## Appendix

TABLE E-1 Per-Protocol Analysis of Primary and Secondary Clinical Outcome Measures

| Outcome Measure | SB* | SS* | P Value† |
|---|---|---|---|
| AOFAS | | | |
| 6 wk (SB: n = 43, SS: n = 45) | 64 (50 to 77) | 58 (49 to 70) | 0.16 |
| 6 mo (SB: n = 41, SS: n = 42) | 90 (87 to 100) | 87 (76 to 90) | 0.01 |
| 1 yr (SB: n = 44, SS: n = 39) | 95 (95 to 100) | 87 (80 to 96) | 0.001 |
| 2 yr (SB: n = 42, SS: n = 41) | 97 (90 to 100) | 86 (80 to 96) | 0.001 |
| OMA | | | |
| 6 wk (SB: n = 41, SS: n = 45) | 30 (15 to 48) | 30 (23 to 43) | 0.89 |
| 6 mo (SB: n = 41, SS: n = 42) | 85 (75 to 95) | 70 (54 to 80) | 0.001 |
| 1 yr (SB: n = 44, SS: n = 39) | 95 (86 to 100) | 85 (75 to 100) | 0.006 |
| 2 yr (SB: n = 43, SS: n = 41) | 100 (95 to 100) | 90 (75 to 100) | <0.001 |
| VAS for pain during rest | | | |
| 6 wk (SB: n = 43, SS: n = 44) | 1.0 (0 to 2) | 1.0 (0 to 2) | 0.74 |
| 6 mo (SB: n = 41, SS: n = 42) | 0.0 (0 to 1) | 0.0 (0 to 1) | 0.62 |
| 1 yr (SB: n = 44, SS: n = 38) | 0.0 (0 to 1) | 0.0 (0 to 2) | 0.20 |
| 2 yr (SB: n = 43, SS: n = 41) | 0.0 (0 to 0) | 0.0 (0 to 1) | 0.05 |
| VAS for pain during walking | | | |
| 6 wk (SB: n = 42, SS: n = 43) | 2.0 (1 to 4) | 2.5 (2 to 5) | 0.16 |
| 6 mo (SB: n = 42, SS: n = 40) | 0.8 (0 to 1) | 1.5 (0 to 2) | 0.04 |
| 1 yr (SB: n = 44, SS: n = 37) | 0.0 (0 to 1) | 1.0 (0 to 3) | 0.001 |
| 2 yr (SB: n = 43, SS: n = 41) | 0.0 (0 to 1) | 1.0 (0 to 2) | 0.01 |
| VAS for pain at night | | | |
| 6 wk (SB: n = 41, SS: n = 44) | 1.0 (0 to 2) | 1.0 (0 to 2) | 0.99 |
| 6 mo (SB: n = 41, SS: n = 42) | 0.0 (0 to 0) | 0.0 (0 to 0) | 0.47 |
| 1 yr (SB: n = 44, SS: n = 38) | 0.0 (0 to 0) | 0.0 (0 to 1) | 0.07 |
| 2 yr (SB: n = 43, SS: n = 41) | 0.0 (0 to 0) | 0.0 (0 to 1) | 0.21 |
| VAS for pain during daily activity | | | |
| 6 wk (SB: n = 42, SS: n = 44) | 3.0 (1 to 6) | 3.0 (2 to 6) | 0.28 |
| 6 mo (SB: n = 41, SS: n = 42) | 0.0 (0 to 2) | 2.0 (1 to 4) | 0.006 |
| 1 yr (SB: n = 44, SS: n = 38) | 0.0 (0 to 1) | 1.0 (0 to 2) | 0.02 |
| 2 yr (SB: n = 43, SS: n = 41) | 0.0 (0 to 1) | 0.0 (0 to 2) | 0.08 |
| EQ-5D Index | | | |
| 6 wk (SB: n = 41, SS: n = 45) | 0.69 (0.4 to 0.8) | 0.62 (0.5 to 0.7) | 0.14 |
| 6 mo (SB: n = 41, SS: n = 40) | 1.0 (0.8 to 1.0) | 0.80 (0.7 to 1.0) | 0.07 |
| 1 yr (SB: n = 38, SS: n = 36) | 1.0 (0.8 to 1.0) | 0.82 (0.8 to 1.0) | 0.16 |
| 2 yr (SB: n = 43, SS: n = 41) | 1.0 (1.0 to 1.0) | 0.88 (0.8 to 1.0) | 0.009 |
| EQ-5D VAS | | | |
| 6 wk (SB: n = 42, SS: n = 43) | 75 (60 to 85) | 65 (50 to 80) | 0.03 |
| 6 mo (SB: n = 40, SS: n = 42) | 80 (80 to 90) | 76 (65 to 86) | 0.02 |
| 1 yr (SB: n = 43, SS: n = 39) | 90 (80 to 95) | 80 (70 to 90) | 0.07 |
| 2 yr (SB: n = 42, SS: n = 41) | 88 (75 to 95) | 80 (68 to 93) | 0.25 |

*The values are expressed as the median with the IQR in parentheses. †The statistical analysis was conducted using a nonparametric test (Mann-Whitney U test).

TABLE E-2 Per-Protocol Analysis of Radiographic Results: Difference in Tibiofibular Distance at Level of Syndesmosis*
Between Injured and Uninjured Ankles

| | SB† | SS† | Mean Between-Group Difference (95% CI) | P Value‡ |
|---|---|---|---|---|
| Difference§ in anterior distance | | | | |
| ≤2 wk (SB: n = 44, SS: n = 47) | 0.3 (−2 to 3) | 0.8 (−4 to 8) | −0.4 (−1.2 to 0.4) | 0.6# |
| 1 yr (SB: n = 41, SS: n = 40) | 1.0 ± 1.8 | 2.1 ± 2.4 | −1.1 (−2.1 to −0.2) | 0.02 |
| 2 yr (SB: n = 37, SS: n = 40) | 0.8 ± 1.7 | 2.0 ± 2.2 | −1.2 (−2.2 to −0.3) | 0.008 |
| Difference§ in central distance | | | | |
| ≤2 wk (SB: n = 44, SS: n = 47) | −0.2 (−2 to 2) | −0.1 (−3 to 3) | −0.5 (−0.5 to 0.4) | 0.8# |
| 1 yr (SB: n = 41, SS: n = 40) | 0.6 ± 1.1 | 1.3 ± 1.5 | −0.7 (−1.3 to −0.1) | 0.02 |
| 2 yr (SB: n = 37, SS: n = 40) | 0.7 (−1 to 2) | 1.5 (−1 to 5) | −0.8 (−1.3 to −0.2) | 0.02# |
| Difference§ in posterior distance | | | | |
| ≤2 wk (SB: n = 44, SS: n = 47) | 0.2 ± 1.4 | −0.3 ± 2.0 | 0.5 (−0.2 to 1.3) | 0.1 |
| 1 yr (SB: n = 41, SS: n = 40) | 0.5 ± 1.4 | 1.2 ± 1.6 | 0.7 (−1.3 to 0.002) | 0.05 |
| 2 yr (SB: n = 37, SS: n = 40) | 0.6 ± 1.4 | 1.0 ± 1.6 | −0.4 (−1.1 to 0.3) | 0.2 |

*One centimeter above the tibial plafond. †The values are expressed as the mean with the standard deviation or with the range in parentheses. ‡The Levene test was used to assess equality of variances. The statistical analysis was conducted using the 2-sided t test for independent samples in normally distributed data; otherwise, the Mann-Whitney U test was used. §Difference between injured and uninjured ankles. #The Mann-Whitney U test was used.

TABLE E-3 Radiographic Results with Outliers Excluded: Difference in Tibiofibular Distance at Level of Syndesmosis* Between Injured and Uninjured Ankles

|  | SB† | SS† | Mean Between-Group Difference (95% CI) | P Value‡ |
|---|---|---|---|---|
| Difference§ in anterior distance |  |  |  |  |
| ≤2 wk (SB: n = 46, SS: n = 39) | 0.2 ± 1.3 | 0.05 ± 1.3 | 0.1 (−0.4 to 0.7) | 0.6 |
| 1 yr (SB: n = 42, SS: n = 32) | 0.9 ± 1.8 | 1.7 ± 1.5 | −0.8 (−1.6 to −0.04) | 0.04 |
| 2 yr (SB: n = 40, SS: n = 33) | 0.8 ± 1.6 | 1.7 ± 1.7 | −1.0 (−1.8 to −0.2) | 0.02 |
| Difference§ in central distance |  |  |  |  |
| ≤2 wk (SB: n = 46, SS: n = 39) | −0.3 ± 1.1 | −0.3 ± 1.3 | 0.05 (−0.5 to 0.6) | 0.8 |
| 1 yr (SB: n = 42, SS: n = 32) | 0.6 ± 1.1 | 1.4 ± 1.5 | −0.8 (−1.4 to −0.2) | 0.09 |
| 2 yr (SB: n = 40, SS: n = 33) | 0.7 (−1 to 2) | 1.4 (−1 to 5) | −0.7 (−1.3 to −0.2) | 0.02# |
| Difference§ in posterior distance |  |  |  |  |
| ≤2 wk (SB: n = 46, SS: n = 39) | 0.1 ± 1.7 | −0.5 ± 1.7 | 0.6 (−0.08 to 1.4) | 0.08 |
| 1 yr (SB: n = 42, SS: n = 32) | 0.6 ± 1.3 | 1.3 ± 1.7 | −0.7 (−1.4 to −0.05) | 0.04 |
| 2 yr (SB: n = 40, SS: n = 33) | 0.6 ± 1.4 | 1.1 ± 1.7 | −0.5 (−1.2 to 0.3) | 0.2 |

*One centimeter above the tibial plafond. †The values are expressed as the mean with the standard deviation or with the range in parentheses. ‡The Levene test was used to assess equality of variances. The statistical analysis was conducted using the 2-sided t test for independent samples in normally distributed data; otherwise, the Mann-Whitney U test was used. §Difference between injured and uninjured ankles. #The Mann-Whitney U test was used.

TABLE E-4 Patients with ≥2-mm Difference in Tibiofibular Distance Between Injured and Uninjured Ankles with Outliers Excluded

|  | SB* | SS* | Relative Risk (95% CI) | P Value† |
|---|---|---|---|---|
| Difference‡ in anterior distance |  |  |  |  |
| ≤2 wk (SB: n = 46, SS: n = 39) | 6 (13%) | 4 (10%) | 0.8 (0.2 to 2.6) | 0.7 |
| 1 yr (SB: n = 42, SS: n = 32) | 11 (26%) | 17 (53%) | 2.0 (1.1 to 3.7) | 0.03 |
| 2 yr (SB: n = 40, SS: n = 33) | 8 (20%) | 14 (42%) | 2.1 (1.0 to 4.4) | 0.05 |
| Difference‡ in central distance |  |  |  |  |
| ≤2 wk (SB: n = 46, SS: n = 39) | 2 (4%) | 2 (5%) | 1.1 (0.2 to 8.0) | 1.0 |
| 1 yr (SB: n = 42, SS: n = 32) | 10 (24%) | 16 (50%) | 2.1 (1.1 to 4.0) | 0.03 |
| 2 yr (SB: n = 40, SS: n = 33) | 7 (18%) | 15 (45%) | 2.6 (1.2 to 5.6) | 0.01 |
| Difference‡ in posterior distance |  |  |  |  |
| ≤2 wk (SB: n = 46, SS: n = 39) | 8 (17%) | 3 (8%) | 0.4 (0.1 to 1.6) | 0.2 |
| 1 yr (SB: n = 42, SS: n = 32) | 10 (24%) | 15 (47%) | 2.0 (1.0 to 3.8) | 0.05 |
| 2 yr (SB: n = 40, SS: n = 33) | 10 (25%) | 10 (30%) | 1.2 (0.6 to 2.6) | 0.8 |

*The values are expressed as the number of patients with the percentage in parentheses. †The statistical analysis was conducted using the Fisher exact test. ‡Difference between injured and uninjured ankles.