

References

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1. Agarwal R, Williams K, Umscheid CA, Welch WC. Osteoinductive bone graft substitutes for lumbar fusion: a systematic review. *J Neurosurg Spine*. 2009;11(6):729-40.
2. Agency for Healthcare Research and Quality (AHRQ). Technology assessment: the role of bone growth stimulating devices and orthobiologics in healing nonunion fractures. 2005 Sep 21. Accessed February 15, 2016.
3. Agency for Healthcare Research and Quality (AHRQ). Bone Morphogenetic Protein: The State of Evidence for On-Label and Off-Label Use. August 6, 2010. Accessed January 8, 2013.
4. American Academy of Orthopaedic Surgeons. Nonunions. Updated 2007. September. Accessed February 15, 2016.
5. American Academy of Orthopaedic Surgeons. Spinal fusion. Updated 2007. September. Accessed February 15, 2016.
6. American Academy of Orthopaedic Surgeons. Research. Statistics on Orthopedic Patients and Conditions. 2006. Accessed February 15, 2016.
7. Apatech, Inc. Actifuse. Accessed January 5, 2012.
8. Arora NS, Ramanayake T, Ren YF, Romanos GE. Platelet-rich plasma in sinus augmentation procedures: a systematic literature review: Part II. *Implant Dent*. 2010;19(2):145-57.
9. Bapat MR, Chaudhary K, Garg H, Laheri V. Reconstruction of large iliac crest defects after graft harvest using autogenous rib graft: a prospective controlled study. *Spine (Phila Pa 1976)*. 2008;33(23):2570-5.
10. Baskin DS, Ryan P, Sonntag V, Westmark R, Widmayer MA. A prospective, randomized, controlled cervical fusion study using recombinant human bone morphogenetic protein-2 with the CORNERSTONE-SR allograft ring and the ATLANTIS anterior cervical plate. *Spine*. 2003;28(12):1219-25.
11. Benglis D, Wang MY, Levi AD. A comprehensive review of the safety profile of bone morphogenetic protein in spine surgery. *Neurosurgery*. 2008;62(5 Suppl 2):ONS423-31; discussion ONS431.
12. Block MS, Achong R. Bone morphogenetic protein for sinus augmentation. *Atlas Oral Maxillofac Surg Clin North Am*. 2006;14(1):99-105.
13. Boakye M, Mummaneni PV, Garrett M, Rodts G, Haid R. Anterior cervical discectomy and fusion involving a polyetheretherketone spacer and bone morphogenetic protein. *J Neurosurg Spine*. 2005;2:521-5.
14. Boden SD, Kang J, Sandhu H, Heller JG. Use of recombinant human bone morphogenetic protein-2 to achieve posterolateral lumbar spine fusion in humans: a prospective, randomized clinical pilot trial: 2002 Volvo Award in clinical studies. *Spine*. 2002;27(23):2662-73.
15. Bohner M. Design of ceramic-based cements and putties for bone graft substitution. *Eur Cell Mater*. 2010;1;20:1-12.

16. Boyne PJ, Lilly LC, Marx RE, Moy PK, Nevins M, Spagnoli DB, Triplett RG. De novo bone induction by recombinant human bone morphogenetic protein-2 (rhBMP-2) in maxillary sinus floor augmentation. *J Oral Maxillofac Surg.* 2005;63(12):1693-707.
17. Burkus JK, Sandhu HS, Gornet MF, Longley MC. Use of rhBMP-2 in combination with structural cortical allografts: clinical and radiographic outcomes in anterior lumbar spinal surgery. *J Bone Joint Surg Am.* 2005;87-A(6):1205-12.
18. Calori GM, Tagliabue L, Gala L, d'Imporzano M, Peretti G, Albisetti W. Application of rhBMP-7 and platelet-rich plasma in the treatment of long bone non-unions: A prospective randomised clinical study on 120 patients. *Injury.* 2008;39(12):1391-402. Epub 2008 Nov 22.
19. Camargo PM, Lekovic V, Weinlaender M, Vasilic N, Madzarevic M, Kenney EB. A reentry study on the use of bovine porous bone mineral, GTR, and platelet-rich plasma in the regenerative treatment of intrabony defects in humans. *Int J Periodontics Restorative Dent.* 2005;25(1):49-59.
20. Carragee EJ, Hurwitz EL, Weiner BK. A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned. *Spine J.* 2011; 11(6):471-91.
21. Carragee EJ, Mitsunaga KA, Hurwitz EL, Scuderi GJ. Retrograde ejaculation after anterior lumbar interbody fusion using rhBMP-2: a cohort controlled study. *Spine J.* 2011;11(6):511-6.
22. Carreon LY, Glassman SD, Anekstein Y, Puno RM. Platelet gel (AGF) fails to increase fusion rates in 1 instrumented posterolateral fusions. *Spine.* 2005; 30(9):E243-6; discussion E247.
23. Carreon LY, Glassman SD, Brock DC, Dimar JR, Puno RM, Campbell MJ. Adverse events in patients reexposed to bone morphogenetic protein for spine surgery. *Spine.* 2008; 33(4):391-3.
24. Carlisle E, Fischgrund JS. Bone morphogenetic proteins for spinal fusion. *Spine.* 2005;5:240S-9S.
25. Chaua AMT, Mobbs RJ. Bone graft substitutes in anterior cervical discectomy and fusion. *Eur Spine J.* 2009; 4:449-64.
26. Delawi D, Dhert WJ, Rillardon L, Gay E, Prestamburgo D, Garcia-Fernandez C. A prospective, randomized, controlled, multicenter study of osteogenic protein-1 in instrumented posterolateral fusions: report on safety and feasibility. *Spine (Phila Pa 1976).* 2010; 35(12):1185-91. doi: 10.1097/BRS.0b013e3181d3cf28.
27. Dimar JR 2nd, Glassman SD, Burkus JK, Pryor PW, Hardacker JW, Carreon LY. Clinical and radiographic analysis of an optimized rhBMP-2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis. *J Bone Joint Surg Am.* 2009; (6):1377-86.
28. Dawson E, Bae HW, Burkus JK, Stambough JL, Glassman SD. Recombinant human bone morphogenetic protein-2 on an absorbable collagen sponge with an osteoconductive bulking agent in posterolateral arthrodesis with instrumentation. A prospective randomized trial. *J Bone Joint Surg Am.* 2009; 91(7):1604-13.
29. Dimar JR, Glassman SD, Burkus KJ, Carreon LY. Clinical outcomes and fusion success at 2 years of singlelevel instrumented posterolateral fusions with recombinant human bone morphogenetic protein 12/compression resistant matrix versus iliac crest bone graft. *Spine.* 2006;31(22):2534-9.

30. Dmitriev AE, Lehman RA Jr, Symes AJ. Bone morphogenetic protein-2 and spinal arthrodesis: the basic science perspective on protein interaction with the nervous system. *Spine J.* 2011; 11(6):500-5.
31. Einhorn TA. Clinical applications of recombinant human BMPs: early experience and future development. *J Bone Joint Surg Am.* 2003;85-A(Suppl 3):82-8.
32. Epstein NE. Pros, cons, and costs of INFUSE in spinal surgery. *Surg Neurol Int.* 2011;2:10.
33. Esposito M; Grusovin MG; Coulthard P; Worthington HV. Interventions for replacing missing teeth: bone augmentation techniques for dental implant treatment. The Cochrane Database of Systematic Reviews 2007 Issue 4, Copyright © 2007 The Cochrane Collaboration.
34. Feldman MD. Recombinant human bone morphogenetic protein-2 for spinal surgery and treatment of open tibial fractures. February 16, 2005. Accessed January 5, 2012.
35. Filardo G, Kon E, Buda R, Timoncini A, Di Martino A, Cenacchi A, Fornasari PM, Giannini S, Marcacci M. Platelet-rich plasma intra-articular knee injections for the treatment of degenerative cartilage lesions and osteoarthritis. *Knee Surg Sports Traumatol Arthrosc.* 2010.
36. Fiorellini JP, Howell TH, Cochran D, Malmquist J, Lilly LC, Spagnoli D, Toljanic J, Jones A, Nevins M. 2 Randomized study evaluating recombinant human bone morphogenetic protein-2 for extraction socket 3 augmentation. *J Periodontol.* 2005; 76(4):605-13.
37. Friedlaender GE, Perry CR, Cole JD, Cook SD, Cierny G, Muschler GF, et al. Osteogenic protein-1 (bone morphogenetic protein-7) in the treatment of tibial nonunions: a prospective, randomized clinical trial comparing rhOP-1 with fresh bone autograft. *J Bone Joint Surg Am.* 2001;83-A(Suppl 1 Pt 2):S151-8.
38. Garrison KR, Donell S, Ryder J, Shemilt I, Mugford M, Harvey I, Song F. Clinical effectiveness and costeffectiveness of bone morphogenetic proteins in the non-healing of fractures and spinal fusion: a systematic review. *Health Technol Assess.* 2007; 11(30):1-150, iii-iv.
39. Gautschi OP, Frey SP, Zellweger R. Bone morphogenetic proteins in clinical applications. *ANZ J Surg.* 2007; 77(8):626-31.
40. Glassman SD, Dimar JR 3rd, Burkus K, Hardacker JW, Pryor PW, Boden SD, Carreon LY. The efficacy of rhBMP-2 for posterolateral lumbar fusion in smokers. *Spine.* 2007; 32(15):1693-8.
41. Glassman SD, Dimar JR, Carreon LY, Campbell MJ, Puno RM, Johnson JR. Initial fusion rates with 2 recombinant human bone morphogenetic protein-2/compression resistant matrix and a hydroxyapatite and tricalcium phosphate/collagen carrier in posterolateral spinal fusion. *Spine.* 2005;30(15):1694-8.
42. Govender S, Csimma C, Genant HK, Valentin-Opran A, Amit Y, Arbel R, et al; BMP-2 Evaluation in Surgery for Tibial Trauma (BESTT) Study Group. Recombinant human bone morphogenetic protein-2 for treatment of open tibial fractures: a prospective, controlled, randomized study of four hundred and fifty patients. *J Bone Joint Surg Am.* 2002;84-A(12):2123-34.
43. Granjeiro JM, Oliveira RC, Bustos-Valenzuela JC, Sogayar MC, Taga R. Bone morphogenetic proteins: from structure to clinical use. *Braz J Med Biol Res.* 2005 Oct;38(10):1463-73.
44. Helgeson MD, Lehman RA Jr, Patzkowski JC, Dmitriev AE, Rosner MK, Mack AW. Adjacent vertebral body osteolysis with bone morphogenetic protein use in transforaminal lumbar interbody fusion. *Spine J.* 2011; 11(6):507-10.

45. Helm GA, Gazit Z. Future uses of mesenchymal stem cells in spine surgery. *Neurosurg Focus*. 2005; 15;19(6):E13.
46. Jones AL, Bucholz RW, Bosse MJ, Mirza SK, Lyon TR, Webb LX, Pollak AN, Golden JD, Valentin-Opran A;BMP-2 Evaluation in Surgery for Tibial Trauma-Allgraft (BESTT-ALL) Study Group. Recombinant human BMP-2 and allograft compared with autogenous bone graft for reconstruction of diaphyseal tibial fractures with cortical defects. A randomized, controlled trial. *J Bone Joint Surg Am*. 2006; 88(7):1431-41.
47. Johnsson R, Stromqvist B, Aspenberg P. Randomized radiostereometric study comparing osteogenic protein- 1 (BMP-7) and autograft bone in human noninstrumented posterolateral lumbar fusion: 2002 Volvo Award in clinical studies. *Spine*. 2002;27(23):2654-61.
48. Jung RE, Glauser R, Schärer P, Hämmerle CH, Sailer HF, Weber FE. Effect of rhBMP-2 on guided bone regeneration in humans. *Clin Oral Implants Res*. 2003; 14(5):556-68.
49. Kanayama M, Hashimoto T, Shigenobu K, Yamane S, Bauer TW, Togawa D. A prospective randomized study of posterolateral lumbar fusion using osteogenic protein-1 (OP-1) versus local autograft with ceramic bone substitute: emphasis of surgical exploration and histologic assessment. *Spine*. 2006; 1;31(10):1067-74.
50. Kassolis JD, Reynolds MA. Evaluation of the adjunctive benefits of platelet-rich plasma in subantral sinus augmentation. *J Craniofac Surg*. 2005; 16(2):280-7.
51. Khan SN, Sandhu HS, Lane JM, Cammisa FP Jr, Girardi FP. Bone morphogenetic proteins: relevance in spine surgery. *Orthop Clin North Am*. 2002;33(2):447-63.
52. Leung VY, Chan D, Cheung KM. Regeneration of intervertebral disc by mesenchymal stem cells: potentials, limitations, and future direction. *Eur Spine J*. 2006; 15 Suppl 3:S406-13. Epub 2006 Jul 15.
53. Luhmann SJ, Bridwell KH, Cheng I, Imamura T, Lenke LG, Schootman M. Use of bone morphogenetic protein-2 for adult spinal deformity. *Spine (Phila Pa 1976)*. 2005;1;30(17 Suppl):S110-7.
54. Mariconda M, Cozzolino F, Cozzolino A, D'Agostino E, Bove A, Milano C. Platelet gel supplementation in long bone nonunions treated by external fixation. *J Orthop Trauma*. 2008; 22(5):342-5.
55. McKay WF, Peckham SM, Badura JM. A comprehensive clinical review of recombinant human bone 2 morphogenetic protein-2 (INFUSE((R)) Bone Graft). *Int Orthop*. 2007;31(6):729-734.
56. Medtronic. Infuse Bone Graft. Oral-facial. Updated May 6, 2010. Accessed February 15, 2016.
57. Mehta S, Watson JT. Platelet rich concentrate: basic science and current clinical applications. *J Orthop Trauma*. 2008; 22(6):432-8.
58. Minamide A, Yoshida M, Kawakami M, Okada M, Enyo Y, Hashizume H, Boden SD. The effects of bone morphogenetic protein and basic fibroblast growth factor on cultured mesenchymal stem cells for spine fusion. *Spine*. 2007; 32(10):1067-71.
59. Mulconrey DS, Bridwell KH, Flynn J, Cronen GA, Rose PS. Bone morphogenetic protein (RhBMP-2) as a substitute for iliac crest bone graft in multilevel adult spinal deformity surgery: minimum two-year evaluation of fusion. *Spine (Phila Pa 1976)*. 2008;15;33(20):2153-9.

60. Mussano F, Ciccone G, Ceccarelli M, Baldi I, Bassi F. Bone morphogenetic proteins and bone defects: a systematic review. *Spine*. 2007; 1;32(7):824-30.
61. Nandi SK, Roy S, Mukherjee P, Kundu B, De DK, Basu D. Orthopaedic applications of bone graft & graft substitutes: a review. *Indian J Med Res*. 2010;132:15-30.
62. NuVasive, Inc. Osteocel Plus. Accessed February 15, 2016.
63. Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat. Osteogenic protein-1 for long bone nonunion. *Health Technology Assessment Scientific Literature Review*. Toronto, ON: Ontario Ministry of Health and Long-Term Care; April 2005. Accessed January 9, 2013.
64. Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat. Bone morphogenetic proteins and spinal surgery for degenerative disc disease. *Health Technology Assessment Scientific Literature Review*. Toronto, ON: Ontario Ministry of Health and Long-Term Care; March 2004. Accessed January 9, 2013.
65. Papakostidis C, Kontakis G, Bhandari M, Giannoudis PV. Efficacy of autologous iliac crest bone graft and bone morphogenetic proteins for posterolateral fusion of lumbar spine: a meta-analysis of the results. *Spine*. 2008;33(19):E680-92.
66. Pradhan BB, Bae HW, Patel VV, Delamarter RB. Graft resorption with the use of bone morphogenetic protein: lessons from anterior lumbar interbody fusion using femoral ring allografts and recombinant human bone morphogenetic protein-2. *Spine*. 2006; 31(10):E277-84.
67. Resnick DK. Reconstruction of anterior iliac crest after bone graft harvest decreases pain: a randomized, controlled clinical trial. *Neurosurgery*. 2005; 57(3):526-9; discussion 526-9.
68. Ronga M, Baldo F, Zappala G, Cherubino P; BMP-7 Italian Observational Study (BIOS) Group. Recombinant human bone morphogenetic protein-7 for treatment of long bone non-union: An observational, retrospective, non-randomized study of 105 patients. *Injury*. 2006; 37(9 Suppl):S51-6.
69. Rush SM. Trinity Evolution. *Foot Ankle Spec*. 2010; 3(3):144-7.
70. Russell TA, Leighton RK; Alpha-BSM Tibial Plateau Fracture Study Group. Comparison of autogenous bone graft and endothermic calcium phosphate cement for defect augmentation in tibial plateau fractures. A multicenter, prospective, randomized study. *J Bone Joint Surg Am*. 2008; 90(10):2057-61.
71. Sánchez M, Anitua E, Orive G, Mujika I, Andia I. Platelet-rich therapies in the treatment of orthopaedic sport injuries. *Sports Med*. 2009;39(5):345-54.
72. Singh K, Smucker JD, Boden SD. Use of recombinant human bone morphogenetic protein-2 as an adjunct in posterolateral lumbar spine fusion: a prospective CT-scan analysis at one and two years. *J Spinal Disord Tech*. 2006;19(6):416-23.
73. Smucker JD, Rhee JM, Singh K, Yoon ST, Heller JG. Increased swelling complications associated with offlabel usage of rhBMP-2 in the anterior cervical spine. *Spine*. 2006; 31(24):2813-9.
74. Swiontkowski MF, Aro HT, Donell S, Esterhai JL, Goulet J, Jones A, et al. Recombinant human bone morphogenetic protein-2 in open tibial fractures. A subgroup analysis of data combined from two prospective randomized studies. *Bone Joint Surg Am*. 2006; 88(6):1258-65.

75. Tarnow DP, Wallace SS, Testori T, Froum SJ, Motroni A, Prasad HS. Maxillary sinus augmentation using recombinant bone morphogenetic protein-2/acellular collagen sponge in combination with a mineralized bone replacement graft: a report of three cases. *Int J Periodontics Restorative Dent*. 2010; 30(2):139-49.
76. Termaat MF, Den Boer FC, Bakker FC, Patka P, Haarman HJ. Bone morphogenetic proteins. Development and clinical efficacy in the treatment of fractures and bone defects. *J Bone Joint Surg Am*. 2005; 87-A(6):1367-78.
77. U.S. Food and Drug Administration. INTER FIX Threaded Fusion Device: important medical information. Accessed February 18, 2016.
78. U.S. Food and Drug Administration. New device approval: INFUSE® bone graft-P000054. Updated May 17, 2004. Accessed February 18, 2016.
79. U.S. Food and Drug Administration. New device approval: InFUSE™ bone graft/LT-CAGE™ lumbar tapered fusion device-P000058. Updated 2002 Sep 6. Accessed February 18, 2016.
80. U.S. Food and Drug Administration. Supplement S002. July 2004. InFUSE™ bone graft/LT-CAGE™ lumbar tapered fusion device-P000058. Accessed February 15, 2016. .
81. U.S. Food and Drug Administration. New humanitarian device approval: OP-1™ - H010002. Updated 2001 Nov 30. Accessed February 15, 2016.
82. U.S. Food and Drug Administration. New humanitarian device approval: OP-1 Putty- H020008. Updated 2004 Apr 27. Accessed February 15, 2016.
83. U.S. Food and Drug Administration. InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. Summary of Safety and Effectiveness Data. January 10, 2022. Accessed February 15, 2016.
84. U.S. Food and Drug Administration. Osteofil Allograft Paste. 510(k) summary K043420. Accessed February 16, 2016.
85. Vaccaro AR, Whang PG, Patel T, Phillips FM, Anderson DG, Albert TJ, Hilibrand AS, Brower RS, Kurd MF, Appannagari A, Patel M, Fischgrund JS. The safety and efficacy of OP-1 (rhBMP-7) as a replacement for iliac crest autograft for posterolateral lumbar arthrodesis: minimum 4-year follow-up of a pilot study. *Spine J*. 2008; 8(3):457-65.
86. Lopez-Vidriero E, Goulding KA, Simon DA, Sanchez M, Johnson DH. The use of platelet-rich plasma in arthroscopy and sports medicine: optimizing the healing environment. *Arthroscopy*. 2010; 26(2):269-78.
87. Washington State Health Care Authority. Health Technology Assessment. On- and off- label uses of rhBMP-2 or rhBMP-7 for spinal fusion. February 14, 2012. Accessed February 15, 2016
88. Wood GW. General principles of fracture treatment. Fracture Healing. In: Canale & Beaty: *Campbell's*
89. *Operative Orthopaedics*, 11th ed. CH 50. Copyright © 2007 Mosby.
90. Yu NY, Schindeler A, Little DG, Ruys AJ. Biodegradable poly (alpha-hydroxy acid) polymer scaffolds for bone tissue engineering. *J Biomed Mater Res B Appl Biomater*. 2010; 93(1):285-95.
91. Spine Surgery Guidelines V1.1.2017