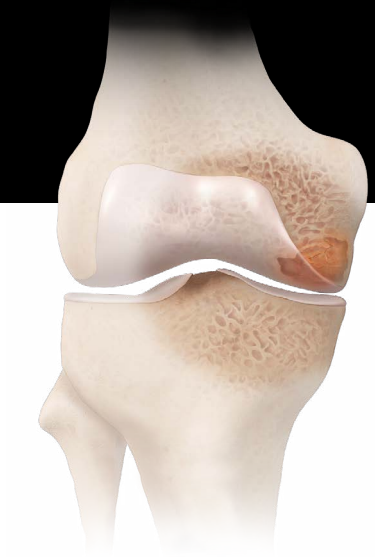

IntraOsseous BioPlasty™ Scientific Update

IntraOsseous BioPlasty (IOBP) is a biologic treatment for persistent subchondral bone pathologies used to decrease intraosseous pressure, return blood supply to normal, and promote bone healing and repair.

Persistent bone marrow lesions (BMLs) are the result of both acute and chronic injuries, including insufficiency fractures, osteoarthritis, persistent bone bruises, avascular necrosis, and osteonecrosis. BMLs are often characterized by increased pressure and decreased blood flow, which limits the body's ability to properly heal.[1-3] These lesions may degenerate to more severe osteochondral lesions or osteoarthritis. Patients with BMLs experience joint pain and an associated loss of function. If the lesion persists, they may eventually need total joint replacement.

Patients with BML who fail to respond to conservative treatment may benefit from the IOBP™ technique. The procedure includes decompression of the lesion and delivery of a concentrated dose of platelet-rich plasma (cPRP) from bone marrow aspirate using the Arthrex Angel® cPRP and bone marrow processing system. When mixed with a flowable demineralized bone matrix, such as AlloSync™ Pure, the biologic material delivered to the BML contains all of the necessary components needed to aid bone repair: an osteoconductive scaffold, osteoinductive factors, and an osteogenic source of stem cells.

Positive clinical outcomes using bone marrow concentrate to treat bone pathologies have been well described.[4] Some of the associated literature is listed below.

Clinical Need

Felson DT, Chaisson CE, Hill CL, et al

The association of bone marrow lesions with pain in knee osteoarthritis. *Ann Intern Med.* 2001;134(7):541-549.

- The identification of BMLs is the strongest predictor of the presence of pain associated with knee osteoarthritis (OA).
- Take home point: An X-ray, while showing joint space narrowing and alignment, won't be effective in diagnosing one potential source of pain. MRI may be utilized to localize BMLs.

Scher C, Craig J, Nelson F

Bone marrow edema in the knee in osteoarthrosis and association with total knee arthroplasty within a three-year follow-up. *Skeletal Radiol.* 2008;37(7):609-617. doi:10.1007/s00256-008-0504-x.

- "Subjects who had BME of any pattern type were 8.95 times as likely to progress rapidly to a TKA when compared to subjects with no BME (p=0.016)."
- Take home point: Improving bone health may alter the course of progression and resulting symptoms in patients with osteoarthritis.

Aaron RK, Dyke JP, Ciombor DM, et al

Perfusion abnormalities in subchondral bone associated with marrow edema, osteoarthritis, and avascular necrosis. *Ann NY Acad Sci.* 2007;1117:124-137. doi:10.1196/annals.1402.069.

- This was a clinical blood flow study to measure the differences in blood flow between bone with or without BMLs.
- The result of increased pressure led to reduced venous outflow, hypoperfusion (not enough blood flow for proper metabolism), and hypoxia (decreased O_2 in blood).
- The associated results of these blood flow concentrations was focal avascular necrosis (AVN), trabecular remodeling, sclerosis, and thickening of the subchondral plate.
- Take home point: Pressure and blood flow can affect the subchondral bone. It's a biologic problem that needs a biologic solution.

Hunter DJ, Gerstenfeld L, Bishop G, et al

Bone marrow lesions from osteoarthritis knees are characterized by sclerotic bone that is less well mineralized. *Arthritis Res Ther.* 2009;11(1):R11. doi: 10.1186/ar2601.

- Histology of BMLs shows micro-cracks/fractures, fibrosis, bone necrosis, and limited bone remodeling.
- MicroCT analysis of BMLs shows gaps and fractures in bone.
- Take home point: These histologic and radiologic findings in BMLs associated with OA are similar to those present in bone nonunions.

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Clinical Treatment

Hernigou P, Poignard A, Beaujean F, Rouard H

Percutaneous autologous bone-marrow grafting for nonunions. Influence of the number and concentration of progenitor cells. *J Bone Joint Surg Am.* 2005;87(7):1430-1437. doi:10.2106/JBJS.D.02215.

- 60 patients with established tibial nonunion aged 18-78 with a mean of 40 years.
- Bone marrow concentrate (BMC) injected into the nonunion site, percutaneously.
- Bone union (healing) observed in 88% of patients.
- Take home point: Percutaneous injection of BMC has a role in treating nonunion and, by correlation, BMLs with similar histologic findings (such as BMLs associated with OA).

Gangji V, De Maertelaer V, Hauzeur JP

Autologous bone marrow cell implantation in the treatment of non-traumatic osteonecrosis of the femoral head: five year follow-up of a prospective controlled study. *Bone.* 2011;49(5):1005-1009. doi: 10.1016/j.bone.2011.07.032.

- Prospective study comparing core decompression (CD) alone vs core decompression + bone marrow mononuclear cells (BMCs).
- Success with CD alone: 27% at 5-year follow-up.
- Success with CD + BMCs: 77% at 5-year follow-up.
- Take home point: Concentrated biologic delivery of BMCs has a beneficial impact on BMLs.

Hernigou P, Beaujean F

Treatment of osteonecrosis with autologous bone marrow grafting. *Clin Orthop Relat Res.* 2002 Dec;(405):14-23.

- Prospective study comparing early- vs late-stage AVN and treatment with core decompression + BMC.
- Success in stage I and II AVN: 94% at 10-year follow-up.
- Success in stage III and IV AVN: 43% at 10-year follow-up.
- Take home point: Treating AVN in the early stages is the best course of action when considering treatment options for BMLs.

Current Subchondroplasty® Literature

Cohen SB, Sharkey PF

Subchondroplasty for treating bone marrow lesions. *J Knee Surg.* 2016;29(7):555-563. doi:10.1055/s-0035-1568988.

Sharkey PF, Cohen SB, Leinberry CF, Parvizi J

Subchondral bone marrow lesions associated with knee osteoarthritis. *Am J Orthop.* 2012;41(9):413-417.

- 30% revision to TKA within 2 years.
- Mean age of arthroplasty conversion was 58.2 years.
- Authors conclude that this procedure "...will become more refined and delivery of cytokines and other cell signaling agents that create some combination of osteogenesis, chondrogenesis, and angiogenesis may further enhance the results."

References

1. Arnoldi CC, Lemperg K, Linderholm H. Intraosseous hypertension and pain in the knee. *J Bone Joint Surg Br.* 1975;57(3):360-363.
2. Reddy AS, Frederick RW. Evaluation of the intraosseous and extraosseous blood supply to the distal femoral condyles. *Am J Sports Med.* 1998;26(3)415-419. doi:10.1177/03635465980260031201.
3. Uchio Y, Ochi M, Adachi N, Nishikori T, Kawasaki K. Intraosseous hypertension and venous congestion in osteonecrosis of the knee. *Clin Orthop Relat Res.* 2001;384:217-223.
4. Hernigou P, Poignard A, Beaujean F, Rouard H. Percutaneous autologous bone-marrow grafting for nonunions. Influence of the number and concentration of progenitor cells. *J Bone Joint Surg Am.* 2005;87(7):1430-1437. doi:10.2106/JBJS.D.02215.

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