informed consent

Project name: Application of Single-Port Robot-Assisted Breast-Conserving Surgery via Axillary Approach for Breast Cancer.

Informed Consent Form Version Number: 2.1, November 25,2024

Research institution: Army Medical Center

Principal investigator: Xu Yan

Patient Name:

Patient name abbreviated:

Dear subjects:

We hereby invite you to participate in a clinical trial as a subject. This informed consent form provides you some information to help you decide whether to participate in this clinical trial. Please use the time to read the following content carefully. If there are any unclear questions or terminology, you can discuss with the doctor concerned.

Your participation in this study is completely voluntary. The current study has been reviewed by the Ethics Committee of the Army Characteristic Medical Center.

1. Research background:

Breast cancer is the second most prevalent female malignancy in China. The most important treatment method for breast cancer is still surgery. Traditional open surgery has a positive efficacy, but it will leave a permanent scar on the chest, not beautiful. Compared with European and American women, Chinese women have more dense breasts and are more likely to form scars. Therefore, minimally invasive breast surgery is necessary for Chinese women.

Minimally invasive surgical methods can achieve better wound healing and less postoperative pain with the same tumor removal effect as open surgery. Robotics is

one of the widely used minimally invasive surgery in breast surgery; compared with open surgery, this minimally invasive technique reduces the occurrence of postoperative complications, enhances the protection of limb function, and meets the needs of patients for beauty.

Single-hole robot (Single-port robot, SPr) has more advantages in minimally invasive nature, convenience, universality, flexibility, multi-directional operation, etc. It is especially suitable for separation, suture, knot tying and other operations in a narrow space. Breast-conserving surgery due to improve the patients with breast cancer postoperative cosmetic effect, quality of life and acceptable tumor safety and become one of the standard treatment for breast cancer from lesion resection integrity and breast beauty preservation integrity of two aspects, the axillary incision single hole surgical approach compared with other approach has more advantages.

In recent years, the domestic single-hole robot surgical system has developed rapidly and its functions are increasingly perfect. The domestic Jingfeng ®SP1000 single-hole robot surgery system will be used in our hospital. The public information shows that Jingfeng ®SP1000 is the first single-hole surgical robot to enter the registered clinical trial in China. At present, it has been approved for gynecological indications, and has completed registered clinical trials in urology, general surgery, thoracic surgery and other fields, and successfully carried out more than 200 clinical operations, demonstrating a wide range of adaptability and excellent performance. In addition, Professor Xu Yans team of mammary thyroid surgery successfully simulated the key steps of the thyroid surgery in the oral thyroid surgery simulator for the first time, realizing the high-definition vision and high stability of single-arm robot surgery system, and its smart arm technology, hidden sleeve function and zero pressure anchor technology are more conducive to ensuring the safety of the operation. This successful practice provided a solid foundation and rich experience for single-hole robot breast surgery and related clinical research. This study aims to fill the gap of robot-assisted breast cancer and compare the efficacy of open breast conserving

surgery and single-hole robot in breast cancer surgery through a prospective, single-center phase II clinical cohort studySafety, to provide a scientific basis for clinical practice, and to promote the development of minimally invasive breast cancer surgery technology. To provide a theoretical and practical basis for the future application of EDGE SP1000 surgical system in breast cancer surgery. In addition, on this basis, we will systematically establish the technical system and standard of single-hole robot breast cancer surgery in our hospital, and lead the formulation of domestic single-hole robot-assisted breast cancer surgery standards, laying a solid foundation for the clinical promotion and application of this surgery

2. purpose of research:

1 To evaluate the efficacy of single-port robots in breast cancer breast-conserving surgery with a transaxillary approach. Including differences in operative time and intraoperative number of lymph nodes detected.

2. To of surgical safety: the incidence of surgical transfer and the incidence of postoperative complications.

3. Study process:

This study aims to evaluate the safety and feasibility of single hole robot used in breast surgery, comparative analysis of single hole robot and open surgery in breast surgery complications, postoperative complications, perioperative recovery effect and safety, so as to choose a more effective and safe surgery.

The expected number of participants in this study was 100, including 20 in the test group (breast preservation surgery) and 80 in the control group (open breast preservation surgery).

The following schedule for subjects (you) for this study:

（1）Enrollment: Subjects who meet the inclusion criteria are entered into the study process, including SPr-breast conserving surgery or open-breast conserving surgery. The choice of the two surgical methods is based on the patients economic situation and the availability of the equipment;

（2）Preoperative hospitalization: collect disease information (including

mammography, breast B ultrasound, breast enhanced MRI, preoperative needle biopsy tumor stage, etc.)

(3) On the day of operation: record the operation time, intraoperative bleeding volume, intraoperative complications, intraoperative adverse events, etc.;

(4) Postoperative hospitalization period: record the postoperative complications (postoperative bleeding, flap or nipple areola complex necrosis, subcutaneous emphysema, infection, capsular spasm, postoperative shoulder pain and discomfort), and record the patients postoperative pain scores.

(5) Postoperative hospital stay: calculated as the number of days from surgery to discharge;

(6) 28 days after surgery: to understand the complication rate and mortality rate within 28 days after surgery, and to record the postoperative cosmetic score of patients;

(7) 90 days after surgery: to understand the complication rate and mortality rate within 90 days after surgery, and to record the postoperative cosmetic score of patients;

(8) 3-year disease-free survival (recurrence was defined as surgical area and distant metastasis by the time from surgery to last follow-up or date of recurrence and metastasis);

(9) 3-year overall survival (calculated from time from surgery to last follow-up or death);

4. Matters requiring your cooperation:

In order to make this study smooth and successful, please cooperate with the following matters:

- Follow the investigator for relevant pre-operative ancillary tests, for example, blood examination, electrocardiogram, breast MRI, chest and abdomen enhanced CT, chest plain film, etc.
- You will not be able to change your current treatment or start any new treatment until confirmed with the study doctor.
- You need to inform the study doctor about your health, or even what you think

is not very important.

- You need to tell the study doctor about all drugs (including Chinese herbs) that you used before and during the study.
- To terminate study treatment prematurely for any reason, you will complete the final evaluation from the study doctor.
- You need a routine inspection to ensure your safety.
- Please truthfully record your postoperative follow-up quality of life related assessment form as required, and give it to your study doctor at the next visit.

5. Potential risks and countermeasures of surgery:

Doctor told me the axillary approach robot assisted breast breast surgery may occur some risks, some uncommon risks may not be listed in this, specific breast surgery according to different patients, the doctor told me to discuss with my doctor about the specific content of my surgery, if I have a special problem can discuss with the doctor.

（1）I understand that there are risks associated with any surgical anesthesia.

（2）I understand that any drug used can have side effects, including mild nausea, rash and other symptoms to severe anaphylactic shock and even life threatening.

（3）I understand the possible risks of this procedure:

1）Anaesthetic complications, severe cases can cause shock, life-threatening;

2）Intraoperative operation changes due to anatomical position relationship;

3）Intraoperative damage to nerves, blood vessels and adjacent organs, such as brachial plexus, thoracodorsal nerve, long axillary nerve, intercostal nerve; necrosis of the nipple; necrosis of flap tissue; mastectomy pain syndrome: chronic pain often after 3 months of mastectomy, often in the anterior chest and lateral chest, axillary and upper limbs; thoracic catheter injury, chylothorax.

4）Wound fluid accumulation, infection, dehiscence, delayed healing, fistula and sinus tract formation, and incisional hernia.

5）During and after surgery, the wound was bleeding and bleeding, and the seroma was compressed, so wound incision and second operation were required.

6）The operation can not cut up the tumor tissue, or the tumor body remains,

after the operation recurrence.

7）Malignant tumor is not excluded. The specific scope of mastectomy by breast preservation depends on the intraoperative situation. If two frozen biopsy of the resection margin during the operation indicates malignancy, the surgical method may be changed, such as robotic surgery to open surgery, and then the scope of surgery may be expanded.

8）If there is any difference between the pathological results and the results of paraffin section, the results of paraffin section shall be prevail, and a second operation may be required.

9）If the amount of bleeding is large and the lesions are found widely during the operation, the lesions can not be completely removed under the robotic surgical conditions, and the lesions of the lesions and surrounding tissues are seriously adhered may be required to be transferred to open surgery.

10）Postoperative complications may occur due to carbon dioxide pneumoperitoneum: gas embolism, subcutaneous emphysema, etc.

11）Postoperative capsule spasm.

12）Post-operative shoulder pain due to surgical position or surgical cause.

13）Cerebral complications: cerebrovascular accident, epilepsy.

14）Respiratory complications: atelectasis, pulmonary infection, pleural effusion, and pneumothorax.

15）Cardiac complications: arrhythmia, myocardial infarction, heart failure, cardiac arrest.

16）Thrombophlebitis, pulmonary thrombosis, cerebral embolism or other embolism.

17）Multiple organ failure (including diffuse intravascular coagulation).

18）Water water electrolyte balance.

19）Induce the deterioration of the original disease.

20）The operation was stopped due to the lesion or the health of the patient.

21）Postoperative tracheomalacia occurred, leading to asphyxia and even death.

22）Postoperative thoracic duct fistula or lymphatic fistula.

23）Postoperative pneumothorax and subcutaneous mediastinum, in severe cases, closed chest drainage should be performed.

24）Antipoglossal nerve and accessory nerve injury, and cervical sympathetic ganglion injury.

25）Phrenic paralysis caused by phrenic nerve injury.

26）Postoperative gastrointestinal bleeding, stress ulcer, and death in severe cases.

27）Severe intraoperative bleeding, resulting in hemorrhagic shock and death in severe cases.

28）If the bed time is too long, it may lead to lung infection, urinary tract infection, bedsores, deep vein thrombosis, pulmonary embolism, cerebral embolism, etc.

29）Other unanticipated risks and complications.

30）With the assistance of the axillary approach robot, local skin numbness and sensory abnormalities may occur from the armpit to the chest, and most patients can gradually recover after surgery.

31）Your puncture and removed tissue and blood samples may be used in scientific research.

You may not have any adverse reactions, or some adverse reactions, whether mild, moderate, or severe. If the above adverse events occur, your doctor will give you a positive and symptomatic treatment. Once the above risks and accidents are found, the doctors will take proactive countermeasures.

（4）Notification and disposal of the above risks:

1) Preoperative preparation: Ensure that you complete all necessary preoperative auxiliary examinations, including blood examination, electrocardiogram, breast MRI, chest and abdominal enhanced CT, chest plain film, etc., to assess the overall health status and surgical risks.

2) Anesthesia assessment: The anesthesiologist will conduct a pre-anesthesia risk assessment, determine the most suitable anesthesia method for you, and prepare emergency measures to deal with anesthesia complications during and after surgery.

3) Surgical team preparation: The operating surgeon is fully prepared for the surgical procedures and possible complications, and makes corresponding coping strategies according to your individual situation.

4) Intraoperative monitoring: During the operation, monitor your vital signs continuously, and detect and handle any abnormal conditions in time.

5) Postoperative care: postoperative care, doctors closely monitor the recovery of patients, timely handle wound infection, bleeding and other complications, and provide necessary pain management together with the pain department.

6) Long-term tracking: to provide you with long-term follow-up and necessary rehabilitation guidance.

7) Intraoperative changes: If the operation is necessary to change your surgical plan, the operating surgeon should communicate with your family member or your agent and obtain written informed consent.

8) Difference in pathological results: intraoperative rapid freezing pathological results and paraffin section results. According to the results of paraffin section, and communicate with you and your family members.

9) Emergency situations: In emergency situations such as intraoperative massive bleeding and cardiac complications, the emergency department and intensive care department shall immediately start the emergency plan for rescue

6. Benefits of participation in the study:

If you agree to participate in this study, you will be likely to receive direct medical benefits, but may not benefit. We hope that the information from your research study on single-hole robot-assisted breast surgery will be instructive in patients with the same condition in the future.

7. Alternative therapy:

Do I have any other medical options other than participating in this study (or if not)?：

In addition to participating in this study, you have the following options:

- expectant treatment
- chemiotherapy
- Open breast-conserving surgery and treatment, etc

Please discuss these and other possible options with your doctor.

8. Costs related to participation in the study:

（1）Free: breast-conserving breast cancer surgery

（2）Self-expense: except for the cost of breast cancer surgery under single-hole robot (including the cost of open breast cancer surgery, examination cost and drug cost)

9. Compensation:

Participation in this study will not increase your cost.

10. Compensation:

During your participation in this clinical study, if any damage or serious adverse events occurs in the context of this study, the Sponsor will bear the treatment costs and make corresponding compensation in accordance with Chinese law.

However, damage associated with the test does not include injuries from:

- The underlying disease, or the natural course of the disease;
- Your negligence or intentional misconduct (such as failure to strictly follow this consent form, study protocol, or guidance provided by the study doctor or study staff);
- Adverse events due to errors or negligence of the study doctor or their team

insurance

The Sponsor has purchased liability insurance for this clinical trial project....

11. Right to refuse to participate or withdraw from the study:

You may choose not to participate in this study, or have the right to withdraw at any stage of the trial without any reason. Any of your medical treatment and interests will not be affected, but the data before the exit, based on the cost, may continue to be used in this study under the premise of protecting your privacy. Once you decide to participate in this study, you should sign this informed consent form indicating your consent. Before entering the study, the physician will screen you to confirm if you are the right candidate.

12. Privacy and confidentiality issues:

During the study, your personally identifiable information, such as your name and gender, will be replaced by code names or numbers and kept strictly confidential. Only the relevant doctor knows your personal information, and your privacy rights will be well protected. The results may be published in a journal, but will not reveal any identifiable information about you.

If you agree to participate in this study, all your medical data will be reviewed by the relevant personnel of the research and development unit initiating the study, or by an independent ethics committee to check the appropriateness of the study. If you sign the informed consent form, you agree to accept the above personnel.

Note: It is suggested to refine the notification of confidentiality measures, especially the personal information protection technology and organizational measures related to big data.

13. How to get help in the study:

You can always know the information and progress of the study. If you have questions about the study, please contact (phone number) and (name of the investigator or relevant person).

If you need to know about the interests of participants during the study, you can contact the Ethics Committee of the Army Specialty Medical Center at 023-68757140.

If you fully understand the contents of this research project and agree to participate in this study, you will sign this informed consent form in duplicate, one retained by the investigator and the subject or the client.

Clinical Research Project Name:

Signed by the subject himself or his legal representative:

Consent statement:

1.I confirm that I have read and understood the informed consent for this study, that possible problems and solutions during the study have been explained to me, and that I have the opportunity to raise my own questions.

2.I have made it clear that my participation in the study is voluntary, and refusing to participate in the study will not harm any of my due interests.

3.I have learned that the ethics committee of the team members should review the study records and case data. I agree that the above personnel will directly obtain my study records and understand that the above information will be kept confidential.

4.I agree to take part in this study

Subject Name:

Full name of the subject:

Relationship with subject (if non-close parent, have subject power of attorney: Yes ）

The following was done by the physician performing the informed consent process

Investigator Statement: I confirm that I have explained and discussed to the patient the nature, purpose, requirements and possible risks of the study, and also explored other alternative treatment options, and ensure that copies of this subject informed consent form are given to the subject for preservation.

Investigator Name: (Full Name)