Single incision mid-urethral slings

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Medical director Pelvic floor center “Bergman clinics”
Honorary professor University of Capetown
Surgical Treatment of Stress Urinary Incontinence

- Kelly slings 1913
- MMK 1949
- Burch needlesuspensions 1961
- 1968
- 1970 – 1990
- TVT 1995
- TOT 1996
- TVT-Secur miniarc 2001
- 2006/7
Continence Mechanisms (CM) at the level of the urethra

CM function
- coaptation
- compression

CM support
- anatomic support
- configuration

Continence

Maintenance of continence

CM function
- intrinsic urethral mechanisms

CM support
- anatomic support
- configuration

(Plzak, Staskin 2002)
Three generations of Mid-Urethral Slings (MUS)

**Type of MUS**

- **TVT (1996)**
  - Course of introducer & tape: through the retropubic space, risk of bladder injury

- **TOT (2001)**
  - Course of introducer & tape: through the obturator membrane, risk of obturator nerve and muscle injury

- **Single-incision Midurethral slings**
  - Vaginal incision only, avoiding penetration of obturator nerve and adductor muscles of the upper leg
single-incision mid-urethral slings

ALL ANIMALS ARE EQUAL,
BUT SOME ANIMALS ARE MORE EQUAL THAN OTHERS.

George Orwell
## What do we know?

<table>
<thead>
<tr>
<th>Feature</th>
<th>MINI ARC</th>
<th>PRECISE</th>
<th>AJUST</th>
<th>SOLYX</th>
<th>TVT SECUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Incision</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Reproducible Pathway</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Inserter curvature</td>
<td>Hook</td>
<td>Hook</td>
<td>L shape</td>
<td>Hook</td>
<td>Hook</td>
</tr>
<tr>
<td>Mesh Length / Shape</td>
<td>Straight (8.5cm)</td>
<td>Straight (8.5cm)</td>
<td>Straight (7.5cm)</td>
<td>Straight (8cm)</td>
<td>Straight (8cm)</td>
</tr>
<tr>
<td>Bilateral adjustability</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Bidirectional adjustability</td>
<td>No</td>
<td>No</td>
<td>Yes (1 side final)</td>
<td>Yes (1 side final)</td>
<td>Yes (2 sides final)</td>
</tr>
<tr>
<td>Implanted Tips</td>
<td>Non-abs Anchor</td>
<td>Non-abs Anchor</td>
<td>Non-abs Anchor</td>
<td>Non-abs Anchor</td>
<td>Absorbable Pad</td>
</tr>
</tbody>
</table>
Figure 3:
Post-operative visual analog scores for pain (0-100)
Values represent means and standard errors, calculated using repeated measurement analysis

Hinoul, J Urol, 2011
TVT-secur versus TVT-O

• Positive stress test
  • 12 months after surgery TVT-O 2%, TVT-S: 16%

• Subjective cure
  • 12 months after surgery TVT-O 92%, TVT-S: 76%

• Repeated SUI surgery
  • The odds ratio to undergo a reintervention for SUI, 1 year after TVT-Secur was 2.3 (C.I.: 1.9-2.7) in comparison to TVT-O.

Hinoul, J Urol, 2011
Study Population

193 patients randomized

97 MiniArc
- 1 received Monarc
- 25 patients incomplete 36 months

72 primary outcome 36 months

96 Monarc
- 1 received MiniArc
- 22 patients incomplete 36 months

74 primary outcome 36 months
# Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>MiniArc&lt;sup&gt;®&lt;/sup&gt; (N=97)</th>
<th>Monarc&lt;sup&gt;®&lt;/sup&gt; (N=96)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong> mean (SD)</td>
<td>53 (11)</td>
<td>53 (11)</td>
</tr>
<tr>
<td><strong>BMI kg/m&lt;sup&gt;2&lt;/sup&gt; mean (SD)</strong></td>
<td>26 (4)</td>
<td>26 (4)</td>
</tr>
<tr>
<td><strong>Parity median (IQR)</strong></td>
<td>2 (2-2)</td>
<td>2 (2-3)</td>
</tr>
<tr>
<td><strong>Postmenopausal status N (%)</strong></td>
<td>26 (47%) ^</td>
<td>20 (36%) ^</td>
</tr>
<tr>
<td><strong>Previous prolapse surgery N (%)</strong></td>
<td>13 (13%)</td>
<td>9 (9)%</td>
</tr>
</tbody>
</table>

^Considerable number missing
## 36 months: subjective cure

<table>
<thead>
<tr>
<th></th>
<th>MiniArc® (N=72)</th>
<th>Monarc® (N=74)</th>
<th>Risk difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective cure (PGI-I)</td>
<td>87%</td>
<td>87%</td>
<td>0.5% (95% CI -11% to 12%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>36 months: subjective cure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective cure (CST)</td>
<td>89%</td>
</tr>
<tr>
<td>Risk difference</td>
<td>0% (95% CI -10% to 10%)</td>
</tr>
</tbody>
</table>
Postoperative pain and surgical parameters

**MiniArc** compared to **Monarc**

- Less pain till day 3 (p<0.01), less pain medication

  - 5 min shorter duration surgery
  - Blood loss (20 vs 50 mL)
Reoperations 0-36 M

MiniArc
- 3 retropubic TVT because of failure
  - 1 exposure correction
  - 1 bladder erosion correction

Monarc
- 2 retropubic TVT because of failure
- 2 exposure correction
- 1 release tape unilateral because of obstruction
## Complications 0 - 36 M

<table>
<thead>
<tr>
<th></th>
<th>MiniArc® (N=72)</th>
<th>Monarc® (N=74)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary tract infection</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>Bladder retention &gt; 150 mL</td>
<td>6</td>
<td>8</td>
</tr>
</tbody>
</table>

Displayed are most frequent complications

Adjudication of (S)AE by independent Clinical Events Committee (CEC)
Conclusion 36 M

MiniArc is non-inferior to Monarc with respect to subjective and objective cure of SUI
MiniArc is superior with respect to postoperative pain first three days
Adverse events rates are comparable
Altis Surgical Procedure

Please follow surgical steps handout while watching the video.
Tensioning and Positioning

Sling placement under the urethra without tension.

- A Metz maybe inserted between the sling and urethra to confirm no tension is placed on the urethra.

Tensioning is different compared to other SIS

- Due to the low elasticity of the sling.

Note:
Some physicians may fill the bladder to determined leak point pressure (LLP) and perform cough stress test (CST).
Altis IDE Study: 24-months

113 implants • 17 sites (16 US and 1 CA) • Patient follow-up 6m, 1yr and 2yrs.

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Measurement</th>
<th>6 Month</th>
<th>12 Month</th>
<th>24 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pad Weight (PW)</td>
<td>50% Reduction</td>
<td>85.4% (88/103)</td>
<td>90.1% (91/101)</td>
<td>90.9% (81/90)</td>
</tr>
<tr>
<td>Cough Stress Test (CST)</td>
<td>% Success in both standing and lithotomy positions</td>
<td>92.2% (95/103)</td>
<td>90.1% (91/101)</td>
<td>87.9% (80/91)</td>
</tr>
<tr>
<td>Patient Global Impression of Improvement (PGI-I)</td>
<td>% Very much or much better</td>
<td>87.5% (92/105)</td>
<td>89.3% (92/103)</td>
<td>90.4% (85/94)</td>
</tr>
</tbody>
</table>

Mesh extrusions -4 (3.5%) all in first 6 months.
Negative CST results: **no significant difference** between groups was observed by 12 and 24 months (p=0.19 at 12 mos, and p=0.13 at 24 mos).
Two-Year Effectiveness of the Altis® Sling Incision Sling for Women with Stress-Predominant Mixed Urinary Incontinence
Erickson T, Crockford J, and Patel M

- The Altis Single Incision Sling System is effective women with stress-predominant MUI at 24-months.
- Both MUI and SUI patients report a high degree of satisfaction over 2-years after Altis Sling placement.
  - Urge symptoms are not exacerbated for patients with MUI or SUI.
When To Consider the Altis Single Incision Sling?

• Very active patient for faster return to normal activity

• Obese patient

• Anticoagulated – Coumadin, ASA, Plavix

• Sacrocolpopexy / Colpocleisis

• Patient Awake
  • High anesthesia risk
  • Cough Testing for ISD
Learning curve
## Learning curve

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (first 10)</th>
<th>Group 2 (second 10)</th>
<th>Group 3 (&gt; 20th)</th>
<th>Total</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( N = 42 )</td>
<td>( N = 42 )</td>
<td>( N = 38 )</td>
<td>( N = 122 )</td>
<td></td>
</tr>
<tr>
<td>any symptom of SUI</td>
<td>14 (33.3%)</td>
<td>9 (21.4%)</td>
<td>6 (15.8%)</td>
<td>29 (23.8%)</td>
<td>0.016</td>
</tr>
<tr>
<td>any symptom of UUI</td>
<td>10 (23.8%)</td>
<td>3 (7.1%)</td>
<td>3 (7.9%)</td>
<td>16 (13.1%)</td>
<td>0.043</td>
</tr>
<tr>
<td>demonstrable SUI on cough-stress test</td>
<td>10 (23.8%)</td>
<td>3 (7.1%)</td>
<td>2 (5.3%)</td>
<td>15 (12.3%)</td>
<td>0.016</td>
</tr>
</tbody>
</table>

Statistical analysis: \( X^2 \)-test
Pain versus efficacy
## Treatment trade-off

### First baseline situation

<table>
<thead>
<tr>
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<th>Transobturator TVT</th>
<th>Mini-MUS</th>
</tr>
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<tr>
<td><strong>Efficacy</strong></td>
<td>70%</td>
<td>10-70%</td>
</tr>
<tr>
<td><strong>Postoperative pain</strong></td>
<td>2 days groin/thigh pain</td>
<td>Only present during the day of the operation</td>
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### Second baseline situation

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Transobturator TVT vs. Mini-MUS

TOT
Efficacy

Mini-MUS
Efficacy

Pain

Only present during the day at the operation

\(\text{Pert, March 2013}\)
Results trade-off study

Patients are willing to hand in:
- 4% median cure rate to prefer the mini-MUS in the situation of two days groin pain
- 6% median cure rate to prefer the mini-MUS in the situation of two weeks groin pain
Mini-arc in office setting
J Min Invasive Gynecol 2012

- N = 38
- Local or sedation
- Length of stay 1.3 hours
- Wong-Baker score = 0.2
- 94% negative cough stress test
- Non-inferior to other studies using general / spinal
Ajust in office setting
Prog Urol 2013

- N = 60
- Sedation +/- local
- At 1 year, cure rate, improvement and failure rate were respectively 89.6%, 6.9% and 3.4%
- 12 moderate postoperative pain
- 11 palpable lateral cords, 2 mesh exposures
Needleless in office setting
Actas Urol Esp 2014

• N = 96
• Local +/- sedation
• Almost everyone is a candidate
• Stay in the hospital less than 2 hours
• 90% satisfied about result
What do patients consider important?

- Long term success
- Surgeon’s experience
- Complication risk
- Post-operative pain
- Use of foreign body
- Hospital stay
Summary of evidence on pain reduction

• More limited dissection and a more medial trocar trajectory of TVT-O seem to reduce postoperative groin pain at 24 h after the procedure, but not the analgesic requirement.
  Tommaselli Int Urogynecol J 2012

• Local infiltration analgesia limits postoperative pain in patients undergoing TVT-O.
  Tommaselli Arch Gynecol Obstet 2012
Results single incision slings

- 31 trials, n=3290
  TVT-Secur, Miniarc, Ajust, Tissue Fixation System, CureMesh, Needleless

- Results vs retropubic slings:
  - More incontinence (41% vs 26%, RR 2.08, 1.04-4.14)
  - Shorter surgery time (2 min)
  - Higher risk on de novo urgency (RR 2.39, 1.25 – 4.56)

- Results vs trans-obturator slings:
  - More incontinence (30% vs 11%, RR 2.55, 1.93-3.36))
  - Less post-operative pain (RR 0.29, 0.20-0.43)
  - More complications (mesh exposure/erosion urethra/blood loss)

Nambiar A, Single-incision sling operations for urinary incontinence in women, Cochrane database 2014
Study design

- Single blinded RCT
- N = 156
- Ajust (n = 100) or TVT-O (n = 56)
- Primary outcome: pain
- Secondary outcomes
  - Objective cure
  - Subjective cure
  - QoL
  - Complications

Schweitzer et al. Postoperative pain after adjustable single-incision or transobturator sling for incontinence, a RCT, Obstet en Gynecol 2015
study: results

- Baseline characteristics: no difference
- Pain scores: significantly lower in Ajust

<table>
<thead>
<tr>
<th>After 12 months:</th>
<th>Ajust ®</th>
<th>TVT-O</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective cure</td>
<td>90.8%</td>
<td>88.6%</td>
<td>0.76</td>
</tr>
<tr>
<td>Subjective cure</td>
<td>77.2%</td>
<td>72.9%</td>
<td>0.58</td>
</tr>
<tr>
<td>(A lot) better</td>
<td>90.0%</td>
<td>87.0%</td>
<td>0.59</td>
</tr>
</tbody>
</table>

Mostafa A et al, single incision mini-slings versus standard midurethral slings in surgical management of female SUI. Eur Urol 2014
Peng Zhang et al, meta-analysis of female SUI treatments with adjustable SIMS and TOT, BMC urology 2015
UK: Ajust under local

- Pre-procedure analgesia
- 0.25% chirocaine para urethral
- No complications
- Short follow up (52 days)
  - Subjective cure: 92%
  - Objective cure: 94%
  - PGII: 96%
  - De novo urge: 12%

Assassa MD et al, data not published, Mid Yorkshire NHS Trust (2009-2013)
Ajust with sedation: study design

- Prospective observational multi-centre cohort study

- Primary outcome:
  - subjective cure SUI

- Secundaire doel:
  - objectieve genezing SUI
  - verbetering van stressincontinentie
  - bijhouden van complicaties
  - pijnsscores postoperatief
Ajust with sedation: study design

- History taking
  - voiding diary and questionnaires UDI/IIQ/PGIS

- Pelvic examination
  - stress test, hypermobile urethra

- Additional investigation
  - Urine analysis, uroflowmetry / PVRV

- Conclusion: ‘pure SUI’:
  - Counseling
Procedure SIMS under sedation

- IV drip
  - sedation protocol AMC: propofol (induction 0.5 mg/kg, maintenance 4 mg/kg/hour) with alfentanil or remifentanil
- Emptying the bladder
- Para urethral injection
  - mepivacaine 1%/bupivacaine 0.25% 30 ml
- Ajust®
- Filling the bladder
- Awake the patient
- Cough stress test
- Adjust tension of the sling
- Closure vaginal wall incision
Postoperative care

- **Directly after surgery: standard care**
  - Completing pain scores
    1) postoperative after 1 & 2 hours
    2) during first 3 days
  - Documentation of complications

- **Follow-up (6 weeks and 1 year):**
  - Documentation of adverse events
  - Completing questionnaires (UDI / IIQ /PGII)
  - Cough stress test with standardized bladder volume
Results

- Inclusion: \( n = 90 \)
- Lost to follow-up: \( n = 7 \)
- Analysed: \( n = 83 \)
- Data incomplete: \( n = 19 \)
Results: baseline

<table>
<thead>
<tr>
<th></th>
<th>Ajust under general /spinal (TOAST data)</th>
<th>Ajust under sedatie</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>95</td>
<td>83</td>
<td>0.358</td>
</tr>
<tr>
<td>Average age</td>
<td>49,5±12.3</td>
<td>51,1±10.5</td>
<td>0.358</td>
</tr>
<tr>
<td>Gynaecologic history</td>
<td>16/87 18.4%</td>
<td>40/83 48.2%</td>
<td>0.000</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>13/83 15.7%</td>
<td>8/83 9.6%</td>
<td>0.350</td>
</tr>
<tr>
<td>Anterior colporraphy</td>
<td>0/82 0%</td>
<td>2/83 2.4%</td>
<td>0.497</td>
</tr>
<tr>
<td>Posterior colporraphy</td>
<td>0/81 0%</td>
<td>1/83 1.2%</td>
<td>1.000</td>
</tr>
<tr>
<td>Ant and post colporraphy</td>
<td>2/83 2.4%</td>
<td>2/83 2.4%</td>
<td>1.000</td>
</tr>
<tr>
<td>Sacrocolpopexy</td>
<td>0/81 0%</td>
<td>5/83 6.0%</td>
<td>0.059</td>
</tr>
<tr>
<td>Adnex extirpation</td>
<td>2/84 2.4%</td>
<td>3/83 3.6%</td>
<td>0.682</td>
</tr>
</tbody>
</table>
## Resultats: baseline

<table>
<thead>
<tr>
<th></th>
<th>Ajust under general /spinal (TOAST data)</th>
<th>Ajust under sedatie</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micturition voids / day</td>
<td>7.42</td>
<td>8.09</td>
<td>0.111</td>
</tr>
<tr>
<td>Episodes loss / day</td>
<td>3.95</td>
<td>3.42</td>
<td>0.306</td>
</tr>
<tr>
<td>Number of pads</td>
<td>2.15</td>
<td>2.53</td>
<td>0.297</td>
</tr>
<tr>
<td>PGIS: not severe / mild</td>
<td>26/94 27.7%</td>
<td>7/80 8.8%</td>
<td>0.003</td>
</tr>
<tr>
<td>PGIS: moderate / severe</td>
<td>68/94 72.3%</td>
<td>73/80 91.3%</td>
<td></td>
</tr>
</tbody>
</table>
Results: after 6 weeks

<table>
<thead>
<tr>
<th></th>
<th>Ajust under general /spinal (TOAST data)</th>
<th>Ajust under sedatie</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective cure</td>
<td>84/95</td>
<td>88.4%</td>
<td>61/73</td>
</tr>
<tr>
<td>Objective cure</td>
<td>74/84</td>
<td>88.1%</td>
<td>72/75</td>
</tr>
<tr>
<td>De novo urgency</td>
<td>2/28</td>
<td>7.1%</td>
<td>2/19</td>
</tr>
<tr>
<td>PGII (much / very much improved)</td>
<td>85/93</td>
<td>91.4%</td>
<td>72/75</td>
</tr>
</tbody>
</table>
Results: pain after surgery

<table>
<thead>
<tr>
<th></th>
<th>Ajust under general /spinal (TOAST data)</th>
<th>Ajust under sedatie</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean±SD</td>
<td>n</td>
</tr>
<tr>
<td>VAS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS 1 hour after surgery</td>
<td>89</td>
<td>0.54±0.97</td>
<td>71</td>
</tr>
<tr>
<td>VAS 2 hours after surgery</td>
<td>89</td>
<td>0.69±0.97</td>
<td>60</td>
</tr>
<tr>
<td>VAS evening of surgery</td>
<td>93</td>
<td>1.64±1.67</td>
<td>70</td>
</tr>
<tr>
<td>VAS day 1</td>
<td>95</td>
<td>1.68±1.67</td>
<td>69</td>
</tr>
<tr>
<td>VAS day 2</td>
<td>95</td>
<td>1.44±1.57</td>
<td>71</td>
</tr>
<tr>
<td>VAS day 3</td>
<td>95</td>
<td>1.03±1.31</td>
<td>71</td>
</tr>
</tbody>
</table>
Complications

- No problems with infiltration or sedation!

- During procedure: \( \frac{3}{83} (3.6\%) \)
  - No major complications
  - 3x tape replacement

- After procedure: \( \frac{5}{83} (6.0\%) \)
  - 1x CAD 1 night, 1x CIC
  - 1x Exposure
  - 2x UWI
Literature about sedation and SIMS:

- **Vandendriessche 2013**
  - after 1 year: cure 89.6%, improved 6.9%, failure 3.4%

- **Boyers 2013**
  - no difference between TVT-O and general anesthesia or Ajust with local analgesia
  - Ajust : less costs

- **Abdel-Fattah 2012**
  - after 1 year: 80% cure
  - feasible
Conclusion

- Ajust with sedation is not better than with general / spinal, but also not significantly worse

- Feasible!
How to tailor stress incontinence surgery?

• There is an ongoing process of improving the outcome of incontinence surgery
• There is a shift towards less invasive with similar outcome
• Retropubic slings have stable results on the long term
• Miniarc is non-inferior to monarc
• Patients are willing to trade a bit pain for efficacy
• To have good outcome of stress-incontinence surgery, perfect understanding of the technique is mandatory
EUGA®
EUROPEAN UROGYNAECOLOGICAL ASSOCIATION
@Amsterdam
9th ANNUAL CONGRESS
Leading Lights in Urogynaecology

Nov 3-5, 2016
Hilton Schiphol Hotel

Meeting Chair
Jan-Paul Roovers

Abstract Submission Deadline
Jul 31st, 2016