

ACL Repair Using the *Internal/Brace*[™] Technique Compared to ACL Reconstruction Up to Two Years Follow-up

Purpose

To report the clinical outcomes of pain, function, and quality of life for patients who have undergone ACL repair using the *Internal/Brace* technique compared to ACL reconstruction.

Methods

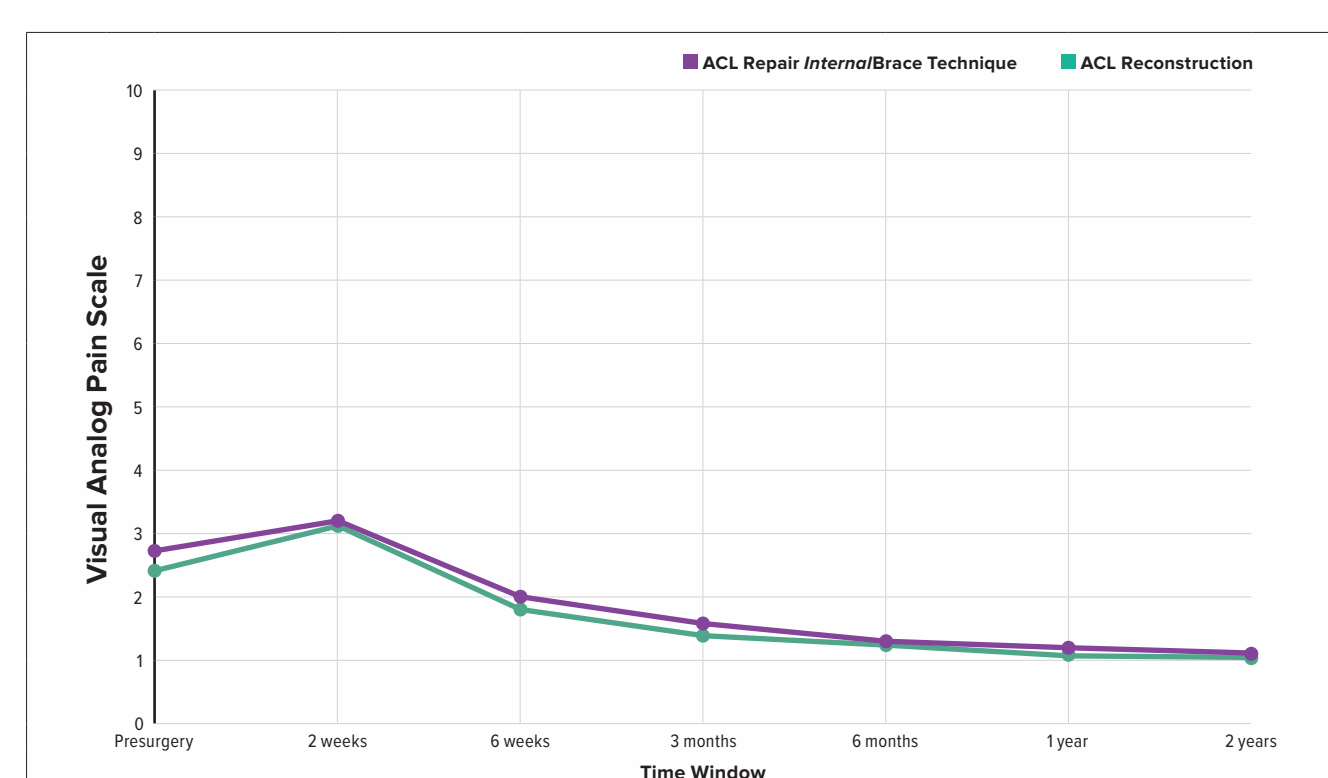
The inclusion criteria for this analysis were patients enrolled in the Surgical Outcomes System[™] registry who underwent ACL repair using the *Internal/Brace* technique or ACL reconstruction procedure. Standard patient-reported outcomes questionnaires for VAS, KOOS ADL, and SANE Knee were administered at standard time points postoperatively. Results were reported from presurgery out to 2 years postsurgery. The number of patients included per group is shown to the right.

Results

| Time Point | Number of Compliant ACL Repair Using the <i>Internal/Brace</i> Technique Patients/ Total Patients | Number of Compliant ACL Reconstruction Patients/Total Patients |
|------------|---|--|
| Presurgery | 301/470 | 6669/10919 |
| 3 months | 326/457 | 6779/10501 |
| 6 months | 294/444 | 5868/10186 |
| 1 year | 243/407 | 4956/9460 |
| 2 years | 168/264 | 3492/7099 |

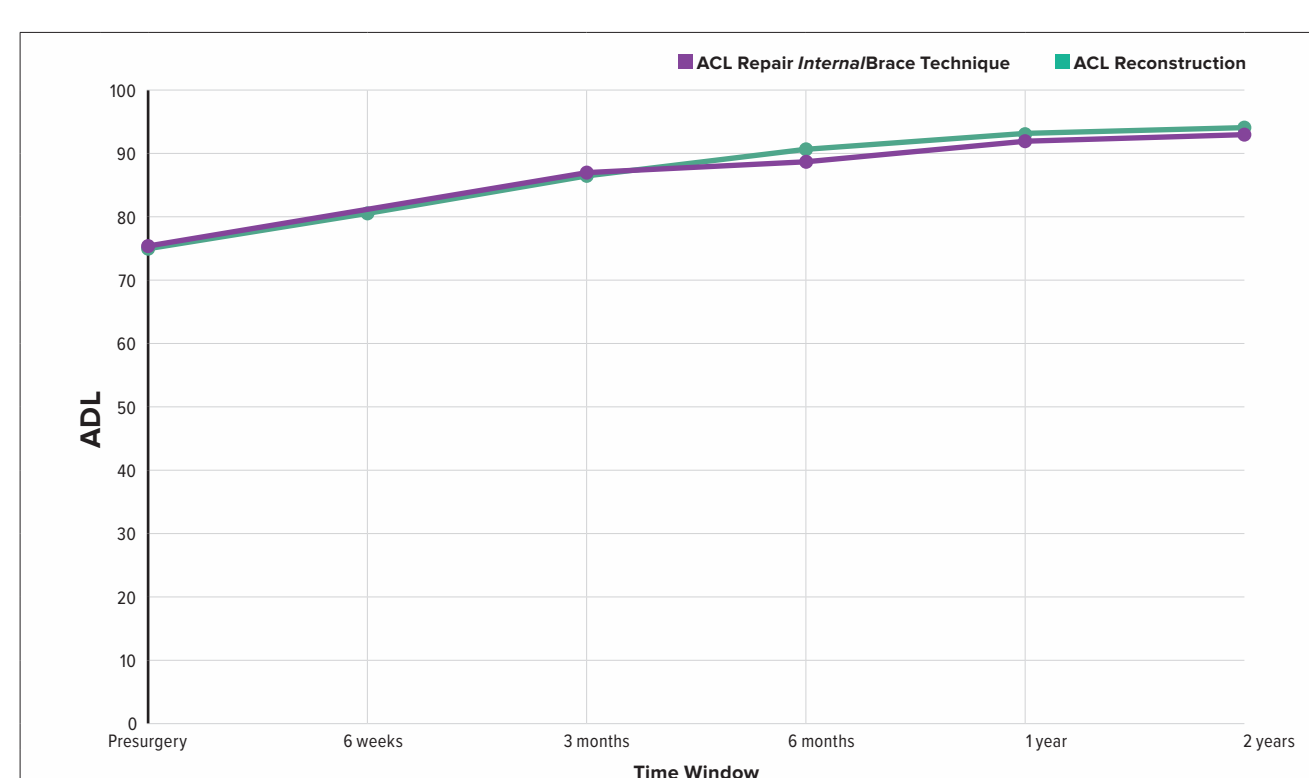
Trend Conclusion

Based on these results, the pain, function, and quality-of-life scores of ACL repair with *Internal/Brace* technique appear to trend toward similar outcomes to ACL reconstruction. However, no claims can be made on the potential of these results without further analysis to determine statistical significance.



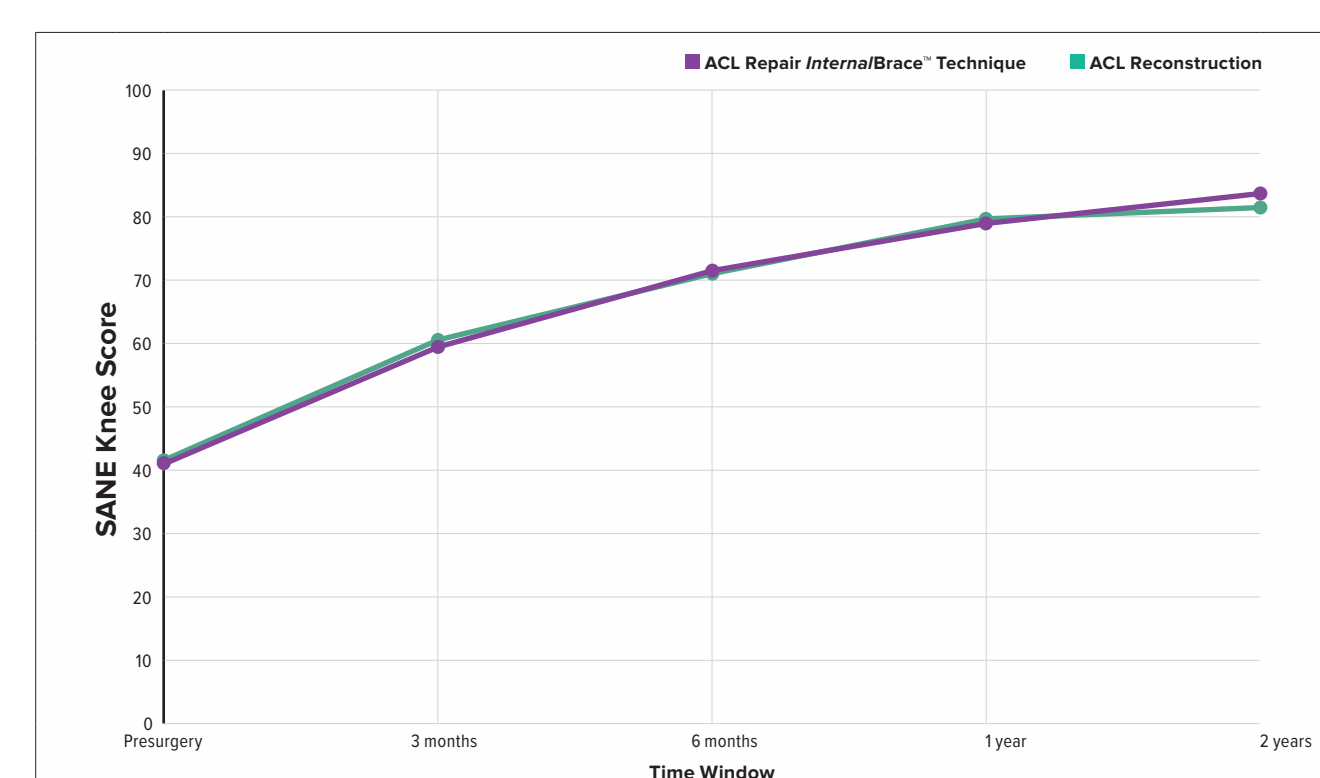
VAS

| Time Point | ACL Repair Using the <i>Internal/Brace</i> Technique Avg ± STD VAS | ACL Reconstruction Avg ± STD VAS |
|------------|--|----------------------------------|
| Presurgery | 2.7 ± 2.3 | 2.4 ± 2.2 |
| 3 months | 1.7 ± 1.8 | 1.4 ± 1.5 |
| 6 months | 1.3 ± 1.6 | 1.2 ± 1.5 |
| 1 year | 1.1 ± 1.6 | 1.0 ± 1.5 |
| 2 years | 1.0 ± 1.6 | 1.0 ± 1.6 |



KOOS ADL

| Time Point | ACL Repair Using the <i>Internal/Brace</i> Technique Avg ± STD KOOS ADL | ACL Reconstruction Avg ± STD KOOS ADL |
|------------|---|---------------------------------------|
| Presurgery | 72.6 ± 20.3 | 75.2 ± 19.4 |
| 3 months | 82.0 ± 18.0 | 86.2 ± 13.0 |
| 6 months | 87.8 ± 14.4 | 90.7 ± 11.7 |
| 1 year | 91.3 ± 12.8 | 93.1 ± 11.0 |
| 2 years | 93.5 ± 12.5 | 94.0 ± 11.0 |



SANE

| Time Point | ACL Repair Using the <i>Internal/Brace</i> Technique Avg ± STD SANE | ACL Reconstruction Avg ± STD SANE |
|------------|---|-----------------------------------|
| Presurgery | 36.7 ± 22.2 | 41.6 ± 23.2 |
| 3 months | 60.9 ± 19.2 | 60.7 ± 18.8 |
| 6 months | 72.4 ± 19.0 | 71.3 ± 17.5 |
| 1 year | 80.2 ± 17.1 | 79.7 ± 17.3 |
| 2 years | 81.5 ± 20.4 | 82.2 ± 18.1 |

The *Internal/Brace* surgical technique is intended only to augment the primary repair/reconstruction by expanding the area of tissue approximation during the healing period and is not intended as a replacement for the native ligament. The *Internal/Brace* technique is for use during soft tissue-to-bone fixation procedures and is not cleared for bone-to-bone fixation.