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FTP2.7 Omental-derived Stromal-vascular Cell Fraction / Alginate Gel Composite Vs Control to Improve Murine Colonic Anastomotic Leak Rate – M-OMENTUM Randomised Controlled Study

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Aim: Colorectal anastomotic leak (AL) remains a significant challenge. The M-OMENTUM study compared omental-derived stromal-vascular cell-fraction (OSVCF) / alginate gel composite vs control subgroups to prevent murine AL.

Methods: C57BL-6 mice were subjected to an AL model with a leak rate (LR) of 40% and randomised (1:1) to OSVCF / alginate gel or control subgroups (gel alone and no treatment) powered to detect a 20% minimum difference (50% absolute reduction in LR); HO Licence PP9886008. Mice underwent laparotomy and colo-colonic anastomoses. In the intervention group, OSVCF was harvested and applied to the anastomosis in an alginate gel. Mice underwent schedule 1 killing at day 7 or earlier if they failed to meet wellness thresholds. The primary outcome was LR. Secondary outcomes included leak severity, weight, and adhesion score. An intention-to-treat analysis was performed.

Results: 128 mice (M:64/F:64), mean age 13.1 weeks (SD,1.2), mean weight, 24.1g (SD,4.3) were randomised. OSVCF/Gel containing mean 3.3x10³ cells/mg (SD,0.3x10³) was applied in the intervention group. Overall LR was 49.2%. There was a numerical difference in LRs between the intervention group (30/64, 46.9%) and control groups (33/64, 51.5%) with a LR reduction of 9.1% (RR 0.91 [95%CI:0.64-1.69]; P=0.72). 12/33(36.4%) that received gel alone and 5/33(15.2%) that
received no treatment developed an abscess rather than feculent peritonitis (RR 2.26 [95%CI:1.11-5.20]; P=0.04).

**Conclusions:** OSVCF/gel produced a 9.1% reduction in LR, but this did not reach statistical significance. The application of gel to an anastomosis alters the severity of anastomotic leak, favouring abscess formation rather than faecal peritonitis.