# Efficacy of i-FACTOR Bone Graft *versus* Autograft in Anterior Cervical Discectomy and Fusion

*Results of the Prospective, Randomized, Single-blinded Food and Drug Administration Investigational Device Exemption Study*

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**Background**: The objective of this study was to investigate efficacy and safety of i-FACTOR Bone Graft (i-FACTOR) compared with local autograft in single-level anterior cervical discectomy and fusion (ACDF) for cervical radiculopathy.

**Methods**: Patients randomly received either autograft (N=154) of i-FACTOR (N=165) in a cortical ring allograft. Study success was defined by non-inferiority in fusion, Neck Disability Index (NDI), and Neurological Success endpoints, and similar adverse events profile at 12 months.

**Results**:

| Responder Analysis: Overall Success (1-Year) | | | | | | |
|---|---|---|---|---|---|---|
| Primary Endpoint | Value | i-FACTOR Putty | | Autograft | | p-value* |
| | | Number | Percentage | Number | Percentage | |
| Fusion Success | Radiographic Fusion | 129 | 88.97% | 121 | 85.82% | 0.4220 |
| NDI Success | >15 point improvement from baseline | 112 | 79.43% | 103 | 74.10% | 0.2907 |
| Neurological Success | Improvement of neurological status | 134 | 93.71% | 133 | 93.01% | 0.8123 |
| Safety Success | Absence of:<br>1) re-operation<br>2) device removal<br>3) device-related SAE | 157 | 97.52% | 145 | 95.39% | 0.3085 |
| Overall Success | Success in all primary endpoints | 99 | 68.75% | 82 | 56.94% | 0.0382 |

*Note: p-value for superiority test

**Conclusions**: i-FACTOR has met all four FDA mandated non-inferiority success criteria and has demonstrated safety and efficacy in single-level ACDF for cervical radiculopathy. i-FACTOR and autograft groups demonstrated significant post-surgical improvement and high fusion rates.