

Managing Tibial Bone Defects: Analysis of Direct Medical Costs Between Distraction Osteogenesis With an Ilizarov Frame and the Masquelet Technique

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Purpose: Successful management of segmental bone defects remains one of the biggest clinical challenges. Primary aim was to define the direct medical cost of the surgical treatment of tibial bone defects in a single tertiary referral center. Secondary end points were (1) to compare the direct cost between Ilizarov bone transport (ILF) versus the internal fixation staged Masquelet (MIF), and (2) to compare the direct cost between cases of acute tibial bone loss versus bone loss generated during the treatment of infections/nonunions.

Methods: Prospectively collected data were analyzed. Patients <18 years of age or with follow-up <12 months were excluded. Random selection of patients treated with MIF or ILF was performed. Data included demographics, comorbidities, severity of trauma, defect size, duration of surgery, exact numbers of sterile kits and types of implants, transfusions, laboratory and imaging investigations, medications, length of hospital stay, visits to clinics, time to union, and time to final discharge. A cost-effectiveness analysis was performed including full inpatient, intraoperative, and follow-up direct medical costs. As the end point of clinical efficacy, the time to union of the bone defect was used. We have utilized the records of the finance departments of our hospital, the 2019/2020 National Tariff, and the British National Formulary, as well as the price list from industry partners in regard to all utilized implants.

Results: 10 patients with acute and 10 with nonunion defects, treated half with ILF and half with MIF, were included. The mean defect size was 5.6 cm (range, 2.7-9.5), the mean time to union was 12.9 months (4.6-22.2), with an overall cost of £453,974. No statistically significant difference (ssd) was proven to the mean age, ISS, American Society of Anesthesiologists class, defect size, follow-up duration, length of stay, and cost of in-hospital stay. The overall direct medical cost of the MIF group was 74% of that of the ILF. There was ssd favoring the MIF group on the average time to union (10 vs 15.6 months, $P = 0.02$), the number of surgical procedures (3 vs 4, $P = 0.049$), the number of admissions (2 vs 3, $P = 0.026$), the intraoperative cost (£8857 vs £14,087, $P = 0.001$), the cost of outpatient clinic follow-up (£2147 vs £5240, $P < 0.001$), the cost per cm of defect (£1935 vs £3799, $P = 0.047$), and the overall cost of treatment (£18,131 vs £26,126, $P = 0.011$). No ssd of cost was found between acute and nonunion defects managed with an ILF. When the MIF was used, the mean time to union (7.91 vs 12.67 months, $P < 0.001$), as well as the cost of outpatient follow-up (£1368 vs £3122, $P < 0.001$) were significantly lower on acute versus nonunion defects.

Conclusion: The successful management of segmental tibial defects requires surgical expertise, time, and significant resources. There were clear differences in the direct medical costs between the 2 most common procedures. Even with an uncomplicated clinical course, the high cost of the implants, the considerable time until defect union, and the need for follow-up and secondary procedures highlight the importance of robust reimbursement, since both techniques are indispensable.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.