Post-Processing of Additively Manufactured Covid-19 Nasopharyngeal Swabs at Scale

K. Rybalcenko*, R. E. Charlesworth*, L. Folgar‡, G. Ioannides* and J. G. Crabtree†

* Additive Manufacturing Technologies Ltd, Letsby Avenue, Sheffield, S9 1XU, UK

‡ Additive Manufacturing Technologies Inc, 1200 BMC Dr, Austin, TX, USA

† Additive Manufacturing Technologies Kft., Gépraktár street 1, Veszprém, 8200, Hungary

Abstract

A methodology to post-process oral/respiratory Additively Manufactured medical components methods is presented. The system involves PostPro3D® smoothing machine by AMT, picking/racking module, industrial robot, conveyors and is used to smooth the surfaces of Covid-19 Nasopharyngeal Swabs manufactured at-scale using powder-based methods. The presented process for large scale post-processing of Additively Manufactured articles has undergone all necessary medical verifications and has been already deployed in the field.

Introduction

Current situation

Covid-19 pandemic has resulted in a surge in demand for specialized medical articles, particularly in Nasopharyngeal Swabs. Widescale population testing for Covid-19 has been put in place by many countries, with testing expected to continue in the foreseeable future. Even with mass rollout of vaccines, continuous testing will be needed long after that. This has resulted in Covid-19 diagnostics market rapidly emerging in 2020 with Nasopharyngeal Swabs taking about 50% of the market [1].

Widescale usage of Nasopharyngeal Swabs has resulted in unprecedented demand in their manufacturing systems, especially in new generation, sustainable and Industry 4.0 compatible technologies. Traditional manufacturing was unable to effectively respond to this sudden spike in demand. In fact, re-adjustment of the traditional manufacturing chains for supplying these products is a costly, time consuming and energy-intensive process. That is why pharmaceutical companies are looking for a new sustainable approach to satisfy global demand for Covid-19 diagnostic items.

AM offers the capability to rapidly yet sustainably create the necessary medical articles locally and at-scale. This ability is of strategic national importance, especially in the times of crisis and shortage of vital components as seen during Covid-19 epidemic. In many cases it is more convenient, sustainable, and environmentally friendly to 3D print parts at the point of use rather than keep large stockpiles manufactured overseas.

The problem

Nasopharyngeal Swabs are small yet complex tools incorporating many engineered features such as flexible neck, efficient tip and break point at the handle. These well-

designed delicate features are difficult to obtain by usual 3D printing and post-processing methods at scale as they produce rough, powdery and porous surfaces. This causes the accumulation and growth of bacteria, fungi and increases the risk of the loose polymer particles attacking the respiratory system as noted by the World Health Organisation (WHO) and FDA guidelines for 3D printing [2]. Furthermore, the abrasive material used during the process cannot reach small cavities and other intricate areas leaving them unprocessed. Very often this abrasive material breaks off thin weakly supported structures of the parts. Therefore, current post-processing techniques are not adequate for the smoothing of articles to be used for medical respiratory purposes.

AMT has designed a modular method to post-process 3D printed Nasopharyngeal Swabs at scale using its commercially available smoothing machine PostPro3D. The required R&D, medical validations and field testing of the system was done in collaboration with the UK government and AMT's international partners. As a result, the system has been validated in the field with around one million of swabs already produced using AMT's technology. Project outcomes include a full commercial production module that can automatically rack, load and condition medically validated 3D printed Nasopharyngeal Swabs. The system can be sold together with the PostPro3D machine, or separately to customers that already have such machines.

Methodology

Hardware development

All design, programming and hardware development was done in-house at AMT's Innovation Facilities in Sheffield, UK as part of the CoNaSPro3D Innovate UK project. This ensured quick iterative development changes of the automated cell while checks were also done for potential expansion to integrate other automated AMT systems. The system is compatible with all existing PostPro3D machines.

Medical tests

Biocompatibility test matrix based on ISO 10993-1 and 2016 FDA was used for testing reference [3]. The matrix suggests Nasopharyngeal Swabs require tests for "Limited ≤24 hours Intact Skin Contact" to be performed (Table 1). Additional testing for Hemolysis was performed for further possible applications of the processing. Clinical validations for 3D printed and smoothed Nasopharyngeal Swabs were also performed and approvals were obtained from the Federal Agency for Medicines and Health Products of Belgium and Belgian Ministry of Health.

Table 1: List of conducted tests on Nasopharyngeal Swabs

Tests conducted	Test method references
Skin Sensitization	ISO 10993-1, 10, 12; EOCD 429
In Vitro Cytotoxicity	ISO 10993-5, 12
Intradermal Reactivity	ISO 10993-10:2013, ISO 10993-1:2012, ISO 10993-1:2018
Hemocompatibility	ASTM F756, ISO 10993-4

Medical study documents and samples for Skin Sensitization, In-Vitro Cytotoxicity and Intradermal Reactivity were archived according to the OECD GLP for 15 years by TOXI-COOP Zrt. (H-8230 Balatonfured, Galamb u. 12/A). The study was inspected by the Quality Assurance in compliance with the Principles of Good Laboratory Practice. Hemocompatibility study was done performed by NAMSA in accordance with the OECD Good Laboratory Practice regulations, ENV/MC/CHEM (98)17, and with the United States Food and Drug Administration Good Laboratory Practice regulations, 21 CFR 58.

Results and Discussion

Hardware

The model of the final constructed system is presented in the Figure 1. The system was designed to be modular to able to accept the input of Nasopharyngeal Swabs form a variety of industrial set-ups that are commonly used in manufacturing facilities. The base of the system is the conveyor and robotics transportation system able to deliver, load and unload the parts into PostPro3D processing module.

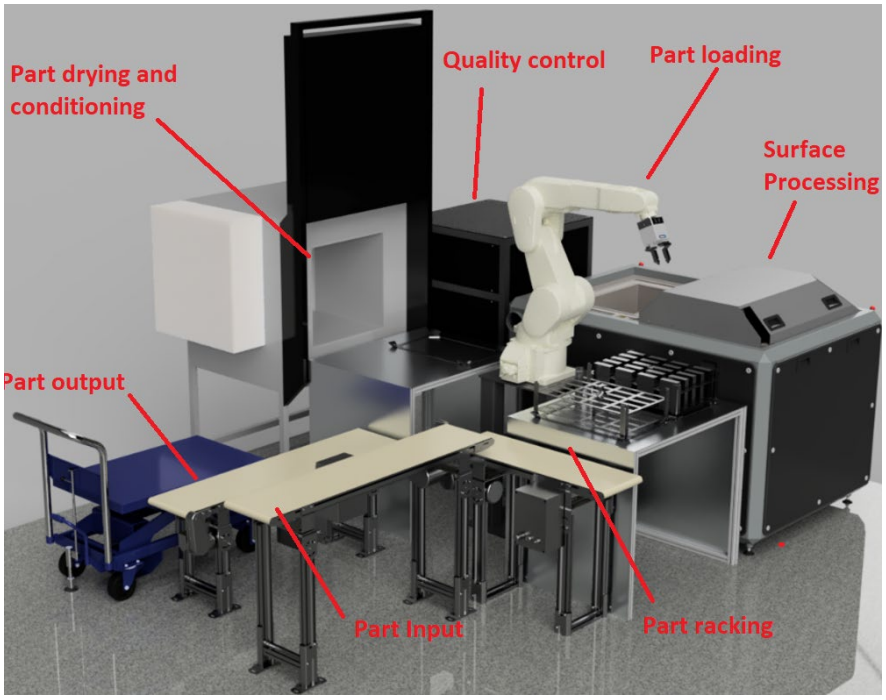

Figure 1. Designed automated modular processing cell for additively manufactured nasopharyngeal swabs

Significant achievements were made during the process parameter generation phase of the project. The goal of this phase was to develop a set of conditions, including pressure, temperature and amount of dosed solvent, to ensure processed Nasopharyngeal Swabs are suitable for their function. Delicate design of the swabs was among the challenges, as too aggressive process conditions could easily damage or deform the parts. On the other hand, the system has to ensure complete processing of full chamber of Nasopharyngeal Swabs. To achieve this delicate balance AMT's surface recognition system was used [4].

Industry 4.0

Further opportunities for development and innovation come from the digital compatibility of the system, as it automates part preparation stage for post-processing and can be easily connected with design and printing stage. This is because PostPro3D can select the processing parameters based on the initial design of the user and printing parameters of the 3D printer, whereas the racking mechanism can be taught how to pick and rack the parts [4, 5]. This in turn enables digitization of the Additive Manufacturing production chain, which will help to push the Additive Manufacturing industry towards Industry 4.0 revolution and opens new development opportunities within the field of robotics and automatization.

Conclusion

Demand for Nasopharyngeal Swabs is projected to increase supported by periodic testing requirements and high awareness levels of population. Additive Manufacturing offers rapid yet sustainable method to produce these diagnostic items at scale and at the point of use. New automated post-processing cell for powder-based Additive Manufacturing produces fully compliant Nasopharyngeal Swabs for the use in Covid-19 testing according to ISO 10993-1 and 2016 FDA guidelines. The system enables millions of people to be tested for Covid-19 and re-join the economy. Different geometry parts can be adapted to the developed system.

References

[1] Grandviewresearch, COVID-19 Diagnostics Market Size, Share & Trends Analysis Report By Product & Service (Instruments, Reagents & Kits, Services), By Sample Type, By Test Type, By Mode, By End Use, And Segment Forecasts, 2021 – 2027, 2020.
[2] U.S. Food & Drug Administration, Technical Considerations for Additive Manufactured Medical Devices, U.S. Department of Health and Human Services, 2017, pp. 17–20.
[3] ISO 2009-2010, ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.
[4] W. S. Syam, K. Rybalcenko, A. Gaio, J G. Crabtree, R. K. Leach, In-process measurement of the surface quality for a novel finishing process for polymer additive manufacturing. Procedia CIRP 2018; Vol 75, pp. 108-113.
[2] W. S. Syam, K. Rybalcenko, A. Gaio, J G. Crabtree, R. K. Leach. Methodology for the development of in-line surface measuring instruments with a case study for additive surface finishing. *Optics and Lasers in Engineering* 2019; 121:271-288.