No Differences in Objective Knee Laxity Measurements Between Fixed and Adjustable Loop Suspensory Fixation in Anterior Cruciate Ligament Reconstruction: 1-Year Results from the GAP Study, A Prospective, Double-Blinded, Randomized Trial

Simon G F Abram[1], Rory Morrison, Adam Christopher Nelson[2], Simon Middleton, Vipul Mandalia
[1]University of Oxford, [2]Knee Unit, PEOC

INTRODUCTION:

Graft choice and fixation remains a topic of controversy in ACL reconstruction. Suspensory fixation is one of the most common techniques and can be performed with either a fixed-loop type device or, more recently, adjustable-loop devices have emerged. There have previously been some concerns that an adjustable loop device could 'slip' and lengthen over time, despite reassuring data from laboratory testing. There has, however, been a paucity of comparative clinical data and a clear need for an adequately powered, double-blinded, and randomized study comparing these devices. The GAP study was designed to address this need.

METHODS:

Over two-years in a single-centre, two-surgeon series, 152 patients were recruited and randomized to receive a hamstring ACL reconstruction using either a fixed-loop or variable-loop suspensory device (Stryker G-Lock or ProCinch, respectively). The patients and outcome assessors were blinded to the intervention. The surgeons were not involved in the follow up assessments, collection of outcomes, or data analysis. Knee laxity measurements were taken by a specialist physiotherapist using the GNRB knee arthrometer, set at 150N and 200N respectively. Measurements were taken from the operated leg and compared to the contralateral leg. Findings were summarised with descriptive statistics. Individual patient between-knee laxity measurements were analysed using a paired t-test. An unpaired t-test was used to compare the operated-knee laxity measurements and between-knee laxity measurements (operated-knee versus contralateral-knee) by intervention (fixed-loop vs. adjustable-loop).

RESULTS:

At 1-year, 121 patients (62% male; mean age 31, SD 9.8) had complete knee laxity assessments. Of these, 58 received the fixed loop fixation and 63 the adjustable loop device. Including all patients, knee laxity measurements at 150N were greater in the operated-knee (mean 5.56mm; 95% CI 5.30-5.81) in comparison to the contralateral knee (mean 4.45mm; 95% CI 4.24-4.66; $P<0.05$). This corresponded to a between-knee difference of 1.11mm (SD 1.29; 95% CI 0.88-1.34; $P<0.05$). At 200N, including all patients, the operated-knee laxity was 6.98mm (SD 1.53; 95% CI 6.70-7.25) and the contralateral knee laxity was 5.86mm (SD 1.28; 95% CI 5.63-6.09; $P<0.05$). This corresponded to a between-knee difference of 1.12mm (SD 1.38; 95% CI 0.87-1.37; $P<0.05$).

Comparing the two interventions (fixed vs. adjustable loop), however, there was no difference in the absolute operated-knee laxity measurements. At 150N, the operated-knee laxity in the fixed-loop group was 5.51mm (SD 1.40; 95% CI 5.13-5.87) versus 5.61mm (SD 1.39; 95% CI 5.26-5.96) in the adjustable-loop group ($P=0.68$). At 200N, the operated-knee laxity in the fixed-loop group was 6.94mm (SD 1.54; 95% CI 6.53-7.34) versus 7.02mm (SD 1.53; 95% CI 6.63-7.40) in the adjustable-loop group ($P=0.78$). There was also no difference by intervention for the relative, between-knee, laxity measurements for patients receiving the fixed-loop versus adjustable-loop device at either 150N (mean 1.23mm; 95% CI 0.93-1.52 versus mean 1.00mm; 95% CI 0.64-1.36; $P=0.33$) or at 200N (mean 1.26mm; 95% CI 0.93-1.58 versus mean 0.99mm; 95% CI 0.61-1.37; $P=0.29$).

DISCUSSION AND CONCLUSION:

The GAP study is the first to compare knee laxity measurements between these two graft fixation devices in a randomized and blinded study. No differences were observed in either the absolute or relative (operated vs. non-operated) knee laxity measurements for patients who received the fixed-loop graft fixation device in comparison to patients who received the adjustable-loop device. These important new findings should inform surgeons and patients when considering graft fixation choice in ACL reconstruction. This study also provides new normative reference data for the operated and non-operated knees of patients following ACL reconstruction.