Evaluation of Wound Healing After Direct Anterior Total Hip Arthroplasty With Use of a Novel Retraction Device

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It is thought that, by placing more emphasis on soft-tissue preservation, minimally invasive surgery total hip arthroplasty (MIS-THA) results in less soft-tissue trauma, less blood loss, and earlier recovery.\(^1\)\(^-\)\(^3\) Despite these improvements over standard methods, there is a concern that the vigorous retraction needed for proper visualization through smaller incisions could injure soft tissues.\(^4\)\(^-\)\(^7\) Single-incision direct anterior THA (DA-THA) has gained in popularity because of the true intermuscular/internervous plane through which the procedure can be performed with relatively minimal muscle dissection using MIS techniques.\(^8\)\(^,\)\(^9\) This approach may offer quicker recovery and superior stability in comparison with nonintermuscular methods, which unavoidably cause more muscle damage.\(^10\)\(^-\)\(^12\)

Although the evidence of these early gains is encouraging, several studies have found high complication rates with DA-THA.\(^8\)\(^,\)\(^13\)\(^-\)\(^17\) Noted disadvantages include a steep learning curve, lateral femoral cutaneous neurapraxia, need for a specialized table, and higher fracture and wound complication rates. Not surprisingly, with increased surgeon experience, the complication rate decreased substantially.\(^14\)\(^,\)\(^15\) However, wound-related complications remained steady, with 2 recent large studies reporting rates of 4.6% and 2.1%.\(^14\)\(^,\)\(^15\) The thin anterior skin, high tensional forces along the groin crease and perpendicular to the typical DA incision, and less resilient soft-tissue envelope are postulated reasons for wound-related issues, which are likely magnified in patients who are more obese.\(^15\)\(^,\)\(^16\)

A novel device designed to lessen tissue damage is the ring retractor (Figure 1). Used initially in general surgery and obstetrics, it consists of 2 semirigid polymer rings connected by a flexible cylindrical polymer membrane.\(^18\)\(^-\)\(^20\) The lower ring is tucked and anchored underneath the wound edge, and then the upper ring is rolled down and cinched onto the skin. The resultant tension on the polymer sleeve—imparted by the rigidity of the ring—provides strong, evenly distributed wound-edge retraction. It also provides a physical barrier between the wound edge and the rest of the operative field. Proponents of the ring retractor claim increased wound-edge moisture, less bruising, and reduced local trauma compared with standard metal retractors alone.
Wound-edge retractor forces are doubled during MIS-THA compared with conventional THA. This may explain reports of worse scar cosmesis with MIS-THA. Given the theoretical benefits of minimized wound-edge trauma, the ring retractor may improve scar appearance compared with standard retraction alone. Any clinically relevant effect on cosmesis should be readily apparent to justify use of the retractor in this regard. Although some surgeons routinely use the device for primary THA, it has not been the subject of any recent orthopedic studies.

In the present study, we prospectively investigated wound cosmesis with and without use of the ring retractor in patients undergoing DA-THA.

**Materials and Methods**

This prospective, single-center, randomized study was reviewed and approved by the institutional review board at our facility. Consent was obtained from all participating patients.

We evaluated 50 surgical incisions in 48 patients. Eligible participants were over age 18 years and undergoing primary DA-THA. Exclusion criteria included previous surgery on the affected hip, a pathological hip condition requiring an extensile exposure, systemic inflammatory illness, chronic corticosteroid use, and dermatologic abnormality of the incisional area. One patient was having simultaneous bilateral THAs, and another was having staged bilateral THAs. Each hip in these patients was given its own case number and treated separately. Of the 49 patients who met all the inclusion criteria, only 1 decided not to participate (Figure 2).
Stratified randomization with permuted block size (sex, body mass index [BMI]) was used to assign patients in a 1:1 ratio to either the treatment group or the control group. In the treatment group, the Protractor Incision Protector and Retractor (Gyrus ACMI, Southborough, Massachusetts) was used with standard metal retractors. In the control group, only standard metal retractors were used. Patients were blinded to their group assignments, and surgeons were informed about each assignment only after the initial incision was made.

Clinical research investigators were blinded to the groups’ prospectively collected data. Collection time points were preoperative clinical visit, day of surgery through discharge, and 2-, 6-, and 12-week postoperative follow-ups. Day-of-surgery data included estimated intraoperative blood loss, operative side, operative time, intraoperative complications, and American Society of Anesthesiologists (ASA) physical status classification. Total length of stay, pain scores (range, 0-10), estimated drain output, and blood-transfusion data were also recorded. To evaluate whether the device had any effect on short-term functional outcome, we collected Harris Hip Scores (HHS) and Short Form–12 (SF-12, Version 2) scores at the preoperative and 6-week postoperative visits. We also documented any wound-healing-related issues or complications that occurred up until the final visit.

To account for any effect of nutrition status on wound healing, we obtained pre-albumin and albumin levels and absolute lymphocyte counts from the preoperative electronic records. We used an albumin level under 3.5 g/dL and an absolute lymphocyte count under 1500/µL for our analysis, as these cutoffs have been associated with wound complications after primary THA. There is no similarly established threshold for pre-albumin level, so we used values under 20 mg/L based on comparable literature.

At each postoperative visit, standardized high-resolution images were obtained. At the 12-week visit, patients completed 2 Likert scales regarding their overall opinion of their scars and how their scars compared with their expectations. They also ranked 5 separate THA-related outcomes in order of importance (Appendix).

Photographs were evaluated by 2 blinded plastic surgeons (Dr. Friedman and Dr. Jack) using 2 grading systems—the Stony Brook Scar Evaluation Scale (SBSES) (Table 1) and a modified Manchester Scar Scale (MSS) (Table 2). We used these systems because they were photograph-based, psychometrically studied, and specifically designed to assess surgical incision healing with established validity and reliability. A particular advantage, strictly related to cosmetic outcome, is their validity in scoring scars from high-definition photographs in a different place or time. The SBSES, an ordinal wound evaluation scale that measures short-term cosmetic outcomes, consists of 6 items, each receiving 1 or 0 point, yielding a total score between 0 (worst) and 5 (best). The modified MSS includes a visual analog scale (VAS), which has a vertical hash marked on a 10-cm line and is scored between 0 (excellent) and 10 (poor) to 1 decimal point. This value is added to grades on color, surface appearance, contour, and distortion, resulting in a score between 4 (best) and 24 (worst). The primary outcome
measures were Likert-scale responses obtained at final visit and SBSES/MSS scores for each visit; 12-week scores were the primary end point.

**Operative Procedure**

Experienced fellowship-trained orthopedic surgeons performed all procedures. A modified Hueter approach was used for exposure. Mean incision length was about 12 cm. For the treatment group, the ring retractor was inserted at the level of the tensor fascia, with the inferior ring resting between the fascia and the subcutaneous layer and the superior ring cinched over the skin (Figure 3). The device is made in 4 different sizes for incisions from 2.5 to 17 cm; our study population required only 1 size. Otherwise, the surgical protocol was based on that described by Matta and colleagues. Wound closure (over a drain) was performed according to a standardized protocol—running No. 1 Vicryl suture for the superficial tensor fascia, interrupted 2-0 Vicryl for the deep dermal layer, and subcutaneous 4-0 Monocryl for the skin followed by application of Dermabond (Ethicon, Somerville, New Jersey) and Tegaderm +Pad (3M, St. Paul, Minnesota) for outer dressing, which was replaced on postoperative day 2 and removed at the 2-week visit.
Statistical Methods

An a priori sample-size calculation was performed. Power performed in a base of a prior study that evaluated anterolateral and posterolateral THA scars using a VAS, a component of the MSS, suggested a sample size of 16 per group to detect the minimal clinically important difference of 1.5 cm: SD (σ) = 1.5 cm, α = 0.05, β = 0.20.29,30 In addition, a general estimate for detecting a 1-unit change on an ordinal scale (σ = 1.0, α = 0.05, β = 0.20) resulted in the same number. We conservatively decided to enroll 25 patients per arm in case of larger true variance.

The Wilcoxon rank sum test was used for comparisons of continuous data between groups. Differences between means were analyzed with 2-sided t tests. Categorical data were compared with the Pearson χ² test or the Fisher exact test, as indicated. Ordinal ranking scores were compared with the Mantel-Haenszel test. Multivariate logistic regression was applied to identify the significant independent predictors of better scar grades for each surgeon by considering candidate variables with Ps < .20 in the univariate analysis.

Results

We found no differences in demographic or perioperative characteristics between treatment and control groups (Tables 3, 4). The groups showed similar mean improvements in their respective 6-week HHS (38.7 and 36.4 points; P = .65), SF-12 physical component summary scores (11.8 and 14.5 points; P = .37), and SF-12 mental component summary scores (5.1 and 3.7; P = .70).
Patient questionnaire outcomes are listed in Table 5. For the control group, 25/25 image sets were obtained at the 2-week visit, 25/25 at the 6-week visit, and 24/25 at the 12-week visit. For the treatment group, there were 23/25, 24/25, and 23/25 images sets, respectively.
When surgeon scoring was analyzed separately, SBSES and MSS scores were similar between treatment and control groups, with 1 exception: 2-week MSS scores were better for the treatment group according to surgeon A \((P = .026)\). When grades were averaged, SBSES scores were again similar at all time points (Figure 4A); MSS scores were better for the treatment group at 2 weeks \((P = .036)\) and equivalent at all other time points (Figure 4B). For the SBSES, Spearman correlation coefficient \(\rho\) with 95% confidence interval (CI) was 0.37 \((95\%\ CI, 0.08-0.66)\) at 2 weeks, 0.48 \((95\%\ CI, 0.20-0.76)\) at 6 weeks, and 0.62 \((95\%\ CI, 0.33-0.91)\) at 12 weeks. Following the same pattern for the MSS, \(\rho\) was 0.20 \((95\%\ CI, -0.09 to 0.49)\), 0.51 \((95\%\ CI, 0.23-0.79)\), and 0.32 \((95\%\ CI, 0.03-0.61)\).

Independent multivariate analysis revealed that age over 65 years was a significant predictor of worse scores. On SBSES, the odds ratio (OR) was 1.15 \((95\%\ CI, 1.07-1.24)\) for surgeon A and 1.11 \((95\%\ CI, 1.05-1.18)\) for surgeon B. On MSS, the OR was 0.89 \((95\%\ CI, 0.84-0.94)\) for surgeon A and 0.95 \((95\%\ CI, 0.91-0.99)\) for surgeon B. The likelihood of having worse SBSES scores according to surgeon A was 4.72 times higher if the pre-albumin level was under 20 mg/L \((95\%\ CI, 1.15-19.36)\). Albumin level under 3.5 g/dL and absolute lymphocyte count under 1500 cells/µL were not found to be independent predictors of poorer scores.

Patients’ overall opinion \((P = .63)\) and assessment of their scars relative to expectations \((P = .25)\) on the Likert scales were not different between groups. More scars exceeded patients’ expectations and had more excellent ratings in the control group. The 2 groups were similar with regard to relative importance of various patient-related outcomes. Factors most important to overall outcome were relief of hip pain, followed by implant longevity and length of recovery. Least important were incision-related variables.
There were only 3 minor noninfectious wound complications (6%), 2 in the treatment group and 1 in the control group. In the treatment group, a 67-year-old man with diabetes (ASA class III; BMI, 32.1 kg/m²; received transfusion) had 2 small areas (<5 mm) of superficial ulceration at 6-week follow-up—one at the proximal aspect of the incision and the other near the midpoint along the flexion crease. Both lesions resolved by 12-week follow-up. Also in the treatment group, a 77-year-old woman (ASA class II; BMI, 24.9 kg/m²; received transfusion) at 6 weeks had a spitting suture, which was removed in clinic without further issue. In the control group, a 55-year-old woman (ASA class II; BMI, 27.4 kg/m²) had a suture reaction near the proximal aspect of her incision 3 weeks after surgery. This reaction, which presented as a mild, localized erythema without pain, tenderness, or drainage, resolved by 6-week follow-up. None of these wound complications required intervention beyond observation.

**Discussion**

This study was designed to provide a bipartisan measure of wound-healing cosmesis after DA-THA. Scar evaluation by blinded plastic surgeons served as a standardized, clinical assessment, whereas the patient questionnaire offered a more subjective appraisal. The modified MMS\textsuperscript{25} and the SBSES\textsuperscript{24} are the only 2 wound-grading systems designed and validated for photographic assessment of postsurgical scars. Most scar evaluation schemes pertain to burn or traumatic scars.\textsuperscript{26,27,31} As a result, many earlier studies intending to compare incisional scars used poorly suited evaluation systems.

The current literature includes reports on 3 studies with scoring-based scar assessment in THA; all used grading systems designed for either burns or traumatic wounds, but 2 also used a VAS.\textsuperscript{32,34} VASs have been validated for measuring wound cosmesis but are entirely subjective and without structure and provide no feedback as to why a scar was rated good or bad.\textsuperscript{24} Mow and colleagues\textsuperscript{32} prospectively compared scars after standard posterior or MIS approaches and found no differences according to a scoring system intended for burn scars. In our study population, we found no group differences in patients’ cosmesis of their scars.

Although scars can take a year or longer to fully mature, researchers from the University of Michigan discovered that scar appearance at 1 year correlates highly with cosmesis 12 weeks after closure, though poorly with cosmesis 10 days after closure.\textsuperscript{25} Therefore, any observed differences in scar cosmesis between groups at 12-week follow-up would likely persist, whereas differences at 2-week follow-up would have little bearing on ultimate appearance. For this reason, our primary outcome measure was healing process and cosmesis at 12 weeks. High wound complication rates have been reported for MIS-DA-THA.\textsuperscript{8,14-16} Jewett and Collis\textsuperscript{15} noted a 4.6% wound complication rate (3% noninfectious ulcerative dehiscence, 1.6% superficial infection), which is comparable to the 6% rate found in this study. However, there likely is some variability across studies in what constitutes a wound complication or superficial infection. Of our 3 wound complications—stitch reaction, spitting suture, small noninfectious ulceration—only the ulceration was of a severity similar to that reported by Jewett and Collis.\textsuperscript{15} Matta and colleagues\textsuperscript{8} reported only 3 wound complications (in 494 patients), all severe enough to require operative intervention. One explanation for this low complication rate is use of a ring retractor, as it is routinely depicted in their technique paper. However, no specific reference is made to gauge how often the device was used.

Rates of superficial infection after DA-THA range from 0.6% to 1.6% in 3 large observational studies (combined deep infection rate, 0.43%).\textsuperscript{8,14,15} In 2 of these studies, all patients with superficial infection underwent formal débridement, though none developed deep infection. A prospective randomized study of 221 patients who underwent colorectal surgery—where perioperative infectious morbidity ranges from 25% to 50%—found that ring retractor use significantly reduced superficial wound infection rates (8.1% vs 0%). A significant reduction in...
wound infection was shown in a similarly designed study involving 48 patients who had open appendectomy (14.6% vs 1.6%). The device had no effect on deep infection in either general surgery study. The wound infection rates reported in these general surgery studies are markedly higher than those in our study population. As a result, the effect of the ring retractor on wound infection in DA-THA may be less. Regardless of the effect on deep infection, fewer superficial infections, which often require operative intervention, would be of considerable benefit.

Below-threshold albumin level and absolute lymphocyte count have been associated with wound-healing complications after hip replacement. In the present study, pre-albumin level under 20 mg/L was the only nutritional marker predictive of poor wound appearance, but this finding was seen only in SBSES scores from surgeon A. Subgroup analysis did not reveal any relationship between wound appearance and any of the recorded demographic or perioperative variables, but for a small predictive influence with age over 65 years.

This study had some limitations. Our findings cannot be generalized to all patients who undergo THA, as only DA incisions were studied. Results also may not be generalizable to non-fellowship-trained orthopedists. In addition, selection bias likely resulted from including patients already selected for the DA approach. Using digital images for evaluation (vs real-life evaluation) may have affected reliability as well. Last, by not incorporating texture, we omitted a potentially informative feature from scoring.

It is paramount that surgeons undergo diligent training before undertaking this approach for minimizing unwanted results; furthermore, higher early complication rates level off with increased surgeon experience. We recommend meticulous soft-tissue handling, cautious retraction, and careful patient selection (relative contraindication for patients with an abdominal pannus overlying the incision) as primary measures for minimizing incisional trauma and potential wound-healing complications. Preservation of the tensor fascia is also crucial, as it is the only closable layer separating deep and superficial compartments. Without good closure of the tensor fascia, there is no containment or tamponade of deep bleeding, which can facilitate hematoma formation.

In the population studied, we found no significant long-term differences in cosmetic appearance (based on clinician or patient evaluation) between wounds managed with and without the ring retractor. Our data do not support routine use of the ring retractor, during DA-THA, for improved wound cosmesis. Whether the device has any significant role in reducing the number of wound complications in THA is yet to be determined. Last, the ring retractor may have a role in other areas of orthopedic surgery, such as hip fractures in the elderly or orthopedic oncology. In situations like these, where adequate nutrition and immunocompetency may be lacking, the added protection provided by the device may translate into a more notable benefit than in elective THA.

Key Info

Figures/Tables
References


12. Meneghini RM, Pagnano MW, Trousdale RT, Hozack WJ. Muscle damage during MIS total hip


**Multimedia**

**Product Guide**
Product Guide

- STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device
- STRATAFIX™ Spiral Knotless Tissue Control Device
- BioComposite SwiveLock Anchor
- BioComposite SwiveLock C, with White/Black TigerTape™ Loop

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