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LITERATURE REVIEW

The short life cycle of a surgical device – Literature analysis using McKinlay's 7-stage model

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Abstract
Objective: In 1981 McKinlay described "Seven Stages in the Career of a Medical Innovation". We wished to examine whether the model fits a modern device life cycle, and to comment on device manufacturers' influence on the life cycle. We chose to study the complete life cycle of TVT Secur, a mesh kit for surgical treatment of stress urinary incontinence in women, from its marketing in 2006 to device discontinuation for commercial reasons in March 2013.
Methods: A PubMed review was undertaken to identify all published literature related to TVT Secur from 2006 to November 2014. Each publication was classified according to McKinlay's seven stages.
Results: Eighty-three relevant publications from 22 countries were identified: 4 promising reports, 1 professional adoption, 0 third-party endorsement, 34 standard procedure, 19 randomised controlled trials (RCTs) from 2010 and mainly describing comparisons with other TVT family members), 0 professional denunciation of RCT findings, and 4 erosion and discreditation.
Conclusions: McKinlay's seven stages model was useful to describe TVT Secur's truncated life cycle. TVT Secur, fully approved and licensed according to all jurisdictional requirements, generated many descriptive cohort studies but more rigorous RCT evidence appeared only half way through its life cycle. Device discontinuation meant that the stage of erosion and discreditation described by McKinlay occurred after TVT Secur was no longer available.

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We suggest that careful premarket evaluation of safety and effectiveness might decrease the need for commercial discontinuation of devices, and that post-marketing evaluation is a crucial mechanism to protect patients from harm.

Contents

Introduction

On March 31, 2013, Gynecare TVT Secur™ (Gynecare, Ethicon Inc., Somerville, MA, USA) was removed from the device market and became no longer available for purchase. TVT Secur, a member of the Ethicon Gynecare TVT family of devices, was a surgical device used to treat stress urinary incontinence in women by placing a polypropylene mesh tape beneath the urethra, via a single vaginal incision. Surgery is used as last resort for women who have not responded to conservative treatments for their stress incontinence, and who find incontinence impacts their activities and reduces their quality of life.

TVT Secur was licensed for marketing in Europe, USA, Canada and Australia in 2005/2006 on the premise that the device was substantially similar to other licensed midurethral sling devices [1] such as Ethicon's existing tension-free retropubic tape, TVT™ and obturator tape, TVT-O™. Device regulations in these jurisdictions did not require new evidence of safety and effectiveness [1] to license TVT Secur, and no studies had been carried out in live humans before the device was approved [2–4].

In June 2012, Ethicon wrote to physicians announcing that TVT Secur would be removed from the market the following year. The announcement emphasized that the company continued to have confidence in the safety and efficacy of TVT Secur, and that the decision to discontinue the device was based on commercial considerations, specifically related to the changing regulatory environment and competitive worldwide market. The regulatory environment is coming under increasing scrutiny as product advisories related to transvaginally-implanted surgical mesh appear [5–7], the number of withdrawals increases [8] and commentators criticize the licensing of devices without evidence of safety or effectiveness [2–4,9]. The pelvic floor device market is fiercely competitive, including many device manufacturers each with a variety of competing devices. It is a market where frequent device changes are needed to ensure competitiveness [1,10]. In the case of Ethicon, the discontinuation of TVT Secur might have been intended to protect the sales of the remaining members of the TVT family of devices (original TVT, TVT-O, TVT Abbrevo™ and TVT Exact™).

In 1981 sociologist John McKinlay developed a model that described "Seven Stages in the Career of a Medical Innovation" [11]. The seven stages were described as follows:

> Stage 1 – *Promising reports*: enthusiastic reports about a new innovation may appear either in the media or as case reports or uncontrolled observational reports in medical journals.
> Stage 2 – *Professional and organizational adoption*: the new innovation is adopted by powerful groups such as professional associations and larger hospitals.
> Stage 3 – *Public acceptance and third-party endorsement*: the public accepts the innovation as a "good thing" and the health care system or insurers (as appropriate) agree to provide or fund the innovation.
> Stage 4 – *Standard procedure and observational reports*: the innovation becomes part of usual clinical care while studies to ascertain its effectiveness begin, usually taking the form of retrospective studies, case-reports or follow-up studies of "an arbitrarily selected series of patients who have already been subjected to the innovation" [11].

Stage 5 – *Randomised controlled trials* (*RCTs*): these more rigorous studies tend to appear after the widespread adoption of an innovation, and often show that it is less effective than indicated by earlier observational studies.
Stage 6 – *Professional denunciation of RCT findings*: RCTs are often criticized because they do not support current practice, denunciation can sometimes appear in published forms such as letters to the editor.
Stage 7 – *Erosion and discreditation*: occurs as more critical reports appear or when a newer and apparently more attractive innovation appears.

McKinlay's stages map loosely into the marketing product lifecycle (of introduction, growth, maturity and decline) [12], but offers an approach that is more relevant to the adoption of medical devices into complex healthcare settings. McKinlay pointed out that innovations would not necessarily follow the same trajectory: the stages may overlap, and not all stages would be relevant to all innovations [11].

McKinlay's model has been used by other authors to examine the careers of new medical innovations. In 2005 Wright applied the model to the adoption of hormone replacement therapy to manage the symptoms associated with menopause [13]. In 2009 Bo and Herbert studied the adoption of new physiotherapy treatments [14]. In 2010, Wall and Brown used the model to describe the history of earlier incontinence devices that were withdrawn [10]. These studies show that McKinlay's model is relevant to very different clinical situations. Like McKinlay, these authors used the model to show that clinical practice is not in fact anchored in evidence and to argue that innovations should be objectively evaluated prior to their adoption, preferably through RCTs.

We wished to investigate the complete life cycle of TVT Secur from first marketing to discontinuation, and believed that applying McKinlay's model to this case would shed light on the possibilities for evidence-driven health care policy. We chose to use a publicly available source of information, and opted to review the published literature about TVT Secur throughout its lifecycle, basing our analysis on McKinlay's seven stages. Our literature review explored the role of evidence and the nature of medical knowledge in the lightly regulated, highly competitive and commercially driven market for midurethral slings.

Method

We carried out a literature review of all papers cited in PubMed between 2006 and November 2014. Our review included abstracts of reports that involved "TVT Secur" (verified using alternative search terms "TVT Secure" and "TVT-S" and "mini sling"). All papers were included if they described new data of any kind, from basic science or case reports to RCTs. If two papers by the same authors described the same study, but reported one year outcome in the first paper and two year outcome in the second, both were included. Clear duplicates were removed, for example a report of the same trial published in different journals in different languages. Papers that mentioned TVT Secur only in their lists of references were excluded.

Data were extracted for each study including year and journal of publication, author names and countries, study design, interventions and brief results. For analysis, each paper was classified according to the McKinlay seven stages. An additional "other "group was used to capture all other types of published report. Details of the data extraction and McKinlay stage are provided in an appendix for each of the papers included in the review.

The unit of analysis was individual papers. Our analysis described the number and McKinlay stage of the papers published over time, and within each year the proportion of papers from each of the relevant McKinlay's stages. Detailed qualitative analysis was undertaken for each McKinlay's stage, with consideration of the presence or absence of papers associated with each individual stage, discussed in the context of TVT Secur, and the circumstances that may have been associated with that stage.

Results

Our review identified 83 unique published papers reports related to TVT Secur (Appendix A). The papers were written by 58 first authors in 23 countries. The reports were distributed across the years 2007–2014 with most being published since 2010 (Table 1). Additional tabulation of the papers classified by McKinlay stage is presented in Table 2. Twenty-one papers did not fit a McKinlay stage classification: eleven technical reports [15–25], five cadaver or animal studies [26–30] and five reviews or commentaries [31–35].

Analysis for each McKinlay stage follows (associated papers from the literature review are cited beside each stage heading).

Table 1 Number of papers by year and McKinlay stage.

Year McKinlay stage	2007 *n*=1	2008 *n*=7	2009 *n*=10	2010 *n*=15	2011 *n*=14	2012 *n*=14	2013 *n*=8	2014 (first 10 months) *n*=14
1 – Promising reports	1 (100%)	3 (43%)	0	0	0	0	0	0
2 – Professional adoption	0	0	0	0	1 (7%)	0	0	0
4 – Standard procedure	0	2 (29%)	6 (60%)	10 (67%)	4 (29%)	7 (50%)	2 (25%)	3 (21%)
5 – RCTs	0	0	0	2 (13%)	5 (36%)	5 (36%)	3 (38%)	4 (29%)
7 – Erosion and discreditation	0	0	0	0	0	0	1 (12%)	3 (21%)
Other reports	0	2 (29%)	4 (40%)	3 (20%)	4 (29%)	2 (14%)	2 (25%)	4 (29%)

Stage 1 - Promising reports, *n* = 4 [36-39]

McKinlay described the first promising reports of a new innovation as generally being of poor methodological quality, and this was the case for the initial reports of TVT Secur. The studies were small, describing the device as simple to use and safe, despite the short postoperative follow-up. Although TVT Secur was the first device of its type, requiring only a single incision and using a much shorter mesh tape and entirely new absorbable fixation tips, few preliminary reports were published. A large consideration for devices is obtaining a license to sell the device in individual jurisdictions, for example UK, Canada, or USA. The evidence provided in the licensing process is not published, and therefore this process is not identified in the medical literature. TVT Secur, like many devices in this area of practice, was licensed in Europe, the US and Canada on the basis of a predicate licensed moderate risk device, so that no additional evidence of safety or efficacy was required [1-4]. Ethicon claimed the device was substantially equivalent to the company's TVT and TVT-O devices already on the market, and released the TVT Secur accompanied by data on the outcome and follow-up of the older devices. Therefore when TVT Secur was initially marketed, likely it was not perceived as being sufficiently novel to merit promising reports. Despite the apparent similarities to TVT, Ethicon needed to convince surgeons that the device was different enough to change their practice, but this type of marketing occurred at clinical meetings, through contact with Ethicon salespeople, and through professional networks rather than through scientific publication.

Stage 2 - Professional and organizational adoption, *n* = 1 [40]

The competitive nature of the urogynaecology device market and lack of data about which procedures and devices are used to surgically treat incontinence means that we are unable to say how widely TVT Secur was adopted, or even the rate of its use. One report described a large industry-funded prospective registry set up to examine the clinical effectiveness of TVT Secur compared to TVT and TVT-O [40]. Choice of device depended on surgeon preference. Data were contributed from February 2007 to June 2009 with follow-up of 1334 women, 49% of who had a TVT Secur device. It is not clear from the paper whether all participating surgeons contributed TVT Secur patients, so it is not obvious whether TVT Secur was widely adopted even by this apparently committed group.

Stage 3 - Public acceptance and third-party endorsement, no papers identified

Third-party endorsement of a new device such as TVT Secur may often be implicit and determined to a greater degree by clinicians than payers, so we would not expect to find published reports documenting when and why health care systems or insurers approved funding for TVT Secur. Because the newer device (TVT Secur) was licensed as equivalent to other devices with the same indication, and was similar in cost, it likely did not trigger cost-benefit analysis or systematic review by third-party payers. Assuming that the device is approved for use in the institution where the surgery is performed, for example through the institution's health technology assessment process [41] or implicitly through inclusion in purchasing contracts, it would be the responsibility of the surgeon to specify which particular device they would use. Therefore few barriers are present to adopt a new moderate risk device once it is cleared for marketing, and the adoption process is likely a matter of local negotiations, rather than programmatic endorsement.

There has been an increase in public demand for, and acceptance of, surgical treatment for stress urinary continence [42] in the wake of the development of the TVT, but our research [43] and experience suggest that for the most part women are not given, or in a position to make, a choice regarding the particular device used for their surgery.

Stage 4 - Standard procedure and observational reports, *n* = 34 [44-77]

Almost half of the research reports identified in our review fell into this category, the first appearing in 2008. The studies used a variety of cohort designs that fall short of formal evaluation to report clinical practice. These studies were subject to biases inherent in cohort studies and many included small numbers of patients. Despite these limitations, sweeping generalizations were made about the safety and effectiveness of TVT Secur (Appendix A). Over time, the outcomes were seen to be less favorable, reporting more adverse events and lower effectiveness.

Stage 5 - RCTs, *n* = 19 [78-96]

Nineteen papers described results from 15 RCTs (Appendix A). These more rigorous studies started to appear in 2010, although the RCTs were small (the largest study recruited 285 subjects [85]). The first trials compared the different approaches used for TVT Secur ("U" where the tape placement is similar to the retropubic TVT tape, versus "H" where the tape placement is similar to the obturator procedure [78,79]), with later trials mainly comparing TVT Secur to Ethicon TVT-O and/or Ethicon TVT. In these RCTs, the comparisons were bound to produce a favorable outcome for Ethicon, even when TVT Secur was found to be less effective than the older types of tape device. Only two RCTs (3 papers) compared outcomes following TVT Secur to devices from another manufacturer, finding outcomes unfavorable to TVT Secur [83,89,95]. It is not possible to comment on the role of Ethicon in sponsoring RCTs, because the published reports seldom mention funding sources. Only four of the RCTs identified in this review were registered in ClinicalTrials.gov: of those, Gynecare was mentioned as a collaborator for only one [91,96].

As anticipated by McKinlay's model, the RCTs produced outcomes that were less favorable than the cohort studies. Reports of RCTs continued to appear after notification of the discontinuation of TVT Secur, as a result of the delays in completing the research, continuing follow-up, and passing through the peer review process.

Table 2 Number (%) of papers reported for each McKinlay stage.

McKinlay stage	Number of reports (n=83)
1. Promising reports	4 (5%)
2. Professional adoption	1 (1%)
3. Third-party endorsement	0
4. Standard procedure	34 (41%)
Prospective cohort study	17
Retrospective cohort study	10
Comparative cohort study	7
5. RCTs	19 (23%)[a]
TVT Secur versus TOT	8
TVT Secur versus TVT	4
TVT Secur "U" versus "H"[b]	2
TVT Secur versus other device(s)	4
Anesthesia (local versus general)	1
6. Denunciation of RCTs	0
7. Erosion and discreditation	4 (5%)
Other reports	21 (25%)
Technical reports e.g. description of managing an adverse event	11
Reviews or commentaries	5
Cadaver or animal studies	5

[a]Trials could include more than two groups.
[b]"U" technique is akin to retropubic tape placement, "H" akin to obturator placement.

Stage 6 - Professional denunciation of RCT findings, no reports identified

McKinlay described vigorous criticism of RCTs, particularly if those RCTs threatened established practice. Our review (which included letters to the editor) found no criticism of the TVT Secur RCTs, likely because TVT Secur did not become the stress urinary incontinence surgery device of choice among surgeons, and many alternative devices continue to be available. It is also possible that denunciation of RCTs may yet follow.

Stage 7 - Erosion and discreditation, n=4 [97-100]

Our review found four papers that provided explicit evidence of erosion and discreditation, all published since 2013. Two reports were rigorous systematic reviews that investigated outcomes following single-incision mini-slings: one a systematic review with meta analysis [97] and one a Cochrane review [98]. Two additional reviews also report on outcomes of TVT Secur versus other slings [99,100]. These reviews came to very similar conclusions: that TVT Secur was not as effective as the more traditional tape devices and leads to more adverse effects (such as tape erosions and reoperations). The reviews found that there was too little evidence about the outcomes of other single-incision mini-slings to comment confidently on the outcomes of those devices: this conclusion is similar to that in earlier reviews about TVT Secur in 2011 [32,33].

Discussion

In his paper, McKinlay identified major elements in the life of a medical innovation, which he abstracted into stages for analytical purposes [11]. McKinlay's model is, essentially, an ideal-type (or, better, an un-ideal-type), the usefulness of which does not depend on whether the model encompasses all the constituent elements in the life of any particular innovation or whether a particular innovation strictly conforms to the stages. McKinlay made clear in this paper that for any particular innovation there may be variations in the order of events and whether and how each stage occurs. We used McKinlay's stages as an heuristic tool for illuminating a particular case, TVT-Secur. McKinlay's essential point was that innovations are often adopted prior to the availability of high-quality clinical evidence (RCTs) of their effectiveness and efficiency, and when this evidence becomes available, it often shows the innovation to be less effective or safe than assumed. Our aim was to compare the events in the life of TVT-Secur against this un-ideal-type. In this paper, we focus solely on the published literature, because it is the type of evidence that would have been available to physicians and policy makers and represents the evidence that contributed to local and national clinical guidelines. We wished to examine if published evidence on the TVT-Secur followed the same course of development McKinlay isolated in his article. It is remarkable that the development of published research evidence on TVT-Secur does indeed display some of the same tendencies McKinlay identified 35 years ago, given how far the evidence-based medicine movement has advanced in the interim. A more fulsome examination of the history of TVT-Secur is beyond the scope of this paper, but would use McKinlay's stages to examine for instance the role of the media in promoting these or similar devices, the role of formal, but unpublished, means of information sharing (through talks, conference presentations, or workshops) and informal information-sharing (through peer discussion, use of advocates, etc.) [101]. The particularities of TVT-Secur also illuminate ways McKinlay's model may fall short as a description of reality and as a set of policy recommendations, given the nature of the market for moderate-risk medical devices.

The complete life cycle of TVT Secur was illustrated by our review of literature identified from PubMed. As predicted by McKinlay's seven stages model [11], the first papers were small case series describing experience with this new device (stage 1), followed by larger cohort studies with various retrospective, prospective and comparative designs and durations of follow-up (stage 4). Finally randomised studies appeared comparing outcome between TVT Secur and other types of sling procedure (stage 5). Stage 7 was represented by reviews that not only addressed outcomes of TVT Secur, but linked lower effectiveness and potential harm from the procedure to the removal of TVT Secur from the market, evidence of discreditation of the device. McKinlay's 1981 model provided a valuable structure to explore the short life cycle of this device; our analysis also shows how the current market and regulatory system altered TVT Secur's career. The analysis of TVT Secur draws attention to the potentially powerful role of device manufacturers as they manage their product portfolio, and to

the challenges created by such derivative moderate risk devices for evidence-driven policy and clinical practice. In particular, rigorous objective evaluation of innovations (preferably through clinical trials) prior to their introduction, as recommended by McKinlay and advocated by critics of the commercialization of medical devices [2-4,9,10], seems increasingly unlikely.

The failure of current regulatory systems for medical devices, particularly for derivations of moderate risk devices from predicate devices, has become apparent [9,102,103]. TVT Secur is only one example of a new device regulators have cleared as equivalent to a prior licensed device and Ethicon Gynecare was compliant with all the requirements of the regulatory bodies worldwide before marketing their device. Before receiving clearance for marketing, Ethicon was required to provide evidence of pull-out strength for the novel, "self-fixating" TVT Secur tips, but changes from the original TVT device (including the tips and significantly shorter mesh tape) seem to have significantly reduced the procedure's effectiveness. Changes that did not register as "new" with regulators turned out to be significant, as has been the case with other much-publicized devices approved on the basis of substantial equivalence [3,102,104]. In 2011, the Institute of Medicine (IOM) recommended the FDA eliminate the current 510 (k) process and recognized the inevitable inadequacy of premarket surveillance [105]. As well, requirement for premarket surveillance of the vast number of devices produced each year, especially derivative and moderate risk devices, would be particularly difficult to regulate. Changes to political-economic institutions that might create a more patient-focused balance of innovation and risk are remote given resistance to regulatory change and the extent to which corporate interests have redefined and lowered regulatory standards internationally [106]. Attempts to harmonize international device regulations have been slow to move forward, although international standards are being increasingly recognized [1].

Systematic post-marketing evaluation has therefore become a crucial mechanism to protect patients from harm [1,107], as recognized in the IOM report [103,105]. This will require resources, but postmarket evaluation is likely to be a more efficient and thorough response to the complexities of innovation in the arena of medical devices, especially those deemed modifications of moderate risk. Even if high-quality evidence from clinical trials was available prior to marketing, such trials would be unable to provide long-term outcome evidence of safety and effectiveness that would be of relevance to clinicians and patients in selecting the best device [103,108]. Investment in postmarket evaluation will require commitment from national or local policy makers to dedicate scarce health care resources to this effort. There is always risk associated with elective surgery. Health policy makers must consider the level and degree of risk that is acceptable without introducing better monitoring and evaluation of new device derivations.

Finally, two features of this case stand out because they were not anticipated in McKinlay's still classic article and they warrant further study and analysis. One is that litigation arguably now plays a central role in representing the welfare of patients and bringing about device discreditation [109-111]. An internet search using "TVT Secur" and "class action" identifies many legal groups who aim to bring class action suits representing women who feel they have been harmed by the device. The US MAUDE Medical Device Reports database [112] provides further insight: between January 2006 and November 2014, the database includes 1655 entries for TVT Secur mainly related to injury. The vast majority of reports (1546 (93%)) were made in the months of June to December 2013, following the removal of TVT Secur from the device market. Many of the MAUDE entries were instigated by attorneys' reports. These reports could be considered as evidence of discreditation of the device, or else a move to support class action lawsuits. We note that litigation may serve as a quasi-regulator of medical markets and clinical practice. Second is the interdependence of the nature of the market and the nature of knowledge. The type and quality of evidence produced about TVT Secur was certainly shaped, perhaps determined, by the question of whether TVT Secur would be profitable. This is especially apparent in the published RCTs identified in our study, where comparisons often included devices solely from the same manufacturer. In the case of TVT Secur, poor quality evidence was a characteristic of the early stages of the device's lifecycle, as McKinlay described, but also its end. The device came *and* went without being subjected to the kinds of assessment now regarded as rigorous and scientific. Notwithstanding Ethicon's explanation for the withdrawal of TVT Secur, the emergence of just enough evidence to call into question the device's effectiveness, and therefore market viability, must have been important to the company's decision, reinforced recently by evidence from systematic reviews that post-dated TVT Secur's discontinuation [97-100].

In the absence of clear strategies to ensure that derivative moderate risk devices are thoroughly evaluated before marketing, there are important issues to be considered by policy makers and clinicians. Policy makers should understand the level of (or absence of) evidence that supports a new device that is adopted for use in their institution. They must realize that adopting a device without evidence may place their institution and patients at greater risk than using a device that is supported by evidence. For clinicians who decide to use a device unsupported by evidence, there is an ethical need for careful, complete and documented informed patient consent, describing the lack of evidence of safety or effectiveness of the new device [113]. Better tracking systems are needed to know which devices are used when and correlate them with outcomes [8,107].

Conclusion

McKinlay's seven stages [11] provided a useful model to explore the lifecycle of TVT Secur. Our analysis pointed to the limitations of the current situation of seeking evidence only after adoption and funding of new devices, truncation of scientific evaluation, lack of rigorous clinical trial evidence, knowledge generation determined by market viability, and inadequate evidence at both the start and end of the device lifecycle. As well, our analysis highlighted the role of surgeons as the ethical gatekeepers when other authorities (professional organizations and institutions) do not provide high standards for adopting new devices.

Our exploration raised many larger issues outside the restricted topic of TVT Secur that need addressing locally, nationally and internationally about the adoption and post-marketing evaluation of moderate risk devices derived from established devices. It will be essential to establish who should be responsible for these evaluations, who will be the best patient advocate and who will pay for this additional extensive work.

Author statements

Ethical approval

Our study used published literature as its data source, and therefore ethical approval was not required.

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Competing interests

Dr. Ross and Dr. Robert accepted grant-in-aid funding from Johnson & Johnson for an investigator-initiated randomised controlled trial of TVT Secur versus TVT. The trial was published online in December 2014 [114], outside the timeframe of our review. Dr. Ducey has no conflicts of interest to declare.

Appendix A

See Table A1.

Table A1 Brief summary details of TVT Secur publications identified from the PubMed search, 2006 to November 2014.

Year	First author	Ref		Type of study	Device description	Study description	TVT Secur cure - subjective	TVT Secur cure - objective	TVT Secur adverse events	Comments/conclusions
McKinlay stage 1: promising reports										
2007	Martan	36	Czechoslo-vakia	Prospective cohort	TVT Secur	15 TVT Secur (10 H, 5 U) follow-up 1–3 months	NA	93% at 1–3 months	2 tape folded, 1 pain in vagina, 1 3 mm vaginal erosion	Both options are recommended – H might be better for larger mobility of urethra, U better for less mobility
2008	Debodinance	37	France	Prospective cohort	TVT Secur	110 TVT Secur (94 H, 16 U) follow-up to 2 months	NA	70%	Bladder wound, vaginal wound, 4 bleeding GT 100 ml. At 2 months de novo urgency 20%, dysuria 13%, 1 tape exposure, 1 urinary infection, 7 lateral cords	Indications of this new device to be defined
2008	Gorlero	38	Italy	Prospective cohort	TVT Secur	15 TVT Secur	NA	87%	No intraoperative complications, technical difficulties – bleeding, dislocation/removal of mesh, need to repeat procedure	Simple, safe, min invasive, with short learning curve
2008	Sola	39	Chile	Retrospective cohort	TVT Secur	16 TVT Secur (6 V, 10 U) , follow-up 1–4 months	NA	100%	No complication	TVT Secur is feasible, safe and effective for SUI, long-term follow-up is needed
McKinlay stage 2: professional adoption										
2011	Tincello	40	UK	Prospective registry	TVT Secur, TVT, TVT-O	1398, Postop data at 1 year – 438 TVT, 237 TVT-O, 659 TVT Secur	"response" 79% TVT-O, 85% TVT, 85% TVT Secur	96% TVT-O, 87% TVT, 84% TVT Secur (cough test)	NA	High effectiveness of all 3 tapes
McKinlay stage 4: standard procedures										
2008	Jimenez	44	Spain	Comparative cohort	TVT Secur, MiniArc	51 TVT Secur, 41 MiniArc (all H) follow-up 5–17 months	NA	80% TVT Secur, 90% MiniArc		Fewer complications than TVT, TVT-O, further studies needed
2008	Neuman	45	Israel	Prospective cohort	TVT Secur (H)	100 Consecutive TVT Secur H (cf 1st and 2nd 50)	NA	89%, 94% (1st cf 2nd 50)	Early group complications – 4 vaginal wall penetrations with inserters, 2 tape tension	TVT Secur associated with early safety and efficacy problems. Need for meticulous and proper

Table A1 (*continued*)

Year	First author	Ref		Type of study	Device description	Study description	TVT Secur cure - subjective	TVT Secur cure - objective	TVT Secur adverse events	Comments/conclusions
									requiring surgery, 1 hematoma, 5 removal when inserters removed, 6 tape extrusion. Technique modified for second group - 4 tape extrusion	dissection before placement of tape
2009	Debodinance	46	France	Prospective cohort	TVT Secur	154 TVT Secur, follow-up 12 months	NA	70%	Peroperative complications: 5 hemorrhage, 12 bladder injury, 1 vaginal wound. Postop, 2 exposed tapes, 1 granuloma, 1 UTI, 7 lateral vaginal bands	Results considered inferior to TVT or TVT-O
2009	Martan	47	Czechoslo-vakia	Prospective cohort	TVT Secur	85 TVT Secur	NA	62% (cough test)		Objective cure was low, perhaps because of insufficient restriction of urethral mobility
2009	Meschia	48	Italy	Prospective cohort	TVT Secur	91/95 TVT Secur, follow-up at 1 year	78%	81%	Voiding difficulty, recurrent UTI, de-novo urgency, dyspareunia	TVT Secur has 80% success rate
2009	Oliveira	49	Portugal	Prospective cohort	TVT Secur	107 TVT Secur, mean follow-up of 15 months	69%	71%	Urgency de novo in 6%, 1 vaginal erosion	Simple and safe, needs long-term follow-up
2009	Sola	50	Chile	Prospective cohort	TVT Secur	110 TVT Secur, follow-up 2–19 months	96%	NA	2 bladder perforations, 2 obstruction	Has potential avantages vs older techniques, long-term follow-up needed
2009	Tartaglia	51	Italy	Retrospective cohort	TVT Secur (H)	32 TVT Secur H, follow-up 12–18 months	100%	NA	No surgical complicatons, 1 erosion	Safe and easy, may have fewer complications
2010	Alvarez	52	Spain	Retrospective cohort	TVT Secur, MiniArc	50 TVT Secur, 105 MiniArc, follow-up over 26 days	NA	NA	Complication rate 22% TVT Secur, 17% MiniArc. 1 bladder perforation. (early comp all in MiniArc.) 5% vaginal erosion, 4% urethral obstruction, 1% recurrent infections	surgery with mini-slings "is not without complications (20%)"
2010	Cornu	53	France	Prospective cohort	TVT Secur	45 consec TVT Secur +/− POP, follow-up at	NA	40% Cure (composite) at last follow-up	5 de novo OAB, 3 UTI. 12 Patients needed additional SUI surgery during follow-up	…"despite its good short-term efficacy, TVT Secur is associated with a high recurrence rate of SUI"

						11–40 months – see also [67]				
2010	Gagnon	54	Canada	Prospective cohort	TVT Secur	48 TVT Secur first 23 H, last 26 U, LA, outcome at 6mo	Improved sympts 69% H vs 100% U	NA	6 partial tape exposures all with H	Short term efficacy better for U, long term outcome to be determined
2010	Jeong	55	Korea	Comparative cohort	TVT Secur, Monarc	64 (31 TVT Secur, 33 Monarc), follow-up over 1 year	NA	71% TVT Secur, 85% Monarc	No significant complications	TVT Secur and Monarc may be comparable for cure and satisfaction
2010	Joo	56	Korea	Comparative cohort	TVT Secur, CureMesh	60 (38 TVT Secur, 22 CureMesh) follow-up to 1 year	NA	68% TVT Secur, 77% CureMesh	No intraoperative complications	Both are safe and simple. Long-term studies needed
2010	Khandwala	57	USA	Retrospective cohort	TVT Secur	141 TVT Secur, follow-up at 6 months	83%	NA	No intraoperative complications	TVT Secur is safe and effective for SUI
2010	Krofta	58	Czechoslo-vakia	Prospective cohort	TVT Secur	86, 84 Followed-up at 1 year	60%	52%	Vaginal defect healing in 5, urethral erosion in 1	"Objective and subjective cure rates following TVT Secur are inferior to other tape procedures"
2010	Liapis	59	Greece	Prospective cohort	TVT Secur (H,U)	TVT Secur (43 H, 39 U) follow-up at 1 year	61% H, 69% U	63% H, 72% U	No significant adverse events	Comment – efficacy of TVT Secur was lower than other (published) TVT cure rates
2010	Lim	60	Australia	Prospective cohort	TVT Secur (U)	TVT Secur 42 (recruitment stopped early), follow-up to 6 months	51%	58%	UTI, voiding difficulty, groin discomfort, hematoma, vaginal pain, tape erosion, intra-op dislodgement of tape, de novo urge 10%	Ceased early because of high of early failures. Claims of advantages "may be at the expense of a significant learning curve and a higher early failure rate". TVT Secur not recommended on basis of this limited study
2010	Tommaselli	61	Italy	Comparative cohort	TVT-O, TVT Secur	84 (38 TVT-O, 37 TVT Secur) follow-up to 1 y ear	82% TVT-O, 84% TVT Secur	NA	Complication rate TVT Secur 8%, TVT-O 16%	Effective, safe and low incidence of complications
2011	Chen	62	China	Retrospective cohort	TVT Secur	30, Follow-up to 12 months	NA	60% at 12 months	OAB in 23% at 12 months	"TVT Secur has a high rate of recurrence of SUI"
2011	Neuman	63	Israel	Comparative cohort	TVT-O, TVT Secur	162 (outcomes available for 60 TVT-O and 77	91% TVT Secur, 87% TVT-O	NA	Transient thigh pain in TVT-O (32% vs 1% in TVT Secur). Dyspareunia	Thigh pain more frequent in TVT-O (32% vs 1%),

Table A1 (*continued*)

Year	First author	Ref		Type of study	Device description	Study description	TVT Secur cure – subjective	TVT Secur cure – objective	TVT Secur adverse events	Comments/conclusions
						TVT Secur) follow-up over 36 months			occurred more frequently in TVT Secur group (8% vs 0%). Other complications similar	dyspareunia more common in TVT Secur (8% vs 0)
2011	Pushkar	64	Russia	Comparative cohort	TVT Secur, TVT-O	32 TVT Secur, 40 TVT-O, follow-up to 6 months	Positive result: 62% TVT Secur, 95% TVT-O	NA	NA	Failed for 5 TVT Secur. TVT-O is more effective than TVT Secur
2011	Shin	65	Korea	Retrospective cohort	TVT Secur	51, Follow-up to 2 years, data available for 46	76%	NA	No complications	"TVT Secur is an efficient and safe procedure"
2012	Bernasconi	66	Italy	Prospective cohort	TVT Secur (H, U)	110 H, 26 U, follow-up to 2 years	93% 6mo, 92% 12 months, 92% 24 months	(cough test) 88% 6 months, 89% 12 months, 89% 24 months	Vaginal erosions in 2% at 24 months	Safe, effective, but "has an appreciable learning curve"
2012	Cornu	67	France	Prospective cohort	TVT Secur	Update on (Cornu 2010 [53]) plus 9 patents (i.e. 54), follow-up at median 59 months	NA	31% Cure (composite)	Reoperation in 29% because of failure	TVT Secur results worsen with time…No severe as during follow-up
2012	Han	68	Korea	Prospective cohort	TVT Secur (H,U)	96 (42 H, 54 U), follow-up for GE 3 years	73% 3-year	NA	3 perforation of anterior vaginal wall, 13% de novo urgency, 19% UUI, vaginal erosion in 1 H and 1 U, 6 had further procedures for new/persistent SUI	Success (but not cure) maintained
2012	Hwang	69	S Korea	Comparative cohort	TVT Secur, TOT	89 TVT Secur, 86 TOT, follow-up GE 1 year	71% vs 91% (survey or stress test)	NA	No significant differences in complications. 2 TVT Secur patients required reoperation	TVT-O superior to TVT Secur
2012	Khandwala	70	USA	Prospective cohort	TVT Secur (H)	50 TVT Secur H, follow-up at 24mo	NA	80% Success (composite), 9% reoperation	No intraop or postop complications. 2 vaginal mesh exposure	In-office procedures are safe, feasible, successful with minimal complications
2012	Richard	71	Canada	Retrospective cohort	TVT Secur (U)	33 TVT Secur, 1 year follow-up	78%	63%	1 BOO, no complaint of voiding symptoms	
2012	Tommaselli	72	Italy	Retrospective cohort	TVT Secur (H)	68 TVT Secur, 2yr follow-up	NA	81%	Intraop – 1 vag wall tear, 1 severe bleed; post-op –	TVT Secur is safe and effective

								5 urgency, 1 retention, 1 tape exposure	
2013	Tang	73	China	Prospective cohort	TVT Secur	33 TVT Secur, follow-up to 12 months	NA	78%	1 erosion found at 12 months	"Objective cure rate not high" TVT Secur said to be "minimally invasive, safe and effective"
2013	Abduljabbar	74	Saudi Arabia	Retrospective cohort	TVT Secur, TVT	230 (81 TVT Secur, 149 TVT) follow-up at 6 months	NA	NA	Note – cannot differentiate between TVT Secur/TVT. 4% bladder perforation, 23% bladder retention at 24 h, 3 cases of erosion	TVT Secur and classical TVT were found to be effective, easy and safe procedures
2014	Angleitner-Flotzinger	75	Austria	Retrospective cohort	TVT Secur	158 TVT Secur – 96 followed-up at 5–50 months	46%	30% (cough test)	8% Reoperation, no tape erosion/exposure, 21% de novo urgency, 4% dyspareunia	TVT Secur appears to have low adverse events but inferior results compared to traditional midurethral slings
2014	Bourdy	76	France	Retrospective cohort	TVT Secur, TVT-O	371 (29 TVT Secur, 342 TVT-O) follow up median 4 years	NA	NA	Exposures: TVT Secur 14%, TVT-O 4%	TVT Secur seems less efficient than traditional slings and gives rise to more exposure
2014	Luo	77	China	Prospective cohort	TVT, TVT-O, TVT Secur	453 Consecutive patients (105 TVT, 243 TVT-O, 90 TVT Secur, 15 TVS)	97% TVT, 100% TVT-O, 99% TVT Secur, 100% TVS	NA	Only minor complications were experienced by the patients	Each sling procedure was found to be safe and effective
McKinlay stage 5: RCTs										
2010	Kim	78	Korea	RCT	TVT Secur (U, H)	115 (53 U, 62 H), follow-up at 1yr	NA	88% U, 87% H	3 Vaginal wall perforation (H), postop retention for 3 (2 U, 1 H)	Comparable effectiveness for U and H
2010	Lee	79	Korea	RCT	TVT Secur (U, H)	285 TVT Secur (144 U, 143 H) follow-up at 1 year	77% U, 76% H	88% U, 80% H	3 intraop vaginal wall perforation, 1 increased bleeding, 3 temporary postop retention (group not explicit)	H and U TVT Secur provided comparable cure rates for women with SUI
2011	Andrada	80	Sweden	RCT	TVT, TVT Secur	125 rand, 123 (62 TVT, 61 TVT Secur) follow-up at 2 months – see [90]	92% TVT, 72% TVT Secur	NA	Tape erosion into urethra, tape placed inside bladder, immed postop bleed from corona mortis	TVT Secur lower subj cure, 3 serious AEs therefore discourage further use. See also 3
2011	Araco	81	Italy	RCT	Local vs general anesthesia	80 TVT Secur (40 local, 40 general)	NA	NA	Postoperative complications 8% in each group	Local anesthesia reduces pain and shortens hospital stay

Table A1 (*continued*)

Year	First author	Ref		Type of study	Device description	Study description	TVT Secur cure – subjective	TVT Secur cure – objective	TVT Secur adverse events	Comments/conclusions
					for TVT Secur(H)					
2011	Hinoul	82	Belgium	RCT	TVT Secur, TVT-O	96 TVT Secur, 98 TVT-O, follow-up 1 year	76% TVT Secur, 92% TVT-O	84% TVT Secur, 98% TVT-O	TVT Secur: 7 tape exposures, 14 reoperations for SUI. TVT-O: 1 tape exposure	TVT Secur gave less postop pain, lower objective cure rate, more re-intervention
2011	Oliveira	83	Portugal	RCT	TVT-O, TVT Secur, MiniArc	90 (30 TVT-O, 30 TVT Secur, 30 MiniArc), follow-up to 12 months	NA	83% TVT-O, 67% TVT Secur, 87% MiniArc	No intraoperative complications. Postop 2 TVT-O required surgical release of tape for retention. Other complications – transient urinary retention, de novo urgency, thigh pain (2 TVT-O, 1 MiniArc)	"TVT Secur may yield an inferior outcome"
2011	Wang	84	China	RCT	TVT, TVT-O, TVT Secur	102 (32 TVT, 36 TVT-O, 34 TVT Secur), follow-up to 1 year	94% TVT, 92% TVT-O, 68% TVT Secur	NA	TVT – 1 bladder perforation, 3 urine retention, 5 urgency; TVT-O – 1 urine retention, 5 pain in thigh, 6 urgency; TVT Secur – 1 bladder perforation, 12 urgency	TVT Secur "had rare complications but unsatisfactory efficacy, and we suggest it is not fit for severe cases"?
2012	Barber	85	USA	RCT	TVT Secur (U), TVT	126 TVT, 136 TVT Secur, follow-up to 1 year	57 % TVT Secur, 61% TVT	NA	TVT Secur – 1 bladder perforation, no mesth exposure, 2 sling release; TVT – 6 bladder perforations, 1 mesh exposure at 6 weeks, 3 sling release	TVT Secur results in "similar subjective cure rates to TVT 1 year after surgery, but postoperative incontinence severity is greater…."
2012	Hota	86	USA	RCT	TVT Secur (H), TVT-O	43 TVT Secur, 44 TVT-O follow-up to 1 year	TVT Secur cure	48% TVT Secur, 91% TVT-O (cough stress test)	TVT Secur – 19%mesh exposure requiring surgery. TVT-O – no mesh exposure	More pos cough in TVT Secur but QOL/satisfaction similar (study terminated early)
2012	Masata	87	Czechoslo-vakia	RCT	TVT-O, TVT Secur (H, U) (3 group)	68 TVT-O, 64 TVT-SH, 64 TVT-SU follow-up 3 months – see [87]	91% TVT-O, 82% TVT-SH, 78% TVT-SU	95% TVT-O, 82% TVT-SH, 78% TVT-SU	Tape exposure, 8% TVT-SH, 6% TVT-SU, 1% TVT-O. Reoperation, 1% TVT-SH, 1% TVT-SU, 0% TVT-O	Lower subj, obj cure in TVT Secur groups at 3 months
2012	Masata	88	Czechoslo-vakia	RCT	TVT-O, TVT Secur (H, U) (3 group)	68 TVT-O, 64 TVT-SH, 64 TVT-SU follow-up	85% TVT-O, 69% TVT-SH, 62% TVT-SU	93% TVT-O, 69% TVT-SH, 69% TVT-SU	TVT-O – 2% erosions, no reoperations: TVT-SH – 8% erosions, 19%	Lower subj, obj cure in TVT Secur groups at 1 year

						median 2 years (GE 0.1 year) – see [87]			reoperations: TVT-SU –6% erosions, 14% reoperations	
2012	Palomba	89	Italy	RCT	TVT Secur, MiniArc, Ajust	40 TVT Secur, 40 MiniArc, 40 Ajust, follow-up at 30 days – see [95]	NA	NA	TVT Secur group – 2 intraoperative hemorrhage, 4 postop pain greater than 7, 1 obturator hemorrhage (Ajust 1 pain greater than 7, MiniArc no complications). At 30 day follow-up, no erosions. Other postop complications included UTI, de novo urge, self-catheterisation of more than 7 days	MiniArc safer than TVT Secur
2013	Andrada	90	Sweden	RCT	TVT vs TVT Secur	133 rand, 121 follow-up at 1yr (61 TVT, 60 TVT S) – see [80]	80% TVT Secur, 98% TVT	71% TVT Secur, 94% TVT-O (cough), 58% TVT Secur, 76% TVT-O (pad)	1 Tape erosion into bladder, one tape placed into bladder, one injury to corona mortis	TVT Secur less effective, 3 serious AEs therefore discourage further use. See also 21.
2013	Bianchi-Ferraro	91	Brazil	RCT	TVT Secur, TVT-O	122 rand, 56 TVT-O, 66 TVT Secur, follow-up 12 months – see [96]	92% TVT Secur, 91% TVT-O	84% TVT Secur, 87% TVT-O	TVT Secur: less thigh pain, complications, vaginal mucosa perforation, urinary retention, urinary infection, de novo urgency	TVT Secur was not inferior to TVT-O
2013	Tommaselli	92	Italy	RCT	TVT-O, TVT Secur	154 rand, 77 TVT-O, 77 TVT Secur, follow-up to 36 months	75% TVT Secur, 80% TVT-O	78% TVT Secur, 86% TVT-O	Postoperative complications 13 TVT Secur, 14%. Mesh exposure 5% TVT Secur, 3% TVT-O	TVT Secur not inferior to TVT-O, causes less postop pain. Cannot rule out possibility of severe blood loss
2014	Tang	93	China	RCT	TVT Secur, TVT-O	39 TVT Secur, 42 TVT-O, follow-up to 2 years	NA	74% TVT Secur, 83% TVT-O (cough)	Groin /thigh pain, 3% TVT Secur, 19% TVT-O 19%; tape erosion, 3% TVT Secur, 7% TVT-O; dyspareunia, 3% TVT Secur, 7% TVT-O	The 2 techniques seem to be equally effective for SUI treatment, but TVT-O resulted in a higher rate of groin/thigh pain
2014	Maslow	94	Canada	RCT	TVT Secur, TVT-O	56 TVT Secur, 50 TVT-O, follow-up to 1 year	63% TVT Secur, 88% TVT-O	63% TVT Secur, 86% TVT-O	Groin pain was more prevalent in TVT-O but resolved over time	TVT-O was superior to TVT Secur in objective cure of stress urinary incontinence
2014	Palomba	95	Italy	RCT	TVT Secur, MiniArc, Ajust	40 TVT Secur, 40 MiniArc, 40 Ajust, follow-up	53% TVT Secur, 65% MiniArc, 53% Ajust	43% TVT Secur, 55% MiniArc, 48% Ajust	Pelvic pain, 3% TVT Secur; new/worse urge, 3% MiniArc, 3% Ajust; erosion, 3% Ajust	The long-term efficacy does not differ between the devices studied

Table A1 (*continued*)

Year	First author	Ref		Type of study	Device description	Study description	TVT Secur cure – subjective	TVT Secur cure – objective	TVT Secur adverse events	Comments/conclusions
						at 24 months – see [89]				
2014	Bianchi-Ferraro	96	Brazil	RCT	TVT Secur, TVT-O	122 rand, 56 TVT-O, 66 TVT Secur, follow-up 2 years – see [91]	76% TVT Secur, 80% TVT-O	77% TVT Secur, 83% TVT-O	Thigh pain: TVT Secur, less thigh pain. Tape exposure: TVT Secur 7%, TVT-O 5%	Efficacy of TVT Secur was similar to that of TVT-O after 2 years
McKinlay stage 7: erosion and discreditation										
2014	Nambiar	97	UK	Systematic review	Single-incision slings	18/31 of the included trials included at least one arm being TVT Secur	Mini slings (mainly TVT Secur) were less effective than transobturator and retropubic tapes	Mini slings (mainly TVT Secur) were less effective than transobturator and retropubic tapes	The adverse event rate was higher for mini slings (mainly TVT Secur}	TVT Secur is inferior to standard midurethral slings for the treatment of women with stress incontinence and has already been withdrawn from clinical use
2014	Mostafa	98	UK	Systematic review	Single-incision slings	26–12 RCTs (1606 patients) compared TVT Secur to "standard midurethral slings"	NA	NA	TVT Secur vs other midurethral slings, mean difference (95% CI) – vaginal tape erosion 2.39 (1.19–4.79). Repeat surgery 4.61 (1.06–20.15), favouring midurethral slings	Analyses of TVT Secur trials were done separately, finding that standard treatment was favoured over TVT Secur for patient reported outcomes. In the analyses without TVT Secur, there was no difference between the outcome of single-incision mini-slings and standard midurethral sling procedures at midterm follow-up
2013	Castellier	99	France	Literature review	Single-incision slings (only mentioned TVT Secur as comparison mini-sling)	Review including 43 papers (comparative and prospective studies) reporting findings for single incision slings	NA	40–83% TVT Secur, 69–92%, MiniArc, 80–91% Ajust, 87% Needleless, 95% Solyx, 85% Ophira	NA	Among single-incision mini-slings, adjustable mini-slings provide the best compromise in terms of effectiveness and complications. Comments on withdrawal of TVT Secur for commercial reasons, because it was

									less effective than other devices
2014	Lizee	100	France	Systematic review	Single-incision slings (only mentioned TVT Secur as comparison mini-sling)	NA	NA	NA	TVT Secur trials were specifically excluded from the review, which concluded there was insufficient data to support single-incision mini-slings as standard of care
Other reports									
2012	Palma	30	Brazil	Animal		Rat model – pull out force of different minislings			
2011	Hubka	27	Czechoslo-vakia	Cadaver studies	TVT Secur	18 Bodies (13 embalmed, 5 fresh frozen)			
2009	Hubka	28	Czechoslo-vakia	Cadaver studies	TVT Secur	19 Bodies (14 embalmed, 5 fresh frozen)			Significant risk of inserting TVT Secur inserters into obturator fossa
2013	Stavropoulou	28	Greece	Cadaver studies	10 Female cadavers				Window of at least 8 mm between margin of TVT Secur and aberrant veins (of corona mortis)
2010	Hubka	29	Czechoslo-vakia	Cadaver studies	TVT Secur				Comment on contact with corona mortis
2008	Molden	31	USA	Commentary	TVT Secur				Little data is available regarding safety and efficacy, long-term follow-up needed
2011	Walsh	32	Australia	Systematic review	TVT Secur	10 Studies included	76%	76%	Vag perf 1.2%, mesh exp 2.4%, OAB de novo 10%. Urinary retn 2%, UTI 4%, dyspareunia 1%. Rpt surgery reqd by 5%	Longer term studies are needed
2011	Oliveira	33	Spain	Review	Single incision slings	16 Papers included				"Techniques (of single incision slings) are easy and seem to require a short learning curve, exception being TVT Secur (TM)"
2012	Zhou	34	China	Meta analysis	TVT Secur, TVT-O/TVT	7 RCTs				TVT Secur gives less postop inner thigh and groin pain, lower objective

Table A1 (*continued*)

Year	First author	Ref		Type of study	Device description	Study description	TVT Secur cure – subjective	TVT Secur cure – objective	TVT Secur adverse events	Comments/conclusions
										cure and higher rates of de novo urgency and re-operation
2014	Leanza	34	Italy	Systematic review	Single-incision slings	Review of TVT Secur, Miniarc, Monarc vs TOT	NA	80–97% TOT, 76–90% TVT Secur, 56–97% MiniArc, 81–95% Monarc	Urethral/vaginal perforation: Rare TOT, 2-5% TVT Secur, 0-3% MiniArc, 2% Monarc	A clear statement in favor of the widespread use of single incision slings cannot be made. More studies must define the efficacy of these techniques
2008	Masata	15	Czechoslo-vakia	Case report	TVT Secur (H)	TVT Secur H			Severe bleeding from internal obturator muscle, required surgical intervention	
2009	Hazenwinkel	16	Netherlands	Prospective cohort	TVT Secur for Ca patients (avoid pelvic cavity)	2 Ca patients, TVT Secur	NA	Both continent	1 Small tape erosion	TVT Secur gives satisfying results postop, additional postop care may be needed
2009	Martan	17	Czechoslo-vakia	Retrospective cohort	TVT Secur (tape shortening)	8 with persistent SUI after TVT Secur	NA	6/8 Patients cured		Repair is simple, effective, cheaper than inserting new tape
2009	Roth	18	USA	Case report	TVT Secur	Dyspareunia for patient and husband because of retained finger pad from device. Sling also malpositioned			Retained finger pad from device	Recommendations for surgeons to avoid such adverse events
2010	Larsson	19	Sweden	Case report	TVT Secur	1 Case, injury of corona mortis				Surgical intervention with removal of 1 L of clotted blood from space of Retzius
2010	Jung	20	Korea	Case report	TVT Secur				Pudendal artery injury (treated with radiological embolization)	Angiography with vessel embolozation should be considered
2011	Gobrecht	21	Switzerland	Case report	TVT Secur					

									Serious bleeding complication due to injury of corona mortis
2013	Tommaselli	22	Italy	Case report	TVT Secur	Report of spontaneous vaginal delivery after TVT Secur	NA	NA	NA
									Sling may not be absolute contraindication to spontaneous vaginal delivery
2014	Zivanovic	23	Switzerland	Case report	TVT Secur	Report of complication and repair	NA	NA	Perforation through bladder wall
2014	Coskun	24	USA	Prospective cohort	Single incision sling removal	Prospective cohort of 17 women having single incision sling removed (2/17 had TVT-Secur)	NA	NA	The TVT Secur problems that brought women to this study were (1) dyspareunia and (2) incontinence+urethral erosion
									This series outlines several complications . . . Caution is required and patient counselling is important
2014	O'Boyle	25	USA	Case report	TVT Secur	Report of complication and repair	NA	NA	1500 ml retropubic hematoma (treated by transvaginal evacuation with installation of hemostatic)
									Significant bleeding can complicate even the least invasive surgical approach to treat stress urinary incontinence

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