

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

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Abstract

Use of shorter incisions in minimally invasive surgery total hip arthroplasty (THA) may come at the cost of poorer cosmesis, possibly a result of the excessive retraction needed for visualization. This may be particularly relevant in the direct anterior approach, in which wound-healing issues are common.

We prospectively investigated whether a specialized ring retractor was effective in minimizing wound-edge trauma, as evidenced by improved scar cosmesis. Fifty patients having direct anterior THA were randomized to surgery with or without ring retractor. Incisional photographs 2, 6, and 12 weeks after surgery were graded by 2 blinded plastic surgeons.

Wound scores and patient satisfaction with scar appearance were similar between groups. Our results suggest no improvement in wound cosmesis with use of this retraction device.

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-

Figure 1. Photograph of ring retractor device as packaged.



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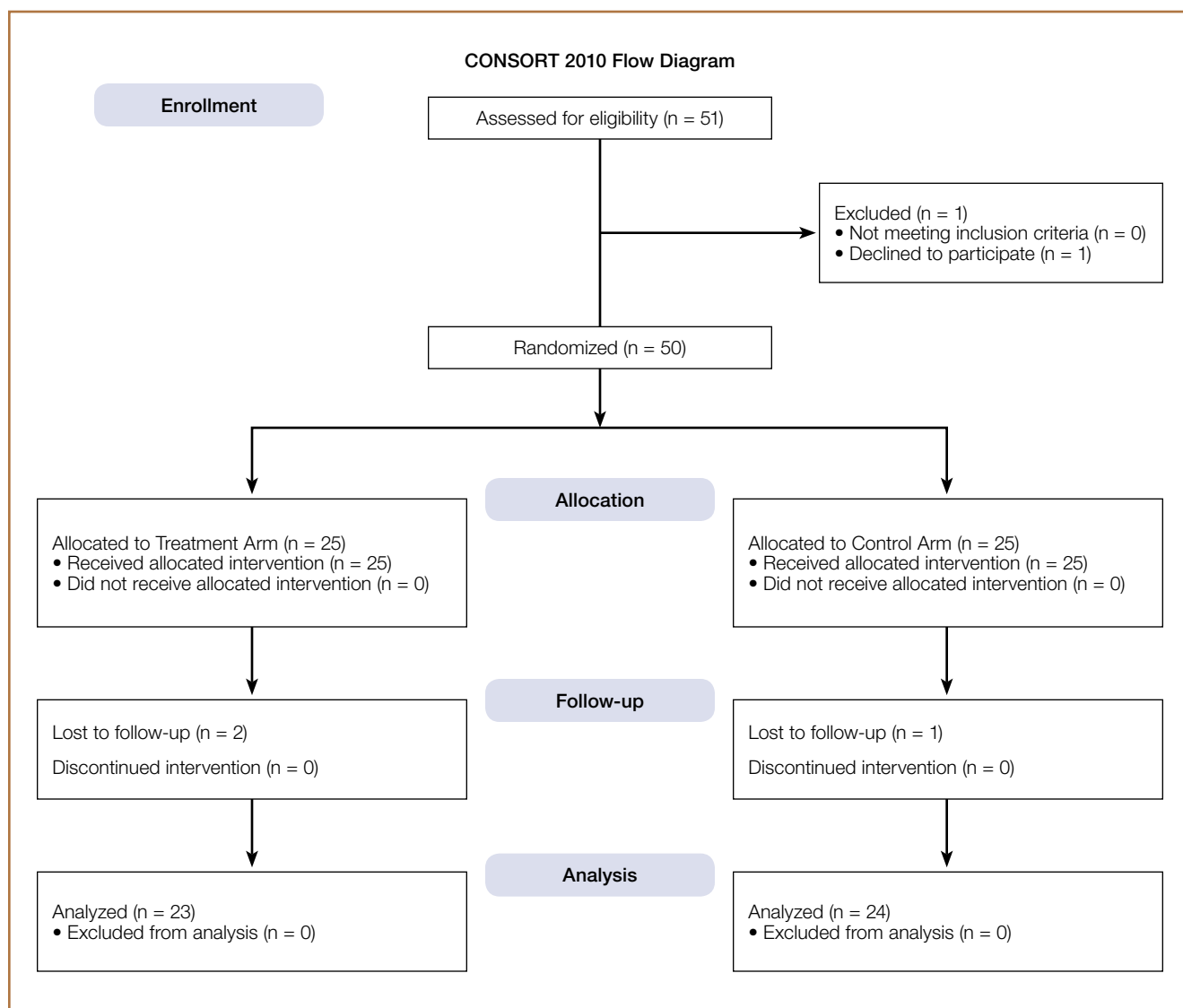


Figure 2. Flow diagram of patient’s progress through phases of study.

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.¹⁴⁻²⁰ 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

the fascia and the subcutaneous layer and the superior ring cinched over the skin (Figure 3). The device is made in 4 dif-

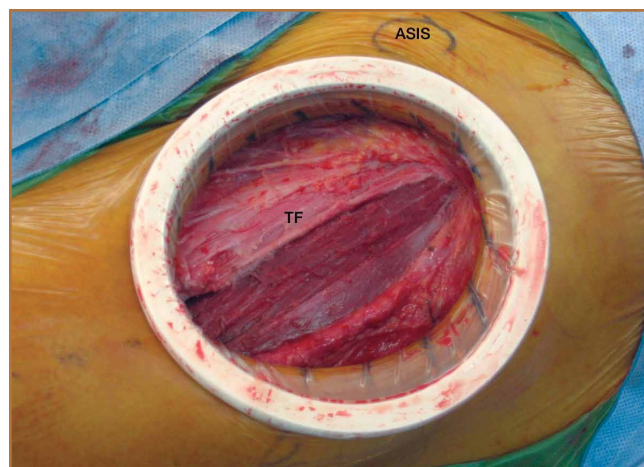


Figure 3. Intraoperative photograph of left hip shows ring retractor after placement in wound during direct anterior total hip arthroplasty. ASIS, anterior superior iliac spine; TF, tensor fascia.

Table 3. Patient Demographic and Perioperative Data^a

Parameter	Group		P
	Treatment	Control	
Patients, n	25	25	—
Age, y	59.6 ± 11.8	62.4 ± 10.5	.56
Sex, n (%)			
Male	17 (68%)	15 (60%)	.56
Female	8 (32%)	10 (40%)	
Body mass index, kg/m ²	27.1 ± 3.2	28.2 ± 4.3	.69
Preoperative diagnosis, n (%)			
Osteoarthritis	17 (68%)	21 (84%)	.19
Avascular necrosis	8 (32%)	4 (16%)	
Tobacco users, n	2	3	.99 ^b
Diabetes mellitus diagnosis, n	1	3	.61 ^b
Pre-albumin level, mg/dL	21.3 ± 4.3	18.4 ± 4.4	.07
Albumin level, g/dL	3.7 ± 0.3	3.6 ± 0.3	.36
Absolute lymphocyte count, cells/μL	1783 ± 618	2182 ± 789	.06
Estimated blood loss, mL	449 ± 220	444 ± 258	.79
Drain output, mL	386 ± 220	460 ± 270	.12
Patients transfused, n (%)	8 (32%)	10 (40%)	.56
Operative side, n (left/right)	12/13	13/12	.78
Operative time, min	116 ± 18	114 ± 26	.35
ASA physical status class, n (I/II/III)	6/15/4	3/18/4	.59 ^b

Abbreviation: ASA, American Society of Anesthesiologists.
^aValues for continuous variables given as means ± standard deviations. Continuous variables analyzed with Wilcoxon rank sum test; categorical variables analyzed with χ^2 test, except where noted otherwise.
^bDetermined with Fisher exact test.

ferent 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.⁸ 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

Table 4. Patient-Related Outcomes^a

Parameter	Group		P ^b
	Treatment	Control	
Length of stay, d	2.7 ± 1.5 (range, 1-9)	2.7 ± 1.1 (range, 2-7)	>.99
Pain level at discharge ^c	2.3 ± 2.3	1.5 ± 2.1	.18
HHS, points			
Preoperative	48.0 ± 13.8	49.9 ± 15.8	.65
Postoperative (6 wk)	86.9 ± 15.0	86.3 ± 13.5	.89
Improvement	38.7 ± 16.6 (95% CI, 31.7-45.7)	36.4 ± 19.6 (95% CI, 28.3-44.5)	.65
SF-12 score, points			
PCS			
Preoperative	30.2 ± 6.4	30.7 ± 6.0	.77
Postoperative (6 wk)	41.6 ± 11.7	44.7 ± 9.5	.30
Improvement	11.8 ± 9.6 (95% CI, 8.0-15.2)	14.5 ± 11.1 (95% CI, 10.1-18.9)	.37
MCS			
Preoperative	48.3 ± 12.1	49.1 ± 11.2	.81
Postoperative (6 wk)	54.1 ± 9.3	52.9 ± 10.8	.68
Improvement	5.1 ± 11.7 (95% CI, 0.4-9.8)	3.7 ± 12.7 (95% CI, -1.4 to 8.8)	.70

Abbreviations: CI, confidence interval; HHS, Harris Hip Score; MCS, mental component summary; PCS, physical component summary; SF-12, Short Form-12.
^aValues given as means ± standard deviations.
^bData analyzed with 2-tailed t test.
^cAverage of last 2 recorded pain scores before discharge.

of continuous data between groups. Differences between means were analyzed with 2-sided *t* tests. Categorical data were compared with the Pearson χ^2 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 *P*s < .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 image 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 ρ 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, ρ 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

Table 5. Patient Questionnaire Results^a

Question	Group		<i>P</i>
	Treatment	Control	
Outcome importance rank ^b			
No hip pain	1.2 ± 0.5	1.2 ± 0.9	>.99
How long hip will last?	2.2 ± 0.9	2.2 ± 0.6	.49
How long with crutches?	3.3 ± 1.1	3.2 ± 0.7	.39
Length of incision	4.5 ± 0.6	4.4 ± 0.9	.78
Perfect scar despite length	3.8 ± 0.9	4.0 ± 0.9	.33
Scar expectation (Likert scale), no. of patients			
Better than expected	11	16	.19
As expected	10	8	.48
Worse than expected	2	0	.23 ^c
Overall			.25 ^c
Scar opinion (Likert scale), no. of patients			
Excellent	15	18	.46
Average	7	6	.68
Unacceptable	1	0	.49 ^c
Overall			.63 ^c

^aNumbers given as means ± standard deviations when applicable. Data analyzed with χ^2 test, except where noted otherwise.

^bPatients ranked each variable in order of importance, from 1 (*most important*) to 5 (*least important*), using each number only once.

^cDetermined with Fisher exact test.

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 lym-

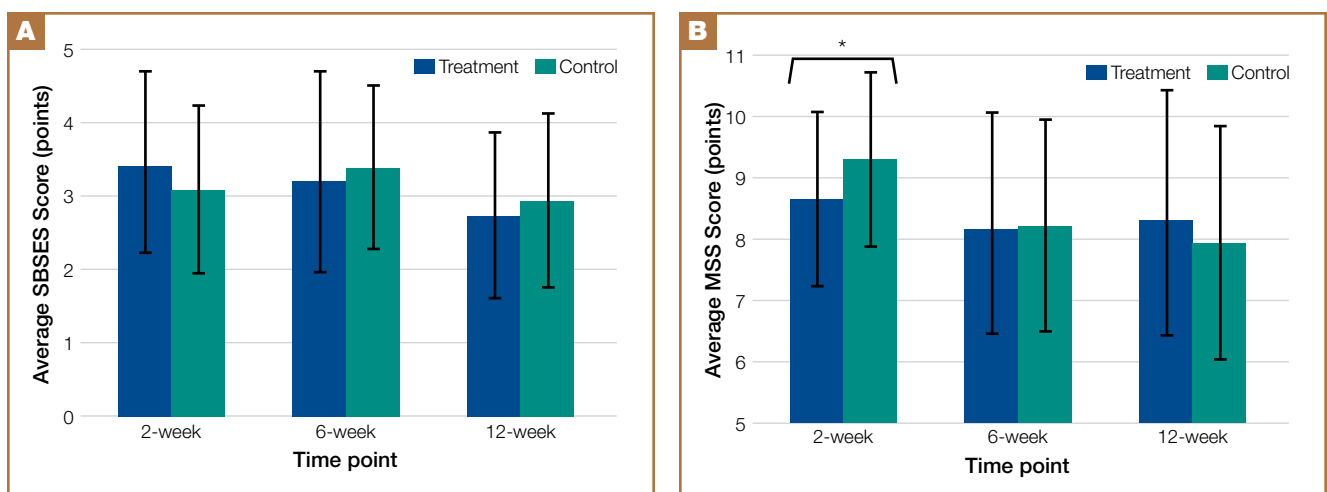


Figure 4. Mean scores and error bars (± 1 SD) across time points by study group, according to (A) Stony Brook Scar Evaluation Scale (SBSES) and (B) modified Manchester Scar Scale (MSS). Asterisk indicates significant difference between groups.

phocyte count under 1500 cells/ μ L 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 MMS²⁵ and the SBSES²⁴ 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.^{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.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.²⁴ Mow and colleagues³² 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.³⁵ 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.^{8,14-16} Jewett and Collis¹⁵ 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.¹⁵ Matta and colleagues⁸ 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%).^{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.²¹ 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.^{14,36,37} 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.³⁸ Preservation of the tensor fascia is also crucial,³⁹ 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.

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Appendix. Patient Outcome Ranking & Scar Assessment

Outcome Importance

Most Important Outcome = 1

Least Important Outcome = 5

Use each number (1 through 5) only once:

_____ The length of my scar

_____ A scar that I can barely see despite its length

_____ The length of time that I needed crutches

_____ No hip pain

_____ How long my hip will last

Scar Assessment

The appearance of my scar is

_____ Better than expected

_____ As expected

_____ Worse than expected

What is your opinion of your scar?

_____ Excellent

_____ Average

_____ Unacceptable