



Case Report

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How Shall We Proceed After Inserting an Unsterile Device for Fracture Fixation: ReTENing or Retaining? A Case Report

Ramin Zargarbashi¹ , Behnam Panjavi¹, Mohammadreza Bozorgmanesh^{2*} 

1. Children's Medical Center, Tehran University of Medical Sciences, Tehran, Iran.

2. Department of Orthopedic Surgery, Vali-e-Asr Hospital, Arak University of Medical Sciences, Arak, Iran.



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Running Title: Inserting Unsterile Devices, ReTENing or Retaining?

ABSTRACT

Background: Limited information is available on how to properly manage to implant nonsterile devices in the medical literature. To the best of our knowledge, there is no guideline for managing nonsterile medical devices implanted inadvertently.

Case Presentation: A 3.5-year-old boy was operated on because of femur fracture malunion. After the completion of the operation and discharging the patient, we were informed that the nail has not been sterilized. The parents were immediately informed about the complication and the patient was re-admitted to the hospital. The situation and its complication were thoroughly discussed with the family. By active involvement of the parents, infectious specialist, and the orthopedic surgeon, a shared decision was made to treat the complication. The patient was closely observed. In a radiograph obtained at the 4th week after the index surgery, the sign of callus formation was observed. At this time, we decided to remove the Titanium Elastic Nail (TEN) and continue casting for another two weeks.

Conclusion: The primary "take-away" lesson of this case report is that honest disclosure of our mistake facilitated the additional necessary treatment. One single case is not enough for making a recommendation or offer a guideline for this kind of error during or after an orthopedic procedure; however, this case presents a successful method. Although the consequences of infection could be dire, it is prudent to take "not-to-harm" as the first step in benefiting.

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* Corresponding Author:

Mohammadreza Bozorgmanesh, MD.

Address: Department of Orthopedic Surgery, Vali-e-Asr Hospital, Arak University of Medical Sciences, Arak, Iran.

E-mail: mhmmdrz_bzrgmsh@yahoo.com

Introduction

For any health care provider, one of the most difficult experiences is when he realizes that he has made a mistake that might have harmed a patient. Previously, mistakes were rarely disclosed to patients. As mentioned by Sigall: “The prevailing ethos was one of professional silence, secrecy, and shame” that has started to change. Full disclosure of mistakes and apologies for the harm that is caused is prevailing in the medical practice as well as law. An atmosphere of openness and honesty is currently believed to lead to a culture of quality and safety [1]. When it comes to human error, medical devices of all varying levels of complexity may impose a multitude of dangers. Some can be catastrophic, among which the most dreaded is a failure to sterilize a medical device that has to be either implanted or inserted into a patient’s body. Failure to do so exposes a patient to all sorts of harm, including fungal, viral, or bacterial infections.

For patients with compromised immune systems, this can even be deadly and cases of individuals becoming sick or even die from infections caught in hospitals and medical centers from unsterilized equipment are all too commonplace [2]. Limited information is available on how to properly manage to implant nonsterile devices in the medical literature. To the best of our knowledge, there is no guideline for managing nonsterile medical devices implanted inadvertently. Herein, we report such an error that we feel can help understand the clinical and ethical spectrum of this rare complication. We have generated the hypotheses that wait-and-see might be a viable option in this situation.

Case Presentation

A 3.5-year-old boy was referred to our hospital orthopedic clinic, (a tertiary center for pediatric orthopedic care in Tehran, Capital of Iran) with femoral fracture malunion. He had a femoral fracture after falling that had been treated with closed reduction and Spica casting. During follow-up, the reduction was lost and a repeated closed reduction and casting were attempted again. The reduction was lost and the fracture displaced after two weeks when the patient was referred to our hospital.

The radiographic at the time of presentation revealed a malunion of a femoral fracture with more than 30 degrees of angulation on Anterior-Posterior (AP) view and considerable callus formation (Figure 1-A). An open reduction and internal fixation were planned to treat

malunion. During the operation, the fracture site was exposed, the callus was debrided, the fracture was reduced, and the reduction was assessed in terms of angulation, displacement, and rotation. Then, as shown in Figure 1-B, final fixation was obtained using a 3-mm Titanium Elastic Nail (TEN). To secure rotational stability, a Spica cast was applied.

After the completion of the operation and discharging the patient, we were informed that the nail had not been sterilized. The parents were immediately informed about the complication and the patient was re-admitted to the hospital. The situation and its complication were thoroughly discussed with the family. Because of limited information regarding how to appropriately manage such complications in the medical literature, we consulted an infectious specialist. By active involvement of the parents, infectious specialist, and the orthopedic surgeon, a shared decision was made to:

- Have the patient on a prophylactic antibiotic regimen of combined intravenous clindamycin and gentamicin.

- Check the wound for any sign of deep or superficial infection by opening a window in the cast over the surgical site.

- Check complete blood cell count for leukocytosis, Erythrocyte Sedimentation Rate (ESR), and C-Reactive Protein (CRP) on a 3-day interval basis in accordance with infectious specialist advice.

The patient was closely observed. No clinical or para-clinical sign of infection was observed during two weeks of follow-up. At this point, we decided to stop antibiotic therapy and discharge the patient; however, we kept checking ESR and CRP weekly.

In a radiograph obtained at the 4th week after the index surgery, a sign of callus formation was observed. At this time, we decided to remove the TEN and continue casting for another two weeks (Figure 1-C).

Discussion

Limited data exist regarding the incidence and nature of the patient- and family-reported medical errors, particularly in pediatrics [3]. The prevention of serious errors in medical care has long been of concern to health professionals, especially to courts and legislatures [4]. However, the recent report by the Institute of Medicine (IOM), “To Err Is Human”, brought to our attention that each year, more Americans die as a result of medi-

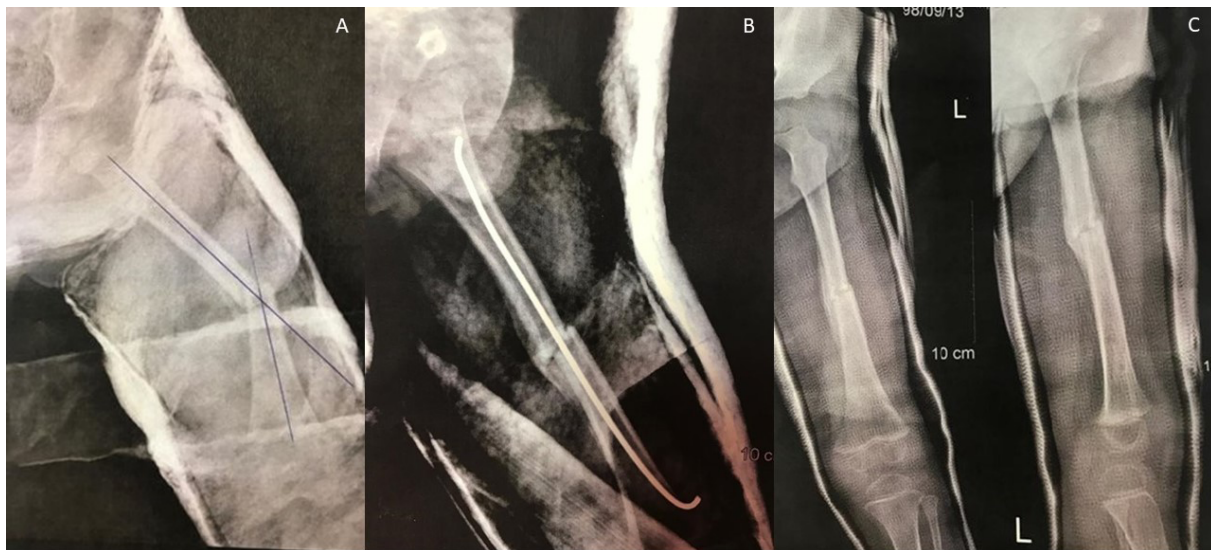


Figure 1. Radiographic study of the malunited fracture (A), intramedullary fixation (B), and final result with callus formation (C).



cal errors made in hospitals than as a result of injuries from automobile accidents [5], although some people disagree with the report's conclusions, arguing that the report overstated the magnitude of the problem [6-8].

Matthias Vautrin et.al propose some cases of sterility error during the orthopedic procedure and conducted a survey on two groups of experienced and inexperienced surgeons. They analyzed the attitudes and practices of the surgeons. They investigated the errors that have become revealed to the surgeons at some time during a procedure when the surgeon still holds the chance to change the plan of surgery before the completion [9].

In 1992, two cases of postsurgical infection were reported to the center of disease control of the US occurring after the implantation of devices labeled and sold as nonsterile. Although there was no evidence that the infections resulted from the implants [10]. Theoretically, when a surgeon inadvertently inserts an unsterile device into a bone, he would be left with few options. Removal of the unsterile device with debridement and irrigation is an option that could be followed by applying an external fixator, inserting a new sterile device, or casting. Because bacteria have already colonized in the medulla of bone during the 1st operation, an antibiotic regimen may be needed. On the other hand, reoperation increases the risk of infection in its own turn.

Within the framework of the therapeutic paradigm for malunion and nonunion that implies "it is easier to treat an infected union than to treat to infected nonunion [11, 12]", we have erred on the side of caution and opted to peruse a course of active close observa-

tion. This method of treatment might make sense when we consider findings from the literature showing that the gloves or skin might be contaminated by bacteria or the contamination due to defects in arthroscopic camera cover is commonly seen after surgery without infection [13]. Therefore, the existence of bacteria does not equal infection [14].

Conclusion

One single case is obviously not enough for making a recommendation or offer a guideline for this kind of error or after the orthopedic procedure; however, this case shows a successful method. Although the consequences of infection could be dire, it is prudent to take "not-to-harm" as the first step in benefiting. The principle of justice recommends disclosure of instructions to patients to obtain what they owe. Honest disclosure facilitated the additional necessary treatment.

Ethical Considerations

Compliance with ethical guidelines

All ethical principles are considered in this article. The participants were informed about the purpose of the research and its implementation stages. They were also assured about the confidentiality of their information and were free to leave the study whenever they wished, and if desired, the research results would be available to them.

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Authors' contributions

Conceptualization and Supervision: Ramin Zargarbashi; Methodology: Mohammadreza Bozorgmanesh Investigation, Writing – original draft, and Writing – review & editing: All authors; Data collection: Behnam Panjavi, Ramin Zargarbashi; Data analysis: Mohammadreza Bozorgmanesh.

Conflict of interest

The authors declared no conflict of interest.

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