

Neuromodulation for Overactive Bladder Symptoms in Women Utilizing Either Motor or Sensory/Motor Provocation With a Minimum Nine-Year Follow-Up

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Introduction: This study is an evaluation of whether motor provocation compared to mixed sensory/motor provocation for tined lead placement affects its efficacy with quality of life measurements and Likert patient satisfaction.

Materials and Methods: An observational, retrospective cohort study was conducted with the analysis of 128 charts of adult women who, between January 2002 and September 2005, underwent a two-staged approach for sacral neuromodulation by the lead author SPM. Both groups did not differ statistically in their mean preoperative American Anesthesiologist Status Classification Score's of two or less, or frequency, urgency, urgency incontinence daily episodes or Urinary Distress Inventory scores. A seven-point Likert Scale was utilized for post-operative patient satisfaction. Sixty-eight patients (Group 1) received pure motor provocation for tined lead placement under general anesthetic and 60 patients (Group 2) received mixed sensory/motor provocation tined lead placement under intravenous sedation and local anesthetic.

Results: Sixty-two of 68 (91%) patients in Group 1 proceeded to Stage Two while 53/60 (88%) in Group 2 proceeded to Stage Two implantation ($p = 0.28$). Median follow-ups were 124.7 ± 21.5 months for Group 1 and 120.4 ± 19.7 months for Group 2 ($p = 0.45$). Mean preoperative/postoperative Urinary Distress Inventory short form and number of voids per 24 hours were for Group 1, $15.5 \pm 6.6/8.9 \pm 4.3$ and $16.3 \pm 5.3/9.2 \pm 3.9$ and for Group 2, $16.3 \pm 6.4/8.4 \pm 3.9$ and $17.82 \pm 7.17/8.34 \pm 4.26$ voids/24 hours ($p < 0.001$). Mean preoperative and postoperative ultrasound post void residual urines were 62.2 ± 29.3 milliliters/ 46.9 ± 20.6 milliliters (Group 1) and 68.0 ± 26.8 milliliters / 42.0 ± 27.8 milliliters (Group 2) ($p < 0.01$). Mean operative times were 29.5 ± 16.8 minutes (Group 1) and 59.3 ± 25.8 minutes (Group 2) ($p < 0.001$). Mean Likert patient satisfaction score (1, 2, 3) for Group 1 was 2.6 and 1.8 for Group 2 ($p < 0.21$). The mean numbers of office visits/year for reprogramming were 1.4 ± 0.7 (Group 1) and 2.8 ± 1.1 (Group 2) ($p < 0.001$).

Conclusion: Women with mixed sensory/motor provocation tined lead placement incurred statistically significant longer operating room times and an increased number of annual reprogramming sessions. Singular motor provocation tined lead placement may, in fact, improve outcomes by significantly decreasing operating room time, improving patient satisfaction, and decreasing mean yearly reprogramming sessions, compared to mixed sensory/motor tined lead placement.

Keywords: General anesthetic, intravenous sedation, local anesthetic, overactive bladder symptoms, sacral neuromodulation

Conflict of Interest: The authors report no conflicts of interest.

INTRODUCTION

Medically recalcitrant bladder symptoms including frequency, urgency, and urgency incontinence afford patients few minimally invasive alternatives, although a number do exist including: sacral and pudendal neuromodulation (1) (as of writing this is an off label utilization and not reimbursed by most insurance carriers), posterior tibial therapy (2) and intravesical Botulinum Type A therapy (3) (only approved for the redress of urgency incontinence in the United States) these can be utilized but only after the failure of conservative methods including biofeedback (4), bladder retraining (5) and/or anticholinergic medication (6). Since the late 1990's, sacral neuromodulation may be the most well studied second tier treatment, and its success with frequency, urgency, and urgency incontinence has been consistently satisfactory. Currently, many practitioners employ a two staged approach (7) and prefer performing sacral neuromodulation with intravenous sedation and local

anesthetic to better precisely ascertain the patient's sensory stimulation with the surgeon/patient inter-operative dialogue helping determine tined lead placement. However, the sensory/motor response obtained may still be compromised by sedation and a very limited motor response because bellows (levator ani contraction)

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For more information on author guidelines, an explanation of our peer review process, and conflict of interest informed consent policies, please go to <http://www.wiley.com/bw/submit.asp?ref=1094-7159&site=1>

Source(s) of financial support: None.

All patients consented to participate in our cohort review.

and ipsilateral big toe plantar flexion achieved in a conscious patient may cause a short duration of distress, impeding the patients from being impartial secondary to this noticeable side effect. Verbal sensory evaluation between the surgeon and conscious patients has been believed to afford improved efficacy in mixed sensory/motor tined lead placement and symptom reduction/improvement, but at the same time, some patients can become forgetful, uncooperative, and incapable of discerning the location of the combined electrical sensory/motor stimulus approach to the bladder, vagina, and rectum. In our study, we query how both of these approaches compare in efficacy, operating room time, patient satisfaction, and average annual number of office visits for pulse generator reprogramming. We present our minimum nine-year assessment of sacral neuromodulation with pure motor or mixed sensory/motor tined lead placement for the medically recalcitrant bladder symptoms of frequency, urgency, and urgency incontinence in healthy adult women.

* Interstim, Medtronic, Minneapolis, MN, USA; implantable pulse generator (IPG) model number 3023 and tined lead with larger lead number one model number 3093 where applicable.

MATERIALS AND METHODS

An observational, retrospective cohort study was initiated with the analysis of 128 consecutive female patients who, between January 2002 and September 2005, underwent stage 1 and then stage 2 were appropriate for sacral neuromodulation implantation by the lead author (SPM). Sixty-eight patients (Group 1) underwent pure motor provocation tined lead placement with general anesthetic and 60 patients (Group 2) had mixed sensory/motor lead placement under intravenous sedation, local anesthetic, without paralytic anesthetic administration to prevent the numbing of the S₃ nerve. Both groups were being treated for recalcitrant frequency, urgency, and urgency incontinence without non-obstructive urinary retention, interstitial cystitis or detrusor sphincter dyssynergia. Workup included a complete history and physical examination, urine analysis with microscopic evaluation and culture, office cystoscopy, 72-hour preoperative and postoperative voiding diary, and as well as technical data on implantation pulse generator power setting and operative revisions. All patients had a multichannel urodynamic assessment for symptoms of frequency, urgency, urgency incontinence, and nocturia. Afterwards, they completed informed consent and permission forms to undergo potential two-stage sacral neuromodulation implantation. All patients had attempted maximal conservative therapies, including biofeedback, Kegel exercises, timed voiding, and two or more anticholinergic medications before undergoing staged sacral neuromodulation. No urodynamics were performed postoperatively to ascertain postoperative voiding parameters. In both instances, Stage 2 was performed under general or intravenous sedation if the patient had a 50% reduction in urgency, frequency, or urgency incontinence episodes with their Stage 1 tined lead implantation noted on their 72-hour voiding diaries. Patients were explained the two approaches of anesthesia and provocation 1. Pure motor provocation or, 2. Mixed sensory/motor provocation lead placement. This study received Institutional Review Board approval. Study exclusionary criteria included myocardial infarction or any malignancy past or current during this studies time frame and are listed in (Table 1). All patients were ambulatory without assistance of any durable medical goods including wheelchair, cane, walker, or assistant. We felt very strongly to not offer sacral neuromodulation to

Table 1. Exclusionary Criteria for Our Study January 2002–September 2005.

1. American Society of Anesthesiologists Classification Rating of >3.
2. Any malignancy treated with chemotherapy or pelvic radiation.
3. Age less than 21 or greater than 65.
4. Central or peripheral neurological disease for assumed injury to bladder nerves.
5. Detrusor sphincter dyssynergia by examination or urodynamics potential for urinary retention

those patients whom are non-ambulatory or in need of ambulating devices as listed above. No patient in Group 1 received any sensory directed tined lead placement so that each group-received exposure only to there agreed to provocation pre-operatively. The S₃ was not tested pre-operatively (by means of the office placement of temporary leads) and for surgery the right side sacral nerve S₃ was always approached first without exception. If after four attempts no success was elicited then we would approach the left sacral nerve S₃. All attempts were performed through the S₃ foramina only. This was out of habit not secondary to any improved protocol for provocation or any procedural betterment. No patient needed to have the type of provocation changed or modified because of incompleteness of tined lead placement. At the onset of this study, few standardized and verified questionnaires existed for urgency symptoms so the following questionnaires were utilized. The Urinary Distress Inventory short form (UDI-6) (8) was used both pre- and post-operatively for frequency, urgency, and urgency incontinence baseline and improvement assessment. UDI-6 and Likert questionnaires were performed between September and November 2014. Patients who reported moderately or markedly improved were considered responders and this correlated with an improvement in the objective measures and validated questionnaires (9).

Pulse generator program settings for all patients were unfortunately not recorded. Sacral neuromodulation failure was defined as less than a 50% improvement (reduction) in symptoms of urgency, frequency, urgency incontinence, and nocturia, with subsequent inability to progress from Stage One to Stage Two, and permanent Implantable Pulse Generator (IPG) placement. Lead displacement was not considered a failure if revisional surgery returned the patient to a 50% improvement in voiding parameters from their 72-hour voiding diaries. Battery replacement also was not considered a therapy revision or failure if due to battery quiescence. Statistical analysis was performed using the Statistical Package for Social Sciences, version 11.0 (SPSS, Chicago, IL, USA). Analysis included simple means, medians, and standard deviations (Table 2). Comparisons of preoperative and postoperative values including but not limited to catheterized post void residual urines were performed with an analysis of chi-square, covariance, multivariable analysis, and regression analysis. There were no funds either requested or received for this project.

RESULTS

Sixty-two (91%) patients in Group 1 proceeded to Stage 2 while fifty-three (88%) patients in Group 2 proceeded to Stage 2 implantation ($p = 0.28$). Median follow-up was 124.7 ± 21.5 months for Group 1 and 120.4 ± 19.7 months for Group 2 ($p = 0.45$). Mean Preoperative/Postoperative Urinary Distress Inventory short form scores for Group 1 were $15.5 \pm 6.6/8.9 \pm 4.3$ while Group 2 were 16.3

Table 2. Patient Demographic Data.

Patient characteristics	Group 1	Group 2	<i>p</i>
Mean age (years)	51.3 ± 22.6	53.7 ± 20.7	0.36
Mean follow-up (months)	124.7 ± 21.5	120.4 ± 19.7	0.45
Stage 1 to 2 success (%)	91.0	88.0	0.28
Mean operating time (minutes)	29.5 ± 16.8	59.3 ± 25.8	<0.001
Mean Preoperative UDI-6 score	15.5 ± 6.6	16.3 ± 6.4	
Mean Postoperative UDI-6 scores*	8.9 ± 4.3	8.4 ± 3.9	<0.001
Mean number of PreOp voids	16.3 ± 5.3	17.8 ± 7.2	
Mean number of Postop voids*	9.2 ± 3.9	8.3 ± 4.3	<0.001
Mean PreOp Ultrasound PVR (mls)	62.2 ± 29.3	68.0 ± 26.8	
Mean Postop Ultrasound PVR	46.9 ± 20.6	42.0 ± 27.8	<0.01
Likert Global Response to Postoperative Satisfaction	2.6	1.8	<0.21
Mean number of annual reprogramming sessions	1.4 ± 0.7	2.8 ± 1.1	<0.001

*The change in pre- and postoperative UDI-6 scores was statistically significant via the described statistical analysis in the Materials and Methods section.

± 6.4/8.4 ± 3.9, ($p < 0.001$). Number of mean preoperative and postoperative voids per 24 hours for Group 1 were 16.3 ± 5.3/9.2 ± 3.9 while Group 2 were 17.8 ± 7.2/8.3 ± 4.3 voids/24 hours ($p < 0.001$). Mean Pre and post-operative urgency episodes per 24 hours for Group 1, 4.1 ± 2.7/1.7 ± 1.2 and Group 2 were 4.5 ± 2.9/1.5 ± 0.8 ($p < 0.001$). Mean preoperative and post-operative urgency incontinence episodes q24 hours for Group 1 were 2.4 ± 1.3 / 0.8 ± 0.4 while Group 2 were 1.9 ± 1.1 / 1.0 ± 0.8, ($p < 0.001$). Urodynamic proven preoperative detrusor over activity for Group 1 was 14.7% (10/68) while Group 2 was 13.1% (8/60) ($p < 0.78$). Mean Preoperative and Postoperative Ultrasound Post void residual urines for Group 1 were 62.2 ± 29.3 mls/46.9 ± 20.6 mls and for Group 2 were 68.0 ± 26.8 mls/42 ± 27.8 mls respectively ($p < 0.01$). Post-void residual urine quantities were included to demonstrate the improvement in bladder emptying with this technology. Group 1 and Group 2 mean operative times were 29.5 ± 16.8 minutes and 59.3 ± 25.8 minutes, respectively ($p < 0.001$). These times were descriptive from time of incision to time of wound closure and dressing application only. Because of different anesthesiologist's technique and reflected times for anesthesiologists induction, maintenance and reversal were not included. Mean Likert (10) patient satisfaction score (1 [no improvement], 2, 3 [best improvement]) for Group 1 were 2.6 and 1.8 for Group 2 ($p < 0.21$). The mean number of office visits/year for reprogramming were 1.4 ± 0.7 (Group 1) and = 2.8 ± 1.1 (Group 2) ($p < 0.001$). Programming changes elicited were not consistently recorded on the medical records to be of any assistance in this retrospective study. Both groups' preoperative demographics and comorbidities did not differ ($p = 0.61$) as per American Anesthesiology Classification Status Scores of 2 or less.

Objective failures were distinguished as follows. In Group 1, 59 of 62 were available for review and had three explantations for trauma with IPG replacement (5%) and three separate lead migrations secondary to falls that were successfully revised (5%). Objective failures were 8/59 (12%) but 4 of 8 were successfully managed by oral anticholinergic medications, and another four of the 8 failures (50%) underwent successful pudendal neuromodulation (with removal of original sacral lead and IPG) and are still successfully managed without anticholinergic medications. So Group 1 success rate was 88%. Group 2, 50 of 53 were available for evaluation. They experienced three explantations for late device failure (greater than one year after implantation). So 6% (3/50) removed for failure of the device. Another 4 treatment failures were successfully managed with pudendal neuromodulation (2/4) and the other 2/4 were suc-

cessfully managed with anticholinergic medications. We experienced 7 of 50 failures in Group 2 for a failure rate of 14%. Comparisons of Group1 (12%) to Group 2's (14%, $p < 0.73$) failure rates were not statistically significant. The three lost to follow-up in Group 1 include two deaths and one relocation. The three lost to follow-up in Group 2 were one death and two relocations.

DISCUSSION

In anticipation of criticism we have included a few self-queries and addressable concerns. Each group consisted of youthful, adult, and healthy women, which is not likely representative of patient content with most other prospective or retrospective study cohorts in the current literature. Why did we obtain such a high success in conversion from Stage 1 to 2 when at the time (2001–2005) success rates at university medical centers were only approaching 50–70%? Because the therapy was so new at this time in Illinois we requested to implement some criteria for inclusion and exclusion into this expensive, new therapy being offered to manage difficult medically recalcitrant patients. The first was to treat only healthy women without debilitating neurologically demyelinating diseases such as diabetes for potential greater early success. Also those patients with central and peripheral nervous system diseases as multiple sclerosis and vascular spinal cord injuries for the same reasons. These two disorders can lead to confounding demyelination making this treatment potentially at that point in time less resourceful. Patients with current or historical malignancies were to be omitted because several chemotherapeutic regimens with or without or radiation additionally lead to demyelination or other neurological or visceral injuries to the nervous system and bladder. Additionally, the need for potential magnetic resonance imaging (MRI) was not recommended at that time because of expected injury to the patients from timed lead displacement. Currently Medtronic has reduced its stance on MRI to allow it with precautions such as having the magnet of the IPG turned off and trying to also not image the pelvis if possible. These problems juxtaposed to its high cost of implementation exceeding \$80,000 USD beckoned for conservative operative resourcefulness until a clear history of treatment usefulness could be appreciated and maintained. So by selecting very healthy adult, women without severe medical ailments we were implementing this therapy with a considerable advantage to other medical facilities

without conservative implementation guidelines. This explains our high and consistent conversion rate from Stage 1 to Stage 2. It also likely explains why we have experienced excellent longevity with patient success rates while approaching a nine-year follow-up. We also practice in a community where most inhabitants do not leave and raise their families in this or a nearby community.

The mean age of our two groups also was younger than most observed studies with Group 1 at 51.3 and Group 2 at 53.7 years ($p = 0.36$). Selection bias from allowing the patient to decide the type of anesthetic was a necessary bias because at that time of surgery it was postured that the sensory/motor approach was better for symptom reduction although there was a small vocal minority which felt that straight motor provocation was more consistent and better at symptom improvement. We have no references for this information but was a common recommendation from the Medtronic (St Paul, MN, USA) representative in our locale. We carefully decided to explain both approaches to every patient and to allow the patient to select their method of provocation. If during the course of implantation a certain approach provided statistically better results than the other we assess changing or limiting our approach to the more successful method. There were no episodes where a patient could or would not decide between the two approaches. Unfortunately, only a few studies have examined the efficacy of a motor versus a mixed sensory/motor provocation approach for tined lead placement. Cohen and associates (10) evaluated a small series with 35 patients with a non-specific follow-up assessment period and concluded that sensory/motor tined lead placement was less reliable for the success of frequency, urgency, and urgency incontinence symptom relief. Approximately 71% of patients who demonstrated improvement had positive sensory response while less than 43% of patients who did not demonstrate a 50% improvement ($p = 0.16$) were able to fulfill the most common criteria for advancement to Stage Two pulse generator implantation. In this same study (10), 20 of 21 patients who demonstrated a greater than 50% improvement (reduction) in frequency, urgency, or urgency incontinence symptoms demonstrated a positive motor response during Stage One quadripolar lead placement and stimulation. The author was cognizant of the study's results but surprisingly both patient cohorts seemed at exit interviews to be very pleased with their clinical results. Another study has recently shown in the frequency, urgency, and urgency incontinence population the most common overactive bladder syndrome symptoms were distributed as follows—frequency (85%), urgency (54%) urgency incontinence (36%) (11). Our study cohorts for Group 1 were frequency (81%), urgency (62%), and urgency incontinence (44%). While Group 2 was no different with frequency (77%), urgency (54%), and urgency incontinence (40%) ($p = 0.41$). Potential faults include the possibility that with mixed sensory/motor tined lead placement that although the patient is communicating their sense of stimulation to the surgeon, under anesthetic, some patients may not be cognizant of the quality and location of the stimulus and may report erroneous sensations and locations. With concomitant administration of sedation, the prone position may additionally become disorienting so the bladder and other vaginal locations may not be accurately reflected. We have experienced this in our operating room on several occasions. But could have been missed if not specifically queried with the patient. Their words were "Being upside down leaves me not knowing which way is up, down or right and left?" Additionally, both groups were young and less than 55 years of age and had less than three comorbidities with both these qualities demonstrated by Amundsen and associates (12) to confer a better outcome with overactive bladder symptoms

like urgency incontinence. These were the cumulative results of our direct intraoperative experience in over 128 patients for this study. Group 1 experienced a much shorter operative time because constant consultation with the patient to optimize placement and certainty of placement was not required and substantial amount of time approaching over 25 minutes was subtracted from the potential total and thus salvaged. It is simply not a question of one or two responses, and you have determined where your tined lead needs to permanently rest. Often on our genitourinary service it required multiple attempts to facilitate patient, surgeon, and anesthesiologist communication and notate responses to each patient question and answer definitively. In more detail women patients were asked where they felt the stimulation. With the answers surrounding the vagina, bladder, rectum and perineum, all terms explained and demonstrated to them on themselves and plastic pelvic floor models in the office a couple of weeks before and during the morning of surgery and where they were quizzed on their meaning until the surgeon and office nursing staff felt secure on their patient's understanding for its future implementation in the operating room. We always hope to have our patients experience a strong bladder or vaginal stimulation with a power level on the pulse generator of three volts or less. Often if good stimulation sensory/motor provocation is achieved with power levels higher than 4 volts, patients may experience more ipsilateral plantar flexion and irritable pelvic pain complaints post-operatively at home and this can be a disabling phenomena. If neither is elicited we hope for a good perineal ano-rectal sensation. The latter is the least effective but still will contribute to the improvement of frequency, urgency, and urgency incontinence. We desire with either (1) pure motor or (2) mixed sensory/motor placement a good bladder or high vaginal sensory/motor stimulation that is not too painful with the pulse generator set at no higher than 3 volts on its power settings. Both patient groups experienced admirable success with their procedures, with the improvements reflected by a statistically significant decrease in 24-hour total number of frequency, urgency and where applicable, episodes of urgency incontinence, all reflecting a greater than 50% improvement (symptom reduction). Curiously, both study cohorts had almost equal efficacy with post void residual urine determinations, as well. However, Group 2 required more than twice the number of annual office reprogramming sessions. Pure motor provocation entails eliciting an ipsilateral levator ani rectal pulling inward (bellows) and ipsilateral plantar flexion of the first toe while the patient is asleep and no communication rendered. Both groups had no difference with regard to changes in lead position, changes in impedance, or any other potential complications. With objective determinations in the Urinary Distress Inventory and Likert (9) (global response assessment) Improvement After Surgery, Group 2 patients demonstrated significantly equal satisfaction with their surgery ($p < 0.23$ and $p < 0.21$). However, seeing a surgeon twice as frequently for reprogramming does not appear to directly affect patient satisfaction, given the added time and expense.

With the increase in office reprogramming sessions reaching statistical significance and patient satisfaction equal as a result, the surgical approaches were still reconsidered. Office reprogramming frequency is a burden to the patient since it implies a less satisfactory surgical control of symptoms (13). Burks and associates (13) and Cameron et al. (14) both discussed their office reprogramming frequency and estimated two annual sessions as their average, both which are less than Group 2's mean annual reprogramming sessions (2.8). How this can be circumvented for the future is debatable, and reprogramming frequency needs to perhaps enter the criteria for sacral neuromodulation efficacy and postoperative success. With

our patients, do we need to strive for a minimal *conditio sine qua non* of less than or equal to two annual reprogramming sessions to affirm effective sacral neuromodulation therapy? What adjustments are needed to improve sensory/motor tined lead approach? The critiques of sensory/motor tined lead placement are potentially ample and include patient movement during the procedure, sensory contamination with the administration of local and sedation anesthetic, and the direct neurologic affect on the S₃ nerve by the intravenous sedative. The sacral neuromodulation cases the author has performed since resorting to motor provocation criteria under a general anesthetic have resulted in the same reduction in urgency, frequency, and urgency incontinence episodes as demonstrated in this study. The number of annual office reprogramming sessions has subsequently reestablished itself and diminished to approximately 1.3 sessions annually.

CONCLUSION

Motor and mixed sensory/motor tined lead placement are two different qualitative modalities for the performance of sacral neuromodulation that are surgeon-dependent for the overactive bladder symptoms of frequency, urgency, and urgency incontinence. Motor-only technique is associated with significantly shorter operative time, decreased need for reprogramming and higher patient satisfaction. However, mixed sensory/motor tined lead method may have a significantly increased longer operating room time, potential decreased patient satisfaction, less improvement in symptom score questionnaires (UDI-6) and increased frequency of office reprogramming sessions when compared to patients with sole motor tined lead placement.

Authorship Statement

All authors contributed equally to this study and the preparation of the manuscript.

How to Cite this Article:

Marinkovic S.P., Gillen L.M., Marinkovic C.M. 2015. Neuromodulation for Overactive Bladder Symptoms in Women Utilizing Either Motor or Sensory/Motor Provocation With a Minimum Nine-Year Follow-Up. *Neuromodulation* 2015; 18: 517–521

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COMMENT

The optimal technique and patient care pathway for sacral neuromodulation (SNM) continues to be debated and evolve. While there is no one perfect way to screen and implant a SNM device, there are several key factors that must be considered. Operating room time and number of reprogramming follow-up encounters are vital metrics, especially in some jurisdictions such as mine, where OR time can be quite limited and where patients must travel great distances, at great expense, for follow-up visits. Improved patient satisfaction is always a benefit when we make improvements in surgical technique. This study demonstrates over a lengthy follow-up, that eliciting a pure motor response while implanting a tined-lead in a staged implant leads to superior operative metrics and patient satisfaction. I believe this study with the contribution of other prospective analyses will shift many practitioners practice to a more streamlined, motor only implantation technique.

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Comments not included in the Early View version of this paper.

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