

A Novel Skin Closure Device for Total Knee Arthroplasty: Randomized Controlled Trial vs. Staples

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Introduction

- Many skin closure methods exist for TKA
- Staples, sutures, and glue products are used to enhance healing, but each have potential negative effects
- A novel skin closure device has been developed that
 - Is noninvasive
 - Utilizes zipties transversing the wound
 - Creates zone of isolation at wound edge
 - Transfers stress away from incision
- Zip skin closure device (Zipline Medical, Inc.*)
 - Does not puncture skin → no staple tracks
 - Easy to remove → may improve patient comfort
 - Small increase in cost
- Two previous studies [1,2] done comparing the Zip device with staples, but neither utilized a randomized, controlled study design

Purpose

The purpose of this study was to evaluate scar appearance/cosmesis, pain ratings, and arc of knee motion associated with the use of the Zip device versus conventional staples used for wound closure in patients undergoing simultaneous bilateral TKA, in which the wound closure method was randomized between knees and patients served as their own control.

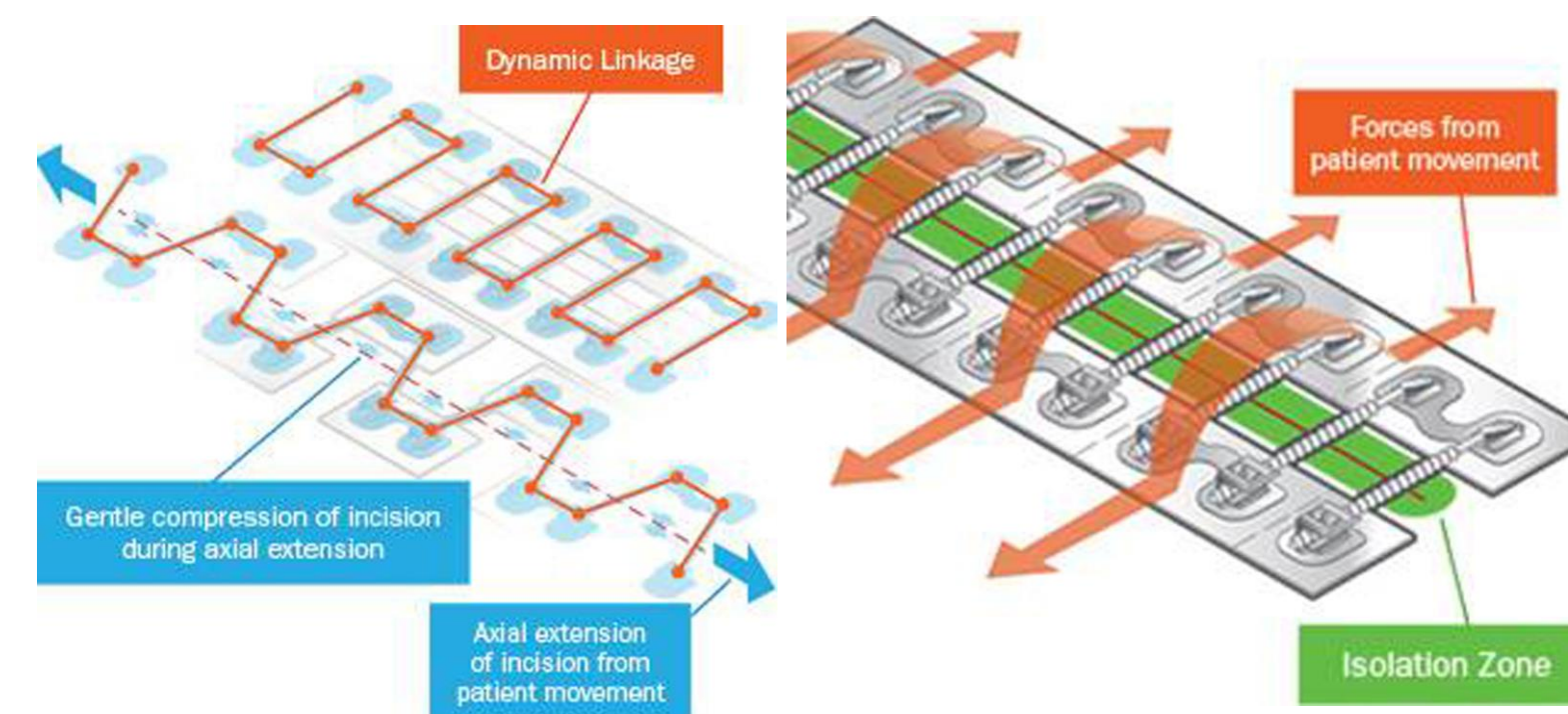
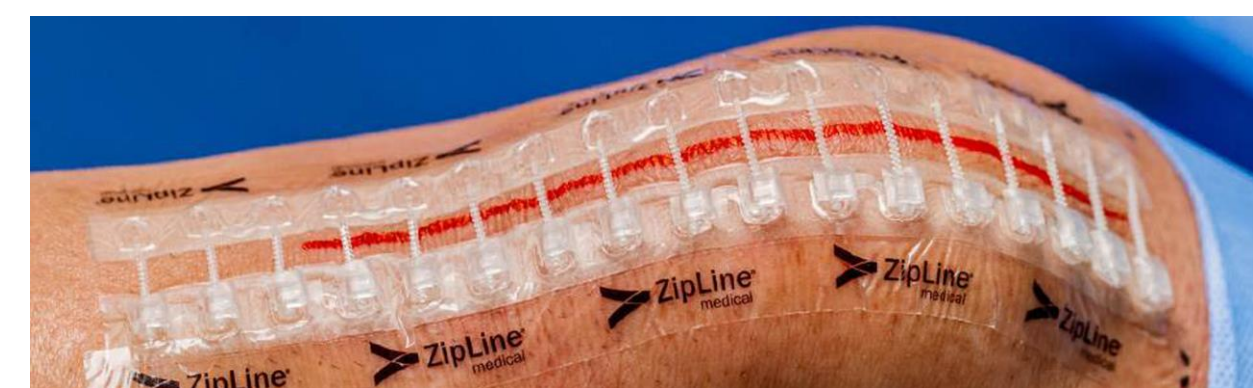
Hypothesis

We hypothesized that the for scar rating appearance, pain ratings, and knee arc of motion would be statistically significantly better with the Zip device compared to standard staples.

The Zip Surgical Skin Closure is a FDA Class I, 510(k) exempt device; This study was funded by Zipline Medical, Inc.

Methods

- Power analysis for study sample determined 22 patients needed to achieve 90% power
- 25 patients undergoing simultaneous, bilateral TKA (Mean age, 66.4 years old; 12 female/13 male)
- Randomized Zip vs. Staple, left or right knee



- Follow-up at 2 and 8 weeks post-op
- Endpoints
 - Pain at discharge from hospital, during device wear, and at device removal (0 - No pain, 10 - Worst imaginable pain)
 - Preference (at 2 weeks and 8 weeks)
 - Scar rating (0 - Best, 10 - Worst)
 - Knee Arc of Motion

Results

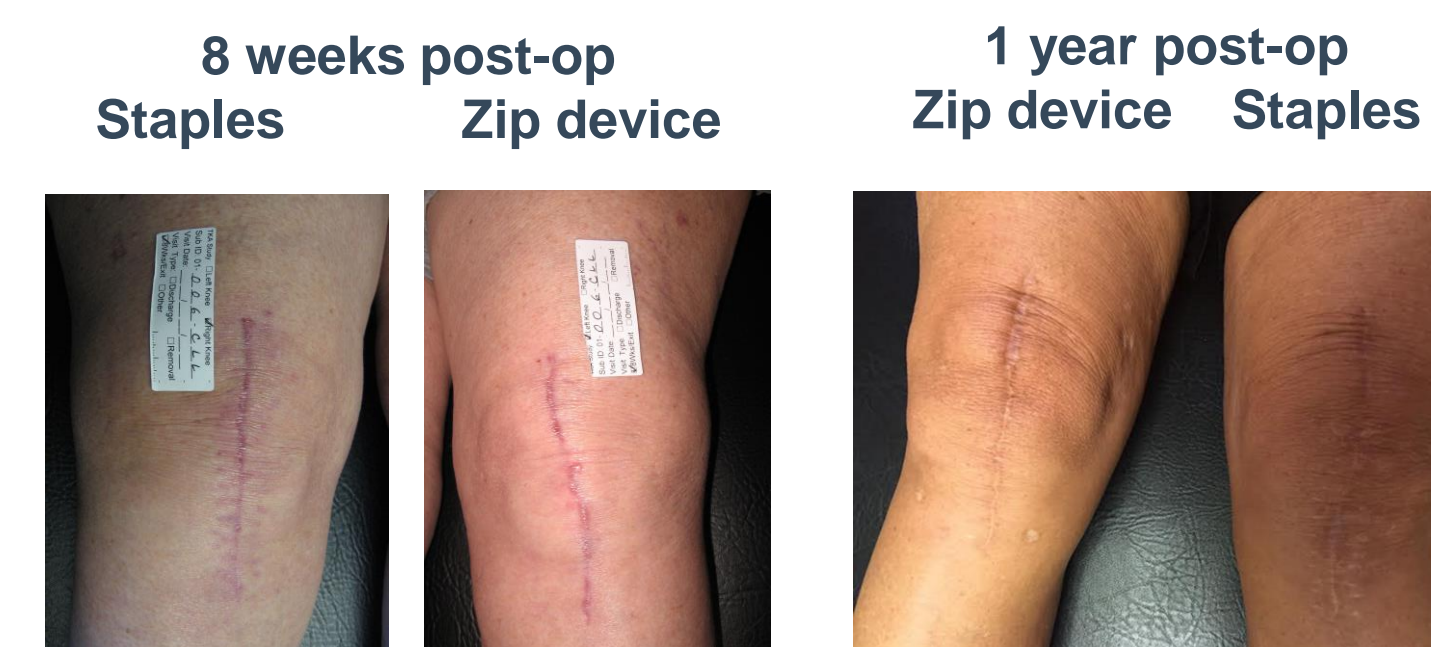
- Pain rating – (0 - No pain, 10 - Worst imaginable pain)

Time post-op	Zip Device Mean ± SD	Staples Mean ± SD	P-value
At discharge from hospital	1.9 ± 2.0	2.5 ± 2.6	.03
During 2-week device wear	1.4 ± 1.7	2.0 ± 1.8	.03
During device removal	0.7 ± 1.1	1.6 ± 1.2	.003

- Scar Rating at 8 weeks post-op (0 - Best, 10 - Worst)

Evaluator	Zip Device Mean ± SD	Staples Mean ± SD	P-value
Patient	1.3 ± 0.5	2.7 ± 2.4	.04
Surgeon	1.8 ± 1.2	3.3 ± 1.0	.0006

- Patient preference for device:
 - At time of device removal - 23/25 (92%) preferred Zip side
 - At 8 week visit - 21/25 (84%) preferred Zip side



- Mean Knee Arc of Motion at 2 week device removal
 - Zip side 107° vs. Staple side 104° (P = .002)
 - 18/25 patients had more ROM on the Zip side, 11 with >5° difference

Zip Device Complications

- One case of superficial skin peeling with device removal at 2 weeks post-op
- Resolved at next follow-up visit 2 weeks later



Zip side, 2 weeks post-op Zip side, 8 weeks post-op

Conclusions

- Zip device showed statistically significantly better results than staples for pain scores, scar quality rating, and knee arc of motion
- There was a clear patient preference for Zip device versus staples

References

1. Carli AV, et al. Using a non-invasive secure skin closure following total knee arthroplasty leads to fewer wound complications and no patient home care visits compared to surgical staples. *Knee*. 2017;24:1221-1226.
2. Ko JH et al. Do zip-type skin-closing devices show better wound status compared to conventional staple devices in total knee arthroplasty. *Int Wound J*. 2017;14:250-254.