Clinical outcomes of Ti-Ni shape-memory patella concentrator combined with cannulated compression screws in the treatment of C2 and C3 patella fracture: a retrospective study of 54 cases

CURRENT STATUS: UNDER REVIEW

Yao Chen
Affiliated Hospital of Nantong University

Sun Jie
Affiliated Hospital of Nantong University

Wu Jiancheng
Affiliated Hospital of Nantong University

Zhou Zhenyu
Affiliated Hospital of Nantong University

Liu Fan
Affiliated Hospital of Nantong University

Tao Ran
Affiliated Hospital of Nantong University

Zhang Yafeng
Affiliated Hospital of Nantong University

Corresponding Author
fcius2004@hotmail.com
ORCiD: https://orcid.org/0000-0002-6823-9961

DOI: 10.21203/rs.3.rs-18139/v1

SUBJECT AREAS
Orthopedics

KEYWORDS
shape-memory patella concentrator, comminuted patella fracture, fixation technique, clinical outcomes
Abstract
Purpose The purpose of this study was to investigate the efficiency of Ti-Ni shape-memory patella concentrator (TNSMPC) combined with cannulated compression screws in the treatment of comminuted patella fracture. Methods Between January 2014 and January 2017, 54 patients of C2 and C3 patella fractures underwent open reduction and internal fixation with TNSMPC combined with cannulated compression screws. All the patients got standard postoperative rehabilitation programs and were regularly followed up for at least 12 months after the operation. X-rays, knee functions and life quality were evaluated during the follow-up. Results All the patients achieved bone healing and recovery of knee function with low incidence of complications according to X-rays and questionnaire surveys. The average operation time and blood loss during surgery were 77.5±25.12 minutes and 24.25±4.70 ml respectively. The Knee Outcome Survey Activities of Daily Living Scale, range of motion, 36-item Short-form heath survey after the operation were all improved. According to the Bostman’s criteria, the excellent to good rate was 92.6%. Conclusion TNSMPC combined with cannulated compression screws is an effective fixation for C2 and C3 patella fracture with excellent clinical outcomes. In addition, the operation does not increase extra technique difficult or tissue damage relatively, which is worth promotion.

Background
The patella is the biggest sesamoid bone inside the human body, located between the quadriceps tendon and the patella tendon. It is an important module in the knee extension system. It can function as a lever and increase the moment of quadriceps, enabling the extension of the knee and helping maintain the stability of knee joint.[1] The incidence of patella fractures in adult ranges from 0.5%~1.5%, accounting for 10% of all fractures.[2, 3] Comminuted patella fractures (AO/OTA 34C2 and 34C3) are common challenges for orthopedists. Accurately reduction and stable fixation are standard management to restore disrupted extension system and articular surface. Regardless of the treatment, there are still some patients suffering poor outcomes from those comminuted patella fractures.[4, 5]

While the operative techniques of patellar fractures have undergone many changes over the past few
decades, anterior tension wiring remains the mostly widely accepted method.[6–8] It can transform tension into pressure forces to achieve dynamic compression between fragments, allowing early joint motion. However, the tension band still has many disadvantages.[9, 10] The traditional tension band was composed of smooth Kirschner wires (K-wire) and stainless wire. The smooth K-wires cannot achieve direct fragmentary compression and the fracture may gap in knee extension.[11] In addition, when the tension band is working, the stainless wire and K-wire may have stress break, wearing, loosening, migration and skin irritation. Some orthopedists have presented different modified tension band methods to avoid the shortcomings of traditional tension band, such as cannulated screws combined with stainless wires or cannulated screws combined with titanium cables. However, the early failure of tension wiring were still reported in the literature with the rate of 12–30% especially in comminuted fractures.[12, 13]

Titanium-nickel (Ti-Ni) alloy is a one-way shape-memory alloy, which can be contoured in low temperature and reconverted to the previous shape in high temperature. Compared to traditional K-wires, the Ti-Ni shape-memory alloy has higher hardness, higher tenacity and better wear resistance. What’s more, it has excellent corrosion resistance and desired histocompatibility.[14, 15] Based on these advantages, some Chinese factories have designed and manufactured patella concentrator out of Ti-Ni shape-memory alloy as an alternative approach for fixation of patella fractures. (Fig. 1)

During the past several years, we applied the special-designed Ti-Ni shape-memory patella concentrator (TNSMPC) combined with cannulated screws in the treatment of C2 and C3 patella fractures and conducted complete follow-up. In this paper, we will present our operation techniques and evaluate the clinical outcomes of this method.

Materials And Methods
Study population
The retrospective study was conducted in Trauma Center of the Affiliated Hospital of Nantong University, approved by the local ethics committee. All work complied with the principles in the declaration of Helsinki. Between January 2014 and January 2017, all patients who came to our institution with patella fractures was evaluated for this study according to the special protocol shown
in Fig. 2. Informed consent was obtained from all patients. Inclusion criteria were: comminuted patella fracture (AO/OTA 34C2 and 34C3), indication for surgery (continuity of knee extensor mechanism, fracture displacement of more than 3 mm, cartilage step-off of more than 2 mm), application of Ti-Ni shape-memory patella concentrator (TNSMPC) combined with cannulated screws, aged 18 years or older at the time of injury. Exclusion criteria were: simple or nondisplaced fracture with indication for conservative treatment (AO/OTA 34A, 34B or 34C1, damaged knee extensor mechanism, fracture displacement of more than 3 mm cartilage or step-off of less than 2 mm), aged younger than 18 years, function limitation of the knee or other severe medical conditions before injury, multiple concomitant injury of the ipsilateral leg or other systems, lost to follow-up.

Perioperative Management
After hospitalization, the injured knee was temporarily fixed with splints in extension to release the pain. Standard anterior-posterior and lateral plain X-rays were proceeded. Computerized tomography and three-dimensional reconstruction were performed for severely comminuted and displaced patella fractures. All fractures were classified according to AO/OTA classification system. Pre-operative function evaluation was gathered from medical documents. Open reduction and internal fixation were performed in five days since injury. Postoperatively, quadriceps contraction exercises and continuous passive motion (CPM) was carried out as soon as possible. Partial weight bearing and active range-of-motion (ROM) exercises with a mobilizable brace was encouraged 1 week later. Full weight-bearing walk was allowed 6 weeks later.

Operation Techniques
All patients got the operation under general anesthesia and supine position. The tourniquet was applied during the operation with 300 mmHg. Anterior longitudinal incision was carried out to expose the fracture. The fractures were reduced and temporarily fixed with reposition forceps and guide pin of cannulated screws, checked by C-arm fluoroscopy simultaneously. If the reduction of the fracture was acceptable, cannulated screws with appropriate length were screwed in to fix the fracture fragments and provide direct fragmentary compression. The pre-patellar bursa was sutured. TNSMPC was contoured in 0°C sterilized normal saline and clasped the patella. The superior and inferior claws
was respectively embedded into the tendon around the upper and lower patellar pole, like a talon catching a prey. The concentrator was reconverted to the previous shape in 37℃ normal saline after implanted, which provided mechanical effect as a tension band. Stability of fracture reduction was confirmed with the knee in flexion of at least 90 degrees. Position of internal fixation and ROM of the joint were checked as well before closing the incision.

Follow-up Assessment
Follow-up assessment was performed at 3, 6, and 12 months after the operation, including X-rays, knee function and life quality. The Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), ROM measurement, Bostman score and 36-item Short-form health survey (SF-36) was applied in the process.

Results
Finally, 54 patients who accepted open reduction and internal fixation with TNSMPC combined with cannulated for comminuted patella fracture were evaluated in this study. All the cases were closed fractures, without other concomitant injuries. Baseline demographic and clinical characteristics of the patients were summarized in Table 1. There were 31 males and 23 females. The patients averaged 54.11±11.24 years old (range: 28–83 years). The average body mass index (BMI) was 23.02±4.30 kg/m². 33 fractures happened in the left side and 21 fractures happened in the right side. The injury mechanism included traffic accident (28 patients), sports (10 patients), work (9 patients) and activities in daily life (7 patients). Patients were classified according to the OA/OTA system as 23 C2 fractures and 31 C3 fractures. The average hospitalization was 14.67±4.40 days. The average operation time was 77.5±25.12 minutes and the average blood loss during the operation was 24.25±4.70 ml (range: 20–40 ml).
Table 1
Baseline demographic and clinical characteristic of patients

| Characteristic                      | Description                  |
|-------------------------------------|------------------------------|
| Age, years (mean±SD)                | 54.11±11.24                  |
| Gender, n%                          |                              |
| Male                                | 31 (57.4)                    |
| Female                              | 23 (42.6)                    |
| Side of injury                      |                              |
| Left                                | 33 (61.1)                    |
| Right                               | 21 (38.9)                    |
| BMI, kg/m² (mean±SD)                | 23.02±4.30                   |
| Mechanism of injury, n%             |                              |
| Daily activity                      |                              |
| Work                                | 9 (16.7)                     |
| Traffic accident                    | 28 (51.9)                    |
| Sports injury                       | 10 (18.5)                    |
| Activities in daily life            | 7 (13.0)                     |
| OTA classification                  |                              |
| C2                                  | 23 (42.6)                    |
| C3                                  | 31 (57.4)                    |
| Hospital stay, day (mean±SD)        | 14.67±4.40                   |
| Operation time, min (mean±SD)       | 77.50±25.12                  |
| Blood loss, ml (mean±SD)            | 24.25±4.70                   |

All the patients got clinical healing 3 months later and bone healing 6 months later according to radiographic and clinical evaluation results. No break, loosening, migration and skin irritation of the internal fixation was detected, showing excellent performance and histocompatibility of TNSMPC. The ROM for extension-flexion of the injured knee improved from 108.91°±4.95° after 3 months to 124.28°±5.09° after 6 months and 136.11°±4.42° after 12 months, close to the uninjured contralateral knee (Fig. 3). The KOS-ADL was evaluated at least 6 months after the operation. The results showed only a few patients had symptoms severely influencing their daily activities (Table 2). Kneeling and squatting were limited for several patients and other functions were not difficult for patients (Table 3). SF-36 survey 1 years after the operation indicated the quality life of the patients was promoted significantly (Table 4). The results of role physical evaluation were relatively lower than other items, which indicated patients may need appropriate physical rehabilitation training respectively after the operation. According to the Bostman score, among all the 54 patients, 38 patients were excellent, 12 cases were good. The Fig. 4 showed a demo case.
Table 2
KOS-ADL evaluation (Symptoms)

|          | I do not have the symptom in my knee | I have the symptom, but it does not affect my activity | The symptom affects my activity slightly | The symptom affects my activity moderately | The symptom affects my activity severely | The symptom prevents me from all daily activity | NO answer |
|----------|---------------------------------------|------------------------------------------------------|----------------------------------------|-------------------------------------------|------------------------------------------|-------------------------------------------------|-----------|
| Pain     | 22                                    | 9                                                    | 14                                      | 4                                         | 5                                        | 0                                              | 0         |
| Stiffness| 30                                    | 4                                                    | 8                                       | 3                                         | 5                                        | 0                                              | 4         |
| Swelling | 28                                    | 8                                                    | 6                                       | 4                                         | 4                                        | 0                                              | 4         |
| Slipping | 20                                    | 9                                                    | 8                                       | 4                                         | 9                                        | 0                                              | 4         |
| Buckling | 19                                    | 9                                                    | 11                                      | 5                                         | 8                                        | 0                                              | 2         |
| Weakness | 29                                    | 6                                                    | 6                                       | 6                                         | 2                                        | 2                                              | 3         |

Table 3
KOS-ADL evaluation (Functional limitations)

|          | Activity is not difficult | Activity is minimally difficult | Activity is somewhat difficult | Activity is fairly difficult | Activity is very difficult | I am unable to do the activity | No answer |
|----------|---------------------------|---------------------------------|-------------------------------|-----------------------------|-----------------------------|--------------------------------|-----------|
| Walk     | 25                        | 13                              | 8                             | 3                           | 3                           | 0                              | 2         |
| Go up stairs | 17                     | 18                              | 5                             | 9                           | 3                           | 0                              | 2         |
| Go down stairs | 12                    | 18                              | 8                             | 11                          | 3                           | 0                              | 2         |
| Stand    | 27                        | 12                              | 5                             | 2                           | 5                           | 0                              | 3         |
| Kneel on front | 4                    | 12                              | 9                             | 6                           | 9                           | 12                             | 2         |
| Squat    | 14                        | 12                              | 2                             | 12                          | 2                           | 6                              | 6         |
| Sit with knee bent | 22                  | 11                              | 12                            | 5                           | 0                           | 0                              | 4         |
| Rise from a chair | 20               | 12                              | 6                             | 8                           | 3                           | 0                              | 5         |

Discussion

The purpose of this retrospective case series was to evaluate the clinical outcomes of TNSMPC combined with cannulated compression screws in the treatment of comminuted patella fractures. The results revealed good clinical outcomes and few complications of this technique, which achieved high level of patient satisfaction. Due to the reliable fixation provided by the implants, patients are allowed full weight bearing and rehabilitation after the surgery as soon as possible. All patients got bone healing 6 months later, without severe complications. The ROM of injured knee, function scores and life quality evaluation indicated full recovery 1 years after surgery. In addition, the average operation time was 77.5 minutes and average blood loss was 25.5 ml, which means this operation method may not increase extra technique difficulty or tissue damage and it worth being promoted widely..

Despite large development of operative techniques for patellar fractures over the past several decades, anterior tension wiring remains the mostly widely accepted method, which can transform anterior tension force into compression force between fragments during knee flexion.[6, 7]
Longitudinal K-wires combined with stainless wire in a figure-8 pattern was a classical fixation method for patella fracture and has been widely applied. Since K-wire was smooth and had no screw thread, the cannulated compression screws can be applied to replace the K-wire to provide direct fragmentary compression with the knee in extension.[16] However, the early failure of the internal fixation due to stress break, wearing, loosening, migration, electrolytic and skin irritation was still reported, particularly for comminuted patellar fractures.[12, 13] To avoid intrinsic shortcomings of tension wiring, some new internal fixations have been designed and applied in clinical trials such as a fixed angle plate, a locking patella plate and TNSMPC in our study.[17-19]

The TNSMPC applied in our study was designed according to the anatomic characteristics of patellar and was made of Ti-Ni alloy with high excellent corrosion resistance and desired histocompatibility. The TNSMPC can provide similar or even stronger dynamic compression between fragments like anterior tension wiring and can avoid many intrinsic shortcomings. The shape of the concentrator fits for the patellar very well and the material is friendly to the soft tissue, reducing risk of skin and electrolytic irritation. In addition, Ti-Ni alloy has excellent corrosion resistance and mechanical properties, which can provide stable fixation for comminuted fractures and avoid early stress break, wearing loosening or migration. In terms of operative techniques, the install of the concentrator is much easier than that of stainless wired and the learning curve is short. After contoured in 0°C sterilized normal saline and installed on the patella, concentrator was reconverted in 37°C normal saline and clasps the patella like a talon strongly, without any extra damage of soft tissue. Other new fixations, such as fixed-angle plating and locking plate, need extra screws to fix the plate on the patella and have limitation in osteoporotic patients or severely comminuted fractures.[20] Differently, the TNSMPC can fix the fracture independently by its claws and causes no extra bone loss, which can achieve excellent outcomes in osteoporotic or comminuted cases. The study conducted by Yutong Zhang et al. described another similar patellar concentrator and report desired outcomes in pole fracture or comminuted patellar fractures.[21] Fracture displacement due to the loosening of the claw is potential complications of the operation while it did not happen in cases with comminuted fractures. Figure 5 shows the failure of the internal fixation in a case with a simple transverse fracture
and the revision surgery was performed by removing the screws, reducing the fracture and fixing it with the claw and additional circle wire. Factors related to the complications are not so clear, which may include choosing inappropriate size of the claw, malposition of the implants, poor bone quality, knee flexion too early after the operation and so on.

Several limitations of our study exist and deserve mention. Actually this is a retrospective case series without a control group and we didn’t compare the outcomes of our method with other osteosynthesis techniques directly, which affected the evidence level. We only chose comminuted fractures according to rigid standard in a single trauma center, so the number of cases are limited. Finally, the time of follow up was not so long. In the future, more cases from multiple trauma center and result of long-term follow up will be collected.

Conclusion
In summary, results of our study showed excellent outcomes of TNSMPC combined with cannulated compression screws in the treatment of C2 and C3 patella fracture. Without extra technique difficult or tissue damage, the TNSMPC and screws provide dynamic and static fragmentary compression respectively, ensuring stable fixation of comminuted patella fractures. Patients are allowed early weight-bearing and rehabilitation without extra complications. As an alternative of traditional tension band, TNSMPC is an appropriate implant for comminuted patellar fractures and worth spreading.

Abbreviations
BMI: Body mass index; CPM: Continuous passive motion; KOS-ADL: Knee Outcome Survey Activities of Daily Living Scale, K-wire: Kirschner wire; ROM: range of motion; Ti-Ni: Titanium-nickel; TNSMPC: Ti-Ni shape-memory patella concentrator.

Declarations

Funding
This work was supported by the National Natural Science Foundation of China (No. 81501913), Natural Science Foundation of Jiangsu province (No. bk20151275) and Postgraduate Research & Practice Innovation Program of Jiangsu Province (NO. SJCX19_0865).

Conflicting Interest
The authors declare that they have no conflict of interest.
Ethics approval
This study was approved by the ethics committee of Affiliated Hospital of Nantong University.

Informed consent:
Informed consent was obtained from all individual participants included in the study.

Code availability
Please contact author for data request.

Acknowledgements
None

Authors’ contributions
Yao Chen, Tao Ran, and Zhang Yafeng conceived and designed the study. Yao Chen, Sun Jie and Wu Jiancheng collected the data. Yao Chen, Zhou Zhenyu and Liu Fan performed the statistical analysis.

Yao Chen wrote the manuscript. All authors approved the final version to be published.

References
1. Koval KJ, Kim YH (1997) Patella fractures. Evaluation and treatment. Am J Knee Surg 10 (2):101-108
2. Dietz SO, Hessmann MH, Gercek E, Rommens PM (2009) [Patella fracture]. Oper Orthop Traumatol 21 (2):206-220. doi:10.1007/s00064-009-1708-5
3. Carpenter JE, Kasman R, Matthews LS (1994) Fractures of the patella. Instr Course Lect 43:97-108
4. LeBrun CT, Langford JR, Sagi HC (2012) Functional outcomes after operatively treated patella fractures. J Orthop Trauma 26 (7):422-426. doi:10.1097/BOT.0b013e318228c1a1
5. Bonnaig NS, Casstevens C, Archdeacon MT, Connelly C, Monaco N, Wyrick JD, Le TT (2015) Fix it or discard it? A retrospective analysis of functional outcomes after surgically treated patella fractures comparing ORIF with partial patellectomy. J Orthop Trauma 29 (2):80-84. doi:10.1097/BOT.0000000000000201
6. Kakazu R, Archdeacon MT (2016) Surgical Management of Patellar Fractures. Orthop Clin North Am 47 (1):77-83. doi:10.1016/jocl.2015.08.010

7. Melvin JS, Mehta S (2011) Patellar fractures in adults. J Am Acad Orthop Surg 19 (4):198-207. doi:10.5435/00124635-201104000-00004

8. Curtis MJ (1990) Internal fixation for fractures of the patella. A comparison of two methods. J Bone Joint Surg Br 72 (2):280-282

9. Choi HR, Min KD, Choi SW, Lee BI (2008) Migration to the popliteal fossa of broken wires from a fixed patellar fracture. Knee 15 (6):491-493. doi:10.1016/j.knee.2008.06.005

10. Carpenter JE, Kasman RA, Patel N, Lee ML, Goldstein SA (1997) Biomechanical evaluation of current patella fracture fixation techniques. J Orthop Trauma 11 (5):351-356. doi:10.1097/00005131-199707000-00009

11. Zderic I, Stoffel K, Sommer C, Hontzsch D, Gueorguiev B (2017) Biomechanical evaluation of the tension band wiring principle. A comparison between two different techniques for transverse patella fracture fixation. Injury 48 (8):1749-1757. doi:10.1016/j.injury.2017.05.037

12. Smith ST, Cramer KE, Karges DE, Watson JT, Moed BR (1997) Early complications in the operative treatment of patella fractures. J Orthop Trauma 11 (3):183-187. doi:10.1097/00005131-199704000-00008

13. Miller MA, Liu W, Zurakowski D, Smith RM, Harris MB, Vrahas MS (2012) Factors predicting failure of patella fixation. J Trauma Acute Care Surg 72 (4):1051-1055. doi:10.1097/TA.0b013e3182405296

14. Kapanen A, Ryhanen J, Danilov A, Tuukkanen J (2001) Effect of nickel-titanium shape memory metal alloy on bone formation. Biomaterials 22 (18):2475-2480. doi:10.1016/s0142-9612(00)00435-x
15. Zhang Y, Zhao X, Tang Y, Zhang C, Xu S, Xie Y (2013) Application of Ni-Ti alloy connector for the treatment of comminuted coronal plane supracondylar-condylar femoral fractures: a retrospective review of 21 patients. BMC Musculoskelet Disord 14:355. doi:10.1186/1471-2474-14-355

16. Tian Y, Zhou F, Ji H, Zhang Z, Guo Y (2011) Cannulated screw and cable are superior to modified tension band in the treatment of transverse patella fractures. Clin Orthop Relat Res 469 (12):3429-3435. doi:10.1007/s11999-011-1913-z

17. Wurm S, Buhren V, Augat P (2018) Treating patella fractures with a locking patella plate - first clinical results. Injury 49 Suppl 1:S51-S55. doi:10.1016/S0020-1383(18)30304-8

18. Thelen S, Schneppendahl J, Jopen E, Eichler C, Koebke J, Schonau E, Hakimi M, Windolf J, Wild M (2012) Biomechanical cadaver testing of a fixed-angle plate in comparison to tension wiring and screw fixation in transverse patella fractures. Injury 43 (8):1290-1295. doi:10.1016/j.injury.2012.04.020

19. Matejcic A, Smiljanic B, Bekavac-Beslin M, Ledinsky M, Puljiz Z (2006) The basket plate in the osteosynthesis of comminuted fractures of distal pole of the patella. Injury 37 (6):525-530. doi:10.1016/j.injury.2004.09.020

20. Taylor BC, Mehta S, Castaneda J, French BG, Blanchard C (2014) Plating of patella fractures: techniques and outcomes. J Orthop Trauma 28 (9):e231-235. doi:10.1097/BOT.0000000000000039

21. Zhang Y, Wang P, Xia Y, Zhou P, Xie Y, Xu S, Zhang C (2017) Application of a Shape-Memory Alloy Concentrator in Displaced Patella Fractures: Technique and Long-Term Results. J Knee Surg 30 (2):166-173. doi:10.1055/s-0036-1584187

Figures
Figure 1

Diagram of the special-designed Ti-Ni shape-memory patella concentrator (SEEMINE, Lanzhou China, TN) for the fixation of patella fractures.

Figure 2

Flowchart of participants through the study
Figure 3

Histogram of the ROM for extension-flexion at follow up.
Figure 4

Comminuted fracture (AO/OTA 34C3) of the patella in a 48-year-old male patient after a car accident (a-d). Open reduction and internal fixation with TNSMPC and compression screws were performed. X-rays immediately after surgery (e, f) and 3 months later (g, h) showed desirable outcomes.
Figure 5

Transverse fracture of the patella (a, b) in a 55-year-old female patient treated with TNSMPC and compression screws (c, d). The internal fixation failed 6 weeks after the surgery (e, f).

The screws were removed and the claw and additional circle wire fixation were applied for revision surgery (g, h).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

Table S1.doc