INTRODUCTION
Clinical ACL reconstruction with synthetic and non-human tissue based devices has led to failure due to a range of factors including material property mismatch, fatigue, abrasion, particulate shedding, poor fixation, anatomical placement, and immunologic rejection. The objective of our investigations was to develop an immunocompatible, dynamic bio-implant xenograft for ACL reconstruction with characteristics matching homologous human tissue. Primate studies have shown that treatment of porcine tissues with $\alpha$-galactosidase enzyme effectively attenuates host to graft immune recognition by $\alpha$-Gal epitope cleavage and have demonstrated gradual graft remodeling and long term ACL function as assessed at 2, 6 and 12 months [1,2]. Additional evaluations supporting development have included static and dynamic biomechanical testing, biomaterials biosafety/biocompatibility, toxicology, sterility and viral inactivation. This study is the first long-term human clinical evaluation of ACL reconstruction with an immunochemically modified porcine patellar tendon device [3].

METHODS
This was an FDA and IRB approved pilot clinical investigation in 10 patients requiring ACL reconstruction. A mixed complex patient population was enrolled to challenge the device in a safety and implantability study. Porcine bone-patellar tendon-bone grafts were processed using $\alpha$-galactosidase, low-level glutaraldehyde and terminally sterilized with 17.8 kGy radiation. All patients received the porcine xenograft. The patient population was extremely athletic with mean age of 41 years (range 21-51), mean pre-injury Tegner Score of 8 (range 6-10). Primary study endpoints were knee stability, serology and MRI findings. Secondary endpoints included subjective measurements of activity level, function and quality of life.

RESULTS
Safety and Implantability: Intra-operative surgical and technical feasibility objectives were met with device handling comparable to human patellar-tendon allografts. Four subjects failed due to non-device related events: (two by non-compliance and trauma; two by graft impingement). One subject failed due to intermittent effusion and was revised at 24 months. Five of six evaluable subjects met success criteria and were athletic and stable at 60 months.

Clinical Outcomes: Initial postoperative effusions resolved by six months. All stability assessments including KT-1000, Lachman’s, anterior drawer and pivot shift demonstrated significant improvement ($p<0.05$) over the study period (Fig 1.). Secondary outcome measures of patient self-evaluations also improved over the study period for Tegner Activity, IKDC and SF-36 measures (Fig 2.).

CONCLUSION
ACL reconstruction with immunochemically modified porcine grafts lead to successful outcomes in compliant patients. Graft long-term function, histopathology, MRI assessments and serology demonstrates host remodeling (ligamentization) of the treated grafts and supports the development of immunocompatible dynamic bioimplants from xenograft sources.

REFERENCES