

A Clinical Study Comparing Helicoll with Scarlet Red & Opsite in the Treatment of Split Thickness Skin Graft Donor Site

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Abstract:

Split thickness skin graft (STSG) is a key method in the reconstructive ladder for covering skin defects utilized widely by surgeons from all specialties. The donor site is often a source of delayed healing, associated with considerable pain and discomfort even more than the recipient wound. Various methods are used for dressing of split thickness skin graft donor sites, unfortunately many of these techniques have the potential for contributing to pain, delayed healing, interference with ambulation and scarring.

The aim of this prospective randomized controlled study was to compare Helicoll®, a type I pure collagen dressing, to Opsite® dressing and to Scarlet Red® dressing in the treatment of standardized split thickness skin graft donor sites. Thirty patients, over a 3-month period, underwent various reconstructive procedures, necessitating the use of split thickness skin grafts. Analysis of data: donor site pain, healing time of the donor site, initial absorption of the applied dressing and rate of infection with the three different dressings form the basis of this paper.

Results:

Patients in the Helicoll group reported significantly less pain and required no dressing change. The infection rate of the donor site in this group was less when compared with the Opsite or the Scarlet red groups. Healing time of the donor site in the Helicoll group was shorter than the Scarlet Red group; however, it was comparable to the Opsite group.

Conclusion:

This study indicates that Helicoll, as a donor site dressing, is successful in providing pain free mobility with a measurable healing rate.

Keywords: Helicoll, Scarlet Red, Opsite, Split thickness skin graft donor site

Table -1
Demographics

	Scarlet Red	Opsite	Helicoll
Number of patients	10	10	10
Sex	6M / 4F	8M / 2F	5M / 5F
Age (years)	6-19	6-19	6-19

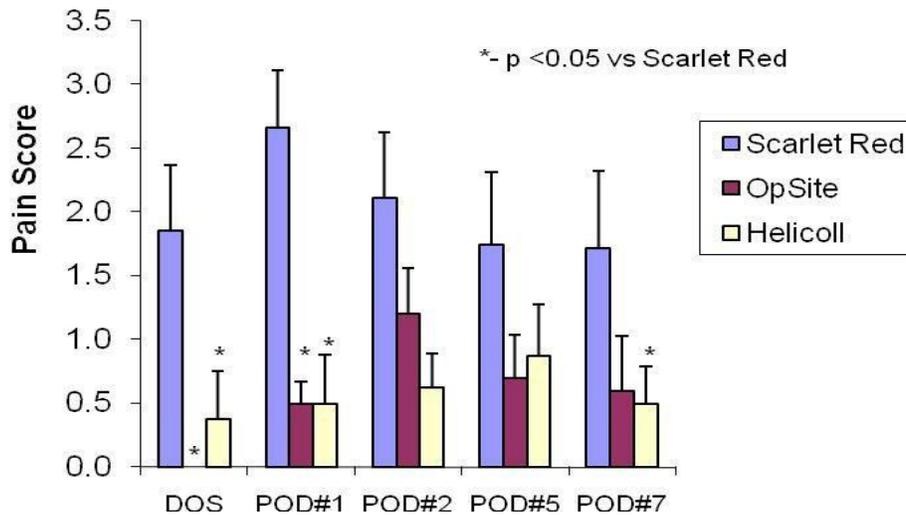


Diagram-1. Illustration of pain score in different patient groups on DOS: day of surgery and postoperative (POD) day #1 through day#7. Statistical significances as shown for pain scores were assessed using two way ANOVA with factors, treatment and time.

INTRODUCTION

Although split thickness skin graft donor sites heal when treated with various methods ranging from simple gauze dressings to complex cultured-cell dressings, many are very painful to the patient^{1,2}. It is well documented that donor sites dressed with closed dressings have shorter healing time both clinically and histologically. They are associated with better patient comfort when compared to the open donor site dressing technique. This has been attributed to protection from dehydration, mechanical trauma and avoidance of exogenous contamination.^{3,4} We undertook a prospective randomized trial to examine the comparative comfort and ease of care of three different donor site dressings. Two standard dressings used at our institution, the Scarlet Red, institutionally prepared by our pharmacy staff; and the Opsite by Johnson & Johnson of Langhorne, PA an occlusive dressing. The two dressings were compared to a new occlusive dressing product, Helicoll, a Type 1 pure collagen by (Encoll Corp. Fremont, CA) We randomized 30 patients requiring split thickness skin grafts to receive one of the three dressings.

Split thickness skin graft donor sites cause painful wounds as the nerve endings in the dermis are left exposed once the split thickness skin graft is harvested. Conventional donor site treatment with mesh

gauze impregnated with various ointments cause pain even with the use of various medications⁵. In order to reduce pain, to provide better infection control and to hasten healing rate of the donor site of split skin graft, a number of closed donor site dressings have been developed in recent years as closed wounds heal faster than those left exposed.^{6,7}

Healing of partial thickness skin defects occurs in three steps: epithelial proliferation, epithelial migration followed by dermal proliferation. Clinicians initially believed that the optimal condition for epithelial proliferation and migration occurred under a scab. *Winter and Lawrence et al*, however, showed that the optimum condition for both epithelial proliferation, migration, and angiogenesis occurred under an occlusive dressing where a moist environment is maintained^{8,9}. Based on this improved understanding, a new class of synthetic adhesive moisture-vapor-permeable dressings (SAM) was introduced. These dressings are impermeable to both liquid and bacteria.¹⁰ The best donor site dressing should be easy to apply, with minimal need for staff care. It should allow the donor site to heal with minimal bleeding, infection or pain. It should permit the patient full ambulation without disturbing the healing process and should be readily available and cost effective.¹¹ At our institution skin graft donor sites are mostly treated with the use of Scarlet Red mesh gauze or Opsite occlusive synthetic dressing.

Although Scarlet Red, 5% o-tolazo-o-tolylazo-B-naphtol blend with lanolin, white petrolatum and olive oil, when applied to a fine mesh gauze, has good results as the azo compound, was shown to promote epithelialization. It is, however, associated with pain¹². On the other hand, Opsite dressing decreased pain but fluid collection, leakage and frequent dressing change requirement remain drawbacks to its use. Also, its application is limited to small donor areas.^{13,14}

This trial consisted of using a new dressing, Helicoll, a bovine skin derivative that has not been cross-linked, but is processed to obtain high quality and purity type 1 collagen. It interacts with wound exudate to form a moist non-adherent gel. It provides hemostasis and accelerates tissue remodeling without causing irritation. In a limited study Helicoll was found to accelerate the wound healing rate and reduce scar formation by depositing oriented and organized collagen fiber^{15,16}.

Other types of Collagen have been used for centuries as temporary biological wound dressings; however, they have not been used as a permanent skin transplant¹⁷. Helicoll is FDA approved as a type 1 pure collagen for permanent replacement for the acellular dermal component of the skin.

MATERIALS AND METHODS

This study was approved by the Institutional review board of the University of Texas Medical Branch (IRB number 08-143). At hospital admission, the research team obtained informed medical consent from the parents and consent from children above 15 years of age. Patients were randomized to receive Opsite, Scarlet Red or Helicoll as a donor site dressing.

Patients stayed in the hospital for 24 hours after their surgery, where dressing were changed if necessary and all patients received a standard postoperative oral analgesic and discharged home to be seen in the clinic on the fifth postoperative day.

Thirty donor sites, one each from 30 patients were studied. The age range was from 6 to 19 years. Data and photographs of the procedure and subsequent evolution were collected from all patients. Age, gender, size of donor area, postoperative donor site pain, time of healing of the donor site, frequency of dressing change and infection rate were compared between the three groups.

All skin grafts were harvested with an electric Padgett dermatome from the thigh approximately 20-80 square centimeters in dimension and 0.015-inches thick. Dressings were applied larger than the donor defect to assure good adherence. To provide additional comfort and better immobilization, an elastic bandage was applied.

Dressings were assessed by interview and questionnaire at 24, 48, 120 hours (5 days) and one-week intervals. The wound was assessed on a daily basis for pain severity, amount and type of exudates underneath the dressing, adherence of the dressing and the rate of infection. Self-assessment of pain was quantified on a scale of zero to five, with five being the most severe pain. In the immediate post-operative period the patient was asked to assess the pain or discomfort when touch or pressure was applied to the donor site by a blinded investigator. In the late post-operative period, patients were requested to record the severity of pain felt while walking; similarly, the requirement of analgesic for donor site pain was evaluated in all cases. Re-epithelialization was assessed by a single observer from the first postoperative day. However, it is beyond the scope of this study to delineate the exact rate of reepithelization in each group, but is an area of interest for future study. Digital images of the wounds were viewed by independent observers.

Method of application:

Helicoll is removed from its package and soaked in sterile saline for five minutes. It is then peeled from the packaging sheet and applied to the donor site while ensuring that all entrapped air is removed. A non-adherent dressing (Adaptic with Bacitracin ointment) was applied over the Helicoll and wrapped with Kerlex® and ace bandage. The material is applied only once to the donor site wound.

Opsite required mastisol application to 2cm of normal skin surrounding the donor site for good adherence. Additional compression is achieved with Kerlex and Ace bandage.

Pressure dressing is needed to reduce the amount of fluid collection. The pressure dressing remained in situ for 24 hours. The following day the dressing was inspected to check for the presence of hematoma and if the dressing was dry it was simply reapplied.

Wet dressings were changed, as needed. Sero-sanguineous fluid collection and leakage from under the edge of the Opsite required aspiration using sterile technique with reinforcement of the Opsite dressing. Scarlet Red was applied directly over the donor site and was dressed with Adaptic –non-adherent gauze between the Scarlet Red and the gauze bandage followed by Kerlex and Surginet. Eight hours after the procedure, both Kerlex and Adaptic were removed and the Scarlet Red was allowed to dry. Scarlet Red dressing was not removed until it fell off on its own as it adheres to the wound and is not easily removed.

Statistical Analysis:

Our initial power analysis of the study was as follows: We were interested in detecting pain score differences of 1.5 or greater as our primary objective of the study and anticipated a SD of one on the pain score. Since we were comparing Helicoll to two other methodologies, we reduced the alpha to 0.025. We are able to detect differences of this magnitude with 10 patients per group with these assumptions.

Descriptive analyses were conducted to compare demographics and medical characteristics. Pain scores were assessed using two-way ANOVA with factors, treatment and time. Post hoc correction was done using Tukey's test.

Follow up visits:

During the follow up visits, patients were examined and digital photographs taken. From the 30 patients, 28 patients returned for a complete set of follow up visits.

RESULTS

Between May 2008 and August 2008, a total of thirty patients were enrolled in this trial. Their ages ranged from 6 to 19 years. Detailed demographics are shown in Table-1. No significant difference was seen in patients' age, and gender in each group.

All patients tolerated the dressings and no allergic reactions were observed. The wounds were assessed for characteristics that include comfort, pain level, ability to ambulate and an overall acceptance of the dressing. Relief from pain was the most frequently identified patient benefit. All patients in the Scarlet Red group (100%) had pain, only 25% in the Opsite group reported pain, and none of the patients in the Helicoll group experienced donor site pain ($P < 0.05$).

There were seven outpatient visits in the Opsite group versus two visits in the Helicoll group and none in the Scarlet Red group. The outpatient visits were more frequent with the Opsite group due to leakage from the edges of the Opsite dressing requiring dressing change. Opsite had to be reapplied in 5 cases. All ten patients in the Opsite group had variable degrees of fluid collection; and four patients treated with Opsite had donor site infections ($P < 0.05$). Infectious complications were not encountered in patients in the other two groups.

Our results compare favorably with other donor site dressings. With respect to patient comfort, Helicoll had the best results and an overall mean healing time was of 7.8 days for both Helicoll and Opsite compared with 10.5 days with Scarlet Red dressing. An overall healing correlates with a complete removal of the dressing as the wound is mature enough to withstand minor trauma without breakdown and bleeding.

Pain was nearly non-existent with Helicoll and Opsite, but overall, Helicoll scored better for pain relief. The

accelerated healing, early mobilization and the reasonable cost make Helicoll a good dressing.

Opsite: Pain started on the fourth or fifth postoperative day in 8 patients due to maceration of the wound attributed to fluid collection beneath the Opsite. The leakage from the Opsite necessitated repeated dressing changes and/or aspiration of fluid collection and did lead to an increased likelihood of infection in this patient group, making it less than ideal as a donor site dressing. The wrinkles associated with Opsite represented an additional difficulty. Fluid collection was seen in all ten Opsite cases. Five patients required a small fenestration of the Opsite to drain the collecting fluid and a new film was used to reinforce the remaining parts of the original dressing followed by a secondary absorbent dressing to prevent constant leaking. At times, repeated dressing changes were needed. Two patients with fluid collection were not drained but left to be absorbed. Although it leaked, the wound healed well in seven days without infection.

Three Patients had yellow discharge under the wrinkled Opsite and required removal and daily dressing change with Adaptic and Bacitracin. Four patients had purulent exudates associated with redness. Patients were diagnosed clinically to have donor site wound infection, but no cultures were obtained. One patient developed a rash and two patients had dry crusts on the donor site. One patient had clots that were removed by making an incision in the Opsite. Six wounds healed in seven days and four healed in 12 days. The transparent dressing appears to offer many advantages over opaque ones and gives a better follow up of the donor site. Opsite promotes more rapid and less painful healing; however, it tends to be labor intensive, especially if associated with large fluid collection. This problem requires frequent dressing changes. It is our observation that fluid collections are best untreated and wrinkled or dislodged Opsite should be removed to prevent infection.

Scarlet Red: Scarlet Red used to be manufactured by Tyco and Kendall, Mansfield, MA.

Once its supply was discontinued, it was formulated by our pharmacy staff as a 2% scarlet red ointment dressing.

Patients with Scarlet Red experienced pain on the day of surgery which limited their movement. In the early post operative period, patients complained of severe pain when the outer Scarlet Red dressing was removed per protocol to air dry. None of the patients with Scarlet Red had infections. As Scarlet Red dries it shrinks and becomes tight over the donor area and this tightness makes ambulation and movement difficult and painful. Although absorption was good in this patients group, three Scarlet Red wounds required unplanned dressing changes because the dressings were soggy and lifted off the donor site. Two cases had crust formation.

Delayed wound healing was seen in three cases. Wounds healed in 10-12 days. The Scarlet Red dressing is best for scalp donor site grafts. The open technique of leaving the wound uncovered is the least expensive, but is very painful and associated with prolonged healing times. Patients seemed to complain most when the rolled gauze fluff was removed on the first post operative day. The coagulum caused the Scarlet Red to stick to the gauze and removal was quite painful.

Helicoll: Helicoll, on the other hand, was well tolerated by patients because of the absence of pain in the

donor site and the resulting freedom of movement. Pain was reported on the fourth postoperative day, by eight of our patients, probably due to the degradation of the product and its incorporation into the wound leaving behind a closed wound. The first two cases initially had daily inspection of the wound bed to evaluate the wound healing progress, but this disturbed the rate of wound healing. Two patients, who walked on the same day of their surgery, had their Helicoll slide down. None of the Helicoll patients had infections. A yellow colored gel observed on the fourth postoperative day is due to the degradation of the product. Helicoll wounds healed in 7-10 days. The most valuable aspects of Helicoll include much greater patient comfort on the day of surgery and easier removal of dressings later on. The average cost of the product, in relation to our donor site size wound (20-80 cm²), was \$87 to \$126 for a single application with minimal postoperative wound care follow-up.

DISCUSSION

Split thickness skin graft donor sites often can be more painful and uncomfortable for patients than the recipient wound. Several authors have observed that the creation of a moist environment on the wound reduces pain considerably. In 1962 Winter and Chang, et al demonstrated that moisture enhances wound re-epithelialization and angiogenesis thus accelerating the healing rate.^{21, 22,23} Many new dressings have been introduced for use on STSG donor sites in an effort to reduce pain, improve healing time, reduce infection rate and cost. Transparent semi-occlusive dressing with a hydrocolloid base, such as Biobrane, allows fast, yet stable healing with reduced donor site pain.^{18,19,20} Though Biobrane proved superior to other conventional dressings with respect to pain and accelerated healing time, it was associated with high infection rates secondary to exudate accumulation. Another standard donor site management is to use an alginate dressing. The calcium particles in this dressing on contact with blood, at the donor site, is exchanged for the sodium in the blood, thus increasing the dressing solubility and allowing it to gel. This exchange of ions also activates the clotting mechanism and produces a hemostatic effect at the donor site. However, alginate dressings desiccate and adhere tightly to the wound bed making it difficult and painful to remove.^{24, 25, 26} Helicoll is a reconstituted type 1 pure collagen sheet; derived from a bovine source and free of contaminants such as lipids, elastin or other immunogenic proteins. It is a semi-occlusive, self adhesive collagen membrane with unique advantages of biocompatibility and flexibility. Since it maintains a physiologically moist environment at the wound surface and is biodegradable, it is associated with minimal postoperative wound pain. There were two objectives of this study. One to compare Helicoll with our standard donor site dressings, and two to assess the amount of pain relief associated with the selected dressings.

The traditionally used dressing for donor sites at our institution has been mesh gauze impregnated with Scarlet Red and a synthetic polymer, Opsite. These forms of dressings continue to be cost effective compared with other types of dressings. Scarlet Red dressings are simple and the most commonly used dressing due to its easy availability, ease of application and low cost. It, however, is associated with delayed healing rates²⁴ when compared to other dressings. Problems include pain between and during dressing changes. There is even more pain if the dressing has to be removed after being incorporated into the healing site, as it does not always fall off easily. The fine mesh gauze allows a dry eschar to form. The dressing is adherent and associated with trivial trauma liable to damage the new epithelium.^{27, 28}

Opsite is a transparent polyurethane dressing which significantly reduces pain relative to open dressings, but the wound exudates gets trapped under it and the dressings have to be changed several times to allow for fluid removal. The high leakage rate has also been noted in other dressing such as DuoDerm®, a hydrocolloid dressing, which contributes significantly to its cost when used. These types of dressings are difficult to use on large donor sites due to fluid collection. The accumulated fluid tends to be thicker in consistency over time rendering dressing change more laborious. Even though the fluid is usually sterile²⁹,³⁰ clinical infection has been reported, and was observed in four cases in this group. In some cases, hematoma formed under the Opsite dressing after ambulation and could not be aspirated. These circumstances contributed further to the increased infection rate in this group³¹.

The comparison of Helicoll with mesh gauze and Opsite on donor sites demonstrated a reduction in pain when compared to the traditional and time-tested approach. Other collagen dressings are available and are composed of type-I and type-3 bovine collagen.

They are commercially available in a sterile package and are thus easy to use. The difference between these collagen sheets and Helicoll dressing is that the collagen³² provides a scaffolding for epithelial regrowth and prevents exudation from the raw area. After 48 hours the film is transformed into a stiff sheet that is stable enough to withstand pressure and shearing from clothes. Thus, it protects the donor site from mechanical trauma and infection. When re-epithelialization is completed, the overlying film and coagulated blood separates spontaneously. Thus, removal of the dressing is easy and pain free. If a donor site infection occurs, it would result in complete degradation of the film and is associated with significant donor site pain.⁴ In contrast Helicoll, a type-I pure collagen, has the advantage of being a permanent skin transplant which replaces the acellular dermal component. It undergoes degradation on the fourth post-operative day and gets incorporated into the wound. Thus, Helicoll dressings appear to have a greater advantage over other dressing materials in providing a pain-free donor site, early mobilization of the patient and a decreased morbidity. An average donor site healing time of 8.2 days with Helicoll is comparable to the results with the regular Opsite dressings^{33,34}; however, it is beyond the scope of this study to delineate the exact rate of re-epithelialization in each group. In this study dressing changes with Helicoll were in general not painful and the overall comfort was high.

CONCLUSION

Based on the results of this prospective study of STSG donor sites in 30 patients, we conclude that Helicoll is a reliable donor site dressing. Its ease of application, documented safety, reasonable cost, and evident capacity to promote measurable healing place Helicoll in line with other components of our armamentarium of dressings for STSG donor sites.

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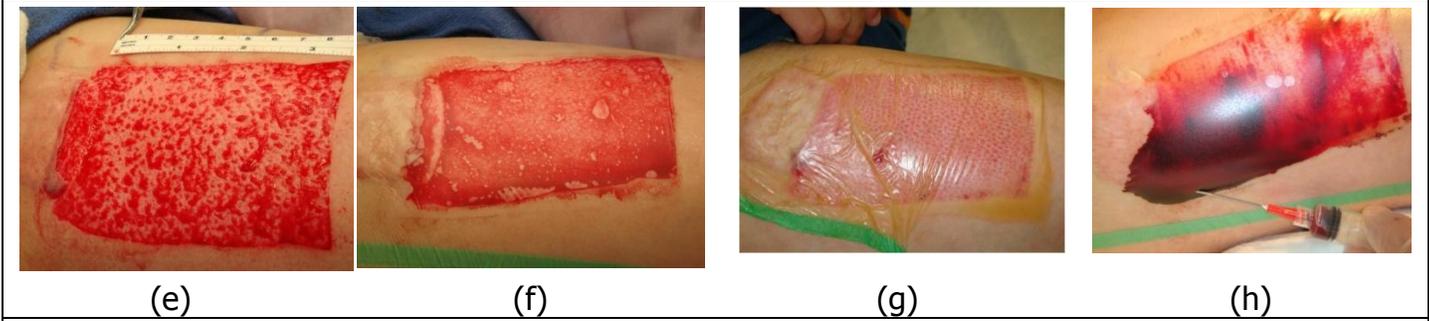
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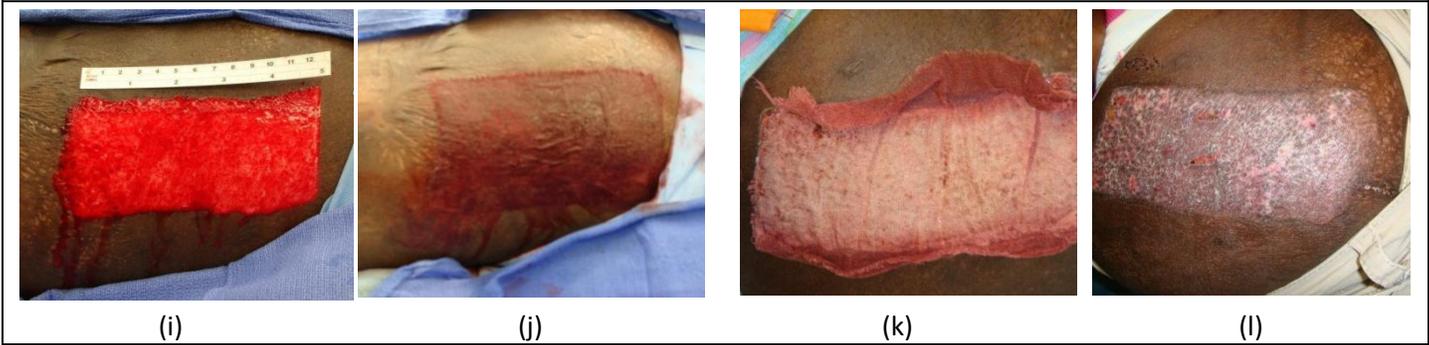
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Helicoll illustration (A) intraoperative picture of donor site and (B) Helicoll application to it followed by Adaptic and Bacitracin dressing. (C) Donor site on post operative day 5 notice the incorporation of the Product. (D) Donor site dressing removal on postoperative day 8.



Opsite dressing illustration : (E) Intraoperative pictures of donor site, (F) application of Opsite to donor site wound. (G) Postoperative serosanguinous collection and attempt at its aspiration under sterile technique. (H) donor site wound on postoperative day 8



Scarlet Red illustration (I) donor site at harvest (J) application of scarlet red to donor site wound. (K) donor site at postoperative day 5, (L) donor site at postoperative day 22