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APPENDIX

MATERIALS & METHODS

Males and females with localized or generalized severe periodontal disease and between the ages of 30 and 75 yrs were recruited (Appendix Fig.). Inclusion criteria included serum calcium and parathyroid hormone levels within the normal range, as well as 25(OH)D levels of at least 16 ng/mL at the time of screening. Dental inclusion criteria included ≥ 6 mm probing depth (PD) and ≥ 6 mm clinical attachment loss (CAL) in the presence of a vertical infrabony defect. Study participants could have more than one site with the periodontal inclusion criteria, although only 1 site was randomly selected prior to surgery for analysis. Exclusion criteria included the presence of Paget's disease, metabolic bone disease, prior radiation treatment, malignancy, growth hormone deficiency, conditions affecting calcium absorption, kidney disease, heavy smoking (>1 pack/day), pregnancy, or the use of medications that affect bone metabolism.

An inter-examiner calibration session was held at the beginning of the study and again at the mid-point of the study. The

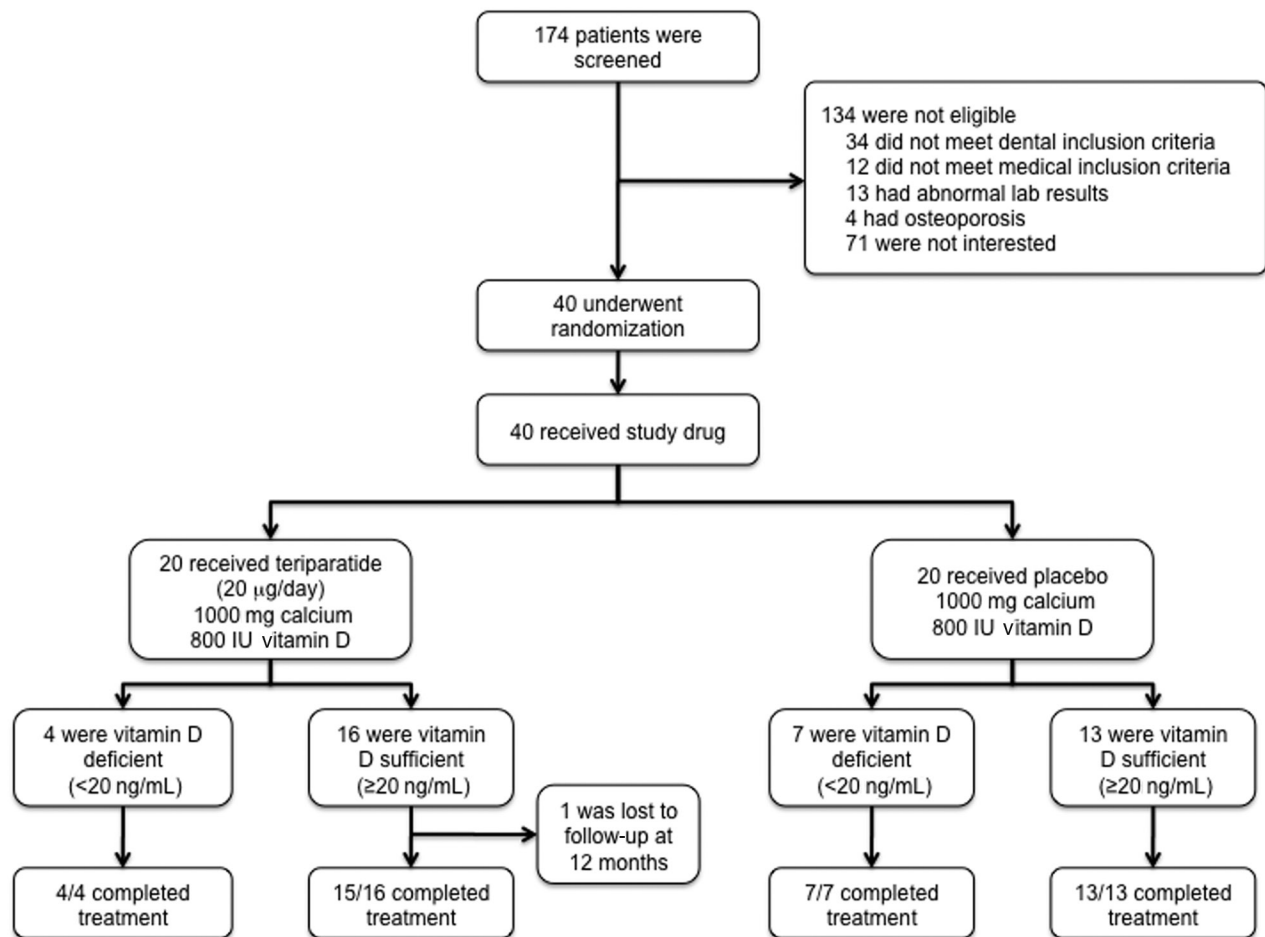
The Impact of Vitamin D Status on Periodontal Surgery Outcomes

standard deviations of the examiner measurements were 0.41 mm for CAL and 0.58 mm for PPD.

Randomization was done so that 20 individuals received teriparatide and 20 received placebo medication. Participants were instructed to self-administer calcium, vitamin D, and teriparatide/placebo in the morning once daily beginning 3 days prior to surgery. Calcium (1000 mg) and vitamin D (800 IU) were given in a single oral dose. Serum bone-specific alkaline phosphatase levels were significantly elevated at 6 wks relative to baseline in teriparatide patients ($p = 0.003$; Bashutski *et al.*, 2010), indicating compliance through the drug administration phase. There were no significant differences in adverse events between groups.

APPENDIX REFERENCE

Bashutski JD, Eber RM, Kinney JS, Benavides E, Maitra S, Braun TM, *et al.* (2010). Teriparatide and osseous regeneration in the oral cavity. *N Engl J Med* 363:2396-2405.



Appendix Figure