PROTOCOL TITLE:

Investigation of a New Skin Closure Device, Dermabond PRINEO, for Total Shoulder Arthroplasty: A Randomized, Controlled Trial

Principal Investigator: Josef K. Eichinger, MD

1.0 Objectives/ Specific Aims

Our study aims to compare the efficacy of a deep-layer, knotless closing method using the Dermabond PRINEO skin closure device (2-octyl cyanoacrylate adhesive glue in combination with self-adhesive polyester mesh tape) to the current practices of wound closure after total joint arthroplasty. While surgeons utilize a variety of incision closure techniques, most use a layered closure with deep fascial closure consisting of interrupted, knotted sutures combined with either staples (Figure 1) or sutures (Figure 2) for superficial closing. In this Phase 4 clinical trial, we hypothesize that the Dermabond PRINEO wound closure system with running knotless sutures for deep and superficial closure) (Figure 3) will significantly reduce closure time in the operating room and achieve similar or better incision healing after shoulder arthroplasty.

Primary aims:

1.1 Aim 1: To quantify differences the time required for wound closure with the PRINEO closure method (Figure 3) and that of traditional closure methods (interrupted deep fascial suture with either subcuticular sutures and traditional Dermabond (Figure 2) or metal staples for superficial closure (Figure 1)

H_0: There are no differences in wound closure times between PRINEO and subcuticular sutures or metal staples in time to close incisions

H_A: There are differences between PRINEO and subcuticular sutures or metal staples in time to close incisions such that staples will be significantly faster than PRINEO and PRINEO will be significantly faster than sutures.

1.2 Aim 2: To quantify differences between PRINEO and subcuticular sutures or metal staples in wound healing over three postoperative follow-up points

H_0: There are no differences between PRINEO and subcuticular sutures or metal staples in wound healing (dehiscence and drainage) over three postop follow-up points.

H_A: There are differences between PRINEO and subcuticular sutures or metal staples in wound healing (dehiscence and drainage) over three postop follow-up points such that PRINEO demonstrates superior healing to both sutures and staples.

Exploratory Aims:

1.3 Aim 3: To quantify differences between PRINEO and subcuticular sutures or metal staples in observer-evaluated and patient-evaluated cosmetic outcomes for the surgical scar over four postoperative follow-up points

H_0: There are no differences between PRINEO and subcuticular sutures or metal staples in cosmetic outcomes over four postop follow-up points.

H_A: There are differences between PRINEO and subcuticular sutures or metal staples in wound healing (dehiscence and drainage) over four postop follow-up points such that PRINEO demonstrates superior cosmetic outcomes to both sutures and staples.

1.4 Aim 4: To quantify differences between PRINEO and subcuticular sutures or metal staples in complication rates (defined as allergic reaction, inflammation, irritation, drainage, or infection)

H_0: There are no differences between PRINEO and subcuticular sutures or metal staples in wound complication rates over four postop follow-up points.

H_A: There are differences between PRINEO and subcuticular sutures or metal staples in wound complication rates.

1.5 Aim 5: To evaluate the overall cost-effectives of PRINEO for wound closure relative to subcuticular sutures and metal staples

H_0: There are no differences between PRINEO, subcuticular sutures, and metal staples in cost-effectiveness over four postop follow-up points.

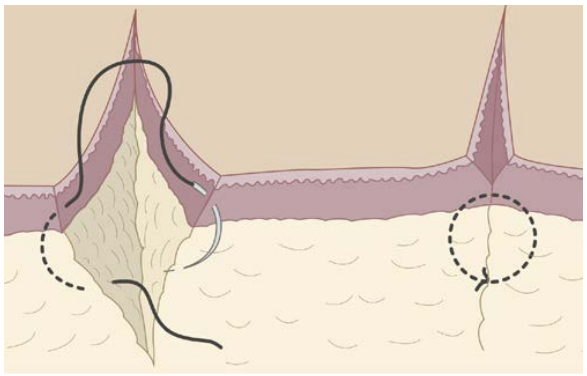
H_A: There are differences between PRINEO, subcuticular sutures, and metal staples in cost-effectiveness such that staples are superior to PRINEO and PRINEO is superior to subcuticular sutures.

2.0 Background

Figure 1. Dr. Richard Friedman treatment arm – control closure system.

Deep layer – interrupted sutures

- Interrupted sutures (0-0 vicryl)
- Placed completely under the epidermal skin layer
- Not removed post-operatively



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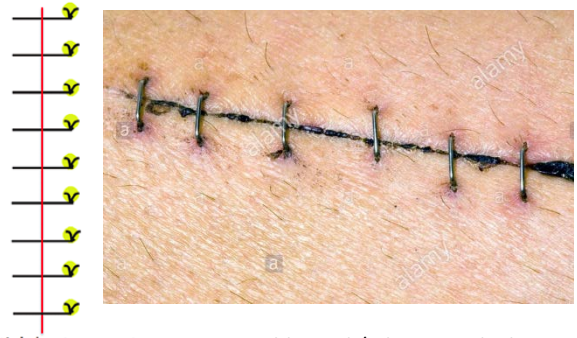
Superficial layer – metal staples

- Removed Post-Operatively 10-14 days



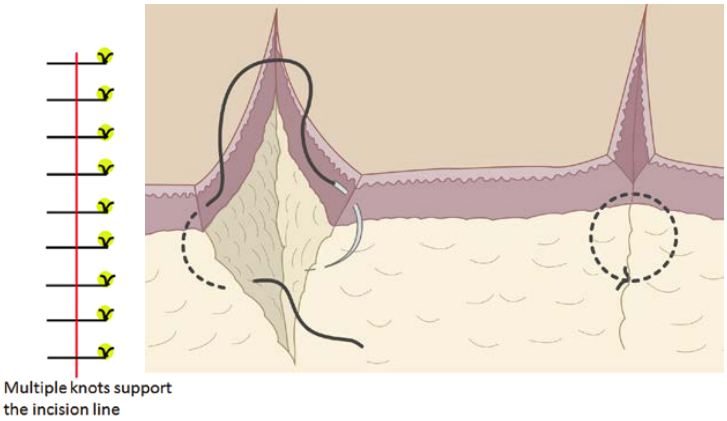
Multiple knots support the incision line

Pablo Paul / Alamy Stock Photo

Figure 2. Dr. Josef Eichinger treatment arm – control closure system.

Deep layer – interrupted sutures

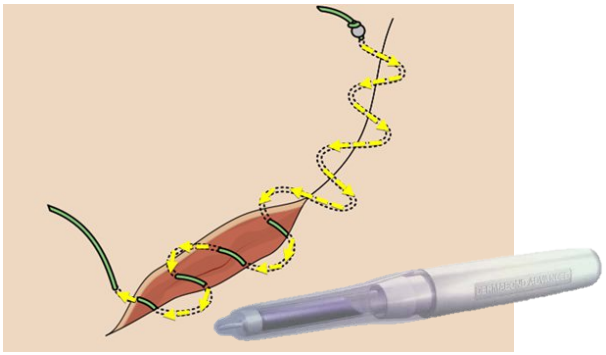
- Interrupted sutures (2-0 vicryl)
- Placed completely under the epidermal skin layer
- Not removed post-operatively



Subcuticular suture. Wikimedia Commons.
Dermabond, Sutureonline.com

Superficial layer - subcuticular sutures

- Running, subcuticular sutures (~~32~~-0 Stratafix)
- Traditional Dermabond applied to incision



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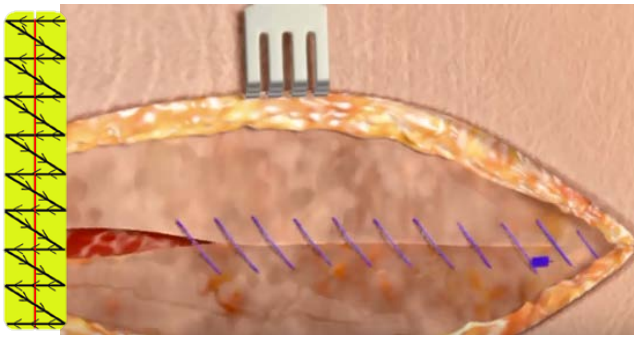
Adapted from Yasuda et al (2017)

Figure 3. Dermabond PRINEO closure system.

Deep layer – running sutures

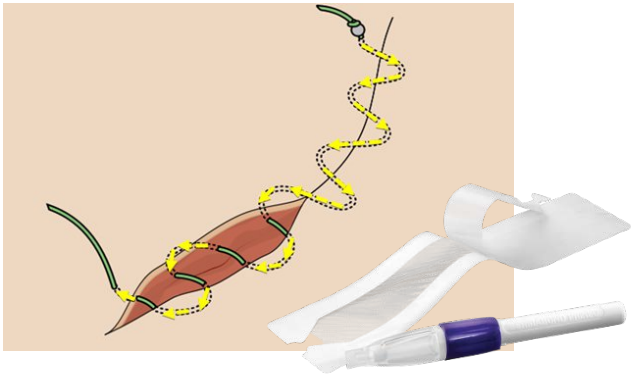
- Running, unidirectional sutures (2-0 Stratafix)
- Placed completely under the epidermal skin layer
- Not removed post-operatively



Adapted from Stratafix Best Practices Video, Youtube
Adapted from Yasuda et al (2017)

Superficial layer –
subcuticular sutures + Dermabond PRINEO

- Running, bidirectional sutures (3-0 Stratafix)
- Dermabond PRINEO (60cm) or (22cm)



Subcuticular suture. Wikimedia Commons
Dermabond PRINEO, ethicon.com

A wound closure system requires proper closure of both deep and superficial tissue. Traditionally, knotted (interrupted) sutures are used for deep layer closures, in combination with either staples or subcuticular sutures for superficial skin closure. However, tissue adhesives such as Dermabond PRINEO act as an effective microbial barrier and effectively prevents wound dehiscence. With Dermabond PRINEO, running sutures can be used for both deep and

superficial closing, saving significant time. In this proposal, we define the PRINEO skin closure system as one that uses running unidirectional sutures for deep layer sutures and running bidirectional suture for superficial skin closure, followed by the Dermabond PRINEO with Medipore and 4x4 cotton gauze as additional wound dressing.

Tissue adhesives like PRINEO are well-researched as alternatives for wound closure [1-5]. The common tissue adhesive, 2-octyl cyanoacrylate (OCA), has been used in surgical procedures since the 1950s and was FDA approved for use in wound closure in 1998 [6]. The OCA adhesive has been shown to reduce operating time, produce similar or improved cosmetic outcomes, similar or improved dehiscence and infection rates, and concurrent reduction in costs relative to the standard subcuticular suture method of closure [7-10]. The adhesive is also more flexible, allowing for easier application to incisions which span the joint [11].

Although the PRINEO system is not uncommonly used for wound closure after joint replacement, there is limited research to document the relative outcomes of a PRINEO closing system in contrast to other methods. This prospective study will randomize shoulder arthroplasty patients to wound closure with the PRINEO adhesive-mesh system, metal staples, or by subcuticular system to determine the relative efficacy, safety, and cosmetic outcomes of the Dermabond PRINEO system for the shoulder. As the delto-pectoral incision for shoulder arthroplasty can be a visible scar and the shoulder joint is highly mobile, the successful implementation of the PRINEO system may have substantial effects on patient satisfaction with their wound healing and surgical scar.

The efficiency and outcome of wound closure has also significance to operating room and clinic staff alike. Improving efficiency of wound closure, which may be particularly time consuming for long incisions in major surgery such as joint replacement, has cumulative effects in improving operating room flow and schedule adherence, and potentially, allowing for additional caseload. Removing sutures post-operatively may also be a time consuming process for clinic staff, in addition to being a source of discomfort for patients [1]. For this reason, interventions to optimize wound closure and ease of care are a highly relevant area of research.

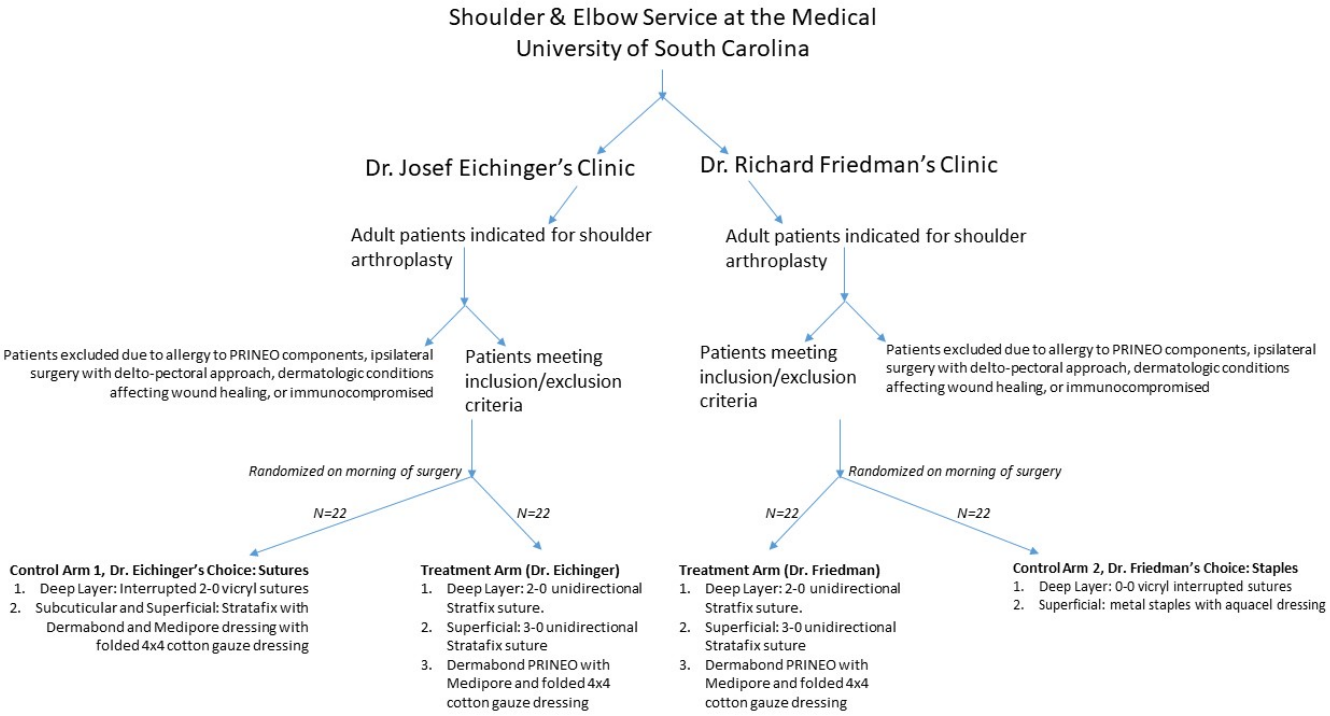


Figure 4: Outline of study design

3.0 Intervention to be studied

Specifically, in the 510(k) cleared Dermabond PRINEO skin closure system (Ethicon Inc.), the 2-octyl cyanoacrylate adhesive is used in combination with a polyester mesh tape, either 22cm or 60cm in width. This mesh tape is designed to provide for tighter sealing of the incision and may further protect against discharge in more mobile wounds. Use of the tape may strengthen the wound closure and also simplify and improve alignment and apposition of wound edges [[12] and Ethicon internal testing]. Several prospective randomized, controlled trials have demonstrated consistently lower wound closing times and equivalent or significantly improved cosmetic outcomes and complication rates with this system [13-16]. More flexibility in application due to "body-contouring" has also been noted [17]. Observational studies of the PRINEO system report success use of the device as evaluated by surgeon and patient satisfaction [11, 17, 18]. Research of the PRINEO system used after total joint replacement are at present limited to retrospective studies [11, 18] and case reports of allergic reactions [19, 20].

Dr. Richard Friedman currently closes incisions after shoulder arthroplasty with metal staples, and Dr. Josef Eichinger currently closes incisions after shoulder arthroplasty using subcuticular sutures with Dermabond. Both surgeons use interrupted deep-layer sutures. This study will consist of two parallel comparisons to these distinct control arms. The PRINEO closing method, which utilizes running deep and superficial sutures with Dermabond PRINEO, will be directly compared to each surgeon's wound closure technique, as half of each surgeon's patients will be randomized to the PRINEO treatment condition while the other half continue to undergo wound closure with the current technique utilized by the

surgeon. This will result in two parallel treatment arms and two distinct control arms (Fig. 1). Both surgeons have significant experience in the application of Dermabond PRINEO for wound closure.

4.0 Study Endpoints

The duration of wound closure is primary endpoint for this study. Wound closure timing outcomes will be collected in the operating room towards the conclusion of each surgery. Closure time is the time between the first stitch for closure and the completion of application of dressing to the wound. The incision length will be measured to calculate time per centimeter.

Cost per minute of operation time is another endpoint for the study. It will be conservatively approximated using existing reports of personnel capacity rates for orthopaedic surgeon. Cost-effectiveness analysis will be conducted by comparing the total cost of all wound closure materials for each technique, and a cost per minute applied to wound closure time.

Wound outcomes, both clinical and cosmetic, will be another primary endpoint for this study. Patient-centered outcomes for wound and scar evaluation will be collected at 6 weeks and 3 month postoperative appointments in clinic. These outcomes will be measured using the Modified Hollander Cosmesis Scale [14, 21], the Patient and Observer Scar Assessment Scale (POSAS) [14, 22, 23], and the Acute Inflammatory Response Evaluation (AIRE) score as described in the 2015 study by Blondeel et al [14].

5.0 Inclusion and Exclusion Criteria/ Study Population

All adult (18 and older) patients undergoing primary total shoulder arthroplasty by Dr. Josef Eichinger or Dr. Richard Friedman will be considered for the study. Patients will be included if they are willing and have the capacity to provide informed consent, and if they expect to continue their post-operative follow up care with their operating surgeons at MUSC.

Subjects will be excluded if:

- They have a unique, identifying tattoo or skin marking within 2 inches of intended site of surgical incision
- They self-report a known hypersensitivity to cyanoacrylate, formaldehyde, benzalkonium chloride, or pressure sensitive adhesive;
- They self-report or have a documented prior ipsilateral shoulder arthroplasty or other open ispilateral shoulder surgery utilizing the delto-pectoral approach;

- Their medical record shows that they are HIV positive or otherwise immunocompromised;
- Their medical record shows a skin abnormality or dermatological condition which affects skin healing;
- They report a personal or family history of significant keloid or significant hypertrophic scar formations, or other problems with wound healing.

6.0 Number of Subjects

A total of 88 patients, with 22 in each treatment group, will be enrolled. With a treatment and control arm for each surgeon, this results in a total of 44 patients in a treatment arm and 44 in a control.

7.0 Setting

All research will be conducted at sites within the Medical University of South Carolina (MUSC) in Charleston, SC

8.0 Recruitment

Only patients of the treating physicians (Dr. Eichinger and Dr. Friedman) who are indicated for total shoulder arthroplasty and meet all inclusion and exclusion criteria will be recruited. The treating physicians (either Dr. Eichinger or Dr. Friedman) will determine eligibility based on the indication for surgery and the patient's medical history. Recruitment restricted to the surgeons' patient base only.

9.0 Consent Process:

After patient's eligibility is confirmed, patients will be approached by either the treating physician or other study staff to obtain informed consent. The consent process will take place in their private clinic room.

There will be no dedicated waiting period between informing the subject of the study and obtaining consent. Patients who express interest in participating will then review the consent document with a member of the research team, who will explain the study and answer any questions that the patient has. They will be told that by signing they understand and are agreeing to the nature of the study but that consent is voluntary and can be withdrawn at any time. To ensure proper understanding, patients will be asked to summarize main components of the study, e.g. types of data collected and post-operative clinic visits. HIPAA authorization will be obtained with informed consent.

Once the patient signs consent he/she will be given a copy of the signed form for his/her records.

10.0 Study Design/ Methods

Randomization will take place the morning of surgery based on a randomly organized, computer-generated order.

Patients in Dr. RJ Friedman's clinic will be randomized to one of two treatment conditions for wound closure after shoulder arthroplasty: 1) deep layer closure with 0-0 vicryl interrupted sutures followed by superficial skin closure with metal staples with aquacel dressing and 2) deep layer closure with a running 2-0 unidirectional Stratafix suture followed by superficial closure with subcuticular bidirectional 3-0 Stratafix suture followed by the Dermabond PRINEO (60cm or 22cm polyester mesh and 2-octyl cyanoacrylate adhesive) with Medipore and folded 4x4 cotton gauze dressing.
Patients in Dr. JK Eichinger's clinic will be randomized to one of two treatment conditions for wound closure after shoulder arthroplasty: 1) deep closure with interrupted 2-0 vicryl sutures followed by a running subcuticular bidirectional 3-0 Stratafix with Dermabond and Medipore dressing with folded 4x4 cotton gauze dressing and 2) deep layer closure with a running 2-0 unidirectional Stratafix suture followed by superficial closure with subcuticular bidirectional 3-0 Stratafix suture followed by the Dermabond PRINEO (60cm or 22cm polyester mesh and 2-octyl cyanoacrylate adhesive) with Medipore and folded 4x4 cotton gauze dressing.

The rationale for investigating the current practice of deep closure with interrupted sutures is as follows: Using running suture introduces a potential risk of wound dehiscence if the suture fails at any juncture despite the presence of the barbs. The Dermabond PRINEO represents a powerful closure mechanism that in all probability eliminates the risk of wound dehiscence regardless of the skin closure method. Therefore, using a rapid wound closure method with deep layer running sutures is now a possibility with the Dermabond PRINEO that was not available before.

Patients will not be made aware of the treatment they are randomized to until their first follow up visit or when wound dressing is removed to reveal the device used for wound closure.

At the conclusion of the surgery, the assigned wound closure technique will be implemented. The following data points to measure the primary outcome, wound closure efficiency, will be collected in the operating room:

1. Total operating time in minutes and seconds, from the first incision to the application of wound dressing.
2. Total time for wound closure in minutes and seconds, from the first stitch for closure to the application of wound dressing.
3. The incision length in centimeters

4. The cost of materials utilized for wound closure (suture, Dermabond, PRINEO, staples, dressings, etc.)

All patients will be seen in clinic 2 weeks post operatively during which time the wound closure technique (sutures, or staples) will be removed by a nurse according to the manufacturer and standard technique. The patients who are randomized to ~~o~~ Dermabond PRINEO will be instructed to keep their polymer mesh on for an additional 2 weeks after their 2 weeks visit. Any complications such as drainage, acute inflammation, or signs of infection will be recorded at this time and treated per clinical standards. The following data points to measure wound clinical and cosmetic outcomes, will be collected at 6 weeks and 3 months postoperatively:

1. mHCS score
2. AIRE score
3. POSAS score
4. Complications and adverse events

mHCS, AIRE, and POSAS scores are all dependent on aspects of the physical exam, such as evaluation of pliability, temperature, edema, pain, and contour. To mitigate any observer bias, all incisions will be photographed and additionally evaluated by a plastic surgeon (MLT) blinded to the treatment condition using the POSAS-Observer characteristics which may assessed through standardized photography alone (Vascularity, Pigmentation, Thickness, Relief, Surface Area, and Overall Opinion).

A medical record review will also be performed to collect the following data:
Age; gender; BMI (including height and weight), race, diabetes status (type, insulin dependency, years diagnosed); history of smoking/tobacco use; frequency of alcohol consumption.

11.0 Data Management

Justification of sample size:
The Cohen's effect size of 0.93 corresponds to a difference of means of 7.5 minutes with a pooled standard deviation of 8 minutes. The PI has determined that a difference of 10 minutes will be the minimum significant difference for clinical and economic relevance. 5 minutes alternatively would be an irrelevant amount of time savings. Therefore, designing the investigation to detect 7.5 minutes would ensure that we would determine if 10 minutes difference exists between the different wound closure techniques. Economically, at an estimated cost of $30 per minute of operative time [24], this corresponds to $300 saved per procedure. Ten fewer minutes of operative time across six consecutive shoulder arthroplasties would save an hour total of operative time, which allows for the possible inclusion of a seventh surgery in the operative room schedule.

In our study, differences in time to closure between the groups will be compared by two-sample T-tests for independent means. With a Cohen's effect size of 0.93, a standard

alpha of 0.05 to determine statistical significance, and a target power of 0.80, an apriori power analysis indicates 76 total for the sample size, or 19 per group. A sample size of 88 total patients, with 22 in each group (two parallel treatment arms and two distinct control arms each representing surgeon's choice), will ensure sufficient power to detect economically relevant, statistically significant differences in time to closure outcomes between the three wound closure methods, while leaving room to accommodate patients who withdraw from the study or are lost to follow up.

Data storage and management:
As multiple data points will be collected for each patient over the course of their treatment, an enrollment log will be established, assigning patients unique identifiers, and a data sheet will be started where the total operating time, the wound closure time, the cost of wound closure, and the incision length will be recorded. Furthermore, the mHCS score, the AIRE score, the POSAS scores, and complications will be recorded in this data sheet for each postoperative visit to the clinic (at 6 weeks and 3 months).
Upon enrollment, patients will be assigned unique identifiers to be used in statistical analysis. Enrollment logs, data sheets and photographs will be electronically stored within a MUSC password protected secured computer, in a MUSC supported password-protected digital folder, accessible only to the members of the research team. Copies of consent forms, visit report forms, and adverse event forms will be stored in a locked cabinet in a locked room on the Medical University of South Carolina campus in downtown Charleston, SC. If a patient has a unique, identifying tattoo near his/her incision site, the tattoo will be avoided during photographing or blurred out digitally before storage. If the tattoo is within 2 inches of the site and therefore difficult to avoid or blur without compromising the image quality of the wound, the patient will be excluded from the study.

Data analysis plan:
Data from patients' medical records to be included in the data sheet to include as covariates during data analysis will include age, gender, BMI, race, diabetes status, history of smoking/tobacco use, and alcohol consumption. The differences in mHCS, AIRE, and POSAS scores between treatment groups will be tested through ANOVA tests and subsequent Tukey-HSD post-hoc tests, and difference in complication rates will be evaluated by Chi-square tests. Analysis will be conducted on MUSC registered computers through IBM SPSS 25.0.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects (if applicable)

Adverse events will be collected at follow up visits and PI will review them regularly and report them per MUSC IRBs policy.

13.0 Withdrawal of Subjects (if applicable)

Subjects may opt to withdraw from the study at any time point between enrollment and the conclusion of data analysis. Patients can withdraw from the study by communicating their desire to do so through email, over the phone or in person with any study team member.

14.0 Risks to Subjects

There are no additional risks to subjects in the subcuticular sutures and metal staples (control) treatment arms. For these control groups, the only potential risks to subjects arise from the standard of care for shoulder arthroplasty wound treatments.

However, there is risk associated with randomization to the treatment group. PRINEO is a well-established and widely available method of wound closure. While several case reports of allergic contact dermatitis reactions after use of PRINEO for wound closure have been published, the overall rate of allergic reaction remains fairly low (between 0% to 1.8% in the literature) [19, 20, 25, 26]. Cases of contact dermatitis around the incision have been successfully managed with topical and oral steroids and have not resulted in a higher risk for superficial or deep wound infection [20]. Nonetheless, all patients will be informed of the risk of allergic reaction, will be excluded based on prior history of hypersensitivity to cyanoacrylate, formaldehyde, benzalkonium chloride, or pressure sensitive adhesive, and will be monitored closely at their 2 week follow up appointment to promptly manage any signs of irritation, blistering, or inflammation. Any adverse event experienced by patients in the experimental arm will be addressed per the standard clinical treatments.

There is also a risk of loss of confidentiality which will be mitigated by coding the research data set and storing study data securely. Finally, there might be unknown risks of using PRINEO on the shoulder that will be monitored throughout the study.

15.0 Potential Benefits to Subjects or Others

Patients assigned to the control treatment arms will not receive any additional benefits from participating in the study. Patients randomized to the PRINEO treatment arm may benefit from less time in the operating room and greater ease of care postoperatively, such as reduced pain and no need to remove suture or staples at the first postoperative appointment. Prior randomized, controlled clinical studies of the PRINEO closure system have demonstrated that use of the system is associated with shorter operating times, equivalent or lower complication rates, and equivalent or improved cosmetic outcomes [13-16].

16.0 Drugs or Devices (if applicable)

The PRINEO system, subcuticular sutures, and metal staples are all readily available at MUSC operating room settings and are commonly used by various surgeons in these settings.

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