Technical Data on the RBM
Surface Roughening Treatment

Orchid Detroit, 23149 Commerce Drive, Farmington Hills, MI 48335
Phone (248) 352-4570 Fax (248) 352-5543
sales@orchid-ortho.com

ISO 13485 Registered

ORCHID

Abstract

The role of a roughened surface to aid in implant fixation has been well established. However, recent concern regarding embedded media from glass beading and grit blasting operations has prompted interest in developing a method to avoid this contamination. Osteolysis is the primary concern, and has been shown to be related to particulate debris. Bio-Coat has succeeded in developing a process that provides a roughened surface to aid in osseo-integration, without the presence of unwanted debris embedded in the implant surface.

SEM and surface roughness analyses were performed to evaluate different finishing techniques including: an Al_2O_3 (alumina) grit blast finish, an acid etched finish, a glass bead (satin) finish an 'as machined' finish, and a new process (RBM) developed to roughen the surface. These finishes were compared to an Al_2O_3 finish provided by a commercial supplier, APS Materials (Dayton, Ohio).

The RBM process produced a comparable roughness to a 100mesh Al_2O_3 finish, without leaving any embedded debris. The RBM process produced a rougher surface than the 'as machined' control, glass bead or acid etched conditions.

This study demonstrated a new surface finish, which should provide an improvement in the roughness and subsequent fixation of implants without the risk of foreign body reactions associated with embedded media.

Materials and Methods

All substrate materials were made from Ti-6Al-4V. Surface preparation for the Al_2O_3, glass bead and RBM finishes was performed in accordance with Bio-Coat specification MPS-002 (1) using a Trinco 20/CPH blaster. Pressures were varied to achieve the maximum roughness for each material. The mesh sizes used were as follows:

Media	ASTM Mesh Size
Aluminum Oxide	100 mesh
Glass Bead	-100/+170 mesh
RBM	-40/+80 mesh

Processing was performed to most closely match those processes that are currently being used for implants. Subsequent to blasting, all three surfaces were ultrasonically cleaned in accordance with Bio-Coat specification MPS-021 (2). The RBM surface was then passivated and cleaned in accordance with Bio-Coat specification MPS-004 (3) to dissolve the media from the surface. Acid etching was performed using a proprietary process. Lastly, the surface of the sample prior to any surface finish was used as a control.

Scanning Electron Micrographic Analysis (SEM)

SEM analysis was performed at Climax Research Services (Farmington Hills, Michigan) on an Amray 1645 SEM with an energy dispersive x-ray analysis set-up (EDAX).

SEM micrographs were taken at 100X to assess the appearance of each surface for all of the samples.

Roughness Measurements

Roughness measurements were performed using a Mitotoyo Surftest 211 Profilometer, in accordance with Bio-Coat specification MPS-011 (4). An average of five readings was performed for each surface.

Results

Scanning Electron Micrographic Analysis (SEM)

'Charging' is a phenomenon created in an SEM when a non-conductive material (such as alumina or glass bead) is exposed to the beam. This will result in the non-conductive particle appearing white, with an adjacent dark halo. Figure 1 shows the control surface used prior to the finishing operations. This surface exhibited a relatively smooth appearance.

Figure 2 shows the 100-mesh alumina finish. Aluminum oxide entrapment was observed, as evidenced by regions of charging.

Figure 3 shows the RBM surface. It appeared slightly rougher than the 100-mesh surface, but did not exhibit charging. Therefore, the passivation process was successful in removing the embedded media.

Figure 4 shows the glass bead surface, which appeared slightly rougher than the control surface. While no entrapped media was observed, at this magnification it is likely that some does exist (5).

Figure 5 shows the acid etched surface. It appeared to be microscopically rougher than the control.

Surface Roughness Analysis

Figure 6 and Table 1 show the roughness measurements for the materials processed at Bio-Coat:

TABLE I

Surface Roughness Measurements

Surface Preparation	Roughness (μm.)
Control	1.32 ± 0.20
Glass Bead	0.73 ± 0.25
Acid Etch	1.17 ± 0.27
100 mesh Al_2O_3	2.14 ± 0.48
RBM	3.09 ± 0.48

The glass bead and acid etching procedures both lowered the roughness, relative to the control. The RBM finish was found to be rougher than the 100-mesh finish, both being rougher than the control.

Discussion

Osteolysis (bone resorption) resulting from debris surrounding implants is a well-known phenomenon. The issue is of such widespread concern, that a symposium was held to specifically address this area (6). Clarke et al (6) describes the process as being a cascade phenomenon involving motion, wear, particulate generation, macrophage induction and subsequent bone lysis. Typically debris from polyethylene, bone cement and the metallic constituents of the implant have been cited as the causes for osteolysis. An article by Ricci et al (5) warned of the possibility of this phenomenon resulting from bead blasting using sand, glass or alumina. Five retrieved implants were evaluated, and all five exhibited extensive surface inclusions consisting of silicon and/or aluminum containing materials. The adjacent soft tissues were also found to contain these materials.

The glass beading process showed a decreased roughness relative to the control. This was a result of the spherical nature of the media, which also fractures readily. This would therefore smooth asperities, resulting in the satin finish. The acid etching process will tend to also smooth asperities when mild acid concentrations are employed, as seen in this study. More aggressive acid concentrations would likely increase roughness by preferential grain boundary attack and eventual matrix attack. Unfortunately, if the attack is too aggressive, it will degrade the implant fatigue strength.

The roughening created by the 100-mesh finish was typical of these type of commercially available finishes. Larger grit sizes would have created an increased roughness, but this would also begin to destroy the geometry of the implant (i.e./ threads, corners, etc.).

It is obvious that there must be a trade-off between the occurrence (or awareness) of particulate mediated osteolysis, and the added benefits that these treatments provide (both cosmetic and functional). Bio-Coat has developed a textured surface that will provide the benefits of the increased roughness (surface area) without leaving any foreign entrapped materials. Regardless of the process, glass and aluminum oxide are relatively inert materials and therefore cannot be removed without removing substrate. In this study it was demonstrated that it was possible to produce a roughness similar to that of an aluminum oxide blast, without leaving any potentially harmful debris.

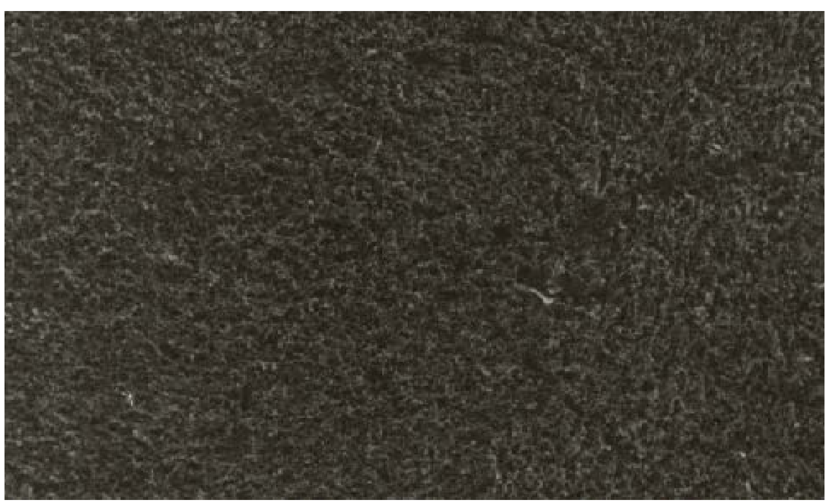

Figure 1 - SEM Micrograph of the 'As Received' Finish (100X)

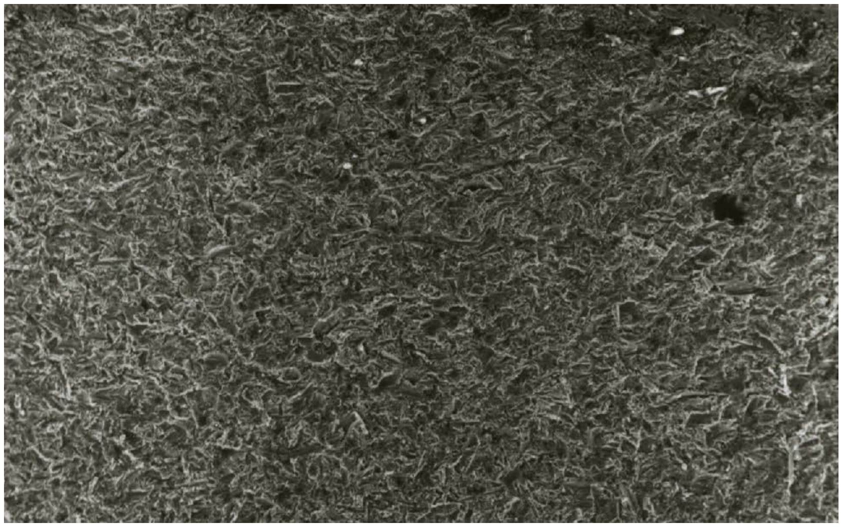

Figure 2 - SEM Micrograph of the 100 Mesh Finish (100X)

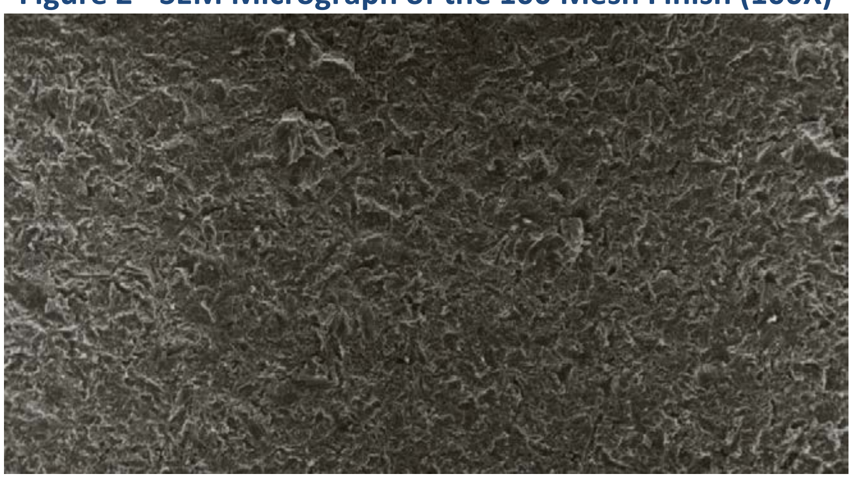

Figure 3 - SEM Micrograph of the RBM Finish (100X)

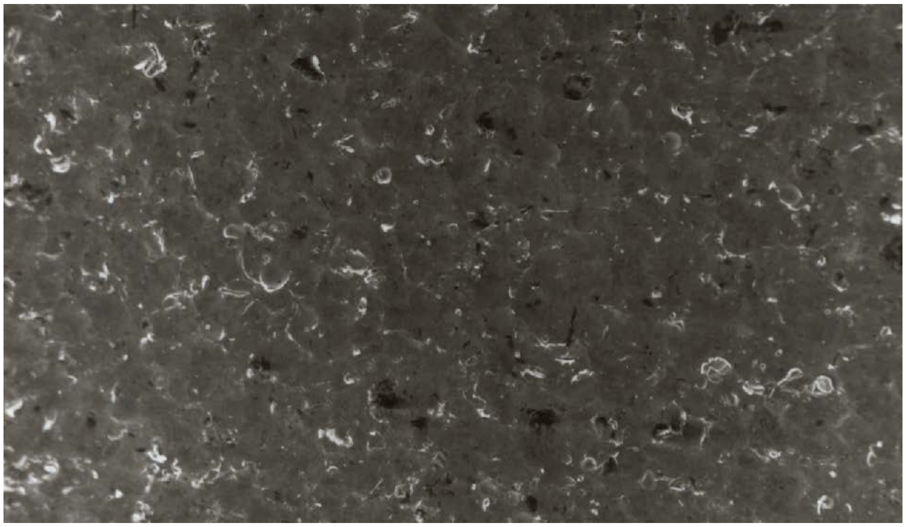

Figure 4 - SEM Micrograph of the Glass Bead Finish (100X)

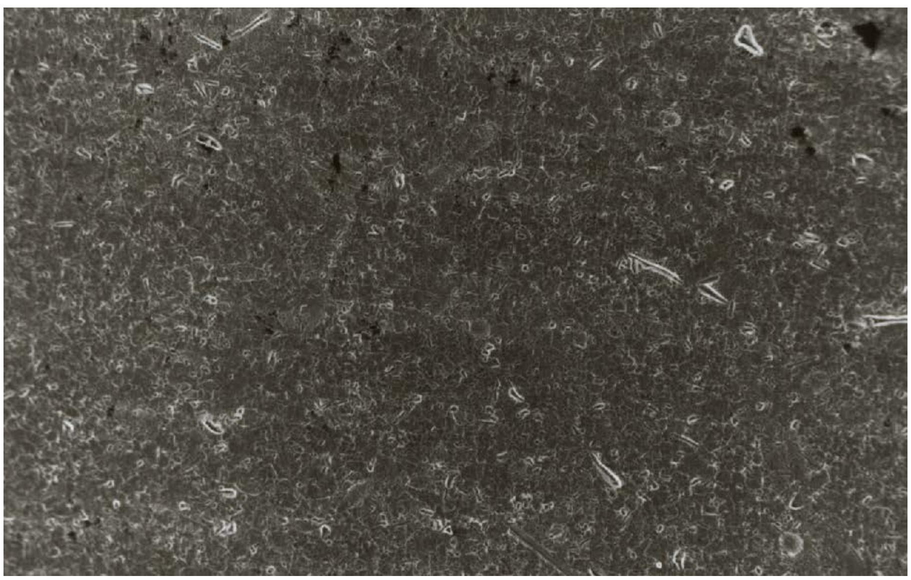

Figure 5 - SEM Micrograph of the Acid Etched Finish (100X)

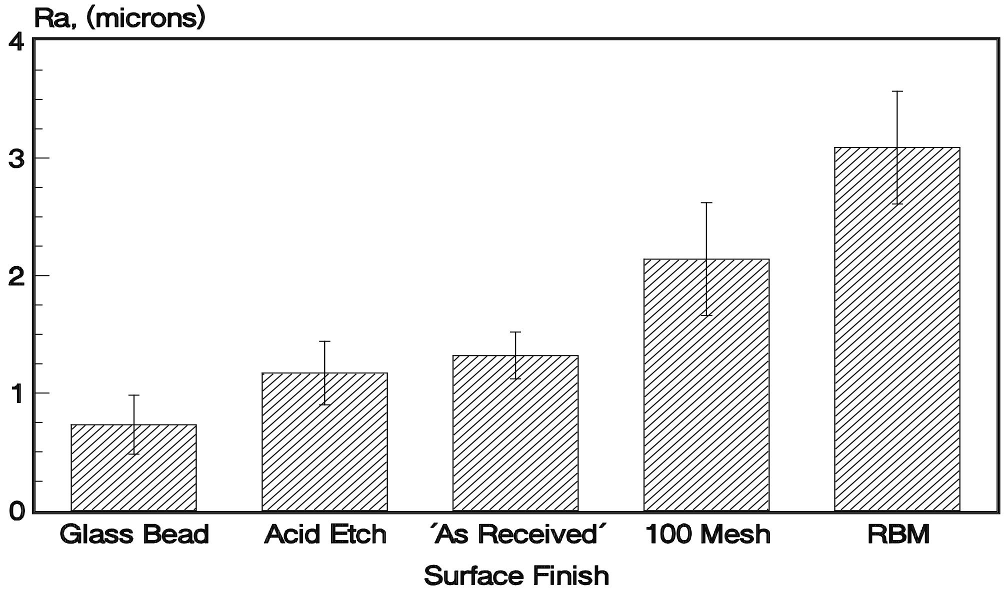

Figure 6 – Surface Roughness Measurement

References

1) MPS-002 - Blasting Procedure for the Medium and Medium Large Blasters

2) MPS-021 - Dental Implant Cleaning Line

3) MPS-004 - Cleaning, Passivation and Rework Line

4) MPS-011 - Procedure for the use of the Profilometer

5) Ricci, J.L., Kummer, F.J., Alexander, H. and Casar, R.S., "Embedded Particulate Contaminants in Textured Metal Implant Surfaces," J. Appl. Bio, Vol. 3,1992.

6) Particulate Debris from Medical Implants, edited by Kenneth R. St. John, ASTM STP 1144, 1992.