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A Detailed Prospective and Blinded Analysis of Complications/Adverse Events in Patients Having ACL Reconstruction

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Summary:
This report represents a detailed and unbiased evaluation of the complications/adverse events experienced by 330 patients participating in a prospective double-blind randomized clinical trial for ACL reconstruction. Overall, 13% of patients required a repeat surgical procedure. Five percent of patients required revision, with more occurring for the Hamstring and Double-Bundle reconstructions.

Abstract:
Rationale:
It is well recognized that there is bias towards publication of positive results in the literature. Therefore, complications and adverse events of surgical procedures are inevitably under-reported.
The purpose of this study was to prospectively identify all complications/adverse events experienced by patients after having undergone ACL reconstructive surgery and the frequency at which they occur.

Methods:
This prospective study utilized patient information that was collected in a double-blind Randomized Clinical Trial (RCT), where 330 patients were equally distributed to receive an anatomic: patellar tendon (PT), quadruple-stranded hamstring (HT) and double-bundle hamstring (DB) autograft ACL reconstruction. All of the study patients, as well as the independent assessor were blinded to the assigned ACL surgical technique. All patients underwent the procedure with the same graft harvest and arthroscopic portal incisions. The assessor evaluated patients at two weeks, 3 months, 6 months, 1 year and 2 years post-operatively. Patients with a complication or an adverse event were followed more frequently as required.

Patients reported complications and adverse events by phone, e-mail, in person or at their pre-determined follow-up visits. All of these occurrences were documented, investigated, diagnoses were confirmed and blinding of the surgical technique was maintained at all times where possible.

Descriptive analyses were performed on all occurrences and sub-group comparisons were made between the three surgical techniques where appropriate.

Results:
There was one life threatening massive pulmonary embolism identified at 2 weeks post-op and successfully treated with anticoagulation and an IVC filter (0.3%). There was one severe complication of a septic arthritis, which was detected at one month post-op, treated with arthroscopic washout, IV antibiotics and successful preservation of the graft (0.3%). Fourty-five patients (13%) required repeat surgery, during the follow-up period.which included 62 separate operations. Repeat surgery was required in 9 (8.2%), 20 (17.3%) and 16 (14.5%) of the patients with PT, HT and DB procedures respectively. This was not statistically significant. Seventeen patients (5.1%) suffered a re-rupture of their ACL reconstruction. Sixteen required revision surgery; with 13 having 2-stage revision surgery and 3 having 1-stage revisions. One patient declined to have a recommended revision procedure. There was more that 2 times the

chance of requiring a revision in the HT and DB groups with the 17 patients distributed as follows: 3 PT, 7 HT and 7 DB. Thirteen patients had a repeat arthroscopy for meniscal (3.9%) and 2 patients for chondral pathology (0.6%). Nine patients required arthroscopic treatment for symptoms related to graft hypertrophy/ Cyclops lesions/arthrofibrosis (2.7%). Seven patients (2.1%)had a repeat arthroscopy to identify and manage a partial graft rupture. One patient required repeat surgery for wound dehiscence and one for the septic arthritis noted above. A total of 30/305 (9.8%) patients on examination at 2 years, demonstrated moderate to severe kneeling pain (17 PT, 9 HT, 4 DB). Eighteen patients experienced a hamstring strain (5.5%; 6HT, 12 DB); one patient experienced a traumatic single hamstring tendon rupture (0.3%; 1 PT). Seventeen patients suffered contralateral ACL injury (5.1%). Other complications included 1 DVT requiring anticoagulant therapy; 7 patients with minor wound infections/cellulitis treated with oral antibiotics; 5 patients with tibial periostitis treated with NSAIDs, 8 patients with infrapatellar branch saphenous nerve injury treated locally (one with significant dysesthesia; unresolved); one patient with tibial fixation screw pain and 2 patients with wound dehiscence requiring local treatment.

Conclusions:
Overall, 13% of patients required a re-operation at a minimum of 2 years after ACL reconstruction. Revision surgery was required in 5% of patients, with a greater chance in patients having Hamstring Tendon or Double Bundle reconstructions. Contralateral ACL injuries occurred in 5.1% of patients. Hamstring injury was much more common in the HT and DB groups. Nearly 10% of patients had kneeling pain, which was higher in the PT group. Fibrosis related problems requiring surgical treatment occurred in 3% of patients. Major complications of pulmonary embolism and septic arthritis were uncommon, but reported. Minor complications were more common, but readily treated with non-surgical management.