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ORIGINAL PAPER

Outcomes of distal femur fractures treated with the Synthes 4.5 mm VA-LCP Curved Condylar Plate

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Abstract

Purpose Given the recent controversy in the literature and the alarming reports of early mechanical failure associated with the use of the Synthes 4.5 mm VA-LCP Curved Condylar Plate in acute distal femur fractures, the goal of our study was to examine the outcomes and mechanical failure rates of this implant in a larger patient population.

Methods Patients 18 years of age and older who underwent plate fixation of their acute distal femoral fracture using the Synthes 4.5 mm VA-LCP Curved Condylar Plate were included in this retrospective study. The study data was collected through a retrospective chart review and review of the existing radiographic studies. Primary outcome measure was mechanical hardware failure while secondary outcome measures included nonunion, malunion, and medical and surgical complications.

Results A total of 74 patients (77 fractures) were included in this study. The fractures were classified according to the OTA/AO classification as 33-A2 ($n = 6$), 33-A3 ($n = 19$), 33-C1 ($n = 5$), 33-C2 ($n = 25$), and 33-C3 ($n = 22$). Thirty-two out of 77 fractures presented as open fractures (41.6%). A mechanical failure was observed in 7 patients (9.1%). Twenty additional patients needed a re-operation of the surgical site including two nonunion repairs, one malunion repair, 15 staged treatments of traumatic segmental bone defects, and two soft tissue debridements.

Conclusions In our experience, the Synthes 4.5 mm VA-LCP Curved Condylar Plate is a safe and effective implant with a relatively low mechanical failure rate.

Keywords Distal femur · Fracture · Locked plate · Complication

Introduction

Historically, the treatment of distal femur fractures has been challenging, and high rates of varus collapse have been reported with the use of lateral condylar buttress plates [1]. Recently, lateral-based locked plates have become a standard treatment for patients with distal femur fractures. These allow for the insertion of multiple distal fixation points and provide a fixed-angle construct with the potential to resist varus collapse [2]. Several studies demonstrated promising outcomes with low mechanical failure rates [3–9]. However, recent studies have also reported less favourable results [10–14]. Risk factors suggested to be associated with fixation failure include diabetes, smoking, increased body mass index, open fracture, loss of posterior cortical contact, shorter plates, screw density, construct rigidity, and the use of stainless steel plates [11–13, 15, 16].

Recent advances have resulted in the development of variable angle locked plates. While traditional locked plating systems only permit screw insertion in one specific trajectory, variable angle locked plates allow for insertion of locked screws in variable angles. Biomechanical and clinical studies have reported favourable results with available variable angle locked distal femur plates [3, 17–21]. However, a recent study by Tank et al. [22] suggested high early mechanical failure rates associated with the use of the Synthes 4.5 mm VA-LCP Curved Condylar Plate (DePuy Synthes, West Chester, PA) reporting a mechanical failure rate of 22.2%, which was significantly higher than in other locked plating systems used in their series.

Given the alarming reports of catastrophic early mechanical failure associated with the use of the Synthes 4.5 mm VA-LCP Curved Condylar Plate, the goal of our study was to examine the outcomes and mechanical failure rates of this

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implant in a larger patient population. We hypothesize that the early failure rates and surgical outcomes associated with this plating system compare favourably with the results of other plate fixation systems.

Materials and methods

This retrospective study was performed at an urban university-based level 1 trauma centre and an urban level 3 trauma centre. The study data was collected through a retrospective chart review and review of the existing radiographs. Patients were identified through the coding database of our institution. Approval of the study protocol was obtained from the Institutional Review Board (IRB) of our institution (Protocol# HSC20160687H).

Patients 18 years of age and older who underwent plate fixation of their acute distal femoral fracture using the Synthes 4.5 mm VA-LCP Curved Condylar Plate between May 2012 and April 2016 were included in this investigation. Fractures were classified using the OTA/AO fracture classification [23]. Distal femur fractures treated with dual plating or other plating systems were excluded from this study. Patients with pathologic fractures from neoplastic disease were also excluded from this study.

The surgical technique was according to widely established recommendations as described in the literature [3–9]. Patients were made non-weight bearing of the injured lower extremity for six to 12 weeks as per discretion of the treating surgeon. Patients were considered as incomplete follow-up if clinical and radiographic outcome data was not available for a minimum of 12 weeks after surgery. A minimum follow-up of 12 weeks was chosen for inclusion in the analysis since previous reports emphasized high failure rates within this time period [22].

The primary outcome measure was a mechanical hardware failure. Mechanical hardware failure was defined as any failure of the implant including breakage of the plate, bending of the plate, screw breakage, and screw disengagement from the plate. Secondary outcome measures included (1) need for re-operation, such as nonunion repair, malunion repair, staged treatment of traumatic segmental bone defect, and soft tissue debridements and (2) post-operative medical complications, such as thromboembolic events, pneumonia, urinary infection, and myocardial infarction. Nonunion was defined as the lack of a bridging callus of at least three out of four cortices at six months after surgery in the absence of visible progressive healing on consecutive radiographs.

Statistical analysis

All statistical analysis was performed using Stata 14 (StataCorp, College Station, TX). Given the relatively small number of events encountered for our main outcome measure (mechanical implant failure), no statistical comparisons between the mechanical failure group and the non-mechanical failure group were performed. All continuous variables were tested for normal distribution. Normally distributed data was reported as means with standard deviation (SD). Not normally distributed data was reported as median with range. The clinical and demographic data was compared between patients lost to follow-up and patients who completed the minimum follow-up. The *t* test was used for continuous variables, and the Fisher's exact test was used for non-continuous variables.

Results

Based on the Current Procedural Terminology (CPT) codes 27511, 27513, and 27514, a total of 170 patients were screened for participation in this study. Seventy-nine patients, who were screened based on their CPT code, did not meet the inclusion criteria. This included the following reasons: treatment with a different implant or fixation construct or implant ($n = 75$), less than 18 years of age at the time of injury ($n = 3$), and duplicate subject ($n = 1$). Thus, a total of 91 patients were enrolled in this study.

Seventeen out of 91 patients (18.7%) did not complete the minimum 12-week follow-up appointment. Among the 17 patients lost to follow-up, we recorded eight female and nine male patients with an average age of 56.8 years (SD = 22.0). Six of them had open fractures, and 11 fractures were closed. These clinical and demographic data were not significantly different from patients who completed the minimum follow-up ($p = 0.05$). None of these 17 patients with incomplete follow-up data was found to have any signs of mechanical hardware failure at their latest follow-up appointment. The outcome data reported herein are based on 74 patients (77 distal femur fractures), for who complete follow-up data was available (Table 1).

The initial surgeries were performed between May 2012 and April 2016. The median plate length was a 10-hole plate (range 6 to 18). The median proximal plate length was six screw holes (range 4–18). The median number of proximal screws was five (range 3–8). The median number of proximal cortices engaged by a screw was nine (range 6–12). The median number of distal screws engaged into the plate was five (range 4–6). The median working length of the plate was 87.2 mm (range 18.5 to 182.7 mm). In five closed fractures, the treating surgeon chose to augment the fixation with allograft bone during the index surgery. The median estimated blood loss was 200 mL (range 50–900 mL). The median follow-up time was 52 weeks (range 12 to 222 weeks).

With regard to the primary outcome measure, mechanical hardware failure, we encountered a total of seven mechanical implant failures (study IDs 11, 15, 18, 29, 47, 52, 54) among

Table 1 Patients' demographics and clinical data

Age [years]	Mean 55.2 (SD 18.6)
Gender	
Female	47 (63.5%)
Male	27 (36.5%)
Diabetes mellitus	
No	49 (66.2%)
Yes	25 (33.8%)
BMI [kg/m^2]	29.2 (range 17.0 to 66.6)
Obesity	
Non-obese (BMI < 30.0 kg/m^2)	40 (54.1%)
Obese (BMI > 30.0 kg/m^2)	34 (45.9%)
Tobacco	
No	48 (64.9%)
Yes	26 (35.1%)
Injury mechanism	
Motor vehicle collision	23 (31.1%)
Motorcycle collision	6 (8.1%)
Fall from height	7 (9.5%)
Ground level fall	30 (40.5%)
Gunshot injury	3 (4.1%)
Motor vehicle versus pedestrian collision	4 (5.4%)
Airplane crash	1 (1.4%)
Type of fracture	
Closed	45 (58.4%)
Open	32 (41.6%)
Periprosthetic	
No	65 (84.4%)
Yes	12 (15.6%)
OTA/AO fracture classification	
33-A2	6 (7.8%)
33-A3	19 (24.7%)
33-C1	5 (6.5%)
33-C2	25 (32.5)
33-C3	22 (28.6%)

BMI body mass index, *SD* standard deviation

77 implanted distal femur plates (9.1%). The details of these seven mechanical hardware failures are described below.

Three patients (study IDs 11, 18, 54) presented with a nonunion and broken plate at the fracture site. These three plate failures were detected during follow-up visits at six months, 6.5 months, and seven months, respectively. In all three plate failures, the break within the plate went through two adjacent locked holes at the fracture site (Fig. 1). These three patients underwent surgical repair with revision plate fixation and bone grafting and subsequently went on to successful fracture healing. In another patient initially treated for a periprosthetic distal femur fracture above a total knee arthroplasty (study ID 29), the mechanical failure included disengagement of the locking screws from the plate within the distal fracture segment. This was noticed at the four month follow-up visit. The patient was referred for a distal femoral replacement. In another patient initially treated for a periprosthetic fracture above a total knee arthroplasty (study ID 15), it was noticed at the 12-month follow-up appointment that the shafts of the screws were broken within the proximal fracture segment (Fig. 2). Since the fracture was appropriately healed, no further surgical intervention was performed in this patient.

Two mechanical hardware failures occurred as the result of a second high-energy injury (study IDs 47, 52). The first patient (study ID 47) was initially treated for his open distal femur fracture with irrigation and debridement of the open fracture, placement of an antibiotic spacer into the bone defect, and bridging plate fixation. He was then involved in a documented dirt bike accident at 25 days following the index procedure. He was re-admitted to our trauma centre, and upon evaluation, a deformity of his lower extremity was apparent. The radiographs showed that the distal femur plate was bent at the fracture site (Fig. 3). Subsequently, this patient underwent revision fixation and conversion to an intramedullary nail fixation construct. The second patient (study ID 52) initially presented with a closed distal femur fracture as the result of a high-speed motor vehicle collision. He underwent plate fixation of his distal femur fracture in a standard fashion. He was instructed to stay non-weight bearing to the injured lower extremity but became involved in an altercation. Following the altercation, he noticed pain and deformity and presented to our trauma clinic at 26 days following the index surgical procedure. The radiographs showed significant plate bending at the fracture site (Fig. 4), which was treated with revision plate fixation.

Besides the 7 patients with mechanical hardware failures, a total of 20 patients needed a re-operation of the surgical site. These included two patients with aseptic nonunions requiring bone grafting. Thus, including the four patients with nonunions reported among the mechanical failures, a total of six nonunions were encountered in our entire series (7.8%). One patient presented with a 7° valgus malunion due to inadequate fracture reduction requiring a distal femur osteotomy. Two patients with soft tissue complications (one seroma, one wound dehiscence) required appropriate soft tissue debridements. A total of 15 patients with open fractures required additional surgical procedures for planned staged management of their traumatic segmental bone defects (median bone defect size 81.5 mm, range 28.3 to 143.5 mm). None of these 20 patients requiring re-operations demonstrated any signs of mechanical hardware failure throughout their treatment course.

Medical complications included three deep vein thrombosis, three pulmonary emboli, three urinary tract infections, two cases of pneumonia, two myocardial infarctions, five acute renal insufficiencies, one stroke, and one upper gastrointestinal bleed. All of these were treated very successfully by appropriate medical management. One 87-year-old female patient, who had been discharged after an uneventful postoperative course, was re-admitted to the hospital at 14 weeks after

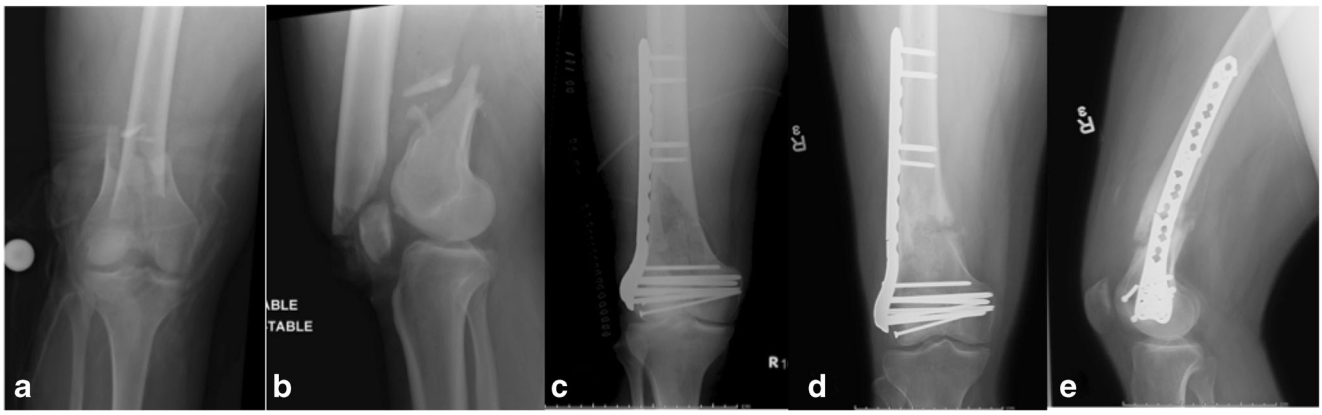

Fig. 1 **a**, **b** Twenty-four-year-old male presented after motorcycle collision with right open distal femur fracture. **c** Underwent immediate irrigation and debridement, open reduction and internal plate fixation followed by staged bone grafting. **d**, **e** At 7 months after the index procedure, he presented with plate breakage at the fracture site and loss of reduction

surgery with congestive heart failure and deceased during her readmission.

Discussion

Locked plating technology has been established as a standard treatment for distal femur fractures as it allows for a fixed angle construct. A recent report suggested a catastrophic early mechanical failure rate of 22.2% associated with the use of the Synthes 4.5 mm VA-LCP Curved Condylar Plate [22]. In contrast to these reports, early mechanical failures (within the first 3 months after surgery) were not recorded in our series, except for two patients, who had a well-documented second high-energy injury within four weeks following the index surgery. The results of our retrospective study confirmed our hypothesis that patients treated with the Synthes 4.5 mm VA-LCP Curved Condylar Plate experienced outcomes and mechanical failure rates that compare favourably with other plating systems.

Biomechanical and clinical data have suggested favourable results associated with the use of locked plating technology in the treatment of distal femur fractures [3, 17–21]. In a series including 103 distal femur fractures, Kregor et al. [5] recorded that 93% of the fractures treated with a lateral locked plate healed without any loss of distal fixation, mechanical failure, or varus collapse. Haidukewych et al. [3] reported a nonunion rate of 4% among 25 patients with distal femur fractures treated with a variable angle locked plating system. These authors attributed their low mechanical complication rate to the availability of variable angle screw placements. Similarly, Erhardt et al. [17] reported a high union of 92% in a series of 25 patients with 26 distal femur fractures. Other studies reported less favourable outcomes. Henderson et al. [10] investigated 86 distal femur fractures treated with lateral based locked distal femur plates. These authors observed a 40% complication rate and 20% of fractures failed to unite. Pascarella et al. [24] reported a 24.7% nonunion rate in 77 patients treated with a variable angle locked plating system. Using the Synthes 4.5 mm VA-LCP Curved Condylar Plate, Tank et al. [22] reported a high early mechanical failure rate of 22.2% in their

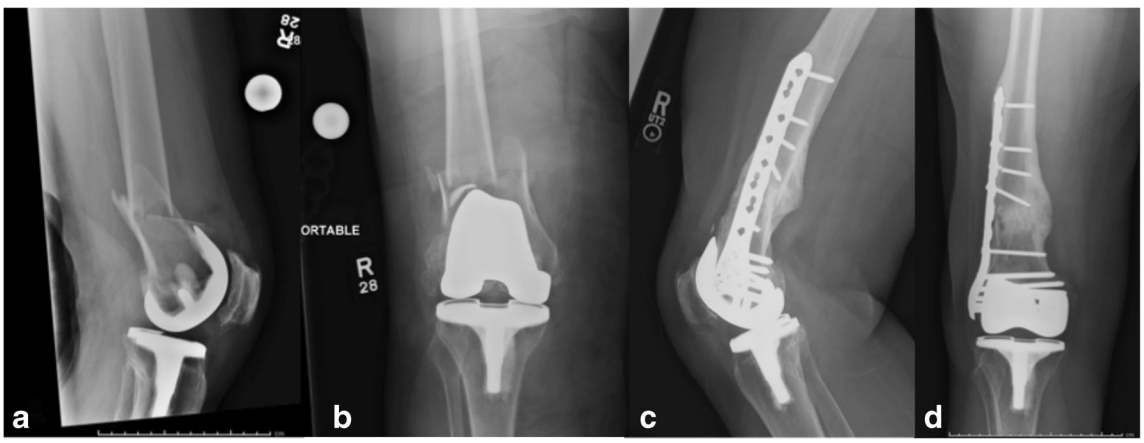

Fig. 2 **a**, **b** Sixty-eight-year-old female with periprosthetic fracture. **c**, **d** Twelve-month follow-up radiographs show broken screws with the fracture appropriately consolidated in acceptable alignment

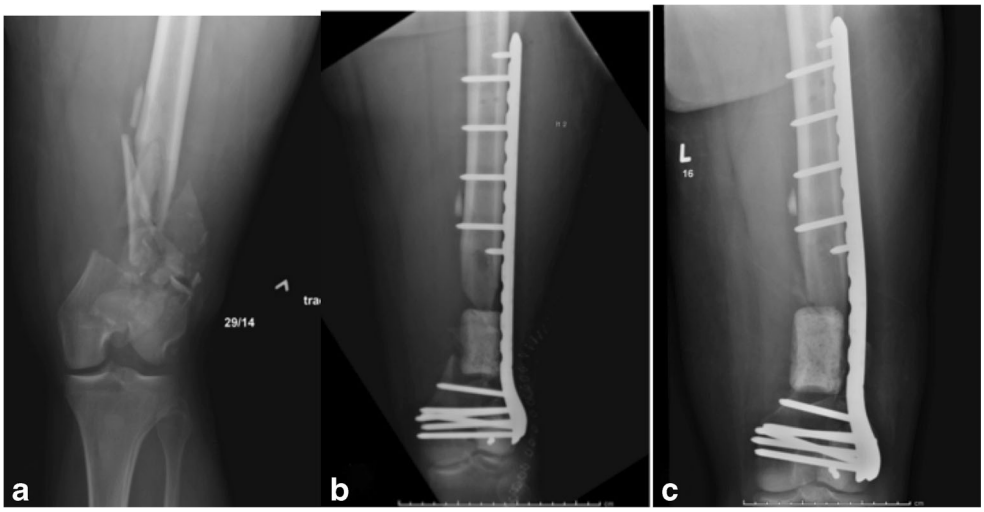

Fig. 3 **a** Thirty-nine-year-old male presented with a left open distal femur fracture. **b**, **c** At 25 days after the index procedure, he presented with plate bending after a dirt bike accident

population of 36 patients. The specific modes of failure included three broken plates at the level of the fracture site, and five cases with distal screw disengagement. These authors further reported that the Synthes 4.5 mm VA-LCP Curved Condylar Plate had significantly higher failure rates than other plating systems and cautioned surgeons against the use of this plating system. To our best knowledge, no other reports in the literature have recorded similar problems with this particular plating system.

The results of this study must be interpreted in the context of the patient demographics. The patients included in this study reflect the challenges that are encountered at urban trauma centres including relatively high rates of patients with diabetes (33.8%), obesity (45.9%), and tobacco use (35.1%). Moreover, 41.6% of the injuries presented as open fractures as an indicator of high-energy injuries. In these patients, appropriate staged bone grafting may provide an additional protection against plate failure. We suggest that the results recorded in our study, with a mechanical failure rate of 9.1% and a nonunion rate of 7.8%, compare favourably with the results of other locked distal femur plating systems. We did not encounter the relatively high early mechanical failure rates as reported by Tank et al. [22]. The only early failures included the two patients with a documented second high-energy injury (altercation and dirt bike accident), who presented within four weeks following the index surgery. Similar to the report by Tank et al. [22], we observed that the primary mode of failure associated with this plating system is a break at the fracture site through two adjacent locked holes. However, we did not observe this mode of failure until a minimum of six months after the index surgery.

Limitations of our study include the retrospective design. In addition, we did not have a comparison group treated with a different plating system, and we can only compare our results with historical data from the literature. We encountered a loss of follow-up of 18.7%, and we acknowledge that this may have potentially biased the study results. Moreover, we would like to emphasize that our minimum follow-up only allows for

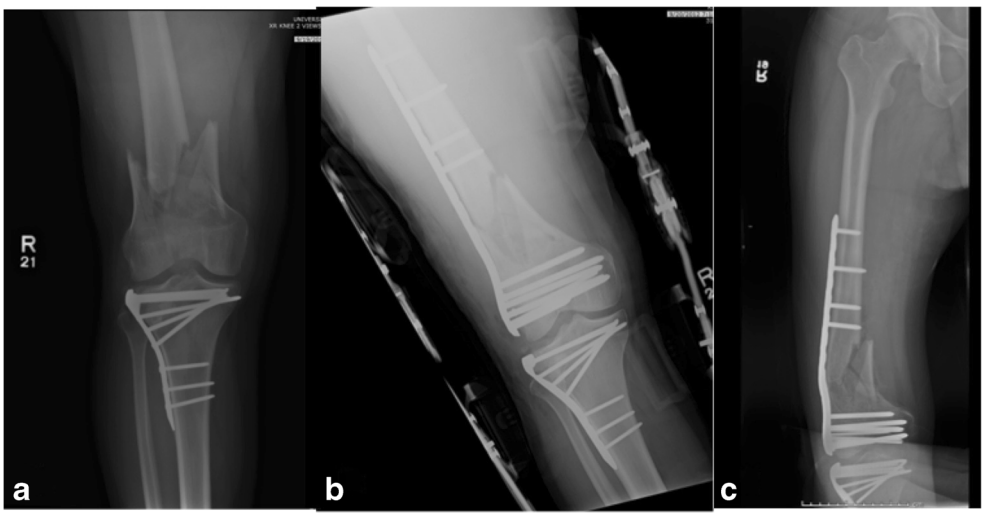

Fig. 4 **a** Thirty-year-old male previously treated for tibial plateau fracture, who presented after motor vehicle collision with a right distal femur fracture. **b** Underwent open reduction and internal plate fixation. **c** Presented at 26 days after surgery with the plate bent at the fracture site after he had been involved in an altercation

conclusions on early mechanical failure rates associated with this implant. Our study does not allow for conclusions on long-term outcomes.

In conclusion, the Synthes 4.5 mm VA-LCP Curved Condylar Plate demonstrated a relatively low early mechanical failure rate of 9.1% which compares favourably to the results recorded for other locked plating systems. This implant can be suggested as a safe and effective fixation device. Our study did not confirm the catastrophic early failure rate that has been suggested in recent reports.

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