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“Soft-tissue QUadriceps autograft ACL-reconstruction in the Skeletally-immature vs. Hamstrings (SQuASH): A Multi-Centre Pilot Randomized Controlled Trial”

Injuries to the anterior cruciate ligament (ACL) occur at annual frequencies ranging from 100,000-200,000 and have an annual economic impact exceeding \$1 Billion US. In paediatric patients, there has been a near exponential rise in the incidence of ACL injuries – possibly due to a combination of increased sports participation/specialization, and a heightened awareness/improvement in the detection of injuries. However, despite largely satisfactory outcomes and continued technique and technological innovation, surgical reconstruction failure rates among active paediatric patients approximate 10-25%; with this particular population being 15 times more likely to re-injure their graft within the first post-operative year. Broadly speaking, failures of primary ACL reconstruction can be categorized according to one or a combination of traumatic, technical, and/or biologic causes, with optimal

selection and effect of graft choice on ACL reconstruction outcomes, for both adult and paediatric patients, long remaining a matter of intense controversy. In adults, the two autograft options that have predominated include the bone-patella tendon-bone (BPTB) and hamstrings – with randomized controlled trial (RCT) data showing similar outcomes between both options. However, “children are not small adults,” and therefore, the optimal graft for adults may not be ideal for paediatric patients. Most notably, is the presence of open physes in the paediatric population that present several technical challenges in an effort to avoid growth arrest, leg-length discrepancy, and/or angular deformity from iatrogenic physeal violation. As a result, it is recommended that paediatric ACL reconstruction only use soft-tissue autografts (not allografts), particularly in those furthest from skeletal maturity, given the close physeal proximity of a bone-block graft and/or interference screw. Currently, a hamstring autograft is the standard of care for primary paediatric soft-tissue ACL reconstruction. However, more recent research suggests that the hamstring tendons may not be the most ideal in some cases, potentially due to: its tendency to stretch over-time; associated unpredictable intra-operative graft lengths and diameters; cutaneous sensory loss at the donor site; injury to neurovascular structures; and/or bone tunnel osteolysis. Within the adult ACL population, there is a renewed interest in the biomechanical and biologic potential of the all-soft-tissue quadriceps tendon autograft; possibly due a combination of its: increased tensile strength; predictable pre-operative templating; less kneeling pain; less graft site donor morbidity; and/or comparable subjective/objective clinical outcomes to the traditional adult BPTB “gold-standard”. In addition, compared to hamstring autografts in adults, soft-tissue quadriceps autografts have evidence for less overall post-operative pain and analgesic requirements. Moreover, 3 separate systematic reviews from our group (two currently under manuscript review) focusing on quadriceps autograft ACL reconstruction, have demonstrated no difference in outcomes as it pertains to use of a full or partial thickness soft-tissue graft; the method of graft fixation; or with/without concomitant harvest of a patella bone-block (unpublished data). To date, the use of the quadriceps tendon as an autograft option in primary paediatric ACL reconstruction has not been well studied. Recent case series demonstrated: no angular deformities/leg length discrepancies; 92% return-to sport; no re-tears, and no re-operations due to graft failure. However, no RCT has examined the efficacy of the quadriceps tendon autograft in primary paediatric ACL reconstruction compared to the historical “gold-standard” soft-tissue hamstring in this population. In light of its evidence for favourable outcomes in the adult population, and the (albeit limited) evidence showing safety and promise in the paediatric population, clinical equipoise exists for assessing its impact on outcomes in paediatric patients at the index surgery. As a result, the

purpose of this pilot study is to prove feasibility of a global RCT that will evaluate the effectiveness of soft-tissue quadriceps versus hamstring autograft tendon on re-operation, return to sport, and knee function among paediatric patients undergoing primary ACL reconstruction. In order to assess the feasibility of a large-scale RCT, we will conduct a 30-patient pilot study at 3 clinical sites. Measures of feasibility will include rates of participant enrollment and protocol compliance as primary objectives. Secondary objectives include determining the effect of graft choice on the following outcomes at 9 months: 1) rate of return-to-sport (at any level and to pre-injury level), 2) knee function, 3) range of motion and stability, and 4) incidence of physeal injury causing growth arrest and/or angular deformity.