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AAO Foundation Final Report Form
(a/o 1/3/2018)

Type of Award
Biomedical Research

Name(s) of Principal Investigator(s)
F. Kurtis Kasper

Institution
The University of Texas Health Science Center at Houston

Title of Project
Development of Optimized Methods for the Direct Fabrication of Orthodontic Aligners via 3D Printing

Period of AAOF Support
07-01-17 to 06-30-19
No Cost Extension 07-01-2018 to 06-30-19

Amount of Funding
$30,000

Summary/Abstract
Objectives: Emerging 3D printing resins cleared for intraoral use could enable the fabrication of clear aligners directly via 3D printing, which may mark a paradigmatic shift in the efficiency of clear aligner production. However, the effects of tunable aspects of the 3D printing process on the dimensional accuracy of 3D-printed aligners have not been reported. Additionally, the ability of current 3D printing technologies to realize designed aligner thicknesses is unknown and could impact the clinical utility of the parts. Accordingly, the objectives of this project were to investigate the impact of print orientation and post-print ultraviolet light curing duration on the dimensional accuracy of clear aligners fabricated directly via 3D printing. An additional aim of the project was to investigate the effect of the designed aligner thickness on the realized thickness of the printed aligner. Collectively, this project seeks to guide selection of appropriate conditions for direct fabrication of clear aligners via 3D printing.

Materials and Methods: A master clear aligner standard tessellation language (STL) file was designed digitally with a wall thickness of 0.500-mm and 3D-printed using a stereolithography-based 3D printer (Form 2; Formlabs, Inc.) and a Class IIa biocompatible resin (Dental Clear LT, Formlabs, Inc.). Three different angles were used during the build process: parallel to the build

platform (Horizontal), perpendicular to the build platform (Vertical), and 45-degrees to the build platform (45-Degree) (n=10/group). The printed aligners were processed according to the manufacturer's instructions then coated with an opaque spray to facilitate scanning. Each part was digitally scanned using an intraoral scanner (iTero® Element Flex, Align Technology, Inc.). The 3D digital files of the scanned parts were exported as STL files then superimposed with the input STL file using Geomagic® Control™ 2015 software (3D Systems). A generalized linear mixed model was applied to evaluate the effects of the build angle on the various response variables. Tukey's post-hoc tests were applied, when appropriate, for pairwise comparisons. The level of significance for all analyses was set at $p<0.05$. A clinical tolerance limit of 0.250-mm was applied.

The 45-Degree orientation then was used to print 30 aligners of 0.500-mm thickness. The aligners were separated into the following treatment groups: 0 minutes of ultraviolet (UV) light and heat exposure (No Cure); 20 minutes of UV light exposure at 80 degrees Celsius (20 Minute), and 40 minutes of UV light exposure at 80 degrees Celsius (40 Minute) (n=10/group). After post-processing, each part was sprayed, scanned, and superimposed in the same manner previously described. A generalized linear mixed model was applied to evaluate the effects of the post-print treatment on the various response variables. Tukey's post-hoc tests were applied, when appropriate, for pairwise comparisons. The level of significance for all analyses was set at $p<0.05$. A clinical tolerance limit of 0.250-mm was applied.

Next, digitally-designed aligners of 3 different thicknesses (0.500, 0.750 & 1.00-mm) were 3D-printed in 2 different resins (Dental Clear LT and Grey V4) with (n = 10 per thickness for each resin). Geomagic® Control™ 2015 metrology software was applied to digitally superimpose surface scans of the printed aligners and the respective aligner design file. The average wall thickness of printed parts and 3D surface deviations between the printed aligners and the respective design files were computed in the software using Wall Thickness and 3D Compare tools, respectively. A generalized linear mixed model was applied to evaluate the effects of designed wall thickness on the various response variables. Tukey's post-hoc tests were applied, when appropriate, for pairwise comparisons. The level of significance for all analyses was set at $p<0.05$.

Results: The 45-Degree group had a statistically significantly lower standard deviation than the Horizontal and Vertical groups (Table I). However, the standard deviations for all treatment groups were <0.178 mm, which falls below reported limits for clinical acceptability (0.250-mm). The average positive and negative deviations for all treatment groups were not statistically significantly different and also fall within the limits of clinical acceptability. Three-dimensional surface deviation maps indicated that print orientation affects dimensional deviation differently across the part (Figure 1).

Table I. Effect of aligner print orientation on dimensional deviation. Generalized linear mixed model (GLMM) and Tukey's Post Hoc tests, where appropriate.

	45 Degrees	Horizontal	Vertical	GLMM	Tukey's Post Hoc		
	Mean ± SD	*Mean ± SD*	*Mean ± SD*	p	45 to H	45 to V	H to V
Mean Pos. Deviation (mm)	0.135 ± 0.009	0.139 ± 0.014	0.153 ± 0.014	0.143			
Mean Neg. Deviation (mm)	-0.079 ± 0.014	-0.093 ± 0.018	-0.102 ± 0.020	0.102			
Mean Standard Deviation	0.133 ± 0.012	0.152 ± 0.018	0.167 ± 0.011	**0.008****	**0.020***	**0.003****	0.322
Mean % Out of Bounds	8.61 ± 2.31	11.7 ± 3.27	12.8 ± 3.77	0.063			

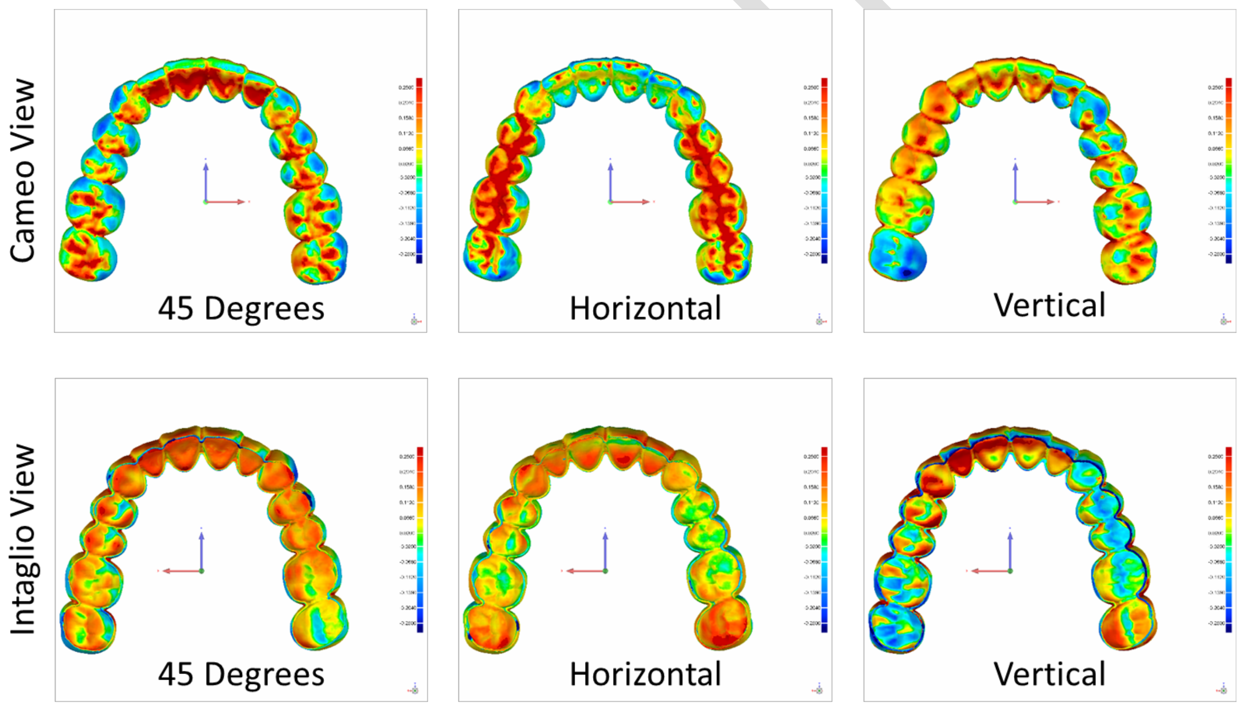

Figure 1. Representative 3D comparisons of the printed aligner surfaces with respect to the reference file used for 3D printing. Warm/red colors indicate positive deviations, and cool/blue colors indicate negative deviations (scale in mm).

The aligners that were not exposed to heat or UV light were not included in the statistical analysis due to scanning challenges. The 40 Minute treatment group had a statistically significantly lower standard deviation than the 20 Minute treatment group (Table II). However, the standard deviations for both treatment groups were <0.180 mm, which falls below reported limits for clinical acceptability (0.250-mm). The average positive and negative deviations for both treatment groups were not statistically different, and they fall within the limits of clinical acceptability. Three-dimensional surface deviation maps indicated that magnitudes and directions of deviations vary across the treatments (Figure 2).

Table II. Effect of post-print UV curing duration on dimensional deviation. Generalized linear mixed model (GLMM).

	20 minute	40 minutes	GLMM
	Mean ± SD	*Mean ± SD*	p
Mean Pos. Deviation (mm)	0.161 ± 0.013	0.152 ± 0.008	0.132
Mean Neg. Deviation (mm)	-0.100 ± 0.023	-0.083 ± 0.008	0.079
Mean Standard Deviation	0.163 ± 0.017	0.148 ± 0.006	**0.049****
Mean % Out of Bounds	15.6 ± 3.84	12.8 ± 1.43	0.095

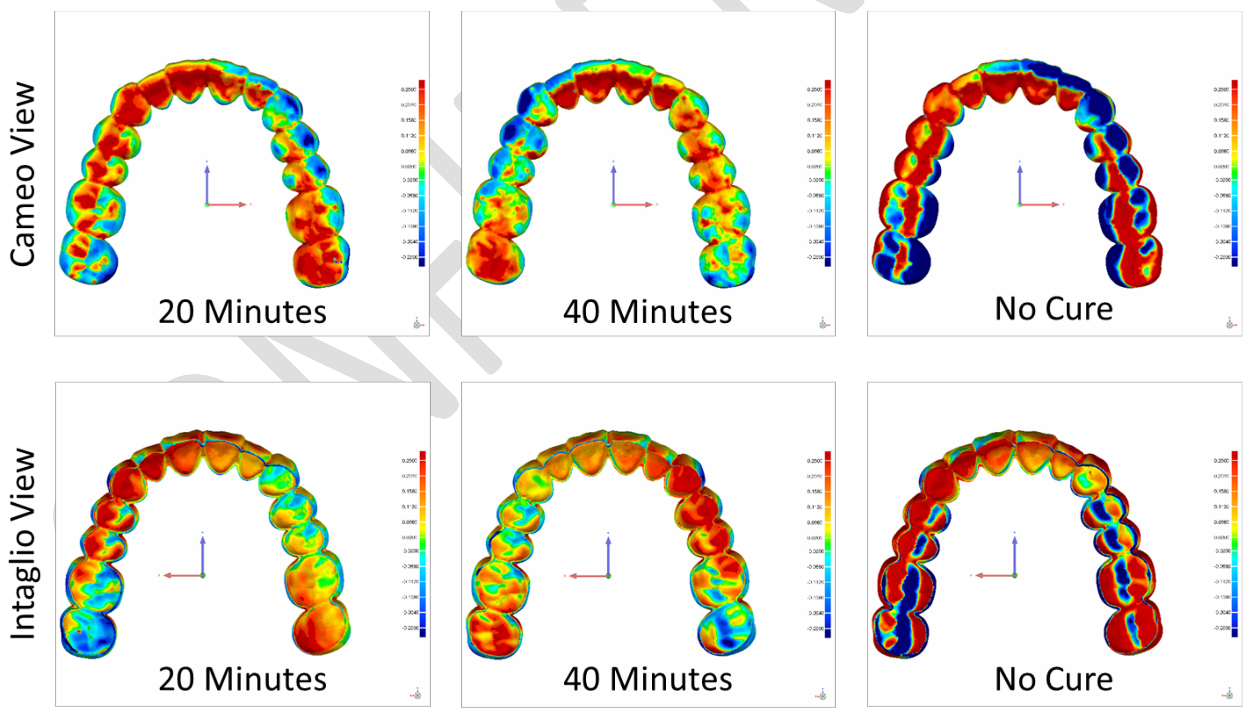

Figure 2. Representative 3D comparisons of the printed aligner surfaces with respect to the reference file used for 3D printing. Warm/red colors indicate positive deviations, and cool/blue colors indicate negative deviations (scale in mm).

The average wall thickness of the 3D-printed aligners (Dental Clear LT) for each group exceeded the corresponding designed part thickness by approximately 0.250-mm (Figure 3). Visual 3D surface comparison was also collected and indicated that the excess thickness in the printed clear aligners (Dental Clear LT) involved the cameo and intaglio surfaces (Figure 4). The post-processing required to scan clear objects involved application of an opaque contrast spray. To investigate the potential contribution of the spray to the measured aligner thicknesses, the study was repeated using an opaque grey resin, which was scanned before and after application of spray. Differences in wall thickness with the grey aligners indicated approximately 0.080-mm wall thickness excess with application of spray.

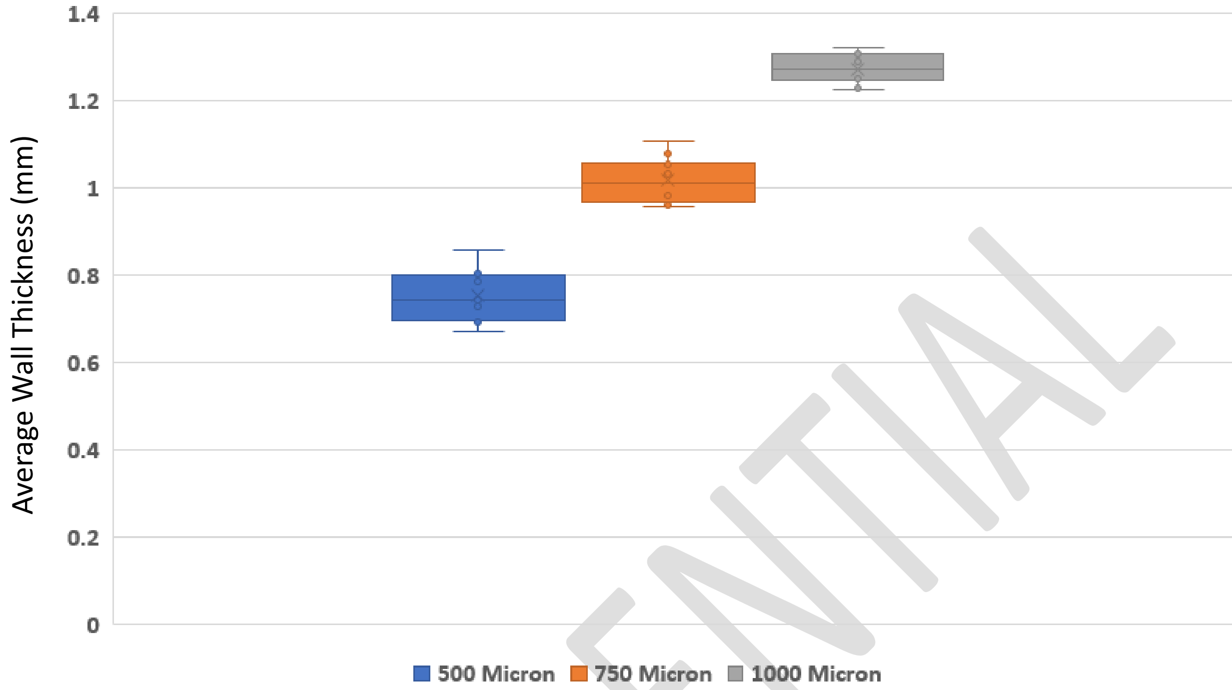

Figure 3. Box and whisker plots of the average wall thickness values measured for 3D-printed aligners designed with 0.500-mm (500 micron), 0.750-mm (750 micron), and 1.00-mm (1000 micron) thicknesses.

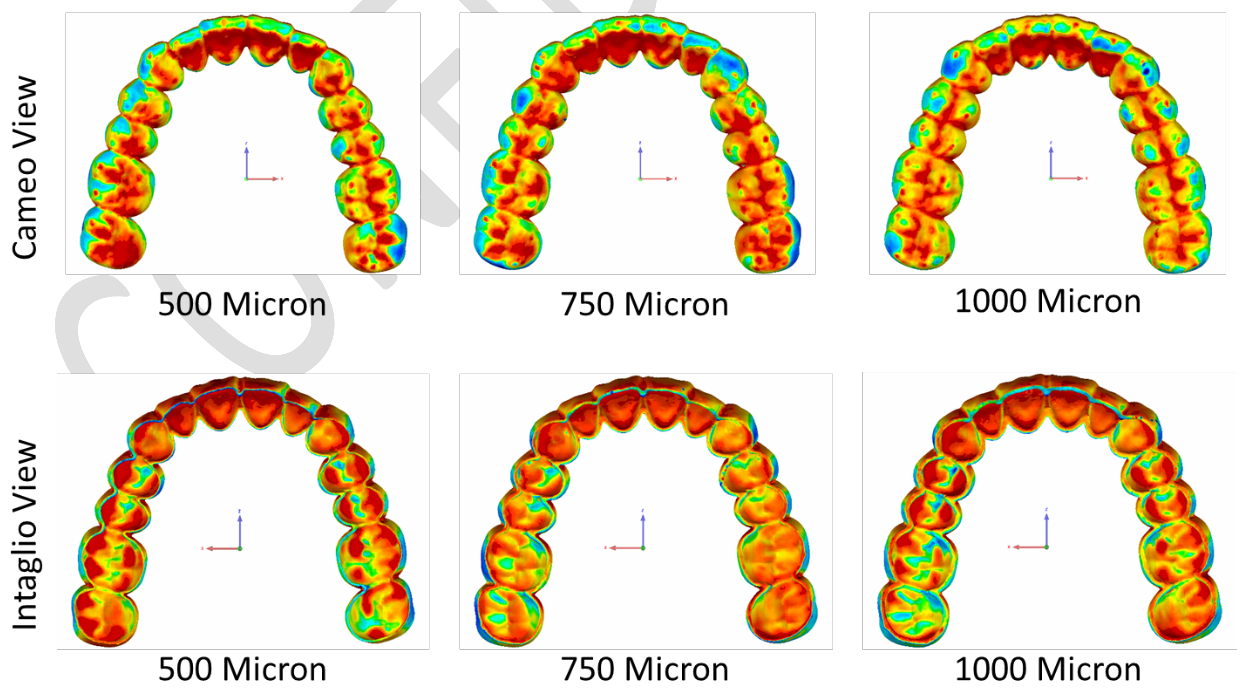

Figure 4. Representative 3D comparisons of the printed aligner surfaces with respect to the reference file used for 3D printing. Warm/red colors indicate positive deviations, and cool/blue colors indicate negative deviations (scale in mm).

Conclusions: The print orientation has little effect on the overall accuracy of 3D-printed aligners under the conditions investigated. All three orientations: parallel to the build platform, perpendicular to the build platform, and offset at a 45-degree angle to the build platform, yield parts that are within limits of clinically acceptability overall. Additionally, increasing the duration of heat exposure and UV curing from 20 to 40 minutes did not have an effect on the overall dimensional accuracy of the parts. All printed parts were within limits of clinical acceptability when cured at 80 degrees Celsius for 20 or 40 minutes. However, the overall deviations do not necessarily reflect the location specific deviations and their clinical impact on the utility of 3D-printed aligners. 3D printing was not able to accurately realize the part thicknesses under the conditions investigated, which may detrimentally impact the potential clinical utility of 3D-printed aligners. Additional advances in materials science and 3D printing technologies are warranted to support potential clinical utility of 3D-printed aligners.

1. **Were the original, specific aims of the proposal realized?**
   Yes

2. **Were the results published?**
   a. **If so, cite reference/s for publication/s including titles, dates, author or co-authors, journal, issue and page numbers**
      No, please see below for details of publications in preparation for submission

   b. **Was AAOF support acknowledged?**
      Yes, AAOF support will be acknowledged in each planned publication

   c. **If not, are there plans to publish? If not, why not?**
      Yes, the project involved contributions from two residents in partial completion of the requirements of the degree of Masters of Science in Dentistry, and the results will be published in the respective theses, as follows.

      1. Edelmann A. "Analysis of Thickness of 3D Printed Orthodontic Aligners," Masters of Science in Dentistry Thesis, Department of Orthodontics, The University of Texas School of Dentistry at Houston, Houston, Texas. (in preparation)

      2. McCarty M. "Effect of Print Orientation and Duration of Ultraviolet Curing on Dimensional Accuracy of 3-dimensional Printed Orthodontic Clear Aligners," Masters of Science in Dentistry Thesis, Department of Orthodontics, The University of Texas School of Dentistry at Houston, Houston, Texas. (in preparation)

      In addition, two research manuscripts based on the results of the project are presently under preparation for submission to orthodontic journals, and work from the project will be included in a monograph presently under preparation for submission to the Proceedings of the Annual Moyers Symposium and International Conference on Craniofacial Research. In each case, the submissions will acknowledge AAOF support, as appropriate.

3. **Have the results of this proposal been presented?**
   a. **If so, list titles, author or co-authors of these presentation/s, year and locations**

      1. "Evidence-based Guidance for 3D Printing Applications in Dentistry," Kasper FK.

The Houston Center for Biomaterials and Biomimetics (HCBB) Seminar Series, The University of Texas School of Dentistry at Houston, Houston, Texas. (June 6, 2019)

2. “Analysis of Thickness of 3D Printed Orthodontic Aligners,” Edelmann A. Masters of Science in Dentistry Thesis Defense, Department of Orthodontics, The University of Texas School of Dentistry at Houston, Houston, Texas. (May 29, 2019)

3. “Effect of Print Orientation and Duration of Ultraviolet Curing on Dimensional Accuracy of 3-dimensional Printed Orthodontic Clear Aligners,” McCarty M. Masters of Science in Dentistry Thesis Defense, Department of Orthodontics, The University of Texas School of Dentistry at Houston, Houston, Texas. (May 15, 2019)

4. “3D Printing Applications in Clear Aligner Fabrication,” Kasper FK. 44th Annual International Conference on Craniofacial Research (Moyers’ Presymposium), University of Michigan, Ann Arbor, Michigan. (March 1, 2019)

5. “From Stone to Bone: Emerging Applications of 3D Printing in Orthodontics,” Kasper FK. The Rolanette and Berdon Lawrence Bone Disease Program of Texas Bone Research Club, Houston, Texas. (February 13, 2019)

6. “Leaving the Stone Age: Applying Biomaterials and 3D Printing to Meet Clinical Needs,” Kasper FK. Sigma Xi – Rice University/Texas Medical Center Chapter, 2018 Annual Awards & Member Induction Banquet, Houston, Texas (April 20, 2018) (Keynote Talk)

b. Was AAOF support acknowledged?
Yes, in each presentation

c. If not, are there plans to do so? If not, why not?
The results will continue to be included in presentations, as appropriate, with proper acknowledgement of the support from AAOF for the work.

3. To what extent have you used, or how do you intend to use, AAOF funding to further your career?
As a bioengineer, I am thrilled to explore exciting new frontiers at the interaction of engineering and orthodontics, and funding from the AAOF has been vital to enable my investigations in these areas that traditionally are not targets for funding from federal sources. The funding from AAOF provides me with opportunities to expand my exposure to the challenges of clinical orthodontics, to collaborate with clinicians and researchers in the field, to increase my research profile, and to broaden my professional network. The benefits enabled by AAOF support provide a firm foundation upon which I plan to continue to build my research program in topics of relevance to orthodontics.