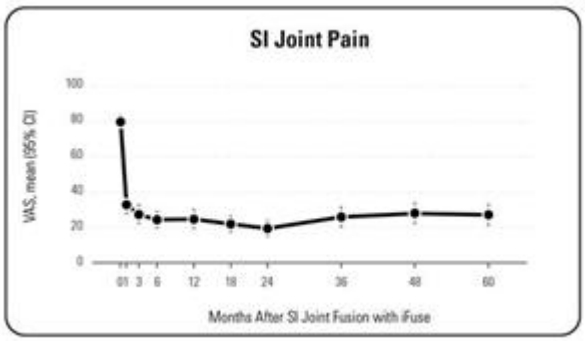
SI-BONE, Inc. Announces Publication of Five-Year Prospective Study Results on 103 Patients Treated with Triangular Titanium iFuse Implant System

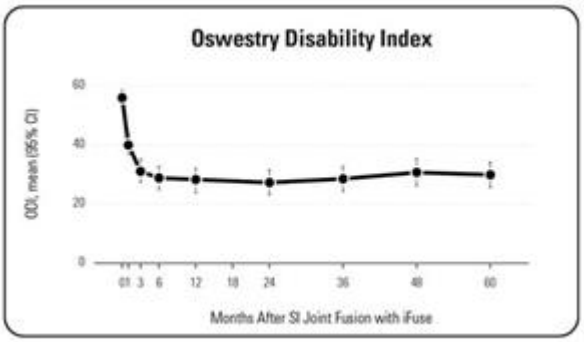
September 26, 2019

Long-term follow-up results show excellent durability of clinical responses and positive radiographic outcomes for SI joint fusion using triangular titanium implants

SANTA CLARA, Calif., Sept. 26, 2019 (GLOBE NEWSWIRE) -- SI-BONE, Inc., (Nasdaq: SIBN), a Silicon Valley-based medical device company dedicated to solving musculoskeletal disorders of the sacro-pelvic anatomy, today announced the publication of 5-year results from a long-term prospective study called LOIS (Long Term Outcomes from INSITE and SIFI). The publication, titled *Long-term prospective clinical and radiographic outcomes after minimally invasive lateral transiliac sacroiliac joint fusion using triangular titanium implants*[1] reports 5-year outcomes from a subset of patients who participated in INSITE (Investigation of Sacroiliac Fusion Treatment)[2], a U.S. randomized controlled trial and SIFI (Sacroiliac Joint Fusion with iFuse Implant System)[3], a prospective multicenter trial.



SI Joint Pain



Oswestry Disability Index

The LOIS study included 103 subjects treated at 12 centers who were diagnosed with sacroiliac (SI) joint dysfunction and underwent SI joint fusion with the iFuse Implant in either of the two feeder studies (INSITE and SIFI). Study subjects were evaluated at study start (approximately 2 years after surgery) and again at 3, 4 and 5 years postoperatively. 5-year follow-up was obtained for 93 study subjects (90%) with no loss to follow-up between year 3 to 5. Mean SI joint pain scores decreased 54 points from baseline prior to surgery with iFuse (0–100 point scale). Disability scores (Oswestry Disability Index) decreased 26 points (0–100 scale) and quality of life improved 0.29 points (0 – 1 scale) all of which are statistically significant, clinically meaningful and consistent with previously published LOIS 3-year and 4-year results.

“Now, more than ever, patients, providers and payers require evidence that procedures are safe and effective as demonstrated through long-term results from prospective randomized controlled clinical trials. Five-year outcomes have become the standard by which new technologies are measured to ensure treatment durability,” said Jeffrey Dunn, President, Chief Executive Officer, and Chairman at SI-BONE. “This milestone publication demonstrates the long-term durability of clinical outcomes and radiographic evidence of the effectiveness of the iFuse Implant as a treatment option for patients with SI joint dysfunction.”

The five year results from LOIS demonstrated that improvements in pain, patient function and quality of life demonstrated at 2-years in INSITE and SIFI were durable and sustained at 5 years (Figures 1 and 2). Independent radiographic analysis of CT scans at 5 years showed a high rate of bony apposition to implants on both the sacral and iliac sides (98%) as well as a high rate of SI joint fusion (88% bridging bone). Patient satisfaction remained high for patients treated with the iFuse Implant. There were no reported adverse events related to the study device or procedure at 5 years.

Photos accompanying this announcement are available at:

https://www.globenewswire.com/NewsRoom/AttachmentNg/6be3451f-d339-4937-a56d-a74189b07bb1

https://www.globenewswire.com/NewsRoom/AttachmentNg/600cba36-3cab-4b7f-9da8-78361d35dc7b

About SI-BONE

SI-BONE is a medical device company that pioneered the iFuse Implant System, a minimally invasive surgical system for fusion of the sacroiliac joint

to treat sacroiliac joint dysfunction. The SI joint is believed to be the last major joint with a clinically proven surgical treatment. The iFuse Implant, commercially available since 2009, is believed to be the only SI joint fusion device supported by multiple prospective clinical studies showing improved pain, patient function and quality of life resulting from treatment. There are over 75 peer-reviewed publications supporting the safety, effectiveness, and biomechanical and economic benefits unique to the iFuse Implant. This body of evidence has enabled multiple government and private payors to establish coverage of the SI joint fusion procedure exclusively when performed with the iFuse Implant System.

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. The iFuse Implant System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit.

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Citations

1. Whang PG, Darr E, Meyer SC, Kovalsky D, *et al*. Long-Term Prospective Clinical and Radiographic Outcomes after Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion using Triangular Titanium Implants. *Med Devices (Auckl)*. 2019;12:411-422. DOI: https://doi.org/10.2147/MDER.S219862
2. Polly DW, Swofford J, Whang PG, *et al*. Two-year outcomes from a randomized controlled trial of minimally invasive sacroiliac joint fusion vs. non-surgical management for sacroiliac joint dysfunction. *Int J Spine Surg*. 2016;10:28. DOI: https://doi.org/10.14444/3028
3. Duhon BS, Bitan F, Lockstadt H, *et al*. Triangular titanium implants for minimally invasive sacroiliac joint fusion: 2-year follow-up from a prospective multicenter trial. *Int J Spine Surg*. 2016;10:13. DOI: https://doi.org/10.14444/3013

Source: SI-BONE, Inc.