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Optimizing Donor Site Pain after Skin Grafting: An Analysis of Optimal Donor Site Dressings

Prospective, Non-Blind Trial

Yolancee Nguyen
ANNE BURNETT SCHOOL OF MEDICINE AT TCU MD
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Abstract

Research Question

Will patients who undergo a thigh split thickness skin graft (STSG) for a wound defect, who are given a 3M Tegaderm Absorbent dressing for the skin graft donor site, have better pain control and lower donor site morbidity than patients who undergo a thigh STSG, who are given an Aquacel Ag (alginate ag) with an abdominal (ABD) gauze pad dressing for the skin graft donor site?

Background, Significance, and Rationale

STSG harvesting is a common procedure performed for patients who have an acute wound due to a traumatic injury, surgical complication, or other pathological causes. However, many patients stated suffering from moderate pain from the STSG donor site. Current literature has shown there is no establishment of a standard postoperative donor site dressing protocol.

Some studies have shown when comparing the Aquacel Ag (alginate ag) with ABD pad dressing to another moist postoperative dressing for the donor site, there have been documented cases of longer wound healing times and increased risk of postoperative infection.

The goal of this research effort was to evaluate the 3M Tegaderm Absorbent against the Aquacel Ag dressing efficacy in reducing donor site morbidity.

Materials and Methods

A prospective, randomized, and nonblind clinical trial was performed. STSG were harvested

from either the right or left thigh – measuring 0.014 inches. After procuring the graft, a mixture of 0.25% Marcaine and 1% lidocaine with epinephrine was injected into the dermis of the donor site intraoperatively.

Upon operating wound surgeon, the patient either received a 3M Tegaderm absorbent (Mapula) or Aquacel Ag (Chen) dressing to the donor site at the time of surgery. All patients were seen, in clinic, at standard one-week postoperation and given a patient survey to fill out describing their donor site pain and wound evaluation and documentation, and the primary surgical dressing was removed and replaced with the Aquacel Ag. Another standard two-week post-operation was scheduled in the clinic for survey administration, pain control (if necessary), wound evaluation and documentation.

At six- and twelve-week postoperation visits, phone call follow up was done by trained medical personnel with IRB approved phone scripts and study participants emailed photos of donor site graft sites for proper evaluation by Dr. Mapula or Dr. Chen. With every single postoperation visit, narcotic pain medication is asked and filled, based on clinical expertise of Dr. Mapula or Dr. Chen, and documented in the excel file for type of medication, how much administered, and when the individual patient discontinued use in the acute postoperation period.

Results

We anticipated the 3M Tegaderm Absorbent dressing to have better postoperative pain control, better wound healing outcomes, and shorter time for full re-epithelialization of the donor site tissue.

Conclusion and Discussion

Although final conclusions cannot be made at this time due to ongoing data analysis, favorable preliminary data suggest proving our original hypothesis correct regarding the 3M Tegaderm Dressing in reducing donor site morbidity. Regardless of outcome, this study is hopeful in producing a more standardized approach in STSG care and may spark additional studies to include more chronic, co-morbid patients suffering from long- term wounds.

Research Question

Would the 3M Tegaderm Absorbent dressing would perform clinically better and be statistically significant in achieving better postoperative pain control, promoting faster re-epithelization of donor site wound bed, and be more efficient in reducing donor wound site morbidity?

Introduction

Skin grafting is the process of transferring cutaneous tissue from one portion of the body to another portion of the body where there is a defect.[1] The purpose of the skin grafts is to cover the wound with maximal coverage, minimal patient rejection, and once healed, restore natural skin function that was originally compromised – fluid retention, protection from the environment, temperature regulation, and a physical barrier against pathogenic organisms.[1]

There are two types of skin grafts that can be used to cover a wound: split thickness and full thickness. STSG refers to a graft that contains the epidermis and a portion of the dermis layer, which can vary in amount, ranging between 8/1000 of an inch (0.196 millimeters) and 12/1000 of an inch (0.294 millimeters).[1,2] In contrast, a full thickness skin graft (FTSG) contains the epidermis and the entire dermis layer (figure 1).[1, 2]

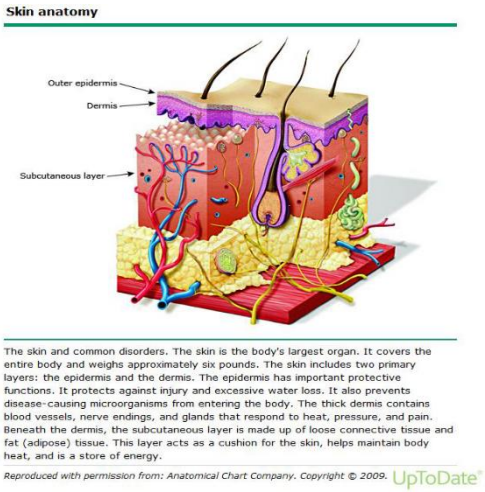

Figure 1: Pictorial representation of skin anatomy to distinguish different layers taken between a split thickness vs full thickness skin graft.

Source: Leon-Villapalos J, Dziewulski P. UpToDate: Skin autografting. Reprinted with permission from: Anatomical Chart Company.

There are many different sources skin grafts can be made from (autograft, homograft, allograft, or xenograft)[1], but autografts tend to be the preferred method in clinical practice.

STSG have become the clinical gold standard technique to use to cover a wide range of large wound defects.[2] This allows for sufficient dermis to be left behind in the wound bed for healing via re-epithelialization.[3] Local donor site management is equally important as managing the wound defect, and by providing an optimal healing environment, it can increase rapid re-epithelialization of the donor site with minimum postoperative pain, discomfort and shortened hospital stay.[3-6]

Management of the local donor site remain a clinical issue as patients most often report more pain at the donor site rather than the wound recipient site.[3-4,6-7] A reliable indicator of a successful re-epithelialization of the skin graft to the wound defect bed is deemed the “Moriarty Sign”: If the recipient site of a split skin graft become more painful than the donor site, it is a sign that the graft is unlikely to take 100% and suggests that early inspection of the site should be undertaken. If, however, the donor site is consistently the more painful, good take is likely.[7] However, studies have shown acute wound pain impacts patient stress and consequently negatively impacts quality of life delaying wound healing.[3,8-9] Thus, a pain-free dressing is recommended in both the adult and pediatric population to minimize discomfort and distress in order to maximize the healing process of both wounds.[3,10]

Studies have shown wet dressings contribute to better reepithelization of the donor site and wound defect than dry dressings. [11] However, there have been documented variation of

dressings across different practicing institutions in management of the donor site due to the various commercially available products on the market and management modalities. [3,12-14] A previous randomized controlled trial study has shown 3M Tegaderm Absorbent provided a significant improvement of donor site pain, healing, and ease of management when compared to the use of a standard Alginate dressing – which is a biopolymer that is naturally occurring, anionic, and it is obtained from brown seaweed.[15-17]Although the 3M Tegaderm Absorbent was evaluated against the standard Alginate dressing, such studies are scarce, and additionally, 3M Tegaderm Absorbent has not been extensively evaluated against other common wound dressing use for split thickness skin grafts – like more currently used clinical dressings Aquacel Ag (hydrofiber dressing impregnated with silver).[18-19]

The goal was to evaluate the 3M Tegaderm Absorbent against the Aquacel Ag (hydrofiber impregnated with silver) dressing to determine better postoperative pain and wound outcomes from the donor site.

Significance

The World Health Organization (WHO) estimates that 11 million burn injuries of all types occur annually worldwide, 180,000 of which are fatal.[20-21] Additionally, a 2018 retrospective analysis of Medicare beneficiaries identified that ~8.2 million people had wounds with or without infections.[20-22] Medicare cost projections for all wounds ranged from $28.1 billion to $96.8 billion, including costs for infection management, among which surgical wounds and diabetic ulcers were the most expensive to treat.[22-23] Though wounds are costly, STSG have become a basic reconstructive practice due to previous studies showing significantly shortened

epithelialization time, reduced pain and prevention hyperplastic scar formulation of the wound.[24] However, care is not only about the main wound defect, but also the donor site.[24] Donor site reported complications include hyperpigmentation (55.4%), dyschromia (37.5%), hypertrophic scar (3.6%), and itching (3.6%).[24-25] The goal of donor site dressings, as reiterated previously, is to accelerate healing, minimize pain, and minimize scarring that will lead to a shortened hospital stay.[3-6, 24, 26]

The current debated issue is there is no proven universally applicable standard protocol in place for donor site dressings to achieve the goals of minimizing postoperative pain and donor site complications.[24-26] If there can be a step closer towards a standard protocol, the goal is to achieve a reduction in rate of donor site complications. This will allow for minimal pain, better wound healing from the donor site and wound recipient, and lower hospital costs for both the patient and practicing institutions.

Rationale

It has been shown with the use of a film dressing as a secondary dressing promotes the optimal moist wound-healing environment. [3,28] Based on the current evidence, it was determined that moist wound-healing dressing products have a clear clinical advantage via increased healing and less painful approach over non-moist dressing products in the management of STSG donor site wounds.[3] Another study has shown 9 out of 10 patients showed improvements in wound-related assessment parameters when their treatment was changed to include the [3M Tegaderm Absorbent] superabsorbent dressing.[3,27] However, because of the small sample size, it calls for additional research investigating the efficacy of

the 3M Tegaderm Absorbent against other common commercially used products for donor site dressings amongst a larger population. By starting to compare the 3M Tegaderm Absorbent against commonly used dressings, like Aquacel Ag, in postoperative management of donor sites, it can lead to a more universally accepted and applicable protocol for optimal wound management.

Additionally, our research wants to produce additional case studies comparing the different commercially available dressings to further add to the discussion on what is the best postoperative wound management protocol that is safe, effective, minimize pain and donor complications, and promote optimal reepithelization of both the wound defect and the donor site.

Materials and Methods

In wound patients who received a STSG from the thigh as a donor site, we are evaluating the 3M Tegaderm Absorbent (polyurethane film barrier) against the Aquacel Ag (hydrofiber colloid impregnated with silver) dressing to determine which postoperative dressing results in better pain control and wound outcomes from the donor site.

The study was designed as a prospective, randomized, and nonblind clinical trial with a simple survey administration format with the Wong-Baker Pain Scale included to provide qualitative data into interpretable, quantitative data while maximizing ease of use for the study subjects – regardless of limited literacy. Additionally, choosing a prospective, nonblind approach allowed for more collection of wound care data, as there have not been enough reported studies showing 3M Tegaderm efficacy in donor site graft sites, and allowed for better individualized care for the recruited study subjects at this one site.

Recruitment and outlined inclusion criteria for patient participation in this study included all patients, ages 18-80 years old and of all genders and races, undergoing a STSG on right or left thigh only, and not having a wound larger than 0.014 inches in depth – regardless of mechanism of wound creation. All study participants were actively recruited with the clinical expertise of Dr. Steven Mapula and Dr. Patrick Chen to determine initial precise wound measurements.

Exclusion criteria included patients with a hemoglobin A1C of greater than 7.5; patients requiring skin grafts from other anatomical areas other than the right or left thigh; patients who

have adhesive or silver allergies; patients who are immunocompromised or currently on immunosuppressive therapy (steroids, immunomodulators, chemotherapy, radiation, ect); and patients who are active smokers (must have stopped smoking for four weeks). These exclusion parameters were set to limit confounding factors on wound healing to fully evaluate the efficacy of the applied dressing.

All patients with an acute wound necessitating evaluation by a wound surgeon – either Dr. Steven Mapula or Dr. Patrick Chen – will be assessed for inclusion criteria based on either surgeon's clinical expertise. If the wound is assessed and determined to necessitate a skin graft procedure, the study team will discuss the study and share the informed consent document with the patient. After obtaining informed consent from the subject, a contact sheet will be created containing the Subject's Name, phone number and Subject ID number for reference when contacting and administering the Wong- Baker Pain Scale over the phone at the six-week and twelve-week postoperation follow up. Dr. Mapula, the principal investigator, will utilize 3M Tegaderm wound dressings during STSG procedures, while Dr. Patrick Chen, the co-investigator, will utilize Aquacel Ag wound dressings during STSG procedures. Patients who decline to participate in the research study will receive one of the two standard-of-care wound dressings – either 3M Tegaderm or Aquacel – depending on the surgeon (Dr. Mapula or Dr. Chen) conducting the STSG procedure.

Each patient received either a right thigh or left thigh donor site for STSG harvesting, determined preoperatively and intraoperatively on which side to graft by either Dr. Steven Mapula or Dr. Patrick Chen to optimize graft success, and properly marked preoperatively to

ensure correct side operation and harvesting. Skin harvested from the donor site was done in a sterile environment and measured at 0.014 inches in depth for their wound coverage. After procurement of the donor graft, local anesthetic nerve block, mixed in a 1:1 ratio of 0.25% Bupivacaine and 1% Lidocaine with Epinephrine, was injected sub dermally of the donor site intraoperatively. Depending on the randomized assignment of patients based on operating wound surgeon, patients received a 3M Tegaderm Absorbent dressing or Aquacel Ag with ABD pad and paper tape dressing postoperatively.

All patients were seen for the standard one-week postoperative care – either inpatient or outpatient deemed clinically appropriate by Dr. Steven Mapula or Dr. Patrick Chen. At one-week follow up, previously consented study participants were administered the approved Post-Operative Pain Assessment survey using the Wong-Baker Pain Scale for the first time and photo documentation of wound for research purposes (figure 2).

At this standard one-week visit, the primary surgical dressings were removed, and either the Tegaderm or Aquacel Ag, and replaced with a standard silver alginate dressing if wound was deemed to not be fully re-epithelized based on the clinical judgment of Dr. Mapula or Dr. Chen. Re-epithelization was clinically categorized in quartile categories (0-25%, 25-50%, 50-75%, 75-100%) and photo documentation was added to HIPPA secure storage for each enrolled subject at one-week, two-week, four-week, six-week, and twelve-week intervals.

After the standard one-week postoperation visit, active study patients were seen at the standard two-week postoperative visit and four-week postoperation visit. These visits, once again, included administration of the IRB-approved Post-Operative Pain Assessment survey with the Wong-Baker Pain Scale, examination of the wound with photo documentation of wound progression, and determination of the presence of epithelization or hypergranulation tissue (a sign of delayed wound healing).

Post-Operative Pain Assessment

Circle the best answer below.

Wong-Baker FACES® Pain Rating Scale

1. Utilizing the scale above, what is your pain level today at your skin graft donor site?
   1 2 3 4 5 6 7 8 9 10
2. Have you had any drainage from your donor site dressing since your surgery or last visit? Y N
   a. If yes, have you had to reinforce or change your dressing? Y N
3. If you have had to change your dressing, did you experience pain? Y N
4. If you experienced pain, please use the scale above to rate the pain associated with dressing changes.
   1 2 3 4 5 6 7 8 9 10
5. Have you experienced any itching at your donor site? Y N
   If yes, did it require medication to aid your symptoms? Y N

Figure 2: North Texas IRB approved post-operative assessment survey

At six-weeks and twelve-weeks postoperation, trained clinical staff and supporting medical personnel will call active study participants to administer the Wong-Baker Pain Scale survey with phone script (figure 3), and to request patients to send photos of donor wound site to a HIPPA compliant and approved encrypted email (MapulaSkinGraftStudy@jpshealth.org) for evaluation by the investigators. With every single postoperation visit, narcotic pain medication is asked and filled, based on clinical expertise of Dr. Mapula or Dr. Chen, and documented in the excel file for type of medication, how much administered, and when the individual patient discontinued use in the acute postoperation period.

IRB Approved Phone Script

"Hello, I'm calling from JPS Health Network to speak with _____. Is this _____? I am a member of Dr. Steven Mapula's research team, and we're conducting a research study to help us assess post-operative pain and donor site healing after split thickness skin grafting. Twelve weeks ago, we discussed the research study purpose and the pain scale survey we are inviting participants to complete over the phone. It is the same pain scale survey you completed at your 1-, 2-, and 4-week in-person follow-up visits. I am calling you today to complete this pain scale survey a final time, which will take no more than 10 minutes each to complete. I would also like to remind you to take the final photos of your wound site and send the photos to the following secure JPS email address: MapulaSkinGraftStudy@jpshealth.org.

Figure 3: North Texas IRB approved phone script for six-week to twelve-week postoperation visits.

We anticipated sufficient subjects, approximately 100 subjects, to produce a significant effect. Once sufficient data was collected, we compiled the data using Excel spreadsheet and running statistical analysis to determine if there is a significant difference between both dressings in wound management and reported postoperative pain. While exact methods have not yet been determined, analysis could involve t-tests, chi-square, or ANOVA with significance set at 0.05. Additionally, a confidence interval will likely be calculated due to the current study's small sample size compared to the local, larger population. This ensured applicable interpretation of data.

Collected data was conducted under thorough analysis by the data analytic team at JPS working with Dr. Mapula and his research team. The data collected was assigned a Subject ID number, and a master list was stored on a secure JPS shared drive. The master list contained the consented patient's MRN and assigned Subject ID number.

This master list, and the contact sheet of protected patient information, was password protected, and dual verification needed for access. This data was only accessible to investigators and study personnel. The assigned statistician utilized programs, such as Excel, SPSS, and SAS, to store and currently analyze data with final tests used to be determined under the discretion of the JPS statistician.

Results

The final recruitment period has ended, and all data collected have been organized and stored on an Excel spreadsheet with data analysis still ongoing. Per hypothesis, despite extensively studied and proven studies outlining silver alginate antimicrobial properties, we believed the polyurethane film in 3M Tegaderm created a better environment for wound healing due to the barrier created around the wound, creating an ideal, anti- microbial blocking barrier to promote adequate wound healing and re-epithelization.

Data collection included manual input in HIPPA approved secure Excel file, stored only on JPS computers and main campus, with Subject ID number (assigned upon admission to hospital or randomization numerical generator), with consistent tracked data over the twelve-week follow up postoperation for every active and consenting study subject.

Clinic visits with these patients began, first, with addressing all concerns of the patients upon standard postoperation visits and treating accordingly. Then, once all of the acute concerns were addressed, the questionnaire was administered near the end of the scheduled postoperation visit to allow for adequate time for thoughtful consideration of indicated donor site wound. Then, all questionnaires were collected and saved for later input of data by one of the trained medical personnel. This process allowed for adequate efficiency while still allowing Dr. Mapula and Dr. Chen to deliver the utmost empathetic and adequate clinical care. With every single postoperation visit, narcotic pain medication is asked and filled, if clinically appropriate, based on clinical expertise of Dr. Mapula or Dr. Chen and documented in the excel file for type of medication, how much administered, and when the individual patient

discontinued use in the acute postoperation period. Then, Dr. Chen or Dr. Mapula provided an appropriate pain regimen and sent a prescription to ensure pain control and comfortability for the enrolled patient.

Obtaining IRB approval proved to be more difficult during the COVID-19 pandemic. Due to the rise in urgent studies regarding COVID-19 virus and treatments related to the illness, the study was deemed non-urgent and was delayed in review. However, because of Dr. Mapula and the research team's persistence and efforts in pushing for IRB approval, the study was approved for study enrollment on September 22, 2022 – 2.5 years after the peak of the COVID-19 Pandemic. Potential study subjects were immediately identified within the John Peter Smith (JPS) community and began to carry out the study – following IRB approval.

The final study documents, to include questionnaire with Wong-Baker Pain Scale, Excel spreadsheet documented data spreadsheet, and phone script, were created by Dr. Mapula and Dr. Chen's clinical research team (Shelly Cochran, RN; Angela Ramirez, CMA; Yolancee Nguyen, MS2) and sent for final editing by Dr. Mapula prior to submission to North Texas IRB Review Board. With assistance with JPS research team and lead research specialist (Carissa Jensen, MPH, CPMP, Research Integrity Specialist), final edits of all study documents, phone script, and overall IRB form was reviewed, edited, and sent to North Texas IRB with successful IRB approval obtained in September 2022.

Although final data analysis has not yet been completed, it is still to be determined whether to use chi-square, t-test, or ANOVA to determine clinical and statistical significance in determining efficacy of the 3M Tegaderm dressing against Aquacel Ag in reducing donor site

morbidity. Likely favorable for survey arm studies is to utilize two sample t-test and ANOVA with 0.05 parameter to indicate clinical and statistical significance/insignificance, respectfully. As stated previously, likely, obtaining a confidence interval was appropriate for more broad-spectrum applicability of data.

Discussion/Innovation

In a meta-analysis of literature done in 2018, there has been no ideal standard split thickness skin graft donor site dressing identified.[30] Traditionally, dressings have been categorized into moist and non-moist dressings with additional previous studies showing moist dressings have significant beneficial impact on patient reports of pain and better wound healing.[30] Despite this distinction and a push to move towards moist dressings for better postoperative control of pain and wound management, because of the continuous new dressing technologies on the market, there has not been enough evaluation of moist dressings to definitively identify what can be considered the ideal STSG donor site post-operative wound dressing.[30]

We continue to wait for final analysis to be completed to determine how to approach future studies and comparisons to further push for standardization of donor site wound care. If our hypothesis is proven to be true, where the 3M Tegaderm absorbent dressing fairs better in performance than the Aquacel Ag dressing in pain control, wound healing, and offer less post-operative donor site infections or complications, it could signify a step towards optimal patient wound care and management.

As stated previously, 11 million burn injuries happen worldwide, and are expensive to treat.[20-21] These patients most likely suffer immense trauma, accident, or advanced pathological disease to accrue a large and deep enough wound to undergo a necessary STSG to allow for wound coverage. Without proper skin coverage, the wound may be at an increased risk of infection, higher reports of pain, and delayed wound healing that may progress to where amputation and/or large scars may be a topic of discussion – dependent on the location of the wound and

patient health status and comorbidities. By harvesting an autologous graft, there is lowered risk of autoimmune host rejection of the graft as well as providing the adequate wound coverage needed to lower risks of infection at both donor and wound sites.[14]

By standardizing the postoperative donor site dressing, potential complications and delayed wound healing concerns can be anticipated and efforts can be taken to address those complications early in the wound healing course. Additionally, by moving towards standardization, and eliminating unnecessary use of expensive equipment that may raise Medicare and hospital cost of care per patient, there would be a financial benefit to the patient with a shortened hospital stay, lower pain reports with less use of stronger pain medication and/or narcotics, and faster wound healing times overall with lessened wound morbidity.

Future Directions

Although this study is still undergoing data analysis, there is a predicted favorable outcome towards better donor site wound healing with use of the 3M Tegaderm dressing.
Although this study is still undergoing data analysis, there is a predicted favorable outcome towards better donor site wound healing with use of the 3M Tegaderm dressing.

The 3M Tegaderm dressing is a semi-permeable, self-adhesive dressing made of polyurethane film.[31] Because of the 3M Tegaderm properties, pending the results of this study, possible future studies could include how different donor sites dressings perform compared to 3M Tegaderm. Because there is no standardized way to dress the donor site skin graft wound to reduce overall morbidity, we are hoping for this study, and its' results, can create a more universal approach to wound care.

Additionally, although controversial, it can be possible to further pursue a follow up study on more at-risk-for-wounds patients – like the diabetic population. Among the US population, alone, approximately 29.7 million people, of all ages, are diagnosed with Type 1 or Type 2 diabetes.[32] STSG have a low morbidity and high reliability when it comes to wound coverage, but in diabetics, it is controversial due to high-risk factors (inadequate wound preparation, end stage renal disease (ESRD), neuropathy, microvascular changes[14]) leading to potential wound and graft breakdown – prolonging overall re-epithelization and wound healing.

Yasmin et al performed a meta-analysis on the use of STSG as treatment for noninfected recurrent of recalcitrant ulcers of the leg and dorsal foot.[34] This shows promise in diabetic

patients with chronic wounds to allow for adequate wound healing, thus, can infer if there is successful graft uptake of the wound, the donor site wound morbidity can be reduced in diabetic patients – with the caveat of selecting those patients who are well-controlled with their diabetic status.

Although this was a limited study, as with our study, it does continue to promote the drive to find better wound site care to reduce overall morbidity of wounds – both from the donor site and the accepting site.

Conclusions

Although this study is still incomplete and undergoing data analysis, it has been preliminary favorable towards the 3M Tegaderm dressing to provide better donor site outcome and less site morbidity. This study is hopeful in acting as an early catalyst on standardization on STSG wound care with lessened site morbidity with the hope to change standard of practice amongst seasoned wound care physicians and medical practitioners.

Compliance

All members of the research team underwent CITI Biomedical Research training and presented a certificate of complete training to fulfill competency for North Texas Regional IRB. Every member signed a conflict-of-interest form stating any conflict-of- interest present. In this case, no conflict-of-interest was identified, thus did not have to be presented to every enrolled patient in this study. A copy of every complete patient questionnaire was documented, compiled, and ready for submission to North Texas Regional IRB upon conclusion of this study.

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