# SMART Trial

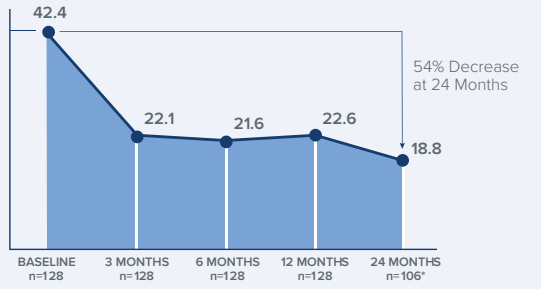
## Study Design

- Randomized, double-blind, sham-controlled
- Multi-Center: 15 US and 3 EU sites
- 225 Patients; Randomized to treatment (147) or sham (78) intervention
- Patients were evaluated preoperatively and at 2 weeks and 6 weeks and 3, 6, 12 and 24 months postoperatively
- Skeletally mature patients with chronic (≥ 6 months), isolated lumbar pain, who had not responded to at least 6 months of non-operative management
- All patients had Type 1 or Type 2 Modic changes of the treated vertebral bodies
- Outcome Measures: ODI, SF-36, and VAS
- Optional crossover for sham patients after all 12 month evaluations were performed

## Key Findings

### ODI SCORE

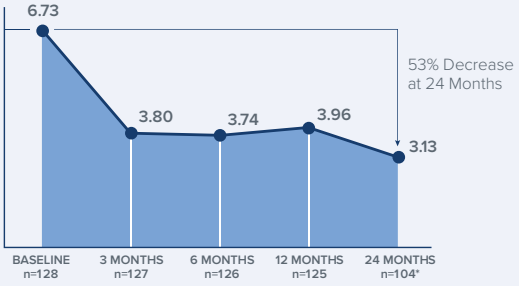
*Treatment Arm (per protocol population)*




**LOCF imputation used at all time points except 24 months where all observed data without imputation used*

### VAS SCORE

*Treatment Arm (per protocol population)*

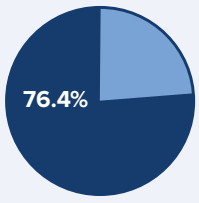



**LOCF imputation used at all time points except 24 months where all observed data without imputation used*

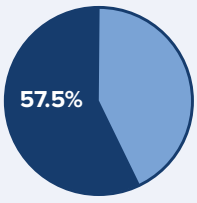
### RESPONDER RATE AT 24 MONTHS

*Treatment Arm (per protocol population)*

**ODI**

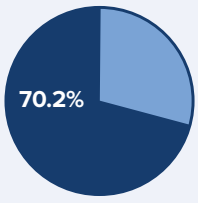



% of Patients with ≥ 10 Point Improvement in ODI
**n=106**




% of Patients with ≥ 20 Point Improvement in ODI
**n=106**

**VAS**




% of Patients with ≥ 1.5 CM Improvement in VAS
**n=104**

**All observed data without imputation used*

Fischgrund J et al., Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain: 2-Year Results from a Prospective Randomized Double-Blind Sham-Controlled Multicenter Study. *International Journal of Spine Surgery*, Vol. 13, No. 2, 2019, pp. 1–10.

Per Protocol population included subjects in the Intention to Treat population who met all study entrance criteria, did not take any interfering concomitant medications, attended all follow-up visits, and were a procedural success. For additional information please refer to: Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled mutli-center study. European Spine Journal 2018.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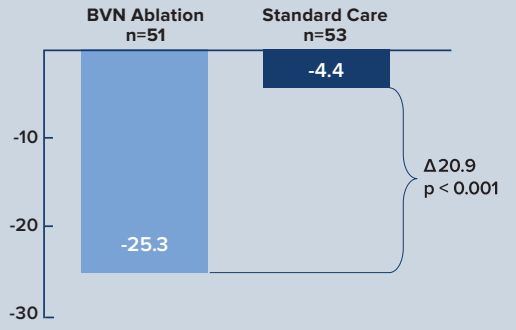
# INTRACEPT Study

## Study Design

- Prospective, randomized, multi-center
- 20 US Sites
- 104 Patients; Randomized to Intracept (51) or standard care (53)
- Subjects in Standard Care arm continue non-surgical management therapies to treat their CLBP
- Patients were evaluated at baseline and at 3, 6, 9, and 12 months post-treatment
- Skeletally mature patients with low back pain >= 6 months who had not responded to at least 6 months of conservative care
- All patients had Type 1 or Type 2 Modic changes at up to 4 vertebral bodies (L3-S1)
- Primary Endpoint: Between-arm comparison of the mean change in ODI from baseline to 3 months post-treatment

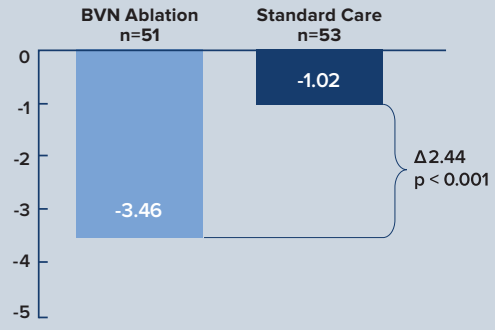
## Key Findings

### ODI CHANGE AT 3 MONTHS




*LS Mean difference (p < 0.001 per ANCOVA) in ODI between the BVN ablation and SC arms, adjusted for baseline ODI*

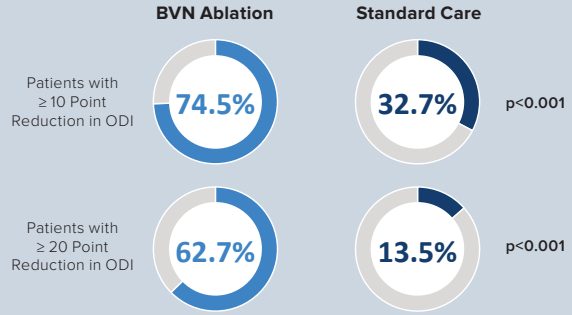
### VAS CHANGE AT 3 MONTHS




*LS Mean difference (p < 0.001 per ANCOVA) in ODI between the BVN ablation and SC arms, adjusted for baseline ODI*

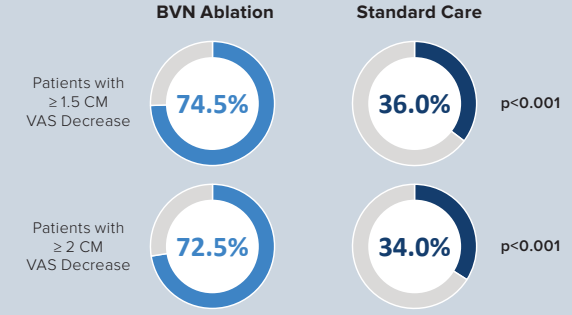
### ODI RESPONDER RATES

*Baseline to 3 months*




### VAS RESPONDER RATES

*Baseline to 3 months*




Khalil J, Smuck M, Koreckij T, Keel J, Beall D, Goodman B, Kalapos K, Nguyen D, Garfin S. A Prospective, Randomized, Multi-Center Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain presented at the American Society of Spine Radiology Annual Symposium; February 22, 2019; Miami, FL.



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# Prospective, Single-Arm Study

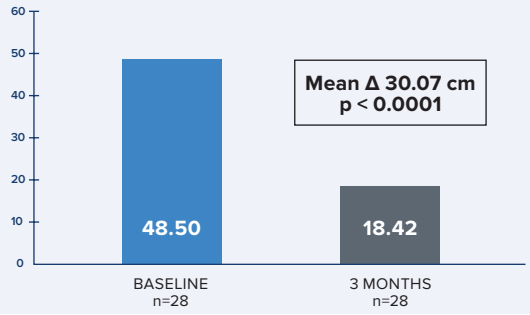
Truumees et al. - European Spine Journal

## Study Design

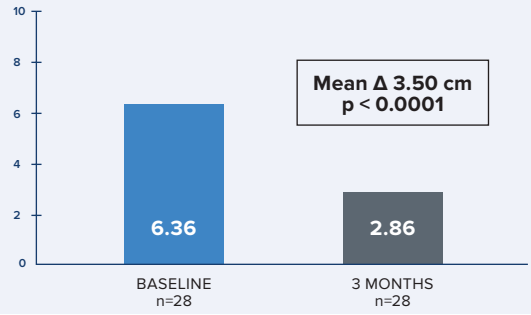
- Prospective, single-arm, multi-center and open label
- 2 US Centers: Typical spine practice settings
- 28 Patients enrolled consecutively using permissive criteria for study inclusion
- Patients were evaluated preoperatively and postoperatively at 3, 6, 9 and 12 months
- Skeletally mature patients with chronic (≥ 6 months), isolated lumbar pain, who had not responded to at least 6 months of non-operative management
- All patients had Type 1 or Type 2 Modic changes of the treated vertebral bodies
- Primary Endpoint: Patient report ODI change from baseline to 3 months
- Secondary Endpoints: VAS, SF-36, EQ-5D-5L and Responder Rates

## Key Findings

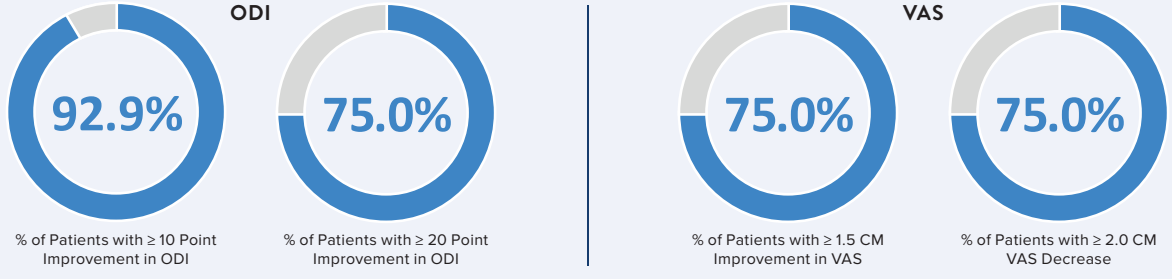
### ODI SCORE AT 3 MONTHS




### VAS SCORE AT 3 MONTHS




### RESPONDER RATE AT 3 MONTHS




Truumees, E., Macadaeg, K., Pena, E. et al., A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain Eur Spine J (2019). doi.org/10.1007/s00586-019-05995-2



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