Screw locking elements: A means to modify the flexibility of osteoporotic fracture fixation with DCPs without compromising system strength or stability

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ABSTRACT

This paper analyses whether it is possible to use dynamic compression plates (DCPs) and screw locking elements (SLEs) to vary the flexibility of osteoporotic fracture fixation without compromising the strength and stability of the construct.

Compression, torsion and four-point bending static strength tests were conducted. Cyclic load tests of up to 10,000 load cycles were also carried out to determine stiffness performance. Four fixation systems were mounted onto polyurethane bone models. Group 1 consists of the DCP and six cortical screws. Group 2, idem, but with the addition of two SLEs. Group 3, idem, but with the addition of six SLEs. Group 4 used the locking compression plate (LCP) and locking screws.

The results indicated no significant difference (p > 0.05) in the strength of groups 2–4. It was also observed that the torsional stiffness of group 3 (0.30 Nm/°) was higher than that of group 2 (0.23 Nm/°) and similar to that of group 4 (0.28 Nm/°). Compression stiffness of group 4 (124 N/mm) was higher than that of group 2 (102 N/mm), but lower than that of group 3 (150 N/mm). No notable differences were observed for structural bending stiffness.

It is concluded that by using the DCP with SLEs it is possible to modify the stiffness of the fixation construct for the repair of osteoporotic fractures and, in this way, facilitate the conditions suitable on secondary bone healing.

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1. Introduction

The internal fixation system based on the use of the locking compression plate (LCP) and locking screws has been extremely successful as a treatment for osteoporotic fractures [1,2]. The system provides the fracture with a high degree of stability and the risk of screw loosening is limited [3–5]. However, in some cases, this high degree of stability can give rise to excessive stiffness of the fixation construct. Comminuted fractures are one such example, where contact between bone fragments is impaired and, consequently, primary bone healing prevented. Excessive stiffness can lead to a significant decrease in interfragmentary movement. This could compromise the optimum conditions on secondary bone healing [6,7]. As a result, this might give rise to the formation of inadequate bone callus, delays to bone healing or pseudoarthrosis [8,9]. Methods have been proposed in the scientific bibliography aimed at reducing the excessive stiffness of fixation systems. These include proposals to increase the distance between plate and bone [10] and methods, which prefer the use of more flexible materials [11,12]. However, such strategies cause a reduction in the strength of the system and may even give rise to the opposite effect. That is, excessive micromovement between fragments and fixation loss on the part of some of the screws. The LCP also has the drawback of being an expensive technique when compared with other widely used systems in the market, such as the dynamic compression plate (DCP) [13–15]. Throughout the history of orthopaedics, the principle of dynamic compression has proven to be highly efficient in the repair of bone fractures. However, a number of papers have been published which point out the high failure rate of this technique in the repair of osteoporotic fractures [16–19].

A new screw fixation system has been proposed to increase cortical screw fixation strength with the DCP plate [20]. This consists of the use of elements made from a biocompatible polymer material known as PEEK (polyetheretherketon). These act as lock nuts and have been given the name of SLEs or screw locking elements. The SLEs are placed on the ends of the screw shafts after they have passed through both cortical bones. The pull-out resistance is thereby considerably increased and fixation is ensured. In addition, the construct gains in stability, regardless of the bone quality [20]. A purpose-designed instrument has been developed to ensure
the correct placement of these locking elements without having to perform another incision on the side opposite to the plate during the surgical intervention (Fig. 1).

In this paper, an analysis is conducted of the use of the DCP plate with SLEs in the repair of osteoporotic fractures. The aim is to determine whether it is possible to adjust fixation construct stiffness without compromising its strength and efficacy and, in this way, to facilitate secondary bone healing.

2. Methods

2.1. Test preparation

Cylindrical polyurethane bars (Synbone, Malans, Switzerland) were used to simulate the behaviour of low density bones. These bars, manufactured with a length of 380 mm and a diameter of 25 mm, have been specially designed for the testing of devices used on bones with a high degree of osteoporosis [20,21]. Two areas are distinguishable in the cross-section of these bars: an outer area with a thickness of 1.6 mm which simulates the cortical bone, and an inner area of lower density which simulates the trabecular bone. A total of 54 bars were used (30 for the cyclic tests and 24 for the static tests). Each bar was cut into half to give two parts of equal length. A gap of 10 mm was chosen for the tests to simulate the worst case scenario. This gap was used to represent comminuted fractures [10,18]. After the two parts of the bar had been placed into position with the 10 mm gap, the corresponding plates were assembled, centring them over the fracture.

Four different fixation system configurations were used. Group 1 used a 12 mm wide, 135 mm long and 4 mm thick DCP. This plate, manufactured in stainless steel, has 8 holes. However, 4.5 mm diameter bicortical screws were only placed in the six holes furthest from the fracture (Fig. 2). The screws were positioned in the central part of the holes of the plate so no compression was applied to the fragments of the fracture, thereby conserving the initial gap. Group 1 was only subjected to cyclic tests, while the other groups were tested under both cyclic and static loads. Group 2 differed from the first in that two SLEs were added to the two outer screws of the model. That is, in the holes furthest from the fracture (Fig. 2). Group 3 differed from group 1 in that SLEs were placed on all six screws (Fig. 2). Finally, group 4 used a 13.5 mm wide, 152 mm long, and 4.4 mm thick LCP (Synthes, Soleura, Switzerland). This plate, made from titanium alloy, has 8 mixed holes and six 4.5 mm diameter screws were placed in the threaded part of the holes furthest from the fracture (Fig. 2). The ends of the screws in all four groups were made to protrude at least 3 mm beyond the second cortical bone (or the SLE) in order to guarantee a sufficiently firm hold [22].

Initial torque had to be applied to each of the screws to avoid loss of stiffness in the construct. The amount of torque applied depended on whether the screw was a locking screw or not and whether it had an SLE or not. The torque applied to the screws of the DCP was completely absorbed by the bone. This torque had to be sufficient to guarantee the stiffness of the construct without damaging the bone. To avoid the damage the thread might cause to the bone, a torque of 0.3 Nm was applied to the group 1 and group 2 screws, which did not have SLEs. A torque of 1.5 Nm was applied to the screws of groups 2 and 3 with SLEs. This torque was applied to avoid encrustation of the SLE in the cortical area of the bone. Each of these torques is less than half the minimum value of the maximum torque obtained in six tests, which have not been presented in this paper, performed for each case, following guidelines of the ASTM [23]. In the case of the LCP, a large part of the torque was absorbed by the plate itself. Following the recommendations of the LCP manufacturer, a torque of 4 Nm was applied to the group 4 screws. All torques were applied at less than 10 rpm, using a dynamic measuring gauge (Lorenz Messtechnik GMBH, Alldorf, Germany).

2.2. Biomechanical testing

A total of 45 static tests (15 compression, 15 torsion and 15 four-point bending) and 60 cyclic tests (20 compression, 20 torsion and 20 four-point bending) were performed, making an overall total of 105 tests. The bending and compression tests, both cyclic and static, were performed with a servohydraulic dynamic testing machine (Model EH/5/FK Microtest, Madrid, Spain). The torsion tests were performed with a dynamic torsion testing machine (Model MT-10Nn + PCD-2K, Servoss, Madrid, Spain).

The type of load acting on fracture repair devices varies according to the bone type and its position in the body. Generally speaking, a combination of different types of load will usually be present. However, this load combination can be broken down into static loads and simple cyclic loads (bending, torsion and compression), as reported in the scientific bibliography [17,24,25]. According to the scientific literature, there are usually two types of bending test employed, one of which is the four-point bending test (two outer and two inner supports for load application) [26,27]. The other type of test is known as cantilever bending (system comprising one fixed bone end, a support in the centre and a load applied to the opposite free end). Compression, torsion and four-point bending tests have been performed separately in this study although, in reality, these stress types are found in combination.

2.2.1. Static tests

The groups 2–4 constructs were positioned in each of the machine for the torsion, compression and four-point bending tests. The load in the four-point bending tests was applied at a speed of 5 mm/min until fracturing occurred. In the compression tests, the load was applied at a speed of 5 mm/min until the gap was reduced to 5 mm. Gap reductions of a higher value were considered to be construct failures. The load in the torsion tests was applied at a speed of 0.1°/s, until an angular deformation of 10°.
was obtained. Angular deformations higher than this value were considered to be construct failures.

The magnitude of the applied load and the actuator displacement were registered at a frequency of 100 Hz in the three types of test. In all cases, the value of the maximum load obtained for each of the failure criteria was registered.

2.2.2. Cyclic tests

In the cyclic compression tests, stiffness, expressed in N/mm, was determined from the slope of the load–displacement curve. The constructs were subjected to a sinusoidal cyclic load at a frequency of 2 Hz [28] between 0 N and 350 N. This type of test was characterised by a reference load of 175 N with an alternating load amplitude of 175 N. The displacement and load values obtained by the machine’s sensor system were used to determine stiffness. In this case, system stiffness or the maximum load–total displacement relationship was determined by the ratio $F/δ$ (where $F$ is the force applied by the machine in N and $δ$ is the total displacement, from 0 to the current value, expressed in mm).

In the cyclic torsion tests, the ends of the bone were covered with bone cement to ensure they were held in place by the grips. In addition, one of the grips was allowed free axial movement to avoid the appearance of axial loads during the test. A fully reversed sinusoidal load was applied to the constructs with a torque amplitude of 1 Nm. Torsional stiffness, expressed in N m$^2$/rad, was calculated from the slope of the torque–rotation angle curve. In this case, system stiffness was expressed by the value of the relationship between total applied torque and total rotation.

In the cyclic four-point bending tests, structural bending stiffness ($EI$) was determined in accordance with Eq. (1)

$$EI = \frac{Fa^2(3L - 4a)}{12y}$$

where $F$ is the total applied load, $L$ is the distance between lower supports (300 mm), $a$ is the distance between the upper and lower support (55 mm), and $y$ is the displacement of the upper support.

The load and displacement values were registered for 3 cycles each 1000 cycles in the three types of test, starting with the first cycle and finishing after 10,000 cycles. At this point the test was concluded. The data were taken with a sampling frequency of 30 Hz.

The cyclic load values for the three types of tests were adopted on the basis of the preliminary static tests that were carried out. These loads were chosen so that the constructs would not be permanently deformed.

2.3. Statistical analysis

Analysis of variance (ANOVA) of a single factor was performed to compare the different samples. A Tukey’s multiple comparison was also performed to find significant differences between the samples. The significance level was set at an error probability of 5% ($p < 0.05$). The "Statistical Package for the Social Sciences" software (SPSS version 17.0) was used for the statistical analyses.
3. Results

It should be mentioned that the LCP was made from titanium alloy and the DCP from stainless steel. If a titanium limited contact-dynamic compression plate (LC-DCP) system had been used instead of the DCP, the results for system stiffness would have varied significantly, though not the results for strength. Lower stiffness values would have been obtained in this case as a result of the fact that the elasticity modulus of the steel is higher than that of titanium. So, using titanium instead of steel would allow the DCP system with SLEs to be even more flexible.

At the present time, there is a clear tendency towards the use of artificial bones when assessing the performance of fixation systems [14,18,29]. Cylindrical polyurethane bars (Synbone, Malans, Switzerland) were used in this study to simulate the behaviour of low density bones. These bones have been specially designed for the testing of devices applied to metaphyseal or epiphyseal areas of bones with a high degree of osteoporosis [21]. Synthetic models are available in the market, which more accurately simulate the mechanical characteristics of osteopenic bone [30]. However, with the model chosen for this present study changes in stiffness in more adverse conditions were easier to appreciate as a result of the poor mechanical characteristics of the model. This paper does not suggest that the results of the work presented here can be compared with the results published in the scientific literature for in vivo tests. The present study is limited to a comparison of systems, which use the same model and load conditions.

3.1. Static tests

Static tests were performed with all the groups except for group 1. The option of undertaking static studies with the DCP system without SLEs (group 1) was discarded since it has been demonstrated that there is total loss of stability during the load cycles [20].

Fig. 3 shows the means and standard deviations of the maximum obtained loads for each of the three study groups. These loads were registered before system failure occurred in the static compression, four-point bending and torsion tests.

The statistical analysis of these values indicated that there were no significant differences between the means (p > 0.05) of groups 2–4 in any of the three types of test (p = 0.182 compression; p = 0.527 four-point bending and p = 0.104 torsion).

3.2. Cyclic compression tests

Fig. 4 shows the results obtained for the cyclic compression tests. That is, the mean values and deviations of compression stiffness measured in N/mm for each of the four fixation systems as a function of the number of cycles.

An ANOVA analysis of the results indicated that there were significant differences (p < 0.05) between the compression stiffness of the four groups for all the interval of cycles. The maximum stiffness was obtained with the DCP + 6SLEs system. Initial stiffness of the LCP system was 21% lower than that of the DCP + 6SLEs system (136.63 ± 3.79 compared with 172.25 ± 2.99 N/mm; p = 0.0010 < 0.05), though final stiffness was only 17% less (124.02 ± 3.83 compared with 149.66 ± 1.95 N/mm; p = 0.0001 < 0.05). However, initial stiffness of group 2 (DCP + 2SLEs) was 11% lower than the LCP group (121.08 ± 4.04 compared with 136.63 ± 3.79 N/mm; p = 0.0001 < 0.05). This difference rose to 18% when comparing final stiffness (101.94 ± 2.01 compared with 124.02 ± 3.83 N/mm; p = 0.0001 < 0.05).

The lowest values for both initial and final stiffness were in group 1 (DCP without SLEs). The highest loss of stiffness was also registered in this group, this being a loss of 39% (96.47 ± 4.57 compared with 58.41 ± 2.27 N/mm).

3.3. Cyclic torsion tests

Fig. 5 shows the results obtained for the cyclic torsion tests. That is, the mean values and deviations of torsional stiffness measured in N m/° for each of the four fixation systems as a function of the number of cycles.

An initial ANOVA analysis of the results indicates that there were significant differences (p < 0.05) between the means of the four groups for all the interval of cycles. A second analysis, using Tukey’s multiple comparison method, indicated that there were no significant differences (p > 0.05) for all the interval of cycles between the group 3 (DCP + 6SLEs) and group 4 (LCP with locking screws) systems.

Initial stiffness of group 2 (DCP + 2SLEs) was 5% lower than that of the LCP group (0.2679 ± 0.0038 compared with 0.2834 ± 0.0021 N m/°; p = 0.353 < 0.05). Final stiffness of the group 2 constructs was 15% lower than that of group 4 (0.2344 ± 0.0105 compared with 0.2769 ± 0.0033 N m/°; p = 0.014 < 0.05).

As with compression stiffness, the group 1 systems had the lowest initial and final torsional stiffness values. Likewise, these systems also exhibited a strong drop in stiffness, with a difference between initial and final stiffness of 67% (0.2088 ± 0.0117 compared with 0.0695 ± 0.0126 N m/°).

3.4. Cyclic four-point bending tests

Fig. 6 shows the results obtained for the cyclic four-point bending tests. That is, the mean values and deviations of structural bending stiffness, measured in N m², for each of the four fixation systems as a function of the number of cycles.

An ANOVA analysis of the results indicated that there were significant differences (p < 0.05) between the means of the four groups for all the interval of cycles.

The initial stiffness of the system of lowest stiffness (group 1) was 11% lower than the initial stiffness of the system of highest stiffness (DCP + 6SLEs) (4.94 ± 0.14 compared with 5.57 ± 0.05 N m²; p = 0.038 < 0.05). The final stiffness of the system of lowest stiffness (DCP + 2SLEs) was 13% lower than the final stiffness of the system of highest stiffness (group 3) (4.68 ± 0.18 compared with 5.36 ± 0.07 N m²; p = 0.040 < 0.05). As can be seen in Fig. 6, the stiffness values of the different systems alternated throughout the cycles.

4. Discussion

At the present time, surgical treatment of osteoporotic fractures continued to be a major challenge for the surgeon. Plates and screws are often required to stabilize a fracture. However, even though the technique may have been correctly performed, there is a strong possibility that the screws may loosen. With the above in mind, one of the best internal fixation systems is the type based on the locking compression plate with locking screws. These screws are threaded into the plate, minimizing the importance of bone quality for the stabilization of the fixation system [1,2]. When it comes to repairing osteoporotic fractures, there are many advantages to an LCP-based fixation system compared with other internal fixation systems [5,9,17,31,32]. The success of the system is particularly determined by the high level of stiffness of the fixation system during the formation of scar tissue. In cases where there is anatomical reduction and interfragmentary compression, on primary bone healing there is nothing but advantages with an LCP system. However, when there is no contact between fragments (as
is the case with comminuted fractures), secondary bone cicatrisation is necessary. Since this process of scar formation is induced by interfragmentary movement, a certain flexibility is required in the fixation system. It is estimated that on secondary bone healing, stimulation of interfragmentary axial movement has to be in the range between 0.2 and 1 mm [33,34]. With this in mind, it should be mentioned that it is normally considered that locking plates act as internal fixators with excessive stiffness. Therefore, they can cause inadequate bone callus, slow down bone healing or even result in the bone failing to heal [7,8,35].

A remarkable number of methods have been proposed to enable a reduction in the stiffness of the locking plate. In some cases, this reduction is achieved by increasing the plate span or raising the plate with respect to the bone [10]. However, any reduction in stiffness is gained at the cost of a parallel decrease in construct strength [8]. Proposals have also been made to lower construct stiffness by using plates manufactured from materials with a lower elasticity modulus [11,12]. Huang and Fujihara [12] suggest the use of plates based on carbon fibres in a PEEK matrix. By controlling the amount of carbon fibres and their orientation, it is possible to vary the flexibility of the construct [11,12]. However, this system has a problem similar to that of the DCP in terms of screw loosening. That is, screw fixation may be defective in the case of osteoporotic bone.

Likewise, there are proposals to lower the stiffness of LCP constructs without compromising their strength. Bottlang et al. [8] propose the use of a strategy called ‘far cortical locking’. This basically involves increasing the drill diameter for the first (near) cortical bone, allowing the screw to only engage with the second (far) cortical bone. According to the authors, a significant reduction in axial stiffness was achieved with a modest reduction in axial strength and an increase in torsional and bending strength [8,36]. Along similar lines, Gardner et al. [37] concluded that, by replacing slots for holes in the near cortex under a locked plate, axial stiffness of the LCP was reduced while maintaining construct stability.

The aforementioned references base their proposals on the use of the LCP. However, the drawback to this technique of a relatively high economic cost has been reported in the scientific literature. The DCP, which is a widely used technique, is usually employed as a reference system for comparison [13,15,33]. However, it should be pointed out that the high failure rate of the DCP internal fixation system in the repair of osteoporotic fractures has been made clear in the scientific bibliography [14,16–18,38].
The hypothesis is proposed in this present study that the incorporation of locking elements (SLEs) [20] in the DCP system with cortical screws can reduce stiffness when compared to LCP systems. It is considered that use of the proposed system can result in conditions suitable on secondary bone healing. It is also considered that the above can be achieved while maintaining construct strength and providing stability to poor quality bones.

This present study has shown that torsional stiffness of the DCP+6SLEs system (group 3) was similar to that of the LCP system (group 4) after 10,000 load cycles (0.30 compared with 0.28 N m/°). It has also been shown that this stiffness can be lowered if the number of SLEs is reduced. In the case of group 2 (DCP+2SLEs) torsional stiffness fell to 0.23 N m/° after the cyclic test. Compression stiffness of the DCP+6SLEs system (group 3) was higher than that of the LCP system after 10,000 load cycles (150 compared with 124 N/mm). However, the DCP+2SLEs system (group 2) showed lower compression stiffness than the LCP system (102 compared with 124 N/mm). When a plate is used in a bridging application,
the construct stiffness must be neither too low nor too high for uneventful healing [39]. The results of this present study permit speculation with the idea that use of longer plates could enable modification of construct stiffness by varying the number of SLEs.

No type of stiffness variation is evident from the results obtained in this study, either between groups or during the load cycles, in the four-point bending tests. This conclusion concurs with the work undertaken by Bottlang et al. [8]. In this work, a higher difference in torsional and compression stiffness compared to structural bending stiffness was also observed between the far cortical locking and LCP systems.

With the incorporation of SLEs, construct strength is guaranteed thanks to the pull-out resistance of the screw–SLE combination. In addition, certain axial movement of the bone fragments is permitted. It was deduced from the static tests undertaken to verify the initial strength that there was no significant difference between the DCP + 2SLEs (group 2), DCP + 6SLEs (group 3) and LCP (group 4) systems. The chosen failure standards were maximum gap displacement (5 mm) in compression, maximum rotation angle (10°) in torsion and fracture of the bone model in bending.

New in vitro tests need to be conducted in the future with models, which better simulate the mechanical characteristics of human bones. In this way, interfragmentary movements could be precisely measured, providing information that would enable a prognosis of the type of bone healing. For this paper, cylinders with diameters similar to the diameter of human femurs were chosen. As the DCP system with SLEs is designed for use with any type of bone, tests also need to be performed with smaller models where the load conditions and geometry are different.

By using synthetic models, the biological processes which are so important for the determination of the type of bone healing are ignored. Consequently, in vivo studies with animals need to be carried out to verify the applicability and success of bone healing when using the DCP system with SLEs. With this in mind, the authors of this paper are currently developing a project subsidised by the Ministry for Science and Innovation of the Spanish Government. As part of this project, preliminary studies performed with sheep promise good results in the application of the new DCP system with SLEs.

5. Conclusions

Locked plating is a widely used and highly successful system in the repair of both healthy and osteoporotic bones. Though it normally works as a system of low flexibility, there are methods which enable that flexibility to be increased without compromising the strength and stability of the construct. However, a drawback of the LCP technique is its high economic cost. Although a compression plate system is more economic, it is not effective in the repair of osteoporotic fractures. By adding screw locking elements to a DCP construct, lower torsional and compression stiffness is achieved without compromising the strength and stability of the construct. Given all of the above, the DCP with SLEs is a system that is apt for use in the repair of osteoporotic fractures and could help to create the conditions suitable for secondary bone healing.

The interfragmentary movements, which facilitate a prognosis of the type of bone healing have not been quantified in this study. New tests with more realistic models are therefore required, as well as in vivo tests with animals.

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Conflict of interest statement

The authors declare that no benefits in any form have been received from a commercial party related to the subject of this paper.

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