Master Thesis Proposal

Protocol Title: 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

Applicant Organization: Central Taiwan University of Science and Technology

Department of Nursing

Principal Investigator(s):_____ sign:

Co-Investigator(s):_____ sign:

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(Please summarize the purpose, implementation method, expected research results and key words of this project)

Research Background: Pressure injury (pressure injuries, PI) is one of the common complications in surgery, which means PI that occurs immediately after surgery or within hours to 3 days after surgery. The incidence of PI in spinal surgery is about 5%~66%.

Purpose: This study compares the differences in PI in patients undergoing lumbar spine surgery when the positioning device uses cotton roll-coated viscoelastic polymer pads and viscoelastic polymer pads.

Research methods: In this study, the split-body design was adopted as an experimental study of random assignment, and the four parts of the patient's body that were in contact with the positioning device (left chest, left iliac crest and right chest, right iliac crest) were randomly assigned to In the experimental group or the control group, compare the decompression effect of different materials on the positioning device on the patient; the experimental group uses the positioning device ReltonHall prone frame 3 cm cotton roll-coated viscoelastic polymer pads,and the control group uses the positioning device ReltonHall prone frame viscoelastic polymer pads. The research object is lumbar surgery patients in the operating room of a hospital in the north. It is expected to enroll 50 people. The experimental group or the control group will be assigned by random number table.the measurement time is before operation, immediately after operation, 30 minutes after operation, 24 hours after operation, and 48 hours after operation. This study uses SPSS 25.0 Chinese version package software for data analysis, descriptive statistics use frequency, percentage, average value, standard deviation, etc., and inferential statistics use independent sample t test, chi-square test, generalized estimating equation, etc. to analyze data.

Keywords: lumbar spine surgery, pressure injury, positioning device, preventive, split design

II. the content of the plan

1. Research background: Please describe the background and importance of this plan. The content can be written with reference to the following points: (1) Policy or Legislative basis (2) Problem situation or development requirements (3) Literature research on related research at home and abroad or this plan (4)Relevance of health care. (page limit 5 pages)

Research background and motivation

Pressure injuries (pressure injuries, PI for short) are one of the common complications in surgery, which means pressure injuries that occur immediately after surgery or within a few hours to 3 days after surgery. Most of the pressure injuries occur In grades 1 to 2 (Tang et al., 2021); while the incidence of pressure injuries in spinal surgery is between 5% and 66% (Kwee et al., 2015), reports in the United States show that each The average cost of treatment for patients with pressure injuries is US$10,708, with a total annual cost of more than US$26.8 billion (Padula & Delarmente, 2019); it is pointed out in Chinese literature that the cost of treating a patient with pressure injury is about NT$7,000-80,000 Yuan (Chen, 1998); Intraoperative pressure injuries will increase patients' complications, hospitalization time and medical expenses, thus negatively affecting the postoperative recovery care of patients and their families. 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; for the hospital, the operation process can reduce The incidence of pressure injuries of patients can reduce medical resources and labor costs, and provide patients with a safe medical environment and good medical quality.

Regarding the prevention of the incidence of pressure injuries in patients undergoing spinal surgery, in the study of Wu et al. (2011), the decompression materials on the positioning devices (Positioning Devices) of patients undergoing spinal posterior surgery were compared using The effect of high-density foam pad (High-Density Foam Pad, HDFP) viscoelastic polymer pads (Viscoelastic Polymer Pads, VPP) on preventing the incidence of pressure injury. The research results show that although the pressure of skin contact with VPP is significantly lower than that of contact with HDFP, the The effect of preventing the incidence of pressure injury is not significant. The research suggests that when the risk of pressure injury is high in patients undergoing spinal surgery, the fat pad should be considered for the prevention of pressure injury; Zhang et al. In the improvement plan for the incidence of pressure injury in surgical patients, it is suggested that the cotton roll-coated with the viscoelastic polymer pads material can prevent the incidence of pressure

injury, but it does not describe how many layers of the cotton roll need to be coated for the best effect, and its effect has not been verified; In addition, Dai et al. (2022) mentioned in the combined care plan for the prevention of intraoperative pressure injury in surgical patients that the posture of prone surgery can be used to cover the viscoelastic polymer pads with cotton rolls to protect the skin. The article does not detail how many layers of cotton are covered The effect of viscoelastic polymer pads on preventing pressure injuries is the best, and it has not been explained how its single effect is? According to the author's clinical experience, although the intraoperative positioning device (Relton-Hall prone frame) for spinal patients undergoing surgery in the prone position uses viscoelastic polymer pads to prevent pressure injuries , but patients still often suffer from pressure injuries. Therefore, the author explores whether wrapping the fat pad of the positioning device with cotton rolls can reduce the incidence of pressure injuries; The effect of covering fat pad and fat pad material in preventing pressure injury in lumbar spine surgery.

2. Purpose of the test: Please list in detail the goals to be achieved in this plan and the work items to be completed. Avoid empty space.
lack of narrative. For a plan with a period of more than one year, the overall goal of the whole plan and the plans for each year should be listed
purpose. (page limit 2 pages)

Research purposes

For patients undergoing spinal posterior surgery (spinal posterior surgery), the decompression material of the intraoperative positioning device (Relton-Hall prone frame) is used to wrap the fat pad and fat pad material with cotton rolls. Is there a difference in the rate.

3. Test object: The content includes the following points for writing: (1) Inclusion and exclusion conditions (2) Number of subjects (3) Recruitment sources and methods (4) Protection of research subjects' rights and methods of informed consent. (page limit 5 pages)

research object

Patients with lumbar spine surgery in the operating room of a hospital in the north are eligible for inclusion as follows:

1. Patients who underwent lumbar nerve decompression combined with internal fixation and bone fusion.
2. Take the prone position using the ReltonHall rack.
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.

Exclusion criteriaas follows:

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).

Sample Size Estimation

The author refers to the research results of Yang et al. (2020) to estimate the sample size, estimates with G-power 3.1 software, sets the significance level of α value to 0.05, and the test power is 0.80, using the ratio of two groups (chi-square test) To test the sample size, the minimum sample size for this study was determined to be 93 people. According to the estimated number of samples and pre-test results in the above literature, it is planned to collect 93 people. After correcting the sample loss rate, 100 people will be recruited. Since this study adopts a split test (self-experimental group and control group), it is estimated that Enroll 50 people.

research ethics

To follow the principles of patient autonomy, non-injury and confidentiality, before the research is conducted, the purpose and process of the research must be explained to the research subjects or their families, and the patients can request to stop at any time during the research process without affecting the future medical rights and safety. Before the implementation of this study, it is expected to be submitted to the Human Research Ethics Committee of a medical center in central China for review; the data of the research subjects will only be used for academic research to protect the privacy of the research subjects.

4. Research method:	The content includes the following points for writing: (1) The standard and number of subjects to be tested (2) The design and method of the test (3) The duration and progress of the test (4) Tracking or rehabilitation plan (5) Evaluation and statistical methods (6)) Tracking of subjects and necessary care plans.

Research design

This study adopts the split-body design (left chest, left iliac crest and right chest, right iliac crest) as an experimental study, comparing two kinds of decompression materials (positioning device ReltonHall prone frame The effect of wrapping the fat pad with a cotton roll on one side and the fat pad on the other side) in reducing pressure injuries. 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. It is expected to understand the effect of the ReltonHall cotton roll-coated fat pad and the fat pad on the incidence of postoperative pressure injury and the decompression effect of patients undergoing lumbar spine surgery.

Research Design Patterns

group	Pretest	intervention	Posttest I immediately	Posttest II 30 minutes	Posttest III 24 hours	Posttest IV 48 hours
Experimental side	O1	X1	O2	O3	O4	O5
control side	O1	x	O2	O3	O4	O5

Note:

O1: After general anesthesia, the subject was placed supine to measure the integrity of the skin.

X1: Refers to the experimental side chest and iliac crest positioning device ReltonHall fat pad wrapped cotton roll 3 cm.

X: Refers to the ReltonHall, the positioning device of the chest and iliac crest of the control group, which is the fat pad routine.

O2: Immediately after the operation, I was measured after the pressure injury was graded on the experimental side and the control side.

O3: 30 minutes after the operation, the experimental side and the control side were tested for pressure injury grade II.

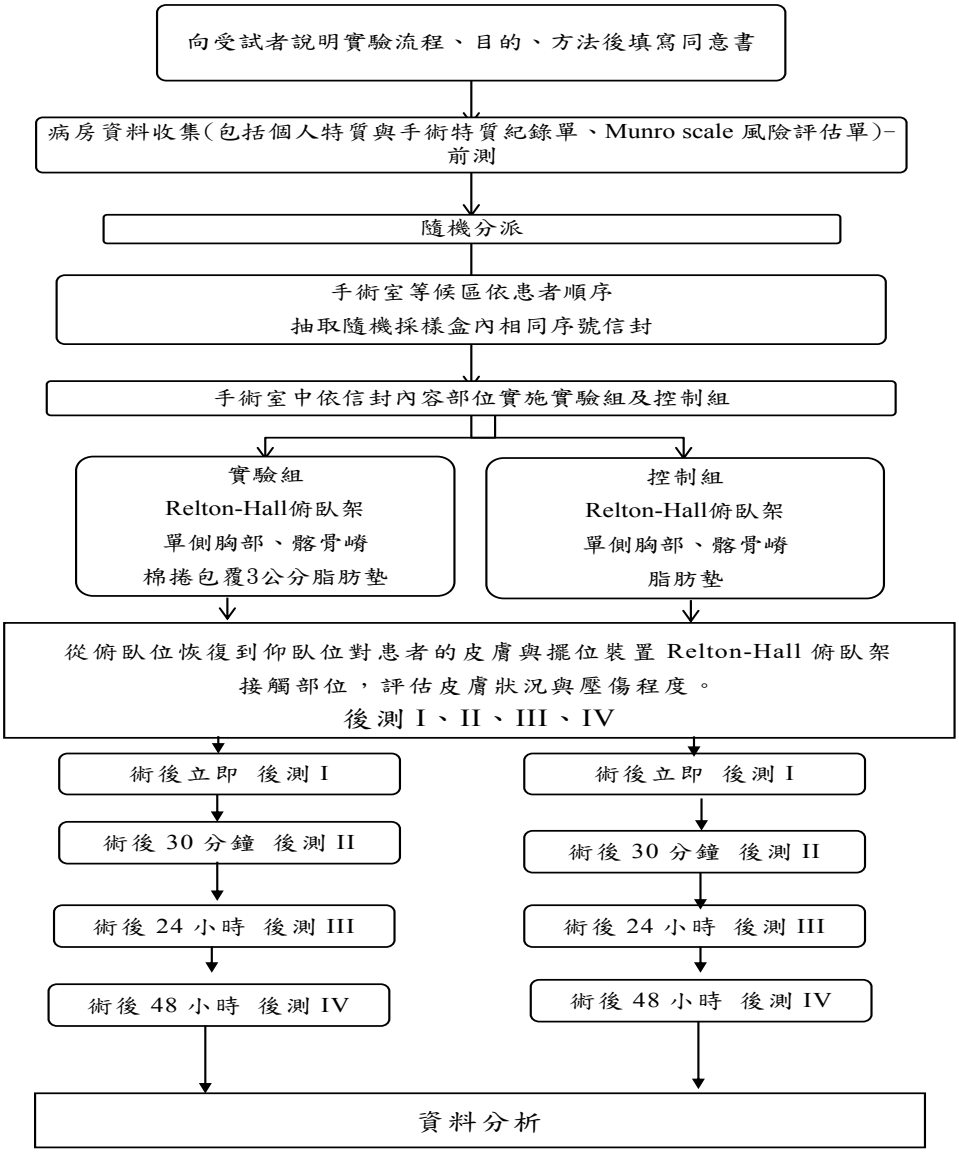
O4: 24 hours after the operation, the experimental side and the control side were tested for pressure injury grade III.

O5: 48 hours after the operation, test the IV after the pressure injury grade was carried out on the experimental side and the control side.

Positioning and intervention methods

The patient enters the operating room, and the four support cushions on the frame have been disposed in advance according to the experimental side and the control side. After general

anesthesia, the surgical team uses standard positioning steps to measure the body length: from the 2 cm mark point of the armpit to the iliac side. between the bony crests; and body width: between the two iliac crests, then adjust the patient's posture and the contact surface of the prone frame according to the markings on the ReltonHall prone frame support pads to ensure that the pressure points on the patient's body are consistent with the marked points; place the patient Lie prone on the ReltonHall prone frame. After the patient is in the prone position, the horizontal line between the scapula and the posterior iliac crest must be parallel to the ground.



1.Experimental side intervention method

Viscoelastic polymer pads (Viscoelastic Polymer Pads) (model 40700; Action, Hagerstown, MD) were used on the 4 support columns of the Relton-Hall prone frame of the positioning device. The dimensions were: 18 cm long, 15 cm wide, and 2 cm thick. The fat pad accessories are designed to cover the four support columns of the Relton-Hall prone frame. The fat pad of the chest and iliac crest on the same side on the Relton-Hall prone frame is covered with a cotton roll for 3 cm. The skin is the experimental side.

2.Control Side Intervention Method

In addition to the experimental side, the fat pad of the chest and iliac crest on the other side of the Relton-Hall prone frame, and the patient's skin contact position is the control side.

Pressure injury record form, this record form is based on the wound evaluation indicators jointly developed by the National Pressure Ulcer Advisory Committee (NPIAP, 2016) and the European Pressure Ulcer Advisory Panel (EPUAP), according to the established Designed according to pressure injury grading standards.

According to this record sheet, the recorded pressureing conditions are divided into "pre-operative assessment", "immediately post-operative assessment", "30-minute post-operative assessment", "24-hour post-operative assessment", and "48-hour post-operative assessment". Nursing staff in the ward and wards should evaluate and record the pressure points that may cause pressure injuries. Including the site of occurrence and the grade of pressure injury. In order to increase the accuracy of the evaluation, the classification and description of the pressure injury are provided at the bottom of each record sheet for reference.

Statistical analysis methods for various data

data item	Statistical analysis method
1. Basic information of subjects: 1. Gender, age, suffering from chronic diseases, BMI, operation time, albumin, intraoperative body temperature, and intraoperative blood pressure.	1. Described in terms of times, percentages, etc. 2. Chi-square was used to test whether there was a significant difference between the experimental group and the control group.
2. Age, days of pressureing.	1. Described by means, standard deviations, etc. 2. Independent sample t test was used to test whether there was a significant difference between the experimental group and the control group.
2. The pressured parts of the two groups of subjects (one-sided chest, iliac crest), whether there is PI in the compressed parts of the two groups, the contact point of one-sided chest and iliac crest (experimental group), the other side of the chest, The contact point of the iliac crest is (control group)	Independent sample t was used to test whether there were significant differences between the experimental group and the control group immediately after operation, 30min, 24hr, and 48hr.

3. To test whether there are significant differences due to time factors between the two groups of subjects under the decompression material immediately after the operation, 30min, 24hr, and 48hr.	Test the experimental group and the control group by the generalized estimating equation In the control group, immediately after operation, 30min, 24hr, 48hr results measure whether there is an iteraction effect.

5.Expected test effect

For lumbar surgery patients undergoing spinal posterior surgery (spinal posterior surgery), the intraoperative positioning device (Relton-Hall prone frame) is used for decompression materials, and cotton rolls are used to cover the fat pad and fat pad material, which is effective in preventing lumbar surgery patients. The incidence of injury is expected to be substantially improved.

6. References

Chinese part

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7.possible injury and treatment

1. Currently available information shows that the incidence of pressure injury risk in spinal surgery is 5% to 66%. Most of the pressure injuries occur in grades 1 to 2, resulting in grade 1 pressure injuries. Treatment: 1. To reduce continuous pressure, check the pressured part to see if there is any redness and broken skin. 2. Avoid friction with clothes or sheets to prevent further injury; second-level pressure injury treatment: use dressings to cover the wound, The purposes of dressing coverage include absorbing exudate, maintaining moist base of the wound, and maintaining a considerable degree of breathability.

2. The research host will keep the results of your interview and diagnosis confidential. You will have a research code to represent your identity. This code will not display your name, ID number, or address. The use or publication of the data obtained by the research institute will be absolutely confidential to the privacy of the research subjects (such as: names, photos that can identify the identity of the research subjects, etc.), and will not be leaked to other units. Your identity will remain confidential. Your personal data and privacy will be protected in accordance with relevant laws and regulations of our country.

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.

4. The research participants participate in the research to reduce their risk. Participating in this research does not require any additional expenses. During the interview process, if you feel any discomfort, you will immediately stop (questionnaire or interview) and provide necessary assistance. If you have any questions, you can also contact the host of this collaborative project, Xing Shengzhi, at any time. The 24-hour emergency telephone number is 0913-966-976.

8. Scheduled progress: Use the Gantt Chart to represent the implementation progress of this year. Multi-year plans should be submitted annually
Scheduled progress.

112Year

moon Second-rate Work projects	first month	February	March	April	May	June	July	August	September	October	November	December	prepare Note
The number of cases scheduled to be accepted is 5								■					
Scheduled to accept 5 people									■				
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The number of cases scheduled to be accepted is 5	■												
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Project Analysis						■	■						
result report						■							