Comparison of forces generated using compression plating versus a magnetic lengthening nail in a sawbones femur model

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ABSTRACT

Background: The purpose of this study is to compare compression generated by a Precice magnetic lengthening intramedullary nail and a 5.0 mm limited contact dynamic compression plate.

Methods: Transverse osteotomy sites were created in the femoral shaft of ten Sawbones fourth generation composite femurs. Antegrade 10-degree trochanteric Precice nails and 8-hole, 5.0 mm plates were used for fixation. The plates were compressed by placing a neutral screw and three eccentrically drilled compression screws on alternating sides of the osteotomy. Average compression and distribution of compression were compared, and P-values <0.05 were considered statistically significant.

Findings: The Precice nail generated an average of 2.38 megapascal across the osteotomy sites. The plate generated an average of 0.70 megapascal (P < 0.001) with the initial compression screw, 0.93 megapascal (P < 0.001) after the second screw, and 1.04 megapascal (p < 0.001) after the final screw. The distribution of compression was assessed utilizing a polar transformation to compare pressure values. We found that the distribution of compression was more circumferentially uniform in the Precice nail group (P = 0.046).

Interpretation: This study demonstrates that an electromagnetic intramedullary device is capable of generating significantly higher compression, in a more uniform distribution, than a 5.0 mm limited contact dynamic compression plate in a Sawbones model. The results indicate that electromagnetic intramedullary nail systems may be an ideal alternative to compression plating for treatment of at-risk fractures, nonunions, delayed unions, and intercalary allograft reconstruction.

1. Introduction

The use of plate fixation has increased dramatically since the introduction of the dynamic compression plate (Stryker Orthopaedics, Mahwah, NJ) in 1969. At that time, Allgower et al. demonstrated the effectiveness of the “sloping cylindrical oval hole in the plate, so that driving home the spherical-headed screws applies compression without the need for a separate compressor” (Allgower et al., 1970). The compression generated by these plates provides absolute stability and primary bone healing by reducing shearing forces across the fracture site, preventing instability and decreasing resorption. Limited contact dynamic compression plates (LDCP) were subsequently developed to decrease periosteal stripping and vascular insult, which are commonly used in clinical practice for open reduction and internal fixation of fractures, nonunions and intercalary allograft reconstruction (Antabak et al., 2015; Vercio et al., 2018). Compression plating as well as augmentation plating are common options for treating nonunions in the femur, humerus and tibia (Rupp et al., 2018).

An alternative to compression plating is using an intramedullary nail. Multiple studies have compared the effectiveness of intramedullary nailing versus plate fixation for long bone fractures with mixed results (Shin et al., 2017; Zhao et al., 2015). In terms of intercalary allograft reconstruction, compression plating is more likely to result in union (Vercio et al., 2018). The advantages of intramedullary nailing include preservation of the periosteal blood supply, minimization of surgical trauma adjacent to the fracture site and earlier patient mobilization (Shin et al., 2017; Zhao et al., 2015). While open plating causes a significant vascular insult, it has been shown that intramedullary nailing increases blood flow and delivery of osteogenic materials to the fracture site through reaming (Kalbas et al., 2018; Sagi et al., 2012; Schlickewei et al., 2019; Yoon and Liporace, 2018). Still, standard intramedullary nails lack the ability to provide compression across fracture and

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osteotomy sites (Miller and Virkus, 2010). They provide relative sta-

bility which allows for micromotion at the fracture site resulting in secondary bone healing via peripheral callus formation. When a nonunion of the femur occurs, dynamization of the nail or exchange nailing is less effective than augmentation plating in obtaining union (Rupp et al., 2018).

The Precice nail (NuVasive Specialized Orthopedics, Aliso Viejo, CA, USA) is an FDA approved, magnetically controlled distraction and compression nail which has primarily been used to correct limb length discrepancy (Wiebking et al., 2016). The Precice nail assembly includes a generic rare earth magnet connected to a gearbox and screw shaft assembly. An external remote controller (ERC) generates an electromagnetic field which interacts with the Precice nail magnet, gearbox and screw shaft resulting in distraction or shortening. The Precice nail provides a less invasive method of compressing or expanding osteotomy sites during limb lengthening and shortening procedures due to its intramedullary position. While studies have demonstrated the clinical efficacy of the Precice nail in limb lengthening surgery, to our knowledge, there has been no biomechanical study to investigate the amount of compression or distribution of compression generated by the Precice nail system (Kirane et al., 2014). This biomechanical study aims to determine the amount and distribution of the forces generated by a Precice nail in compression and to compare these values to a standard 5.0 mm LCDCP.

2. Methods

For each trial, a transverse osteotomy (AO/OTA 32-A3) was created in the shaft of fourth generation composite femur Sawbones (Sawbones, Vashon Islands, WA, USA). A sagittal saw was used to perform the osteotomy at the same location in the middle of the shaft, equidistant from the tip of the greater trochanter and the lateral femoral condyle. For the nail group, an antegrade 10 degree trochanteric Titanium Precice nail measuring 10.7 mm in diameter and 245 mm in length was placed with two 5 mm pegs proximally and two 4 mm pegs distally for fixation. For the plate group, an 8-hole, 5.0 mm stainless steel LCDCP (Stryker Orthopaedics, Mahwah, NJ, USA) was used for fixation with 4.5 mm cortical screws. The length and width of the compression holes are 12 mm and 8 mm, respectively, and each hole allows for up to 2 mm of compression. Five separate nails and five separate plates were used in a total of ten Sawbones. A miniature C-arm was used to provide fluoroscopic guidance for Precice nail placement and to evaluate for failure during testing.

A pressure mapping sensor (Model 5051, 55.9 × 55.9 mm, TekScan Inc., Boston, MA, USA) was placed at the osteotomy site to measure compression. Sensor calibration was performed before each test according to the best practice recommended in the manufacturer’s user manual. For both groups, a 3 mm thick silicone pad was added during calibration and actual testing to ensure accurate measurements across the surface and prevent damage to the sensor. In order to accurately measure compression for the Precice nail group, a hole punch was used to create a hole in the sensor. The hole punch resulted in interruption in the electrodes distal to the hole punch as indicated by the box in Fig. 1. As a result, each nail compression test was performed a second time with the same sensor rotated 180 degrees, such that the missing portion of the pressure map could be derived from the two measurements.

For the LCDCP group, the plate was uniformly pre-bent in order to apply uniform compression across the osteotomy site. Plates were bent utilizing a standard plate bending press. Each plate was bent in the center by 2 mm to provide uniformity, as described by Ya’ish et al. (Ya’ish et al., 2011). This resulted in a 10-degree bend in the LCDCP plates, and uniformity was confirmed with each plate. All plates were applied at the same location over the osteotomy site on the lateral aspect of the Sawbones. A 3.2 mm drill bit and drill guides were used to place the 4.5 mm cortical screws. A neutral screw was first placed two holes away from the osteotomy site. The sensor was placed in order to cover the entire osteotomy articulation and calibrated to ensure uniformity of measurement. A compression screw was then added in the second hole of the LCDCP on the opposite side of the osteotomy site. Compression was recorded in megapascal (MPa) one minute following each screw insertion in order to allow for any stress relaxation. Compression screws were added in an “alternating side” sequence which has been shown to deliver maximum compression (Ya’ish et al., 2011). The second compression screw was added to the third hole from the osteotomy site on the same side as the neutral screw. A third compression screw was added to the third hole from the osteotomy site on same side as the first compression screw. The order of the screw placement and experimental set-up are shown in Fig. 2A-C. Once all compression measurements were recorded, the plates were removed from the Sawbones and the plates, Sawbones, and sensors were inspected for any evidence of failure.

For the Precice group, each nail was pre-distracted 10 mm using the ERC in order to ensure full compression could occur. Each motor was tested prior to compression to ensure uniformity of the nails. The Sawbones were prepared for placement of the nail per the manufacturer’s protocol and sequentially reamed up to 12 mm. The Precice nail was placed using a trochanteric starting position and was locked proximally and distally using two 5 mm pegs proximally and two 4 mm pegs distally. The sensor was calibrated prior to compression in order to obtain uniformity. The motor inside the nail has a protective mechanism that prevents damage to its components from too much compression and will make an audible click when maximum compression for the individual nail is obtained. The nail was then compressed using the ERC at the recommended distance from the magnet of 57 mm until stalling of the nail was audible and no further compression was observed (Fig. 2D-F). Compression values (MPa) were documented one minute after full compression was achieved. The nail was then distracted, and the pressure sensor was rotated 180 degrees. The nail was compressed again using the ERC until stalling of the nail was again audible and no further compression was observed. Compression (MPa) was again documented after one minute. The overlapping measurements obtained were compared to confirm uniformity of the measurements, and if applicable, the lesser of the two values was used in analysis. The data from both trials was then stitched together to create a complete pressure map (Fig. 3). The nail was then removed, and the nails, Sawbones and sensors were inspected for any evidence of failure. The nails were then individually tested per the manufacturer’s protocol to ensure that they were still able to compress and distract without loss of force and that no failure of the motor had occurred.

Statistical analysis was conducted using SPSS 21.0 (IBM, Chicago, IL, USA). The outcome measures were average compression (MPa) and distribution of compression. The average compression (MPa) was compared between the two groups by averaging pressure values detected by the TekScan pressure sensor. Normality was confirmed using a Wilk-Shapiro test. The comparison was made using a two-sided t-test using the Satterthwaite approximation, and p-values of <0.05 were considered statistically significant. The distribution of compression was compared utilizing a polar transformation (increments of 1 degree) that
converted the pressure values originally recorded in the Cartesian coordinate system to a polar coordinate system (Fig. 4). At each degree increment, the sum of the pressure values along the radius from the center to the periphery of the sensor (indicated by the red line in Fig. 4), was calculated and normalized into percentages by the sum of pressure values of the entire sensor (Fig. 5). The standard deviations of the resulting 360 percentage pressure values were then calculated to represent the variation in pressure experienced circumferentially around the femoral Sawbones. Normality was confirmed using a Wilk-Shapiro test. An independent two-sample \( t \)-test was used to compare the standard deviations between the two groups.

Fig. 2. (Color) The experimental set-up with for the nail and plate groups are shown. (A) The plate, screw and pressure sensor placements are shown in two views. The Sawbones are represented in yellow, screws in red, plate in black and sensor in blue. The screws are placed sequentially in the neutral hole (N) followed by three compression screws (C1, C2 and C3). (B) The 5.0 mm limited contact dynamic compression plate is shown. (C) The Sawbones are fixed at one end with an industrial clamp while the screws are sequentially placed, and measurements recorded with the pressure sensor. (D) The nail, external remote controller (ERC) and pressure sensor placements are shown in two views. The Sawbones are represented in yellow, ERC in red, nail in black and sensor in blue. The ERC is placed 57 mm away from the magnet inside the nail. (E) The antegrade 10 degree trochanteric entry Precice nail is shown. (F) The Sawbones set-up is demonstrated with the nail and sensor in place. The Sawbones will be fixed at one end and the ERC (*) is then placed 57 mm above the magnet in the Precice nail. The location of the magnet was localized under fluoroscopy and marked (†). The magnet is then activated, and measurements are recorded with the pressure sensor. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Fig. 3. (Color) Pressure distribution map demonstrating higher compression (MPa) in the Precice nail group when compared to the plate group. Mega-pascal (MPa).

Fig. 4. (Color) Pressure values along the line indicated by the black arrow are transformed from the left image to the right image. The distance from center in the left image is expressed as a percentage from center on the Y-axis in the right image. Each degree increment in the left image is displayed on the X-axis in the right image. This conversion was carried out for each Precice nail and each plate. Megapascal (MPa).
deformity correction surgery (Laubscher et al., 2016; Szymczuk et al., compression that has been previously used in limb lengthening and

Table 2 summarizes the distribution forces recorded between the

Limited contact dynamic compression plate (LCDCP); Megapascal (MPa); Stan-

### Results

There was no evidence of fracture or failure of the ten Sawbones used in this study. All plates and screws were without failure and no stripping of the screws or loss of purchase occurred during placement. The Precice nails had no evidence of failure. The motors were found to be uniform prior to compression and there was no loss of force that the motor was able to achieve after the testing occurred. The areas of overlap on the sensor in the Precice group had minimal variation and were not significantly different.

The Precice nail generated significantly greater magnitude of pressure across the osteotomy site compared to each compression screw. An average of 2.38 ± 0.41 MPa of pressure across the osteotomy site was achieved with the nail compared to 0.70 ± 0.05 MPa with the first compression screw (p = 0.007), 0.93 ± 0.09 MPa with the second screw (p = 0.001), and 1.04 ± 0.12 MPa with the third screw (p = 0.0012). Table 1 summarizes the compression forces recorded between the nails and plates.

The distribution of the compression was also found to be significantly more uniform in the Precice nail group compared to the LCDCP group. The average standard deviation for the Precice nails was 0.0087 ± 0.0022 MPa compared to 0.0122 ± 0.0025 MPa for the plates (p = 0.046). Table 2 summarizes the distribution forces recorded between the nails and plates.

### Discussion

The Precice nail is an intramedullary device capable of controlled compression that has been previously used in limb lengthening and deformity correction surgery (Laubscher et al., 2016; Szymczuk et al., 2019). This novel intramedullary fixation compression device has also been proposed as a viable alternative to traditional orthopaedic implants in special cases where fractures or nonunions are unlikely to heal and its use has been on the rise (Fragomen, 2017). However, no previous study has compared the amount of force generated or the distribution of force generated by a magnetic intramedullary device versus an LCDCP. This biomechanical study demonstrated that a magnetic intramedullary device is capable of generating significantly higher compression when compared to standard 5.0 mm LCDCP in a Sawbones model. This study also demonstrated that magnetic intramedullary devices are capable of more evenly distributing force across transverse osteotomy sites than the traditional LCDCP.

One consideration for the differences in distribution of compression is that the LCDCPs were not bent appropriately in order to obtain uniform compression. Pre-bending compression plates 2 mm has been shown to provide both more uniform compression as well as more compression at the opposite cortex compared to pre-bending 1 mm or not pre-bending (Ristow et al., 2020). Although a standard plate bending press was used to pre-bend the plates and they were evaluated for uniformity, it is possible that this was not optimal. Still, in the clinical setting, optimal bending of the plate may not be possible. Conversely, the Precice nail is able to achieve uniform compression without alteration of the implant.

Treatment of nonunions and delayed unions of the femur after standard nailing have multiple options, such as dynamization of the nail, exchange nailing, compression plating with removal of the nail and augmentation with compression plating while keeping the nail in place (Luo et al., 2019). Exchange nailing has been found to have a higher union rate when compared to dynamization in nonunions (Vaughn et al., 2018). More recently, a lower nonunion rate in addition to a shorter time to union has been described when using augmentative plating when compared to exchange nailing (Jin et al., 2020; Lai et al., 2019; Luo et al., 2019). This is likely due to the compression that can be obtained with plating that is not possible with a standard intramedullary nail but could be achieved with the Precice nail. Further clinical studies could compare augmentation plating with exchange nailing with a Precice nail to determine union rates and clinical outcomes.

One concern regarding the Precice nail is the fact that it remains unclear how much compression is required for primary bone healing, or when compression becomes deleterious, resulting in pressure osteonecrosis. Traditionally, compression with an intramedullary nail would be obtained by backslapping the nail, which was not evaluated in this study. In the clinical setting, the force generated by backslapping is surgeon dependent and there is risk of hardware failure and causing comminution at the fracture site if the nail is hit too hard. This study confirmed that compression of the Precice nail was limited by the protective mechanism of the motor and the maximum compression of each nail was defined. This provides standardization of the compression in the clinical setting that would not occur with standard backslapping. In addition to this, the Precice nail allows for slow, controlled compression both during and after surgery, and therefore it can overcome both stress relaxation and normal resorption at the fracture site that can occur postoperatively.

### Table 1

<table>
<thead>
<tr>
<th>Specimen #</th>
<th>Precice nail (MPa)</th>
<th>LCDCP Screw 1 (MPa)</th>
<th>LCDCP Screw 2 (MPa)</th>
<th>LCDCP Screw 3 (MPa)</th>
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<tr>
<td>1</td>
<td>2.37</td>
<td>0.63</td>
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<td>2</td>
<td>1.89</td>
<td>0.70</td>
<td>1.05</td>
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<td>0.77</td>
<td>0.85</td>
<td>1.05</td>
</tr>
<tr>
<td>4</td>
<td>2.96</td>
<td>0.70</td>
<td>0.92</td>
<td>1.00</td>
</tr>
<tr>
<td>5</td>
<td>2.12</td>
<td>0.69</td>
<td>0.83</td>
<td>1.08</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>2.38 (0.41)</td>
<td>0.70 (0.05)</td>
<td>0.93 (0.09)</td>
<td>1.04 (0.12)</td>
</tr>
<tr>
<td>Student’s T value</td>
<td>0.0007</td>
<td>0.0010</td>
<td>0.0007</td>
<td>0.0012</td>
</tr>
</tbody>
</table>

Limited contact dynamic compression plate (LCDCP); Megapascal (MPa); Standard deviation (SD).
Several studies have demonstrated successful clinical results with the use of Precice nail, although the optimal post-operative compression protocol is unclear. Watson and Sanders demonstrated successful treatment of complex humeral shaft fractures at risk for nonunion utilizing the Precice nail (Watson and Sanders, 2017). It should be noted that Precice nails were used in this setting for fractures that failed initial functional bracing and were at risk for nonunion. The fracture sites were manually compressed, or the nails were backslapped during surgery and then the ERC was used to compress the fracture site further and prevent any gapping at the time of fixation. Their post-operative protocol involved obtaining radiographs every two weeks and measuring any gapping at the fracture site that may have occurred from normal resorption during healing. The nail was compressed in the office based on any gapping identified until no gapping was observed or callus had formed. Once this had occurred, the nails were compressed 0.33 mm every 3 weeks until union was obtained. Subsequently, Dang et al. reviewed six patients with humeral fractures that were treated with the Precice nail after failure of conservative treatment (Dang et al., 2021). Post-operatively, the nails were compressed 2.5 mm per week until the nail stopped compressing or the locking screws were noted to bend. They noted that over-compression or shortening at the fracture did not occur due to the protective mechanism in the motor. All of the patients went on to union. Fragomen et al. also demonstrated successful management of thirteen out of fourteen nonunions in the tibia or femur with the use of the Precice nail (Fragomen et al., 2019). Of note, the authors also utilized additional non-invasive compression post-operatively to maintain a constant compressive force to overcome stress relaxation which could not be performed with a plate. Furthermore, there was no evidence of osteus injury or damage to the implants as a result of possible over-compression. In their series, they noted that the nail was shortened an average of 9.5 mm (range 3–18 mm) by the ERC post-operatively, but the actual nail only shortened an average distance of 6.7 mm (range 2–10 mm) based on radiographs. This confirms our findings that use of the ERC did not cause continued compression or shortening of the nail once the maximum compression was obtained. They also noted that the bone was shortened by 3.1 mm on average (range 0–7 mm) and the locking screws bent an average of 2.5 degrees (range 0–6 degrees). These studies demonstrate clinical evidence that magnetic intramedullary compression devices are capable of providing a mechanical environment conducive to bone healing in the femur, humerus and tibia but further study is warranted to determine the optimal compression protocol for clinical healing.

Intramedullary nails have several other advantages over compression plates and multiple studies have demonstrated the biological advantages of intramedullary fixation (Goh et al., 2018; Li et al., 2018; Tas et al., 2019). As they are load sharing devices, they allow for earlier weight bearing and are able to deliver osteogenic precursors to the fracture site during the reaming process (Kalbas et al., 2018; Sagi et al., 2012; Schlickewei et al., 2019; Yoon and Liporace, 2018). Other studies have noted the limitations of intramedullary fixation devices including elevated rates of tibia nonunions when post-reduction fracture gapping greater than 3 mm persists (Drosos et al., 2006). Compared to plates and standard nails, magnetic intramedullary compression devices are capable of eliminating fracture gapping in a controlled fashion, and as they allow for non-invasive compression post-operatively, any stress relaxation that occurs can be addressed. These results indicate that magnetic intramedullary compression nail systems may provide all the advantages of both compression plating and intramedullary nailing while avoiding the noted limitations of either system. Limb deformity and limb length discrepancy are secondary complications in fractures with bone loss and fracture gapping. In these circumstances, intramedullary compression nails may be used to facilitate fracture healing and later to correct limb deformity through planned osteotomy and distraction osteogenesis without the need for addition or removal of hardware (Vercio et al., 2018). Similarly, if a limb length discrepancy occurs due to bone loss, a limb lengthening could be performed utilizing the same device. Therefore, treatment utilizing these nails may provide an ideal alternative to traditional implants for treatment of fractures, delayed unions or nonunions that have significant bone loss or fracture gapping.

Limitations of this study include the inability to assess functional outcomes, possible damage from over-compression, and healing potential due to the use of a Sawbones model. While femoral Sawbones have been validated for biomechanical studies, further studies will be needed to assess clinical outcomes following fixation with an intramedullary compression device (Gardner et al., 2010). The current study also used a 10.7 mm diameter nail and further studies are needed to assess whether the maximum compression generated by the internal motor differs with alternate nail diameters. Furthermore, while this study assessed compression generated with the ERC at the recommended 57 mm from the magnet, and this may not be possible or practical in patients with very thick soft tissue envelopes. Further research is needed to assess the amount of compression generated with the ERC at alternate distances from the intramedullary magnet. Lastly, pressure data for the LCDCP group was obtained from an intact pressure sensor while the Precice group stitched together two data sets using hole punched pressure sensor. This may introduce error as slightly different instruments were utilized to collect data. Still, the overlapping data demonstrated equivalent pressure values, and the lesser value was used for analysis. Therefore, it is less likely that the differences between the testing methods are insignificant.

5. Conclusions

This biomechanical study demonstrated that a magnetic intramedullary nail is capable of generating significantly higher compression over a more evenly distributed area when compared to a 5.0 mm LCDCP in a femoral Sawbones model. Although further study is necessary, these results indicate that intramedullary fixation with a magnetic compression nail may be a viable alternative for the treatment of delayed unions, nonunions and fractures at-risk for nonunion.

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Authorship
All authors were fully involved in the study and preparation of the manuscript. The material within has not been and will not be submitted for publication elsewhere. All the authors approved the final submitted version of this article.

Declaration of Competing Interest
Dr. Williams has received an educational stipend from Stryker Orthopaedics. Dr. Zuckerman is a consultant and paid speaker for NuVasive Specialized Orthopedics.

References