The Use of Integra© in Coverage of Radial Forearm Free Flap Donor Site Defect
Comprehensive Cancer Center of Wake Forest University (CCCWFU)
CCCWFU # 99915A

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1.0 Introduction and Background

The radial forearm fasciocutaneous free flap (hereafter referred to as RFFF) was described more than 30 years ago as a fasciocutaneous flap for microsurgical transfer.[1] It was soon after established as a safe and reliable flap for transfer of fascia and cutaneous tissue.[2, 3] Currently, it is used to repair any defect in which a relatively thin island of skin is needed with a fascial strength layer .[4-6] While the flap itself is very reliable, it leaves a donor site that can be very unsightly and has multiple known complications including loss of pronation, pain, paresthesias, cold intolerance, and skin graft necrosis.[7-9] The donor site is typically covered with a split thickness skin graft (hereafter referred to as STSG). In an effort to minimize these complications, several groups have described a technique of placing Integra© dermal substitute (hereafter referred to as Integra) underneath the STSG to provide a thicker support and decrease overall morbidity associated with the defect. These studies have shown success in decreasing overall morbidity including increasing range of motion and improving aesthetic quality of the donor site. However, the largest study to date has included only 29 subjects. Furthermore, these studies do not provide a comparative cohort of subjects repaired with a classic STSG to show effectiveness of this technique when compared to a classic repair.[10-14] Our goal is to perform a prospective study comparing subjects repaired with a classic STSG and those repaired with one step Integra and STSG applied at the same time. These subjects will be evaluated for overall donor site aesthetic quality and functional outcome as described below.

1.1 Primary Objective(s)

Compare donor site aesthetic quality and functional outcomes of subjects with a classic STSG and those repaired with Integra and STSG**.**

2.0 Subject Selection

This clinical trial can fulfill its objective only if subjects appropriate for this trial are enrolled.

2.1 Inclusion Criteria

2.1.1 All subjects who receive a radial forearm free flaps in the included time period, including subjects with head and neck cancer, traumatic defects, chronic wounds, or any other problems that require a radical forearm free flap for reconstruction.

2.1.2 Have had a distal, anterograde fasciocutaneous flap

2.1.3 Age ≥ 18 years

2.1.4 All smokers and tobacco users will be included in this study.

2.2 Exclusion Criteria

2.2.1 Subjects who have had an osteocutaneous or musculocutaneous flap.

2.2.2 Subjects who have a radial forearm flap with a proximal skin flap or subjects that receive a "reverse" radial forearm flap
2.2.3 Pregnant women will be excluded due to the lack of clinical studies evaluating INTEGRA template in pregnant women.

2.3 Inclusion of Women and Minorities

Men and women of all races and ethnicities who meet the above-described eligibility criteria are eligible to participate in this study.

4.0 Registration Procedures

All subjects entered on any CCCWFU trial, whether treatment, companion, or cancer control trial, **must** be registered with the CCCWFU Protocol Registrar or entered into ORIS Screening Log. Subjects **must** be registered prior to the initiation of treatment.

You must perform the following steps in order to ensure prompt registration of your subject:

1. Complete the Reduced Review Registration Form (Appendix A)
2. Complete the Race Verification Form (Appendix B)
3. Send the Reduced Review Protocol Registration Form, and the Race Verification Form to the registrar, either by fax or e-mail.

   Contact Information:
   Protocol Registrar PHONE (336) 713-6767
   Protocol Registrar FAX (336) 713-6772
   Protocol Registrar E-MAIL (registra@wakehealth.edu)

   *Protocol Registration is open from 8:30 AM - 4:00 PM, Monday-Friday.

To complete the registration process, the Registrar will:

- assign a subject study number
- randomize the subject
- register the subject on the study

5.0 Study Outcomes and Study Measures

For this study, we will include all subjects that meet the above criteria that are receiving distal, anterograde fasciocutaneous Radial Forearm Free Flaps. For inclusion in the study, only those receiving proximally based flaps with the skin paddle located over the tendons will be included.

Informed consent will be take place in the clinic in a private exam room. After reviewing the consent form and all questions and concerns have been addressed, if the subject or legally

authorized representative chooses to participate, then a signature will be obtained on the informed consent document.

Subjects will be randomized to either receive both Integra and a STSG or a regular STSG. Consideration of treatment of the donor site will be the same regardless of the final destination of transferred tissue.

The subjects will receive the assigned reconstruction as dictated by the protocol. They will either receive 1) a 0.012mm STSG or 2) A sheet of Integra directly on the wound bed with subsequent removal of the overlying silicone sheet and immediate application of a 0.008mm STSG. The skin grafts will be meshed 1:1 for minimal graft distortion and to avoid variability of "pie crusting." The RFFF donor site will then be covered by a non-adherent dressing, such as Adaptec, and a vacuum assisted closure (VAC) device. The VAC will stay in place for 5 days following surgery, and during this time a simple removable thumb spica splint will be placed to prevent wrist motion. Subjects with free tissue transfer will typically have a 4-5 day hospital admission. The plastic surgery team will follow them during their admission and will schedule appropriate follow up at both one and two weeks following surgery. Follow up appointments following this time will be at the discretion of the attending physician. Scheduled post-operative assessments following the initial assessment will include a 3 month, 6 month, and one year follow up appointment. Evaluation at the 3-month and 6-month follow-up appointment,will include photos of the surgical site, evaluation of the skin graft and any areas of necrosis or tendon exposure, survey of presence of pain and paresthesia, and the QuickDASH survey. During the 1 year follow-up, in addition the assessments described above, the Vancouver Scale Assessment will be performed by a Co-Investigator who is blinded Areas of tendon exposure will be treated with xeroform dressing changes.

During surgery and at the scheduled follow up all subjects will have standardized photographs taken utilizing a custom backdrop and a centimeter scale. These pictures will be used to assess wound size and dimension at each encounter, including the original surgery. This will allow us to measure the rate of wound healing, contracture, and rate of skin graft necrosis. The pictures will be analyzed with the SigmaScan planimetry program. This protocol has been previously validated and published.[15]

Subjects will be evaluated by the occupational therapy team prior to their surgery in the pre-operative holding area and during their admission to the hospital. They will be assessed using standard measurement from a goniometer and dynamometer and also given instructions for wrist range of motion exercises. During follow up, subjects will be referred to occupational and physical therapy at the discretion of the attending physician.

Subjects removed from study for unacceptable adverse events will be followed until resolution or stabilization of the adverse event.

6.0 Data Management

Race Verification Form	ORIS
Protocol registration form	ORIS
Survey Data Capture	REDCap
PHI Data Capture	REDCap

13.0 Statistical Considerations

Endpoints:

1. Rate of tendon exposure. Previously reported from 12-55%.[7, 16-19]
2. Rate and percent of skin graft necrosis. Rate previously reported to be from 7%-51%.[7, 9, 16, 20-22] Percentage of skin graft loss ranges from ≤5%- ≥20%.[9, 16]
3. Rate of paresthesia. Previously reported to be 36%- 50%. [9, 20]
4. Aesthetic outcome of donor site on Vancouver Scar Scale, a validated objective assessment of scar appearance.[23] Previous scores are reported to be 4.7/13 without Integra and 4.2/13 with Integra.[14, 24] In particular, we will be focusing on the pliability aspect of the Vancouver Scar Scale, which will be a measure of the functionality of the skin overlying the donor site. The scores will be taken at the 3,6, and 12 month follow up.
5. The Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure is a 30 question survey used to quantify the symptoms and function of any person with musculoskeletal disorders of the upper limb. It is used to determine the impact that a particular disorder has on an individual's life.[25, 26] The QuickDASH is a shortened version of the DASH that has been validated to be as significant as the full questionnaire.[27] While the QuickDash scores of RFFF subjects have not been reported, previous DASH scores have been reported to be 6.93 ± 5.54 in RFFF subjects compared to 2.95 ± 4.42 in non-RFFF subjects.[28]
6. Differences in range of motion at the hand, previously reported to be 22-27 degrees difference [8]
7. Differences in grip and pinch strength in the donor site hand, previously reported to be about a 7kg difference in pinch strength and a 0.75kg difference in grip strength. [29]
8. Wound contracture and Skin Pliability. Normal results are reported below.

Statistical Analysis:
We plan to enroll 50 subjects in each group. All hypothesis testing will two sided and performed at the 0.05 significance level. All analysis will be performed in SAS Version 9.4 (Cary, NC). No interim monitoring is planned for this study.

The analysis and estimated power for each endpoint is described below.

1. Rate of tendon exposure
    a. We expect about a 25% rate of tendon exposure in the group that does not use Integra, while in the Integra group we hope to have a rate of tendon exposure of below 5%. We will test this hypothesis using a chi-squared test of equal proportions. We will have 81% power to detect this difference with 50 subjects in each group.
2. Rate and percent of skin graft necrosis
    a. We expect about a 20% rate of skin graft necrosis in the STSG group and about a less than 5% rate of skin graft necrosis in the Integra group. To test for a significant difference in the STSG and STSG with Integra groups, we will employ a chi-squared test of equal proportions. We will have 62% power to detect the difference between the two groups.

b. In the STSG group, we expect about 10% of the graft to become necrotic, while we believe that below 5% of the STSG with Integra group to become necrotic. We will have approximately 16% power to detect this difference using a chi-squared test.
c. While the study may be underpowered to make this particular observation statistically significant, this parameter is not a primary objective of the study but will be easy to measure.

3. Presence of pain and paresthesia and severity on a 1-10 scale
    a. In the split thickness skin graft group, we expect about 20% of the subjects to still have pain at the radial forearm site, while about 35% of these subjects will have significant paresthesias. In the Integra group, we expect about 10% of the subjects to have pain at the radial forearm site, while about 20% of these subjects will likely have paresthesias. To tests for significant difference in the two groups, we will again employ a chi-sqaured test. We will have 29% power to detect a significant difference in pain at the radial forearm site and 39% power to detect a significant difference in the rates of paresthesias.
    b. Of the subjects that have pain we expect those who have had Integra© placed to have pain at a level of an average of about 3, while those who have not had Integra© will have pain at an average level of 7. After evaluating the distribution of the scaled scores, we will test if these means are equal using a t-test if data appear normal and a Wilcoxon Rank sum test if not. Assuming the two groups share a common standard deviation of 3, we will have over 99% power to detect this difference using a t-test. If data appears non-normal, assuming the probability that an observation in the Integra© group has lower severity of pain is 0.75, we will have 99% power to detect this difference.
4. Aesthetic outcome of donor site on Vancouver Scar Scale
    a. The Vancouver Scar Scale encompasses 4 separate outcomes to be objectively assessed. Each has been separately reported in the literature for each group in different papers as previously mentioned. We will compare the final score as well as scores within each outcome.
        i. Vascularity (0-3): STSG group will likely average a 1, while Integra group will likely average around 0
        ii. Pigmentation (0-2): STSG group will likely average a 1 while Integra group will likely average a 2
        iii. Height (0-3): STSG group will be an average of about 1, while the Integra group will likely average a 0
        iv. Pliability(1-5): We expect the STSG group to average about a 2, while the Integra group will average about a 1
        v. Based on these scores, we would expect the STSG group to have a score of 5 while the Integra group will have an average score of about 3

    We will compare these measures between the two groups using t-tests or Wilcoxon rank sum tests as appropriate. Assuming a standard deviation within each group of one and that data appears normal, we will have over 99% power to detect a difference of one and two scoring units for these tests.

5. Functional outcome as measured by pre and post-operative assessment on the QuickDASH (Disabilities of the Arm, Shoulder, and Hand) scale

a. The survey asks the subject to rate the ease of 11 daily activities from 1-5, 1 being no difficulty, and 5 being unable to perform.
    i. The scores are then averaged (Giving a score between 1 and 5), and one is subtracted from the average. This number is then multiplied by 25
        1. As the lowest possible rating on each activity is 1, this accomplishes bringing the lowest possible score to 0.
        2. As the highest possible rating on each activity is 5, this bring the highest possible score to be 100
    ii. We will expect similar values as previously cited in the literature. About 70 for the subjects receiving a STSG, and values closer to 30 for the Integra group
    iii. We will compare these two groups using t tests or Wilcoxon Rank Sum tests as appropriate. Assuming a standard deviation of 10 and that the data appears normal, we will have over 99% power to detect this difference using a two sample t test.

6. Functional outcome as measured by hand strength and Range of Motion
    a. Range of motion will be measured by resident physicians taking part in the project who will be trained by the occupational therapy team at our institution. The measurements will be taken using electric goniometers so as to standardize the measurements as much as possible.
        i. Previously reported differences in pre and postoperative range of motion of wrist flexion and extension have ranged from non-statistically significant to about 27 degrees and 22 degrees, respectively.[1]
            1. We will expect the difference in wrist flexion and extension in the non-Integra group to be 25 degrees and 20 degrees, respectively.
            2. We will expect the difference in flexion and extension in the Integra group to be 15 and 10 degrees, respectively.[8]
            3. We will again employ two sample t-tests (or Wilcoxon Rank Sum Tests) to test for differences in these angle measurements. Assuming a common standard deviation of five degrees, we will have 99% power to detect a difference in five degrees using a two sample t test.
    b. Hand strength will be measured by pinch and grip strength dynamometers obtained from the occupational therapy department at our institution. These measurements will be taken at 3 month, 6 month, and 1 year follow up clinic visits.
        i. Grip strength has been reported to be about a 7kg difference between pre-operative and post-operative measurements, while Pinch strength has been shown to differ by approximately 0.75kg. [29]
        ii. For the non-integra group, we predict a difference in grip strength of approximately 5kg, while the pinch strength will differ but about 0.75kg
        iii. For the Integra group, we predict that the difference in grip strength will be approximately 3kg while the pinch strength will differ by approximately 0.25kg.
        iv. At each time point, we will compare the hand strengths of the Integra and non-Integra groups using two sample t-tests or Wilcoxon Rank Sum Tests as appropriate. Assuming a 5kg grip strength standard deviation in each group, we will have over 99% power to detect differences of 5kg and 7 kg in each group.

v. For pinch strength, we assume both groups have a standard deviation of 1kg. To detect a difference 0.75kg, we will have 95% power using a two sample t-test.

7. Wound Contracture and Skin Pliability
    a. We will use the same planimetry software to determine the percent of wound contracture.
        i. Utilizing a dermal substitute, wound contracture has been shown to be as low as 15% of total area. We will expect the same amount from our study. [30]
        ii. Wound contracture utilizing standard STSG has been shown in animal models to cause wound contracture of up to 38-41%. We will expect wound contracture of about 30% from our study. [31,32]
    b. Skin Pliability
        i. We plan to use a Cutometer MPA 580 for measurements of skin pliability. We currently have this device on our budget for next year awaiting approval and are separately applying for a Plastic Surgery Foundation grant to fund these measurements.
        ii. We plan to measure Pliability (Ua), Elasticity (Ue), Retraction (Ur). Viscoelasticity (Uv), and Extension (Uf)
            1. Previously measured values for these parameters in reconstruction utilizing Integra are as follows. [33]
                a. Ua= 0.083 (0.192 Control)
                b. Ue=0.088 (0.153 Control)
                c. Ur= 0.037 (0.086 Control)
                d. Uv=0.039 (0.068 Control)
                e. Uf= 0.098 (0.221 Control)
                f. Ur/Uf (Gross Elasticity)=0.377
                g. Ur/Ue (Elastic Function)=0.125
                h. Ua/Uf (Biological Elasticity)=0.846
            2. Previously measured values for these parameters in STSG are reported as ratios and are listed here. [34]
                a. Ur/Uf (Gross Elasticity)=0.553
                b. Ur/Ue (Elastic Function) =0.818
                c. Ua/Uf (Biological Elasticity)=0.881
            3. For our study, we will expect the following parameters
                a. Integra+STSG
                    i. Ur/Uf=0.4
                    ii. Ur/Ue=0.1
                    iii. Ua/Uf=0.8
                b. STSG
                    i. Ur/Uf=0.6
                    ii. Ur/Ue=0.8
                    iii. Ua/Uf=0.9
        iii. Should we not obtain funding for a cutometer, we will obtain measurements of maximal skin distension over the grafted area and compare it in a ratio to the maximal skin distension over the same area in the opposite arm.

1. In this manner, we would expect the Integra and STSG to give a ratio of about 0.75, while the STSG would give a ratio of about 0.4

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APPENDIX A: REDUCED REVIEW** REGISTRATION FORM

Protocol#: 99915A *Required Field

Protocol Title: The Use of Integra® in Coverage of Radial Forearm Free Flap Donor Site Defect
CCCWFU#99915A

DEMOGRAPHICS

Name (last, first) : _____, _____
(or initials)

UNIT # (MRN): _____ (required if exists) Zip Code:_____ (required if no MRN)

*SEX ( ) MALE ( ) FEMALE

*ETHNICITY (choose one): ( ) HISPANIC( ) NON-HISPANIC

*RACE (choose all that apply): □ WHITE □ ASIAN

□ AFRICAN-AMERICAN □ PACIFIC ISLANDER (HAWAIIAN)

□ NATIVE AMERICAN (ALASKAN) □ Unknown (Other, Refused}

*DIAGNOSIS : _____

BIRTH DATE: _____(include if no MRN is provided)

*MD Name (last, first): _____

*DATE CONSENT WAS SIGNED: _____

Date of Registration (if different): _____

PID#: _____ (to be completed by Registrar)

The Comprehensive Cancer Center requires that all registrations be sent to the CCCWFU Centralized Registrar the day the patient is consented; if this is not possible we require that all registrations be communicated to the Centralized Registrar within 72 hours of consent.
**Reduced review means eligibility and other review are not performed by CRM registrar. Questions: call 713-6767

Submit by Email*** Print Form

*** If not using the full wfubmc edu outlook client (full outlook, not web outlook), save this file and attach to an email to regjstra@wfubmc .edu
Submitter of this form is responsible for insuring that all regulatory and eligibility requirements are met for this registration.

Appendix B – Race Verification Form

Thank you so much for helping us to verify your race and ethnicity to ensure the quality of our information. As a brief reminder, the information you provide today will be kept confidential.

1. Are you:

☐Hispanic or Latino/a

☐Not Hispanic or Latino/a

2. What is your race? One or more categories may be selected.

☐White or Caucasian

☐Black or African American American Indian or

☐Alaskan Native Asian

☐Native Hawaiian or Other Pacific Islander

☐Other, Please Specify: _____

Internal use only:

Was the self-reported race and ethnicity of the participant verified at the time of consent?

☐**Yes** ☐ **No**

Was a discrepancy found? ☐**Yes** ☐ **No**

If yes, please provide what is currently indicated in the EMR:

Ethnicity: _____Race: _____

Additional comments: _____

_____

_____