The outcome of Polyax Locked Plating System for fixation distal femoral non-implant related and periprosthetic fractures

Kalliopi Lampropoulou-Adamidou a, Theodoros H. Tosounidis a,b, Nikolaos K. Kanakaris a, Axel Ekkernkamp c, Michael Wich c,d, Peter V. Giannoudis a,b,*

a Academic Department of Trauma & Orthopaedic Surgery, University of Leeds, Clarendon Wing, Floor A, Great George Street, Leeds General Infirmary, LS1 3EX Leeds, UK
b NIHR Leeds Biomedical Research Unit, Chapel Allerton Hospital, West Yorkshire, LS7 4SA Leeds, UK
c Department of Trauma and Orthopedic Surgery, Unfallkrankenhaus Berlin, Warnere Str. 7, 12683 Berlin, Germany
d Klinikum Dahme-Spreewald, Koepenicker Str. 29, 15711 Koenis Wusterhausen, Germany

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ABSTRACT

The objective of this study was to report on the safety, efficacy and clinical outcomes of the Polyax™ Locked Plating System (Biomet, Warsaw, IN, USA) in the management of acute (non-implant related and periprosthetic) distal femoral fractures. We retrospectively reviewed 71 patients with 73 distal femoral fractures. Thirty-three of the included fractures occurred around previously placed implants. The average patients’ age was 67 years (range 18–98). There were 7 early postoperative complications (9.5%) including one deep surgical site infection, 2 pulmonary embolisms and 4 urinary or respiratory infections. At final follow-up (mean 12, range 9–55 months) all fractures progressed to clinical and radiological union. However, major revision surgery for healing problems was required in 5 cases (6.8%) and minor in 3 cases (4.1%). The average time to healing was 6 (range 3–23) months. Angulation less than 5 degrees in any plane was observed in 66 cases (89.7%), within 5–10 degrees in 5 cases (7.3%) and within 10–15 degrees in 2 cases (2.9%). The mean pre-injury and final follow-up values of Glasgow Outcome Scale were 1.5 (1–3) and 1.7 (1–3) respectively. Overall 61 patients (83.53%) retained their pre-injury activity status. The Polyax™ Locked Plating System offers a safe and efficient fixation in distal femoral fractures.

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Introduction

Distal femoral fractures often occur in injured or elderly patients and their surgical management is challenging due compromised bone stock from coexistent osteoporosis and/or the presence of a pre-existing femoral implant (total hip and/or knee replacement femoral components or femoral intramedullary nail/osteosynthesis implants) [1]. Internal fixation techniques used in the past were associated with complications and poor results [2]. Traditional methods of fixation such as condylar buttress plates, condylar blade-plates, dynamic condylar screws are currently disfavoured due to their invasive nature, high complication and failure rate [3,4]. Surgical management over the last years has evolved and the modern understanding for the need of a combination for less invasive/biologically friendly and reliable fixation coupled with recent advances in locked plating technology has prevailed. In the contemporary orthopaedic era intramedullary nails and locking plating systems such as the LISS and polyaxial locking plates have largely replaced the above-mentioned old devices [2,5].

Variable axis screws were initially used in spine fixation [6] but more recently this technology has been transferred to locked plates. Polyaxial plates allowing 30 degree of freedom for screw insertion in a variable plane mode have been recently introduced for the fixation of the distal femoral fractures in order to overcome inherent difficulties in their surgical management [5,7]. To-date, paucity of high quality evidence surrounds their use, clinical and radiological outcomes [7–12]. The aim of this study is to report on the safety, efficacy and clinical outcome of Polyax™ Locked Plating System (Biomet, Warsaw, IN, USA) in the management of acute (non-implant related and periprosthetic) fractures of the distal femur.
Patients and methods

We retrospectively reviewed all the patients admitted with a distal femoral fracture in our institution from January 2009 to December 2013. Patients eligible to participate were identified from a prospectively documented hospital database. All adult patients with distal femoral fractures surgically treated with the Polyax Plating System were included in this study. Patients with fractures treated with different fixation modalities, pathological fractures and inadequate follow-up (i.e. less than 9 months) were excluded. Institutional board approval was obtained for the study (IB Number: 1657).

Standard demographics (sex, age, comorbidities), mechanism of injury, concomitant injuries, time to surgery, length of hospital stay and complications (local and systemic) were recorded. Fracture related data i.e. type of injury, the presence of an implant proximally and/or distally, time to union, malunion were also documented. Non-implant related fractures were classified according to AO/OTA [13]. Periprosthetic fractures around total knee (TKR) and hip replacement (THR) were classified according to Rorabeck [14] and Vancouver [15] classification systems respectively.

Surgery was performed under general anaesthesia on a standard radiolucent table. Tourniquet was not used in any of the cases. A Transarticular Retrograde Plate (lateral parapatellar approach) was utilized for complete intra-articular fractures (AO/OTA type C). A lateral/anteralateral approach to the distal femur was used for extra-articular or partial articular (AO/OTA type A and B). No bone grafting was used in the index operation. Open fractures were treated by emergency debridement, tetanus prophylaxis, intravenous antibiotics, and with or without temporary external fixation. Postoperatively, thromboprophylaxis was given for 6–8 weeks or until the patients were fully mobile. Mobilization exercising toe-touch weight bearing along with range of movement and quadriceps strengthening exercises was instructed to all patients from the first postoperative day. Gradual progression to full weight bearing based on clinical and radiological signs of healing was instituted from the sixth postoperative week for extra-articular fractures. Full weight bearing was initiated from the twelfth postoperative week for intra-articular fractures.

All patients attended the outpatient clinics for follow-up appointments at 6, 12, 24 and 36 postoperative weeks for clinical and radiological review. Patients demonstrating signs of delayed union of the fracture had a longer follow-up, up to fracture union.

Union was considered as the presence of combination of fracture consolidation in at least 3 cortices and painless weight bearing. Malunion was defined as the radiographic angulation of more than 10 degrees in any plane. The clinical outcome was assessed using the pre-injury and final follow-up values of Glasgow Outcome Scale (GOS) as described and used in relevant previous studies in this field [8,9]. The GOS was graded as: (1) in patients with normal daily activity, (2) in patients with moderate disability with independency, (3) in patients with severe disability needing assistance in daily life, and (4) in patient with persistent vegetative state. The minimum follow-up in this cohort of patients was 9 months.

Results

Seventy-one patients with 73 fractures from the initially 88 identified patients were included in this cohort. From the 17 excluded patients, ten died before the completion of the required follow-up (11%), 6 could not complete their follow-up and one patient had an above-the-knee amputation due to severe vascular injury from the initial injury shortly after the osteosynthesis of the distal femur and vascular reconstruction. The average patients’ age was 67 years (range 18–98) and the average number of co-morbidities was 3 (range 0–9). The mechanism of injury was reported to be low energy in 58 cases and high energy in 13. Nine patients were classified as polytrauma having an ISS > 16. Five fractures were open. Thirty-three fractures were periprosthetic/peri-implant and 40 were non-implant related. In 2 cases the Polyax plate was used as a salvage osteosynthesis solution at intraoperative fractures during intramedullary nailing procedures (intraoperative fractures at the tip of intramedullary nail). The average time to surgery was 4 days (range 1–20). Surgery delay more than two days from the admission to the hospital was due to compromised local soft-tissues and/or suboptimal patient’s general health that required optimization prior to surgery. Preoperative details are summarized in Table 1.

The transarticular and retrograde plate osteosynthesis (TARPO) was used in 60 cases and lateral/anteralateral approach and retrograde plate osteosynthesis in 13 cases. There were 7 early postoperative complications (9.5%) including one deep surgical site infection, 2 pulmonary embolisms and 4 urinary or respiratory infections. The acute deep surgical site infection was successfully treated with multiple surgical debridements, retention of implant and intravenous antibiotics followed by oral intake. All early postoperative complications were resolved before the patients’ discharge from the hospital. The mean length of hospital stay was 25 days (2–88).

Overall, at final follow-up all cases progressed to clinical and radiological union.

The average time to healing was 6 (range 3–23) months. However, major revision surgery to achieve osseous healing was required in 5 cases (6.8%). The Polyax Plate was revised to a retrograde intra-medullary nail and to a blade plate in four and one

<table>
<thead>
<tr>
<th>Table 1</th>
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<tbody>
<tr>
<td>Preoperative details of patients included in the study.</td>
</tr>
<tr>
<td>Number of patients (fractures)</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Mean age (range)</td>
</tr>
<tr>
<td>Mean number of comorbidities (range)</td>
</tr>
<tr>
<td>Mechanism of injury</td>
</tr>
<tr>
<td>Open/closed fractures</td>
</tr>
<tr>
<td>Fracture type</td>
</tr>
<tr>
<td>8 periprosthetic THR</td>
</tr>
<tr>
<td>12 periprosthetic TKR</td>
</tr>
<tr>
<td>9 Rorabeck type II</td>
</tr>
<tr>
<td>6 inter-prosthetic</td>
</tr>
<tr>
<td>4 Rorabeck type II/Vancouver type C</td>
</tr>
<tr>
<td>7 peri-implant</td>
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<tr>
<td>Mean time to surgery (range)</td>
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</table>
cases respectively. In two (2.7%) of these cases early implant failure occurred at 1 and 5 months postoperatively. In the remaining three (4.1%) cases revision osteosynthesis was required due to observed nonunion at 13, 15 and 16 months after the index osteosynthesis. Minor intervention was required in another three (4.1%) cases of atrophic nonunion that were managed with single percutaneous injection of bone marrow aspiration (concentrated osteoprogenitor cells) and application of BMP-7 at 4, 7 and 30 months. In total, 8 cases (11%) of revisions were observed i.e., early implant failure requiring repeat osteosynthesis, nonunions requiring secondary grafting and nonunions requiring implant revision. In 6 of these cases, the osteosynthesis was considered to be inadequate (4 too flexible, one too stiff and one related to varus malreduction).

Removal of symptomatic prominent screws was performed in 3 cases (4.1%). There were no cases of varus collapse or screw loosening in the distal femoral fragment. From the 68 fractures that reached uneventfully to healing, angulation less than 5 degrees in any plane was observed in 61 cases (89.7%), within 5–10 degrees in 5 cases (7.3%) and within 10–15 degrees in 2 cases (2.9%).

In patients with united fractures, the mean pre-injury and final follow-up values of Glasgow Outcome Scale were 1.5 (1–3) and 1.7 (1–3) respectively, with 61 cases (83.53%) retaining their pre-injury activity status.

Discussion

Distal femoral fractures usually occur in polytrauma or elderly patients. These fractures may also occur in the setting of a pre-existing total knee/total hip replacement and/or previous osteosynthesis (i.e. intramedullary nail) [1,16,17]. Despite the recent advances in surgical techniques and new implants used to treat these fractures, the complications and especially the non-union rates are documented to be high [1,18]. Inadequate fixation leads to prolonged immobilization and subsequent recumbency related complications. Stable internal fixation, restoration of limb alignment, preservation of blood supply and early safe mobilization are of paramount importance for a good clinical outcome [19].

Various treatment modalities including external fixators, plating systems and intramedullary nails have been used for the surgical management of distal femoral fractures. External fixators are mainly useful for temporary fracture stabilization in polytrauma patients and open fractures. Their limited use for definitive treatment of distal femoral fractures is based on the difficulty to maintain anatomic reduction, and the increased risk of infection and knee stiffness [20].

Conventional plates such as condylar buttress plates, condylar blade-plates, dynamic condylar screws [3,4] have been extensively used in the past but are currently disfavoured mainly due to their poor biomechanical properties and the fact that their application requires a full open approach to the distal femur. Biomechanically, conventional plating is based on frictional forces between the bone and plate and requires absolute anatomical reduction. Safe fixation of osteoporotic bone in elderly patients might not be optimal to using conventional osteosynthesis techniques [21]. Furthermore, specific disadvantages of these devices, such as the poor varus stability of buttress plates, the technical difficulties encountered during the application of blade plates and the substantial amount of bone required for the insertion of a dynamic condylar screw, pose additional challenges. In addition to the specific biomechanical disadvantages, conventional technique requires extended soft tissue dissection along with compressive epi-periosteal application that disturbs the bone blood supply and adds a significant biological insult to the already poor bone quality of metaphyseal and comminuted fractures [22,23]. Furthermore in the case of periprosthetic fractures around a TKR that extend distal to the anterior flange of the femoral component the application of the aforementioned devises has specific difficulties due to lack of sufficient bone stock and the fixed-angle nature of these implants.

Locking plating systems such as LISS and polyaxial locking plates [2,5] were introduced to solve many of the above-described problems. Strong evidence is currently available supporting their biomechanical advantages over traditional constructs [23–26]. Along with intramedullary nailing, locked plating systems constitute the contemporary gold standard of fixation of distal femoral fractures. Screws that are locked in the plate minimize the

Fig. 1. Anteroposterior (a) and lateral (b) preoperative radiographs of 58-year-old male patient with a high energy AO/OTA 33-C2 fracture. Anteroposterior (c) and lateral (d) radiographs nine months postoperatively. The patient was fully mobile and returned to all of his pre-injury activities.
compressive forces exerted between plate and bone interface [23,27]. Locking plates are less disturbing to the periosteal blood supply since compression to the bone is not needed. They are ideal for application of bridging techniques in comminuted fractures and implementation of the minimally invasive and indirect fracture reduction and fixation principles [28].

The latest development in locking plating is the polyaxial locking technology. Polyaxial plates allow multiple angle stable screw fixation and enable the fixation of fracture patterns, which would be either very difficult or even impossible to treat with standard types of devices (Figs. 1–3). The advantages of their application becomes even more evident in periprosthetic fractures around the knee when the locking screws need to be placed around the central peg/stem of the femoral component and at the same time provide a reliable and stable fixation. Comparison of stability between polyaxial and conventional locking plating showed that polyaxial plates have greater axial and torsional stiffness and present less irreversible deformation and higher ultimate load to failure [29]. Despite the fact that biomechanical efficiency of polyaxial plates is undisputed, there is relative paucity of high quality evidence supporting their clinical superiority [30–33].

The use of intramedullary nails in some types of distal femoral fractures may have advantages over plate fixation devices. Biomechanically, fixation with nails provides greater axial stiffness and plastic deformation but lower torsional stiffness than plate osteosynthesis [34,35]. Additionally, nails have biologic advantage
<table>
<thead>
<tr>
<th>Authors, year of cases</th>
<th>Implant</th>
<th>Mean age of patients (years)</th>
<th>Mechanism of injury</th>
<th>Fracture type</th>
<th>Mean follow-up (months)</th>
<th>Early postoperative complications unrelated to the surgical site</th>
<th>Complications treated conservatively related to the operation</th>
<th>Minor revision rate</th>
<th>Major revision rate</th>
<th>Union rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruchholtz et al., 2013</td>
<td>NCB DF, Zimmer</td>
<td>79.8 ± 11</td>
<td>33 low energy, 6 no adequate mechanism reported, 2 postoperative fractures</td>
<td>17 periprosthetic THR, 10 periprosthetic TKR, 3 interprosthetic, 11 peri-implant</td>
<td>N/A/results at 12 months</td>
<td>24 patients (59%)</td>
<td>3 (7%)</td>
<td>2 (5%)</td>
<td>3 (7%)</td>
<td>93%</td>
</tr>
<tr>
<td>El-Zayat et al., 2012</td>
<td>NCB DF, Zimmer</td>
<td>76.1 (39–99)</td>
<td>64 low energy, 8 high energy</td>
<td>22 periprosthetic THR, 12 periprosthetic TKR, 5 interprosthetic, 13 peri-implant, 20 non-implant related (12A, 3B, 5C)</td>
<td>N/A/results at 52 weeks</td>
<td>36 (50%)</td>
<td>5 (7%)</td>
<td>5 (7%)</td>
<td>2 (3%)</td>
<td>N/A/after 52 weeks, bony consolidation in 48 patients</td>
</tr>
<tr>
<td>Erhardt et al., 2008</td>
<td>NCB DF, Zimmer</td>
<td>80 ± 11</td>
<td>23 low energy, 1 high energy (all closed)</td>
<td>12 periprosthetic THR, 12 periprosthetic TKR/ all closed</td>
<td>12 (3–31)</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
<td>2 (8%)</td>
<td>90%</td>
</tr>
<tr>
<td>Erhardt et al., 2014</td>
<td>NCB DF, Zimmer</td>
<td>53 (19–86)</td>
<td>11 traffic accident, 9 simple falls, 2 occupational accidents, 3 fall from height</td>
<td>All non-implant related (5A, 2B, 19C)/ 10 open</td>
<td>36.5 (13.0–76.4)</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
<td>7 (27%)/8 (31%) implant removals</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Pascarella et al., 2014</td>
<td>Polyax Plate, DePuy</td>
<td>62 (16–96)a</td>
<td>26 polytraumaa</td>
<td>9 periprosthetic THR, 4 periprosthetic TKR, 4 peri-implant,a Missing data/23 opena</td>
<td>19 (6–57.5)</td>
<td>N/A</td>
<td>11 (14%)</td>
<td>2 (2.6%)/5 (6.5%) implant removals</td>
<td>10 (13%)</td>
<td>87%</td>
</tr>
<tr>
<td>Haidukewych et al., 2007</td>
<td>Polyax Plate, DePuy</td>
<td>57 (15–99)b</td>
<td>N/A</td>
<td>All non-implant related (15A, 10C)b</td>
<td>9 (6–25)b</td>
<td>N/A</td>
<td>0</td>
<td>1 (4%)</td>
<td>2 (8%)</td>
<td>91.3%</td>
</tr>
</tbody>
</table>

a Data given from the total number of identified patients, before the study exclusions.
b Mixed results with proximal tibial fractures difficult to interpret.
because typically they do not disturb the fracture haemotoma or the soft tissues around fracture. Closed reduction and intramedullary nail fixation is useful technique for treatment of type A and of some selected cases of type B and C distal femoral fractures but are not recommended for fractures with marked displacement of the articular fragments or when there is comminution of the articular surface [36]. Intramedullary nailing of type A fractures can be performed through either antegrade or retrograde fashion, with both approaches offering comparable good results [1,36,37]. Clinical studies comparing intramedullary nailing and plating for fixation of distal femoral fractures did not demonstrate significant difference in complication and union rates [38]. However, unlike to plate fixation of the distal femur, intramedullary nailing has restriction in the use in periprosthetic, severe comminuted or displaced intraarticular fractures [37], difficulties in anatomical reduction resulting in high rates of non-union (6–15%) [34,39] and malrotation (11–22%) [34,39,40]. Additionally, retrograde nailing requires opening of the knee joint that it has been reported to lead in persistent knee pain in 25–55% of cases [34,39,41].

Our study reports on 73 distal femoral fractures treated with the Polyax Locked Plating System. At the final follow up clinical and radiographic union was achieved in all fractures. Major revision surgery was required in 2 (2.7%) cases due to early implant failure and in 3 (4.1%) cases for the management of a non-union. A single percutaneous injection of bone graft was necessary in another 3 (4.1%) cases to enhance healing. In 6 cases out of 8, which presented healing problems, including non-unions, implant failures and secondary need of healing enhancement, osteosynthesis considered as inadequate. The final clinical outcome was satisfactory with 83.25% of patients retaining their initial activity. That was evident despite the advanced age of most of the patients. Results of recent studies from English literature of polyaxial plates for the fixation of distal femoral fractures are shown in Table 2 [7–12]. The present study demonstrated comparable satisfactory results with the other similar studies that had nonunion rates from 0% to 13% and regain of pre-operative function from 55% to 92% [2,9,10]. Also, in periprosthetic fractures the union rate of our series was 100% that is better to other studies using polyaxial plates (reported range 87–93% [8,10,12]). In clinical practice, the two polyaxial locked plating systems currently in use – NCB® Distal Femur plate (Zimmer, Warsaw, USA) and Polyax™ Locked Plating System (Biomet, Warsaw, IN, USA) – seem to be equally effective and safe choices for osteoporotic, periprosthetic fractures or in the presence of compromised bone stock at the distal fragment. Non-union rates with the use of first generation locking systems has been reported to ranged from 0% [42–46] to 19% [38,47–54]. In these studies, the failure of implant ranged from 0% to 20% and the fracture healing problems (e.g. nonunions and secondary bone grafting) ranged from 0% to 32%. As for periprosthetic fractures, the results are worse with important complication rates of up to 41% and revision rates of 29% [2,55,56].

Up-to-date there is paucity of large randomized controlled studies comparing first generation and polyaxial locking plates and the reported results are variable and insufficient to draw a safe conclusion. Nevertheless it is our impression that polyaxial plates fixation should be promoted at least in complex cases since they are surgeon-friendly in their use, offer distinct application and fixation advantages in periprosthetic fractures and the reported results/outcomes of their use have been reported to be similar to that of standard locking plating systems. Limitations of this study can be considered its retrospective nature, the relatively small number of cases, the heterogenic patient group including young and elderly, periprosthetic/peri-implant and non-implant related fractures and the short-term follow-up in terms of posttraumatic osteoarthritis development.

We are also aware that the score we used to measure the outcomes is rather rudimentary. In summary, reconstruction of distal femoral fractures with Polyax plating technology appears to be associated with a low complication rate and satisfactory clinical results in a variety of fracture patterns and compromised bone quality as seen in this series of patients. We advocate their use in cases with increased surgical complexity of reduction and fixation such as periprosthetic fractures. Larger studies with strict inclusion criteria and patient reported outcome measures are desirable to provide further evidence about the effectiveness of this new technology in distal femoral fracture fixation.

Conflict of interest

There is no conflict of interest related to the content of this article.

References


