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ORIGINAL ARTICLE • HIP - ARTHROPLASTY

The learning curve following adoption of a novel short-stem prosthesis in total hip arthroplasty: implications on short-term patient outcomes

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Abstract

Background Short-stem (SS) hip prostheses for total hip arthroplasty (THA) have gained popularity as surgeons strive to reproduce physiological stress distributions at the proximal femur. Additionally, as THA indications continue to target younger populations, preservation of femoral bone stock for potential revision surgeries is particularly appealing. However, little is known regarding the short-term complications of each variety of short stem during the learning curve period. The purpose of this study is to evaluate the short-term complications among the THA recipients with the use of a novel SS hip prosthesis.

Methods A retrospective chart review was performed of all patients undergoing primary THA utilizing an Echo Bi-Metric Microplasty hip stem. Patient demographics, surgical factors, complications and quality outcomes were collected utilizing our institution's data warehouse and verified by chart review.

Results In total, 182 SSs were implanted in 168 patients undergoing primary THA. Of these, 5 (2.9%) patients sustained a periprosthetic fracture. Two fractures occurred during the index hospital admission, and 3 occurred in the post-discharge period. Subset analysis demonstrated that 4 (80%) fractures had occurred during the initial learning curve period, within the first 30 surgical cases with a SS.

Conclusion Short-stem hip prostheses are a safe alternative for THA. The results of the present study demonstrate a fracture incidence of 2.9% among patients. However, surgeons should remain cautious when utilizing new implant system and expect a learning curve. In this study, 80% of periprosthetic fractures following SS THA occurred within the first 30 cases for experienced arthroplasty-trained surgeons.

Keywords Short stem · Dual taper · Total hip arthroplasty · Learning curve · Outcomes · Periprosthetic fracture

Introduction

Total hip arthroplasty (THA) is widely recognized as one of the most common and quintessential surgical procedures substantially improving patients' quality of life [1–3]. Accordingly, over the past decades, there has been a significant increase in the number of THAs done worldwide [1, 4–7]. In addition, expanding surgical indications have led to an increasing number of younger individuals undergoing THA. These younger THA candidates are at a higher risk of requiring revision surgery in the future and would benefit from preservation of femoral bone stock [3].

The increased demand along with the desire to further improve THA patient outcomes has resulted in an exploration for alternative implant designs which more physiologically recreate the native hip, while preserving patient outcomes. Short-stemmed prostheses are one of the novel designs which have gained popularity over the last decade. This is also partially due to the increasing prevalence of "minimally invasive" THA, which often requires a smaller stem. The short-stemmed prosthesis has further gained popularity as surgeons strive to achieve a more physiological distribution of the joint forces, reduce the severity of stress

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shielding, and postoperative thigh pain all the while preserving femoral bone [2, 8–15]. However, there is no universal definition for the short-stemmed prosthesis and outcomes for each design are not clearly defined; although the majority of studies have reported excellent short and mid-term outcomes with these smaller profile stems, few have fully investigated the risk in regard to the learning curve associated with the integration of a novel implant [2, 3, 16–20].

The Zimmer-Biomet Echo Bi-Metric Microplasty femoral stem (Zimmer, Warsaw, IN) is a novel implant with a dual taper design allowing for improved fill of proximal canal in comparison with the conventional straight implant design. Furthermore, the dual taper design aims to achieve early metaphyseal fixation by circumferentially engaging the proximal femoral cortex [21]. Despite the numerous benefits that are clearly defined in literature for some short-stemmed prostheses, the technical challenges involved in the learning process of adequate implantation of such design remain unknown. The primary purpose of this study is to investigate the incidence of short-term complications among THA recipients who underwent THA with this novel short-stemmed prosthesis and analyze the effects the learning curve has on outcomes of the aforementioned.

Materials and methods

This study is a retrospective cohort study conducted at an urban, tertiary academic care center. Inclusion criteria for our study included all patients who underwent THA utilizing the Zimmer-Biomet Echo Bi-Metric Microplasty hip stem (Zimmer, Warsaw IN) between June 2016 and April 2018. All surgeons who participated have received fellowship training in adult reconstruction and had greater than 10 years of experience.

Data query

The present study retrospectively analyzed de-identified data for institutional quality improvement initiative and was therefore exempted from human-subjects review by our Institutional Review Board (IRB). These patients were identified by using the Zimmer-Biomet Echo Bi-Metric Microplasty hip stem's product catalog numbers. Product catalog numbers were queried against our electronic data warehouse, Epic Caboodle (Epic, Version 15; Verona, WI), using Microsoft SQL Server Management Studio 2017 (Microsoft, Richmond, WA). Demographics characteristics (patient age, gender, body mass index (BMI), race, marital status, smoking status, insurance type, and American Society of Anesthesiologists (ASA) score) and perioperative variables (anesthesia type, laterality, length of stay (LOS), surgical time and discharge disposition) were obtained directly from our electronic data warehouse. Complications and quality outcomes were also obtained by manual chart review, which included periprosthetic fractures and 30/90-day readmissions.

Statistical analysis

All descriptive statistical analyses were performed using Microsoft Excel 2017 (Microsoft, Redmond, WA). Visualizations were derived using Microsoft Power BI (Microsoft, Redmond, WA). Demographic characteristics and perioperative surgical variables were summarized by standard descriptive summaries (e.g., means and standard deviations [SD] for continuous variables).

Results

Patient demographics

After applying the aforementioned exclusion and inclusion criteria, a total 182 SSs in 168 patients undergoing primary THA were included in this study. The mean age of the patient population was 62.6 years (± 9.8) and consisted of 101 (55.5%) females and 81 (45.5%) males. The average BMI of all the patients was 30.6 (± 0.6). See Table 1 for a detailed description of patient characteristics.

Outcomes

The average length of surgery for THA with short-stemmed prosthesis in this patient population was 106 min (± 17.3) with a maximum time of 183 min and a minimum time of 63 min. The average length of stay was 2 days (± 1.2) with a maximum of 8 days and a minimum of 1 day. See Table 2 for detailed perioperative and quality outcomes. Of these cases, 5 (2.7%) patients sustained a periprosthetic fracture with an average time from index surgery of 14.0 days ± 12.29 (range 3–31) days (Table 3). A total of 2 (40%) fractures occurred during the index hospital admission, and 3 (60%) occurred in the post-discharge period. Subset analysis demonstrated that 4 (80%) of the fractures subsequently occurred within the first 30 surgical cases completed with the SS (Fig. 1).

An additional 8 (4.1%) patients required reoperation: 7 (4.1%) for acute infection and wound complications, and 1 (0.5%) for dislocation. A total of 12 patients were readmitted following discharge; 3 (1.6%) following periprosthetic fracture, 7 (4.1%) patients due to infection, 1 (0.5%) following dislocation of prosthesis, 1(0.5%) postprocedural hematoma. See Table 3 for a detailed list of complications.

Table 1 Demographics

	Short stems ($n=182$)
Age	62.6 ± 9.8
Gender	
Female	101 (55.5%)
Male	81 (44.5%)
BMI	30.6 ± 0.6
ASA	
1	4 (2.2%)
2	104 (57.1%)
3	71 (39.0%)
4	3 (1.6%)
Median	2
Race	
African American	24 (13.2%)
White	147 (80.8%)
Other	11 (6.0%)
Marital status	
Divorced	19 (10.4%)
Married/partner	111 (61.0%)
Single	33 (18.1%)
Widowed	17 (9.3%)
Unknown	2 (1.1%)
Smoking status	
Current	22 (12.1%)
Former	66 (36.3%)
Never	93 (51.1%)
Unknown	1 (0.5%)
Insurance	
Commercial	85 (46.7%)
Medicaid	17 (9.3%)
Medicare	78 (42.9%)
No fault	2 (1.1%)

Table 2 Surgical and inpatient factors

Anesthesia type	
General	25 (13.7%)
Spinal	157 (86.3%)
Laterality	
Left	25 (13.7%)
Right	157 (86.3%)
Length of surgery (min)	106 ± 17.3
Length of stay (days)	2.0 ± 1.2
Discharge disposition	
Home with self-care	6 (3.3%)
Home with health services	156 (85.7%)
Skilled nursing facility	18 (9.9%)
Acute rehabilitation facility	2 (1.1%)

Table 3 Complications and quality outcomes

Periprosthetic fractures	5 (2.7%)
Inpatient	2 (40.0%)
Post-discharge	3 (60.0%)
Survival (days until reoperation)	14 ± 12.3
Occurred within first 30 cases for surgeon	4 (80%)
30 Days readmissions	9 (4.9%)
90 Days readmissions	12 (6.6%)
Readmission breakdown	
Infection with I & D	7 (4.1%)
Periprosthetic fracture	3 (1.6%)
Hip dislocation with reoperation	1 (0.5%)
Hematoma formation	1 (0.5%)

Discussion

Total hip arthroplasty is a successful inpatient surgical procedure used for the treatment of end-stage degenerative hip disease, which in the past decades has seen a significant increase in demand [1, 4]. Short-stemmed prosthesis has recently gained popularity as orthopedic surgeons continue to pursue a more physiological distribution of forces in order to further improve outcomes and patient quality of life while maintaining adequate fixation equivalent to conventional stems. Surgeons have also found them helpful when using MIS approaches. Short-stemmed prosthesis was first designed in the 1970s but were not popularized until the mid-2000 s. Currently, there are several dozen implants available; however, few designs have long-term outcomes. To further complicate matters, there is no universal definition for the short-stemmed prosthesis; however, they are frequently described as neck-sparing, with a length ranging from 45–135 mm [2, 3, 15, 17, 22]. There is a substantial volume of literature which reveals the numerous benefits of using short-stemmed prosthesis for THA, for instance, a significant decrease in the severity of stress shielding and improved femoral bone stock preservation in comparison with conventional stems [2, 8–15]. Several studies have demonstrated good short and mid-term outcomes with the use of the short-stemmed prosthesis [2, 15–19]. However, there is a dearth of literature that has fully investigated the risk of complications during the learning curve period for experienced surgeons who convert to the use of novel short-stemmed prosthesis for THA. Furthermore, the characterizing risks associated with specific stem designs, such as the dual-tapered design of the Zimmer-Biomet Echo Bi-Metric Microplasty hip stem (Zimmer, Warsaw IN) utilized in this studies patient population.

The results of the present study demonstrate an overall incidence of 2.7% of intraoperative periprosthetic fracture

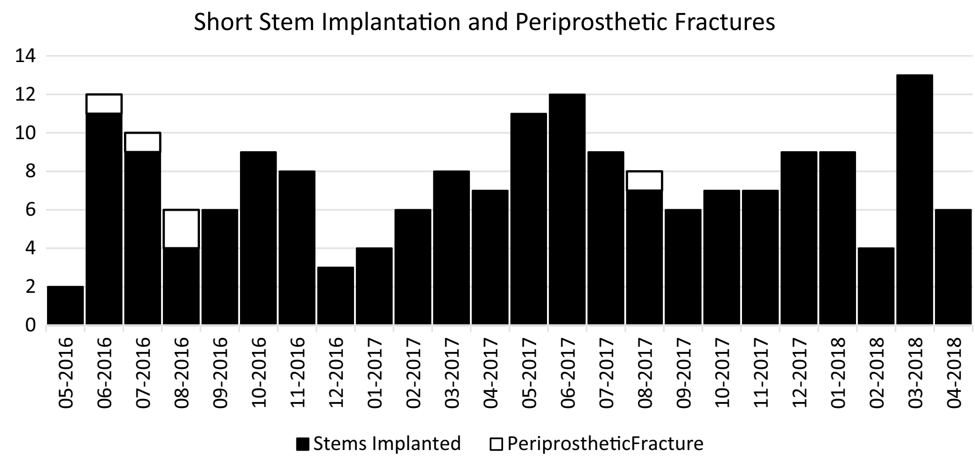

Fig. 1 Short-stem implantation and fracture incidence shown above are the number of short stems implanted (black bars; *y* axis) per month (*x* axis). White bars represent the number of fractures

following THA with the use of this novel short-stemmed prosthesis. However, 4 (80%) fractures had occurred within the first 30 surgical cases using this stem. The high fracture rate during this period is attributed to the experienced surgeon's learning curve. Inconsistencies remain in the current literature in regard to the reported incidence of this burdensome complication [2, 3, 16–20]. Therefore, surgeons, regardless of their level of experience, should remain cautious when utilizing a new implant system due to the higher rate of complications encountered during transitioning (learning curve) to the use of a novel prosthesis.

Rates of periprosthetic fracture with different stem types vary. Stulberg et al. [2] performed a prospective study and reported an increased risk of periprosthetic fracture with longer stemmed prosthesis due to the more invasive nature of the procedure and decreased muscle sparing. However, they also report one incident of intraoperative periprosthetic fracture with the use of a short-stemmed prosthesis and suggested further studies investigate the prevalence of fractures with this implant type. Braun et al. [18] similarly performed a short-term prospective study with 50 patients who underwent THA with short-stemmed prosthesis and reported no intraoperative periprosthetic fractures. However, they failed to report the results of 2 of their patients and reported one (2%) periprosthetic fracture that occurred within 4 weeks following the procedure. The overall periprosthetic fracture rate present by Braun et al is similar to the overall rate presented in the current study. However, it is of great importance to note that the vast majority (80%) of fractures in the present study occurred during the learning curve, in this case, the first 30 cases.

Our findings regarding the incidence of periprosthetic fracture are supported by Arnholdt et al. who performed a retrospective analysis of 41 THA with the use of short-stemmed prosthesis during their learning curve and reported a total of 5 (12.1% incidence) intraoperative periprosthetic fractures. A prospective study published by Khemka [22] investigated the learning curve of a single, high-volume surgeon with the use of a short-stem prosthesis and found an overall periprosthetic fracture rate of 4.3% (6 of 138). The same authors reported 4 (67.7%) of the periprosthetic fractures occurred during the first 25 cases and 5 (83.3%) of the fractures occurred during the first 69 cases. Lim et al performed a prospective randomized study and reported 2 intraoperative periprosthetic fractures with the use of short-stemmed prosthesis within a total of 27 patients [20]. Their study demonstrated a 7.4% incidence of intraoperative periprosthetic fractures. The reported incidence of intraoperative periprosthetic fractures with the use of a short-stemmed prosthesis remains poorly characterized. These discrepancies may possibly be representative of varying techniques utilized by surgeons to surpass the learning curve or due to varying rates with different prosthetic designs. During the learning curve period, surgeons and patients are at increased risk of suffering surgical complications. As surgeons transition from the use of conventional stems to short-stemmed prosthesis, the risk of periprosthetic fractures is likely greater than the overall risk as demonstrated in the current study. Von Lewinski [16] performed a single-centered retrospective study and also reported 5 cases of intraoperative periprosthetic fractures (0.2%) with the use of the short-stemmed prosthesis for THA. They did not, however, describe when the fractures took place in regard to the learning curve. The results presented in the Von Lewinksi study further support the results of the present study by demonstrating a reduced fracture rate by surgeons who have transcended the learning curve and have implanted a countless number of short-stemmed prosthesis.

In the present study, despite the impact of the learning curve, the overall periprosthetic fracture incidence using a dual-tapered short stem was 2.7%, comparable to the 2–5% fracture rate in the general THA population [2, 3, 16, 18, 22, 23]. There are several potential reasons for the periprosthetic fractures seen. The dual-tapered design of the Echo

Bi-Metric Microplasty stem may alter the subjective fit and fill perceived by the surgeon. It was noted by the authors that there is mismatch between the stem and broach sizes, causing the femoral stem to sit proud despite being the same size as the final broach. The clinical significance of the dual-tapered short-stem sitting proud relative to the broach is unknown. However, previous reports have suggested that improper seating of prosthesis components is a risk factor for revision surgery [24]. Additionally, the dual-tapered short-stem geometry improves proximal fixation through a fit and fill design which increases the intraoperative stress across the proximal femur during stem impaction therefore, placing the femur at increased risk for intraoperative fracture. Another difficulty that surgeons must overcome is the loss of distal diaphyseal stabilization, placing short stems at risk for varus malalignment [25–28]. Previous studies have reported substantially increased stress placed upon the proximal femur and an increased risk for future periprosthetic fracture secondary to varus malalignment [25, 27–29]. A study by Lombardi et al. [30] suggested that surgeons should be aggressive with broaching, sizing, and positioning of the stem in valgus. The final position of the stem relative to the final broach requires careful observation and proper insertion technique to avoid fracturing the femur.

The adoption of novel medical devices and techniques by surgeons has been driven by the professional obligation to improve expertise along with the increased demand for medical innovation, improved outcomes, and minimally invasive interventions [31]. The ethical implications associated with the inherent learning curve of these medical advancements, as surgeons acquire proficiency, are increasingly burdensome particularly for the patient at risk of suffering complications. Historically, innovative efforts in the surgical fields have been associated with varying complication rates which are widely apparent and publicly more open to scrutiny [31, 32]. Governing agencies have mandated supervision of surgeons during the unavoidable periods of learning to minimize the rate of complications during this time [32]. While the regulations involving clinical research are stringently governed, those involving the learning curve associated with the adoption of novel implants remain undefined. Overregulation of medical innovation can potentially hinder surgical advancements focused on improving outcomes. However, the ethical risks, burdens and outcomes of the learning curve must be recognized by the physician, steps to minimize the impact of this should be undertaken, and it should be properly discussed with the patient as part of the consenting process [31]. Failure to do so may result in subsequent legal action due to violation of the patient's rights [31].

In addition to being incognizant of the total cost of implants, most surgeons are unaware of the process for approving the use of novel medical devices. In the past, this process was predominantly unregulated. In 1976 congress passed the Medical Device Amendments (MDA), outlining the application procedure for medical devices [33]. Under MDA, most manufactures submit their novel device through 510(k) for approval, a relatively permissive approval pathway. Through the 510(k) pathway, "reasonable assurance of safety" of a novel device is acquired by demonstrating "equivalence" to a previously existing device regardless of the quality of data associated with it or lack thereof [33, 34]. By contrast, the approval process for new drugs requires them to undergo extreme scrutiny and report substantial evidence [34]. The data needed for approval of medical devices would be considered insufficient if passed through the comparable drug application process. The Echo Bi-Metric Microplasty Hip stem design is one of many which have undergone approval through the 510 (k) [33].

When should an experienced arthroplasty surgeon abandon attempts for the adoption of a novel system whose benefits may be speculative, knowing that early patients will likely be exposed to increased complication rates? Reports of previously published investigations, describing the outcomes of similar transitions with "equivalent" prosthesis will likely provide surgeons with some guidance to make patient-centered, evidence-based decisions. However, further definition of these guidelines may prove beneficial. In the context of the results presented in the current study, the overall fracture rate is comparable to previous reports. Therefore, the added clinical benefits provided by the use of novel short stems such as the Echo Bi-Metric Microplasty stem may be considered justifiable despite the initial effect on outcomes due to the learning curve.

Limitations

The authors of the present study acknowledge that several limitations may exist due to the utilization of a single, urban, tertiary orthopedic specialty center. Performance bias is one possible limitation which may result from this single-centered study. However, patient selection varies and all surgeons who participated in the present study have over 10 years of experience in hip arthroplasty. The learning curve is attributed for the increased incidence of intraoperative periprosthetic fracture during the first 30 cases. Furthermore, younger, less-experienced orthopedic surgeons may consequently experience a longer learning curve with an elevated rate of complications resulting in an increased overall fracture incidence than the one presented in this study. The number of cases needed to achieve peak performance with a novel implant likely varies relative to the prosthesis used and surgeon adaptability. Another limitation of the study is the use of a single type of short-stem prosthesis; therefore, future investigations should address the effects of the learning curve with varying stem designs, preferably in a comparative study analysis. Despite our studies limitations, the relatively large size of the present study, with 168 patients who underwent THA with short-stemmed prosthesis, provides orthopedic surgeons valuable insight into the perioperative and postoperative outcomes they may encounter when adopting new techniques and a novel short-stemmed prosthesis.

Recommendations

The results of the present study demonstrate that for experienced surgeons, the majority of periprosthetic fractures (80%) following primary short stem THA using this dual taper design occurred within the first thirty surgical cases, representing the initial learning curve period. Accordingly, surgeons must be aware and should proceed with caution during the initial learning phase following integration of a novel short-stem THA prostheses. Additionally, proper discussions of the associated risk should be discussed with the patient during the consenting process.

Conclusion

Short-stem hip prostheses are a safe alternative for total hip arthroplasty and may provide a more physiological recreation of the native hip, preserve femoral bone stock, decrease the severity of stress shielding and postoperative thigh pain. In the present study, we demonstrate an overall periprosthetic fracture incidence of 2.7% among these patients, with 80% of these fractures following THA using a novel dual taper short-stem design occurring within the first 30 cases. These results represent the learning curve period for the experienced arthroplasty-trained surgeons and may fluctuate among surgeons with varying levels of experience. Surgical outcomes undoubtedly improve with experience and in the current study peak performance regarding periprosthetic fractures achieved after the first 30 cases. Future studies should comparatively analyze the risk of periprosthetic fractures in THA with the use of several short-stemmed prosthesis designs versus the conventional femoral stem prosthesis designs with longer follow-up periods. Additionally, guidelines for learning curves relating to the adoption of novel implants should be investigated and defined.

Authors' contribution R.S., J.S., and M.S. conceived the study design. J.P., A.A., and J.F. investigated the learning curve associated with adopting a novel prosthetic design. J.P., A.A., and J.F. carried out the experiment, performed the analytic calculations and wrote the manuscript under the supervision of R.S., J.S., and M.S. All authors provided critical feedback and helped revise the final manuscript.

Compliance with ethical standards

Conflict of interest Jorge A. Padilla MD, Afshin A. Anoushiravani MD, and James E. Feng MD declare no conflicts of interest. Ran Schwarzkopf MD is a paid consultant for Smith & Nephew and Intellijoint; owns stocks in Intellijoint and Gauss Surgical; is a board members/committee for AAOS and AAHKS. James Slover MD has received research support from Biomet and is a board member/committee of AAHKS. Scott Marwin MD is a paid consultant for Zimmer and Integer Consulting.

Ethical approval All procedures performed were in accordance with ethical standards. This study analyzed de-identified data and thus was exempted from human-subjects review by our Institutional Review Board (IRB).

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