Urogynaecological mesh devices (mid-urethral slings)

Review of comparative clinical and cost-effectiveness to support the Prescribed List Post-Listing Review

Final Report

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Abbreviations

ACSQHC	Australian Commission on Safety and Quality in Health Care
AIHW	Australian Institute of Health and Welfare
APFPR	Australasian Pelvic Floor Procedure Registry
ARTG	Australian Register of Therapeutic Goods
CEA	cost-effectiveness analysis
CI	confidence interval
CUA	cost-utility analysis
DoHAC	Department of Health and Aged Care
DRG	diagnosis related group
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HTA	health technology assessment
HRQoL	health-related quality of life
ICER	incremental cost-effectiveness ratio
ICUR	incremental cost-utility ratio
IHPA	Independent Hospital Pricing Authority
INMB	incremental net monetary benefit
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
MID	minimum important difference
MUI	mixed urinary incontinence
MUS	mid-urethral sling
NHS	National Health Service (United Kingdom)
NICE	National Institute for Health and Care Excellence
NMA	network meta-analysis
PBS	Pharmaceutical Benefits Scheme
PICO	Research question defined as population, intervention, comparator/s, and outcomes
PL	Prostheses List
PLAC	Prostheses List Advisory Committee
POP	pelvic organ prolapse
PVS	autologous pubovaginal sling
RACS	Royal Australasian College of Surgeons
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCT	randomised controlled trial
RP	retropubic
RR	relative risk/risk ratio

QALY	quality-adjusted life year
QoL	quality of life
SAE	serious adverse events
SUI	stress urinary incontinence
TGA	Therapeutic Goods Administration
TO	transobturator
TOT	transobturator tape
TVT	tension-free vaginal tape
UK	United Kingdom
US	United States
a	Urological Society of Australia and New Zealand
UTI	urinary tract infection
WTP	willingness to pay (cost-effectiveness threshold)

Terminology

Surgical procedure	Description
Bulking agent *Synonyms: injectable agents, urethral injections, urethral bulking*	Urethral bulking refers to the injection of a substance into the urethral submucosa at the bladder neck (Valderrama 2020). Urethral bulking agents may be particulate (particles suspended in biodegradable carrier gel) or non-particulate (homogeneous gels) (Valderrama 2020). *Examples: Macroplastique, Bulkamid.*
Colposuspension	A surgical procedure whereby the neck of the bladder is lifted and suspended in position using synthetic stitches (NICE 2019a; NICE 2019c). Colposuspension can be performed via an open or laparoscopic approach (Brazzelli 2019).
Mid-urethral sling (MUS)	A type of urogynaecological mesh used in the treatment of stress urinary incontinence. The sling is placed beneath the middle part of the urethra, providing support during exertion to prevent urine leakage (RANZCOG 2020, amended 2022). The sling is a narrow, synthetic polypropylene mesh tape (RANZCOG 2020, amended 2022) inserted via a minimally invasive retropubic (RP) or transobturator (TO) approach. **Retropubic mid-urethral sling (RP-MUS):** the sling is inserted via an incision in the vagina. It is positioned in a U shape under the mid-urethra, with the ends of the sling exiting the retropubic space via incisions in the skin of the abdomen above the pubic bone (ACSQHC 2018b). *Examples: TVT, SPARC, Advantage, TVT-EXACT* **Transobturator mid-urethral sling (TO-MUS):** the sling is inserted via an incision in the vagina and placed under the mid-urethra. The ends of the sling exit through incisions in the skin on both sides of the groin (ACSQHC 2018b). *Examples: TVT-O, TOT, Obtryx, TVT-ABBREVO*
Pubovaginal sling (native tissue) *Synonym: autologous fascial sling*	An abdomino-vaginal surgery using the patient's own tissue to support the urethra, with an abdominal wall fixation site (Valderrama 2020). The tissue is usually taken from the rectus fascia in the abdomen (rectus fascial sling) but may be taken from the thigh (fascia lata) (Valderrama 2020).

Executive Summary

Introduction

Urogynaecological mesh devices have been the subject of ongoing regulatory review and safety monitoring in Australia due to concerns about adverse events related to their use. In November 2017, the Therapeutic Goods Administration (TGA) removed two types of urogynaecological mesh from the Australian Register of Therapeutic Goods (ARTG)[1]:

1. Urogynaecological mesh inserted through the vagina for pelvic organ prolapse (POP)
2. Single incision mini-slings for stress urinary incontinence (SUI).

Mid-urethral slings (MUS) for the treatment of SUI continue to be approved for supply in Australia and are included in the Prostheses List (PL).

As these devices have not been assessed by the Medical Services Advisory Committee (MSAC) or the Prostheses List Advisory Committee (PLAC), the purpose of this post-listing review is to review the comparative clinical effectiveness and cost-effectiveness of MUS for the treatment of SUI, and to inform decisions regarding the associated listings on the PL. The relevant comparisons are based on the Australian Commission on Safety and Quality in Health Care (ACSQHC) care pathway for the management of SUI (ACSQHC 2018a) and are:

- MUS compared to colposuspension (native tissue), pubovaginal sling (native tissue) or bulking agents
- Retropubic MUS (RP-MUS) compared to transobturator MUS (TO-MUS).

The findings are based on consideration of key documents supplied by the Department of Health and Aged Care (DoHAC), a pragmatic review of the published literature and targeted stakeholder consultation.

Summary of findings

The findings relating to the comparative clinical effectiveness of MUS are based predominately on the 2019 NICE Guideline *Urinary incontinence and pelvic organ prolapse in women: management* (NICE 2019c). The NICE evidence review identified no eligible studies comparing bulking agents to MUS.

Clinical effectiveness – colposuspension versus MUS

The findings by outcome and follow-up time for MUS compared to colposuspension are summarised in Table ES 1.

Table ES 1 Summary of findings for clinical effectiveness colposuspension vs. MUS

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[1]
Change in continence status				
subjective cure	4, N=625 (S)	Low	No difference (S)	No difference (S)
	4, N=619 (M)	Very low	No difference (M)	No difference (M)
	1, N=72	Very low	No difference (L)	No difference (L)
objective cure	5, N=689 (S)	Very low	Favours MUS (S)	No difference (S)
	7, N=844 (M)	Low	Favours MUS (M)	No difference (M)

[1] https://www.tga.gov.au/products/medical-devices/urogynaecological-transvaginal-surgical-mesh-hub [Accessed 31 March 2023]

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[1]
Patient-reported outcomes				
continence-specific health-related HRQoL	1, N=286 (S); 1, N=177 (M)	Very low	No difference (S), (M)	No difference (S), (M)
patient-satisfaction/patient-reported improvement	5, N=441 (M)	Low	Favours MUS (M)	No difference (M)
	1, N=72 (L)	Very low	No difference (L)	No difference (L)
Adverse events				
bladder injury	11, N=1,086	Low	Favours colposuspension	Favours colposuspension
severe bleeding requiring blood transfusion	3, N=259	Very low	No difference	No difference
bowel injury	1, N=72	Very low	No difference	No difference
Complications				
infection	2, N=429 (S); 4, N=539 (M)	Very low	No difference (S, M)	No difference (S, M)
POP	2, N=302 (M)	Low	Favours MUS (M)	Favours MUS (M)
pain	2, N=189 (S); 2, N=161 (M)	Very low	No difference (S, M)	No difference (S, M)
mesh extrusion	2, N=429 (S); 5, N=598 (M)	Very low	No difference (S, M)	No difference (S, M)
need for catheterisation	3, N=289 (S); 3, N=502 (M)	Very low	No difference (S, M)	No difference (S, M)
de novo urgency	1, N=87 (S); 3, N=338 (M)	Very low	No difference (S, M)	No difference (S, M)
de novo urge incontinence	2, N=155 (S); 3, N=315 (M)	Very low	No difference (S, M)	No difference (S, M)
fistula	1, N=90 (M)	Low	No events	No events
wound complications	1, N=90 (M)	Low	No events	No events
Repeat surgery				
for any reason	2, N=168 (S)	Very low	No difference (S)	No difference (S)
	1, N=316 (M)	Low	Favours MUS (M)	Favours MUS (M)
for SUI	2, N=166 (M); 1, N=53 (L)	Very low	No difference (M, L)	No difference (M, L)
for mesh complications	1, N=68 (S); 1, N=72 (L)	Very low	No difference (S, L)	No difference (S, L)

Source: based on data from NICE Evidence review (NICE 2019b)

Abbreviations: HRQoL, health-related quality of life; L, long-term; M, medium-term; MUS, mid-urethral sling; No., number; POP, pelvic organ prolapse; RP, retropubic; S, short-term; SUI, stress urinary incontinence; TO, transobturator

[1] NICE defined clinically important outcomes based on published literature and consultation with the Guideline Committee. If no published or acceptable minimally important difference (MID) was identified, the committee considered whether to use GRADE defaults.

Key: orange = very low quality evidence; yellow = low quality evidence; green = favours MUS; blue = favours colposuspension.

Clinical effectiveness – Autologous rectus fascial sling (pubovaginal sling) versus MUS

The findings by outcome and follow-up time for MUS compared to autologous rectus fascial sling (pubovaginal sling) are summarised in Table ES 2.

Table ES 2 Summary of findings for clinical effectiveness – autologous rectus fascial sling (pubovaginal sling) vs. MUS

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[3]
Change in continence status				
subjective cure	2, N=197 (S)[1]	Very low	Borderline favours RP-MUS (S)[1]	Favours RP-MUS (S)[1]
	1, N=41 (M)	Very low	No difference (M)	No difference (M)
	1, N=156 (L)	Very low	No difference (L)	No difference (L)
objective cure	3, N=192 (S)	NR[2]	No difference (S)	NR[2]
	3, N=187 (M)	Very low	No difference (M)	No difference (M)
Patient-reported outcomes				
patient-satisfaction/patient-reported improvement	2, N=65 (M)	NR[2]	No difference (M)	NR[2]
Adverse events				
any	3, N=192 (S)	NR[2]	No difference (S)	NR[2]
	3, N=187 (M)	NR	No difference (M)	NR
Complications				
pain	2, N=133 (S)	NR[2]	No difference (S)	NR[2]
	1, N=53 (S)[1]	Very low	No difference (S)[1]	May favour RP-MUS
	2, N=193 (L)	Very low	No difference (L)	No difference (L)
mesh extrusion	1, N=63 (M)	NR[2]	No difference (M)	NR[2]
	2, N=193 (L)	Very low	No difference (L)	No difference (L)
need for catheterisation	4, N=320 (S)	NR[2]	No difference (S)	NR[2]
	1, N=124 (L)	Very low	No difference (L)	No difference (L)
de novo urgency	2, N=65 (M); 2, N=193 (L)	Very low	No difference (M, L)	No difference (M, L)
	2, N=256 (L)	Very low	No difference (L)	No difference (L)
Repeat surgery				
for any reason	2, N=197 (S); 1, N=69 (L)	Very low	No difference (S, L)	No difference (S, L)

Source: based on data from NICE Evidence review (NICE 2019b)

Abbreviations: L, long-term; M, medium-term; MUS, mid-urethral sling; NR, not reported; RP, retropubic; S, short-term.

[1] Sub-group comparison: rectus fascial sling versus RP-MUS

[2] Quality of evidence and clinical significance not available in NICE report for sub-set of studies excluding single-incision mini-slings

[3] NICE defined clinically important outcomes based on published literature and consultation with the Guideline Committee. If no published or acceptable minimally important difference (MID) was identified, the committee considered whether to use GRADE defaults.

Key: orange = very low quality evidence; purple = favours RP-MUS; light purple = may favour RP-MUS

Clinical effectiveness – TO-MUS versus RP-MUS

The findings by outcome and follow-up time for TO-MUS versus RP-MUS are summarised in Table ES 3**.**

Although the NICE direct comparison showed no clinically important differences in subjective cure or objective cure in the short, medium or long-term, a network meta-analysis (NMA) (Brazzelli 2019) did show a statistically significant difference in favour of RP-MUS in both objective cure and the number of women improved.

Table ES 3 Summary of findings for clinical effectiveness – TO-MUS vs. RP-MUS

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[1]
Change in continence status				
Subject cure	15, N=2,638 (S); 6, N=1,340 (M)	Low	No difference (S, M)	No difference (S, M)
	2, N=288 (L)	Very low	No difference (L)	No difference (L)
Objective cure	15, N=2,176 (S)	Low	Favours RP-MUS (S)	No difference (S)
	10, N=2,057 (M)	Low	No difference (M)	No difference (M)
	2, N=288 (L)	Very low	No difference (L)	No difference (L)
Negative cough stress test	9, N=2,292 (S); 5, N=1,352 (M)	Low	No difference (S, M)	No difference (S, M)
Number of incontinence episodes per day	1, N=36 (M)	Low	No difference (M)	No difference (M)
Continence-specific HRQoL				
ICIQ-UI-QoL score (M)	1, N=100 (M)	Very low	Favours RP-MUS (M)	Favours RP-MUS (M)
I-QoL score (S)	1, N=125 (S)	Very low	Favours RP-MUS (S)	Favours RP-MUS (S)
ICIQ-UI-QoL score (S)	1, N=100 (S)	Very low	No difference	May favour RP-MUS (S)
King's Health Questionnaire – Intercourse score (M)	1, N=331 (M)	Very low	Favours TO-MUS (M)	Favours TO-MUS (M)
All other health-related QoL measures	1 to 5, N= 100 to 887	Very low or Low	Variable	No difference
Other patient-reported outcomes				
Patient-satisfaction/patient-reported improvement	13, N=2,771 (M); 1, N=140 (L)	Low	No difference (M, L)	No difference (M, L)
Adverse events				
bladder injury	40, N=6,654	Moderate	Favours TO-MUS	Favours TO-MUS
severe bleeding requiring blood transfusion	10, N=2,041	Very low	No difference	No difference
bowel injury	12, N=1,455	Moderate	No events	No events
Complications				
infection	17, N=3,245 (S); 7, N=1,838 (M); 2, N=268 (L)	Very low	No difference (S, M, L)	No difference (S, M, L)
POP	1, N=87 (L)	Very low	No difference (L)	No difference (L)
pain	19, N=3618 (S)	Moderate	Favours RP-MUS (S)	Favours RP-MUS (S)
	11, N=1,953 (M); 2, N=207 (L)	Very low	No difference (M, L)	No difference (M, L)
mesh extrusion	22, N=3,829 (S)	Low	Favours RP-MUS (S)	Favours RP-MUS (S)
	12, N=2,279 (M)	Very low	Favours RP-MUS (M)	Favours RP-MUS (M)
need for catheterisation	16, N=3,039 (S)	Low	Favours TO-MUS (S)	Favours TO-MUS (S)
	4, N=822 (M)	Very low	No difference (M)	No difference (M)
de novo urgency	8, N=1,164 (S); 7, N=761 (M)	Very low	No difference (S, M)	No difference (S, M)
de novo urge incontinence	5, N=1,243 (S); 4, N=987 (M)	Very low	No difference (S, M)	No difference (S, M)
de novo nocturia	1, N=88 (S)	Very low	No difference (S)	No difference (S)

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[1]
	1, N=71 (M)	Very low	Favours RP-MUS (M)	Favours RP-MUS (M)
wound complications	4, N=443 (S); 2, N=248 (M)	Very low	No difference (S, M)	No difference (S, M)
Repeat surgery				
for SUI	5, N=1,114 (S)	Low	Favours RP-MUS (S)	Favours RP-MUS (S)
	6, N=1,022 (M); 1, N=87 (L)	Very low	No difference (M, L)	No difference (M, L)
for POP	1, N=554 (S)	Very low	No events (S)	No events (S)
	1, N=87 (L)	Very low	No difference (L)	No difference (L)
for mesh complications	13, N=2,447 (S); 8, N=1,688 (M); 1, N=87 (L)	Very low	No difference (S, M, L)	No difference (S, M, L)

Source: based on data from NICE Evidence review (NICE 2019b)
Abbreviations: HRQoL, health-related quality of life; L, long-term; M, medium-term; MUS, mid-urethral sling; POP, pelvic organ prolapse; RP, retropubic; S, short-term; SUI, stress urinary incontinence; TO, transobturator
[1] NICE defined clinically important outcomes based on published literature and consultation with the Guideline Committee. If no published or acceptable minimally important difference (MID) was identified, the committee considered whether to use GRADE defaults.
Key: orange = very low quality evidence; yellow = low quality evidence; blue = moderate quality evidence; purple = favours RP-MUS; pink = favours TO-MUS.

Clinical Practice Guidelines and Regulatory Advice

Ten clinical practice guidelines or position statements were considered. All recommend MUS as a surgical option for the treatment of SUI. Those that make a statement on the type of MUS recommend RP-MUS over TO-MUS unless there are specific clinical circumstances.

Cost-effectiveness and cost-analysis

Although cost-effectiveness analyses from other jurisdictions may have limited applicability to the Australian setting, four modelled economic studies that compared MUS to alternative surgical interventions all found MUS to be cost-effective. Most of the included economic studies found that cost-effectiveness was driven by the cost of the device itself or the device procedure, and were limited by the extrapolation of effectiveness and complication rates over the long-term.

In considering the cost of the MUS procedure in the Australian setting, the main costs are for the device ($822 PL benefit) and the procedure, which has a total MBS cost of $1,287. Additional costs may include pre-surgical tests such as urodynamic analysis and post-surgical pharmaceutical costs. Estimates of hospital costs are uncertain as there is no specific AR-DRG for the procedure.

Considerations for PLAC

The evidence base supports the place of MUS in the treatment of SUI, demonstrating comparable effectiveness to alternative surgical interventions. In international analyses, MUS is cost-effective based on lower procedure costs than alternative surgical interventions. Of the two types of MUS device listed on the PL, the evidence base appears to favour RP-MUS over TO-MUS and this is consistently recommended in clinical practice guidelines. However, a role for TO-MUS appears to remain in limited clinical circumstances. Therefore, the comparative clinical effectiveness, long-term outcomes and clinical practice guidelines are all consistent with the care pathway as specified by the ACSQHC (see **Figure 1**) (ACSQHC 2018a). On this basis, it is recommended that PLAC:

- Continue to list both RP-MUS and TO-MUS devices on the PL.
    - As both approaches are for similar clinical indications and both types of devices have similar technical characteristics there is no justification for listing them in separate groups.
    - MUS is likely to be cost-effective at the current benefit based on a lower expected procedure cost than the comparators, with similar effectiveness. The annual cost to the PL

in 2021-22 was $822,000. No evidence was located to support a change to the current benefit.

- In collaboration with the TGA, continue to monitor the long-term safety of MUS based on:
    - data collected via the Australasian Pelvic Floor Procedure Registry (APFPR), when data from a sufficiently sized sample is able to ensure it is representative
    - ongoing advice from international regulators.
- In collaboration with the TGA and/or DoHAC, continue to monitor utilisation data for RP and TO MUS devices to ensure use aligns with clinical recommendations in favour of a RP-MUS approach.

1 Background

1.1 Context for the Review

1.1.1 Prostheses List post-listing review framework

The Department of Health and Aged Care (DoHAC) has developed a Prostheses List (PL) Post-Listing Review Framework (the Framework) to facilitate the review of post-listing concerns as required. The Framework was developed as part of the Prostheses List Reforms. This review is being conducted to trial the Framework and inform its further development.

1.2 About this post-listing review of urogynaecological mesh devices (mid-urethral slings)

Mid-urethral slings (MUS) for the treatment of stress urinary incontinence (SUI) are included in the Prostheses List Group 05.01.03.02 (Incontinence Prostheses, Sling, Female). There is an associated Medicare Benefits Schedule (MBS) item for the insertion of a female mid-urethral sling (35599), which was first listed on the MBS on 01 December 1991. Two MBS items exist (37340 and 37341) for division or removal of a urethral sling due to urethral obstruction, sling erosion, pain or infection following previous surgery for urinary incontinence, listed on 01 May 2001.

1.2.1 Why review mid-urethral slings?

Urogynaecological mesh is primarily used for the treatment of pelvic organ prolapse (POP) and SUI (TGA 2021). MUS are a type of urogynaecological mesh used for the treatment of SUI. Urogynaecological mesh devices have been the subject of ongoing regulatory review and safety monitoring in Australia due to concerns about adverse events related to their use (TGA 2023).

In November 2017, the Therapeutic Goods Administration (TGA) removed two types of urogynaecological mesh from the Australian Register of Therapeutic Goods (ARTG)[1]:

3. **Urogynaecological mesh inserted through the vagina for POP**: the TGA believed the benefits did not outweigh the risks to patients (TGA 2019).
4. **Single incision mini-slings for SUI**: there was a lack of evidence for the TGA to be satisfied that the benefits to patients outweighed the risks (TGA 2019).

The TGA imposed further restrictions in 2018, including the up-classification of all urogynaecological mesh devices from Class IIb to Class III (high risk) (TGA 2023). All urogynaecological mesh devices were also required to undergo a comprehensive review by the TGA (TGA 2023).

Subsequent to these actions, MUS for the treatment of SUI continue to be approved for supply in Australia. There has, however, been no Health Technology Assessment (HTA) of these devices by the Medical Services Advisory Committee (MSAC) or the Prostheses List Advisory Committee (PLAC). The purpose of this post-listing review is to review the comparative clinical effectiveness and cost-effectiveness of MUS for the treatment of SUI, and to inform decisions regarding the associated listings on the PL.

1.2.2 Undertaking the post-listing review

Analysis and evaluation of scientific literature, utilisation data and additional relevant information

Health Research Consulting (hereco) was contracted by DoHAC to review the comparative clinical effectiveness and cost-effectiveness of MUS currently listed on the PL, and to advise DoHAC on appropriate actions and/or policy considerations (if any). The services provided in this review are detailed in **Table 1**.

This review has been undertaken in accordance with the *Prostheses List Guide to Listing and Setting Benefits for Prostheses (DoHAC 2017).*

Table 1 Services to be provided in this post-listing review

Service	Description

1	Review the evidence base for the comparative clinical effectiveness and cost-effectiveness of mid-urethral slings for the treatment of SUI:
	• Review the following key documents provided by DOHAC:
	  ○ Information and submissions from sponsors
	  ○ Information and submissions from stakeholders (including relevant clinical guidelines and expert opinion)
	  ○ ACSQHC Care pathway
	  ○ May 2022 PLAC discussion paper
	  ○ Casemix utilisation data (noting its limitations)
	  ○ TGA materials including: literature review, a summary report and Urogynaecological (transvaginal) surgical mesh hub
	• Undertake a search for systematic reviews of the comparative clinical effectiveness of mid-urethral slings (including comparison between retropubic and obturator approaches)
	  ○ Include data on long-term complication rates
	• Undertake a search for economic evaluations of mid-urethral slings.
	• Undertake an analysis of the total cost of mid-urethral sling implantation for SUI in the Australian health care setting, including the cost of the device, implantation procedure and associated resource use.

2	Review current clinical practice guidelines, HTAs and advice from international regulators on the comparative clinical effectiveness and long-term safety of mid-urethral slings for SUI.
3	Based on the information and evidence in Q1-2, and guided by the PL Post Listing Review Framework, compile information to support the Department to assess what actions or policy initiatives should be considered for the mid-urethral slings PL listings.

Abbreviations: ACSQHC, Australian Commission on Safety and Quality in Health Care; DOHAC, Department of Health and Aged Care; HTA, health technology assessment; PL, Prostheses List; PLAC, Prostheses List Advisory Committee; SUI, stress urinary incontinence; TGA, Therapeutic Goods Administration.

Targeted consultation

Sponsors and stakeholders were invited to submit information and evidence for this review. The review scope was provided to sponsors and stakeholders via email on the 27 January 2023, with responses due by 28 February 2023.

Sponsors and stakeholders were asked to consider the following information in their response:

1. Please provide or point to clinical evidence to inform the comparative clinical effectiveness assessment of mid-urethral slings for the treatment of SUI:
   - highest level comparative clinical evidence available i.e. randomised controlled trials if possible, or other designs which are sufficiently powered and enable comparison
     - the comparator will need to be the current standard of care (i.e. based on the ACSQHC Care pathway) or a comparator device

2. Please submit or point to any evidence to inform cost-effectiveness of mid-urethral slings for the treatment of SUI
    - data on projected utilisation and cost items (e.g. DRGs, MBS items etc.) or consider undertaking your own economic evaluation for the devices
        - If you choose to undertake an economic evaluation as part of your input to the review, the MSAC guidelines provide useful information to help prepare your assessment. *(This is not a mandatory requirement and the review will not be considered by MSAC)*.

1.3 Mid-urethral slings for stress urinary incontinence

1.3.1 Description of the condition

Urinary incontinence is "any accidental or involuntary loss of urine from the bladder" (ACSQHC 2018b). Stress urinary incontinence (SUI) refers to the leaking of urine during activities such as coughing, sneezing and running, when the pressure inside the abdomen increases and pushes down on the bladder (ACSQHC 2018b). Leaking of urine occurs when weakness of the urethra or neck of the bladder causes it to open in response to the increased pressure (RANZCOG 2020, amended 2022). SUI can be caused by pregnancy, childbirth, weight gain, and chronic straining or coughing (ACSQHC 2018b).

Obtaining current and accurate prevalence estimates for incontinence is challenging. The Australian Institute of Health and Welfare *Incontinence in Australia* report (AIHW 2013) notes large variations in prevalence estimates between studies due to inconsistency in the definition of incontinence used, as well as methodological limitations such as selection bias and small sample sizes. Prevalence estimates also vary by age and incontinence type (AIHW 2013). The report cited estimates of incontinence prevalence ranging from 12.8% to 46.0% in Australian women, with SUI prevalence peaking at 25.3% in females aged 35-44 years (AIHW 2013).

Incontinence has a significant impact on mental and physical health-related quality of life (HRQoL) (Avery 2004). People who experience incontinence may have difficulty completing activities of daily living and physical activity (Avery 2004). Feeling depressed, helpless, and becoming socially isolated may also occur due to the impact of incontinence on a woman's mental health (Avery 2004).

1.3.2 Description of the intervention

Urogynaecological mesh (mid-urethral slings)

Urogynaecological mesh (also known as 'sling', 'tape', 'ribbon' or 'hammock') is a netlike device that may be placed in, or attached to, the pelvis (TGA 2021). It is most commonly used to treat POP and SUI (TGA 2021).

Mid-urethral slings are a type of urogynaecological mesh used in the treatment of SUI. The sling is placed beneath the middle part of the urethra, providing support during exertion (e.g. coughing, sneezing, running) to prevent urine leakage (RANZCOG 2020, amended 2022). The sling is a narrow, synthetic polypropylene mesh tape (RANZCOG 2020, amended 2022). MUS are inserted via a minimally invasive retropubic (RP) or transobturator (TO) approach:

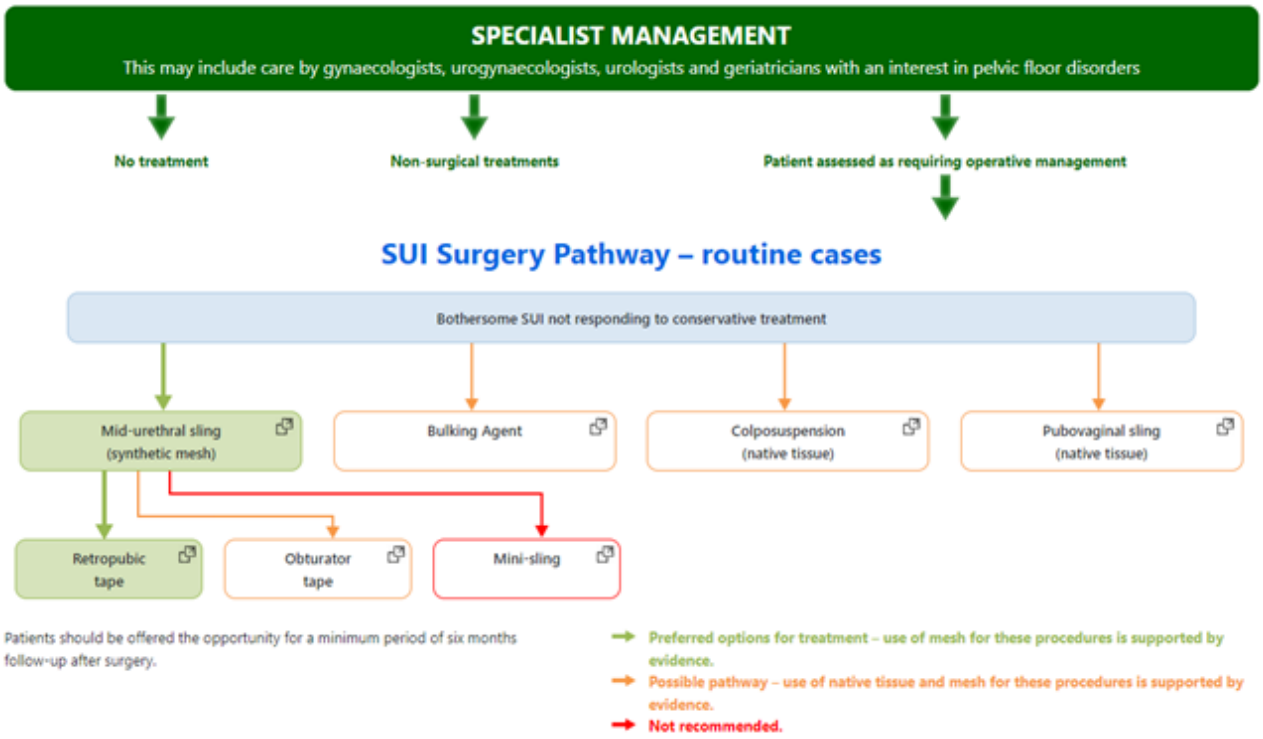
- **Retropubic (RP-MUS)**: the sling is inserted via an incision in the vagina. It is positioned in a U shape under the mid-urethra, with the ends of the sling exiting the retropubic space via incisions in the skin of the abdomen above the pubic bone (ACSQHC 2018b).

- **Transobturator (TO-MUS)**: the sling is inserted via an incision in the vagina and placed under the mid-urethra. The ends of the sling exit through incisions in the skin on both sides of the groin (ACSQHC 2018b).

According to the Australian Commission on Safety and Quality in Health Care (ACSQHC) care pathway, MUS are the preferred approach for the surgical management of SUI (ACSQHC 2018a) (see **Figure 1**).

Single-incision mini-slings have been developed in an attempt to overcome some of the complications associated with MUS (Kim 2020). The mini-sling is inserted via a single incision in the vagina, and does not need to pass through the retropubic or obturator space (Kim 2020). Single-incision mini-slings are not currently approved for use in Australia (see Section 1.2.1) and are not in scope for this review.

Figure 1 **ACSQHC Care pathway for the management of stress urinary incontinence (SUI)**



Source: Reproduced with permission from the Care Pathway for the Management of Stress Urinary Incontinence (SUI), developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC). ACSQHC: Sydney (2018)

Devices for review

This post-listing review will include all MUS currently on the PL (see **Table 2**). The six MUS on the PL are from two sponsors, Boston Scientific Australia Pty. Ltd. (n=3) and Johnson & Johnson Medical Pty. Ltd. (n=3).

Table 2 **Mid-urethral slings currently on the Prostheses List (March 2023) under product sub-group 05.01.03.02 Urogenital – Incontinence Prostheses – Sling - Female**

Device	Description	Type	Sponsor	ARTG Number	GMDN Code	Billing Code	Benefit
Advantage	Transvaginal Mid-Urethral Sling System with Blue Prolene Polypropylene Mesh	RP	Boston Scientific Australia Pty. Ltd.	373424	47986	BS402	$822
Obtryx II	Transobturator Mid-Urethral Sling System with Blue Prolene Polypropylene Mesh	TO	Boston Scientific Australia Pty. Ltd.	373426	47986	BS403	$822

Device	Description	Type	Sponsor	ARTG Number	GMDN Code	Billing Code	Benefit
Advantage Fit	Transvaginal Mid-Urethral Sling System with Blue Prolene Polypropylene Mesh	RP	Boston Scientific Australia Pty. Ltd.	373425	47986	BS404	$822
GYNECARE TVT™: Device Tension Free Vaginal Tape / EXACT™ Continence System	Female stress urinary incontinence surgical mesh	RP	Johnson & Johnson Medical Pty. Ltd.	351636 351635	47986 47986	JJ070	$822
GYNECARE TVT™ Obturator System	Female stress urinary incontinence surgical mesh	TO (inside-out)	Johnson & Johnson Medical Pty. Ltd.	351637	47986	JJ442	$822
GYNECARE TVT™ ABBREVO™ Continence System	Female stress urinary incontinence surgical mesh	TO (inside-out)	Johnson & Johnson Medical Pty. Ltd.	351638	47986	MN039	$822

Source: Prostheses List [accessed April 2023], ARTG public summary documents, NICE Evidence Reviews [E] (NICE 2019b) p26, Boston Scientific Advantage Fit and Advantage Brochure (https://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-group/sling-systems/advantage-fit/pdf/WH-465202-AD-adv-adv-fit-brochure.pdf), Boston Scientific Obtryx II brochure (https://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-group/sling-systems/obtryx-II/pdf/WH-118616-AG-obtryx-II-brochure.pdf)
Abbreviations: ARTG, Australian Register of Therapeutic Goods; GMDN, Global Medical Device Nomenclature; RP, retropubic; TO, transobturator.
Note: GMDN 47986 = Female stress urinary incontinence surgical mesh

Utilisation

MBS item number 35599

The procedure to insert a female synthetic MUS is claimed under MBS item number 35599 *'Stress incontinence, procedure using a female synthetic mid-urethral sling, with diagnostic cystoscopy to assess the integrity of the lower urinary tract, other than a service associated with a service to which item 36812 applies (H)'*. Historical utilisation data for MBS item 35599 for MUS procedures in females are presented in **Table 3**. It should be noted that the MBS item descriptor used prior to the 13 August 2021 did not restrict this MBS item to use in females. Data presented in **Table 3** includes only procedures performed in females.

Table 3 Utilisation of MBS item 35599 from January 2013 to December 2022 for females

Calendar Year	Age (yrs)									
	5-14	**15-24**	**25-34**	**35-44**	**45-54**	**55-64**	**65-74**	**75-84**	**≥85**	**Total**
2013	0	4	107	892	1,585	1,395	1,087	405	48	**5,523**
2014	1	4	85	856	1,635	1,307	1,087	370	45	**5,390**
2015	0	1	73	849	1,497	1,213	1,098	465	42	**5,238**
2016	0	1	86	672	1,307	1,040	1,053	390	63	**4,612**
2017	0	0	62	539	1,109	894	921	361	47	**3,933**
2018	0	0	38	384	763	578	632	243	44	**2,682**
2019	0	1	41	338	623	511	569	267	31	**2,381**
2020	0	1	26	219	500	352	360	167	23	**1,648**
2021	0	0	22	224	365	318	308	156	18	**1,411**
2022	0	0	12	161	302	254	250	155	20	**1,154**
Total	**1**	**12**	**552**	**5,134**	**9,686**	**7,862**	**7,365**	**2,979**	**381**	**33,972**

Source: Services Australia Medicare Item Reports
Abbreviations: yrs, years.

The MBS data demonstrates a consistent decrease in utilisation of MUS over the last 10 years. The number of female MUS procedures claimed under this item number in 2022 was 21% of the number claimed in 2013. Public concern regarding the safety of urogynaecological mesh in response to regulatory action by the TGA and other jurisdictions may have contributed to the decline in utilisation. Restrictions on elective surgery, as well as patient willingness to undergo treatment during the COVID-19 pandemic could also be a contributing factor from 2020 to 2022.

1.3.3 Description of the comparators

Appropriate comparators for this review were selected based on the ACSQHC care pathway (see **Figure 1**) for the management of SUI (ACSQHC 2018a) and include colposuspension (native tissue), pubovaginal sling (native tissue) and bulking agents.

Colposuspension

Colposuspension (native tissue) is a surgical procedure whereby the neck of the bladder is lifted and suspended in position using synthetic stitches (NICE 2019a; NICE 2019c). Colposuspension can be performed via an open or laparoscopic approach (Brazzelli 2019). The ACSQHC care pathway recommends colposuspension as a possible pathway for the management of SUI in women for whom conservative management has not been successful (ACSQHC 2018a).

Pubovaginal sling

Pubovaginal sling (native tissue) is an abdomino-vaginal surgery using the patient's own tissue to support the urethra, with an abdominal wall fixation site (Valderrama 2020). The tissue is usually taken from the rectus fascia in the abdomen (rectus fascial sling) but may be taken from the thigh (fascia lata) (Valderrama 2020).

This procedure may also be referred to as an **autologous fascial sling**, or **(autologous) rectus fascial sling** (when the native tissue is taken from the rectus fascia). The ACSQHC SUI pathway recommends consideration of this approach in women wishing to avoid mesh-related complications, and for whom conservative management has not been successful (ACSQHC 2018a).

Bulking agents

Urethral bulking refers to the injection of a substance into the urethral submucosa at the bladder neck (Valderrama 2020). The injection of bulking agents is a minimally invasive procedure that can be performed in the outpatient clinic under local anaesthesia (Kim 2020). The aim of urethral bulking is to provide cushioning around the urethra, increasing the urethral resistance at rest and during periods of increased abdominal pressure, to restore continence (Valderrama 2020). The ACSQHC SUI pathway recommends consideration of bulking agents in women wishing to avoid mesh-related complications, and for whom conservative management has not been successful (ACSQHC 2018a).

Four types of bulking agents are listed on the PL in group 05.01.04 with a benefit ranging from $504 for 1 ml to $1,262 for 2.5 ml. *An incidental finding of relevance to the PL is that three of these four items have invalid or incorrect ARTG numbers listed on the PL.*

2 Comparative clinical effectiveness

2.1 Methodology

The research questions to focus the review of comparative clinical effectiveness are:

1. *What is the comparative clinical effectiveness of mid-urethral slings compared to the use of colposuspension, pubovaginal sling (native tissue) or bulking agents for women with stress urinary incontinence?*
2. *What is the comparative clinical effectiveness of retropubic mid-urethral slings compared to transobturator mid-urethral slings for women with stress urinary incontinence?*

These were assessed using a rapid review methodology. The approach to evidence identification was multipronged, consisting of:

- search of HTA agency websites
- search for clinical practice guidelines
- targeted evidence scan
- review of key documents supplied by DoHAC (see **Table 1**)
- review of responses from sponsors and stakeholders.

A pragmatic approach was taken with a focus on identifying the most comprehensive and high-quality systematic review that addressed the research questions, and supplementing this with additional studies if necessary. Further details regarding the search strategy for the comparative clinical effectiveness evidence review are provided in **Appendix A.1**.

2.2 Summary of evidence for clinical effectiveness

2.2.1 Systematic review (NICE Guideline NG123)

The National Institute for Health and Care Excellence (NICE) systematic review conducted to inform NICE Guideline (NG123) *Urinary incontinence and pelvic organ prolapse in women: management (2019)* (NICE 2019c) was identified as the most high-quality applicable and comprehensive evidence source.

After publication of the NICE guideline in 2019, surveillance was conducted by NICE in 2021 to identify new evidence relating to full or partial mesh removal for managing mesh-related complications. The surveillance activities identified six references directly relevant to the guideline scope, with two of these being relevant to SUI (Brown 2020; Huang 2018). Huang et al. 2018 provided non-comparative effectiveness data for TO-MUS at a median follow-up of 13.5 months and Brown et al. 2020 provided quality of life and qualitative data from seven women who experienced mesh-related complications. No guideline updates were required on the basis of the evidence identified.

The NICE Guideline is broader in scope than this post-listing review; however, NICE's review question 5.1 provides relevant data:

Review question 5.1: *What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?*

Methods

The PICO criteria for review question 5.1 from the NICE Guideline are summarised in **Table 4**.

The interventions and comparators included in the NICE guideline were broader in scope than those included in this post-listing review. Single-incision mini slings, for example, are not included in this review as they are not approved for use in Australia. Interventions and comparisons included in the NICE guideline that are not relevant to this review are listed in grey italic text in **Table 4**. Findings for the comparisons listed in black text will be presented in this review.

Table 4 PICO criteria for NICE Guideline (NG 123) review question 5.1

Patient populations	Interventions	Comparisons	Outcomes

1. Women (aged ≥18) with SUI who have failed or declined conservative treatment; OR, women with mixed UI with confirmed stress predominance who have failed or declined conservative treatment
2. Women who are naïve to treatment
3. Women having repeat surgery
4. Women with USI; concurrent ISD; concurrent OAB; or concurrent POP (as indicated by the POP-Q system)
	1. Suburethral slings (synthetic mesh)
	• Retropubic bottom-up
	• Retropubic top-down
	• Transobturator inside-out
	• Transobturator outside-in
	• *Single-incision mini-slings*
	  ○ *Non-adjustable*
	  ○ *Adjustable*
	2. Colposuspension (Burch, paravaginal fascial repair)
	• Open abdominal retropubic suspension
	• Laparoscopic retropubic suspension with sutures
	3. Biological slings
	• Autologous rectus fascial sling
	• Non-autologous slings
	4. Para or transurethral injections (bulking agents)
		1. Synthetic sling vs. colposuspension
		2. Synthetic sling vs. autologous sling (e.g. rectus fascial sling)
		3. Synthetic sling vs. non-autologous biological sling
		4. Retropubic route vs. transobturator route
		5. (Non-adjustable) Single-incision mini-sling vs. other synthetic sling
		6. Adjustable sling vs. other synthetic sling
		7. Laparoscopic colposuspension vs. open colposuspension
		8. Colposuspension vs. biological sling
		• *Colposuspension vs. autologous sling*
		• *Colposuspension vs. non-autologous biological sling*
		9. Bulking agent vs. other surgical technique
		10. Artificial sphincter vs. other surgical technique
			Continence-specific HRQoL
			Adverse events (immediate post-op or perioperative)
			Complications, stratified by short-term (≤1 year), medium-term (>1 year to ≤5 years), and long-term (>5 years)
			Change in continence status
			Patient satisfaction/ patient-reported improvement
			Repeat surgery for UI or POP, or mesh complications

Source: NICE Evidence review (NICE 2019b)
Abbreviations: HRQoL, health-related quality of life; ISD, intrinsic sphincter deficiency; OAB, overactive bladder; POP, pelvic organ prolapse; POP-Q, Pelvic Organ Prolapse Quantification System; SUI, stress urinary incontinence; UI, urinary incontinence; USI, urodynamic stress incontinence.
Note: Interventions and comparisons listed in grey italic text are out of scope for this post-listing review.

The original literature search for the NICE Guideline was conducted in June 2018, with surveillance for new studies reporting full or partial mesh removal in 2022 (as noted above). NICE assessed the quality of evidence for each outcome (excluding long-term complications) using Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methods. Clinically important outcomes were defined based on published literature and consultation with the Guideline Committee. If no published or acceptable minimally important difference (MID) was identified, the committee considered whether to use GRADE defaults. Further detail regarding the methodology for research question 5.1 is provided in Appendix A of the NICE Guideline Evidence Review (NICE 2019b).

In relation to terminology, NICE use the term synthetic mesh sling/suburethral slings (synthetic mesh) to include MUS (RP-MUS and TO-MUS) and single-incision mini-slings. As single-incision mini-slings are excluded from this review, studies of single-incision mini slings included by NICE have been excluded from our interpretation and presentation of the clinical effectiveness findings.

Three sources of evidence were considered in the development of recommendations for the NICE Guideline:

1. Individual meta-analyses conducted by NICE to compare outcomes of surgical interventions (see comparisons in **Table 4**) in the short-term (≤ 1 year after surgery), medium-term (> 1 year to ≤ 5 years after surgery) and long-term (> 5 years after surgery) (see the **NICE Findings** section below for results for comparisons relevant to this review).
2. Non-comparative data on the rate of long-term complications associated with individual surgical interventions (see **Section 2.3** for results relevant to this review).
3. Network meta-analysis (NMA) conducted by Brazzelli and colleagues for the outcomes of cure (a composite of subjective and objective cure measures) and patient satisfaction/patient-reported improvement at approximately 1 year after surgery.

   The Brazzelli NMA cited in the NICE evidence review was a draft version of the manuscript (dated 2018), which was subsequently published in 2019. For the purposes of this review, findings from the NMA are presented in **Section 2.2.2** based on the 2019 publication (Brazzelli 2019).

Included studies

NICE included randomised controlled trials (RCTs) for the clinical effectiveness outcomes presented in this section. Non-comparative observational studies were included by NICE in their assessment of long-term rates of complications (see **Section 2.3**).

The risk of bias in the included RCTs was generally moderate to high. Insufficient information about randomisation and/or allocation concealment was identified as a key source of bias across the included studies. Most studies were unblinded or incompletely blinded and the critical outcomes were subjective measures; nevertheless the guideline committee considered this comparable to clinical practice (NICE 2019b).

GRADE quality assessments were low to very low for most outcomes and treatment comparisons. Imprecision in the effect estimates and indirectness were identified as the main reasons for the overall GRADE assessments. Indirectness was due to studies including women with concurrent POP or allowing concomitant POP surgery, and/or not being explicit about whether participants had failed or declined conservative treatment for SUI (NICE 2019b).

The included studies for the comparisons relevant to this review are summarised in **Table 5**.

Table 5 Summary of relevant studies included in NICE Guideline evidence review

Comparison	Number of RCTs	Number of participants (range)
Colposuspension vs. MUS	12	1,214 (46-344)
Autologous rectus fascial sling vs. MUS	8	576 (24-156)
Bulking agents vs. synthetic mesh sling	0	N/A
TO-MUS vs. RP-MUS	40	6,800 (30-597)

Source: based on data from NICE Evidence review (NICE 2019b)
Abbreviations: MUS, mid-urethral sling; RP, retropubic; TO, transobturator.

Colposuspension versus synthetic mesh sling

Of the 12 RCTs comparing colposuspension to synthetic mesh sling, the colposuspension procedure was laparoscopic in four studies and open in eight studies. The synthetic mesh sling procedure was RP-MUS in ten studies and TO-MUS in two studies. There were no studies of single-incision mini-slings, and as such all 12 RCTs were relevant to this review. A summary of the study characteristics is provided in Appendix B.1.1, **Table App. 3**

Autologous rectus fascial sling (pubovaginal sling) versus synthetic mesh sling

Of the 11 RCTs comparing rectus fascial sling to synthetic mesh sling, 3 were of single-incision mini-slings and as such were not relevant to this review (Sharifiaghdas 2015; Silva-Filho 2006; Tcherniakovsky 2009). Of the remaining eight studies, seven were of RP-MUS and one was of TO-MUS. A summary of the study characteristics of these eight RCTs is provided in Appendix B.1.2, **Table App. 4**.

TO-MUS versus RP-MUS

The NICE evidence review identified 40 RCTs comparing TO-MUS to RP-MUS. All 40 RCTs are relevant to this review and their characteristics are summarised in Appendix B.1.3, **Table App. 5**.

NICE Findings

Colposuspension versus MUS

The findings for colposuspension versus MUS are summarised below by outcome. An overview of these findings is provided in Section 6.1.1 (**Table 32**), including the number of RCTs and participants, and the quality of the evidence.

Continence-specific health-related quality of life

Based on very low quality evidence (one RCT), there was no clinically important difference between colposuspension and MUS in continence-specific HRQoL for *sex life spoilt by urinary symptoms* in the short or medium-term as measured by the Bristol Female Lower Urinary Tract Symptoms- scored form (BFLUTS-SF) questionnaire. No other continence-specific HRQoL outcomes were reported.

Change in continence status

There was a statistically significant difference in the number of women objectively cured, favouring MUS over colposuspension in both the short-term (5 RCTs; RR 0.88, 95% CI 0.8 to 0.96) and medium-term (7 RCTs; RR 0.84, 95% CI 0.74 to 0.95) (very low to low quality evidence). This difference, however, was not clinically important.

There was no clinically important difference between colposuspension and MUS in the number of women subjectively cured in the short-term (seven RCTs), medium-term (five RCTs) or long-term (one RCT) (very low to low quality evidence).

Adverse events

Perioperative bladder injury was more prevalent with MUS compared to colposuspension (RR 0.23, 95% CI 0.1 to 0.51). This finding was based on low quality evidence from 11 RCTs.

There were no clinically important differences between colposuspension and MUS in the number of women with severe bleeding requiring blood transfusion during surgery (three RCTs), or the number of women with bowel injury (one RCT) (very low quality evidence).

Complications

POP occurred more frequently in the medium-term in women who had undergone colposuspension compared to MUS (3 RCTs; RR 1.64, 95% CI 1.1 to 2.24) (low quality evidence).

There were no clinically important differences between colposuspension and MUS in the number of women with infection in the short-term (two RCTs) or medium-term (four RCTs), pain in the short or medium-term (two RCTs), mesh extrusion in the short-term (two RCTs) or medium-term (five RCTs), the need for catheterisation in the short or medium-term (three RCTs), de novo urgency in the short-term (one RCT) or medium-term (three RCTs), or de novo urge incontinence in the short-term (two RCTs) or medium-term (three RCTs) (very low quality evidence).

There were no occurrences of wound complications (one RCT) or fistula (one RCT) in the medium-term for colposuspension or MUS.

Patient satisfaction/patient-reported improvement

There were no clinically important differences in patient-reported improvement in continence status between colposuspension and MUS in the medium-term (five RCTs, low quality evidence) or long-term (one RCT, very low quality evidence). While the medium-term finding showed a statistically significant difference in favour of MUS (RR 0.89, 95% CI 0.79 to 0.99), the difference was not clinically important.

Repeat surgery

Low quality evidence demonstrated a clinically important difference favouring MUS compared to colposuspension regarding the number of women who have repeat surgery for any reason in the medium-term following surgery (1 RCT; RR 2.66, 95% CI 1.13 to 6.29).

Based on very low quality evidence, there were no clinically important differences between colposuspension and MUS in regard to the number of women requiring repeat surgery for any reason in the short-term (two RCTs), due to SUI in the medium-term (two RCTs) or long-term (one RCT), or due to mesh complications in the short or long-term (one RCT each).

Autologous rectus fascial sling (pubovaginal sling) versus MUS

Results reported in NICE GRADE tables comparing autologous rectus fascial sling with synthetic mesh sling could not be used in their entirety for this review as three trials included single-incision mini-slings as the synthetic mesh sling. It was not always possible to ascertain from the GRADE tables which meta-analyses these studies contributed to. Findings reported here are primarily based on interpretation of the forest plots presented by NICE, in which the excluded studies could be readily identified. Data were also drawn from GRADE tables where possible.

An overview of the findings by outcome and follow-up time is provided in Section 6.1.2 (**Table 33**), including the number of RCTs and participants, and the quality of the evidence (where available).

Change in continence status

There was a borderline statistically significant difference favouring RP-MUS over rectus fascial sling in short-term subjective cure (2 RCTs; RR 0.75, 95% CI 0.57 to 1.00) (very low quality evidence). The difference was interpreted to be clinically important by NICE.

There was no statistically significant difference in subjective cure between rectus fascial sling and MUS in the medium-term (1 RCT; RR 0.88, 95% CI 0.54 to 1.44) or long-term (1 RCT; RR 1.33, 95% CI 0.83 to 2.12) (very low quality evidence).

Three studies reporting on short-term objective cure between rectus fascial sling and MUS consistently showed no statistically significant difference. There was also no statistically significant difference in objective cure in the medium-term (3 RCTs; RR 0.98, 95% CI 0.85 to 1.13) (very low quality evidence).

Adverse events

Studies reporting on adverse events in the short-term consistently showed no statistically significant difference between rectus fascial sling and MUS (3 RCTs). There was also no statistically significant difference in adverse events in the medium-term (3 RCTs; RR 0.98, 95% CI 0.85 to 1.13).

Complications

There was no statistically significant difference in short-term pain between rectus fascial sling and MUS (2 RCTs; RR 0.72, 95% CI 0.02 to 34.42). For the sub-group analyses of rectus fascial sling versus RP-MUS, the difference was not statistically significant (1 RCT; RR 3.92, 95% CI 0.90 to 17.15); however, NICE considered that the difference may be clinically important, favouring RP-MUS (very low quality evidence). Long-term pain was not significantly different between rectus fascial sling and MUS (2 RCTs; RR 1.12, 95% CI 0.36 to 3.52) (very low quality evidence).

The single study reporting mesh extrusion rates of rectus fascial sling versus MUS in the medium-term showed no statistically significant difference (RR 0.21, 95% CI 0.01 to 4.92). There was also no statistically significant difference in the number of women reporting mesh extrusion in the long-term (2 RCTs; RR 0.22, 95% CI 0.03 to 1.87) (very low quality evidence).

Studies reporting on the need for catheterisation in the short-term (4 RCTs) consistently reported no statistically significant difference between rectus fascial sling and MUS. There was also no statistically significant difference in the need for catheterisation in the long-term between rectus fascial sling and MUS (1 RCT; RR 1.38, 95% CI 0.32 to 5.90) (very low quality evidence).

There was no statistically significant difference in de novo urgency between rectus fascial sling and MUS in the medium-term (2 RCTs; RR 0.96, 95% CI 0.46 to 2.01) or long-term (2 RCTs; RR 0.77, 95% CI 0.31 to 1.93) (very low quality evidence).

Patient satisfaction/patient-reported improvement

Studies reporting patient-reported improvement in the medium-term consistently reported no statistically significant difference between rectus fascial sling and MUS (2 RCTs). There was also no statistically significant difference in patient reported improvement in the long-term (2 RCTs; RR 0.85, 95% CI 0.69 to 1.04) (very low quality evidence).

Repeat surgery

There were no statistically significant differences in the number of women requiring repeat surgery for any reason between rectus fascial sling and MUS in the short-term (2 RCTs; RR 1.39, 95% CI 0.13 to 14.50) or long-term (1 RCT; RR 1.16, 95% CI 0.08 to 17.75) (very low quality evidence).

TO-MUS versus RP-MUS

An overview of the findings for TO-MUS versus RP-MUS is presented in Section 6.1.3 (**Table 34**), including the number of RCTs and participants, and the quality of the evidence.

Continence-specific health-related quality of life

Continence-specific HRQoL was assessed using a variety of measurement tools across the included RCTs. For most of the continence-specific HRQoL outcomes and timepoints assessed by NICE, there were no clinically important differences between TO-MUS and RP-MUS (very low to low quality evidence).

Based on very low quality evidence, clinically important differences favouring RP-MUS were found for International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Quality of Life (ICIQ-UI-QoL) scores in the medium-term (1 RCT; MD 8.34 lower[2], 95% CI 14.4 to 2.8 lower) and Urinary Incontinence Quality of Life Scale (I-QoL) scores in the short-term (1 RCT; MD 4.54 lower[2], 95% CI 7.43 to 1.65 lower). Very low quality evidence showed that there may be a clinically important difference favouring RP-MUS over TO-MUS for ICIQ-UI-QoL scores in the short-term (1 RCT; MD 6.37 lower[2], 95% CI 13.22 lower to 0.48 higher).

A clinically important difference favouring TO-MUS was identified for King's Health Questionnaire – Intercourse score in the medium-term (1 RCT; MD 25.6 lower[3], 34.46 to 16.74 lower) based on very low quality evidence.

Change in continence status

There were no clinically important differences between TO-MUS and RP-MUS for any change in continence status outcome at any timepoint. This included subjective cure in the short (15 RCTs), medium (6 RCTs) and long (2 RCTs) term; objective cure in the short (15 RCTs), medium (10 RCTs) and long (2 RCTs) term; negative cough stress test in the short (9 RCTs) and medium (5 RCTs) term; and number of incontinence

[2] Better indicated by higher values
[3] Better indicated by lower values

episodes per day in the medium-term (1 RCT). The quality of evidence was very low to low. There was a statistically significant difference in short-term objective cure in favour of RP-MUS (15 RCTs; RR 0.95, 95% CI 0.91 to 0.99); however, this was not considered clinically important.

Adverse events

Moderate quality evidence from 40 RCTs demonstrated a clinically important difference favouring TO-MUS over RP-MUS in the number of women experiencing a perioperative bladder injury (RR 0.15, 95% CI 0.1 to 0.24).

There was no clinically important difference between TO-MUS and RP-MUS in the number of women with severe bleeding requiring a blood transfusion during surgery (10 RCTs, very low quality evidence).

Across 12 RCTs there were no occurrences of perioperative bowel injury in women undergoing either the TO-MUS or RP-MUS (moderate quality evidence).

Complications

Clinically important differences favouring RP-MUS over TO-MUS were detected for pain (short-term) (19 RCTs; RR 2.8, 95% CI 2.04 to 3.86, moderate quality evidence), mesh extrusion (short-term) (22 RCTs; RR 1.66, 95% CI 1.02 to 2.71, low quality evidence), mesh extrusion (medium-term) (12 RCTs; RR 2.17, 95% CI 1.14 to 4.14, very low quality evidence) and de novo nocturia (medium-term) (1 RCT; RR 2.6, 95% CI 1.16 to 5.83, very low quality evidence).

Low quality evidence from 16 RCTs demonstrated a clinically important difference favouring TO-MUS over RP-MUS in the number of women needing catheterisation in the short-term (RR 0.61, 95% CI 0.46 to 0.81).

No clinically important differences were detected between TO-MUS and RP-MUS for infection in the short (17 RCTs), medium (7 RCTs) and long (2 RCTs) term; POP occurrence in the long-term (1 RCT); pain in the medium (11 RCTs) or long (2 RCTs) term; need for catheterisation in the medium-term (4 RCTs); de novo urgency in the short (8 RCTs) and medium (7 RCTs) term; de novo urge incontinence in the short (5 RCTs) and medium (4 RCTs) term; de novo nocturia in the short-term (1 RCT); or wound complications in the short (4 RCTs) and medium (2 RCTs) term.

Patient satisfaction/patient-reported improvement

There were no clinically important differences between TO-MUS and RP-MUS in the number of women reporting an improvement in continence status in the medium-term (13 RCTs) or long-term (1 RCT) (low quality evidence).

Repeat surgery

Low quality evidence from five RCTs showed a clinically important difference in the number of women requiring repeat surgery for SUI in the short-term, favouring RP-MUS over TO-MUS (RR 8.98, 95% CI 1.53 to 52.59).

Based on very low quality evidence, there were no clinically important differences between TO-MUS and RP-MUS in the number of women having repeat surgery for SUI in the medium-term (6 RCTs) or long-term (1 RCT), repeat surgery for POP in the long-term (1 RCT), or repeat surgery for mesh complications in the short (13 RCTs), medium (8 RCTs) or long (1 RCT) term following surgery.

Very low quality evidence from one RCT showed no occurrences of repeat surgery due to POP in the short-term for women who received either TO-MUS or RP-MUS.

2.2.2 Network meta-analysis (Brazzelli 2019)

Surgical treatments for women with stress urinary incontinence: the ESTER systematic review and evaluation was a health technology assessment (HTA) funded by the National Institute for Health Research (NIHR) in the UK (Brazzelli 2019). The HTA included a network meta-analysis (NMA) to estimate the relative effectiveness of different types of surgery for SUI.

Recommendations developed for the NICE Guideline (NG123) considered evidence from the NMA for the outcomes of composite cure (i.e. a composite of subjective and objective cure measures) and patient satisfaction/patient-reported improvement.

Methods

The HTA included a systematic review to assess the clinical effectiveness and safety of surgical interventions for SUI. The evidence synthesis was conducted in accordance with the principles of the Centre for Reviews and Dissemination (CRD) guidance for undertaking reviews in healthcare (CRD 2009), the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) and the NICE guide to the methods of technology appraisal (NICE 2013).

Evidence identified via the systematic review was used to conduct direct pairwise (head-to-head) meta-analyses, as well as an NMA. For the purposes of this review, only the NMA will be discussed. Head-to-head comparisons for the interventions relevant to this review have been presented based on the NICE evidence review findings (see **Section 2.2.1**).

The PICO criteria for the Brazzelli evidence review are summarised in **Table 6**. RCTs and quasi-RCTs were eligible for inclusion, and there were no restrictions on publication status, year of publication or publication language. The last literature search was in June 2017.

Table 6 PICO criteria for Brazzelli (2019) clinical effectiveness evidence synthesis

Patient population	Interventions	Comparisons	Outcomes[2]
Adult women with SUI or stress-predominant MUI, including: • primary or repeat continence surgery • SUI and concomitant prolapse • concomitant prolapse surgery	1. Retropubic MUS operations 2. Transobturator MUS operations 3. Open retropubic colposuspension 4. Laparoscopic colposuspension *5. Traditional suburethral sling procedures* *6. Single-incision sling operations* *7. Anterior vaginal repair* *8. Bladder neck needle suspension* 9. Urethral injection therapy (periurethral injections/ injectable bulking agents)	Comparison of two or more of the surgical interventions listed OR *Comparison of a listed surgical intervention with pelvic floor muscle training (PFMT)[1]*	**Primary** Number of women cured (defined as resolution of clinical symptoms) Number of women cured or improved (referred to as ' improvement') **Secondary**[3] Repeat continence surgery (long-term) Adverse events Resource use

Source: (Brazzelli 2019)

Abbreviations: MUI, mixed urinary incontinence; MUS, mid-urethral sling; PFMT, pelvic floor muscle training; SUI, stress urinary incontinence.

[1] Studies comparing a surgical intervention with PFMT were used to develop the NMA treatment diagram for assessing direct and indirect treatment comparisons

[2] Inclusion of these outcomes was not an eligibility criteria for selecting studies for inclusion

[3] Not included as an outcome in the NMA

Note: Interventions and comparisons listed in grey italic text are out of scope for this post-listing review

For the primary outcome of 'cure', women's self-report of cure was used where available. In the absence of subjective cure, a composite measure of subjective and objective cure was used. Pad tests and urodynamic tests were only used if self-reported or composite cure data were not available. Similarly, for the primary

outcome of 'improvement', women's self-report of improvement was given priority. Self-reported satisfaction rate was used if self-reported improvement was not available. Improvement based on pad tests and urodynamic tests were considered in the absence of self-reported improvement or satisfaction.

The NMA was performed for the primary outcomes only (see **Table 6**) and included all surgical interventions listed in **Table 6**, with the exception of urethral injection therapy (bulking agents), which was judged not to add any information to the network.

Traditional suburethral sling procedures were defined as "A procedure that improves urethral support by lifting the urethra–vesical junction and supporting it with autologous or synthetic material" (Brazzelli 2019). While data on pubovaginal slings using native tissue may have been included in this category, the data could not be used for the purposes of this review as it was combined with traditional suburethral sling procedures using synthetic materials (not in scope for this review).

The quality of the evidence included in the NMA was rated using the GRADE approach. Outcomes measured at 12 months (or a timepoint closest to 12 months) were included. Studies with a time point of <2 weeks or >36 months were excluded.

Included studies

A total of 105 trials contributed to the NMA for assessing the outcome of number of women cured, and 120 trials were included for assessing the number of women improved. The interventions included in the NMA were not all relevant to the scope of this post-listing review. The comparisons and number of trials providing direct evidence for each comparison relevant to this review is summarised in **Table 7**. The study characteristics and references for these studies are summarised in **Appendix C**.

Table 7 Number of trials providing direct evidence to NMA by treatment comparison and outcome

Comparison	No. trials (Cure)	No. trials (Improvement)
Open colposuspension vs. RP-MUS	6[1]	6[1]
Laparoscopic colposuspension vs. RP-MUS	2	4
Open colposuspension vs. TO-MUS	1	1
Laparoscopic colposuspension vs. TO-MUS	0[2]	0[2]
TO-MUS vs. RP-MUS	36[1]	40[1]

Source: based on data from Brazzelli (2019)

Abbreviations: MUS, mid-urethral sling; NMA, network meta-analysis; RP, retropubic; TO, transobturator.

[1] Analyses also informed by three-arm trials

[2] No trials provided direct evidence of this comparison to the NMA

The number of women randomised to each relevant intervention in the NMA is summarised in **Table 8**.

Table 8 Number of participants randomised by intervention and outcome in the NMA

Intervention	No. participants (Cure)	No. participants (Improvement)
RP-MUS	3,907	4,282
TO-MUS	4,218	4,809
Open colposuspension	1,351	1,342
Laparoscopic colposuspension	596	671

Source: based on data from Brazzelli (2019)

Abbreviations: MUS, mid-urethral sling; NMA, network meta-analysis; RP, retropubic; TO, transobturator.

Findings

Effect sizes are reported as posterior odds ratios (ORs) and 95% credible intervals (CrIs) (see **Table 9** and **Table 10**). Brazzelli 2019 also assessed the probability of an intervention in the NMA being ranked 1 (the highest) to 9 (the lowest) using rankograms. The surface under the cumulative ranking curve (SUCRA) was

reported as a numerical presentation of the overall ranking (reported as a value from 0% to 100%). The closer the SUCRA value is to 100% the more likely the intervention is to be in the top (or one of the top) ranks. Odds ratios, CrIs and SUCRA values are reported here for the comparisons relevant to this post-listing review (see **Table 9** and **Table 10**).

Cure

The NMA demonstrated a statistically significant difference favouring RP-MUS over TO-MUS in the number of women cured (OR 0.74, 95% CrI 0.59 to 0.92) based on moderate quality evidence.

There was no statistically significant difference in the number of women cured between open or laparoscopic colposuspension and RP-MUS (low quality evidence) or between open or laparoscopic colposuspension and TO-MUS (low quality evidence).

Table 9 NMA results for number of women cured for relevant treatment comparisons

Treatment 1	Treatment 2	OR	95% CrI	Quality of evidence
Open colposuspension	RP-MUS	0.85	0.54 to 1.33	Low
Laparoscopic colposuspension	RP-MUS	0.58	0.31 to 1.05	Low
Open colposuspension	TO-MUS	1.16	0.72 to 1.86	Low
Laparoscopic colposuspension	TO-MUS	0.79	0.42 to 1.46	Low
TO-MUS	RP-MUS	0.74	0.59 to 0.92	Moderate

Source: Brazzelli 2019

Abbreviations: CrI, credible intervals; MUS, mid-urethral sling; NMA, network meta-analysis; RP, retropubic; TO, transobturator.

The SUCRA values for the cure outcome were 89.1% for RP-MUS, 76.7% for open colposuspension, 64.1% for TO-MUS and 48.9% for laparoscopic colposuspension.

Improvement

The NMA demonstrated a statistically significant difference in the number of women improved, favouring RP-MUS over TO-MUS (OR 0.76, 95% CrI 0.59 to 0.98) (moderate quality evidence) and laparoscopic colposuspension (OR 0.52, 95% CrI 0.29 to 0.91) (low quality evidence).

There was no statistically significant difference in the number of women improved between RP-MUS and open colposuspension, or between TO-MUS and either open or laparoscopic colposuspension (low quality evidence).

Table 10 NMA results for number of women improved for relevant treatment comparisons

Treatment 1	Treatment 2	OR	95% CrI	Quality of evidence
Open colposuspension	RP-MUS	0.65	0.41 to 1.02	Low
Laparoscopic colposuspension	RP-MUS	0.52	0.29 to 0.91	Low
Open colposuspension	TO-MUS	0.85	0.52 to 1.41	Low
Laparoscopic colposuspension	TO-MUS	0.69	0.37 to 1.26	Low
TO-MUS	RP-MUS	0.76	0.59 to 0.98	Moderate

Source: Brazzelli 2019

Abbreviations: CrI, credible intervals; MUS, mid-urethral sling

The SUCRA values for the improvement outcome were 97% for RP-MUS, 76.1% for TO-MUS, 63.8% for open colposuspension and 45.8% for laparoscopic colposuspension.

2.3 Summary of evidence for long-term complications

2.3.1 Systematic review (NICE Guideline NG123)

Included studies

The review of long-term complications (>5 years) conducted by NICE identified mainly non-comparative case series. Of the studies identified, 40 studies (including 5 RCTs) provided long-term complication data on interventions relevant to this post-listing review. A summary of these studies is provided in **Appendix D**.

Findings

Due to the non-comparative nature of the data, it was not possible for NICE to conduct a meta-analysis for long-term complications. Instead, rates of complications were calculated as weighted averages. A summary of the long-term complication rates for the interventions and comparators relevant to this review is provided in **Table 11**.

The majority of studies providing data on long-term complications were assessed by NICE to be at serious risk of bias (see Appendix D, **Table App. 10**) using the Cochrane Risk of Bias tool for randomised controlled studies or the Cochrane ROBINS-I (Risk of Bias In Non-randomised Studies – of Interventions) tool for non-RCTs. The key concerns regarding risk of bias in the included observational studies related to confounding, participant selection and outcome measurement.

NICE also reported data on rate of infection for synthetic mesh slings of unspecified type. The data were based on a single case series of 59,556 women in Canada (Punjani 2017). The study reported an infection rate of 19.7% for synthetic mesh slings (type not specified). The weighted average infection rates calculated by NICE for RP-MUS and TO-MUS were substantially lower at 8.4% and 3.4% respectively (see **Table 11**).

Table 11 Long-term complication rates (>5 years) calculated as weighted averages

Surgery type	RP-MUS		TO-MUS		Colposuspension (unspecified)		Colposuspension (laparoscopic)		Colposuspension (open)		Fascial sling	
Complication	**No. studies (No. women)**	**Rate (%)**	**No. studies (No. women)**	**Rate (%)**	**No. studies (No. women)**	**Rate (%)**	**No. studies (No. women)**	**Rate (%)**	**No. studies (No. women)**	**Rate (%)**	**No. studies (No. women)**	**Rate (%)**
Pain	10 (1610)	9.0	8 (1074)	7.1	-	-	-	-	-	-	1 (132)	16.7
Mesh erosion/exposure	15 (2252)	1.5	9 (1335)	2.3	-	-	-	-	1 (127)	0.0	2 (93)	0
Fistula	-	-	-	-	1 (225)	0.0	1 (145)	0.0	-	-	-	-
Need for catheterisation	6 (997)	2.5	-	-	-	-	-	-	2 (402)	1.1	2 (193)	3.6
Infection	11 (2424)	8.4	4 (468)	3.4	3 (526)	5.5	-	-	1 (374)	26.2	1 (132)	6.1
De novo urge incontinence	12 (1409)	14.1	6 (851)	8.7	1 (109)	7.3	-	-	1 (50)	4.0	1 (37)	8.1
De novo frequency	-	-	-	-	-	-	-	-	1 (94)	37.2	-	-
De novo urgency	11 (1448)	13.7	2 (633)	4.0	1 (109)	8.3	-	-	1 (96)	10.4	2 (93)	6.5
De novo nocturia	-	-	-	-	-	-	-	-	1 (170)	11.8	-	-
POP occurrence	8 (638)	4.7	2 (200)	0.5	1 (109)	21.1	-	-	1 (50)	4.0	-	-
Wound complications	-	-	-	-	1 (225)	0.4	-	-	-	-	-	-

Source: (NICE 2019b) Table 13, p48

Abbreviations: No., number; POP, pelvic organ prolapse; RP-MUS, retropubic mid-urethral sling; TO-MUS, transobturator mid-urethral sling.

2.3.2 Primary studies

Two primary studies reporting on long-term complications were identified through stakeholder feedback.

Karmakar and colleagues from the Department of Urogynaecology at Mercy Health, Melbourne, conducted a matched (1:3) cohort study of 1344 women who underwent Burch colposuspension (n=336) or RP-MUS (n=1,008) for the treatment of SUI (Karmakar 2021). Mean follow-up was 13.1 years for the Burch colposuspension group and 10.1 years for the RP-MUS group. The study reported similar rates of long-term complications for both procedures, except for the requirement for prolapse surgery during follow-up, which was higher in the Burch colposuspension group (3.3% vs. 1.1%, p=0.01). The mesh exposure rate in the RP-MUS group was 1.0% (n=10). Of the 10 women with mesh exposure, 4 required excision of the vaginal portion of the MUS. Five patients (n=2 in Burch colposuspension group, n=3 in RP-MUS group) reported long-standing pain (≥ 6 months post-operatively), which was therefore considered a rare outcome by the authors (0.4%).

Chughtai and colleagues reported on long-terms risks following MUS procedure for SUI in a retrospective cohort study of 36,195 women in the United States (Chughtai 2021). Of the total cohort, 76.8% had isolated MUS procedures, 20.1% had MUS and concurrent transvaginal POP repair with native tissue, and 3.2% had MUS and concurrent abdominal POP repair. Median follow-up was 4.8 years, and Kaplan-Meier analysis was performed to estimate risks of erosion and reoperation. At 7 years, estimated risk of erosion was 3.7% and estimated risk of reoperation was 6.7% in the total cohort. At the same timepoint, estimated risk of reoperation for repeat SUI was 2.4% and for mesh complications was 1.9%.

The potential biases associated with the retrospective nature of these studies may limit the generalisability of the findings.

2.3.3 Health Canada summary safety review (2022)

In November 2022, Health Canada released a Summary Safety Review on MUS made from non-absorbable synthetic material[4]. Further information regarding this review is provided in **Appendix F**. While the data used to inform the review is not publicly available, findings relating to long term complications include the following:

- There were no new (not previously known) or increased risks of complications associated with the long-term (≥ 5 years) use of MUS compared to previous reviews.
- The risk of developing chronic pain and/or mesh erosion is lower over the longer term (≥ 5 years).
- Long-term (≥ 5 years) safety and effectiveness of MUS for SUI is equivalent to surgical alternatives that do not use vaginal surgical mesh.

[4] https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00288 [accessed: 01 February 2023]

3 Clinical practice guidelines and regulatory advice

3.1 Methodology

Clinical practices guidelines, HTAs and regulatory advice was identified from the evidence search described in **Section 2** including information provided by sponsors and stakeholders. Due to the volume of potentially relevant guidelines, position statements, HTAs and regulatory advice, only those that are recent, comprehensive and/or from Australian jurisdictions were considered. The key recommendations and advice contained in these documents are summarised in Appendix E (**Table App. 11**).

3.2 Clinical practice guidelines and position statements

The consensus across all guidelines, position statements and care pathways reviewed is that MUS is an appropriate surgical treatment option for SUI, with some advice noting the importance of appropriate patient selection and other additional considerations or requirements. Examples of additional requirements include appropriate surgeon training in the procedure and management of complications, and appropriate informed consent, including a discussion of alternative treatment options and the risks and benefits (advantages and disadvantages) of each option.

The key Australian documents were the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZOG) Position Statement on midurethral slings (RANZCOG 2020, amended 2022) and the ACSQHC Care pathway for the management of SUI (ACSQHC 2018a). Both documents support the use of MUS for the treatment of SUI, with both recommending that the TO-MUS approach be reserved for specific clinical circumstances (see Appendix E, **Table App. 11** for specific recommendations).

Recommendations from the included clinical guidelines addressing the use of MUS for the treatment of SUI are summarised below.

3.2.1 EAU Guidelines on management of non-neurogenic female lower urinary tract symptoms (2023)

The European Association of Urology (EAU) Guidelines (Harding 2023) strongly recommend that patients with SUI who have explored/failed conservative treatment are offered a choice of surgical procedures (where appropriate) and participate in shared decision-making to decide on an appropriate treatment. It is strongly recommended that colposuspension (open or laparoscopic), autologous sling placement, urethral bulking agents and MUS are offered as surgical options for the treatment of SUI, with a thorough discussion of the relative risks and benefits (advantages and disadvantages) of each approach. The guideline recommends that urethral bulking agents be offered "to women with SUI who request a low-risk procedure with the understanding that efficacy is lower than other surgical procedures, repeat injections are likely, and long-term durability and safety are not established" (strong recommendation, p 49). In relation to MUS route, the guideline recommends that RP-MUS is superior to TO-MUS in terms of long-term outcomes, and that patients should be informed as such (strong recommendation). In response to publicity regarding surgical mesh, the guideline strongly recommends informing women of the complications associated with MUS procedures and discussing all alternative treatment options.

3.2.2 FIGO recommendations: use of midurethral slings for the treatment of stress urinary incontinence (2023)

The International Federation of Gynecology and Obstetrics (FIGO) Guidelines (Lau 2023) highlight MUS as the surgical gold standard for the treatment of SUI. The guideline recommends MUS as the preferred approach over Burch colposuspension or pubovaginal sling "due to similar or superior cure rates but reduced morbidity, and shorter operative time and length of hospital stay" (p 7). No recommendations are provided in the guideline on the use of bulking agents. In relation to MUS route, the guideline highlights the different risk profiles of the RP and TO approaches and advises that the RP-MUS results in higher subjective and objective cure rates than TO-MUS, particularly for patients with more severe SUI and intrinsic sphincter deficiency.

3.2.3 NICE Guideline [NG123]

Consistent with the EAU Guideline, the NICE Guideline (NICE 2019c) recommends patient participation in shared and informed decision-making regarding SUI surgery (Recommendation 1.5.1). For women who have failed conservative treatment for SUI and wish to consider surgical options, NICE recommend offering the choice of colposuspension (open or laparoscopic), autologous rectus fascial sling or RP-MUS (Recommendation 1.5.2). In determining whether to include RP-MUS sling amongst the options in the recommendation, the NICE guideline committee acknowledged the evidence of life-changing adverse events for some women related to RP-MUS, noting that the incidence of these is uncertain. They also considered the length of hospital stay, anaesthesia requirements and recovery period, noting these to be more favourable for RP-MUS than colposuspension or autologous rectus fascial sling. Considering all of this information, the committee agreed that some women, when fully informed of the risks, may prefer to have a RP-MUS, and that these women would be significantly disadvantaged if this option were not available (NICE 2019b).

A 'do not offer' recommendation is made for TO-MUS (Recommendation 1.5.10), advising that TO-MUS should be used only in specific clinical circumstances where RP-MUS is not appropriate. This recommendation was made based on the evidence, combined with the knowledge and experience of the committee.

A 'do not use' recommendation is made for the 'top-down' RP-MUS approach (Recommendation 1.5.11), except as part of a clinical trial. There is currently no top-down RP-MUS device listed on the PL.

Regarding bulking agents, NICE recommends considering these only if alternative surgical procedures are not suitable or acceptable to the patient (Recommendation 1.5.3). Given the lack of evidence, this recommendation was made by consensus, based on the knowledge and experience of the committee.

For a list of the NICE Guideline recommendations relevant to this post-listing review see **Appendix E**.

3.3 Regulatory advice

3.3.1 Health Canada

In November 2022, Health Canada released a Summary Safety Review on non-absorbable synthetic MUS[4]. The purpose, methodology, findings, conclusions and actions from the report are summarised in Appendix F (**Table App. 12**)

Key findings from the report include the following:

- There were no new (not previously known) or increased risks of complications associated with the long-term (≥ 5 years) use of MUS compared to previous reviews.
- The risk of developing chronic pain and/or mesh erosion is lower over the longer term (≥ 5 years).
- Long-term (≥ 5 years) safety and effectiveness of MUS for SUI is equivalent to surgical alternatives that do not use vaginal surgical mesh.
- Effectiveness and patient satisfaction over the long-term (≥ 5 years) are relatively high in most patients.

Following the report, MUS for the treatment of SUI continue to be available in Canada. Health Canada continues to monitor the safety of vaginal surgical mesh devices.

3.3.2 Therapeutic Goods Association

Mid-urethral slings for the treatment of SUI continue to be approved for supply in Australia (see **Section 1.2.1**).

4 Comparative cost-effectiveness

The scope of this review included a search for economic evaluations of MUS. The research questions to focus the review are:

1. *What evidence is available on the cost-effectiveness of mid-urethral sling compared to the use of bulking agents, colposuspension or pubovaginal sling (native tissue) for women with stress urinary incontinence?*

2. *What evidence is available on the cost-effectiveness of retropubic mid-urethral sling compared to a transobturator mid-urethral sling for women with stress urinary incontinence?*

Can any conclusions be drawn from the evidence base for these questions?

4.1 Methodology

The evidence base was assessed following a literature review of existing comparative cost-effectiveness studies and synthesis with any additional evidence provided by DoHAC, sponsors or stakeholders.

A literature search was undertaken to identify published comparative economic evaluations that focus on surgical interventions for SUI including MUS. The economic evaluations included for assessment were cost-effectiveness analyses, cost-utility analyses, and cost-benefit analyses. Studies that included only comparative cost analyses were not included.

The search strings and a summary of the search results are presented in **Appendix A.2**.

4.2 Summary of the evidence

Refer to the Section on Terminology at the beginning of this document for an explanation of terms.

4.2.1 Systematic reviews of economic evaluations

A systematic review of economic studies and a *de novo* economic analysis was reported in *Surgical treatments for women with stress urinary incontinence: the ESTER systematic review and evaluation* (Brazzelli 2019). This HTA, which was commissioned for NICE by the NIHR HTA Programme, was discussed in **Section 2.2.2** in relation to clinical effectiveness. The HTA's systematic review of economic studies was re-published with an expanded list of included studies (Javanbakht 2020a) but has been excluded as it was primarily conducted to inform development of the *de novo* economic model undertaken within the same project and provides insufficient detail of the included studies. The *de novo* economic analysis was published separately (Javanbakht 2020b) and is included below.

4.2.2 Modelled economic studies

The literature search identified six modelled economic studies, which are summarised below. No relevant Australian economic evaluations were identified.

Jia (2023)

The characteristics of the economic analysis by Jia and colleagues (Jia 2023) are summarised in **Table 12**. The authors presented a comparison of RP-MUS versus autologous pubovaginal sling.

Table 12 Study characteristics of Jia (2023)

Study ID Country	Research question	Perspective Time horizon EE type	Population	Intervention Comparator	Source of effectiveness inputs	Funding Author COIs
Jia 2023 USA	What is cost-effectiveness of PVS versus RP-MUS?	US hospital system; US health care payer 1 yr CUA: Decision analytic model; 2021 costs	SUI	Autologous PVS RP-MUS	Literature review	Funding: NR Conflicts: none

Abbreviations: COI, conflict of interest; CUA, cost-utility analysis; EE, economic evaluation; MUS, mid-urethral sling; NR, not reported; PVS, autologous pubovaginal sling; RP-MUS, retropubic MUS; RCT, randomised controlled trial; SUI, stress urinary incontinence; yr, year.

Findings

The findings of the cost-utility analysis are presented in **Table 13**, from a US hospital perspective and a US health care perspective. *Note that the paper is from conference proceedings and as such has not been subject to peer-review.*

Table 13 Outcomes of Jia (2023) – at 1 year

Study ID	Effectiveness (QALYs)	Costs (USD)	ICER	Sensitivity analysis	Conclusion
Jia 2023 USA	Hospital perspective RP-MUS: 0.82 PVS: 0.80 Incremental: 0.02 Health care perspective RP-MUS: NR PVS: NR Incremental: NR	Hospital perspective RP-MUS: $2,349 PVS: $2,114 Incremental: $235 Health care perspective RP-MUS: $4,630 PVS: $4,657 Incremental: - $26	Hospital perspective $17,453/QALY Health care perspective - $1,943/QALY (<$50,000 threshold)	If PVS surgery >$2,219 ICER: - 468/QALY. If RP-MUS surgery <$1,959 ICER: - 2,881/QALY. RP-MUS is cost-effective and dominant (cost-saving) in these scenarios.	RP-MUS was more cost-effective than rectus fascial sling.

Abbreviations: ICER, incremental cost-effectiveness ratio; NR, not reported; PVS, autologous pubovaginal sling; QALY, quality-adjusted life year; RP-MUS, retropubic mid urethral sling; USD, US dollars; yr, year.

QALYs were calculated from published health utility scores. QALY values were reported for the hospital perspective but not the health care perspective. The authors concluded that RP-MUS was more cost-effective than rectus fascial sling from a hospital perspective and was the dominant treatment (less costly and more effective) from the health care perspective.

Chang (2022)

The characteristics of the economic analysis by Chang and colleagues (Chang 2022) are summarised in **Table 14**. The authors chose the two-year time horizon given that most mesh complications should have emerged within two years post-surgery. The authors presented treatment pathways commencing with different interventions as first-line and taking into account likely subsequent treatment alternatives or re-treatments.

Table 14 Study characteristics of Chang (2022)

Study ID Country	Research question	Perspective Time horizon EE type	Population	Intervention Comparator	Source of effectiveness inputs	Funding Author COIs
Chang 2022 USA	What is the cost-effectiveness of non-surgical and surgical options for SUI?	US health care 2 yr CUA: Model based (TreeAge Pro); 2019 costs	SUI	MUS (RP-MUS & TO-MUS) No treatment Incontinence pessary Pelvic floor muscle physical therapy Bulking injection[1] Open & laparoscopic Burch colposuspension, PVS	RCTs cited in reviews of relevant modality in CDSR; minimum 12 mo follow-up	Funding: No funding received Conflicts: None

Abbreviations: CDSR, Cochrane Database of Systematic Reviews; COI, conflict of interest; CUA, cost-utility analysis; EE, economic evaluation; MUS, mid-urethral sling; PVS, autologous pubovaginal sling; RCT, randomised controlled trial; RP-MUS, retropubic MUS; SUI, stress urinary incontinence; TO-MUS, transobturator MUS; yr ,year.

[1] Bulking agents cited: dextranomer/hyaluronic acid co-polymer, glutealdehyde cross-linked bovine collagen (or comparable), polydimethylsiloxane, and calcium hydroxylapatite.

Note: comparators listed in grey text are out of scope for this post-listing review.

Findings

The findings of the cost-utility analysis are presented in **Table 15**, from a US health care perspective. A second set of analyses where it was assumed MUS were not available has not been included.

Table 15 Outcomes of Chang (2022) – at 2 years

Study ID	Pathway Effectiveness / (Pathway Increment) (QALY)	Pathway Costs (USD)	ICER	Sensitivity analysis	Conclusion
Chang 2022 USA	MUS: 1.863 (0.098) Open colpo.: 1.733 (n/a) PVS: 1.683 (n/a) Lap. Colpo.: 1.647 (n/a) Bulking agents: 1.774 (n/a)	MUS: $5,816 Open colpo.: $6,865 PVS: $7,666 Lap. Colpo.: $7,961 Bulking agents: $8,789	MUS: $46,518 Open colpo.: Dominated PVS: Dominated Lap. Colpo.: Dominated Bulking agents: Dominated	Cost-effectiveness changes if bulking agents cost decreases 12.6%	MUS is the only cost-effective first-line treatment option for SUI

Abbreviations: ICER, incremental cost-effectiveness ratio; Lap. Colpo., laparoscopic colposuspension; MUS, mid-urethral sling; Open. Colpo., open colposuspension; PVS, autologous pubovaginal sling; SUI, stress urinary incontinence; USD, US dollars; yr, year.

The treatment pathway commencing with MUS was the lowest cost, whereas that commencing with bulking agents was the highest cost. The high cost for urethral bulking (compared to other studies) appears to be due to the authors assumption that patients would receive up to three injection procedures. Of the available options, commencing treatment with MUS was the only cost-effective option; all other surgical approaches were dominated (that is, less effective as well as more expensive).

Javanbakht (2020b)

The characteristics of the economic analysis commissioned for NICE (Javanbakht 2020b) are summarised in **Table 16**. Comparators in grey are not relevant to this post-listing review but are included for completeness. The NMA that underpins the effectiveness inputs is discussed in **Section 2.2.2**.

Table 16 Study characteristics of Javanbakht (2020b)

Study ID Country	Research question	Perspective Time horizon EE type	Population	Intervention Comparator	Source of effectiveness inputs	Funding Author COIs
Javanbakht 2020b UK	What are the costs and effectiveness of 9 surgical interventions for SUI?	UK NHS & personal social services 1 yr; 10 yr; lifetime CUA: Markov micro-simulation model; 3.5% annual discount rate; 2018/19 costs	SUI; stress-predominant MUI, Age 45-55 yr	Retropubic MUS (reference) Single incision mini-sling Transobturator MUS Bladder neck needle suspension Bulking agents Traditional suburethral sling Anterior repair Open colposuspension Laparoscopic colposuspension	Brazzelli (2019) NMA	Funding: NIHR HTA Programme Conflicts: none

Abbreviations: COI, conflict of interest; CUA, cost-utility analysis; EE, economic evaluation; HTA, Health Technology Assessment; mo, month(s); MUI, mixed urinary incontinence; MUS, mid-urethral sling; NHS, National Health Service; NIHR, National Institute for Health and Care Research; NMA, network meta-analysis; NR, not reported; RCT, randomised controlled trial; SUI, stress urinary incontinence; UK, United Kingdom; yr, year.
Note: comparators listed in grey text are out of scope for this post-listing review.

Findings

The findings of the cost-utility analysis are presented in **Table 17**, from the perspective of the UK NHS and personal social services. Of the interventions studied, four comparisons are relevant:

- RP-MUS versus TO-MUS
- RP-MUS versus bulking agents
- RP-MUS versus open colposuspension
- RP-MUS versus laparoscopic colposuspension.

The comparison with traditional suburetheral slings has been excluded, consistent with **Section 2.2.2**, on the basis that it includes studies of both synthetic and native tissue.

Table 17 Outcomes of Javanbakht (2020b) – at 10 years and lifetime

Study ID	Incremental effectiveness (QALYs)	Incremental costs (GBP)	ICER	Sensitivity analysis	Conclusion
Javanbakht 2020b UK	10-yr time horizon RP-MUS vs. TO-MUS −0.163 RP-MUS vs. open colpo. −0.066 RP-MUS vs. lap colpo. −0.164 RP-MUS vs. bulking agents −0.202 Lifetime time horizon RP-MUS vs. TO-MUS −0.580 RP-MUS vs. open colpo. −0.175 RP-MUS vs. lap colpo. −0.492 RP-MUS vs. bulking agents −0.503	10-yr time horizon RP-MUS vs. TO-MUS £614 RP-MUS vs. open colpo. £2,691 RP-MUS vs. lap colpo. £3,092 RP-MUS vs. bulking agents £977 Lifetime time horizon RP-MUS vs. TO-MUS £1,103 RP-MUS vs. open colpo. £2,535 RP-MUS vs. lap colpo. £3,369 RP-MUS vs. bulking agents £1,221	10-yr time horizon RP-MUS vs. TO-MUS Dominated RP-MUS vs. open colpo. Dominated RP-MUS vs. lap colpo. Dominated RP-MUS vs. bulking agents Dominated Lifetime time horizon RP-MUS vs. TO-MUS Dominated RP-MUS vs. open colpo. Dominated RP-MUS vs. lap colpo. Dominated RP-MUS vs. bulking agents Dominated	Using (higher) mesh complication rates from Keltie 2017 makes no difference to CEA outcome. If complication rate is 10% or 20%, sub-urethral sling is more cost-effective.	RP-MUS is the most cost-effective over 10-yr and lifetime time horizons.

Abbreviations: CEA, cost-effectiveness analysis; GBP, Britain pound; ICER, incremental cost-effectiveness ratio; lap colpo, laparoscopic retropubic colposuspension; open colpo, open abdominal retropubic colposuspension; MUS, mid-urethral sling; NR, not reported; RP-MUS, retropubic MUS; TO-MUS, transobturator MUS; yr, year.

Costs and QALYs were modelled over 1-year, 10-year and lifetime horizons. The reference intervention for the 1-year analysis was single incision mini-sling, which is out of scope for this work and as such only the 10-year and lifetime horizon analyses are reproduced here. RP-MUS was the reference intervention for the other time horizon analyses as it was the most likely to be cost-effective. The authors conducted sensitivity analyses using a range of complication rates, including those reported in an 8-year study of 92,246 women (Keltie 2017).

Over a 10-year time horizon, RP-MUS was found to be the dominant strategy (less costly and more effective than all other surgical interventions for the treatment of SUI) with a greater than 90% probability of being cost-effective at a £20,000 willingness-to-pay threshold.

Over a lifetime horizon, RP-MUS is also the dominant strategy over the relevant comparators. The traditional (suburethral) sling is the only intervention not dominated by RP-MUS (ICER of £45,340) and with a high probability of being cost-effective. Open colposuspension had a 6% probability of being cost-effective at a £20,000 willingness-to-pay threshold.

The authors note that the findings are largely driven by the low initial cost of RP-MUS as it is conducted in a day procedure and further that the results "should be interpreted with caution as the long-term performance of all surgical treatments in terms of both continence and unanticipated adverse effects is not reliably known."

Kunkle (2015)

The characteristics of the economic analysis by Kunkle and colleagues (Kunkle 2015) are summarised in **Table 18**. The studied comparator was MUS (both RP and TO were acceptable).

Table 18 Study characteristics of Kunkle (2015)

Study ID Country	Research question	Perspective Time horizon EE type	Population	Intervention[1] Comparator	Source of effectiveness inputs	Funding Author COIs
Kunkle 2015 USA	What is the cost utility of urethral bulking agents compared with MUS in the treatment of SUI?	US health care 1 yr CUA: Decision analytic model (+Monte Carlo simulation); 2013 costs	SUI without urethral hypermobility	Bulking agents MUS	RCTs identified by literature search	NR Conflicts: none

Abbreviations: COI, conflict of interest; CUA, cost-utility analysis; EE, economic evaluation; MUS, mid-urethral sling; NR, not reported; RCT, randomised controlled trial; SUI, stress urinary incontinence; USA, United States of America; yr, year.

[1] Bulking agents cited: calcium hydroxylapatite particles (Coaptite; Bioform, San Mateo, Calif), polydimethylsiloxane (Macroplastique; Uroplasty, Minneapolis, Minn), and pyrolytic carbon-coated zirconium oxide beads (Durasphere; Advanced UroScience Inc, St Paul, Minn)

The target population, SUI *without* urethral hypermobility, was chosen as a subset where bulking agents have been found effective, according to the American Urological Association (Dmochowski 2010).

Findings

The findings of the cost-utility analysis are presented in **Table 19**, from a US health care perspective. The authors reported the incremental cost-effectiveness ratio (ICER) defined as the marginal cost per utility gained, per 100 women treated in a hypothetical population.

Table 19 Outcomes of Kunkle (2015) – at 1 year

Study ID	Effectiveness (utility gained)	Cost (USD)	Cost/utility gained ICER	Sensitivity analysis	Conclusion
Kunkle 2015 USA	MUS: NR Bulking agents: NR Incremental: 6.2%	MUS: NR Bulking agents: NR Incremental: $436,465	MUS: NR Bulking agents: NR ICER: $70,400/ utility gained	MUS <$5,132 is cost-effective 1st line treatment MUS <$2035 is cost saving	Bulking agents are cost-effective in 47.6% of scenarios compared to <1% for MUS at a $USD50,000 WTP threshold

Abbreviations: ICER, incremental cost-effectiveness ratio; MUS, mid-urethral sling; NR, not reported; SUI, stress urinary incontinence; USD, US dollars; WTP, willingness to pay (cost-effectiveness threshold); yr, year.

As well as studying probabilities and costs set at base case values, a range for each was nominated as inputs for one-way and two-way sensitivity analyses. Results of base case and sensitivity analyses were not reported in any detail so it was not possible to explore the values reported. The initial cost of MUS was US$6,397 and bulking agents was US$1,374.

The model gave an ICER of $70,400 per utility gained for MUS versus bulking agents. The authors assumed a willingness-to-pay threshold of $50,000 and concluded that MUS are not cost-effective as a first-line treatment for their hypothetical population compared with bulking agents. The authors note the outcome is for initial treatment and findings may differ over a longer time horizon.

Seklehner (2014)

The characteristics of the economic analysis by Seklehner and colleagues (Seklehner 2014) are summarised in **Table 20**. The authors compared MUS implanted via the two different approaches, RP or TO.

Table 20 Study characteristics of Seklehner (2014)

Study ID Country	Research question	Perspective Time horizon EE type	Population	Intervention Comparator	Source of effectiveness inputs	Funding Author COIs
Seklehner 2014 USA	What is the cost-effectiveness of RP-MUS versus TO-MUS for women with SUI?	US health care 10 yr CUA: Markov-chain decision model; 2.26% annual discount rate; 2012 costs	Women; SUI or predominantly SUI	RP-MUS TO-MUS	21 RCTs (min. 12 mo follow-up)	NR Conflicts: none

Abbreviations: COI, conflict of interest; CUA, cost-utility analysis; EE, economic evaluation; mo, month(s); MUS, mid-urethral sling; NR, not reported; RCT, randomised controlled trial; RP-MUS, retropubic MUS; SUI, stress urinary incontinence; TO-MUS, transobturator MUS; yr, year.

Findings

The findings of the cost-utility analysis are presented in **Table 21**, from a US health care perspective.

Table 21 Outcomes of Seklehner (2014) – based on objective cure at 10 years

Study ID	Effectiveness (QALYs)	Cost (USD)	Cost/QALY ICER	Sensitivity analysis	Conclusion
Seklehner 2014 USA	RP-MUS: 6.275 TO-MUS: 6.272 Incremental: 0.003	RP-MUS: $9,579 TO-MUS: $9,017 Incremental: $562	RP-MUS: $1,527 TO-MUS: $1,438 ICER: $177,027/QALY	TO-MUS more cost-effective than RP-MUS if: Price <$1,852, or Efficacy >76.1% In-patient surgery RP-MUS more cost-effective than TO-MUS if: Price <$603, or Efficacy >94% Ambulatory surgery	TO-MUS is cost-effective compared to RP-MUS

Abbreviations: ICER, incremental cost-effectiveness ratio; MUS, mid-urethral sling; QALY, quality-adjusted life year; RP-MUS, retropubic MUS; SUI, stress urinary incontinence; TO-MUS, transobturator MUS; USD, US dollars.

The two types of MUS were similar in their efficacy, with the RP approach slightly superior to the TO approach at 10 years based on objective cure outcome, though it was not clear if the quality-adjusted life year (QALY) increment was clinically meaningful. Costs of the RP procedure were higher than for TO, mainly driven by shorter operative time and associated hospital costs for TO-MUS. Therefore, overall cost-effectiveness favoured TO-MUS.

It is unclear how applicable these findings would be to the Australian setting given the device and medical service costs in Australia are similar for RP-MUS and TO-MUS, and the differences reported by Seklehner 2014 for procedure time (29.07 mins for RP-MUS vs. 22.58 mins for TO-MUS) and length of hospital stay (2.83 days for RP-MUS vs. 2.18 days for TO-MUS) are not substantial.

Laudano (2013)

The characteristics of the economic analysis by Laudano and colleagues (Laudano 2013) are summarised in **Table 22**. The authors compared RP-MUS (tension-free vaginal tape [TVT]) to colposuspension (Burch procedure).

Table 22 Study characteristics of Laudano (2013)

Study ID Country	Research question	Perspective Time horizon EE type	Population	Intervention Comparator	Source of effectiveness inputs	Funding Author COIs
Laudano 2013 USA	What is the cost-effectiveness of TVT compared to Burch colposuspension for female SUI?	US health care 10 yr CUA: Markov-chain decision model (+ Monte Carlo simulation); 4.54% annual discount rate; 2006 costs	Primary SUI	TVT (RP-MUS) Burch colposuspension	Literature search (7 RCTs; min. 12 mo follow-up)	NR Conflicts: none

Abbreviations: COI, conflict of interest; CUA, cost-utility analysis; EE, economic evaluation; mo, month(s); MUS, mid-urethral sling; NR, not reported; RCT, randomised controlled trial; RP-MUS, retropubic MUS; SUI, stress urinary incontinence; TVT, tension-free vaginal tape; yr, year.

The authors presented a model based on seven RCTs comparing open colposuspension to RP-MUS. One-way and two-way sensitivity analyses varied the cost of the sling device and/or its success rate. It was not explained how efficacy (cure rate) was defined, though the health state to which patients with successful surgery transitioned was “no leakage (dry)”. Also, it was not clear that either the efficacy or complication rates, which were extracted from studies with 12-24 months follow-up, would remain applicable at 10 years as the authors contended.

Findings

The findings of the cost-utility analysis are presented in **Table 23**, from a US health care perspective.

Table 23 Outcomes of Laudano (2013) – at 10 years

Study ID	Effectiveness (QALYs)	Costs (USD)	Cost/QALY ICER	Sensitivity analysis	Conclusion
Laudano 2013 USA	TVT: 5.79 BC: 5.78 Incremental: 0.01	TVT: $8,651 BC: $10,545 Incremental: - $1,894	TVT: $1,495 BC: $1,824 ICER: - $296,877/QALY	TVT is cost-effective only if: TVT price <$3,220 TVT success >42%	At 10 yr, TVT was more cost-effective than BC

Abbreviations: BC, Burch colposuspension; ICER, incremental cost-effectiveness ratio; NR, not reported; QALY, quality-adjusted life year; SUI, stress urinary incontinence; TVT, tension-free vaginal tape; USD, US dollars; yr, year.

The authors reported similar effectiveness for the two procedures but a higher procedure cost for colposuspension. Hence, it was concluded that over ten years of follow-up, RP-MUS (TVT) was more cost effective than Burch colposuspension "despite the risk of mesh erosion, bladder perforation and other sling-specific complications" (Laudano 2013). Sensitivity analyses showed that this depended on the price of the sling device remaining below US$3,220 and the success rate above 42% (the actual mesh unit cost was US$1,170). Note that it is not likely that complications from studies with only 24 months follow-up could be used to reflect rates over a ten-year period.

4.2.3 Trial-based economic evaluations

The literature search identified two trial-based economic studies which are summarised below.

Casteleijn (2023)

The characteristics of the economic analysis by Casteleijn and colleagues (Casteleijn 2023) are summarised in **Table 24**. The authors presented a prospective, two-arm cohort study conducted in four countries, which compared MUS to a silicone bulking agent. The study converted trial quality of life (QoL) scores (disease specific IIQ and general EQ-5D-5L) to QALYs and used bootstrap sampling to explore variation/uncertainty.

Table 24 Study characteristics of Casteleijn (2023)

Study ID Country	Research question	Perspective Time horizon EE type	Population	Intervention Comparator	Source of effectiveness inputs	Funding Author COIs
Casteleijn 2023 [1]Netherlands	What is the cost-effectiveness of PDMS-U bulking agent compared with MUS at 1 yr follow-up?	Dutch health care & societal 1 yr CUA: Trial based, unadjusted & adjusted (net benefit regression); 2021 costs	Moderate to severe SUI	MUS (n=153) PDMS-U bulking agent (n=131)	This study	Funding: Research grants from Urogyn BV and ZonMw COI: Research Grants (Fotona, Medtronic); Expert testimony (Dekra); Safety and advisory boards (Kuste.ICS, EAU, NVU, AAEU); Consulting fees, honoraria (Astellas, BSCI, Coloplast, Kuste, Medtronic, Promedon, Urogyn)

Abbreviations: COI, conflict of interest; CUA, cost-utility analysis; EE, economic evaluation; MUS, mid-urethral sling; PDMS-U, polydimethylsiloxane (Urolastic®); SUI, stress urinary incontinence; yr, year; ZonMw, Netherlands Organisation for Health Research and Development.
[1]The economic evaluation is applied to Netherlands but the clinical centres were in four countries (Netherlands, Slovakia; South Africa and Canada)

The MUS arm included both RP-MUS (n=15 [9.8%]), TO-MUS (n=66 [43.2%]) and single-incision mini-sling (n=72 [47%]). Thus, almost half the comparator patients received an intervention that is out of scope for this post-listing review. Further, the authors noted several marked differences in baseline characteristics, *"the PDMS-U group were on average twice as old, had more severe SUI, more mixed urinary incontinence (MUI) and a higher number of previous surgical treatments for SUI"*, thus likely to be at higher risk of poorer

outcomes than the MUS group. An adjusted analysis using logistic regression attempted to correct for this source of bias. Total costs included societal costs such as loss of productivity.

Findings

The findings of the cost-utility analysis are presented in **Table 25**, from a Dutch health care and societal perspective.

Table 25 Outcomes of Casteleijn (2023) – at 1 year

Study ID	Incremental effectiveness, QALY (IQR)	Incremental costs, Euro (95% CI)	ICER Cost/QALY (95% CI)	Sensitivity analysis (95% CI)	Conclusion
Casteleijn 2023 NL	Mean difference, MUS vs. PDMS-U: IIQ 0.20 (0.15, 0.25) EQ-5D-5L 0.08 (0.05, 0.12)	Mean difference, MUS vs. PDMS-U: €3,120 (€2,382, €3,861)	MUS vs. PDMS-U: IIQ €15,598 (€10,950, €21,966) EQ-5D-5L €37,408 (€22,817, €67,102) *(favours PDMS-U)*	*Assuming zero leave days for missing data:* IIQ €12,365 (€7,823, €18,283) EQ-5D-5L €29,889 (€16,777, €56,204) *(favours PDMS-U)* *Using 12 mo. scores only:* IIQ €12,365 (€7,823, €18,283) EQ-5D-5L €47,526 (€26,400, €134,600) *(favours PDMS-U)*	*Silicone bulking agent was more cost-effective.* *Based on €25,000 WTP threshold* MUS: 84% chance of being cost-effective; PDMS-U: 99% chance of being cost-effective

Abbreviations: CI, confidence interval; EQ-5D-5L, Euro-QoI five-domain QoL questionnaire; ICER, incremental cost-effectiveness ratio; IIQ, Incontinence Impact Questionnaire; IQR, inter-quartile range; mo, month(s); MUS, mid-urethral sling; NR, not reported; PDMS-U, polydimethylsiloxane (Urolastic®); QALY, quality-adjusted life year; WTP, willingness to pay (cost-effectiveness threshold); yr, year.

For the analysis using the disease-specific IIQ scores, 100% of bootstrap samples appeared in the north-east plane of cost-effectiveness, meaning MUS was more expensive than PDMS-U, but also more effective.

The authors concluded that MUS surgery is more cost-effective for improving disease-specific QoL, while the bulking agent PDMS-U is more cost-effective in improving QoL in general.

Lier (2017)

The characteristics of the economic analysis by Lier and colleagues (Lier 2017) are summarised in **Table 26**. The authors presented an economic evaluation of two types of MUS, TO versus RP (referred to in the article as TOT and TVT), using outcomes at five years' follow-up from an RCT in 195 women in Canada. This work was a five-year follow-up report of the authors' initial economic analysis at 12 months (Lier 2011).

Table 26 Study characteristics of Lier (2017)

Study ID Country	Research question	Perspective Time horizon EE type	Population	Intervention Comparator	Source of effectiveness inputs	Funding Author COIs
Lier 2017 Canada	What is the cost–utility and cost-effectiveness of TOT versus TVT?	Canadian public payer (health care) 5 yr CEA & CUA: Trial based, unadjusted & adjusted, multiple imputation; 3% annual discount rate; 2011 costs	SUI	TOT (TO-MUS) TVT (RP-MUS)	RCT (this study) NCT00234754	CIHR; Alberta Heritage Fund for Medical Research; Boston Scientific COI per funding above

Abbreviations: CEA, cost-effectiveness analysis; CIHR, Canadian Institutes of Health Research; CUA, cost-utility analysis; COI, conflict of interest; EE, economic evaluation; SUI, stress urinary incontinence; RCT, randomised controlled trial; RP-MUS, retropubic mid-urethral sling; TO-MUS, transobturator mid-urethral sling; TOT, transobturator tape; TVT, tension-free vaginal tape; yr, year.

The five-year report presents two economic analyses as follows:

- cost-utility analysis: health utilities collected using the 15D instrument (non-disease-specific 15-domain patient HRQoL questionnaire)
- cost-effectiveness analysis: proportion of women with no serious adverse events at five years (for example, tape erosion, re-operation).

These primary outcomes for the five-year analyses were different to that reported for the initial phase of the RCT, which was objective cure (Ross 2009).

Findings

The findings of the economic analyses are presented in **Table 27**, from a Canadian health care perspective.

Table 27 Outcomes of Lier (2017) – at 5 years

Study ID	Effectiveness (95% CI)	Cost (95% CI), CAD	ICER	Sensitivity analysis	Conclusion
Lier 2017 Canada	QALY gain TOT: 0.80 TVT: 0.77 Incremental (adjusted): 0.04 (-0.06, 0.14) Proportion of women with no SAE TOT: 0.79 TVT: 0.73 Incremental (adjusted): 0.03 (-0.10, 0.16)	TOT: $13,007 TVT: $16,081 Incremental (adjusted): -$2,368 (-$7,166, $2,548)	Cost/QALY not presented TOT dominant in >71% of replications for CUA (QALYs) and >60% for CEA (proportion with no SAEs)	Removal of TVT high cost outlier: TOT remains dominant Analysis only of patients with complete data: TOT dominant, though less favourable	TOT (TO-MUS) is more cost effective than TVT (RP-MUS) over 5 yr

Abbreviations: CAD, Canadian dollars; CEA, cost-effectiveness analysis; CI, confidence interval; CUA, cost-utility analysis; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; RP-MUS, retropubic mid-urethral sling; SAE, serious adverse event; TO-MUS, transobturator mid-urethral sling; TOT, transobturator tape; TVT, tension-free vaginal tape.

The primary cost-utility analysis indicated that TO-MUS was less costly and had slightly higher efficacy based on QALY gain (from 15D utility scores). The cost-effectiveness analysis, based on proportion of women with no SAEs, also showed TO-MUS was slightly more effective (with the same cost difference as for the cost-utility analysis). TO-MUS remained dominant in the sensitivity analyses.

The authors noted that the procedure and device costs for the two slings were essentially identical. The difference in healthcare costs was post-operative – costs for RP-MUS were higher over 5 years of follow-up for in-patient and out-patient services and also physician consultations. The authors did not comment on what events was driving these higher rates of health service use. It was not clear to what extent costs for treating complications were reflected in these figures. Neither the incremental cost nor effect estimates were statistically significant.

5 Cost analysis

The scope of this review included an analysis of the total cost of MUS implantation for SUI in the Australian health care setting, including the cost of the device, implantation procedure and associated resource use. *Note the cost information presented is only that associated with MUS use and is not comparative.*

5.1 Procedure cost of mid-urethral sling implantation

Healthcare resource costs for implantation of MUS are estimated in **Table 28**. Costs can be considered as split between the following:

- costs to the Commonwealth (PL benefit, any other MBS or Pharmaceutical Benefits Scheme (PBS) benefit)
- costs to the States and Territories (public hospital in-patient services; unfunded out-patient services)
- private costs (private hospital in-patient services; unfunded out-patient services; gap charges).

All MUS currently listed on the PL are in sub-group 05.01.03.02 at a benefit of $822 (see **Table 2**). Following benchmarking by the Independent Hospital Pricing Authority (IHPA), a component of recent PL reforms, this benefit has remained unchanged indicating there is no, or minimal difference, between the supplied price in the public system and the listed benefit on the PL[5]. Note that the PL benefit may be used to set the supplied price and benchmarking should be considered in that context.

The MBS includes an item for MUS surgery, which covers diagnostic cystoscopy necessary for the procedure (MBS item 35599; fee $801.20). The Item 35599 descriptor includes "(Anaes.) (Assist.)" and so qualifies for further items to be co-claimed for an anaesthetist and an assistant surgeon. For simplicity, MBS fees are cited without adjusting for patient co-payments, thus actual costs for most in-patient services or resources would be 75% of the fee assuming all are in-patients.

The hospital costs are estimated based on Australian Refined Diagnosis Related Groups (AR-DRG) L07B, which is not specific to MUS surgery and likely overestimates hospital costs as the average length of stay for this DRG is 1.3 days whereas most patients undergoing MUS surgery will be discharged within 24 hours.[6] However, since PL benefits are only payable to patients whose procedures are paid for by private health insurance, the cost estimates are for private patients in private hospitals only. For the small number of private patients in the public hospital system, costs for in-patients would be a cost to the State and Territory hospital system. Therefore, the hospital costs do not accrue to the Commonwealth.

Urodynamics and urinalysis have not been included as they are part of diagnostic work-up that would be undertaken as part of standard care for SUI patients regardless of the treatment option chosen. The costs of consumables are not included (for example, incontinence pads, catheter and urine bag, etc.).

[5] See https://www.health.gov.au/resources/publications/advice-on-the-prostheses-list-adjusted-benefit-amounts
[6] https://www.thewomens.org.au/images/uploads/fact-sheets/Urinary-incontinence-Mid-Urethral-Sling.pdf

Table 28 Proposed MUS procedure costs to the Commonwealth (private setting only)

Item	Provider	Price per unit	Quantity	Source
Prosthesis Cost				
RP-MUS or TO-MUS	Prostheses	$822.00	1	PL Benefit (Group 05.01.03.02, March 2023)
Medical Services - pre-procedural screening				
Surgeon attendance - initial consult	Specialist	$91.80	1	MBS # 104
Urodynamic studies	Specialist	$452.90	1	MBS # 11919
Medical Services - device placement				
MUS surgery and diagnostic cystoscopy	Specialist	$801.20	1	MBS # 35599
Assistant fee	Surgical assistance	$160.24[1]	1	MBS # 51303 (1/5 of MBS # 35599)
Pre-anaesthesia consult	Anaesthetist	$46.15	1	MBS # 17610
Anaesthesia initiation - vaginal surgery	Anaesthetist	$104.75	1	MBS # 20942
Anaesthesia perfusion time (45 mins - 1.0 hour)	Anaesthetist	$83.80	1	MBS # 23045
Hospital Services				
Other Transurethral Interventions, Minor Complexity	Hospital	$5,020	1	AR DRG L07B minus prostheses cost (NHCDC Round 24, version 10.0)
Total cost of MUS placements per patient		**$7,582,84**		

Abbreviations: h, hour; MBS, Medicare Benefits Schedule; NHCDC, National Hospital Cost Data Collection – Public; PL, Prostheses List; RP-MUS, retropubic mid-urethral sling; TO-MUS, transobturator mid-urethral sling.

[1] This value has been calculated as item 51303 provides for a fee at a fifth of the corresponding surgical procedure fee.

Resource use items associated with MUS surgery are listed in **Table 29**. Medicines are only included where they would be dispensed on discharge as those for in-patients are not eligible for PBS scripts.

A number of the analgesics that may typically be prescribed for post operative pain after abdominal surgery are not listed on the PBS for this indication. Instead, these would be dispensed on discharge at the patient's expense. For example, paracetamol, celecoxib, and oxycodone + naloxone (combination to manage constipation for those with abdominal pain) are not available on the PBS for this purpose. Diclofenac and oxycodone are listed in **Table 29** for analgesia as indicative.

Costs arising from complications are only included for urinary tract infections (UTIs) and mesh requiring removal. A full costing of adverse event treatment costs would rely on robust long-term safety data and could potentially include:

- long-term pain
- voiding difficulty
- SUI requiring re-treatment.

Cost of incontinence pads due to SUI not adequately managed by the sling procedure would be a cost to the patient.

Table 29 Resource use and other costs to the Commonwealth for mid-urethral sling surgery

Resource	Detail	Unit Price	Source
Post-operative analgesia	Diclofenac	† $17.56	e.g. PBS 1299J
	Oxycodone	† $21.31	e.g. PBS 12031F
UTI treatment	Level B GP consult	$39.75	MBS # 23
	Oral antibiotics course: Amoxicillin, or; Amoxicillin/Clavulanic Acid	† $14.85 † $18.76	pbs.gov.au e.g. PBS 1884E e.g. PBS 11933C
Re-operation	Synthetic sling removal (not including other costs as in Table 28 for anaesthetist, assistant, specialist consult, etc.)	$963.40	MBS 37340

Abbreviations: DPMQ, dispensed price for maximum quantity; GP, general practitioner; MBS, Medicare Benefits Schedule; PBS, Pharmaceutical Benefits Scheme; UTI, urinary tract infection.

† Cost is DPMQ. For both these antibiotic items, DPMQ is under the patient co-payment threshold ($30.00 for Financial Year 2022-2023) and does not represent a cost to the Commonwealth except for concessional and safety net patients.

5.1.1 Comparison with international studies

Little information is available regarding the current unit costs charged in other countries for MUS kits. Unit prices for mesh kits were available from a small number of US-based low cost supplier websites and are reproduced in **Table 30**. Given that prices are usually high in the US due to differences in health care systems, these can be considered an upper bound of the likely range of prices for these devices outside Australia.

Table 30 Device unit costs outside Australia – USA

Brand	USA (USD)
Advantage	[1] $695.00
Obtryx II	[1] $999.00 (Transobturator, curved) [1] $799.00 (Transobturator, halo)
Advantage Fit	[1] $969.00 (clear) [1] $995.00 – $999.00 (blue)
GYNECARE TVT EXACT Continence System	[2] $800.00
GYNECARE TVT Obturator System	[2] $565.00
GYNECARE TVT ABBREVO Continence System	[2] $721.00

Abbreviations: MUS, mid-urethral sling; PL, Prostheses List; TVT, tension-free vaginal tape.

[1] www.westcmr.com, accessed 31 March 2023.

[2] www.shopsps.com, accessed 31 March 2023; www.geosurgical.com, accessed 4 April 2023.

Belgium has a list of reimbursable medical devices[7] which lists suburetheral mesh for SUI at a basic price of €356.95 and a maximum price €410.49.

Procedure cost inputs cited in the included economic studies were highly variable, even within the same health care setting, summarised in **Table 31**. In some cases, procedures costs included resource use and consumables but not in other cases. It was not always clear whether services such as cystoscopy had been included in the procedure cost or not included at all. Where possible, the unit cost for the device is stated in **Table 31** if the authors reported it.

[7] Available at: https://www.riziv.fgov.be/fr/professionnels/sante/fournisseurs-implants/Pages/implants-liste-prestations-nominatives.aspx

Table 31 Procedure costs used in the included economic studies and relevant cost analyses (mesh only)

Study ID	$	Procedure	Device	Theatre	Hospital stay	Cystoscopy	Re-operation
Laudano 2013	$USD	2,324	1,170	0.7h at 2,153/h	1.5d at 1,074/d	459	1,836
Seklehner 2014	$USD	2,324	1,170 (RP-MUS) 1,295 (TO-MUS)	1,043 8,10.25	3,039.52 2,341.32	*	*
Kunkle 2015	$USD	6,397	*	*	*	*	*
Javanbakht 2020b	£GBP	1,550.29	*	*	*	*	1,396.57
Chang 2021	$USD	4,937	*	*	*	*	4,913
Jia 2023	$USD	2,226.19	*	68 min	*	*	1,000.03
Castelijn 2023	€Eur	930	353.54 (RP-MUS) 938.50 (TO-MUS)	143.75	517	*	*

Abbreviations: €Eur, Euros; $USD, US dollars; d, day; h, hour; mo, month(s); MUS, mid-urethral sling; RP-MUS, retropubic MUS; TO-MUS, transobturator MUS.

* Costs were not specified and / or assumed to be included in procedure

6 Summary of findings and considerations for PLAC

6.1 Comparative clinical effectiveness

The findings relating to the comparative clinical effectiveness of MUS are based predominately on the 2019 NICE Guideline *Urinary incontinence and pelvic organ prolapse in women: management (NICE 2019c).* The NICE evidence review identified no eligible studies comparing bulking agents to MUS.

6.1.1 Colposuspension versus mid-urethral sling

The findings by outcome and follow-up time for MUS compared to colposuspension are summarised in **Table 32**, including the number of RCTs and participants, and the quality of the evidence.

Table 32 Summary of NICE findings for colposuspension versus MUS

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[1]
Change in continence status				
subjective cure	4, N=625 (S)	Low	No difference (S)	No difference (S)
	4, N=619 (M)	Very low	No difference (M)	No difference (M)
	1, N=72	Very low	No difference (L)	No difference (L)
objective cure	5, N=689 (S)	Very low	Favours MUS (S)	No difference (S)
	7, N=844 (M)	Low	Favours MUS (M)	No difference (M)
Patient-reported outcomes				
continence-specific health-related HRQoL	1, N=286 (S); 1, N=177 (M)	Very low	No difference (S), (M)	No difference (S), (M)
patient-satisfaction/patient-reported improvement	5, N=441 (M)	Low	Favours MUS (M)	No difference (M)
	1, N=72 (L)	Very low	No difference (L)	No difference (L)
Adverse events				
bladder injury	11, N=1,086	Low	Favours colposuspension	Favours colposuspension
severe bleeding requiring blood transfusion	3, N=259	Very low	No difference	No difference
bowel injury	1, N=72	Very low	No difference	No difference
Complications				
infection	2, N=429 (S); 4, N=539 (M)	Very low	No difference (S, M)	No difference (S, M)
POP	2, N=302 (M)	Low	Favours MUS (M)	Favours MUS (M)
pain	2, N=189 (S); 2, N=161 (M)	Very low	No difference (S, M)	No difference (S, M)
mesh extrusion	2, N=429 (S); 5, N=598 (M)	Very low	No difference (S, M)	No difference (S, M)
need for catheterisation	3, N=289 (S); 3, N=502 (M)	Very low	No difference (S, M)	No difference (S, M)
de novo urgency	1, N=87 (S); 3, N=338 (M)	Very low	No difference (S, M)	No difference (S, M)
de novo urge incontinence	2, N=155 (S); 3, N=315 (M)	Very low	No difference (S, M)	No difference (S, M)
fistula	1, N=90 (M)	Low	No events	No events
wound complications	1, N=90 (M)	Low	No events	No events

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[1]
Repeat surgery				
for any reason	2, N=168 (S)	Very low	No difference (S)	No difference (S)
	1, N=316 (M)	Low	Favours MUS (M)	Favours MUS (M)
for SUI	2, N=166 (M); 1, N=53 (L)	Very low	No difference (M, L)	No difference (M, L)
for mesh complications	1, N=68 (S); 1, N=72 (L)	Very low	No difference (S, L)	No difference (S, L)

Source: based on data from NICE Evidence review (NICE 2019b)
Abbreviations: HRQoL, health-related quality of life; L, long-term; M, medium-term; MUS, mid-urethral sling; No., number; POP, pelvic organ prolapse; RP, retropubic; S, short-term; SUI, stress urinary incontinence; TO, transobturator
[1] NICE defined clinically important outcomes based on published literature and consultation with the Guideline Committee. If no published or acceptable minimally important difference (MID) was identified, the committee considered whether to use GRADE defaults.
Key: orange = very low quality evidence; yellow = low quality evidence; green = favours MUS; blue = favours colposuspension.

6.1.2 Autologous rectus fascial sling (pubovaginal sling) versus mid-urethral sling

The findings by outcome and follow-up time for MUS compared to autologous rectus fascial sling are summarised in **Table 33**, including the number of RCTs and participants, and the quality of the evidence (where available).

Table 33 Summary of findings for autologous rectus fascial sling versus MUS based on relevant studies from NICE review

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[3]
Change in continence status				
subjective cure	2, N=197 (S)[1]	Very low	Borderline favours RP-MUS (S)[1]	Favours RP-MUS (S)[1]
	1, N=41 (M)	Very low	No difference (M)	No difference (M)
	1, N=156 (L)	Very low	No difference (L)	No difference (L)
objective cure	3, N=192 (S)	NR[2]	No difference (S)	NR[2]
	3, N=187 (M)	Very low	No difference (M)	No difference (M)
Patient-reported outcomes				
patient-satisfaction/patient-reported improvement	2, N=65 (M)	NR[2]	No difference (M)	NR[2]
Adverse events				
any	3, N=192 (S)	NR[2]	No difference (S)	NR[2]
	3, N=187 (M)	NR	No difference (M)	NR
Complications				
pain	2, N=133 (S)	NR[2]	No difference (S)	NR[2]
	1, N=53 (S)[1]	Very low	No difference (S)[1]	May favour RP-MUS
	2, N=193 (L)	Very low	No difference (L)	No difference (L)
mesh extrusion	1, N=63 (M)	NR[2]	No difference (M)	NR[2]
	2, N=193 (L)	Very low	No difference (L)	No difference (L)
need for catheterisation	4, N=320 (S)	NR[2]	No difference (S)	NR[2]
	1, N=124 (L)	Very low	No difference (L)	No difference (L)

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[3]
de novo urgency	2, N=65 (M); 2, N=193 (L)	Very low	No difference (M, L)	No difference (M, L)
	2, N=256 (L)	Very low	No difference (L)	No difference (L)
Repeat surgery				
for any reason	2, N=197 (S); 1, N=69 (L)	Very low	No difference (S, L)	No difference (S, L)

Source: based on data from NICE Evidence review (NICE 2019b)
Abbreviations: L, long-term; M, medium-term; MUS, mid-urethral sling; NR, not reported; RP, retropubic; S, short-term.
[1] Sub-group comparison: rectus fascial sling versus RP-MUS
[2] Quality of evidence and clinical significance not available in NICE report for sub-set of studies excluding single-incision mini-slings
[3] NICE defined clinically important outcomes based on published literature and consultation with the Guideline Committee. If no published or acceptable minimally important difference (MID) was identified, the committee considered whether to use GRADE defaults.
Key: orange = very low quality evidence; purple = favours RP-MUS; light purple = may favour RP-MUS

6.1.3 TO-MUS versus RP-MUS

The findings by outcome and follow-up time for TO-MUS versus RP-MUS are summarised in **Table 34**, including the number of RCTs and participants, and the quality of the evidence.

Although the NICE direct comparison showed no clinically important differences in subjective cure or objective cure in the short, medium or long-term, the NMA (Brazzelli 2019) did show a statistically significant difference in favour of RP-MUS in both objective cure and the number of women improved.

Table 34 Summary of NICE findings for TO-MUS versus RP-MUS

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[1]
Change in continence status				
Subject cure	15, N=2,638 (S); 6, N=1,340 (M)	Low	No difference (S, M)	No difference (S, M)
	2, N=288 (L)	Very low	No difference (L)	No difference (L)
Objective cure	15, N=2,176 (S)	Low	Favours RP-MUS (S)	No difference (S)
	10, N=2,057 (M)	Low	No difference (M)	No difference (M)
	2, N=288 (L)	Very low	No difference (L)	No difference (L)
Negative cough stress test	9, N=2,292 (S); 5, N=1,352 (M)	Low	No difference (S, M)	No difference (S, M)
Number of incontinence episodes per day	1, N=36 (M)	Low	No difference (M)	No difference (M)
Continence-specific HRQoL				
ICIQ-UI-QoL score (M)	1, N=100 (M)	Very low	Favours RP-MUS (M)	Favours RP-MUS (M)
I-QoL score (S)	1, N=125 (S)	Very low	Favours RP-MUS (S)	Favours RP-MUS (S)
ICIQ-UI-QoL score (S)	1, N=100 (S)	Very low	No difference	May favour RP-MUS (S)
King's Health Questionnaire – Intercourse score (M)	1, N=331 (M)	Very low	Favours TO-MUS (M)	Favours TO-MUS (M)
All other health-related QoL measures	1 to 5, N= 100 to 887	Very low or Low	Variable	No difference
Other patient-reported outcomes				
Patient-satisfaction/patient-reported improvement	13, N=2,771 (M); 1, N=140 (L)	Low	No difference (M, L)	No difference (M, L)

Outcome	No. of RCTs, No. participants	Quality of evidence	Statistical significance	Clinical importance[1]
Adverse events				
bladder injury	40, N=6,654	Moderate	Favours TO-MUS	Favours TO-MUS
severe bleeding requiring blood transfusion	10, N=2,041	Very low	No difference	No difference
bowel injury	12, N=1,455	Moderate	No events	No events
Complications				
infection	17, N=3,245 (S); 7, N=1,838 (M); 2, N=268 (L)	Very low	No difference (S, M, L)	No difference (S, M, L)
POP	1, N=87 (L)	Very low	No difference (L)	No difference (L)
pain	19, N=3618 (S)	Moderate	Favours RP-MUS (S)	Favours RP-MUS (S)
	11, N=1,953 (M); 2, N=207 (L)	Very low	No difference (M, L)	No difference (M, L)
mesh extrusion	22, N=3,829 (S)	Low	Favours RP-MUS (S)	Favours RP-MUS (S)
	12, N=2,279 (M)	Very low	Favours RP-MUS (M)	Favours RP-MUS (M)
need for catheterisation	16, N=3,039 (S)	Low	Favours TO-MUS (S)	Favours TO-MUS (S)
	4, N=822 (M)	Very low	No difference (M)	No difference (M)
de novo urgency	8, N=1,164 (S); 7, N=761 (M)	Very low	No difference (S, M)	No difference (S, M)
de novo urge incontinence	5, N=1,243 (S); 4, N=987 (M)	Very low	No difference (S, M)	No difference (S, M)
de novo nocturia	1, N=88 (S)	Very low	No difference (S)	No difference (S)
	1, N=71 (M)	Very low	Favours RP-MUS (M)	Favours RP-MUS (M)
wound complications	4, N=443 (S); 2, N=248 (M)	Very low	No difference (S, M)	No difference (S, M)
Repeat surgery				
for SUI	5, N=1,114 (S)	Low	Favours RP-MUS (S)	Favours RP-MUS (S)
	6, N=1,022 (M); 1, N=87 (L)	Very low	No difference (M, L)	No difference (M, L)
for POP	1, N=554 (S)	Very low	No events (S)	No events (S)
	1, N=87 (L)	Very low	No difference (L)	No difference (L)
for mesh complications	13, N=2,447 (S); 8, N=1,688 (M); 1, N=87 (L)	Very low	No difference (S, M, L)	No difference (S, M, L)

Source: based on data from NICE Evidence review (NICE 2019b)
Abbreviations: HRQoL, health-related quality of life; L, long-term; M, medium-term; MUS, mid-urethral sling; POP, pelvic organ prolapse; RP, retropubic; S, short-term; SUI, stress urinary incontinence; TO, transobturator
[1] NICE defined clinically important outcomes based on published literature and consultation with the Guideline Committee. If no published or acceptable minimally important difference (MID) was identified, the committee considered whether to use GRADE defaults.
Key: orange = very low quality evidence; yellow = low quality evidence; blue = moderate quality evidence; purple = favours RP-MUS; pink = favours TO-MUS.

6.1.4 Long term complications

Data on long-term complications (>5 years) was derived from both comparative and non-comparative studies. NICE reported a weighted average rate of mesh erosion or exposure of 1.5% for RP-MUS (15 studies, 1,6010 women) and 2.3% for TO-MUS (9 studies, 1,335 women).

6.1.5 Summary on clinical effectiveness

Although based on RCTs, the evidence is predominantly of low or very low certainty with NICE downgrading the available evidence due largely to key limitations in the reporting of participant characteristics. Firstly, for the majority of studies, it was unclear whether participants with POP received concomitant POP surgery

at the time of surgery for SUI. Secondly, the majority of studies did not report whether participants had failed or declined conservative treatment prior to surgical intervention. These limitations should be taken into account when interpreting the findings and considering their generalisability. Nevertheless, the evidence synthesis finds few differences in the clinical effectiveness of MUS versus either colposuspension or pubovaginal slings. With respect to MUS types, a greater number of outcomes favour RP-MUS over TO-MUS.

The Urological Society of Australia and New Zealand (USANZ) noted in their submission to this review that the technique for placement of pubovaginal slings has evolved in recent years towards a technique more similar to the placement of MUS. They raise the possibility that more recent, or future research, may identify different outcomes regarding modern pubovaginal sling placement compared to MUS than historical studies. This post-listing review relies on the NICE evidence reviews with literature searches in June 2018; it is possible that more recent studies may have reached different conclusions, particularly regarding pubovaginal slings. Nevertheless, no pivotal studies were identified in stakeholder consultation that would have altered the overall findings.

The key challenge in interpretation of the clinical and economic evidence was the variation in terminology and categorisation of different surgical techniques for SUI. In particular, the term sub-urethral sling and whether this referred to a type of MUS or a traditional sling, as varying definitions were used across the included studies.

Data on long-term complication rates is of low-quality and uncertain.

6.2 Clinical Practice Guidelines and Regulatory Advice

Ten clinical practice guidelines or position statements are summarised in **Appendix E**. All consistently recommend MUS as a surgical option for the treatment of SUI. Those that make a statement on the type of MUS recommend RP-MUS over TO-MUS unless there are specific clinical circumstances.

6.3 Cost-effectiveness and cost analysis

The economics literature for MUS is dominated by studies of cost-effectiveness in US health care which may have limited applicability to the Australian setting given the different factors driving costs of medical devices and medical services in the US.

Of the four modelled economic studies that compared MUS to alternative surgical interventions (Chang 2022; Javanbakht 2020b; Jia 2023; Laudano 2013), all found MUS to be the most cost-effective. Where the two types of MUS were compared, the two studies considering the pairwise comparison only (Lier 2017; Seklehner 2014) found TO-MUS to be more cost effective than RP-MUS, whereas the study that compared MUS within a suite of options (Javanbakht 2020b) found that RP-MUS dominates TO-MUS. Similarly, bulking agents were found to be more cost-effective at one year than MUS in two studies (Casteleijn 2023; Kunkle 2015) but not in the larger analyses with a longer time horizon (Chang 2022; Javanbakht 2020b).

The pivotal economic analysis is (Javanbakht 2020b) based on comprehensiveness, methodology and source of funding. The study found RP-MUS to dominate all relevant comparators at 10-year and lifetime horizons. One of the comparators in Javanbakht 2020b was ‘traditional slings’, which included both autologous and synthetic suburethral slings. Traditional slings also had a high probability of being cost-effective over a lifetime horizon. The most significant source of uncertainty in the study is the extrapolation of both effectiveness and complication rates beyond trial data, although varying complication rates were tested in sensitivity analysis.

An overview of cost-effectiveness findings from the included studies is presented in **Table 35**.

Table 35 Summary of cost-effectiveness findings

Study ID	Intervention	Comparator(s)	Time horizon	Effectiveness	Cost	Cost-effectiveness
Modelled evaluations						
Jia 2023	RP-MUS	PVS	1 yr	RP-MUS slightly more effective	RP-MUS less costly	RP-MUS more cost-effective
Chang 2022	MUS (RP- or TO-)	Open colposuspension PVS Laparoscopic colpo. Bulking agents	2 yr	MUS most effective	MUS least costly	MUS is only cost-effective option
Javanbakht 2020b	RP-MUS	TO-MUS Bulking agents Open colposuspension Laparoscopic colpo.	10 yr, lifetime	RP-MUS most effective	RP-MUS least costly	RP-MUS is most cost-effective
Kunkle 2015	Bulking agents	MUS (retro- or trans-)	1 yr	MUS more effective	Bulking agents less costly	Bulking agents more cost-effective
Seklehner 2014	RP-MUS	TO-MUS	10 yr	RP-MUS slightly more effective	TO-MUS less costly	TO-MUS more cost effective
Laudano 2013	RP-MUS	Open colposuspension	10 yr	RP-MUS similarly effective	RP-MUS less costly	RP-MUS more cost-effective
Trial-based evaluations						
Casteleijn 2023	Bulking agent (PDMS-U)	MUS (retro-, trans- *or mini*-)	1 yr	MUS more effective	Bulking agent less costly	Bulking agent more cost-effective
Lier 2017	TO-MUS	RP-MUS	5 yr	TO-MUS slightly more effective	TO-MUS less costly	TO-MUS more cost-effective

Abbreviations: COI, conflict of interest; EE, economic evaluation; MUS, mid-urethral sling; NR, not reported; PVS, autologous pubovaginal sling; RCT, randomised controlled trial; RP-MUS, retropubic MUS; SUI, stress urinary incontinence; TO-MUS, transobturator MUS; yr, year.

Most of the included economic studies found that cost-effectiveness was driven by the cost of the device itself or the device procedure, so colposuspension – as a more expensive procedure than MUS – was always less cost-effective. Therefore, an accurate measure of costs for each procedure would be essential before a conclusion can be drawn regarding cost-effectiveness of MUS and other surgical options for SUI in the Australian clinical setting. It will also be critical to understand long-term complication rates, which may reduce the cost-effectiveness of MUS.

In considering the cost of the MUS procedure in the Australian setting, the main costs are for the device ($822 PL benefit) and the procedure, which has a total MBS cost of $1,287. Additional costs may include pre-surgical tests such as urodynamic analysis and post-surgical pharmaceutical costs. Estimates of hospital costs are uncertain as there is no specific AR-DRG for the procedure. As MUS insertion is often a same day procedure, the estimate of $5,020 is likely to be an overestimate; nevertheless, these costs do not accrue to the Commonwealth.

6.4 Considerations for PLAC

The evidence base supports the place of MUS in the treatment of SUI, demonstrating comparable effectiveness to alternative surgical interventions. In international analyses, MUS is cost-effective based on lower procedure costs than alternative surgical interventions. Of the two types of MUS device listed on the PL, the evidence base appears to favour RP-MUS over TO-MUS and this is consistently recommended in clinical practice guidelines. However, a role for TO-MUS appears to remain in limited clinical circumstances. Therefore, the comparative clinical effectiveness, long-term outcomes and clinical practice guidelines are

all consistent with the care pathway as specified by the ACSQHC (see **Figure 1**) (ACSQHC 2018a). On this basis, it is recommended that PLAC:

- Continue to list both RP-MUS and TO-MUS devices on the PL.
    - As both approaches are for similar clinical indications and both types of devices have similar technical characteristics there is no justification for listing them in separate groups.
    - MUS is likely to be cost-effective at the current benefit based on a lower expected procedure cost than the comparators, with similar effectiveness. The annual cost to the PL in 2021-22 was $822,000. No evidence was located to support a change to the current benefit.
- In collaboration with the TGA, continue to monitor the long-term safety of MUS based on:
    - data collected via the APFPR, when data from a sufficiently sized sample is able to ensure it is representative
    - ongoing advice from international regulators.
- In collaboration with the TGA and/or DoHAC, continue to monitor utilisation data for RP and TO MUS devices to ensure use aligns with clinical recommendations in favour of a RP-MUS approach.

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Appendix A Search strategy

A.1 Comparative clinical effectiveness

Table App. 1 Search strategy to identify comparative clinical effectiveness evidence on mid-urethral slings

Source of information	Database/website	Date limit	Search terms
Electronic databases	Epistemonikos (https://www.epistemonikos.org)	Last 5 years	mid-urethral sling midurethral sling
	Cochrane library (cochranelibrary.com/search)	Last 10 years	mid-urethral sling midurethral sling stress urinary incontinence urogynaecological mesh urogynecological mesh
HTA websites	**International** International Network of Agencies for Health Technology Assessment (INAHTA) **Australia** Australian Safety and Efficacy Register of New Interventional Procedures – Surgery (ASERNIPS) Centre for Health Economics, Monash University Medical Services Advisory Committee (MSAC) **Austria** Institute of Technology Assessment, HTA unit **Canada** Institut national d'excellence en santé et en services sociaux (INESSS) Alberta Heritage Foundation for Medical Research (AHFMR) Alberta Institute of Health Economics Canadian Agency for Drugs and Technology in Health (CADTH) The Canadian Association for Health Services and Policy Research (CAHSPR) Institute for Clinical and Evaluative Studies (ICES) Saskatchewan Health Quality Council (Canada) **Denmark** Danish National Institute Of Public Health **Finland** Finnish National Institute for Health and Welfare **Germany** Institute for Quality and Efficiency in Health Care (IQWiG) **The Netherlands** Health Council of the Netherlands (Gezondheidsraad) **New Zealand** New Zealand Health Technology Assessment (NZHTA) **Norway** New Zealand Health Technology Assessment (NZHTA) **Sweden** Center for Medical Health Technology Assessment Swedish Council on Technology Assessment in Health Care (SBU) **United Kingdom** National Health Service Health Technology Assessment/ National Coordinating Centre for Health Technology Assessment (NCCHTA) NHS Quality Improvement Scotland National Institute for Health and Care Excellence (NICE)	Last 10 years	mid-urethral sling midurethral sling stress urinary incontinence urogynaecological mesh urogynecological mesh

Source of information	Database/website	Date limit	Search terms
	University of York NHS Centre for Reviews and Dissemination (NHS CRD) **United States** Agency for Healthcare Research and Quality (AHRQ) Harvard School of Public Health Institute for Clinical and Economic Review (ICER) Institute for Clinical Systems Improvement (ICSI) Office of Health Technology Assessment Archive Veteran's Affairs Research and Development Technology Assessment Program		
Guidelines	Guidelines International Network (GIN) (https://guidelines.ebmportal.com/) National Institute for Health and Care Excellence (NICE)	Last 10 years	mid-urethral sling midurethral sling stress urinary incontinence urogynaecological mesh urogynecological mesh

A.2 Comparative cost-effectiveness

Search strings used to query EMBASE.com (which concurrently searches Medline and EMBASE) for evidence of cost effectiveness are presented in **Table App. 2**, showing the number of results taken through each step of the literature search.

The literature search (15 March 2023) returned 64 articles, of which eight were eligible for inclusion following full text review. The eight articles comprised six economic modelling studies and two comparative clinical studies (one prospective observational and one RCT). The majority of the remaining 64 results were excluded because the interventions did not match the PICO (for example, MUS versus physiotherapy; MUS versus mini-sling). Studies were only included if an economic evaluation / analysis of cost-effectiveness was presented.

Table App. 2 Search strategy to identify comparative cost effectiveness evidence on mid-urethral slings

No.	Search strings	Results	Review
#1	mid-urethral sling*':ti,ab,kw OR 'midurethral sling*':ti,ab,kw OR 'mid-urethral tape*':ti,ab,kw OR 'midurethral tape*':ti,ab,kw OR 'tension free vaginal tape'/de OR 'tension-free vaginal tape procedure'/de OR 'transobturator tape'/de	7,628	EMBASE/Medline
#2	stress incontinence'/de OR 'stress incontinence':ti,ab,kw OR 'stress urinary incontinence':ti,ab,kw	29,287	EMBASE/Medline
#3	economic evaluation'/exp OR 'health care cost'/de OR 'economic model'/exp OR 'health utility'/de OR 'economics'/de OR 'utilities' OR 'modeled evaluation' OR 'modelled evaluation'	708,877	EMBASE/Medline
#4	(((cost* OR economic OR markov) NEAR/3 (model OR analysis OR analyses)):ti,ab,kw) OR 'cost impact$':ti,ab,kw OR 'economic impact$':ti,ab,kw OR 'cost outcome$':ti,ab,kw OR 'budget impact$':ti,ab,kw	126,565	EMBASE/Medline
#5	life year$':ti,ab,kw OR qaly$:ti,ab,kw OR LYG$:ti,ab,kw	42,850	EMBASE/Medline
#6	#3 OR #4 OR #5	759,543	EMBASE/Medline
#7	#1 AND #2 AND #6	202	EMBASE/Medline
#8	#7 AND [2013-2023]/py	114	EMBASE/Medline
#9	#8 NOT ([conference abstract]/lim OR [editorial]/lim OR [letter]/lim OR [note]/lim OR [book]/lim OR 'case report'/de)	66	EMBASE/Medline
#10	#9 AND english:la AND [english]/lim	64	Abstract Screening

No.	Search strings	Results	Review
—	—	21	Full text review
—	—	8	Studies for inclusion

Appendix B NICE relevant included studies for clinical effectiveness

B.1 Study characteristics

B.1.1 Colposuspension versus MUS

Table App. 3 Summary of included RCTs for colposuspension versus MUS

Study ID	Participants	Intervention Comparator	Outcomes	Follow-up (months)
Bai 2005[1]	Grade 1 or 2 SUI N=64[2]	Open Burch colposuspension TVT	Change in continence status	12
Bandarian 2011	Incontinence surgery-naïve SUI who failed medical or conservative treatment N=62	Open Burch colposuspension TOT	AEs Complications Change in continence status Improvement in continence status	25 (mean)
El-Barky 2005	USI N=50	Open Burch colposuspension TVT	AEs	3-6
Foote 2006	USI N=97	Laparoscopic colposuspension SPARC	AEs Complications Improvement in continence status	6, 24
Liapis 2002	Incontinence surgery-naïve genuine SI and ≤ stage 1 anterior wall prolapse N=71	Open Burch colposuspension TVT	AEs Complications Change in continence status Improvement in continence status	24
Paraiso 2004/ Jelovsek 2008	Primary USI N=72	Laparoscopic colposuspension TVT	AEs Complications Change in continence status Improvement in continence status Repeat surgery	20.6 (mean)/65 (median)
Persson 2002	USI or stress-predominant MUI N=79	Laparoscopic colposuspension TVT	AEs Complications Change in continence status	12
Sivaslioglu 2007	Incontinence surgery-naïve USI N=100	Open Burch colposuspension TOT	AEs Complications Change in continence status Repeat surgery	12, 24
Trabuco 2016/2018	SUI, stress-predominant MUI, or occult SUI and apical or anterior prolapse stage ≥2 N=113	Open Burch colposuspension TVT	AEs Complications Change in continence status Improvement in continence status Repeat surgery	12/24
Ustun 2003	Proven genuine SI N=46	Laparoscopic colposuspension TVT	AEs Change in continence status	25 (mean)
Wang 2003	USI N=116	Open Burch colposuspension TVT	AEs Complications Change in continence status Improvement in continence status	22 (median)
Ward 2002/2004/2008	USI who failed PFMT N=344	Open Burch colposuspension TVT	Continence-specific HRQoL AEs Complications Change in continence status Repeat surgery	6/24/60

Source: NICE Guideline Evidence review (NICE 2019b)

Abbreviations: AE, adverse event; HRQoL, health-related quality of life; MUI, mixed urinary incontinence; PFMT, pelvic floor muscle training; RCT, randomised controlled trial; SI, stress incontinence; SPARC, retropubic top-down suprapubic arch sling; SUI, stress urinary incontinence; TOT, transobturator outside-in tape; TVT, retropubic bottom-up tension-free vaginal tape; USI, urodynamic stress incontinence.

[1] Bai was a 3-arm study (see Table App. 4 for results of rectus fascial sling (n=28) versus TVT)

[2] Sample size is for TVT and colposuspension arms only

B.1.2 Autologous rectus fascial sling versus MUS

Table App. 4 Summary of included RCTs for autologous rectus fascial sling versus MUS

Study ID	Participants	Intervention Comparator	Outcomes	Follow-up (months)
Al-Azzawi 2014	SUI or stress-predominant MUI N=80	Rectus fascial sling TOT	AEs Complications Change in continence status	12
Amaro 2009	SUI and USI N=41	Rectus fascial sling TVT	AEs Complications Change in continence status Improvement in continence status	12, 44 (median)
Bai 2005[1]	Grade 1 or 2 SUI N=59[2]	Rectus fascial sling TVT	Change in continence status	12
Guerrero 2010/ Khan 2015[3]	SUI and USI N=156[2]	Rectus fascial sling TVT	Continence-specific HRQoL AEs Complications Change in continence status Improvement in continence status Repeat surgery	12/120 (median)
Sharifiaghdas 2008/ Sharifiaghdas 2017	History of SUI and USI N=100	Rectus fascial sling TVT	AEs Complications Change in continence status Improvement in continence status Repeat surgery	12, 39 (mean)/126 (mean)
Teleb 2011[4]	Primary SUI and USI N=24[2]	Rectus fascial sling TVT	AEs Complications Change in continence status Improvement in continence status	18 (mean)
Wadie 2005	Primary SUI N=53	Rectus fascial sling TVT	AEs Complications Change in continence status	6
Wadie 2010	SUI N=63	Rectus fascial sling TVT	AEs Complications Change in continence status	54 (median)

Source: NICE Guideline Evidence review (NICE 2019b)

Abbreviations: AE, adverse event; HRQoL, health-related quality of life; MUI, mixed urinary incontinence; SUI, stress urinary incontinence; TOT, transobturator outside-in mesh sling; TVT, retropubic bottom-up tension-free vaginal mesh sling; USI, urodynamic stress incontinence.

[1] Bai 2005 was a 3-arm study (see Table App. 3 for results of Burch colposuspension (n=33) versus TVT)

[2] Sample size is for TVT and rectus fascial sling arms only

[3] Guerrero 2010 was a 3-arm study (porcine dermis sling comparator out of scope for current review)

[4] Teleb 2011 was a 3-arm study (vaginal wall sling comparator out of scope for current review)

B.1.3 TO-MUS versus RP-MUS

Table App. 5 Summary of included RCTs for TO-MUS versus RP-MUS

Study ID	Participants	Intervention Comparator	Outcomes	Follow-up (months)
Aigmuller 2014/ Tammaa 2017	Incontinence surgery-naïve USI N=569	TVT-O TVT	Continence-specific HRQoL AEs Complications Change in continence status Repeat surgery	3/60
Alkady 2009	Pure USI or mixed UI without Urodynamically confirmed contraction N=30	TVT-O TVT	AEs Complications Change in continence status Repeat surgery	12
Andonian 2007	SUI or stress-predominant MUI N=190	TOT TVT or DUPS	Continence-specific HRQoL AEs Complications Change in continence status Repeat surgery	12

Study ID	Participants	Intervention Comparator	Outcomes	Follow-up (months)
Aniuliene 2009	SUI and no OAB N=264	TVT-O TVT	AEs Complications Change in continence status	12
Aniuliene 2015	History of SUI, USI and no predominant-OAB N=154	SLING-IUFT TVT-EXACT	AEs Complications Change in continence status	12
Araco 2008	Symptomatic Grade 1 or 2 SUI and no OAB N=240	TVT-O TVT	AEs Complications Change in continence status Repeat surgery	12
Barber 2008	USI and no DO N=170	TOT TVT	AEs Complications Change in continence status Improvement in continence status Repeat surgery	18.2 (mean)
Barry 2008	Symptomatic SUI who failed conservative treatment or surgery for occult SUI during POP repair N=187	TOT TVT	AEs Complications Change in continence status Repeat surgery	3
David-Montefiore 2006/ Darai 2007/ Ballester 2012	SUI and USI N=88	TOT TVT	AEs Complications Change in continence status	10 (mean)/52.9 (mean)
Deffieux 2010	USI or MUI, and positive cough stress test N=149	TVT-O TVT	AEs Complications Change in continence status Improvement in continence status Repeat surgery	12, 2
El-Hefnawy 2010	USI N=40	TOT TVT	AEs Complications Change in continence status Repeat surgery	19.7 (mean)
Feng 2018	SUI and USI N=148	TVT-ABBREVO TVT-EXACT	Continence-specific HRQoL AEs Complications Change in continence status Repeat surgery	6, 12, 24
Freeman 2011	USI or stress-predominant MUI who failed PFMT N=192	TOT TVT	Continence-specific HRQoL AEs Complications Change in continence status Repeat surgery	12
Jakimuk 2012	Incontinence surgery-naïve USI N=35	TVT-O TVT	Continence-specific HRQoL AEs Complications Change in continence status	6
Karateke 2009	Incontinence surgery-naïve USI and no DO or OAB N=167	TVT-O TVT	AEs Complications Change in continence status	12, 14 (mean)
Krofta 2010	Incontinence and prolapse surgery naïve USI who failed conservative treatment N=300	TVT-O TVT	Continence-specific HRQoL AEs Complications Change in continence status Repeat surgery	12
Laurikainen 2007/ Rinne 2008/ Laurikainen 2014	History of SUI, positive cough stress test, detrusor instability score ≤7 N=273	TVT-O TVT	AEs Complications Change in continence status Repeat surgery	2/12/60

Study ID	Participants	Intervention Comparator	Outcomes	Follow-up (months)
Liapis 2006	Incontinence surgery-naïve SUI and no OAB N=91	TVT-O TVT	AEs Complications Change in continence status Repeat surgery	12
Meschia 2007	Incontinence surgery-naïve SUI, urethral hypermobility and no DO N=231	TVT-O TVT	Continence-specific HRQoL AEs Complications Change in continence status	6 (median)
Nyyssonen 2014	SUI or stress-predominant MUI who failed conservative treatment N=100	TOT TVT	AEs Complications Change in continence status Improvement in continence status	14 (median), 46 (median)
Palos 2018	Incontinence surgery-naïve USI N=92	TOT Unitape VS	AEs Complications Change in continence status Repeat surgery	12
Porena 2007/ Costantini 2016	Incontinence surgery-naïve SUI or stress-predominant MUI N=148	TOT TVT	AEs Complications Change in continence status Repeat surgery	35 (median)/100 (median)
Rechberger 2009	SUI N=537	IVS-04 IVS-02	AEs Complications Change in continence status Improvement in continence status Repeat surgery	18
Richter 2010/ Brubaker 2011/ Albo 2012/ Wai 2013/ Kenton 2015 / Zyczynski 2012	SUI N=597	TOT or TVT-O TVT	Continence-specific HRQoL AEs Complications Change in continence status	12/24/60
Ross 2009/2016	Incontinence surgery-naïve SUI, positive cough stress test and no OAB N=199	TOT TVT	Continence-specific HRQoL AEs Complications Change in continence status Repeat surgery	12/60
Scheiner 2012	Incontinence surgery-naïve USI or stress-predominant MUI N=160	TOT or TVT-O TVT	Continence-specific HRQoL AEs Complications Change in continence status Repeat surgery	12.6 (mean)
Schierlitz 2008/2012	SUI and ISD who failed conservative treatment N=164	TOT TVT	AEs Complications Change in continence status Repeat surgery	6/36
Shirvan 2014	Stress-predominant UI and positive cough stress test who failed conservative treatment N=100	TOT TVT	Continence-specific HRQoL AEs Complications Change in continence status	12, 18
Tanuri 2010	SUI N=30	TOT Retropubic midurethral sling	Continence-specific HRQoL AEs Complications Change in continence status	12
Tarcan 2014	Pure or stress dominant USI N=54	Obtryx-TO Advantage	AEs Complications	48.5 (median)
Teo 2011	Incontinence surgery-naïve USI and no DO N=127	TVT-O TVT	AEs Complications Change in continence status Repeat surgery	12

Study ID	Participants	Intervention Comparator	Outcomes	Follow-up (months)
Ugurlucan 2013b	SUI or MUI N=36	TVT-O TVT	AEs Complications Change in continence status Improvement in continence status	18.4 (mean)
Wadie 2013	Stress-predominant UI and positive stress test N=87	TOT TVT	AEs Complications Change in continence status	12, 24
Wang 2006	Incontinence surgery-naïve USI N=60	TOT SPARC	AEs Complications	9 (median)
Wang 2009	Mild, moderate or severe SUI who failed conservative treatment N=315	TVT-O TVT	AEs Complications Change in continence status	20 (median)
Wang 2010	USI N=140	TOT TVT	AEs Complications Change in continence status	12
Wang 2011[1]	Incontinence surgery-naïve stress-predominant MUI N=68	TVT-O TVT	AEs Complications	12
Zhang 2016	Symptomatic SUI and no ISD N=140	TVT-O TVT	AEs Complications Change in continence status Repeat surgery	95 (mean)
Zhu 2007	Mild or moderate SUI who failed conservative treatment N=56	TVT-O TVT	AEs Complications Change in continence status Improvement in continence status	27.6 (median)
Zullo 2007/ Angioli 2010	SUI and no OAB, ISD or DO N=72	TVT-O TVT	AEs Complications Change in continence status Repeat surgery	16 (median)/60 (median)

Source: NICE Guideline Evidence review (NICE 2019b)

Abbreviations: AE, adverse event; DO, detrusor overactivity; DUPS, retropubic distal urethral polypropylene sling; HRQoL, health-related quality of life; MUI, mixed urinary incontinence; OAB, overactive bladder; ISD, intrinsic sphincter deficiency; PFMT, pelvic floor muscle training; SUI, stress urinary incontinence; TOT, transobturator outside-in tape; TVT, retropubic bottom-up tension-free tape; TVT-O, transobturator inside-out tape; USI, urodynamic stress incontinence.

[1] Wang 2011 was a 3-arm trial (single-incision mini-sling arm out of scope for this review). Sample size is for transobturator and retropubic arms only.

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Appendix C NMA included studies for clinical effectiveness (Brazzelli 2019)

C.1 Study characteristics

C.1.1 Open colposuspension versus RP-MUS

Table App. 6 Summary of included RCTs for open colposuspension versus RP-MUS

Study ID	Participants	Outcomes	Length of or last follow-up (months)
Bai 2005 (ID:145)	USI (DO excluded) N=92[1]	Cure Improvement	12
Drahoradova 2004 (ID: 46)	SUI N=139	Cure Improvement	12
El-Barky 2005 (ID: 201)	USI only (no MUI) N=50	Cure Improvement	24
Téllez Martínez-Fornés 2009 (ID: 202)	USI (OAB excluded) N=49	Cure Improvement	36
Trabuco 2014 (ID: 32)	SUI, predominant SUI N=113	Cure Improvement	6
Wang 2003 (ID: 203)	USI N=98	Cure Improvement	22
Ward 2002 (ID: 100)	USI (DO excluded) N=344	Cure Improvement	60

Source: (Brazzelli 2019)

Abbreviations: DO, detrusor overactivity; MUI, mixed urinary incontinence; MUS, mid-urethral sling; OAB, overactive bladder; RCT, randomised controlled trial; SUI, stress urinary incontinence; USI, urodynamic stress incontinence; UUI, urge urinary incontinence.

[1] Three-arm trial of RP-MUS, open colposuspension and traditional sling. N = total participants across all three arms.

C.1.2 Laparoscopic colposuspension versus RP-MUS

Table App. 7 Summary of included RCTs for laparoscopic colposuspension versus RP-MUS

Study ID	Participants	Outcomes	Length of or last follow-up (months)
Foote 2006 (ID: 146)	USI (DO excluded) N=97	Improvement	28.8
Maher 2004 (ID: 63)	SUI N=82	Cure Improvement	6
Paraiso 2004 (ID: 147)	USI (DO excluded) N=72	Cure Improvement	65
Valpas 2006 (ID: 279)[1]	N/A	Improvement	N/A

Source: (Brazzelli 2019)

Abbreviations: DO, detrusor overactivity; USI, urodynamic stress incontinence; MUS, mid-urethral sling; RP, retropubic; RCT, randomised controlled trial.

[1] Unclear if Valpas 2006 is correctly cited in source as this is a cost-effectiveness study.

C.1.3 Open colposuspension versus TO-MUS

Table App. 8 Summary of included RCTs for open colposuspension versus TO-MUS

Study ID	Participants	Outcomes	Length of or last follow-up (months)
Sivaslioglu 2007 (ID: 162)	USI only (no UUI) N=100	Cure Improvement	24

Source: (Brazzelli 2019)

Abbreviations: MUS, mid-urethral sling; RCT, randomised controlled trial; TO, transobturator; USI, urodynamic stress incontinence; UUI, urge urinary incontinence.

C.1.4 TO-MUS versus RP-MUS

Table App. 9 Summary of included RCTs for TO-MUS versus RP-MUS

Study ID	Participants	Outcomes	Length of or last follow-up (months)
Aigmuller 2014 (ID: 83)	USI (DO or predominant OAB excluded) N=554	Cure Improvement	3
Alkady 2009 (ID: 120)	USI, SUI, MUI (DO excluded) N=30	Cure Improvement	12
Andonian 2007 (ID: 117)	SUI, MUI N=190	Cure Improvement	12
Aniuliene 2009 (ID: 84)	SUI (OAB excluded) N=264	Cure Improvement	12
Aniuliene 2015 (ID: 121)	SUI (predominant OAB excluded) N=154	Cure Improvement	12
Araco 2008 (ID: 86)	SUI (OAB excluded) N=240	Cure Improvement	12
Barber 2008 (ID: 122)	USI, MUI (DO excluded) N=170	Cure	24
Barry 2008 (ID: 123)	USI (some had OAB) N=187	Improvement	3
David-Montefiore 2006 (ID: 124)	USI, MUI N=88	Cure Improvement	48
de Oliveira 2006 (ID: 44)	SUI N=83	Cure Improvement	12
de Tayrac 2004 (ID: 125)	USI, predominant SUI N=61	Cure Improvement	12
Deffieux 2010 (ID: 126)	USI, MUI N=149	Cure Improvement	24
El-Hefnawy 2010 (ID: 127)	USI, predominant SUI N=87	Cure Improvement	24
Freeman 2011 (ID: 128)	USI, predominant SUI N=192	Cure Improvement	12
Hammoud 2011 (ID: 56)	SUI, MUI N=110	Cure Improvement	NR
Jakimiuk 2012 (ID: 129)	USI only (no MUI) N=35	Cure Improvement	6
Kamel 2009 (ID: 58)	USI N=120	Cure Improvement	NR
Karateke 2009 (ID: 130)	USI (DO/OAB excluded) N=167	Cure Improvement	NR
Kiliç 2007 (ID: 131)	USI N=20	Improvement	12

Study ID	Participants	Outcomes	Length of or last follow-up (months)
Kim 2005 (ID: 132)	SUI N=130	Cure Improvement	3
Krofta 2010 (ID: 94)	SUI only (no UUI) N=300	Cure Improvement	12
Laurikainen 2007 (ID: 96)	SUI N=273 randomised; N=268 analysed	Improvement	60
Lee 2007 (ID: 107)	USI, predominant SUI N=120	Cure Improvement	13
Liapis 2006 (ID: 133)	SUI (OAB/DO excluded) N=89	Cure Improvement	12
Mansoor 2003 (ID: 64)	SUI N=102	Cure Improvement	6
Meschia 2007 (ID: 97)	USI (DO excluded) N=231	Cure Improvement	6
Nerli 2009 (ID: 110)	SUI, predominant SUI N=36	Cure Improvement	12
Nyyssonen 2014 (ID: 135)	SUI, predominant SUI N=100	Cure Improvement	46
Rechberger 2009 (ID: 98)	SUI N=537	Cure Improvement	18
Richter 2010 (ID: 99)	SUI, predominant SUI N=597	Cure Improvement	60
Riva 2006 (ID: 71)	SUI N=131	Cure Improvement	12
Ross 2009 (ID: 137)	SUI (UUI included; OAB excluded) N=199	Cure Improvement	60
Rudnicki 2016 (ID: 72)	SUI, predominant SUI N=305[1]	Improvement	12
Scheiner 2012 (ID: 119)	SUI, predominant SUI N=160	Cure Improvement	12
Schierlitz 2008 (ID: 138)	USI N=164	Cure Improvement	63
Tanuri 2010 (ID: 139)	SUI only N=30	Cure Improvement	12
Tarcan 2011 (ID: 31)	USI, predominant SUI N=54	Cure Improvement	12
Teo 2011 (ID: 140)	USI (DO excluded) N=127	Cure Improvement	12
Wang 2009 (ID: 37)	USI only (no UUI) N=315	Improvement	20
Wang 2010 (ID: 142)	USI only (no UUI) N=140	Cure Improvement	12
Wang 2011 (ID: 116)	SUI, predominant SUI N=108 randomised[2], N=102 followed-up[2]	Cure	12
Zullo 2007 (ID: 144)	SUI (DO/OAB excluded) N=72	Cure Improvement	60

Source: (Brazzelli 2019)

Abbreviations: DO, detrusor overactivity; MUI, mixed urinary incontinence; MUS, mid-urethral sling; NR, not reported; OAB, overactive bladder; RCT, randomised controlled trial; RP, retropubic; SUI, stress urinary incontinence; TO, transobturator; USI, urodynamic stress incontinence; UUI, urge urinary incontinence.

[1] Three-arm trial of RP-MUS, TO-MUS and single-incision mini-sling. N = total participants across all three arms.

[2] Three-arm trial of RP-MUS, TO-MUS and single-incision mini-sling. N = total participants across all three arms.

Note: Barber 2008 (ID: 87) included in source but unable to identify corresponding reference.

C.2 References

C.2.1 Open colposuspension versus RP-MUS

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C.2.4 TO-MUS versus RP-MUS

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Appendix D NICE included studies for long-term complications

Table App. 10 Summary of studies with relevant interventions and long-term (>5 years) complication data

Surgery type/s	Study ID	Study type N	Outcomes	Follow-up (months)	Study quality
SYNTHETIC MESH SLING					
Retropubic	Aigmuller 2011	Case series N=141	De novo urgency	115.7 (mean)	Serious risk of bias
Retropubic	Ala-Nissila 2010	Prospective cohort N=130	POP occurrence	96 (mean)	Serious risk of bias
Retropubic	Betschart 2011	Retrospective cohort N=422	Mesh extrusion Infection	66	Serious risk of bias
Retropubic	Braga 2018	Case series N=52	Mesh erosion De novo urge incontinence POP occurrence	204	Serious risk of bias
Retropubic	Chevrot 2016	Case series N=463	Pain Mesh exposure Infection De novo urge incontinence	71 (mean)	Serious risk of bias
Retropubic	Doo 2006	Case series N=134	Pain Need for catheterisation Infection	67 (mean)	Serious risk of bias
Retropubic	Han 2014	Case series N=88	Pain Need for catheterisation De novo urge incontinence De novo urgency	144	Serious risk of bias
Retropubic	Heinonen 2013	Case series N=138	Pain Infection	126.5 (mean)	Serious risk of bias
Retropubic	Holmgreen 2007	Case series N=463	Pain Infection De novo urgency	62.4 (median)	Serious risk of bias
Retropubic	Kuuva 2006	Case series N=129	Mesh extrusion Infection De novo urge incontinence	72 (median)	Serious risk of bias
Retropubic	Lee 2010	Case series N=107	De novo urge incontinence De novo urgency	72	Serious risk of bias

Surgery type/s	Study ID	Study type N	Outcomes	Follow-up (months)	Study quality
Retropubic	Nilsson 2004, 2008, 2013	Case series N=80	Infection De novo urge incontinence POP occurrence Mesh extrusion Need for catheterisation Mesh extrusion POP occurrence	91 (mean) 141 (median) 201 (mean)	Serious risk of bias
Retropubic	Olsson 2010	Case series N=124	De novo urge incontinence POP occurrence	138 (median)	Serious risk of bias
Retropubic	Reich 2011	Case series N=108	Pain Mesh extrusion Infection De novo urge incontinence POP occurrence	102 (median)	Serious risk of bias
Retropubic	Schauer 2017	Case series N=139	De novo urge incontinence	120	Serious risk of bias
Retropubic	Serati 2017b	Case series N=55	Pain Mesh extrusion De novo urge incontinence POP occurrence	156	Serious risk of bias
Retropubic	Song 2017	Case series N=206	Mesh extrusion De novo urgency	162.4 (mean)	Serious risk of bias
Retropubic	Svenningsen 2013	Case series N=327	Mesh extrusion Infection De novo urge incontinence	129 (median)	Serious risk of bias
Retropubic	Tsivian 2006	Case series N=81	Mesh extrusion Infection De novo urgency	65 (median)	Serious risk of bias
Transobturator	Abougamrah 2015	Prospective cohort N=431	Pain Mesh extrusion De novo urgency	79 (generic transobturator tape), 87 (Monarc TOT)	Serious risk of bias
Transobturator	Athanasiou 2014	Case series N=124	Mesh extrusion De novo urge incontinence	90.3	Serious risk of bias
Transobturator	Chun 2014	Retrospective cohort N=215	Pain Infection De novo urge incontinence	85.2 (median)	Serious risk of bias
Transobturator	Montera 2018	Case series N=50	Pain Mesh extrusion	126 (median)	Serious risk of bias

Surgery type/s	Study ID	Study type N	Outcomes	Follow-up (months)	Study quality
Transobturator	Serati 2017a	Case series N=160	Pain Mesh extrusion De novo urge incontinence POP occurrence	120	Serious risk of bias
Transobturator	Sivaslioglu 2010	RCT N=80	Pain Mesh extrusion	64	Unclear risk of bias
Transobturator	Tutolo 2017	Retrospective cohort N=381	Mesh extrusion De novo urge incontinence	65 (mean)	Serious risk of bias
Transobturator	Ulrich 2016	Case series N=71	Pain Mesh extrusion De novo urge incontinence	120	Serious risk of bias
Retropubic, transobturator	Al-Zahrani 2016	Retrospective cohort N=330	Mesh extrusion De novo urge incontinence De novo urgency	128.4 (transobturator), 153.6 (retropubic)	Serious risk of bias
Retropubic, transobturator	Porena 2007	RCT N=148	Pain Infection POP occurrence Wound complications	100 (median)	High risk of bias
Retropubic, transobturator	Zhang 2016	RCT N=140	Pain Infection	95 (mean)	Unclear risk of bias
COLPOSUSPENSION					
Method not specified	Alcalay 1995	Case series N=109	Infection De novo urge incontinence De novo urgency POP occurrence	165.6 (mean)	Serious risk of bias
Method not specified	Kjolhede 2005	Case series N=192	Infection	168 (median)	Serious risk of bias
Laparoscopic	Antovska 2013	Prospective cohort N=145	Fistula	103.6 (mean)	Serious risk of bias
Open	Greenwell 2015	Retrospective cohort N=96	Need for catheterisation De novo urge incontinence POP occurrence	108.5 (median)	Serious risk of bias
Open	Ladwig 2004	Case series N=374	Infection De novo frequency De novo urgency De novo nocturia	110.4 (median)	Serious risk of bias
Open	Riggs 1986	Case series N=719	Fistula Infection Wound complications	192 (mean)	Serious risk of bias

Surgery type/s	Study ID	Study type N	Outcomes	Follow-up (months)	Study quality
PUBOVAGINAL SLING					
Autologous rectus fascial sling	Hawkins 2002	Case series N=132	Pain Need for catheterisation Infection	72 (median)	Serious risk of bias
VARIOUS					
Retropubic synthetic mesh sling, open colposuspension	Holdo 2017	Retrospective cohort N=614	Mesh extrusion Need for catheterisation	≤ 144	Serious risk of bias
Retropubic synthetic mesh sling, autologous rectus fascial sling	Guerrero 2010	RCT N=211	Pain Mesh extrusion Need for catheterisation De novo urgency	120 (median)	Low risk of bias
Retropubic synthetic mesh sling, autologous rectus fascial sling	Sharifiaghdas 2008	RCT N=100	Pain De novo urgency De novo urge incontinence Wound complications	126 (mean)	High risk of bias

Source: (NICE 2019b) Table 11, p48

Appendix E Clinical practice guidelines and position statements

Table App. 11 Summary of clinical practice guidelines and position statements addressing MUS for the treatment of SUI

Title *Developer* Date	Recommendation development methodology	Key points
Management of non-neurogenic female lower urinary tract symptoms *European Association of Urology* March 2023 (Harding 2023)	Systematic evidence search focussed on high-level evidence (SRs and meta-analysis). De novo SR conducted on overactive bladder syndrome. Strength of recommendations reported as strong or weak drawing from guiding principles of GRADE methodology.	**Recommendations** • Offer patients who have explored/failed conservative treatment options a choice of different surgical procedures, where appropriate, and discuss the advantages and disadvantages of each approach. (Strong recommendation) • Employ a shared decision-making approach when deciding on appropriate treatment for SUI. (Strong recommendation) • Offer colposuspension (open or laparoscopic) to women seeking surgical treatment for SUI following a thorough discussion of the risks and benefits relative to other surgical modalities. (Strong recommendation) • Offer autologous sling placement to women seeking surgical treatment for stress urinary incontinence following a thorough discussion of the risks and benefits relative to other surgical modalities. (Strong recommendation) • Offer urethral bulking agents to women seeking surgical treatment for stress urinary incontinence (SUI) following a thorough discussion of the risks and benefits relative to other surgical modalities. (Strong recommendation) • Offer urethral bulking agents to women with SUI who request a low-risk procedure with the understanding that efficacy is lower than other surgical procedures, repeat injections are likely, and long-term durability and safety are not established. (Strong recommendation) • Do not offer autologous fat and hyaluronic acid as urethral bulking agents due to the higher risk of adverse events. (Strong recommendation) • Offer a mid-urethral sling (MUS) to women seeking surgical treatment for stress urinary incontinence following a thorough discussion of the risks and benefits relative to other surgical modalities. (Strong recommendation) • Inform women that long-term outcomes from MUS inserted by the retropubic route are superior to those inserted via the transobturator route. (Strong recommendation) • Inform women of the complications associated with MUS procedures and discuss all alternative treatments in the light of recent publicity surrounding surgical mesh. (Strong recommendation)
FIGO recommendations: Use of midurethral slings for the treatment of stress urinary incontinence *International Federation of Gynecology and Obstetrics (FIGO)* 2023 (Lau 2023)	Recommendations developed based on the NICE manual, the SIGN 50 handbook, the Taiwan Clinical Practice Guidelines Development and Update Manual, and other guideline development manuals. Systematic evidence search conducted. Questions assigned to Task Force subgroups. LOE assigned according to University of Oxford Centre for Evidence-based Medicine framework. EBRs classified as strong (Grade 1) or weak (Grade 2) by GRADE working group.	**MUS Recommendations** • The surgical gold standard for SUI is represented by MUS (LOE 3, grade 1C) • MUS has a high efficacy in subjective and objective cure rates among patients with SUI, especially retropubic and transobturator MUS (LOE 1, grade 1A) • The effectiveness and safety of MUS has been reported in systematic reviews, with a follow-up time of up to 12 months (LOE 1, grade 1A) • Long follow-up data of retropubic MUS of up to 17 years have been reported with good efficacy (LOE 4, grade 1D) **MUS vs Burch colposuspension and PVS** • The treatment of SUI with MUS is preferable to a Burch colposuspension and PVS, due to similar or superior cure rates but reduced morbidity, and shorter operative time and length of hospital stay (LOE 1, grade 1A) • There are no differences in de novo urgency or urgency incontinence, voiding difficulties, and complications between the Burch colposuspension, PVS and retropubic MUS (LOE 1, grade 1A) • Retropubic MUS had higher rates of bladder perforation compared with Burch colposuspension and PVS (LOE 1, grade 1A) **Retropubic MUS vs Transobturator MUS**

Title *Developer* Date	Recommendation development methodology	Key points
	Example: grade 1A = strong recommendation with high-quality evidence, grade 2D = weak recommendation with very low-quality evidence.	• Patients treated with retropubic MUS have higher subjective and objective cure rates than those treated with transobturator MUS, especially in those with more severe SUI and ISD (LOE 1, grade 1A) • Compared with retropubic MUS, transobturator MUS has a lower risk of intraoperative bladder or vaginal perforation, major vascular complications and pelvic hematoma, a lower rate of suprapubic pain, UTI, voiding dysfunction, and LUT symptoms (LUTS) (LOE 1, grade 1A) • The safety profile of these procedures has shown that transobturator MUS has a higher rate of repeat procedures and a higher occurrence of groin pain than retropubic MUS (LOE 1, grade 1A) • The rate of tape or mesh exposure/extrusion along the mid-vagina is similar between retropubic MUS and transobturator MUS (LOE 1, grade 1A) **Recurrent SUI** • Repeat anti-incontinence surgery (including MUS) for recurrent or persistent SUI has a lower cure rate than primary procedures (LOE 3, grade 1C) • Both the retropubic and transobturator MUS can be effective in treating recurrent SUI. However, there is a higher cure rate with the retropubic MUS than the transobturator MUS (LOE 2, grade 1B) **Complications** • The incidence of major vascular injury and operative blood loss are higher in retropubic MUS sling procedures (LOE 1, grade 1B) • After a MUS, the reported incidence of de novo OAB is approximately 9%. However, there is no reported difference between the retropubic MUS, transobturator MUS, and SIS (LOE 2, grade 1B)
Position statement on midurethral slings *The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZOG)* March 2022 (RANZCOG 2020, amended 2022)	Developed by the RANZCOG Women's Health Committee. Methodology not reported.	**Recommendation 1** (Evidence based recommendation Grade A): MUS surgery is a recommended surgical procedure for SUI in routine cases **Recommendation 2** (Consensus based recommendation): It is recommended that the transobturator approach should only be offered in exceptional circumstances and following discussion in a multi-disciplinary or peer review forum. **Good practice point**: Local credentialling, provision of written information (particularly from the Australian Commission of Safety and Quality in Health Care); Clinical Audit (logging of cases and follow-up) and Patient Reported outcomes are essential for gynaecologists undertaking MUS procedures • The surgeon should discuss the type of MUS (including the sling material and proposed route), risks, success rates and alternative surgical procedures with the patient considering surgery. Discussion of alternative surgical approaches should include success rates, recovery time, longevity and complications. Reference to the class action relating to gynaecological mesh is needed as part of this discussion. • Patients should only be offered MUS surgery following failure of conservative treatment (i.e. pelvic floor exercises and bladder retraining). • Monitoring efficacy and safety should include: logging outcomes in a registry, regulatory reporting of adverse events, providing details of the product (including batch number and information for use) to the patient, a minimum patient follow-up of 6 months with appropriate documentation of outcomes. • Surgeons performing MUS procedures need to be appropriately trained to perform the surgery and manage any possible complications. • *"RANZCOG supports the use of synthetic MUS for surgical treatment when conservative treatment has been unsuccessful"* (p8)
Position Statement on the use of the transobturator approach in incontinence surgery	Not reported	• The Roundtable *"recommends that the transobturator approach only be offered in exceptional circumstances and following discussion in a multi-disciplinary or peer review forum"*. This advice is consistent with NICE guideline NG123 (NICE 2019c) recommendation 1.5.10 "*Do not offer a transobturator approach unless there are specific clinical circumstances (for example, previous pelvic procedures) in which the retropubic approach should be avoided."* (p28)

Title *Developer* Date	Recommendation development methodology	Key points
Surgical Mesh Roundtable[1] December 2020 (*Position Statement on the use of the transobturator approach in incontinence surgery* 2020)		
Position statement on the use of vaginal mesh for the surgical treatment of stress urinary incontinence (SUI) *American Urological Association* May 2019 (AUA 2019)	Not reported	• Midurethral slings are a suitable treatment option for SUI in appropriately selected patients under the following circumstances: o The surgeon is rigorously trained in the principles of pelvic anatomy and pelvic surgery, the placement of the sling device, and the recognition and management of potential complications o The patient is appropriately counselled by the surgeon about the procedure o The physician must discuss the risks and benefits of mesh, as well as alternative options to mesh
Urinary incontinence and pelvic organ prolapse in women: management *National Institute of Health and Care Excellence (NICE)* April 2019 (NICE 2019c)	NICE methods (Developing NICE Guidelines: the manual 2014) Systematic evidence review. Evidence from RCTs summarised using GRADE profiles. Data from non-comparative observational studies (on long-term complications) summarised and presented as weighted averages. NMA by Brazzelli et al. considered by guideline committee.	**Recommendation 1.5.1** If a woman is thinking about a surgical procedure for stress urinary incontinence, use the NICE patient decision aid on surgery for stress urinary incontinence to promote informed preference and shared decision making. Discussion with the woman should include: • the benefits and risks of all surgical treatment options for stress urinary incontinence that NICE recommends, whether or not they are available locally • the uncertainties about the long-term adverse effects for all procedures, particularly those involving the implantation of mesh materials • differences between procedures in the type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery period • any social or psychological factors that may affect the woman's decision. [2013, amended 2019] **Recommendation 1.5.2** If non-surgical management for stress urinary incontinence has failed, and the woman wishes to think about a surgical procedure, offer her the choice of: • colposuspension (open or laparoscopic) or • an autologous rectus fascial sling. Also include the option of a retropubic mid-urethral mesh sling in this choice but see the recommendations in the section on mid-urethral mesh sling procedures for additional guidance on the use of mid-urethral mesh sling procedures for stress urinary incontinence. [2019]

Title *Developer* Date	Recommendation development methodology	Key points
		Recommendation 1.5.3 Consider intramural bulking agents to manage stress urinary incontinence if alternative surgical procedures are not suitable for or acceptable to the woman. Explain to the woman that: • these are permanent injectable materials • repeat injections may be needed to achieve effectiveness • limited evidence suggests that they are less effective than the surgical procedures listed in recommendation 1.5.2 and the effects wear off over time • there is limited evidence on long-term effectiveness and adverse events. [2019] **Recommendation 1.5.4** If an intramural bulking agent is injected, give the woman written information about the bulking agent, including its name, manufacturer, date of injection, and the injecting surgeon's name and contact details. [2019] **Recommendation 1.5.5** If the woman's chosen procedure for stress urinary incontinence is not available from the consulting surgeon, refer her to an alternative surgeon. [2019] **Recommendation 1.5.6** Providers must ensure that data on surgical procedures for stress urinary incontinence are recorded in a national registry, as outlined in the section on collecting data on surgery and surgical complications in this guideline. [2019] **Mid-urethral mesh sling procedures** **Recommendation 1.5.7** When offering a retropubic mid-urethral mesh sling, advise the woman that it is a permanent implant and complete removal might not be possible. [2019] **Recommendation 1.5.8** If a retropubic mid-urethral mesh sling is inserted, give the woman written information about the implant, including its name, manufacturer, date of insertion, and the implanting surgeon's name and contact details. [2019] **Recommendation 1.5.9** When planning a retropubic mid-urethral mesh sling procedure, surgeons should: • use a device manufactured from type 1 macroporous polypropylene mesh • consider using a retropubic mid-urethral mesh sling coloured for high visibility, for ease of insertion and revision. [2013, amended 2019] **Recommendation 1.5.10** Do not offer a transobturator approach unless there are specific clinical circumstances (for example, previous pelvic procedures) in which the retropubic approach should be avoided. [2019] **Recommendation 1.5.11** Do not use the 'top-down' retropubic mid-urethral mesh sling approach or single-incision sub-urethral short mesh sling insertion except as part of a clinical trial. [2019]
Position statement. Mesh midurethral slings for stress urinary incontinence *American Urogynecologic Society (AUGS); Society of*	Developed by a joint task force between AUGS and SUFU. Methodology not reported.	• *"The purpose of this position statement by the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) is to support the use of the midurethral sling in the surgical management of stress urinary incontinence"* (p1) • *"This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence."* (p2)

Title *Developer* Date	Recommendation development methodology	Key points
Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) February 2018 (*Position Statement Mesh Midurethral Slings for Stress Urinary Incontinence* 2018)		
Care pathway for the Management of Stress Urinary Incontinence (SUI) *Australian Commission on Safety and Quality in Health Care (ACSQHC)* 2018 (ACSQHC 2018a)	Adapted from UGSA Surgical treatment of SUI pathway (2016). Grade of Recommendation derived from the 5th International Consultation on Incontinence (see Int Urogynecol J. 2013 Nov;24(11):1781) and expert opinion.	**Mid-urethral sling (synthetic mesh)** • The most extensively researched option for SUI establishing efficacy and safety profile (Grade A) • As effective or more effective than colposuspension or pubovaginal sling with less perioperative and post-operative morbidity (Grade B) • Recommended surgical treatment female SUI (Grade C) **Retropubic versus transobturator mid-urethral sling** • In the short-term there are similar success rates for retropubic and transobturator mid urethral slings (Grade A) • Obturator tapes are slightly quicker, with less blood loss, bladder perforation and voiding dysfunction difficulties. Most of these differences were small and the complications are readily able to be managed. (Grade A) • However in the medium-term (>5 years) the reoperation for recurrent SUI greater in obturator group and a small number developed groin pain (3-4%) that is difficult to treat. (Grade B) • Retropubic considered as the preferred procedure with transobturator reserved for those patients with a hostile abdomen (Grade C) **Bulking agent** • May be a useful option for recurrent SUI with a well supported urethra (Grade B) • Greater symptomatic improvement was observed with surgical treatments, although the advantage needs to be balanced against risk of intervention (Grade C) • Consider in women wishing to avoid mesh-related complications (ungraded) **Colposuspension (native tissue)** • Inferior outcomes to pubovaginal slings for primary repair, possibly with less voiding dysfunction (Grade B) • Outcomes similar or slightly less than synthetic MUS however longer operating time and recovery, slower return to activities of daily living and more prolapse in medium-term (Grade B) • Laparoscopic approach when performed same technique as open has similar success rate with less morbidity than open approach (Grade B) • Lower rates of success, with higher retreatment rates, when compared to pubovaginal slings for primary repair (Grade B) **Pubovaginal sling (native tissue)** • Similar success rates compared to MUS with longer operating time and possibly higher voiding dysfunction; fascial sling has lower rates of chronic pelvic pain, no risk of erosion or extrusion, and higher rates of post-operative morbidity (Grade B) • Lower rate of bladder perforation during surgery compared to MUS. (Grade B) • Fascial sling has higher patient satisfaction and treatment success compared to colposuspension (Grade B)

Title *Developer* Date	Recommendation development methodology	Key points
		• Involves a longer operation, post-operative hospital stay (2–3 days) and recovery period than MUS (Grade B) • Consider in women wishing to avoid mesh-related complications (ungraded)
Position statement. Mesh midurethral slings *Urological Society of Australia and New Zealand (USANZ)* August 2015 (USANZ 2015)	Drawn in part from AUGS, UGSA and the International Urogynaecological Society and the Urogynaecological Society of Australasia statements on mid-urethral slings.	• *"USANZ acknowledges that the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence is a reasonable treatment option."* (p1)
Position statement on mid-urethral slings for stress urinary incontinence *International Urogynecological Association (IUGA)* July 2014 (IUGA 2014)	Not reported	• *"IUGA supports the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence"*

Abbreviations: AUGS, American Urogynecologic Society; EBR, evidence-based recommendation; ISD, intrinsic sphincter deficiency; LOE, level of evidence; LUT, lower urinary tract; MUS, midurethral sling; NICE, National Institute for Health and Care Excellence; NMA, network meta-analysis; OAB, overactive bladder; PVS, pubovaginal sling; SIGN, Scottish Intercollegiate Guidelines Network; SUFU, Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction; SUI, stress urinary incontinence; SR, systematic review; UGSA, UroGynaecological Society of Australasia; UTI, urinary tract infection.

[1] The roundtable includes representation from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), the Royal Australasian College of Surgeons (RACS), the Urological Society of Australia and New Zealand (USANZ), the Royal New Zealand College of General Practitioners (RNZCGPs), nursing, Accident Compensation Corporation, the New Zealand Private Surgical Hospitals Association and consumers.

Appendix F Health Canada summary safety report

Table App. 12 Summary of Health Canada safety review of standard synthetic mid-urethral sling (SMUS) made from non-absorbable synthetic material

Purpose	To assess the long-term (at or beyond 5 years) safety and effectiveness of SMUS for SUI in women, including the risk of complications.

Information sources	• Information from the following sources was reviewed:
	  ○ Manufacturers
	  ○ Canadian and American incident reporting databases
	  ○ Canadian health professional associations
	  ○ International regulatory agencies
	  ○ Medical and scientific literature
	• Health Canada conducted a literature review of systematic reviews, RCTs and meta-analyses that included long-term clinical data on the safety and effectiveness of SMUS

Findings	• Since Health Canada's previous review (2014), no reports have been received by Health Canada describing new risks of complications associated with the use of SMUS for SUI.
	• Some reports received since 2014 continue to describe serious and permanent issues known to be associated with synthetic vaginal surgical mesh devices (including infection, pain, bleeding, urinary dysfunction, mesh erosion/migration, sexual dysfunction, nerve and/or muscle damage causing mobility issues, damage to pelvic structures/surrounding tissues, need for surgical correction).
	• Rates of AEs and causal links between SMUS and various atypical complications reported to Health Canada could not be confirmed due to a lack of necessary details documented in incident reports (e.g. potential medical co-morbidities) and/or a lack of medical assessments.
	• Health Canada's literature review supports that:
	  ○ long-term (≥ 5 years) safety and effectiveness of SMUS for SUI is equivalent to surgical alternatives that do not use vaginal surgical mesh
	  ○ there are no newly identified risks of complications associated with long-term (≥ 5 years) use of SMUS
	  ○ effectiveness and patient satisfaction over the long-term (≥ 5 years) are relatively high in most patients
	  ○ the risk of developing chronic pain and/or mesh erosion is lower over the longer term (≥ 5 years)
	  ○ there is currently no clear causal association in the literature between SMUS and the development of systemic issues such as allergy, immune system dysfunction, rheumatic pain, fibromyalgia and/or fatigue
	• Health Canada assessed publicly available position papers[1,2,3] developed by national health care professional associations about the use of SMUS for SUI. Generally, these associations support the use of SMUS for SUI when certain criteria have been met, including clear informed consent and consideration for conservative treatment options, such as perineal rehabilitation (pelvic floor physiotherapy) and incontinence pessary.
	• Health Canada reviewed the regulatory actions taken in other countries (e.g. the US, Australia, Singapore, Switzerland and the UK) and determined that the actions they have taken are consistent with what is taking place in those countries. SMUS indicated for the treatment of SUI continue to be available in Canada and internationally.

Conclusions & Actions	• The review did not identify new (not previously known) or increased risks of complications associated with the long-term (≥ 5 years) use of SMUS compared to previous reviews.
	• The risk of developing chronic pain and/or mesh erosion is lower over the longer term (≥ 5 years).
	• Health Canada will:
	  ○ continue to monitor safety information involving vaginal surgical mesh devices
	  ○ enhance its existing communications products with more patient-focused information
	  ○ continue to work with stakeholders to support women in their decision-making

Source: Health Canada (2022) Summary Safety Review – Standard synthetic mid-urethral sling (SMUS) made from non-absorbable synthetic material (synthetic vaginal surgical mesh device) - Health Canada. Available: https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00288 [accessed 1 February 2023].

Abbreviations: AE, adverse event; RCT, randomised controlled trial; SMUS, synthetic mid-urethral sling; SUI, stress urinary incontinence; UK, Unite Kingdom; US, United States.

[1] SOGC statement in response to College des Médecins in Quebec's report on urethral slings. The Society of Obstetricians and Gynaecologists of Canada (SOGC)

[2] Welk, B., Carlson, K. V., Baverstock, R. J., Steele, S. S., Bailly, G. G., & Hickling, D. R. (2017). Canadian Urological Association position statement on the use of transvaginal mesh. Canadian Urological Association Journal, 11(6S2), S105-7.
[3] Walter, J.E., Brennand, E.A., Lemos, N., Cundiff, G.W. (2021). Letter: Canadian Society of Pelvic Medicine Response to the Collège des Médecins du Québec Rapport d'Enquête. Journal of Obstetrics and Gynaecology Canada, 43 (3), 298-299.