

Safety First

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Within the past 6 months the headlines have been sprinkled with new episodes from the saga on breast implants. These have ranged from *"Breast implants given for 18th birthday gift"* and *"High school graduate receives implants as congratulations gift,"* to *"Women to sue implant manufacturers"* and *"Company quits implant business."* The spokesperson for a firm withdrawing from the implant business acknowledged some errors on the company's part and gave credit to the FDA for its fairness in trying to resolve the issue. Whether pursuing implants purely for the purpose of enlarging their breasts or as part of reconstruction following mastectomy for the removal of a cancerous breast, recipients of silicone implants who were pleased with the results and experienced no complications have refused company offers to underwrite the cost of implant removal.

With "inert, innocuous, medical-grade" silicone appearing to be the offending agent, what has gone wrong to precipitate the controversy that seems to have evolved from reports of leaking gel causing potentially severe disorders of the immune system? Was premarket approval based on appropriate but unenforced criteria, or were the criteria inadequate? In looking back to the 1960s, when silicone was being injected directly into the posterior pharyngeal wall for the treatment of palatopharyngeal insufficiency or onto atrophic alveolar ridges to enhance ridge height for improved denture stability, one shudders to think what could have been or might yet be.

On another front, the FDA has recently urged that patients with Proplast-coated Vitek TMJ implants see a dentist to have them removed. According to an FDA study, "the implants significantly wear, migrate, tear, fragment, delaminate, and perforate." Not life-threatening complications, perhaps, but significant enough to cause pain, dysfunction, and irreversible change. Was premarket approval given and, if so, based on what criteria?

In discussing the management of soft tissue complications around dental implants recently, a concerned practitioner asked about the possible use of laser irradiation. The FDA gave marketing clearance for laser use in soft tissue applications in 1990. Both the ADA and American Academy of Periodontology have subsequently advised that laser therapy not be extended to clinical situations beyond those recommended by the FDA. In light of reports that hygienists were using lasers to treat patients, the Florida Board of Dentistry has appointed a committee to establish criteria for the in-office control and use of this treatment modality.

In the March 9, 1992, *ADA News*, it was reported that an investigational device exemption (IDE) had been granted by the FDA to a Nd:YAG laser manufacturer for

clinical trials on hard tissues. Until now, this application has been discouraged because of unknown sequelae associated with use on hard tissues and dental pulp. Perceiving the potentially large spectrum of procedures to which the laser mode could be applied (ie, caries removal, root surface hypersensitivity, pit and fissure sealing, root canal procedures, anesthesia, etc), new companies are now appearing on the scene to capitalize on what promises to be rapid growth in an expanding field with significant potential. For the present, laser use in the dental implant patient should be viewed with extreme caution because there is already some evidence suggesting that laser beams produce changes in implant coatings and material interfaces.

Because of the wide use of lasers for applications in areas other than the health sciences, technological development has been closely monitored. It appears that the FDA has prudently focused intently on the use of dental lasers to prevent the recurrence of the retrospective assessment process that has necessarily involved dental implants. Progress must not be stifled by unwarranted time-consuming and costly obstacles. However, there are lessons to be learned from the aforementioned experiences involving implants of other types. Monitored procedures for premarket testing must remain comprehensive, have laboratory and clinical components, and provide an assessment of the product's safety for implantation that is as thorough as possible. Well-designed and well-executed research need not be an unreasonable and costly deterrent, especially if patient suffering, inconvenience, and expense can be circumvented in the long term. Manufacturers will have attractive opportunities in the marketplace in due time. In spite of exuberant anecdotal reports of immediate and lasting success, professional and/or consumer-driven demand must not be permitted to encourage bypassing of the premarket approval process and dictate the use of procedures, materials, or devices with less than optimal confirmed reports of safety and long-term health.