

# One-time abutment placement versus 4 times abutment removal on interproximal levels and peri-implant soft tissues: a prospective randomized clinical trial

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## Justification

Previous data from our research group suggests that placing the final abutment at the moment of surgery and its non-removal, can help preserve the crestal bone levels, when compared to a conventional protocol where healing abutments are removed once.

## Hypothesis

The null hypothesis to be tested is there are no differences in terms of crestal bone resorption between placing the final abutment during surgery (one-time abutment protocol) versus placing a healing abutment that will be removed four times during the subsequent visits for the final prosthesis delivery (conventional protocol).

## Objectives

The **primary** objective of the present multicenter, randomized clinical trial is to evaluate the changes in peri-implant crestal bone levels between two prosthetic protocols, the control being the conventional protocol where healing abutments are placed during surgery and removed four times before the delivery of the final abutment and prostheses, and the test protocol where definitive abutments are placed immediately after implant placement and are not removed ever again.

## Material & Methods

80 implants

Platform switching

### INCLUSION

Male or female adult patients, aged 18 or older, with at least 2 adjacent missing teeth in the posterior maxilla or mandible (positions 4 to 7).

### EXCLUSION

Bone augmentation in the last 6 months or needed at the time of implant placement  
Less than 5mm of keratinized mucosa  
Tooth extraction less than 12 weeks ago

**Target population:** Male or female adult patients, aged 18 or older, with at least 2 adjacent missing teeth in the posterior maxilla or mandible (positions 4 to 7).

**Sample size calculation:** Power calculation was carried out for calculating the sample size. The criteria for significance was set at  $\alpha = 0.05$  (type I error) and the power at  $\beta = 0.20$  (type II error). Assuming a mean difference in bone level of 0.20mm between groups, with a standard deviation (SD) of 0.157 (according to Canullo et al. 2010), and taking into consideration a foreseen 10% of likely drop-outs, 40 patients (20 per group) and 80 implants (40 per group) will be needed to achieve an adequate recruitment.

### Statistical analysis:

**Quantitative:** means and SD. T-test intergroup differences  
**Categorical:** frequency distribution. Chi-square for intergroup differences

3 months and a half

- Primary stability (mandatory)  
- Definitive abutment

- 1.Impresions  
- 2.Metal try-in  
- 3.Ceramic try-in  
Over definitive abutment

Final prosthesis  
Soft tissue biopsy

Surgery

8 weeks

14 weeks - day 0

Follow  
up

- Primary stability (mandatory)  
- Healing abutment (non-submerged)

- 1.Impresions  
- 2.Metal try-in  
- 3.Ceramic try-in  
Over implant

Final prosthesis  
Soft tissue biopsy

- Periapical x-ray  
- Clinical data (PPD,BOP,QM ....)  
- Cuestionario de satisfacción

- 1 calibrated examiner

- 6M, 12M, 24M, 36M

## References

Molina A, Sanz-Sánchez I, Martín C, Blanco J, Sanz M. (2016) The effect of one-time abutment placement on interproximal bone levels and peri-implant soft tissues: a prospective randomized clinical trial. Clin Oral Implants Res; 2016 Mar 25