The Journal of Arthroplasty 38 (2023) 1565–1570

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Primary Hip

A New Dressing System for Wound in Enhanced-Recovery Total Hip Arthroplasty: A Randomized and Controlled Trial

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ARTICLE INFO

Article history:
Received 8 November 2022
Received in revised form
3 February 2023
Accepted 11 February 2023
Available online 18 February 2023

Keywords:
enhanced recovery after surgery
wound
dressing
dressing change
total hip arthroplasty
satisfaction

ABSTRACT

Background: Currently, there is a paucity of recommendations in regards to dressing selection within the enhanced recovery after surgery protocol. We devised a new dressing system to accelerate the recovery after total hip arthroplasty (THA). We aimed to present our experience with this new dressing system as an adjunct to wound management in THA and to evaluate its performance.

Methods: From September 2020 to August 2021, we prospectively enrolled 124 patients who underwent a primary THA. The patients were randomly assigned to the intervention (the new dressing system group) or the control (the traditional gauze dressing) group. The primary outcome measures of this study were numbers of dressing changes, postoperative lengths of stay, wound scores including the Stony Brook Scar Evaluation Scale and ASEPSIS scores and wound-related complications. The secondary outcomes include satisfaction scores, dressing-related costs, and pain and functional recovery scores.

Results: The intervention group numbers of dressing changes and postoperative lengths of stay were significantly less than the control group ($P < .001$, $P < .001$). During the one-month follow-up, the Stony Brook Scar Evaluation Scale in the intervention group was significantly better than that in the control group ($P < .001$). The intervention group satisfaction was significantly higher than that in the control group ($P < .001$). There were no statistically significant differences between the two groups in terms of dressing-related costs and pain and function scores.

No author associated with this paper has disclosed any potential or pertinent conflicts which may be perceived to have impending conflict with this work. For full disclosure statements refer to https://doi.org/10.1016/j.arth.2023.02.029.

Chinese Clinical Trial Registry: ChiCTR2000033822.

Consent for Publication: The patient provided a written informed consent for the publication of this study and any accompanying images. A copy of the written consent is available for review by the Editor of this journal.

Availability of Data and Materials: More data of the submission including unpublished data will be available on reasonable request.

Competing Interests: The authors report no conflict of interest.

Funding: This study was supported by the National Natural Sciences Foundation of China (Grant No. 81974360, 82002277, and 81672656), the Innovation Foundation of National Orthopedics and Sports Rehabilitation Clinical Medicine Research Center (Grant No. 2021-NCRC-CXJJ-PY-37), the Natural Science Foundation of Hunan Province, China (Grant No. 2018JJ3844, 2019JJ40499, and 2022JJ30934), the Scientific Research Project of Health and Family Planning Commission of Hunan Province, China (Grant No. B2019188), the Key research and development program of Hunan Province, China (Grant No. 2020SK2008 and 2021GK2012), and the Major science and technology projects of Changsha City (Grant No. kh2003016).

Author Contributions: P.L., D.Z., and S.S. conceived the original ideas of this manuscript. S.S., F.G., J.Q., H.W., and Z.L. executed the follow-up examination and materials collection. D.Z., L.L., and P.L. read the examination results, participated in the surgical and medical treatment. S.S. prepared the figures. P.L. and S.S. prepared the manuscript.

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https://doi.org/10.1016/j.arth.2023.02.029

Conclusion: The new dressing system could significantly reduce the number of dressing changes and postoperative lengths of stay and increase patient satisfaction scores, which can be an ideal adjunct to wound management in enhanced-recovery THA.

To improve postoperative rehabilitation and reduce postoperative complications, the concept of enhanced recovery after surgery (ERAS) has gained attention in joint arthroplasty surgery [1]. Total hip arthroplasty (THA) is one of the most common orthopedic procedures, which can effectively reduce pain in patients [2]. Wound management is an important part of the perioperative period. If wound complications occur, it can lead to wound pain and even surgical site infection (SSI) [3]. One of the worst consequences of THA is prosthetic joint infection (PJI), a major reason for THA revision [4].

However, postoperative wound management and surgical dressings are often a neglected area of study. A perfect dressing should absorb sufficient exudate, while being permeable enough to control a moist environment. In addition, a dressing must act as a watertight barrier against the external environment, while also allowing the wound to breathe—the capacity to act as a barrier to bacteria while still allowing moisture vapor transmission [5]. Dressings over joint arthroplasties should accommodate motion allowing a wide and free range of movements with no risk of friction. Currently, in our hospital, after surgery, a traditional occlusive dressing of sterile gauze and adhesive tape is placed. In some cases, we have observed the appearance of blistering, a situation that increases the risk of infection, pain, and overall costs of the procedure [6]. Also, changing dressings remains often a painful procedure [7], which is time-consuming and cost-consuming, and still represents a contamination risk. At the moment, smart dressings, especially the silver-impregnated occlusive dressings can be used in the novel wound care strategy, which can be successful in encouraging wound healing and preventing bacterial colonization infection [8]. However, sometimes they are high-cost items, which can be a major obstacle to widespread use, particularly in developing nations and for some low-income patients in rural areas.

To address this clinical problem, we devised a new dressing system and have confirmed its effectiveness and feasibility in a prior study [9]. The combination of semi-occlusive, transparent adhesive films and calcium alginate dressing was used to address surgical wounds in THA patients. It not only uses use of the benefits of calcium alginate dressing in promoting wound healing and a strong ability to absorb wound exudate but also uses characteristics of semi-occlusive, transparent adhesive films, such as breathable and waterproof, skin-friendly, and allowing a wide and free range of movements with less risk of friction. At the same time, this dressing system is low in cost and suitable for popularizing and using in developing nations.

The purpose of this prospective randomized controlled trial (RCT) was to evaluate and compare the number of dressing changes, postoperative lengths of stay, wound scores, and complications between this new dressing system and traditional gauze dressings. Secondary objectives were to analyze and compare patient satisfaction scores, dressing-related costs, and functional recoveries between dressings.

Methods

Study Design and Setting

From September 1, 2020 to August 31, 2021, we prospectively enrolled the consecutive patients who underwent a primary unilateral THA in our institute. This RCT was carried out under the principles of the Helsinki Declaration (as revised in 2013). A written informed consent was obtained from all patients before their participation in the study. The study was approved by the medical ethics committee of the Xiangya Hospital of Center South University (No.202010128) and was registered at the Chinese Clinical Trial Registry (ChiCTR2000033822). All patients were enrolled in accordance with the Consolidated Standards of Reporting Trials (CONSORT).

Participants

The inclusion criteria were as follows: (1) diagnosed with osteonecrosis of femoral head or hip osteoarthritis; (2) primary THA; (3) age 18 to 85 years; and (4) operation on one side alone. Patients who were unable to complete the regular follow-up, had skin diseases like psoriasis or eczema, or other serious systemic diseases like systemic lupus erythematosus or diabetes, had previous open hip surgery on either hip, had previous major trauma to either hip resulting in deformity or scarring, or had allergies to skin adhesives were excluded. Sample size calculation: as per the previous study [10,11] and our preliminary results, we set alpha = 0.05, beta = 0.1, the mean difference of dressing change was 2.0. A minimum of 50 patients would be needed for each group to provide 90% power.

During the study period, 162 adult patients underwent a primary unilateral THA at the study center, among which, 38 patients were excluded. Finally, 124 patients were randomized to the intervention group (the new dressing system group) (n = 62) (the traditional gauze dressing group) (n = 62) by a random number generator. The computer-generated randomization technique was carried out using opaque envelopes, which were opened intraoperatively before skin closure of the hip. One patient in the intervention group was removed because he changed other dressings by himself after being discharged. Two patients in the control group were excluded after failing to complete the regular one-month follow-up. Finally, 121 patients were included in the analyses (Fig. 1). The basic demographic data were similar between the two groups.

Surgical Procedures

An expert in joint surgery performed all THA operations. The operation was performed using a standard postero-lateral approach and the prostheses were all cementless. The incision was closed by two fixed residents. A prophylactic antibiotic was regularly administered 30 minutes before surgery. Tranexamic acid (1.0 gram) was given intravenously twice before exposure and wound closure. During the operation, all patients had a standard three-layer continuous suture approach.

Application of the Dressing

The application of the new dressing system has been described in detail in our previous study [9]. In brief, after suturing the surgical incision, place the calcium alginate dressing (Algisite M, Smith & Nephew, London, United Kingdom) folded into three layers on the incision; choose 3 or 4 pieces of the semi-occlusive, transparent

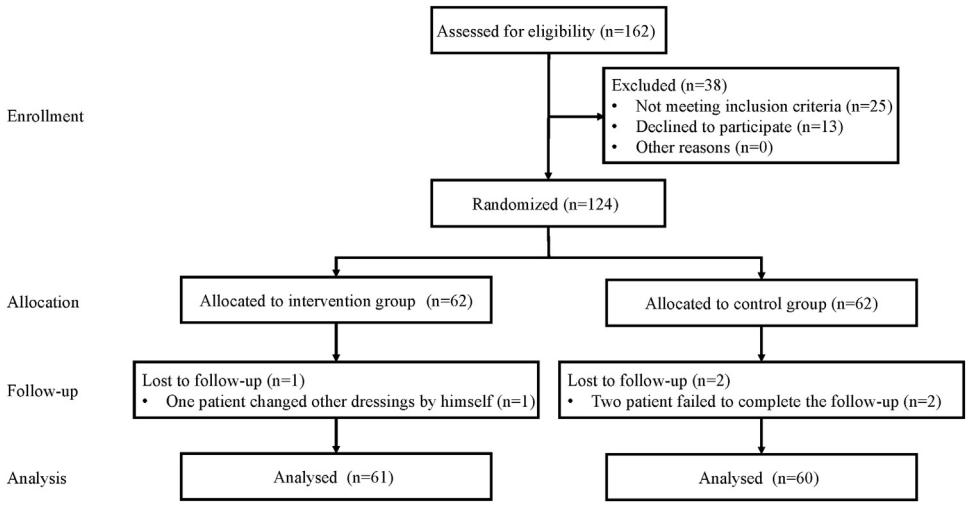

Fig. 1. Flow diagram of the allocation of patients in the intervention group (the new dressing system group) and the control group (the traditional gauze dressing group).

adhesive film (IV3000, Smith & Nephew) as per the length of the incision to paste and fix. There were no air bubbles between the films and the skin, thus they adhered to the skin.

In the control group, after suturing of the surgical incision, the wound was covered with eight layers of aseptic gauze, then one layer of aseptic cotton pad, and finally secured with plastic tape along the long axis of the wound (Fig. 2).

Following the operation, all patients used the same nursing measures. All patients were given antibiotics within 24 hours of surgery and 1 gram intravenous tranexamic acid 3 hours later. Patients were given oral thromboembolic prophylaxis in the form of 10 milligram rivaroxaban tablets once daily for 35 days beginning 6 to 8 hours after surgery. All patients were allowed immediate postoperative mobilization without restrictions. All patients should have their dressings changed when the dressing has been soaked through, the dressing has become loose or fallen off, or the patient felt uncomfortable. Patients using the new dressing system were allowed to bath as usual based on their lifestyle except for submerging wounds and dressings in the water. Patients who had traditional gauze dressing can only brush their bodies 2 weeks following the operation and they are not allowed to take showers or bubble baths to avoid wetting the dressings. All patients' dressings were removed 2 weeks after operation and wounds were evaluated. If the wound healed completely, it was no longer covered with dressing and was directly exposed to air. If the wound did not completely heal, we continued to change dressing until the wound healed. After discharge, the patients were assigned to a chat group and the dressings were photographed and evaluated under the guidance of a fixed medical staff.

Follow-Up and Outcome Measures

The patient demographics were recorded prior to surgery, including age, sex, body mass index, and surgical site. The primary outcome measures of this study were the number of dressing changes, postoperative lengths of stay, wound scores, and wound-related complications. The secondary outcomes include satisfaction scores, dressing-related costs, and pain and functional recovery scores.

Patients were discharged from the hospital if they met specific criteria, such as the ability to perform independent personal care, walk at least 70 meters on crutches, get in and out of bed and get up from chairs, treated with oral pain relief, no major exudation of wound dressings, and basically normal blood indicators [12]. The postoperative lengths of stay were computed as the whole days, whereas the part less than one day was also calculated as one day. We also kept track of the total number of dressing changes. The Stony Brook Scar Evaluation Scale (SBSES) and ASEPSIS scores were recorded one month after the operation. The SBSES [13] is a wound evaluation scale designed to measure the cosmetic effect of a wound, including the width, height, color, remaining suture marks, and an overall view of the scar. Each index has a score of 0 or 1 and the total score is calculated, ranging from 0 (worst) to 5 (best). Furthermore, the ASEPSIS score [14] is a widely used wound assessment score that has been suggested for orthopedic infection surveillance [15]. This score comprises sections of wound assessment, wound treatment management, and infection consequences. We only used the objective wound assessment section of the score in this study [16] because we only wanted to know the clinical

Fig. 2. The appearances of wound dressings (left: new dressing system; right: traditional gauze dressing).

appearance of the wound. Simultaneously, the wound-related complications of patients were recorded and photographed within one month of operation. Wound-related complications included redness, dehiscence, subcutaneous hematoma, SSI, and resuture for whatever reason.

To measure patient satisfaction, we created a satisfaction survey. The satisfaction measure recorded patient satisfaction with eight categories, including their comfort with dressings, ability to take a bath, pain treatment, physician visits, hospital stay, number of dressing changes, hospitalization costs, and overall satisfaction. All measurements were recorded numerically, with a score of 0 to 10, with a maximum score of 80. The patients filled up the data as per their actual circumstances one month after the operation. The dressing-related costs were the total costs of dressing change operation and dressings during the treatment cycle. In our hospital, the new dressing system cost 33 US dollars for a single change and traditional gauze dressings cost 10.4 US dollars for a single change. Among them, the cost of their dressing change operation is the same, both 6.45 US dollars. We used the visual analogue scale (VAS) score [17,18] and The Harris Hip Score (HHS) [19] to record the joint pain and function of patients and evaluate the changes of perioperative patients. The evaluation was carried out and data were recorded between 1 week before and 1 month after the operation.

Data Analyses

All statistical analyses were performed by SPSS 25.0 software (SPSS Inc, Chicago, Illinois). All quantitative data are showed as means ± standard deviations and analyzed by independent sample *t*-tests. Qualitative data were analyzed by chi-square tests. A *P* value of less than .05 was considered to be significant.

Results

The intervention group number of dressing changes and postoperative lengths of stay were significantly less than the control group (0.72 ± 0.49 versus 4.67 ± 0.63, $P < .001$; 3.90 ± 1.21 versus 5.12 ± 2.02, $P < .001$). During the one-month follow-up, the SBSES in the intervention group was significantly better than that in the control group (4.41 ± 0.72 versus 3.90 ± 0.63, $P < .001$). There was no statistically significant difference in ASEPSIS between the two groups. However, two patients in the control group had a subcutaneous hematoma on day 3 postoperatively and required pressure dressing and antibiotics for an extended period. The wound healed completely before they were discharged. Figure 3 depicts the postoperative one-month appearances of the wound in one patient in the intervention group and one from the control group. The intervention group satisfaction was significantly higher than that in the control group (73.20 ± 4.10 versus 68.43 ± 3.82, $P < .001$). There were no statistically significant differences between the two groups in terms of dressing-related costs and VAS or HHS between the two groups.

Discussion

Our team has creatively designed this dressing system by merging semi-occlusive, transparent adhesive films and calcium alginate dressing in a specific way. This RCT aimed to assess its clinical outcomes and applicability in an ERAS pathway. Also, the results showed that the new dressing system can significantly minimize the number of dressing changes and postoperative lengths of stay when compared with traditional gauze dressings. Furthermore, the new dressing system can greatly improve patient satisfaction and wound appearance scores.

One of the ERAS goals is to reduce hospitalization days. However, the healing of surgical wounds generally takes about 2 weeks [20]; consequently, this may increase awareness of the importance of wound care as complications can potentially compromise these enhanced recovery programs. The new dressing system can significantly reduce the number of dressing changes, while reducing the postoperative lengths of stay or even no dressing changes after surgery. As recently summarized by Brindle et al, tissue trauma during dressing changes, frequency of dressing changes, and wound healing in a timely manner because of uninterrupted wound healing phases are, among others, key characteristics for adequate wound healing requirements [21]. Additionally, such a dressing system is particularly effective with fluid management by decreasing excessive exudate accumulation that can lead to wound maceration and increased frequency of dressing changes, exposing the wound to outside environment pathogens [22]. Good fluid management and undisturbed wound healing processes can accelerate wound healing, enable patients to meet discharge criteria more quickly, and reduce the postoperative lengths of stay.

Compared to traditional gauze dressings, the new dressing system was found to significantly increase patient satisfaction. There are currently very few studies on patient-centered satisfaction evaluations. This area is now starting to be taken seriously and the studies by Kong et al completed surveys related to patient satisfaction but they were primarily concerned with wound closure aspects rather than dressings [23,24]. The improvement in satisfaction involves several aspects. Prerequisites for discharge in arthroplasty patients include a satisfactory surgical wound: no obvious signs of wound exudation and infection, oral pain killers that can relieve pain and do not hinder the rehabilitation of the hip joint, and satisfactory patient mobility. The new dressing system evaluated in this RCT satisfies both requirements. We observed that the patients had a higher score of wound healing appearance and

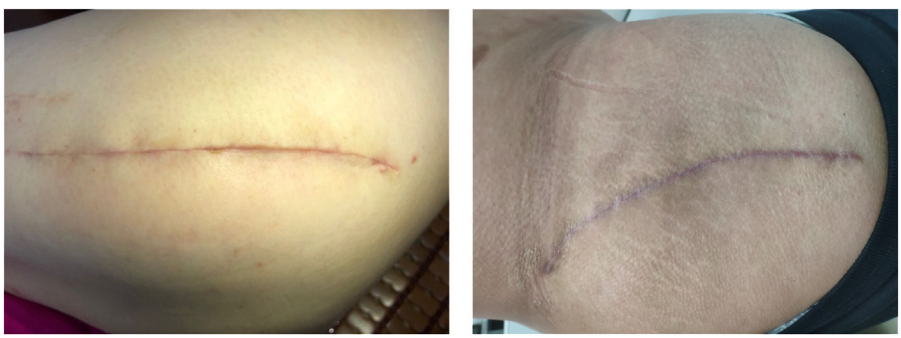

Fig. 3. The appearances of hip wound at postoperative one month (right: intervention group; left: control group).

the new dressing system did not restrict joint motion or patient mobility. Clinical data further demonstrated that early mobilization was directly linked to lengths of hospital stays [1,25] and also positively influenced physiological effects such as increased insulin resistance, muscle atrophy, and reduced pulmonary function [1,26]. For early mobilization of patients, therapies are required (such as postoperative wound dressings) that are fit for purpose and allow the patient to increase their full range of movement with ease of application and patient comfort being key factors for clinical utility [27]. Also, the new dressing system allowed the patient to bathe normally except for submerging wounds and dressings in the water, which has important implications for the improvement of the patients' quality of life after surgery [28]. While there is a moderate level of evidence to support, it based on a decreased risk of wound complications [22] and SSI/PJI [8,29]. In addition, reductions in the number of dressing changes and hospital stays are also important aspects. It can reduce the difficulty and pain associated with frequent dressing changes and reduces overall medical costs. We found no statistically significant difference in VAS and HHS results, which were similar to those of Langlois et al [10]. The current scoring methods are mainly used to evaluate the recovery of postoperative joint function, which is mainly related to the characteristics of the patients, the technical experience of the surgeon, and the postoperative rehabilitation exercise. The management of wound dressings is only a small part of these scores.

At present, several studies have reported that some dressings that can be used for joint arthroplasty surgical wounds, which can reduce the number of dressing changes and reduce wound complications [8,11,27,30]. Currently, some smart dressings have good clinical outcomes, but medical costs are prohibitive, limiting their widespread use, especially in developing countries [29,31]. The average cost of the incision negative pressure wound therapy dressings in the 7-day treatment cycle was about 153.14 US dollars (125 pounds in the original article) [32]. The silver-impregnated occlusive dressings can cost up to 38.05 US dollars for a single change [31]. The new dressing system costs 33 US dollars for a single change and 56.80 US dollars for the entire treatment cycle. The new dressing system did not increase the dressing-related costs during the treatment cycle, which is of great importance for its popularization.

This study is not without potential limitations. Since this RCT aimed to investigate the new dressing system on enhanced-recovery THA, we only followed up patients in postoperative 1 month. Small sample size and short follow-up period were not sufficient for a more detailed and comprehensive analyses. For example, the short follow-up period limits the evaluation of postoperative complications such as PJI. Also, because of the specificity of wound dressings, it cannot be blinded, which may bias the subjective scoring results. In addition, medical consumptive material pricing system in our institutes might be different from others, so the cost performance of the new dressing system would vary among institutes.

Conclusion

The new dressing system could reduce the number of dressing changes and postoperative lengths of stay and increase patient satisfaction, which can be an ideal adjunct to wound management in enhanced-recovery THA.

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