Subject Consent

1.Project name: Comparison of the effectiveness of positioning device cotton roll-coated viscoelastic polymer pads versus viscoelastic polymer pads for preventing pressure injuries in patients undergoing lumbar spine surgery

2.research basic information
1. Project number:
   IRB Case Number/Application Number: 202300040B0　/2307050001
2. Test institution:
3. The unit to which the executor belongs:
4. Host:__Service Units:
   job title:__Telephone:
   Co-host:_ Service Units:
   job title:_Telephone:

3.Introduction: Pressure injuries (pressure injuries, PI for short) are one of the common complications in surgery, which means that the pressure injuries that occur immediately after surgery or within hours to 3 days after surgery, most of them occur The bruise grades are on the 1st to 2nd grades. The operating room is an important place to prevent intraoperative pressure injury, so it is important for the nurses in the operating room to provide effective nursing measures to prevent pressure injury, which can reduce the risk of pressure injury and the cost of nursing care; the operation process can reduce the occurrence of pressure injury in patients It can reduce the cost of medical resources and manpower, and provide patients with a safe medical environment and good medical quality.

4. Research purposes:
This study is an experimental study to compare the effect of Relton-Hall prone frame cotton roll viscoelastic polymer pad and viscoelastic polymer material in preventing pressure injury in lumbar spine surgery.

5. Inclusion/Exclusion Conditions: The moderator or researcher in charge of this study will help you to evaluate first, and discuss with you the conditions necessary to participate in this study. If you are eligible for inclusion in this study and are willing to participate, you must sign this consent form before entering the study.
1. You are eligible to participate in this trial if you meet the following inclusion/exclusion criteria
   1. Inclusion criteria
      (1) Patients who underwent lumbar nerve decompression combined with internal fixation and bone fusion.
      (2) Positioning device Relton-Hall frame in prone position.
      (3) The operation time is greater than 2.5 hours.
      (4) The surgical anesthesia is general anesthesia.
      (5) Routine surgery registered in the surgery schedule.
      (6) Before the operation, the skin was intact and there was no pressure injury.
   2. Exclusions
      (1) Patients undergoing emergency lumbar surgery.
      (2) Are younger than 18 years old.
      (3) The operation time is less than 2.5 hours.
      (4) Preoperative skin incompleteness (obvious chest and iliac crest pressure phenomenon).
      (5) Percutaneous minimally invasive disc herniation decompression (percutaneous endoscopic lumbar disc, PELD).

6. Test method and procedure description:
The number of subjects is about 50, and this study adopts the split-body design (the left chest, left iliac crest and right chest, right iliac crest) as an experimental study of random assignment,

comparing two decompression materials (positioning device Relton- Hall One side of the prone frame is covered with cotton rolls, and the other side is the viscoelastic polymer) to reduce the effect of pressure injury. The split design is that each patient is an experimental group and also a control group to remove biological variability, such as demographic characteristics: potential factors such as gender, age, disease history, nutritional status, and overall health status. Looking forward to understanding the positioning device Relton-Hall viscoelastic polymer with cotton roll and the effect of viscoelastic polymer on the incidence of postoperative pressure injury and decompression effect in patients undergoing lumbar spine surgery.

7. Predictable occurrence rate and treatment methods:
Studies have pointed out that the incidence of pressure injury in surgical patients ranges from 3.7% to 23.8%, and most of the pressure injuries occur in grades 1 to 2.
1. Physiological aspects:Depending on the individual and the severity of the injury, pressure injuries can cause localized pain and inflammation, which are the body's natural response to injury.
2. Psychological aspect: pressure injury may cause increased anxiety and stress in the patient.
3. Social aspect: The project host ensures himself and avoids leakage of the subjects' data.
4. If you have any questions or conditions now or during the study, please feel free to contact the researchers
(Telephone:****-******).
5. If you have any opinion on the rights as a subject or suspect that you have been victimized by participating in the research, you can contact the Human Research Ethics Committee of Dali Renai Hospital for consultation. Contact time: Monday to Friday 09:00~12:00, 13 :30~16:30, the phone number is: (04)24819900 ext. 11160

8. Expected test results:
Participation in research itself cannot directly reduce the risk of pressure injury or reduce the occurrence of pressure injury, but it can improve the prevention and management of pressure injury through the application of research methods and results.

9. Subsidies, Burden of Expenses and Compensation for Damages:
1. Subsidy:
Please help for free.
2. Burden of expenses:
There is no cost to you to take part in this trial.
3. Compensation for damages:
(1) If the clinical trial/research plan is formulated in accordance with this study, and any adverse reactions cause damage, the Chung Tai University of Science and Technology and the test host shall be liable for compensation according to law. However, the expected adverse reactions recorded in the subject's consent formOr the complications and adverse reactions caused by the lumbar spine-related surgery, without compensation.
(2) Chung Taiwan University of Science and Technology is willing to provide professional medical care and medical consultation if adverse reactions or damages occur due to the clinical trial/research plan formulated in this study. You do not have to pay for medically necessary treatment for adverse reactions or injuries.
(3) Except for the compensation and medical care in the first two items, this research does not provide other forms of compensation. If you are unwilling to accept the risks, please do not take part in the trial/research.
(4) You will not lose any legal rights by signing this agreement.

10. Protection of Privacy and Confidentiality:
1. There will be a research code to represent your identity, and this code will not display your name, ID number, or address.
2. Regarding the results and diagnosis of your interview, the research host will keep a confidential attitude and carefully maintain your privacy. If the research results are published, your identity will remain confidential.
3. Please also understand that if you sign the consent form, you agree that your interview records

can be directly reviewed by monitors, auditors, research ethics committees and competent authorities to ensure that the research process and data comply with relevant laws and regulations. The aforementioned persons also undertake not to violate the confidentiality of your identity.
11. Statement: The content of this experiment and the consent form have been fully informed and explained orally, and the subjects themselves have fully understood and agreed. This consent form is in duplicate.

A. Subject: (Signature) date: years day

B. Co/Co-Moderator: (Signature) Date: years day

C. Study Chair: (Signature) date: years day