

Effect of Tissue Processing on Clinical Outcomes of Primary Anterior Cruciate Ligament Reconstruction Using Allograft

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Summary:

Primary anterior cruciate ligament reconstructions (ACLRs) using non-irradiated allografts provide superior clinical outcomes than low-dose (less than 2.5 Mrad) irradiated allografts.

Abstract:

INTRODUCTION:

The use of allografts in primary anterior cruciate ligament reconstructions (ACLRs) has slowly increased over the last two decades. Concerns with viral and bacterial disease transmission have resulted in many tissue banks sterilizing allografts with gamma irradiation. It is unclear whether the use of low-dose irradiation, or other tissue processing methods such as preservation by fresh-frozen (FF), freeze-drying (FD), or cryopreservation (CP) methods, affect the clinical outcomes of primary ACLRs using allograft.

METHODS:

A computerized search of multiple electronic databases was conducted for both prospective and retrospective studies involving primary allograft ACLRs between January 1980 and September 2012. Inclusion criteria were English-language publications with a minimum of two-year follow up. Studies were excluded if they involved revision surgery, open or mini-open arthrotomy, multiple ligament procedures, use of autograft, non-human graft, or meniscal allograft, skeletally immature patients, grafts treated with ethylene oxide, Tutoplast, or irradiation greater than 2.5 Mrad, or if the tissue processing methods were not specified. Tissue processing methods such as low-dose irradiation (less than 2.5 Mrad) and preservation by FF, FD, or CP techniques were identified within each study. Clinical outcomes were evaluated using the Lysholm score, Tegner score, International Knee Documentation Committee (IKDC) score, KT-1000/2000 arthrometer score, Lachman test, and Pivot-shift test, as well as complications related to graft rupture, revision surgery, and deep graft infections. Two sets of statistical analyses were performed. First, meta-analyzed irradiated allograft data was compared against meta-analyzed non-irradiated data. Second, statistical comparisons were performed between meta-analyzed data from FF versus FD versus CP allografts. Sub-analyses were then performed to examine the effect of preservation method within the irradiated and non-irradiated data, and the effect of irradiation within each preservation technique.

RESULTS:

Twenty-six publications met the inclusion and exclusion criteria, involving a total of 1,802 patients, with 633 irradiated and 1,169 non-irradiated allografts. Non-irradiated allografts had higher mean Lysholm scores (89.8 vs. 84.4, $p < 0.05$) and a higher proportion of knees with less than 5 mm difference from contralateral knee using the KT-1000/2000 arthrometer (0.97 vs. 0.84, $p < 0.0001$), grade 0 and 1 Pivot-shift (0.99 vs. 0.94, $p < 0.0001$), and grade 0 and 1 Lachman (0.94 vs. 0.89, $p < 0.01$) than irradiated grafts. Irradiated allografts had a higher proportion of grade A and B IKDC outcomes (0.91 vs. 0.86, $p < 0.05$) and revision surgery (0.0250 vs. 0.0022, $p < 0.001$) than non-irradiated allografts, with no statistically significant differences in deep graft infections. The lack of data for FD and CP allografts meant no statistical analysis could be made for comparing FF vs. FD vs. CP allografts, examining the effects of preservation method within the irradiated and non-irradiated groups, and examining the effects of irradiation within

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the FD and CP groups. Within the FF preservation group, results similar to the irradiated versus non-irradiated comparison were seen.

CONCLUSION:

These results suggest that primary ACLRs using non-irradiated allografts provide superior clinical outcomes than low-dose (less than 2.5 Mrad) irradiated grafts. Due to insufficient numbers, the effects of preservation technique on clinical outcomes could not be determined.