Original Article

A long-term comparative study between two different designs of cemented stems: Distal-cylindrical versus distal-taper

Yuki Okutani^{a,*}, Koji Goto^a, Tomotoshi Kawata^a, Yaichiro Okuzu^a, Kazutaka So^b, Yutaka Kuroda^a, Shuichi Matsuda^a^a Department of Orthopaedic Surgery, Kyoto University, 54 Kawaharacho, Shogoin, Sakyo-ku, Kyoto, 606-8507, Japan^b Department of Orthopaedic Surgery, Osaka Red Cross Hospital, 5-30 Fudegasakicho, Tennoji-ku, Osaka, 543-8555, Japan

ARTICLE INFO

Keywords:

Highly cross-linked polyethylene
Cemented THA
Polyethylene wear
Stem design

ABSTRACT

Introduction: The aim of this study was to calculate the wear rate of highly cross-linked polyethylene (HXLPE) and investigate long-term clinical and radiographic outcomes related to two femoral stem designs, the distal-cylindrical (DC) and distal-taper (DT) stems.**Materials and methods:** Outcomes for the DC and DT stems were evaluated in 110 patients, who underwent total hip arthroplasty using an HXLPE socket, over a 5-year follow-up period. There were 56 hips (53 patients) in the DC group and 60 hips (57 patients) in the DT group. Clinical outcomes were measured using the Japanese Orthopaedic Association (JOA) score and radiographic changes. Polyethylene wear rate was calculated using a computer software.**Results:** The mean follow-up period was 135.7 and 124.0 months for the DC and DT groups, respectively. Both stem designs improved hip function. On radiographic assessment, osteolysis around the tip of the stem was more frequent in the DC than in the DT group. Three cases of aseptic loosening of the stem were identified in the DC group, and no cases were identified in the DT group. The 10-year stem survival, using aseptic loosening as the primary endpoint, was 94.1% and 100% for the DC and DT groups, respectively ($p = 0.06$). The polyethylene wear rate was comparable for both stem groups.**Conclusion:** Better clinical outcomes were obtained with the DT stem than with the DC stem regardless of the equivalent polyethylene wear rate for the two designs. The DC shape of the stem may increase the risk of aseptic loosening.

1. Introduction

Total hip arthroplasty (THA) is considered a successful treatment for hip disability, improving pain and hip function. Cemented or cementless THAs are performed worldwide, with a 10-year survival of primary THA of about 90%.¹ Various cement types, cement techniques, implant designs, materials, and surgical procedures have been developed to improve the outcomes of cemented THA. Among these innovations, the design of the femoral stem is one of the most important factors for long-term survival of cemented stems.

The use of highly cross-linked polyethylene (HXLPE) can also improve outcomes, with the wear rate of HXLPE being 14% of that of conventional polyethylene (CPE).² At our institute, two different titanium alloy stem designs for cemented THA are used with HXLPE sockets. In a previous report, one of these stem designs, the distal-cylindrical (DC) stem, used with a CPE socket, was found to induce

characteristic loosening of the stem, resulting in a high rate of aseptic loosening.³ In contrast, good clinical and radiographic outcomes have been reported for a distal-taper (DT) stem used with an HXLPE socket.⁴

The main difference between the DC and DT stems is the shape of the distal portion of the stem. The DC stem has a proximal-taper and distal-cylindrical shape, while a DT stem has a distal-taper shape. Our aim in this study was to compare the clinical and radiographic outcomes for the two stems designs, DC and DT, used with an HXLPE socket over 10 years, and investigate whether the difference in the distal shape of the stem was sufficient to affect the polyethylene wear of the socket and outcomes of primary cemented THA.

2. Material and methods

After an institutional review board approval, we retrospectively evaluated the clinical and radiographic outcomes of primary THAs

* Corresponding author.

E-mail addresses: okutanij@kuhp.kyoto-u.ac.jp (Y. Okutani), k.g.bau@kuhp.kyoto-u.ac.jp (K. Goto), kawata@kuhp.kyoto-u.ac.jp (T. Kawata), yokuzu@kuhp.kyoto-u.ac.jp (Y. Okuzu), so_kazu@kuhp.kyoto-u.ac.jp (K. So), ykuromd@kuhp.kyoto-u.ac.jp (Y. Kuroda), smat522@kuhp.kyoto-u.ac.jp (S. Matsuda).<https://doi.org/10.1016/j.jor.2018.01.019>

Received 11 October 2017; Accepted 13 January 2018

Available online 02 February 2018

0972-978X/ © 2018 Prof. PK Surendran Memorial Education Foundation. Published by Elsevier, a division of RELX India, Pvt. Ltd. All rights reserved.

Fig. 1. The distal-cylindrical and distal-taper stem designs of the femoral head component.

Fig. 2. Inclusion or exclusion flow diagram of cases treated using the DC and DT stem designs.

performed between 2000 and 2006. The DC stems were used from August 2000 to June 2004, and the DT stems from January 2004 to October 2006. The two stem designs are shown in Fig. 1. Patients with a 5-year follow-up period were eligible for enrollment. Prospective cases were screened to exclude (1) patients with insufficient follow-up data, (2) patients who received a subtrochanteric osteotomy in addition to primary THA, and (3) patients who were lost to follow-up or did not complete their follow-up due to death or transfer to another location. Among all THAs performed between 2000 and 2006, a DC stem was used in 66 hips and a DT stem in 74. After screening cases based on the exclusion criteria, 56 hips, contributed by 53 patients, formed the DC group, and 60 hips, contributed by 57 patients, formed the DT group. The allocation of cases is shown in Fig. 2.

Our overall follow-up rate was 82.9%. The mean age of patients at

the time of surgery was 65.3 years (range, 45–82 years) in the DC group and 62.7 years (range, 44–81 years) in the DT group. Male patients contributed to 6 hips in the DC group and 7 hips in the DT group. The mean follow-up duration was 135.7 months (range, 60–186 months) for the DC group and 124.0 months (range, 65–150 months) for the DT group. The original diagnoses for THA in the DC group included secondary osteoarthritis (OA), 35 hips; primary OA, 18 hips; ankylosing spondylitis (AS), 1 hip; osteonecrosis (ON), 1 hip; and post-tuberculosis arthropathy, 1 hip. Diagnoses for the DT group were as follows: secondary OA, 44 hips; primary OA, 11 hips; ON, 2 hips; AS, 1 hip; post-traumatic arthropathy, 1 hip; and post-tuberculosis arthropathy, 1 hip. The mean body mass index (BMI) of the overall participants in both groups was 23.0 kg/m².

Self-report function was assessed using the Japanese Orthopaedic

Table 1

Relevant patient information prior to surgery.

	DC	DT	Between-group difference
Follow-up, months	135.7	124.0	$p = 0.0218^*$
Age, years	65.3	62.7	$p = 0.122^*$
Female	50	53	$p = 0.871^{**}$
BMI	23.0	23.0	$p = 0.881^*$
JOA score	45.8	47.5	$p = 0.426^*$

BMI, body mass index; DC, distal-cylindrical; DT, distal-taper.

* *t*-test.

** Chi-squared test.

Association (JOA) score, which includes pain, range of motion, gait ability, and daily activity. The JOA score is expressed from 0 to 100 points, with a higher score indicative of better function. Preoperatively, the mean JOA score was 45.8 for the DC group and 47.5 for the DT group. Relevant demographic data of the study group are summarized in Table 1.

2.1. Radiographic assessment

Anterior-posterior plain radiographs were obtained pre- and post-operatively and at yearly follow-up. Radiographs were reviewed for evidence of osteolysis, cortical hypertrophy, and stem loosening. Stem loosening was defined according to the criteria of Harris and McGann, including fracture or bending of the stem, fracture of the cement, stem subsidence, and appearance of a radiolucent line at a cement-stem interface.⁵ Cortical hypertrophy was defined by a widening of the cortex > 1 mm, compared to measures obtained on immediate post-operative radiographs. The location of cortical hypertrophy was classified according to Gruen's seven zones.⁶ The angle between the stem and the femoral shaft was measured, and a varus and valgus position was defined by an angle > 2°. The cement technique was assessed using Barrack's classification.⁷

2.2. THA procedure

H3 and H3 taper stems (Kyocera Medical, Osaka, Japan) were used in our study. Both stems are made of Ti-15Mo-5Zr-3Al alloy and have a non-polished but smooth surface. The DC stem is an H3 stem with a proximal-taper and DC shape. The smaller-sized H3 stems have a single proximal taper, while larger-sized stems have a double proximal taper. The DT stem is an H3 stem with a double taper over its entire length. Femoral head components, 22 mm in diameter and made of zirconia, were mainly used. All stems in the DC group were cemented using Endurance cement (DePuy Orthopaedics, Inc., Warsaw, IN, USA). For the DT group, Endurance cement was used for 27 hips and Simplex P (Stryker, MI, USA) for the other 33 hips. A CoCr femoral head component was used in 5.4% of hips in the DC group and in 8.3% in the DT group (chi-squared test, $p = 0.525$). Either FL or CLHO sockets were used (Kyocera Medical). All sockets were made of HXLPE and annealed by radiation, 60 kGy for FL sockets and 75 kGy for CLHO sockets. The materials, including the cement type, and diameter of the components are summarized in Table 2.

All THAs were performed with patients in the lateral decubitus position, using a direct lateral (Dall's) approach. Prior to socket implantation, after final reaming of the acetabulum, bone grafting was performed using the bulk bone created from the resected femoral head if coverage by the acetabular bone wall was insufficient. The size of the bone graft was sufficiently large to completely cover the superior aspect of the socket. In some cases with severe loss of acetabular bone coverage, KT plates (Kyocera Medical) were used in combination with morselized bone grafting. Femoral stems were implanted using the third cement technique without centralizers. In postoperative rehabilitation, full weight bearing was initiated on postoperative day 1.

Table 2

Type of cement, type of material for the femoral head component, and diameter of the femoral head component.

	DC	DT
Zirconia 22 mm	52	48
Zirconia 26 mm	1	7
CoCr 22 mm	3	5
Endurance/Simplex P	56/0	27/33

DC, distal-cylindrical; DT, distal-taper. A CoCr femoral head component was used in 3/56 cases in the DC group and 5/60 cases in the DT group; between-group difference, $p = 0.525$ (chi-squared test).

2.3. Wear measurement

Polyethylene wear was evaluated to specifically determine if the stem design influenced HXLPE wear rate and clinical and radiographic outcomes. The wear rate was measured using the WEAR MEASUREMENT software, version 1.5.⁸ Three measurements were obtained at 2 time points, at approximately 1 year post-THA and at the final follow-up. The 1-year post-THA time point was selected as the initial reference value to minimize effects of bedding and creep on the measured width of the HXLPE. The wear rate per year was calculated from the total wear rate calculated by the software. The polyethylene wear rate was not calculated for the 3 patients implanted with KT plates in the DC group, as KT plates obscure the lines between the sockets and acetabulum, which are necessary for the exact measurement of HXLPE width.

2.4. Statistical analysis

Intra-class correlation coefficients (ICC) were calculated using SPSS version 22 (IBM, Armonk, NY, USA), with all other statistical parameters calculated using JMP Pro 12 (SAS, Cary, NC, USA). The methods used to calculate *p*-values are indicated in the table and figure legends. The Kaplan-Meier method was used to calculate the stem survival for the primary endpoint, aseptic loosening, and secondary endpoint, revision surgery. Between-group differences were evaluated using *t*-test and chi-squared test as appropriate for the data type. A *p*-value < 0.05 was considered to be statistically significant.

3. Results

The mean JOA score at the final follow-up was 82.4 for the DC group, at a mean 135.7 months post-THA, and 86.0 for the DT group, at a mean 113.8 months post-THA. Aseptic loosening was identified in 3 hips in the DC group, with no incidence in the DT group. Stem revision was required for 3 hips in the DC group and 1 hip in the DT group. In the DC group, the 2 hips required stem revision due to aseptic loosening in one and socket loosening in the other (Fig. 3). One patient in the DT group required THA revision due to prosthetic joint infection. The Kaplan-Meier survival curves for the two stem groups are shown in Fig. 4. The 10-year survival rate with aseptic loosening of the stem as the endpoint was 94.1% for the DC group and 100% for the DT group. The 10-year survival rate with stem revision as the endpoint was 94.4% in the DC group and 97.3% in the DT group. For aseptic loosening as the endpoint, the incidence rate of stem loosening was higher for the DC than DT group ($p = 0.0683$). The mean JOA score at the final follow-up was 82.4 for the DC group and 86.0 for the DT group ($p = 0.132$).

3.1. Radiographic assessment

The cementing was classified as a Barrack A technique in 85.7% of cases in the DC group and 80% of cases in the DT group ($p = 0.414$), with osteolysis identified in 6 patients in the DC group. There was no incidence of osteolysis in the DT group. The incidence rate of

Fig. 3. An example of a case of loosening of a DC stem.

A 68-year-old woman underwent primary cemented THA with a DC stem for treatment of secondary osteoarthritis due to a dysplastic hip. (a) Preoperative radiograph: preoperative JOA score was 63; the cement technique was classified as Barrack A, and stem alignment was good in neutral position. (b) Postoperative radiograph: at 78 months post-THA, radiograph reveals severe osteolysis around the tip of the stem and stem subsidence. (c) Pre-revision radiograph, with evidence of stem loosening; revision surgery was performed using a longer stem; JOA score before revision THA was 73.

malalignment of the femoral stem was higher in the DT than DC group ($p = 0.0020$). The Barrack classification and stem alignment for both stem groups are presented in detail in Table 3. The incidence rate of

cortical hypertrophy was also higher for the DC than DT group, typically observed around the tip of the femoral stem and Gruen's zones 3 and 5. The location of cortical hypertrophy is shown in Table 3. A radiolucent line was observed in zone 1 in one patient who experienced loosening of the stem at the cement-bone interface in the DC group; the radiographic and functional data for this patient are shown in Table 3.

3.2. Polyethylene wear rate calculation

Polyethylene wear rate was calculated over an average of 404 days (range, 273–730 days) post-THA, from final radiographs obtained on an average of 3151 days (range, 548–4830 days) post-THA. The mean and 95% confidence interval of wear rates for both stem designs are summarized in Table 4. ICC (3.1) between the 3 measurements obtained at each of the 2 points of measurement was 0.577. There was no significant difference in the wear rate between the DC and DT groups. Rates of osteolysis, component loosening, and material used for the head component were also comparable between the two groups.

4. Discussion

We compared the long-term clinical and radiographic outcomes for the two different stem designs coupled to HXLPE sockets. The DT design induced stem malalignment, while the DC design induced osteolysis and cortical hypertrophy around the stem tip and was associated with a higher rate of component loosening. Therefore, although the HXLPE wear rate was comparable for both stem designs, we consider the DT design to be superior, as previously reported. Despite worse radiographic outcomes for the DC stem, JOA scores were not significantly different between the two groups. Therefore, although localized mechanical stress with the DC design induced negative radiographic abnormalities^{3,9}, these effects did not impair hip function or activities of daily life, unless loosening of the stem occurred. However, a head-to-head comparison of JOA scores and radiographic outcomes is not possible as the follow-up period was longer for the DC group than the DT group.

Although radiographic abnormalities were more frequently observed in the DC group, there was a higher occurrence of stem malalignment in the DT group. These differences between the stems are likely to result from the difference in the shape of the stems. Unlike cementless stems, cement stems are fully covered with cement and are designed for longevity. However, the cylindrical portion of the DC stem provides a better fit in the medullary canal than the tapered design of the DT stem, which allows some space around the tip of the stem and the potential for deviation from a vertical position. The tight fit of the DC stem, in contrast, reduces the risk of malalignment. Despite these differences in the intramedullary canal fit, a previous study has reported on the better clinical outcomes obtained from an Exeter stem, which has a distal-taper design.¹⁰ The concentration of mechanical load on the cement at the tip of the DC stem is the main cause of stem loosening³, as shown by the higher incidence of osteolysis for the DC than DT group in our study. The tighter fit of the DC stem is not necessarily a negative factor, with a recent study reporting good outcomes if the cement mantle is maintained below 2 mm, the so-called “French paradox.”¹¹ Therefore, negative outcomes of the DC stem design occur when the mechanical load cannot be transmitted effectively to the surrounding cement. In fact, a study comparing the DT stem with the DC stem using a finite element model analysis showed that the DT stem can transfer the mechanical load to the tip of the stem more gently than the DC stem.³ Moreover, rotational stability is lower for the DC than DT stem design. The rectangular-shaped tip of the DT stem offers greater stability against a rotation load¹² than the cylindrical tip of the DC stem, and, consequently, the DC stem is prone to micromotion, which can cause the cement to fracture and the stem to loosen over time.

In our study, we used 2 types of medium-viscosity bone cement. A previous report from the Norwegian Arthroplasty Register identified

Fig. 4. Survival rate of DC and DT stems.

Log-rank test of aseptic loosening, $p = 0.0683$; the dotted lines showing the 95% confidence interval for each type of stem.

Log-rank test of revision for any reason, $p = 0.2874$; the dotted lines showing the 95% confidence interval for each type of stem.

Table 3
Radiographic and functional assessment.

	DC	DT	
Stem alignment and cement technique			
Valgus/varus/total	2/1/56	7/10/60	$p = 0.0020^{**}$
Barrack A/B	48/8	48/12	$p = 0.414^{**}$
Patients' data at last follow-up			
JOA score	82.4	86.0	$p = 0.132^*$
Osteolysis +	6/56	0/60	$p = 0.0026^{**}$
Cortical hypertrophy			
Zone 3–4	7	3	$p = 0.0001^{**}$
Zone 4–5	6	0	
Zone 3–4–5	11	7	

DC, distal-cylindrical; DT, distal-taper.

* t -test.

** Chi-squared test.

Table 4
Polyethylene wear rate calculated using the “wear” measurement.

	Hips	Mean wear rate	
DC stem	53	0.0160 mm/year	$p = 0.9749^*$
DT stem	60	0.0157 mm/year	
Aseptic loosening +	3	0.0107 mm/year	$p = 0.8356^*$
Aseptic loosening –	110	0.0160 mm/year	
Osteolysis +	6	0.0177 mm/year	$p = 0.9171^*$
Osteolysis –	107	0.0157 mm/year	
CoCr head	8	0.0163 mm/year	$p = 0.9757^*$
Zirconia head	105	0.0158 mm/year	

DC, distal-cylindrical; DT, distal-taper.

* t -test.

significantly higher rates of failure for prosthesis inserted using low-viscosity cement.¹³ For the medium-viscosity Endurance and Simplex P cements used in our study, we consider any difference in mechanical properties to be negligible. However, we did use several types of femoral head components. The effects of the femoral head component on

polyethylene wear of the socket have been shown to be negligible for alumina femoral heads, 22–26 mm in diameter.¹⁴ Another study reported a lower wear rate of HXLPE sockets using CoCr and zirconia femoral head components.² In our study, the proportion of CoCr femoral heads used was equivalent between the two groups, and the wear rate of the HXLPE sockets was minimal for both groups. Therefore, we did not identify an effect of the femoral head type on the wear rate of the HXLPE sockets.

Regarding the calculation of polyethylene wear rate, the ICC in the measurement of HXLPE width was lower than expected for both groups, likely due to the fact that the line between the acetabulum and cement sockets on anterior-posterior radiographs is not completely obvious. Moreover, measurements to calculate the wear rate were only taken at two time points, at approximately 1 year post-THA and at the final follow-up. A more accurate wear rate could be calculated from yearly radiographs. Regardless of the lower ICC, we deem our measurement data as sufficiently consistent to report a wear rate of HXLPE of 0.01–0.031 mm/year, which is comparable to previously reported values.²

Our study had several limitations. Foremost, we conducted a retrospective observational study, which includes the bias inherent to this study design. Our outcomes should be verified in a prospective randomized controlled trial. Although mean age, sex, BMI, preoperative JOA score, and underlying hip joint disease were comparable between the two groups, past medical history and comorbidities were not available, which are factors that could have influenced measured outcomes. However, it is important to note that OA was the primary diagnosis for THA in the majority of patients, and none of our patients had rheumatoid arthritis, with a low incidence of ON. Moreover, the follow-up period was insufficient to evaluate HXLPE wear. A previous study reported that HXLPE did not reduce the 10-year rate of aseptic loosening.¹⁵ Our 10-year survival rate in the DC group was 94.1%, which is comparable to a previously reported survival of DC stems with CPE sockets.³ Thus, future studies are needed to completely evaluate the effect of the stem design on HXLPE wear.

In conclusion, we conducted a retrospective observational long-term

(over 10 years) study, reporting a higher rate of stem loosening for DC stems compared to DT stems. We did not identify an effect of stem design on HXLPE wear of the socket, recognizing that HXLPE has a very low polyethylene wear rate. However, the cylindrical shape of the DC stem reduces rotational stability, causing micromotion that increases the risk of osteolysis around the tip of the stem and component loosening. It is important to note that THAs are designed for longevity of femoral stems, and therefore, our 10-year follow-up period is relatively short, with longer-term follow-up necessary.

Conflict of interest

The authors declare that they have no conflict of interest.

References

1. Malchau H, Herberts P, Eisler T, Garellick G, Soderman P. The Swedish total hip replacement register. *J Bone Joint Surg.* 2002;84-A(Suppl. 2):2–20 American volume.
2. Fukui K, Kaneuji A, Sugimori T, Ichiseki T, Kitamura K, Matsumoto T. Wear comparison between a highly cross-linked polyethylene and conventional polyethylene against a zirconia femoral head: minimum 5-year follow-up. *J Arthroplast.* 2011;26:45–49.
3. Kimura G, Onishi E, Kawanabe K, Kazutaka S, Tsukanaka M, Akiyama H. Characteristic loosening of the distally straight cylindrical femoral stem. *J Orthop Sci: Off J Jpn Orthop Assoc.* 2014;19:437–442.
4. Akiyama H, Kawanabe K, Yamamoto K, So K, Kuroda Y, Nakamura T. Clinical outcomes of cemented double-tapered titanium femoral stems: a minimum 5-year follow-up. *J Orthop Sci: Off J Jpn Orthop Assoc.* 2011;16:689–697.
5. Harris WH, McGann WA. Loosening of the femoral component after use of the medullary-plug cementing technique: follow-up note with a minimum five-year follow-up. *J Bone Joint Surg.* 1986;68:1064–1066 American volume.
6. Gruen TA, McNeice GM, Amstutz HC. Modes of failure of cemented stem-type femoral components: a radiographic analysis of loosening. *Clin Orthop Relat Res.* 1979;1:7–27.
7. Barrack RL, Mulroy Jr RD, Harris WH. Improved cementing techniques and femoral component loosening in young patients with hip arthroplasty. A 12-year radiographic review. *J Bone Joint Surg.* 1992;74:385–389 British volume.
8. Ise K, Kawanabe K, Tamura J, Akiyama H, Goto K, Nakamura T. Clinical results of the wear performance of cross-linked polyethylene in total hip arthroplasty: prospective randomized trial. *J Arthroplast.* 2009;24:1216–1220.
9. Ritter MA, Fechtman RW. Distal cortical hypertrophy following total hip arthroplasty. *J Arthroplast.* 1988;3:117–121.
10. Williams HD, Browne G, Gie GA, Ling RS, Timperley AJ, Wendover NA. The exeter universal cemented femoral component at 8 to 12 years: a study of the first 325 hips. *J Bone Joint Surg.* 2002;84:324–334 British volume.
11. Langlais F, Kerboul M, Sedel L, Ling RS. The ‘French paradox’. *J Bone Joint Surg.* 2003;85:17–20 British volume.
12. Glyn-Jones S, Gill HS, Beard DJ, McLardy-Smith P, Murray DW. Influence of stem geometry on the stability of polished tapered cemented femoral stems. *J Bone Joint Surg.* 2005;87:921–927 British volume.
13. Espehaug B, Furnes O, Havelin LI, Engesaeter LB, Vollset SE. The type of cement and failure of total hip replacements. *J Bone Joint Surg.* 2002;84:832–838 British volume.
14. Kawanabe K, Tanaka K, Tamura J, et al. Effect of alumina femoral head on clinical results in cemented total hip arthroplasty: old versus current alumina. *J Orthop Sci: Off J Jpn Orthop Assoc.* 2005;10:378–384.
15. Johanson PE, Digas G, Herberts P, Thanner J, Karrholm J. Highly crosslinked polyethylene does not reduce aseptic loosening in cemented THA 10-year findings of a randomized study. *Clin Orthopaed Relat Res.* 2012;470:3083–3093.