

Editorial **Should We Continue to Perform Human Histologic En Bloc Investigations?**

When considering the propriety of human histologic investigations, the first issue to be addressed is the substantial knowledge to be gained regarding new products' efficacy in achieving periodontal regeneration. It is impossible to know whether this end point goal of therapy has been achieved without histologic evidence since the universally accepted definition is the formation of new bone, new periodontal ligament, and new cementum on a root surface previously exposed to disease, with the level of disease demarcated by a root surface notch at the apical extent of the calculus. This histologic situation can only be established through biopsy that includes the tooth and surrounding periodontium and is processed with the greatest of care. Proof of principle must be complemented by research activities that assess the reliability of the product through randomized trials. This will result in valuable knowledge regarding the predictability of the product's effects.

The importance of histologic evidence is clearly demonstrated by the publication of monkey research by Caton and Zander,¹ which showed osseous repair of an infrabony pocket without new attachment of connective tissue between the new bone and root surface, a situation that would not be detected radiographically and without histologic investigation might be misinterpreted. Although many would suggest the substitution of animal investigation for human trials and the preclinical information to be gained from such research is of great interest, history has demonstrated that on too many occasions optimistic results cannot be replicated in clinical treatment.

Moreover, it is important that we consider the recipient of our contemporary regenerative treatment regimens when selecting appropriate materials. All new and emerging technologies are handsomely packaged and offer user-friendly procedures, but is there the highest form of evidence available as to their effectiveness? Are we aware of their limitations for treating defects of lesser containment that challenge space maintenance and clot stabilization? Recognizing regenerative limitations of a material guides the clinician to select the appropriate product to treat a specific problem.

The second issue to be considered is whether human histologic studies are humane and ethical. This is a multifactorial question that must be addressed.

It is obvious that the tooth or teeth in question must present with advanced periodontal disease and have a questionable prognosis to be considered for histologic investigation. There must be exclusionary rules in patient selection relative to general health status and the use of tobacco products. The patient should be at least 18 years old and should not be pregnant, have uncontrolled type 1 diabetes, be a recent oncologic patient, or be taking medications that affect bone metabolism.

In addition, an informed consent form should be provided and discussed with the patient before the surgery has been scheduled. It should then be reviewed by the patient at home and with the clinician again at the time of surgery to ensure complete understanding.

The final consideration relates to the postsurgical outcome and wellness of the patient. It is possible to judiciously harvest a block graft and provide an exceptional benefit to the donor patient. It is obligatory to correct the damage from block section harvesting and then to provide an appropriate prosthesis that will offer optimal mastication, esthetics, and phonetics. This treatment will provide a significant improvement in the dental prognosis in return for invaluable information for future patient treatment.

Reference

1. Caton J, Zander H. Osseous repair of an infrabony pocket without new attachment of connective tissue. *J Clin Periodontol* 1976;3:54-58.