THE JOURNAL OF
SEXUAL MEDICINE

ORIGINAL RESEARCH & REVIEWS

FEMALE SEXUAL FUNCTION

Sexual Function Following Treatment for Stress Urinary Incontinence With Bulk Injection Therapy and Mid-Urethral Sling Surgery

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ABSTRACT

Background: Peri-urethral bulking injections (PBI) gain popularity for the treatment of stress urinary incontinence (SUI), but — in contrast to mid-urethral sling (MUS) surgery — little is known about its impact on sexual function.

Methods: This was a secondary analysis of a prospective cohort study that included patients with moderate to severe SUI undergoing either MUS surgery or PBI with polydimethylsiloxane Urolastic (PDMS-U). The validated Dutch and English version of the 'Pelvic Organ Prolapse and/or Urinary Incontinence Sexual Function Questionnaire — IUGA Revised' (PISQ-IR) was used to assess sexual function at baseline, at 6 and 12 months of follow-up. For between-group analysis, differences in baseline characteristics were corrected using multivariate analysis of covariance.

Outcomes: The primary outcome was the PISQ-IR single summary score of sexually active (SA) women following both procedures, calculated by mean calculation. Secondary outcomes were the PISQ-IR subscale scores of SA and non-sexually active (NSA) women, the proportions of sexual activity and subjective improvement ('Patient Global Impression of Improvement' (PGI-I)).

Results: A total of 259 women (MUS: n = 146, PBI: n = 113) were included in this study. The PISQ-IR single summary score of SA women improved following both interventions (in the MUS group from 3.2 to 3.4 and in the PBI group from 3.0 to 3.3 after 12 months). After correcting for differences in baseline characteristics, the PISQ-IR summary score at 6 and 12 months was similar for both treatment groups. For SA women, condition-specific and condition-impact subscale scores significantly improved following both procedures.

Clinical implications: In treating SUI, PBI is inferior to MUS surgery. However, there is a need for less invasive strategies, especially for women who are unfit for surgery or have contraindications. Sexual function improves after PBI using PDMS-U, which is relevant for the counselling of women with SUI about available treatment options.

Strengths & limitations: Strength: until this study, there was a lack of knowledge about the effects of PBI on sexual function. Limitation: there may be indication bias as we did not perform a randomized controlled trial.

Conclusion: PBI using PMDS-U and MUS surgery for the treatment of SUI improve sexual function equally in SA women, mainly by decreasing the condition's impact on sexual activity and quality. **Latul YP, Casteleijn FM, Zwolsman SE, et al. Sexual Function Following Treatment for Stress Urinary Incontinence With Bulk Injection Therapy and Mid-Urethral Sling Surgery. J Sex Med 2022;XX:XXX–XXX.**

Key Words: Sexual Function; Urinary Incontinence, Stress; Bulking Agents; Suburethral Slings

Received September 1, 2021. Accepted March 31, 2022.

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https://doi.org/10.1016/j.jsxm.2022.03.620

INTRODUCTION

Stress urinary incontinence (SUI) is a common condition in women of all ages with prevalence rates up to 35%.[1–3] Besides the negative impact on women's social, physical and psychological wellbeing, SUI negatively influences sexual function and wellbeing in up to 68% of affected women.[4] Physically, frequent

urinary leakage irritates the vulvovaginal region which can lead to dyspareunia. On emotional level, SUI negatively affects self-esteem, sexual desire and sexual satisfaction.[4] Up to 45% of women with urinary incontinence completely avoids sexual activity because of their symptoms.[5,6] SUI seems to affect the sexual function of patients' partners as well.[7,8]

Multiple studies demonstrate that treating SUI − either conservatively or surgically − improves sexual well-being, function and self-esteem.[9−14] Surgical interventions are highly effective at controlling urinary incontinence and thereby improve the overall quality of life.[15] Therefore, it is reasonable to presume that surgical interventions improve sexual function. However, treatment-specific complications may impair sexual function. Following mid-urethral sling (MUS) surgery, sling exposure and neurovascular tissue damage may cause sensory loss, pelvic pain, dyspareunia.[16−19] Accordingly, studies do not consistently report improvement of sexual function following surgical interventions for SUI.[20,21] Some studies demonstrate no effect on, or even deterioration of sexual function and *de novo* dyspareunia is reported even in studies that demonstrate improved sexual function after surgery.[12,22−25]

An alternative, minimally invasive surgical intervention to treat SUI comprises peri-urethral bulking injections (PBI). PBI involves the injection of material around the urethra intending to increase urethral coaptation and thereby restoring urinary continence.[26] PBI can be performed under local analgesia in an ambulatory setting and enables fast return to daily activities. Compared to invasive surgical approaches, PBI has a lower cure rate, but a more favourable safety profile.[26,27] Therefore, it should be presented as a treatment option to women who have contraindications for MUS surgery or recurrent SUI. PBI is associated with minor tissue damage and even though complications (such as retention, pain at the injection site, haematuria and infection) do occur, they are mild and transient. Therefore, these complications may cause less sexual impairment than the complications associated with MUS surgery. Polydimethylsiloxane Urolastic (PDMS-U) is a nonbiodegradable bulking agent that polymerises after injection, resulting in encapsulated deposits with a low risk of migration. As PDMS-U is non-absorbable and non-deformable, long-term treatment effects are expected.[28] In patients that are not optimal candidates for MUS surgery, PBI using PDMS-U results in good subjective and objective cure outcomes.[29] The effect of PBI using PDMS-U on sexual function has not been evaluated yet. Moreover, there is a lack of knowledge about the effects on sexual function of PBI in general. In the present study, we evaluated and compared the impact of MUS surgery and PBI using PDMS-U on sexual function over a follow-up period of 1 year.

MATERIALS AND METHODS

Data for this study was obtained from a multicentre, prospective cohort study on efficacy, safety and cost-effectiveness of peri-urethral bulking agent polydimethylsiloxane Urolastic (PDMS-U) injections versus MUS surgery in women with SUI. We added monitored data from another single-arm prospective cohort study of PDMS-U with the same study protocol. The trial was registered in the Dutch Trial Register (Identifier NTR7590).[30] The study was reviewed and approved by the ethical committee of the Amsterdam UMC and the boards of all participating centres. All participants received verbal and written explanation of the study procedures and provided informed consent. The current study on sexual function includes data obtained from 13 institutes worldwide (see appendix A).

Study Design

The validated Pelvic Organ Prolapse and/or Urinary Incontinence Sexual Function Questionnaire − IUGA Revised (PISQ-IR) was used to assess sexual function at baseline and after 6 and 12 months of FU.[31] The primary outcome was the PISQ-IR single summary score of sexually active (SA) women.[32] The primary objective was to evaluate the impact of both MUS surgery and PBI using PDMS-U on the PISQ-IR single summary score and to compare the PISQ-IR single summary scores between treatment groups after 12 months of FU. The secondary objectives were to evaluate the impact of both procedures on (i) the PISQ-IR subscale scores of SA and non-sexually active (NSA) women, (ii) the proportions of sexual activity, and (iii) subjective improvement.

Population

Women with moderate to severe SUI or stress predominant mixed urinary incontinence (Sandvik severity scale ≥ 3)[33] were eligible for participation if they were at least 18 years old, had a positive cough stress test and had opted for treatment with either MUS surgery or PBI by shared decision making. Exclusion criteria were: predominant urge incontinence, pelvic organ prolapse with POP-Q of point Aa or Ba ≥ 0, pregnancy, untreated urinary tract infection, bladder capacity <250mL, post-voiding residue of >150mL and flow <15mL/sec.

Interventions and Study Procedures

MUS Procedures. Surgical (MUS) procedures were performed following established institutional protocols and national standards of care. Under general anaesthesia, spinal analgesia or sedation, a retropubic-, transobturator- or single incision mid-urethral sling was placed.

Peri-Urethral Bulking Injections. The bulking agent used in this study was Urolastic (Urogyn BV, Nijmegen, the Netherlands), which is a CE-certified product that consists of PDMS-U. Procedures were performed under local analgesia by certified physicians who had followed specific training to perform this

procedure. The exact procedures of this bulking agent have been described before.[28,34] In short, the bulking agent is injected into the submucosal tissue around the mid-urethra at 10, 2, 5 and 7 o'clock positions. Several seconds after injection, the deposits solidify, creating artificial cushions compressing the mid-urethra and thereby improving urethral coaptation.

Assessment of Sexual Function. The validated Dutch and English versions of the PISQ- IR were used to assess sexual function.[31] The PISQ-IR is a disease-specific questionnaire that was developed based on the PISQ-12, to assess sexual function in both SA and NSA with pelvic floor dysfunction. As SUI causes avoidance of sexual activity in many affected women, treating SUI might change the proportions of sexual activity and inactivity, which makes the evaluation of sexually inactive women relevant. The provided answers result in ten subscale scores. The subscales for NSA women are NSA-CS (condition-specific reasons for not being active), NSA-PR (partner-related reasons for not being active), NSA-GQ (global quality rating of sexual quality) and NSA-CI (condition impact on sexual quality). Higher NSA subscales indicate a greater impact of the condition on sexual function. For SA women, subscales are SA-AO (assessment of arousal, orgasm), SA-PR (assessment of partner-related impacts), SA-CS (assessment of condition-specific impacts on activity), SA-GQ (global quality rating of sexual quality), SA-CI (condition-specific impact on sexual quality) and SA-D (assessment of sexual desire). In the subscales for SA women, higher scores indicate better sexual function. PISQ-IR questionnaires were completed at baseline and after 6 months and 12 months of FU.

Assessment of Subjective Improvement of SUI Symptoms. Subjective improvement of SUI symptoms following both procedures was evaluated after 6 and 12 months of FU by the 1 item questionnaire 'Patient Global Impression of Improvement' (PGI-I), which includes a 7-point Likert scale ranging from "1 = very much better" to "7 = very much worse."[35]

Statistical Analysis

As recommended by the authors of the original publication, the PISQ-IR results were analysed separately for SA and NSA women.[36] The summary score was calculated by mean calculation according to instructions published by Constantine et al. (2017).[32] To calculate the summary score, a minimum of provided responses is required (11 of 21 specific question items for SA women with a partner and 9 of 18 for SA women without a partner).[32] If insufficient items were responded to, the questionnaire was excluded from the evaluation of summary scores. The different subscale scores were scored by mean calculation using the scoring program provided by IUGA (available at https://www.iuga.org/resources/pisq-ir). Means and standard deviations (SD) are reported for normally distributed continuous variables, medians (μ) and interquartile ranges (IQR) for non-normally distributed continuous variables and absolute and relative frequencies for categorical variables. For the between-group comparative analysis of continuous and categorical variables, an independent t-test, Mann-Whitney U or Pearson Chi-Square test was used. For between-group analysis of PISQ-IR single summary scores, differences in baseline characteristics were corrected using multivariate analysis of covariance (MANCOVA).[37] Comparative analysis within groups over time was performed using a Wilcoxon signed ranks test for non-normally distributed continuous data and the McNemar test for categorical data. A 2 sided P value below 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics (IBM Corp. Released 2020. IBM SPSS Statistics for Macintosh, Version 27.0. Armonk, NY: IBM Corp).

RESULTS

A total of 259 women were enrolled in this study, of which 146 (56%) underwent MUS surgery and 113 (44%) underwent the PBI using PDMS-U. Of these women, 236 (91%) completed the PISQ-IR questionnaire at baseline, 168 (65%) after 6 months of FU and 174 (67%) after 12 months of FU. PGI-I was completed by 195 participants (75%) after 6 months and 175 participants (77%) after 12 months of FU. For the evaluation of PISQ-IR summary scores, respectively 1, 20 and 9 completed questionnaires had to be excluded at baseline, 6 and 12 months of FU because of an insufficient number of provided responses.

The clinical characteristics of the participating women are presented in Table 1. Women who underwent PBI were significantly older than women who underwent MUS surgery (69 (21) vs 48 (11) years old, $P < 0.01$). In the PBI treated group, more women were postmenopausal (67.9% vs 26.4%, $P < 0.01$), more were using vaginal oestrogen therapy (11.5% vs 2.9%, $P < 0.01$) and more had undergone prior surgical interventions for pelvic organ prolapse or UI (40.7% vs 10.3%, $P < 0.02$) than the MUS treated group. Of the women who underwent PBI, fewer had a partner (53.9% vs 77.4%, $P < 0.01$), and fewer were sexually active at baseline (51.0% vs 80.3%, $P < 0.01$) than women who underwent MUS surgery (Table 1).

Women who reported to be sexually active at baseline were younger (49 (12) vs 68 (21) years old, $P < 0.01$) and more frequently had a partner (81.2% vs 44.8%, $P < 0.01$) than women who considered themselves not sexually active. The proportion of sexually active women did not change over time following both procedures (MUS: 80% (baseline) vs 85% (6 months) vs 82% (12 months), PDMS-U: 51% (baseline) vs 54% (6 months) vs 54% (12 months)).

Women reported subjective improvement (PGI-I) of SUI symptoms following both procedures, which was greater following MUS surgery ("very much better") than PBI ("a little better", Table 1).

Table 1. Patient characteristics

	MUS (N = 146)	PDMS-U (N = 113)	*P* value	SA (N = 159)	NSA (N = 77)	*P* value
Patient characteristics						
Age at inclusion in years, μ (IQR)[‡]	48 (11)	69 (21)	**<0.01**	49 (12)	68 (21)	**<0.01**
Vaginal deliveries, μ (IQR)[‡]	2 (1)	2 (1)	0.73	2 (1)	2 (1)	0.40
BMI, μ (IQR)[‡]	25.8 (5.8)	27.2 (6.4)	0.12	25.6 (5.5)	28 (5.7)	**<0.01**
Postmenopausal patients, %[§]	26.4%	67.9%	**<0.01**	35.9%	74.3%	**<0.01**
Prior surgical intervention for POP or UI*, %[§]	10.3%	40.7%	**<0.01**	20.8%	31.2%	0.08
Vaginal oestrogen therapy, %[§]	2.9%	11.5%	**<0.01**	6.1%	9.1%	0.44
Prolapse grade II or higher, %[§]	22.6%	27.9%	0.43	23.4%	21.2%	0.76
Has a partner, %[§]	77.4%	53.9%	**<0.01**	81.2%	44.8%	**<0.01**
Questionnaire outcomes						
Sexually active baseline, %[§]	80.3%	51.0%	**<0.01**	100%	0%	
PGI-I 6 months[†], μ (IQR)[‡]	1 (1)	3 (1)	**<0.01**	2 (2)	2 (2)	0.23
PGI-I 12 months[†], μ (IQR)[‡]	1 (1)	3 (2)	**<0.01**	1 (2)	2(2)	**<0.01**

*Includes anterior and/or posterior vaginal wall repair with and without Mesh, colposuspension (sacrocolpopexy, sacrospinal fixation, Manchester operation, Burch colposuspension), TVT (retropubic sling), TVT-O/TOT (transobturator sling), SIMS, bulking agent.
†PGI-I responses are: 1 = "very much better", 2 = "much better", 3 = "a little better", 4 = "no change", 5 = "a little worse", 6 = "much worse" and 7 = "very much worse").
‡Mann-Whitney U.
§Pearson Chi-Square.
BMI = body mass index; IQR = interquartile range; MUS = mid-urethral sling; N = number of patients; NSA = non-sexually active; PDMS-U = bulking agent polydimethylsiloxane Urolastic; POP = pelvic organ prolapse; PGI-I = patient global impression of improvement; SA = sexually active; UI = urinary incontinence; μ = median.
Comparison between treatment groups (MUS and PDMS-U) and between SA and NSA. Bold P values indicate statistical significance (ie, $P < 0.05$).

PISQ-IR Single Summary and Subscale Scores

Single summary and subscale scores of SA women are presented in Table 2. Both procedures resulted in an increased single summary score 12 months after treatment. At 6 months of FU, this improvement was only significant for MUS and not for PDMS-U procedures. After correcting for differences in baseline characteristics, the PISQ-IR summary score was similar for both treatment groups at 6 months (MUS: 3.3 (95% CI [3.25-3.41]) vs PBI: 3.4 (95% CI [3.2-3.58])) and 12 months of FU (MUS: 3.4 (95% CI [3.35-3.51]) vs PBI: 3.5 (95% CI [3.29-3.60])). Condition-specific (SA-CS) and condition-impact (SA-CI) subscale scores significantly improved after 6 and 12 months of FU following both procedures, which indicates less impact of the condition on sexual activity (less urinary leakage and consequently less fear and shame during sexual activity) and less impact of the condition on sexual quality. The global quality subscale score did not change following PDMS-U procedures and even deteriorated following MUS surgery (Table 2). The arousal and orgasm subscale score was significantly higher at 6 months of FU for the PDMS-U treated group and at 12 months of FU for the MUS treated group. For NSA women, none of the subscale scores significantly changed following either procedure.

DISCUSSION

The results of this study demonstrate that sexual function improves equally following bulk injection therapy with PMDS-U and MUS surgery in sexually active women with SUI after 6 and 12 months of follow-up, mainly by decreasing the condition's impact on sexual activity and quality.

Many studies have evaluated the impact of MUS surgery on sexual function before.[11–14] A meta-analysis combining results of 23 studies demonstrated that the majority (67%) of women that underwent MUS surgery experienced unchanged or improved sexual function.[17] Recently, Freitas et al. (2021) were the first to evaluate sexual function following PBI using polyacrylamide hydrogel injection (PAHG) in a randomized controlled trial using the PISQ-12.[38] They demonstrated that overall sexual function improved equally following TVT and PBI 1 year after procedures.[38] They observed a particular improvement of the physical subscale, which was greater for TVT than PAHG. We observed improved physical subscales (condition-specific and condition impact) following both MUS and PDMS-U as well. After correction for differences in baseline characteristics, we demonstrated that sexual function was similar following both procedures. However, the reported subjective improvement (PGI-I) following both procedures differed substantially: improvement was significantly greater in the MUS treated group. Thus, even though PBI was less effective in treating SUI than MUS surgery, improvement of sexual function was similar, indicating that factors different from symptom-relief affect sexual function.

One such factor might be sexual quality; for example, are sexual experiences enjoyable, satisfactory and pleasurable? Following MUS surgery, we observed a worsening of the global quality subscale score of SA women. Multiple studies have described *de novo* dyspareunia as a contributing factor for decreased sexual global quality following MUS surgery.[12,39] Vaginal surgery can cause neurovascular tissue damage which may result in dyspareunia or sensory loss and thereby impair

Table 2. PISQ-IR scores of SA women

	Baseline		6 months			12 months		
	N	Mean ± SD	N	Mean ± SD	*P* value*	N	Mean ± SD	*P* value*
Single summary score								
MUS	106	3.2 ± 0.5	68	3.4 ± 0.3	**<0.01**	72	3.4 ± 0.3	**<0.01**
PDMS-U	52	3.0 ± 0.6	26	3.3 ± 0.4	0.47	32	3.3 ± 0.4	**<0.05**
Subdomains								
SA-AO								
MUS	104	3.7 ± 0.8	94	3.9 ± 0.6	0.09	86	3.9 ± 0.5	**<0.01**
PDMS-U	52	3.4 ± 0.7	30	3.4 ± 0.7	**<0.05**	35	3.3 ± 0.7	0.12
SA-CS								
MUS	100	3.8 ± 1.0	88	4.5 ± 0.6	**<0.01**	81	4.6 ± 0.6	**<0.01**
PDMS-U	45	3.7 ± 0.9	27	4.1 ± 0.8	**<0.05**	33	4.3 ± 0.8	**<0.01**
SA-PR								
MUS	101	3.6 ± 0.6	72	3.6 ± 0.7	0.63	80	3.6 ± 0.6	0.87
PDMS-U	46	3.5 ± 0.5	25	3.5 ± 0.5	0.32	30	3.5 ± 0.5	0.13
SA-D								
MUS	104	3.1 ± 0.7	80	3.2 ± 0.7	0.82	83	3.2 ± 0.6	0.26
PDMS-U	53	2.9 ± 0.9	26	3.0 ± 0.7	0.98	33	2.8 ± 0.6	0.48
SA-CI								
MUS	105	3.2 ± 0.8	80	3.7 ± 0.5	**<0.01**	83	3.8 ± 0.6	**<0.01**
PDMS-U	51	2.9 ± 0.9	27	3.4 ± 0.8	**<0.05**	33	3.3 ± 0.7	**<0.01**
SA-GQ								
MUS	105	2.7 ± 0.6	79	2.5 ± 0.6	**<0.01**	82	2.4 ± 0.6	**<0.01**
PDMS-U	49	2.8 ± 0.9	26	2.9 ± 0.9	0.65	34	3.1 ± 0.8	0.17

*Wilcoxon signed ranks test.

AO = Arousal and orgasm; CS = Condition-specific; CI = Condition impact; D = Desire; GQ = Global quality; MUS = mid-urethral sling; N = number of included questionnaires; PDMS-U = polydimethylsiloxane Urolastic; PR = Partner related; SD = standard deviation; SA = sexually active.

Mean PISQ-IR single summary and subscale scores of sexually active women at baseline, 6 and 12 months of follow up. Means and SDs are rounded to 1 decimal. *P* values compare follow up moment (6 or 12 months) to baseline. Bold *P* values indicate statistical significance (ie, $P < 0.05$).

sexual function.[19,40] Szell et al. (2017) demonstrated that despite overall improved sexual function following MUS surgery, only 33% of treated women experience improved orgasm function.[17] Besides dyspareunia and decreased sensibility, patients with SUI report on multiple other factors that contribute to sexual satisfaction, including loss of self-esteem and psychological distress.[4] These psychological, rather than functional factors, might underly the impaired global quality observed in the women undergoing MUS surgery.

For sexually inactive women, none of the subscale scores significantly improved following either procedure. Women who were not sexually active before treatment remained sexually inactive after treatment. Multiple other studies describe no or little increase in sexual activity following treatment for SUI as well.[11,38] Up to 45% of women with urinary incontinence completely avoid sexual activity because of their symptoms.[5,6] In our population, resolving or relieving SUI symptoms did not result in improved function or increased activity. Therefore, it seems that the presence of SUI itself might not determine sexual inactivity. Other factors — such as sexual interest and partner status — might play a more prominent role. Within our study population, only 45% of NSA women had a partner, compared to 81% of SA women.

This study presents unique data on the impact of PBI on sexual function. We have used a validated disease-specific questionnaire (PISQ-IR) to assess the sexual function of women undergoing treatment for SUI.[36] In contrast to other disease-specific questionnaires on sexual function, the PISQ-IR also encompasses both sexually active and inactive women. Thereby, we have provided insight into the impact of treating SUI on sexual activity and function in sexually inactive women with SUI, which gives a more comprehensive presentation of the sexual function of all women.

Some limitations of our research need to be addressed. First, we should be careful when comparing the outcomes of the MUS surgery group to the PDMS-U group because treatment allocation was not randomized, so we cannot correct for all potential confounders. In the study performed by Freitas et al. (2021), randomized treatment allocation resulted in similar baseline characteristics between both treatment groups.[38] Because of the outspoken treatment preferences of physicians and patients, treatment allocation in our present study was not randomized. As a consequence, patient characteristics were substantially different at baseline: women who underwent PDMS-U were much older, had undergone more prior surgical interventions, less frequently had a partner and were considerably less sexually active.

As fewer women within this group were sexually active compared to the MUS treated group, fewer of their questionnaires could be included for evaluation of the summary score and SA-subscale scores. To enable comparison between treatment groups, we have corrected for these differences using MANCOVA. Second, we did not perform subgroup analysis with regards to the type of sling (eg, TOT, TVT, mini-sling), which might influence orgasm scores.[17] Third, we studied the impact of 1 single bulking agent that might not reflect the impact of all other bulking agents. When translating our findings to other bulking agents, their specific characteristics such a biodegradability, absorbability and deformability should be taken into account.

Our present study demonstrates that overall sexual function improves equally following PBI using PDMS-U and MUS surgery. MUS surgery remains the more efficacious option for the treatment of SUI. PBI should be presented as a treatment option for SUI to women who have contraindications for MUS surgery or recurrent SUI. Sexually active women undergoing PBI using PDMS-U can expect an improvement in their sexual function. These findings will benefit the counselling of women with SUI about available treatment options. In order to implement PBI in common practice, efficacy and safety need to be studied more extensively.

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Funding: A grant was provided by ZonMw for the programme of efficiency studies. Urogyn BV the Netherlands supported this research with an unrestricted grant. They had no involvement in the study design, data collection, data analysis or interpretation of data, nor in the writing of the report or the decision to submit this article for publication.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.jsxm.2022.03.620.

APPENDIX A: PARTICIPATING INSTITUTES

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