UNIVERSITY OF MINNESOTA

Division of Oral and Maxillofacial Pathology
Michael D. Rohrer, D.D.S., M.S., Director.

Twin Cities Campus *School of Dentistry*

Malcolm Moos Health Sciences Tower
515 Delaware Street S.E.
Minneapolis, MN 55455

1/29/2001

Mr. Bernard Weissman, President
Dentatus USA, Ltd.
192 Lexington Ave., Suite 901
New York, NY 10016

Dear Mr. Weissman:

I understand that you have had inquiries concerning your product, the MTI, from various regulatory agencies and interested parties. This transitional implant has been studied in my laboratory on numerous occasions from human retrievals.

We have performed computerized image analysis and histomorphometric measurements to determine the percentage of bone in contact with the metal implant on almost all of these specimens. As I have told you numerous times and as you have seen from my analyses, the percentage of bone in contact with the implant is very high. In fact, it is in the same range and sometimes higher than what we usually see with the standard titanium "permanent" implants. At first I was surprised to see this high percentage of bone/implant contact with what was considered a "temporary" or transitional implant, but the more MTI specimens we saw, the more we came to expect the high bone contact. The results from my laboratory show that the MTI is performing very well in its intended application.

Please contact me if you have any other specific questions.

Sincerely,

Michael D. Rohrer, D.D.S., M.S.
Professor and Director, Division of Oral and Maxillofacial Pathology
Director, Hard Tissue Research Laboratory
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Wednesday, March 07, 2001

Dear Mr. Weissman;

Modular Transitional Implants (MTIs) have been used at New York University Department of Implant Dentistry since 1995. Forty two patients have been treated, with 202 MTIs placed.

Histologic and histomorphometric data on at least 28 of these implants show good bone to implant contact (integration). MTIs have been used to support fixed provisional appliances and to protect permanent implants and areas of ridge augmentation from premature loading during healing.

Contraindications include lack of space, or bone for MTI placement. Risks include possible damage to an adjacent tooth or implant if the MTI is placed too close to either. Infection or mobility may result in loss of bone around the MTI. Overbending to facilitate implant parallelism may result in fracture of the MTI. In all cases proper surgical planning and technique will minimize these potential complications

Our experiences with MTIs at NYU Department of Implant Dentistry has been very positive. We have found them to be very useful in providing patients with fixed restorations from the time of tooth extraction through

fixed prosthetic delivery. They have been used in both fully and partially edentulous cases. Patients report being more comfortable and functioning better with fixed provisionals than with removable appliances. The outcomes of ridge augmentation surgery have been more positive with provisional supported MTIs without the post surgical interference of an overlying removable tissue borne appliance. One stage implants may also heal better because the MTI supported provisional allows them to heal without occlusal loading.

Please feel free to contact me if you need any further information.

Sincerely,

Dennis P. Tarnow, DDS
Professor and Chairman
Ashman Department of Implant Dentistry
New York University College of Dentistry

Cc: Sang-choon Cho, DDS
Associate Research Scientist

Stuart Froum, DDS
Research Director
Ashman Department of Implant Dentistry
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