Single-Incision Slings (SIS) – a New Option for the Surgical Treatment of Female Stress Urinary Incontinence

Single-Incision-Schlingen (SIS) – neue Entwicklungen in der operativen Behandlung der Belastungsinkontinenz der Frau

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Abstract

The new development of single-incision slings (SIS) for the treatment of female stress urinary incontinence offers comparable results with only minimal side effects and will find wide acceptance in modern incontinence surgery. This mini-sling is inserted over a single vaginal incision and fixed on both sides to the pelvic wall tissue with special anchors, without passing through the groin and avoiding a blind tape passage. Compared with the established sub-urethral tapes, there are comparable success rates with fewer complications. Randomised prospective studies are needed to evaluate whether, in the long run, the benefits of the single incision technique can be correlated with satisfying continence results.

Zusammenfassung

Die Neuentwicklung von Single-Incision-Schlingen (SIS) bei der operativen Therapie der Belastungsinkontinenz der Frau ist mit vergleichbaren Kontinenzraten und nur geringsten Nebenwirkungen verbunden und kann in Zukunft breite Anwendung in der Inkontinenztherapie finden. Diese minimalinvasiven Schlingen werden über eine singuläre vaginale Inzision eingebracht und bds. an der Beckenwand über verschiedene Haltesysteme verankert. Bei gleicher Wirkung durch suburethralen Bandsupport wird hier jedoch eine Blindpassage wie bei den bekannten retropubischen oder transobturatorischen Systemen vermieden. Im Vergleich zu den etablierten suburethralen Schlingen zeigen sich in den ersten Untersuchungen äquivalente Erfolgsraten und deutlich geringere Nebenwirkungen. Hierzu müssen prospektive Studien die Wertigkeit im Vergleich zu den etablierten Verfahren noch belegen.

Introduction

With a prevalence of up to 35%, the number of cases of female stress urinary incontinence requiring operative treatment has risen drastically in recent years. On the one hand, there is growing public awareness of the problem, with increasing freedom from taboos, and increasing willingness of the affected women to undergo therapy. On the other hand, newer operative techniques and materials with a trend towards minimally invasive methods have been developed over the past 15 years.

The successful application of synthetic, tension-free vaginal slings with punctum maximum in midurethra, an implementation of the integral theory of Ulmstem and Papa Petros, has been confirmed in several studies with LoE I and II. Since 1995, more than five million tapes have been implanted around the world, making this the most frequently performed of all incontinence operations. In the meantime, over 16 years, there have been numerous modifications to one of the materials and the insertion aids, and differing sub-urethral access paths for insertion have been developed.

In respect to the material, there is a clear consensus: the tapes used are of polypropylene material, type I in accordance with the amide classification of 1994. This monofilamentous and macroporous material has a pore size > 75 µg and is characterised by fewer reactions from foreign bodies and infections. Rejection reactions and persistent infections can therefore be practically disregarded.

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We Differentiate between Different Access Paths:

1. Retro-pubic route

First described in 1996 by Ulmsten, the retro-pubic route was the original passage for tension-free tapes according to the currently existing conventional sling method. The retro-pubic approach with introduction of the tape via a small colpotomy in the mid-part of the urethra and in supra-symphysary design (bottom-top = TVT® plastic, Gynecare) has been used the longest and has the most study results. Current data from 2008, with a follow-up time of 11.5 years, confirm the high efficiency of the method, with an objective continence rate of 90%, a subjective continence rate of 77% and an improvement of 20% (LoE II) [1]. According to a Cochrane analysis, the retro-pubic route with needle guided from the abdomen to the vagina (top-bottom, e.g. Sparc®, AMS) shows a poorer continence rate compared with the TVT® (77 vs. 82%).

A number of studies comparing TVT and other incontinence operations exist. Burch colpo-suspensions and retro-pubic slings give equally good success rates in respect to continence and negligible side effects, even after five years, LoE I [2].

The retro-pubic passage entails risks and side effects; here, for example, one can mention bladder lesion rates of 3–4% and possible lesions affecting the intestine, blood vessels or nerves on the pelvic wall. Overall, large national complication registers, such as the Finnish register of Kuuva (2002) [3] or the Austrian register of Tamussino (2001) [4], show negligible and acceptable side effects. However, they also report severe problems, including death.

2. Trans-obturator approach

The trans-obturator route introduced by Delorme in 2001 avoids the retro-pubic path and passes the obturator fossa on both sides, but also requires a distinct blind passage.

In a comparison by Latthe et al. between retro-pubic and trans-obturator routes in 2007, no significant differences were found in terms of the continence rate; however, significant differences were found in the examination of the side effects and complications. In the TVT group, there were more bladder lesions and micturition disturbances due to obstruction. At the same time, the trans-obturator method resulted in significantly more vaginal erosions and pain syndromes, with dyspareunia and trouble bending the legs [5].

A recent comparison by Latthe at al. of the trans-obturator method with the TVT-O® (Gynecare) as an inside-out (introduction from the vagina to the abdomen) or Monarc® (AMS) as an outside-in (introduction from outside and leading towards the vagina) reported similar success rates, but indicated differences in terms of side effects and complications. With the inside-out method, there were fewer bladder lesions and fewer micturition disturbances, but more pain syndromes. With the outside-in method, there were significantly more vaginal sulcus injuries [6].

3. Single-incision slings = mini-slings (SIS)

Since the end of the 1990s, developments have also taken place concerning the use of the first mini-slings, which showed still less invasiveness due to a singular access. With these new systems, blind passage is vastly reduced; that is, the tape is not blindly inserted retro-pubically or via the obturator foramen. At the same time, this utilises a considerably shorter sling of around 6.5–12 cm, thereby introducing less foreign material. The objective is to achieve adequate continence rates compared with the established sling methods, with a further significant reduction of possible complications.

Table 1 lists the single-incision slings available on the market together with their specific properties.

Initially, different tapes were used, including bio-materials with non-ready-to-use insertion aids. For this reason, the classification of the initial data is very difficult today.

In 1999, Palma et al. introduced the tendinous urethral support System (TUS system), using a sub-urethral sling of bio-material. A bovine pericardium mini-sling was inserted vaginally in 10 patients and anchored on both sides to the tendinous arch. Following an initially high success rate after four weeks, distinct infections and erosions, with an incontinence rate of 50%, were found after one year [7]. In a subsequent trial, a porcine sling made from small bowel sub-mucosa was used. Here again, initially there were high continence rates; initial results after six months with 25 patients indicated a good continence rate of 87%, dropping to 65% after 72 months [8,9]. With the use of synthetic tape materi-

Table 1 List of the available single-incision slings.

Tape	Manufacturer	Material	Length	Insertion aid	Attachment	Adjustability
DynaMesh® minor	FEG Textiltechnik mbH, Aachen, Germany	PVDF monofilament	6 cm	no	self-adhesive surface	no
TFS®-System	TFS Surgical, Adelaide, Australia	Polypropylene monofilament	variable	yes	anchors	yes
Solyx®	Boston Scientific, Natick, MA, USA	Polypropylene monofilament	9 cm	yes	barbs	no
Minitape®	Gyneldas, Glasgow, UK	Polypropylene monofilament	14 cm	yes	anchors	no
Contasure Needleless®	Neomedic Int., Barcelona, Spain	Polypropylene monofilament	11.4 cm	no clamp	self-adhesive pocket system	no
TVT-secur®	Gynecare/Ethicon, Somerville, NJ, USA	Polypropylene monofilament	8 cm	yes	vicryl and PDS anchor tips	no
MiniArc-Precise®	AMS, Minnetonka, MN, USA	Polypropylene monofilament	8.5 cm	yes	anchors	no
Ajust®	C. R. Bard Inc., Murray Hill, NJ, USA	Polypropylene monofilament	6.5 cm	yes	anchors	yes
Ophira®	Promedon, Cordoba, Argentina	Polypropylene monofilament	3.8 cm mesh	yes	barbs	no

al, Palma was able to achieve a success rate of 88% and an improvement of 5.5 in 20 women in 2005 [10].

Since 2005, commercial systems with pre-fabricated slings and standardised insertion aids have been available on the market. **Table 2** summarises the study results from this time onwards.

In 2005, Petros et al. [11] introduced the tissue fixation system (TFS), using a multi-filamentous polypropylene mini-sling, which was fixed in the muscle tissue underneath the symphysis. In a follow-up of nine months, a continence rate of 83.4% was determined with 36 patients without additional complications. A subsequent telephone survey three years later of 31 of these women indicated a continence rate of 80% and 6.5% improvement. In a prospective, randomised study by Sivaslioglu et al. (2009), the TFS system was compared with an outside-in TOT sling. In a follow-up time of 36 months, the TFS group (n = 39) showed a success rate of 90%, compared with 84% for the TOT group (n = 38). 12 women in the TOT group (31.5%) had distinct pain symptoms during inguinal extensor movements [13]. Currently, there are no further relevant German publications or evidence of expansion of this system in Germany.

Since 2006, a number of different ready-made systems with further simplification of the tape system have been developed in order to encourage their widespread use. As with the conventional tension-free slings, the Type I propylene material has gained widespread acceptance. These systems are inserted into the vagina by a small colpotomy and are generally guided and attached via both sides of the obturator internus muscular fasciae in the obturator membrane directly, or less frequently, retro-pubically. This attachment is implemented either by absorbable patches, such as TVT Secur® (Gynecare), by a self-adhesive surface, such as DynaMesh SIS® minor (FEG Textiltechnik mbH), or otherwise by mini-anchor systems, such as MiniArc Precise® (AMS), Ajust® (Bard) or Ophira® (Promedon). With a tape length of around 6.5 to 8.5 cm, the blind passage and accompanying possible complications are reduced to a minimum.

3.1. TVT Secur (Gynecare)

The TVT S system was the first widely used mini-sling system since 2006. A tape of around 8 cm in length with absorbable patches at the end is fixed with a fine metal lance to both sides in a U-form retro-pubically or in an H-form (hammock) trans-obturatorically (**Fig. 1**). A release mechanism frees the tape from the inserter. The initial clinical euphoria with good success rates was followed by a sobering decline in its use. The reasons were the poorer results in the long term and some problems with serious outcomes such as distinct haemorrhaging.

An unsolved problem with all mini-sling systems is the method of applying tension to the inserted tape. In the, up to now, entirely tension-free TVT insert, particularly the TVT Secur showed considerably poorer results; a significant improvement in the continence rate was observed only with the introduction of a less tension-free insertion of the tape with contact to the urethra and without additional interspace.

The data available from the literature vary between 40 and 87% [14–20]. Investigations in our own hospital showed a continence rate of 63%, with 23% improvement. However, recent data from 2010 indicate overall high efficiency, with continence rates of more than 80% and negligible side effects. In 2010, Tincello et al. introduced a TVT S global register with a total of 676 patients from 29 centres and, in a 12 month follow-up, found an objective continence rate of 84.8% with overall minimal complications [22]. The data from Han et al. [23] from the first two years also show a good success rate of 82.6%. A current review by Walsh (2011) [24] evaluates 10 studies with a total of 1178 patients and a minimum follow-up time of 12 months. The review reports a subjective and objective continence rate of 76%, with better results obtained when employing an insert in a "U"-form. In Germany, there are no current publications.

Fig. 1 TVT Secur® sling (Gynecare).

3.2. MiniArc Precise® (AMS)

The MiniArc system utilises a distinctly smaller insertion aid. Here, the tape with a length of around 8 cm is attached by two anchors, on both sides in the obturator internus muscular fasciae. In a further development to the MiniArc Precise®, the tape is fixed to the insertion needle by a special attachment mechanism and freed by a special release mechanism (**Fig. 2**). This system can be comfortably inserted, shows only minimal side effects and is particularly convincingly because it is practically pain free, which would also allow insertion under local anaesthesia.

Current publications from 2010 and 2011 report that the method is highly efficient, is without significant side effects, and has a success rate of 82–93% [20,21,25–31]. Although this tape, due to the specific length and the defined attachment points, cannot be subsequently adjusted, problems such as obstruction, residual urine formation or urgency occur with the same negligible frequency as with the established slings. Compared with the established trans-obturator method, the MiniArc Precise® shows the same good success rates [20–21,27–28].

In the meantime, the first study results of a two-year follow-up period have been published. These results also indicate high success rates in the long-term (one-year follow-up 84–93.5% continence rate, two-year follow-up 82–93% continence rate) [21,26, 28,31].

3.3. Ajust® (C.R. Bard Inc.)

In 2008, the Ajust® sling, another single-incision sling, was introduced. This system is inserted with a special arcuate inserter and attached by a special anchor directly to the membrane of the obturator foramen (**Fig. 3**). The special feature with this system is the direct, intra-operative bilateral adjustability of the tape. The two anchors are placed and the tape is then loosened and tight-

Table 2 List of the different studies on the use of single-incision slings (SIS) with success rates and complication rates.

Author	Year	System	Study	Number	Follow-up	Success rate	Complications
Palma [7]	1999	TUS	prospective	10	12 months	50%	n = 2 removing tape due to infection n = 3 tape extrusion
Palma [8]	2001	TUS	retrospective	25	6 months	87%	
Palma [9]	2007				72 months	65%	
Petros [11]	2005	TFS	retrospective	36	9 months	83.4%	n = 1 granuloma due to incorrect attachment
Petros [12]	2009	TFS	retrospective	31	36 months	80% 6.5% improvement	telephone survey 31 of 36 from [11]
Sivaslioglu [13]	2009	TFS	randomised clinical trial	39	36 months	90%	n = 1 incorrect attachment
		TOT		38		84%	n = 2 residual urine
							n = 12 groin pain
Debodinance [14]	2009	TVT-S®	prospective	154	12 months	70.3% continence	n = 5 haemorrhaging
						11% improvement	n = 1 bladder lesion
							n = 21 residual urine > 100 ml
							n = 2 unattached tape
							n = 7 injury to the vaginal sulcus
Lee [15]	2010	TVT-S®	prospective	144 U	12 months	87.5%	n = 2 residual urine formation
				141 H	12 months	80.1%	n = 3 residual urine formation
							n = 3 injury to the vaginal sulcus
							n = 2 haemorrhaging > 500 ml
Liapsis [16]	2010	TVT-S®	prospective	39 U	12 months	71.8% obj. cont.	
				43 H	12 months	62.8% obj. cont.	
Tommaselli [17]	2010	TVT-S®	prospective	37	12 months	83.8%	n = 1 tape erosion
		TVT-O®		38	12 months	81.6%	n = 3 leg pain; n = 2 residual urine
Cornu [18]	2010	TVT-S®	prospective	45	1 month	62.2%	n = 10 post-operative pain
					6 months	53.3%	n = 5 de novo urgency
					30.8 months	40%	
Khandwala [19]	2010	TVT-S®	retrospective	141	14.1 months	83.0% subj. cont.	n = 5 unattached tape
Oliveira [20]	2011	TVT-S®	prospective	30	12 months	67%	n = 3 de novo urgency
		TVT-O®		30		83%	n = 3 de novo urgency, n = 2 split tape n = 2 groin pain
		MiniArc®		30		87%	n = 3 de novo urgency
							n = 1 groin pain
Oliveira [21]	2011	TVT-S®	prospective	25	24 months	63%; 13% improvement	
		TVT-O®		24		82%; 7% improvement	
		MiniArc®		25		87%; 7% improvement	
Tincello [22]	2010	TVT-S®	prospective	676	12 months	81.4% subj. 84.8% obj.	n = 1 bladder lesion n = 4 haemorrhaging > 500 ml n = 2 residual urine formation n = 16 de novo urgency
Han [23]	2010	TVT-S®	prospective	94	6 months	89.4%	n = 1 bladder lesion
				77	12 months	88.3%	n = 3 vaginal perforation
				23	24 months	82.6%	n = 2 tape extrusion
Walsh [24]	2011	TVT-S®	review	1178	12 months	76% subj. 76% obj.	1.5% vaginal perforation 2.4% tape erosion 10% de novo urgency 2.3% micturition disturbances
Kennelly [25]	2010	MiniArc®	prospective	188	12 months	90.6%	n = 3 injury to the vaginal sulcus n = 5 de novo urgency n = 6 pain n = 4 dyspareunia
Kenelly [26]	2011	MiniArc®	prospective	142	24 months	85%	
De Ridder [27]	2010	MiniArc®	retrospective	75	12 months	85%	n = 3 groin pain n = 5 de novo urgency
		Monarc®		56		89%	n = 1 haemorrhaging > 500 ml
							n = 1 erosion
							n = 2 groin pain
							n = 8 de novo urgency

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Table 2 *Continued*

Author	Year	System	Study	Number	Follow-up	Success rate	Complications
Enzelsberger [28]	2010	MiniArc®	prospective	45	24 months	82%	n = 1 erosion n = 2 de novo urgency
		Monarc®		45		86%	n = 1 erosion n = 2 de novo urgency n = 1 required therapy for haematoma n = 11 groin pain
Oliveira [29]	2011	MiniArc®	prospective	105	12 months	80%, 11% improvement	n = 7 de novo urgency
Pickens [30]	2011	MiniArc®	prospective	120	12 months	94%	n = 3 bladder lesions n = 1 tape loosening n = 5 de novo urgency
Pickens [31]	2011	MiniArc®	prospective	108	24 months	93%	n = 5 de novo urgency
Naumann [32]	2010	Ajust®	prospective	52	12 months	86.5%	n = 1 intra-operative new tape n = 1 14 days post-operative new tape
Naumann [33]	2011	Ajust®	prospective	51	24 months	82.4% 4% improvement	n = 4 no follow-up no complications
Meschia [34]	2011	Ajust®	prospective	111	6 months	91.4% obj. cont.	n = 6 intra-operative new tape n = 1 tape cutting due to residual urine n = 9 de novo urgency
Abdel-Fattah [35]	2011	Ajust®	prospective	90	12 months	80% subj. cont. 6% improvement	n = 1 intra-operative new tape n = 2 tape erosion
Palma [10]	2008	Ophira®	retrospective	20	12 months	88%	none
Palma [36]	2010	Ophira®	prospective	91	12 months	90.2%	n = 3 mesh exposure n = 1 tape loosening n = 1 tape cutting
Serels [39]	2010	Solyx®	retrospective	63	6.5 months	95%	none
Tardiu [40]	2011	Contasure Needleless	prospective	72	12 months	87.5%	n = 1 haemorrhaging > 500 ml n = 1 bladder lesion n = 1 post-operative pain n = 4 residual urine
		TVT-O®		60		90%	n = 1 bladder lesion n = 7 post-operative pain n = 3 residual urine
Navazo [41]	2009	Contasure Needleless	retrospective	120	24 months	84% 8% improvement	n = 1 sling extrusion

U: U-position; H: H-position (Hammock); RH: residual urine

Fig. 2 MiniArc Precise® sling (American Medical Systems).

ened as required on the basis of a mesh extension in order to adapt to the optimal tape length for the individual.

The developers of this system were able to insert the first tape world-wide in 2008 and were able in 2009 to report on the data from the first 12 months, which showed a good continence rate of 86.5% and no complications. Continued observation after 24 months confirmed the high success rate, with results of 82% [32, 33]. Meschia et al. [34] again confirm these results in a prospective study with a follow-up time of six months, reporting an objective continence rate of 91.4%, and an on-going, 2011 prospective study from Abdel-Fattah [35] indicates 80% subjective continence after 12 months and the possibility of surgically inserting under purely local anaesthesia.

3.4. Ophira® (Promedon)

The Ophira® mini-sling employs anchoring arms with numerous barbs. A thin insertion aid positions the tape and can be disconnected without problems (**Fig. 4**).

To date, there is a lack of publications with convincing data. In 2008, Palma et al. published the first data with a success rate of 88% after 12 months for 20 patients [10]. A more recent prospective analysis of the same group of 91 women reports a continence rate of 90.4% without side effects after 12 months [36]].

In a first review published in 2010 [37], the data for n = 2734 TVT Secur®, n = 557 Miniarc® and n = 30 Ajust® were evaluated. Success rates of 70–80% were determined, which at the present time is slightly less than rates for the established sling systems. The

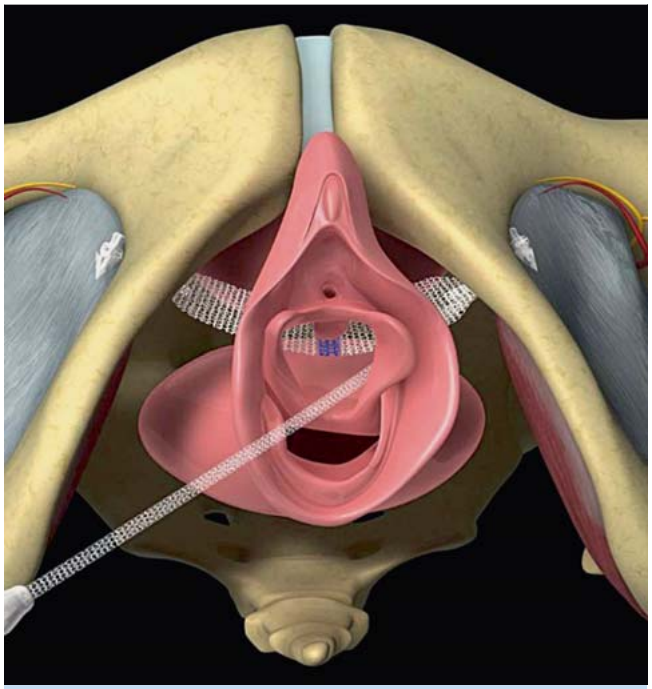

Fig. 3 Ajust® sling (C. R. Bard).

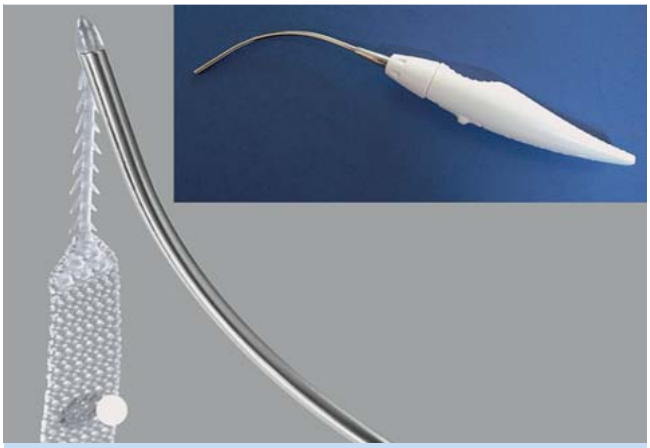

Fig. 4 Ophira® sling (Promedon).

problem here is evidently the requirement of a somewhat less tension-free insertion of the tapes, which only achieves full effectiveness when the tape is in contact with the urethra. The analysis also included early studies from this learning phase. At the same time, however, the complication rates were found to be minimal; the bladder perforation rate was 0.45% (compared with 3–4% with the TVT or TOT), with a de novo urgency of 6.6% and 0.65% for inguinal extensor complaints. Another review from Abdel-Fattah in 2011 [38] summarising nine randomised clinical trial studies and comparing single-incision slings with conventional slings (n = 548 TVT Secur®, n = 160 MiniArc® and n = 50 Ophira®) confirms this trend. Here also, the success rates of the single-incision slings were only slightly lower, with reduced side effects.

3.5. Other single-incision slings

Besides the mini-slings employed widely in Germany described here, there are also other types of slings. The Solyx® system also utilises a small insertion aid and the tape is fixed with barbs. Initial analyses indicate high success rates and no side effects [39].
With the Contasure Needleless® system, the sling is attached with a clamp to both sides by a pocket with a self-adhesive surface. Even without fixed attachment, the results are also between 84 and 87%, however bladder lesions and post-operative pain were also reported [40, 41].

Practical Notes for the Use of Single-Incision Slings

The short-term and long-term data available to date for the new single-incision slings allow us to assume that the success rates with these instruments is comparable with those of established slings. At the same time, however, initial analysis underscores the significantly reduced side effect rate and complication rate due to the lack of a blind passage for fixation of the sling.

So far, retro-pubic and trans-obturator established slings have shown equivalent results and, to the same extent, a negligible rate of various complications.
For certain indications, a specific access path is clearly favoured. In the presence of intrinsic closure weakness of the urethra, the retro-pubic access path gives significantly better results. For pre-operative interventions in the retro-pubic region, the trans-obturator access path is clearly preferable.
In the opinion of the authors, single-incision slings will be able to replace trans-obturator slings in the long term or sooner. With stable fixation, a tape passage in the obturator foramen is then no longer necessary; therapy for the particular problems occurring here, such as haemorrhaging, infection or nerve lesions, is very difficult.

Advantages of mini-incision slings

- further dramatic reduction of possible complications
- practically pain-free insertion of the tape, possible even under local anaesthesia
- use of less foreign material

Possible indications for single-incision slings

- operative correction for female stress urinary incontinence
- avoids retro-pubic passage during pre-operative interventions
- suitable for use with patients with a higher morbidity (e.g. adiposity, increased risk of haemorrhaging, pre-operative vaginal interventions)
- patients with mixed incontinence

Conclusion for Practice

Single-incision slings combine the proven functional principle of sub-urethral slings with a high success rate and the advantages of using less foreign mesh material, while virtually eliminating the blind passage during insertion.
Our experience in recent years with single-incision sling for women requiring surgery for stress incontinence has been good, in particular for those women with a high operative risk, previous operations in the retro-pubic space, an increased tendency to haemorrhaging or excessive scar formation. Particularly evident are the greatly reduced invasiveness of the mini-slings and the low rate of pain symptoms.

Conflict of Interest

G. Naumann gives lectures for AMS and Bard.

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