Medial migration in cephalomedullary nail fixation of pertrochanteric hip fractures

A BIOMECHANICAL ANALYSIS USING A NOVEL BIDIRECTIONAL CYCLIC LOADING MODEL

Objectives
The paradoxical migration of the femoral neck element (FNE) superomedially against gravity, with respect to the intramedullary component of the cephalomedullary device, is a poorly understood phenomenon increasingly seen in the management of pertrochanteric hip fractures with the intramedullary nail. The aim of this study was to investigate the role of bidirectional loading on the medial migration phenomenon, based on unique wear patterns seen on scanning electron microscopy of retrieved implants suggestive of FNE toggling.

Methods
A total of 18 synthetic femurs (Sawbones, Vashon Island, Washington) with comminuted pertrochanteric fractures were divided into three groups (n = 6 per group). Fracture fixation was performed using the Proximal Femoral Nail Antirotation (PFNA) implant (Synthes, Oberdorf, Switzerland; n = 6). Group 1 was subjected to unidirectional compression loading (600 N), with an elastomer (70A durometer) replacing loose fracture fragments to simulate surrounding soft-tissue tensioning. Group 2 was subjected to bidirectional loading (600 N compression loading, 120 N tensile loading), also with the elastomer replacing loose fracture fragments. Group 3 was subjected to bidirectional loading (600 N compression loading, 120 N tensile loading) without the elastomer. All constructs were tested at 2 Hz for 5000 cycles or until cut-out occurred. The medial migration distance (MMD) was recorded at the end of the testing cycles.

Results
The MMDs for Groups 1, 2, and 3 were 1.02 mm, 6.27 mm, and 5.44 mm respectively, with reliable reproduction of medial migration seen in all groups. Bidirectional loading groups showed significantly higher MMDs compared with the unidirectional loading group (p < 0.01).

Conclusion
Our results demonstrate significant contributions of bidirectional cyclic loading to the medial migration phenomenon in cephalomedullary nail fixation of pertrochanteric hip fractures.

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Keywords: Medial migration, Pertrochanteric hip fractures, Intramedullary nail, Cephalomedullary nail, Hip fractures

Article focus
Medial migration is the paradoxical migration of the femoral neck element (FNE) superomedially against gravity, with respect to the intramedullary component of the cephalomedullary device. This is a phenomenon increasingly seen in the management of pertrochanteric hip fractures with the intramedullary nail that is poorly understood but can result in devastating consequences. Our study aims to investigate the role of bidirectional loading on the medial migration phenomenon, based on unique wear patterns seen on scanning electron microscopy of retrieved implants suggestive of the FNE toggling.
Key messages
- Discrete biomechanical conditions are required for medial migration to occur.
- Bidirectional cyclic loading on the femoral head simulating loading and unloading of the hip joint in the setting of an unstable pertrochanteric fracture configuration plays a major role in the medial migration phenomenon with the cephalomedullary nail.
- With better understanding of the underlying driving factors behind medial migration, implant modifications can be more appropriately made to avert the medial migration phenomenon and its associated morbidity.

Strengths and limitations
- Reliable reproduction of the medial migration phenomenon was seen across all groups, with the bidirectional loading groups showing significantly higher medial migration distances compared with the unidirectional loading group. Our study findings are in support of earlier biomechanical studies suggestive of the FNE toggling in the medial migration phenomenon.
- Compared with the existing unidirectional compression models in the literature, our study’s use of bidirectional cyclic loading simulating loading and unloading of the hip joint is more physiologically relevant in representing the loading mechanics at the hip in the investigation of the medial migration phenomenon.
- Earlier biomechanical studies have shown that the hip joint sustains two to three times its body weight during gait. Ideally, our study would have been more robust if we had used these loads. The choice of smaller loads in our study was made to accommodate the loading capacity of our biomechanical tester (±1000 N).

Introduction
Fragility hip fractures are becoming increasingly common, with estimates to reach 2.6 million cases in 2025 and 4.5 million cases in 2050 worldwide, from 1.26 million cases in 1990. Pertrochanteric fractures, defined as the extracapsular region extending from the basicervical level of the femoral neck to the level of the lesser trochanter just above the medullary canal, account for 50% of these fractures. Fixation failure is seen in 5% of these pertrochanteric fractures and is associated with doubling of healthcare costs, a two-fold increase in the length of hospital stay, reduction in quality of life, and an increased likelihood in subsequent social dependency. With hip fractures becoming more common and complex in the ageing population, the economic and clinical strains on healthcare systems are expected to increase.

In recent years, load-sharing devices such as fixation with intramedullary nails have gained popularity. These cephalomedullary devices offer biomechanical advantages and have been shown to have superior outcomes when compared with the traditional extramedullary sliding screw devices, particularly in unstable, multifragmentary fractures (AO type A2/A3).

Medial migration is a phenomenon seen almost exclusively in the management of pertrochanteric hip fractures with the cephalomedullary nail (Fig. 1). Though infrequent, medial migration can result in complications with considerable morbidity including femoral head perforation, penetration of the acetabulum, and migration into the pelvic cavity. A review of the literature shows that there is an increased number of reports of medial migration in the last decade (Table I).

There are limited studies that have investigated the biomechanics of the medial migration. To our knowledge, Weil et al. conducted the only study that was successful in replicating the medial migration phenomenon in a laboratory setting. Using a biomechanical model specifically engineered to simulate a deficient femoral calcar and the lack of lateral cortical support, along with a layer of elastomer at the femoral head-neck interface to simulate the elastic properties of the nail/bone interface, reliable reproduction of the medial migration was achieved in all five different nail designs tested (Trochanteric Fixation Nail (TFN; Synthes, Paoli, Pennsylvania), Proximal Femoral Nail (PFN; Synthes, Switzerland), Proximal Femoral Nail Antirotation (PFNA; Synthes, Switzerland), Gamma-3 nail (Stryker/Howmedica, Mahwah, New Jersey), and Intramedullary Hip Screw (IMHS; Smith and Nephew, Memphis, Tennessee). This was using unidirectional axial loading.

This study aims to investigate the medial migration phenomenon with the use of a more physiologically relevant biomechanical model with bidirectional cyclic loading on the femoral head simulating loading and unloading of the hip joint.

Materials and Methods
A total of 18 fourth-generation synthetic femurs (Sawbones, Vashon Island, Washington) were used in our study. These synthetic femurs have been reported to be similar to the biological range of healthy adult bones with respect to flexural rigidity and torsional rigidity, and have also demonstrated mechanical failure modes close to published findings for human bones.

Comminuted fractures in the pertrochanteric region of the synthetic femurs were created using an oscillating saw. The loose, comminuted fragments were removed to simulate fracture nonunion, an unstable calcar pattern, and the lack of a proximal lateral buttress. The PFNA implant (Synthes, Oberdorf, Switzerland) was...
used for fracture fixation in our synthetic bone-implant construct (Fig. 2).

The PFNA implants were inserted in accordance with the manufacturer’s recommendations and were fixed distally with the locking screw. Over-reaming of the femoral neck and femoral head was performed to allow free sliding of the cephalic blade forwards and backwards across all constructs. This is to ensure that there was less resistance to medial migration than superior cut-out. Frictional hold between the cephalic blade and synthetic bone within the femoral neck and femoral head was then controlled via the use of a set screw, which was tightened to a torque of 0.5 Nm using a calibrated torque wrench (Fig. 3).

The synthetic bone-implant constructs were divided into three groups (n = 6 per group). Six PFNAs were used in our study. The dimensions of the implant were as follows: 1) nail length 200 mm, proximal diameter 17 mm, diameter 10 mm; 2) cephalic blade 90 mm; and 3) distal locking screw length 40 mm. Each PFNA was reused twice. All constructs were rigidly held at the distal end of the synthetic femur and tested using a biomechanical tester (Electropuls E1000; Instron, Norwood, Massachusetts) with loading applied to the femoral head via a customised anvil (Fig. 4). The sampling frequency of the Instron was 1000 Hz. The software used was WaveMatrix v1.8.383.0 (WaveMatrix Ltd, London, United Kingdom). The edge of the customised anvil was equipped with sharp teeth to ensure firm contact and to prevent rotation. A mechanical vice tightly secured onto the tester bed was used to fix the distal femur in the anteroposterior plane. Caution was taken to ensure that the epicondyles were flush and level to the horizontal tester bed. Placement markings were made on the vice and tester bed to ensure accuracy and consistency in the positioning of the synthetic bone-implant constructs. These were checked pre- and post-testing to ensure that there was no change in position or loading vector with respect to the constructs during testing. No preconditioning was required for the implants or the synthetic femurs as the loads applied do not exceed the limits of plasticity of the materials used to result in deformation.

Taking the weight of a single lower limb as one-sixth body weight, the assumed compressive load from body weight alone on the supporting hip joint during unilateral stance is taken as five-sixths of body weight. Using a hypothetical case of an individual weighing 72 kg, the compression load during unilateral stance on the supporting hip joint will be 600 N and the tensile load on the hip joint will be 120 N when the lower limb is lifted off the ground.

Group 1 was subjected to unidirectional compression loading of 600 N, with an elastomer (70A durometer) replacing the loose comminuted fragments removed earlier to simulate surrounding soft-tissue tensioning forces and elastic properties of the nail-bone interface that allow the nail to return toward its original position as the load is reduced. Group 2 was subjected to bidirectional loading with compression loading of 600 N followed by tensile loading of 120 N, also with the elastomer (70A durometer) replacing the loose comminuted fragments removed earlier. Direct compression loading was applied via the customised anvil, while tensile loading was applied via the pulling of the metal wires, which are
wrapped around the femoral head. Group 3 was subjected to bidirectional loading with compression loading of 600 N and followed by tensile loading of 120 N, this time without the elastomer. Compression loading was applied via the customized anvil, while tensile loading was applied via the metal wires wrapped around the femoral head (Fig. 5). All three groups were tested at 2 Hz for 5000 cycles in the axial plane at a loading vector of 149°, consistent with the physiological loading vector.

The starting points of the cephalic blades with respect to the lateral edge of the synthetic bone were standardized at 5 mm across all groups (Fig. 5). Cumulative medial migration in the direction of the axis of the cephalic blade (Femoral Neck Element (FNE)) was recorded at the end of the testing cycles by an electromagnetic (EM) sensor (3D Guidance trakSTAR Electromagnetic 6DoF Tracking Solution; Ascension Technology Corporation, Northern Digital Inc, Shelburne, Vermont) attached to the cephalic blade. The limit of resolution was 0.5 mm and 0.1°. The sampling frequency of the EM sensor output was 80 Hz. The software used was Cubes v36.0.20.3 (Cubes Software A/S, Kongens Lyngby, Denmark).

**Table I.** Literature on medial migration

| Authors | Title | Cases, n | Age, yrs (sex) | Morbidity of medial migration | Implant/construct |
|---------|-------|-----------|----------------|------------------------------|-------------------|
| Lee et al (2017) | Intrapelvic penetration of lag screw in proximal femoral nailing: a case report. | 1 | 72 (male) | Femoral head perforation with penetration into acetabulum and pelvis. | Short Gamma-3 nail (Stryker, Kalamazoo, Michigan)/lag screw |
| van Hoef et al (2016) | Late occurring medial migration of a lag screw in gamma nailing. | 1 | 81 (female) | Femoral head perforation with acetabulum penetration. | Short Gamma-3 nail (Stryker, Kalamazoo, Michigan)/lag screw |
| Pinheiro et al (2016) | Medial migration of the intramedullary Gamma 3 nail – a case report. | 1 | 92 (female) | Femoral head perforation with penetration into acetabulum and pelvis. | Short Gamma-3 nail (manufacturer not specified)/lag screw |
| Nagura et al (2015) | Medial migration of the lag screw in gamma nailing system: a case report. | 1 | 92 (female) | Femoral head perforation with penetration into acetabulum and pelvis. | Short Gamma-3 nail (Stryker, Tokyo, Japan)/lag screw |
| Liu et al (2014) | Reason and treatment of failure of proximal femoral nail anterotation internal fixation for femoral intertrochanteric fractures of senile patients. | 3 | N/A | 2 femoral head perforations with penetration into hip joint; 1 femoral head perforation with penetration into acetabulum and pelvis. | Proximal Femoral Nail Anterotation (PFN); manufacturer not specified)/helical blade |
| Takasago et al (2014) | Intrapelvic migration of the lag screw in intramedullary nailing. | 1 | 63 (female) | Femoral head perforation with penetration into acetabulum and pelvis. | Short Gamma-3 nail (Stryker, Tokyo, Japan)/lag screw |
| Akçay et al (2013) | Pelvic migration of lag screw following fixation of an intertrochanteric femur fracture with proximal femoral nail. | 1 | 90 (male) | Femoral head perforation with penetration into acetabulum and pelvis. | Proximal Femoral Nail (PFN; manufacturer not specified)/lag screw |
| Takigami et al (2011) | Acetabular perforation after medial migration of the helical blade through the femoral head after treatment of an unstable trochanteric fracture with proximal femoral nail anterotation (PFN): a case report. | 1 | 79 (female) | Femoral head perforation with penetration into acetabulum. | PFNA (Synthes, Oberdorf, Switzerland)/helical blade |
| Frank et al (2011) | Forward progression of the helical blade into the pelvis after repair with the Trochanter Fixation Nail (TFN). | 1 | 87 (female) | Femoral head perforation with penetration into acetabulum and pelvis. | Trochanter Fixation Nail (TFN; Synthes, Inc, West Chester, Pennsylvania)/helical blade |
| Li et al (2010) | Medial pelvic migration of the lag screw in a short gamma nail after hip fracture fixation: a case report and review of the literature. | 1 | 77 (female) | Femoral head perforation with penetration into acetabulum and pelvis. | Short Gamma-3 nail (Stryker, Kalamazoo, Michigan)/lag screw |
| Lucke et al (2010) | Medial migration of lag screw with intrapelvic dislocation in gamma nailing—a unique problem? A report of 2 cases. | 2 | 75 (male); 68 (male) | Femoral head perforation with penetration into acetabulum and pelvis; femoral head perforation with penetration into acetabulum and pelvis. | Short Gamma-3 nail (Stryker, Mahwah, New Jersey)/lag screw |
| Weil et al (2008) | Medial migration of intramedullary hip fixation devices: a biomechanical analysis. | 8 | N/A | Distance of medial migration reported (1.9 mm to 22.6 mm) | TFN (Synthes, Paoli, Pennsylvania)/helical blade |
| Brunner et al (2008) | The PFNA proximal femur nail in treatment of unstable proximal femur fractures—3 cases of postoperative perforation of the helical blade into the hip joint. | 1 | 67 (female) | Femoral head perforation with acetabulum penetration. | PFNA (Synthes, Solothurn, Switzerland)/helical blade |
| Tauber and Resch (2006) | Sigmoid perforation after medial migration of lag screw in gamma nailing. | 1 | 84 (female) | Femoral head perforation with penetration into acetabulum and pelvis. | Short Gamma-3 nail (Stryker, Mahwah, New Jersey)/lag screw |
| Werner-Tutschku et al (2002) | Intra- and perioperative complications in the stabilization of per- and subtrochanteric femoral fractures by means of PFN. (Article in German) | 5 | N/A | N/A | PFN (manufacturer not specified)/lag screw |

N/A, not applicable
Results

Reliable reproduction of the medial migration was seen in all three groups. Bidirectional loading with elastomer had the greatest medial migration distance (MMD) at 6.27 mm (SD 2.59), followed by bidirectional loading without elastomer at 5.44 mm (SD 1.99). These were significantly more (p < 0.01) compared with unidirectional loading with the elastomer with the least MMD at 1.02 mm (SD 0.64; Fig. 6). Although bidirectional loading with elastomer had more medial migration compared with bidirectional loading without elastomer, this difference was not statistically significant (p = 1.00). Femoral head cut-out occurred in both bidirectional loading groups.

Discussion

Weil et al. proposed that toggling is required for medial migration of the FNE in the cephalomedullary device to occur based on the consistent fracture pattern involving the medial calcar and the greater trochanter seen in their case series of eight pertrochanteric hip fractures where medial migration occurred. They went on to prove their hypothesis with a biomechanical model specifically engineered for toggling to occur and were successful in recreating the medial migration phenomenon in all five different nail designs tested (TFN, PFN, PFNa, Gamma-3 nail, and IMHS nail). No medial migration was seen when toggling was intentionally restricted in all of the cephalomedullary nail designs with a single FNE with the exception of the PFN, which has two FNEs.

Medial migration was first seen in the description of the Z-effect phenomenon by Werner-Tutschku et al. in their series of 70 proximal femur fractures managed with the PFN where the proximal lag screw migrated medially and the distal lag screw migrated laterally. In the study by Weil et al., preventing nail toggle did not prevent medial migration of the distal FNE when two femoral neck implants were used. Migration was prevented only with clamping of the nail and removal of the superior neck element. This suggests a different mechanism of migration in two-screw devices, consistent with earlier observations.
of the peculiar behavior of the lag screws in the Z-effect phenomenon.

In our earlier scanning electron microscopy study comparing retrieved implants from revision surgeries of patients with prior fixation of their pertrochanteric hip fractures with the PFNA complicated by either cephalic blade cut-out or cut-through, we found repetitive, linearly arranged, regularly spaced, unique transverse scratch marks only on the cephalic blades with medial migration corresponding to the specific segment of the cephalic blade that had passed through the intramedullary component of the PFNA during medial migration, at the intramedullary nail–cephalic blade interface (Figs 7 to 9). These findings from our retrieval study are in support of the toggling hypothesis and suggest that there is an underlying repetitive, cyclical process driving the ‘toggling’ behind the medial migration phenomenon.

We postulate that medial migration requires two criteria to occur: 1) toggling; and 2) propagation of the FNE medially with respect to the proximal fracture fragment. Perforation of the femoral head and acetabulum occurs during the compression phase (e.g. single-leg stance) as the clockwise moment prevents lateral migration of the femoral element with respect to the intramedullary component, while the anticlockwise moment of the femoral element with respect to the intramedullary component allows propagation of the FNE medially during the tension phase (e.g. when the lower limb is lifted off the ground). Figure 10 shows a diagrammatic representation of the postulated mechanism. This leads to FNE motion only in one direction while preventing motion in the opposite direction similar to that of a ratcheting mechanism, accounting for the antigravity movement of the FNE in the medial migration phenomenon. The structural configurations that facilitate toggling include the lack of
Medial migration can occur due to comminution at the greater trochanter, an unstable medial calcar, an unstable fracture pattern, and fracture nonunion. The driving factors behind propagation of the FNE medially include repeated cycles of loading-unloading at the hip joint (e.g., during gait, transfers, or stance changes) and forces that return the FNE to its original position as the load is reduced (e.g., soft-tissue tensioning and the elastic properties at the nail-bone interface).

For medial migration to occur, the resistance in the bone medial to the tip of the FNE must be lower than the resistance in the bone superior to the tip of the FNE. The low incidence of medial migration, despite having commonly found predisposing factors mentioned earlier, could be due to the high variability of bone quality in patients, fracture pattern, quality of reduction, and implant placement leading to other more common complications, such as superior cut-outs and varus collapse occurring before medial migration can occur.

Compared with the existing unidirectional compression models in the literature, our study’s use of bidirectional cyclic loading simulating loading and unloading of the hip joint is more physiologically relevant in representing the loading mechanics at the hip in the investigation of the medial migration phenomenon.

We implemented several measures in order to reduce the number of confounding variables so that the medial migration phenomenon can be studied in isolation. These include: 1) the use of overreaming to allow free sliding of the cephalic blade forwards and backwards across all constructs to ensure that there was less resistance to medial migration than superior cut-out; and 2) the use of a set screw tightened to a torque of 0.5 Nm using a calibrated torque wrench to control frictional hold between the cephalic blade and the synthetic bone within the femoral neck and femoral head. This was similar to the study by Weil et al,22 where the authors allowed free sliding back and forth in the femoral head fixture by creating a hole specific to the diameter of the femoral neck implant and controlled frictional hold using a set screw.

Medial migration has been reported in both lag screw constructs and helical blade constructs in the literature (Table 1). Earlier studies have demonstrated that the helical blade behaves differently to a screw in the resistance to perforation of the femoral head.28,29 In our study, we investigated the phenomenon only with the PFNA, which has a helical blade construct. With overreaming of the femoral head to allow free sliding, the properties of the helical blade are neutralized, hence future studies will be needed to assess the influence of threads or blades in

Fig. 7
Light microscopy image from inferior ridge of the cephalic blade showing both transverse scratch marks and longitudinal scratch marks (black dots were placed as markers to facilitate identification of the location of the transverse scratch marks on the blade). Magnification 63×.

Fig. 8
Scanning electron microscopy (SEM) images from inferior ridge of the cephalic blade showing both transverse scratch marks and longitudinal scratch marks. Transverse marks seen only on the apex of the inferior ridge limited to the specific segment of the cephalic blade that traversed through the intramedullary component during medial migration. Magnification 160×.

Fig. 9
Scanning electron microscopy (SEM) images from inferior ridge of the cephalic blade. At higher-powered magnification (300×), more transverse scratch marks can be seen at closer intervals with varying depths. Magnification 300×.
Earlier biomechanical studies have shown that the hip joint sustains two to three times its body weight during gait. Ideally, our study would have been more robust if we had used these loads. In the study by Weil et al., compressive loads of up to 800 N were used. Our choice of 600 N to simulate the compression load during unilateral stance at the supporting hip joint was made based on calculations from an individual with a body weight of 72 kg with the assumption that the weight of a single lower limb is one-sixth of body weight. This was chosen to accommodate the limitation of the loading capacity of our biomechanical tester (ElectroPuls E1000; Instron), limited at 1000 N.

One other limitation in our study is the use of the elastomer to simulate surrounding soft-tissue tensioning forces and elastic properties of the nail-bone interface that allow the nail to return toward its original position as the load is reduced. Our choice of the use of a 70A durometer elastomer was based primarily on the successful recreation of the medial migration phenomenon by Weil et al. using the same elastomer, given that they were the only ones successful in recreating the phenomenon in the literature. There are no studies at present validating whether the use of the 70A durometer elastomer is appropriate or representative of the actual local forces surrounding the pertrochanteric region.

No medial migration occurred in our earlier attempts to replicate the phenomenon with the PFNA using unidirectional loading without the elastomer. This was similar to the study by Weil et al., where no medial migration occurred when the elastomer was substituted with a set screw in the testing of all implants with single FNEs (TFN,
PFNA, Gamma-3 nail, and IMHS), suggesting that the elastomer is required in the recreation of the phenomenon in single FNE cephalomedullary devices with unidirectional loading.

Significantly greater MMDs were seen in the two groups with bidirectional loading compared with the group with unidirectional loading (p < 0.01). Interestingly, these bidirectional loading groups, with or without elastomer, demonstrated no significant difference in their MMDs (p = 1.0). This suggests that the role of the elastomer, although previously crucial in recreating the medial migration with unidirectional loading, became negligible when bidirectional loading was used.

Our follow-up protocol following cephalomedullary nail fixation of pertrochanteric hip fractures were at two weeks, six weeks, three months, six months, and 12 months postoperatively or until bone union occurred. We advocate a high index of suspicion for medial migration in managing patients with unstable pertrochanteric fracture configurations managed with the cephalomedullary nail. Patients who develop onset of new hip pain postoperatively should be seen urgently and evaluated with repeat x-rays. Revision surgery should be considered if medial migration is seen, before femoral head perforation occurs. As medial migration is a progressive process, closer monitoring with regular, more frequent outpatient reviews with serial x-rays may be considered in those at low risk of perforation. Modification of weightbearing status and rehabilitation protocols may be useful in mitigating the risk of continued medial migration as this directly changes loading-unloading of the hip joint. As toggling is required for medial migration in these pertrochanteric fractures with unstable configurations, these modifications should be continued until there is adequate restoration of structural support with bone union at the medial calcar.

Having identified the discrete biomechanical conditions and underlying driving factors required for medial migration to occur, implant modifications can be made to avert the phenomenon. These modifications should address issues of toggling and/or propagation of the FNE medially with respect to the proximal fracture fragment, in order to deconstruct the underlying mechanism leading to medial migration.

In conclusion, discrete biomechanical conditions are required for medial migration to occur. Bidirectional cyclic loading on the femoral head simulating loading and unloading of the hip joint in the setting of an unstable pertrochanteric fracture configuration plays a major role in the medial migration phenomenon with the cephalomedullary nail. With better understanding of these driving factors, implant modifications can be more appropriately made to avert the medial migration phenomenon and its associated morbidity.

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G. W. Law: Designed the study, Acquired, analyzed, and interpreted the data,
Drafted and critically revised the manuscript.
Y. R. Wong: Designed the study, Acquired, analyzed, and interpreted the data,
Critically revised the manuscript.
A. K-S. Yew: Designed the study, Analyzed and interpreted the data, Critically
revised the manuscript.
A. C. T. Choh: Acquired and analyzed the data.
J. S. B. Koh: Designed the study, Critically revised the manuscript.
T. S. Howe: Designed the study, Critically revised the manuscript.

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Ethical review statement
This study did not require ethical approval.

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