Need for Standardization During Cable Tensioning: An In Vitro Experimental Study on a Femoral Osteotomy Model

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Abstract

Objective: The ideal tension on a cable is affected by several factors, and the tensioning process is a relatively complex procedure. Individual variations can occur during tensioning, and the strain applied by residents at different training levels has not been previously questioned. For this purpose, we investigated the variations in the peak tensions applied by orthopedic residents, using a cable fixation model created on sheep femur.

Methods: The experiment was conducted on the distal diaphysis of a 1-year-old sheep femur. A cobalt chrome cable, tensioned with a strain-meter integrated tensioner, was utilized to stabilize a prosthetic stem. The minimum tension required for a stable fixation under 8 N/m torque was recorded. Strain measurements of 120 trials of 12 residents were recorded and compared to their experience level and to the measured optimal tension.

Results: The mean tension required for a stable fixation was 550 ± 45 N. The overall measured tension load was 540.3 ± 262.9 N. The mean tension provided by the 12 residents were between 175.7 ± 33.7 N and 875.5 ± 222.9 N. A significant difference was found between their highest and the lowest values (P < .0001). The level of experience was not correlated with the mean tension applied (P = .89) or with the difference of the minimum and the maximum tension (P = .81). The intraclass correlation coefficient was calculated as 0.1361 (95% CI, 0.02338-0.4242).

Conclusion: Our results suggest that the residents' decisions for the cable strain are not consistent or predictable, with high variations from the optimal value, regardless of their experience level.

Keywords: Cable tensioning, torsional stability, strain measurement, resident training

Introduction

Cobalt chrome (CoCr) or steel cables, with multiple bundles formed from multiple wire strands, are one of the essential implants of orthopedic practice. They are superior to simple monofilament steel cerclage wires, with higher durability under strain and a reliable tensioning method using a specific device.

Various cable fixation techniques and their ideal torsional strength have already been studied.^{1,2} Ideal conditions for in vitro testing are well described and optimized for accurate measurement of strength and durability.³⁻⁵ However, many in vivo conditions and material properties interfere with the outcome, such as the inner and outer cortical diameters of the bone or the graft, osteoporosis, length and width of the bone fragment, quantity and quality of the cables used, diameter, porosity, and tribology of the prosthesis.^{6,7} Ideal circumstances can be hard to achieve during operations for the surgeon, and even harder for a resident. In our daily practice, the cable is tensioned by an assistant while the surgeon maintains the correct position for the graft or the prosthesis. Especially in departments with trainees, the assistant is usually a resident with varying level of experience. And finally, tension

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Setup Fourte

Fourteen one-year old fresh frozen sheep femora were obtained, and their medullary width was measured using standardized radiographs. One of the specimens, with a 12 mm inner diameter for a 5 cm long segment, was dissected from soft tissues and prepared for the study. The proximal femur up to the eligible segment was transected and discarded. A Restoration HA femoral revision stem (Stryker, Kalamazoo, Mich, USA) with a diameter of 13 mm and a length of 255 mm was used as the femoral component. The femur was reamed up to 12 mm, as suggested in the surgical technique for the size 13 implant (Stryker 2104 Reamer). The anterior half of the remaining bone segment was longitudinally split with an oscillating saw (Aesculap Elan System, Center Valley, Pensylvania,

applied to the cable is usually tested with macroscopic rotational motions of the prosthesis or the graft, or simply with the tone of the tensioned cable in the tensioner, which are both highly subjective.

In this study, we hypothesized that the residents in training would not be able to apply a consistent cable tensioning force, regardless of their experience level, rendering the results of the practice unpredictable. To test this hypothesis, a prototype cable tensioning model was designed to assess the level of tension applied by residents of different experience levels in a standardized cable tensioning scenario. The ethical committee of our institution did not request approval for our study since it does not include patients or living animals.

Methods

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Figure 1. The femur with a 12 mm of medulla width was thawed, dissected from soft tissues, and reamed up to 12 mm for the size 13 femoral stem. A 5 cm long anterior bone segment consisting of 50% of the bone was cut.

Pa, USA), and a semi-cylindrical 5 cm long bone window was prepared (Figure 1). The distal continuity of the posterior half was carefully preserved. The femoral component was implanted in a standard fashion. The free bone section was fixed with a single cable, and the tensioner was placed anteriorly. The whole setup was fixed to the table from the distal femur, and the femoral component was fixed to a vise (Figure 2). Two millimeter wide CoCr multifilament cables (Dall-Miles Cable, Stryker) were used for the experiment.

The cable tensioner was produced from an aluminum alloy identical to the original cable tensioner device of the femoral revision set (Stryker). The load on the cable was documented using strain gauges placed on the tensioner and a strain indicator and recorder device (Model P3 Strain Indicator and Recorder, Vishay Micro-Measurements) (Figure 3).

Experiment

The experiment consisted of 3 steps: (1) estimation of mean load for achieving rotational stability of 8 Nm with a single cable placed centrally, (2) testing of forces applied by the residents, and (3) measurement of cable tension at the failure of the bone construct.

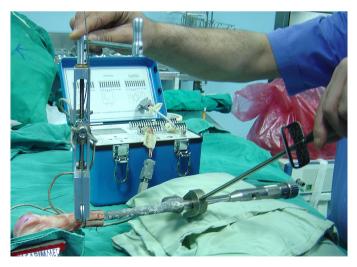


Figure 2. A cable tensioner produced (left) aluminum alloy to match the strain characteristics of the cable (Identical to Stryker) and the strain indicator and recorder (right; Model P3 Strain Indicator and Recorder, Vishay Micro-Measurements, NJ, USA).

For the first step of the experiment, a manual torque-meter (Smith & Nephew, Memphis, Tenn, USA) was used to apply a torque of 8 Nm at the proximal end of the femoral component. Three measurements were conducted to determine the minimum cable tension necessary to provide rotational stability at the bone–stem interface, and the mean value was noted as the tension required for stable fixation.

In the second step of the study, 12 residents of the orthopedics and traumatology department were asked to participate in the study, and an informed consent form was obtained from each participant. They were instructed about the task; however, they were blinded to the context of the study to avoid a performance bias. The experience level of the residents was not randomized, but their experience was normally distributed over years related to their consecutive appointment every 6 months (Table 1). All subjects had performed cable tensioning intraoperatively with a similar device at least once prior to the study. Subjects were instructed to tighten the cable as tight as to safely fix the stem without breaking either the femoral stem or the graft. Residents were allowed to check the stem stability manually without knowing the exact torsional force applied. The tension loads that the residents assumed adequate to provide rotational stability were recorded. The test was repeated for 10 attempts, completely releasing the cable between every attempt.

Following completion of all experiments on the subjects, the cable was tensioned until the failure of the graft or the host side, and the highest tension achieved was recorded.

Statistical analyses were performed with the MedCalc Statistical Software (Mariakerke, Belgium) and the Statistical Package for Social Sciences, version 19.0 software (SPSS Inc.; Chicago, IL, USA). In addition to descriptive statistical methods (e.g., mean, standard deviation), the Kolmogorov–Smirnov test was used to assess the normality of the sample. Student's *t*-test was used for comparison of two groups, while ANOVA for comparison of multiple groups. The intraclass correlation coefficient was calculated for reliability testing. A *P* value <.05 was considered statistically significant.

Results

Under 8 Nm torque, the minimum cable tension required for a stable grip was measured as 550 ± 45 N (range: 503-592) in the first step of the experiment. The force required for the ultimate failure of the bone–stem construction was 2010 N.

The mean seniority level of the 12 residents included in the study was 27.8 months (3-55). The mean tension loads provided by 12 residents ranged between 176 \pm 34 N and 876 \pm 223 N. The mean tension load of the total 120 tightening trials was 540 \pm 263 N (range; 130-1289) (Table 1 and Figure 4). A significant difference was found between the highest and the lowest values (P < .0001). The intraclass correlation coefficient (ICC) was calculated as 0.1361 (95% CI, 0.02338-0.4242)

The seniority level of the residents was not correlated to their mean applied tension on the cables (P = .89), the difference between their minimum and maximum values (P = .81), or to their standard deviation (P = .67) (Figure 5).

Discussion

Experience of an orthopedic surgeon is an important factor in the accuracy of performed interventions, especially for manual skills such as cable tensioning. A safe tension interval that will ensure secure fixation without causing a fracture should be acknowledged by every orthopedic surgeon, and the applied tension should fall within these ranges. In this in vitro experimental

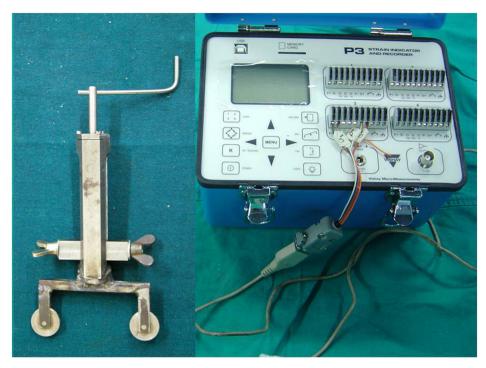


Figure 3. Experiment setup was fixed to the table from the prosthetic stem, the cut bone segment was fixed with a single cable, and the tensioner was connected to the strain indicator. Subjects applied the adequate tension to the cable.

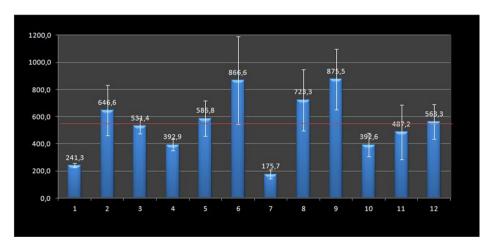


Figure 4. Average strain values of the residents with standard deviation lines. The red horizontal line represents the measured minimum tension required to fix the stem.

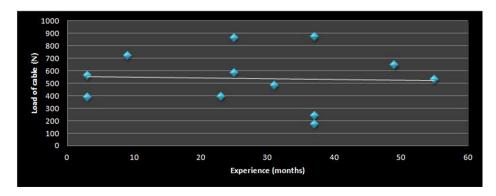


Figure 5. Average strain values of the residents, compared to their experience level in months.

Table 1. Average Strain Levels, Standard Deviations, and their Ranges for Each Subject

#	Experience (month)	Average and SD	Range	95% CI
1	37	241.3 ± 16	210-260	229839-252761
2	49	646.6 ± 187	380-910	512798-780402
3	55	531.4 ± 57.3	420-610	490434-572366
4	23	392.9 ± 43.3	280-429	361 908-423 892
5	25	586.8 ± 131	337-760	493 081-680 519
6	25	866.6 ± 321.9	365-1248	636 335-1 096 865
7	37	175.7 ± 33.7	130-222	151 570-199 830
8	9	723 ± 224.8	320-919	562 512-884 088
9	37	875.5 ± 222.9	461-1289	716 082-1 034 918
10	3	392.6 ± 85.4	283-483	331 533-453 667
11	31	487.2 ± 200.5	260-790	343 746-630 654
12	3	563.3 ± 129.7	305-721	470537-656063

pilot study, we have compared the individual assessment of secure fixation while using a cable tensioner to achieve a minimal tension providing rotational stability without compromising the integrity of the bone. Our results suggest that the decision for rotational stability depends largely on the person who evaluates it, regardless of the experience level.

Manufacturer recommendation for the cable tension varies from 400 N to 550 N; however, the ideal tension that ensures rotational stability is highly dependent on the fixed elements. Although the cable tensioning process and the applied rotational force can be standardized using appropriate devices, there is no method to measure the micro or macro motions of the implanted stem in vivo. The process remains subjective regardless of the techniques and devices used. In the first part of the experiment, we mimicked the in vivo practice and determined the minimum force which generates the required tension. A manual torque-meter was used to test the rotational stability manually against 8 N/m torque. An average of 550 ± 45 N cable tension was found to be adequate for a macroscopically stable stem grip, similar to the manufacturer's recommendation.

The main objective of the study was to assess the mean tension exerted by the residents in training. Although their average tension of 540 N was very close to the minimum required tension for stem stability, the dataset showed a wide range (130-1289 N) and high variation, with a high standard deviation of 264 N. Furthermore, an ICC value of 0.1361 suggests low agreement among subjects. These results show that the tension on the cable applied by the residents is unreliable.

This study was conducted on a small group of residents training in a single institution. The role of experience on the standardization of tensioning can be further investigated by including senior surgeons in a similar study. Further studies with a randomized design, involving different training facilities and structured groups based on level of experience, would be beneficial.

Conclusion

The improvement of manual dexterity is usually underestimated in orthopedic training, and thus, unreliable results are inevitable. Therefore, we recommend close mentorship for residents in training, especially during surgical gestures that require dexterity, such as cable tensioning. Another possible solution to this problem is to implement a torque-sensitive device. After determining the force interval for secure fixation, a torque-sensitive crank can be designed and embedded into the cable tensioner. Such a device would provide a safe and secure fixation during the tightening of cables and cerclage wirings.

Ethics Committee Approval: The ethics committee did not require any application for this study since it does not include any patients or any living animal. The tests were performed on animal specimens (femur bones) that were sacrificed for non scientific reasons. This is why the study has not an ethical committee approval.

Informed Consent: Informed consent was not necessary for this study since it does not include any patients or any living animal.

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