

The Preliminary Application of Socket-shield Technique in Orthodontic Extraction and  
Fixed Orthodontic Treatment

NCT06510621

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## 1. Software and Statistical Significance

All statistical analyses will be conducted using SPSS statistical software version 20.0 (IBM Corp., Armonk, NY, USA). A significance level of  $P < 0.05$  will be considered statistically significant for all tests.

## 2. Data Screening and Assumptions

**Normality Testing:** The Shapiro-Wilk (S-W) test will be used to assess the normality of the data distribution. This test is suitable for small to medium-sized samples and will determine whether the data within each group approximate a normal distribution.

**Homogeneity of Variance:** The F-test will be used to assess whether the variances of the test group and control group are homogenous, which is an assumption necessary for parametric tests such as the paired samples t-test. Homogeneity of variance will be assumed if the F-test yields a P-value  $> 0.05$ .

## 3. Primary Analysis

**Paired Samples T-Test:** To compare outcomes between the test group and the control group, a paired samples t-test will be conducted. This test is chosen due to the paired nature of data collected, which allows for a direct comparison of each subject under different conditions. Results with a P-value  $< 0.05$  will be considered statistically significant, indicating a meaningful difference between the two groups.

## 4. Adjustment for Multiple Comparisons

If multiple outcomes are analyzed simultaneously, the Bonferroni correction will be applied to adjust the significance threshold and control for the risk of Type I errors. The corrected P-value will be calculated by dividing the significance level (0.05) by the number of comparisons. This adjustment will ensure that the findings remain robust and reduce the likelihood of false-positive results.

## 5. Additional Statistical Analyses

For exploratory analysis and if data do not meet normality or variance assumptions, the following non-parametric tests may be applied as alternatives:

**Wilcoxon Signed-Rank Test:** To compare medians between paired groups if normality assumptions are not met.

**Levene's Test:** As an alternative check for homogeneity of variances, particularly if sample sizes are unequal.

## 6. Handling Missing Data

Missing data will be addressed by assessing the pattern and mechanism of missingness. If data are missing completely at random (MCAR), listwise deletion will be employed. However, if data are missing at random (MAR), multiple imputation will be applied to generate a complete dataset. The approach will depend on the proportion of missing data and its assumed mechanism.

## 7. Data Presentation

All data will be presented as mean  $\pm$  standard deviation (SD) or median and interquartile range (IQR) depending on the data distribution. P-values, confidence intervals (CIs), and effect sizes will be reported for primary and secondary outcomes to provide a comprehensive understanding of the treatment effects.

This Statistical Analysis Plan ensures that the data are analyzed rigorously, assumptions are checked, and adjustments are applied to mitigate the risk of errors, making the findings robust and clinically meaningful.