

Simulation Study of Different Fixation Materials in Nephrostomy Tube Fixation

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Abstract

Purpose: We are aiming to compare the three kinds of tapes of medical adhesive plaster, medical athletic tape, medical non-woven tape on their fixing strengths of renal fistula and harm to the skin.

Patients and Methods: In February 2022, 30 healthy people from a community activity center in Wuhan were selected to conduct a randomized block experiment with their ages used as the block factor. Three different fixation materials were used: medical rubber paste, medical breathable tape and medical non-woven tape for nephrostomy tube fixation. The extubation force and skin redness of three kinds of medical tapes were compared to evaluate the fixation strength and skin injury severity of three kinds of medical tapes.

Results: The experimental results show that the three medical tapes have significant differences in their fixing strength and damage size on the skin ($p < 0.05$). The medical adhesive plaster has the largest fixation strength and the maximum damage to the skin ($p < 0.05$), and the medical athletic tape and medical non-woven tape show no obvious statistic difference in the fixing strength and damage size to the skin ($p > 0.05$).

Conclusions: The randomized block experiment was used to study the fixation strength and skin damage of different fixation materials of nephrostomy tube. The experiment was carried out under the simulated experiment of force display. The operation was simple and intuitive, which could provide reference and basis for the selection of clinical tube fixation scheme.

Keywords: Nephrostomy Tube, Drainage Tube Fixation, Randomized Block Experiment, Medical Tape, Skin Lesions Associated with Medical Adhesives

1. Introduction

Unplanned extubation (UEX) is caused by extubation by accidental shedding of the tube or removal of the catheter without medical staff consent or improper operation by medical staff. Unplanned extubation may induce physical and mental harm to the patient and is even detrimental to the patient's life [1]. The incidence rate of unplanned extubation in the world was 0%~14.2%, while the incidence rate was 0%~14.6% in China [2, 3]. Standardizing the pipe fixation method is an important way to prevent pipe slippage [4]. In foreign countries, the mechanical instruments are used to evaluate the fixation performance of the tape, while in China, the fixation effect is mainly evaluated by the evaluation indices such as pipeline slip rate after clinical fixation [5, 6]. The studies by Michael, et al have shown that too many experiments are not repeatable, which cannot reach the real randomness or minimize

the effects of non-experimental factors [7]. The random block design, also known as the compatibility group design, can improve the efficiency of statistical test and make the experimental data more convincing. The specific approach is to first allocate the experimental objects into regional groups according to the non-processing factors affecting the experimental results, and then the experimental subjects in each district group are randomly assigned to different levels of processing factors for the experiment. Randomized block group experiments are widely used in the fields of medical drug clinical trials and agronomy field experiments. In this study, by using the force display through the method of random block experiment for pull tube experiment, we compare the medical rubber cream, medical breathable tape, medical non-woven tape about their different fixing strength of nephrostomy tube and the damage to the skin [8]. This study can provide

important evidences and references for clinical pipeline fixation. The results of this study are provided as follows.

2. Patients and Methods

2.1. Data Source and Study Population

Thirty healthy people of different ages were labeled numbers 1 to 30. They were assigned into 10 blocks. Every group had three healthy persons with age of <30 years, 30-60 years and > 60 years. Inclusion criteria: ① female yellow population; ② BMI was between 18 and 24; ③ no arm bathing or immersion within 1 hour; ④ informed consent to participate in the experiment. Exclusion criteria: ① contraindications of ulceration or redness on the medial forearm, application of skin-related products; ② diseases affecting skin appearance, such as albinism and systemic lupus erythematosus; ③ history of contact dermatitis and hypersensitivity; ④ other people assessed not suitable for this study.

2.2. Experimental Personnel and Equipment

① Set up an experimental team: We carried out relevant training after consulting a doctor with the title of associate senior physics and set up an experimental team. Three chief nurses with a master's degree were responsible for the implementation and record of the experiment. This study was reviewed by the hospital ethics committee with the review number TJ-IRB20210949. ② The main equipment of this experiment includes force display, nephrostomy tube, medical rubber paste, medical breathable tape, medical non-woven tape, scissors, etc. The force display is produced by the deep survey electronic production company. The model is horizontal digital display NK-50N, with an accuracy of 0.01N and a force measurement range of 0~50N. Polyethylene panel specification is 300mm 300mm 4mm, white, friction coefficient skin friction coefficient 0.5; the renal fistula tube model is 14 Fr silicone double cavity straight head, white, produced by Jiangsu Conuo Medical Device Co., Ltd., batch number is D20070230. Medical rubber ointment is 26cm 500cm, white, Cotton cloth material, The pad material is anti-sticker, Trade name fish-diving (yuwell), Produced by Jiangsu Nan fang Eisai Pharmaceutical Co., Ltd.; The breathable tape is 5.0cm 500cm, colour of skin, Gracillaceous material, The paste material is acrylic glue, The adding material is detached paper, Equipment No.20150483, Imported by the Minnesota Shanghai International Trading Corporation; Medical non-woven cloth tape specification is 10.0cm 1000cm, colour of skin, Non-woven fabric material, The paste material is the acrylic resin glue, The liner is of isolation paper, The trade name is Lanlo (LANLUO), Equipment No.20210066, Lanluo Medical (Changzhou) Co., LTD.

2.3. Implementation Method

① Prepare fixed materials: cut 3 kinds of fixed materials of medical rubber paste, medical breathable tape and medical non-woven tape by 9cm long and 4cm wide respectively, and fix them according to the "I-word" method. A represents medical plaster 9cm long and 4cm wide fixed by "I" method, B represents medical breathable tape 9cm and 4cm wide fixed by "I" method, C represents medical non-woven tape 9cm and 4cm wide fixed

by "I" method. ② Random number method: take 30 consecutive random numbers, and then rank the random numbers from small to large. Healthy people of different ages and fixed schemes are matched into regional groups, corresponding to the healthy person application plan A of the smallest number, corresponding to the health person application plan B of the second largest number, and corresponding to the healthy person application plan C of the largest number. ③ Preparation experimental environment: The indoor experiment environment require : temperature was 22~25°C, humidity was 50%~70%. ④ Random block experiment: The force display was put on the horizontal desktop. Experimenter and subjects sit face to face at the table. Lay the arm of subjects flat on the table, gently wipe the arm ventral skin with a dry paper towel. The 10cm * 4cm below the elbow fossa above the wrist was designated as the experimental area for tension experiment. The tape was used to fix the nephrostomy tube on the healthy arm, shape it for 5 seconds, and wait for 10 seconds to make it fully fit. Press the force display power button to open the display, and then press the reset key to make the force display reading to zero. We timed it using a stopwatch and turned the instrument clockwise at a speed of 1 lap / second (0.2cm). We stopped turning the handle and recorded the tension value when the nephrostomy tube was shifted by 2cm along the long axis. After each experiment, the polyethylene board was cleaned with detergent and left to dry. Each subject was performed one tension test in the left arm and the right arm with the same fixation method. The average value of the two experiments was taken as the final tension value. A total of 60 tension experiments were conducted. The skin condition was assessed 30 minutes after we finished the experiment.

2.4. Outcome Measures and Data Collection

① The tape was fully fitted with the polyethylene display board, with no curling edges and no wrinkles. Three experimenters simultaneously evaluated the fixed normality. When the nephrostomy tube was shifted by 2cm along the long axis, the force display reading was viewed and recorded. Record the fixed tension values twice. ③ At 30 minutes after the experiment, subjects were evaluated for their arm skin condition, and the number of skin redness was recorded.

2.5. Statistical Analysis

Statistical analysis was performed with SPSS25.0, with analysis of variance and further Bonferroni test for multiple comparisons; multiple sample rates were compared with multiple sample rates 2Test, multiple comparisons using Fisher exact probability method and Bonferroni correction method, the test level was $\alpha = 0.05$.

3. Results

3.1. Data Characteristics

Through the normality test, the data were normal ($P > 0.2$), and the random block experimental results showed homogeneity of variance by White test and residual scatter plot (White test $P = 0.414$). The scatter plots of the residues were shown below (Figure 1).

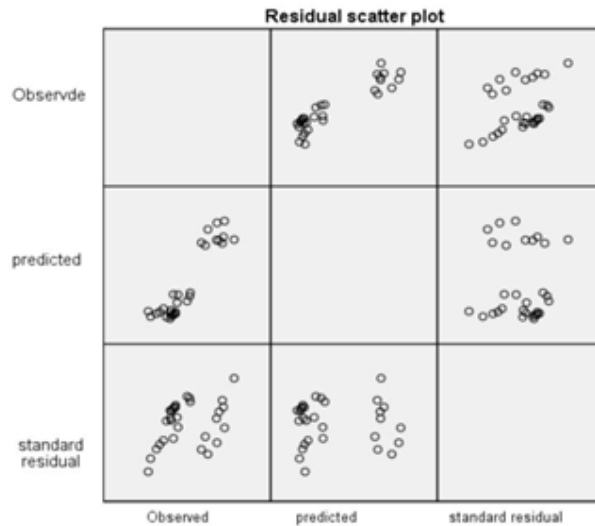


Figure 1: A Residual Scatter Plot of the Pull Value F

3.2. Comparison of the Fixation Strength of Different Medical Tapes

The experimental results showed that the three medical tapes have significant differences in their fixing strength (between group

factors) ($p < 0.05$), but there was no significant difference in the fixing strength (within group factors) in the arms of the subjects of different ages ($P > 0.05$) (Table 1).

source of variation	SS	Df	MS	F	P
Total variation	128.422	29			
error	18.616	18	1.034		
Inter-group variation	103.818	2	51.909	50.191	0.000
Intra-group variation	5.988	9	0.665	0.643	0.747

Table 1: Analysis of Variance of Different Medical Tapes

Note: SS: total variation, Df: degree of freedom, MS: mean square, F: statistic of test, P: probability.

The fixation strength of different medical tapes was further compared pairwise. The fixation strength of medical rubber (A) and the other two kinds of medical tape was significantly different

($P < 0.05$), and the fixation strength of medical breathable tape (B) and medical non-woven tape (C) was not statistically significant ($P > 0.05$) (Table 2).

95% CI

material	contrast	SD	P	lower limit	superior limit
A	B	0.45480	0.000	2.7017	5.1023
	C	0.45480	0.000	2.7887	5.1893
B	A	0.45480	0.000	-5.1023	-2.7017
	C	0.45480	1.000	-1.1133	1.2873
C	A	0.45480	0.000	-5.1893	-2.7887
	B	0.45480	1.000	-1.2873	1.1133

Table 2: Further Pairwise Comparison Results of Different Medical Tapes

Note: A stands for medical plaster; B for medical breathable tape; C for medical non-woven tape

3.3. Comparison of Skin Redness Rate Caused by Different Medical Tape

By Fisher exact probability test, the number of skin redness caused by the three medical tape was statistically different ($P < 0.05$) (Table 3).

Different materials	Skin redness (example)	No redness of the skin (example)	Total (example)	χ^2	P
A	12	8	20		
B	2	8	20		
C	4	16	20	12.521	0.002

Table 3: Comparison of Skin Redness Rate Caused by Different Medical Tapes

Note: A stands for medical plaster; B for medical breathable tape; C for medical non-woven tape

Further pairwise comparison results showed that the rate of skin redness caused by the medical rubber paste was statistically significant with the other two medical tapes ($P < 0.05$), and there

was no statistical difference between the medical breathable tape and the medical non-woven tape ($P > 0.05$) (Table 4).

Different materials	contrast	χ^2	P
A	B	10.714	0.03
	C	6.500	0.033
B	A	10.714	0.03
	C	0.765	0.993
C	A	6.500	0.033
	B	0.765	0.993

Table 4: Pairwise Comparison of Skin Redness Rate Caused by Different Medical Tapes

Note: A stands for medical plaster; B for medical breathable tape; C for medical non-woven tape

4. Discussion

Human skin cannot withstand the damage caused by repeated fixation and avulsion, so this experiment adopts polyethylene display board with similar friction coefficient to the skin for simulation study, laying the foundation for further clinical research. As early as the end of the 19th century, the stripping experiment of medical tape using the principle of physical double force balance has been reported, and the approximately constant duration of the stripping force was 0 to 36S [9]. And Monteiro et al In the guidelines for the assessment of the biomechanical properties of human skin and its attachments, it is stated that the number of participants for studies that quantify the impact of the mechanical properties of the intervention is at least 30 to 40 [10]. Therefore, 30 healthy people were selected for this experiment, and a fixed waiting time of 10 seconds is scientific. The friction force of human skin is affected by temperature, humidity, skin moisture, age, gender and other factors, with the growth of age, the skin moisture is gradually lost, and age is an important factor affecting the friction characteristics of the skin [11]. In this experiment, age was selected as the regional factor, and the influence of other factors such as sex was controlled. Since this experiment was based on a small sample size, the district factors were not statistically significant, but the random block experiment better controlled and balanced the influence of confounding factors, and the experimental results were more convincing.

Medical rubber plaster has the greatest fixation strength, but also causes the greatest damage to the skin. ANOVA by White test after normality test. The results of the experimental ANOVA showed that the treatment factors were statistically significant ($P < 0.05$)

and the district factors were not statistically significant ($P > 0.05$). That is, different materials differ in fixation strength, but different ages have little influence on fixation strength. The fixation strength of medical rubber paste was different from the other two kinds, and there was no significant difference between medical breathable tape and medical non-woven tape. This study also found that the rate of skin redness caused by different medical tape varied, and the difference of skin redness caused by medical rubber paste was statistically significant ($P < 0.05$), and the difference of skin redness caused by medical breathable tape and medical non-woven tape was not statistically significant ($P > 0.05$). Medical rubber paste is a medical tape with pure cotton cloth as substrate, natural rubber and pure zinc oxide as packaging material. It has the characteristics of firm paste effect and is widely used in surgical drainage tube fixation. Chaves class it is believed that the number of dissected keratinocytes is closely related to the degree of skin irritation, and the tape with greater adhesive strength is more irritating to the skin because of the more dissected keratinocytes of the skin [12]. Medical rubber paste fixed strength is larger, the skin irritation is also larger, this with Sun Haiyan After such as clinical application, the research result is consistent [13].

Safety and comfort should be fully considered in the clinical application of medical tape. This experiment found that although the medical rubber strength is the largest, it is also the most harmful to the skin. The medical breathable tape has a good fit with the skin, good air permeability, and less damage to the skin. The medical adhesive-related skin injury (Medical adhesive-related skin injury, MARSIS) consensus statement defines MARSIS as persistent erythema and / or other skin abnormalities occurring within 30

minutes or more after removal of the adhesive product [14]. M ARSI Can lead to patient pain, infection, scar formation, physical and mental discomfort, etc. [15]. And Age is an important risk factor for MARSI [16]. Because the liquid dressing can effectively protect the local skin in clinical practice, liquid dressings can be used to reduce local skin irritation [17]. The adhesive strength of medical adhesive tape is different in different environments, while the same adhesive tape is different in different states [18]. Due to the limitation of time, the adhesive performance of three medical tapes was not further studied under different conditions of tape (wet and sticky grease).

5. Conclusion

This study showed that in the fixation of 14 Fr silicone nephrostoma tubes, medical rubber paste had the most strength but caused the most skin damage than medical breathable tape and medical non-woven tape. In clinical pipeline fixation, for people with high risk of pipeline removal or pipeline, if the skin sensitivity is not high, medical rubber paste can be considered for fixation, but at the same time, attention should be paid to the appropriate use of skin protective agents and other methods to reduce the incidence of skin damage related to medical adhesives. The next step is to expand the sample size or conduct multicenter clinical trials to further verify the results.

Statement of Ethics

The study was conducted in accordance with the Declaration of Helsinki, and was approved by Ethics Committee of the Tongji Hospital (TJ -IRB20210949).The informed consent was obtained from each participant prior to enrolment.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Authors Contributions

Qiuxia Qin: Conceptualization, Writing - original draft, Data curation.Juan Liu: Formal analysis, Software, Supervision.

Xiao qin Chen: Writing - review & editing, Project administration, Resources.

Data Availability Statement

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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