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Increased risk of time-dependent K-wire and wound contamination and the effect of covering on K-wire contamination: A randomized controlled trial

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Abstract

Aim: This was a prospective randomized controlled study to evaluate the time-dependent incidence of contamination of K-wires and wounds in patients who underwent osteosynthesis and the effect of covering the K-wires on this incidence rate of infection.

Materials and Methods: The study sample included 90 patients who underwent open reduction and internal fixation between 2018 and 2019. Patients were randomized to two groups: use of covered K-wires during surgery (using a sterile towel) and use of uncovered K-wires. Bacterial samples were obtained from the K-wires and wound at the following time points: 0 (just after opening of the K-wire packages) and at 15, 30, 60, 90, and 120 min after. Samples with bacterial growth at 48 h were considered contaminated. Microscopic, staining, and biochemical properties were used for bacterial typing.

Results: Bacterial growth was detected at the 30- and 60-min time points for the uncovered and covered groups, respectively. Wound contamination was identified within 15 min for the uncovered group. Wound and K-wire contamination progressed as a function of time, being consistently more significant in the uncovered group ($p < 0.005$).

Conclusion: Time-dependent K-wire and wound contamination rates may be decreased by covering the K-wires (and other instruments) with a sterile towel. Frequent wound irrigation during surgery and postoperative prophylactic antibiotics targeting the bacteria we identified might further be useful in lowering the incidence rate of infection.



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Introduction

Infection following osteosynthesis of a closed fracture is uncommon but, when present, is associated with high rate of morbidity and healthcare cost [1, 2]. Moreover, the rate of infection associated with osteosynthesis is expected to rise with the increasing use of internal fracture fixation [3]. Of further concern is the increase in antibiotic-resistant micro-organisms which has the potential to further complicate treatment [4]. Therefore, the prevention of infection has become a critical component of patient care in hospitals. Currently, there is no consensus regarding optimal strategies for the management of osteosynthesis-associated infections [5]. Various risk factors for infection after internal fracture fixation have been identified, with these risk

factors generally classified as *host-related* and *perioperative* factors. Effects of antibiotics [6], duration of surgery [7, 8], surgical site preparation [9], reaming and drilling [10], number of implants used [1], grafting [11, 12], use of surgical drains and indwelling catheters [13], blood transfusion [14], external fixation time [15], and contamination of surgical trays, back table, and implants [16-20] have been evaluated. Kirschner (or K-) wires are widely used in orthopedic trauma surgery, including for provisional or definitive fixation of fracture fragments, to guide implantation of screws and nails, for external fixation, and to provide an anchor for skeletal traction [21]. Pin tract infection is a common complication that has been associated with implant loosening, fracture instability, and deep infection [22]. Although the incidence rate and factors associated with pin tract infection have previously been evaluated [23], to the best of our knowledge, contamination of K-

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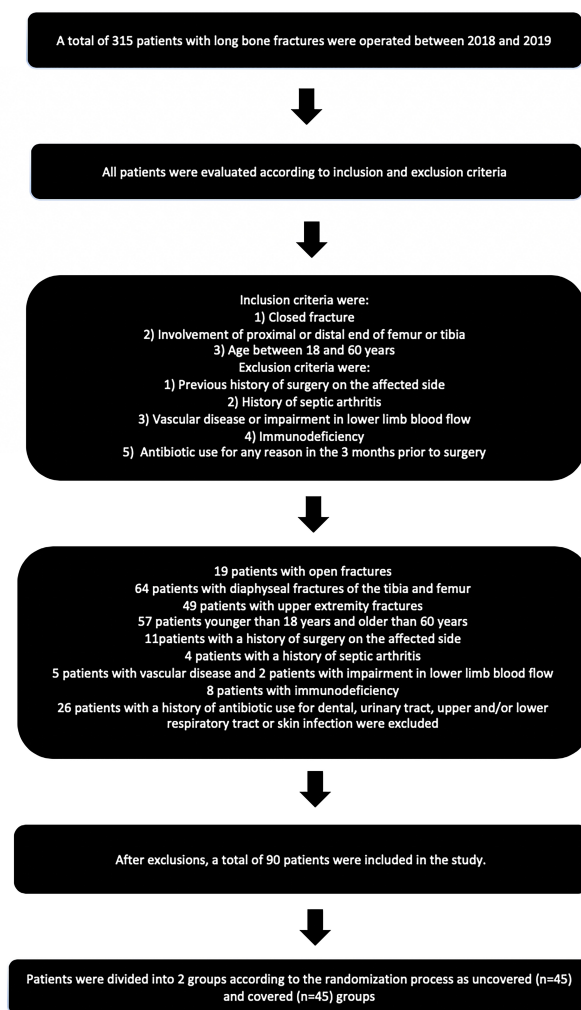


Figure 1. The flowchart showing exclusion steps and exact numbers of exclusions.

wires used during trauma surgery, which may also be a source of infection, has not previously been reported. The primary aim of our study was to evaluate the incidence rate of time-dependent contamination of K-wires and associated wound infection, as well as to evaluate the effect of applying a sterile covering to the back table of the K-wire on this rate of infection. The main outcomes were [1] time-dependent intraoperative contamination rates and [2] postoperative infection rates. Our secondary aim was to identify the most common contaminating microorganisms of K-wires. A priori, we hypothesized that covering of the K-wires would reduce the rate of contamination.

Materials and Methods

Our study was approved by our Institutional Research Ethics Review Board. Contamination of K-wires on the back table and surgical wound was prospectively evaluated. All orthopedic procedures were performed by two experienced trauma surgeons, with the same surgical team and in the same laminar flow operating room. Single dose 1 g cefazolin was used for prophylaxis. For all procedures, room traffic was strictly controlled by the circulating nurse. The door to the operating theatre was closed prior to the start of the procedure and kept closed until

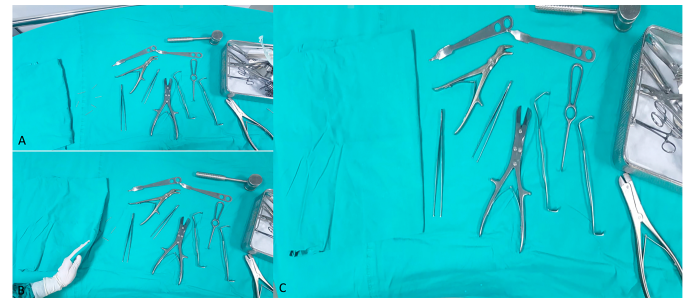


Figure 2. a, Uncovered K-wires. b, Covering the K-wires immediately after use. c, Covered K-wires.

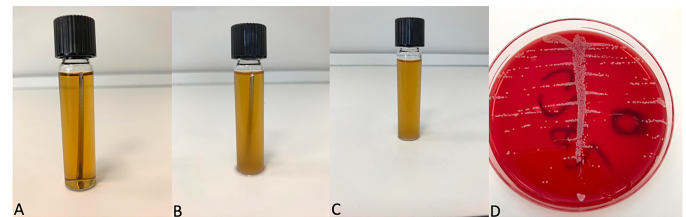


Figure 3. a, Clear appearance of non-bacterial growth K-wire sample. b, Turbid appearance of bacterial growth following contamination on K-wire sample. c, Turbid appearance of bacterial growth following contamination of wound sample. d, the appearance of bacterial growth on blood agar.

wound closure was completed.

Prospective patients (228 patients) were those who underwent open reduction and internal fixation (ORIF) for lower extremity long bone fractures, between 2018 and 2019. The inclusion criteria were as follows: closed fracture of the proximal or distal end of femur or tibia; age between 18 and 60 years; no previous history of surgery on the affected side, septic arthritis, soft tissue infection, vascular disease or impairment in lower limb blood flow, immunodeficiency, and antibiotic use, for any reason, in the 3 months prior to the surgery (Fig. 1). Randomization was performed using an envelope, with two possible options, covering or no covering of the K-wires with a sterile towel during the surgery. For analysis, patients were classified into the no covering (Group 1) or covering (Group 2) groups, according to the randomized allocation. The baseline demographic data for patients in the two groups is presented in Table 1.

Before sterilization, 6 K-wires (TST, Istanbul, Turkey) were cut to a length of 2 cm and thickness of 2 mm. A total of 90 surgical trays, 45 uncovered and 45 covered were included. All trays were opened, using a standardized method, 5 min before the surgeon was ready to use them. The standardized method was as follows: the circulating nurse first opened the top wrapper flap and then each of the two sides; the scrubbed nurse took out the instruments and K-wires from the wrapper using sterile forceps; and sterilization of the contents was confirmed using indicator strips. Wet and damaged packages were considered contaminated and excluded from the study.

In Group 1, the surface of the surgical instrument table, including all surgical instruments, was left uncovered. In

Group 2, the table and surgical instruments were immediately covered with a sterile towel (Fig. 2). This sterile covering was also placed over the tray every time a surgical instrument or implant (including K-wire) was used to avoid contact with possible surgical instruments that may have been contaminated during the surgery. Culture samples from the K-wires were obtained and placed in a liquid culture medium immediately after opening (time zero) and at 15, 30, 60, 90, and 120 min after opening of the package. Liquid culture samples were taken from the wound at the same time points, plus at time '0', just after the incision. All culture mediums were placed in an incubator. Patients were followed-up for a minimum of six months after surgery.

For analysis, K-wires and wound samples were placed in sterile tryptic soy broth (TSB) liquid culture mediums (RTA, Kocaeli, Turkey), using aseptic techniques, and incubated at 37 °C for 24 h. At the end of the incubation period, the samples were retrieved from the liquid culture medium using sterile loops (Fig. 3). Each plastic calibrated loop was removed from its package aseptically. Each 0.001-mL loop was inserted vertically into the TSB, allowing it to adhere to the loop. Next, liquid from the loop was spread on the surface of a 5% sheep blood agar plate (RTA, Kocaeli, Turkey), and the plates were incubated at 37°C. Microbiological procedures and evaluations were performed by an expert microbiologist, with presence of growth on the plate at the end of 48 h recorded (Fig. 2). Microscopic, staining and biochemical properties of the microorganisms were evaluated by the expert microbiologist. The number of colony-forming units (CFU) was multiplied by 1000 as a 0.001-mL loop was used to determine the number of CFU/mL in the original specimen.

All statistical analyses were performed using SPSS (version 28.0.0.1.0; IBM, Armonk, NY, USA). Distribution of the data was evaluated using the Shapiro-Wilk test. Independent samples t-test was used for comparison of normally distributed data based on contamination, and the Mann-Whitney U-test for comparison of non-normally distributed data. The chi-squared test was used to examine categorical data. A post-hoc power analysis was performed to determine the statistical power of our findings. Values were reported as the mean $\pm$ standard deviation for continuous data and as the frequency (percentage) for categorical data. A p-value <0.05 was considered significant.

Results

After screening for inclusion and exclusion criteria, 90 patients who underwent open reduction and internal fixation (ORIF) for lower extremity long bone fractures, between 2018 and 2019, were included in the study group. Forty-five patients in each group were included for the intervention and final analysis. No bacterial growth was identified in any of the samples at time zero. Growth was detected in 8 samples (17.8%) in the uncovered group at 30 minutes, compared to 4 samples (8.9%) in the covered group at 60 min. Bacterial growth was identified in 11 (12.3%) of the wound samples at 15 min. Contamination of the K-wires and wound samples increased with time (Table 2), with contamination being more prominent in uncovered, and associated wound, samples. Contamination rates at

Table 1. Patient demographics and surgery related variables in the uncovered and covered groups.

	Uncovered group (n=45)	Covered group (n=45)	p
Age (Mean $\pm$ SD)	43.9 $\pm$ 24.5	46.1 $\pm$ 22.6	0.286
Sex			
Female	10	8	0.725
Male	35	37	
Side			
Right	20	17	0.964
Left	25	28	
BMI (Mean $\pm$ SD)	25.2 $\pm$ 2.8	26.5 $\pm$ 2.6	0.314
ASA score (Median) (range)	2 (1 to 4)	2 (1 to 3)	0.810
Fracture to surgery interval (day) (Mean $\pm$ SD)	1.6 $\pm$ 1.2	2.4 $\pm$ 1.8	0.512
Operation time (Min) (Mean $\pm$ SD)	129.3 $\pm$ 10.9	133.9 $\pm$ 15	0.461
Soft tissue injury (Tscherne grade)			
C0	9	11	0.653
C1	16	11	
C2	16	18	
C3	4	5	
Fracture distribution			
Proximal femur	5	7	0.299
Distal femur	14	11	
Proximal tibia	17	20	
Distal tibia	9	7	
AO fracture subtype			
A3	3	2	0.856
B2	6	7	
B3	8	8	
C1	6	4	
C2	8	11	
C3	14	13	

120 min were 68.9% in the wound samples, and 46.7% and 20%, respectively, for the uncovered and covered samples (Table 2). There was a significant difference in contamination rates at the 30-, 60-, 90-, and 120-min time points between the uncovered and covered K-wire samples (Table 2). In addition, there was a significant difference in contamination rates detected at the 15-, 30-, 60-, 90-, and 120-min time points between wound and uncovered K-wire samples (Table 2).

Coagulase-negative *Staphylococci* (58.7%) was the most common bacteria detected on the contaminated K-wires and wound samples, followed by *Staphylococcus epider-*

Table 2. Time dependent contamination rates in the uncovered and covered K-wire samples.

Time point (min)	Uncovered (n=45) (%)	Covered (n=45) (%)	p
0	0 (0)	0 (0)	1.000
15	0 (0)	0 (0)	1.000
30	8 (17.8)	0 (0)	0.016
60	13 (28.9)	4 (8.9)	0.035
90	17 (37.8)	6 (13.4)	0.013
120	21 (46.7)	9 (20)	0.020

Table 3. Distribution of growing bacteria type according to K wire and wound samples.

Bacteria	K-wires (n) (%)	Wound (n) (%)	Total (n) (%)
Coagulase-negative <i>Staphylococci</i>	15 (50)	39 (62.9)	54 (58.7)
<i>Staphylococcus epidermitis</i>	8 (26.7)	12 (19.4)	20 (21.7)
<i>Staphylococcus aureus</i>	5 (16.7)	6 (9.7)	11 (12)
<i>Streptococcus agalactiae</i>	2 (6.6)	5 (8)	7 (7.6)
Total	30 (100)	62 (100)	92 (100)

midis (21.7%), *Staphylococcus aureus* (12%), and *Streptococcus agalactiae* (7.6%) (Table 3). Postoperative infection developed in 3 patients (3.4%) within 3 weeks after surgery. All 3 patients (1 distal femur and 2 proximal tibia fractures) were in the uncovered group, with positive contamination of wound and instruments. In all of infected patients, plate fixation was used after open reduction. From the debrided tissue, coagulase-negative *Staphylococcus* was isolated in one of these patients, with *Staphylococcus epidermidis* isolated in the other two. All 3 patients were treated with implant removal and serial radical debridement, followed by antibiotic loaded cement application, external fixation and intravenous antibiotic therapy, with resolution of the infection achieved in all 3 patients.

With regard to the clinical significance of our results, we conducted a post-hoc power analysis. A between-group comparison d-value effect size of 0.251 was calculated. Therefore, approximately 130 patients would be needed to obtain statistical power at the recommended 0.80 power level.

Discussion

The most important finding of our study was that K-wire contamination was identified as early as 30 min after opening of the package in the uncovered samples, compared to

60 min in the covered samples, with wound contamination being observed as early as 15 min after the start of surgery. As well, the rate of contamination increased as a function of time in both the covered and uncovered groups. Although modifying host and perioperative risk factors, infection after ORIF remains an important clinical issue [24].

One of our aims was to identify potential sources of infection after ORIF. The development of infection after surgery is multifactorial. However, in our sample group, all 3 patients who developed infection had wound contamination and were in the uncovered group, as well as having a Tscherne grade of soft tissue injury ≥ 2 [25]. A longer operative time has been associated with a higher risk of postoperative complications [26]. Bleeding, soft tissue damage, and wound contamination, which are associated with a prolonged surgery, provide a facilitating environment for infection development [27]. In our study, although a post-operative infection developed in only 3 of 90 patients, contamination of the wound and K-wires remained significant causes of infection, regardless of operative time.

Bacteria are susceptible to host defense and antibiotics at inoculation [28]. In the presence of implant material, tissues become more sensitive to biofilm formation and infections [29]. Wound and K-wire contamination in the early period of the surgery, as we identified in the uncovered group in our study, increases the likelihood of bacterial growth at the wound site and the possibility of biofilm formation on the K-wire (and other implants) and infection. As a simple method, covering of the surgical instrument table, including K-wires, with a sterile towel may help to decrease contamination and contamination-associated infections. Furthermore, frequent irrigation of the wound may reduce the chance of infection due to contamination [1].

Previous studies have evaluated the effectiveness of covering surgical trays, the back table, surgical instruments, and implant sets in lowering the risk of contamination [16-20]. Dalstrom et al. [17] reported a 30% rate of contamination of surgical trays left uncovered, with no contamination of covered surgical trays. They further reported a positive correlation between positive bacterial culture and the duration of the surgery. A point of comparison is that Dalstrom et al. [17] used real surgical trays but did not remove instruments from the trays, while in our study, the K-wires were placed on the nurse’s desk before being used, rather than on the surgical tray to prevent contamination through contact with other surgical instruments. In this way, contamination due to possible wound contamination did not affect K-wire contamination.

We found a positive correlation between bacterial culture positivity and the duration of the surgery. Menekse et al. [18] reported the onset of bacterial growth within 30 min of the start of surgery in uncovered pedicle screws, compared to 60 min in covered pedicle screws. In our study, we identified a time-dependent increase in K-wire contamination, which started after 30 min in uncovered tables, compared to 60 min in the covered tables. Uzun et al. [20] also evaluated the time-dependent contamination of surgical instruments, during total knee arthroplasty in their case. In that study, the K-wire samples were placed on

the back table and were in contact with surgical instruments. Consistent with our findings, they reported bacterial growth within 30 min in the uncovered samples and after 50 min the covered samples. Menekse et al. [18] also reported similar results. We extended the findings from these studies by further evaluating wound contamination, which would also affect K-wire contamination, as well as identifying the contaminating microorganisms. We also emphasize that the K-wires in our study were maintained away from the surgical instruments.

The relationship between the degree of soft tissue injury and the incidence of postoperative infection has previously been reported [30]. In our study, the 3 patients who developed infection had a Tscherne soft tissue injury grade ≥ 2 . Intra-operative deep soft tissue and subcutaneous tissue irrigation before skin closure, using saline or antiseptic solutions, has been frequently used in clinical practice to reduce the risk of surgical site infections [5]. According to our results, wound contamination begins in the early stages of the surgery. As the exposure time to bacteria increases as a function of the elapsed time before irrigation, performed just prior to skin closure, a longer operative time will directly increase the risk of postoperative infection risk. Therefore, we recommend that frequent wound irrigation during surgery might reduce the effect of a time-dependent increase in the risk of contamination.

There are several strengths and limitations to our study which should be acknowledged in the interpretation of results. The most important strength is that this is the first attempt to evaluate both time-dependent K-wire and wound contamination in closed fracture surgery. In addition, the bacterial typing in contaminated samples that we report may provide a reference to inform targeted postoperative infection prevention. The limitations of our study include a relatively small sample size. In particular, a postoperative infection developed in only 3 patients, which is insufficient for a clinically meaningful difference between the covered and uncovered groups. As well, the duration of surgery was limited to 2 h in all cases and, therefore, effects of longer operative time could not be evaluated. Various other implants were used in the fracture fixation and so they have added additional variables to our study. Only K-wires should have been used in the fracture fixation. Obviously, this was not possible because the fractures required internal fixation with other internal fixation devices. Since postoperative infection is dependent on many factors, a correlation between contamination and infection could not be identified. We also note that different microorganisms might grow after 24 h; however, we only used an incubation time of 24 h to detect the most commonly expected bacteria. Antibiotic susceptibility test, which could be useful in selecting postoperative empirical antibiotics, was not performed. Due to limited study budget, only 90 patients could be included. According to our post-hoc power analysis, a limited statistical power was detected due to modest sample size ($n=90$) that may have played a role in limiting the significance of comparisons conducted. Future studies including larger sample size and adequate statistical power may support our findings.

Conclusion

Contamination of the K-wire and wound is time-dependent. K-wire contamination rates may be decreased by covering the back table with sterile towels. Also, opening some surgical instruments just before their use may be beneficial to reduce the rate of time dependent contamination. In clinical practice, in addition to covering the K-wires and frequent wound irrigation, empiric antibiotic regimens, based on the bacteria identified in our study, may be developed as prophylaxis against postoperative infection.

Ethics approval

Ethical approval for this study was obtained from the Clinical Research Ethics Committee of Kırşehir Ahi Evran University Faculty of Medicine (2019-06/73, 26.03.2019).

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