

Unstable Vancouver B1 Periprosthetic Femoral Fracture Fixation: A Biomechanical Comparison Between Cerclage Wiring and C-Shaped Shape Memory Alloy Implant

Seog-Hyun Oh

Inje University, Kimhae

Yu-Sung Suh

Soonchunhyang University

Emmanuel Eghan-Acquah

Inje University, Kimhae

Kollerov Mikhail Yurevich

Moscow Aviation Institute

Sung-Hun Won

Soonchunhyang University

Min Jung Baek

Bundang CHA Hospital, Seongnam

Sung-Jae Lee

Inje University, Kimhae

Sung-Woo Choi (✉ osfx1209@naver.com)

Soonchunhyang University

Research Article

Keywords: Femur, Fracture-Periprosthetic, Arthroplasty, Biomechanical Phenomena, Cable, Cerclage wire

Posted Date: December 7th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-113117/v1>

License:  This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Although cerclage wiring is a very useful implant, it has many problems. We manufactured an alphabet C-shaped clip with nitinol (C-clip) that has superelastic property to replace the cerclage wiring. This study aimed to compare the biomechanical stability of cerclage cable and the C-clip. Eighteen synthetic femora were tested. An unstable VB1 fractures model was constructed that oblique fracture line was 8cm below the lesser trochanter with fracture gap. The distal fixation was repaired with a locking plate and four bi-cortical screws. The proximal fixation was repaired two different methods: (1) four-threaded cerclage cables and (2) four new C-clip. In axial compression test, the C-clip was stiffer than the cerclage cable (median stiffness of C-clip = 39.28 N/mm [IQR; 38.84-41.19], cerclage cable = 34.90 N/mm [34.84-35.08], $p < 0.05$). In the torsion test, the C-clip was 0.44 Nm/° [IQR; 0.44-0.45] and cerclage cable = 0.30 Nm/° [0.30-0.33], $p < 0.05$). In the four-point bending test, the C-clip = 39.35 N/mm [IQR; 38.91-40.97] and cerclage cable = 28.38 N/mm, [28.33-30.79], $p < 0.05$) The C-clip may be biomechanically superior to cerclage wiring in terms of stiffness, axial compression, torsion, and four-point bending tests and is a valuable alternative in Vancouver type B1 periprosthetic femoral fracture.

Introduction

Cerclage wiring is the only implant that can use centripetal force to reduce and keep radially displaced fragments together¹. Although it is a very useful implant, it is regarded as a limited use method due to the many problems encountered such as blockage of blood supply, the possibility of blood vessel damage, complicated surgical technique, prolonged operation time, and mechanical weakness as a stand-alone use. However, cerclage wiring has garnered attention and interest due to the increasing occurrence of periprosthetic femoral fractures (PFF) after hip arthroplasty especially in the active aging population^{2,3,4}. Periprosthetic fractures around, just below, or well below the tip of a well-fixed prosthesis (Vancouver type B1 [VB1] and C [VC]) are routinely treated with open reduction and internal fixation (ORIF). Standard bi-cortical screws are generally efficient in distal fixations. However, the biomechanical procurement of the proximal segment can be difficult because of the presence of cemented or cementless mantle of the hip prosthesis. For proximal fixations, cerclage cables, allograft struts, and locking or non-locking uni-cortical screws are available options. Most recently, plate designs that allow bi-cortical fixation by directing offset locking screws tangentially around either side of the hip stem⁵. Consequently, there is still no gold standard method for fixing the proximal portion.

The authors thought that if the implant was made in a partially opened, alphabet C shape that does not wrap the bone 360 degrees, it will have the advantages (centripetal force, wrapping the bone) of the cerclage wiring and the disadvantages (circulation block, mechanical weakness, and the risk of major vessel injury) can be improved. We manufactured the C-shaped implant with nitinol (C-clip) that has superelasticity to replace the cerclage wiring.

The purpose of this study was to compare the biomechanical test of traditional cerclage wiring and the partially opened C-clip.

Methods

1. Specimens and fracture models

A total of 18 left artificial femurs (model #LD2386, SYNBONE, Switzerland) were prepared. The geometry for each femur provided by the manufacturer was standard, with length 450 mm, mid-shaft mediolateral outer diameter 30 mm, mid-shaft anteroposterior diameter 26 mm, condylar width 85 mm, neck angle 122°, anteversion 15°, head diameter 48 mm, and intramedullary canal diameter 12 mm. The fracture model was designed as follows: An oscillating saw was used to create a 45-degree oblique osteotomy at an 8-cm distal midportion from the tip of the lesser trochanter (LT). We intended to represent the VB1 PFF (Fig. 1). To simulate the worst-case scenario, an additional transverse osteotomy was added on the medial side 8 cm below the tip of the LT, where there was no bony contact across the fracture, and a gap was left across the fracture site. This represents an unstable fracture pattern. To make the same fracture model for all 18 samples, cutting jigs to guide the osteotomy were prepared. The same fracture model was made by a single orthopaedic surgeon. The osteotomies were provisionally stabilized with a noncontact bridging curved femur shaft plate using bone holding forceps.

2. Application of constructs for femur fracture fixation

The 18 left artificial femurs osteotomized to simulate an unstable VB1 model have been randomly assigned to either C-clip or cerclage cable fixation. The fractures were repaired with a ten-hole custom made titanium plate. The distal fixation for all constructs was with four locking bi-cortical screws (Ø 5.0 mm, 35 mm x 3, Ø 5 mm x 37 mm x 1).

The proximal fixations were as follows:

- **Cerclage Cable Construct:** Cerclage cables were placed in scallops 1, 2, and 3 of the plate. Cerclage cables (DePuy Synthes Co., Paoli, PA, USA, Ø 1.7 mm) were tensioned up to 50 kg using a standard DePuy cable tensioner and fixed with crimps.
- **C-clip Construct:** C-shaped nickel–titanium (Ni–Ti) shape memory alloy (SMA) implants (KIMPF Co., Ltd., Moscow, RUS) were used at the proximal site of the artificial bone. It was designed with a width of 7 mm, a profile of 2 mm, a maximal inner diameter of 22 mm, and a distance of 3 mm at room temperature. Submerged in sterile saline below 10 °C, the ends of the fixator were extended for use with special forceps. A C-clip was placed in the scallops of the plate. Once the position of the C-clip was ensured, it was warmed with hot saline (40–50 °C)⁶. With the alteration in temperature, the memory effect of the material resulted in the restoration of the original shape, resulting in secure fixation. C-clips were positioned in scallops 1, 2, and 3 of the plate (2).

3. Biomechanical test

In order to evaluate the fixation force in the in vivo environment (about 36.5 °C) of C-shaped implants made of Nitinol alloy, a SMA material, an experimental environment similar to the in vivo environment

was implemented. The experimental chamber was fabricated using an extruded thermal insulation board having the lowest thermal conductivity among the insulators, and two 300-W incandescent bulbs were fixed on both sides of the chamber to maintain a temperature of approximately 36.5 °C similar to the in vivo environment (**Fig. 3**)⁷. A pre-test was conducted to verify the test environment established prior to the present study, and it was confirmed that the temperature was maintained at 36–37 °C for 30 min. The distal condyle of the artificial femur used for compression and torsion test was removed 30 cm from the greater trochanter (GT) tip. This is because the intact femur model might be broken at the femoral shaft during the loading test, and it was mounted on a steel square holder using resin⁸. Biomechanical testing of each specimen was performed in a vise at 25° adduction in the frontal plane and neutral in the sagittal plane to simulate one-legged stance⁸. A material testing machine (MTS 858 Mini Bionix Biomechanical Test System, MTS Systems Corp., USA) with a 25kN load cell was used for all mechanical tests. For the mechanical test, loading was applied to the femoral head through the flag jig, and each test was performed 3 times.

For the compression tests, a preload of 100 N at a rate of 20 N/min was loaded to each specimen to ensure complete contact between the femoral head and the test equipment. Next, the vertical force was applied at a speed of 10 mm/min until 10-mm axial deformation of the construct while recording load–displacement curves (clinical failure). Failure was defined as sudden fall observed at the load–displacement curve or displacement of the proximal fragments in excess of 10mm⁹. For the torsion test, a support block was placed 220 mm from the loading point to minimize long-axis bending. And distal femur was fixed by steel jig with screw. The preload of 50 N was applied to each specimen. Next, the vertical force was applied at a speed of 8 mm/min(=0.005rad/min) while recording load–displacement curves⁹. Then the load–displacement graph was converted into a moment–angular displacement graph using the following equation in a previous study¹⁰. The four-point bending test used an intact bone model without distal condyle removal. Biomechanical testing of each specimen was performed with the specimen freely positioned between the contact points, allowing free bending movement. The upper contact points were placed symmetrically between the lower contact points (loading span = 130mm, support span = 50mm). The test was conducted until the end of the plate of the tension surface touching the support roller. The mechanical test was conducted three times for each type of test (axial, torsion and bending). The vertical force was applied at a speed of 0.5 mm/min while recording load–displacement curves. Stiffness of the construct was defined as the slope of the load-displacement curve. The slope was corresponded to the linear section within elastic deformation. In the torsion and four-point bending tests, all specimens remained within the linear elastic region to avoid permanent specimen damage, as demonstrated in a previous study^{9,11,12}.

4. Statistical Analysis

A wilcoxon rank-sum test was used to assess differences between the fixation method variables. All statistical evaluations were completed using SPSS, V22 (SPSS Inc., Chicago, IL, USA) software. Two-tailed p-values < 0.05 were considered statistically significant.

Results

All planned tests were successfully completed and there was no incomplete data. There were no observed failures of the specimens and at no point was fixation lost or deformed. A comparison of the stiffness of the construct using two different fixation methods in the three types of tests is presented in **Fig. 3**. With regard to stiffness, a notable finding was that C-clip was stronger than cerclage wiring in the three types of tests. In axial compression test, the C-clip was stiffer than the cerclage cable (median stiffness of C-clip = 39.28 N/mm [IQR; 38.84-41.19], cerclage cable = 34.90 N/mm [34.84-35.08], $p < 0.05$). In the torsion test, the C-clip was stiffer than the cerclage cable (median stiffness of C-clip = 0.44 Nm/° [IQR; 0.44-0.45], cerclage cable = 0.30 Nm/° [0.30-0.33], $p < 0.05$). In the four-point bending test, the C-clip was stiffer than the cerclage cable (median stiffness of C-clip = 39.35 N/mm [IQR; 38.91-40.97], cerclage cable = 28.38 N/mm, [28.33-30.79], $p < 0.05$) (**Fig. 4**) (**Table. 1**).

Discussion

This study demonstrates the notable improvements in compressive, torsional, and bending strength associated with partially opened C-shaped SMA implants (C-clip) for fixation of the proximal segment compared to the traditional cerclage cables. Although the C-clip has less wrapping area to the bone than the cerclage cable, the holding stiffness appears stronger than cerclage cable. We think that this is because the shape memory effect of SMA is reformed to the shape that was originally designed. Although it depends on the degree, almost all metals have a ductile property, so they tend to loosen slightly over time from the initial fixation. In particular, cerclage wiring has a natural tendency to slip and loosen when any part of the bone tapers¹³. However, although the effect of underneath C-clip was not evaluated yet, this made of SMA is still holding the bone and plate tightly.

Cerclage wiring has advantages and disadvantages from wrapping the cable around the bone. Tension in the cable can pull radially displaced fragments together, an advantage that neither nails nor screws can offer. The disadvantage of the 360-degree wrap is the potential for nerve and blood vessel damage. However, because of the 360-degrees wrapping method, it has several demerits and make problems. Contrary, the C-clip that did not wrap 360-degrees get several merits than cerclage. First, it can reduce the possibility of a large vessel and nerve injury; Surgeons dissect the femur in PFF from the safe lateral or anterolateral side which does not exist anatomical fatal structure such as large vessel and nerve, advanced and penetrated the wire passer to a medial and posterior direction which located anatomical fatal structure without direct vision. This is entirely dependent on the surgeon's skill, experience, and sense. Although most cases are without any accident, there are reported serious complication about cerclage wiring¹⁴. Second, it enables early rehabilitation. Most muscles and tendons acting on the thigh are attached to the linea aspera. The 360-degree wrapping method inevitably has to dissect the linea aspera to some extent and be penetrated the tendon attached area in several places. If we could preserve the linea aspera (if we could fix femur and implant with similar stiffness without penetrating through the linea aspera), it will be very helpful for the movement of thigh muscles and will allow for early rehabilitation. Third, it enables less skin incision and dissection. The method of full cerclage wrapping

inevitably requires more incisions and soft tissue dissection than the method of using an internal fixation that can use only when the front is visible. When the dissection site increased, prolonged surgical time, increased bleeding, and an increased likelihood of surgical site infection are accompanied naturally. Although some recently developed wire clamp for minimal invasive aimed was used, it has to be used under the fluoroscopy and influenced by the surgeon's feeling¹⁵. Therefore, it is not possible to be free from radiation hazards and the complication of large vessel injury^{16,17}. Of course, C-clip has not only advantages. In order to obtain the effect of shape memory effect, it is necessary to have high and low-temperature conditions. In this regard, it will be necessary to develop a heat conduction tray using electricity in the future.

Treatment of PFF following hip arthroplasty presents a major clinical challenge in orthopaedic surgery¹⁸. Patients with PFF are typically elderly individuals with varying degrees of osteoporosis and medical comorbidity. The fixation is very difficult because of the hip stem and poor bone quality. Fixation of the proximal portion, which contained a huge hip stem, was limited with a standard screw technique. Moreover, when the host bone is in osteoporotic condition, the screw does not work and may be pulled out easily. Our authors contemplated whether a partially wrapped implant could have enough holding power, like a 360-degree wrapped cerclage cable. The present study shows that the partially wrapped implant may have the same or better holding power as the 360-degree cerclage methods.

There are some limitations to the present study. First, we did not insert a hip stem. Although not to be used as a hip stem, this study has clinical implications for the treatment of unstable VB1-type PFF. Many other biomechanical tests of PFF have been conducted using cemented hip stem^{5,11,19,20}. Using a hip stem would introduce more variables, such as femoral stem position and cementing technique, and increase the cost. This study compared the stiffness of cable and C-clip under the same conditions. We think that the presence or absence of a hip stem would affect both groups equally. This is supported by another study in which biomechanical tests were performed without inserting the hip stem^{21,22}.

Second, synthetic bones were used in this study in order to avoid the discrepancies associated with cadaveric tissues. This poses an inherent limitation to this study. Nonetheless, synthetic models have been proven to be valuable in biomechanical studies involving fracture fixations because of the relatively lower cost involved and the reduced level of variability between the specimens²³. They are designed and developed to represent the average geometry and more accurately match the ideal bone properties²⁴. In fact, synthetic bones generally show lower standard deviations in the parameters measured as compared to cadaveric specimens²⁵.

Third, our study did not use the proximal uni- or bi-cortical screw as a control group. Recent biomechanical tests commonly compare the experimental method and control as a screw fixation method. However, clinically, cerclage cable systems are still widely used implants in PFF.

Fourth, the present study used a small sample size. While previous authors have typically used more than 5 specimens per test group, the current study is limited to three (n=3) specimens per each construct

group. This could yield low statistical power to detect all statistical differences between the test groups. Contrarily, the small sample size of the present study suggests that the various statistical differences detected were, in fact, present ¹¹.

Fifth, we were unable to accurately simulate all of the physiologic force components in femur when standing or walking. So, present study did not test physiologic loading but isometric loading modes such as axial compression, pure bending, and torsion. This makes it easier to identify if specific modes cause instability, but it may be that these cases do not occur in vivo. ²⁵.

Sixth, in a previous study, to simulate torsional load, the hip stem was oriented parallel to the floor and the MTS 858 universal testing machine was used to apply a downward force to the femoral ball. In this configuration, the applied force was offset from the axis of the femoral shaft creating a twisting moment thereby simulating a torsion test ¹².

An ideal implant should not only maintain prosthesis stem stability but also provide stable fixation of poor-quality bone around the prosthetic stem ⁶. This study shows that partially opened C-shaped implants made with SMA (C-clip) have superior strength in axial compression, bending, and torsion than traditional cerclage cables. Although the C-clip may require many further studies to be used clinically, it is encouraging to show superior stiffness to traditional cerclage wiring in biomechanical tests.

Conclusion

The current cerclage cable system, which must wrap the entire bone, has several shortcomings such as obstructing the periosteal blood supply, the risk of major vessel injury, and technical demands. However, cerclage wiring is essential in human and/or animal orthopaedic fields. Because of these limitations, endeavours to develop an implant that will replace the cable system are meaningful. This study supports the hypothesis that fixation stability of the proximal segment of a VB1 PFF is improved with the use of partially opened C-shaped implants compared to traditional cable techniques. Further research is necessary to support these results.

Declarations

Conflicts of Interest and Source of Funding:

This study was funded by research grant from National research foundation of Korea (2019R1A2B5B01005924) and Soonchunhyang University.

References

1. Perren, S., Fernandez Dell'Oca, A., Lenz, M. & Windolf, M. Cerclage, evolution and potential of a Cinderella technology. An overview with reference to periprosthetic fractures. *Acta Chir Orthop Traumatol Cech***78**, 190-199 (2011).

2. Angelini, A. & Battiato, C. Past and present of the use of cerclage wires in orthopedics. *European Journal of Orthopaedic Surgery & Traumatology***25**, 623-635 (2015).
3. Kurtz, S. M. *et al.* Future young patient demand for primary and revision joint replacement: national projections from 2010 to 2030. *Clinical Orthopaedics and Related Research***467**, 2606-2612 (2009).
4. Holley, K. *et al.* Periprosthetic fractures of the femur after hip arthroplasty: an analysis of 99 patients. *HSS Journal***3**, 190-197 (2007).
5. Lewis, G. S. *et al.* Tangential bicortical locked fixation improves stability in vancouver B1 periprosthetic femur fractures: a biomechanical study. *Journal of orthopaedic trauma***29**, e364 (2015).
6. Zhao, X. *et al.* Nickel-titanium shape-memory sawtooth-arm embracing fixator for periprosthetic femoral fractures. *International orthopaedics***36**, 619-626 (2012).
7. Zheng, S. *et al.* The effects of a new shape-memory alloy interspinous process device on the distribution of intervertebral disc pressures in vitro. *Journal of biomedical research***24**, 115-123 (2010).
8. Kuzyk, P. R. *et al.* Femoral head lag screw position for cephalomedullary nails: a biomechanical analysis. *Journal of orthopaedic trauma***26**, 414-421 (2012).
9. Zdero, R., Walker, R., Waddell, J. P. & Schemitsch, E. H. Biomechanical evaluation of periprosthetic femoral fracture fixation. *JBJS***90**, 1068-1077 (2008).
10. Lenz, M. *et al.* Enhancing fixation strength in periprosthetic femur fractures by orthogonal plating—A biomechanical study. *Journal of Orthopaedic Research***34**, 591-596 (2016).
11. Lever, J. P., Zdero, R., Nousiainen, M. T., Waddell, J. P. & Schemitsch, E. H. The biomechanical analysis of three plating fixation systems for periprosthetic femoral fracture near the tip of a total hip arthroplasty. *Journal of orthopaedic surgery and research***5**, 45 (2010).
12. Kim, S. Y. Biomechanical Evaluation of Periprosthetic Femoral Fracture Fixation (Master thesis, Ryerson University, Toronto, Canada, 2010).
13. Profile, V. Principles and Application of Cerclage Wire Full and Hemicerclage Wiring World Small Animal Veterinary Association World Congress Proceedings, 2003.
14. Mehta, V. & Finn, H. A. Femoral artery and vein injury after cerclage wiring of the femur: a case report. *The Journal of arthroplasty***20**, 811-814 (2005).
15. Apivatthakakul, T., Phornphutkul, C., Bunmaprasert, T., Sananpanich, K. & Dell’Oca, A. F. Percutaneous cerclage wiring and minimally invasive plate osteosynthesis (MIPO): a percutaneous reduction technique in the treatment of Vancouver type B1 periprosthetic femoral shaft fractures. *Archives of orthopaedic and trauma surgery***132**, 813-822 (2012).
16. Ehlinger, M. *et al.* Vascular complication after percutaneous femoral cerclage wire. *Orthopaedics & Traumatology: Surgery & Research***104**, 377-381 (2018).
17. Gunadham, U. & Kongkreangkrai, T. Femoral artery entrapment after cerclage wiring of distal femoral shaft fracture: A case report. *Journal of Orthopaedics, Trauma and Rehabilitation***26**, 39-42 (2019).

18. Mukundan, C., Rayan, F., Kheir, E. & Macdonald, D. Management of late periprosthetic femur fractures: a retrospective cohort of 72 patients. *International orthopaedics***34**, 485-489 (2010).
19. Graham, S. M. *et al.* Periprosthetic femoral fracture fixation: a biomechanical comparison between proximal locking screws and cables. *Journal of orthopaedic science : official journal of the Japanese Orthopaedic Association***20**, 875-880. <https://doi.org/10.1007/s00776-015-0735-3> (2015).
20. Lenz, M. *et al.* A biomechanical study on proximal plate fixation techniques in periprosthetic femur fractures. *Injury***45**, S71-S75 (2014).
21. Haddad, F. *et al.* A biomechanical evaluation of cortical onlay allograft struts in the treatment of periprosthetic femoral fractures. *Hip International***13**, 148-158 (2003).
22. Stevens, S. S., Irish, A. J., Vachtsevanos, J. G., Csongradi, J. & Beaupré, G. S. A biomechanical study of three wiring techniques for cerclage-plating. *Journal of orthopaedic trauma***9**, 381-387 (1995).
23. Roberts, J. W., Grindel, S. I., Rebholz, B. & Wang, M. Biomechanical evaluation of locking plate radial shaft fixation: unicortical locking fixation versus mixed bicortical and unicortical fixation in a sawbone model. *The Journal of hand surgery***32**, 971-975 (2007).
24. Cristofolini, L., Viceconti, M., Cappello, A. & Toni, A. Mechanical validation of whole bone composite femur models. *Journal of biomechanics***29**, 525-535 (1996).
25. Moazen, M., Jones, A. C., Jin, Z., Wilcox, R. K. & Tsiridis, E. Periprosthetic fracture fixation of the femur following total hip arthroplasty: a review of biomechanical testing. *Clinical Biomechanics***26**, 13-22 (2011).

Tables

Table 1. Results of the mechanical test

		Stiffness (N/mm)	Mean	SD	Median	Q1	Q3	p-value
Axial compression Test	C-clip	43.09	40.26	2.49	39.28	38.84	41.19	0.0495*
		39.28						
		38.4						
	Cerclage cable	35.25	34.98	0.24	34.9	34.84	35.08	
		34.9						
		34.78						
Torsion Test	C-clip	0.46	0.44	0.02	0.44	0.44	0.45	
		0.44						
		0.43						
	Cerclage cable	0.3	0.32	0.03	0.3	0.3	0.33	
		0.36						
		0.3						
Four-Point Bending Test	C-clip	42.58	40.13	2.16	39.35	38.91	40.97	0.0495*
		38.47						
		39.35						
	Cerclage cable	28.27	29.95	2.82	28.38	28.33	30.79	
		33.2						
		28.38						
wilcoxon rank-sum test, *p-value < 0.05								

Figures

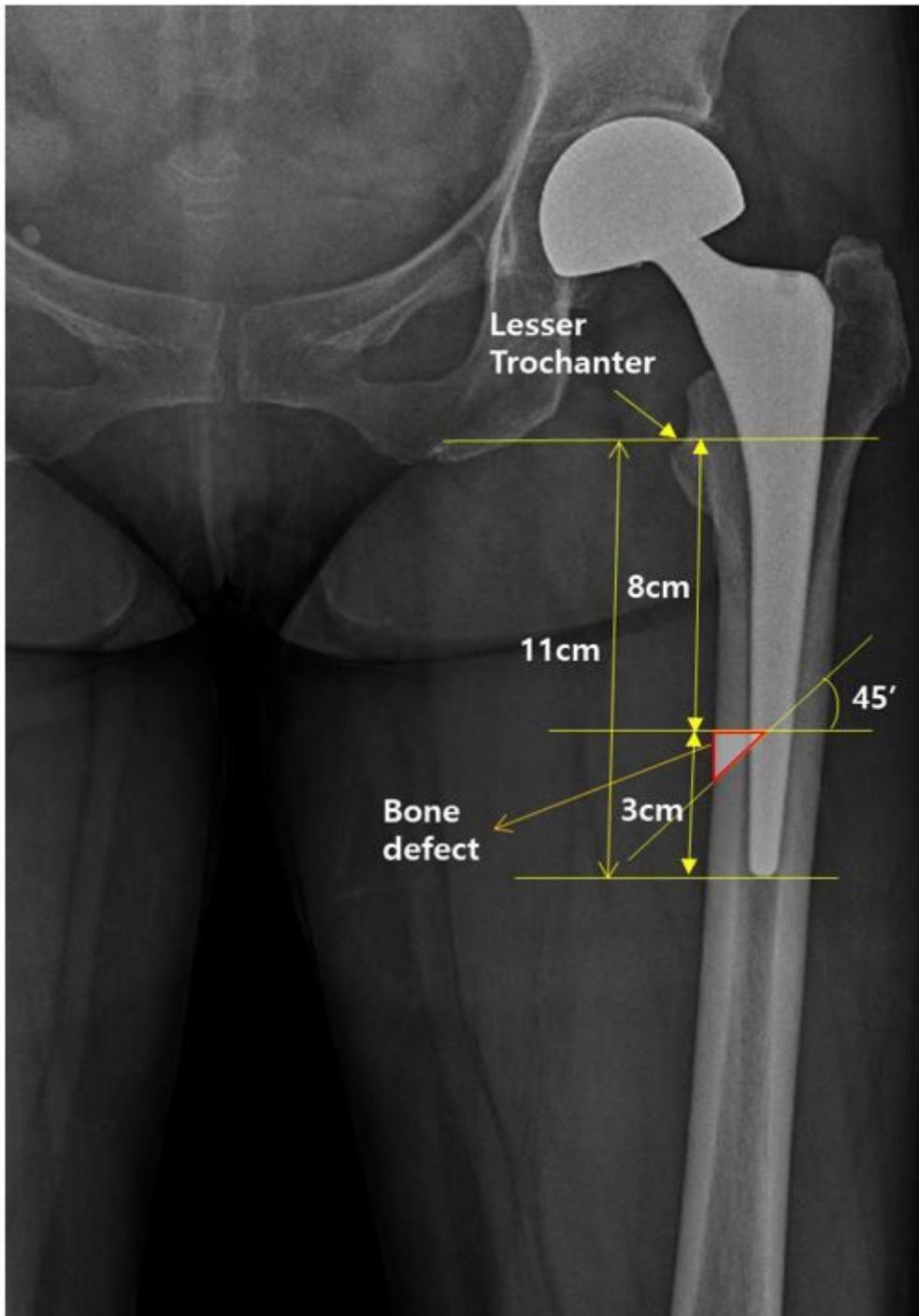


Figure 1

Fracture model of Vancouver B1 periprosthetic femur fractures The VB1 fracture model was designed on radiographs with left artificial joint replacement. A 45-degree oblique osteotomy at 8-cm distal midportion from the tip of the lesser trochanter (LT). To simulate the worst-case scenario, additional transverse osteotomy was added on the medial side 8 cm below the tip of the LT, where there was no bony contact across the fracture



Figure 2

Fabricated constructs that repaired the proximal segment with a C-clip or cerclage wiring. For the C-shaped implant setup, construct A had three pieces of implant applied proximally as shown, whereas construct B had three cables at the proximal location. The distal location of PFF was repaired with four \emptyset 5.0-mm bi-cortical screws equally.



Figure 3

Mechanical test modes (A) Compression test, (B) torsion test, (C) four-point bending test Setup for testing of (A) compression, (B) torsion, and (C) bending stiffness. Compression tests were performed in a vise at 25° adduction in the frontal plane and neutral position in the sagittal plane to simulate the one-legged stance. Torsion tests were performed in a vise at 25° adduction in the frontal plane with the long axis of the femur horizontal. The bending test was performed with the specimen positioned in between the contact points, allowing free bending movement. The same positioning of all specimens was assured of each test type

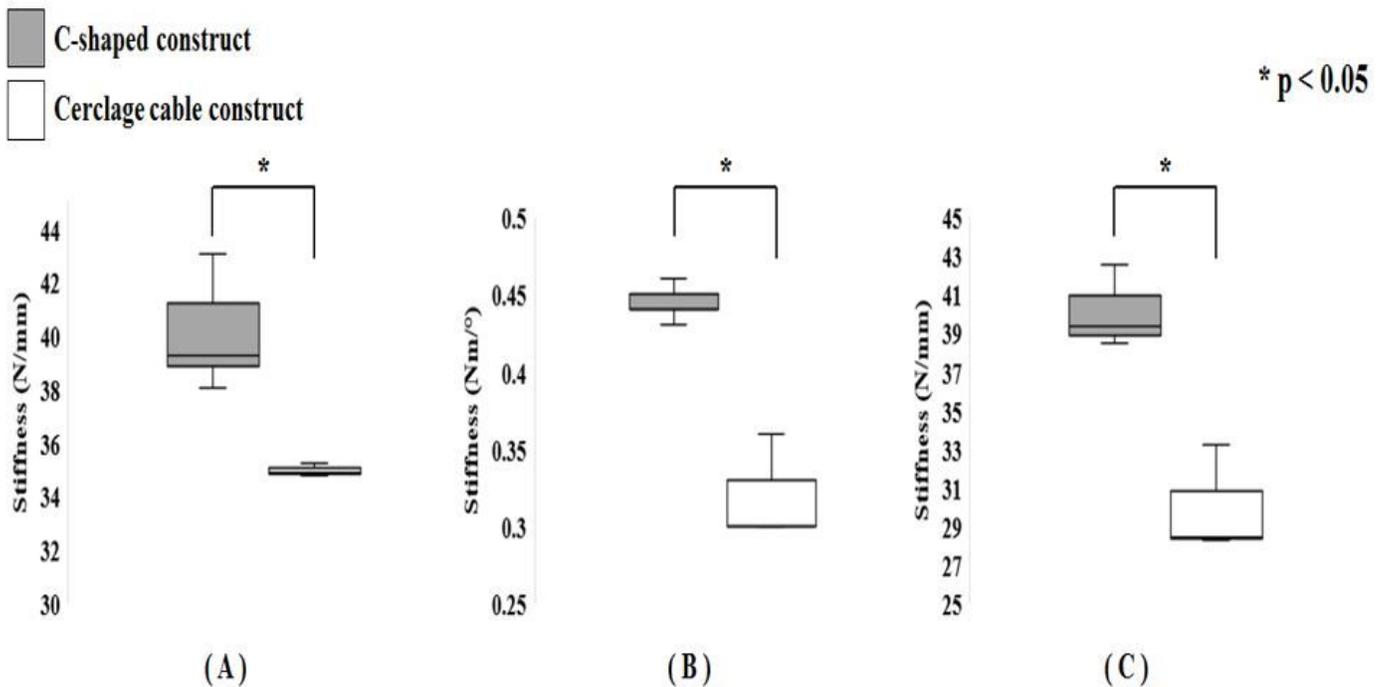


Figure 4

Results of the mechanical test (A) Axial compression test, (B) torsion test, (C) four-point bending test