# i-Factor

i-Factor™ Bone Graft (Cerapedics Inc, Westminster, Colorado) is a composite bone substitute material consisting of P-15 synthetic collagen fragment adsorbed onto anorganic bone mineral suspended in an inert biocompatible hydrogel carrier. A pivotal, noninferiority, US FDA Investigational Device Exemption study demonstrated the benefits of i-Factor™ compared to local autograft bone in single-level anterior cervical discectomy and fusion at 1-yr postoperative. OBJECTIVE: To report 2-yr follow-up. METHODS: Subjects randomly received either autograft (n = 154) or i-Factor™ (n = 165) in a cortical ring allograft and followed using radiological, clinical, and patient-reported outcomes. RESULTS: At 2 yr, the fusion rate was 97.30% and 94.44% in i-Factor™ and autograft subjects, respectively ( P = .2513), and neurological success rate was 94.87% (i-Factor™) and 93.79% (autograft; P = .7869). Neck Disability Index improved 28.30 (i-Factor™) and 26.95 (autograft; P = .1448); Visual Analog Scale arm pain improved 5.43 (i-Factor™) and 4.97 (autograft) (p = .2763); Visual Analog Scale neck pain improved 4.78 (i-Factor™) and 4.41 (autograft; P = .1652), Short Form-36 (SF-36v2) Physical Component Score improved 10.23 (i-Factor™) and 10.18 (autograft; P = .4507), and SF36v2 Mental Component Score improved 7.88 (i-Factor TM ) and 7.53 (autograft; P = .9872). The composite endpoint of overall success (fusion, Neck Disability Index improvement >15, neurological success, and absence of re-operations) was greater in i-Factor™ subjects compared to autograft subjects (69.83% and 56.35%, respectively, P = .0302). Twelve (7.45%) i-Factor™ subjects and 16 (10.53%) autograft subjects underwent re-operation ( P = .3411). There were no allergic reactions associated with i-Factor™.

Use of i-Factor™ in anterior cervical discectomy and fusion is effective and safe, and results in similar outcomes compared to local autograft bone at 2 yr following surgery [1].

1)
Arnold PM, Sasso RC, Janssen ME, Fehlings MG, Heary RF, Vaccaro AR, Kopjar B. i-Factor™ Bone Graft vs Autograft in Anterior Cervical Discectomy and Fusion: 2-Year Follow-up of the Randomized Single-Blinded Food and Drug Administration Investigational Device Exemption Study. Neurosurgery. 2017 Sep 8. doi: 10.1093/neuros/nyx432. [Epub ahead of print] PubMed PMID: 28945914.