# Venous Thromboembolism Chemoprophylaxis in Plastic Surgery: A Randomized Controlled Trial of Apixaban versus Enoxaparin

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**Background:** Venous thromboembolism (VTE) remains an important safety issue in surgery. Although enoxaparin is the most common medication for VTE chemoprophylaxis in plastic surgery, several limitations have been discussed that may contribute to breakthrough VTE events. These include the following: (1) the need for weight-based dosing; (2) the need for factor Xa monitoring to ensure adequate therapeutic levels; and (3) the need for subcutaneous injection. Apixaban may represent a potential solution; however, experience with direct factor Xa inhibitors in the plastic surgery literature is limited. Thus, the authors present a first-of-its-kind randomized controlled trial of apixaban versus enoxaparin for VTE chemoprophylaxis among high-risk breast cancer patients undergoing autologous breast reconstruction.

**Methods:** This was a single-center, blinded, randomized controlled trial comparing enoxaparin versus apixaban VTE chemoprophylaxis among women undergoing microsurgical breast reconstruction with free abdominal flaps.

**Results:** Seventy-nine eligible patients were enrolled, of whom 40 (51%) were randomized to enoxaparin and 39 (49%) were randomized to apixaban. Treatment groups demonstrated similar demographics and comorbidities. Overall, of bleeding events that occurred after initiation of VTE chemoprophylaxis, 1 (3%) occurred in the apixaban arm and 1 (3%) occurred in the enoxaparin arm. On multivariable logistic regression adjusting for demographic/clinical characteristics, the adjusted odds of a bleeding event for apixaban versus enoxaparin was 1.0 (99% CI, 0.9 to 1.1). There were no symptomatic VTE events reported in either treatment arm.

**Conclusions:** Apixaban is a safe fixed-dose, oral VTE chemoprophylaxis agent for use after autologous breast reconstruction. It presents a novel paradigm shift in VTE prevention after reconstructive surgery. *(Plast. Reconstr. Surg.* 156: 809, 2025.)

**CLINICAL QUESTION/LEVEL OF EVIDENCE:** Therapeutic, II.

Venous thromboembolism (VTE) remains an important patient safety issue in plastic surgery, especially when considering high-risk reconstructive surgery populations such as cancer and trauma patients. Baseline propensity for hypercoagulability in these patients in

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combination with lengthy reconstructive procedures makes VTE a nonnegligible source of severe postoperative morbidity, with the literature demonstrating that there is up to a 20% rate of asymptomatic VTE in breast cancer patients who undergo autologous reconstruction.[1,2] Furthermore, multicenter data from the Venous Thromboembolism Prevention Study has demonstrated that even despite guideline-compliant postoperative chemoprophylaxis, breakthrough VTE events remain prevalent, affecting 1 in 25 plastic surgery patients with elevated Caprini scores.[3–5] As such, there is a pressing need to optimize VTE chemoprophylaxis in high-risk plastic surgery populations.

Although enoxaparin is the most common medication for VTE chemoprophylaxis in plastic surgery, several limitations have been discussed that may contribute to breakthrough VTE events. These include (1) the need for weight-based dosing; (2) the need for factor Xa monitoring to ensure adequate therapeutic levels; and (3) the need for subcutaneous injection. Although the first 2 factors can result in inadequate dosing and duration of therapy, the third can limit patient adherence because of the discomfort and inconvenience associated with subcutaneous administration. Direct factor Xa inhibitors such as apixaban may address many of these shortcomings, given their oral formulation and their simplicity of dosing without the need for drug level monitoring. In fact, apixaban has been demonstrated to be superior to enoxaparin for VTE chemoprophylaxis in landmark trials from the orthopedic surgery literature, without increasing the risk of bleeding events.[6,7] Accordingly, apixaban may represent an important paradigm shift in VTE chemoprophylaxis in plastic surgery, by serving as an easy-to-administer and well-tolerated alternative to enoxaparin.

The growing popularity of plastic surgery procedures associated with high postoperative VTE risk, such as autologous breast reconstruction,[8,9] mandates identification of novel approaches for VTE chemoprophylaxis that can more effectively reduce the rate of this preventable disease process. Apixaban may represent a potential solution; however, experience with direct factor Xa inhibitors in the plastic surgery literature is limited and mixed. Thus, we present a first-of-its-kind randomized controlled trial of apixaban versus enoxaparin for VTE prevention among high-risk breast cancer patients undergoing autologous breast reconstruction who would benefit from chemoprophylaxis (Caprini score ≥7).[5,10] As a primary objective, we investigate the safety of apixaban VTE chemoprophylaxis by studying the noninferiority of apixaban versus enoxaparin with respect to postoperative bleeding events. As a secondary objective, we investigate the rate of symptomatic VTE with apixaban versus enoxaparin. Ultimately, we hypothesize that apixaban is a safe and effective oral alternative to enoxaparin for VTE prophylaxis in autologous breast reconstruction.

## PATIENTS AND METHODS

### Study Design

This was a single center, blinded, randomized controlled trial with 1:1 randomization between the 2 study arms. All study protocols and analyses were performed in accordance with Patient-Centered Outcomes Research Institute standards. The study protocol was approved by the Stanford institutional review board.

### Patients and Randomization

Eligible adult women (>18 years) with a breast cancer diagnosis who were (1) scheduled to undergo unilateral or bilateral microsurgical breast reconstruction with free abdominal flaps (ie, muscle-sparing transverse rectus abdominis musculocutaneous flaps and/or deep inferior epigastric artery perforator flaps) and who (2) had a preoperative Caprini score of 7 or greater were eligible for study inclusion. Of note, a threshold Caprini score of 7 has been validated in the literature as the cut point at which the benefit of VTE chemoprophylaxis in surgical patients outweighs risk of postoperative bleeding events.[5,10] As such, initiation of VTE chemoprophylaxis is indicated in these patients at high risk for postoperative VTE.

Study exclusion criteria included contraindication to the use of apixaban or enoxaparin, active bleeding, history of bleeding disorder, coagulopathy, heparin-induced thrombocytopenia, liver disease, renal disease (creatinine clearance ≤30 mL/minute; serum creatinine >1.6 mg/dL), major neurosurgical intervention (brain/spine) within the past 90 days, ophthalmologic procedure within the past 90 days, uncontrolled hypertension, history of alcohol and/or substance abuse, or need for therapeutic anticoagulation. Postoperatively, patients who experienced flap complications requiring takeback and initiation of a heparin drip were removed from the study to prevent confounding. In addition, bleeding events that occurred before initiation of VTE

chemoprophylaxis were not included in study analyses.

Following an informed consent process, enrolled patients were randomized into 1 of 2 treatment groups: (1) apixaban 2.5 mg twice daily, and (2) enoxaparin 40 mg daily. VTE chemoprophylaxis was initiated 12 hours after finishing skin closure. Randomization was performed postoperatively on arrival in the postanesthesia care unit, thereby allowing surgeons to be blinded to study group assignment at the time of surgery and for the duration of the procedure.

### Intervention

VTE chemoprophylaxis with either apixaban or enoxaparin at the aforementioned dosages was initiated at 12 hours postoperatively, continued throughout the duration of the hospitalization, and discontinued on discharge from the hospital. This timing of initiation and duration were chosen based on guidelines from the VTE Prevention Study, and were consistent with prior randomized clinical trials investigating chemoprophylaxis in plastic surgery.[3,11] All patients concurrently received mechanical prophylaxis in the form of sequential compression devices before the induction of general anesthesia, which was continued while in bed for the duration of inpatient stay. In addition, all patients were mobilized on the morning of postoperative day 1 from bed to chair and were walking by the evening of postoperative day 1 versus the morning of postoperative day 2, in accordance with our institutional enhanced recovery after surgery pathway.

### Outcomes

The primary outcome of interest was overall risk of clinically significant bleeding events that occurred after initiation of VTE chemoprophylaxis in the 90-day postoperative period. Secondary patient-oriented outcomes included risk of symptomatic VTE events in the 90-day postoperative period. Tertiary outcomes included clinically significant wound complications (infection, dehiscence, partial or total flap loss) within 90 days of surgery. Bleeding episodes that occurred before initiation of VTE chemoprophylaxis were not attributed to the therapy itself and were instead documented as a complication of surgery alone.

### Statistical Analysis

Pre hoc power analyses were completed for the primary study objective using conservative estimates obtained from the literature. Prior large retrospective studies of breast patients receiving daily dosed enoxaparin report a bleeding event rate of 3.2% over 90 days.[12] A conservative bleeding risk estimate for oral factor Xa inhibitors was based on a randomized controlled trial in the setting of body contouring procedures, which demonstrated an event rate of 29.6% before early stopping of this trial.[13] Of note, this study used rivaroxaban rather than apixaban, and rivaroxaban was used in conjunction with nonsteroidal antiinflammatory agents, which heightened bleeding risk. Using standard formulas, with 80% power to detect a noninferiority margin of 2%, and assuming a 3.2% baseline bleeding event rate among patients dosed on daily enoxaparin compared with a 29.6% rate in the apixaban arm, our pre hoc power analyses suggested an enrollment size of 19 patients per arm.

After study exclusions, study analyses were performed on an intention-to-treat basis. Study variables were compared between study arms to ensure integrity of randomization. Schapiro-Wilk testing was used to determine whether continuous variables were normally distributed. Chi-square and *t* test analyses were used as appropriate to compare study arms, whereas nonparametric testing was used for nonnormally distributed variables or if cell counts were low. Odds of study outcomes were investigated using unadjusted Fisher exact testing, followed by Firth penalized logistic regression analyses with stepwise forward selection of predictor variables (age, race, body mass index, Caprini score, Elixhauser Comorbidity Index, procedure duration, and unilateral versus bilateral reconstruction). Noninferiority of apixaban versus enoxaparin for study outcomes was declared based on a priori criteria established before patient enrollment: apixaban would be found noninferior to enoxaparin if the upper limit of the one-sided 97.5% CI for the event rate in the experimental group did not exceed a relative margin of 2% from the event rate in the control group. All analyses were performed using Stata v. 17 (StataCorp, LLC., College Station, TX).

## RESULTS

During the study period, 86 patients were screened, and 79 eligible patients were enrolled for study participation, of whom 40 (51%) were randomized to the enoxaparin arm and 39 were randomized to the apixaban arm (49%). Two patients from the apixaban group and 1 patient from the enoxaparin group were removed from study analyses following randomization because

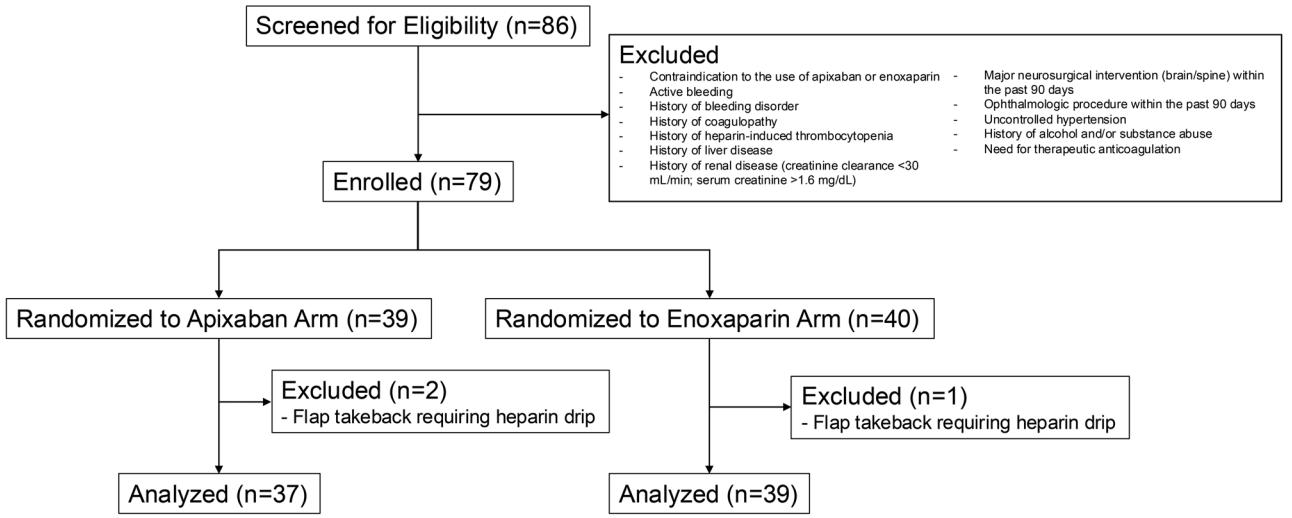


**Fig. 1.** Consolidated Standards of Reporting Trials diagram of patient enrollment.

**Table 1. Patient Demographics by Treatment Arm**

| Characteristic | Apixaban (%) | Enoxaparin (%) | *P* |
|---|---|---|---|
| No. | 37 | 39 | |
| Mean age ± SD, yr | 53 ± 10 | 53 ± 11 | 1.0 |
| Race/ethnicity | | | |
| White | 25 (68) | 28 (72) | 0.4 |
| Black | 0 (0) | 1 (3) | |
| Asian | 5 (13) | 4 (10) | |
| Hispanic | 7 (19) | 6 (15) | |
| Mean BMI ± SD, kg/m$^2$ | 29 ± 5 | 28 ± 4 | 0.3 |
| Elixhauser Comorbidity Index | | | |
| Median | 1 | 1 | |
| IQR | 1–2 | 1–2 | 1.0 |
| Caprini score | | | |
| Median | 7 | 7 | |
| IQR | 7–9 | 7–9 | 1.0 |

BMI, body mass index; IQR, interquartile range.

of postoperative complications requiring operative takeback and anastomotic revision, resulting in initiation of a heparin drip protocol to preserve anastomotic patency (Fig. 1). Mean plastic surgery operative time was 378 ± 145 minutes and mean time under anesthesia was 455 ± 152 minutes, which did not significantly differ between study arms.

### Patient Demographics and Clinical Characteristics

Table 1 demonstrates demographic and baseline clinical characteristics of the enrolled patients in each of the 2 study treatment arms. Patients in each treatment arm demonstrated similar baseline demographics and comorbidities including median Elixhauser Comorbidity Index and Caprini scores. In addition, there were no significant differences between treatment arms with regard to the mastectomy type and reconstructive details (Table 2). Mean duration of VTE prophylaxis corresponded to hospital length of stay (2.4 ± 0.3 days).

### Bleeding Events

Overall, 2 postoperative bleeding events were reported following initiation of VTE chemoprophylaxis among study patients, of which 1 (3%) occurred in the apixaban arm and 1 (3%) occurred in the enoxaparin arm (Table 3). Using penalized logistic regression, the adjusted odds of a bleeding event for apixaban versus enoxaparin was 1.0 (99% CI, 0.9 to1.1; pseudo-$R^2$ = 0.91). (**See Table, Supplemental Digital Content 1**, which shows bleeding events, ***https://links.lww.com/PRS/I57***.)

### Breakthrough Symptomatic VTE Events

The secondary outcome of interest was incidence of symptomatic VTE within the 90-day postoperative period. There were no symptomatic VTE events reported in either treatment arm (Table 3).

### Additional Complications

Overall, 90-day postoperative complication rates did not differ significantly between study treatment arms. Among the enoxaparin group, 5 (13%) patients experienced a postoperative

**Table 2. Patient Clinical Characteristics by Treatment Arm**

| Characteristic | Apixaban (%) | Enoxaparin (%) | *P* |
|---|---|---|---|
| Mastectomy type | 37 | 39 | |
| Nipple-sparing | 19 (51) | 20 (52) | 0.9 |
| Skin-sparing | 18 (49) | 19 (48) | |
| Flap timing | | | |
| Immediate | 27 (73) | 29 (75) | 0.4 |
| Delayed-immediate | 7 (19) | 4 (10) | |
| Delayed | 3 (8) | 6 (15) | |
| Flap type | | | |
| DIEP | 8 (22) | 10 (26) | 0.2 |
| MS-TRAM | 29 (78) | 29 (74) | |
| Mean procedure duration ± SD, hr | 9 ± 2 | 8 ± 3 | 0.1 |
| Procedure laterality | | | |
| Unilateral | 16 (43) | 19 (49) | 0.6 |
| Bilateral | 21 (57) | 20 (51) | |
| Mean hospital length of stay ± SD, days | 2.5 ± 0.4 | 2.3 ± 0.3 | 0.7 |

DIEP, deep inferior epigastric artery perforator; MS-TRAM, muscle-sparing transverse rectus abdominis musculocutaneous.

**Table 3. Surgical Outcomes**

| Characteristic | Apixaban (%) | Enoxaparin (%) | OR (99% CI) | *P* |
|---|---|---|---|---|
| No. | 37 | 39 | | |
| Any complication | 6 (16) | 5 (13) | 1.3 (1.0–1.5) | 0.7 |
| Bleeding event | 1 (3) | 1 (3) | 1.0 (0.8–1.4) | 1 |
| Symptomatic VTE | 0 (0) | 0 (0) | 1 | 1 |

complication, versus 6 (16%) patients in the apixaban group (Table 3). Most reported complications were superficial infections of the donor or recipient sites that resolved with antibiotics or mastectomy skin necrosis requiring wound care. On multivariable logistic regression adjusting for baseline demographic and clinical characteristics, the adjusted odds ratio for overall complications in the apixaban versus enoxaparin groups was 1.1 (99% CI, 1.0 to 1.2; pseudo-$R^2 = 0.86$). (**See Table, Supplemental Digital Content 2**, which shows the 90-day postoperative complication rate, ***https://links.lww.com/PRS/I58***.)

## DISCUSSION

Breakthrough VTE remains a pressing issue in plastic surgery, despite guideline-directed chemoprophylaxis with enoxaparin. Although enoxaparin is widely used for VTE prevention, this therapy faces several limitations, including the potential for weight-based dosing, blood level monitoring, and subcutaneous injection, all of which can limit adequate duration and dosing of therapy and patient compliance. Apixaban is a fixed-dose oral agent that has been demonstrated in the orthopedic surgery literature to be a safe and effective form of postoperative VTE chemoprophylaxis, but this drug has not been extensively investigated in plastic surgery. Thus, the current trial investigated fixed-dose, orally administered apixaban for VTE chemoprophylaxis amongst high-risk women (Caprini score ≥7) undergoing autologous breast reconstruction, ultimately demonstrating that apixaban was noninferior in terms of (1) bleeding events and (2) symptomatic breakthrough VTE events when compared with the current standard of care with enoxaparin.

In this study, apixaban administered at a dose of 2.5 mg twice daily starting 12 hours after surgery completion and continued throughout the duration of hospitalization was noninferior to subcutaneous enoxaparin dosed at 40 mg daily in terms of bleeding events, thus establishing its safety as a VTE chemoprophylaxis agent. The rate of postoperative bleeding events in the enoxaparin arm noted in the current trial corresponds to prior literature (3%), and the apixaban arm was noninferior. Prior literature in plastic surgery has demonstrated mixed results with regard to the safety of apixaban for VTE chemoprophylaxis. Although some studies have demonstrated that oral anticoagulants such as apixaban are comparable to enoxaparin with regard to safety and VTE chemoprophylaxis, others have demonstrated an increased rate of bleeding events with the use of oral factor Xa inhibitors.[13–16] However, most of these studies were retrospective investigations, and the prior literature demonstrating increased bleeding events with oral factor Xa inhibitors and the predominantly used rivaroxaban, which

is known to have a higher clinical risk for major bleeds than apixaban.[16,17] In fact, a commonly referenced trial investigating oral factor Xa inhibitors for plastic surgery chemoprophylaxis by Dini et al. studied rivaroxaban in conjunction with nonsteroidal antiinflammatory drugs, which could help to explain the heightened bleeding risk seen in the study group.[13] In contrast, this study represents the first randomized controlled trial explicitly comparing apixaban and enoxaparin in plastic surgery patients without concurrent use of confounding agents such as nonsteroidal anti-inflammatory drugs, demonstrating the specific safety of apixaban chemoprophylaxis in this patient population.[16] In addition, it should be noted that prior concerns regarding bleeding risk with oral factor Xa inhibitors was partly centered on the lack of availability of effective reversal agents, which is now mitigated with the wide accessibility of andexanet alfa.

Although the current study specifically investigated autologous breast reconstruction with abdominal flaps, the results could be reasonably extrapolated to other plastic surgery procedures. Traditionally, plastic surgeons have been wary of VTE chemoprophylaxis because of concern for postoperative bleeding, given the wide areas of dissection involved in flap procedures or body contouring.[18] In fact, the VTE Prevention Study demonstrated such operations involving wide undermining are an independent risk factor for postoperative bleeding.[19] The safety of apixaban for VTE chemoprophylaxis after abdominal breast reconstruction noted in our study suggests that this form of chemoprophylaxis could be safe for a variety of plastic surgery procedures, given that abdominal flap dissection and donor-site closure resemble excisional body contouring procedures with respect to the extent of surgical dissection. Thus, the current study investigated a population that is not only at risk for VTE events, but also at risk for postoperative bleeding. Despite this risk, the current study demonstrated the noninferiority of postoperative VTE chemoprophylaxis with apixaban versus enoxaparin with regard to bleeding events, suggesting the safety of this oral anticoagulant agent for postoperative use in plastic surgery patients.

Although the current study was not adequately powered to investigate the secondary outcome (incidence of symptomatic breakthrough VTE), it is important to note that there were no symptomatic VTE breakthrough events noted in either treatment arm, thus demonstrating the noninferiority of apixaban therapy for this study outcome. Prior orthopedic surgery literature has demonstrated that VTE thromboprophylaxis with apixaban resulted in a lower overall rate of VTE (symptomatic and asymptomatic).[7] Although the current study demonstrates no significant difference in breakthrough symptomatic VTE events between apixaban and enoxaparin treatment arms, asymptomatic screening for VTE was not completed in the current study population. Future work specifically investigating this endpoint will help to illuminate whether the superiority of apixaban in preventing all VTE events established in the orthopedic surgery literature translates to plastic surgery as well.

This study was not without limitation. As a single-center trial, generalizability of study results may be limited. However, standard techniques for abdominal flap harvest, inset, and donor-site closure were used, and patients were recruited for study participation across multiple providers, suggesting that study results can be reasonably extrapolated beyond the study institution. Future multicenter work can help to establish more comprehensive guidelines regarding VTE chemoprophylaxis after autologous breast reconstruction. In addition, as mentioned previously, the current trial was not powered to investigate the secondary outcome of breakthrough symptomatic VTE events. As this is an initial investigation to establish the safety of apixaban as VTE chemoprophylaxis in autologous breast reconstruction, the current work was powered to the primary outcome of bleeding events. Further work will focus on investigating the relative efficacy of apixaban versus enoxaparin in preventing breakthrough VTE events as has been done in the orthopedic surgery literature. In addition, future larger scale trials will be powered to investigate apixaban prophylaxis in different subgroups with greater granularity (eg, immediate versus delayed reconstruction).

Apixaban represents an important paradigm shift in VTE chemoprophylaxis in plastic surgery, helping to overcome many of the practical limitations of current VTE prophylactic techniques. Oral factor Xa inhibitors were developed with the intent to maximize convenience along with safety and efficacy, and the current randomized controlled trial is the first of its kind to demonstrate the safety of using apixaban postoperatively for VTE chemoprophylaxis in plastic surgery patients. As procedures at higher risk for postoperative VTE such as autologous breast reconstruction continue to gain popularity, it is important to continue investigating the safety and efficacy of

such oral VTE chemoprophylaxis agents to establish standardized guidelines for this morbid yet preventable disease process.

## CONCLUSIONS

In this randomized controlled trial of apixaban versus enoxaparin for VTE chemoprophylaxis in high-risk women undergoing autologous breast reconstruction, apixaban was demonstrated to be a safe alternative for enoxaparin with no significant differences in postoperative bleeding events. In addition, there were no breakthrough VTE events noted in either apixaban or enoxaparin treatment arms. Apixaban is thus a safe fixed-dose, oral VTE chemoprophylaxis agent for use after autologous breast reconstruction, allowing for greater ease of use for both patients and providers. Further work will involve multicenter trials powered to investigate the relative efficacy of apixaban versus enoxaparin in preventing breakthrough VTE events.

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## DISCLOSURE

*Dr. Momeni is a consultant for AxoGen, Gore, and RTI. Dr. Pannucci reports unrelated direct research funding from Mentor, a Johnson and Johnson company, and he performs practice consulting and expert witness work for venous thromboembolism in plastic surgery. None of the remaining authors has a conflict of interest to report. None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this article. No funding was received for this work.*

## DATA SHARING STATEMENT

*Study data will be shared upon reasonable request to the corresponding author.*

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