



High incidence of intraoperative calcar fractures with the cementless CLS Spotorno stem

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Abstract

Introduction This study reports on the incidence of intraoperative calcar fractures with the cementless Spotorno (CLS) stem, and the potential role of a learning curve and implant positioning is investigated.

Methods After introduction of the CLS stem, 800 consecutive cementless total hip arthroplasties (THA) were analyzed. The incidence of calcar fracture in the first 400 THA was compared with the second 400 THA, in order to study a potential learning curve effect. According to the instruction for users, varus positioning of the stem was avoided and a femoral neck osteotomy was aimed relatively close to the lesser trochanter since these are assumed to be correlated with calcar fractures. Implant positioning (neck-shaft angle, femoral offset and osteotomy-lesser trochanter distance) was measured on postoperative pelvic radiographs of all THA with calcar fractures and 100 randomly selected uncomplicated control cases.

Results Seventeen (2.1%) intraoperative calcar fractures were recorded. The incidence of calcar fracture differed between the first 400 THA ($n = 11$) and the second 400 THA ($n = 6$). This difference was not statistically significant ($p = 0.220$); however, these numbers indicate a trend toward a learning effect. No significant difference in stem positioning nor the height of the femoral neck osteotomy was measured between THA with a calcar fracture ($n = 17$) and the control cases ($n = 100$).

Conclusions We report on a high incidence of intraoperative calcar fractures with the use of a CLS stem. The risk for calcar fractures remains clinically significant even after adequate implant positioning in the hands of experienced hip surgeons. Surgeons should be aware of this implant related phenomenon and be alert on this phenomenon intraoperatively.

Keywords Total hip arthroplasty · Fissure · Calcar fracture · CLS · Hip geometry · Cementless

Introduction

Total hip arthroplasty (THA) is the treatment of choice in patients with debilitating hip impairment due to osteoarthritis, inducing relief of pain and improving mobility. Nowadays THA is one of the most successful and frequently executed orthopedic procedures with a reported patient satisfaction rate of more than 95% [1]. Clinical outcome of cementless femoral stems has been further improved by using tapered designs for press fit fixation combined with a rectangular cross-sectional shape for rotation–stability [2, 3]. In 1984, the tapered cementless Spotorno (CLS) stem

was introduced (Zimmer, Warsaw, USA) and is currently one of the most widely used cementless femoral components. Attracted toward the excellent track record and low revision rates of the CLS stem with an ODEP ‘10A*’ rating (ODEP 2014), the CLS stem was introduced in our practice in March of 2013 [4–7]. After introduction the intraoperative calcar fracture rate seemed to increase notably; in fact this phenomenon was basically new to us. Femoral fracture is a recognized complication of cementless THA, especially in tapered and rectangular designs. Intraoperative calcar fractures increase the risk of revision, add to operation time and frequently require further surgical exploration while also possibly delaying recovery after the index operation [8, 9]. As such this is an important complication with potentially hazardous consequences for patients especially when missed intraoperatively. There is limited literature available on this topic and the problem may be underestimated by publication bias. Incidence rates for intraoperative calcar fractures with cementless THA have been reported ranging 0.4–5.4%

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[3, 8–11]. (Only) three articles reported on calcar fractures in cohorts with the CLS stem, fracture occurrence ranging from 2.2 to 13.4% [6, 12, 13].

Numerous cementless stem designs have reported a different incidence of calcar fractures, which indicates that an ‘implant factor’ plays an important role in this phenomenon. From a biomechanical perspective, calcar fractures may be induced by varus positioning of the stem during implantation and a relatively high femoral neck osteotomy [14, 15]. A learning curve could also be involved, which then in combination with radiographic implant positioning would represent a ‘surgeon factor’ in regard to this complication.

From our observation, we performed a retrospective analysis on the first 800 consecutively implanted CLS prostheses from introduction in our clinic in March 2013. Our main goal was to determine the incidence of calcar fractures with this particular implant design and how to avoid or decrease its occurrence. Secondly, to determine to which extent a learning curve could be held responsible for the incidence of calcar fractures. Thirdly, to identify radiographic hip geometry aspects, a surgeon could avoid during implantation to limit the surgeon factor. Since the occurrence of calcar fractures was a relatively new phenomenon in a high-volume hip arthroplasty clinic with over a decade of experience with another tapered and rectangular cementless stem design, we hypothesized a dominant role for the implant design related factor.

Materials and methods

In the authors’ clinic, patients with primary osteoarthritis of the hip in otherwise anatomically normal hip joints without significant comorbidities are operated on in a joint rapid recovery program. In this highly protocolled program, patients are operated on by one of five experienced hip surgeons (> 100 implants/year). Patients younger than 70 years of age at the time of surgery with normal anatomy and bone stock receive a cementless THA (CLS Spotorno cup and stem, Zimmer, Warsaw, USA).

Prosthesis (CLS)

The CLS Spotorno stem is a cementless stem with a characteristic coronal three-dimensional wedge shape and sharpened ribs in the proximal region for predominantly proximal anchorage, providing press-fit and a long-lasting mechanical stability through a large contact area for osseointegration. These factors should ensure primary and rotational stability (from: The CLS Spotorno Stem, Zimmer 2008). The manufacturer of the CLS stem recommends to avoid a varus position when introducing the stem into the femoral canal and to aim for a femoral neck osteotomy of 1.0–1.5 cm above the

lesser trochanter (from: CLS Spotorno Hip Stem, Surgical technique, Zimmer 2008–2011). Following these recommendations, the incidence of calcar fractures may be minimized.

Cohort selection

The first 800 cementless THA with the CLS femoral component from the rapid recovery program operated on between March 2013 and January 2016 were retrospectively evaluated for implant positioning and intra- and postoperative calcar fractures. In order to evaluate a possible learning curve concerning calcar fractures, we divided this cohort in two consecutive groups; the first 400 THA implanted (Group 1), and the second group of 400 THA implanted (Group 2). The group was simply split in half since we felt that at least 70–100 implants should have been placed by each surgeon before a potential learning curve effect would have disappeared. From the literature, a number of at least 50 cases is recognized as an acceptable learning curve [16, 17]. All cases with calcar fracture, intraoperative identified or on the postoperative pelvic X-ray, followed geometrical analysis. A group of 100 uncomplicated THA was randomly selected from Group 1 as a control group for geometrical comparison.

Surgical technique

All surgeries were performed by an experienced hip surgeon with at least 5 years of experience in total hip arthroplasty (> 100 implants/year). A posterolateral approach was used in all cases. Main technical objectives during surgery were to restore hip anatomy, prevent hip instability and avoid leg length discrepancy. In achieving these objectives, preoperative implant planning was performed using digital templating software (Easyvision, Philips, Eindhoven, The Netherlands). Perioperative positioning of the stem was targeted at 15°–20° anteversion and a neutral varus/valgus angle. The femoral neck osteotomy was aimed at 1 cm above the lesser trochanter. In order to detect any potential calcar fissuring intraoperatively, we routinely measure stem depth in the femoral canal of the final implant against the trial stem. With the press-fitted trial implants in place, we measure the distance from the osteotomy toward the end of the neck-taper (typically around 35–40 mm). Subsequently, the final stem is placed and this distance is measured again (Fig. 1). In case, the final stem position is any deeper than the well-fitted trial stem one should be alert on fissuring and check for it posteriorly. Fissuring occurs as the robust proximal ribs of the final stem are press-fitted in the canal after reaming. The radial stresses applied on the calcar may become too high and cause cortical fracturing. Typically, this fracture occurs below the posterior corner of the rectangular stem and can easily be missed. In case of fissuring, one can decide to provide a cerclage around the proximal femur or convert

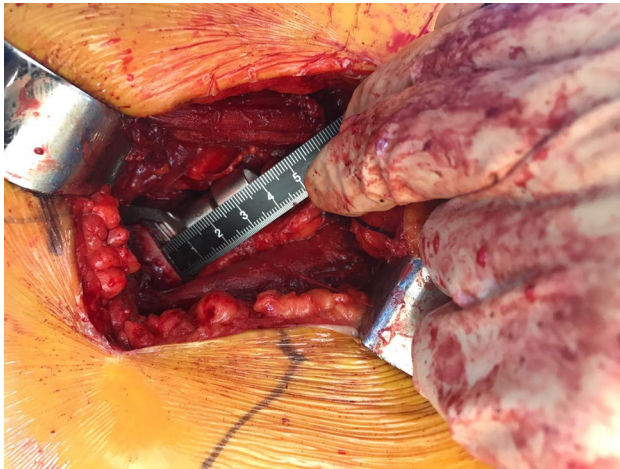


Fig. 1 Intra-operative image. Typical example how the distance of the femoral osteotomy toward the end of the neck-taper is measured (37 mm in this example). This distance should match with the trial implant situation

toward a cemented implant. Most importantly, a missed fracture may easily result in an early postoperative periprosthetic fracture after mobilization.

Radiographic analysis

Postoperative standard anterior–posterior (AP) pelvic radiographs were obtained in all patients at 6 weeks postoperatively. Radiographic measurements were executed using Philips Easyvision with an extended Ortho-toolbox (Philips Medical Systems, Eindhoven, The Netherlands). Postoperative AP pelvic X-rays were calibrated on the prosthesis femoral head with a standard diameter of 36 mm (cup diameter ≥ 50 mm) or 32 mm (cup diameter ≤ 48 mm). Next, three key radiographic parameters were used to evaluate postoperative hip geometry. Femoral off set (OFF) was measured; the distance between the center of rotation and a line through the center of the femoral shaft (Fig. 2). Secondly, distance of the femoral neck osteotomy toward the lesser trochanter was measured (FC) (Fig. 2). Finally, the neck-shaft angle represents the angle between the prosthesis neck and a line through the center of the femoral shaft (NSA); a negative NSA corresponds to a valgus positioning and a positive value corresponds to a varus positioning of the stem (Fig. 2).

Statistical analysis

Data were processed in SPSS (SPSS version 21.0 Inc. Chicago, IL, USA) for statistical analysis. All data were controlled for normal distribution by means of the Shapiro–Wilk test. Normally distributed data are presented as mean with standard deviation. Normally distributed measurements will be compared with use of the independent

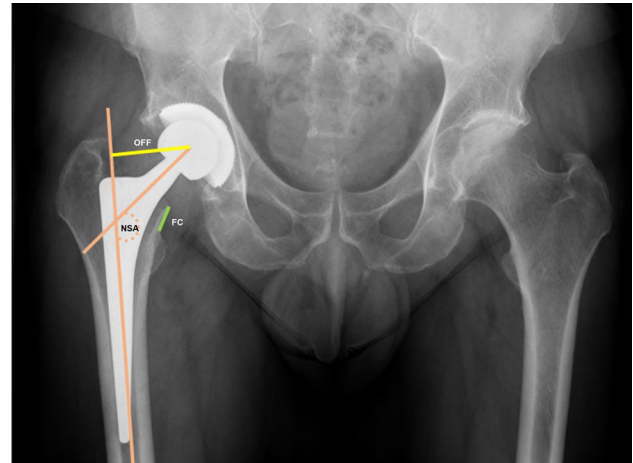


Fig. 2 Six weeks postoperative pelvic anteroposterior radiograph. Template of the geometric parameter measurements in total hip arthroplasty: offset (OFF), neck-shaft angle (NSA), femoral neck osteotomy distance (FC). AP anteroposterior, THA total hip arthroplasty

Students' *T* test. When appropriate the Pearson χ^2 test was used. Differences were considered statistically significant with a $p < 0.05$.

Results

Eight hundred consecutive THA were performed with a CLS Spotorno Stem. Group 1 consisted of 400 THA implanted between March 2013 and September 2014. In the time period between September 2014 and January 2016, the next 400 THA were implanted (Group 2). The groups were well comparable at baseline; no significant differences in baseline characteristics were recorded (Table 1).

Table 1 Patient characteristics at baseline

	Total ($n = 800$)	Group 1 ($n = 400$)	Group 2 ($n = 400$)	<i>p</i> value
Age	64.0 (8.8)	64.6 (8.3)	63.4 (9.4)	0.060
Side (<i>n</i>)				
Right	417 (52.1%)	202 (50.5%)	215 (53.8%)	0.358
Gender (<i>n</i>)				
Male	315 (39.4%)	161 (38.5%)	154 (40.3%)	0.612
Calcar fractures (<i>n</i>)	17 (2.1%)	11 (2.8%)	6 (1.5%)	0.220

Results are presented as number of cases (*n*) and percentages or as means with SD

Calcar fractures

A total of 17 (2.1%) calcar fractures were recorded in our cohort of 800 THA. All five orthopaedic surgeons experienced one or more calcar fracture without any outliers among them. One calcar fracture was identified on the post-operative radiograph; this patient was treated with a weight bearing restriction for 6 weeks. Two cases were intraoperatively converted to a cemented stem because of a calcar fracture. The remaining calcar fractures ($n = 13$) were successfully treated with one or two cerclage wires intraoperatively and limited weight bearing the first 6 weeks after surgery.

In Group 1 a total of 11 (2.8%) calcar fractures were encountered compared to 6 (1.5%) in Group 2 (Table 1). This difference was not statistically significant ($p = 0.220$); however, a trend toward a gradual decrease was present. Different cut-of points, such as 100 versus 700 and 300 versus 500, were also assessed with similar outcome.

Geometrical characteristics

A flowchart regarding patient selection for geometrical comparison is presented in Fig. 3. As noted previously, Fig. 2 shows the method of measurement of the different characteristics. Geometrical characteristics were compared between the THA with a calcar fracture and 100 THA from the control group. Table 2 represents the comparison of the key geometrical characteristics measured. The femoral neck osteotomy was 10.3 mm [standard deviation (SD) 3.9 mm] above the lesser trochanter in the control group and 11.7 mm (SD 4.3 mm) in THA with a calcar fracture ($p = 0.18$). Patient with a calcar fracture had a mean offset of 47.6 mm (SD 8.4 mm), while the control group had a mean of 46.0 mm (SD 5.3 mm) ($p = 0.45$). The mean neck-shaft angle was 1.4°

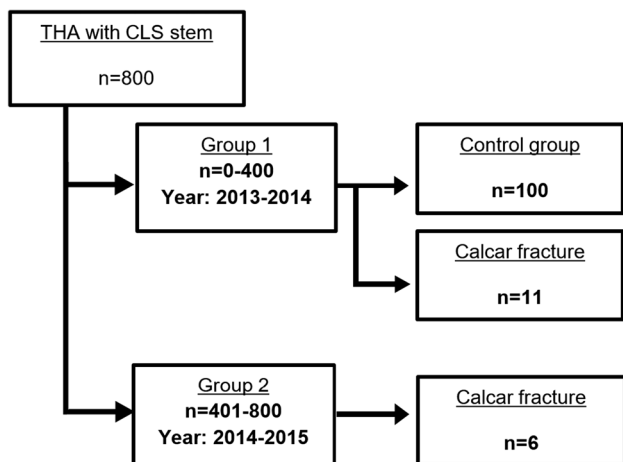


Fig. 3 Flowchart: patient inclusion for radiographic assessment. THA total hip arthroplasty, CLS cementless Spotorno

Table 2 Mean geometric parameter measurements on AP pelvic radiographs of uncomplicated total hip arthroplasty (THA) and THA complicated by intraoperative calcar fractures

	Control group ($n = 100$)	Calcar frac- ture ($n = 17$)	p value
Osteotomy distance (mm)	10.3 (3.9)	11.7 (4.3)	0.18
Offset (mm)	46.0 (5.3)	47.6 (8.4)	0.45
Delta neck-shaft angel (°)	-1.4 (2.8)	-2.6 (3.1)	0.11

Results are presented as means with SD

valgus in the control group with an SD of 2.8°, while THA with a calcar fracture had a mean valgus alignment of 2.6° (SD 3.1°) ($p = 0.11$). All three parameters did not differ statistically significant.

Discussion

In this retrospective study, the incidence of calcar fractures was 2.8% in the first 400 cases, which decreased toward 1.5% in the subsequent 400 cases. With numbers available, this difference was not statistically significant; however, a trend toward a learning effect appeared to be present. In contrast to the suggested correlation between the risk for calcar fractures as described in the manufacturer's instruction for users (IFU) and varus positioning or high femoral neck osteotomy, we could not establish a trend supporting this claim. In our cohort, the incidence of calcar fractures was not linked to the positioning of the stem, or the height of the femoral neck osteotomy. Obviously profound varus positioning and high osteotomy should still be avoided; however, we feel that calcar fractures may still occur irrespective of adequate implant positioning of this particular design and that the IFU as such may be too reassuring. The learning curve and thus the surgeon factor could have played a role in the incidence of calcar fractures in this series; however, to our opinion the implant factor plays a dominant role with this particular stem design.

Calcar fracture is a known complication of THA, and is notably more common in cementless THA [18–20]. Our overall incidence rate of 2.1% is comparable with the available literature. It also compares to the incidence rates reported concerning the CLS stem specifically [6, 12]. Only Min et al. and Hwang et al. reported on calcar fractures in non-selected cohorts with the CLS stem, finding 5 in 106 (4.7%) and 5 in 227 (2.2%) THA, respectively [6, 12]. Kim et al. [13] found 3 calcar fractures in 23 THA in patients with rheumatoid arthritis, resulting in a high occurrence rate of 13.4%.

An intraoperative calcar fracture is associated with a longer operating time and cost, necessitating further exposure and risk of nerve or vascular damage [21]. While

a calcar fracture is a significant complication, literature shows appropriate treatment does not necessarily compromise the long-term results, when considering both survival and clinical results, of total hip arthroplasty [18, 22–24]. However, when not recognized intraoperatively and thus not treated appropriately, a periprosthetic fracture generally warrants reoperation and potentially risks survival of the implant due to the re-do accompanied with an increased infection risk. Therefore, we believe attention should be paid toward the incidence and risk factors predisposing for this complication and that recognition of this phenomenon intraoperatively is of key importance to be able to deal with adequately.

Several potential risk factors have been previously identified for intraoperative femoral fractures in THA, including female sex [8, 18, 19, 22, 25], osteoporosis [14, 21, 22, 26], anterolateral and direct lateral approaches [8, 10, 18], stem design and surgical technique [3, 14, 22, 26]. Regarding stem design, press-fit stems are associated with a higher risk of calcar fracture [3, 14, 22]. This is probably due to the fact that in press-fit designs, the corresponding reamer has a smaller diameter than the implanted stem. As demonstrated by Berend et al. and Jasty et al., this results in higher proximal strain during implantation thus creating more risk of a proximal fracture [3, 27]. We believe this to be an important contributing factor to the incidence of calcar fractures with the CLS stem. On the contrary, an antero-posteriorly flat and medio-laterally wedge tapered design has been reported to have the lowest rate of intraoperative fractures [3].

Despite the incidental occurrence of calcar fractures, we continue to use the CLS stem in our hospital. It has an excellent record of survival and revision rate [4–7]. Intraoperative calcar fractures are a clinically significant risk with this particular femoral stem design and hip surgeons should be aware of this. The surgeon factor seems not to be the main causative factor; as no difference in incidence on calcar fractures between surgeons was seen and no significant correlation between osteotomy level, stem positioning and the onset of calcar fractures was measured. We believe the problem remains mainly implant related. We recommend aiming for a straight position of the CLS stem during introduction and planning for a femoral neck osteotomy of 1 cm above the lesser trochanter, according to the IFU. These recommendations, however, clearly do not prevent the occurrence of calcar fractures. Surgeons should actively check for cortical fissuring in the posterior corner behind the stem, for example by assessing the distance between the femoral osteotomy and the end of the neck-taper after final stem implantation against the trial implant situation, as a missed fracture may easily result in an early postoperative periprosthetic fracture after mobilization.

Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

Ethical approval For this research, IRB statement was not necessary, as it involves retrospective research making use of an existing database. Patient data were processed anonymously.

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