Spinal Cord Stimulation Lead Configurations Employing S-Series Paddle Lead(s) Offer Greater Pain Relief than Dual 8-Contact Cylindrical Leads

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INTRODUCTION

Typically, paddle type leads offer several advantages over percutaneous leads. For example, the electrodes lay closer to the spinal cord due to the dimensions and surgical placement of the paddle lead. This allows for increased stimulation of the posterior region, while avoiding uncomfortable stimulation of the anterior region, enhancing the likelihood of capturing elusive back pain. Paddle leads also provide greater energy efficiency by unilaterally directing current towards the spinal cord, thereby reducing power requirements and the likelihood of painful dysesthesia caused by stimulating the ligamentum flavum.[1,2] In addition, cylindrical type leads are more likely to migrate post operatively due to postural changes and this movement within the epidural space can result in changes in the paresthesia coverage and inadequate pain relief. Despite these advantages, paddle leads require a laminectomy, which is a more invasive surgical procedure than a percutaneous procedure. A newly developed SCS accessory called the Epiducer™ lead delivery system was developed to percutaneously implant slim line paddle leads, much like implantation of a percutaneous lead through a Tuohy needle. This analysis compared the efficacy of dual 8-contact cylindrical leads to lead configurations employing a single S-Series™ paddle lead used with a single cylindrical lead.

METHODS

Data analysis was performed on results obtained in an IRB-approved, prospective clinical research study and an IRB-approved, prospective, multicenter, international registry. Patients were stratified by lead configuration (dual cylindrical leads or single S-Series/single cylindrical lead combination) and the following outcomes were compared across groups at 3 and 6 months post-implant: direct patient report of percentage of pain relief, categorical rating of pain relief, global impression of satisfaction, quality of life and power usage. The power and current settings of each patient's favorite program was recorded and analyzed to calculate charge requirements. Percentages of device-related adverse events were analyzed across the groups. Group comparisons were performed using t-tests or Fisher's exact test.

RESULTS

Pain Relief

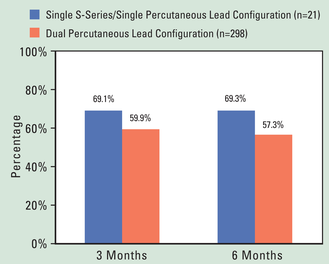


Figure 1. On average, patients implanted with a single S-Series/single percutaneous lead configuration reported higher patient-reported pain relief than patients implanted with dual 8-contact percutaneous leads. However, this difference did not reach statistical significance at either 3 (p=0.055) or 6 (p=0.058) months post-implant.

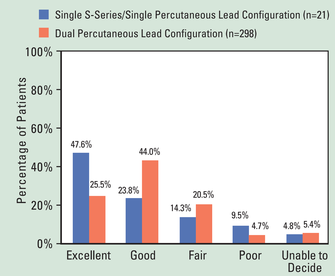
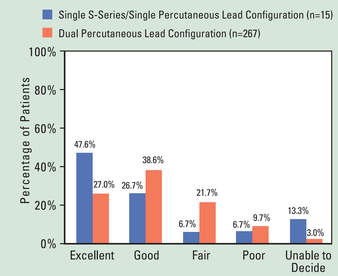


Figure 2. Significantly more patients implanted with a single S-Series/single percutaneous lead configuration reported "Excellent" pain relief than patients implanted with dual 8-contact percutaneous leads at 3 months post-implant (p=0.04).



Figures 3. More patients implanted with a single S-Series/single percutaneous lead configuration reported "Excellent" pain relief than patients implanted with dual 8-contact percutaneous leads at 6 months post-implant. However, this difference was not statistically significant (p=0.14).

Power Consumption

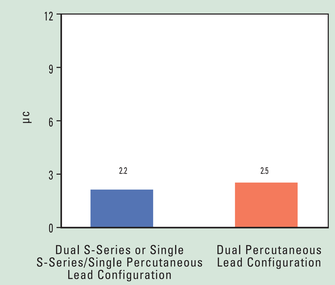
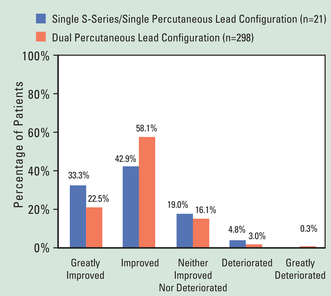
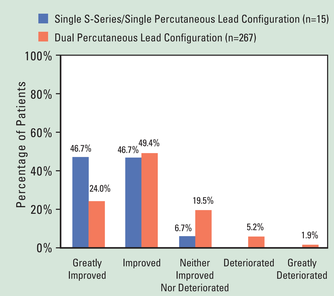


Figure 4. Favorite programs among patients implanted with dual S-Series leads or a single S-Series/single percutaneous lead combination required, on average, 12% less charge than the favorite programs among patients implanted with dual 8-contact leads.

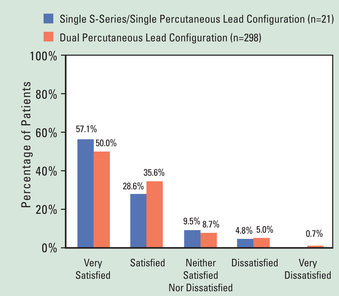
Quality of Life

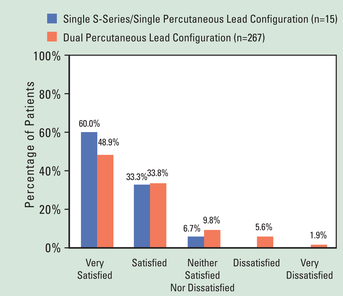




Figures 5 and 6. More patients implanted with a single S-Series/single percutaneous lead configuration reported "Greatly Improved" quality of life than patients implanted with dual 8-contact percutaneous leads. However, this difference was not statistically significant at either 3 (p=0.28: left) or 6 (p=0.06; right) months post-implant.

Satisfaction





Figures 7 and 8. More patients implanted with a single S-Series/single percutaneous lead configuration reported being "Very Satisfied" than patients implanted with dual 8-contact percutaneous leads. However, this difference did not reach statistical significance at 3 (p=0.65: left) or 6 (p=0.44: right) months post-implant.

SUMMARY & CONCLUSIONS

- Data were collected from a total of 326 patients across 41 study sites.
- On average, patients implanted with a single S-Series/single percutaneous lead configuration reported greater pain relief, quality of life and satisfaction than patients implanted with dual 8-contact percutaneous leads.
- The proportion of device-related adverse events observed among patients implanted with at least one S-Series paddle lead and patients implanted with dual 8-contact percutaneous leads were similar at 18.5% and 19.0%, respectively (p=1.0).
- These preliminary results suggest that use of SCS lead configurations containing an S-Series paddle lead may result in better efficacy than that seen with traditional cylindrical leads, without any compromise in device-related adverse events.

REFERENCES

1. North RB, Lanning A, Hessels R, Cutchis PN. Spinal cord stimulation with percutaneous and plate electrodes: side effects and quantitative comparisons. *Neurosurg Focus.* 1997;2(1):e3.
2. North RB, Kidd DH, Olin JC, Sieracki, JM. Spinal cord stimulation electrode design: prospective, randomized, controlled trial comparing percutaneous and laminectomy electrodes-part I: technical outcomes. *Neurosurgery.* 2002;51(2):381-9; discussion 389-90.

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