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Testing the Sterility of Expired Healing Abutments to Determine Post-Expiration Date Clinical Safety

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Short Running Title: Sterility of expired healing abutments in original packaging

Summary: Titanium healing abutments in their original unopened packaging remain sterile for at least eight years past their expiration dates.

Abstract

Background: Surgery requires the use of myriad devices and materials, most of which have manufacturer-assigned expiration dates. For many practitioners, a sizable percentage of these materials reach their expiration dates prior to use and thus must be discarded to comply with manufacturers' instructions for use. This represents a lamentable waste of limited resources and, for the authors of this article, U.S. taxpayers' dollars. We analyzed the sterility of expired Biomet 3i healing abutments to help determine the safety of use beyond their expiration dates.

Methods and Materials: 128 expired Biomet 3i healing abutments in their original unopened packaging that expired during the years of 2011-2019 were tested for bacterial growth. For the positive control, an unexpired healing abutment was exposed to *Staphylococcus aureas* ATCC 6538 at a concentration of 1 x 10^7 CFU/mL. One unexpired healing abutment was tested for growth and used as the negative control. The healing abutments were first placed in an Enriched Thioglycollate Medium and any growth that occurred there would be subsequently subcultured on Trypticase Soy Agar with 5% Sheep Blood (BBL 221261) and MacConkey II Agar (BBL 221270). Any bacterial growth would have been gram stained and identified using the BioMerieux Vitek 2 Compact System.

Results: None (0%) of the expired healing abutments from 2011-2019 had bacterial growth.

Conclusions: Results from this study indicate that expired Biomet 3i healing abutments (2011-2019) in their original unopened packaging remain sterile up to 8 years past their expiration dates and could reasonably be considered safe for use.

Key Words

Implants, healing abutments, expired, sterile, packaging, Biomet 3i

Introduction

Surgery requires the use of myriad devices and materials, most of which have manufacturer-assigned expiration dates. In order to comply with manufacturers' instructions for use, clinicians routinely discard a sizeable percentage of these materials which reach their expiration dates prior to use. Regrettably, their disposal wastes limited resources and, in some settings, U.S. taxpayers' dollars. While one could intuitively conclude that some materials are no longer suitable for human use beyond their expiration dates (due to biodegradation or chemical decomposition), it isn't clear why many devices are suitable for use today but are unsafe tomorrow. While the safety of our patients should never be jeopardized, do we have sound scientific data to support the notion that the use of expired medical / dental devices always translates to an increase in risk or a compromise of quality? Herein, we explore this question as it pertains specifically to titanium healing abutments for dental implants.

Healing abutments are a critical component of implant placement which support the soft tissues during healing and protect the internal aspect of the implant body from impaction of debris during the osseointegration-healing phase (Wadhwani, Schonnenbaum, Audia, & Chung, 2016). The soft tissue in direct contact with a healing abutment is comprised of a marginal zone of junctional epithelium and an apical zone of fiber-rich connective tissue. A fully functional implant-mucosal seal is formed at 6-8 weeks. (Salvi, Bosshardt, Lang, 2015). This implant-mucosal seal helps prevent infection, crestal bone loss and soft tissue recession (Wadhwani, Schonnenbaum, Audia, & Chung, 2016). The quality of the mucosal attachment is significantly influenced by the properties of the healing abutment materials and its surface qualities, which can also play a role in tissue recession, and prevention of crestal bone loss (Welander, Abrahamsson, & Berglundh, 2008).

The average cost of a new healing abutment in the U.S. from premium implant manufacturers is about 15% of the cost of a dental implant (Bidra, Kejriwal, & Bhuse, 2020). Nearly all providers have, at one time or another, considered the question of whether healing abutments – and indeed numerous implant components – remain safe for use past their expiration dates. It is highly unlikely that a healing abutment, which is comprised of commercially pure titanium or titanium alloy, should experience any clinically relevant biodegradation or corrosion when appropriately stored with intact packaging (Prando, Brenna, Diamanti, Beretta, Bolzoni, Ormellese, & Pedeferri, 2018). The question about safety for use must then consider their sterility.

Dental healing abutments come in sterile packages to ensure they are free of microbes, which could risk infection and ultimately lead to implant failure, and these packages are labeled with expiration dates. The product is no longer considered safe for use if it is expired or if the package is damaged, torn, perforated or shows any evidence of previous opening/tampering (Biomet 3i, 2019; Nobel Biocare, 2019).

One might consider simply sterilizing expired healing abutments to obviate the risk of compromised sterility. However, this is not an ideal alternative, since it has been demonstrated that ethylene oxide and steam autoclave sterilization contaminate and alter the titanium surface resulting in decreased levels of fibroblasts and their ability to attach and spread. (Vezeau, Koorbusch, Draughn, Keller, 1996). Decreased levels of fibroblasts could impede the formation of the implant-mucosal seal that is seen at 6-8 weeks, which serves to prevent crestal bone loss and recession.

We contend that if expired healing abutments remain sterile, then they should be considered safe for use in patients, and their use is preferable to other alternatives such as

sterilizing used or expired healing abutments. The ability to use expired healing abutments would be an environmentally friendly option with significant benefits for providers and patients. It would reduce financial and material waste for private practices, universities, and military/federal treatment facilities. It would also reduce delays in treatment, especially for practitioners in remote locations or austere environments who may not be able to obtain a specific abutment in a timely manner. The purpose of this study was to analyze the sterility of expired healing abutments to help determine the safety of their use. Our hypothesis was that no bacterial growth would occur on any of the tested healing abutments based on expiration date.

Materials & Methods

128 expired Biomet 3i titanium healing abutments in their original unopened packaging that expired within the years of 2011-2019 were tested for bacterial growth. Fifteen healing abutments from the years 2011, 2012, 2015-2019, ten healing abutments from 2013, and thirteen healing abutments from 2014 were tested. For the positive control, an unexpired healing abutment was exposed to *Staphylococcus aureus* ATCC 6538 at a concentration of 1 x 10^7 CFU/mL. For the negative control, one unexpired healing abutment was tested for growth. The expired healing abutments and controls were placed in Enriched Thioglycollate Medium (ETM) tubes (BBL 221742) and incubated (Becton Dickinson and Company, Sparks, Maryland) at 35°C with 5% CO_2 for 5 days. Any growth in the ETM was subcultured on Trypticase Soy Agar with 5% Sheep Blood (BBL 221261) and MacConkey II Agar (BBL 221270), then incubated at 35°C with 5% CO_2 for 24 hours. Any bacterial growth was gram stained and identified using the BioMerieux Vitek 2 Compact System (BioMerieux, Durham, North Carolina). The primary outcome was whether or not bacterial growth occurred. The bacteria growth occurrence rates

among the expired years were computed and reported. If there had been bacterial growth, the quantity would have been measured. Continuous bacterial growth data would have been assessed for normality by the Shapiro-Wilks test. Normally distributed continuous outcomes would have been presented as mean and standard deviation, and one-way analysis of variance (ANOVA) testing with a Tukey's post hoc test would have been performed to determine significant differences among different years. However, since no bacterial growth occurred, no statistical comparison was performed.

Results

Of the 128 expired healing abutments, none (0%) had bacterial growth (See Table 2 for the bacteria growth rate by expired year). The unexpired healing abutment (negative control) did not experience any bacterial growth. The healing abutment that was exposed to *Staphylococcus aureus* ATCC 6538 at a concentration of 1 x 10^2 CFU/mL (positive control) experienced bacterial growth in the ETM tube which was then subcultured and showed bacterial growth on both the Trypticase Soy Agar with 5% Sheep Blood (BBL 221261). No statistical comparison was performed since all the expired healing abutments remained sterile and experienced 0% bacterial growth.

Table 1. Frequency of Expired Healing Abutments by Expired Year

ExpYear	N	%
2011	15	11.72
2012	15	11.72
2013	10	7.81
2014	13	10.15
2015	15	11.72
2016	15	11.72
2017	15	11.72
2018	15	11.72
2019	15	11.72
Total	128	100.00

Table 2. Bacteria Growth Rate by Expired Year		
ExpYear	**Growth**	
	No	**Yes**
2011	15 100%	0 0%
2012	15 100%	0 0%
2013	10 100%	0 0%
2014	13 100%	0 0%
2015	15 100%	0 0%
2016	15 100%	0 0%
2017	15 100%	0 0%
2018	15 100%	0 0%
2019	15 100%	0 0%
Total	128	128

Discussion

All Biomet 3i titanium healing abutments (2011-2019) in their original unopened packaging remained sterile at least 9 years past their expiration dates. Our results support the findings of a 2005 study which determined that various implant components (i.e., titanium screw taps, twist drill, drill-countersink and implants) in their original glass vial and peel-back packages remained sterile for 6 to 11 years after expiration dates (Worthington, 2005).

If appropriately stored with intact packaging, one should not expect any clinically relevant biodegradation or corrosion in a healing abutment comprised of commercially pure titanium or titanium alloy (Prando et al., 2018). Thus, we contend that if expired healing abutments in sealed and intact packaging remained sterile, then they should be considered safe to use on patients.

The use of expired healing abutments is environmentally friendly and offers benefits to both providers and patients. Discarding perfectly acceptable materials amounts to a waste of the energy and raw materials involved in their production, packaging and shipment and is thus poor environmental stewardship. If they are instead retained and used, it would translate to financial savings to clinicians who are not forced to discard them and replace them with unexpired counterparts. The ability to use these products well beyond their current manufacturer-determined shelf lives would also reduce delays in treatment, especially for practitioners in remote locations who may require a healing abutment of a specific size, yet only have timely access to one, which is expired. Additionally, results from this study and future studies which assess the sterility of expired implant components could help mitigate possible medical-legal risks associated with the use of expired implant components (Bidra et al., 2020).

This practice is safer and more predictable than alternative cost-saving methods like sterilizing and recycling used healing abutments. Although manufactures consider healing abutments to be single use only (Biomet 3i, 2019; Nobel Biocare, 2019), some practitioners advocate recycling them (Wadhwani et al., 2016). In an effort to save money and reduce waste, some practitioners will clean, sterilize and re-use the abutments on different patients. While understandable from the perspective of financial stewardship, this practice is ill-advised as recent studies have shown that re-sterilizing healing abutments will not remove all residual protein contamination and could interfere with implant success (Wadhwani et al., 2016).

Wadhwani et al. 2016 evaluated the surface characteristics of 100 used healing abutments, which were sterilized at various practices according to their respective protocols. Results from this study indicated that even after cleaning and sterilization, all (100%) of the healing abutments had residual protein contamination. Cakan et al. 2015 investigated implant healing abutments that had been sterilized and re-packaged according to the product catalog and sterilization principles by dealers of six different implant manufacturers (Cakan, Delilbasi, Er, & Kivanc, 2015). Their results indicated that the methods they used to sterilize healing abutments did not remove all contaminants. Five of the 57 sterilized healing abutments had microbial growth to include *P variabile, E faecalis and E faeceum* and microscopic evaluation revealed dirty grooves and driver slots on several implants. Remnants of contaminants could pose a risk for cross contamination, soft tissue inflammation, potential for marginal bone loss, and possible mechanical issues related to stripping of the screwdriver slot or connection with the implant (Bidra et al., 2020). Therefore, the use of re-sterilized healing abutments is not without risk and raises concerns about the possibility for complications and failures.

Limitations of this study lie largely with its narrow focus. We only tested one brand of healing abutment – Biomet 3i. Biomet 3i's packaging is notable in that it is made entirely of durable plastic and forms a hermetic seal from the external environment. This no doubt plays a significant role in maintaining the contents' sterility and chemical stability. Since this study is essentially an evaluation of the ability of the manufacturer's processing and packaging to keep healing abutments sterile, we can draw no conclusions about other manufacturers' healing abutments with different packaging materials and techniques.

Areas of further study might include testing for the sterility of additional brands of healing abutments, testing package seal integrity as well as other implant components. Additionally, future studies could compare clinical parameters such as bleeding on probing, recession, marginal bone loss, loss of grafting material, etc. when using expired versus unexpired healing abutments. Furthermore, it would be worthwhile to evaluate the physical surface of expired implant components for evidence of biodegradation or corrosion.

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