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Clinical and radiological results of cemented proximal femoral nails

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Abstract

Aim: Osteoporotic interthoracanteric fractures are an important health problem affecting the elderly population. Cement augmentation is a modification that has been applied with increasing frequency in recent years. In our study, we aimed to retrospectively analyze the clinical and functional results of proximal femoral nails (PFN) with cemented augmentation.

Materials and Methods: Sixty-five patients who met the inclusion criteria were included in the study. PN1 PFNA Nail - Tasarım Medikal ® - İstanbul nails were applied to all patients. Information such as spreading area of cement, closest distance of cement to cartilage, number of additional fluoroscopy for cementing procedure, amount of cement were collected. Reductions were evaluated according to the Modified Baumgaertner Criteria and rehabilitation protocols were applied. Pain of the patients was evaluated with the vas score, and hip functionality with the Harris score. Patients with a minimum follow-up of 2 years were included in the study.

Results: The amount of cement placed in the femoral heads of 37 patients with Singh index values of 1 and 2 was found to be 2.9±0.5 ml, significantly higher than the amount of cement placed in the femoral head (2.1±0.3 ml) of patients with Singh index 3, 4, 5 ($p < 0.001$). After the PFN application, an average of 4.8 ± 2.0 more fluoroscopy was taken for the cementing process. VAS scores were 4.1 ± 2.2, and Modified Harris scores were 75.3 ± 8.5 at the 6th month postoperatively. At the 2nd year postoperatively, the vas scores were 3.5 ± 2.5, while the Modified Harris Scores were 74 ± 10.5.

Conclusion: In conclusion, cement-augmented proximal femoral nails appear to be an implant with both good functional results and good quality of life results with early mobilization. But it is clear that both cement and nail design do not solve all the problems in interthoracanteric fractures.

Introduction

Intertrochanteric fractures are an important health problem affecting the elderly and osteoporotic population [1]. Augmentation of the nail into the femoral head with cement using proximal femoral nails (PFN) is a modification that has been applied with increasing frequency in recent years [2].

This method especially increases the stability of the implant against rotational and shear forces [3]. As a result of this effect, a higher rate of stabilization can be achieved as osteoporosis progresses [3]. The search for novel kinds of implants and current modifications for the treatment of intertrochanteric femur fractures suggests that the gold standard method for treatment has non yet to be discovered. Cemented PFN may become an alternative option for this situation [2-6].

Based on the literature review, the number of studies on cemented PFNs is quite limited [2-6]. In addition, the majority of these studies are biomechanical studies, and the number of clinical studies is again very few [2,7]. On the other hand, cemented PFN applications can also be associated with earlier weight bearing and better functional results as it increases stability in hip fracture problems of the elderly people. The purpose of this study is to examine the clinical and radiological results of cases with cement-augmented proximal femoral nails.

Materials and Methods

For the study, the patient medical records of 271 patients who were operated on due to hip fracture between 2015

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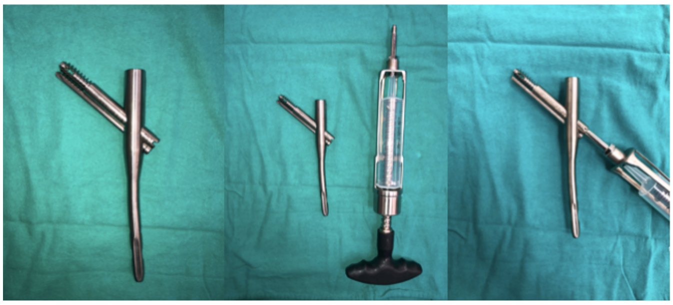

Figure 1. The nail implant and the cement augmentation apparatus (PN1 PFNA Nail ® - Tasarım Medikal ® - İstanbul)

and 2017 were examined retrospectively, after obtaining due approvals from the ethics committee of our institution. Selection criteria were defined as having a follow-up period of more than 2 years, being over 65 years old, having an intertrochanteric hip fracture, and having experienced an application of cemented PFN. There were 89 cases with cemented PFN. Among these, 18 patients who ceased their follow-up, 4 patients under 65 years of age, and 2 patients with active malignancies were not included in the study. After this exclusion, a total of 65 patients were included in the study.

The indications of operation for these patients had been determined by the council of our clinic, and the type of surgery to be performed was decided by the same council as well. All patients were operated by two senior surgeons.

Surgical technique

The patients were operated on using spinal or general anesthesia, in the lateral decubitus position, without the use of a traction table. Closed reduction was performed under fluoroscopy. A skin incision of approximately 5 cm was used proximal to the trochanter major. Under fluoroscopy, one Kirschner wire was inserted through the trochanter major type and the femoral medulla was reamed. Then, a PFN nail with appropriate diameter and length was placed intramedullary. The lag screw and derotation screw were placed to the femoral head and locked via the external guide. Fluoroscopy control was performed after the locking of the nail distal. Then, with the help of cement augmentation apparatus

(Figure 1) that can be screwed to the back of the lag screw of the nail, high viscosity cement was applied to the femoral head through the slotted lag screw.

Cementing process was continued until the cement could no longer be injected and there was too much cement orientation to the fracture line under fluoroscopy control, and the injected amount of cement was observed through the injector and duly noted (Figure 2).

After waiting for the cement setting time, the cement augmentation apparatus was removed and a suitable cover was placed behind the lag screw. Penetration of the femoral head was checked with the utmost care at each stage of the application, and cement was not applied if there was any doubt that femoral head penetration was not achieved at any stage.

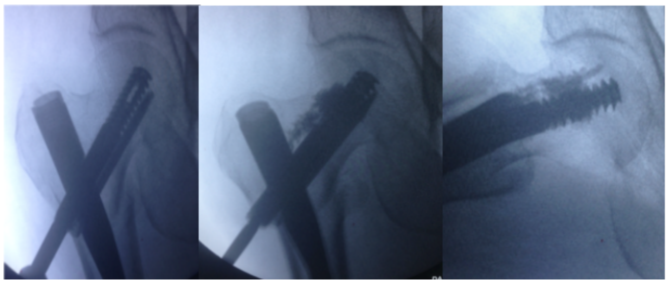

Figure 2. Intraoperative application of cement

In accordance with the Modified Baumgaertner Criteria (8) Tables:

(Table 1), those included in the good reduction were mobilized with the full weight with the assistance of a walker on postoperative day one. Those in the acceptable reduction were mobilized with fingertip pressure only on postoperative day 1, and mobilized with full weight at the 6th week. Those with poor reduction were mobilized with the assistance of a walker after bed rest at postoperative 6th week. In the postoperative 3rd week, the patients were called to the outpatient clinics for wound control and removal of sutures. Afterwards, the patients were called for radiographic and routine outpatient controls at the 6th week, 3rd month, 6th month, 1st year and 2nd year postoperatively.

Singh indexes of the patients were determined according to the preoperative radiographs, and the types of fractures experienced by the patients were determined according to the AO (Arbeitsgemeinschaft für Osteosynthesefragen) classification. The patients with Singh index values of 1 and 2 were considered as patients with severe osteoporosis (9). Tip apex distance, spreading area of cement.

(Figure 3), the closest distance of cement to cartilage were calculated from postoperative radiographs. The necessary information on the number of additional fluoroscopy for the cementing procedure and on the amount of cement injected in the femoral head was obtained from the surgical notes of the patients. All these radiological assessments and measurements were performed and calculated (averaged) by 2 different surgeons who did not perform the operations. Preoperative and postoperative radiographic measurements were performed with the imaging software named INFINITT PACS (Picture Archiving and Communication Systems) version 3.0.11.4 (BN13)® used in our hospital.

At the 6th month and 2nd year postoperatively, Harris Hip Scores and VAS pain scores for the operated areas of patients were subjected to assessment.

PN1 PFNA Nail - Tasarım Medikal ® - İstanbul nails and G21 V-Fix ® cement were applied to all patients.

Health Sciences University Okmeydanı Training and Research Hospital Ethics Committee Presidency was found ethically appropriate according to the decision numbered 713, which was reviewed at the meeting dated 22.08.2017.

IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp. was used for statistical analysis. Mean, standard deviation; median, minimum and maximum values were given for numerical variables as descriptive statis-

Table 1. Modified Baumgaertner Criteria

Alignment	Anteroposterior x-ray-Anteroposterior x-ray Lateral x-ray-Lateral x-ray	Normal collodiaphyseal angle or mild valgus Angle less than 20°
Displacement	More than 80% contact on both x-rays] More than 80% contact on both x-rays Less than 5 mm shortening]- Less than 5 mm shortening	
Good reduction		Both criteria are available
Acceptable reduction		One criteria are available
Poor reduction		No criteria are available

Table 2. Table 2: Distribution of fracture types of patients based on the AO classification

Number of patients, n	8	6	4	21	15	2	1	4
%	12.4	9.2	6.2	32.2	23	3.1	1.5	6.2

tics and number and % values were given for categorical variables. As a result of the power analysis made before the study. In our study, a power test of 0.80 and alpha error of 0.05 were calculated, and the sample size was calculated as 20 patients. The compliance of the data to normal distribution was tested through the Shapiro Wilk test. Student t-test was performed for the normally distributed features in comparison of numerical data in 2 independent groups while Mann Whitney U test was performed for non-normally distributed features. The relationships of two independent variables at the categorical measurement level with each other were tested via using Chi-square test and Likelihood ratio. $P < 0.05$ was considered statistically significant. The results were analyzed based on the 95% confidence level.

Results

Of the cases, 30 (46.2%) were male and 35 (53.8%) were female. The average age was 75.51 (66-90). There were various injury mechanisms for 1 patient (1.5%) due to non-vehicle traffic accident, for 3 patients (4.6%) due to in-vehicle traffic accident, and for 2 patients (3%) due to falling from a height. Simple fall was observed as the mechanism of injury for 59 patients (90.7%). Of the cases, 36 (55.4%) had right-sided fractures, and 29 (44.6%) had left-sided fractures. As additional injuries, distal radius fracture was observed for 3 of the patients and ipsilateral pubic arm fracture was observed for 1 of the patients. The fracture types of the patients were classified according to the AO classification (Table 2).

Of the patients, 48 (73.8%) were classified as good reduction, 12 (18.4%) as acceptable reduction, and 5 (7.6%) as bad reduction, based on the Modified Baumgartner Criteria.

Cut-out complication was observed in 2 (3%) of our patients, and these patients were treated with calcar replacement prosthesis. Both patients with cut-out are classified as bad reduction. The rate of cut-out cases for the bad reduction group was found to be statistically significantly higher than the other groups (p=0.004).

The tip apex distance was found to be 26.1 ± 4.1 mm on average. The average tip-apex distance was found to be 32.6 ± 3.2 mm for the group with bad reduction.

The average amount of cement injected through the lag screw was 2.7 ± 0.5 ml. The amount of cement that can be injected into the femoral heads of 37 patients with the most severe osteoporosis problem and with Singh index values of 1 and 2 was found to be 2.9±0.5 ml, and the amount of cement that can be injected into the femoral heads of patients with Singh index values of 3, 4 and 5 (2.1±0.3 ml) was found to be significantly higher ($p < 0.001$).

With the anteroposterior radiograph, the spreading area of the cement within the head was evaluated as center, tip and base (Figure 3).

We did not observe the spread of cement towards the tip of lag screw for any of our cases. We evaluated the cement distribution around the cement exit slots of the lag screw as the central and the cement progression towards the distal of the cement exit holes as central+basal. While 32 (49.2%) of our cases had a central cement distribution, 33 (51.8%) had a central+basal distribution, and all of these cases were from the group that had Singh index values of 1 and 2 ($p < 0.001$).

The point where the cement was closest to the articular cartilage was assessed through the anteroposterior and lateral radiographs and was found to be 3.5 (0-10mm) mm on average.

Radiographically, the average time to union was observed as 8.6 ± 2.5 weeks.

After the application of the proximal femoral nail, an average of 4.8 ± 2.0 additional fluoroscopes were applied for the cementing procedure.

For the 6th month postoperative controls, the VAS scores of the patients were 4.1 ± 2.2, and the Modified Harris Scores were 75.3 ± 8.5. For the postoperative 2nd year controls, the VAS scores were 3.5 ± 2.5, while the Modified Harris Scores were 74 ± 10.5. The clinical results of the patients according to the reduction quality are given in Table 3.

Table 3. Clinical results of patients according to reduction quality

Median[min-max values]		Good reduction***(n****= 48)	Acceptable/Poor reduction***(n****= 17)	P*****
Postoperative 6th month	Vas*	3[1-6]	4[1-7]	=0.458
	Harris score**	75[56-90]	72[48-86]	< 0.001
Postoperative2nd year	Vas*	3[1-6]	4[1-7]	=0.366
	Harris score**	78[60-92]	72[56-90]	< 0.001

* :Visüel analog scale, ** :Harris Hip Score, *** :According to the Modified Baumgaertner Criteria, **** :Number of patients, ***** :Mann Whitney U test

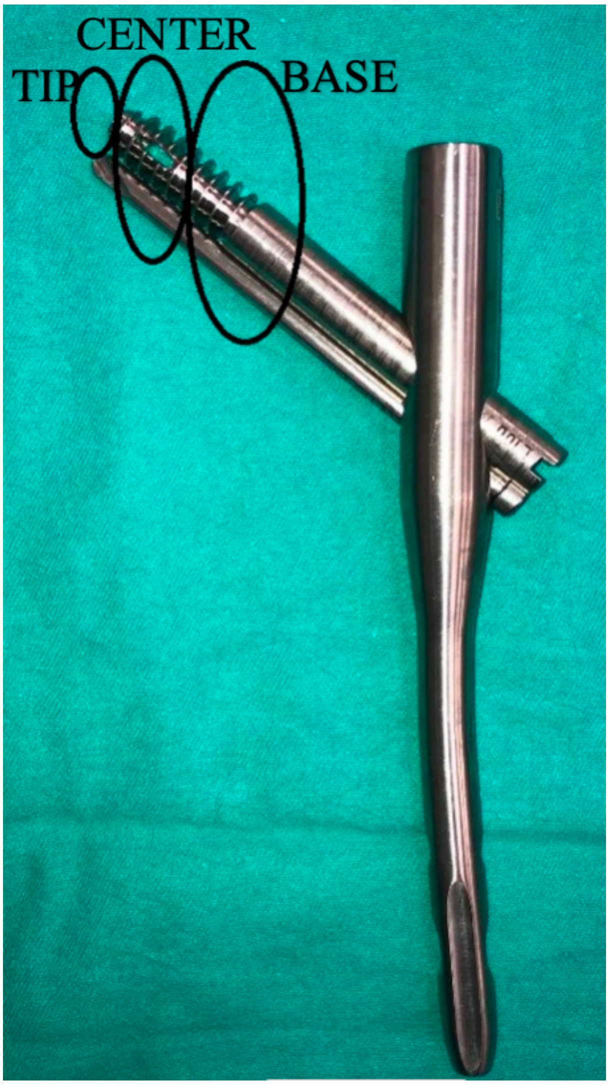

Figure 3. Spreading areas of cement within the femoral head.

Discussion

Osteoporosis was observed as an important factor for intertrochanteric fractures, not only the formation of the fracture but also the implant failures during treatment [4]. It has been demonstrated by biomechanical studies that cement augmentation increases stability as osteoporosis progresses and the implant moves away from its central location in the femoral head [3, 5, 6, 10]. This stability, which has been proven to be increased by many biomechanical studies, may contribute significantly to the clinical functional scores and low cut-out rate of patients.

One of the most important parameters in terms of the stability of the implant is the tip apex distance [11, 12, 13]. The cut-out rate of 3% in our study is significantly lower than rates found in the other studies of the medical literature. However, the cut-out ratios in the cement-augmented proximal femoral nails study are similar to those in our study [2, 7]. Cement augmentation seems to reduce the cut-out complication with its high stability. However, the fact that all patients with cut-out had bad reduction at the same time suggests that cement augmentation cannot solve all problems. This situation can be demonstrated by prospective randomized controlled long-term studies.

As osteoporosis progresses, the risk of implant failure increases as well [4]. Clinically, the Singh index can help us understand the severity of osteoporosis [14, 15]. Preoperative estimations regarding osteoporosis may help us decide better in terms of augmentation methods for treatment [4]. As the osteoporosis progresses, more cement can be injected into the femoral head. As a result, this may increase the stability of the implant and reduce the risk of implant failure.

The maximum amount of cement that can be injected into the femoral head regarding patient safety is controversial in the literature [16]. However, we think that anesthetic complications of PMMA (polymethylmethacrylate], the vascular problems of the subchondral area of the femoral head due to its size and area, and therefore the feeding problems of the femoral cartilage, and the effects of the exothermic reaction of the cement on the articular cartilage will increase in direct proportion to the amount of cement [2, 17]. Especially as the amount of cement increases, the heat released increases as well, and this condition can cause chondral damage [7, 18]. In this study, we did not experience any complications or adverse effects for the amount of cement we applied to the femoral head. However, it is clear that larger series are requaried for clearer results.

In the medical literature, injecting cement to the tip area of the lag screw resulted in the maximum biomechanical stability with the least amount of cement [16]. When we used nail, we never observed the outflow of cement from the areas we classified in our study towards the tip area. All clinical studies of cement-augmented proximal femoral nails in the literature were performed with implants placed by driving the lag screw into the femoral head without using a drill [2, 7]. For this application, it is recommended to wash the inside of the lag screw by using high-pressure washing method [2, 5]. The fact that the nail we used in our study was designed with larger cement exit holes and on both sides of the lag screw, and the fact that the lag screw was placed after the drilling process, may have caused the cement to not be injected to the tip area by passing through these large exit holes to the low pressure area that it can easily find. However, in order to understand whether this situation has a clinical significance, both biomechanical studies and series with high patient numbers are needed with this nail.

In the presence of severe osteoporosis, increased cement volume at the femoral head may cause the cement to spread towards the fracture line [7]. It should be taken into consideration that there may be cement leakage towards the fracture line and this should be controlled with fluoroscopy. Fluoroscopy during cementing causes a fluoroscopy exposure that is not normally included in non-augmentation methods. We think that this exposure is one of the negative aspects of cemented augmentation methods.

The limitations of our study can be listed as the retrospective nature of the study, the small number of cases, the absence of a control group, and the absence of longer-term follow-ups.

In conclusion, cement-augmented proximal femoral nails appear to be an implant type with both good functional results and good quality of life results due to early mobilization. However, it is clear that both the cement and the nail design cannot be the answer to all the problems of intertrochanteric fractures.

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