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Original Article

# Two-year evaluation of the MiniArc in obese versus non-obese patients for treatment of stress urinary incontinence

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**Abbreviations & Acronyms**
BMI = body mass index
CST = cough stress test
IIQ-7 = Incontinence Impact Questionnaire 7
LFCF = last failure carried forward
PWT = pad weight test
QoL = quality of life
RP = retropubic
SUI = stress urinary incontinence
TOT = transobturator
TVT = tension-free vaginal tape sling
UDI-6 = Urogenital Distress Inventory 6

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**Objectives:** Obesity is a well-established risk factor of stress urinary incontinence, which affects up to 35% of adult women worldwide. We evaluated whether there is a difference in outcomes with MiniArc sling for treatment of stress incontinence in obese women versus non-obese women at 24 months.

**Methods:** A 2-year subanalysis of obese (body mass index >30 kg/m$^2$) versus non-obese patients enrolled into a multicenter, prospective study evaluating the effectiveness of MiniArc sling was carried out. Qualitative (Urogenital Distress Inventory 6 and Incontinence Impact Questionnaire 7) and quantitative measurements, including the cough stress test, were carried out. Secondary outcome measures included procedure time, estimated blood loss, length of stay, perioperative complications, Wong–Baker Faces Pain Scale and adverse events.

**Results:** Of 188 patients, 62 were obese. The mean procedure time, blood loss and length of stay were no different between groups. Obese patients reported significantly more pain immediately postoperatively (2 *vs* 1, Wong–Baker, $P = 0.042$), but there was no difference at postoperative day 7. There was no difference in objective cure using the cough stress test (81% obese *vs* 86% non-obese; $P = 0.449$). Urogenital Distress Inventory 6 and Incontinence Impact Questionnaire 7 median scores showed no difference between groups in improvement ($P = 0.126$ and $P = 0.087$, respectively). No serious device-related complications were reported in either group.

**Conclusions:** The MiniArc sling represents a safe and effective treatment option for both obese and non-obese patients with stress incontinence. Comparable outcomes at 2 years can be obtained in terms of cure rates using the cough stress test or questionnaires, as well as complication rates.

**Key words:** mesh complications, midurethral sling, obesity, surgical mesh, urinary stress incontinence.

## Introduction

Obesity is considered not only a risk factor for SUI, but there is also a concern about a higher failure rate for SUI procedures. RP and TOT slings, however, have been shown to be efficacious in obese patients.[1,2] The single-incision mini-sling was developed as a less invasive alternative to the RP or TOT approach (Figure 1). A concern of a shorter mesh tape, as used in the mini-sling, for treatment of SUI in obese women is that it might not have as much surface area to hold the mesh in place as with a RP or TOT sling, and therefore this might affect its safety and/or efficacy. The current trial evaluated a subset of obese patients that underwent placement of the MiniArc single-incision sling and compared their outcomes with non-obese patients in the same trial.

## Methods

An international, multicenter, prospective, single-arm clinical trial was carried out at 16 centers (USA 13, Canada 1, Belgium 1 and UK 1) in women aged ≥1 years with confirmed

**Table 1** Baseline characteristics in obese and non-obese group

| Body weight | Non-obese (<30 kg/m$^2$) | Obese (≥30 kg/m$^2$) | *P*-value |
|---|---|---|---|
| | *n* = 126 | *n* = 62 | |
| Age, years (mean ± SD) | 51.5 ± 11.2 | 50.3 ± 9.4 | 0.477 |
| Parity (mean ± SD) | 2 ± 1 | 2 ± 1 | 0.716 |
| Menopausal, *n* (%) | 63 (50%) | 34 (54.8%) | 0.533 |
| Diabetic, *n* (%) | 5 (4.0%) | 3 (4.8%) | 0.781 |
| Ethnicity, *n* (%) | | | 0.615 |
| Caucasian | 107 (84.9%) | 50 (80.6%) | |
| Black/African American | 5 (4.0%) | 2 (3.2%) | |
| Hispanic/Latina | 14 (11.1%) | 10 (16.1%) | |
| UDI-6 score (mean ± SD) | 48.1 ± 18.8 | 53.0 ± 19.6 | 0.099 |
| IIQ-7 score (mean ± SD) | 38.9 ± 23.1 | 53.8 ± 26.5 | 0.001 |
| 1-h PWT (grams) (mean ± SD | 25.2 ± 38.5 | 28.3 ± 37.9 | 0.602 |

SUI. The protocol was approved by each site's internal review board, and conformed to the provisions of the Declaration of Helsinki. All participants provided written informed consent before enrolment.

To be eligible for inclusion, women had to be aged ≥18 years, desire surgical treatment for SUI and show one of the following objective SUI criteria: (i) evidence of SUI on urodynamics; (ii) a 1-h PWT >2 g; or (iii) a standing positive CST. Exclusion criteria included previous synthetic sling, pelvic organ prolapse stage ≥3, any coexistent pelvic pathology, pregnancy, primary urgency incontinence or detrusor overactivity, renal insufficiency and/or upper urinary tract obstruction, elevated post-void residual volume >100 mL, blood coagulation disorder, or morbid obesity (BMI >40 kg/m$^2$). Obesity is defined as BMI >30 kg/m$^2$.

Baseline evaluation included urogynecological history and physical examination, completion of the UDI-6 and IIQ-7, Wong–Baker Pain Scale, CST, and 1-h PWT.

CST, PWT, UDI-6 and IIQ-7 were completed at 6, 12, and 24 months, whereas safety data were assessed at each visit. The objective cure rate was analyzed, with a negative CST at 24 months. A 1-h PWT ≤1 g at 24 months was considered negative and analyzed independently. Other data collected included surgical location, anesthesia method, procedure time, estimated blood loss, length of stay, complications, and pain scores at discharge and 7 days post-surgery.

## Statistical analysis

Objective efficacy from the CST and PWT were evaluated using the LFCF method, which carries forward patients' objective failure at 6 months if their 24 months test results were missing. The LFCF analysis also considers patients who had a revision for recurrent SUI within 24 months from the initial implant as failures regardless of their 6-months and 24-months test results.

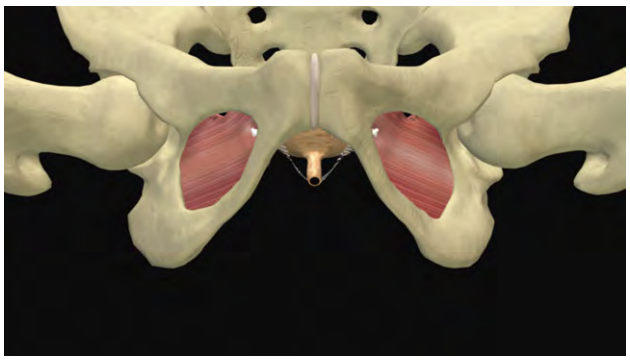

**Fig. 1** The self-fixating tip anchors the sling into the obturator internus muscle fixing it in a "hammock" position.

Continuous variables were compared between obese and non-obese groups using two-sample *t*-test or Wilcoxon test as appropriate; categorical variables were compared between groups using $\chi^2$-test. QoL at 24 months was compared with the baseline value using the paired *t*-test (if the difference was normally distributed) or Wilcoxon signed rank test (if the difference was not normally distributed). Statistical significance was determined at the $P \leq 0.05$ level. All statistical analyses were carried out using SAS, version 9.1.3 (SAS Institute, Cary, NC, USA).

## Results

Baseline characteristics are shown in Table 1. A total of 45 of 62 obese patients (73%) completed the 24 months, and 97 of 126 non-obese patients (77%) completed their 24 months.

Procedural data are shown in Table 2. There was one reported intraoperative complication that occurred in the obese group. This was felt to be a result of the procedure location (office) and not the size of the patient. The procedural time, estimated blood loss and length of stay showed

**Table 2** Procedural parameters in obese and non-obese group

| Procedure variables | Non-obese (<30 kg/m²) | Obese (≥30 kg/m²) | *P*-value |
|---|---|---|---|
| | *n* = 126 | *n* = 62 | |
| Procedure time, min (mean ± SD) | 10.6 ± 6.6 | 11.7 ± 7.1 | *0.267* |
| Estimated blood loss, mL (mean ± SD) | 41.5 ± 46.4 | 42.2 ± 48.7 | *0.922* |
| Length of stay, h (mean ± SD) | 8.5 ± 12.7 | 11.5 ± 16.5 | *0.185* |
| Wong–Baker Faces Pain Scale, scale 0–10 (mean ± SD) | 1 ± 2 | 2 ± 2 | *0.042* |
| Procedure location | Non-obese (<30 kg/m²) | Obese (≥30 kg/m²) | *P*-value |
| *n* (%) | *n* = 126 | *n* = 62 | |
| Office | 29 (23%) | 9 (14.5%) | 0.394 |
| Hospital | 82 (65.1%) | 45 (72.6%) | 0.394 |
| Ambulatory surgery center | 15 (11.9%) | 8 (12.9%) | 0.394 |
| Anesthesia type | Non-obese (<30 kg/m²) | Obese (≥30 kg/m²) | *P*-value |
| *n* (%) | *n* = 126 | *n* = 62 | |
| General | 57 (45.2%) | 36 (58.1%) | 0.360 |
| I.V. sedation | 44 (34.9%) | 16 (25.8%) | 0.360 |
| Local only | 24 (19.0%) | 9 (14.5%) | 0.360 |
| Other (no general, no I.V. and no local only) | 1 (0.8%) | 1 (1.6%) | 0.360 |

**Table 3** LFCF analysis

| 24 Month objective cure rates | Non-obese (<30 kg/m²) | Obese (≥30 kg/m²) | *P*-value |
|---|---|---|---|
| Negative CST | 85.9% (85/99) | 81.4% (35/43) | 0.499 |
| PWT ≤1 gram | 85% (85/100) | 69.6% (32/46) | 0.030 |

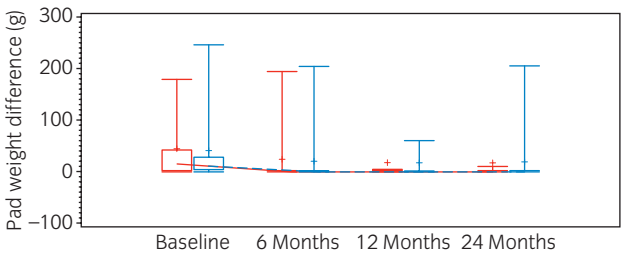


**Fig. 2** Changes from baseline in pad weight difference at 24 months in obese and non-obese patients. Line connects median, +denotes mean. **P*-value from Wilcoxon test <0.05 comparing different groups at the same visit. Obesity: ——, Yes; – – –, No.

no significant statistical difference between the two groups. The obese group reported a higher level of pain per Wong–Baker scale than the non-obese group ($P = 0.042$) at time of discharge; however, at 7 days, pain scores were no different ($P < 0.05$).

Objective cure rates at 24 months are shown in Table 3. The objective cure rates for a negative CST and PWT ≤1 g at 24 months were 81% and 70%, respectively, in the obese group, and 86% and 85% in the non-obese group. There was no statistical difference in CST between the two groups. However, the PWT was statistically significant ($P < 0.030$), where the obese group showed a lower cure rate with PWT. As seen in Figure 2, the median pad weight decreased from 15.0 at baseline to 0.0 in the obese group, and from 11.5 to 0.0 in the non-obese group at 24 months ($P < 0.001$). Seven patients underwent a second sling procedure within the 2 years of follow up, with one (1.6%) in the obese group and six (4.8%) in the non-obese group ($P = 0.429$).

As shown in Figures 3 and 4, significant improvements occurred from baseline to 24 months in UDI-6 ($P < 0.001$) and IIQ-7 ($P < 0.001$) scores. The proportions of patients who showed improvement by UDI-6 in the obese and non-obese group were 84% and 93% ($P = 0.126$), respectively, and 100% and 94% by the IIQ-7 ($P = 0.087$). Of those with bothersome urge urinary incontinence symptoms at baseline on UDI-6 question #2 (score of 2 or 3), 72% of the obese patients reported resolved symptoms at 24 months and 85% in the non-obese group ($P < 0.196$). The UDI-6 subscales: irritative, stress and obstructive were also evaluated. The results showed statistically significant improvement from baseline to 24 months in the two groups ($P < 0.001$). The details of this analysis can be seen in Table 4. De novo urgency incontinence was reported in 10% (2/20) of obese patients at 24 months based on the UDI-6, question #2 as a

**Table 4** UDI-6, subscales changes from baseline to 24 months, paired data

| Questionnaire (*n*) | Preoperative score | Postoperative score | Mean improvement | Within group *P*-value |
|---|---|---|---|---|
| IIQ-7 | | | | |
| Obese (45) | 51.0 ± 24.9 | 6.8 ± 14.2 | 44.2 ± 25.6 | <0.001[P] |
| Non-obese (96) | 36.1 ± 21.3 | 4.8 ± 12.2 | 31.3 ± 21.8 | <0.001[S] |
| *t*-test(between groups) | <0.001[T] | 0.405[T] | 0.002[T] | |
| UDI-6 | | | | |
| Obese (45) | 50.1 ± 19.7 | 16.4 ± 18.3 | 33.7 ± 24.0 | <0.001[P] |
| Non-obese (96) | 46.2 ± 16.6 | 11.2 ± 14.1 | 35.0 ± 20.3 | <0.001[P] |
| *t*-test (between groups) | 0.099[T] | 0.066[T] | 0.737[T] | |
| UDI-6 subscales | | | | |
| Irritative (sum of Q1 & Q2) | | | | |
| Obese (45) | 3.5 ± 1.9 | 1.2 ± 1.4 | 2.3 ± 2.1 | <0.001[P] |
| Non-obese (96) | 2.9 ± 1.9 | 0.9 ± 1.2 | 2.0 ± 2.0 | <0.001[S] |
| *t*-test(between groups) | 0.038[T] | 0.196[T] | 0.470[T] | |
| Stress (sum of Q3 & Q4) | | | | |
| Obese (45) | 4.4 ± 1.4 | 1.3 ± 1.5 | 3.1 ± 2.0 | <0.001[S] |
| Non-obese (96) | 4.3 ± 1.2 | 0.8 ± 1.2 | 3.5 ± 1.7 | <0.001[S] |
| *t*-test(between groups) | 0.535[T] | 0.055[T] | 0.205[T] | |
| Obstructive (sum of Q5 & Q6) | | | | |
| Obese (45) | 1.2 ± 1.5 | 0.5 ± 1.2 | 0.7 ± 1.5 | 0.002[S] |
| Non-obese (96) | 1.1 ± 1.4 | 0.3 ± 0.6 | 0.8 ± 1.4 | <0.001[S] |
| *t*-test (between groups) | 0.511[T] | 0.220[T] | 0.729[T] | |

[P]Paired *t*-test. [S]Signed rank test. [T]Two-sample *t*-test.

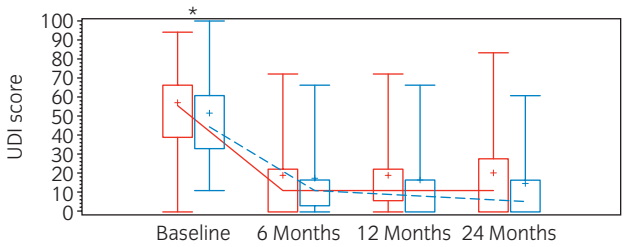


**Fig. 3** Changes from baseline in UDI-6 at 24 months in obese and non-obese patients. Line connects median, +denotes mean. **P*-value from Wilcoxon test <0.05 comparing different groups at the same visit. Obesity: ——, Yes; – – –, No.

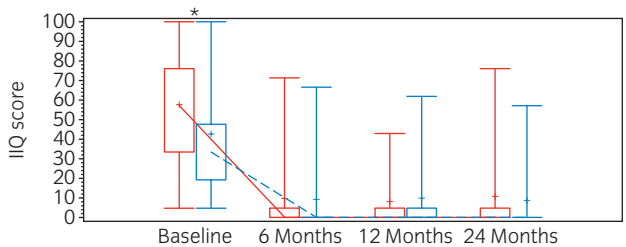


**Fig. 4** Changes from baseline in IIQ-7 scores at 24 months in obese and non-obese patients. Obesity: ——, Yes; – – –, No.

change of a score at baseline of 0 or 1 to a score of ≥2 at 24 months and 10.0% (5/50) in the non-obese group ($P = 1.000$). At 7 days postoperatively, there was no statistical difference between the groups in regards to the number of patients reporting normal voiding, and feeling they were able to return to normal activities (Table 5). Relevant postoperative device or procedure related complications in the obese and non-obese group are listed in Table 6. No difference was found in overall complication rates between the groups ($P = 1.0$, Fisher's exact test).

## Discussion

Obesity is a well-known risk factor for female SUI and weight loss has been shown to be an effective treatment.[3,4] However, as ideal as this might seem, many women are unable to lose weight or keep it off, and many other women note that urinary leakage prevents them from exercising or caused them to stop exercising in the first place. There has been hesitancy in the past to operate on obese patients for an elective procedure for SUI secondary to their comorbities, and the perceived notion of higher complication rates and higher failure rates of obese patients. This unfortunately has led to many women not being offered treatment and ultimately having to continue to suffer from QoL issues secondary to urinary leakage. Traditional surgeries for SUI, such as Burch, Marshall–Marchetti–Krantz or pubovaginal slings, have been shown to be efficacious without increase complications.[1] However, it was also noted in these studies that the procedures took longer and were technically more difficult to carry out in obese patients.

**Table 5** Seven days post-operative evaluation

| | Obesity (BMI ≥30 kg/m²) | | *P*-value |
|---|---|---|---|
| | No (*n* = 126) | Yes (*n* = 62) | |
| Able to return to normal daily activities? | | | 0.106 |
| Yes (%) | 100 (80.0%) | 43 (69.4%) | |
| No (%) | 25 (20.0%) | 19 (30.6%) | |
| Are you voiding OK? | | | 0.373 |
| Yes (%) | 122 (97.6%) | 59 (95.2%) | |
| No (%) | 3 (2.4%) | 3 (4.8%) | |
| 7 Days post-op pain level | | | 0.173 |
| Mean ± SD | 1 ± 2 | 1 ± 2 | |

**Table 6** Obese and non-obese patients device or procedure related adverse events

| Adverse event | Obese patients (*n* = 62) | | Non-obese patients (*n* = 126) | |
|---|---|---|---|---|
| | *n* | % | *n* | % |
| Urinary tract infection | 5 | 8.1% | 4 | 3.2% |
| Urinary incontinence – de novo urge | 2 | 3.2% | 6 | 4.8% |
| Urinary retention | 3 | 4.8% | 3 | 2.4% |
| Dyspareunia | 2 | 3.2% | 2 | 1.6% |
| Urinary urgency – de novo | 3 | 4.8% | 1 | 0.8% |
| Extrusion | 1 | 1.6% | 2 | 1.6% |
| Pain/discomfort – urogenital | 0 | 0% | 3 | 2.4% |
| Pain/discomfort – leg | 0 | 0% | 2 | 1.6% |
| Dysuria | 2 | 3.2% | 0 | 0% |
| Urinary frequency | 1 | 1.6% | 1 | 0.8% |
| Urinary urgency | 2 | 3.2% | 0 | 0% |
| Perforation – vaginal | 1 | 1.6% | 0 | 0% |

The development of the RP tension-free vaginal tape sling has led to a very successful ambulatory procedure to treat female SUI. The RP sling has been studied in obese patients and the consensus is that it seems to be effective in this population with no increase in complications. Raffi *et al*. evaluated the effectiveness of the TVT in overweight and obese women.[5] After 27 months of follow up, they did not find a difference in cure rates between the groups. Killingsworth *et al*. evaluated 195 women who underwent TVT.[6] At 1 year, they found similar outcomes among 68 normal weight (BMI <20–24.9), 65 overweight (BMI 25–25.9) and 62 obese (BMI >30) women. The proportions of participants with SUI at 1 year were 18% in obese, 14% overweight and 19% normal weight, with no statistical differences between groups. Other studies have confirmed these results and also showed no increase in complications in the obese patient.[7,8]

Studies have also confirmed the TOT sling's safety and efficacy in the obese population.[2,9,10] Rechhberger *et al*. in a randomized trial, compared both the retropubic ($n = 201$) and TOT ($n = 197$) sling in the non-obese and obese population, and found that clinical effectiveness did not depend on the patient's BMI or type of sling. Both the RP and TOT sling were equally effective in both the obese and non-obese groups.[2] Tchey *et al*. confirmed these findings in a group of 107 women undergoing the TOT sling for SUI.[10] They also found no difference in cure rates between the non-obese ($n = 55$) and obese ($n = 52$) patients after TOT sling. Despite the finding that the obese group ($n = 52$) had a worse grade of SUI, and worse urge and urgency incontinence than the non-obese group ($n = 55$) preoperatively, no differences were found in surgical outcomes, cure rates or complication rates between the two groups.

The single incision mini-sling approach was developed to eliminate blind needle passage through the abdomen or groins in an attempt to make suburethral mesh tape sling placement even less invasive and safer. The MiniArc single incision sling was released in 2007 and is one of the least invasive procedures to date to treat female SUI. It is FDA approved and available in the USA without restriction.

Initial studies of the MiniArc sling in the general population have been very encouraging, with cure rates in the same range as TOT and RP slings with fewer complications reported.[11–13] We previously published the 1-year cure rates in the current study, and found a 90.6% objective cure rate in 188 patients.[14] De Ridder *et al*. compared the efficacy of the MiniArc to TOT slings and found no difference in cure rates.[13] There is concern, however, with the smaller size of the MiniArc sling and the decreased surface area of mesh attachment versus exiting in the groins, if this will have adequate holding force for larger obese women.

In the current prospective multicenter trial this did not seem to be the case, as there was no difference in objective cure rates using CST between obese and non-obese patients. The objective cure rate through the CST at 2 years follow up was 81.4% in the obese group versus 85.9% in the non-obese group ($P = 0.49$), despite the obese group having worse UDI-6 scores preoperatively as well as worse overall IIQ-7 scores ($P < 0.001$). The PWT cure rate was found to be lower in the obese group; however, this might be secondary to the fact that PWT failures might also be a result of urgency incontinence and not specific to just stress leakage. This is supported by the fact that the obese subgroup was found to have statistically worse preoperative urge subscale scores, showing more of an issue with urge leakage preoperatively. Secondary to this, the PWT might not be the most ideal outcome test for obese patients, as urge leakage can impact PWT outcomes. Additionally, other issues in addition to not being able to distinguish types of incontinence, including user error and conflicting values for cut-off values for a positive test, have been noted for the PWT.[15]

It has also been shown in the past that obese patients have a higher rate of persistent urge leakage after the sling procedure.[5] However, in the current trial, there was no difference in the reported rates of urge resolution symptoms between the two groups ($P < 0.196$). It is also worth noting that significant improvement in UDI-6 and IIQ-7 scores in both groups indicates that the MiniArc procedure indeed improves QoL regardless of BMI. Additionally, both groups showed statistically significant improvement in UDI-6 subscale scores for stress incontinence, with no significant difference in outcomes between the groups.

Operative procedures to treat SUI have been known to be more technically challenging in obese patients. This did not seem to be the case with the MiniArc procedure, as there was no difference in operative time, blood loss or length of stay. The obese group did have higher pain scores at discharge, however by 7 days postoperatively, there was no difference. There was also no difference in overall complication rates between the two groups. Additionally, 42% of the obese patients were able to be treated with local anesthesia only or local anesthesia with sedation, eliminating the risks of general anesthesia in this higher risk population.

The present study had several strengths, including the fact that this was a large cohort of patients in a prospective multicenter trial. The follow up was one of the longest to date regarding the MiniArc sling at 2 years follow up. The definition of objective cure was rigorous, with objective CST as well as PWT. Additionally, validated QoL indices were used and the reporting of complications was comprehensive. The limitations of the study were that this was a post-hoc analysis and therefore sample size was larger in the non-obese versus the obese group. Some of the findings might be the result of the small sample size or uneven group numbers, and therefore should lend caution to interpretation. Additionally, overall cure rates might be affected by attrition or patients lost to follow up, the CST has not been formally validated as an outcome measure in obese patients and although 2 years is the longest follow up to date regarding mini-slings, this might not be enough time to see final outcomes for obese patients.

The current study showed that the objective and subjective outcomes of the MiniArc sling procedure were similar at 2 years follow up in women with SUI regardless of BMI. Both obese and non-obese women had significant improvement in postoperative QoL and a low rate of complications. There was no difference in objective cure rates by CST in obese versus non-obese patients, nor any difference in complication rate. It was also shown that the procedure could be completed easily in obese patients. Secondary to the fact that obese patients are a population that might be at higher risk of intra- and postoperative complications, the very minimally-invasive MiniArc sling procedure might be considered as therapy in obese patients.

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## Conflict of interest

Robert D Moore, MD: American Medical Systems – Research, Grant, Speaker Fees, Consultant.
Dirk De Ridder, MD, PhD: American Medical Systems – Research, Speaker/Honorarium, Consultant.
Michael J Kennelly, MD: American Medical Systems – Research, Paid travel expenses/honoraria, Consultant.

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