604 cases. Eur Urol 47:102–106