# Impact of convex ostomy appliances on leakage frequency, peristomal skin health and stomal protrusion

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## Abstract

#### Aim:

The Convexity in Ostomy (ECOS) study measured the impact of soft convex ostomy appliances on leakage frequency, peristomal skin health, and patient satisfaction, as well as stomal protrusion and body profile.

#### Methods:

This prospective non-randomised controlled trial included people with a stoma, divided into a control group using a convex appliance throughout (Alterna Confort Convex or Easiflex Confort Convex Light, Coloplast A/S, Humlebæk, Denmark), and an intervention group who were using a flat appliance at baseline before switching to a convex appliance for the rest of the study. Leakage frequency was counted within the past 2 weeks; peristomal skin health was assessed using the discolouration, erosion and tissue overgrowth (DET) Ostomy Skin Tool; and patient satisfaction was measured with a 0-10 Likert scale of self-reported satisfaction with the appliance. Measurements were taken at three visits: baseline (V1), 2-8 weeks (V2) and 6 months (V3). The Kruskal-Wallis and analysis of variance (ANOVA) tests were used for comparison. Multiple regression analysis was used to evaluate the effect of independent variables on the change in leakage frequency and DET score between baseline and 6 months.

### Findings:

Of 253 participants screened, 245 completed the follow-up, with 151 in the intervention group and 94 in the control group. Mean leakage frequency period went from  $5.85 \pm 5.55$  (V1) to  $0.63 \pm 1.42$  (V2) and  $0.23 \pm 0.75$  (V3) (p<.0001). Mean DET score changed from  $4.8 \pm 3.47$  (V1) to  $1.41 \pm 2.17$  (V2) and  $0.54 \pm 1.57$  (V3) (p<.0001). Mean satisfaction changed from  $6.0 \pm 2.25$  (V1) to  $8.6 \pm 1.14$  (V2) and  $9.17 \pm 0.93$  (V3) (p<.0001). From V1 to V3, the proportion of patients with a depressed peristomal area went from 45.7% to 31.4%, a normal peristomal area went from 45.3% to 65.3%, stoma protrusion went from 31.4% to 47.3% and stoma retraction went from 28.6% to 15.5%. By group, mean leakage frequency decreased in the intervention group by 7.65, from 7.57 to 0.11, and in the control group by 2.37, from 2.94 to 0.46 (p<0.0001). Multiple ANOVA analysis confirmed independent variables in reducing leakage to be initiating convexity and appliance

coupling. By group, mean DET score decreased in the intervention group by 4.82, from 5.24 to 0.42, and in the control group by 3.52, from 4.34 to 0.76. Multiple ANOVA analysis showed independent variables for DET score to be initiating convexity, emergency surgery and stoma siting.

#### Conclusion:

People with a stoma experiencing repeated leakage benefitted from shifting from a flat to a soft convex appliance in terms of leakage frequency, peristomal skin health, stomal protrusion and body profile.