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ORIGINAL ARTICLE

# A comparison of exchange nailing and plate augmentation over a retained intramedullary nail in aseptic oligotrophic and atrophic femoral shaft pseudoarthrosis

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## ABSTRACT

**Objectives:** This study aims to evaluate the success of plate augmentation over a retained intramedullary nail (IMN) against exchange nailing performed with autologous bone grafting in oligotrophic and atrophic pseudoarthrosis of the femoral shaft.

**Patients and methods:** Between May 2005 and October 2020, a total of 42 of 56 patients (28 males, 14 females; mean age: 47.3±17.2 years; range, 19 to 84 years) with aseptic atrophic or oligotrophic femoral nonunion were retrospectively analyzed. The patients, 20 were operated with plate over a retained IMN, and the rest (n=22) by exchange nailing. Data including demographic and clinical characteristics of the patients, treatment success, duration of surgery, blood loss during surgery, infection rates, length of hospital stay, time to bridging of the nonunion site, and time to obliteration of the fracture line (solid union) were recorded.

**Results:** The mean follow-up was 23.8±20.4 (range, 12 to 96) months in the plate over an IMN group and 34.7±27.4 (range, 12 to 90) months in the exchange nailing group. At the final follow-up, solid union occurred in all of the patients in the plate augmentation over a retained IMN group, and 21 of 22 (95.45%) patients in the exchange nailing group. Blood loss during surgery was significantly less in the plate augmentation over IMN group (p=0.027). There was no statistically significant difference in the other variables between the two groups (p>0.05).

**Conclusion:** Our study results demonstrate that plate over a retained IMN is effective as exchange nailing in the surgical treatment of oligotrophic and atrophic pseudoarthrosis of the femoral shaft. However, it can be speculated that plate application over IMN is more advantageous in terms of blood loss during surgery.

***Keywords:*** Bone grafting, bone plates, exchange nailing, intramedullary nailing, femur, pseudoarthrosis.

Fractures of femoral diaphysis are common injuries that usually occur with high-energy trauma such as traffic accidents, and more rarely after low-energy trauma.[1] Surgical treatment with a reamed intramedullary nail (IMN) is a widely preferred treatment option for those fractures such as in nonunion and delayed union of tibial fractures.[2,3] Pseudoarthrosis of the femoral shaft after IMN is still a serious problem that occurs in 0 to 57%.[4] Treatment of the nonunions that occur after IMN of the femoral diaphysis fractures are very challenging.[5] Moreover, the femoral shaft pseudoarthrosis has been shown to cause permanent physical and psychological impairment in patients, subsequently resulting in a significant economic and functional impact.[6]

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The most common treatment method for aseptic pseudoarthrosis of the femoral diaphysis is exchange nailing.[7,8] In the literature, different exchange nailing methods with varying success rates attributed to factors such as bone graft use, medullary reaming

size, and different IMN locking methods have been reported.[9,10]

Plate over a retained IMN is considered an effective method in managing nonunions of the femoral diaphysis in recent years, since it strengthens the fracture site biomechanically without causing extra damage.[11-13] In the literature, to the best of our knowledge, no clinical study has compared the effectiveness and the results of exchange nailing against plate augmentation over a retained IMN in patients with a nonunion of the femoral shaft. To contribute to the international literature, in this study, we aimed to investigate the efficacy and results of exchange nailing versus plate augmentation over a retained IMN in patients with atrophic and oligotrophic pseudoarthrosis of the femoral shaft.

## PATIENTS AND METHODS

This single-center, retrospective study was conducted at Ministry of Health Metin Sabancı Baltalimanı Bone and Joint Diseases Training and Research Hospital, Department of Orthopedics and Traumatology between May 2005 and October 2020. A detailed search was performed using the online database of our hospital. The area in the femoral diaphysis between 5 cm distal to the lesser trochanter and 5 cm proximal to the adductor tubercle was defined as the femoral shaft.[14] According to the United States Food and Drug Administration (FDA) definition, a fracture ununited nine months after injury or one in which there is a failure of progression toward union over the previous three months can be classified as a nonunion. Follow-up X-rays of the patients after fracture surgery was performed by using IMN. There were 56 femoral shaft nonunion patients who met with the FDA definition of pseudoarthrosis with negative intraoperative culture, normal C-reactive protein (CRP) level and erythrocyte sedimentation rate (ESR). Pseudoarthrosis was considered as atrophic, if there was no callus formation and considered as oligotrophic, if there was partial or minimal callus formation.

Patients older than 18 years with aseptic atrophic or oligotrophic femoral nonunion, operated on with plate augmentation over a retained IMN, or operated by exchange nailing after a femoral shaft fracture that was followed at least for one year were included in the study. Patients with a femoral diaphysis pseudoarthrosis with infection, pathological fractures and missing data were excluded from the study. Finally, a total of 42 of 56 patients (28 males, 14 females; mean age: 47.3±17.2 years; range, 19 to 84 years) were included in the study. Of them, 20 were operated with plate over a retained IMN, and the rest (n=22) by exchange nailing. Comminution of the fracture classified by using the Winquist-Hansen classification.[15] Severity of nonunions of two treatment groups was compared using the Non-Union Scoring System (NUSS) (Table I).[16]

**Surgical data**

The patients in both groups were operated by different surgeons, following the same surgical technique in the same surgical steps.

Exchange nailing surgery was performed in the lateral decubitus or supine position. The direct lateral splitting tensor fascia lata and vastus lateralis muscle technique was used to reach to the pseudoarthrosis site. The medullary canal was reamed step by step with increasing-sized reamers. After reaming, an IMN with a diameter of 2 mm larger than the initial nail was placed. The pseudoarthrosis site was debrided, adequate compression was achieved, and an autologous bone graft harvested from the ipsilateral iliac crest was placed. Finally, the new nail was locked proximally and distally.

Plate augmentation over a retained IMN was performed in the lateral decubitus position, using the direct lateral approach by splitting the tensor fascia lata and vastus lateralis muscle technique to reach the pseudoarthrosis site. The IMN locking screws were removed to achieve compression at the pseudoarthrosis site before plating. The pseudoarthrosis was debrided and the autologous bone graft harvested from the ipsilateral iliac crest was placed. Dynamic compression plates (DCPs) or locked compression plates (LCPs) were placed and fixed to the lateral surface of the femur. Bicortical and unicortical locking screws were used for fixation. Fixation was achieved with at least four cortices proximally to the nonunion area and four cortices distally.

At least five samples were obtained via aseptic non-touch technique for intraoperative culture and patients who had samples taken seven days after the operation that did not grow a pathogen considered as culture-negative in both groups.

In both treatment groups, passive range of motion (ROM), partial weight-bearing, and isometric quadriceps exercises were allowed from the second postoperative day. Active ROM exercises, dynamic quadriceps exercises, and full weight-bearing were

**TABLE I**
Non-Union Scoring System[16]

| | Non-union Scoring System | Score* | Max. score |
|---|---|---|---|
| **The bone** | | | |
| Quality of bone | Good | 0 | 3 |
| | Moderate (e.g. mildly osteoporotic) | 1 | |
| | Poor (e.g. severe porosis or bone loss) | 2 | |
| | Very poor (Necrotic, appears avascular or septic) | 3 | |
| Primary Injury- open or closed fracture | Closed | 0 | 5 |
| | Open 1° grade | 1 | |
| | Open 2-3° A grade | 3 | |
| | Open 3° B-C grade | 5 | |
| Number of previous interventions on this bone to procure healing | None | 1 | 4 |
| | <2 | 2 | |
| | <4 | 3 | |
| | >4 | 4 | |
| Invasiveness of previous interventions | Minimally-invasive: Closed Surgery (screws, K wires…) | 0 | 3 |
| | Internal intra-medullary (nailing) | 1 | |
| | Internal extra-medullary | 2 | |
| | Any osteosynthesis which includes bone grafting | 3 | |
| Adequacy of primary surgery | Inadequate stability | 0 | 1 |
| | Adequate stability | 1 | |
| Weber and Cech Group | Hypertrophic | 1 | 5 |
| | Oligotrophic | 3 | |
| | Atrophic | 5 | |
| Bone alignment | Non- anatomic alignment | 0 | 1 |
| | Anatomic alignment | 1 | |
| Bone defect- Gap | 0.5-1 cm | 2 | 5 |
| | 1-3 cm | 3 | |
| | > 3 cm | 5 | |
| **Soft tissues** | | | |
| Status | Intact | 0 | 6 |
| | Previous uneventful surgery, minor scarring | 2 | |
| | Previous treatment of soft tissue defect (e.g. skin loss, local flap cover, multiple incisions, compartment syndrome, old sinuses) | 3 | |
| | Previous complex treatment of soft tissue defect (e.g. free flap) | 4 | |
| | Poor vascularity: absence of distal pulses, poor capillary refill, venous insufficiency | 5 | |
| | Presence of actual skin lesion/defect (e.g. ulcer, sinus, exposed bone or plate) | 6 | |
| **The patient** | | | |
| ASA grade | 1 or 2 | 0 | 1 |
| | 3 or 4 | 1 | |
| Diabetes | No | 0 | 2 |
| | Yes- well controlled (HbA1c <10) | 1 | |
| | Yes- poorly controlled (HbA1c >10) | 2 | |
| Blood tests: WCC, ESR, CRP | WCC> 12 | 1 | 3 |
| | ESR> 20 | 1 | |
| | CRP> 20 | 1 | |
| Clinical infection status | Clean | 0 | 4 |
| | Previously infected or suspicion of infection | 1 | |
| | Septic | 4 | |
| Drugs | Steroids | 1 | 1 |
| | NSAIDs | 1 | |
| Smoking status | No | 0 | 5 |
| | Yes | 5 | |

ASA: American Society of Anesthesiologists; HbA1c: Glycosylated hemoglobin level; WCC: White blood cell count; ESR: Erythrocyte sedimentation rate; CRP: C-reactive protein; NSAIDs: Non-steroidal anti-inflammatory drugs; * Higher scores indicate more difficult to procure union.

allowed at about two weeks after the surgical pain relief. The patients were followed regularly at the second week, sixth week, and third month after surgery, and then every three months until fracture healing. After fracture healing, outpatient visits continued on a yearly basis until the final follow-up.

**Outcome assessment**

Treatment was considered unsuccessful in patients who did not develop union at the end of follow-up. The radiographic criteria used to measure the healing in nonunion sites were the time to bridging of the pseudoarthrosis site and the time to obliteration of the initial fracture line (solid union).

Demographic data, duration of pseudoarthrosis, duration of surgery, blood loss during surgery, length of hospital-stay, number of surgeries for each patient, total follow-up time, and complications, if any, were recorded.

Blood loss was calculated using the amount of blood given to the patient, the amount of surgical area washing liquid (surgery nurse calculates), the amount of liquid accumulated in the aspirator chamber and the sponge count (partially wet sponge: 3 to 5 mL, fully wet sponge: 10 mL blood loss). At the end of surgery, the amount of blood loss was routinely noted in the patient's file. The blood loss data were obtained retrospectively from these records.

**Statistical analysis**

Statistical analysis was performed using the IBM SPSS for Windows version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (min-max) or number and frequency, where applicable. The chi-square test was used to compare the success of both treatment methods. The Fisher

**TABLE II**
Demographic, fracture and treatment characteristics of patients

| | Plate over intramedullary nail group (n=20) | | | Exchange nailing group (n=22) | | |
|---|---|---|---|---|---|---|
| | n | Mean±SD | Range | n | Mean±SD | Range |
| Age (year) | | 47.6±14.6 | 25-77 | | 47.0±20.0 | 19-84 |
| Sex | | | | | | |
| Male | 16 | | | 12 | | |
| Female | 4 | | | 10 | | |
| Fracture site | | | | | | |
| Proximal third | 5 | | | 2 | | |
| Middle third | 13 | | | 19 | | |
| Distal third | 2 | | | 1 | | |
| Nonunion type | | | | | | |
| Oligotrophic | 7 | | | 5 | | |
| Atrophic | 13 | | | 17 | | |
| Winquist and Hansen classification | | | | | | |
| Type 0 | 2 | | | 5 | | |
| Type 1 | 11 | | | 8 | | |
| Type 2 | 3 | | | 4 | | |
| Type 3 | 4 | | | 2 | | |
| Type 4 | 0 | | | 3 | | |
| Duration of pseudoarthrosis (month) | | 23.4±17.5 | 5-60 | | 42.0±26.5 | 6-90 |
| Follow-up time (month) | | 23.8±20.4 | 12-96 | | 34.7±27.4 | 12-90 |
| Duration of surgery (min) | | 147.5±51.5 | 80-240 | | 147.1±51.7 | 60-240 |
| Blood loss (mL) | | 513±230.6 | 280-900 | | 729.1±284.7 | 300-1500 |
| Length of hospital stay (day) | | 5.2±1.5 | 3-10 | | 4.6±0.9 | 3-6 |
| Time to bridging of the nonunion site (week) | | 12.6±5.4 | 4-25 | | 14±5.8 | 5-28 |
| Time to solid union (week) | | 41.3±19.7 | 13-78 | | 55.5±38.9 | 21-156 |
| Number of previous interventions | | 1.3±0.5 | 1-2 | | 2.5±1.8 | 1-7 |
| Non-union Severity Score | | 30.5±6.1 | 18-40 | | 33±5 | 26-46 |

SD: Standard deviation.

exact test was used to compare complication rates of both treatment groups. The differences between the variables between two independent groups (type of treatment) were examined using the Mann-Whitney U test. A $p$ value of <0.05 was considered statistically significant.

## RESULTS

Data regarding age, sex, site of the fracture, type of the fracture according to Winquist-Hansen classification, nonunion type, duration of surgery, pseudoarthrosis period, number of surgeries carried out for pseudoarthrosis, blood loss during surgery, follow-up time, time to bridging of the nonunion site, time to solid union, duration of hospitalization, and NUSS scores for both groups are presented in Table II. In Figure 1, radiological images of a 54-year-old male with femur pseudoarthrosis treated with exchange nailing and, in Figure 2, radiographs of a 33-year-old male treated with plate over a retained IMN are presented.




**FIGURE 1.** Radiological images of a 54-year-old patient with femur pseudoarthrosis treated with exchange nailing. Preoperative **(a)** anteroposterior radiograph and **(b)** lateral radiograph. Early postoperative **(c)**anteroposterior and **(d)** lateral radiograph. Last follow-up **(e)** anteroposterior and **(f)** lateral radiograph.




**FIGURE 2.** Radiological images of a 33-year-old patient with femur pseudoarthrosis treated with plate over a retained intramedullary nail. Preoperative **(a)** anteroposterior and **(b)** lateral radiograph. Early postoperative **(c)** anteroposterior and **(d)** lateral radiograph. Last follow-up **(e)** anteroposterior and **(f)** lateral radiograph.

The mean follow-up was 23.8±20.4 (range, 12 to 96) months in the plate over IMN group and 34.7±27.4 (range, 12 to 90) months in the exchange nailing group. At the final follow-up, union was achieved in all patients in the plate augmentation over a retained IMN. In the exchange nailing group, union was achieved at 21 of 22 (95.45%) patients. The mean time to solid union after plate application was 41.3±19.7 (range, 13 to 78) weeks in the plate over IMN group and 55.5±38.9 (range, 21 to 156) weeks in the exchange nailing group.

Retrograde nailing was chosen in the treatment of femoral fractures in one patient in the plate over IMN group and in three patients in the exchange nailing group. Retrograde nailing was also preferred for pseudoarthrosis surgery in the same four patients.

Although solid union occurred in all of the patients in the plate augmentation over a retained IMN group, there was no union in one of 22 patients in the exchange nailing group. Nevertheless, there was no significant difference between the two treatment groups in terms of treatment success (p=0.335).

As a complication, plate irritation was observed in two patients in the plate augmentation over a retained IMN group. Plate removal was performed in one of these patients and his complaints were resolved. The same procedure was also recommended to the other patient, but the patient refused. In the exchange nailing group, deep wound infection developed in two patients, and a superficial infection developed in one. *Methicillin-resistant Staphylococcus aureus* was isolated in one of the patients with deep wound infection, and *methicillin-resistant*

*Staphylococcus epidermidis* was isolated in the other. In these patients, infection resolved with wound debridement, intravenous and consecutive oral antibiotic therapy. Superficial infection was resolved by oral antibiotics. Both treatment groups were statistically compared in terms of infection development. There was no significant difference between the two treatment groups (p=0.109).

There was no statistically significant difference in the duration of surgery (p=0.868), length of hospital stay (p=0.288), time to bridging of the nonunion site (p=0.432), time to solid union (p=0.434), and NUSS scores (p=0.099) between the two groups. However, blood loss during surgery was significantly less in the plate over a retained IMN group than the exchange nailing group (p=0.027).

## DISCUSSION

There are many biological and mechanical factors that can cause pseudoarthrosis in the diaphyseal region of the femur including multiple surgeries, poor bone quality, technical problems in IMN, bone loss, insufficient mechanical stabilization, comminution of the fracture, soft tissue damage and smoking.[10] Therefore, NUSS was developed to assist surgeons by taking into account all possible risk factors in the complex analysis of pseudoarthrosis.[16] The lack of a statistically significant difference between the two groups in terms of NUSS scores in our study indicates that both groups included for this study are comparable.

Exchange nailing is a widely preferred minimally invasive treatment choice in pseudoarthrosis of the femoral shaft. The use of thicker nails provides better stability against rotational and bending forces. Reaming of the intramedullary canal also stimulates osteogenesis. Plate augmentation over a retained IMN is an alternative way of maintaining fracture stability that is required for fracture healing and avoiding the negative effects to the abductor muscles while exchanging the IMN.

Different results of exchange nailing have been reported in the literature, with varying rates of success attributed to factors such as the use of bone grafting, size of medullary reaming, rotational instability, severity of the trauma, comminution of the fracture, presence of polytrauma, and the use of different nail locking methods.[9,10,17-19] Tsang et al.[20] reported 96.2% union rate in a series of 40 patients operated with or without bone grafting. While Weresh et al.[19] reported a high failure rate of 47% in exchange nailing of the femoral pseudoarthrosis in 19 patients, Furlong et al.[21] reported a union rate of 92% and Hierholzer et al.[17] 82%, following a single exchange nailing in aseptic nonunion cases. Successful union rates obtained using this technique reported in the literature were between 28.6 and 100%.[2,17,18,20] In several studies, the reason for using grafts is not clear, and there are certain discrepancies in the graft type used. In the current study, union was achieved in 21 of 22 (95.45%) patients operated with exchange nailing with autologous bone grafting.

There are numerous studies showing the benefits of plate augmentation over a retained IMN.[9,11-13,19,22-24] In the study of Chiang et al.,[11] fracture healing occurred in 29 of 30 patients, of whom 25 had avascular nonunion (oligotrophic and atrophic) and five hypertrophic nonunion. In their study, bone morphogenetic protein (BMP) and autologous bone grafting was used for patients with avascular nonunion. In a retrospective study, Vaishya et al.[24] recounted successful union in all of their 16 patients with pseudoarthrosis of the femoral shaft. The authors used autologous bone grafts only in patients with avascular nonunion, and interfragmentary compression was not performed at the nonunion site. Ueng et al.[22] used the same technique in 17 aseptic femoral nonunions and reported no treatment failure. Lin et al.[23] operated 22 femoral nonunions with plate augmentation, achieving uncomplicated healing in all cases, while Choi and Kim[14] reported 100% union within 7.2 months after plate augmentation and bone grafting with the nail *in situ* in 15 cases of femoral pseudoarthrosis. In many studies in the literature, the patients are heterogeneous in terms of nonunion type, the reason for using grafts in many patients is not clear, and that there are differences in terms of the graft type used. In the current study, solid union was achieved in all patients operated with plate over a retained IMN with autologous bone grafting.

Review of the literature reveals no clinical studies comparing both treatment methods, except for a comprehensive review published by Medlock et al.[8] In this review, the authors reported that a direct comparison between the two treatment methods was difficult due to the differences in the study designs. In most of the studies, the patients are heterogeneous in terms of the type and location of pseudoarthrosis, whether they were performed bone grafting, and the type of the graft (autograft, allograft, or BMP). Therefore, we attempted to ensure homogeneity among the compared groups by including only patients with avascular nonunion operated using the autograft taken from the iliac crest. Medlock et al.[8]

also reported that plate augmentation provided a better union rate than exchange nailing, leading to fewer complications. The union rate and complication rates were 99.8% and 4.0% in the plate augmentation over a retained IMN group, and 74% and 20% in the exchange nailing group, respectively. In our study, the union rate was 100% in plate augmentation over a retained IMN and 95.45% in exchange nailing group. Complication rates were 10% (two plate irritation) in the plate augmentation over a retained IMN group and 18.18% (n=3 infection, n=1 nonunion) in the exchange nailing group. The time to solid union was statistically similar for both surgical techniques.

Previous researchers have emphasized the necessity of biological supplementation in avascular nonunions.[11,12,25] The use of autologous iliac crest bone grafts has been recommended by most researchers, regardless of the bone defect size.[11-13] In the current study, autologous bone grafts were used in all patients and 97.42% (n=41) union rate was achieved.

The literature review reveals that there is a plenty of evidence to support plate augmentation as an alternative method. Plate application over a retained IMN eliminates rotational instability in femoral pseudoarthrosis. Leaving the nail *in situ* protects the plate from the bending forces and provides an easy, less invasive, and effective solution for this challenging clinical problem. In addition, using thicker nails in exchange nailing provides better stability against the rotational and bending forces, and reaming of the intramedullary canal also stimulates osteogenesis. Also, reaming to insert a thicker nail into the intramedullary canal has the potential to damage endosteal blood vessels and affect the biological healing response.[25] Furthermore, exchange nailing is not preferred in comminuted and distal femur fractures, as it does not provide sufficient stabilization in the large distal segment.[9] Although the plate application over a retained IMN seems to be more advantageous in the surgical treatment of femoral pseudoarthrosis, in the current comparative study, there was no statistically significant difference between the two treatment protocols in terms of treatment success, duration of surgery, infection rates, time to bridging of the nonunion site, time to obliteration of the initial fracture line (solid union), and the length of hospital stay. Of note, in the plate over IMN group, solid union occurred approximately 14 weeks earlier than the exchange nailing group. In addition, although infection was observed in three (13.64%) of 22 patients in the exchange nailing group, no infection was observed in the plate augmentation over a retained IMN group. This finding indicates a clinically relevant difference, but with the small sample size it is likely to be underpowered to detect a statistically significant difference. In addition, blood loss during surgery was significantly less in the plate over a retained IMN group than the exchange nailing group in our study.

Nonetheless, the current study has some limitations. First, the study has inherent limitations of a retrospective design. Second, our sample size is insufficient. Another limitation is the use of different types of plating and variations in the nailing method (antegrade and retrograde). The uncertainty regarding the existence of such factors such as obesity, diabetes, smoking, non-steroidal anti-inflammatory drugs, and steroid use is another limiting factor. The lack of patient-reported outcome measures can be defined as another limitation. Also, in the current study, there is a patient group with a wide age variability ranging from 19 to 84 years, which is also a potentially biasing factor. Finally, there are some differences that may be considered as limiting factors between the patients such as comminution of the fractures, location of the fracture site (wide proximal and distal intramedullary canal), and the severity of the trauma causing the fracture. On the other hand, the literature has no other clinical study comparing both treatment methods in pseudoarthrosis of the femoral shaft, apart from the review published by Medlock et al.[8] Using the same type of autologous bone graft in all patients and including only femoral shaft nonunion patients requiring biological support can be considered as the factors that strengthen our study.[26]

In conclusion, our study results demonstrate that plate over a retained IMN is an effective method as an exchange nailing procedure in the surgical treatment of avascular nonunion of the femoral shaft. However, it can be speculated that plate application over a retained IMN is more advantageous in terms of blood loss during surgery. Further studies are needed to draw more reliable conclusions on this subject.

**Ethics Committee Approval:** The study protocol was approved by the Metin Sabanci Baltalimani Bone Diseases Training and Research Hospital Medical Specialty Education Board (date: 26.11.2020, no: 65/448). The study was conducted in accordance with the principles of the Declaration of Helsinki.

**Patient Consent for Publication:** A written informed consent was obtained from each patient.

**Data Sharing Statement:** The data that support the findings of this study are available from the corresponding author upon reasonable request.

**Author Contributions:** Study design, writing the article: O.Ç.; Evaluating patients and last control: A.Ö.; Clinical evaluation of patients: A.K.; Collecting the data: F.D.; Radiological Measurement: M.M.; Study design and last control: D.K.

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