Original Article

Combined partially threaded cancellous lag screws offer advantages in terms of the optimal stopping time for screw tightening during compression

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Abstract: The partially threaded cancellous lag screw (PTLS) is the standard approach to provide compressive force (CF) for rigid fixation. However, it continues to be clinically challenging to stop screw tightening in such a manner that one gains the optimal CF while avoiding screw stripping and keeping the pullout strength (POS) intact. In this study, we tested whether the combined partially threaded cancellous lag screw (CPTLS) could offer advantages regarding the appropriate time at which to stop tightening the screw during compression. CF and POS were determined at six rotational angles during the CPTLS compression before screw overtightening in a surrogate of cancellous block (0.12 g/cm^3) . In this block, 60 pilot holes of 3.2 mm in diameter were prepared at equal distance perpendicular to the surface. During the CPTLS compression before screw overtightening, CF increased while POS did not decrease. CF was significantly lower than POS in each angle (P < 0.007). CF differed significantly at each angle (P < 0.001) and its relationship with the angle was significant (r = 0.944, P < 0.001) which fitted a cubic regression model $(R^2 = 0.958, P < 0.001)$. POS did not differ significantly across angles (P = 0.855), correlate to the angle (P = 0.077, P = 0.558), or change with the angle $(R^2 = 0.03, P = 0.632)$. The trend of increasing CF plateaued when CF approached POS in value. The CPTLS could provide advantages in terms of the time at which screw tightening should be stopped during compression.

Keywords: Combined partially threaded cancellous lag screw, compressive force, pullout strength, insertion torque

Introduction

The therapeutic principles of displaced intraarticular fractures are anatomic reduction and rigid fixation, for which lag-screw techniques are important [1, 2]. The partially threaded cancellous lag screw (PTLS) is the standard approach to provide compressive force (CF) in intra-articular fragments for rigid fixation [3]. The PTLS design demands a subjective manual judgment of the tightness of the screw to gaining optimal CF. Incomplete tightness cannot create sufficient CF, while overtightening can cause screw stripping, resulting in loss of CF. Therefore, the choice of when to stop tightening the PTLS is crucial, and considerable skill and experience are necessary when using PTLSs for compression. However, even with skill and experience, screws are occasionally subject to unexpected stripping [4, 5]. Further, the probability of inadvertent screw stripping is elevated in osteoporotic fractures [6].

CF and pullout strength (POS) are two important parameters during screw compression. Sufficient CF is desirable for rigid fixation, while POS should not be comprised in operations involving lag screws [7]. POS decreases significantly when screw stripping happens and causes failure of fixation [5]. An optimal stopping time for lag screw tightening demands an ideal balance between CF and POS, thereby gaining optimal CF while keeping POS intact.

Insertion torque (IT) is the most obvious parameter during the operation of the PTLS for compression. Many studies hypothesized that IT could provide effective clues regarding the optimal stopping time for screw tightening and investigated the relationships among CF, POS,

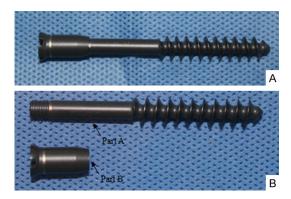


Figure 1. Photographs showing the combined partially threaded cancellous lag screw (CPTLS) that were used. A: The CPTLS: total length, 65 mm; thread diameter and length, 6.5 mm and 32 mm, respectively; shank length, 28.4 mm. B: The CPTLS shank consisting of Part A and Part B. Part A is a cylindrical construction (outer diameter, 4.5 mm) and contiguous to the thread, containing fine threads (thread pitch, 0.85 mm) on the surface. Part B is hollow cylindrical construction (outer diameter, 6.5 mm) and contiguous to the head, containing identical fine threads in the interior space.

and IT [7-10]. CF has a linear relationship with IT [7]. However, POS cannot be assessed exactly from IT, although IT and POS do have a significant correlation, [8] and IT prior to compression might be used as a parameter to assess POS [9, 10]. Therefore, it is a challenge for surgeons to form an optimal judgment of the tightness of the screw by IT and IT change when using the PLTS.

Another strategy is to change the design of the screw to offer advantages for appropriate timing at which screw tightening should be stopped during compression. Accordingly, we designed the combined partially threaded cancellous lag screw (CPTLS), which has a novel shank with a compound construction [11]. The CPTLS differs from the PTLS in that the PTLS has a shank with a single structure. During compression, the CPTLS compresses the bone surrounding the thread by shortening the shank length, while the PTLS compresses the bone surrounding the thread by rotating the thread.

The purpose of this study was to determine (1) how CF and POS change as the rotational angle increases, (2) the relationship between CF and rotational angle, and (3) the relationship between POS and rotational angle when using the CPTLS before screw over tightening in a synthetic specimen.

Materials and methods

The CPTLS was tested in surrogates of cancellous block, and CF and POS were determined for six rotational angles.

Test screws

The CPTLS tested was custom-manufactured by a company specializing in the production of orthopedic implants (Weihai Wego Medical Systems, China) (Figure 1A). The screw length was 62.7 mm, the thread length was 32 mm (thread pitch, 2.75 mm) with an outer diameter of 6.5 mm, and the shank length was 28.4 mm. The screw shank, a novel compound structure, consisted of Part A and Part B, connected by fine threads (thread pitch 0.85 mm) (Figure **1A**). Part A was a cylinder with fine threads on the surface, was contiguous with the thread, and had an outer diameter of 4.5 mm (Figure 1B). Part B was a hollow cylinder with identical fine threads in the interior, was contiguous with the head, and had an outer diameter of 6.5 mm (Figure 1B). The custom-designed screwdriver for this screw consisted of two components that locked with each other via a bolt, including an inner screwdriver that matched Part A and an outer screwdriver that matched Part B. The screwdriver had a locked setting for screw insertion, which could be used by tightening the bolt, and an unlocked setting for screw compression, used by loosening the bolt.

Specimen

A surrogate specimen of cancellous bone block (Pacific Research Laboratories, Vashon, WA) was used to minimize intra-specimen variability [12]. The specimen density was 0.12 g/cm³ to mimicries severely osteoporosis and its dimensions were 180×130×40 mm³ (#1522-09).

The specimen was drilled in an equally spaced grid for insertion using a drill press, and 60 pilot holes were prepared. These pilot holes were 3.2 mm in diameter and 40 mm in length, allowing them to engage the threads completely.

Mechanical testing

Compression test: A custom-designed device was used to measure CF. The device included a 62×25×21 mm³ wood block with a 7-mm round

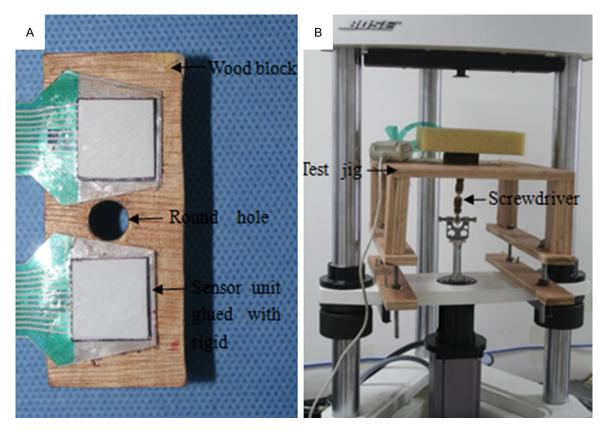
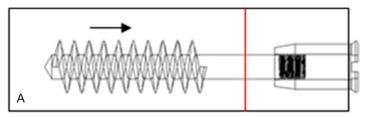


Figure 2. Photographs showing that the assembly can generate and measure the compressive force (CF) for the combined partially threaded cancellous lag screw (CPTLS). A: The custom-designed device for measuring CF, which consists of a wood block with a round hole and two sensors glued with rigid plastics. B: The assembly can generate and measure CF. It consists of the CPTLS, a screw extraction grip, a custom-designed device, a synthetic bone block, a custom-designed screwdriver, and testing machine for rotation.

hole in the middle, through which the thread could be passed. The device also included a Tekscan pressure transducer with four sensor units (Sensor type: 6900, Tekscan Inc., South Boston, Massachusetts) (Figure 2A). Rigid plastics were glued with two sensors on each surface, thereby ensuring that the CF would be transmitted completely through the two sensors. The two sensors were glued symmetrically on two sides of the 7-mm round hole in the wood block. On the opposite side, a customdesigned screw extraction grip was used to prevent the head from sinking and to measure POS. The total thickness of the custom-designed measuring device and screw extraction grip was 24 mm. As this was shorter than the shank length, it excluded the possibility of the thread entering in the round hole.

The CPTLS was inserted manually through the screw extraction grip, through the custom-designed device, and into a pilot hole in the speci-

men. Hence, two sensors on the wood block were sandwiched between the wood block and the specimen. First, the custom-designed screwdriver was used in the locked setting, and the CPTLS was inserted manually as a whole until the head of the CPTLS was very near to the screw extraction grip. The next step was to unlock the custom-designed screwdriver, rotate the outer screwdriver until CF reached 2 N on the sensor monitors. Then the complex was established that consisted of the CPTLS, the screw extraction grip, the custom-designed device and the specimen. Next, the complex was positioned on the custom-made test jig for rotating the CPTLS (Figure 2B). The testing machine (Bose Corporation, ElectroForce Systems Group, Eden Prairie, MN) was used for automatic rotation at 2.62° with a rotation accuracy rate of 0.001°. The second custom-designed screwdriver that matched Part B connected the CPTLS and the testing machine. During this procedure, Part A was not rotated and Part B



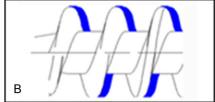


Figure 3. Illustration depicting the combined partially threaded cancellous lag screw (CPTLS) for compression. At During the CPTLS compression, the shank length of the CPTLS shortened along the axis of the CPTLS and the thread displaced in a linear manner (red line: fracture line; black arrow: the direction of the thread displacement). B: The bone surrounding the CPTLS thread was compressed in a linear manner (blue area: the compressed bone surrounding the CPTLS thread).

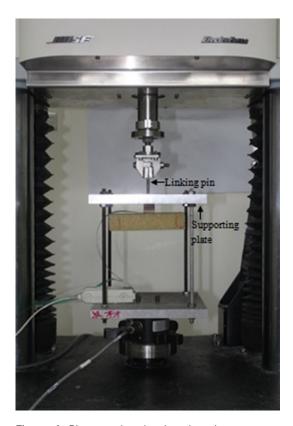


Figure 4. Photographs showing that the construct can measure the pullout strength (POS) for the combined partially threaded cancellous lag screw. It consists of a linking pin that was custom designed to connect the screw extraction grip and testing machine, as well as an aluminum support plate.

was rotated around Part A, thereby shortening the shank length, extracting Part A (**Figure 3A**), compressing the bone surrounding the thread (**Figure 3B**), and producing CF along the axis of the CPTLS.

Our preliminary experiments demonstrated that the CPTLS was overtightened and screw stripping occurred when the rotational angle

exceeded 700° in a 0.12 g/cc specimen. Therefore, the maximum rotational angle should be less than 700° to avoid screw overtightening, and the rotational angles were set to 0°, 150° , 300° , 450° , 550° , and 650° in the study. CF was recorded from the transducer at 10 Hz (10 replications per angle, amounting to 60 evaluations in total).

Pullout test: An aluminum test jig was designed and constructed for measuring POS and converting CF values with Newton. The test jig included a linking pin that was custom-designed to connect the screw extraction grip and the testing machine, as well as an aluminum support plate (Figure 4). After CF was recorded for a set angle, CF was set to 0 N by rotating the outer screwdriver counter-clockwise while keeping the inner screwdriver immobile on the transducer monitor. Subsequently, the CPTLS was pulled using the BOSE3510-AT testing machine (Bose Corporation, Electro Force Systems Group, Eden Prairie, MN) with a pullout rate of 0.02 mm/s. POS was detected at 100 Hz by 75 load cells in the BOSE3510-AT testing machine (10 replications per angle, amounting to 60 evaluations in total).

When using this aluminum test jig for the pullout test, the custom-designed device for measuring CF was sandwiched between the supporting plate and the specimen (**Figure 4**). Therefore, POS data was detected by two systems, including the BOSE3510-AT testing machine and the Tekscan pressure transducer in the custom-designed device. Therefore, we could calculate the proportion relation between the numerical value from the Tekscan pressure transducer and from the BOSE3510-AT testing machine. Compression test and pullout test which were done in sequence. And thus, the CF

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Table 1. CF and POS of each group in the specimen

	GO	G150	G300	G450	G550	G650	P Value†
CF (N)	2 (-)	104.98 (91.45-118.50)	239.14 (216.06-262.22)	314.45 (282.40-346.50)	358.17 (332.37-383.98)	368.91 (354.76-383.06)	< 0.001
POS (N)	389.59 (362.07-417.10)	405.00 (391.17-418.82)	405.77 (383.03-428.52)	399.80 (381.12-418.48)	405.39 (379.61-431.16)	401.93 (379.50-424.36)	= 0.855
P Value*	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.007	

N = 10 for each testing group from G0 to G650. Values are shown as mean (95% confidence interval). †The column of p-values pertains to the comparison among all groups. *The row of p-values pertains to the comparison between the CF and POS of each group. CF, compressive force; POS, pullout strength.

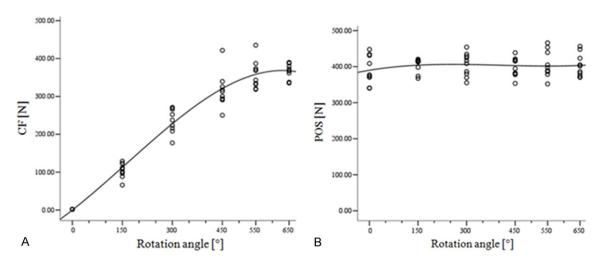


Figure 5. A cubic regression model was used to analyze the compressive force (CF) and pullout strength (POS) change as the rotational angles increased before screw overtightening. A: The CF was positively correlated with the rotational angle ($R^2 = 0.958$, P < 0.001). B: The POS did not increase and was not correlated with the angle ($R^2 = 0.03$, P = 0.632).

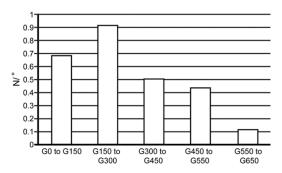


Figure 6. The rates of the mean compressive force (CF) per degree from G0 to G650 were 0.69 N/° , 0.91 N/° , 0.50 N/° , 0.44 N/° , and 0.11 N/° , respectively. The rate of mean CF per degree differed across the phases and decreased rapidly when the rotational angle increased from 550° to 650° .

values were converted with Newton according to the proportion relation.

In this manner, our preliminary experiments found that POS decreased when the rotational angle of the CPTLS exceeded 700° in a 0.12 g/cc specimen. And meanwhile, we gained the proportion relation used to establish the numeric value in the Tekscan pressure transducer which was equal to 2 N at the beginning.

Data and statistical analysis

Data were divided into six groups according to the rotational angle that was investigated: G0, G150, G300, G450, G550, and G650. K-independent samples tests were used to assess CF and POS across groups. Paired-samples *t*-tests were used to detect differences between the CF and POS in each group. Spearman's correlation was used to analyze the relationships between CF and POS with the rotational angle. A cubic regression model was used to detect the change of CF and POS with the rotational angle. Significance for all analyses was set at α < 0.05.

Results

CF and POS at six different rotational angles (**Table 1**)

During the CPTLS compression before screw overtightening, CF increased while POS did not decrease.

CF differed significantly across the six groups (P < 0.001). There was a strong relationship between CF and rotational (r = 0.944, P < 0.001), which was fitted using a cubic regression model (R^2 = 0.958, P < 0.001) (**Figure 5A**). Confidence intervals (95%) for mean CF were (91.45-118.50) N in G150, (216.06-262.22) N in G300, (282.40-346.50) N in G450, (332.37-383.98) N in G550, and (354.76-383.06) N in G650. The rates of mean CF per degree for G0, G150, G300, G450, G550, and G650 were 0.69 N/°, 0.91 N/°, 0.50 N/°, 0.44 N/°, and 0.11 N/°, respectively (**Figure 6**). The rate of mean CF per degree differed across phases, and decreased rapidly when the rotational

angle increased from 550° to 650°, and the trend of increasing CF plateaued during this phase (Figure 5A).

POS did not differ significantly across the six groups (P = 0.855). There was not significant relationship between POS and the rotational angle (r = 0.077, P = 0.558), and the change in POS was not associated with the rotational angle ($R^2 = 0.03$, P = 0.632) (**Figure 5B**). Confidence interval (95%) for mean POS were (362.07-417.10) N in G0, (391.17-418.82) N in G150, (383.03-428.52) N in G300, (381.12-418.48) N in G450, (379.61-431.16) N in G550, and (379.50-424.36) N in G650.

CF was always lower than POS (P < 0.007) in all groups. CF was close to POS numerically in G650, and the ratio of the mean CF to the mean POS was 91.79%. In other words, CF gradually approached POS in value as the rotational angle increased.

Discussion

The PTLS is the standard approach for compression between intra-articular fragments, for which rigid fixation is needed [1, 2]. It is difficult to achieve flawless operation of a PTLS, and the chances of obtaining good results depend heavily on experience [4, 5]. In the study, we evaluated changes in CF and POS across six different rotational angles during the CPTLS compression. We analyzed the relationships between CF and POS, CF and rotational angle, and POS and rotational angle. Three important findings emerged. First, as the rotational angle increased, the CF was always lower than the POS (P < 0.007). The CF gradually approached the POS, but the rates of increasing speed differed as the rotational angle increased. Second, CF increased as rotational angle increased. The difference of CF was significant in different rotational angles (P < 0.001), and the relationship between CF and the rotational angle was significant (r = 0.944, P < 0.001), which fitted a cubic regression model ($R^2 = 0.958$, P < 0.001). Thirdly, POS did not decrease as rotational angle increased. There was not significant difference in POS across angles (P = 0.855), and POS did not correlate with the rotational angle (r = 0.077, P = 0.558). The change in POS did not associate with rotational angle ($R^2 = 0.03$, P = 0.632).

During the CPTLS compression, the compound shank was shortened and the thread was continuously extracted along the axis of the screw in the bone, thereby producing CF continuously until the bone surrounding the thread was compressed to failure. This process of the CPTLS compression was similar to the pullout test of a lag screw, in which the thread was also extracted along the axis of the screw and POS did not decrease until the bone surrounding the thread failed and screw stripping occurred [13]. Therefore, when using CPTLS for compression, CF increased and POS did not decrease until the bone surrounding the thread was compressed until failure. Our results confirmed these anticipated performance of the CPTLS in a severely osteoporotic specimen (0.12 g/cc), demonstrating that CF increased and POS did not decrease as rotational angle increased prior to screw stripping.

CF and POS should ideally be balanced when stopping the tightening of the PTLS during compression. Therefore, it is difficult to form an optimal judgment of the tightness because of the design of the PTLS. First, CF and POS are significantly affected by bone mineral density (BMD) [13, 14]. Second, CF and POS are not synchronous. Several biomechanical studies have demonstrated that POS decreases before CF achieves its maximum [15, 16]. Third, CF can be evaluated by surgeons based on IT, whereas POS cannot be evaluated directly until the screw has stripped and POS decreases suddenly [15, 17]. Finally, CF and POS change quickly in the region surrounding the maximal CF [15, 17]. Small changes of rotational angle can lead to very different results, including either flawless operation or screw stripping. Therefore, surgeons have not had enough of a rotational angle scope to judge and assess when to stop rotating the screw.

The CPTLS could provide advantages in judgment of the tightening the screw during compression, thereby providing beneficial performance in term of CF and POS. First, CF increased and POS did not decrease before screw stripping during the CPTLS compression. Therefore, CF was the only factor that is taken into consideration, and CF and POS might be balanced easily when stopping the tightening of the CPTLS. Second, CF and rates of CF change might provide clues for when to stop rotating

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the screw. Our results demonstrated that the rates of mean CF per degree were different in different phases (0.69 N/°, 0.91 N/°, 0.50 N/°, 0.44 N/°, and 0.11 N/°). Third, the fine thread (thread pitch, 0.85 mm) that connected Part A and Part B of the CPTLS provided extra benefits, providing a good rotational angle range for surgeons to observe CF changes, judge them, and assess when to stop rotating the screw. Finally, the trend of increasing CF plateaued before screw overtightening, and CF in this spectrum might be optimal for compression, thereby decreasing the difficulty of gaining optimal CF.

When to stop tightening the lag screws is a critical decision during lag screw compression for the treatment of intra-articular fractures [3]. In the clinical setting, surgeons subjectively tighten lag screws for compression, and incomplete tightening may not provide sufficient CF, whereas overtightening may cause screw stripping, resulting in loss of CF and POS [3]. Therefore, it is beneficial to help surgeons judge the point at which lag screw tightening should cease-when the optimal CF has been gained and POS is not compromised. Our results demonstrated that the CPTLS could provide advantages in regard to the optimal stopping time for screw tightening, and might be a desirable choice for compression. These advantages might be more obvious in severely osteoporotic fractures because of the higher probability of stripping when using a PTLS for compression [6].

There are some limitations to our study. First, we only investigated changes in CF and POS for the CPTLS before screw overtightening. Second, the densities of the specimens were not sufficient to demonstrate the effects of BMD completely, and investigation of more densities may be necessary to provide more details. Finally, the synthetic cancellous blocks were selected as a simulated cadaveric bone model to identify the relative differences between constructs under highly reproducible test conditions [12].

Conclusion

CPTLSs offered advantages in regard to the optimal stopping time for screw tightening during compression. During the CPTLS compression before screw overtightening, surgeons can judge when to stop screw tightening based on

the CF and changes in the CF with IT. Therefore, the CPTLS may provide an attractive alternative to achieve and maintain rigid fixation during the treatment of displaced intra-articular fractures.

Disclosure of conflict of interest

None.

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