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Original Article

Nickel-titanium shape memory alloy embracing fixator benefits the determination of the implantation angle of prosthesis stem in tumor-type artificial joint replacement

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Abstract: Background: Hip tumors often require tumor-type artificial joint replacement. The selection of the prosthesis stem (hip tumor prosthesis stem) implantation angle during the operation is important to prevent the complication of postoperative prosthesis dislocation. The aim of this study was to evaluate the role of a nickel-titanium (Ni-Ti) shape memory alloy embracing fixator in determination of the implantation angle of a hip tumor prosthesis stem and analyze its efficacy. Methods: 36 patients with proximal femur tumor were treated with extended tumor resection and prosthetic replacement. 14 patients received prosthetic replacements with the embracing fixators fixing between the junction of the prosthesis stem and the femur temporarily, while the other 22 patients received the same replacements but without the fixators. The two groups were compared regarding occurrence of complications, limb function, and active hip range of motion (ROM). Results: There was no case of hip dislocation in the group that received prosthetic replacements with the use of embracing fixators. Occurrence of deep infection had no difference between the two groups. However, better limb function and higher active (ROM) on abduction or flexion were observed in the group using embracing fixators. Conclusion: Ni-Ti shape memory alloy embracing fixator plays a key role in assisting the accurate implantation angle of the prosthesis stem in prosthetic replacement. The prosthesis stem can be adjusted to the optimal angle with the help of the embracing fixator. Patients have a lower risk of dislocation, better limb function, and higher active hip ROM.

Keywords: Ni-Ti shape memory alloy, hip tumor prosthesis stem, implantation angle

Introduction

The proximal femur is the most frequent region for primary and metastatic bone tumors. The invasion of the tumor with a concomitant pathological fracture cause great suffering and seriously affect quality of life. In the past, amputation has been the main treatment for bone tumors, which causes severe physical and psychological trauma [1, 2]. With the continuous improvement of surgical technique, imaging technique, and pathological diagnosis, prosthetic replacement after tumor resection has become the preferred treatment for proximal femoral tumor on the basis of chemotherapy, radiotherapy, and immunotherapy [3, 4]. The prosthetic replacement after tumor resection can preserve the patient's limb, relieve pain, prompt early recovery of limb function, and improve the patient's life quality significantly [5-7].

Tumor-type artificial joint replacement, also called prosthetic replacement following tumor resection, is one of the most widely used and effective methods in limb salvage surgery [8]. One must use a prosthesis stem to replace the violated femur that was resected during the operation. This prosthesis stem is also called a hip tumor prosthesis stem. The key point of the prosthetic replacement following tumor resection is seeking balance between limb function, the stability of the prosthesis and the complete clearance of the tumor. However, in order to clear the involved site completely, surgeons are compelled to cut off the femur at a lower plane, especially the greater trochanter and lesser trochanter that are the important anatomic landmarks for surgery, resulting in the loss of the marker for determining the implantation angle of the prosthesis stem, which causes great difficulties in determining the accurate implantation angle of the prosthesis stem after osteotomy [9]. Moreover, the inappropriate implantation angle often leads the high incidence of hip dislocation, which is a common complication after prosthetic replacement in previous reports. In general, the implantation of the prosthesis stem mainly depends on the experience of the surgeon, and the angle must be adjusted before the bone cement is completely shaped and solidified. Therefore, there is an urgent need to temporarily fix the prosthesis stem so that the surgeon can adjust the angle after implantation.

Nickel-titanium (Ni-Ti) shape-memory alloys first appeared in the 1960s, are characterized by smart mechanical properties, and have been gaining increasing importance in diagnostic applications and minimal invasive surgery, such as the neurosurgical [10], cardiovascular [11], and orthodontic fields [12]. With its shape-memory effect, corrosion resistance, super-elasticity, and favorable biocompatibility, nitinol has been used for internal fixation since the 1990s [13-17]. Our group designed a novel Ni-Ti shape memory alloy embracing fixator for temporary fixation in the implantation of the prosthesis stem, which has achieved favorable outcomes in clinical practice. However, the effect of embracing fixator on postoperative complications and function of patients is uncertain. This study intended to explore the role of Ni-Ti shape memory alloy embracing fixator in determining the implantation angle of hip tumor prosthesis stem and its efficacy by comparing with traditional technique.

Materials and methods

Study design and patients

In this retrospective observational cohort study, the medical records and radiographs of patients who presented with hip bone tumor were retrieved from May 2014 to December 2019 in our department. The inclusion criteria were: (1) Proximal femur tumor treated with tumor resection and prosthetic replacement; (2) Surgeries were performed by one senior orthopaedic surgeon. The exclusion criteria were: (1) pre-existing medical condition(s) that severely limited physical or mental health; (2) lost to follow-up or with incomplete medical records; (3) patients referred after failure of their primary surgery at other hospitals; (4) patients who had had other hip surgery. Out of the initial 113 hip bone tumor that were screened during the period, totally 36 patients, including 22 males and 14 females, aged from 12-72 years old were enrolled for the study. Their pathologic diagnoses were as follows: 4 cases of osteosarcoma, 4 cases of chondrosarcoma, 20 cases of bone metastasis, and 8 cases of giant cell tumor of bone. Their disease durations ranged from 12 months to 2 years (mean duration 0.8 years).

The 36 patients were classified into two groups: 14 had received prosthetic replacements with embracing fixators fixing at the junction of the prosthesis stem and the femur temporarily after proximal femur tumor resection, and 22 had received the same replacements but without the use of embracing fixator. Results were compared between the groups to assess whether the application of the embracing fixator would reduce the incidence of hip dislocation and provide better post-operational outcomes. The study was approved by the Committee on Ethics of Biomedicine Research of Changhai Hospital.

Structure and working principles of the Ni-Ti shape memory alloy embracing fixator

The Ni-Ti shape memory alloy embracing fixator device (Huzhou Swan Biological Memory Medical Devices Co., Ltd., Zhejiang, China) was designed based on the anatomical structure of femoral shaft and manufactured with 2 mm-thick Ti-Ni shape memory alloy. The embracing fixator comprised 50%-53% nickel, with the remainder comprising titanium. The device had six pairs compression arms that were connected to the waist. The embracing fixator was malleable at lower temperatures (martensite phase), thus, it was placed in 0-4°C ice water for cooling before implantation. When the fixation was completed, 40°C-50°C water was used to warm the device to stimulate its memory mechanical memory functions (austenite phase), providing a continuous lateral compressive force for temporary fixation. Brief illustrations of the embracing fixator application process are shown in **Figure 1**.

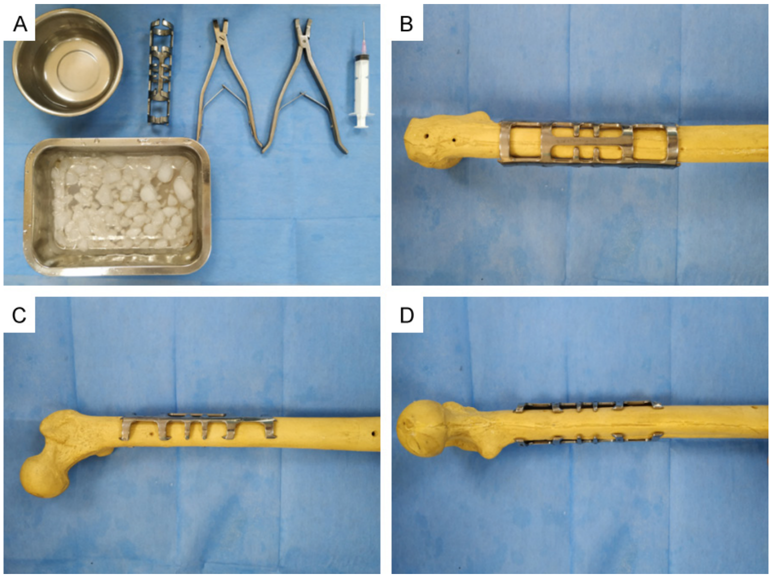

Figure 1. Illustrations of the embracing fixator application process. A. Supporting equipment used by the embracing fixator. B-D. Triangular view of the femur after the embracing fixator is implanted.

Surgical methods

Preoperative MRI and PET-CT were performed to assess the extent of tumor invasion and provide basis for determining the scope of resection. All operations were performed using posterolateral hip incision. The piriform muscle and the externally rotating muscle were cut off. The capsule of the hip joint was then cut open with an H-shaped incision (It was resected if it was tumor-invaded). The surgical margin of osteotomy was 2-3 cm distal to the invasion extent of the tumor, in accordance with preoperative MRI imaging. The resection extent of soft tissue was acme distal to the reactive zone, and the extent of resection was determined again according to the result of intraoperative frozen section. The acetabular cup was biologically fixed. According to the preoperative design, we selected the appropriate femoral stem and femoral head. After implanting the prosthesis stem, a Ni-Ti memory alloy embracing fixator was used temporarily to fix between the junction of the prosthesis stem and the femur so that the fixator could keep the prosthesis stem stable. Then the prosthesis joint was reduced and moved in all directions to assess its stability. If the prosthesis joint was easily dislocated, the implantation angle of the prosthesis stem was readjusted. When the prosthesis stem was adjusted to an optimal angle at which the prosthesis joint was the most stable and flexible, the implantation angle of the prosthesis stem was marked on the femur. Then the embracing fixator and prosthesis stem were removed. Bone cement was injected into the pulp cavity, and the prosthesis stem was inserted according to the marked angle. The prosthesis joint was reduced after coagulation of the bone cement. The prosthesis joint was moved in all directions again to observe prosthesis stability. Then the muscles around the hip joint were reconstructed in sequence before closing the incision. The external rotation muscles and the piriform muscle were fixed on the greater trochanter ring of the prosthesis, and the iliopsoas muscle was fixed on the lesser trochanter ring (**Figure 2**). For detailed surgical procedures please refer to the sketch map of the application of embracing fixator in the replacement of proximal femur tumor prosthesis (**Figure 3**). Preoperative MRI of proximal femur tumor, the resected tumor part, and postoperative imaging are displayed (**Figure 4**).

Postoperative management

Patients were placed in the supine position after surgery and triangular pillows were placed between the legs. The patients were told to practice muscle contraction and relaxation, as well as joint flexion and extension, turn over in bed, and take deep breaths. Low-molecular-weight heparin was subcutaneously injected in all patients for 35 days to prevent thrombosis. The drainage tubes were removed in 2 to 3 days and the sutures were removed 10 to 12 days after the operation. The patients began to practice sitting up, sitting at the bedside, and standing on the floor 3 weeks postoperatively, and began to practice walking with walking aid instruments 4 weeks postoperatively. Radiotherapy and chemotherapy were also administered when needed. Professional physical therapy was suggested for all patients after being

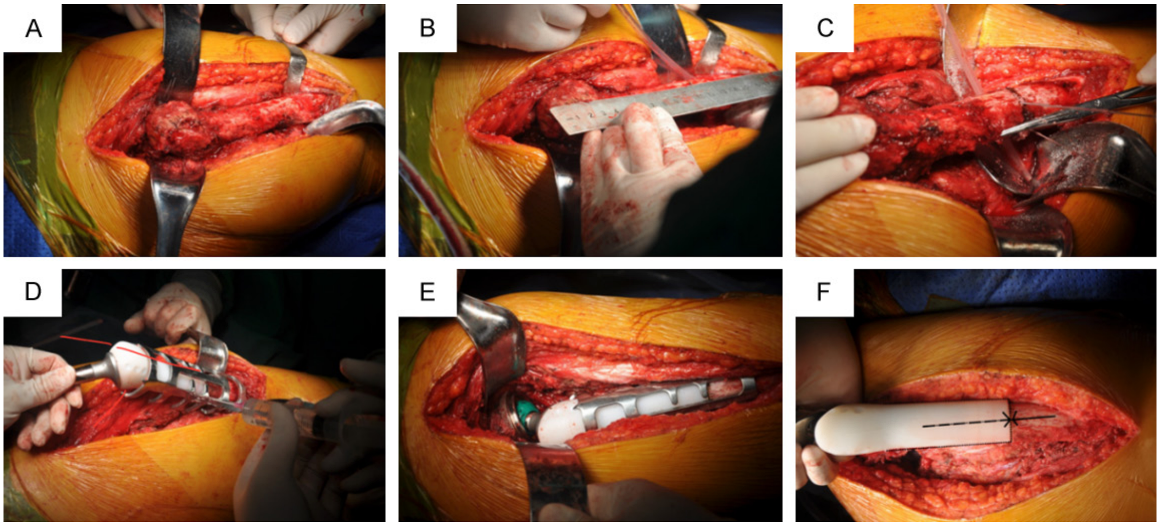

Figure 2. Application of nickel-titanium shape memory alloy embracing fixator in the replacement of tumor prosthesis. A. The tumor of the proximal femur was exposed using the posterolateral hip incision. B. The extent of tumor invasion and osteotomy plane were determined according to the preoperative MRI of the tumor. C. The femur was cut at the marked plane of the osteotomy using a wire saw. D. The nickel titanium memory alloy embracing fixator fixed between the junction of the prosthesis stem and femur. E. The prosthesis joint was reduced and moved in all directions to assess its stability. F. After ensuring the stability of the joint and the best matching of the femoral head and the acetabular cup, the implantation angle of the prosthesis stem relative to the femur was marked. Bone cement was then injected into the femoral medullary cavity and the prosthesis stem was inserted according to the angle marked before. After coagulation of the bone cement, the prosthesis joint was reduced.

discharged. Post-operational follow-ups were done every three months for every patient, including clinical examination and imaging assessment.

Clinical outcomes evaluation

Follow-up and radiographic assessments were routinely performed at 1, 3, and 6 months after prosthesis stem implantation and long-term postoperative review was conducted for 12-18 months once. The average follow-up was 14.0 (range, 12-24) months according to our team experience. Complications including hip dislocation, infection, aseptic loosening, tumor progression, and procedure-related minor complications were counted and compared between the two groups. Regarding functional evaluation, the Musculoskeletal Tumor Society Scores (MSTS), Harris hip score (HHS), and range of motion (ROM) were also documented in the previous records. The MSTS score [18, 19] (Musculoskeletal Tumour Society Score) is a doctor-based questionnaire which evaluates the functional condition after tumor treatment. This examination assesses six criteria. For the lower limb the components are pain (evaluated by VAS), function, emotional acceptance of the treatment outcome, walking, gait and need for walking aids. Among all criteria, an assessment is made from bad to very good with parallel awarding of points (0 to 5). Harris hip score is also a common functional evaluation that has been used in proximal femoral replacement surgery post-operative assessment [20]. Range of motion (ROM) included flexion, abduction, and external rotation, and was evaluated after the replacement.

In the study, hip dislocation was the primary outcome, and occurrence of deep infection, limb function (MSTS93 scores; HHS scores) and higher active ROM on abduction or flexion were the secondary outcomes.

Statistical analysis

Chi square test was used for comparison of the rate. The independent-sample t-test was used to determine the statistical significance of differences in measured data between the two groups. We used the Chi-square test for analysis of enumerated data. $P<0.05$ was considered to be significant.

Results

All 36 patients received prosthetic replacements with or without the use of embracing fix-

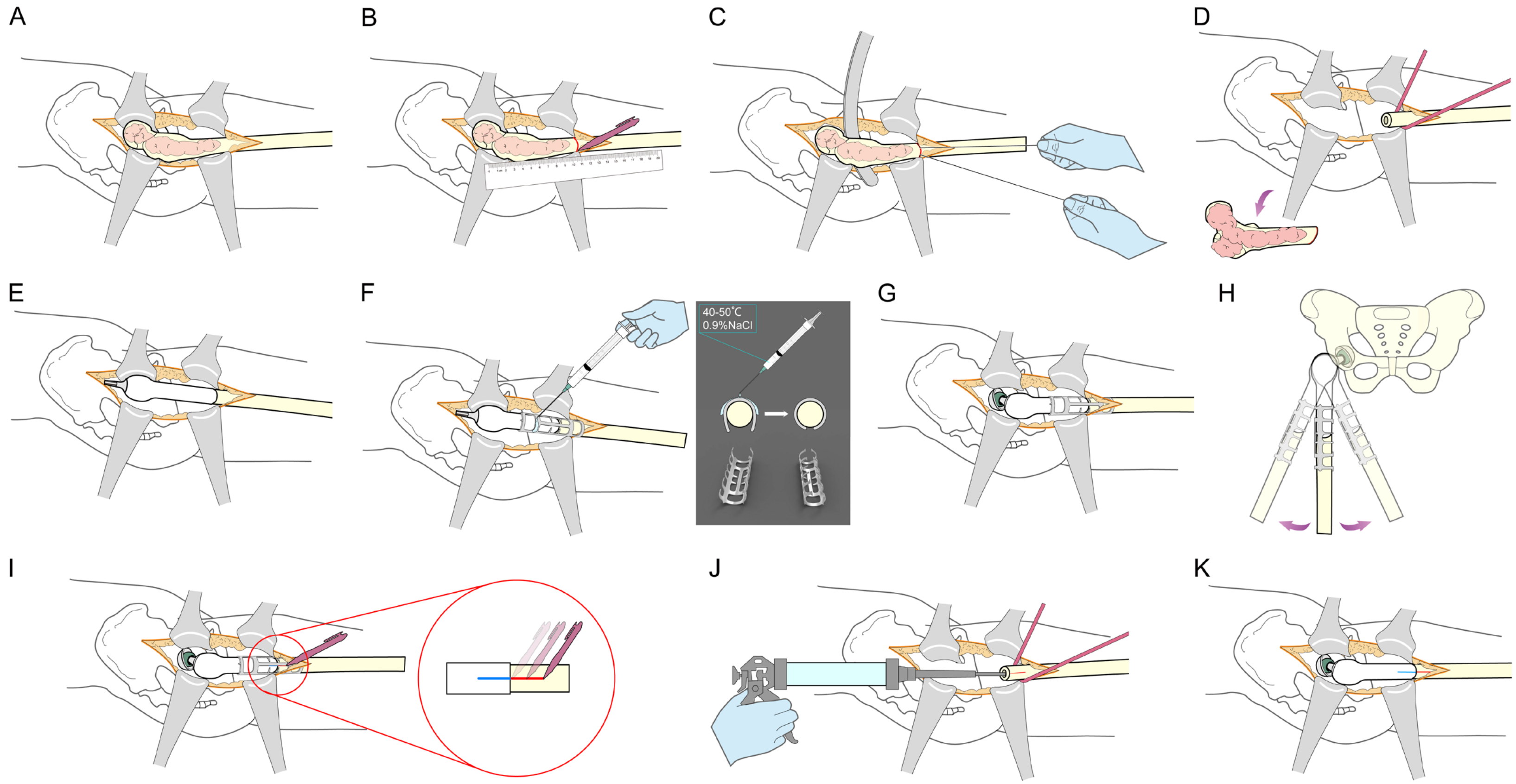

Figure 3. Sketch map of the application of nickel-titanium shape memory alloy embracing fixator in the replacement of proximal femur tumor prosthesis. A. The piriform muscle and the externally rotating muscle were cut off. B. The margin of the osteotomy was marked. C. The surgical margin of osteotomy was 2-3 cm distal to the invasion extent of the tumor. D. The extent of soft tissue was resected according to the intraoperative frozen section. E. The implant of the prosthesis stem. F. Ni-Ti memory alloy embracing fixator was fixed temporarily. G. The acetabular cup was biologically fixed. H. The prosthesis joint was reduced and moved in all directions to evaluate its stability. I. The implantation angle of the prosthesis stem was marked on the femur. J. Bone cement was injected into the pulp cavity. K. The prosthesis stem was inserted according to the marked angle.

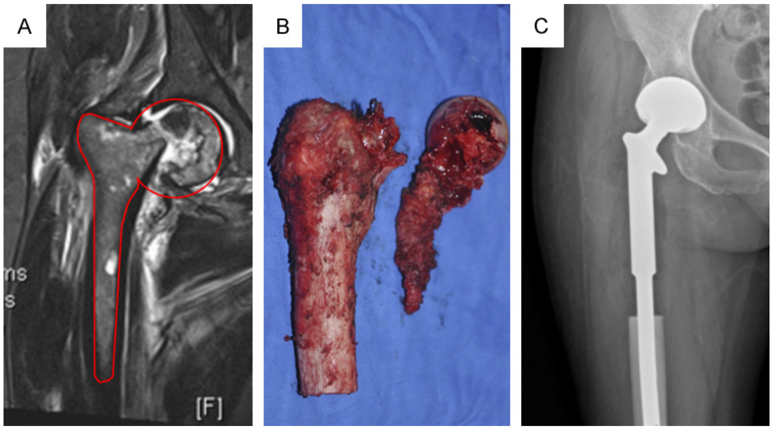

Figure 4. A. Preoperative MRI shows proximal femur involvement by the tumor. B. The tumor in the proximal femur was resected. C. Postoperative radiography data.

ators survived the perioperative period. The two patient groups presented no significant difference in age (P=0.399), length of femur resection (P=0.949), operation time (P=0.664), blood loss (P=0.765) and chemotherapy (P=0.810) (**Table 1**).

Complication occurrence

The group that used embracing fixators during prosthetic replacements had lower incidence of hip dislocation than the group that did not use embracing fixators. The incidence of hip dislocation in the group with the use of embracing fixators was 0% (0/14), compared to 27.3% (6/22) in the group without the use of embracing fixators (P=0.032). The incidence of infection exhibited no significant difference between the 2 groups: 0% (0/14) and 4.5% (1/22) (P=0.429). The incidence of aseptic loosening, and tumor progression showed no difference between groups (**Table 2**). Procedure-related minor complications also included 1 case of leg-length discrepancy in the group with the use of embracing fixator compared to 3 cases in the group that did not use embracing fixator (no difference), and 1 case of deep vein thrombosis in the no embracing fixator group (**Table 2**).

Functional results and active hip ROM

Patients who received prosthetic replacements with the use of embracing fixators acquired better functional scores than those without the use of embracing fixators. The MSTS93 scores were significantly higher in patients with the use of embracing fixators (24.00±0.432; 80.0%) than in those without the use of embracing fixators (21.86±0.457; 72.9%) (P=0.003). The two groups had no significant difference regarding pain (P=0.698), emotional acceptance (P=0.452), support (P=0.564), or walking (P=0.896). Patients who received prosthetic replacements with the use of embracing fixators had better performance in function and gait (P=0.003). The average total HHS scores for patients treated with and without the use of embracing fixator were 85.71±1.563 and 79.18±1.661, respectively (P=0.011). The two groups had a significant difference in function scores (38.29±0.980 vs. 32.95±1.062, P=0.002). The average scores for pain (P=0.926) and deformity (P=0.241) did not differ between the two groups. Patients with the use of embracing fixators had better ROM of flexion (89.29±3.004 vs. 81.14±2.547, P=0.049) and abduction (39.64±1.432 vs. 32.27±1.385, P=0.001) than patients without the use of embracing fixators. The average ROM of external rotation did not differ between the two groups (28.57±1.848 vs. 26.59±1.872, P=0.480) (**Table 3**).

Discussion

The proximal femur is one of the most frequent regions for primary and metastatic bone tumors [21, 22]. Prosthetic replacement after tumor resection has become the gold standard of treatment. However, due to tumor invasion and severe damage of soft tissue around the bone and joint caused by the surgery, postoperative joint stability is affected, and joint dislocation is more likely to occur than with common hip replacement [23-25]. In previous studies, hip joint instability (hip dislocation) resulted in most cases of failure of proximal femur prosthetic replacement, and limb function after surgery was unsatisfactory [26]. Puchner et al. reported that the general rate of dislocation following proximal femoral prosthetic replacement was 13% after an average period of 7±8 months (range from 0.3 to 33 months) after

Table 1. Comparative features, diagnoses, and complications between groups with and without the use of embracing fixator

	With embracing fixator	Without embracing fixator	*P* Value	95% CI
Age (y)	70.07±1.832	71.95±1.320	0.399	-6.370 to 2.603
Gender				
Men	8	14		
Women	6	8		
Length of femoral resection (cm)	14.21±0.921	14.14±0.774	0.949	-2.397 to 2.553
Operative time (min)	154.8±5.864	151.6±4.463	0.664	-11.63 to 18.02
Blood loss (mL)	841.3±53.70	819.0±48.01	0.765	-128.1 to 172.6
Chemotherapy			0.810	0.1527 to 4.349
Yes	11	18		
No	3	4		
Dislocation	0	6	0.032	0.0045 to 1.693
Infection	0	1	0.419	0.0188 to 13
Diagnose			0.059	0.1569 to 1.045
Osteosarcoma	2	2		
Chondrosarcoma	1	3		
bone metastases	8	12		
Giant cell tumor	3	5		

Table 2. Mode of failure of the prosthetic replacements with or without the use of embracing fixator

Complication	With embracing fixator (n=14)	Without embracing fixator (n=22)	Total Number of Patients (n=36)	X^2	*P*
Major complication				6.476	0.039
Dislocation	0	6	6		
Aseptic loosening	0	0	0		
Infection	0	1	1		
Tumor progression	2	3	5		
Minor complication				3.955	0.856
Leg-length discrepancy	1	3	4		
Deep vein thrombosis	0	1	1		

surgery. From 1982 to 1986 the dislocation rate was about 33% and slowly dropped to 9% in the following two decades (1987-2008) [23]. Postoperative dislocation of the hip joint causes pain to patients, increases treatment cost, and brings difficulties for doctors. Therefore, it is of great importance to determine the accurate implantation angle of the prosthesis stem during the procedure [27, 28].

The main factors related to joint stability after replacement include the accurate implantation angle of the prosthesis stem and the reconstruction of the soft tissue around the joint [29]. In order to remove tumor tissue as thoroughly as possible, prosthetic replacement after tumor resection will cause more serious damage to the soft tissue around the joint than common joint replacement. Moreover, the soft tissue around the joint might not be completely and effectively reconstructed during surgery, which leads to postoperative joint dislocation. Under these circumstances, accurate implantation angle of the prosthesis stem appears to be particularly important, which requires the surgeon to ensure that the implantation angles of the acetabular cup and prosthesis stem are appropriate and accurate. To ascertain the implantation angle of the acetabular cup, the surgeons could refer to the normal acetabular angle, because typically the proximal tumor of the femur does not invade the acetabulum. There have been many studies exploring methods for positioning the acetabular cup, includ-

Table 3. Functional outcome scores and ROM in patients with and without the use of embracing fixator

	With embracing fixator	Without embracing fixator	*P* Value	95% CI
MSTS (points [%])	24.00±0.432 (80.0%)	21.86±0.457 (72.9%)	0.003	0.774 to 3.500
Pain	4.143±0.177	4.027±0.131	0.698	-0.524 to 0.355
Function	4.429±0.173	3.627±0.135	0.003	0.259 to 1.144
Emotional acceptance	3.714±0.163	3.545±0.143	0.452	-0.282 to 0.620
Support	3.929±0.165	3.773±0.185	0.564	-0.388 to 0.700
Walking	3.714±0.194	3.682±0.153	0.896	-0.468 to 0.533
Gait	4.071±0.165	3.258±0.153	0.003	0.281 to 1.226
HHS	85.71±1.563	79.18±1.661	0.011	1.587 to 11.48
Pain	39.57±1.806	39.36±1.344	0.926	-4.299 to 4.714
Function	38.29±0.980	32.95±1.062	0.002	2.186 to 8.476
Deformity	3.786±0.114	3.545±0.143	0.241	-0.170 to 0.650
Range of motion (°)	4.071±0.195	3.364±0.180	0.015	0.148 to 1.267
Flexion	89.29±3.004	81.14±2.547	0.049	0.028 to 16.27
Abduction	39.64±1.432	32.27±1.385	0.001	3.138 to 11.60
External rotation	28.57±1.848	26.59±1.872	0.480	-3.664 to 7.625

MSTS: Musculoskeletal Tumor Society Scores; HHS: Harris hip scores

ing the use of anatomical markers, pre-evaluation with CT scans, and three-dimensional directional monitoring [29]. However, there are few reports about the detailed procedure to determine the correct implantation angle of the prosthesis stem.

Because of tumor invasion of the proximal femur, it is often necessary to cut off the greater trochanter and lesser trochanter during the osteotomy, thus losing the anatomic markers as a reference for implanting the prosthesis stem [30]. Surgeons usually make marks on the junction before resecting the involved bone, and make marks on the corresponding part of the prosthesis stem to offer a reference when implanting the prosthesis stem [31, 32]. After implanting the prosthesis stem, it will be fixed with bone cement. Once the prosthesis has been fixed, even if the implantation angle of the prosthesis stem is not satisfactory, the surgeon cannot readjust it, resulting in the prosthetic head and acetabular cup not being optimally matched, leading to a greater tendency towards hip joint dislocation [33, 34]. Therefore, temporary fixation before using bone cement during the surgery is convenient for surgeons.

In this study, a novel embracing fixator made of the Ni-Ti shape memory alloy was used to help us determine the implantation angle of the prosthesis stem. Ni-Ti alloy is a shape memory alloy with high strength, flexible plasticity, and good biocompatibility that can automatically restore its original shape at a specific temperature [35]. Thus, the embracing fixator can be artificially spread to permit a surgeon to adjust the prosthesis stem as required. After heating to 40°C~50°C (by lavaging warmed normal saline), the embracing fixator can recover the original memorized shape and contract to grasp tightly the prosthesis and the distal bone together. During the operation, we did not use bone cement to fix it after implanting the prosthesis stem immediately. Instead, we temporarily used the Ni-Ti shape memory alloy embracing fixator to fix between the junction of the prosthesis stem and the femur to keep the prosthesis stem stable. Then the hip joint was reduced by temporary fixation and moved in all directions to assess the stability of the joint. If the surgeon feels that the implantation angle of the prosthesis stem was not ideal, he can remove the embracing fixator easily and readjust the implantation angle of the prosthesis stem. When the prosthesis stem is at the optimal implantation angle, the surgeon marks the angle of the prosthesis stem relative to the femur and then fixed the prosthesis stem with bone cement. In this way, the implantation angle of the prosthesis stem can be repeatedly tested to determine the best implantation angle of the prosthesis stem, which greatly reduces the incidence of postoperative dislocation.

In our study, it was found that patients who received prosthetic replacements with the use of embracing fixators had a lower rate of hip dislocation, better limb function, and greater range of active hip movement on flexion and abduction than those without the use of embracing fixators. The most significant complication is dislocation. Puchner et al. reported in his study that 8%-33% of patients treated without the embracing fixators suffered dislocation [23], which is similar to our study finding that 6 (27.3%) patients experienced dislocation in the control group. Often, postoperative dislocations are caused by poor placement of a prosthesis. In our research, we inserted the prosthesis stem according to our experience and then used the embracing fixator to fix between the junctional part of the prosthesis stem and the femur to keep the prosthesis stem stable. Then the joint was reduced and moved in multiple directions to test the stability of the joint. If dislocation occurred at a certain angle, we could remove the embracing fixator and readjust the implantation angle of the prosthesis stem until dislocation did not occur at any angle. The use of embracing fixator allows surgeons to adjust the implantation angle of the prosthesis stem repeatedly until the satisfactory angle is reached, so that the prosthesis can be optimally matched. This method avoids the disadvantage of traditional methods in determining the implantation angle of prosthesis stem only one time, which can not be adjusted even if it is not satisfied. This is very helpful for preventing post-operational dislocation. In addition, the best matching of the prosthesis can effectively accelerate the recovery of limb function and ROM of hip joint after operation [36, 37]. In this study, the MSTS and HHS scores for the patients with the use of embracing fixators were better than those without the use of embracing fixators ($P<0.05$). This may be attributed to the accurate placement of the prosthesis and the absence of post-operational dislocation, which are very important for the rehabilitation of limb function and hip joint movement.

Our study had some limitations because it was a retrospective study. First, low morbidity resulted in a small sample size, though we collected data covering a 5-year span. Second, during the 5 years of the study, the progress in surgical technique and prosthesis design might have also played a role in lowering the dislocation rate and improving limb function. Third, due to the long-time span, the study was not registered with a public trials registry initially which may lead to the loss of patient follow-up. These biases may have affected our interpretation of the results.

Conclusion

Ni-Ti shape memory alloy embracing fixator plays a key role in determining the accurate implantation angle of the prosthesis stem in the prosthetic replacement following the proximal femur bone tumor resection. The implantation angle of the prosthesis stem can be adjusted repeatedly with the aid of the Ni-Ti embracing fixator, so that the prosthesis stem can be implanted at an optimal angle and the prosthetic head and the acetabular cup can be optimally matched. This technique can prevent hip dislocation effectively, with better limb function recovery and fewer complications.

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Disclosure of conflict of interest

None.

Abbreviations

NiTi, nickel-titanium; ROM, Range of motion; MSTS, Musculoskeletal Tumor Society Scores; HHS, Harris hip scores; VAS, Visual Analogue Scale/Score.

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