Argus-T adjustable male sling

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Argus-T adjustable male sling: A follow-up study on urinary incontinence and patient's satisfaction

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Abstract

Aims: The use of Argus-T adjustable sling may be a promising alternative option for the treatment of urinary incontinence after radical prostatectomy, however long-term data is lacking. The aim of this study is to evaluate the long-term results of the Argus-T sling on incontinence rates, patient's quality of life and tape-related complications.

Methods: Patients were eligible if persistent stress incontinence was present ≥12 months after radical prostatectomy. Measurements included 24 h frequency volume micturition list, 24 h pad test, 24 h pad count and quality of life questionnaires. Argus-T adjustable sling was placed with a single perineal route incision approach.

Results: Seventy-eight patients were included, 69 ± 6 years, pre-intervention 24 h urinary loss 212 (75–385) g. Directly after surgery, 63.6% of the patients was completely dry, 79.2% of the patients reported greater than 90% improvement of their urinary loss and 92.2% > 50% improvement. Median follow-up time was 3.2 (2.5–6.1) years. After 5 years of follow-up, 53.3% of the patients were completely dry, 71.5% reported an improvement greater than 90% and 79.6% reported an improvement of greater than 50%. Patients with preoperative urinary loss less than 250 g reported significantly higher improvement of their urinary loss compared to patients with urinary loss ≥250 g ($p = .02$). Patients satisfaction was still increased after 5 years follow-up (70 ± 21 vs.16 ± 9, $p < .001$) and patients quality of life remained high (85 ± 20 vs. 88 ± 13, $p = .1$). Complications were mainly observed directly after surgery. Two patients (2.6%) needed reimplantation of the sling.

Conclusion: These data indicate that Argus-T sling is an effective treatment option in obtaining substantial long-term incontinence relief in patients with invalidating moderate stress urinary incontinence after radical prostatectomy.

KEYWORDS

male sling, post radical prostatectomy incontinence, stress urinary incontinence, transobturator sling suspension

1 | INTRODUCTION

The most common cause of stress urinary incontinence in male patient is iatrogenic injury during radical prostatectomy.[1] The prevalence of persistent post prostatectomy incontinence is estimated around 10%, but varies to 1%–40%.[2] The artificial urinary sphincter (AUS) is still considered the gold standard to treat incontinence after radical prostatectomy, but several new techniques have been introduced during the past decade to treat post prostatectomy incontinence.[1,3–5] One of these techniques is the Argus-T adjustable sling, a radiopaque cushioned system with a silicone foam pad for soft compression of the bulbar urethra which is implanted via a trans-obturatoric approach. The use of Argus-T adjustable sling may be a promising alternative option due to lower risk for erosion, urethral atrophy and infection.[5]

Several studies concluded that Argus-T sling use resulted to a similar improvement compared to AUS on social incontinence rates and quality of life.[6–8] After a follow-up of 18 months Lima et al observed a significant improvement of daily urine loss based on 24-h pads.[9] In addition the authors found that quality of life enhanced significantly based on validated questionnaires.[9] In a previous study from our clinic, we reported similar promising results regarding incontinence rates based on 24-h urinary loss after implantation of the Argus-T sling.[10] We also introduced in this study a single perineal route incision approach and we still use this approach as standard procedure because less complications were observed, especially limited number of wound infections.[10]

For a reliable comparison between the AUS and Argus-T sling long-term data should be available, preferably in a randomized clinical trial setting. At the moment, to our knowledge, no long-term follow-up data in a relatively large cohort of patients is reported. Therefore, the aim of this study is to evaluate the long-term results of the Argus-T sling on incontinence rates, patient's quality of life, the need for tape explantation and long-term tape related complications.

2 | MATERIALS AND METHODS

2.1 | Study population

Patients were screened for eligibility between January 2012 and May 2019 at our regional teaching hospital. Patients were referred by their treating urologist. Patients were eligible if persistent stress incontinence was present ≥12 months after radical prostatectomy and residual sphincter function by voluntarily contraction of the sphincter mechanism, observed by urethra-cystoscopy. Exclusion criteria were: radical prostatectomy less than 12 months, no pelvic floor physiotherapy post-surgery, trans urethral resection of prostate or green light laser transurethral surgery, past or current neurological disorders (e.g., neurogenic bladder, multiple sclerosis, Parkinson's disease), and postoperative radiotherapy. The institutional research board concluded that this protocol was exempted from IRB approval, because it was considered to be protocolized patient care.

2.2 | Study assessments

Preoperatively, all patients received the following work-up: frequency volume micturition list, two times 24-h pad test, flowmetry and residual urine measurement.[11] All patients underwent an urethra-cystoscopy excluding those with urethral stricture, bladder neck stenosis and intravesical pathology for surgery. Moreover, during urethra-cystoscopy all candidates had to demonstrate residual sphincter function by voluntarily contraction of the sphincter mechanism. The visual analog scale (VAS) score measured the severity of post prostatectomy incontinence and patient satisfaction (VAS 0–100) as well as two times 24-h pad test.

2.3 | Surgical procedure

The single perineal incision route for Argus-T (Promedon) was used based on other single incision techniques for the male sling.[10] Pre-operatively all patients received 2 g cefazolin intravenously. After general or loco-regional anesthesia patients were placed in lithotomy position and carefully shaved, disinfected and draped. All patients were catherized transurethrally with a 16Fr Foley catheter. Bladders were emptied and retrograde leak point pressure was measured preoperatively as described by Bochoove–Overgauw.[12]

In short, a seven cm median perineal incision, one cm cranial of the anus, was made with the patient in dorsal lithothomy position. After dissecting subcutaneous fatty tissue, the bulbospongiosum muscle was reached and the top of the triangle between corpus spongiosum and corpus cavernosum was identified. The lower arch of the os pubis was reached through the perineal incision moving the skin upwards to get access to the fascia of the obturator internal and external muscle. One cm below and lateral to the insertion of the adductor longus tendon the medial border of the obturator foramen was searched with a needle on both sides. After identifying the medial border, the needle was guided to the finger tip of the urologist, which was in the top of the triangle between

corpus spongiosum and corpus cavernosum. After tacking the column of the Argus-T, the column was pulled to the inguinal area left and right. The silicone cushion of the Argus-T was positioned around the bulbar urethra and a silicone ring was placed on both sides over the conut columns and positioned on the fascia of the obturator internal and external muscle. The tension was adjusted to achieve an increase of retrograde leak point pressure of 10–20 cmH_2O.[12] The perineal incision was closed in layers. The transurethral catheter was left in situ for 12–24 h. After catheter removal and successful trial of voiding (urinate volume and post void residual were measured) patients were discharged and advised to avoid heavy physical activity for 4 weeks.

2.4 | Follow-up

Follow-up evaluation at 1, 6, and 12 months postoperatively and yearly thereafter included VAS for continence, patient satisfaction and pain complaints, two times 24 h frequency volume charts and two times 24 h pad test to objectively assess the effect of the Argus-T Sling procedure.

We defined success of the procedure as dry (no urinary loss) or greater than 90% improvement of their urinary incontinence. In literature success is defined as dry (no urinary loss) or greater than 50% improvement of urinary loss.[4] For a transparent comparison with current literature we reported all rates for no urinary loss, greater than 90% improvement, and greater than 50% improvement of urinary loss.

2.5 | Statistical analyses

Normally distributed variables are expressed as mean ± *SD*, whereas non-normally distributed variables are given as median (interquartile range). Differences in patient characteristics between preoperative incontinence less than 250 g and ≥250 g were calculated with a χ^2 test for categorical data, and for continuous data with Student's *t* test or a Mann–Whitney *U* test in case of non-normally distributed data. A paired Student's *t* test or Wilcoxon signed rank test for non-normally distributed data was used to compare VAS-score for incontinence and patient's satisfaction and PAD test score before and after surgery. Statistical analyses were performed using SPSS 23 (SPSS Statistics, Inc.). A two-tailed $p < .05$ was considered to indicate statistical significance.

3 | RESULTS

3.1 | Patient characteristics

A total of 78 patients with symptomatic burden of their incontinence complaints after radical prostatectomy were included in this study. Mean operation time was 44 ± 10 min. Patient characteristics were shown in Table 1 for the overall population and stratified for rate of incontinence. Overall, mean age was 69 ± 6 years with a median duration of incontinence after radical prostatectomy of 1.7 (1.2–3.0) years. Preoperative quality of life was affected with a mean impact of 70 ± 21 out of 100. Patients characteristics did not differ between both incontinence groups except for urinary loss in grams (90 [50–195] vs. 476 [295–569], $p < .001$). All patients used urinary pads with a median of 2.0 (2–3) pads of which the majority used median pads (67.9%) (Table S1). Implantation of the sling resulted to a significant retrograde leak point pressure increase of 19 ± 5 cmH_2O, $p < .001$, no obstructive flows were observed after surgery.

3.2 | Short-term follow-up

Success of the procedure was defined as dry (no urinary loss), greater than 90% improvement, and greater than 50% improvement of urinary loss [4] (Table 2). Four weeks

TABLE 1 Patient characteristics

	All ($n = 78$)	Preoperative inco <250 g ($n = 48$)	Preoperative inco ≥250 g ($n = 30$)	*p* Value
Age, years	69 ± 6	69 ± 6	70 ± 6	.2
Incontinence duration, years	1.7 (1.2–3.0)	1.8 (1.3–2.9)	1.4 (1.1–4.4)	.2
Urinary loss, grams	212 (75–385)	90 (50–195)	476 (295–569)	<.001
Impact of urinary loss on QoL (0–100)	69 ± 21	67 ± 18	73 ± 24	.2
Operation time (min)	44 ± 10	46 ± 11	42 ± 8	.1

Abbreviations: inco, incontinence; QoL, quality of life.

TABLE 2 Procedure success and failure

	All ($n = 78$)	Preoperative inco <250 g ($n = 48$)	Preoperative inco ≥250 g ($n = 30$)	p Value
After 1 month	($n = 78$)	($n = 48$)	($n = 30$)	
Dry	63.6	64.6	62.1	.9
>90% improvement	79.2	79.2	79.3	
>50% improvement	92.2	91.7	93.1	
Failure	7.8	8.3	6.9	
After 6 months	($n = 78$)	($n = 48$)	($n = 30$)	
Dry	68.8	75.0	58.6	.3
>90% improvement	87.0	89.6	82.4	
>50% improvement	96.1	97.9	93.3	
Failure	3.9	2.1	6.7	
After 1 year	($n = 78$)	($n = 48$)	($n = 30$)	
Dry	64.8	71.4	55.2	.07
>90% improvement	90.1	92.1	80.4	
>50% improvement	95.8	97.9	85.7	
Failure	4.2	2.1	10.3	
After 2 years	($n = 67$)	($n = 41$)	($n = 26$)	
Dry	52.9	70.7	40.0	.045
>90% improvement	91.0	91.5	80.8	
>50% improvement	94.5	97.6	92.3	
Failure	4.5	2.4	7.7	
After 3 years	($n = 42$)	($n = 23$)	($n = 19$)	
Dry	52.9	62.5	35.7	.02
>90% improvement	82.4	80.0	71.4	
>50% improvement	91.2	95.0	85.7	
Failure	8.8	5.0	14.3	
After 4 years	($n = 33$)	($n = 16$)	($n = 17$)	
Dry	50.0	58.6	27.3	.04
>90% improvement	76.5	82.9	70.7	
>50% improvement	86.4	91.9	81.8	
Failure	13.6	9.1	18.2	
After 5 years	($n = 26$)	($n = 11$)	($n = 15$)	
Dry	53.3	54.2	28.6	.02
>90% improvement	71.5	76.8	66.7	
>50% improvement	79.6	83.3	74.8	
Failure	20.4	16.7	26.2	

Note: p Values were calculated to analyze the difference in continence success between the preoperative incontinence <250 and ≥250 g group.

Abbreviation: inco, incontinence.

after surgery 63.6% of the patients was completely dry, 79.2% of the patients reported greater than 90% improvement of their urinary loss and 92.2% > 50% improvement. No difference in success rate were monitored in patients with low and high preoperative urinary loss ($p = .9$). Success rates slightly, but not significantly, increased after 6 months. Overall 87.0% of the patients reported greater than 90% improvement of their urinary loss. After 1 year 64.8% of the patients did not report urinary loss, 87.0% had an improvement of greater than

90% and 96.1% an improvement of greater than 50%. A borderline significant difference in success rates were observed after 1 year between the low and high preoperative urinary loss patients ($p = .07$). Implantation of the Argus-T sling resulted to a significant decrease in the use of urinary pads as well as in the size of urinary pads overall as well as in both urinary groups ($p < .001$) (Table S1). Patients satisfaction enhanced directly after surgery and was persistent improved during follow-up ($p < .001$) (Table S2).

3.3 | Long-term follow-up

Median follow-up time was 3.2 (2.5–6.1) years. After 2 years the success rates regarding urinary loss modestly decreased every year. However, after 5 years, still 53.3% of all patients were completely dry, 71.5% reported an improvement greater than 90% and 79.6% reported an improvement of greater than 50%. Patients with preoperative urinary loss less than 250 g reported significantly higher improvement of their urinary loss compared to patients with urinary loss ≥250 g ($p = .045$ after 2 years, $p = .02$ after 3 years, $p = .04$ after 4 years and $p = .02$ after 5 years). The number of pad use did not differ during follow-up ($p = .7$). Patients did not increase the amount of pads or had to use larger pads after long-time follow-up. Patients satisfaction was still increased after long-term follow-up (70 ± 21 vs. 16 ± 9; $p = .01$). In addition, patients quality of life remained high (85 ± 20 vs. 88 ± 13; $p = .1$) and pain complaints were low (19 ± 10 vs. 8 ± 5; $p = .6$). Patients with preoperative urinary loss less than 250 g reported a significant higher quality of life and satisfaction compared to patients with preoperative urinary loss ≥250 g during long-term follow-up (Table S2).

3.4 | Complications

During implantation of the Argus-T sling, no complications were observed. Postoperatively 50 (64.1%) patients reported a complication in the first 6 months (Table 3). Twenty-five patients developed a short-term period of acute urinary incontinence after surgery, which recovered spontaneously in all patients. Perineal pain was seen in 27 (34.6%) patients and could be well controlled with analgesics. In the majority this perineal pain was transient, however 8 (10.3%) patients had persistent pain after 6 weeks. After 6 months no patients had a persistent feeling of discomfort in the perineal area.

Surprisingly no urinary tract infections were reported, however two patients developed a wound infection for which antibiotics were prescribed with good effect. Three other patients also developed a wound infection, resulting to one abscess formation and two sling infections which finally resulted to sling removal in all these three patients. No further action was taken in all these three patients, they all refused implantation of an AUS prosthesis. During follow-up no other complications were noticed, except for two patients who needed reimplantation of their slings due to column transection after 2 and 3 years. In both patients first the initial male sling was completely removed and a new Argus-T adjustable male sling was implanted. No significant difference in complications were found between patients with preoperative low and high incontinence loss ($p = .8$).

4 | DISCUSSION

These data show that implantation of the Argus-T sling results in substantial decrease in urinary complaints in patients with stress urinary incontinence after radical prostatectomy. After a follow-up of 5 years, the majority of patients experienced a sustained improvement in their urinary incontinence and quality of life. Furthermore we observed limited long-term complications.

Despite the incidence of stress urinary incontinence decreases after radical prostatectomy, stress urinary incontinence is still an important postoperative complication, resulting to a physical and emotional burden in these patients. It is known that post prostatectomy incontinence is caused by a diminished urethral resistance to abdominal pressure.[13–15] In line with this mechanism, Argus-T sling may be help, because this sling use this aforementioned concept by providing suburethral tension to create a slight urethral resistance to obtain continence.

Up to now several studies investigated the effect of Argus-T sling on urinary incontinence after radical prostatectomy.[6,8,9,16] All authors found a significant improvement regarding daily urinary loss. Success rates as defined greater than 50% improvement of their urinary loss differ between 75% to 95%. In addition, in some of these studies quality of life was also assessed and in these studies patient satisfaction improved after sling implantation. In our study we found comparable results, 94.5% of the patients experienced a greater than 50% improvement of their urinary complaints after 2 years follow-up. Of these patients, 91.0% reported a greater than 90% improvement, a promising result. To compare our data with current literature, all incontinence rates were expressed as dry, greater than 90% improvement, and greater than 50% improvement of incontinence. In our eyes, success should be defined as dry or greater than 90% improvement of incontinence rates. We observed

TABLE 3 Complications

	All	Preoperative inco <250 g ($n = 48$)	Preoperative inco ≥250 g ($n = 30$)	p Value
Complications (n, %)	50 (64.1)	30 (62.5)	20 (66.7)	.8
Clavien Grade 1				
Complications (n, %)				
Acute urinairy retention	25 (32.1)	15 (31.3)	10 (33.3)	.9
Hematoma	3 (3.8)	2 (4.2)	1 (3.3)	.9
Insensibility scrotum	12 (15.4)	8 (16.7)	4 (13.3)	.8
Perineal pain <6 weeks	27 (34.6)	17 (35.4)	10 (33.3)	.9
Perineal pain <6 months	8 (10.3)	3 (6.3)	5 (16.7)	.1
Erectile dysfunction	3 (3.8)	3 (6.3)	-	.2
Clavien Grade 2				
Complications (n, %)				
Urinary tract infection	-	-	-	.9
Wound infection	2 (2.6)	2 (4.2)	-	.3
Clavien Grade 3				
Complications (n, %)				
Adjustment sling	11 (14.1)	6 (12.5)	5 (16.7)	.5
Reimplantation sling	2 (2.6)	2 (4.2)	-	.3
Removal sling	3 (3.8)	2 (4.2)	1 (3.3)	.9

Abbreviation: inco, incontinence.

that the majority of patients after 6 months (87.0%) as well as after 5 years (71.5%) had an improvement above 90% of their incontinence complaints, an encouraging result. Surprisingly our success rates slightly increased between 1 month and 6 month. We postulated that this may become that directly after the procedure patients could experience pain that may differ their micturition process. Patients should therefore adequately be advised and instructed that the effect of sling could be determined after several months. Furthermore, we also assessed quality of life and found a significant improvement of quality of life in our study population, which is in line with previous reported studies.

However, in all known studies follow-up was relatively short with a median period between 9 and 22 months.[6–9] In our study patients were followed for 5 years. Still after 5 years, nearly 55% of all patients was completely dry, more than 70% reported an improvement greater than 90% and around 80% reported an improvement of greater than 50%. Patient's satisfaction was still increased after 5 years follow-up and patients quality of life remained high. We therefore conclude that Argus-T sling may be an alternative option for the treatment for urinary incontinence after radical prostatectomy based on the urinary incontinence rates.

Previous radiotherapy and severe urinary incontinence after radical prostatectomy were well-known risk factors for treatment failure.[5,8,9] We therefore decided to exclude patients with previous pelvic radiotherapy and to stratify our study population for preoperative incontinence rate. Indeed, patients with preoperative urinary loss less than 250 g reported significantly higher improvement of their urinary loss compared to patients with urinary loss ≥250 g. Nonetheless, patients with preoperative urinary loss ≥250 g still could have benefit from the Argus-T sling, around 75% of these patients experienced greater than 20% improvement of their urinary complaints. As mentioned before, severe urinary incontinence after radical prostatectomy is a known risk factor for treatment failure.[5,8,9] Physicians are therefore reserved to place a male sling in patients with severe urinary incontinence and an AUS is the preferred option. However, based on our study finding, Argus-T sling could be also considered in patients with relatively severe urinary incontinence after radical prostatectomy.

It is described that Argus-T sling may has a higher intra- and postoperative complication rate compared to AUS.[5] In our study group, remarkably no intraoperative complications were observed. This may be caused by the design of the study. We made a conscious choice to perform this as a single center study because we considered that the success rate of this procedure is related to the experience of the surgeon. It should be noticed that after the procedure a relatively high number of patients

reported complications (64%), of which transient perineal pain within the first 6 weeks (30%) and acute urinary retention (30%) were most frequent. These complications were described before in current literature and the numbers are in line with previous studies.[5]

However, minor long-term complications were seen. A small number of patients reported transient erectile dysfunction or an insensibility of their scrotal skin, known complications of this procedure. It is acknowledged that sling removal is necessarily needed due to infection or erosion and occurred in 10%–20% of all patients.[5,8,9] In our cohort the Argus-T sling was only removed in three patients (3.8%) within the first 12 weeks due to infection. Since we used a single incision implantation technique, we hypothesized that there may be a lower risk for infection.[10] No sling erosions or infections were monitored during long-term follow-up, except for two sling column transections. Based on our low long-term complication rates, Argus-T sling may still be an attractive alternative option for the treatment for urinary incontinence after radical prostatectomy.

Furthermore Kumar et al.[17] reported that the majority of patients, when given a choice, prefer treatment with a nonmechanical device. In addition, the sling is much less expensive than the AUS, allowing the patient to maintain physiologic voiding. Finally, it is known that on the long-term, the AUS could have mechanical failure of the reservoir or pump, which is observed in up to 13.8% of the patients, resulting to reimplantation of the device.[5] Our study showed that this is not the case with the Argus-T sling. Therefore, an adjustable male sling is a valuable treatment option in this patient group.

Nowadays several male slings systems are commercially available besides the Argus-T sling. Is the Argus-T sling the preferred choice or are other sling systems more effective at this moment? The AdVance sling (Boston Scientific) is the most frequently used retrourethral transobturator sling and is placed under the membranous urethra.[18] The key mechanism of this non-adjustable sling is entirely different compared to the Argus-T adjustable sling. The mechanism seems to be a dynamic support of the sphincter during stress by repositioning the lax and descended supporting structures of the sphincter to the former preoperative position.[19–21] Several studies reported success rates defined as dry around 70% and improvement of urinary complaints around 90% after 3 years of follow-up.[19–21] However, in a randomized controlled setting was observed that Argus-T compared to AdVance sling resulted to significant better improvement of urinary incontinence based on 24-h pads.[9] The use of AdVance sling was also analyzed in our center, in multicenter setting design, with unsatisfying outcomes on urinary incontinence, resulting that this sling not be used anymore in our center.[13–15] As mentioned before, post prostatectomy incontinence is caused by a diminished urethral resistance to abdominal pressure.[13–15] In line with this concept, the mechanism of Argus-T sling may be more effective, because the functional effect of the Argus-T sling is created by a passive increase in intraurethral pressure to achieve continence. We cannot confirm this postulation with our study results, because we did not investigate the workings mechanism of the Argus-T sling, but our results confirm the hypothesis that Argus-T sling is effective to achieve long-term urinary incontinence.

Another adjustable male sling system is the ATOMS, that consists of a silicone cushion that is placed under the membranous urethra, and is attached to two MESH sling arms located around the ramus inferior os pubis.[18] This system is easily adjustable in the outpatient clinic via an inguinal or scrotal port. A retrospective study in 287 men reported that after a median readjustment of three times, a success rate, defined as dry of 64% and any improvement of incontinence of 90% could be reached after follow-up of more than 2 years.[22] Promising results, however explanation rate is around 20%. This may be explained by local titanium intolerance at the port side resulting to infection. To our knowledge, no randomized controlled study is performed to compare Argus-T with ATMOS to investigate their effect on incontinence and patient's satisfaction.

This study has limitations, of which the most important is the single center design. We chose to perform this study in such setting, because we considered that the success rate of this procedure is related to the learning curve as well as the experience of the surgeon. Since not all medical centers have expertise with this procedure due to centralization, and the prevalence of such patients is relatively low, treatment was preferably performed in one center. Our hospital is one of the nationwide referral centers for male sling implantation in the Netherlands. Another limitation is the follow-up time. Not all patients had a follow-up time for at least 5 years. However, with a median follow-up time of 3.2 (2.5–6.1) years, this study has, to our knowledge, a relatively longer follow-up time compared to current literature. The main strength of our study is the systematic and prospective nature of data collection, including information on quality of life, that resulted in a well-characterized population.

5 | CONCLUSION

This study reports the first long-term results of Argus-T sling in a relatively large cohort with patients with stress urinary incontinence after radical prostatectomy. We

found excellent results after 5 years follow-up, more than 50% of all patients were completely dry, and the majority of all patients reported an improvement greater than 90% of their urinary incontinence complaints. We suggest that Argus-T sling may be an competitive alternative for stress urinary incontinence after radical prostatectomy in selected patients with moderate urinary complaints.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

DATA AVAILABILITY STATEMENT

The data that support the finding of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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