

BunionBrace™ Medial Capsule Repair System

Arthrex Research

Background

Hallux valgus is a complex deformity characterized by both osseous malalignment and soft-tissue imbalance.^{1,2} Although numerous surgical techniques have been described to correct this condition, restoration of coronal plane soft-tissue balance remains a critical end-step of successful correction regardless of the procedure performed. Adequate soft tissue closure is essential for achieving joint congruity, restoring normal soft-tissue tension and joint kinematics, and minimizing the risk of deformity recurrence.^{1,3,4}

The purpose of this study was to biomechanically evaluate the *BunionBrace* capsular repair system and determine whether it provides greater repair strength than a standard primary capsular repair technique under worst-case cantilever loading conditions.⁵

Methods

Eight fresh-frozen matched pairs of lower-limb cadaveric specimens (N = 16) were thawed at room temperature overnight. The primary toe, extending from the medial cuneiform to the distal phalanx, was resected. All soft tissue proximal to the mid-metatarsal region was resected, and the specimens were embedded in cylindrical potting. Within each matched pair, one specimen was randomly assigned to the Primary Repair group, while the contralateral specimen was assigned to the *BunionBrace* group. The skin and superficial fascial layers were removed to expose the medial capsular tissue surrounding the 1st metatarsophalangeal joint (MTPJ). A full-thickness transverse capsulotomy was then created at the midline of the MTPJ, extending approximately 2 cm proximally and 1 cm distally from the joint line.

In the Primary Repair group, the capsulotomy was repaired using a pants-over-vest capsular imbrication technique consisting of 3 interrupted sutures placed along the length of the incision. For specimens assigned to the *BunionBrace* group, the capsulotomy first underwent the identical primary repair procedure described above, after which the *BunionBrace* augment was applied according to the published surgical technique guide.⁶

Specimens were mounted on a mechanical testing system (Instron E10000) with the medial aspect of the repair oriented superiorly and an elongated concave plunger with a 16.3 mm radius of curvature (designed to conform to the convex dorsal contour of the proximal phalanx) was positioned on the proximal phalanx. (Figure 1). A compressive preload of 2 N was applied to the metatarsal, after which a mini C-arm was positioned

around the testing fixture and a transverse-plane radiograph was obtained to confirm specimen alignment and to document the axial plane distance from the MTPJ to the plunger's center. Specimens were subsequently loaded at a rate of 20 mm/min until catastrophic failure. The following biomechanical outcomes were determined for this test: rotational stiffness (Nm/deg) and bending moment (Nm). Bending moment was calculated as $M = Fd\cos(\theta)$ where F is the maximum applied load (N), d is the distance from the center of the first metatarsal head to the loaded region of the proximal phalanx, and θ is the angle between the loading vector and proximal phalanx measured from fluoroscopy. Rotational stiffness was calculated as $K_{rot} = M/\theta$ (Nm/deg), where M is the bending moment at maximum load, and θ is the first metatarsophalangeal joint angle measured between the longitudinal axes of the first metatarsal and proximal phalanx. These calculations were performed to evaluate construct performance using specimen-specific rotational mechanics rather than load alone.

Differences between the *BunionBrace*™ and Primary Repair constructs were calculated and evaluated using paired t tests within JMP statistical software, with significance set at $\alpha = .05$.

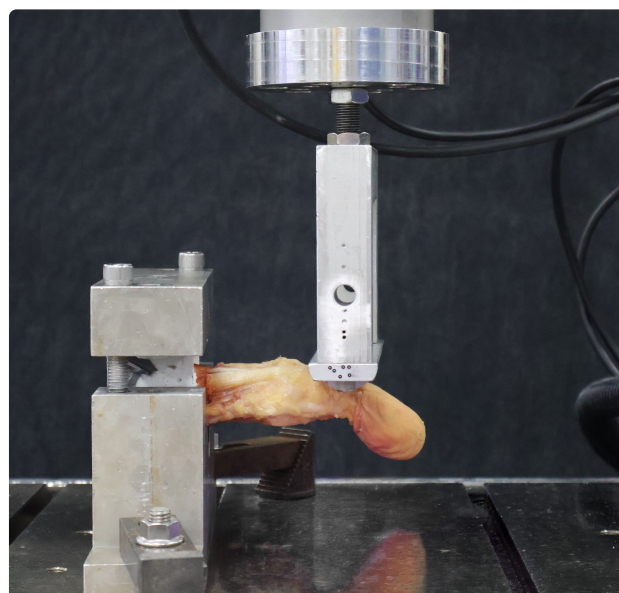


Figure 1. Cantilever loading test setup for medial capsular repair. Medial aspect of the primary toe faces the loading frame.



Results

BunionBrace[™]-repaired specimens demonstrated significantly greater construct stiffness compared to Primary Repair specimens ($P = .036$). Likewise, the maximum bending moment at failure was significantly higher in the *BunionBrace* group than in the Primary Repair group ($P = .007$).

Failure mode analysis revealed consistent behavior among *BunionBrace* constructs, with all specimens (100%) failing through suture slippage past the anchor.

In contrast, Primary Repair specimens exhibited greater variability in failure mechanism, with 5 of 8 specimens (62.5%) failing due to suture unraveling and 3 of 8 specimens (37.5%) failing through capsular tearing.

Conclusion

BunionBrace constructs provided significantly greater rotational stiffness and bending strength compared to Primary Repair while exhibiting a more uniform failure pattern.

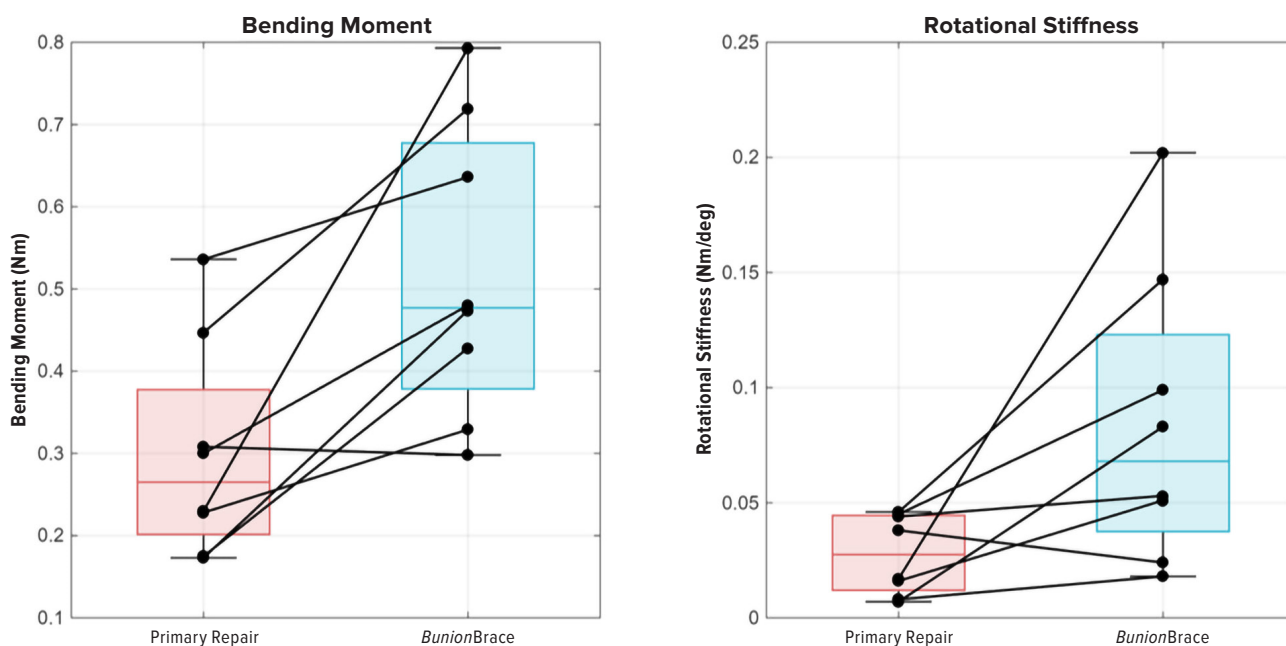


Figure 2. Matched-pair comparison of bending moment (left) and rotational stiffness (right) between Primary Repair and *BunionBrace* constructs.

References

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