Sterility of Packaged Implant Components

Philip Worthington, MD, DDS, BSc

Several implant components in their original glass vial and peel-back packages were subjected to sterility testing to determine whether the contents remained sterile after the expiration date marked on the package had passed. The results from a university microbiology laboratory showed that the contents remained sterile for 6 to 11 years after the expiration dates. Int J Oral Maxillofac Implants 2005;20:461

Key words: *implant components, implants, packaging, sterility*

Most implant surgeons maintain a stock of commonly used implant components and implants of various types and sizes to meet the requirements of potential patients. At one time some manufacturers, eg, Nobel Pharma (now Nobel Biocare, Yorba Linda, CA) marked their packaging with an expiration date. This led to some misunderstandings, and the practice has been abandoned. Nevertheless, from time to time a clinician with "old stock" may find and use an item beyond the stated expiration date and may wonder if it is safe to do so. Furthermore, it is possible for questions to arise in the course of medicolegal proceedings regarding the safe use of such items. It was therefore decided to test the sterility of such "time-expired" components.

MATERIALS AND METHODS

A group of "expired" Brånemark System (Nobel Biocare) implant components was assembled, all still in their original sealed glass vials within their peel-pack packaging. The expiration dates marked on the packages varied; 6 to 11 years had passed since the expiration dates. Macroscopically the packs and vials were intact. The components included 3 titanium screw taps, 1 twist drill, 1 drill-countersink, and 1 implant. All were submitted to the microbiology laboratory for sterility testing.

Table 1 Sterility of Packaged Implant Components

Item	Expiration date	Time since expiration date (y)	Growth
Drill-countersink	Aug 1993	11	Nil at 7 d
Screw tap 1	Feb 1995	9	Nil at 9 d
Screw tap 2	Feb 1995	9	Nil at 7 d
Screw tap 3	June 1996	8	Nil at 7 d
Twist drill	Aug 1996	8	Nil at 7 d
Implant	May 1998	6	Nil at 7 d

RESULTS

For periods of 7 to 9 days, all of the submitted components remained free from any microbiologic growth (Table 1).

DISCUSSION

The results shown are hardly surprising but may be reassuring to those who have used old stock items in clinical practice. The question of the safety of these items centers more on the maintenance of sterility rather than on any change in physical characteristics over time. This investigation indicates that, providing the glass vial is intact within the peel pack, the contents remain bacteriologically inert for years. The expiration date appears not to have real validity. Even if the peel-pack were to be damaged, the glass vial (if intact) could be resterilized by heat, and the contents should be safe to use.

[1]Professor, Department of Oral and Maxillofacial Surgery, University of Washington, Seattle, Washington.

Correspondence to: Dr Philip Worthington, Department of Oral and Maxillofacial Surgery, University of Washington, Box 357134, Seattle, WA 98195. Fax: +206 221 5354.
E-mail: worthington03@comcast.net