

Management of hypertrophic femoral diaphyseal nonunion due to sclerotic bone formation (corticalization) at the intramedullary nail tip after dynamization

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The aim of this study was to investigate the effect of the presence of the “cortex sign” (corticalization) in femoral diaphysis fractures determined by the dynamization of nails because of delayed union. The study included 12 patients with a closed transverse femoral fracture (AO 32a3) treated with dynamization (all the screws distal of the nail were removed) because of delayed healing and followed up for at least 2 years. These patients were evaluated for the presence of bone union, cortex-like sclerosis (corticalization) distal to the nail, and the distance of the corticalization from the joint during follow-up after dynamization. The nail lengths and diameters, and time of dynamization were evaluated. In cases that developed pseudarthrosis and were treated with nailing, the length and diameter of the new nails were evaluated. Corticalization and hypertrophic pseudarthrosis were present in 12 patients after dynamization. The old nail was removed and nail exchange was performed with a longer and larger diameter nail to pass the region formed in the cortex approximately 2-3 cm inferior to the old nail. Union was obtained in 3-4 months in all patients. When corticalization is seen during follow up after dynamization is performed because of non-union of a transverse femoral fracture, nail exchange should be performed without further delay. More rigid fixation should be applied with a longer and thicker nail crossing the area of corticalization.

Keywords: corticalization, dynamization, hypertrophic pseudarthrosis.

INTRODUCTION

The definition of non-union accepted by the United States Food and Drug Administration (FDA) in 1988 is that there are no visibly progressive signs of healing at a minimum of nine months after the fracture¹. Delays in diagnosis, and therefore treatment, can cause prolonged morbidities, delayed return to work, dependence on pain relief, and emotional depression². Nail exchange involves first removing the old nail, then reaming the canal, and placing a broader diameter nail³. The reaming procedure has positive effects on biology by increasing periosteal blood flow and stimulating the formation of new bone⁴, while the use of a larger diameter nail has positive effects on the mechanical balance by increasing cortical contact^{4,5}. The mechanical balance can also be positively affected by increasing the number of locking screws or increasing the length as well as the diameter of the nail⁵.

Consequently, there is no single tool or technique for all cases of non-union. The surgeon must try to understand the reason for non-union in each case. Then, a well-planned surgical technique is required that addresses the reason and respects the tissue.

The aim of this study was to investigate the effect of corticalization formed in the distal after dynamization of the nail on non-union of the fracture.

PATIENTS AND METHODS

Approval for this prospective study was granted by the Institutional Review Board (decision no:67). The Clinical Trials application was submitted retrospectively on 06/14/2022 and its ID number was NCT05423561.

Through retrospective chart review, we identified 618 patients who underwent closed reduction and antegrade intramedullary nailing for femoral shaft fractures between 2010 and 2020. Among them, we determined

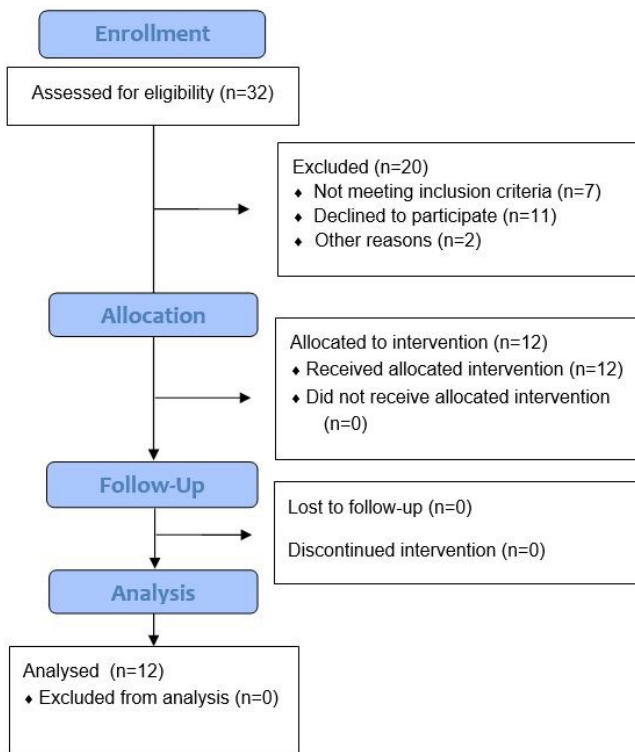


Figure 1 — Consort Flow Diagram.

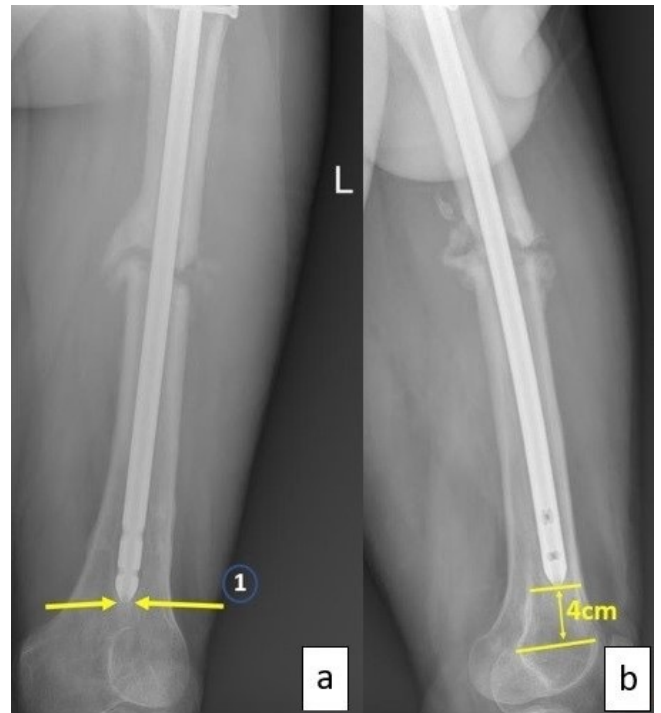


Figure 3 — a-preoperative A/P radiograph showing nail tip sclerosis; b-preoperative distance of distal nail tip to the joint (4 cm).

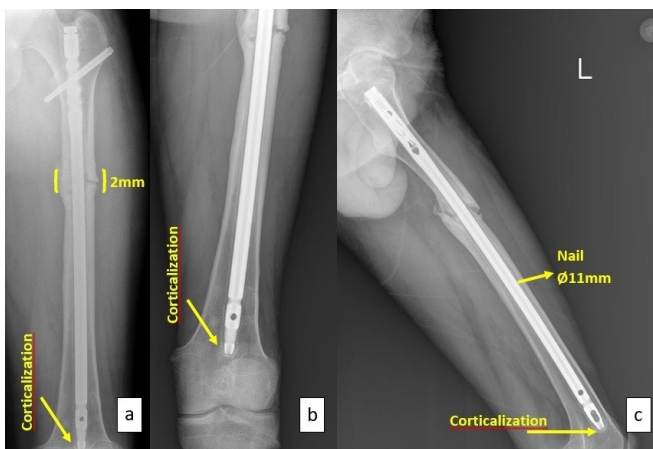


Figure 2— a,b-preoperative A/P radiograph showing corticalization and gap distance; b-preoperative thick corticalization image on lateral radiograph.

that there were 32 cases with nonunion of transverse shaft fractures (AO32A3). At the initial presentation all of these patients had undergone reamed femoral nail insertion fixed with a single static distal interlocking screw in urgent setting, and none had received prior external fixation. There were no associated injuries in any of the patients, and their fractures were not open. At the end of the third month, patients who did not exhibit at least 3 cortical hard calluses formation or continued to experience pain, thus leading to a diagnosis of

delayed union, underwent dynamization by removal of the static distal locking screw and full weight-bearing was initiated. Out of these 32 patients, complete union was achieved by the sixth month with this method in 20 patients, however, by the ninth month, the 12 patients (8 males; 4 females) who continued to experience pain and nonunion were re-evaluated radiologically in detail. Of them we identified a distal cortex-like lesion that we believed impeded adequate dynamization (shown in Figure 1).

The mean age of these 12 patients was 38.58 ± 6.99 years (range, 28-49 years) and follow-up was at least 2 years. Cortical sclerosis or thickening resembling the cortex was observed approximately 1-2 mm from the distal nail tip at the fifth month postoperatively (illustrated in Figure 2). This corticalization occurred approximately 3-4 cm from the joint (depicted in Figure 3). In all cases, the nails were observed not to completely fill the medullary canal on computed tomography (CT) images (shown in Figure 4), and on three-dimensional CT images, the corticalization of the distal nail tip appeared to have the same density and appearance as the cortical bone of the femoral diaphysis (shown in Figure 5). The average diameters of the existing nails in the patients were 13.50 ± 0.522 mm, and none of them completely filled the medullary canal. These patients underwent replacement of the

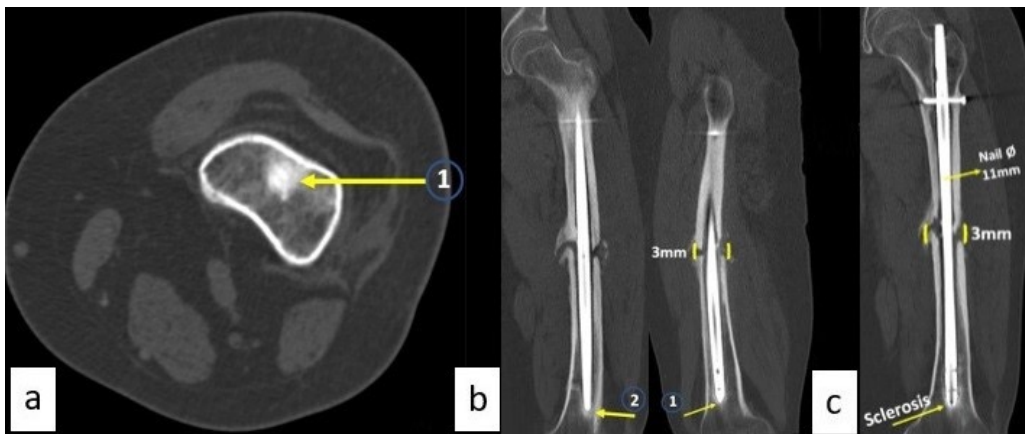


Figure 4 — a,b-preoperative axial and sagittal views of nail tip corticalization; c- preoperative CT showing the gap and nail tip sclerosis; d-preoperative CT showing nail diameter, gap, and sclerosis.

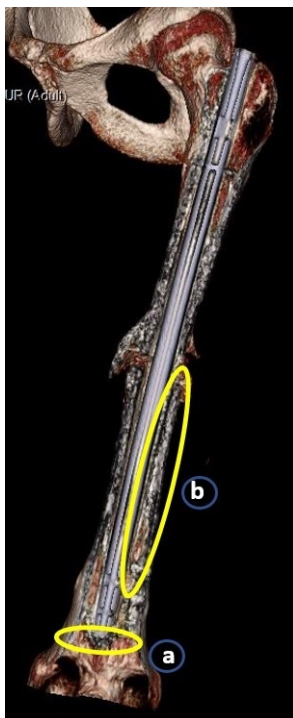


Figure 5 — a- preoperative 3D CT showing nail tip sclerosis (corticalization); b- preoperative 3D CT showing cortex with the same density as the nail tip sclerosis.

nails with longer and thicker ones that would pass beyond the distal cortical lesion.

Under combined spinal epidural anesthesia, all the patients were placed in the lateral decubitus position. Entering over the old excision, first the old proximal nail was reached. The proximal screws of the nail and then the previously placed femoral nail were removed. The length and diameter of the nail were measured (11-12 mm diameter), then a nail guidewire was advanced from the previous entry hole. The point at which the end of the previous nail had become caught was visualized

under fluoroscopy. Then, under fluoroscopy guidance, the corticalization region was penetrated with a rigid, fine 7 mm reamer. A guidewire was again placed, and the corticalization region was reamed to a diameter larger than that of the previous nail, starting with a 9 mm reamer up to a maximum of 15 mm diameter. An antegrade femoral nail (Tasarimmed®, Istanbul) 1 mm smaller in diameter than the last reamer was placed and 2 screws at the proximal and distal. The layers were then closed appropriately.

The standard treatment regimen for these fractures is given in our clinic provided both in the initial nail application after the fracture and in revision cases. All the patients were mobilized on postoperative day 1 with partial weight-bearing. Ambulation was permitted with two crutches. Exercises were given for the knee and hip region. Sutures were removed after 15 days. Full weight-bearing mobilization was obtained with the use of a single crutch in the 3rd week. All the patients returned to work in the 6th week.

SPSS for Windows version 15.0 software (SPSS Inc., Chicago, Ill., USA) was used for statistical analysis. Descriptive statistics of the data were stated as mean \pm standard deviation, median minimum and maximum values, frequency (n) and percentage (%).

RESULTS

After being treated with a short nail for transverse femoral fracture (AO32a3), 12 patients who developed hypertrophic pseudarthrosis were evaluated. The mean age of the patients was 38.58 ± 6.99 years (range, 28-49 years). Dynamization of the patients was at 12.92 ± 0.99 weeks (range 11-14 weeks) after the first femoral nailing. Cortex-like sclerotic bone formation

Table I. — Nail length and diameter of all the patients

Patient No	Diameter of the nail removed from the femur	Diameter of the new nail applied	Length of the removed nail	Length of the new nail applied
1	11	13	36	40
2	12	14	34	38
3	11	14	36	38
4	12	14	36	38
5	12	13	34	40
6	11	13	34	38
7	11	13	36	38
8	11	14	36	42
9	11	13	36	38
10	11	13	36	40
11	12	14	36	38
12	11	14	34	40

Table II. — Patient characteristics

Patient No	Age	Comorbidities/ Smoker (Pre/Post Operative)	Sex	Time of dynamization (weeks)	Time of nail exchange (weeks)	Time to corticalization (months)	Distance to distal joint	Gap in the fracture line
1		+	M	13	11	5	3 cm	2 mm
2	42	+	M	14	12	5	4 cm	2.2 mm
3	49	+	M	12	14	6	3 cm	2.6 mm
4	29	+	M	14	15	5	4 cm	2.4 mm
5	28	+	F	11	12	6	4 cm	2.3 mm
6	41	+	F	12	13	5	3.2 cm	2.7 mm
7	47	+	M	13	12	6	3.6 cm	2.6 mm
8	46	+	F	14	12	5	4.2 cm	3 mm
9	40	+	M	14	12	6	3.8 cm	2.4 mm
10	37	+	F	12	14	5	3.6 cm	2.1 mm
11	34	+	M	13	14	5	3.5 cm	2 mm
12	31	+	M	13	13	6	4.2 cm	2.4 mm

determined after dynamization was seen at mean 5.42 ± 0.51 months (range, 5-6 months).

The distance of the previous nail from the distal joint was measured as 3.67 ± 0.43 cm (range, 3.4-4.2 cm). Before removing the nail, the gap between the proximal and distal fracture lines was 2.39 ± 0.29 mm (range, 2-3 mm). The diameter of the extracted nails was mean 11.33 ± 0.49 mm (range, 11-12 mm) and the length was 35.33 ± 0.93 cm (range, 34-36 cm). The diameter of the new nails applied to the patients was mean 13.50 ± 0.52 mm (range, 13-14 mm) and the length was 39 ± 1.34 cm (range, 38-42 cm) which were larger diameter to increase mechanical balance and was long enough to pass corticalization⁵ (Table I).

All patients had a minimum of 9 months without signs of bone healing and were therefore diagnosed

with nonunion according to FDA definition⁶. The previous nail was removed nail exchange was made with a thicker nail passing through the region of corticalization (Table I). Static locking was applied together with the nail exchange and full union was obtained in all cases at 3-4 months (shown in Figure 6).

All patients underwent internal fixation with closed reduction and no bone grafting was performed.

A common feature of all the patients was that they all smoked more than 2 packets of cigarettes per day and they continued to actively smoke despite all postoperative counseling efforts. (Table II).

On the 3D CT scans of all the patients with non-union, the nail tip sclerosis was seen to have the same appearance as the cortex, which was of the same density and color on the frontal slice.

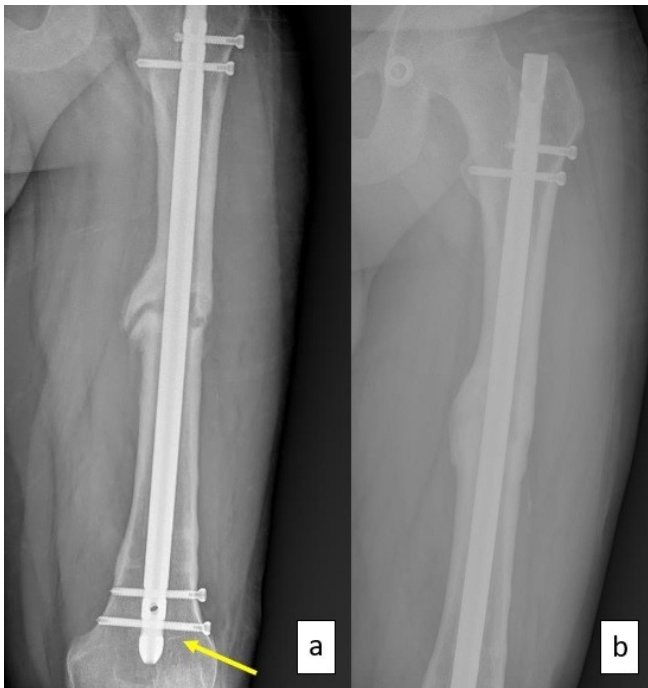


Figure 6 — a- postoperative view showing rigid fixation with the nail passing the sclerosis formed at the edge of the nail; b- 2 years after surgery shows the achievement of union.

DISCUSSION

In the treatment of hypertrophic non-union, an additional treatment to improve the biology is not needed, and the main requirement is mechanical correction of the shape deformity if present and to increase the balance in the area of non-union⁷.

It is recommended in literature that radiological examinations are made to determine the length of nail to be applied in a femoral fracture, and that it should fill the medulla⁸. After the application of a short nail, a series of complications may develop. In the current study, it was thought that corticalization occurred as short nails had been applied.

Vaughn et al reported that when there is a gap in the fracture region in femoral fractures, applying dynamization first is more advantageous in terms of cost⁹. In the current study, dynamization was applied to these patients but after 5 months there was seen to be sclerosis of the distal nail tip preventing dynamization. While waiting for bone union, pain continues in the non-union region and the return to social life is prolonged for these patients. The visualization of sclerosis in the distal nail tip in cases applied with dynamization shows that the benefit of dynamization has been destroyed and bone union may not be achieved.

In a study by Ebraheim et al, the windshield wiper effect of the distal nail tip in hypertrophic non-union

was treated with broad diameter nail and fibula allograft¹⁰. In the current study, the cortex finding which developed in the nail tip was treated with a longer and thicker nail without the need for a graft, and it was thought that this result could be a component of the effect.

It is stated in the literature that the average length of femoral nails applied to young adults is between 37-45 cm⁸. The nail length of 36 cm used in the current study was shorter than that reported in literature. However, consistent with the literature, the cortex-like formation at the tip of the short nail was treated with nail exchange and union was obtained by applying the nail exchange treatment along the whole femur. This suggests that the primary factor facilitating bone union involves surpassing the bone obstruction formed as a result of dynamization in the existing nail type, rather than extending the length of the nail.

Dynamization was previously recommended for all diaphyseal fractures; however, due to the issues it causes, such as shortening and rotation, it is primarily recommended for transverse femur fractures in recent years. It has been reported that union is achieved by allowing axial loading on the nail applied¹¹. In the current study, it was thought that the sclerosis formation because of nail movement in the distal nail tip after dynamization had an effect on non-union. Therefore, late dynamization in patients applied with intramedullary nails should not be recommended because of this corticalization.

In animal model studies by Durall et al, sclerosis was seen radiologically after nail application¹². In the current study, sclerosis at the nail tip was seen to be the same density and color as the cortex, more evidently on the frontal slice with 3D CT¹³. Successful bone union results have been obtained with long nails of a large diameter filling the medulla¹⁴. However, non-union causes several difficulties for patients in respect of return to work and social life¹⁵. In the current study, although hypertrophic callus formation was seen in the fracture region, it was thought that the planning of nail exchange after the early determination of the cortex finding would lead to early rehabilitation and shorten the return to work. No radiological visualization of callus at 3 different times or during the 9-month period for fracture union has been reported in literature to show that the bone will not unite¹. In the current study, that non-union continued in the 9th month despite the visualization of callus formation on radiographs taken in the 5th month after corticalization suggests that nail exchange or additional treatments should be applied after the 5th month.

CONCLUSION

Non-union can also be seen in the presence of a gap and when nails are applied which do not fill the gap, and in patients with lengthy non-union this leads to complications such as nail breakage and infection¹⁶. In the cases in the current study seen with distal corticalization, reaming was performed with a wider reamer and nail exchange was performed. No nail breakage or infection developed in any case.

Early rehabilitation and an early return to social life are important, as when these are prolonged because of fracture non-union, this can lead to psychosocial effects⁷. This was given attention in the current study, and it can be considered that when orthopedic surgeons are aware of this and the need for early surgery to provide union, the return to social life will be accelerated and the loss of workforce will be reduced.

Although there are studies stating that dynamization is the first treatment when there is a gap, there are also publications that do not recommend this for absolute stability and current nail design^{17,18}. From the current study results, it can be considered that dynamization at 12-14 weeks when there is a gap in femur fractures could provide a cost advantage. However, in the follow-up of patients who have undergone dynamization, when nail tip sclerosis is determined after the 5th month, early nail exchange should be considered. Nail tip bone sclerosis has been described in literature, but no information has been given about the distance of the sclerosis from the joint¹⁹. Despite the low number of cases in the current study, it was measured to have formed approximately 4-5 cm from the joint in the proximal region of the medulla, which is widest in the distal diaphyseal metaphyseal region. Membrane is thought to form here with movement of small diameter nails in this region, resulting in the triggering of sclerosis.

Limitations can be identified within the scope of this study. Firstly, the sample size, particularly the subset of patients was relatively small, potentially limiting the generalizability of the findings to broader populations. Secondly, the retrospective nature of the chart review may have introduced biases or limitations in data collection, as well as constraints in obtaining comprehensive clinical information. Thirdly, the reliance on radiological evaluation alone for diagnosing nonunion may have overlooked potential clinical nuances that could affect patient outcomes. Finally, it is considered that smoking in all patients may contribute to the nonunion process and also affect the formation of distal cortical callus; this hypothesis should be further investigated through more comprehensive studies.

In conclusion, the results of this study demonstrated the importance of timely treatment on costs and return to work and social life of the patient. Rigid fixation applied with good planning of the nail diameter and length will avoid the complication of non-union in the first surgery for femoral transverse diaphyseal fractures and the necessity for treatment of distal nail tip corticalization in non-union that can develop in the future as a result of short thin nails.

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