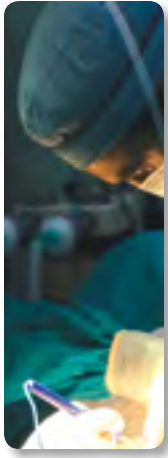


## Representative Clinical Reports

### Using LifeNet Health Allograft Bio-Implants in Sports Medicine Procedures





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LifeNet Health distributes more than 30,000 sports medicine allograft bio-implants annually. We understand the safety and quality of your allograft bio-implants are critical to you and your patients. We have high-quality allograft bio-implants with the biomechanical specifications you need to perform successful sports medicine surgeries. LifeNet Health offers a variety of safe and clinically proven ligament and tendon bio-implants to enhance mobility and stability for recipients. This list of articles below demonstrates the efficacy of our sports medicine allograft bio-implants.

#### Human Clinical Reports Using LifeNet Health FlexiGraft Sports Medicine Tendons and Ligaments

Tejwani SG, Chen J, Funahashi TT, Maletis GB, Love R. "Revision Risk After Allograft Anterior Cruciate Ligament Reconstruction: Association With Graft Processing Techniques, Patient Characteristics, and Graft Type" Am J Sports Med published online June 11, 2015. DOI: 10.1177/0363546515589168

- A retrospective cohort from a US health care system's ACL registry looked at 5,968 primary ACL reconstructions performed between 2005 - 2012 and examined the association of graft processing techniques, patient characteristics, and graft type with risk of revision surgery. The paper found that the use of Allowash® processing and donor age did not affect revision rate significantly, but did find BioCleanse graft processing to be associated with a higher risk of clinical failure. [Click here for link.](#)

Rihn, J.A., Irrgang, J.J., Chhabra, A. Fu, F.H., & Harner, C.D. "Does irradiation affect the clinical outcome of patellar tendon allograft ACL reconstruction?" Knee Surg Sports Traumatol Arthrosc. 2006; 14(9):885-96.

- Authors investigated the irradiation variable for ACL reconstruction in a clinical study involving 102 patients with an average follow-up of 4.2 years. The study found that not only is using 2.5 Mrad of gamma irradiation on LifeNet Health BPTB allografts effective in eliminating bacteria, but it did not apparently compromise the clinical effectiveness of the grafts. The authors concluded "These data suggest that irradiation can be used to sterilize BPTB allograft without adversely affecting clinical outcome." [Click here for link](#)

Petterson S, Green A, Plancher KD. "Greater Laxity in Females Following Autograft or Allograft Bone-Patellar Tendon-Bone Anterior Cruciate Ligament Reconstruction." 2015 ISAKOS Biennial Congress ePoster #1375 presented June 7-11, 2015.

- Authors compared AP knee laxity between BTB allograft and autograft ACLR. Retrospective review of 98 patients (33 autograft and 65 LifeNet Health allograft BTB tendons) by a single surgeon with an average follow up of 5.3 years were included. There were no significant differences in graft type in outcome scores or laxity. [Click here for link.](#)

Hampton, D.M., Lamb, J., & Klimkiewicz, J.J. "Effect of Donor Age on Patellar Tendon Allograft ACL Reconstruction." Orthopedics. 2012; Vol 35, Issue 8: e1173-31176. doi: 10.3928/01477447-20120725-15.

- Data from 75 patients with an average follow-up of 24 months were obtained. Average donor age was 44 years (range, 14-65 years), and average patient age was 37 years (range, 18-60 years). Statistical analysis of pre- and postoperative Lysholm scores demonstrated statistically significant improvement (P<.001). Using donor age as a continuous variable, no effect was found on postoperative improvement in Lysholm score or Tegner score (P=.6)." [Click here for link.](#)

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Klimkiewicz, J.J., Samsell, B.J., Riff, A., DeBerardino, T.M., & Moore, M.A. "Comparison of human tendon allografts and autograft used in knee reconstruction." Current Orthopaedic Practice. 2011; Vol 22, Issue 6: 494-502.

- Investigators compared the effectiveness of allografts and autografts in ACL reconstruction. The authors conclude that there is much data regarding the choice to use either allograft or autograft tendons for ACL reconstruction. While the "gold standard" designation given to the BPTB autograft is a commonly stated advantage by some literature sources, more surgeons using allografts are reporting equivalent results to autografts. As surgeons gain confidence with these reports and the results of their own patients, allografts have become an acceptable and even desirable option to autograft tissue for ACL reconstruction procedures. [Click here for link.](#)

Chun, C.H., Han, H.J., Lee, B.C., Kim, D.C., & Yang, J.H. (2004). "Histologic findings of anterior cruciate ligament reconstruction with Achilles allograft." Clin Orthop Relat Res (421):273-6.

- Investigators used LifeNet Health Achilles tendon allografts for anterior cruciate ligament (ACL) reconstruction in 12 patients over 24 months. Notably, gross and light microscopic examination showed similar histologic findings as a normal ACL by 12 months incorporation. [Click here for link.](#)

Burrus MT & Chhabra AB. "Distal biceps reconstruction 13 years post-injury." Ther Adv Musculoskel Dis 2015;7(2):56-59.

- Authors present a case study of a 13 year chronic distal biceps tendon rupture that was repaired utilizing an allograft Achilles from LifeNet Health. Patient has regained full function of the extremity and returned to work without limitations by 12 months post-op. [Click here for link.](#)

Harner, C.D., Chhabra, A., Cha, P.S., Rihn, J.A., Cole, B., Bennett, C.H., & Waltrip, R.L. "Surgical management of knee dislocations. Surgical technique." J Bone Joint Surg Am. 2005; 87 Supple 1(Pt 1): 1-21.

- Investigators used LifeNet Health irradiated Achilles tendons and bone patellar-tendon bone (BPTB) allografts in a retrospective, cohort study consisting of 47 patients with dislocated knees. In patients needing graft replacement, the Achilles tendons were used to replace PCLs and BPTBs were used to reconstruct ACLs. The authors reported satisfactory clinical success with a 2 - 6 year follow-up. [Click here for link.](#)

Sekiya, J.K. and Kurtz, C.A. "Posterolateral corner reconstruction of the knee: surgical technique utilizing a bifid Achilles tendon allograft and a double femoral tunnel." Arthroscopy. 2005; 21(11):1400.

- Investigators used LifeNet Health Achilles tendon allografts for posterolateral knee corner reconstruction in a technique article. They concluded that "a single allograft is sufficient to reconstruct all three key structures of the posterolateral corner: the LCL, popliteus tendon and the popliteofibular ligament." [Click here for link.](#)

Sekiya, J.K., Kurtz, C.A., & Carr, D.R. "Transtibial and tibial inlay double-bundle posterior Cruciate ligament reconstruction: Surgical technique using a bifid bone-patellar tendon-bone allograft." Arthroscopy. 2004; 20 (10):1095-100

- Investigators described their technique for PCL reconstruction using LifeNet Health whole patellar tendon allografts. The authors "believe the advantages of allograft, including less morbidity...outweigh the disadvantages." [Click here for link.](#)

Sotereanos, D.G., Gobel, F., Vardaka, D.G., and Sarris, I. "An Allograft Salvage Technique for Failure of the Darrach Procedure: A Report of Four Cases." J Hand Surg Br. 2002. 27(4):317-21.

- Investigators used LifeNet Health Achilles tendon allografts in the Darrach procedure with an average of 26 months follow-up. Three of four patients exhibited success, and the authors were supportive of using Achilles tendons for future cases. [Click here for link.](#)

#### Biomechanical or Literature Reports Using LifeNet Health FlexiGraft Sports Medicine Tendons and Ligaments

DeGeorge Jr BR, Rodeheaver GT, Drake DB. "The Biophysical Characteristics of Human Composite Flexor Tendon Allograft for Upper Extremity Reconstruction." Annals of Plastic Surgery. 2014. 72(6):S184-90.

- Authors found no difference in the biophysical properties between pre-processed and post-processed tendons using Allowash technology. [Click here for link.](#)

Representative Clinical Reports

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Samsell, B.J., and Moore, M.A. “Use of controlled low dose gamma irradiation to sterilize allograft tendons for ACL reconstruction: biomechanical and clinical perspective.” Cell Tissue Bank. 2012. 13(2):217-223.

- Authors reviewed numerous biomechanical and clinical studies supporting the use of controlled, low temperature irradiation of allograft tendons. Authors conclude that “As reviewed here, numerous biomechanical and clinical studies support the use of controlled, low temperature irradiation of allograft tendons, to provide both excellent clinical results and medical-device grade sterile allografts with minimal risk of disease transmission.” (68-20-023.00) [Click here for link.](#)

Moore, M.A. “Inactivation of enveloped and non-enveloped viruses on seeded human tissues by gamma irradiation.” 2012. Cell Tissue Bank. 13(3):401-7. doi: 10.1007/s10561-011-9266-0.

- Author studied effect of low dose gamma irradiation on viruses seeded onto both human tendons and cortical bone samples. “... Data presented here indicate that terminal sterilization using a low temperature, low dose gamma irradiation process inactivates both enveloped and non-enveloped viruses containing either DNA or RNA, thus providing additional assurance of safety from viral transmission.” [Click here for link.](#)

Moore, M.A. and Wolf, C. “Peroneus Longus and Posterior Tibialis Bio-Implants in Knee Reconstruction.” Bio-Implants Brief. 2010. (68-20-012.00)

- LifeNet Health white paper summarizes available literature and LifeNet Health biomechanical studies supporting the use of Peroneus longus and posterior tibialis for knee reconstruction. [Click here for link.](#)

Greaves, L.L., Hecker, A.T., & Brown, Jr., C.H. “The Effect of Donor Age and Low-Dose Gamma Irradiation on the Initial Biomechanical Properties of Human Tibialis Tendon Allografts.” AJSM. 2008. 36(7):1358-66. doi: 10.1170/0363546508314394.

- Authors evaluated the biomechanical properties of LifeNet Health tibialis tendons based on donor age. They conclude that “Donor age up to 65 years does not significantly affect the initial failure load, stiffness, or displacement at failure of tibialis allografts. An age-related decrease in failure stress was observed among no irradiated tendons but not in tendons subjected to irradiation.” [Click here for link.](#)

Balsly, C.R., Cotter, A.T., Williams, L.A., Gaskins, B.D., Moore, M.A., & Wolfinbarger, Jr., L. “Effect of low dose and moderate dose gamma irradiation on the mechanical properties of bone and soft tissue allografts.” Cell Tissue Banking. 2008. 9(4):289-98. doi: 10.1077/s10561-008-9069-0.

- Investigators studied the mechanical properties of bone and soft tissue allografts irradiated on dry ice at a low absorbed dose and a moderate absorbed dose using conventional compressive and tensile testing. The results support use of low dose and moderate dose gamma irradiation of bone grafts; however, results support use of only low dose irradiation on soft tissue grafts. [Click here for link.](#)

Moore, M.A. and Eisenlohr, L.M. “The Effect of Donor Age & Terminal Sterilization on Biomechanical Properties of Tendon Allografts.” Bio-Implants Brief. 2007. (68-20-007)

- This paper summarizes the findings of various biomechanical studies available in the literature and though LifeNet Health data, showing the lack of impact of donor age on the mechanical properties of soft tissue allografts. Available upon request.

Eisenlohr, L.M. “Allograft Tissue Sterilization Using Allowash XG®” Bio-Implants Brief. 2007. (68-0089)

- Author concludes that “the Allowash XG process does not adversely affect the biomechanical or biochemical properties of tissues needed for the intended clinical application.” Available upon request.

Wolfinbarger, Jr., L. “Gamma irradiation of Allograft Tendons.” 2003.

- This paper summarizes some mechanical and chemical findings supporting the use of gamma irradiation. Available upon request.

Representative Clinical Reports

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Other Published Articles Using Sports Medicine

Allograft Tendons and Ligaments

Swank KR, Behn AW, Dragoo JL. “The Effect of Donor Age on Structural and Mechanical Properties of Allograft Tendons.” Am J Sports Med. 2015; 43(2):453-9.

- Authors examined effect of donor age on the structural and mechanical properties of posterior tibialis tendons. They conclude that even though differences were observed between age groups, they were relatively small and most likely not clinically relevant. “The age of the donor will not likely affect the suitability of a graft for use in surgical reconstruction.” [Click here for link.](#)

Elenes EY & Hunter SA. “Soft-Tissue Allografts Terminally Sterilized with an Electron Beam Are Biomechanically Equivalent to Aseptic, Nonsterilized Tendons.

- Authors evaluated the biomechanical properties of tibialis and bisected bone-patellar tendon-bone (BTB) tendons treated with gamma irradiation (17.1 – 21.0 kGy), high dose e-beam (17.1 – 21.0 kGy), and low dose e-beam (9.2 – 12.2 kGy) and compared results to those of nonsterilized controls. There were no differences in biomechanical properties observed between the tendon groups for both tibialis and BTB tendons. [Click here for link.](#)

Mascarenhas R, Erickson BJ, Sayegh ET, Verma NN, Cole BJ, Bush-Joseph C, Bach Jr, BR. “Is There a Higher Failure Rate of Allografts Compared With Autografts in Anterior Cruciate Ligament Reconstruction: A Systematic Review of Overlapping Meta-analyses.” Arthroscopy. 2015 Feb;31(2):364-72.

- Authors reviewed meta-analyses containing 15,819 patients and concluded that “the current best available evidence suggests no differences in rupture rates and clinical outcomes.” [Click here for link.](#)

Bhatia, S., Bell, R., Frank, R.M., Rodeo, S.A., Bach, Jr., B.R., Cole, B.J., Chubinskaya, S., Wang, V.M., & Verma, N.N. “Bony Incorporation of Soft Tissue Anterior Cruciate Ligament Grafts in an Animal Model. Autograft Versus Allograft With Low-Dose Gamma Irradiation.” AJSM. 2012; 40(8):1789-98. doi: 10.1177/036354651143637

- Investigators studied the difference of ACL reconstruction in 48 rabbits comparing autograft and allograft, as well as irradiated versus non-irradiated. Concluded that maximum load and stiffness of a healing tendon are unaltered by low-dose irradiation. At 8 weeks, there were no biomechanical differences between allografts and autografts. [Click here for link.](#)

Ghodadra, N.S., Mall, N.A., Grumet, R. Sherman, S.L., Kirk, S., Provencher, M.T., and Bach, Jr., B.R. “Interval Arthrometric Comparison of Anterior Cruciate Ligament Reconstruction Using Bone-Patellar Tendon-Bone Autograft Versus Allograft: Do Grafts Attenuate Within First Year Postoperatively?” AJSM. 2012; 40(6):1347-54. doi: 10.1177/0363546512440685.

- Retrospective review of 238 patients from a single surgeon was made looking at data from preoperatively and from 6 weeks to 1 year postoperatively. Found there is no increased laxity after initial 6 weeks for either autograft or allograft during the first year postoperatively. There is no correlation between age, gender, concomitant injury, interval to surgery, or radiation of the graft with instrumented laxity results. [Click here for link.](#) Available upon request.

Ellis SJ, Williams BR, Pavlov H, Deland J. “Results of Anatomic Lateral Ankle Ligament Reconstruction with Tendon Allograft.” HSS J. 2011 Jul;7(2):134-40.

- Authors reconstructed lateral ankle ligaments using allograft tendons processed with Allowash technology and were gamma irradiated in 11 patients with good outcomes. [Click here for link.](#)

Greenberg, D.D., Robertson, M., Vallurupali, S., White, R.A., & Allen, W.C. “Allograft compared with autograft infection rates in primary anterior cruciate ligament reconstruction.” J Bone Joint Surg Am. 2010. 92(14):2402-8. doi: 10.2106/JBJS.1.00456.

- Investigators at the University of Missouri-Columbia compared infection rates between procedures using allograft and autograft tissue in primary ACL reconstructions in 861 patients. They “found no increased clinical risk of infection with the use of allograft tissue with autologous tissue for primary anterior cruciate ligament reconstruction.” [Click here for link.](#)

Wolfinbarger, Jr., L. and Eisenlohr, L. “Ensuring the Safety of Allograft Tissue.” Bio-Implants Brief. 2007. (68-0090).

- Authors discuss risk of disease transmission and tissue sterilization techniques, such as Allowash XG®. They conclude that “using a validated methodology, controlled dose, low-temperature gamma, irradiation can be used to obtain sterile allografts.” Available upon request.



LifeNet Health helps to save lives, restore health and give hope to thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

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