


# Comparison of Bending Stiffness between String of Pearls Plate-Bone Substitute Constructs with and without Bending Tees in a Fracture Gap Model

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## Abstract

**Objective** The aim of this study was to compare the bending properties of String of Pearls plate-bone substitute constructs with and without bending tees in the nodes over a simulated fracture gap. It is hypothesized that the constructs with tees will have higher bending stiffness.

**Study Design** Acetal polymer tubes and 12-hole, 3.5-mm String of Pearls plates were used to create plate-bone substitute constructs simulating stabilization in a bridging fashion over a 45-mm gap. Twenty-four constructs were made with 12 containing tees in the nodes over the fracture gap. Single-cycle load-to-failure 4-point bending was performed in mediolateral and craniocaudal planes. Bending stiffness was compared with a *t*-test ( $p < 0.05$ ).

**Results** All plate-bone substitute constructs had a permanent loss of structural integrity via plastic deformation of the plate. The bending stiffness (mean  $\pm$  standard deviation) of the craniocaudal group was  $59.11 \pm 1.98$  N/mm with tees and  $59.25 \pm 1.69$  N/mm without tees ( $p = 0.88$ ). In the mediolateral group, the bending stiffness was  $43.17 \pm 0.75$  N/mm with tees and  $41.09 \pm 0.91$  N/mm without tees ( $p = 0.0042$ ).

**Conclusion** In 4-point bending, the plate-bone substitute constructs with tees had equivalent bending stiffness in the craniocaudal plane and increased bending stiffness in the mediolateral plane. However, with a small absolute difference in values, the clinical significance is unclear. Future studies for cyclic bending, torsional, and axial compression tests should be performed to further investigate the value of tees in the nodes over a comminuted or gap fracture repaired in a bridging fashion.

## Keywords

- ▶ bending tees
- ▶ mechanical testing
- ▶ 4-point bending
- ▶ String of Pearls
- ▶ fracture gap model

## Introduction

The String of Pearls (SOP; Orthomed, Halifax, West Yorkshire, United Kingdom) is a locking plate system first introduced

and applied in veterinary orthopaedics in 2006. The SOP plate is composed of spherical nodes or pearls linked by cylindrical internodes. The unique spherical structure gives the plate a more circular cross-section compared with

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standard rectangular bone plates resulting in a higher area moment of inertia (AMI) and, thus increased bending stiffness and strength compared with comparable-sized plates.<sup>1-4</sup> With the ability to be contoured in three dimensions, SOP plates can be applied relatively easily over an irregular surface compared with other plate systems.

The SOP plate system has been widely reported in a variety of clinical fracture repairs in small animals with favorable outcomes, including long bone,<sup>5-9</sup> pelvic,<sup>10-12</sup> spinal,<sup>13</sup> and peri-prosthetic fractures.<sup>14</sup> However, all implant systems have weaknesses, and SOP implant failures have been reported. In one retrospective study including 33 appendicular long bone fractures repaired with SOP plates, major complications necessitating revision surgery occurred in 7 fractures (21%) due to implant failure.<sup>5</sup> Five of the seven implant failures that occurred were repaired in a bridging fashion.<sup>5</sup> In another retrospective study with seven femoral fractures repaired with SOP plates, two plate failures were reported.<sup>7</sup> In these clinical reports, the SOP construct failures included plate breakage at the internode and screw breakage at the screw-plate or screw-bone interfaces.<sup>5,7</sup> Several in vitro biomechanical testing studies, show SOP implant failure via plastic deformation of the plate,<sup>2,4,15-17</sup> nodal deformation,<sup>15</sup> and screw bending.<sup>16-18</sup>

Bending tees are reusable pieces fitted within the nodes that are unique to the SOP locking plate system. Bending tees are placed during the plate-contouring process to preserve the thread and node integrity by limiting deformation. The use of the bending tees or short (nonengaging) cortical screws as a retained part of the final implant construct in empty holes over a fracture gap or comminuted segment has been witnessed by the authors and was reported previously.<sup>5</sup> Field and colleagues proposed that this was performed to increase the overall strength of the implant construct.<sup>5</sup> Since bending tees are known to help prevent nodal deformation during plate contouring, it is speculated that it might help prevent nodal deformation during loading in clinical cases but these are yet to be extensively tested. According to the findings of a previous study, there was no significant difference in the bending stiffness of a 12-hole, 3.5-mm SOP plate with or without bending tees in all 12 nodes.<sup>1</sup> However, the study only tested the isolated plate with and without bending tees in one bending plane with the 4-point bending setup resulting in tension across the underside of the plate and compression across the topside of the plate. In fracture stabilization, plating on the tension side of the bone is advised with the resulting load causing tension across the topside of the plate. Additionally, a previous biomechanical study showed that isolated plates as standalone devices behave differently than plate-bone substitute constructs.<sup>4</sup> To the authors' knowledge, there are no studies investigating mechanical differences between placing the bending tees in the empty nodes overlying a fracture gap in a plate-bone substitute construct versus leaving the nodes empty.

The objective of this study was to compare the mechanical bending properties of the SOP plate-bone substitute construct with and without bending tees placed over a simulated fracture gap in two bending planes, mediolateral and craniocaudal. It was hypothesized that with bending tees

over the simulated fracture gap, the SOP plate-bone substitute constructs with tees would have a higher bending stiffness than constructs without tees.

## Materials and Methods

### Study Design

This was a pre-post-study design using two plate conditions and two loading directions (craniocaudal and mediolateral) under mechanical stress.

### Sample Size and Statistical Methods

The sample size was calculated based on the bending stiffness in the mediolateral bending plane of a 12-hole 3.5-mm SOP plate in a prior mechanical testing study.<sup>1</sup> With an  $\alpha$  of 5% and a power of 90%, the sample size was calculated to be 5 in each group to detect a difference of 10 N/mm with a standard deviation (SD) of 4.5.<sup>1</sup> The normality of the data was checked using the Shapiro-Wilk normality test. *t*-test was performed, and significance was noted when the *p*-value was  $<0.05$ . A 95% confidence interval (95% CI) was estimated for the difference in means. A total of 24 plate-bone substitute models were tested with 6 in each control and each test group. The extra construct in each group was to allow a small buffer above the calculated sample size.

### Synthetic Bone Model

Delrin® polyoxymethylene hollow tube (Plastic International, Eden Prairie, MN) as described in a previous study was used.<sup>19</sup> The outer diameter of the tube is 15.9 mm and the inner diameter is 9.5 mm. The synthetic bone model comprises two segments (100 mm in length each), divided by a 45-mm gap to simulate a canine femoral mid-diaphyseal comminuted fracture.

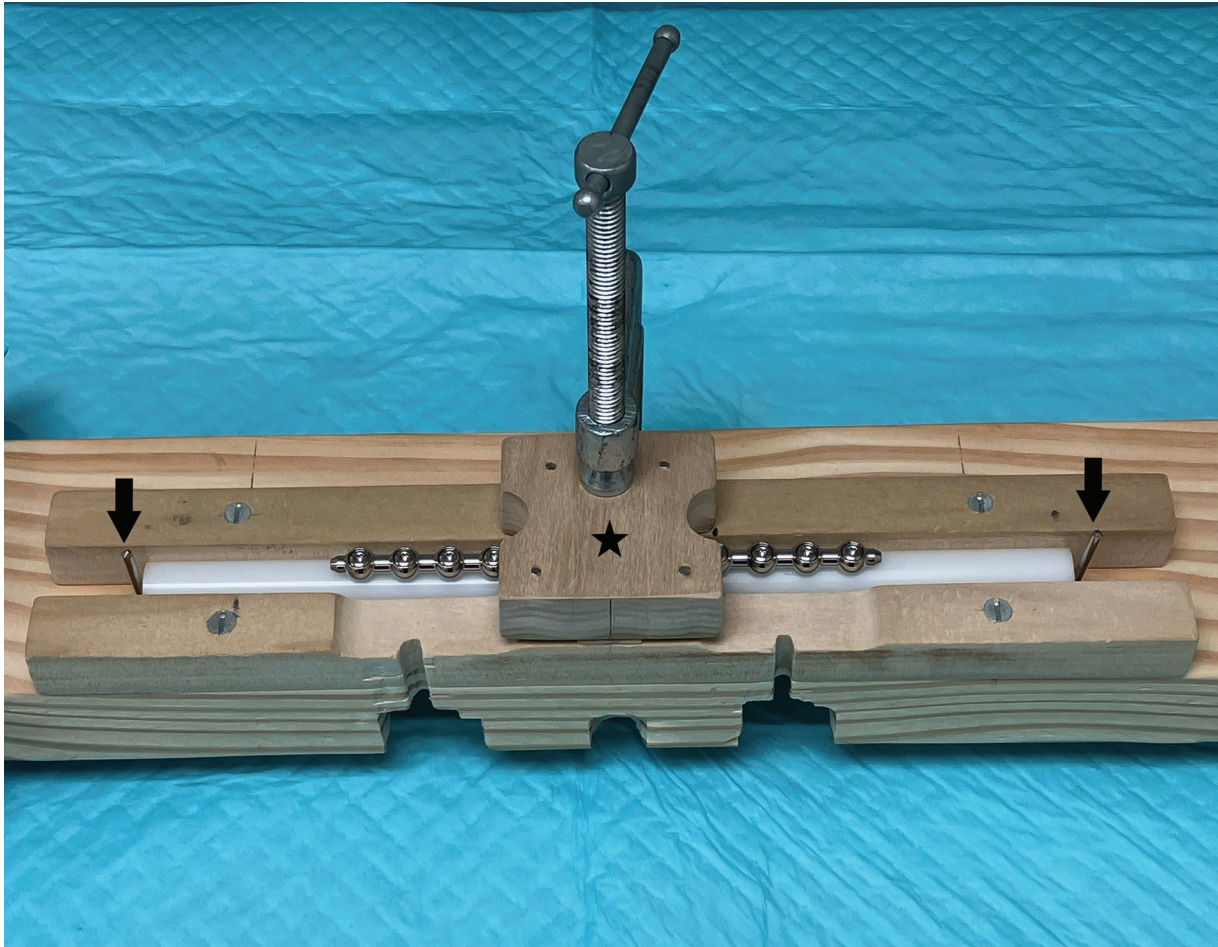
### Plate and Screws

Twelve-hole, 3.5-mm SOP stainless steel plates with self-tapping, 3.5-mm standard cortical screws (24 mm in length) were used.<sup>a</sup> The 3.5-mm SOP plate featured 5 mm in diameter cylindrical internodes separating the screw accommodating pearl nodes. The pearl nodes were 6 mm in height and 9 mm in maximum width. In each synthetic bone segment, four bicortical screws were inserted in the outermost nodes, leaving four empty nodes over the fracture gap. The plate length and screw distribution were chosen to simulate bridging osteosynthesis over an area of mid-diaphyseal comminution while adhering to the user guide recommendations to apply four screws per fracture segment.

### Plate-Bone Construct Assembly

All plate-bone substitute assemblies were constructed with a customized jig following the plate application guidelines from Orthomed™.<sup>20</sup> Two segments of polyoxymethylene hollow tube were placed into the customized jig (► Fig. 1) with a 45-mm spacer between them to maintain a standardized gap during setup and construct assembly. The plate implant was then temporarily secured in position using customized blocks

<sup>a</sup> The plate and screws are from Orthomed, Halifax, West Yorkshire, United Kingdom.



**Fig. 1** Image of the custom-designed 3.5-mm String of Pearls jig used in this study to build consistent plate-bone substitute constructs. A 45-mm central spacer, end-pin stoppers (arrows), contoured plate centralizer (star), and clamps were used to prevent movement and improve the uniformity of the constructs. A total of three clamps were used but two are not present in the picture to allow easier viewing of the jig.

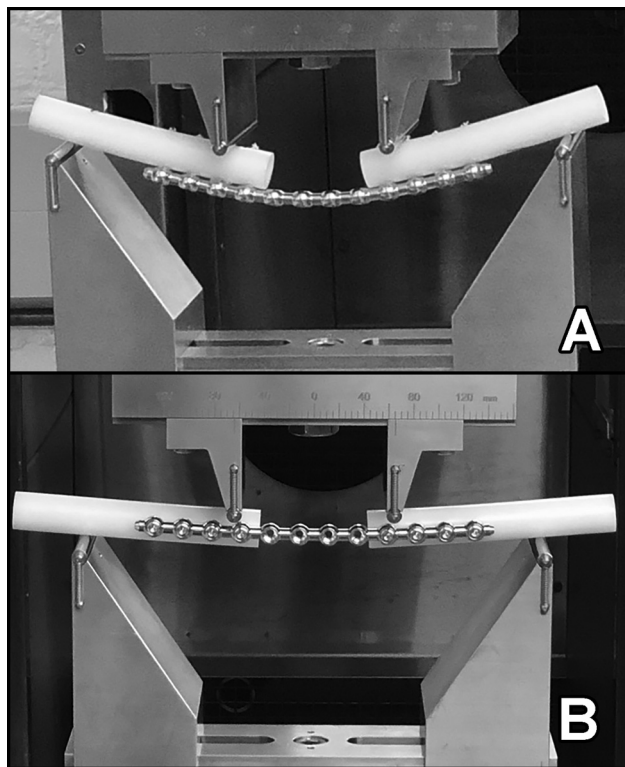
and clamps to ensure centralized placement of the plate. The plate was secured to each synthetic bone segment with sequential drilling and self-tapping screw placement of four bicortical bone screws per segment. The construct was then removed from the jig, resulting in plate-bone substitute constructs with a 45-mm gap, simulating plate application in bridging function. In the control group, all four pearl nodes over the 45-mm gap were left empty. In the test group, all four pearl nodes over the 45-mm gap were filled with bending tees. The insertion torque applied to each screw and bending tee was standardized to 1.5 Nm using a torque limiter.

### Mechanical Testing

Pilot testing was performed in 4-point bending with single-cycle load to failure before actual testing in the current study. All pilot plate-bone substitute constructs with and without tees in mediolateral and craniocaudal bending showed loss of structural integrity via plastic deformation of the plate before a 5% strain (15 mm deflection) was reached. As a result, a 15-mm or more deflection distance was used as the end-point in the subsequent testing.

The set-up of the 4-point bending test followed ASTM 382-17 guidelines.<sup>21</sup> Samples were tested using an electromechanical Universal Testing Machine (Model 5982 Electromechani-

cal Universal Testing Machine: Instron®, Norwood, MA) for the application of a controlled bending force. Each plate-bone substitute construct was manually centered in the testing machine. The distance between the support pins was 189 mm while the distance between the load pins was 63 mm to maintain a proper 3:1 ratio. Support span and load span distance remained constant for all samples. Single-stroke, monotonic, ramped load-to-yield testing at a rate of 0.10 mm/s was performed on all samples until 5% strain (15 mm deflection) or more was achieved. Bending stiffness was calculated on the basis of ASTM 382-17 guidelines.<sup>21</sup> Load-deflection data were collected, and curves were generated simultaneously using machine-specific software (Bluehill Universal Version 4.13 Testing Software: Instron®, Norwood, MA). In the load versus deflection curve, bending stiffness is defined as the maximum slope of the curve from each sample. Bending structural stiffness is the normalized effective bending stiffness affected by the load and center span distance of the test set-up. Instead of maximum load, the yield load at an offset of 0.2% was considered for calculating bending strength. To simulate femoral fracture repair in which the implant is placed on the lateral side of the bone, mediolateral bending was defined as the bending load applied parallel to the plane of the screw trajectory (– Fig. 2A). Craniocaudal bending was



**Fig. 2** Mechanical testing configuration for 4-point bending of plate-bone substitute constructs in the (A) mediolateral plane and the (B) craniocaudal plane using the electromechanical testing machine.

defined as the bending load applied perpendicular to the screw trajectory (► Fig. 2B).

## Results

All of the plate-bone substitute constructs were built and tested without issue. None of the plate-bone substitute constructs experienced implant breakage, screw pull-out, or substitute bone failure. All of the plate-bone substitute constructs had a permanent loss of structural integrity via plastic deformation of the SOP plates. At the mediolateral bending plane, one outlier was noted each from with tees and without tees group. The two were therefore excluded from the statistical analysis. The mean ( $\pm$  SD) yield loads in the craniocaudal plane were  $365.45 \pm 12.21$  N with tees and  $360.72 \pm 29.73$  N without tees ( $p = 0.73$ ). The yield loads in the mediolateral plane were  $285.67 \pm 25.39$  N (95% CI: 254.14, 317.19) with tees and  $308.36 \pm 17.39$  N (95% CI: 286.77, 329.96) without tees ( $p = 0.14$ ).

The mean ( $\pm$  SD) bending stiffness in the craniocaudal plane was  $59.11 \pm 1.98$  N/mm (95% CI: 57.03, 61.18) with tees and  $59.25 \pm 1.69$  N/mm (95% CI: 57.48, 61.02) without tees ( $p = 0.89$ ). In the mediolateral plane, the mean bending stiffness was  $43.17 \pm 0.75$  N/mm (95% CI: 42.24, 44.1) with tees and  $41.09 \pm 0.91$  N/mm (95% CI: 39.96, 42.22) without tees ( $p = 0.0042$ ). The mean ( $\pm$  SD) bending structural stiffness in the craniocaudal plane was  $7.41 \pm 0.25$  Nm<sup>2</sup> (95% CI: 7.14, 7.67) with tees and  $7.43 \pm 0.21$  Nm<sup>2</sup> (95% CI: 7.21, 7.64) without tees ( $p = 0.88$ ). In the mediolateral plane, the mean

bending structural stiffness was  $5.41 \pm 0.09$  Nm<sup>2</sup> (95% CI: 5.30, 5.52) with tees and  $5.15 \pm 0.12$  Nm<sup>2</sup> (95% CI: 5.01, 5.29) without tees ( $p = 0.014$ ). When the two bending planes were compared, bending in the craniocaudal plane resulted in a 37% increase in stiffness compared with the mediolateral plane in constructs with tees. In constructs without tees, bending in the craniocaudal plane resulted in a 44% increase in stiffness compared with the mediolateral plane.

## Discussion

The current study is the first to compare SOP in a plate-bone substitute fracture gap model with and without bending tees in two bending planes. With or without tees, the bending stiffness in the craniocaudal plane was greater than in the mediolateral plane. This difference was similarly reported by Benamou and colleagues who found a bending stiffness increase of 49% in the craniocaudal plane compared with the mediolateral plane in plate-bone substitute constructs without tees.<sup>3</sup> The difference in bending stiffness between the two bending planes can be explained by the difference in the AMI in the load application axis.<sup>3</sup> AMI is calculated based on the cross-sectional shape of the implant,<sup>22</sup> which is positively related to the height or radius in the direction of applied load. When we exclude the uniform cylindrical internode in the evaluation of AMI, the SOP plate's cross-sectional shape differs greatly at the node or pearl when comparing mediolateral and craniocaudal bending. The AMI of the SOP node in mediolateral bending is  $49.3$  mm<sup>4</sup> with a direct relationship to the node height of 6 mm. The AMI of the SOP node in craniocaudal bending is  $231$  mm<sup>4</sup> with a direct relationship to the node diameter of 9 mm.<sup>3</sup> When considering the load application axis, mediolateral bending is when the load was applied to the shorter or minimal axis versus the craniocaudal plane when it was applied to the maximal axis. The maximal axis has the larger structural bending stiffness.<sup>23</sup> While these are expected findings based on the difference in plate structure in the two planes, the authors felt it was pertinent to report these testing results for completeness and to ensure biomechanical expectations were being met in this plate-bone substitute construct model.

When evaluating bending stiffness and bending structural stiffness in the presence or absence of bending tees, there was no significant difference between the constructs during craniocaudal testing. The craniocaudal bending results fail to support the hypothesis that plate-bone substitute constructs with bending tees are stronger than those without tees. In the mediolateral testing plane, the plate-bone substitute constructs with bending tees over the fracture gap had a significantly increased bending stiffness and bending structural stiffness than constructs without tees. The mediolateral bending results support the hypothesis that plate-bone substitute constructs with bending tees are stronger than without tees which is in contrast to the findings in the study by Ness.<sup>1</sup> This difference could result from a type II error in the original Ness study design, the difference in the 4-point bending setup with a compressive force across the topside of the plate in the Ness study, or the result of differences between isolated plate testing and plate-bone substitute construct testing.

While significance in bending stiffness and bending structural stiffness was reached in the mediolateral bending plane when tees were added, the difference in absolute values is small (2.08 N/mm in bending stiffness and 0.26 N/mm in bending structural stiffness) and may not be clinically significant. Unlike conventional plate systems where an empty screw hole could be more susceptible to loading forces and subsequent implant failure, the SOP nodes are not generally considered a weak point. The cylindrical internode as the lowest AMI section (30 mm,<sup>4</sup> in both bending planes) is considered a weaker segment of the plate.<sup>3</sup> However, as previously suggested by Benamou and colleagues, the role of the node in bending properties might have been underestimated.<sup>3</sup> In the current study, an attempt was made to measure the internal diameter of the nodal void at the topside and underside of the plate with a digital internal caliper; however, any differences remained constrained to the hundredth decimal place, which we felt the digital caliper could not reliably perform. A previous *in vitro* study testing load to failure in axial compression of two pearl-type plate implant systems showed minimal to marked deformation of empty nodes over the fracture gap suggesting that these empty nodes could be another location for implant failure.<sup>15</sup> While a measurable nodal deformation was not clearly obtained in the current study, some nodal deformation is expected to play a role in the difference in bending stiffness and bending structural stiffness between constructs with or without bending tees in the mediolateral bending plane. A plausible explanation is that the presence of the bending tees as a separate unfused component in the nodal void cannot resist the longitudinal tension forces on the topside of the node opening but they could be resisting compressive forces across the underside node opening. Additionally, if tension is causing proximal–distal node elongation of the topside of the void as demonstrated by Tremolada and colleagues, it is possibly accompanied by transverse node narrowing which could be resisted by the *in situ* bending tee.

As with most *in vitro* mechanical evaluation studies, there are several limitations to the current study. First, there are inconsistent and varying definitions of construct failure and testing endpoints in the literature. Plastic deformation of the structure, screw breakage or loosening, and a displacement distance of 4 to 48 mm had all been reported.<sup>1,2,24–26</sup> In a study testing the same plate as the current study, 12-hole, 3.5 mm SOP, a 10-mm displacement distance was defined as the end-point in single-cycle 4-point bending testing.<sup>26</sup> Pilot testing was performed before actual testing in the current study. All plate–bone substitute constructs with and without tees, loaded in the mediolateral or the craniocaudal plane, showed loss of structural integrity via plastic deformation of the plate before a 15-mm displacement distance was reached. As a result, a 15-mm displacement distance was used as the endpoint in the subsequent testing.

Another limitation of the current study is that there are no standardized guidelines for plate–bone substitute construct testing. According to ASTM 382-17, Delrin® can be considered rigid extension segments as part of the metallic plate testing. The variability of bone surrogates as well as differ-

ences between species make it impossible to establish standardized guidelines for plate–bone substitutes or plate–bone constructs. To minimize the variance, a substitute synthetic bone was chosen in the current study to simulate a comminuted femoral fracture. The mechanical features of Delrin®, polyoxymethylene, is an acceptable synthetic bone model with a similar Young's modulus to a cadaver bone.<sup>27</sup> However, it is still essentially different from living bones.

Lastly, in clinical settings, most implant failures in long bone fracture repair occur after repetitive weight-bearing on the limb. Repetitive weight-bearing creates a cyclic fatigue load instead of a single-cycle load to failure, which is more compatible with a traumatic event and therefore may not be applicable to clinical outcomes. In addition, bending is not the only force experienced by the bone and implants. Torsional force and axial compression also play a role. Further mechanical testing using cyclic, nondestructive bending methods, and torsional and axial compression testing should be investigated.

## Conclusion

With higher AMI, resulting from plate structural differences, the SOP has an increased bending stiffness in the craniocaudal testing plane compared with the mediolateral testing plane. There is no significance noted in bending stiffness or bending structural stiffness in the craniocaudal testing plane with or without bending tees in the nodes over the fracture gap. The bending stiffness and bending structural stiffness in the mediolateral plane are significantly increased when bending tees are present in the nodes over the fracture gap than without tees. However, with a small absolute difference in values, the clinical significance is unknown. At this time, no clear recommendations can be made about the use of bending tees in the empty nodes of SOP implant constructs in clinical cases despite this being common practice in some surgeons' experience. Future *in vitro* and *in vivo* studies should be performed to determine if bending tees are beneficial for comminuted or gap fracture repair in a bridging fashion.

## Note

Content from this study was presented as an abstract at the Veterinary Orthopedic Society Annual Conference; March 11–18, 2023; Big Sky, Montana.

## Authors' Contribution

P.-H.L. and K.M.C. contributed to the conception, study design, acquisition of data, data analysis and interpretation. R.F. contributed to acquisition of data, data analysis and interpretation. E.H. contributed to the study design, data analysis and interpretation. K.K. contributed to study design. B.M. contributed to the conception and study design. All authors drafted, revised, and approved the submitted manuscript and are publicly responsible for the relevant content.

## Conflict of Interest

None declared.

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