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# A non-manufacturer-sponsored, retrospective study to assess 2-year safety outcomes of the BellaGel® SmoothFine as compared with its competitors in the context of the first Korean case of a medical device fraud

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## Abstract

### Background

We conducted this study to assess preliminary 2-year safety outcomes of an implant-based augmentation mammaplasty using the BellaGel® SmoothFine in the context of the first Korean case of a medical device fraud.

### Methods

Our clinical series of the patients (n = 579; 1,158 breasts) received augmentation using the BellaGel® SmoothFine, Naturgel™, Motiva Ergonomix™, Eurosilicone Round Collection™, Natrelle® INSPIRA™, Natrelle® 410, Mentor® MemoryGel Xtra or Microthane®. The patients were evaluated for incidences of postoperative complications and Kaplan-Meier survival and hazards.

### Results

Overall, there were a total of 101 cases (17.4%) of postoperative complications; these include 31 cases (5.4%) of shape deformity, 21 cases (3.6%) of CC, 18 cases (3.1%) of early seroma, 8 cases (1.4%) of infection, 5 cases (0.9%) of early hematoma, 1 case (0.2%) of delayed hematoma, 1 case (0.2%) of rupture and 1 case (0.2%) of ripping. Moreover, there were also 15 cases (2.6%) of other complications. There were significant differences in incidences of postoperative complications between the breast implants from different manufacturers (P = 0.034). The Natrelle® 410 showed the longest survival (333.3±268.2 [141.5–525.1] days). A subgroup analysis showed that there were no significant differences in incidences of postoperative complications between the breast