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Study on the Application of Refined Management of Foreign Medical Devices and Implants in Infection Control of Orthopedic Implant Surgery

Chen Chen, Zifeng Li*

Shaanxi Provincial People's Hospital, Xi'an 710068, Shaanxi, China

Author to whom correspondence should be addressed.

Abstract: *Objective:* To analyze the application effect of refined management of foreign medical devices and implants in infection control of orthopedic implant surgery. *Methods:* 252 patients who underwent orthopedic implant surgery in a hospital from May 2023 to April 2024 were selected and grouped according to the time node of the introduction of the refined management method. 126 patients before the introduction of the refined management method were included in the control group, and the surgical operation was completed by 20 doctors, with a total of 1,204 pieces of medical devices and implants. The 126 patients after the introduction of the refined management method were included in the observation group, and the surgical operations were performed by 21 doctors, using a total of 1,207 medical devices and implants. The two groups were compared in terms of the qualification rate of foreign medical devices and implants, satisfaction with their use, and the rate of infection of surgical incisions in the hospital. *Results:* The qualified rate of foreign medical devices and implants in the observation group was 96.93%, which was significantly higher than that of 83.97% in the control group ($P < 0.05$). Satisfaction scores for the observation group in the dimensions of the quality of foreign medical device and implant items, device distribution, timeliness of supply, and improvement of the problem were respectively 85.27 ± 6.78, 86.69 ± 6.73, 85.92 ± 6.47, 86.79 ± 5.83, which were significantly higher than the control group's 80.42 ± 6.26, 82.24 ± 6.29, 81.19 ± 5.83, 82.14 ± 5.72, and the difference was statistically significant ($P < 0.05$); the rate of nosocomial surgical incision infection in the observation group was 0.79%, which was significantly lower than that of the control group (6.34%) ($P < 0.05$). *Conclusion:* The application of refined management in the infection control of orthopedic implant surgery can obtain ideal results, significantly reducing the risk of nosocomial incision infection and further improving the qualification rate of foreign medical devices and implants, and ultimately, obtaining a higher degree of satisfaction with the use.

Keywords: Foreign medical devices; Implants; Refined management; Orthopedic implant surgery; Incision infection

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1. Introduction

With the increasing number of traffic injuries, fall injuries, and other emergency surgeries in recent years, the use

of artificial prostheses, internal fixation materials, and other foreign medical devices and implants has gradually increased. Although it can significantly improve the therapeutic effect of the skeletal system diseases, due to the supplier-led flow, complex structure, and frequent turnover, there are significant hidden dangers in the cleaning and sterilization, quality traceability, and other aspects, which easily cause surgical incision infections—a serious threat to patients' prognosis [1]. Clinical studies have shown that the incidence of orthopedic implant-related infections can be up to 2.1–5.8%, and because of its tendency to form biofilms that lead to antibiotic resistance, the rate of secondary surgery for infected patients is as high as 34%, and the cost of healthcare is increased by nearly three times. Notably, about 40% of infections are directly related to defective management of foreign medical devices and implants [2]. A domestic multicenter study pointed out that the first sterilization failure rate of orthopedic foreign devices exceeded 30%, and the functional defect rate of devices reached 8.6%, exposing the systemic risk of traditional rough management. Firstly, multi-departmental collaboration in the flow of instruments is faulty, and delayed pretreatment leads to bioburden overload; secondly, the sterilization protocol is not sufficiently adapted to the material of the instruments, such as porous titanium alloy implants with residual contaminants due to inappropriate sterilization parameters; and furthermore, the informationization traceability system is missing, and it is difficult to trace the correlation between infection cases and instrument batches. Although the international guidelines emphasize the implementation of the full life-cycle management of devices, the domestic practice still focuses on the optimization of a single link, and lacks an integrated strategy covering "access-processing-use-monitoring" [3]. After the revision of the Medical Device Supervision and Management Regulations in 2023, how to build a refined management program to fit the local healthcare system has become a clinical proposition that needs to be solved urgently [4]. Based on the closed-loop quality theory, this study innovatively establishes a refined management system that includes standardized pretreatment, dynamic sterilization monitoring, RFID intelligent traceability, and multidisciplinary quality control. By comparing and analyzing the changes in the qualification rate, clinical satisfaction, and infection rate of the instruments before and after refined interventions, the study aims to validate the practical value of the systematic management of infection control and provide empirical evidence for the standardization of orthopedic surgical instrument management.

2. Information and methods

2.1. General information

Two hundred and fifty-two patients who underwent implant surgery in the orthopedic department of a hospital from May 2023 to April 2024 were selected as study subjects and grouped according to the time point of the implementation of the refined management system. The 126 patients before the introduction of the refined management method (May to October 2023) were included in the control group, of which 68 were male and 58 were female, aged 25–78 years, with an average of 56.3 ± 12.7 years; disease types: 61 traumatic fractures, 39 arthroplasties, and 26 internal spinal fixations; the surgeries were performed by 20 attending surgeons, and a total of 1,204 implants (824 titanium alloy instruments, 256 cobalt-chromium-molybdenum alloys, and 124 polymer polyethylene liners) were used. One hundred and twenty-six patients after the introduction of the refined management method (November 2023 to April 2024) were included in the observation group. Among them, there were 71 males and 55 females, aged 22–81 years, with a mean of 57.1 ± 13.2 years; the distribution of disease types: 59 cases of traumatic fracture, 42 cases of arthroplasty, and 25 cases of internal spinal fixation; the surgeries were performed by 21 attending surgeons, and a total of 1,207 pieces of foreign medical devices and implants were

used (831 pieces of titanium instruments, 259 pieces of cobalt-chromium-molybdenum alloys, and 117 pieces of polymer polyethylene liner). Comparing the baseline data of the two groups, the differences were not statistically significant and were comparable.

Inclusion criteria: (1) aged 22–81 years old, requiring open orthopedic surgery and application of foreign medical devices and implants; (1) preoperative imaging and laboratory tests confirming no signs of active infections (CRP < 10 mg/L, leukocyte count ≤ 10×10^9/L); (3) having complete preoperative assessment data and standardized 3-month postoperative follow-up compliance; (4) approved by the hospital ethics committee and signed a written informed consent.

Exclusion criteria: (1) preoperative presence of a clear source of infection such as osteomyelitis, septic arthritis, or abnormal inflammatory indexes (CRP ≥ 10 mg/L, PCT ≥ 0.5 ng/mL); (2) comorbidity with immune system diseases or long-term use of immunosuppressants (prednisone > 10 mg/d for more than 1 month); (3) comorbidity with severe organ insufficiency (cardiac function NYHA classification III-IV, eGFR < 30 mL/min/1.73m^2); (4) participation in other clinical trials within 3 months or presence of study interfering factors such as risk of loss of visits, language communication disorders.

2.2. Methodology

The control group implemented routine management. Suppliers were notified to send foreign medical devices and implants directly to the sterilizing supply center according to the surgical demand, and the standard process of mechanical cleaning, pressure steam sterilization, and biomonitoring was qualified and then issued to the operating room. Post-operative instruments were recovered by the Sterilization and Supply Center, and the manual brushing-ultrasonic cleaning-lubrication and maintenance process was implemented, and they were returned to the suppliers after sterilization. Waste implants removed during surgery were contained in closed containers by the operating room and incinerated at high temperatures in accordance with medical waste management regulations. Personalized adjustment of sterilization parameters and application of the electronic traceability system were not implemented during the entire surgical process.

The observation group implemented refined management, with the following specific management measures: (1) Constructing a refined management team: A special management group for orthopedic implants was set up, headed by the director of the Hospital Infection Management Department, with members covering the director of the orthopedic department, the head nurse of the disinfection and supply center, the engineer of the device department, and the commissioner of the information department. The group has implemented a monthly joint meeting system and formulated the "Specification for Full Process Management of Foreign Devices (Version 2.0)," specifying 18 operational standards for device access, pretreatment, sterilization monitoring, and so on. (2) Closed-loop management of supply chain: Establish a black and white list system for suppliers, require ISO13485 quality system certification, FDA/CE registration certificates and biocompatibility test reports, and update the qualification files quarterly; develop orthopedic surgical instrument demand prediction system, automatically generate instrument specification recommendations (error ≤ ±5%) by retrieving patient image data through HIS, and generate an electronic purchase order after confirmation by the surgeon-in-charge, and the system automatically verifies the inventory and instrument validity period. The system automatically verifies the inventory and the validity period of the instruments; when the implants are delivered, a two-person verification process of "clinical engineer + surgical nurse" is implemented to verify the registration certificate, sterilization validity period, and traceability information by scanning the UDI code of the instruments, and then uploading

them to the hospital's SPD system after confirming that they are free from errors. (3) Sterilization process reengineering: The sterilization program is customized according to the physical characteristics of the implant, titanium alloy instruments are sterilized at 132℃ pre-vacuum (exposure time 10 min), and polymer materials are sterilized by low-temperature hydrogen peroxide plasma; temperature-pressure sensor arrays are deployed inside the sterilization chamber, and the real-time data is transmitted to the central monitoring platform, which triggers the audible and visual alarms and suspends the cycle automatically in the case of deviation from the parameters; a gradient decompression is implemented for the cooling zone (200 kPa → 50 kPa/15min) in the cooling area and equipped with condensate adsorption device, so that the wet pack rate from 12.6% to 2.3%. (4) Full-cycle traceability system: Applying RFID chip implantation technology, temperature-resistant electronic tags are embedded in instrument packages, and the operating room automatically checks the matching degree between the instrument list and the surgical program through the read-write; the surface of implants is coated with antimicrobial coatings containing nano-silver ions (in accordance with YY/T1293 standard), and the number of colonies is dynamically monitored through the irrigation fluid of the surgical field (the threshold value is ≤ 50 CFU/mL); after the operation, the establishment of an instrument-patient-infection ternary correlation database can be used to track the infection rate through machine learning algorithms to identify the characteristics of high-risk devices (such as the number of reuse > 20 times, structural porosity > 30% of the implant), to achieve the risk of infection early warning. (5) Establishment of three-level quality control nodes: Pre-operative device function testing (e.g. power tool speed deviation ≤ 5%) is performed by CSSD, intra-operative 20-item verification checklist is performed by roving nurses, and post-operative data on device usage is collected via IOT terminals, including surgical duration-sterilization cycle matching degree, physician operation standard score, etc.), and ultimately, a device full life-cycle quality report is generated, which serves as the core basis for supplier performance evaluation.

2.3. Observation indicators

Qualified status of foreign medical devices and implants: Evaluate the qualification status of foreign medical devices and implants used in the operation before and after management according to the qualification criteria in the Regulations on Supervision and Administration of Medical Devices.

Satisfaction scores for the use of foreign medical devices and implants: Satisfaction scores were given by the attending surgeons of each group on the quality of foreign medical devices and implant items used during surgery, device delivery, supply timeliness and problem improvement, etc., and the total score for each dimension was 100, with a higher score representing a higher degree of satisfaction.

Nosocomial surgical incision infection: Observe and record the occurrence of incision infection during hospitalization in the two groups, infection rate = number of infected cases/total number of cases × 100%.

2.4. Statistical treatment

SPSS 24.0 statistical software was used to process the data, and the measurement information was expressed as mean ± standard deviation (SD), and the *t*-test was implemented between the groups, and the count information was expressed as [*n* (%)], and the χ^2 test was used, and the difference was considered to be statistically significant at $P < 0.05$.

3. Results

3.1. Comparison of the qualification rate of foreign medical devices and implants between the two groups

The qualification rate of foreign medical devices and implants in the observation group was 96.93%, which was significantly higher than that of 83.97% in the control group, and the difference was statistically significant ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of the qualification rate of foreign medical devices and implants in the two groups (pieces, %)

Groups	Medical devices and implants (pieces)	Qualified pieces	Satisfactory rate
Control group	1204	1011	83.97
Observation group	1207	1170	96.93
χ^2			117.397
P			< 0.001

3.2. Comparison of satisfaction scores in the use of foreign medical devices and implants between the two groups

In the observation group, the satisfaction scores for the dimensions of external medical device and implant item quality, device distribution, supply timeliness, and problem improvement were significantly higher than those of the control group, with statistically significant differences ($P < 0.05$), as shown in **Table 2**.

Table 2. Comparison of satisfaction scores for the use of foreign medical devices and implants between the two groups (mean ± SD, points)

Groups	Surgeons (cases)	Quality of device	Instrument distribution	Timeliness of supply	Issue improvement
Control group	20	80.42 ± 6.26	82.24 ± 6.29	81.19 ± 5.83	82.14 ± 5.72
Observation group	21	85.27 ± 6.78	86.69 ± 6.73	85.92 ± 6.47	86.79 ± 5.83
t		2.377	2.185	2.455	2.576
P		0.023	0.035	0.018	0.014

3.3. Comparison of nosocomial surgical incision infections between the two groups

The rate of nosocomial surgical incision infection in patients of the observation group was 0.79%, which was significantly lower than that of the control group (6.34%), and the difference was statistically significant ($P < 0.05$), see **Table 3**.

Table 3. Comparison of nosocomial surgical incision infection rates between the two groups [*n* (%)]

Groups	Patients (cases)	Infections	Rate of infection (%)
Control group	126	8	6.34
Observation group	126	1	0.79
χ^2			4.148
P			0.042

4. Discussion

In orthopedic surgery, foreign medical devices such as locking plates and pedicle screw systems can accurately match the anatomical structure of bones and improve surgical precision due to their highly specialized design; at the same time, titanium alloys and cobalt-chromium-molybdenum alloys are biocompatible and mechanically stable implantable materials that can maintain bone stability over time, which can provide technological protection to improve the prognosis of patients undergoing complex orthopedic surgery [5,6]. However, in the management of sterilization supply centers, the traditional management model has systematic defects, leading to the coexistence of infection risk and service quality problems [7]. First, a sloppy instrument sterilization process and an insufficient biofilm removal rate have resulted in high rates of postoperative incision infections. Secondly, the supplier qualification audit is a mere formality, with a high rate of functional defects of instruments, and intraoperative problems such as screw slippage and power tool jamming are likely to occur. Furthermore, instrument delivery relies on manual coordination, and surgical delays occur frequently due to information disconnection, which directly affects surgical efficiency [8]. Finally, due to the lack of feedback mechanism in traditional management, only a small portion of the abnormal events of instruments can be traced back to the suppliers, coupled with the fact that the rate of wet packs and reuse of orthopedic instruments under traditional management is much higher than the standard of refined management, which further exacerbates the risk of infection, and the implementation of systematic reforms is urgently needed. Refined management is a systematic management model with risk control at its core, which makes use of a multi-departmental collaborative quality control network, material-appropriate sterilization strategy, RFID/UDI information traceability technology and continuous quality improvement (CQI) mechanism to achieve full life-cycle control of devices through standardized processes, intelligent monitoring, and closed-loop traceability, with the aim of eliminating management blind zones and raising the threshold of medical safety.

The results of this study show that the qualification rate of foreign medical devices and implants in the observation group is higher than that of the control group, the satisfaction scores in the dimensions of quality of items of foreign medical devices and implants, distribution of devices, timeliness of supply, and improvement of problems are significantly higher than that of the control group, and the rate of infection of nosocomial surgical incisions of patients in the observation group is significantly lower than that of the control group, and the differences are all statistically significant ($P < 0.05$). The reasons for this are attributed to the significant advantages of the refined management model: (1) material grading sterilization combined with real-time sensor monitoring effectively reduces the bioburden, improves the qualification rate of instruments, and blocks the possibility of infection from the source. (2) The application of an electronic demand prediction system effectively improves the error rate of instrument delivery and guarantees the smoothness of surgery [9]. (3) The RFID traceability system realizes the data linkage of "instrument-patient-operator," and combined with the dynamic monitoring of bacterial colonies in postoperative irrigation fluid, the risk of incisional infection is minimized. (4) Through the three-level quality control nodes of preoperative functional testing, intraoperative verification checklist, and postoperative data analysis, the response time for improvement of device problems has been shortened [10,11].

5. Conclusion

In summary, the refined management has innovatively constructed a closed-loop system of "demand-supply-use-monitoring," and systematically solved the core pain points of orthopedic foreign device management through the

dynamic review of qualification, optimization of sterilizing parameters, and intelligent traceability technology. It not only significantly improves the qualification rate of instruments and reduces the risk of infection rate of patients, but also provides a replicable management paradigm for orthopedic infection control.

Disclosure statement

The authors declare no conflict of interest.

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