



ACL Reconstruction With *Internal/Brace*™ Technique vs ACL Reconstruction

Purpose

To report the clinical outcomes of pain, function, and quality of life for patients who have undergone ACL reconstruction using the *Internal/Brace* technique compared to patients who have undergone ACL reconstruction without using the *Internal/Brace* technique.

Methods

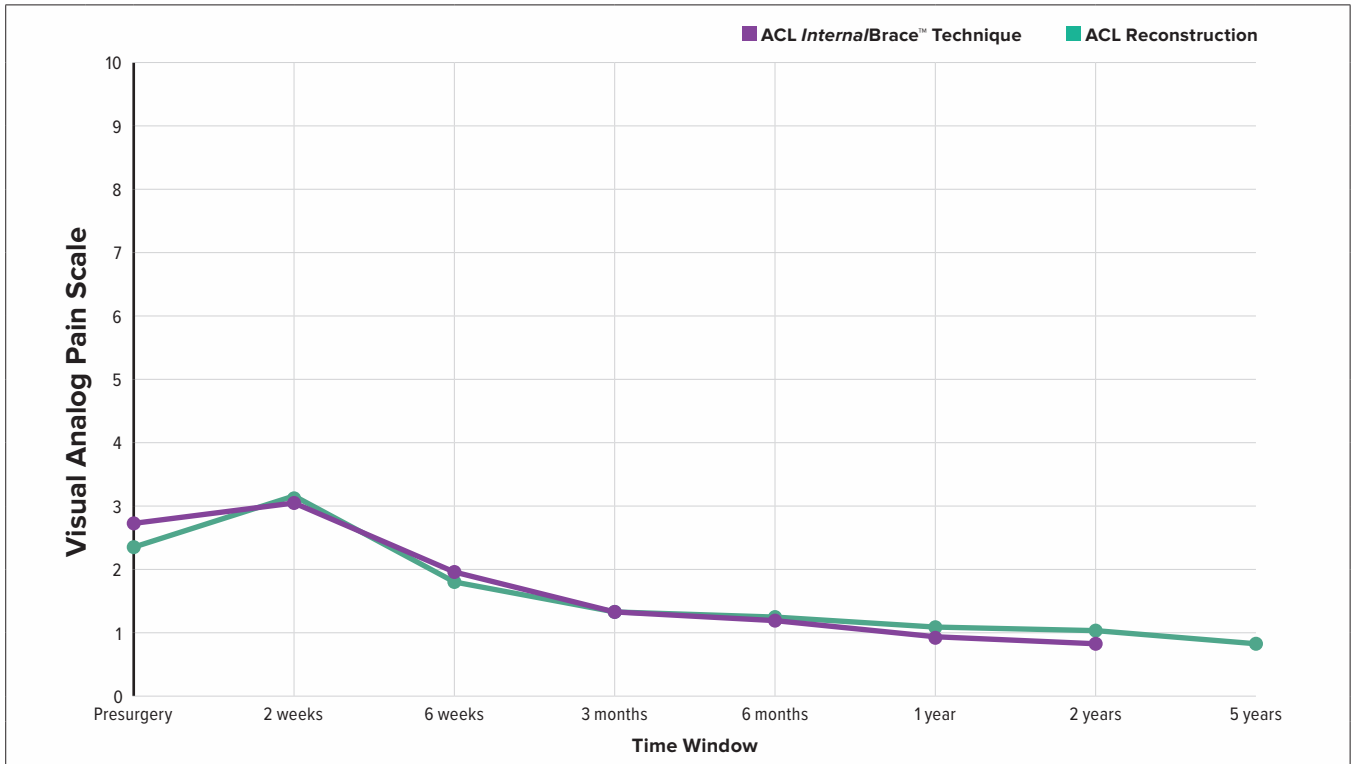
The inclusion criteria for this analysis were patients enrolled in the Surgical Outcomes System™ global registry who underwent ACL reconstruction using the *Internal/Brace* technique or ACL reconstruction without using the *Internal/Brace* technique. Standard patient-reported outcomes questionnaires for VAS, KOOS ADL, and SANE Knee were administered at standard time points postoperatively. Results were reported from presurgery to 5 years postsurgery. The number of patients included per group is shown below.

Time Point	# of Compliant ACL Reconstruction <i>Internal/Brace</i> Technique Patients/ Total Patients	# of Compliant ACL Reconstruction Patients/ Total Patients
Presurgery	130/237	6101/9658
1 year	136/202	4008/7657
2 years	88/136	2608/5337
5 years	N/A	274/871

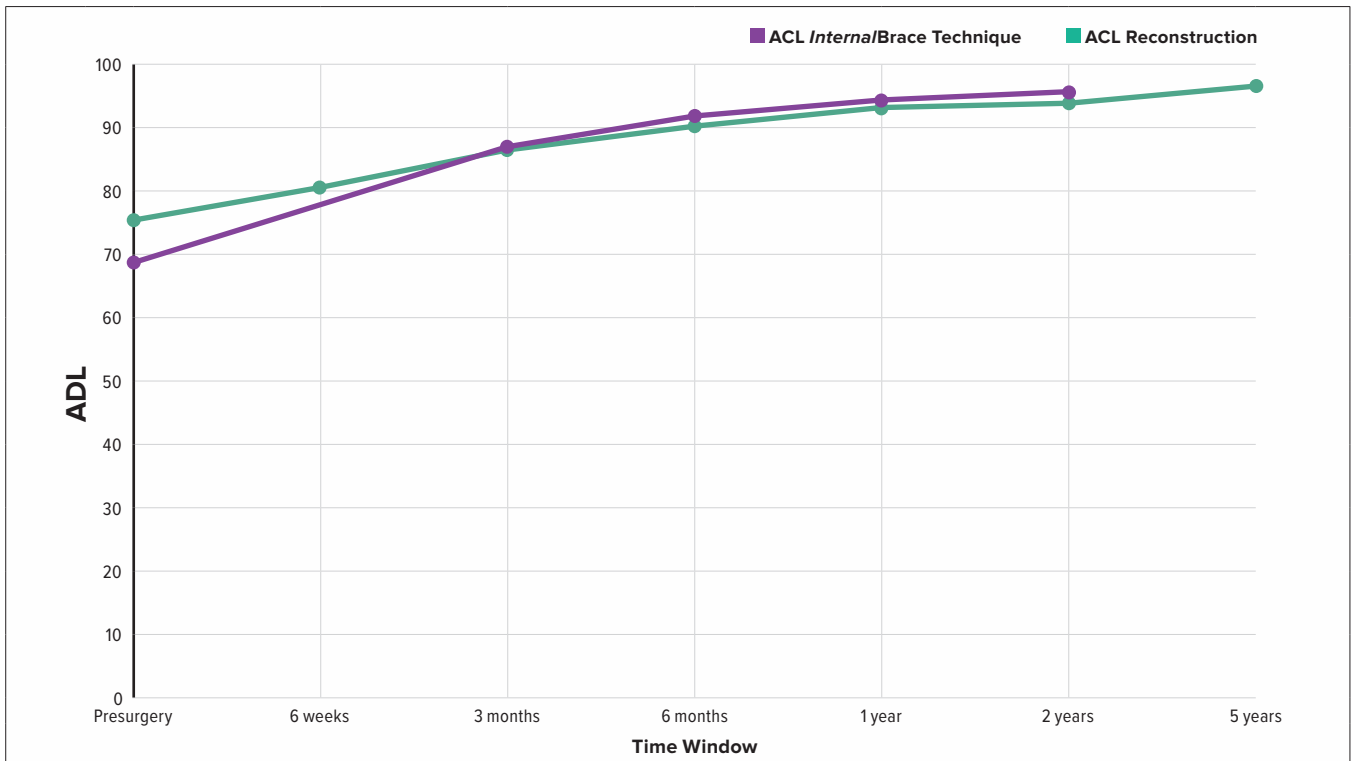
Trend Conclusion

Based on these results, the pain, function, and quality-of-life scores of ACL reconstruction using the *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.

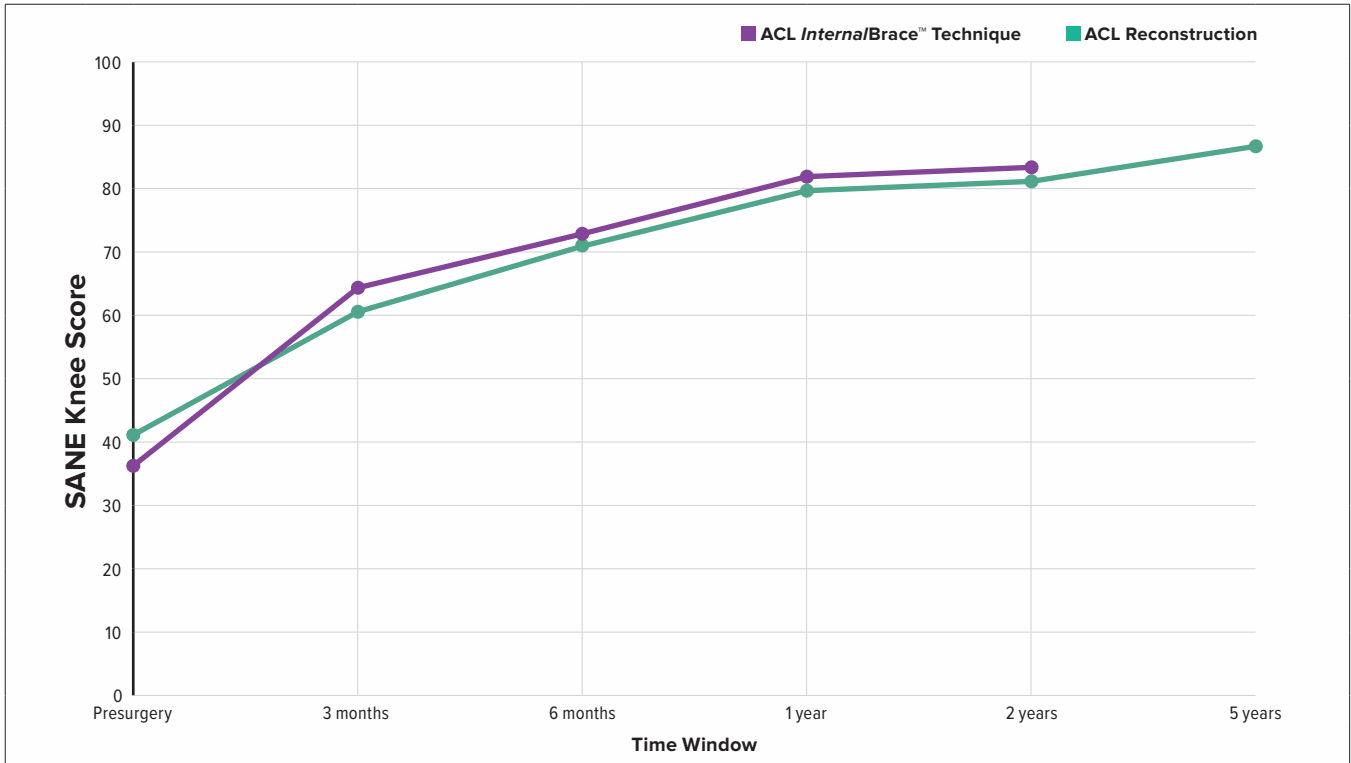
Results



VAS



KOOS-ADL



SANE



Time Point	ACL Reconstruction With <i>InternalBrace</i> ™ Technique Avg ± STD VAS	ACL Reconstruction Avg ± STD VAS
Presurgery	2.8 ± 2.3	2.4 ± 2.2
1 year	0.9 ± 1.4	1.1 ± 1.6
2 years	0.8 ± 1.3	1.0 ± 1.6
5 years	N/A	0.8 ± 1.4

Time Point	ACL Reconstruction With <i>InternalBrace</i> Technique Avg ± STD KOOS ADL	ACL Reconstruction Avg ± STD KOOS ADL
Presurgery	68.8 ± 21.4	75.1 ± 19.3
1 year	94.4 ± 10.1	92.8 ± 11.3
2 years	95.5 ± 9.4	93.8 ± 11.2
5 years	N/A	95.8 ± 9.1

Time Point	ACL Reconstruction With <i>InternalBrace</i> Technique Avg ± STD SANE	ACL Reconstruction Avg ± STD SANE
Presurgery	36.0 ± 22.0	41.5 ± 23.3
1 year	82.2 ± 16.0	79.3 ± 17.4
2 years	84.3 ± 15.0	81.8 ± 18.1
5 years	N/A	86.1 ± 17.6

The *InternalBrace* 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 *InternalBrace* technique is for use during soft tissue-to-bone fixation procedures and is not cleared for bone-to-bone fixation.