

Blair Peters

PROJECT TITLE: A Randomized Clinical Trial Comparing Breast and Abdominal Related Morbidity of DIEP and SIEA Flaps

STUDENT'S NAME: Blair Peters **SUPERVISOR'S NAME:** Dr. Leif Sigurdson
DEPARTMENTAL AFFILIATIONS: Plastic Surgery

SUMMARY:

Background: The deep inferior epigastric perforator flap (DIEP) is the current standard of care in autologous breast reconstruction. The newer superficial inferior epigastric artery flap (SIEA) is felt to be an improvement as it does not damage the abdominal wall. The SIEA flap unfortunately is reported to have smaller vessels which put the flap at higher risk of developing flap loss and fat necrosis. The uncertainty regarding the tradeoffs inherent in the choice of procedure has not been resolved by the current literature. As such we have aimed to perform a randomized single blinded trial to evaluate the abdominal and breast related morbidity associated with DIEP and SIEA flaps. **Methods:** A blinded, randomized, prospective cohort study is being performed involving Manitoban women over 18 years undergoing unilateral or bilateral breast reconstruction. Women are randomized to either receive the DIEP or SIEA flap procedure. Objective isokinetic abdominal muscle and back extensor strength testing is being done pre-operatively and 3, 6 and 12 months post-operatively. A validated abdominal wall and breast outcome questionnaire (Breast-Q) is being administered pre-operatively and at 3 and 12 months post. Secondary outcomes measured include: fat necrosis, flap loss, abdominal wound breakdown, seroma rate and length of hospital stay. Statistical analyses include a combination of parametric and non-parametric tests. **Results:** Preliminary analyses have shown some post-operative decreases in the DIEP abdominal assessments. Some of the complication rates appear to be higher in the SIEA group, however sample sizes are currently too small for the differences to be called significant. At this point there does not appear to be any significant difference in the intra-operative findings between groups. **Conclusions:** Although the data in this report is preliminary we believe that upon completion of this study, we will go further than others in controlling variability and providing pure data for analysis. By examining outcomes on both donor site morbidity and breast flap complications, we hope to clearly delineate the benefits and tradeoffs inherent in the choice of procedure.

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Student's Signature

Supervisor's Signature

Introduction:

Breast reconstruction following mastectomy is currently performed using one of two methods: implants or autologous tissue reconstruction. It is well documented that secondary procedures are more common following reconstruction with implants (89% of delayed reconstructions and 57% of immediate reconstructions). The incidence is lower with autologous tissue flaps, with secondary procedures performed in 59% of delayed reconstructions and 18% of immediate reconstructions.¹ One of the main reasons why women choose implant reconstruction over autologous tissue flaps is the avoidance of donor site morbidity. However, the field of autologous tissue breast reconstruction has seen many advances in minimizing the morbidity of the donor site, which has made this reconstruction option much more popular in the past few years.

A transverse section of skin and subcutaneous tissue from the lower abdomen has proven to be both an effective and reliable method of breast reconstruction. The use of autologous tissue from the lower abdomen for breast reconstruction was first reported by Holmstrom² in 1979 as a free flap and became more popular in 1982 when the pedicled transverse rectus abdominis myocutaneous (TRAM) flap was introduced by Hartrampf et. al.³ This flap had the advantage of an improved abdominal contour and a scar that could be easily hidden. However, since the TRAM flap harvests a portion of the rectus muscle using the superior epigastric artery as a support system, significant risks such as abdominal weakness, and post-operative hernia formation are inherent to the procedure. The post-operative recovery time following TRAM flap reconstruction can also be quite significant. Since the TRAM flap was introduced, the field of autologous tissue breast reconstruction has sought to decrease the morbidity of the donor site (i.e. the abdomen). As the field of microsurgery evolved, it became clear that the free TRAM flap described by Holmstrom² has better perfusion as compared to the pedicled TRAM flap. Since the perfusion of the free TRAM flap, using the inferior epigastric artery was better than the pedicled flap, more tissue was able to be transferred and used for breast reconstruction when the free flap was utilized, with the additional benefit of there being less post-operative fat necrosis occurring in the reconstructed breasts. It was presumed that the free TRAM flap also resulted in less donor site morbidity since the free flap harvested less of the rectus muscle than it's pedicled equivalent. As better microsurgical techniques were developed, the trade-offs of increased complexity of the surgery and increased intra-operative time, as well as increased risk of complete flap loss due to microvascular thrombosis, became less of an issue and the free TRAM flap became more dominant.

As the breast reconstruction field continued to push for decreased donor site morbidity, the free TRAM flap became what is currently known as the muscle-sparing TRAM (msTRAM) flap. This variant of a free flap resulted in even less rectus abdominis muscle being harvested than in the free TRAM flap. The msTRAM flap utilizes vascular perforators to supply the flap. These perforators are individually identified and dissected. Only one set of perforators is used for this flap, which usually occur in a single medial or lateral row, which results in less of the rectus muscle having to be harvested than with a free TRAM flap. With the msTRAM there are medial and lateral strips of the rectus muscle that are left intact, compared to the free TRAM flap, where the full width of muscle is harvested. Since the muscle is not completely transected, it is

presumed that the decreased harvest of the rectus and its fascia results in decreased donor site morbidity compared to the free TRAM flap.

The next great advance in the use of autologous abdominal tissue for breast reconstruction came in the form of the deep inferior epigastric perforator (DIEP) flap. The DIEP flap is the current standard of care in breast reconstruction. The tissue from the abdomen via its pedicle is connected to the internal thoracic artery in the chest wall. On the rare occasion that the internal thoracic vessels are not sufficient, or there are other indications present, the thoracodorsal vessels can be used as recipients. This flap was first introduced in 1989 by Koshima and Soeda, originally in a case report⁴, followed by a publication that included a series of 13 patients in 1992.⁵ In these publications, the DIEP flaps were not used for breast reconstruction, in fact they were not even referred to as “DIEP” flaps. The important thing was that Koshima and Soeda found that a single perforator could be used to support a large amount of tissue. The DIEP flap was first described as being used for breast reconstruction in 1994 by Allen and Treece.⁶ Various other plastic surgeons popularized the technique throughout the 90’s. Harvesting the DIEP flap only requires incisions through the rectus fascia and the rectus muscle, as opposed to harvesting whole sections of the muscle like in the TRAM flaps. The DIEP flap, therefore results in less post-operative donor site morbidity than its TRAM predecessors, as demonstrated by the study published by Blondeel et al.⁷ It is important to note that although the rectus is not harvested in the DIEP flap, it can still be injured by dissecting out the deep inferior epigastric artery perforator(s), as well as dividing portions of its motor innervation. The key steps in DIEP flap breast reconstruction are summarized in Figure 1. Pre and post-operative pictures of a patient who underwent DIEP reconstruction are shown in Figure 2.

The newest development has been the reemergence of the superficial inferior epigastric artery (SIEA) flap. Anatomy of this flap was first described in 1975 by Taylor⁸ and was first described for breast reconstruction in a case report by Grotting⁹, where it was referred to as a “free abdominoplasty flap”. Since this time, the SIEA flap has been described and used by many other plastic surgeons for autologous tissue breast reconstruction. It is felt to be an improvement to the DIEP flap as it does not damage the rectus muscle or its fascia. The SIEA flap utilizes the same skin and subcutaneous tissue as the TRAM and DIEP flaps and has the potential to further minimize the donor site morbidity involved in autologous tissue breast reconstruction. Unfortunately the SIEA flap has previously been reported to have smaller vessels (smaller pedicle diameter and pedicle length) when compared to the pedicles found in the TRAM and DIEP flaps. This puts the flap at higher risk of developing significant fat necrosis or total flap loss. In some patients, the arterial pedicle used for the SIEA flap is either absent or inadequate to be the sole vascular support for the tissue flap as previously described by Arnez and colleagues.¹⁰

Perforator flaps from other donor sites, including the anterolateral thigh^{11,12} and gluteal¹³ donor sites have been described for breast reconstruction. These flaps are not used very often and have more significant risks and disadvantages compared with flaps from the abdomen as a donor site, but are worth mentioning as they do still have a role in certain patients undergoing breast reconstruction.

The risks and benefits of both DIEP and SIEA flaps have been defined previously in observational cohorts by Selber et. al^{14,15}, but have not been compared in a systematic fashion. There is a lack of clear data on the abdominal wall outcomes following reconstructive breast surgery using DIEP and SIEA perforator flaps. The uncertainty regarding the tradeoffs inherent in the choice of procedure has not yet been resolved. As such we have aimed to perform a randomized single blinded trial to evaluate the abdominal and breast related morbidity associated with DIEP and SIEA flaps.

Hypothesis: It is expected there will be less abdominal wall morbidity with the SIEA flap. The improvement may however be trivial in relation to the suspected higher degrees of flap related morbidity associated with the SIEA flap.

Materials and Methods:

Our study is a blinded prospective cohort study on the abdominal wall and breast morbidity seen with the DIEP and SIEA flap procedures. A 10% difference in abdominal isometric contraction strength between groups would be considered to be clinically relevant. With mean isometric peak torque contraction values from prior studies being 75Nm¹⁶, a difference of 7.5 Nm would be clinically relevant. To power the study at 90%, the required same size is 91 patients. Enrollment is currently taking place with 18 patients currently participating in the study. With approximately 200 DIEP/SIEA flaps being consistently performed at HSC by the operating surgeon each year, we are hoping to have enrollment completed within the next year.

The primary inclusion criteria are (1) female subjects older than 18; (2) with satisfactory abdominal tissue for unilateral or bilateral DIEP or SIEA perforator flap breast reconstruction; (3) fluent in English. Patients are excluded if reconstruction is planned using (1) latissimus dorsi flap, (2) a gluteal artery perforator flap, or (3) tissue expansion. Patients are also excluded from the study if they suffer from (4) neurological back problems or (5) inguinal hernias.

Upon enrollment in the study, the patient is assigned a number (starting at 125) and is given a card with that number on it, which is used for all of the patient's future appointments and assessments. Patient demographic information is obtained. Information gathered includes age, date of birth, ethnicity, body mass index and medical history; including hypertension, smoking, diabetes mellitus etc. Some social history is taken as well, including alcohol and drug use. This data is collected in order to tabulate confounding variables and check the efficacy of randomization.

Patients are randomized into either the DIEP or SIEA procedural group using a random number generator (even = DIEP, odd = SIEA). A card designating the group the patient is assigned to is then placed in an envelope, sealed and opened by the operating surgeon just prior to the patient's surgery. As previously mentioned, not all patients have a superficial inferior epigastric artery of sufficient caliber to support the tissue flap and thus cannot have this procedure performed. If patients randomized to the SIEA group are found to have improper anatomy to support an SIEA

flap, than a DIEP flap is used. The analysis on these patients will then be done as intention to treat.

The primary outcome of the study is abdominal wall (donor site) morbidity, which is being assessed in 3 ways:

1) Isokinetic dynamometry: Strength of the abdominal muscles and the back extensors is being objectively measured by isokinetic strength testing on an isokinetic dynamometer (Biodex System III with dual position back extension/flexion attachment). The abdominal strength testing is being performed pre-operatively and at 3, 6 and 12 months post-op. Objective measurements are used to address the strength of the rectus abdominus muscle and all data is collected by personnel at PanAn Clinic who have been trained in the required techniques. The technician performing the assessments is blinded to the type of breast reconstruction that has been performed. At the beginning of each assessment the patient warms up for 2-3 minutes on a stationary bike and is instructed on how to contract their abdominal muscles and avoid using their legs. The patient is positioned in the isokinetic dynamometer in a sitting position with their arms across their chest and the axis of rotation is set at the level of the anterior superior iliac spine. Before each test is done, 2-3 sub-maximal trial measurements are taken to familiarize the patient with the range of motion and the correct way to exert their force against the force of the machine. Once the technician is satisfied that the patient understands how to properly perform the test, the technician will proceed. Throughout each test the technician encourages the patients to give maximal efforts and continually checks to make sure the patient is utilizing the correct muscles. Each strength measurement is divided by the woman's mass in kg to allow for more accurate comparison between women of different body sizes.

Concentric, eccentric and isometric measurements are all taken. Concentric activity of a muscle takes place when the muscle is contracting and simultaneously shortening, as in sit ups. With eccentric muscle activity, the muscle lengthens while simultaneously maintaining tension, as with lifting a heavy object. An isometric contraction is a contraction of the muscle where the length remains constant.¹⁷ Note that rotational strength is not being assessed as it has previously been shown that there is no decrease in rotational strength in DIEP patients post-operatively.⁷ See Table 1 for a summary of the different types of muscle contractions. First, concentric trunk flexion and extension measurements are taken from 15° extension to 30° flexion at a speed of 30°/sec. Two sets of 5 repetitions are performed. Note that 15° extension is a position of mechanical advantage for the rectus abdominis and 30° flexion is the end of range of normal trunk flexion that is solely performed by the abdominal muscles.¹⁷ Eccentric trunk flexion and extension measurements are then taken, also at a speed of 30°/sec, with two sets of 5 repetitions. The last tests to be done are the isometric measurements. Isometric trunk flexion and extension measurements are taken at 3 different positions, 15° extension, 0° (neutral) and 30° flexion. These different positions are illustrated in Figure 3. The contractions are maximal, for 5 seconds each and 3 repetitions are done. There is 20 seconds of rest between each effort. In the concentric and eccentric measurements, both peak torque (Nm) and average power (W) are recorded. For the isometric tests, peak and average peak torque (Nm) are recorded. If the coefficient of variance is greater than 10%, the patient is re-instructed on the proper technique and the

measurements are repeated. The measurement with the lowest coefficient of variance is then taken.

2) Clinical Examination: Patients are examined in the plastic surgery department both in the supine and upright positions for asymmetric positioning of the umbilicus, abdominal wall asymmetry, lower abdominal bulging, hernias and abdominal wound breakdown (post-operatively using calipers). Any pre-existing scars are also noted to see if this affects complication rates. This clinical examination is completed pre-operatively by the operating surgeon and during the regular follow-up appointments (1 week, 2 weeks, 6-8 weeks, 3 months post-op) by the head nurse, who has been instructed to do these assessments on every patient receiving DIEP or SIEA breast reconstruction. She therefore, does not know who is actually enrolled in the study.

3) Questionnaire: The Breast-Q¹⁹, a previously validated questionnaire containing questions related to the breast as well as the abdominal wall is being administered to patients both pre-operatively and at 3 and 12 months post-operatively. There are several questions that directly ask patient's about their abdomen, providing subjective data that will be used to compare patient satisfaction with the donor site outcomes they experience.

Intra-operative data is also being collected with the intention of using it to identify any variables of the DIEP and SIEA procedures associated with the breast and abdominal outcomes being assessed in the study. The intra-operative data being collected includes whether or not the superficial inferior epigastric vessels are present in both treatment groups. If the vessels are present, it is recorded whether or not they are of sufficient calibre to support an SIEA flap. This information is to show how many patients enrolled would be candidates to receive the SIEA procedure had they not been randomized to a treatment group pre-operatively. The size of the SIEA/DIEA at the femoral artery/external iliac artery and the size of the SIEV/DIEV at the femoral vein/external iliac vein is also recorded, along with the size of the venous coupler used to anastomose the donor and recipient vein. This data is used to determine how often the superficial vessels are present and if there is a significant difference between the vessel size in DIEP and SIEA flaps. During the procedure the operating surgeon comments on how good the flap perfusion is as well as his opinion on the probability that flap complications will occur; this is all recorded. The size of the vascular perforator bundle and the pedicle length as well as the location of the DIEP perforator(s) are noted. For patients in the DIEP group, the percentage of the rectus abdominis muscle that appears damaged after dissection, as well as whether or not the nerve(s) to the rectus are left intact are also recorded. This information is used to see whether or not loss of innervation and percent damage to the rectus correlate with decreased abdominal strength measurements. The operating surgeon also indicates by drawing on a diagram of the rectus, the number, location and direction of the muscle cut(s). For DIEP patients, it is additionally noted whether just a medial row or lateral row perforator is utilized and how many perforators are used to support the flap.

Several secondary outcomes are measured as well, related to both the donor site as well as the flap. These include fat necrosis and flap loss in regards to the reconstructed breasts, and abdominal wound breakdown, related to donor site morbidity. Seroma rates and drainage volumes are measured for both the reconstructed breasts, as well as the donor site (abdomen). Length of hospital stay is also being recorded to see if a difference in post-operative complication rates is affecting the length of hospital stay between the two groups.

1) Fat necrosis: Fat necrosis is the end result of prolonged ischemia to fatty tissue. It presents as a firm lump or area within the reconstructed breast. The patients are examined for fat necrosis by a plastic surgeon who has not done the patient's reconstruction and therefore is blinded to the procedure that was performed. Ultrasonography assessments are done at both 3 and 6 months post-op. Previous studies^{20,21} have reported the incidence of fat necrosis in DIEP flaps to be approximately 12%. The rate of fat necrosis occurring in SIEA²² flaps is less certain but is expected to be and has previously been reported to be higher than the rate occurring in DIEP flaps. The features of fat necrosis in reconstructed breasts have been previously summarized by Taboada et. al.²³ The surgeon will also make an attempt to quantify the amount of fat necrosis present in the breast(s). If the amount is significant enough and further intervention is required to deal with the fat necrosis, this is recorded as well.

2) Flap loss: Partial flap loss being defined as tissue loss greater than 10% of the flap or fat necrosis greater than 5cm in diameter, and total flap loss being complete loss of the flap. These assessments are also done during regular follow-up appointments with the plastics care team (1 week, 2 weeks, 6-8 weeks, 3 months post-op). Previous rates of partial flap loss and total flap loss in DIEP flap reconstruction have been reported as 2.5% and 0.5% respectively.²⁰ Rates of flap loss are less well defined for SIEA flaps, but the incidence is again expected to be higher than that observed with the DIEP flaps, with total SIEA flap loss having previously been reported to be 2.9%.²⁴

3) Seroma rates: A seroma is a pocket of clear fluid that sometimes develops in the body after surgery. The rates of seroma formation are tabulated and drainage volumes measured during regular follow-up appointments with the plastics care team (1 week, 2 weeks, 6-8 weeks and 3 months post-op). Breast seroma rate as a complication of DIEP flap breast reconstruction has been documented to be 4.6%.²⁰ Once again, with the lack of definitive data on SIEA flap complications, no clear rate has been established, but it is expected to be higher than the rate reported for DIEP flaps. A recent study by Moradi et. al.²⁵, published data showing a significantly higher rate of abdominal seromas in patients undergoing SIEA flap reconstruction, which corresponded to a longer hospital stay for these patients. For these reasons seroma rates and drainage volumes are being recorded from the abdomen as well.

4) Breast-Q: All patients fill out this questionnaire, previously validated by Pusic et. al.¹⁹ The Breast-Q was designed to measure the subjective outcomes associated with breast reconstruction including six main domains: satisfaction with breasts, overall outcome, process of care, psychosocial, physical and sexual well-being. In it there are both breast and abdominal related

items. This same questionnaire is being filled out both preoperatively as well as 3 and 12 months postoperatively.

Methods of Analysis:

The data is to be analyzed every time a new cohort of 25 patients has been enrolled, until the targeted sample size is achieved, at which time enrollment will cease. Data is being analyzed periodically in accordance with Research Ethics Board requirements. If one group is found to have significantly worse outcomes, the study is to be terminated prematurely and the patient's notified of the findings. The abdominal isokinetic data is continuous and is expected to conform to a normal distribution. The Kolmogorov Smirnov test is used to test for conformity. If the data conforms a 2 group (SIEA vs DIEP) x 4 time (pre-op, 3 month, 6 month, 12 month) mixed ANOVA will be used to test within and between group differences. In the less likely situation that the data is not normal, non-parametric tests are employed. Friedmann's test is used to compare abdominal strength, within muscle groups, over time.

All of the secondary outcomes where means can be calculated are assessed using 2-tailed t-tests. In the event that the parametric assumptions are not met Mann-Whitney U test will be substituted for t-tests. Chi-square analysis are performed for any variables that are yes/no categorical variables (i.e. complication rates). For all tests the significance level is being set at $p < 0.05$.

Results:

Enrollment began in March of 2012 and there are currently 18 patients enrolled in the study; 10 randomized to the SIEA group and 8 to the DIEP group. The average age in the SIEA and DIEP groups are 50.2 and 50.8 years respectively. Average BMI of the women in each group is 31.5 kg/m² for the SIEA group and 28.1 kg/m² for the DIEP group. Of the variables measured (hypertension, smoking, diabetes, alcohol use, drug use), there are no significant differences between groups, indicating efficient randomization up to this point.

The results from the pre-operative Breast-Q completed by patients in each group are quite similar. Note that each question on the Breast-Q is scored from 1 to 5. There are a few things to mention from the preliminary results. Patients in the SIEA group have reported a lower score ($M = 3.6$, $SD = 1.19$) compared to the DIEP group ($M = 4.6$, $SD = 0.52$) in regards to feeling feminine in their clothes. This difference is significant; $p = 0.049$. There is a trend of patients in the DIEP group reporting a lower amount of tenderness in their breasts than those in the SIEA group; the means being 1.6 ($SD = 1.64$) and 2.9 ($SD = 1.19$), respectively; $p = 0.10$. As we recruit more patients these pre-operative differences would be expected to equalize.

Of the 18 patients currently enrolled, 6 of the patients from the SIEA group (6 of 10) have had their reconstructions and all 8 patients in the DIEP group have had their reconstructions. One patient (1/8) from the DIEP group had a delayed reconstruction. All other patients in the DIEP and the SIEA group had immediate reconstructions. Of the patients in the SIEA group pre-operatively, 66.7% (4 of 6) had superficial inferior epigastric vessels (SIEVs) present. Of these 6 patients randomized to the SIEA group pre-operatively, 50% (3) were found to have vessels of

sufficient calibre to support an SIEA flap and went on to receive SIEA flap reconstruction (note: all 3 of these SIEA flap reconstructions were unilateral). Thus of the 4 patients with SIEVs present, 75% (3 of 4) had vessels that were of a sufficient calibre (SIEA >1 mm). The 3 patients randomized pre-operatively to the SIEA group that were found not to have present/sufficient SIEVs all had pre-operative abdominal scars (one right lower quadrant appendectomy, 1 transverse lower abdomen, 1 wide Pfannenstiel scar). These patients had reconstruction(s) performed with the use of a DIEP flap. Of the patients randomized to the DIEP group, 87.5% (7 of 8) had SIEVs present. In these patients, all 7 (100%) were found to have SIEVs of sufficient calibre to support an SIEA flap. These patients because they were randomized to the DIEP group, had DIEP flap reconstructions. A Chi-square analysis was conducted to examine whether there was a difference in the presence of SIEVs in the pre-operative groups, it showed that there was no significant difference, $\chi^2(1, N=14) = 0.88, p = 0.35$. For the 11 patients who underwent DIEP reconstruction (all 8 from DIEP group, and 3 from SIEA group, for a total of 11), 16 DIEP flaps (i.e. 5 bilateral, 6 unilateral reconstructions) were performed. In these patients, the DIEP perforator(s) used was medial in 45% (9 - 7 left, 2 right), lateral in 40% (8 - 2 left, 6 right), periumbilical in 10% (1 left, 1 right) and medial-periumbilical in 5% (1 left). In the unilateral DIEP reconstructions, the average number of perforators used to support each flap was 1.33 (SD = 0.52). In the bilateral DIEP flaps, the average number of perforators used to support each flap was 1.20 (SD = 0.42). There was no significant difference in the number of perforators used to support each DIEP flap in the unilateral and bilateral groups, $t(14) = 0.56, p = 0.58$. Collapsing across unilateral and bilateral groups, the average number of perforators used to support each DIEP flap was 1.25 (SD = 0.45). In these DIEP patients, all innervation to the rectus was left intact in 68.8% of patients, and of the 16 DIEP flaps performed, 10 resulted in damage to the rectus muscle. Of those flaps that resulted in damage to the rectus, the average percentage of damage was 5.35%. In the 3 patients who received SIEA reconstruction, the average size of the SIEA at the femoral artery was 1.17 mm (SD = 0.29) while the average size of the SIEV was 2.17 mm (SD = 0.29). In the 11 patients who received DIEP reconstruction, the average size of the DIEA at the external iliac artery was 1.14 mm (SD = 0.45) while the average size of the DIEV was 2.05 mm (SD = 0.42). There was no significant difference in the size of the SIEA (M = 1.17, SD = 0.29) and the DIEP (M = 1.14, SD = 0.45) used to support the flap, $t(12) = 0.11, p = 0.92$. There was also no significant difference in the size of the superficial inferior epigastric vein (SIEV, M = 2.17, SD = 0.29) and the DIEV (M = 2.05, SD = 0.42) used to drain the flap, $t(12) = 0.47, p = 0.65$. Collapsing across flap type, the average pedicle length was 8.22 mm (SD = 1.73). There was no significant difference in the pedicle length for SIEA flaps (M = 7.50, SD = 0.71) and the DIEP flaps (M = 8.31, SD = 1.82), $t(16) = 0.61, p = 0.55$. T-tests were performed to test whether there was a difference in the operating surgeon's opinion on flap perfusion and the probability of flap related complications in each group. There was no significant difference between SIEA (M = 2.00, SD = 0.00) and DIEP (M = 1.94, SD = 0.43) in regards to the surgeon's opinion on the quality of flap perfusion, $t(18) = 0.23, p = 0.82$. There was no significant difference between SIEA (M = 3.00, SD = 1.00) and DIEP (M = 2.69, SD = 0.70) on the surgeon's opinion of the likelihood of flap related complications, $t(17) = 0.67, p = 0.51$.

Of the 18 patients enrolled, 16 have had their pre-operative abdominal strength tests completed, 8 from each pre-operative group. All of the measurements taken are explained in depth in the methods section of this report. No significant differences were found between the pre-operative abdominal strength measurements of the SIEA and DIEP groups in any of the variables assessed. All 14 of the patients who have had their reconstructions had pre-operative clinical assessments of their abdomens. From the DIEP group 12.5% (1/8) had an asymmetric umbilicus. From the SIEA group 16.67% (1/6) and 37.5% (3/8) from the DIEP group had abdominal wall asymmetry. No patients from either group had lower abdominal bulging present pre-operatively, but 12.5% (1/8) from the DIEP group had a hernia on clinical examination. In the SIEA group, 66.67% (4/6) and in the DIEP group, 62.5% (5/8) had pre-operative scars on the abdomen. In regards to these pre-operative clinical assessments of the abdominal wall, there were no significant differences between the two groups. Three of the patients from the DIEP group have had their 3 month post-operative follow-up abdominal strength assessments. Due to the fact that only one post-op abdominal assessment (the 3 month assessment) was available and all patients with the 3 month assessment were in the DIEP group the data was analyzed using a series of paired t-tests. Of these 3 patients, two had unilateral reconstructions and one had a bilateral reconstruction. Compared to the means of the pre-operative measurements, all 3 patients showed post-operative decreases in the means of all of the isometric, concentric and eccentric measurements taken. However, only the differences in peak and average peak torque (Nm) of the back extensors at 30° were significant, $t(2) = 4.17, p = 0.05$ and $t(2) = 3.95, p = 0.06$, respectively. There is a trend for there to be a decrease in post-operative peak and average peak torque of the back extensors at 0°, $t(2) = 2.90, p = 0.10$ and $t(2) = 2.79, p = 0.11$, respectively. One of these patients had bilateral DIEP flap reconstruction, while the other two had unilateral DIEP flap reconstruction. Examining the unilateral DIEP patients over time revealed no significant difference on any of the abdominal strength assessments. The bilateral patient had $\leq 5\%$ damage to the rectus muscle on the left side only, the right side did not appear to be damaged. In this patient, one of the nerves to the rectus was also sacrificed. One of the unilateral DIEP flap reconstruction patients had $\leq 5\%$ damage to the rectus and no nerves were sacrificed. The other unilateral patient had no visible damage to the rectus and all nerves were left intact. At this time, none of the SIEA patients have had 3 month follow-up assessments.

Examination of the clinical follow-up data revealed 4 patients (4/14) with complications. Three patients who received DIEP reconstruction (3/11) and 1 patient who received SIEA reconstruction (1/3). Of the DIEP patients, subscarpal fat necrosis was detected in one patient (1/16 DIEP flaps for a rate of 6.25%). There was no flap loss in the DIEP patients but minimal breast wound breakdown was seen in two of these patients. One of these patients also had a hematoma and was put on IV antibiotics. The SIEA patient had a seroma and abdominal wound breakdown. Breast drainage volume for the SIEA group averaged 114.33 ml (SD = 66.53), compared to an average 60.15 ml (SD = 90.79) for the DIEP group. Abdominal drainage volume for the SIEA group had a mean of 158.67 ml (SD = 106.20). The DIEP group had a mean of 106.05 ml (SD = 73.85). Breast and abdominal drainage volumes were not significantly different between the SIEA and the DIEP groups, $t(14) = 0.96, p = 0.35$ and $t(22) = 1.35, p = 0.19$ respectively. The mean number of days spent in hospital for patients receiving SIEA flap

reconstruction (n = 3) was 4.00 days (SD = 0.00), compared to 4.56 days (SD = 1.24) for the DIEP reconstruction patients (n = 11). This difference was not significant, $p = 0.21$.

Discussion:

It is clear that there are advantages and disadvantages to the use of both the DIEP and the SIEA flap for breast reconstruction. Although some of these have been hypothesized, and some demonstrated in previous studies, they have yet to be clearly defined. With the component of randomization in our trial, we hope to further the research base surrounding autologous tissue breast reconstruction and provide guidance for plastic surgeons in their choice of procedure.

In theory because the DIEP flap involves an incision through the rectus fascia, and sometimes some damage to the rectus muscle itself, it should be associated with greater abdominal strength deficits post-op, when compared to the SIEA flap. The reasoning behind this is that the SIEA flap involves no dissection of the rectus muscle or incision through the rectus fascia. In some DIEP cases, the nerve(s) to the rectus muscle are severed as well, which would suggest further strength deficits to be present when compared to SIEA cases and DIEP cases where the nerve(s) are left intact. Overall it is expected that patients from the SIEA group will have less abdominal wall morbidity when compared to patients from the DIEP group in those receiving unilateral breast reconstruction. In patients undergoing bilateral reconstruction, we are expecting to see significantly greater abdominal morbidity in those receiving DIEP/DIEP, than those receiving SIEA/SIEA procedures. Patients receiving the DIEP procedure on one side and the SIEA procedure on the other would be expected to experience morbidity somewhere between that observed in the DIEP/DIEP and SIEA/SIEA patients.

From the extensive literature review performed, we believe this study will go far in adding clean data to a controversial field of research. Many studies have reported on abdominal bulge and/or hernia incidences, some of which compared incidences between different flaps. Some studies have also examined subjective functional post-operative weakness as reported by patients, while others have examined objective muscle strength. The pros and cons and differences in outcomes between TRAM and DIEP flaps has been quite well described, and it is the data surrounding DIEP and SIEA flaps that is lacking. Of the data that is available on this topic, the major limitation is that the majority of these studies are retrospective and lack a comparison group. None of them are randomized.

The best data available describing abdominal wall and breast outcomes in DIEP and SIEA flap patients is that published by Selber et al.^{14,15} They did find differences in abdominal strength between treatment groups, but the differences were not significant across all time intervals, and some of the findings were counterintuitive. So at best, the current data suggests a difference in abdominal wall strength between the two procedures for bilateral reconstruction, but that difference may or may not be clinically relevant. Additionally, in the Selber studies the sample size of patients in the unilateral SIEA group was too small for any meaningful analysis to be done. Our trial improves on this model by randomizing the patients and analyzing other outcomes in addition to the abdominal strength measurements, to provide a more complete

picture of both the donor site and breast complications encountered post-operatively. It is also crucial to note that the studies done by Selber et. al. assessing abdominal strength, were done with subjective measurements using sit up scales to evaluate the patients. Until now, no objective analysis of the SIEA flap compared with DIEP flaps has been performed. Our data is being collected objectively with an isokinetic dynamometer, which has been shown to be an effective way to evaluate post-operative abdominal wall function in previous DIEP vs. TRAM studies, done by Blondeel⁷ and Bonde.¹⁶ In the Selber studies, the post-operative time periods were not clearly defined, being designated as “early” or “late” post-operative. Our trial has a strict follow-up schedule that is closely adhered to, with the abdominal strength measurements being performed as close to 3, 6 and 12 months post-operative as possible. The data published by Selber et al. furthered the debate around SIEA v. DIEP flap reconstruction, and we are aiming to take this another step forward and provide a sound set of data that can hopefully answer these questions definitively.

Although we are expecting the DIEP group to show greater post-op abdominal weakness compared to the SIEA group, it is important to determine how large that difference is, especially whether or not it is significant. We think a difference of 10% between the two treatment groups would be clinically significant. If it is less than that, then this may indicate that surgeon's can be less worried about the functional impact of the DIEP procedure on the rectus. Isokinetic dynamometry can be very specific for rectus muscle strength, and may demonstrate changes in strength that are subclinical. This is one reason why other studies have attempted a more functional approach using sit up performance, as this measurement of abdominal strength may be more relevant to the day to day functioning of the patients. This may represent a limitation in our study. The subjective data being collected from the Breast-Q will help determine whether or not the difference in abdominal strength (if) observed between the two groups is noticed by the patients, and whether or not it is affecting their day to day functioning. A previous study by Wu et al.²⁶ examined SIEA patient's subjective perception of abdominal wall function and rated them more favorable compared to their DIEP flap counterparts. We expect our findings to be similar, further supporting the notion of improved abdominal donor site morbidity with the SIEA flap.

Since it is well known that eccentric contractions involve a greater work intensity than concentric or isometric contractions, if there are strength differences between groups we are expecting there to be a greater difference in eccentric measurements, than the differences in concentric and isometric measurements. As the dissection of the rectus that is performed for the DIEP flap is quite minimal, it is reasonable to assume that the greatest difference in strength, if present, would be between eccentric measurements, as has been suggested by another study comparing abdominal wall morbidity, using the MS-TRAM and DIEP flaps¹⁶, where there was a trend of decreased eccentric strength post-operatively in the DIEP group. Eccentric and isometric muscle strength are of greater functional importance than the concentric activity of the rectus. Since we are including the Breast-Q which assesses the functional impact of the reconstruction, we can see whether or not the differences in muscle strength correlate with differences seen in functional impact between the DIEP and SIEA groups. The eccentric activity of the rectus abdominis forms part of the postural control mechanism that stabilizes and controls the trunk.²⁶ In any activity

involving an external resistance where the trunk is in a position of sustained flexion (e.g. lifting, vacuuming), the rectus is acting eccentrically, in conjunction with the internal oblique and transversus abdominis, to stabilize the pelvis and rib cage and counteract the effects of the external force. The isometric function of the rectus has a similar postural role. In a standing position, gravity acts to flex the trunk and therefore the role of the rectus muscle when working concentrically is of less consequence than when working eccentrically and weakness of concentric contraction can be compensated for.¹⁶ It is for these reasons why it is thought that weakness in eccentric and isometric strength, if demonstrated, will be seen in patients reporting significant functional impairments on the Breast-Q. Even though none of the rectus muscle is being removed with the DIEP procedure, past studies have suggested there may be a detrimental effect on the rectus that cannot be ignored without a proper study. It is possible that scarring within the muscle, caused by the dissection of the perforators reduces its contractile strength. As only a few patients have had their 3 month follow up assessments it is too early to draw any conclusions based off of the abdominal strength data. However, all 3 DIEP patients did show decreases in their post-operative measurements compared to the measurements taken pre-operatively and two of those measurements were indeed significantly lower, suggesting that there is some post-operative strength loss inherent in this procedure. These significant differences were found in the isometric measurements taken on the back extensors at 30°. There was also a trend of decreased isometric strength measurements of the back extensors at 0°. These findings, although extremely early in the trial, suggest that the back extensors may lose strength post-operatively as a result of the DIEP procedure. Whether these decreases are due to the perforator dissection and the damage it can cause, or the post-operative recovery period where the patient is significantly less active than usual is something that still needs to be determined. It is possible that as the number of patients participating in the study swells, that more of the measurements will show significant differences between time periods. It is too early in the trial to comment on the post-operative abdominal strength differences between the two groups.

Most of the serious complications that can arise following reconstruction with DIEP or SIEA flaps are due to venous congestion in the flap. This presents as rapid capillary refill (<1 second) with a blue color to the flap. Since it is suspected that the superficial inferior epigastric vessels tend to have a shorter pedicle length as well as a smaller pedicle diameter, it is reasonable to assume that the flaps utilizing these vessels are on average, at a greater risk of venous congestion and therefore of the complications that follow. Several steps are taken intra-operatively to optimize the flap drainage. The donor and recipient vein are connected utilizing a coupling device. Not only does the coupling device make the anastomosis easier and quicker, it stents the vein open after the vessels are joined. Additionally, when the flap is deepithelialized, the dermis is left in place. This is to take advantage of the dermal plexus to help drain the flap and prevent congestion from occurring. Previous studies have not yet proven higher incidences of venous congestion related complications (fat necrosis and flap loss) with SIEA flaps, and we aim to provide further data to help clarify the frequency with which these events occur and demonstrate how significant the difference is between groups. Although the results of this trial thus far are preliminary, it is important to note that we have not seen a significant difference in the size of the vessels used to support the DIEP and SIEA flaps, nor have we seen significant differences in

pedicle length. Collapsing across flap type, superficial vessels were found in 11 of 14 (78.6%) patients, and these vessels were sufficient to support a SIEA flap in 10/14 (71.4%) of patients. These findings challenge the notion that the superficial vessels (when present) are smaller and insufficient to support a tissue flap in comparison to the sometimes more dominant deep system perforators. They also suggest that the frequency of the superficial vessels is higher than previously reported by Taylor⁸ who found a 35% absent rate, supporting recent publications by Reardon²⁸, citing a higher frequency of the SIEA vessels. This suggests that more patients may be eligible candidates for SIEA flap reconstruction than previously thought. Our preliminary findings also show that previous abdominal surgery/scars are a significant risk factor for the absence or insufficient calibre of the superficial vessels. Perhaps by better defining the criteria for SIEA flap reconstruction and improving on intra-operative algorithms²⁹, plastic surgeons can use this flap more in the future.

The SIEA pedicle passes superiorly and laterally in the femoral triangle, supplying lymph nodes before piercing the cribriform fascia to travel in the subcutaneous tissue superficial to Scarpa's fascia. Dissection of the SIEA pedicle can cause inadvertent damage to the blood supply of the superficial inguinal lymph nodes. Higher rates of abdominal seroma have been reported in SIEA flaps²⁵, and this is likely the cause of the increased drainage volumes seen in SIEA patients post-operatively. The data we are collecting on drainage volumes and seroma rates is expected to support this theory. Preliminary analysis has shown a large difference in the mean drainage volumes for the breast and abdomen between groups, with the higher volumes occurring in the SIEA group. As the study is still very early, the sample size is too small and the standard deviations are too large for these differences to be called significant. However, based on the current data and past research we are expecting these differences to become significant as the sample size increases. It is too early on to comment on other complication rates (fat necrosis, flap loss, abdominal wall complications) between the two groups.

We have identified some challenges in the performance of the research so far. Ours is the first study to date to randomize patients to receive either SIEA or DIEP flap reconstructions. As a result of patient related anatomic features it has been difficult to ensure comparable numbers in each group. It has previously been reported in the classic dissection series by Taylor⁸ that the SIEA was 'absent' in 35% of patients. Additionally, of the patients that do have the SIEA, the caliber may not be sufficient to support a flap, or there may be other factors preventing the surgeon from performing an SIEA reconstruction (e.g. significant size discrepancy between the SIEA and the IMA, with the absence of IMA perforators) that compromises these vessels. For our patients in the SIEA group that are found to not be appropriate candidates for the procedure, we default back to the DIEP procedure and will analyze as intention to treat. The only issue here, is the sample size we may need to achieve in order to have a sufficient number of patients who have undergone SIEA reconstruction to perform a meaningful analysis. However, more recent dissection series by Reardon²⁸ have shown the SIEA vessels to be present in over 90% of patients, with the mean size being 1.9 mm. This suggests that the SIEA is more consistently present and larger in calibre than previously reported. Typically the SIEA needs to be larger than 1 mm for reconstruction with the SIEA flap to be performed. In his practice, the operating

surgeon in the study typically performs over 30% of his breast reconstructions with SIEA flaps, which is much higher than the typical 10% or so for most other practicing surgeons. Due to the high volume of SIEA and DIEP flaps performed at the study site each year (>200), and the relatively large proportion of them that are done as SIEA flaps, we are hopeful that we can continue to randomize the patients to the two procedural groups and still achieve a large enough population of patients who have undergone the SIEA reconstruction for meaningful conclusions to be drawn.

The most obvious limitation in this report is the small sample size currently accrued. This introduces several problems in regards to our analyses. T-tests have several assumptions including homogeneity of variance, normal distribution and independent samples. Although a lot of the data is normally distributed, due to our small sample size not all of the data fits a normal curve, particularly for the SIEA group. Chi-square analyses performed assume there are at least 5 scores per cell, which is also problematic in regards to our sample size. We have currently only recruited and analyzed approximately 15% of our calculated sample size of 91 patients. The work to date should be considered a preliminary report in fulfillment of the B.Sc. (Med.) criteria and no firm conclusions should be made regarding the findings. When we reach the appropriate power level we expect to be able to make some definitive recommendations.

Conclusions and Future Directions:

We believe that this study will go further than others in controlling variability and providing robust data for analysis, by having methodology that is an improvement over those used in previous studies. By collecting data on both donor site and breast complications, we aim to provide sufficient information to clearly delineate the benefits of each procedure. The trial will continue to run until enough data has been collected, at which time a final analysis will be performed. In due course we should be able to make solid recommendations with regards to proper selection of procedures for autologous breast reconstruction.

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Tables and Figures:

1)

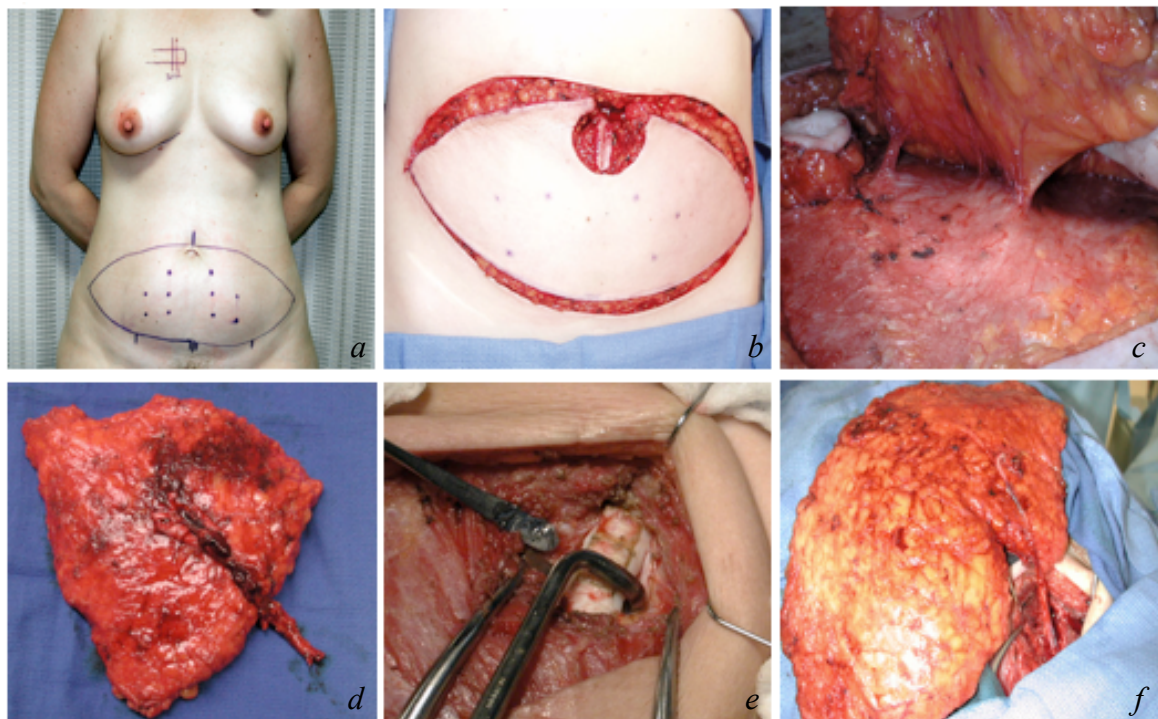


Fig. 1. Key steps in DIEP/SIEA free flap reconstruction. (a) pre-operative markings; the medial and lateral row of perforators as well as the SIEA are dopplered out. (b) skin incisions are made with the umbilicus preserved on a stalk. (c) perforators are dissected out. (d) flap of skin and fat is removed with only the vascular pedicle attached. (e)

dissection of the internal mammary vessels through the 3rd rib costal cartilage. (f) DIEP or SIEA flap vessels are anastomosed to internal mammary vessels.

2)

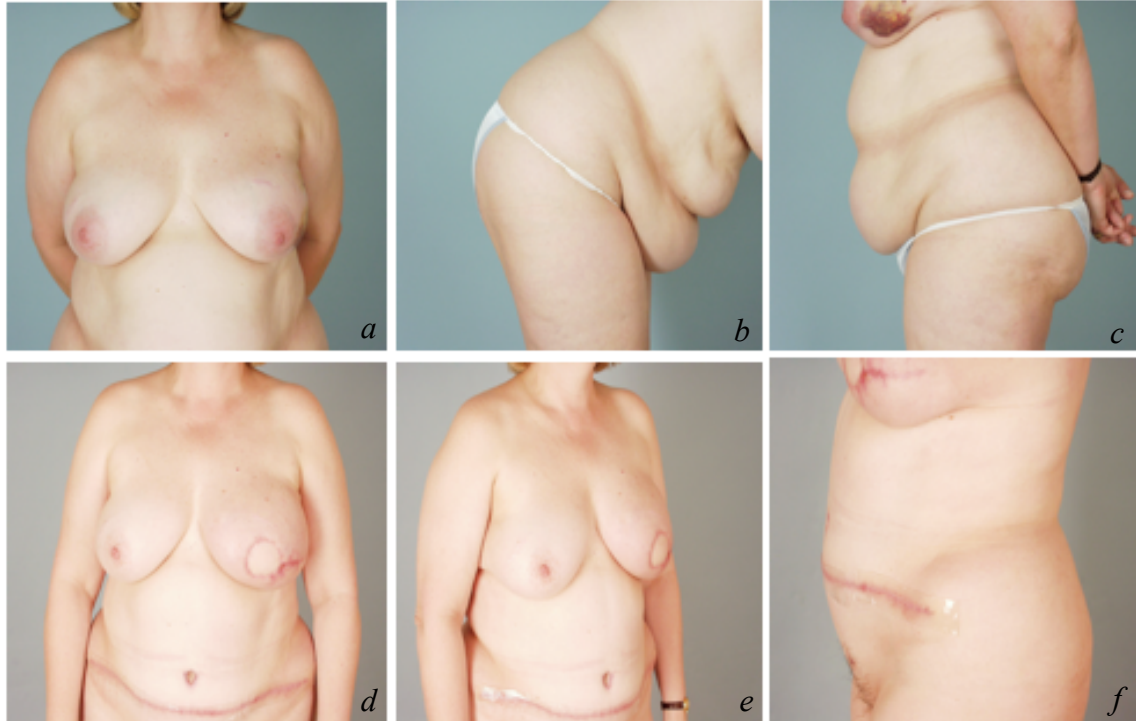


Fig 2. 61 year old patient pre and post-op mastectomy and free DIEP flap. The top row of images (*a to c*) are of the patient before surgery. The bottom row (*d to e*) show the results of the procedure. The surgical scars seen on the bottom row of images are typical of this procedure. Comparing *c* to *e* the additional benefit of the procedure, an improved abdominal contour is quite obvious. She will go on to have her areolas tattooed.

3)

	Concentric	Eccentric	Isometric
Result:	Contraction while the muscle is shortening	Muscle lengthens under constant tension	Muscle contracts at a constant length
Used for:	Trunk flexion	Trunk flexion	Trunk stability
Example:	Sit ups	Lifting, vacuuming	Postural stability, standing

Table 1. Summary of the different types of muscle contractions.

4)

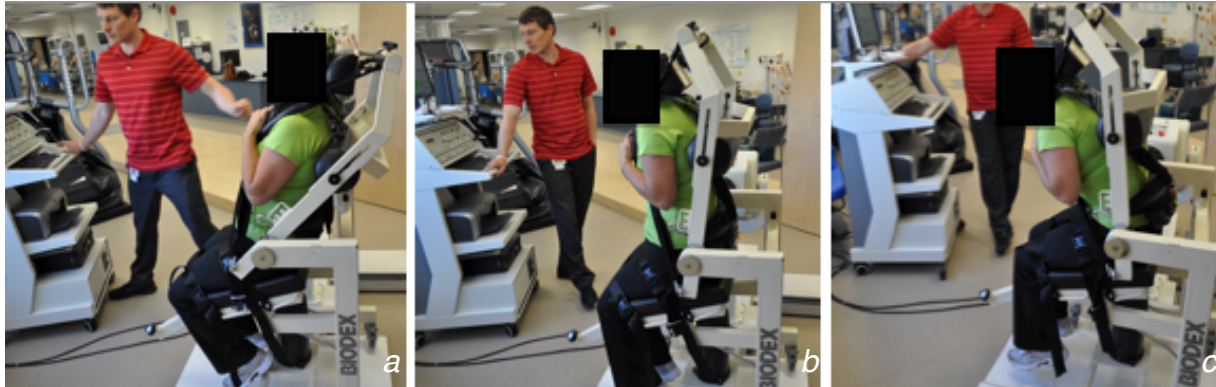


Fig 3. Patient performing abdominal muscle and back extensor muscle strength testing on the isokinetic dynamometer. The equipment in the photos is the Biodex System III with dual position back extension/flexion attachment. (a) 15° extension; position of mechanical advantage for the rectus. (b) 0°; neutral. (c) 30° flexion; end of normal range of trunk flexion performed solely by the abdominal muscles.