



Treatment of tibial plateau fractures with a novel fenestrated screw system for delivery of bone graft substitute

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Abstract

Purpose The purpose of this study was to describe the incidence of subsidence in patients with AO/OTA 41 (tibial plateau) fractures which were repaired with a novel fenestrated screw system to used to deliver CaPO₄ bone substitute material to fill the subchondral void and support the articular reduction.

Methods Patients with unicondylar and bicondylar tibial plateau fractures were treated according to the usual technique of two surgeons. After fixation, the Zimmer Biomet N-Force Fixation System®, a fenestrated screw that allows for the injection of bone substitute was placed and used for injection of the proprietary calcium phosphate bone graft substitute into the subchondral void. For all included patients, demographic information, operative data, radiographs, and clinic notes were reviewed. Patients were considered to have articular subsidence if one or more of two observations were made when comparing post-operative to their most recent clinic radiographs: > 2 mm change in the distance between the screw and the lowest point of the tibial plateau, > 2 mm change in the distance between the screw and the most superior aspect of the plate. Data were analyzed to determine if there were any identifiable risk factors for complication, reoperation, or subsidence using logistic regression. Statistical significance was set at $p < 0.05$.

Results 34 patients were included with an average follow-up of 32.03 ± 22.52 weeks. There were no overall differences between height relative to the medial plateau or the plate. Two patients (5.9%) had articular subsidence. Six patients (15.2%) underwent reoperation, two (6%) for manipulations under anaesthesia due to arthrofibrosis, and four (12%) due to infections. There were 6 (19%) total infections as 2 were superficial and required solely antibiotics. One patient had early failure.

Conclusion Use of a novel fenestrated screw system for the delivery of CaPO₄ BSM results in articular subsidence and complication rates similar to previously published values and appears to be a viable option for addressing subchondral defects in tibial plateau fractures.

Level of evidence IV.

Keywords Tibial plateau · Subsidence · Screw · Bone mineral substitute · CaPO₄

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Introduction

Treatment goals for tibial plateau fractures include restoring the mechanical axis and knee stability. Anatomic reduction of the articular surface is important for stability and efficient

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load transfer between the femur and tibia. Failure to recreate a stable, well-aligned knee can result in adverse outcomes such as knee pain, post-traumatic arthrosis, and the need for total knee arthroplasty [1–3].

Maintaining articular reduction to union can be challenging. Many materials have been proposed to fill the subchondral void and support the articular reduction: autograft, allograft chips or struts, and various bone substitute materials (BSMs) [4–6]. Calcium phosphate (CaPO₄) is widely used due to its compressive strength in biomechanical [7–9] and clinical series [10–14]. Traditionally, CaPO₄ is available in multiple forms, including chips, putty, or a viscous injectable through a drill hole in the proximal tibial metaphysis. However, during injection egress of the material can prove problematic; some material is often extruded back through the injection portal, thus reducing available volume in the defect. Moreover, intra-articular material seepage in the post-operative period may necessitate a revision operation [15, 16].

A novel CaPO₄ delivery system intended to optimize the delivery of subchondral bone void fillers is commercially available. The N-Force Fixation System (Zimmer Biomet, Warsaw, IN) consists of 4.0- and 7.0-mm fenestrated screws intended to deliver a proprietary CaPO₄ bone substitute material (N-Force Blue, Zimmer Biomet, Warsaw, IN) along the screw and into bone defects. However, no data exist to guide surgeons in the potential adoption of this new technology. We sought to define the effectiveness of the system in preventing articular subsidence and to define complications associated with its use.

Methods

We identified patients treated for tibial plateau fractures between August 2016 and October 2018 at three hospitals. Thirty-four patients underwent open reduction internal fixation of tibial plateau fractures with standard plate and screw constructs and fenestrated screw CaPO₄ delivery system (OTA/AO 41) by two surgeons (JAS, GSM) and at least one follow-up visit. These fractures represent a series of all patients treated with the device during this time period, beginning with the first use of the device. The decision to use the device was made at the discretion of the operating surgeon. Typically, a contained void (closed space without comminution through which the BSM can egress) with an adjacent surface amenable to screw placement (the screw must be placed orthogonal to the surface to avoid premature egress of BSM) was considered optimal. In fractures for which an “open-book” approach to reduction or those with extensive cortical comminution, alternate defect management strategies were employed. Patient demographic and injury information was recorded. Clinic notes were reviewed

for clinical information and complications. We identified all-cause reoperation, superficial infection (requiring antibiotics), deep infection (requiring surgical debridement), and nonunion.

Procedure

After open reduction internal fixation was performed according to the surgeons’ standard techniques, the defect was assessed for use of the fenestrated delivery system. The fenestrated screw is ideally placed through the bone defect. The screw cannot be placed through a plate at this time. For use in the proximal tibia, 4.0 mm screws was chosen in all cases. A 1.2 mm guidewire was placed in the desired location and assessed fluoroscopically. The desired screw length was measured, and the pilot for the screw was drilled over the wire. The injection system consists of an interlocking cannulated system; the first cannula was threaded onto the head of the screw prior to insertion which was then inserted until the cannula was flush with the bone. At this point, the BSM was mixed according to the manufacturer’s specifications. The second injection cannula was then threaded into the previously inserted cannula: screw construct, allowing for injection of BSM under fluoroscopic control. Once the BSM was fully injected, both cannulas were removed and the screw was fully seated flush with the cortex (Supplemental Fig. 1). No other bone graft was used. The joint was inspected via direct visualization for extravasation of the cement, though none was observed. Closure then proceeded according to the surgeons’ preferred technique. Patients were kept non-weight bearing for 12 weeks according to the surgeons’ typical protocol. No patients underwent arthroscopy postoperatively to evaluate for cement extravasation. Unlimited range of motion was permitted except with associated tubercle fractures.

Radiographs obtained immediately post-operative and at final follow-up were used to identify articular subsidence. Subsidence was determined as a change in articular height relative to the medial plateau > 2 mm or a change in height of the articular surface relative to the proximal aspect of the plate of > 2 mm. A single positive criterion was sufficient to qualify as subsidence. Measurements were performed on a picture archiving and communication system (PACS) (Synapse, Fujifilm, Tokyo, Japan, and AGFA Impax, Agfa-Gevaert, Mortsel, Belgium) by an orthopaedic traumatology fellow (AT) and senior resident (DD) in previously described methodology [15]. A sample measurement is shown in Fig. 1.

Statistics

Statistics were performed using SPSS software (IBM, Armonk, NY) and Prism GraphPad (Graphpad Software,

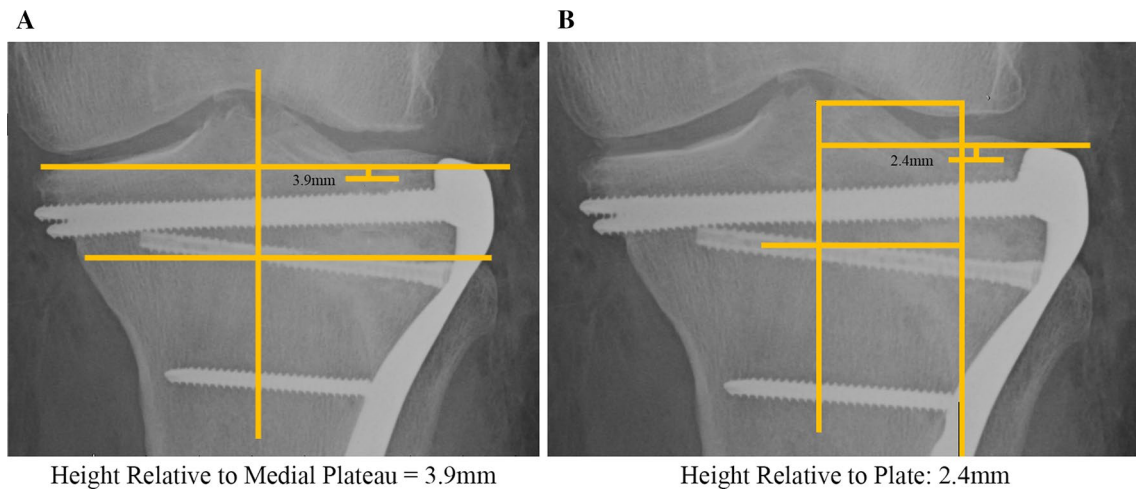


Fig. 1 Representative images for measures of height relative to the medial plateau and height of plate AP XR of the right knee demonstrating the method of measurement for **a** Height relative to the

medial plateau and **b** height related to plate. These measurements were used to calculate subsidence with > 2 mm qualifying as a patient with subsidence

La Jolla, CA). We utilized a Student’s t-test for continuous variables. A Fisher’s exact test was used to compare categorical variables. Univariate and multivariate analysis was performed. Significance was placed at $p < 0.05$.

Results

34 patients were included in this study. The mean age of the patients was 54.06 ± 14.57 years. There were 19 (55%) women. Mean body mass index (BMI) was 28.11 ± 9.88 . The average time to surgery was 14.19 ± 14.16 days. Five patients

(15%) had a meniscal injury in addition to their tibial plateau fracture that was repaired at the time of surgery. Medical comorbidities included osteoporosis ($n=2$, 6%), tobacco use ($n=9$, 21%), diabetes mellitus ($n=6$, 18%), renal disease or chronic kidney disease ($n=3$, 9%), anxiety ($n=3$, 9%), and depression ($n=2$, 6%). Demographic information is available in Table 1.

The most common mechanism of injury (Supplemental Table 1) was fall from height ($n=9$, 26%), followed by pedestrian struck by auto ($n=8$, 24%). All fractures were classified according to the Schatzker and OTA/AO classification systems [17, 18]. The predominant fracture types

Table 1 Patient demographics and comorbidities for patients treated with N-force

Demographic	Number	Percent (%)			
Female	19	56			
Right side	19	56			
Meniscus injury	5	15			
1 N-Force Screw	21	62			
<i>Comorbidities</i>					
Tobacco use	7	20.59			
Diabetes mellitus	6	17.65			
ESRD/CKD	3	8.82			
Anxiety	3	8.82			
Depression	2	5.88			
Hypothyroidism	2	5.88			
	Mean	Standard deviation	Median	Minimum	Maximum
Age	54.06	14.57	55.00	27.00	87.00
BMI	28.11	9.88	26.50	16.36	73.63
Time to surgery	14.19	14.16	10.00	1.00	54.00

were Schatzker II ($n = 15$, 44%) and 41B3 ($n = 15$, 44%). A full analysis of fracture type is available in Supplemental Table 1. There were no open fractures.

Mean follow-up was 32.03 ± 22.52 weeks. Average time to weight bearing was 11.72 ± 2.67 weeks (Table 2). Mean overall height relative to the medial plateau postoperatively was 2.25 ± 2.05 mm (Fig. 2). At final follow-up, it was 1.86 ± 2.01 mm (change of 0.39 ± 1.43 mm) (Fig. 2c, d). The mean articular height relative to the plate was 4.42 ± 3.19 mm post-operative and 3.25 ± 3.41 mm at final follow-up (change of 1.16 ± 2.38 mm). There was no significant difference between mean post-operative and final values for either measurement ($p = 0.88$ and 0.19 , respectively). Average range of motion at most recent follow-up ($n = 18$) was $119^\circ \pm 17.4^\circ$.

Overall, six patients (15.2%) underwent reoperation (Table 2). Reasons included two (6%) manipulations under anaesthesia due to arthrofibrosis and four debridements for deep infection. There were six (19%) total infections; two were superficial and required solely antibiotics. One of the operative treated patients had implant removal during secondary surgery due to infection. One patient had early failure. Two patients (5.9%) had articular subsidence at 11 and 24 weeks postoperatively. Figure 2 shows representative AP radiographs of patients with no measurable subsidence (A), and a patient with subsidence (B). A summary of patients with subsidence is found in Table 3.

Discussion

The rate of articular subsidence for a wide variety of tibial plateau fractures treated with a novel fenestrated screw for the delivery of CaPO₄ BSM was 5.9%. This rate is superior to a large randomized-controlled trial by Russell et al. that reported 9% subsidence in 69 patients with a similar variety of fracture types. However, as a prospective trial, they excluded patients with diabetes and other

comorbidities, while we included all patients who had been treated with this device. Similar exclusion criteria would put our rate at 3.4% (1/29).

More recent studies have reported lower rates. A 2014 study of Schatzker II fractures reported no subsidence in 77 patients [15]. A second study in 2017 reported 3.4% subsidence (1/29) across fracture types but was a single-centre, single-surgeon cohort [11]. Comparison among these studies is challenging owing to the different BSM used. We also utilized very strict criteria for subsidence while many studies only used one measurement or grading technique.

It is important to identify the BSM used in these studies, as each has different mechanical properties and compressive strength. The BSM in this study (N-Force Blue, Zimmer Biomet, Warsaw, IN) is designed specifically to be inserted through the N-force fenestrated screw. As such it has unique flow properties but lower compressive strength (7–9 MPa) compared even to other BSM from the same manufacturer (28–42 MPa). This suggests that perhaps other properties besides compressive strength such as flow, volume, percentage fill of the defect, or administration technique may play a part in preventing subsidence. Further study should attempt to characterize how these factors may influence success.

The complication rate in our study was comparable to previously published rates, which range between 2 and 23.6% [19–23]. We report a mix of superficial ($n = 2$) and deep/operative ($n = 4$) infections, and of these superficial and deep infections only one required implant removal. Only one patient in our cohort went on to delayed union and this was likely due to several medical comorbidities known to limit the healing process (diabetes mellitus, chronic kidney disease with end organ damage). This nonunion rate of 3% is within the range reported (0–10%) [19, 22, 24, 25]. Studies have shown a range of 0–20% [10, 19, 21, 22, 24] of tibial plateaus require reoperation for reasons such as infection, malalignment, or arthrofibrosis. With our limited cohort, our study results were comparable with previous investigations.

Table 2 Outcomes and complications for patients treated with N-force screw

Outcome	Mean	Standard deviation	Median	Min	Max
Overall follow-up (weeks)	32.03	22.52	25.07	2.14	103.86
Time to weight bearing (weeks)	11.72	2.67	12.00	6.00	20.00
Range of motion	118.89	17.37	115.00	90.00	140.00
Complication	Number		Percentage		
Infection	6		18.75%		
Reoperation	5		15.15%		
Subsidence	2		5.88%		
Arthrofibrosis	2		5.88%		
Nonunion	1		3.45%		

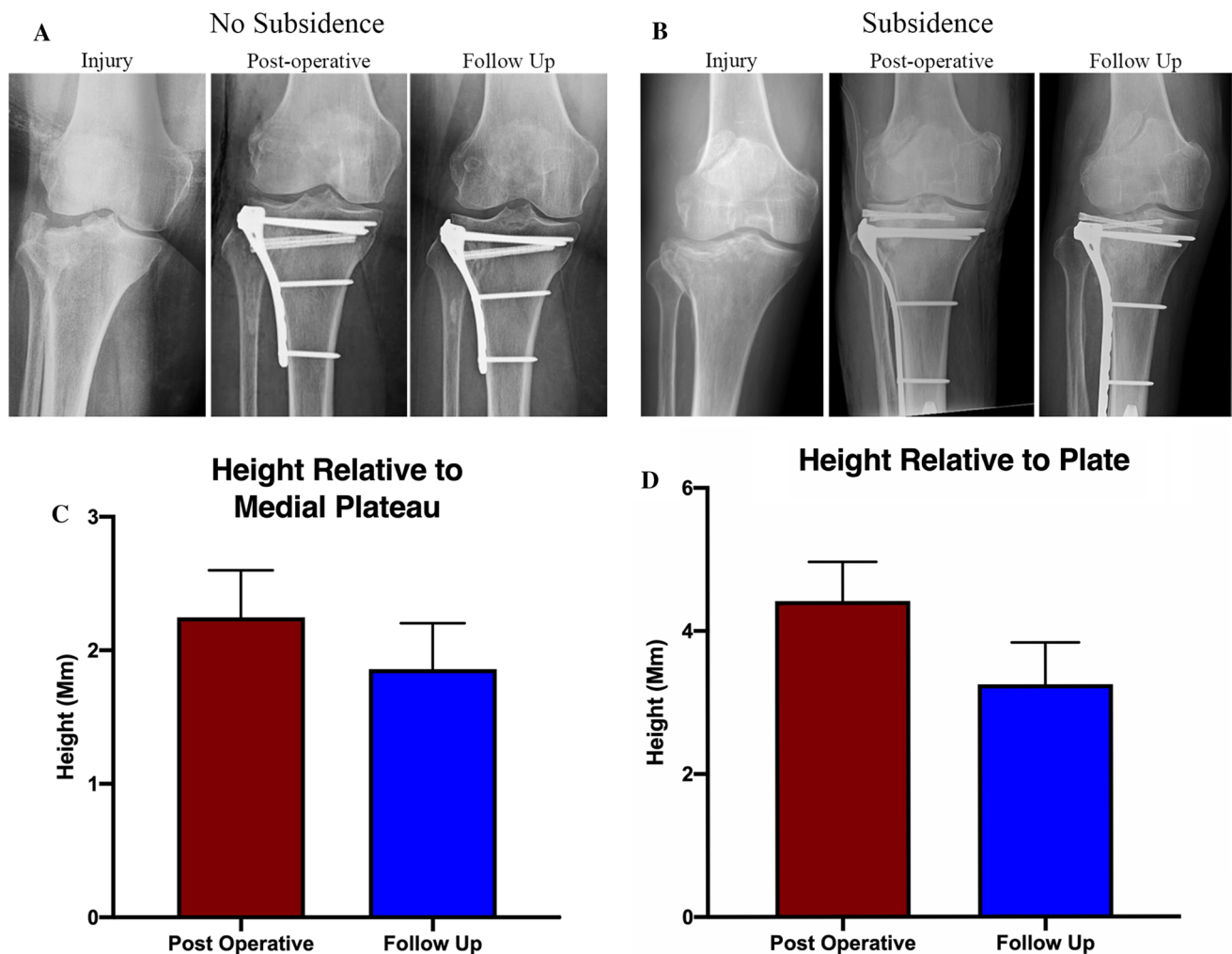


Fig. 2 Representative Images and overall measures of subsidence for patients receiving N-force screw. **a** Injury, post-operative and follow-up AP images of patient who received N-force screw and did not suffer from subsidence. **b** Injury, post-operative, and follow-up AP images of patient who received N-force screw and suffered

from subsidence. **c** Mean height relative to the medial plateau for patients immediately post-operative and at most recent follow-up for patients treated with N-force ($p > 0.05$). **d** Mean height of the plate for patients immediately post-operative and at most recent follow-up for patients treated with N-force ($p > 0.05$)

The strengths of this study include that this was a series of patients with a wide variety of fracture types and comorbidities making the results generalizable. Additionally, this series includes the surgeons' initial cases using this system suggesting that this system may have a short learning curve as indicated by our low rate of subsidence. Additionally, a strict criterion for subsidence was used.

There are several limitations to the study. It was a retrospective review and therefore subject to selection bias as the decision to use this delivery system was made at the discretion of the treating surgeons, and the use of the screws was heterogenous varying the exact number and location of the screws. Therefore, patients who may have been ideal candidates, presented problematic scenarios, or benefited from a particular construct may not have been included, which may limit generalizability of the findings. The radiographs

were not taken with magnification correction or according to a specified protocol, which may have masked smaller differences, and accounts for the mean subsidence being less in the final post-operative radiographs than initial. However, we compared radiographs taken within the same institutions with similar protocols in all settings with relatively consistent values suggesting that there was little change between initial and final follow-up. Additionally, we did not use advanced imaging in the post-operative period to assess proper placement within the subchondral defect, or subsequent subsidence. This study was underpowered for one of the outcome measures. A post hoc power analysis revealed that 165 patients would be needed to detect a 2 mm difference in height relative to the medial plateau when comparing pre- and post-operative subsidence, which was not feasible in this early cohort. Additionally, this new technology has

Table 3 Characteristic of patients who suffered subsidence

Patient	Gender	BMI	Age	Diabetes	Tobacco	Comorbidities	Fracture pattern (AO, Schatzker)	Time to surgery (Days)	Other complications	Change in height to plate	Change in height to medial plateau	Time to subsidence (Weeks)
Patient 1	Female	24.8	52	Type Two	No	ESRD, HTN, HLD	41B3.1, II	54	Malunion	-4.9	2.4	24
Patient 2	Male	33.24	44	No	No	None	41B3.1, II	10	Minimal settling at lateral plate	3.4	0.9	11

the potential for increased cost to standard methods. Lastly, we were unable to obtain functional outcome data from most patients, which would be valuable in assessing true long-term clinical outcomes.

Conclusion

Use of a novel fenestrated screw system for the delivery of CaPO₄ BSM results in subsidence and complication rates similar to previously published values and appears to be a viable option for addressing subchondral defects in tibial plateau fractures.

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Compliance with ethical standards

Conflict of interest G. S. Marecek has received research support funding from BoneSupport AB and is a paid consultant for DePuy Synthes Globus Medical, Nuvasive, Stryker, Smith & Nephew, and Zimmer Biomet. G.S. Marecek is a committee member for the Orthopaedic Trauma Association and Western Orthopaedic Association. Donald Desanto has stock or stock options in AbbVie, Amgen Co, Becton Dickinson, and Company, Cardinal Health, Inc., Celgene, Hill-Rom Holdings, Inc., Johnson & Johnson, Masimo, Novartis, Procter & Gamble, Sangam Therapeutics, Shockwave Medical, and Stryker. John Scolaro is a paid consultant for Globus Medical, Nuvasive, Smith & Nephew, Stryker, and Zimmer Biomet. John Scolaro receives IP royalties from Globus Medical. Alexander Telis, Edward Compton, Douglass Tucker, John Carney, and Adam K. Lee have no competing interests.

Ethical approval This study received no outside funding and was initiated following after Institutional Review Board (IRB) approval.

Human and animal rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent As this study included human subjects informed consent was obtained from all individual participants included in the study.

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