CLINICAL SUMMARY

AlloFuse® Select CM

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Authors	**Title**	**Publication**	**Study Design**	**Key Takeaway**
SPINE PEER-REVIEWED PUBLICATIONS				
Lane P, Cox J, Gaskins R, Santoni B, Billys J, Castellvi A	Early radiographic and clinical outcomes study evaluating an integrated screw and interbody spacer for one- and two-level ACDF	Intl J Spine Surg 2015:9(39)	A retrospective review of one- and two-level ACDFs was performed from 2010 to 2013 on patients who received an integrated interbody implant with one of four different bone grafts.	The cellular allograft matrix group achieved 100% fusion, which was more than the Grafton DBM Putty (93%) and DBX Putty (50%) groups.
Eastlack R, Garfin S, Brown C, Meyer C	Proprietary cellular allograft matrix in anterior cervical discectomy and fusion (ACDF): Evaluation of clinical and radiographic outcomes from a prospective multi-center study	Spine 2014;39(22):E1331-37	Prospective, multi-center, nonrandomized clinical and radiographic study evaluating two-year outcomes of patients treated with a cellular allograft matrix as part of an ACDF procedure.	Improvements in clinical results at two years, high patient satisfaction and high radiographic and clinical fusion rates provide confidence in this proprietary cellular allograft matrix as an effective alternative to structural allograft or autograft in anterior cervical discectomy and fusion procedures.
Ammerman J, Libricz J, Ammerman M	The role of a proprietary cellular allograft as a fusion substrate in minimally-invasive, instrumented transforaminal lumbar interbody fusion (TLIF)	Clin Neurol Neurosurg 2013 Jul;115(7):991-4	A retrospective chart review of patients who had undergone a minimally-invasive TLIF with proprietary cellular allograft for degenerative lumbar conditions.	Twenty-one patients (91.3%) and 24 levels (92.3%) achieved radiographic evidence of solid bony arthrodesis by 12 months post-op. Six patients (26%) demonstrated clear evidence of early interbody bone growth within 6 months of surgery. The use of this cellular allograft matrix resulted in robust and reproducible lumbar interbody fusion.
McAfee P, Shucosky E, Chotikul L, Salari B, Chen L, Jerrems D.	Multilevel extreme lateral interbody fusion (XLIF) and osteotomies for 3-dimensional severe deformity: 25 consecutive cases	Int J Spine Surg 2013;7:e8–e19	A consecutive series of 25 patients (78 levels) illustrates the primary advantages of XLIF in correcting deformities along with a proprietary cellular allograft matrix and supplemental fixation with pedicle screw instrumentation.	With a mean follow-up of 24 months, 85% of patients showed evidence of solid arthrodesis and no subsidence on computed tomography and flexion/extension radiographs.
Caputo A, Michael K, Chapman T, Massey G, Howes C, Isaacs R, Brown C	Clinical outcomes of extreme lateral interbody fusion (XLIF) in the treatment of adult degenerative scoliosis	Scientific World J 2012; Article ID 680634: 5 pages	Thirty consecutive patients with adult degenerative scoliosis treated by a single surgeon at a major academic institution were followed for an average of 14.3 months. Interbody fusion was completed using the XLIF technique with a proprietary cellular allograft matrix and supplemental posterior instrumentation.	Based on the significant improvement in validated clinical outcome scores, XLIF with a proprietary cellular allograft matrix and supplemental fixation is effective in the treatment of adult degenerative scoliosis.
Tohmeh A, Watson B, Tohmeh M, Zielinski X	Allograft cellular bone matrix in extreme lateral interbody fusion (XLIF): preliminary radiographic and clinical outcomes	Scientific World J 2012; Article ID 263637: 8 pages	Forty patients were treated at 61 levels with XLIF and a proprietary cellular allograft matrix and included in the analysis.	Interbody fusion was shown in 90.2% of treated levels, with the remaining 9.8% being partially consolidated and progressing towards fusion at 12 months.
Kerr E, Jawahar A, Wooten T, Kay S, Cavanaugh D, Nunley P	The use of osteoconductive, stem-cells allograft in lumbar interbody fusion procedures: an alternative to recombinant human bone morphogenetic protein	J of Surgical Ortho Advances 2011; 20 (3): 193-197	Retrospective study of 52 consecutive patients to analyze the clinical effectiveness of a proprietary cellular allograft to achieve radiological arthrodesis in adult patients undergoing lumbar interbody fusion surgeries.	The use of a proprietary cellular allograft is safe and effective in adult patients undergoing lumbar interbody spinal fusion procedure as solid arthrodesis was achieved in 92.3% of patients at median followup time of 5 months.
SPINE CONFERENCE ABSTRACTS				
Ashraf N, Fields AC, McAnany S, Qureshi S.	Fusion rates in anterior cervical discectomy and fusion procedures using mesenchymal stem cell allograft	American Association of Orthopaedic Surgeons, 2014 Annual Meeting, P377 Spine Poster Presentation	Fifty-six consecutive patients undergoing one or two level ACDF were prospectively followed. All patients were fused using a structural interbody allograft packed with non-structural mesechymal stem cell allograft.	This study presents the first report on radiographic fusion rates using mesenchymal stem cell allograft in one and two level ACDFs. Given the high fusion rate without graft related complications, we believe mesenchymal stem cell allograft provides an effective alternative, especially in those patients with comorbid conditions, that may pose a challenging fusion environment.
Eastlack R, Brown C, Meyer C	Proprietary cellular allograft matrix in anterior cervical discectomy and fusion (ACDF): evaluation of patient outcomes from a prospective multi-center study	International Meeting on Advanced Spinal Techniques, 2013 Annual Meeting, Final Program p. 129, #119 Abstract	Prospective, randomized study across 17 centers and 181 patients evaluating the use of a proprietary cellular allograft in ACDF procedures.	Improvements in clinical results at 2 years, limited revision rate and high patient satisfaction provide confidence in this proprietary cellular allograft as an autograft alternative in ACDF procedures.
Putney E, Blumberg K	The effect of mesenchymal stem cell allograft on cervical and lumbar spinal fusion	Orthopaedic Research Society, 2013 Annual Meeting, Poster 0871A	Retrospective surgeon review of 126 patient charts from 03/2009 to 06/2012 who received mesenchymal stems cell matrix during spinal fusion.	This review examined the outcomes of cervical and lumbar spine fusion patients in whom stem cells were utilized. Mesenchymal stem cells may be a viable alternative to autologous iliac crest bone grafting towards achieving bone fusion.

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Authors	Title	Publication	Study Design	Key Takeaway
SPINE CONFERENCE ABSTRACTS CONTINUED				
Mohan V, Templin C, Lorenz M, Zindrick M	Allograft mesenchymal stem cells for anterior cervical discectomy and fusion	International Meeting on Advanced Spinal Techniques, 2010 Annual Meeting, Final Program, p57, Paper Abstract #22	Prospective collection of data on 46 consecutive patients who underwent anterior cervical discectomy and fusion with allograft MSC and a PEEK interbody spacer for radiculopathy and/or myelopathy.	Based on our short-term results, allograft stem cells are safe and effective for anterior cervical fusions with significant benefit in multiple level fusions and in smokers.
Torres R, Lieberson R, Parivash S	The efficacy of mesenchymal stem cells in thoraco-lumbar spine fusion surgery for trauma: a retrospective review of operated cases	American Association of Neurological Surgeons, 2009 Annual Meeting Abstract	A review of 15 patients who underwent anterior or anterior-posterior fusions of the thoraco-lumbar spine using MSC-DBM in combination with allograft in a one-year period with a minimum of six months follow-up.	Fusion rates using MSC-DBM are comparable to published fusion rates using autograft, allograft or BMP in our study population.
BASIC SCIENCE PEER-REVIEWED PUBLICATIONS				
Baboolal T, Boxall S, El-Sherbiny Y, Moseley T, Cuthbert R, Giannoudis P, McGonagle D, and Jones E	Multipotential stromal cell abundance in cellular bone allograft: comparison with fresh age-matched iliac crest bone and bone marrow aspirate	Regen Med 2014;9(3):15	MSC characterization used functional assays, confocal/scanning electron microscopy and whole-genome microarrays. Resident MSCs were enumerated by flow cytometry following enzymatic extraction.	Allograft material contained live osteocytes and proliferative bone-lining cells defined as MSCs by phenotypic and functional capacities. Without cultivation/expansion, the allograft displayed an 'osteoinductive' molecular signature and the presence of MSCs; with a purity over 100-fold that of iliac crest bone.
Neman J, Duenas V, Kowolik C, Hambrecht A, Chen M, Jandial R	Lineage mapping and characterization of the native progenitor population in cellular allograft	Spine J 2013; 13 (2) p162-74	Benchtop testing and analysis to map and characterize the native progenitor cells in proprietary cellular allograft.	Data provides corroborative evidence that the proprietary cellular allograft contains a heterogeneous cell population with some cells demonstrating the capacity for extensive self-renewal and multipotential differentiation in this in vitro environment. Both of these findings suggest these cells could be stem/progenitor cells in this in vitro investigation.
BASIC SCIENCE CONFERENCE ABSTRACTS				
Moseley T	Angiogenic characterization of allograft cellular bone matrix	2015 Tissue Engineering and Regenerative Medicine International Meeting World Congress Transactions. Boston, MA. Published in: Tissue Engineering: Part A 2015 ;21 (Supplement 1): S-168	Cryopreserved cellular bone matrix was prepared and placed into explant culture for 24 hours. RNA was extracted from the cells. Gene expression patterns were compared to those found in RNA from primary human adult fibroblasts. Additionally, a retrospective analysis of 581 consecutive released lots of the cellular allograft was conducted to determine the cell viability and yield immediately upon thawing.	Cells within allograft cellular bone matrix expressed high levels of angiogenic genes relative to fibroblasts, complementing previous evidence of an overall up regulation of osteogenic genes relative to bone marrow-derived MSCs. The data indicate that the cellular components contribute to the angiogenicity of the cellular bone matrix which may help drive bone formation.
Williams G, Moseley T	Osteoinductivity of allograft cellular bone matrix	North American Spine Society 28th Annual Meeting Proceedings, Spine J 2013; 13: p98S	Cryopreserved cellular bone matrix and its DBM component were obtained. The DBM component was assessed relative to a DBM fiber putty. Additional testing was performed on the cellular allograft. RNA was extracted and gene expression patterns were compared to those found in RNA from primary human fetal osteoblasts and adult fibroblasts. In vitro osteoinductivity assay was also performed. Also, bone morphogenetic proteins were quantified. Finally, rat ectopic implantation was performed and after 8 weeks, animals were imaged via plain radiographs and microCT. Implants were retrieved and processed for histological assessment.	Cells within allograft cellular bone matrix expressed high levels of BMPs relative to osteoblasts and fibroblasts, complementing previous evidence of an overall up regulation of osteogenic genes relative to human bone marrow-derived MSCs. Moreover, osteoinductive capacity was demonstrated. Higher inductive capacity and BMP concentrations were shown versus DBM fiber putty, which may reflect differences in processing, formulation or storage conditions. Together, the data indicate that both the cell and DBM components con- tribute to the osteoinductivity of allograft cellular bone matrix which may drive osteogenesis at a fusion site.

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