Finishing 3D Printed Devices with MATRIX MCD® Apatitic Abrasive

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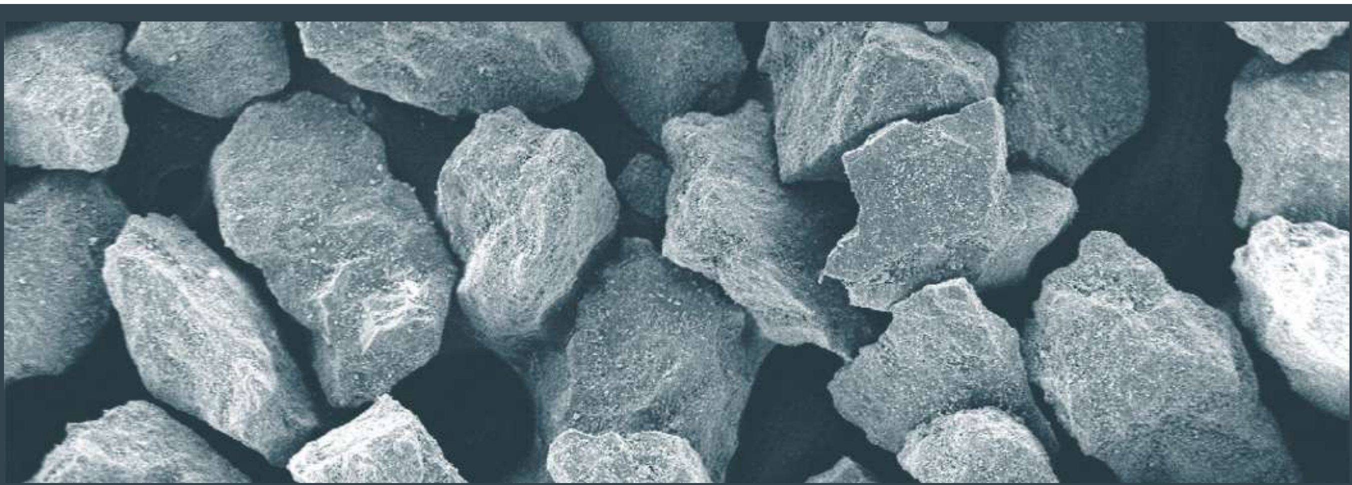


Himed's MCD Apatitic Abrasive is a granular, multi-phase calcium phosphate. MATRIX MCD® grit-blasting can create complex surface morphologies on dental, medical, and orthopedic implants by providing precise control in the rendering of a textured surface. This soluble abrasive avoids contaminants introduced via traditional grit-blast media and can be used to produce an intricate biocompatible surface for enhanced osseointegration. **This article reviews the suitability of the proprietary abrasive in a more novel application — as a surface finishing technique for additively manufactured titanium implants.**

INTRODUCTION

The emergence of additive manufacturing technologies into the medical and orthopedic fields has been transformative, advancing device intricacy and performance while offering patient-specific solutions. Additive manufacturing continues to be one of the fastest growing technologies in the orthopedic field. While 3D print resolution has steadily advanced during this evolution, post-processing is often a necessity to remove surface imperfections, including visible layer lines, loosely adherent residual beads, irregularities on the build surface, and other surface defects.[1] These post-processes offer critical improvements to the aesthetic appearance and overall device functionality.

Himed's MATRIX MCD® grit-blasting has been demonstrated as a highly effective option for removing material traces and abnormalities resultant from the additive manufacturing process. Elimination of these surface imperfections will result in a more uniform finish of superior quality and consistency. As an added value, the inherent formation of micropits on the device surface can provide an even more complex textured structure for improved osseointegration.

This article will review recent Himed developments and introduce BONEZONE® readers to the multiple benefits of MATRIX MCD® for additive manufacturing and related applications in the medical and orthopedic fields. These studies will include comprehensive qualitative and quantitative surface evaluations. All represent engineered accomplishments between Himed and successful FDA 510(k) approved or approval pending additive device systems.

MCD Apatitic Abrasive Product Specification

Physical Properties

Property	Description
MORPHOLOGY:	Angular Granules, Free-flowing
COLOR:	White with blue-green tint
BULK DENSITY:	Approximately 1.2 g/cc
MICRO HARDNESS:	Approximately 500 HV100

Particle Size Distribution

Catalog #	Particle Size
MCD180	425–250 µm
MCD160	425–180 µm
MCD140	300–180 µm
MCD120	< 300 µm
MCD100	< 180 µm
MCD20	< 53 µm

Chemical Properties

Phase Composition	Specification
HYDROXYAPATITE	≥ 70%
b-TCP, a-TCP, TTCP	≤ 25%
OTHER CaP PHASES	≤ 5%

Element	Specification
ARSENIC (As)	< 3 ppm
CADMIUM (Cd)	< 5 ppm
MERCURY (Hg)	< 5 ppm
LEAD (Pb)	< 30 ppm
TOTAL HEAVY METALS	< 50 ppm

Trace Elements conforms to ASTM F1185

Application Process

MATRIX MCD®

- **Highly uniform macro and micro surface texturing with biocompatible resorbable abrasive**
- **Customizable surface roughness Ra up to 3.2 µm**
- **Virtually residue-free surface after ASTM F86 passivation**

Figure 1: MCD Apatitic Abrasive, a multi-phase calcium phosphate principally composed of hydroxyapatite and tricalcium phosphate, is manufactured directly by Himed and available globally for MATRIX MCD® grit-blasting applications.

ABOUT MCD APATITIC ABRASIVE

MCD Apatitic Abrasive is a granular, multi-phase calcium phosphate that is specially manufactured to be as hard as possible to texture titanium implants. The cornerstone of Himed's proprietary line of MATRIX® surfaces, grit-blast applications with MCD will result in a highly textured surface, virtually residue-free after passivation per ASTM F86. The blasting process removes minimal material, thus preserving dimensional accuracy, which is critical for device performance. MCD Apatitic Abrasive conforms to ASTM F1185 for trace elements and is available in a range of standard sizes up to 425 µm. The product specification is listed in ***Figure 1***.

ABOUT MATRIX MCD® PROCESS

Blasting operations are performed using Himed's Fully Automated Blasting System (FABS), a custom designed, dual station shuttle system with dual micro-grit blasters. The system has proven capable of grit-blasting implants with great precision and accuracy. As MCD media is fired through the micro-grit blaster nozzle using compressed pressurized air, it is accelerated and forcefully directed against the work piece. By adjusting the process inputs, such as MCD particle size, blast pressure, and blast duration, a customizable output can be achieved to create surface textures ranging from smooth to rough. The process has been validated under ISO 13485:2016 and has been filed with the FDA under MAF 1239.

In traditional grit-blasting applications, this surface treatment offering can be used either as a precursor to a bioactive MATRIX HA® or MATRIX Ti® coating or as a final texture that increases the surface area that comes in contact with the bone during implantation. Himed engineers can design custom masking if treatment is only desired on select regions of the device.

In more novel additive manufacturing applications, the MATRIX MCD® process benefits may range from aesthetic-based to functional-based. We will consider three case studies in demonstrating the many benefits of using MATRIX MCD® as a surface finishing technique.

EVOLUTION OF ADDITIVE MANUFACTURING IN THE MEDICAL AND ORTHOPEDIC FIELDS

The World Health Organization estimates that 30 million people are in need of prosthetic and orthotic devices.[2] Senior citizens of age 65 and older represent approximately 10% of the world's population, and with continued advancements to modern medicine and overall improvements expected to social, health, and hygienic lifestyle, this number projects to double by 2050.[3,4] One can extrapolate that the number of expected surgeries to repair severe bone fractures and soft tissue loss with age is likely to increase, thus triggering a need for increased manufacturing demand. Enter additive manufacturing via rapid prototyping technologies — mass production of implantable devices with low cost, quicker lead time, high repeatability, and end-patient customizability.

CASE STUDY #1

Goal: To remove loosely adherent residual beads on the porous additive surface.[5,6]

NextStep™ Arthropedix's iNSitu Total Hip System is an artificial hip replacement system. It features a titanium-alloy acetabular cup (***Figure 2***) which is additively manufactured with an engineered and fully interconnected porous surface, porosiTi™. The acetabular cups are manufactured to a variety of sizes, and the porous structure is designed to provide both initial mechanical fixation as well as long term biologic fixation.[7]

As a by-product of the additive process, loosely adherent residual beads are randomly present throughout the porous lattice following 3D printing operations. In a related comparative analysis of various additively manufactured acetabular cups, researchers have expressed clinical concern that these partially molten titanium beads may fall off and potentially be released in the body if not eliminated prior.[8]

Grit-blasting via MATRIX MCD® has proven to be an effective way to dislodge the beads as a post-print finishing while further increasing the surface texture, resulting in a cleaner and more complex bioactive surface. Due to the sub-500 μm porosity, a finer size MCD120 Apatitic Abrasive (< 300 μm) and MCD100 Apatitic Abrasive (< 180 μm) is most appropriate for this application. A final processing step such as color anodizing via Himed MATRIX Color® can be optionally added, as shown in ***Figure 2***, for part identification and enhancement to the overall surface appearance.

Figure 2: NextStep™ Arthropedix's acetabular cup features an additively manufactured porous surface that has been subsequently grit-blasted using Himed's MATRIX MCD®.

CASE STUDY #2

Goal: To remove surface abnormalities and defects on the additive build surface, while roughening the entire device to create a more uniform textured surface.[9,10]

Build orientation is an important consideration for additive manufactured devices, as it directly impacts to the manufacture cost, time, device strength, and dimensional accuracy.[11] Many devices are printed with a critical surface in direct contact with the additive build platform. For more complex printing alignment, temporary support structures may be required to properly position the build for stability. In both scenarios, either the resultant build surface or the support surface is likely to have material traces, extrusions, and related surface abnormalities resultant from the additive process.

Consider the 3D printed titanium-alloy spinal spacers shown in ***Figure 3***. The first image features a device immediately following additive manufacture and MATRIX Color® anodizing that has not been introduced to any post-print surface finishing. The surface irregularities on the featured face – which was in direct contact with the additive build platform during 3D printing – are consistent and apparent throughout. With increased grit-blast time via MATRIX MCD®, these surface defects are eliminated via blast deburring and the overall device appearance becomes much more uniform and consistent.

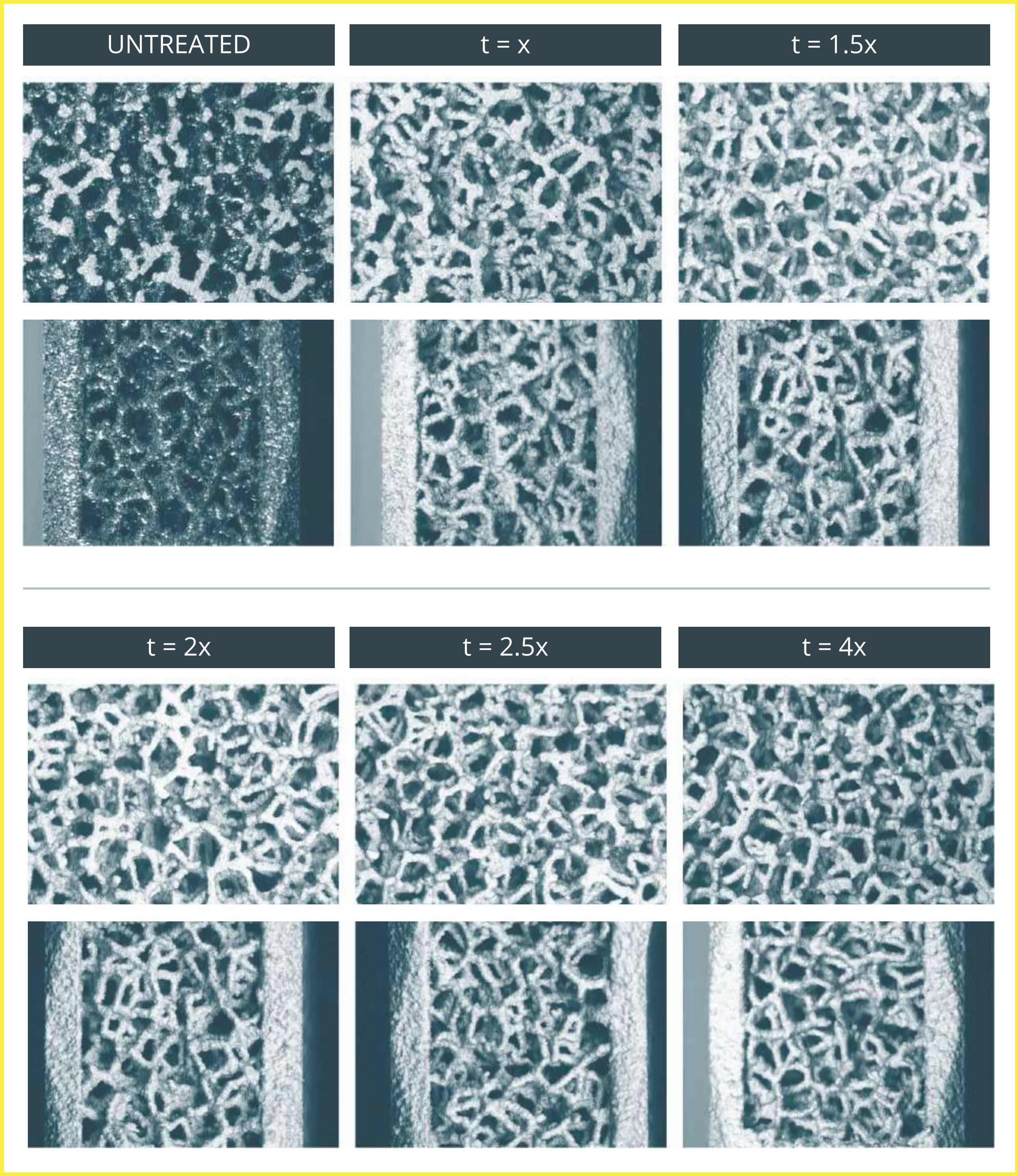


Figure 3: With increased grit-blast time via Himed's MATRIX MCD®, the surface of these additive manufactured spinal spacers becomes more uniform and imperfections are removed.

CASE STUDY #3

Goal: To quantify the change to surface profile with increased MATRIX MCD® grit-blast application time.[12]

The first two studies we have discussed thus far offer more of a qualitative characterization. This third study aims to quantitatively characterize the surface profile with increased MATRIX MCD® grit-blast time. To do so, let us first define[13] select areal parameters used to evaluate the resultant surface profile (***Table 1***):

ROUGHNESS PARAMETERS

- Average Roughness, Sa
- Root-Mean-Square Roughness, Sq

HEIGHT PARAMETERS

- Peak to Valley Height / Maximum Height of Profile, St
- Ten-Point Height, Sz

SHAPE PARAMETERS

- Kurtosis, Sku
- Skewness, Ssk

HYBRID PARAMETERS

- High Spot Count, HSC

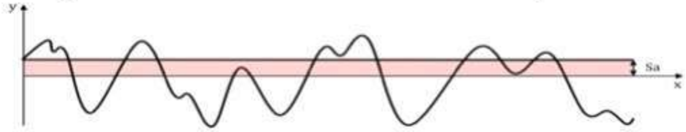
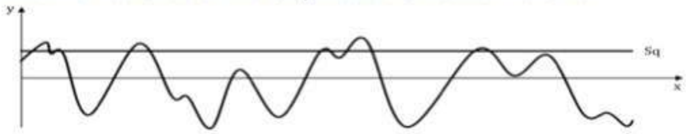
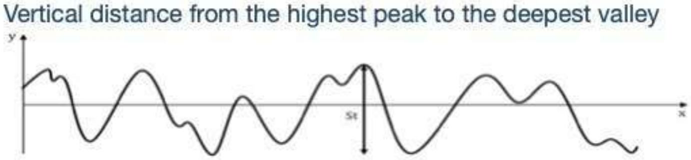
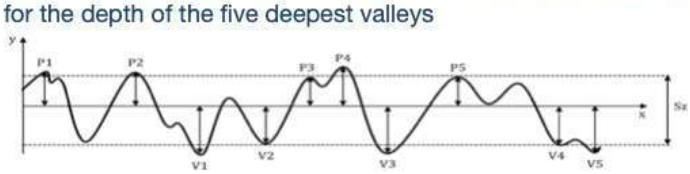
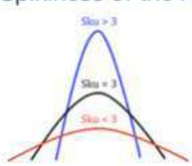
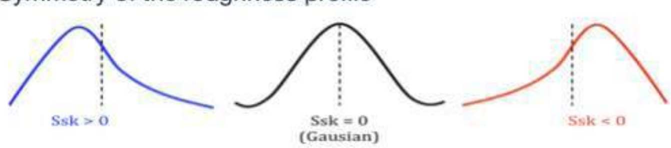
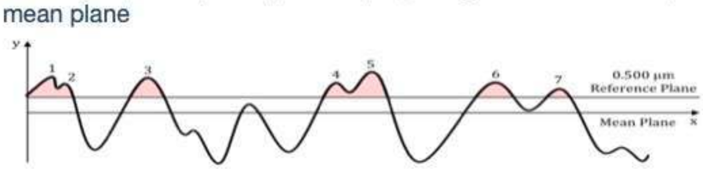
This study evaluated the surface profile across four test groups. Group A consisted of an additive manufactured flat, non-porous surface without post-print Himed surface finishing (control). Group B, Group C, and Group D each consisted of an equivalent additive print and were subsequently grit-blasted for time t = x, t = 2x, and t = 3x, respectively, using Himed MCD160 Apatitic Abrasive (425-180 µm). With the exception of a variable grit-blast duration, all MATRIX MCD® process parameters such as blast distance, pressure, nozzle orifice, and FABS program automation remained unchanged throughout. Each test group consisted of n = 17 components to reduce the potential for processing variability.

Following Himed post-print MATRIX MCD® finishing, the resultant surfaces were evaluated using laser profilometry. In this technique, a light beam reflected off the surface contours is collected to render a 3D surface profile topography. The SmartScope® Flash 302 by Optical Gaging Products (OGP) features a TTL (through-the-lens) laser integrated within the optical system, allowing for a non-contact optical analysis of all surfaces. A 20 µm nominal spot diameter and 15 µm delta was used to scan the surface across a 4 mm by 0.5 mm array, ensuring sufficient coverage with minimal scan overlap. Each laser scan featured over 10,000 measured points, proving to be a statistically representative sampling based upon Himed test methodologies.[14] The resultant 3D surface renderings were generated and analyzed with TrueGage Surface Metrology software. Since all laser scans were performed normal to the analyzed surface, the evaluation did not require a filter to separate the roughness from the nominal shape, or form, of the substrate surface.

Upon completion of grit-blast operations, all test devices were passivated in 25% HNO3 per ASTM F86, dissolving the soluble MCD Apatitic Abrasive from the surface to yield a virtually residue-free and contaminant-free finish.

The resultant surface profile topographies are comparatively presented in ***Figure 4***. Graphically, it should be immediately apparent that the control surface (Group A) lacking the post-print finishing process is comparatively rougher with a much larger degree of surface variation present. Following prolonged MATRIX MCD® grit-blast time, MCD Apatitic Abrasive effectively adds micro texture while creating a more uniform macro textured surface.

Table 1 Surface Profile Areal Parameters

Parameter	Description
Sa [µm]	**Average Roughness:** Average of the absolute distances of the surface profile from the reference plane 
Sq [µm]	**Root-Mean-Square Roughness:** Width or variance of the amplitude distribution function 
St [µm]	**Peak to Valley Height / Maximum Height of Profile:** Vertical distance from the highest peak to the deepest valley 
Sz [µm]	**Ten Point Height:** Sum of the mean value for the height of the five tallest peaks and the mean value for the depth of the five deepest valleys 
Sku [no units]	**Kurtosis:** Spikiness of the roughness profile 
Ssk [no units]	**Skewness:** Symmetry of the roughness profile 
HSC [pks/mm²]	**High Spot Count:** Number of profile peaks per area projecting above a user set plane parallel to the mean plane 

Statistically, all surface profile areal parameters listed in ***Table 1*** were reviewed across all test groups. After initial grit-blasting for time t = x (Group B), with just enough media to ensure uniform coverage across the external body, the measured Sa and Sq reduced significantly by around 60%. For prolonged exposure for time t = 2x (Group C) and t = 3x (Group D), there was a less significant change — around 10% reduction. It is noteworthy to point out the reduced standard deviation with increased grit-blast time; that is, the overall surface uniformity increased with MCD coverage, as expected.

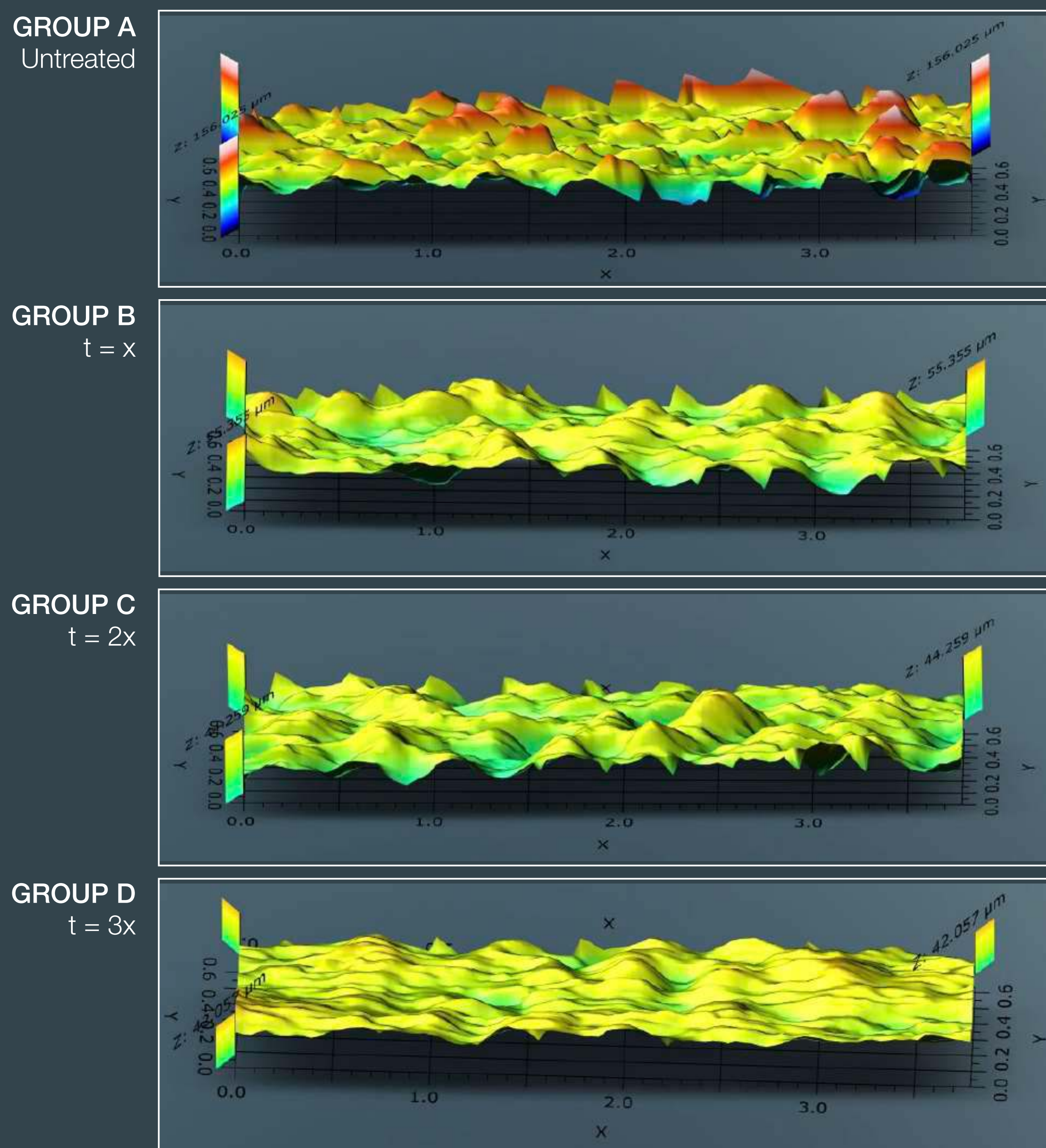


Figure 4: Comparative surface profile topographies showing the inter-variations between Groups A-D.

Height parameters St and Sz trended in a similar manner. After initial grit-blasting for time t = x (Group B), large surface peaks were reduced, resulting in a significant decrease to St and Sz by approximately 75%. For longer grit-blast time of t = 2x (Group C) and t = 3x (Group D), a less significant change well within one standard deviation was reported.

The shape of the surface profile can be analyzed using parameters Sku and Ssk. Per Table 1, initial analysis of the as-printed additive surface (Group A) produced Sku measurements of >> 3. This signified the presence of very sharp, distinct peaks and supported our visual observations. After blast coverage for time t = x (Group B), Sku measurements reduced significantly by 35%. The Sku remained at or above 3 for all test groups, demonstrating that while the blast was effective in creating a uniform surface, it did not overly blunt the peaks beyond a Gaussian shape. Unsurprisingly, minimal change was observed to Ssk and it measured ≈ 0 throughout the study. The skewness parameter can be conceptualized as the relative number of peaks to valleys. Visualize a completely flat plateau with a skew of zero. If one adds peaks on the plateau, it now has a skew greater than zero. Conversely, if valleys are added on the plateau, it now has a skew less than zero. For mixtures of peaks and valleys on the plateau, reflective of all surface profile topographies displayed in ***Figure 4***, the resultant value averages to 0.

Lastly, the HSC values were reduced by nearly 50% after a blast time of t = x (Group B). A less significant change well within one standard deviation was reported for prolonged blast time of t = 2x (Group C) and t = 3x (Group D). These statistics should come to no surprise, as from previous case studies, the MATRIX MCD® process has successfully demonstrated the ability to remove large peaks and surface irregularities from the additive manufactured body.

CONCLUSION

Since 1991, Himed has been on the vanguard of biomaterial manufacture and innovative surface treatment processes developments. MCD Apatitic Abrasive, Himed's core biomaterial invention since the company's inception, is used globally to effectively texturize titanium implantable dental, medical, and orthopedic devices. This comprehensive analysis successfully demonstrates a novel additional application for MATRIX MCD® grit-blasting in the additive manufacturing field.

ABOUT HIMED

Himed provides innovative biomaterial solutions to medical and orthopedic customers around the world. With nearly three decades of operation, Himed has become a global leader in calcium phosphate-based biomaterial production. Our proprietary line of MATRIX® surfaces produce highly customizable bioactive plasma spray coatings and texturing solutions. Himed also serves as a contract research facility, providing analytical services and materials testing in our state-of-the art 25,000 sq. ft. facility in Old Bethpage, New York. We remain at the leading edge of biomaterial development because we never compromise on accuracy, precision, or quality.

Himed is committed to producing solutions that help the body heal.

For more information, please visit: www.himed.com

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