IJVR
ISSN: 1728-1997 (Print)
ISSN: 2252-0589 (Online)

Shiraz University

Vol. 24 No. 3 Ser. No. 84 2023

IRANIAN JOURNAL OF VETERINARY RESEARCH

Original Article

Biomechanical evaluation of the impact of collared cementless total hip arthroplasty stems on implant subsidence: a cadaveric study in German Shepherd

Cho, H. S.[1]; Seo, D. Y.[2**]; Kim, D. S.[2]; Kang, J. S.[3]; Kim, Y. U.[4]; Kwon, Y. H.[5] and Kim, M. S.[6*]**

[1]Department of Veterinary Clinical Science, Cho Hyungsun Animal Hospital, Seoul, Republic of Korea; [2]Ph.D. Student in Veterinary Emergency and Critical Care, Department of Veterinary Clinical Science, College of Veterinary Medicine and Research Institute for Veterinary Science, Seoul National University, Seoul, Republic of Korea; [3]Department of Veterinary Clinical Science, College of Veterinary Medicine, Jeonbuk National University, Iksan, Republic of Korea; [4]Department of Veterinary Clinical Science, Bien Animal Medical Center, Sosagu, Republic of Korea; [5]Department of Veterinary Clinical Science, Yedam Animal Medical Center, Seoul, Republic of Korea; [6]Department of Veterinary Clinical Science, College of Veterinary Medicine and Research Institute for Veterinary Science, Seoul National University, Seoul, Republic of Korea

[*]***Correspondence:*** *M. S. Kim, Department of Veterinary Clinical Science, College of Veterinary Medicine and Research Institute for Veterinary Science, Seoul National University, Seoul, Republic of Korea. E-mail: minsukim@snu.ac.kr*

[**] These authors contributed equally to this work and were considered as the first authors

10.22099/IJVR.2023.47029.6770

(Received 22 Mar 2023; revised version 17 Sept 2023; accepted 27 Sept 2023)

Abstract

Background: With the increasing use of cementless total hip arthroplasty (THA), stem subsidence has emerged as one of the primary complications. Although electron beam melting (EBM)-manufactured stems have been demonstrated to prevent subsidence, there has been limited investigation into the comparative biomechanical impact of collarless and collared EBM cementless stems on stem subsidence in veterinary medicine. **Aims:** This study aimed to compare the stem implant resistance and failure mechanical properties between collarless and collared EBM-manufactured stems. **Methods:** Seven pairs of femurs were harvested from canine cadavers. In each pair of femurs, the left femur was implanted with a collarless, and the right femur with a same-sized collared cementless stem. Specimen constructs were mounted to the loading frame of a testing machine and load was transferred to the femoral stem parallel to the longitudinal axis of the femur until the stem subsided 5 mm. Load and stem displacement data acquired during the tests were used to generate load-displacement curves and obtain stiffness, yield, and failure data for each specimen construct. Yield and failure energies were calculated as the areas under the load-displacement curves to the respective points. The effects of implant type and load during subsidence were analyzed using paired t-tests. **Results:** The yield and failure loads for the collared stems were approximately 40% greater than for the collarless stems (156.39 ± 43.63 kgf vs. 112.01 ± 59.83 kgf, $P<0.05$). **Conclusion:** This study supported the advantages of collared EBM stems, including subsidence prevention and better initial stability for early osteointegration.

Key words: Biomechanical evaluation, Canine cadaver, Cementless, Load, Total hip arthroplasty

Introduction

THA is an established and reliable surgical treatment for chronic lameness in dogs secondary to non-septic coxofemoral osteoarthritis that is nonresponsive or no longer responsive to medical treatment, providing excellent joint function and pain relief (Massat and Vasseur, 1994). Initially, cemented THA systems were used, with polymethylmethacrylate (PMMA) used for stem fixation in the femur. Although cemented THA demonstrated overall high success, it has been associated with diverse complications, including implant luxation, infection, femoral fracture, aseptic loosening, and extraosseous cement granuloma formation (Olmstead, 1995; Cross *et al.*, 2000), Cementless THA systems were developed to overcome the complications associated with the use of PMMA. Cementless THA depends on a tight press-fit fixation for sufficient friction at the bone-implant interface. The press-fit nature of cementless THA achieves short-term stability, while osteointegration into the porous metal surface of the femoral stem provides long-term stability. Clinical studies of cementless THA did not find the failure of osteointegration and long-term instability as complicating factors (Lascelles *et al*., 2010). However, cementless stem placement in the femoral canal was found to lead to a comparatively small surface area of initial osseous contact, resulting in limited osteointegration (Schimmel and Huiskes, 1988). In addition, micromotion was found at the bone-stem interface. Micromotion of 100-500 µm will inhibit osteointegration, leading to fibrous membrane formation and mechanically unstable stem implant (Aspenberg *et al*., 1992). Reported complications of cementless THA systems include continued lameness, the subsidence of the femoral stem, the fracture of the femoral diaphysis and greater trochanter, lucency at the acetabular cup-bone interface, coxofemoral joint luxation, fissure fracture, bone infarction, and acetabular displacement (Hanson *et al*., 2006). Although the data are limited, many cementless THA complications seem to be related to the femoral stems, whereas the survival of acetabular implants is excellent (Barrack *et al*., 1992). Comparisons of outcomes between cemented and cementless implants have not yielded conclusive findings thus, the optimal method for implant fixation remains subject to debate (Iwata *et al*., 2008). Despite the risk of intraoperative femoral fracture and the demand for a more precise surgical technique for good implant fit, cementless THA is widely accepted because of its advantages over cemented THA, including longer potential implant life, decreased risk of postoperative or later infection, and better implant stability.

With the increasing use of cementless THA, stem subsidence has emerged as one of the primary complications. Stem subsidence is the distal displacement of the stem within the femoral canal. In dogs, subsidence results from inadequate initial stability and inability to restrict weight-bearing on the affected femur in the perioperative period (Rashmir-Raven *et al*., 1992). A mild subsidence of 1-3 mm, also referred to as implant settle, is expected and does not result in clinical signs. However, subsidence of >3 mm may result in decreased stem stability, which may predispose to major complications, including hip luxation and femoral fracture (Fitzpatrick *et al*., 2014). The failure of initial stability permits the movement of the stem, which causes alteration in the range of motion, particularly in abduction, change in femoral stem version angle, and increased lateral translation as a result of decreased gluteal muscle pull (Liska and Doyle, 2015). The hoop strain expansion of the femoral cortex during subsidence is the underlying mechanism of most fractures involving cementless THA systems. Therefore, the prevention of subsidence will result in a decreased incidence of THA-associated fractures and luxation. Several studies have suggested that undersized stems and inappropriate stem positioning are the most important factors associated with subsidence (Townsend *et al*., 2017). Accordingly, appropriate stem size selection, the accurate preparation of the femur, and optimal stem positioning are important to prevent subsidence. Various methods have been explored to overcome the limitations of cementless THA to achieve good clinical function with a low incidence of complications, including hybrid cemented/cementless THA, screw-in femoral implants, helica femoral implant system using traditional and modified techniques, interlocking universal hip cementless stems, and titanium (Ti) EBM-manufactured collared cementless femoral stems (Buks *et al*., 2016). Among these, Ti EBM collared cementless femoral stems were demonstrated to prevent subsidence even with a canal flare index (CFI) less than 1.8. Namely, the collar contact with cancellous or cortical bone in the proximal femur prevented subsidence, and the cranial and caudal stem flutes on the non-porous surface provided additional rotational stability (Liska and Doyle, 2015).

The purpose of this cadaveric study was to compare the stem implant resistance and yield/failure mechanical properties between collarless and collared Ti EBM cementless stems. We hypothesized that collared Ti EBM femoral stem implants would increase initial stem stability, prevent implant subsidence, and increase resistance to femoral fracture.

Materials and Methods

Specimen preparation

In this study, seven German Shepherd male dogs (mean 7 to 8 years old) with an average weight of 20 kg were used. Seven pairs of femurs were harvested from cadavers with no evident orthopedic or neurologic diseases that were euthanized for humane reasons unrelated to this investigation. After all soft tissues were removed, the harvested femurs were stored at -14°C and were left at room temperature (approximately 25°C) for 12 h before the radiographic examination, stem placement, and mechanical testing. Radiographic examinations were performed with a digital radiography system (EVA-HF 525, COMED Medical System, Seongnam, Korea) with 70 kVp and 10 mAs. The craniocaudal and lateral radiographic views of the extracted femurs were fixed in place using tape, ensuring that the radiation beam was precisely centered perpendicular to the femur. The proximal aspect of the femurs was also examined to provide a proximal view. Computed tomography (CT) and three-dimensional imaging were performed with a 64-slice scanner (Aquillion 64™, Toshiba Medical Systems, Tochigi, Japan) to select the appropriate stem size and determine the optimal stem position. The parameters for the CT scan were as follows: 1.0 mm slice thickness, 120 kVp, 200 mAs, 512 × 512 matrix. The present study was performed under the institutional guidelines for the care and use of laboratory animals and was approved by the Ethics Committee for Experimental Animals of Chonbuk National University (CBNU-2017-00224).

Surgical implants and surgical technique

BioMedtrix Ti EBM collarless and collared cementless biologic fixation femoral stem implants (BioMedtrix LLC, Whippany, New Jersey, USA) were used (Liska and Doyle, 2015). In each pair of femurs, the left femur was implanted with a collarless and the right femur had a same-sized collared cementless stem. The femur was positioned by aligning the proximal aspect of the patellar surface with the proximal aspect of the femur parallel to the surgical table. After placing the neck resection guide on the central axis of the femur, the femoral head and neck were excised using an oscillating saw. Femoral neck resection was performed parallel to the neck cutting guide when the guide was properly aligned. A pilot hole was created using a power drill with a 3.2-mm intramedullary pin. Once the pilot hole was made, the remaining femoral neck was removed using rongeurs. The power reamer was driven into the femoral canal along the central axis of the femur. Sequential broaching was completed to the appropriate size and alignment. Once the femoral canal was prepared, a collarless or collared stem was inserted into the femoral canal and impacted using a mallet. The stems were driven into the femoral canal with the femoral component impactor and mallet until the “shoulder” of the femoral stem reached 2-3 mm below the most proximal aspect of the greater trochanter. Postoperative digital radiographs and computed tomography images were acquired immediately after the surgical manipulation of the femur until precise projections were obtained with the matching preoperative radiographic protocols.

Mechanical testing and data processing

The specimen constructs were mounted to the loading frame of the testing machine (WL2100C, Withlab Co., Ltd., Kyunggi do, Korea) with the long axis of the femur placed parallel to the long axis of the testing machine. To secure the femur, the distal femur was potted in the loading frame with PMMA. An impactor handle and head were used to transfer the load to the femoral stem parallel to the longitudinal axis of the femur. Compressive loading stopped on each femur when the stem subsided 5 mm (Fig. 1) based on the load-displacement curve. The load applied was recorded for all specimens. During the 5-mm stem subsidence, the specimens were loaded to subside in a single axial load at a rate of 500 N/s (Buks *et al*., 2016). Load and stem displacement data acquired during the tests were used to generate load-displacement curves for obtaining yield/failure data for each specimen construct using the WL2100C testing software (Withlab Co., Ltd., Kyunggi do, Korea). The curves and data were used to quantify the following structural construct properties: stiffness (the slope of the linear region of the load-displacement curve), yield (the initiation of curve nonlinearity), and failure (the point of maximum load before the construct no longer sustained load). Yield and failure energies were calculated as the areas under the load-displacement curves to the respective points.

Statistical analysis

Data were presented as mean ± standard deviation. The effects of implant type (collarless vs. collared) and load during subsidence were analyzed using paired t-tests. All statistical analyses were performed using PASW Statistics 18.0.0 (IBM Co., Armonk, New York, USA) and GraphPad Prism 5.0 (GraphPad Software, Inc., San Diego, California, USA). P-values of less than 0.05 were considered statistically significant.

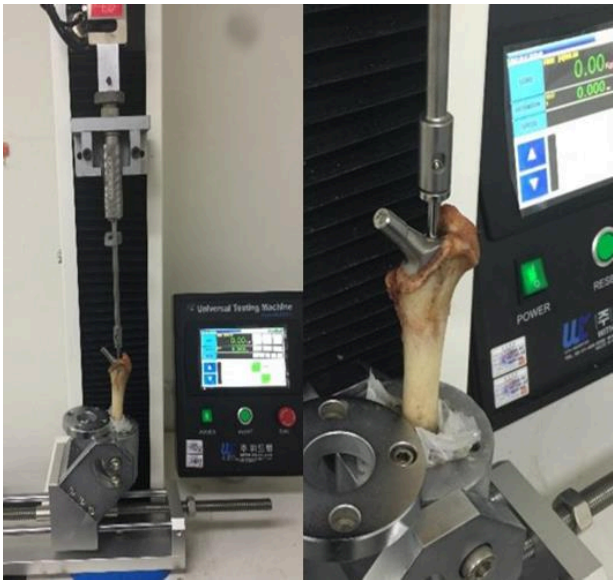

Fig. 1: Images of the yield and failure loading testing of a collarless BFX stem during 5-mm subsidence. After the distal femur was potted in the load frame with polymethyl-methacrylate following osteotomy, the load was applied to the femoral stem parallel to the longitudinal axis of the femur

Results

Specimens and implants

Seven collared and seven collarless Ti EBM cementless stems were successfully implanted in seven pairs of femurs. The implanted stem size numbers were #8 (n=2), #9 (n=3), and #10 (n=2). Although the dogs from which the femurs were harvested had no clinical signs of orthopedic or neurologic disease, dog #6 had proximal femoral bone sclerosis, and dog #7 had osteoarthritis with the deformation of femoral heads. No stem implantation-associated complications, such as fissure and fracture, were encountered during the procedure or observed during postoperative examination.

Failure properties during 5-mm subsidence

The yield and failure loads during the 5-mm subsidence for the collared and collarless Ti EBM stems were 156.39 ± 43.63 kgf and 112.01 ± 59.83 kgf, respectively, with the mean difference (44.37 ± 20.28 kgf) indicating that the yield and failure load for the collared stems was approximately 40% greater than that for the collarless stems ($P<0.05$; Fig. 2). Furthermore, the femurs implanted with collared stems demonstrated greater stiffness than those implanted with collarless stems (Liska and Doyle, 2015). Three of the seven collared stems failed by developing a fissure or a long oblique fracture along the medial aspect of the femoral osteotomy site.

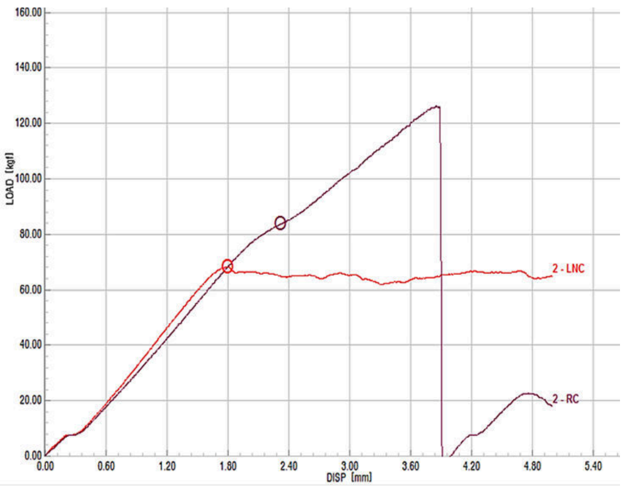

Fig. 2: Graphs of the yield and failure loads for the collarless (red line) and collared (purple line) BFX stems during 5-mm subsidence

Discussion

The results of this *ex vivo* study showed that collared Ti EBM cementless stems subsided 5 mm had higher yield and failure loads than collarless Ti EBM stems, indicating that collared Ti EBM stems resisted subsidence more than collarless stems under the experimental conditions. Our results support the hypothesis that collared Ti EBM femoral stems would increase the stems' initial stability. A concern with the collarless cementless stem is stem subsidence within the femoral canal and several studies have reported that undersized stems and stem malalignment are the major cause of subsidence (Townsend *et al*., 2017). The importance of subsidence is often underestimated because the effects of subsidence may be embedded in other complications; however, previous study indicated that subsidence could contribute to the development of femoral fractures (Pernell *et al*., 1994). Therefore, the appropriate selection of stem size, the accurate preparation of the femur, and optimal stem positioning minimize the risk of subsidence and its related complications. Many studies have explored various methods and techniques including hybrid THA and helica prothesis to prevent subsidence and its related complications (Liska and Doyle, 2015; Buks *et al*., 2016). Hybrid THA has provided short- and long-term stability with an initial low complication rate; however, hybrid THA may be a more complicated procedure with a longer surgery time (Gemmill *et al*., 2011). The helica prosthesis could preserve the femoral neck and only the femoral head is excised. It is speculated that more normal anatomy and original mechanical properties are maintained by preserving the femoral neck version and inclination (Kim *et al*., 2012). However, since the helica system requires normal femoral neck anatomy, dogs with bone deformity or other diseases involving the femoral neck are not suitable for the procedure. Additionally, complications have been reported with the use of this system, including acetabular cup loosening, bony resorption, femoral implant loosening, and sciatic neurapraxia (Hach and Delfs, 2009). Collared stems have many advantages including greater stability, increased vertical, rotational force resistance to subsidence, and subsequent fracture (Demey *et al*., 2011). As traditional collarless stems provide rapid bone ingrowth into the porous surface, the presence of a collar is acceptable for the overall stability, and osteointegration of the femoral endoprosthesis (Manley *et al*., 1995). This study evaluated the effect of Ti EBM collared cementless femoral stems on stem subsidence. In the present study, collared Ti EBM femoral stems, a modification of the traditional collarless cementless stems, increased the stems' initial stability. Collared stems subsided by 5 mm had higher yield and failure loads than collarless stems. Because we used paired femurs, the difference in dog age and femoral morphology were not variables and bone quality was similar between the paired femurs in the study. As a similar loading protocol was used in the paired femurs, and all procedures were performed by one surgeon, the differences in yield and failure loads between the collared and collarless paired femurs were considered to be due to the presence of the collar. The yield and failure loads during 5-mm subsidence for the collared and collarless Ti EBM stems in this study were 156.39 ± 43.63 kgf and 112.01 ± 59.83 kgf, respectively. These loads were higher than the yield and failure load reported in the previous study (85.5 ± 3.3 kgf). This difference may be due to the lack of *ex vivo* variability, such as the absence of torsional loading, altered loading environment, and implant micromotion. Three of the seven collared stems in this study failed by developing a fissure or a long oblique fracture along the medial cortex which is similar to the clinical findings during axial loading. No stem rotation was observed, which is thought to be partially due to the cranial and caudal stem flutes on the non-porous surface of the Ti EBM collared stems which help to provide rotational stability. The characteristics of the fractures observed in this study were similar to those reported in other studies and supported the theory that subsidence propagates a fissure or femoral fracture. The 5-mm subsidence used in this study is considered excessive subsidence that is a risk factor for complications including luxation, soft tissue impingement discomfort, and fracture. A prior study documented that EBM technology decreases subsidence in dogs; however, the advantages of a collar were not studied (Liska and Doyle, 2015). Therefore, the most clinically relevant finding of this study is that the collar withstood extreme force transmitted during early osteointegration. This finding indicates that the risk of subsidence in German Shepherd dogs with a low CFI of ≤1.8 could be overcome by using Ti EBM collared stems (Rashmir-Raven *et al*., 1992). Furthermore, no stem implantation-associated complications, such as fissures and fractures, were observed during and after the surgical procedure. However, as this was a cadaveric study, care must be taken during stem impaction in dogs with proximal femoral medullary sclerosis and advanced degenerative joint disease. The main limitation of this study is the lack of direct correlation to clinical patients and the lack of cyclic loading subsidence. Due to the mechanical construct, the load was not applied to a prosthetic femoral head, and the load applied was in the direction parallel to the femoral axis. The latter seemed more appropriate; however, a study loading on the femoral head should be conducted. Nevertheless, our findings of higher yield and failure loads in collared than in collarless Ti EBM cementless stems suggested that collared Ti EBM stems contribute to better initial stability and limit the risk of complications, such as inadequate biologic fixation and fracture occurrence. The results of this study showed that collared Ti EBM stems resisted subsidence more than collarless stems under experimental conditions. Although this was an *ex vivo* study, our findings supported the advantages of collared Ti EBM cementless stems, including subsidence prevention and better initial stability for osteointegration. Therefore, understanding the press-fit surgical principles and technique, appropriate preparation of the femoral bed, and using collared Ti EBM stems may decrease the incidence of subsidence and related complications.

Acknowledgement

This study was supported by the National Research Foundation of Korea (NRF) grants funded by the Korean Government (MSIT) (No. 2022R1F1A1065215).

Conflict of interest

The authors declare no conflict of interest.

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