Statistical analysis plan.

Sample size

We based our sample size calculation on the postoperative NRS score from the literature. The anticipated percentage of NRS scores >3 postoperatively was 40%. We considered a 50% reduction in the OFA group to be clinically relevant. With a type 1 error of 0.01 and a power of 90%, a sample size calculation determined that 90 patients per group were needed in the study. We aimed to recruit an additional 20% of patients for drop-out or loss to follow-up.

Statistical analysis

Continuous variables were expressed as the means, the standard deviation (SD) or medians (interquartile range, IQR) as appropriate, and discrete variables as counts (percentage). The Kolmogorov–Smirnov test was used to test for normality. The independent samples t test or a Mann–Whitney test was used to compare quantitative variables if necessary. If necessary, a chi-square or Fisher exact test was used to compare qualitative variables. First, we performed a univariate analysis to identify the explanatory variables (type of surgery) with a significant contribution to the response variable (rate of postoperative pain NRS >3). Afterward, we conducted a multivariate analysis to adjust for covariates with the stepwise method by the Aikake Information Criterion (Aic). A two-sided P value < 0.05 was considered significant. The analysis was performed using R software (version 2.6-1).

Summary of the Intervention

