



Prospective, Randomized Comparison of Fascio-cutaneous Flap versus Muscle Flap in Management of Tibial Osteomyelitis

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Abstract

Background: Chronic tibial osteomyelitis is one of the most challenging problems encountered by orthoplastic surgeons. The purpose of this study is to compare the outcome of fascio-cutaneous versus muscle flaps in management of tibial osteomyelitis.

Methods: This is a prospective randomized study that has been conducted in the period from February 2021 to September 2022 for 40 patients with tibial osteomyelitis. The patients have been randomly assigned into 2 equal groups, group (A) and group (B). All the patients have been subjected to adequate bone and soft tissue debridement. Group (A) included 20 patients that were covered by fascio-cutaneous flaps. Group (B) included 20 patients that were covered by muscle flaps.

Results: The results revealed that both methods have provided good soft tissue coverage for the defect and allow a chance for secondary orthopedic intervention. Fascio-cutaneous flaps had some advantages including decreased donor site morbidity, better color matching, better contour, easier debulking as well as more patient aesthetic satisfaction. Muscle flaps were associated with a lower rate of recurrence of infection as well as better filling of dead space after debridement.

Conclusions: Fascio-cutaneous flaps are recommended in cases of low grades of osteomyelitis and when secondary flap re-elevation is intended. However, muscle flaps are recommended in cases with high grade osteomyelitis or when a large dead space is left after debridement.

Keywords: Osteomyelitis - tibia - Fascio-cutaneous flaps - Muscle flaps – PET CT scan.

Introduction

Chronic osteomyelitis represents a large global healthcare burden [1]. Plastic surgeons commonly contribute in management of cases of chronic tibial osteomyelitis because the

surrounding soft tissues may be severely compromised and require reconstruction as a result of the underlying chronic inflammation with the extensive fibrosis and discharging sinuses [2].

The management of osteomyelitis requires a multi-disciplinary approach and a variety of surgical techniques including aggressive surgical debridement, appropriate antibiotic therapy as well as soft tissue coverage with a vascularized tissue. High-quality vascularized soft tissue coverage with rapid healing provides a physical and microbiological barrier between the bone and the external microbiome including nosocomial microorganisms [3-4].

Muscle flaps have been a fundamental resource for providing adequate coverage and blood flow to eradicate infection. They provide good vascular tissue and can conform to dimensional wounds. Therefore they help to obliterate dead space and decrease the risk of residual disease or recurrence [5]. Fascio-cutaneous flaps can also be advantageous in treatment of soft tissue defects, as they are safe and reliable [6]. They provide an aesthetic outcome with high patient satisfaction rates [7]. Advantages of fascio-cutaneous flaps include also less bulkiness, better contour and texture matching, less morbidity at the donor site and fewer revisions postoperatively [3-8-9-10].

In this study, we assessed the outcome of fascio-cutaneous versus muscle flaps in reconstruction of osteomyelitis considering functional outcome as flap viability and eradication of infection, aesthetic outcome, technical difficulties and donor site morbidity.

Patients and methods

This is a prospective comparative randomized study that has been conducted on 40 patients with chronic tibial osteomyelitis from February 2021 to September 2022. Patients have been divided into two groups; Group (A) included 20 patients who have been managed by fascio-cutaneous flap and Group (B) included 20 patients who have been managed by muscle flap. The patients have been randomly selected using block randomization.

All our patients were previous open tibial fractures complicated by chronic tibial osteomyelitis. They presented with history of previous orthopedic procedures, history of soft tissue affection and history of fistula to bone weeping pus. Diagnosis was confirmed by investigations in the form of plain X-ray, PET_CT scan and bone biopsies.

Inclusion criteria:

- Cases of chronic tibial osteomyelitis complicating open tibial fractures.
- Cases of previous instrumentation to the tibia.

Exclusion criteria:

- Cases of chronic osteomyelitis complicating acute haematogenous osteomyelitis.
- Cases of chronic osteomyelitis due to causes other than trauma
- Patients who are unfit for major surgery

Patients were classified according to Cierny-Mader classification system into four types; type 1 which is confined to the intramedullary surface of the bone, type 2 which is a superficial focal lesion, type 3 which is localized with full-thickness defect, type 4 which is diffuse through-and-through process [11].

Nature and possible consequences of the clinical study have been explained to all patients and informed consent was taken. All patients were subjected to full preoperative assessment including history taking, clinical examination, X-ray and PET CT scan at the affected site (Fig

1).During preoperative preparation, smoker patients had to stop smoking for at least 6 weeks before operation and urine Nicotine level was measured for patients preoperatively.

Intra-operatively, we excised the sinus or necrotic skin and extended the wound along the fasciotomy line for better exposure of the osteomyelitic bone. Multiple bone biopsies were taken for histopathology to exclude malignancy and for culture and sensitivity to prescribe adequate antibiotics. Debridement was done to remove sequestra, devitalized tissue, sinus tracts and osteomyelitic bone by an orthopedic surgeon.

Obliteration of the dead space was essential so after bone excision, the bone defect was filled by a heat-resistant antibiotic in polymethyl methacrylate cement as a spacer for later on bone reconstruction.

Bone fixation was done using a temporary simple unilateral external fixator. In some cases we acutely shortened the bone to allow bone contact at the defect and then we lengthened it through separate remote corticotomy (bifocal compression/distraction). When the defect was larger or the soft tissues prevented acute compression, a bone transport technique was performed (Fig 2 a,b). In defects smaller than 6 cm or half-segmental defects, autologous cancellous bone graft was often sufficient. Bone grafting was done in a second stage.

Following excision of osteomyelitis, soft tissue reconstruction in the form of a flap was required because local fibrosis, scarring, and previous soft tissue loss prevented direct closure.

In group (A) we used local or free fascio-cutaneous flaps for reconstruction of the soft tissue defect. These flaps included local transposition, bipediced or propeller fascio-cutaneous flaps (Fig 3). They additionally included cross leg flap or free Antero lateral thigh fascio-cutaneous flap. In cases of local fascio-cutaneous flaps in the leg, we located perforators around the defect using ultrasound Doppler. An extra length of flap was harvested, keeping all the perforators either distal or proximal to the selected perforator then the incision was completed all around the flap and a subcutaneous vein near the base of the flap was preserved if present.

In group (B) we used local or free muscle flaps for reconstruction of the soft tissue defect. They included local gastrocnemius, local peroneus brevis or free latissimus dorsi muscle flaps. In cases of local medial head gastrocnemius muscle flap coverage (Fig4), patient was put supine in the frog-leg position. Care was taken to avoid injury to the great saphenous vein and saphenous nerve. These structures were preserved and retracted laterally. Before detaching any part of the muscle, the plane between the soleus and the gastrocnemius muscle was identified on the medial border of the gastrocnemius and developed using blunt or sharp dissection. The median raphe that separates the two heads of the gastrocnemius was then identified in the distal portion of the muscle. Dissection then proceeded towards the origin of the muscle into the popliteal fossa. The proximal neurovascular structures were protected at all times. In group (B) a split thickness skin graft was harvested to cover the muscle flap.

In postoperative care our flaps were monitored clinically by experienced surgeons on a half-hourly basis for the first 24 h; hourly for the next 24 h; and then 4-hourly. The commonly observed parameters included flap color, tissue turgor, and capillary return. Commonly, handheld Doppler checks were also employed. IV broad spectrum antibiotics have been started post-operatively until the result of culture and sensitivity was available.

After discharge, patient has been followed up every 1 week for 1 month then every one month for 6 months.

Clinical parameters included the following:

- Flap viability (color, temperature, capillary circulation and bleeding from edges of the flap)
- Signs of recurrence of osteomyelitis (wound discharge – development of sinus).
- Donor site morbidity (wound healing – graft take – development of infection – pain – discomfort - disability).
- Development of flap complications (total flap loss - partial flap loss - hematoma – infection - Wound healing problem).
- Aesthetic Outcome (color match – contour - overall appearance of reconstructed area).

In the follow up after 6 months, we assessed aesthetic outcome by simple questionnaire (from one to ten). Both physician (not the operator) and the patient were included in evaluation by a questionnaire, the tissue thickness, texture and aesthetic appearance (e.g. relief, color match and symmetry with healthy side). Plain X-rays were used to evaluate the patients immediate, two months, four months and six months postoperatively. PET CT scan was used after three months to exclude early recurrence of osteomyelitis. All these data were recorded in a chart for each patient.

Analysis of data was performed using SPSS v. 25 (Statistical Package for Social science) for Windows. Description of quantitative variables was in the form of mean and standard deviation (SD) for parametric data and median with interquartile range with non-parametric data. Description of qualitative variables was in the form of numbers (No.) and percent's (%). Mann Whitney U test was used to compare between the subgroups regarding non-parametric scale variables while independent T test was used to compare between groups regarding normally distributed variables [12]. The significance of the results was assessed in the form of P-value that was set at 0.05

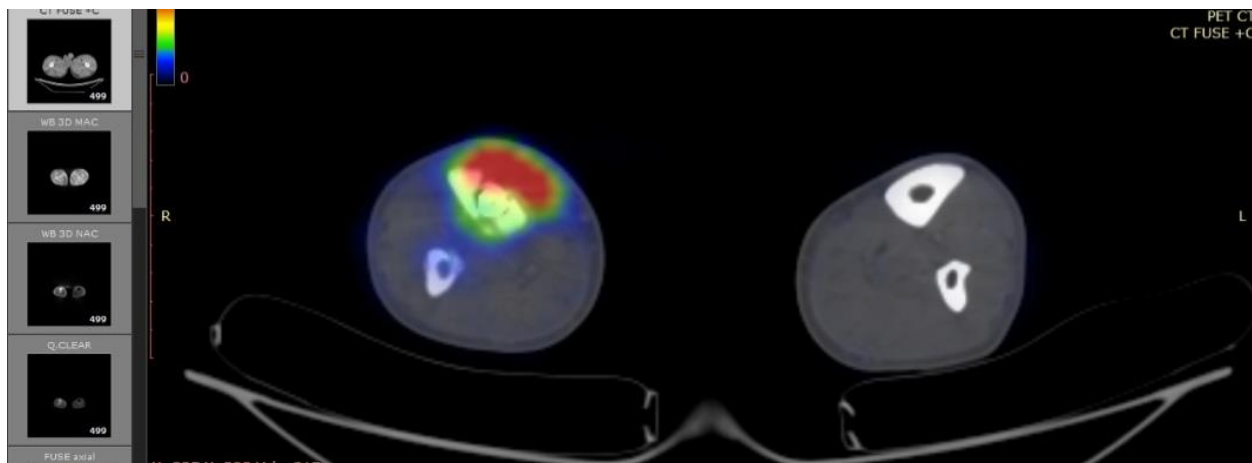


Fig. (1): PET CT scan was done for diagnosis of osteomyelitis and assessment the extent of the disease.



Fig. (2a, 2b):Ilizarov fixator was placed for bone distraction.



Fig. (3): 22 years old male patient presented with osteomyelitis of the left tibia at the lower third. He was managed by bone and soft tissue debridement, polymethyl methacrylate cement insertion and coverage by a local fascio-cutaneous flap with a skin graft at the donor site, (a) Pre-operative clinical photo, (b) Preoperative X- ray of left leg, (c) Intra-operative bone debridement and polymethyl methacrylate cement insertion, (d) Post-operative clinical photo after 7 days.

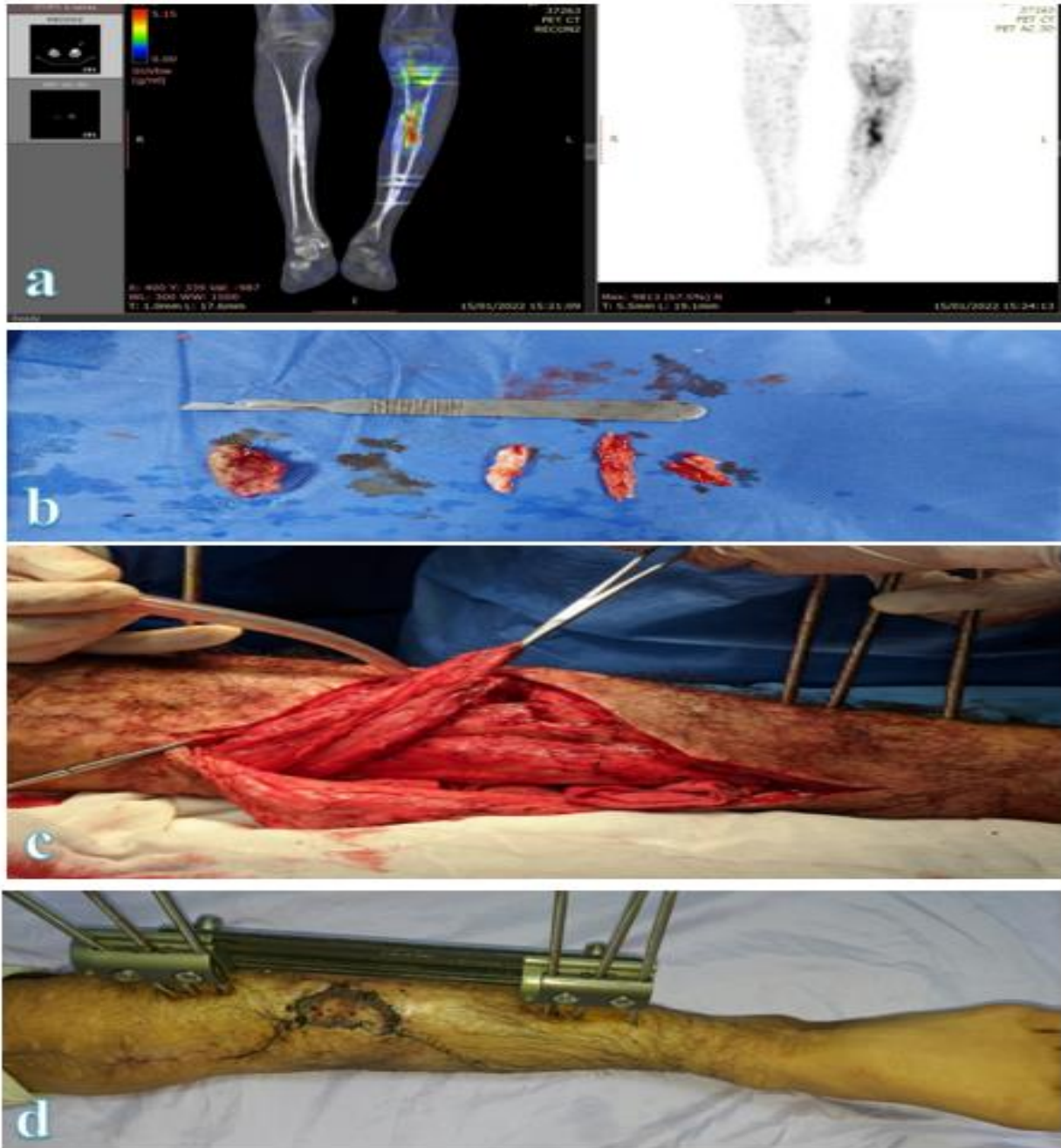


Fig. (4) 17 years old male patient who presented with compound fracture and osteomyelitis of the left tibia. PET CT scan was done to assess the extent of osteomyelitis. He was managed by bone and soft tissue debridement, polymethyl methacrylate cement insertion and coverage by a medial head Gastrocnemius muscle flap with a skin graft, (a) Pre-operative PET CT scan, (b) Intra-operative bone debridement, (c) Intra operative coverage by a muscle flap, (d) Post-operative clinical photo after 3 months.

Results

Table (1) demonstrates the baseline and demographic characteristics of the studied patients. As regarding the time interval from trauma to intervention, there was no difference

between both studied groups (p-value= 0.295). Time interval from trauma to intervention in fascio-cutaneous flap group ranged from (2) to (6) with an average duration of (3.40 ±1.51) months, while in muscle flap group the duration was ranged from (2) to (12) with an average duration of (4.70 ±3.49) months.

Table (2) demonstrates the distribution of the studied participants by Cierny Osteomyelitis Type, there was non-statistically significant difference between both studied groups regarding the Cierny Osteomyelitis Type, (p-value= 0.587). Type II and III was the most prevalent in Fascio-cutaneous flap group (80%), while type III was the most prevalent in muscle flap group (60%).

As shown in table (3), there was non-statistically significant differences between both studied groups regarding the Flap viability (p-value= 0.368), and Donor site morbidity (p-value= 0.263).

Regarding comorbidities, eight cases reported comorbidities (six cases with DM and two cases with brain tumor) without a statistically significant difference between both studied groups (p-value= 0.709).

Eradication of infection was judged by clinical follow up of adequate soft tissue coverage without bone exposure or discharging sinus together with plain X-ray and PET_CT scan to exclude recurrence of osteomyelitis. It has been achieved in 14 cases in Fascio-cutaneous flap group, compared to 18 cases in muscle flap group, with a statistically significant difference (p-value=0.047). Incidence of Complications showed non-statistically significant difference between both intervention groups (p-value= 0.500). Complications of fascio-cutaneous flaps were fracture displacement (2 cases), recurrence of osteomyelitis (2 cases), graft loss and recurrence of osteomyelitis (2 cases). Complications of muscle flaps were partial flap necrosis (2 cases), donor site graft loss (3 cases), donor site wound dehiscence (1 case) and total flap loss (2 cases). Eight cases in Fascio-cutaneous flap group needed secondary procedures compared with four cases in muscle flap but without a statistically significant difference, (p-value= 0.314).

As regard the flap aesthetic satisfaction comparison between the two intervention groups, it was significantly higher among Fascio-cutaneous flap group compared to muscle flap group (6.60 ±2.07 vs. 4.20 ±2.04, p=0.018) in both groups respectively, table (4).

Table (1): Baseline and demographic characteristics of studied patients, (N= 40):

| | | Type of flap | | p-value |
|----------------|--------------|--------------------------------|----------------------|---------|
| | | Fascio-cutaneous flap n= 20 | Muscle flap n= 20 | |
| Sex | Male | 20 | 16 | 0.237 |
| | Female | 0 | 4 | |
| Age | Mean ±SD | 26.60 ±13.49 | 24.10 ±16.16 | 0.712 |
| | Median (IQR) | 26.50 (24.75) | 21.50 (29.75) | |
| | Min – Max. | 5.00 - 45.00 | 4.00 - 50.00 | |
| Special habits | No | 10 | 14 | 0.325 |
| | Smoking | 10 | 6 | |
| Comorbidity | No | 16 | 16 | 0.709 |
| | Present | 4 | 4 | |

Table (2): distribution of the studied participants by Cierny Osteomyelitis Type; (N= 40)

| | Type of flap | | p-value |
|------------|--------------------------------|----------------------|---------|
| | Fascio-cutaneous flap n= 20 | Muscle flap n= 20 | |
| II | 8 | 4 | 0.090 |
| III | 8 | 12 | |
| IV | 4 | 4 | |

p-values ≤ 0.05 considered statistically significant.

Table (3): Flap viability and Donor site morbidity among the studied patients, (N= 40):

| | | Type of flap | | p-value |
|-----------------------------|-------------------------|--------------------------------|----------------------|---------|
| | | Fascio-cutaneous flap n= 20 | Muscle flap n= 20 | |
| Flap viability | Not viable | 0 | 2 | 0.368 |
| | Viable | 18 | 18 | |
| | Partial necrosis | 2 | 0 | |
| Donor site morbidity | No | 20 | 16 | 0.263 |
| | Yes | 0 | 4 | |

p-values ≤ 0.05 considered statistically significant.

Table (4): Flap aesthetic satisfaction (points) among the studied patients, (N= 40):

| | | Type of flap | | p-value |
|------------------------------------|--------------------------------|--------------------------------|----------------------|---------------|
| | | Fascio-cutaneous flap n= 20 | Muscle flap n= 20 | |
| Flap aesthetic satisfaction | Mean \pmSD | 6.60 \pm 2.07 | 4.20 \pm 2.04 | 0.018* |
| | Median (IQR) | 7.00 (3.50) | 4.50 (3.00) | |
| | Min – Max. | 3.00 - 9.00 | 0.00 - 7.00 | |

p-values ≤ 0.05 considered statistically significant.

Discussion

Chronic osteomyelitis is a debilitating condition associated with bone necrosis, soft tissue disruption and pain resulting in significant morbidity and loss of function. The commonest protocol described for management includes initial evaluation of the general condition of the patient, proper and repeated debridement of necrotic tissues, fracture stabilization with external fixation, early soft-tissue coverage with local flaps or microsurgical free soft-tissue transfers, and bone reconstruction [8-13].

Considering comorbidities we had about 15% of cases complaining of diabetes mellitus compared to **Aaron et al, 2019** who had about 19% of cases with diabetes mellitus [14]. DM affects the prognosis of osteomyelitis especially if not controlled. He mentioned in his study that Cierny type IV was predominant in his cases (84%). However in our study we noticed that Cierny type III constituted about 50% of cases and type IV constitutes only 20% of cases. This difference may be due to the use of PET CT scan in our patients that led to early diagnosis of them.

In the current study we had two muscle flap cases non-viable and two fascio-cutaneous flap cases that had partial necrosis with non-statistically significant difference between them. These results were comparable to **Pablo et al, 2018** who had 1 non-viable fascio-cutaneous flap and 2 non-viable muscle flaps [15]. Regarding donor site morbidity there were no cases with

donor site morbidity in the group of fascio-cutaneous flaps, but we had 4 cases with donor site morbidity in the group of muscle flaps in the form of wound dehiscence and infection. **Pablo et al, 2018** mentioned that he had 2 cases with donor site morbidity in the group of fascio-cutaneous flaps, and 1 case with donor site morbidity in the group of muscle flaps [15]. We tried to use the simplest fascio-cutaneous flaps for coverage that resulted in decreased donor site morbidity in the group of fascio-cutaneous flaps.

The mean value of the time consumed intra-operative was 2.85 hours in case of fascio-cutaneous flaps whereas it was 3.2 hours in case of muscle flaps which indicates that harvesting of fascio-cutaneous flaps is more rapid than muscle flaps. Furthermore, the mean duration of hospital stay was 7.4 days in case of fascio-cutaneous flaps and 7.9 days in case of muscle flaps which is nearly the same.

In our study we found that eradication of infection was achieved in 14 cases of fascio-cutaneous flaps and in 18 cases of muscle flaps with no recurrence of infection in these cases which proved superiority of muscle flaps at this point. These results were different from that of **Joon et al, 2017** who reported equal results in both groups as he found that eradication of infection was achieved in 71 cases of fascio-cutaneous flaps (92%) and in 39 cases of muscle flaps (90%) [16].

Musharafieh et al, 1999 mentioned that he had no complications in fascio-cutaneous flap cases and 4 cases of complications in muscle flap cases in the form of recurrence of osteomyelitis or flap loss [17]. But in our study we had 8 cases of complications in fascio-cutaneous flap cases and 6 cases of complications in muscle flap cases in the form of recurrence of osteomyelitis, flap loss or wound dehiscence.

Our study revealed that the limitations for fascio-cutaneous flaps include large dead space after debridement or cases of severe infection. On the other hand, muscle flaps are limited by the need for staged operations when re-elevation of the flap is indicated. The mean flap aesthetic satisfaction was 6.6 out of 10 in fascio-cutaneous group and 4.2 out of 10 in muscle group which proves the superiority of fascio-cutaneous flaps at this point.

In conclusion, Both fascio-cutaneous and muscle flaps can be used successfully in soft tissue coverage after debridement of tibial osteomyelitis. Fascio-cutaneous flaps are recommended in cases of low grades of osteomyelitis and when secondary flap re-elevation is intended. On the other hand, muscle flaps are recommended in cases with high grade osteomyelitis, large dead space and when the patient is not concerned about the aesthetic result.

Ethical approval and declaration of patient consent

This study was approved by the Research Ethical Committee, Faculty of Medicine, Beni-Suef University which is organized and operated according to guidelines of the Declaration of Helsinki, International Conference of Harmonization ICH, and United States Codes of Federal Regulations and registered in under the Federal Wide Assurance (FWA) for the protection of Human Subjects (FWA #: FWA00015574) (Approval No: FMBSUREC/07022021/Zaki). All participants provided written informed consent before enrolment in the study. The privacy and confidentiality of patient records were adhered to in managing the clinical information in conducting this research.

Conflicts of interest and financial declaration statement

There are no conflicts of interest to declare, and the authors have no financial interest or funding concerning this article.

Location where the work was performed: Benisuef University Hospital

Description of Individual Author Contributions

Khaled M Abdel Azeem, Abdel Nasser M El Naggar and Ahmed R Abdel Gawad wrote the main manuscript

Mostafa F Ibrahim and Mohamed A Abdelkader prepared the figures

Abdelrahman G Zaki and Ahmed E Ahmed prepared the statistical data

All authors read and approved the manuscript

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