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Patellar Shape-Memory Fixator for the Treatment of Comminuted Fractures of the Inferior Pole of the Patella

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Comminuted and displaced fractures of the inferior pole of the patella are not easy to reduce and it is difficult to fix the fragments soundly enough to allow early movement of the knee. The purpose of this study is to evaluate the clinical effectiveness of the internal fixation technique with Patellar Shape-Memory Fixator (PSMF) in acute comminuted fractures of the inferior pole of the patella. We retrospectively studied 25 patients with comminuted fractures of the inferior pole of the patella who were treated with PSMF and followed up for a mean period of 26 months (14 to 60). All the fractures healed at a mean of 6 weeks (5 to 7). The mean grading at the final follow-up was 29.5 points (27 to 30) using the Bostman score, with no observable restriction of movement. No breakage of the PSMF or infection occurred. No delayed union, nonunion, and infection were seen. This technique preserved the length of the patella, reduced the comminuted fragments of the inferior pole and avoided long-term immobilization of the knee.

Keywords fracture, Ni-Ti alloy, patella, shape memory

1. Introduction

The patella is a sesamoid bone, situated within the tendon of the quadriceps femoris muscle. Displaced fractures of the patella which disrupt the extensor mechanism of the knee require operative treatment. Patellar fractures comprise 1-2% of all fractures and avulsion fractures account for 9.3 to 22.4% of all patellar fractures that are treated surgically (Ref 1).

The treatment of an avulsion fracture of the distal patellar pole poses a special problem because of the structure of the injured patellar pole. An avulsion fracture with a single solid patellar pole fragment can be treated by tension-band wiring, circumferential wiring or with screws if the fragment is sufficiently large (Ref 1-3). Because of the trauma mechanism, however, the patellar pole is often comminuted and difficult to manage. The treatment in these cases often has been removal of the patellar pole and repair of the patellar ligament (Ref 4), excision of the small fragments of bone with attachment of the patellar tendon by transosseous pull-out suture is usually performed. Weakness of synthetic non-absorbable sutures and partial patellectomy require immobilization of the knee after operation, which delays rehabilitation and may result in weakness of the quadriceps muscle. Some authors advocate patellotibial cerclage or the use of figure-of-eight wiring to protect the pull-out suture to allow early rehabilitation, but these procedures make it difficult to adjust the length of the patellar tendon. This may result in breakage of the wire requiring a second operation for its removal (Ref 2, 5). Some authors, however, have recommended preservation of the patellar pole by means of fixation with separate vertical wiring (Ref 6) and basket plate (Ref 7).

Nickel-titanium shape memory alloy, as a functional metal material, has many advantages such as shape memory effect, remarkable resistance to wear and corrosion, as well as good histocompatibility. Since its approval into the medical market by the US Food and Drug Administration (FDA) in 1989, NiTi shape memory alloy has been applied extensively. NiTi shape memory alloy is regarded as an important discovery in medical material science and a valuable ‘‘biological memory material.’’ The NiTi hemofilter designed by Simon was demonstrated to be effective following application in 147 patients at 19 cardiovascular centers (Ref 8). Later on, with further studies, shape memory alloys were gradually applied in clinical practices such as the department of stomatology, orthopedics (Ref 9-11).

Internal fixation with a Patellar Shape-Memory Fixator (PSMF) (Chinese Patent: ZL 87 2 11370.1) is an alternative method of treatment that, in contrast with other methods, provides an easy and efficacious method for the preservation of the patella. It was permitted to the clinical application in December 1999 by Chinese State Food and Drug Administration. This study aims to introduce the characteristics of the new internal fixation device for acute comminuted fractures of the inferior pole of the patella. We relate our experience retrospectively analyzing 25 acute comminuted fractures of the inferior

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pole of the patella treated using PSMF from March 2000 to May 2005.

2. Materials and Methods

2.1 Patients

The study population comprised 18 men and 9 women (a total of 27 comminuted fractures of inferior pole of the patella) who underwent our PSMF internal fixation, from March 2000 to May 2005. Their mean age was 39 years (14 to 81). There was an associated transverse fracture of the patella in five patients. The follow-up periods ranged from 14 to 60 (mean 26) months. Two were lost to follow-up.

2.2 Structure and Working Principle of the PSMF Device

The PSMF device (Huzhou Swan Biological Memory Medical Devices Co., Ltd., Zhejiang, China) was designed based on full consideration of the patellar bone anatomy and biomechanics, and manufactured with 2 mm thick Ni-Ti shape memory alloy plate (with Ni content of 50-53%). The device, processed with one-way heat treatment and a reversion temperature (a reversion temperature is the finish temperature of austenitic transformation (Af) and is measured by differential scanning calorimetry (DSC)) of 33 ± 2°C, consisted of two head claws for anchoring the superior patellar pole, three tail claws for embracing the inferior patellar pole and a conjunctive waist as shown in Fig. 1. Before use, the device was immersed in ice-cold water at 0-4°C, in which the alloy had good plasticity to allow extension of the hooks to a length greater than the diameter of the fractured bone to be fixed. The five hooks of PSMF was extended dorsally and temporarily secured on the back of the conjunctive waist. After finishing anatomic reduction and fixation, the PSMF was heated with warm water to 40-50°C to cause recovery of the preset shape, during which process the device produced sufficient force to stabilize the fracture. At normal body temperature, the embracing claws of the implanted PSMF recovered their remembered shape and securely embraced the patella. The compressive forces generated by the embracing claws (head and tail claws) thus allowed 3-dimensional stabilization of the patella.

2.3 Surgical Procedures

Under lumbar or local anesthesia, a longitudinal medial arc incision of approximately 10 cm was made and the PSMF was selected according to the size of the patella (Fig. 1). Manually reducing the step-off of the articular surface of the patella caused by the fracture, and observing the site via C-arm x-ray machine, the fracture was carefully reduced. The fixation of the PSMF has been described above. Fibers of the patellar ligament are pushed apart by the claws that can automatically curve to fit the shape and size of the patella without damaging the articular surface when heated (Fig 1). The soft tissue around the site of the fracture was sutured with 1-0 Vicryl to stabilize the small fragments. Removal of the PSMF was convenient. After routine exposure of the fractured area, ices were applied to the PSMF for 3 min, and PSMF could be easily opened for removal.

2.4 Clinical Outcome Evaluation

Rehabilitation exercise was administered in all the cases. Patients started passive motion exercise on the first postoperative day and were encouraged to perform active flexion exercise of the knee in the prone position. Active extension exercises were allowed after the third postoperative week. The patients started bearing weight on the second postoperative day

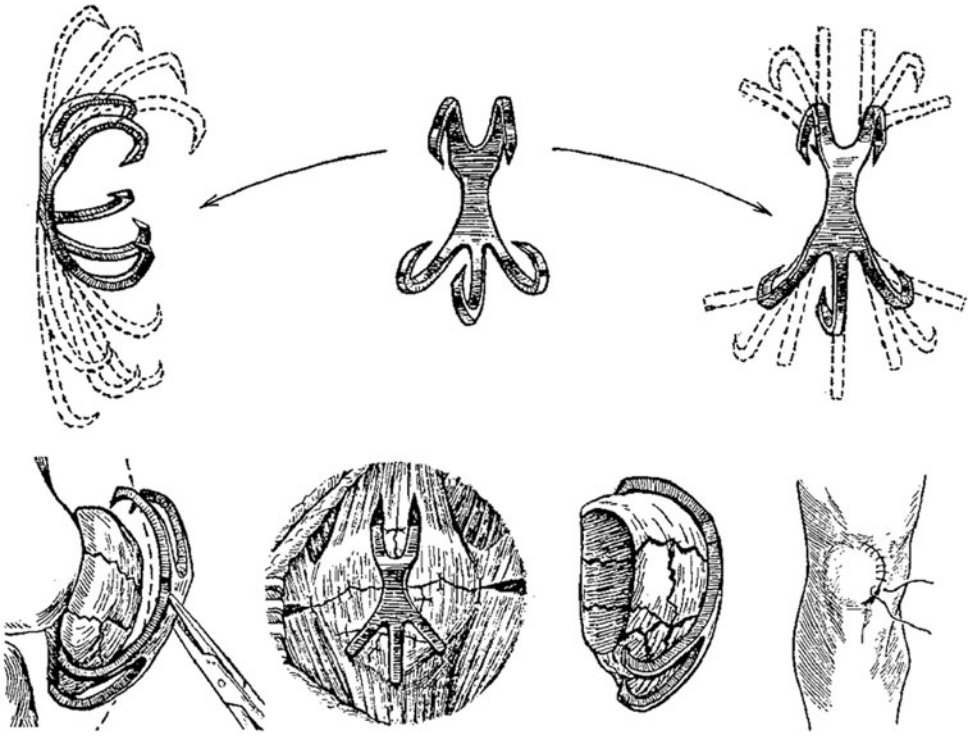

Fig. 1 The schematic diagram of Patellar Shape-Memorial Fixator (PSMF) and its clinical application

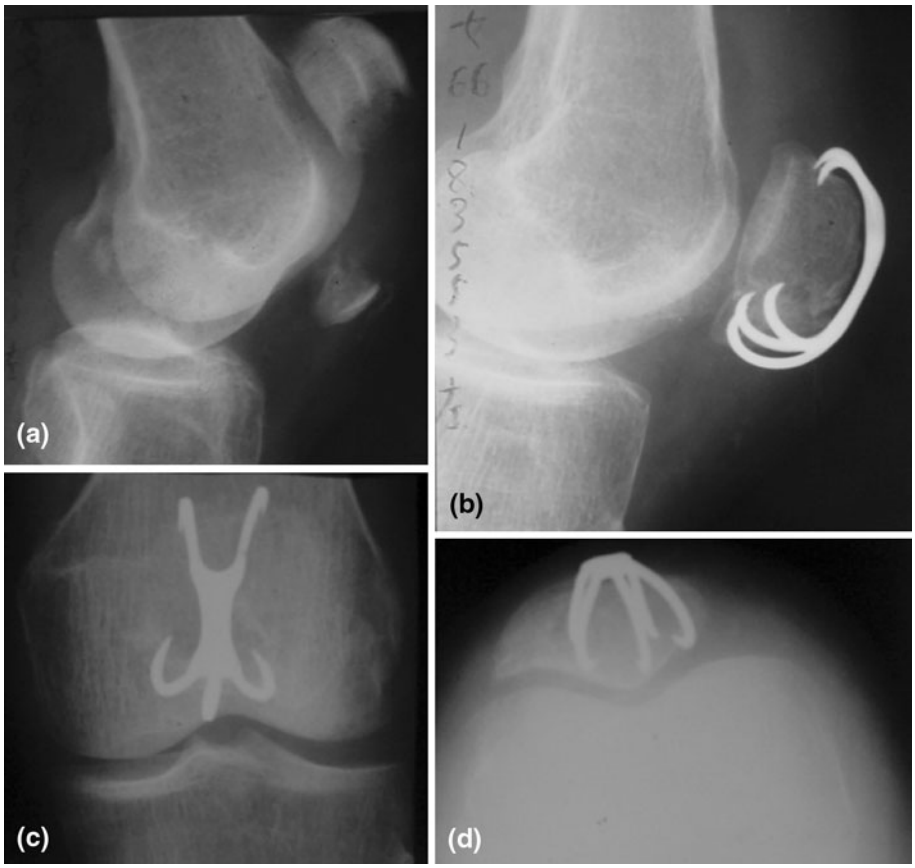

Fig. 2 (a) Lateral radiograph showing displaced and comminuted fractures of the inferior pole. (b), (c), and (d) Anteroposterior, lateral, and skyline radiographs, respectively, showing the comminuted fragments reduced and fixed by the PSMF

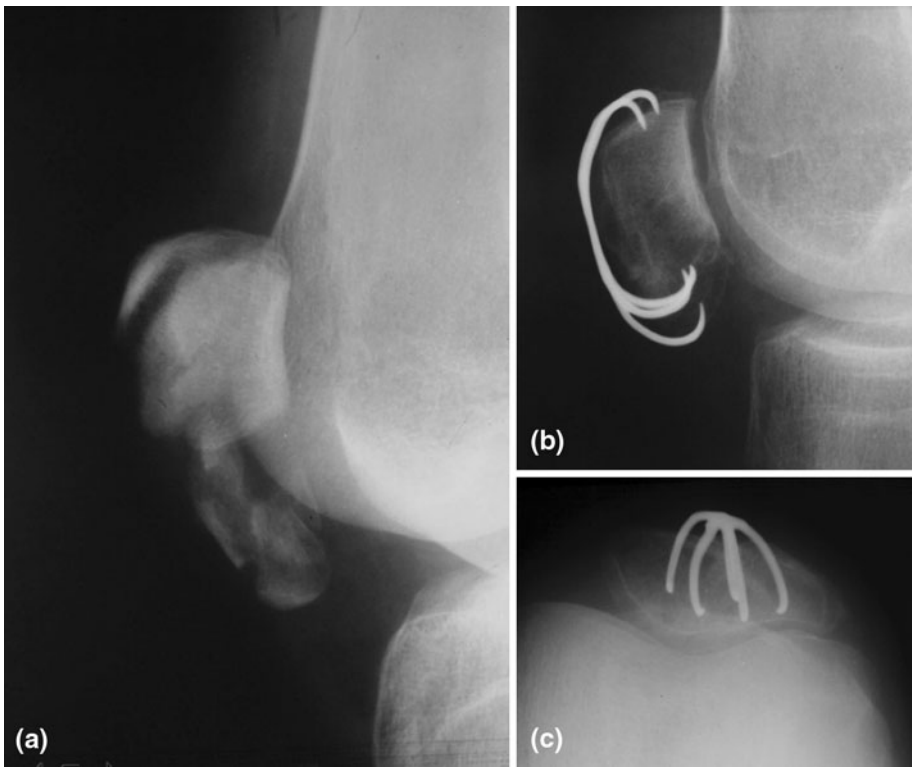

Fig. 3 (a) Lateral radiograph showing displaced and comminuted fractures of the inferior pole. (b) and (c) Lateral and skyline radiographs, respectively, showing the comminuted fragments reduced and fixed by the PSMF

Table 1 Details of the clinical grading scale of Bostman

Variable	Point
Range of movement (ROM)	
Full extension and the ROM >120° or within 10° of the normal side	6
Full extension, movement 90° to 120°	3
Pain	
None or minimal on exertion	6
Moderate on exertion	3
In daily activity	0
Work	
Original job	4
Different job	2
Cannot work	0
Atrophy, difference of circumference of thigh 10 cm proximal to the patella	
<12 mm	4
12 to 25 mm	2
>25 mm	0
Assistance in walking	
None	4
Cane part of the time	2
Cane all the time	0
Effusion	
None	2
Reported to the present	1
Present	0
Giving way	
None	2
Sometimes	1
In daily life	0
Stair-climbing	
Normal	2
Disturbing	1
Disabling	0
Total score	
Excellent	30 to 28
Good	27 to 20
Unsatisfactory	<20

during level walking, and full weight-bearing without limitation was carried out from the third week (Fig. 2, 3).

Radiological union was defined as the obliteration of all fracture lines between the body and the inferior pole in the anteroposterior and lateral views. When there were small separated peripheral fragments, the main fragments were assessed before deciding union. The function of the knee was evaluated using the method described by Bostman, Kiviluoto and Nirhamo (Ref 12) at the latest follow-up (Table 1). The PSMFs were removed in all cases 12 months after surgery.

3. Results

The mean length of operation was 57 min (40 to 72 min). 2 weeks and 1, 2, 3, 6, 12, 24, and 36 months after PSMF implantation, respectively, radiographs of the injured knee were taken. The fracture healed at a mean of 6 weeks (5 to 7 weeks). No delayed union, nonunion, and infection was seen. The PSMF were removed intact. The mean grading at the final follow-up was 29.5 points (27 to 30 points) according to Bostman score (Ref 12), with no observable restriction of movement. Details of the patients were shown in Table 2.

Table 2 Details of the patients

Case	Age, years	Gender	Operation time, minutes	Time to union, weeks	Follow-up, months	Results
1	25	F	44	6	48	30
2	21	M	60	7	24	30
3	35	M	66	7	18	30
4	42	F	40	5	18	28
5	63	M	70	7	14	28
6	14	M	56	5	24	30
7	72	M	46	7	24	30
8	18	M	48	7	15	30
9	22	F	50	5	48	30
10	36	M	68	6	24	30
11	54	M	60	5	36	28
12	69	F	72	7	60	30
13	47	M	60	7	18	29
14	29	M	70	5	24	30
15	58	M	56	5	24	30
16	81	F	48	6	18	30
17	33	F	58	6	18	29
18	36	M	64	6	24	30
19	22	M	62	5	15	29
20	25	M	50	6	36	30
21	41	M	56	6	36	29
22	57	F	68	8	24	30
23	55	M	62	7	24	27
24	28	M	60	7	18	30
25	19	F	50	5	18	30
26	22	M	42		Lost	
27	29	F	52		Lost	

The results are based on the Bostman score at the latest follow-up

As shown in Figure 4, one woman aged 57 years fell 1 week after operation and the PSMF displaced. We repeated the procedure again and obtained bone union at 8 weeks. Breakage of the PSMF was not seen.

4. Discussion

Comminuted and displaced fractures of the inferior pole of the patella are difficult to reduce and fix firmly enough to allow early movement of the knee. The inherent weakness of the bone and the size of the fragments prevent firm stabilization by ordinary wiring or screws. Augmentation with patellotibial cerclage or figure-of-eight wire often results in multiple segmentation of the wire (Ref 13) and may cause discomfort at the anterior aspect of the knee because of the wire loop during flexion and extension. Tightening of the cerclage wire often decreases the length of the patellar tendon and may injure the soft tissue in front of the tendon and the tibial tuberosity causing scarring and subsequent patellar baja. A low-lying patella disrupts the normal physiology of the patellofemoral joint. Our new technique allows restoration of the length of the patella and minimal injury to the tendon.

The intraosseous bone wire suture was first introduced by Labitzke (Ref 14). He constructed oblique bone tunnels in each fragment of a mid-patellar fracture and fixed them by wire loops. Because the fragments of the inferior pole are often too small to make bone tunnels, Yang et al. (Ref 6)

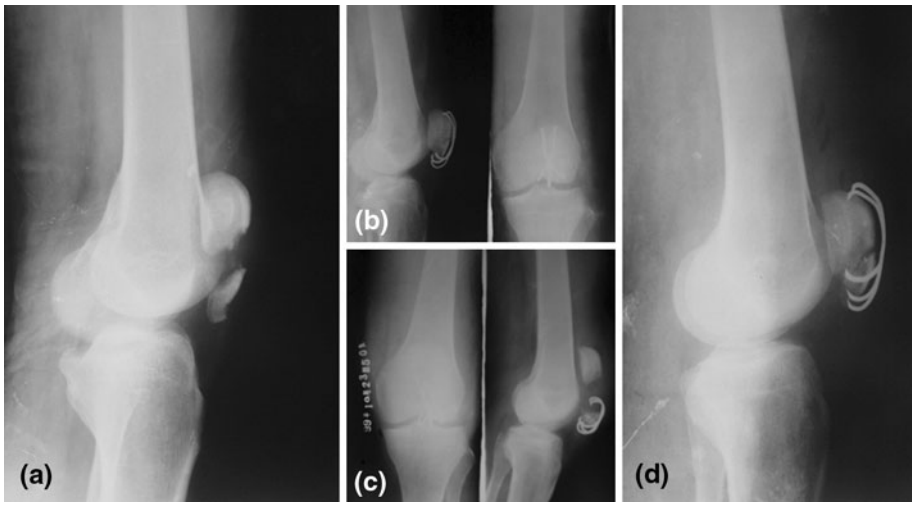

Fig. 4 Lateral and anteroposterior radiographs (b) showing the comminuted and fragments (a) reduced and fixed by the Patellar Shape-Memory Fixator. The patient fell 4 weeks after operation and the PSMF weighed anchor fell loose (c). We repeated the procedure again (d) and obtained union at 8 weeks

modified this method and encircled the patella with separate vertically orientated wires. They reported this method allows the anterior and posterior fragments to be aligned by tightening the wires.

Since partial patellectomy is a final option in the treatment of comminuted fractures of the inferior pole of the patella, we performed open reduction and internal fixation to attempt to retain the inferior pole in every case. Union of the extra-articular fracture may maintain the length of the patella and decrease the risk of patella baja, without increasing the risk of post-traumatic arthritis.

Due to the nature of shape memory alloys, the manipulation and implantation of PSMF must proceed with the following precautions. Before implantation, the PSMF device is immersed in ice-cold water at 0-4°C, and after reduction of the fracture, PSMF is implanted and warmed with water of 40-50°C. Most preferentially, fixation of the fracture with PSMF is performed in a single attempt, and repeated cooling and warming of the device, once implanted, must be totally avoided. In all the subsequent procedures after PSMF implantation, the device has to be washed, when necessary, with warm water above 40°C. Ice-cold water or water below 40°C should never be used for washing the implanted device, or the fixation performance of the device can be lowered.

Internal fixation with the PSMF is stable enough to allow for mobilization and weight-bearing on the first postoperative day. The patient is allowed to bear full weight on the injured extremity during level walking. For walking uphill or downhill, crutches should be used to prevent loading of the flexed knee joint for 6 weeks.

In conclusion, reconstruction of fractures of the inferior pole of the patella via the PSMF can be expected to produce good results. The advantages of PSMF in the treatment of fractures, as we presume, lie mainly in the continuous compression of the fracture and stable biomechanical environment (Ref 15, 16). The above-mentioned features enable the PSMF not only to fix the fractures anatomically position and guarantee early movement of the patient, but also to reach bone union 6 weeks postoperatively, allowing satisfactory movement and weight loading. Based on the encouraging results of our clinical trials, we believe that PSMF can serve as an effective means for management of the inferior pole of the patella.

Conflict of interest

All authors did not receive any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. (Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.)

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