

Reduction of Non-Standard Ophthalmic Surgical Towel Incidences Through Quality Control Circle Practice

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Abstract

Objective: For the insurance, the surgical safety of patients, surgical safety management and risk management in the operating room are key in guaranteeing this happening [1]. In management of the operating room, quality management, means and tools are commonly used to implement surgical safety management [2] along with the application of quality control circle (QCC) activity [3] to the optimize ophthalmic surgery safety verification process, non-standard ophthalmic surgery draping incident improvement, patient's surgical site error and surgical site infection (SSI) reduction and other adverse events caused by non-standard exposure of sterile area in the surgical field.

Methods: Establishing QCC with the additional use of brainstorming, innovation, and selection of the topic of the project according the relevant approximation errors that have occurred. Discussing the feasibility and effectiveness measures, drafting an activity plan to analyse and verify the causes and discuss reason, test results, and countermeasures shown in "the surgical eye exposure error after ophthalmic surgery draping". "The exposure range of the surgical site after ophthalmic surgery draping is not standardized" is the focal point of this activity which is in need of improvement. This is accomplished through countermeasure formulation and implementation, confirmation and maintenance of activity effects, and establishment of standardization of ophthalmic surgical towels.

Results: From 8 pieces/week before QCC activity to 1 piece/week after activity, a moderate reduction in irregular ophthalmic surgical towel incidences were accomplished through the application of QCC activity, maintenance of standardization and normalization, optimization of the surgical safety verification process and the standardization of ophthalmic surgical towels process.

Conclusion: The QCC activity was effective. Reduction in irregular ophthalmic surgical draping incidence was observed. Therefore, the risk of adverse events of ophthalmic surgery such as surgical site errors and surgical incision infection was reduced to eliminate potential safety hazards and ensure the safety of patients undergoing surgery.

Keywords: Quality Control Circle, Optimized process, Ophthalmic Surgical Drapes

1 Materials

1.1 General information

We are a tertiary A general hospital with an eye centre that is well-known and ranked fifth in ophthalmology specialty in China. With independent ophthalmology operating room rankings in ophthalmology specialty affiliated to general hospitals that consists of 14 operating rooms, 56 ophthalmologists and 46 ophthalmology operating room nurses. We specialise mainly in performing cataract, glaucoma, retinopathy, ocular plastic, ocular tumours, ocular surface

diseases, strabismus, refraction and other surgeries with an annual operation volume of more than 5,000. Because of the large volume of daily and reception surgeries, fast rhythm and long delay times, medical staff are prone to burnout which makes it difficult and reflects in the quality of care in the operating room [4].

2 Method

2.1 Establishment of a quality control circle group (QCC)

This was done according to the principle of autonomy and voluntariness. Group name and emblem selection was done by voting. The QCC group is called "Ming Mou Quan (bright eye circle)". "Ming Mou" means the pursuit and dream of each patient with an eye disease which also reflects the service purpose of the Eye Centre

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- "Your light is our wish". The background of the emblem is the healthy fundus anatomy retinal map, with the black part of the background presenting with "Z" and '2', representing the Second Hospital of Zhejiang University School of Medicine, while abstracting the appearance of one eye at the same time, representing ophthalmology. There was a total of 10-panel members, including 7 operating room nurse, 1 chief physician, 1 attending physician, and 1 resident. One group leader, which is presumed by the chief of nurses that possess strong organization, coordination, and specialist abilities among the individuals involved. Within the group was also one counsellor who was the head nurse of the operating room of the Second Zhejiang Ophthalmic Centre responsible for medical quality and control.

2.2 Selection of Activity Topic

2.2.1 Project background

In early March 2019, a patient going through cataract surgery in the left eye mistakenly exposed their right eye as the surgical eye during the application of the surgical drapes. Fortunately, the surgeon initiated and performed patient surgical information verification (TIMEOUT) with all the accompanying doctors and nurses before cutting. The error was spotted, and a serious adverse event was avoided. Ocular surgery is prone to errors during ophthalmic surgery due to its particular anatomy: the eyeball and its accompanying tissues are the most important organs of the human body that are adjacent to each other and are identical in structure. Furthermore, among daily surgical draping work, due to problems of non-standard surgical draping and non-standard exposure of the surgical site, etc., standards are lacking in the exposed sterile area site of surgical fields with examples such as the nostril being exposed through the hole of surgical drapes together with the surgical eye. According to the International Patient Safety Goals (IPSG).4: Establishing a surgical safety verification system to avoid errors with surgical patients, surgical sites and surgical methods; IPSG.6: Reduction in the risk of iatrogenic infection was discussed. When interpreting the evaluation criteria for hospitals at the national level [5], our hospital system concerning the patient safety management system. There is "zero tolerance for patient surgical identity errors" and "zero tolerance for patient site errors". In the management of ophthalmic surgery, prevention and control of surgical infection is also paramount [6]. Postoperative endophthalmitis is a serious complication post- ophthalmology surgery. In ophthalmology, postoperative inflammation is referred to as "inflammatory change". In recent

years, our hospital has achieved remarkable results in the prevention and control of ophthalmic surgery infection [7]. The incidence of postoperative endophthalmitis after ophthalmic surgery is low and equivalent to the level in developed countries around the globe. Therefore, it is the responsibility of all ophthalmology employees to maintain good outcomes. When learning from the "Australian New 4360 Standard" [8] in the hospital management project of our hospital. A vivid explanation of the theory and practice was given by educators during class which has helped broaden the idea of management by attending to risk management. Therefore, a combination with the curriculum content should be applied to daily management.

2.2.2 Topic selection

All candidates involved put forward a topic through the "brainstorming method" followed by the aspects of superior policies, importance, feasibility, urgency and QCC ability. The QCC team used the "531" scoring to assign a score to each of the selected topics and finally identified "reducing the occurrence of irregularities in ophthalmic surgical draping" as the subject of this issue. Through in-depth thematic analysis, the standard operation of "ophthalmic surgery draping" was defined, that is, after the surgical site disinfection, the surgeon and nurse should pave the surgical drapes and open the ophthalmic special surgical drapes according to specifications. This includes align the holes of the drapes to the surgical eye (surgical site), cover the head and face, expose the surgical field, facilitate the surgical operation, isolate the non-surgical area with avoidance of exposure of the patient's hair, nostrils, and mouth. The term on the subject is defined as: "ophthalmic surgery draping": after the surgical site is disinfected, the surgeon and nurse shall aim the hole of the drapes at the surgical eye and cover the head and face according to the draping method, isolate the non-surgical area and expose the surgical area allowing facilitation of the surgical operation, avoid contamination and prevent wound infection. "Non-standard ophthalmic surgery draping": all steps that do not meet the requirements for ophthalmic surgery draping, such as: draping the wrong surgical eye and non-standard exposure of the surgical site after draping.

2.2.3 Reasons for selected topic

(1) For patients: WHO global patient safety challenge, to ensure patient surgical safety [9] and for improvement of patient satisfaction.

(2) For colleagues: practising "patient and service object first" core values in our hospital [10].

Increase work responsibility and reduce work pressure. Optimize the procedure to ensure the correct patient surgical site and eliminate adverse events.

(3) For departments: establishment and optimization of processes to ensure safe and orderly surgery. All surgeons and nurses have a consensus on the goals, rules and evidence that need to be followed.

(4) For hospitals: improve the reputation of the Second Affiliated Hospital of Zhejiang Medical University and the competitive advantage of public hospitals [11]. Implement Article 4 of the Top Ten Safety Goals for Patients in the Second Affiliated Hospital of Zhejiang Medical University in 2019: ensuring the safety of surgery and operation.

2.3 Activity plan preparation

The time frame of this QCC is from March to August 2019. A Gantt chart of activity plan was developed (see Figure 1) with a reasonable allocation of project progress time, of which the "topic selection", "plan preparation", "status grasp and analysis", "goal setting", "cause analysis" and "countermeasure preparation" stages account for 30% of the total activity time. "countermeasure implementation and review" accounts for 40%, "effect confirmation" and "standardization" stages account for 20% "review and improvement" and "achievement publication stages" account for 10%. At the same time, the person in charge of each implementation stage was determined and reported to the hospital quality management office for review and approval. The hospital quality management office shall supervise QCC activity progression.

2.4 Standardization inspection results

The Inspection Form for the number of Non-standard parts of Ophthalmic Surgery drapes was developed according to the standard specification of ophthalmic surgery drapes (see Figure 2) with standardized training provided for those associated. The trained personnel checked the procedure of surgical drapes in the ophthalmic operating room using the inspection form and counted the inspection results present within 1 month. A total of 964 times of surgical drapes were inspected, of which 932 were performed following the standard and 32 were not. Among the 32 irregular surgical drapes, the exposed site of the surgical eye was offset 25 times after draping, accounting for 78.1%. Incorrect surgical eye draped 5 times, accounting for 15.6%, and surgical hole towel was contaminated 2 times during draping, accounting for 6.3%. The weak link within the currently grasped status quo needs to be identified from the current flow chart and improve focus through 80/20. Using inspection results to according to draw Plato with an adaptation of the "80/20" rule and determining that "the excursion of the exposed site of the surgical eye after draping" and "the error of the surgical eye after draping" (the total of two is 93.7% which is the improvement focus) are the topics for current activity improvement.

The improvement focus was 93.7% and the QCC ability was 92% (QCC ability value = average QCC involved individuals QCC ability score during the topic selection process). Therefore, the target value of improvement = 8 pieces/week - (8 pieces/week 93.7% 92%) = 1.1 times/week. i.e., the determined number of non-standard ophthalmic surgical drapes after improvement is 1.1/week, and the improvement range is 86.2%.

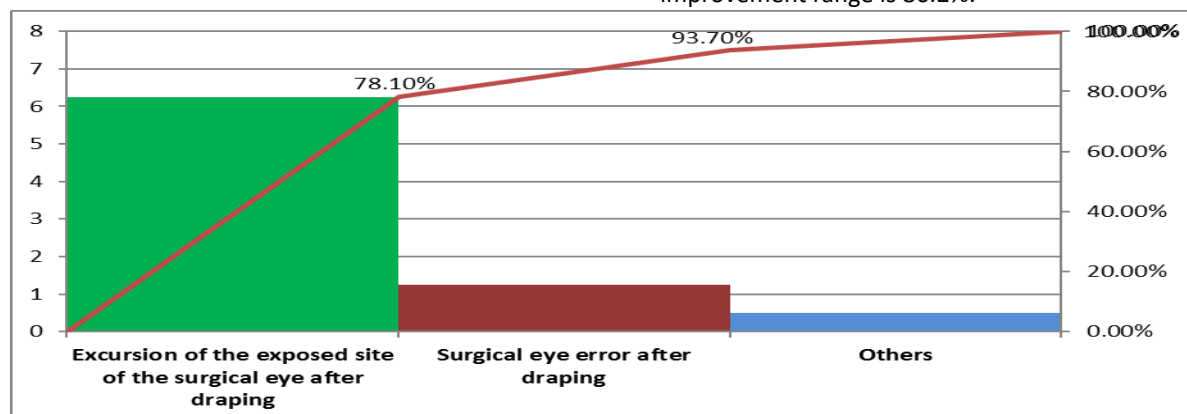


Figure 1. Plato before improvement

Using the principle of 80/20, statistics found that the excursion of the exposed part of the surgical eye after draping; the error of the surgical eye after draping (93.7% in total) was the topic of

improvement of this activity.

2.6 Brainstorming method used for reasoning analysis

From four aspects: environmental, management, medical staff and patient factors a fishbone diagram was developed and drawn with the performance of the causal analysis. The main reasons for determination include (1) Lack of verification when the ophthalmic surgery is draped: in the daily ophthalmic surgery process, the timing of surgical safety verification emphasizes that the surgical personnel should cooperatively check the patient's identity, surgical methods, surgical sites and other relevant information before "before the implementation of anaesthesia", before the start of surgery (TIMEOUT) and before the patient leaves the operating room (SIGNOUT). Due to the particularity of the ocular surgical site: the eyeball and its accompanying tissues are the most important organs of the human body that are adjacent to each other and are identical in structure. If the surgical drape is mishandled, the risk level of surgical eye error increases. (2) Ophthalmic surgery is short in time and has a fast rhythm with a large average daily operation volume. Operating personnel: chief surgeon, assistant and nurses are prone to burnout therefore leading to a reduction in attention within the surgical process. (3) Doctors undergoing further education or residents in standardized training who participate in surgery, nurses undergoing further education and nurses in standardized training along with frequently rotating personnel are less familiar with the surgical safety verification and operating process of surgical draping and operating specifications such as surgical draping that lack standardized training. (4) Therefore, lack effective supervision, inspection and feedback.

2.7 Countermeasures preparation and implementation

This was organized at the group meeting. All associated individuals analysed the essential causes of "non-standard ophthalmic surgery draping" operation behaviour, drafted countermeasures, score feasibility, economy and efficiency of each countermeasure, and finally determine the main countermeasures.

2.7.1 Optimize the safety verification process of ophthalmic surgery

To strengthen the management of medical institutions, guide and standardize the verification of surgical safety of medical institutions and ensure medical quality and safety. In 2010, the National Health and Family Planning Commission organized formulation of the Surgical Safety Verification System per the Law of the People's Republic of China on Medical Practitioners, the Regulation on

the Handling of Medical Accidents, the Regulation on the Administration of Medical Institutions, the Regulation on Nurses and other relevant laws and regulations, and the General Office of the Ministry of Health issued the Notice on Printing and Distributing the Surgical Safety Verification System, Document [2010] No. 41. Surgical safety verification system: 1. Surgical safety verification is the work in which surgeons, anesthesiologists and operating room nurses with practising qualification (hereinafter referred to as the "three parties") cooperatively check the patient's identity and surgical site before the implementation of anaesthesia before the start of surgery and departure of the patient from the operating room. 2. This system applies to various surgeries at all levels while other invasive operations may use this as a reference for implementation. 3. Surgical patients should be accompanied with and wear patient identification information for verification. 4. The verification of surgical safety shall be presided over by the surgeon or anesthesiologist with three parties cooperatively implementing and completing the Surgical Safety Verification Form. 5. The content and process of implementing surgical safety verification. (1) Before the implementation of anaesthesia: The three parties shall check the patient's identity (name, gender, age, medical record number), surgical methods, informed consent, surgical site and identification [12], anaesthesia safety examination, whether the skin is complete, skin preparation of the surgical field, the establishment of venous access, allergic history of the patient, skin test results of antibacterial drugs, preoperative blood preparation, prosthesis, in vivo implants, imaging data and other contents in turn according to the Surgical Safety Verification Form. (2) Before the start of surgery: the three parties together verify the patient's identity (name, gender, age), surgical methods, surgical site and identification, and confirm the initial warning risks and other contents. Verification of surgical item preparation were performed by the operating room nurse and reported to the operating surgeon and anesthesiologist. (3) Before the patient leaves the operating room: the three parties cooperatively verify the patient's identity (name, gender, age), actual surgical methods, verification of intraoperative medication and blood transfusion, count the surgical materials, confirm the surgical specimens, examine the skin integrity, arteriovenous access, drainage tube, confirm the whereabouts of the patient and other contents. (4) The three parties shall sign the Surgical Safety Checklist after confirmation. 6. Surgical safety verification must be carried out in turn according to

the above steps. The following operation can only be carried out after each step of verification is correct, and the form is not to be filled in advance.

7. Verification of intraoperative medication and blood transfusion: Anaesthesiologists or surgeons shall issue medical orders and make corresponding records according to situation needs. Operating room nurses and anaesthesiologists are to verify them accommodatingly.

8. The Surgical Safety Verification Form for hospitalized patients shall be included in the medical records for safekeeping. The Surgical Safety Verification Form for non-hospitalized patients shall be kept by the operating room for one year.

9. The personnel in charge of surgical, anesthesiology departments and operating rooms are the ones that are primarily responsible for implementing the surgical safety verification system in our department.

10. The relevant functional departments of medical institutions are to strengthen the supervision and management of the implemented surgical safety verification system of their institutions, put forward measures for continuous improvement and apply problems and countermeasures in the implemented surgical safety verification system [13]. Surgical safety verification standardizes the surgical identification process, safety verification process before the start of anaesthesia, and before the start of surgery (i.e., Time out) Flow and after the end of surgery (sign Out) Flow. According to relevant literature reports, the promulgation of the Surgical Safety Verification System and the application of the Surgical Safety Verification Form do effectively improve the accuracy of surgical verification, but there are also problems such as the non-standard implementation of the verification process, teamwork, and insufficient attention to the verification [14]. The WHO advocates that the surgical safety verification system should be continuously improved and developed in combination with specific surgical procedures [15]. Our department focuses on ophthalmic surgery. Due to the particularity of eyeball anatomy, when the surgeon paves the patient's surgical eye after disinfection of the surgical field, it is easy to confuse the paved eye from the other, resulting in errors in the surgical site. Therefore, "check before draping of the surgical eye" is added in the surgical safety check process to improve the accuracy of ophthalmic surgery safety and reduce the incidence of surgical site approximation errors and adverse events. Specific methods: Before draping, the surgeon should initiate patient identification verification and surgical eye with the nurse and performed surgical eye draping after confirming. The optimized safety verification process of ophthalmic surgery includes

safety verification before the start of anaesthesia; verification before the draping of surgery; verification before the start of surgery (Timeout); verification after the end of surgery (sign out).

2.7.2 Strengthen the training on ophthalmic surgery draping operation for medical staff, clarify correct draping operation methodology, range and other key points

Organize the main surgeon, assistant, nurse, doctors undergoing further education and standardized training doctors to learn and assess. The specific methods are: ① develop a training plan; ② improve process training and video standard training on surgical draping operation [16]; ③ strengthen the communication between various personnel, such as effective communication between the surgeon and the assistant, nurse, further education or student [17], cooperatively participate in the standardized learning of ophthalmic surgical draping process; ④ assessment after training.

2.7.3 Strengthen supervision

Develop a checklist, strengthen the risk management of ophthalmic surgery [18], timely discover the non-standard behaviours of surgical draping during surgery, timely report the approximate errors or adverse events, hold departmental meetings and organize discussion and study, therefore, achieve continuous quality improvement.

3 Results

3.1 Visible achievements

3.1.1 Comparison of the number of occurrences of irregularities before and after implementation (per week) is shown in Table 2.

3.1.2 Progress rate of non-standard incidence of ophthalmic surgery draping before and after QCC activities:

3.2 Invisible achievements

The QCC ability of all individuals involved have been significantly improved. Such as the application of QCC means, communication and coordination ability, employee work enthusiasm, self-confidence, work responsibility, team spirit, collective pride, statistical analysis ability, etc. The improvement degree of QCC ability before and after the activity is expressed by a radar chart.

3.3 Ophthalmic surgery patient safety check normalization (see Figure 3)

3.4 Maintenance of Effect

After the activity has come to an end, a

continuance to monitor the number of irregularities in ophthalmic surgical draping according to the developed countermeasures was applied. During the effectiveness maintenance period (27th August 2019 to 7th September 2019), the average weekly number of irregularities in the number of surgical

eyes after draping and the exposure range of surgical site after draping remain 1 times/week, which still maintains effectiveness and meets the pre-set goal. All the QCC involved individuals remain confident to continue their efforts in maintaining this effect. (See Figure 6)

Table 1. Investigation on the Nonstandard Rate of Ophthalmic Operation Draping QCC Analysis Results

Improvement items	Feature Factor Analysis	Truth verification	Percentage of non-standard types	Countermeasure implementation
Deviation of exposed part of eye after draping affecting operative field	Surgeon conducted incorrect way of draping	High mobility of surgical assistant staff, lack of standardized training and unfamiliarity with ophthalmic draping standards	78.1% (25 incidences out of 32 operations in total in a month, 25/32=78.1%)	Formulating training plan, strengthening the operation process as well as learning ophthalmic surgery draping and professional knowledge for medical staff
After draping and before wrong eye identification	Unattended before draping	Inadequate safety checking process, unspecified personnel appointed to lead the pre-draping check	15.6% (5 incidences in a month, 5/32=15.6%)	Optimize the safety check process: initiated by the doctor who laid the drape, and checked with the circulating nurse
Others (Contamination of surgical area)	Under local anesthesia patient uncooperative	Claustrophobic syndrome, psychosis, etc.	6.3% (2 incidences in a month, 2/32=6.3%)	

Note: Percentage of non-standard types: based on the Pareto Principle, Improvement Focus=monitoring value/status value of the project=93.7% monitoring value and status value of

project = improvement focus Target = Status - Improvement = Status - (Status * Improvement Focus * QCC Ability) =8 times/week- (8 times/week*93.7%*92%) =1.1 times/week

Table 2. Comparison of the number of occurrences of irregularities before and after implementation (per week)

Time	Wrong-way of draping	Unattended before draping	Other
Before implementation	6.25	1.25	0.5
After implementation	1	0	0

Note: Target achievement rate = [(data before improvement - data after improvement) ÷ (data before improvement - target setting)] 100% = [(8-1) ÷ (8-1.1)] 100% = 101.4% Progression rate = [(data

before improvement - data after improvement) ÷ data before improvement] 100% = (8 times/week - 1 time/week) ÷ 8 times/week 100% = 87.5% (see Figure 4)

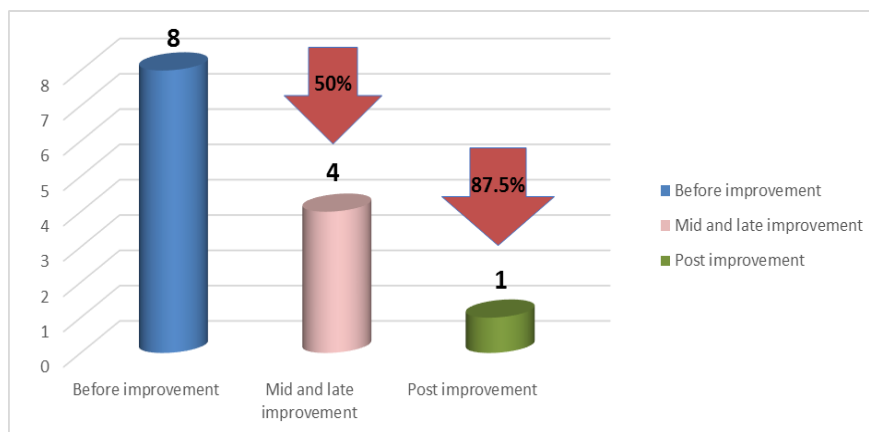


Figure 2. Reduce the number of irregularities on ophthalmic surgery drapes

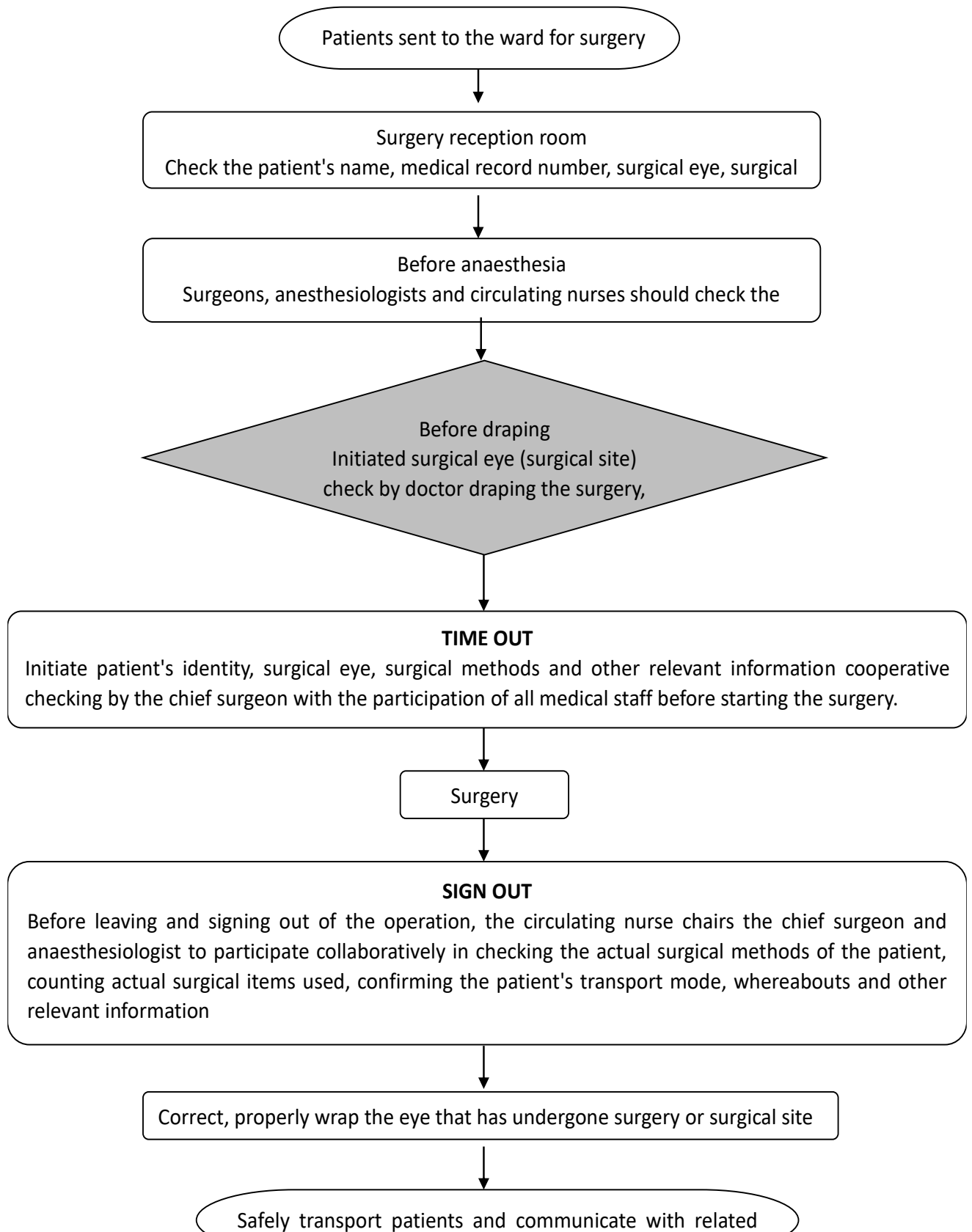


Figure 3. Patient Safety Check Process for Ophthalmic Surgery

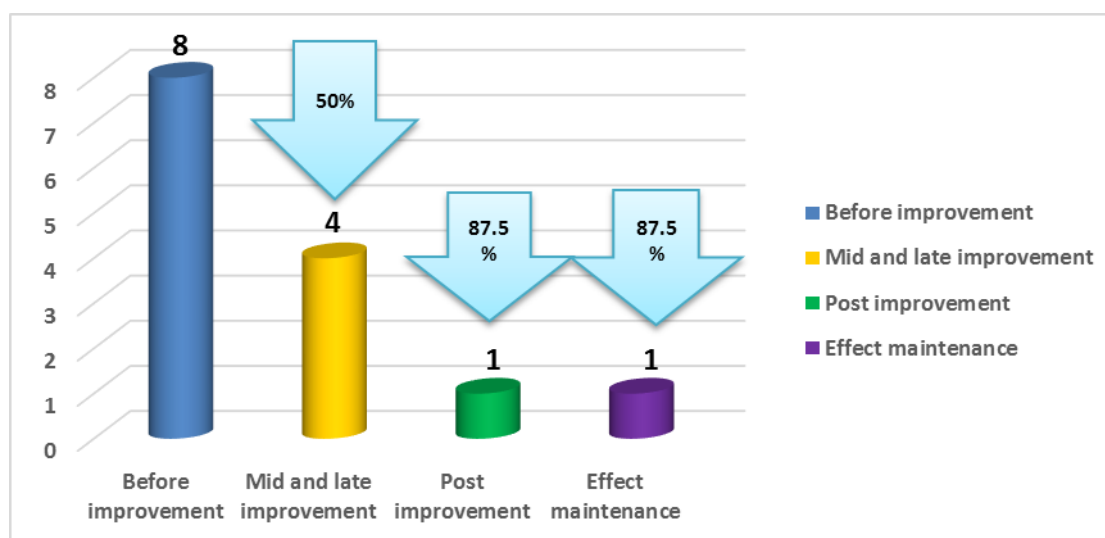


Figure 4. Effect maintenance

4 Discussion

Surgical safety management of patients involves a wide range of departments, with a complex professional division of labour and management difficulties. In this study, the QCC method was used to strengthen and optimize the management process of safety inspection, prospectively handle the problems to make the implementation accuracy rate of safety inspection. Through the application of QCC and discussion and unity cooperation between members. The various inspection forms [19] and scientific management means were used to find the shortcomings in the work, and then effectively improve on them [20]. The reception table for ophthalmic surgery is fast with the operating personnel prone to burnout. Ophthalmic surgery has high complexity due to the high safety verification error risk factors during surgery. Standardized ophthalmic surgery draping not only requires strict implementation of the aseptic operation, standardization of surgical exposure range, but at the same time needs to determine the correct surgical eye to ensure the safety of patients undergoing surgery. Through the management of QCC, the risks and shortcomings in ophthalmic surgical draping were found in time. Through brainstorming, the causes were clarified, and corresponding countermeasures were formulated to improve the surgical draping process, which was finally standardized and achieved outstanding results. Normalization shall be formed after the effect is maintained. The error in the surgical eye was zero during the time out before the start of the operation. In this QCC activity, the member's sense of responsibility and collective pride increased, and tightened the team cooperated. " Reducing the rate

of non-standard ophthalmic surgical draping" has made great achievements in ophthalmic surgery safety management.

5 Conclusion

Through QCC activity, an effective reduction in incidences of non-standard ophthalmic surgery draping was seen therefore, the risk of adverse events of ophthalmic surgery, such as surgical site errors and surgical incision infection also declined. This can eliminate potential safety hazards and ensure the safety of patients undergoing surgery.

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