A Study of the Accuracy of a Prototype Computer Numerical Control Dental Hand-piece Compared to Manual Preparation for a Full Coverage Crown Preparation

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ABSTRACT

Aims and Hypothesis: The objective of this study was the design and testing of a Prototype Computer Numerical Control (CNC) dental handpiece. We predicted that the CNC Prototype would be more accurate than the human participant prosthodontists in clinical simulation.

Materials and Methods: A Prototype CNC dental handpiece was developed from off the shelf components, assigned 100 typodont teeth (#18) for submission and 10 practice teeth. Single operator. Five prosthodontists, given 20 typodont teeth (#18) for submission and 10 for practice. Finished preparations were scanned with 3M True Definition® intraoral scanner outside of typodont, compared with Geomagic Control for RMSE.

Results: RMSE Prototype (N=100) was 0.40mm. RMSE Prosthodontists (N=100) was 0.55mm. One sided T test, mean difference -.15mm ($p<.001$, one sided CI -.09). One Way ANOVA (F stat <1, $F=.526$, $p=.717$), Spearman correlation Prototype RMSE vs order($\rho = .1$, $p=.334$), RMSE vs Bur ($\rho = .36$, $p<.001$); For each prosthodontist individually (N=20) RMSE vs Order Prosthodontist 4($\rho=-.54$, $p= .015$). Prosthodontist 5 ($\rho= .58$, $p = .022$). Prosthodontist 3 ($\rho=.16$, $p=.498$), Prosthodontist 2 ($\rho=-.07$, $p=.772$), and Prosthodontist 1 ($\rho=-.08$, $p=.741$) Spearman correlation (N=20) RMSE vs Bur Prosthodontist 5 ($\rho= .51$, $p = .007$), Prosthodontist 2 ($\rho=.46$, $p= .040$), Prosthodontist 4 ($\rho=-.07$, $p=.758$), Prosthodontist 3 ($\rho=.18$, $p=.445$), and Prosthodontist 1 ($\rho=.43$, $p=.059$)

Conclusion: CNC Prototype achieved superior results in clinical simulation, attained on a modest budget with a modest level of research support. Work should continue on the next iteration of a prototype to address some of the limitations of movement, feedback, and emotional acceptance of a machine performing treatment from the perspective of a patient.

DEDICATION

To Persistence

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LIST OF ABBREVIATIONS

ANSI: American National Standards Institute

ANSI/IEC 60601-1: standard set forth by the IEC and ANSI for electronic medical devices

CAD: Computer Assisted Design

CAM: Computer Assisted Milling

CMM: Coordinate Measuring Machine

CNC: Computer Numerical Control

DARPA: Defense Advanced Research Projects Agency (DARPA)

FDA: Food and Drug Administration

IEC: International Electrotechnical Commission

MCG: Metal Ceramic Gold Crown

NASA: National Air and Space Administration

NC: Numerical Control

PFM: Porcelain Fused to Metal Crown

TOC: Total Occlusal Convergence

TORS: Trans Oral Robotic Surgery

A Study of the Accuracy of a Prototype Computer Numerical Control Dental Hand-piece Compared to Manual Preparation for a Full Coverage Crown Preparation

A Brief Overview of Computer Numerical Control

Computer Numerical Control (CNC), is a technology system used to move a tool along a path defined by x,y,z coordinates in space. CNC is used to manufacture prosthodontic appliances such as crowns, implant frameworks, and prosthetic body parts, and it is commonly referenced in contemporary dental technology research as the Computer Assisted Design, Computer Assisted Milling (CAD/CAM) system. CNC has been broadly used commercially in many disciplines since the 1960's and is currently considered to be the mainstream in general manufacturing (aerospace, automotive, etc.); it has its roots in Numerical Control, NC, milling, which moved a tool along a path in space represented by x,y,z coordinates in the time when machines were operated by punch tapes. CNC offers more breadth of functionality than strictly CAM, although for the purposes of this study a CAM function was selected due to its relative ease of testing in the dental school setting. The tool carried by the machine is interchangeable, as are the directions applied through the design software. Advanced CNC systems switch tools dozens of times to run various aspects within the larger task of manufacturing a part. CNC systems perform a plethora of actions in a diversity of fields including cutting, measuring, scanning, smoothing, lifting, transporting, sewing, or virtually any other task that results from the movement of a tool through space. CNC systems have been scaled to move shipping containers inside warehouses and to mill steel within nanometer tolerances. Feedback systems such as load monitors and sensor integration allow lights out operation. Lights out operation is operation in the absence of an operator by an operating system is either: a) robustly self-correcting in the event of errors in the process; or b) that halts the process when a threshold event occurs and alerts an operator for corrective intervention. [1]

A Brief Overview of Metrology and Digital Scanning

Metrology is the science of measurement. The gold standard in three-dimensional measurement is the Coordinate Measuring Machine (CMM). The CMM has a table or other work surface (which could mean placing the machine in a room or other defined space) onto which the object to be recorded is placed. The CMM can be operated manually or operated by CNC. CNC systems are regarded as the standard operating system for CMM's in the field for high volume work. The end effector can be a contact probe, also known as a touch probe, or it can be a digital scanner. A touch probe generally has a smooth, hard surface of known radius, often a polished industrial ruby, which is attached to a shaft. When the ruby makes contact with the object it is displaced, tripping an electromagnetic switch that delivers information to the software, generating a data point. Other types of contact probes include strain sensing probes that respond to distortion and piezoelectric probes in which a crystal creates an electric pulse upon being distorted. Digital attachments operate by way of laser triangulation, parallel confocal light, accordion fringe interferometry, and three dimensional in motion video imaging. All of the digital methods inherently rely on measuring the angle of reflected light against a predicted value, allowing distances to be measured. The CNC CMM is the gold standard of metrology because of the ability to control the measuring environment and thus allow very accurate calculations.[2]

Dental digital scanning entered mainstream use with the introduction of CEREC® in 1984 and underwent advancements as it and a variety of competitors developed the field. Examples of present systems include CEREC® and Planscan® (which use triangulation), 3M True Definition® (which uses three dimensional in motion video imaging), Itero®, Trios®, and CS3500® (which use parallel confocal light and derivations of it), and Lythos® (which uses accordion fringe interferometry). Since the devices are used on patients, they all must first comply with ANSI/IEC 60601-1, a standard set forth by the International Electrotechnical Commission (IEC) and required by the United States Food and Drug Administration (FDA) for all medical devices. A limiting factor common to all intraoral digital scanners is that, unlike a CNC CMM, a human operator controls the speed, direction, and position of the scanner. Internal gyroscopes are often incorporated into the scanning wand to mitigate uncertainties in orientation, but the gyroscopes add weight and size to the scanning wand. A second limiting factor, common to all systems that depend on light for measurement, is that shinny surfaces reflect light in ways that are difficult for algorithms to predict. To create more predictable, uniform reflectance a powder, commonly based on Titanium Dioxide, is dusted over the teeth. Advancements in triangulation and accordion fringe interferometry have made it possible to have powderless dental digital scanners.[3]

Human Performance in past Crown Accuracy Studies

When preparing a tooth to receive a crown accuracy is paramount. The taper, reduction, and the margin preparation will determine to a large degree the success or failure of the crown. It is important to note that crown preparations are traditionally performed by humans, and discussing reduction of surfaces (buccal, occlusal, etc.) is of value for human learning of the process. When discussing surface contours for milling or manufacturing the concept of a buccal reduction of 1.5mm must be translated to the x,y, and z coordinates of points in the point cloud representing the finished surface. As such, studies of dental preparations, especially those that predate digital imaging, report results in traditional terms such as total occlusal convergence, whereas studies focused on digital accuracy report findings in root mean squared error, percent error, and other expressions of surface deviation.[4]

Leempoel *et al.* (1987) randomly selected 132 single crown dies from two dentists collected over a five year period. A photograph of each die was taken from the buccal, and another from the proximal. Both were enlarged with a projector 18x linearly. Results indicated that the total occlusal convergence angle ranged from 15.5 degrees to 30.2 degrees. These results were statistically significant. The ideal total occlusal convergence cited in the paper was 4 to 6 degrees. Assuming a 5 degree total occlusal convergence as selected by Leempoel *et a.l* (1987), it is possible to calculate the percent error of the observed range of convergence angles as *((15.5-5)/5)x100% = 210%* for the lower bound and as *((30.2-5)/5)x100%= 504%* for the upper bound.[5]

Nordlander *et al.* (1988) obtained 88 dies by 8 residents and 120 dies by two prosthodontists. A photograph was taken of the faciolingual and mesiodistal views and enlarged with a projector. The angle of convergence was measured. Results indicated total occlusal convergence ranged from 13.3 to 30.4 degrees. The results were statistically significant. No statistically significant differences were found between the two groups. The ideal total occlusal convergence cited by Nordlander *et al.* (1988) was 2 to 10 degrees of total occlusal convergence.[6]

Shillingburg *et al.* (1988) saved 418 dies over 12 years. Photographs were taken of the buccal and the mesial. Photographic enlargement was performed. The results indicated an average total occlusal convergence that ranged from 13.4 degrees to 15.8 degrees. The results were statistically significant. Shillingburg *et al.* (1988) stated his ideal as 4 to 6 degrees of total occlusal convergence.[7]

Annerstedt *et al.* (1996) accumulated 127 dies from dental students, and 351 dies from dentists. Photographs were taken from the buccal and the mesial. The photographs were enlarged and the angle of convergence was measured. Results indicated a total occlusal convergence range of -2 degrees to 51 for dental students, and 0 degrees to 70 degrees for dentists. The results were statistically significant. The ideal referenced by Annerstedt *et al.* (1996) was 4 to 6 degrees of total occlusal convergeance.[8]

Ghafoor and Siddiqui (2011) gathered 197 dies, collected randomly from Aga Khan University Hospital, dental section. The buccal and mesial surfaces were photographed. Photographic enlargement and angle measurement was performed. The Mean Total Occlusal Convergence was reported as 23.7degrees +/- 8.9 degrees. The results were statistically significant. There was no difference found between residents and specialists who had been practicing for more than five years post residency. The ideal was given as 4 to 6 degrees by Ghafoor and Siddiqui (2011).[9]

With an increase in total occlusal convergence, resistance to dislodgement decreases exponentially. However, recognizing that clinical success can be achieved even if the ideal is not, ranges of clinical acceptability of between 10 degrees and 22 degrees are reasonable for molars due to their larger surface area.[10]

Bowley and Kieser (2007) demonstrated on molar preparations that reduction of tooth structure to less than 5mm of axial wall height and greater than 10 degrees of taper results in submaximal luting agent surface area, and that when reduction of tooth structure leaves less than 3mm of axial wall height insufficient surface area for luting agent remains regardless of taper.[11]

Parker *et al.* (1991) found that less than half (46% in the study) of molar preparations tested had adequate resistance form to prevent dislodgement by finger pressure because of excessive reduction.[12]

A review of the literature indicates a pattern. It was particularly telling that in the studies which compared dental students to experienced dentists or residents that there was no statistically significant change in the result, which pointed to an inexorable limiting condition that could be overcome by training or practice. Speculation as to the nature of this limit might be that it is the ceiling of human performance in the oral environment with current preparation techniques and armamentarium.

CNC Performance in Dental Prosthetics

The adoption of CNC in dentistry for prosthetic manufacture was first introduced by CEREC® in 1984. CEREC® listed a contemporary model of the 21st century, the MC XL® milling machine as having an accuracy of 7.5 microns.[13] This accuracy is not unique to dental CNC CAD/CAM systems. A wood working hobby company that caters mainly to the enthusiast as opposed to the industrialist, Rockler® lists its Shark® CNC router as having an accuracy of 12.7 microns on a full step setting and 1.59 microns on a 1/8 step setting.[14] A step is an incremental movement of uniform dimension made by a CNC stepper motor. The current design of CEREC®, LAVA®, and E4D® dental prosthesis milling machines employ two dental handpiece heads mounted to a 5 axis CNC. The prosthesis is milled in a chamber with water jets. The workpiece is held with a sprue which is later removed on finishing. Larger laboratory based CNC CAD/CAM systems mill implant frameworks and produce orthodontic appliances.

In a controlled, bench top study, Ortorp *et al.* (2003) selected one master cast for a five implant fixed partial denture. Twenty CNC milled frameworks were fabricated, and five cast gold frameworks were fabricated according to traditional casting methods. The twenty CNC milled and five cast cold frameworks were evaluated for the average distortion along the X, Y, and Z planes. The results indicated and overall distortion for CNC milled frameworks that was 5 microns (0.005mm) and overall distortion of cast gold frameworks was 53 microns (0.053mm). The results were statistically significant.[15]

Ortorp *et al.* started a long term clinical study of the durability of CNC milled frameworks. The initial sample included 368 implants placed in 67 patients for the CNC group (test) and with 361 implants placed in 62 patients for cast group (control)
At one year the cumulative survival rate for the CNC framework 100%; 97.8% for the implants of the test group. The one year cumulative survival rate for the cast framework stood at 98.3% and at 98.6% for the implants of the cast group. The failure seen in the CNC test group was attributed to the implants, not the framework, where as in the cast group the loss was attributed to the framework and the implants. The results were statistically significant, and Ortorp *et al.* concluded that the two treatments equally acceptable over a one year span.[16]

Ten years after the original study began, Ortorp *et al.* (2012) found that 29 of the 67 CNC group patients were lost to follow up and 23 of the 62 cast group patients lost to follow up. The cumulative survival rate for the CNC frameworks stood at 95.6%, with an implant cumulative survival rate of 95.0%. The cumulative survival rate for the cast framework stood at 98.3%, with an implant cumulative survival rate of 97.9%. The results were statistically significant, and Ortorp *et al.* (2012) again concluded the two treatments are equally acceptable when compared at both a 1 year and at a ten year follow up.[17]

Lee *et al.* (2015) prepared a single typodont premolar to receive an all-ceramic crown, and then duplicated the preparation with 40 silicone models. Thirty test crowns were milled using Lava (10), Cercon (10), and CEREC (10) milling systems. For a control group, ten metal ceramic gold (MCG) crowns were fabricated. The marginal gap of each sample was measured after seating and cementation under a stereoscopic microscope at 75x magnification. Lee *et al.* (2015) found that the marginal gaps for the three test groups (all CNC milled) were equivalent to the marginal gaps of the control (MCG crown). The marginal gaps were 87.2 (22.8) μm for Lava, 58.5 (17.6) μm for Cercon, and 72.3 (30.8) μm for CEREC. The control group, MCG, had a marginal gap of 70.5 (34.4) μm.[18]

Katsoulis *et al.* (2015) performed a bench study evaluating the accuracy of two experimental groups of ten unit zirconium oxide (ZrO) implant frameworks made via CAD/CAM with laser (ZrO-L) scanning and with mechanical (ZrO-M) scanning against two controls: similar ten unit implant frameworks fabricated with CAD/CAM in titanium and frameworks made with traditional casting techniques. The authors applied the one screw test and recorded microgaps for the three groups. Both the experimental CAD/CAM groups and the titanium control made via CAD/CAM had equivalent accuracy (ZrO-L (median 14 µm; 95% CI 10–26 µm), ZrO-M (18 µm; 12–27 µm) and TIT-L (15 µm; 6–18 µm)), and were statistically superior to the traditional cast method frameworks (236 µm; 181–301 µm, ($P < 0.001$)). In essence, the CAD/CAM methods delivered results that were an order of magnitude more accurate than the traditional casting technique.[19]

Overview of Contemporary Robotic Surgery

A review of the field of Robotic Surgery conducted roughly a decade ago by Lanfranco *et al*. (2004) provides a good synopsis of the development of robotic surgery. First introduced in 1985, contemporaneous with CEREC®, the Puma 560® was used in neurosurgical biopsies and then transurethral prostate surgery, and area robotic surgery has continued to dominate. Shortly thereafter, ROBODOC® was approved by the FDA for widespread commercialization. The National Air and Space Administration (NASA)'s Ames Research Center became increasingly interested in telepresence surgery at around the same time. In the 1990's the NASA team moved to the Stanford Research Institute, and then partnered with the Defense Advanced Research Projects Agency (DARPA). Out of this effort with DARPA, the AESOP, Zeus, and Da Vinci robotic surgical systems were created. Today, in 2016, the Da Vinci system controls an overwhelming majority of the market share.[20]

Parika, Lin, and Goyal (2015) conducted a review of 390 articles related to Trans Oral Robotic Surgery (TORS). After excluding a number of studies based on tangential coverage of TORS, lack of focus on patient outcomes as a research aim, and small sample size, twenty-six studies remained. Fifteen of these studies were on oropharyngeal cancers, nine on laryngeal cancers, and two on unknown primary lesions. The total patient sample was 585 patients for oropharyngeal cancers, 116 patients for laryngeal cancers, and 69 patients for the unknown primary. TORS was associated with a number of positive outcomes over traditional laparoscopic surgery such as decreased need for free flap reconstruction, shorter hospital stay, fewer postoperative complications – especially related to speech, and lower tracheostomy or gastrostomy tube dependence than traditional full open surgery, with at least comparable oncologic outcomes. In comparison with chemoradiation, an alternative to surgical intervention of any nature, the TORS oropharyngectomy had similar subjective swallowing outcomes, comparable oncologic outcomes, and decreased gastrostomy tube dependence. Patients reported speech and overall health outcomes following TORS oropharyngectomy were equivocal. For patients with unknown primary lesions, the addition of TORS lingual and palatine tonsillectomy significantly increased the rate of identification of the primary site to greater than 70%. Parika, Lin, and Goyal (2015) concluded that TORS was a promising treatment option for head and neck squamous cell carcinoma, but the small sample size of individual studies and the short length of post-operative survival observations (2 years for the oldest study reviewed) made further prospective trials necessary before TORS could be measured against traditional surgical techniques and chemoradiation therapy.[21]

According to Bochner, Sioberg, and Laudone (2014) radical cystectomy was the traditional treatment of choice for nonmetastatic, invasive bladder cancer. To further investigate evidence that robot-assisted laparoscopic surgery had better outcomes than the traditional method, the authors designed and began a randomized, controlled trial. Patients were recruited at Memorial Sloan Kettering Cancer Center. Surgeon experience and proficiency was controlled by selecting only well seasoned surgeons with ten years of practice of post oncology fellowship. Patient specific characteristics were controlled for by ensuring baseline characteristics were similar in the two groups. The study evaluated the rate of complications of grade 2 to 5 on the Clavien system within the first 90 days. A total of 118 patients were randomly divided to open radical cystectomy (58 patients) or robot-assisted radical cystectomy (60). The study was halted prior to completion after a mandated interim analysis showed outcomes that met institutional standards mandating a stoppage in experimentation if the outcomes showed no evidence of superiority for the novel treatment (robot assisted laparoscopy). The authors found that 37 patients (62%) who underwent robot-assisted surgery and 38 (66%) who underwent open surgery had a complication of grade 2 to 5 (difference, −4 percentage points; 95% confidence interval, −21 to 13; P=0.66). Further selection for only high-grade (grade 3 to 5) complications yielded results of occurrences in 22% and 21% of the patients, respectively (P=0.90). The authors concluded that, within the context of their surgeons and hospital, there was no significant advantage to the robot assisted laparoscopic surgery, and they called for more randomized trials as this outcome appeared to contradict the case series evidence that had lead them to their research question and hypothesis.[22]

Ramera *et al*. (2016) investigated robotic pancreatic surgery. The authors found that robotics were either used to perform sections of the overall procedure, augmenting traditional techniques, or used virtually exclusively. Pancreatic cancer spawns metastases early, and the pancreas is a challenging organ both from a location and access perspective and an internal structural perspective within the organ. Thus advances in laparoscopic approaches to pancreatic surgery are the realm of a small, select group of well trained surgeons. Robot assisted surgery further advanced the boundaries of surgical ability by improving the surgeon's range of motion and clarity of vision in the challenging pancreatic environment. The authors further stated that robotic surgery is now considered the gold standard in pancreatic surgery, despite there not being randomized trials. The authors cite that current literature includes almost exclusively case series, cohorts, and case studies. The challenges the authors feel have hindered randomized controlled trials are limited availability of robots and skilled surgeons, problems obtaining consent, and difficulty in cooperation across institutional lines.[23]

Marescaux *et al.* (2002) discussed the first transatlantic robot assisted surgery. The surgery was performed using the ZEUS system. Surgeons in Manhattan, New York controlled a ZEUS system in Strasbourg, France by way of fiberoptic asynchronous transfer mode cables. The surgeons performed a cholecystectomy (removal of the gall bladder). There were no complications, and the patient in France recovered well. Although there were no interruptions in the connection and no issues of delays during the surgery, precautions had been taken such as having a dedicated back up line and calculating anticipated signal latency before attempting the procedure.[24] The ZEUS system, unlike the CNC Prototype tested in this study, relied upon surgeon operator control for every action it took, much in the same way that a scalpel cannot perform a surgery without being under a surgeon's control. Though successful, the famous transatlantic surgery was a case study, not a randomized controlled trial.

Societal Context in 2016 America

Detractors of the efficacy of robotic surgery are growing. A recent report from the Rand Corporation by Scales and Bergmen (2014) outlines key arguments in opposition to adopting robotic surgery. At the crux of the argument against robotic surgery stands a lack of widespread randomized clinical trials to prove that robotics is as good or better than traditional methods, widespread adoption of robotic surgery despite a level of evidence only reaching the cohort level, an average cost increase of 13% per surgery as compared to traditional methods, and a single system, Da Vinci, holding 80% market share in a near monopoly. The authors reference a series of corporate mergers whereby ZEUS was subsumed by Da Vinci in a leveraged equity buy out, and thus far no viable competitor has entered the market place. Scales and Bergmen (2014) call for randomized controlled studies and a number of federal government reforms to drive competitive medical technology development, and an end to what they term a "medical arms race" and escalating costs based on perceived value when true value appears, in their view, to remain stagnant.[25]

The perception that health care is escalating out of reach of the common citizen is not confined to the debate surrounding medicine. Oral health care is also a subject of debate. In Massachusetts, bills have been sent to the house and the senate, several years in a row[26], to address disparities in care by adding a lower cost licensee to the dental workforce who, as idealized, would cost less to train, charge less for procedures than a dentist, and bring care to oral health deserts within the Commonwealth at an acceptable level[27]. Though championed as a benefit to the underserved, it also carries a tinge of class stratification. A call has gone out across the nation for both quality and affordability[28].

Universities represent a powerful source of innovation in America. There is a social responsibility to share new ideas to improve the lives of the people. The Legal Information Institute at Cornell University Law School defines intellectual property (IP) in the United States as a non-rivalrous public good (*Wex*, 2015). Distinct from tangible property, defined as land and chattels (*Wex*, 2015), exclusive public possession of intellectual property is not possible. Congress governs IP by the Commerce Clause of the US Constitution. Patents, copyright, trademarks, and trade secrets to allow the creators of intellectual property to profit from their IP as if it were tangible property, thus incentivizing the production of IP for the benefit of the wider society (*Wex*, 2015). Thus discovery is, by nature and law, a thing which ought to be put to the good of all.[29]

At the end of the Second World War the Director of the Office of Scientific Research and Development, Vannevar Bush, a Tufts and Massachusetts Institute of Technology alumnus, wrote a report, *Science the Endless Frontier*, to Franklin Delano Roosevelt outlining his ideas regarding the role of government in science, higher education, healthcare, and industry. Many advances in medicine and industrial technology had happened during the war. Dr. Bush wished that the importance and organizational effort that had tied a disparate scientific community together during the war might continue to grow in peace time. To this end, Congress continued to bring university research into the public domain for licensing to, in theory, any and all persons or companies who wished to develop it commercially, with the intent of benefiting the wider society. However, no exclusive licenses were given on such patents, no uniform policy regarding a protocol for issuing licenses was created, and thus despite tens of thousands of patents that accumulated in the post war decades there were difficulties in getting new ideas commercialized without large backers due to a lack of protection from competition. It was out of this same period that Federal Student Aid and a host of other reforms were made to improve access to the educational system for motivated and talented individuals who might otherwise not go beyond a high school diploma.[30]

The Bayh-Dole Act of 1980 set forth rules governing the rights of IP created by federal contractors, such as universities. The act came about to incentivize development of intellectual property, again out of recognition of the societal responsibility to not only expand knowledge but to apply that knowledge to benefit mankind. Specifically, the Bayh-Dole amended chapter 30 of Title 35 of the United States Code, allowing the university the choice of retaining the ownership of its IP created with federal funds. The IP, however, must already have been owned by the university, necessitating a contract with the inventor that transferred IP ownership to the university. The language of the Bayh-Dole Act additionally required that the contract between the university and the inventor assign a significant portion of the royalties to the inventor. Furthermore, to exercise its privilege of right of title to the IP, the university had to disclose the invention to the federal government, grant the government a permanent, paid up license to the IP, actively pursue commercial use of the IP with US firms (at the exclusion of foreign firms), and use all excess proceeds after reimbursement of royalties to the inventor and operating expenses to fund additional research at the university. If the university did not satisfy all stipulations set forth in the act, ownership of the IP reverted to the federal government, who could elect to revert it to the inventor. The federal government also retained rights termed march-in-rights that allowed the Department of Commerce to license the IP to any entity it felt prudent if the IP was not being commercialized to the satisfaction of the federal government. (Bayh-Dole Act of 1980).[31]

This study at our University offers strong bench top evidence that the fundamental process of clinical dentistry can be changed to incorporate automated intraoral delivery of care. This is unique. The extant surgical robotics systems are, at their core, a guided tool used by a surgeon. Our research offers autonomous action on the part of a machine. Many aspects of the practice of traditional dentistry may be improved through automation. It may be possible to improve outcomes by equaling or exceeding current limitations in accuracy. Access to care may be improved by allowing a single practitioner to treat a greater number of patients and over a greater distance (because practitioner and patient would not need to be located in the same space – as already demonstrated in the transatlantic laparoscopic surgery). The total cost of oral health across a patient's lifespan may be reduced by increasing the lifespan of dental interventions, reducing iatrogenic damage, and decreasing provider staffing costs. Our prototype was not derived from a multimillion dollar surgical robot. The components of the prototype were of far humbler origin. It demonstrates that technology can be affordable if we allow it to be.

Although this study tests a specific application of a computer numerical control intraoral system to prepare crowns, crown preparation was just a convenient, easily testable procedure for our setting. Any instrument could be substituted for a handpiece as the end effector. A wide range of tasks from intraoral scanning, placing restorations, 3D printing, removing calculus, probing the gingiva, placing orthodontic wires, integrating CT data, and performing osseous surgeries could be performed through the hands off, lights out power of CNC with only modest increases in investment, and almost exclusively using conventional, off the shelf components.

Aim and Hypothesis

The Primary Hypothesis of the thesis was that the Prototype could prepare crowns with an accuracy as good or better than the Prosthodontists. Accuracy would be measured in Root Mean Squared Error (RMSE). The primary hypothesis hinged on a presupposition that the Prosthodontists would be a reasonably cohesive group regarding RMSE performance against which a comparison could be drawn definitively. We tested the hypothesis that the Prototype would experience a statistically significant increase in RMSE with burs that had been used a higher number of times. It was hypothesized that the Prototype would maintain consistent accuracy (RMSE values) throughout the 100 preparations. It was predicted that the prosthodontists would develop better accuracy (a decrease in RMSE) with a greater number of teeth completed. It was also predicted that the prosthodontists would develop poorer accuracy (higher RMSE) with a greater number of bur uses.

Materials and Methods

Handpiece used by Prototype and Prosthodontist

Midwest Tradition® High Speed Dental Handpieces are the standard handpiece used at Tufts University School of Dental Medicine in its predoctoral and postdoctoral clinics. It is the handpiece used by Tufts predoctoral students during the Fixed Prosthodontics portion of the North East Regional Board Exam. For standardization and generalizability, the Midwest Tradition® High Speed Dental Handpiece was the only handpiece used by the Prosthodontists and by the Prototype. All handpieces were new. All handpieces were lubricated after every twentieth preparation for the Prosthodontists and for the Prototype. Lubrication was performed using the Midwest Plus® Handpiece Maintenance Kit by Nicholas Bello for the handpiece attached to the prototype, and the participants were responsible for handpiece lubrication for their handpieces. Those participants who did not have access to a Midwest Tradition® High Speed Dental Handpiece were provided with one by Nicholas Bello for use in the study. The handpieces for both the Prosthodontists and the Prototype were operated with standard water spray for cooling and dust control.

The use of water spray is standard in clinical practice and clinical simulation to prevent overheating during removal of tooth structure. Standard water spray was used in all preparations.

Bur used by Prototype and Prosthodontist

The burs used were SS White Piranha Single Patient Use Diamond Round End Taper® #856-018C and #856-018F 1.8 mm diameter. The SS White Piranha Single Patient Use Diamond Round End Taper® #856-018C was used for general reduction, and SS White Piranha Single Patient Use Diamonds Round End Taper® #856-018F bur was used for refinement. The Prototype and the Prosthodontists were restricted to the use of these two burs for standardization of technique.

All burs were changed at minimum after every fifth preparation for the Prosthodontists and for the Prototype. A visual inspection of the bur was performed by the operator, prior to each preparation. If, in the best judgment of the operator, a bur was clogged or otherwise not to satisfaction, the bur was exchanged for a fresh bur. Thus, no bur was used for more than five preparations, but the operator had the option to elect to change a defective bur sooner than the fifth consecutive preparations. Every change of bur event was recorded. Log sheets were provided by Nicholas Bello and collected from all of the participant prosthodontists. Nicholas Bello maintained the log sheet for the Prototype.

Participant Prosthodontists

Five prosthodontists were recruited from among the faculty of Tufts University School of Dental Medicine. All five prosthodontists successfully completed their full twenty samples for data submission. It was determined by the Thesis Committee that membership on the faculty and certification in the specialty of prosthodontics from a US accredited prosthodontics postgraduate program would be both necessary and sufficient to serve as one of the five participants. A consensus was reached among the Thesis Committee that five educationally qualified faculty members would represent a sufficient diversity to make the results of the study generalizable while also representing a sufficient level of clinical proficiency to make the results valid. It was determined by the Tufts University Institutional Research Board that Committee Members were to be excluded as participant prosthodontists. No Thesis Committee members were participants, and no participants were former Thesis Committee members who had elected to drop off the thesis committee to participate as a research subject. The identity of the participants was not published or otherwise made known. A list of participant prosthodontists was maintained by Nicholas Bello during the study for communication purposes, but the list was destroyed at the end of study. No names were associated with specific tooth preparations or included in any data analysis. Teeth were instead identified with serial numbers. Each participant prosthodontist was assigned an identification number, 1 through 5, and a set of consecutive serial numbers. After this assignment, all record of the name of the participant prosthodontist was destroyed, and no master list was maintained, rendering it impossible to recreate the list of participants from any of the study materials.

These five participant prosthodontists were given the liberty to complete their designated preparations at a time and place of their own arrangement, conforming to the requirements of the study. An in-person check-in was performed by Nicholas Bello every two weeks with the participant prosthodontists to discuss their progress. These check-ins allowed an opportunity for clarification, resupply, or any other needs of the participants, including the decision of a participant to withdraw from the study. A protocol for withdrawal was created by consensus decision with the Thesis Committee and the Advanced and Graduate Education Office. Withdrawal was voluntary and would require the return of all materials and supplies given to the participant prosthodontist. Any replacement participants would start with a fresh set of unprepared teeth, and any preparations performed by the original participant would not be included in the data sample. Any replacement participant must also be a prosthodontist and a member of the faculty. No participant prosthodontists withdrew, and thus there was no need to enact the replacement participant prosthodontist protocol.

Each participant prosthodontist was given thirty consecutively and uniquely numbered, identical plastic teeth representing tooth #18, the left mandibular second molar as manufactured by Kilgore International®, product number A5AN-200. Numbers were placed on the root surface of the tooth to avoid interfering with the preparation. The first ten consecutively numbered teeth were designated practice teeth to allow the participant to acclimate to working in simulated tooth structure. It was left to the choice of the participant to complete all ten practice teeth or to move ahead to the eleventh through thirtieth teeth. These final 20 teeth, prepared sequentially, were submitted and recorded as data. If an egregious error occurred, in the opinion of the participant, the participant was given a replacement plastic tooth and the plastic tooth with the egregious error was excluded from the data. The total number of recorded prepared plastic teeth from the sum of the five participants was 100.

All participant prosthodontists were provided with a #18 Kilgore® Full Crown Prep A21AN-LL72 to use to visually and tactilely model their preparations. The #18 Kilgore Full Crown Prep A21AN-LL72 was a factory made, to scale, fully insertable, pre-prepared full crown preparation typodont tooth to allow 1:1 in situ reference for the participants. No matrices or other mechanical aids were used while attempting to complete a preparation. Periodontal probes and other metric rulers were permissible and were used at the discretion of the participants. The A21AN-LL72 is the prepared A5AN-200 plastic tooth as prepared according to the guidelines set forth in Shillingberg.[32] In addition to the #18 Kilgore® Full Crown Prep A21AN-LL72 , the prosthodontists were given a written description of the standard full coverage all metal crown abutment preparation on a molar, according to the third edition of Shillingburg's *Fundamentals of Fixed Prosthodontics* (the text used at Tufts for the DMD program) calls for an occlusal reduction of 1.0 mm, a functional cusp bevel of 1.5mm terminating superiorly at a line intersecting the peaks of the functional cusps and terminating inferiorly at the inferior termination of the buccal groove, a full circumference chamfered finish line 0.25mm from the gingival margin and 1.0 mm in width when viewed from the occlusal, and an axial reduction with a uniform circumferential taper from gingival to occlusal of 6 degrees (centered on the long axis of the tooth) starting at the interior-most border of the chamfer finish line.

The teeth were mounted in their anatomically correct position in the D81SDP-200-MF Typodont, and that typodont was mounted with full standard Tufts skull and shroud in patient simulation. Tooth #17 was not present, and tooth #19 was removed to simulate the clinical scenario of the partially edentulous patient necessary for the fixed partial denture. All remaining dentition in the typodont were present. Classically a metal skull and rubber shroud are used to simulate the soft tissue of the cheeks, lips, face, and the hard tissue of the skull. This metal skull and shroud was present and its use was required by all participants. Participants were provided with portable adaptors so any dental chair, not just those present in simulation clinic, could be used for the preparation of samples. This adaptor allowed considerable flexibility to the participants to accommodate the research in their busy schedule. A guideline of 60 days to complete and return all study materials was approved by the committee and asked of the participants. In good will, and to maintain a positive research culture for the participant prosthodontists, Nicholas Bello gave the participants as much time as they required beyond the 60 day guideline to complete the materials. Although some of the participants took as much as six months to return the materials, all of the participants completed all materials. All of the teeth were retained after the study as part of the record of this study and to allow future analyses to be performed upon the teeth. A list of the teeth and their serial numbers can be found in Appendix A, Table.

Prototype

A digital representation of the theoretical ideal abutment preparation with supragingival margins for typodont tooth #18 from Kilgore®, product number A21AN-LL72, was developed as a Standard Tessellation Language (STL) file generated by eleven scans of the touch probe attachment of the Rockler® Shark® (resolution 0.025mm) averaged and cleaned using Geomagic Design®. STL files are surface representations created by triangular planar vectors. This STL file was then imported into Cut3D® version 1.11. The axes were oriented to a right handed coordinate system. Clearances for non-cutting tooth paths were set at 2.5mm beyond a virtual box encompassing the tooth. The dimensions of the virtual box were X= 14.5mm, Y = 12mm, Z=7.7mm. The cutter head selection was entered as a 1.8mm diameter, round-end cutter with a length of 8mm. Tool cut depth was set at 0.2mm, and overlap of tool paths was set at 0.9mm. Tool paths were created by the software applying the tip, not the axial sides of the bur, as the surface to engage the material as is customary for CNC tool path creation. Roughing pathways were set to raster Y and then to raster X at a 45 degree angle to the coordinate axes such that the X raster and Y raster were orthogonal. The starting point was selected as the upper bound of the Z axis limit of the virtual box, representing the most distal, buccal, occlusal corner of the preparation. Finishing pathways were set to the same coordinates, again with orthogonal X raster and Y raster patterns. Material type was selected as "plastic", and the feed rate was adjusted to 500mm/minute. Tool paths were calculated. Tool paths were simulated virtually using Cut3D® version 1.11's cut preview feature. Tool paths were then run with no bur engaged and no typodont or head present to ensure that the tool paths represented a complete set of motions and would remain within the spatial limits available in the simulated mouth. The tool paths, satisfactory, were saved as a TAP file. A TAP file is short for Tape, which invokes the punch tapes of Numerical Control, the predecessor to Computer Numerical Control. A TAP file is coded using US-ASCII (United States-American Standard Code for Information Interchange).

The CNC Dental Handpiece Prototype was built using a conventional, off the shelf Rockler® Shark® CNC Router as the starting point. A Midwest Tradition® High Speed Dental Handpiece was mounted to it and set to operate such that the z axis of the bur was in parallel with the z axis of the CNC router head, as oriented in a right handed coordinate axis set. An air compressor and dental handpiece air hose were used, as was a standard water bottle filled with distilled water. This design was the second iteration of the design, and represented the simplest, sterilizable prototype of a 3 axis gantry with accuracy of the same order of magnitude as a CEREC® MC XL® mill. Initial prototype design took place in Uniondale, New York at the Art and Restoration Department of Kellenberg Memorial High School starting in July 2011 and continuing through the summer of 2013. This two year period yielded important insights into design elements. The base machine was a Techno LC® 4896 CNC wood working router with a four foot by eight foot vacuum table. Preliminary design work included a wooden adaptor arm that proved to place too great a strain on the Midwest handpiece because of the stiffness of the arm and the power stepper motors of the Techno LC® 4896 CNC that caused the handpiece to nearly instantly dig in, rotate the workpiece, and then crumple if it encountered resistance that exceeded the cutting power of the bur. The Rockler® Shark® was presented at the Protocol Defense as the second iteration of the prototype, and was initially housed at 1415 Commonwealth Avenue in Brighton, Massachusetts. Shortly after the Protocol Defense, efforts were made in conjunction with the Tufts School of Engineering to obtain grant funding through the Robert Wood Johnson Foundation and through the University of Massachusetts Lowell M2D2 technology contests to produce a five axis prototype with feedback loops, but after a year of unsuccessful proposals for resources the second iteration Rockler® Shark® was selected as the permanent prototype for the thesis research. The long axis of the tooth and the z axis of the CNC were aligned using the laser alignment of the machine at the center of the occlusal table of the typodont tooth. The Prototype was zeroed to the distobuccal (upper left) corner of a virtual box of dimensions X= 14.5mm, Y = 12mm, Z=7.7mm circumscribing the tooth with 2.50mm of clearance around the x axis and y axis of the STL file of the ideal preparation and 2.50mm of clearance in the z axis of the STL file of the ideal preparation. This zero, zero, zero origin position was held constant throughout all testing of the Prototype.

A new Midwest Tradition® High Speed Dental Handpiece was fitted to the Rockler® Shark® CNC Router using a specially designed Lego® custom intraoral adaptor arm. This arm was designed to be rigid and offer a repeatable point of failure that was non catastrophic. During testing of the prototype, this arm frequently broke when the bur encountered excessive resistance, acting as a protective, passive load monitor. In this protective role the Lego® custom intraoral adaptor arm isolated the failure to its easily repairable structure and prevented any damage from occurring to the more difficult to replace components of the prototype, such as the electric stepper motors or the Midwest Tradition® dental handpiece. A total of 437 man-hours of operator time were consumed milling the samples using the prototype. Active computer load monitors were not available within the limited budget, so no lights-out machining occurred. Nicholas Bello sat next to the machine during all of its operation. Repairs to the Lego® custom intraoral adaptor arm (acting as a passive load monitor), corrections of G code glitches, and milling a very large sample size contributed to this total.

The CNC Dental Handpiece was be operated exclusively by the MS student investigator, Nicholas Bello. During all milling the prototype was located on the ground floor of 46 Bay Drive in Canton, MA in a windowless, temperature controlled laboratory space with all accessory equipment (air compressor, dust and water control, computers, measuring devices, etc.). The prototype was privately owned by Nicholas Bello and could not be located on Tufts University grounds for insurance purposes. The ambient room temperature was maintained at a constant 66 degrees Fahrenheit to prevent any thermal influence on the machine. Sunlight was excluded from the room to prevent any components of the machine from unevenly absorbing infrared radiation. All tests involving the CNC Dental Handpiece were planned to be video recorded to record all stages of each tooth's preparation with the intention that it would be valuable resource for making improvements prior to the next study. However, initial videography did not offer, valuable insight as the action of the tool on the tooth surface was not clearly visible extra-orally past the arm of the machine. Videography was abandoned for a simple log.

One hundred and ten consecutively numbered, identical plastic teeth representing tooth #18, the left mandibular second molar as manufactured by Kilgore International®, product number A5AN-200 were presented to the operator of the Prototype. The teeth were mounted in their anatomically correct position in the D81SDP-200-MF Typodont, and that typodont was mounted with full standard Tufts skull and shroud in patient simulation. Tooth

#17 was not present, and tooth #19 was removed to simulate the clinical scenario of the partially edentulous patient necessary for the fixed partial denture. All remaining dentition in the typodont were present. Classically a metal skull and rubber shroud are used to simulate the soft tissue of the cheeks, lips, face, and the hard tissue of the skull. This metal skull and shroud were present and it was used by the operator on all runs of the Prototype. The first ten consecutively numbered teeth were practice teeth to allow the operator to acclimate to working in simulated tooth structure and refine any obvious or noticeable errors in the machine's function as gauged by eye. Burning of tooth structure was corrected during the practice stage by turning on slight water flow. This low water and 500mm per minute feed rate prevented any thermal damage to the tooth, anatomical head, stepper motors of the machine, flooding of the machine with water spray, shaking or shuddering of the machine. The passive load monitoring function of the Lego® custom intraoral adaptor arm with precise separation in the event of excessive resistance further prevented burning and damage to tooth structure. Tool path or other computer generated errors which would prevent operation were tested for during the practice runs and were corrected by locating and correcting errors in the master STL file after they occurred on the practice teeth. This represented a third level of error screening after the initial virtual screening and dry run screenings discussed before. The operator completed all ten practice teeth prior to the sample teeth. These final 100 sample teeth, prepared sequentially, were submitted and recorded as data. If in the opinion of the operator an egregious error in the contour of the sample tooth had occurred during preparation, the operator was given a protocol of inserting a replacement plastic tooth, and the plastic tooth with the egregious error would have been excluded from the data. No egregious errors occurred during data collection, and thus no teeth were excluded. All separations of the Lego® custom intraoral adaptor arm occurred prior to any visible surface gouging or snapping of tooth structure, and it was possible to reattach the arm and resume the tool path on the same tooth. No failures of stepper motors, the handpiece, compressor, or other components of the prototype occurred, indicating success in the protective passive load monitor function of the Lego® custom intraoral adaptor arm. The total number of recorded prepared teeth from the Prototype entered as data was 100. All of the teeth were retained after the study as part of the record of this study. A list of the teeth and their serial numbers can be found in Appendix A, Table 2.

Measurements

To record the accuracy of the preparations finished by the Prosthodontists and by the Prototype, the root mean squared difference between the final surface of the finished preparation and a master #18 from Kilgore®, product number A21AN-LL72 was evaluated. Initially, due to budgetary constraints, the low cost software Wolfram Mathematica 9.0 was selected to perform manual surface to surface calculations. With new resources available from the Department of Prosthodontics at Tufts University and from Nicholas Bello's personal income, it was possible to upgrade the software to the industry standard Geomagic Control®. All 3D surface to surface analysis was performed on the STL files with Geomagic Control®. The accepted clinical tolerance is 0.25mm of variation in any direction from the theoretical ideal abutment preparation. This was the gauge used by the Department of Prosthodontics when grading predoctoral students' abutment tooth preparations during practical exams for a top mark.

All measurements were planned to occur with tooth #18 fully engaged in the typodont, and the typodont was to be mounted in a fixed, identical position on the base of the touch probe table. However, upon obtaining all 200 preparations, it was found that quality of scans performed by the Shark® Touchprobe Attachment, were grossly inadequate for the purposes of the study. A 3M True Definition® Scanner was available for use at Harbor Health Services, the community health center where Nicholas Bello practiced, and after consultation with the thesis advisor, Peter Arsenault, and the permission of Harbor Health Services Corporate Dental Director and Tufts faculty member Omar Ghoneim, it was decided that the 3M True Definition® Scanner offered both quality and the opportunity for an uninterrupted scanning environment. Since the typodont had immovable, hard plastic gingiva, it was not possible to retract the gingiva. A number of the preparations, had margins that were placed subgingivally and were unreadable. To allow clear measurement of all of the margins in a consistent, easily reproducible manner, the 200 teeth were placed on a metrology table, the Mitutoyo® Black Granite Surface Plate, 8 x 12 x 3, Grade AA - Laboratory, 30 lbs #517-700. A disused medical operatory at Harbor Health Services Hyannis at 735 Attucks Lane in Hyannis was converted to a scanning laboratory for an undisturbed 28 day period in March and April 2016. Specimens were transported in a sealed plastic bin and kept separated by subgroups (Prosthodontist 1, Prosthodontist 2, Prosthodontist 3, Prosthodontist 4, Prosthodontist 5, and the Prototype) in smaller, sealable bins. The sample teeth remained continuously in the custody of Nicholas Bello and were not left in the Hyannis facilty during the evenings. A Mitutoyo® Black Granite Surface Plate, 8 x 12 x 3, Grade AA - Laboratory, 30 lbs #517-700 was leveled and used as the metrology inspection surface. The room was windowless, and the temperature was maintained at 66 degrees Fahrenheit. The teeth were placed individually at a marked location on the plate and then evenly coated with the proprietary 3M True Definition® Titanium Dioxide High Resolution Scanning Powder, including a radius of 1cm of the surface of the Mitutoyo® Black Granite Surface Plate. All 3M True Definition® Titanium Dioxide High Resolution Scanning Powder was air puffed off the Mitutoyo® Black Granite Surface Plate between scans to avoid, as much as possible, dust accumulation. The scans were uniformly completed by Nicholas Bello as the sole operator. The scanner was held at the manufacturer's suggested optimal scan distance of 1cm[33]. Scanning began with an approach from mesial to distal orthogonal to the lingual buccal axis over the occlusal surface of the tooth. Once a complete occlusal scan was obtained the scanner was rolled gently to capture the buccal, then mesial, then lingual, then distal surfaces, capturing the full length of the plastic tooth root, including its junction with the Mitutoyo® Black Granite Surface Plate. All 200 sample teeth and a master #18 from Kilgore®, product number A21AN-LL72, were scanned in this manner. Each scan lasted approximately 1 minute and 15 seconds. Scans were inspected for voids or irregularities. Any scans with voids or defects were repeated. Serial numbers of teeth were carefully verified to ensure all 200 teeth were scanned. Scans were uploaded to DSG Yankee Dental Arts and were stored in the 3M Connection Center® [34] as Open STL files. The files were retrieved from the 3M Connection Center® and imported into Geomagic Control®. File sizes were approximately 5000 kilobytes and contained approximately 100,000 unique triangular vector planes. A best fit alignment was performed with a computer randomized three hundred point selection, followed by an N point alignment using factory features present on the plastic root surface, followed by a fine adjustment only best fit alignment of up to 100,000 points. A visual confirmation was performed to ensure the best fit was indeed a reasonable representation of the actual alignment. Any artificial alignments were rejected and a new alignment process was started from the beginning of the alignment protocol. A 3D analysis was then run, generating a Root Mean Squared Error (RMSE). Bounds for the analysis were set at six standard deviations such that the number of extreme error points not included in the sample taken for the RMSEcalculation by the software would approach zero. This assumption was confirmed after each calculation by inspecting the PDF Standard Deviation tables wherein points of six standard deviations of error or more made up a negligible portion of points (less than 1%). Root Mean Squared Error calculations were based on approximately 50,000 points within each point cloud. To enhance the speed of calculations, a laboratory was set up at 80-18 Riverpath Drive in Framingham, MA with five HP Pavilion® 7410/8GB/1TB computers to process the calculations.

Rounding

RMSE data was rounded to the nearest hundredth of a millimeter using standard scientific rounding protocol. Scan data was accurate to approximately 0.005mm, thus the nearest 0.01mm was adopted as the reported measure. All calculations and statistical analyses that made use of RMSE data were rounded to the nearest 0.01mm.

Consent

A study information sheet was provided, and subjects were given an opportunity to ask any questions they had prior to participating in the study.

Recruitment

The prosthodontists who participated were recruited by word of mouth. They were given an information sheet, and when they agreed to participate they were furnished with the plastic teeth, the typodont, the head and shroud assembly, the burs, and if necessary a new

Midwest Tradition® High Speed Dental Handpiece, as described in detail in the Prosthodontists subsection.

Compensation

The participants did not receive nor were offered any monetary compensation; however, they were invited to a BBQ and will be presented with a small wooden plaque at that BBQ.

Risk

This study posed minimal risk to subjects. The risk of breach of confidentiality will be kept minimal as described in confidentiality section and reiterated earlier in the methods section. Participation or the refusal to participate had no effect on a faculty member's employment status.

Location of Research Activities

Tufts University School of Dental Medicine

Nicholas Bello's residence June 2014-December 26, 2015, 46 Bay Drive, Canton, MA 02021, which is the location of the CNC machine. The prototype is privately owned by Nicholas Bello and must be located at 46 Bay Drive for insurance and safety purposes.

Harbor Health Services Hyannis, 735 Attucks Lane, Hyannis MA; spare room converted to lab space as described in the Measurements subsection for scanning.

80-18 Riverpath Drive, Framingham MA, 01701, Nicholas Bello's residence November 5 2016-present, the location of the computer lab for data processing as described in detail in the Measurements subsection for RMSE calculations.

Confidentiality

It was not necessary to publish the record of the names of the prosthodontists, and no comparative data analyses linking names to preparations was made or published. The teeth were consecutively numbered, and each participant was assigned a specific set of consecutively numbered teeth, making any further recording or linking of names or identifying information unnecessary. A list of participant names was maintained during the study for contact and communication purposes only, and this list was destroyed at the end of the study. Confidentiality is also discussed in detail in the Prosthodontics subsection.

Data Storage

Electronic data was kept on a password protected computer. All data collected was maintained in password protected files. The plastic teeth themselves were the raw data, were collected and taken to the location of the CNC machine for recording of measurements. After they were recorded, they were retained in a locked cabinet in the office of the PI, Peter Arsenault, at Tufts University School of Dental Medicine (DHS-452.

Vulnerable Populations

Employees (faculty) of Tufts University School of Dental Medicine were recruited for this study. A letter of support from the Dean of TUSDM was included with the proposal to the Tufts University Institutional Review Board.

Statistical Analysis
Sample Size Calculation

A power calculation was conducted using nQuery Advisor (version 7.0). Assuming that the two groups (CNC and by hand) have a common standard deviation of $\sigma = 0.25$mm, and specifying a tolerance of$\Delta 0 = 0.25$mm between groups, a sample size of $n = 14$ per group is adequate to achieve Type I error rate of $\alpha = 0.05$ and a power of 80%. The size of the groups will be n=100 to increase the power of the study to over 99%. Within the participant prosthodontist group, the size of the subgroups of 20 preparations per prosthodontist allowed for the possibility of statistical analysis within the subgroups if assumptions of standard deviation were reasonably consistent.

Root Mean Squared Error (RMSE) Analysis between Groups

A one sided independent samples T test was performed using SPSS 24.0. Initially, a two one-sided T test for equivalence of means was planned because the expected results of the study were that the RMSE between groups would be similar, but when the results of the study were tabulated the difference in means was large enough that we could demonstrate one group had significantly lower RMSE than the other group, and equivalence was no longer applicable. The null hypothesis was that the machine was not as accurate as the prosthodontists. The mean of the root mean squared error (RMSE) of the prototype (N=100) was compared to the mean RMSE of the participant prosthodontists (N=100). The upper bound of the mean difference was set at 0.25mm. If the mean difference of the prototype RMSE and the participant prosthodontists were a positive number greater than 0.25 the null hypothesis could not be rejected. If however the mean difference were a negative number, zero, or a positive number smaller than 0.25, and if the p value were 0.05 or less, we could reject the null hypothesis. The two-tailed confidence interval was adjusted to 90% such that the upper tail would be 0.05. If this one-sided confidence interval contained zero, we could not reject the null hypothesis. If, however, the one-sided confidence interval did not contain zero, the null hypothesis could be rejected.

RMSE Analysis within the Participant Prosthodontist Group

To determine if the mean RMSE for each individual prosthodontist was consistent with the mean from the group as a whole, One Way ANOVA was performed using SPSS 24.0 on the Prosthodontist Group. Prosthodontists were identified by a number, 1-5. Confidence was tested at 95% and significance at p of less than 0.05.

Correlation Testing between RMSE and Bur Use

Spearman Correlations were calculated using SPSS 24.0 comparing RMSE to the number of times a bur had been used. Intuitively, our aim was to determine if using a bur multiple times would tend to raise the RMSE. This was performed on the RMSE values of the Prototype (N=100), on the preps of the subgroups of the individual prosthodontists (N=20). The prosthodontists were numbered 1, 2, 3, 4, and 5. If a preparation were made with a new bur, it was given a value of 1. If a preparation were made with a bur that had been used once before, it was given a value of 2. If a preparation were made with a bur that had been used twice before, it was given a value of 3. If a preparation were made with a bur that had been used three times before, it was given a value of 4. If a preparation were made with a bur that had been used 4 times before, it was given a value of 5.

Correlation Testing between RMSE and Order

Spearman Correlations were calculated using SPSS 24.0 comparing RMSE to the preparation order. Intuitively, our aim was to determine if there was rise in RMSE as the number of runs increased. This Spearman Correlation was performed on the RMSE values of the Prototype (N=100), on the preps of the subgroups of the individual prosthodontists (N=20).

Results

Table 1: All Results

Test	Variables	Outcome	P Value	Insight
One-Sided Independent Samples T Test with one sided CI (90%)	Mean RMSE Prototype = .40mm, (N=100) Mean RMSE Prosthodontists=.55mm, (N=100)	Mean Dif =-.15 CI Upper Bound =-.09	<.001	Machine beat man by a mean difference of .15mm, and the results were significant
One Way ANOVA	Mean RMSE in mm Group = 0.55, (N=100) Prosthodontist 1=.59, (N=20) Prosthodontist 2=.50, (N=20) Prosthodontist 3=.58, (N=20) Prosthodontist 4=.52, (N=20) Prosthodontist 5=.58, (N=20)	F<1 F= .53	.717	There was no significant difference in RMSE among the five prosthodontists.
Spearman Correlation	RMSE Prototype vs Run Order Number 1-100, (N=100)	ρ = .10	.334	There was no significant correlation
Spearman Correlation	RMSE Prototype Vs Bur Use 1-5, (N=100)	ρ = .36	<.001	There was a weak but significant rise of RMSE with higher bur use
Spearman Correlation	RMSE Prosthodontist 5 vs Order Number 1-20, (N=20)	ρ =.51	.022	There was a moderate and significant rise of RMSE with higher order number
Spearman Correlation	RMSE Prosthodontist 5 vs Bur Use 1-5 (N=20)	ρ =.58	.007	There was a moderate and significant rise of RMSE with higher bur use
Spearman Correlation	RMSE Prosthodontist 4 vs Order Number 1-20 (N=20)	ρ =-.54	.015	There was a moderate and significant decrease of RMSE with higher order number
Spearman Correlation	RMSE Prosthodontist 4 vs Bur Use 1-5 (N=20)	ρ =-.07	.758	There was no significant correlation
Spearman Correlation	RMSE Prosthodontist 3 vs Order Number 1-20 (N=20)	ρ =.16	.498	There was no significant correlation
Spearman Correlation	RMSE Prosthodontist 3 vs Bur Use 1-5 (N=20)	ρ =.18	.445	There was no significant correlation
Spearman Correlation	RMSE Prosthodontist 2 vs Order Number 1-20 (N=20)	ρ =.07	.772	There was no significant correlation
Spearman Correlation	RMSE Prosthodontists 2 vs Bur Use 1-5 (N=20)	ρ =.46	.040	There was a moderate and significant rise of RMSE with higher bur use
Spearman Correlation	RMSE Prosthodontist 1 vs Order Number 1-20 (N=20)	ρ =-.08	.741	There was no significant correlation
Spearman Correlation	RMSE Prosthodontist 1 vs Bur Use 1-5 (N=20)	ρ =.43	.059	There was no significant correlation

Table 1: Shows the outcome of testing the Primary Hypothesis: that the Prototype was as good or better than the Prosthodontists (True), and it also shows the outcome of testing the secondary hypotheses, that the Prototype would show poorer accuracy with higher order number (false) and poorer accuracy with higher bur use (true); that the Prosthodontists would show better accuracy with higher order number (1 true, 4 false), and that the Prosthodontists would show poorer accuracy with higher bur use (2 true, 3 false).

Results of the Primary Hypothesis

The primary hypothesis of the study was that the CNC Prototype would prepare teeth for crowns with accuracy as good as or better than the Prosthodontists could. This hypothesis was measured by calculating the Root Mean Squared Error for each preparation to the nearest 0.01mm and then calculating the arithmetic mean for the Prototype (N=100) and the arithmetic mean for the Prosthodontists (N=100).

To confirm that it was valid to group the prosthodontists as a homogenous group with one arithmetic mean RMSE a One Way ANOVA was performed. The Prosthodontist 1 had an arithmetic mean RMSE of 0.59mm, Prosthodontist 2 an arithmetic mean RMSE of 0.50mm, Prosthodontist 3 an arithmetic mean RMSE of 0.58mm, Prosthodontist 4 an arithmetic mean RMSE of 0.52mm, and Prosthodontist 5 an arithmetic mean of 0.59mm. The group arithmetic mean RMSE for the Prosthodontists was 0.55mm. The result of the One Way ANOVA (F stat <1, F=.526, p=.717) indicated that we could not reject the null hypothesis that the means were representative of a single population mean, and thus it was valid to treat the prosthodontists as a single group for our comparison. See Table 1 for a summary of the findings.

The Arithmetic Mean RMSE for the Prototype was 0.40mm. The Arithmetic Mean RMSE for the Prosthodontists as a group was 0.55mm. The means of the two groups were compared with a one sided T test, and the result was a mean difference of -.15mm (p<.001, one sided CI -.09). Our hypothesis that the CNC Prototype could prepare teeth for crowns with an accuracy that was as good as or better than the Prosthodontists was found to be true. See Table 1 for a summary of the findings.

Regarding RMSE and Bur Use for the Prototype

A secondary hypothesis of the study was that the CNC prototype would show poorer accuracy with an increase in the number of times a bur was used. This hypothesis was evaluated for the Prototype (N=100), and a Spearman correlation was performed to evaluate the number of times a bur was put into use (possible values 1 through 5) against RMSE recorded for that tooth. The prototype showed a weak but significant rise in RMSE with higher bur use numbers ($\rho = .36$, $p<.001$), see Table 1 for a summary and Figure 1 for a scatterplot of the RMSE vs Bur Use for the Prototype. Our hypothesis that the CNC prototype would show poorer accuracy with an increase in the number of times a bur was used was found to be true.

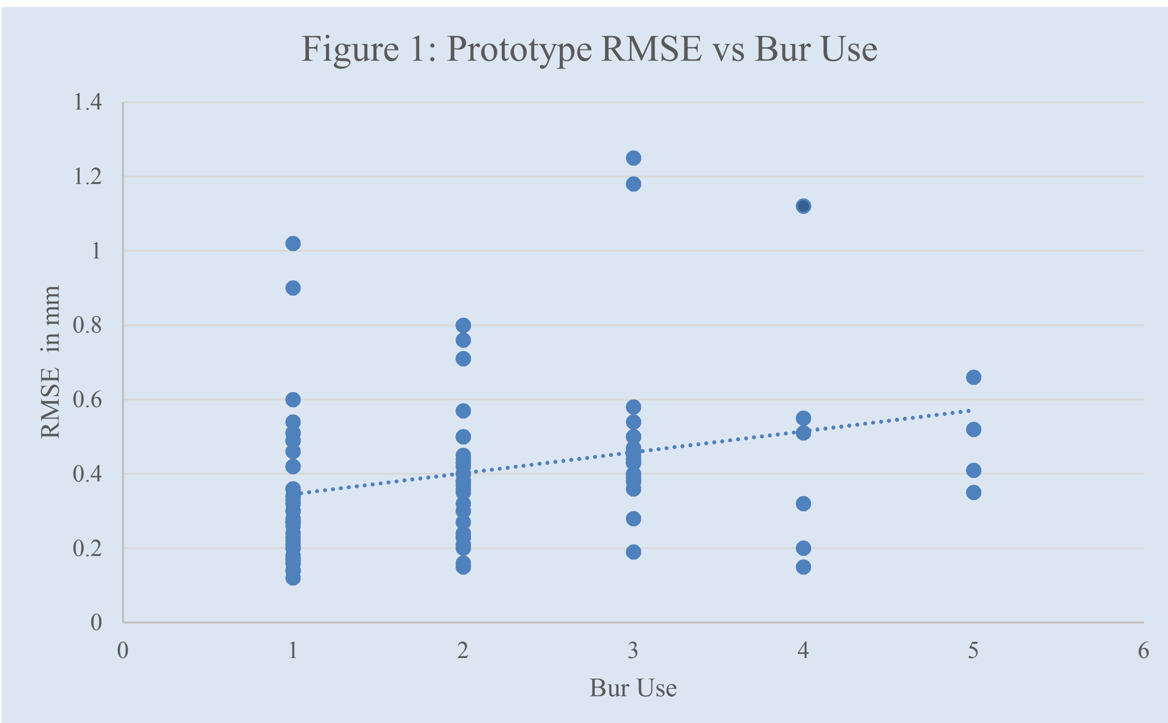


Figure 1: A secondary hypothesis of the study was that the CNC prototype would show poorer accuracy with an increase in the number of times a bur was used. This hypothesis was evaluated for the Prototype (N=100), and a Spearman correlation was performed to evaluate the number of times a bur was put into use (possible values 1 through 5) against RMSE recorded for that tooth. The prototype showed a weak but significant rise in RMSE with higher bur use numbers ($\rho = .36$, $p<.001$), indicated with a trend line. Our hypothesis that the CNC prototype would show poorer accuracy with an increase in the number of times a bur was used was found to be true.

Regarding RMSE and Bur Use for the Prosthodontists

It was also predicted that the individual prosthodontists (N=20) would develop poorer accuracy with a greater number of bur uses. Prosthodontist 5 showed a moderate and significant rise in RMSE with higher bur use numbers (ρ= .51, p = .007) and Prosthodontist 2 showed a moderate and significant rise in RMSE with higher bur numbers (ρ=.46, p= .040). Prosthodontist 4 (ρ=-.07, p=.758), Prosthodontist 3 (ρ=.18, p=.445), and Prosthodontist 1 (ρ=.43, p=.059) showed no significant monotonic correlation between RMSE and bur use. See Table 1 for a summary of the findings and Figure 2.1-2.5 showing a scatterplot of the RMSE vs Bur Use data for the Prosthodontists. We did not find development of poorer accuracy with an increase in bur use among three of the Prosthodontists, but we did find the development of poorer accuracy with an increase in bur use with two of the five Prosthodontists.

Figure 2.1: Prosthodontist 1 RMSE vs Bur Use

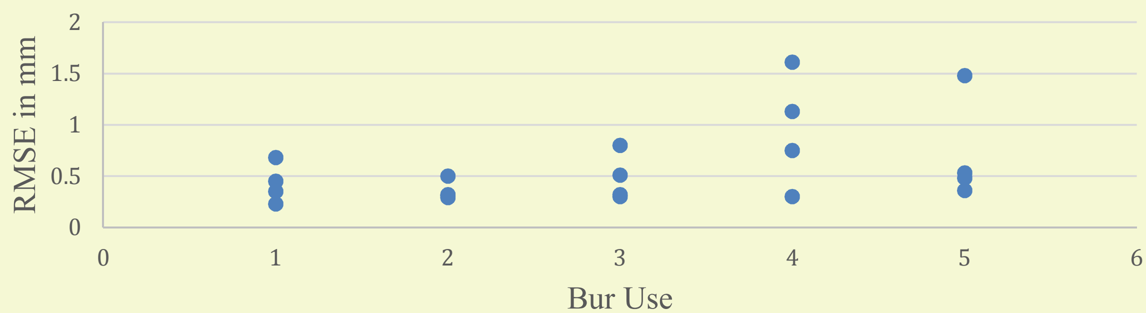


Figure 2.2 : Prosthodontist 2 RMSE vs Bur Use

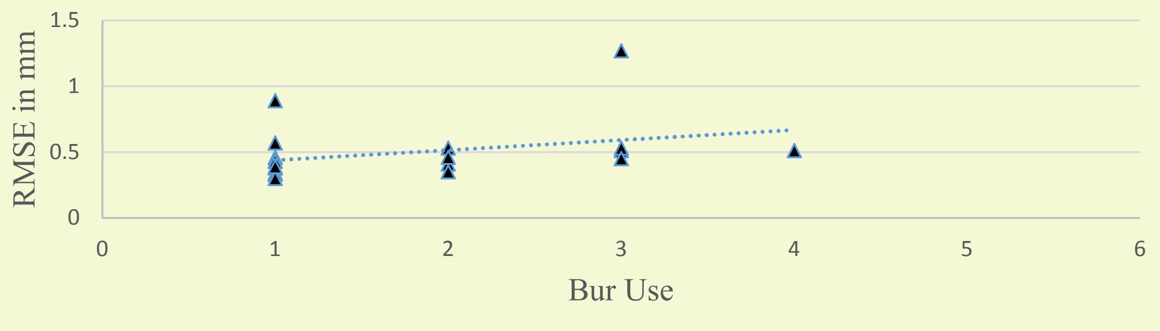


Figure 2.3: Prosthodontist 3 RMSE vs Bur Use

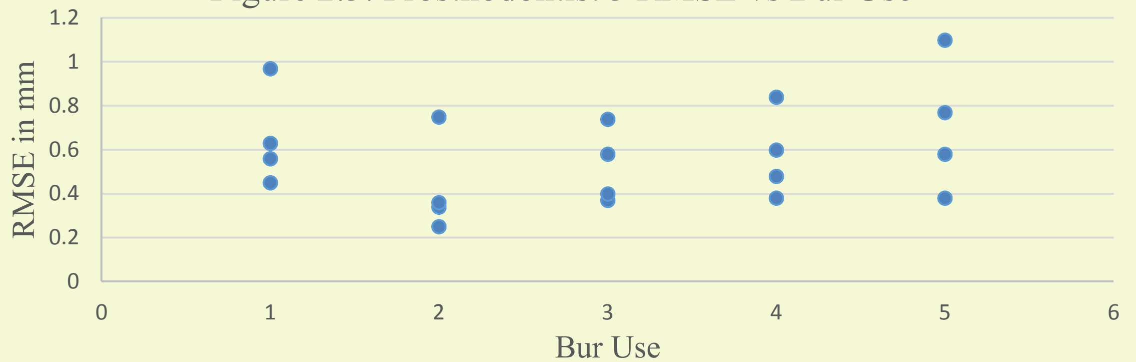
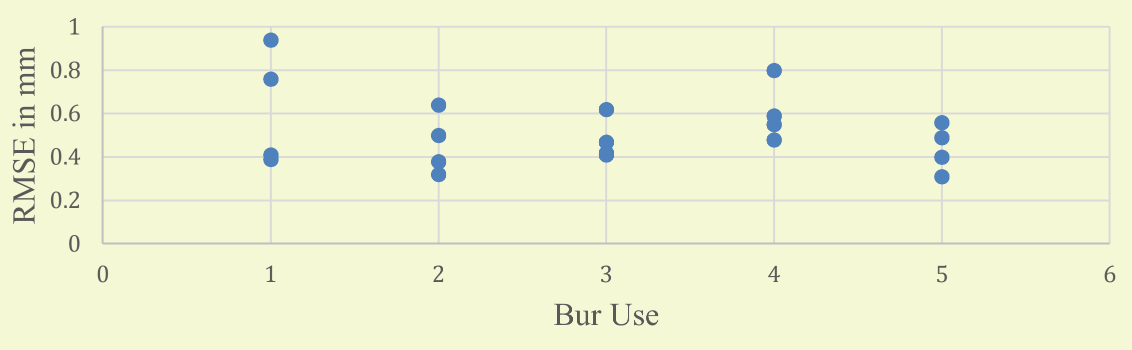


Figure 2.4: Prosthodontist 4 RMSE vs Bur Use



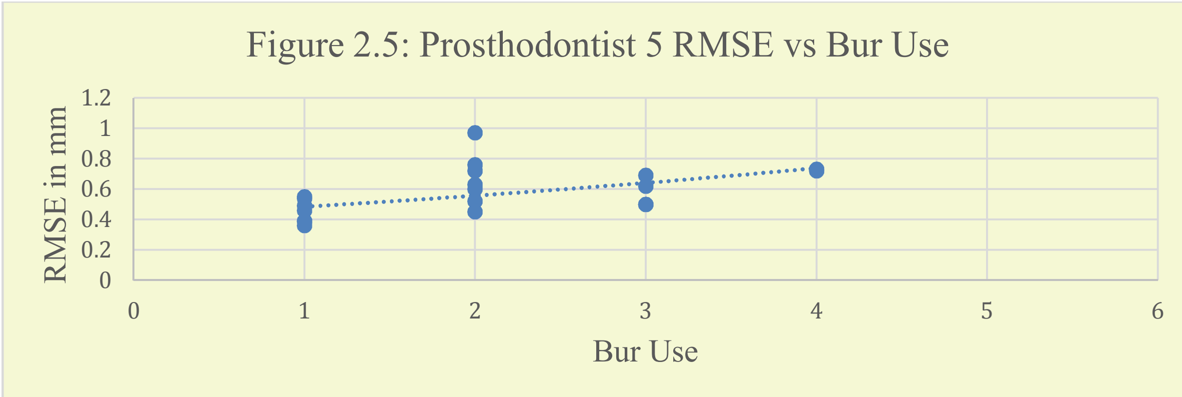


Figure 2.1-2.5: Prosthodontist 5 showed a moderate and significant rise in RMSE with higher bur use numbers ($\rho = .51$, $p = .007$, N=20) and Prosthodontist 2 showed a moderate and significant rise in RMSE with higher bur numbers ($\rho = .46$, $p = .040$, N=20). Prosthodontist 4 ($\rho = -.07$, $p = .758$, N=20), Prosthodontist 3 ($\rho = .18$, $p = .445$, N=20), and Prosthodontist 1 ($\rho = .43$, $p = .059$, N=20) showed no significant monotonic correlation between RMSE and bur use.   We did not find development of poorer accuracy with an increase in bur use among three of the prosthodontists, but we did find the development of poorer accuracy with an increase in bur use with two of the five prosthodontists, as indicated with trend lines.

Regarding RMSE and Order for the Prototype

A secondary hypothesis of the study was that the CNC prototype would not show poorer accuracy with an increase in the number of teeth that had been prepared. This hypothesis was evaluated for the Prototype (N=100). A Spearman correlation was performed for the Prototype to evaluate the order of the tooth (possible values 1 through 100) against RMSE recorded for that tooth. The prototype showed no significant RMSE vs Order correlation ($\rho = .1$, $p = .334$), see Table 1 for a summary and Figure 3 for a scatterplot of the RMSE vs Order data for the Prototype. Thus our hypothesis that accuracy would not become poorer with higher order preparation for the Prototype was true.

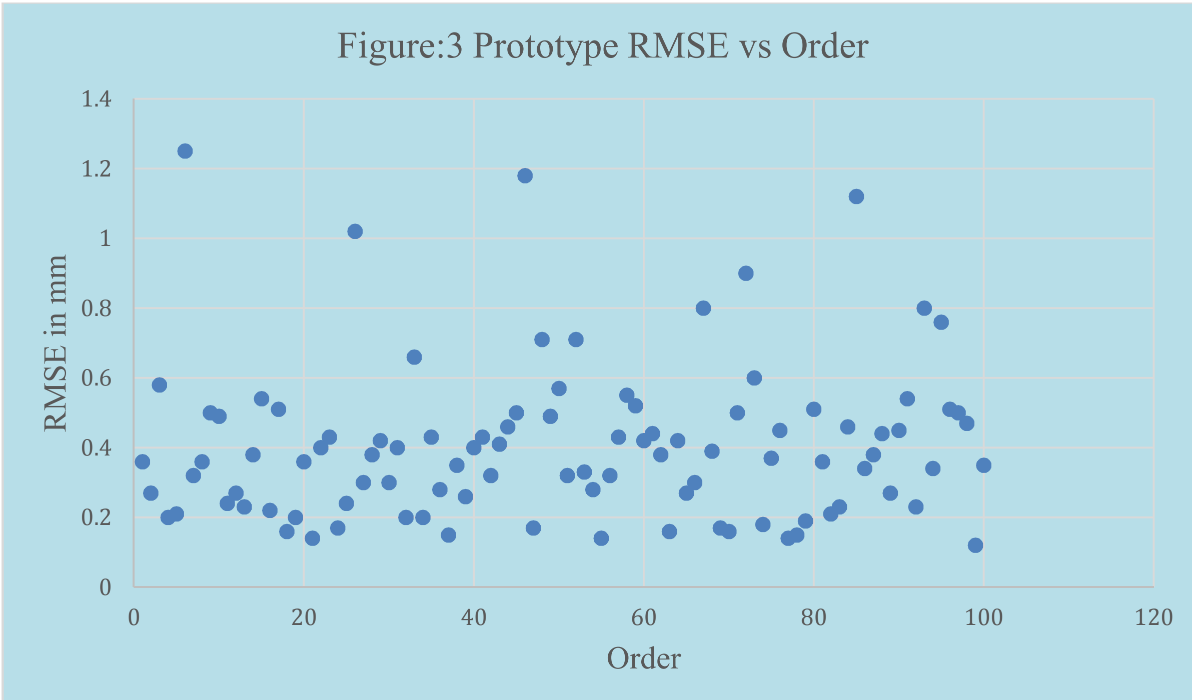
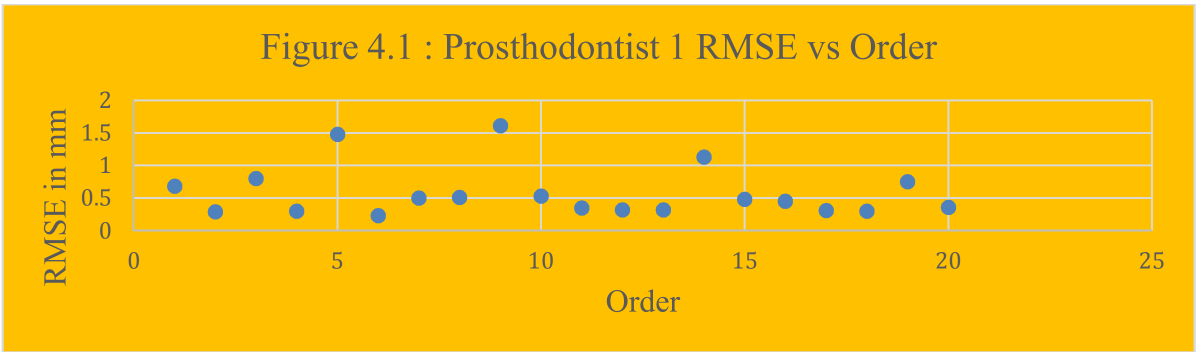


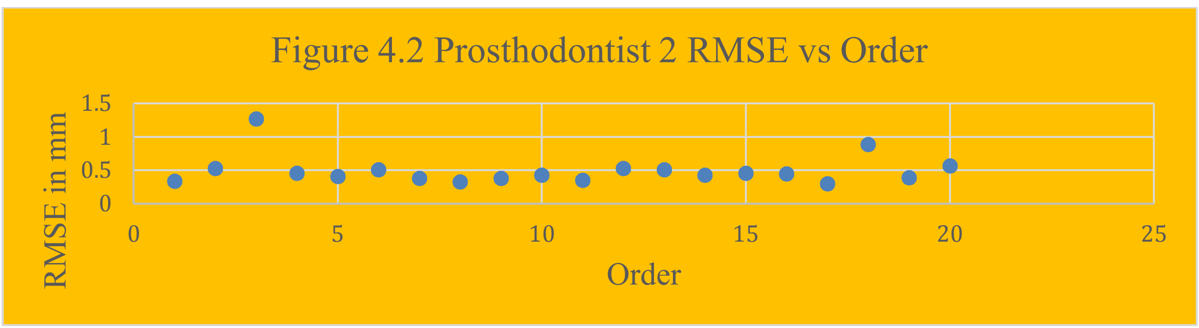
Figure 3:A secondary hypothesis of the study was that the CNC Prototype would show poorer accuracy with an increase in the number of teeth that had been prepared, or in other words intuitively that those teeth ordered first would be more accurate than those teeth ordered last. This hypothesis was evaluated for the Prototype (N=100). A Spearman correlation was performed for the Prototype to evaluate the order of the tooth (possible values 1 through 100) against RMSE recorded for that tooth. The Prototype showed no significant RMSE vs Order correlation (ρ = .1, p=.334). Thus our hypothesis that accuracy would become poorer with higher order preparation for the Prototype was false.

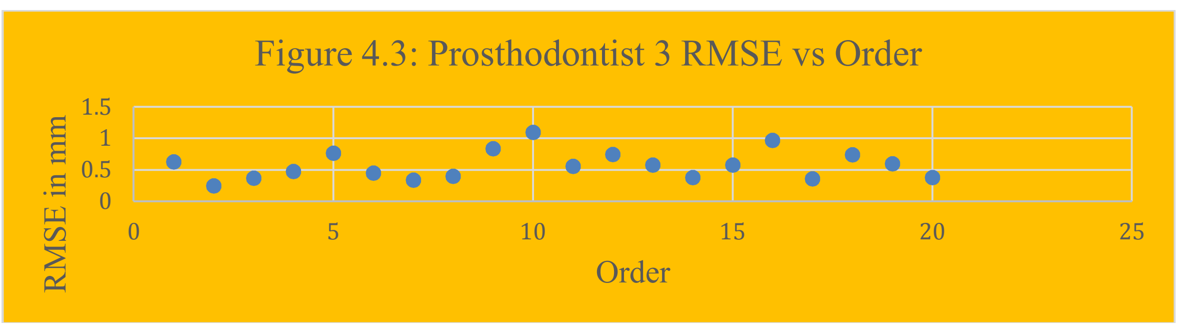
Regarding RMSE and Order for the Prosthodontists

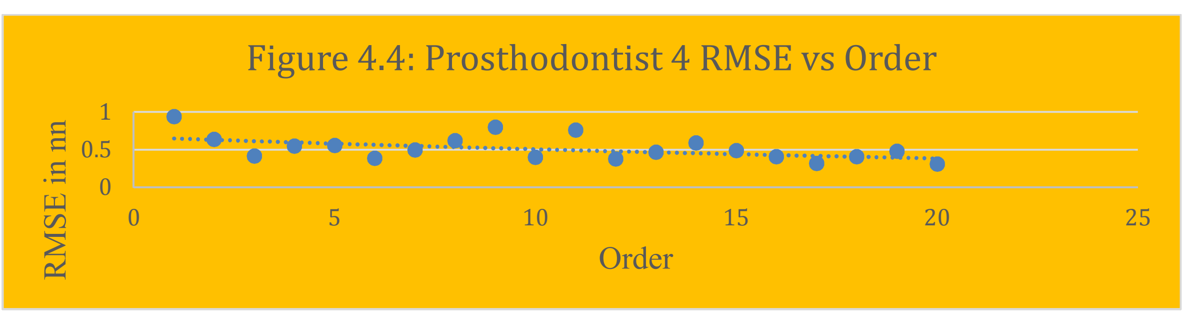
For each prosthodontist individually (N=20), a Spearman correlation was performed to evaluate the order of the tooth (possible values 1 through 20) against RMSE recorded for that tooth. It was predicted that the prosthodontists would develop better accuracy (a decrease in RMSE) with a greater number of teeth completed. Prosthodontist 4 showed a moderate and decrease in RMSE with higher order number (ρ=-.54, p= .015). Prosthodontist 5 showed a moderate and significant rise in RMSE with higher order numbers (ρ= .58, p = .022). Prosthodontist 3 (ρ=.16, p=.498), Prosthodontist 2 (ρ=-.07, p=.772), and Prosthodontist 1 (ρ=-.08, p=.741) showed no significant monotonic correlation between RMSE and order number. See Table 1 for a summary of the findings and Figure 4.1-4.5

showing a scatterplot of the RMSE vs Order data for the prosthodontists. Thus our prediction that the prosthodontists would develop better accuracy with a greater number of teeth completed was true for Prosthodontist 4, but false for Prosthodontists 5,3,2, and 1.









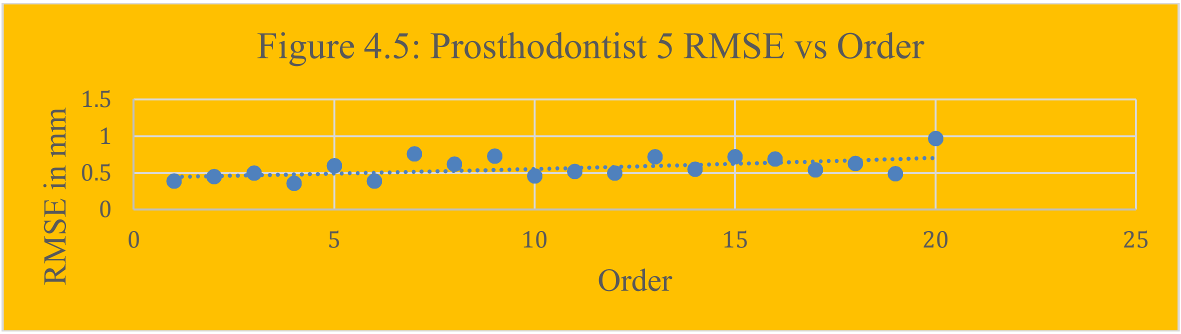


Figure 4.1-4.5: For each prosthodontist individually (N=20), a Spearman correlation was performed to evaluate the order of the tooth (possible values 1 through 20) against RMSE recorded for that tooth. It was predicted that the prosthodontists would develop better accuracy (a decrease in RMSE) with a greater number of teeth completed. Prosthodontist 4 showed a moderate and decrease in RMSE with higher order number (ρ=-.54, p= .015). Prosthodontist 5 showed a moderate and significant rise in RMSE with higher order numbers (ρ= .58, p = .022). Prosthodontist 3 (ρ=.16, p=.498), Prosthodontist 2 (ρ=-.069, p=.772), and Prosthodontist 1 (ρ=-.08, p=.741) showed no significant monotonic correlation between RMSE and order number. Thus our prediction that the prosthodontists would develop better accuracy with a greater number of teeth completed was true for Prosthodontist 4, but false for Prosthodontists 5,3,2, and 1. Trend lines are shown on figures 5 and 4, which had statistically significant outcomes of the Spearman correlation.

Discussion

The Primary Hypothesis of the thesis was that the Prototype could prepare crowns with an accuracy as good or better than the prosthodontists. The results were measured using root mean squared error (RMSE). The Arithmetic Mean RMSE for the Prototype (N=100) was 0.40mm. The Arithmetic Mean RMSE for the Prosthodontists as a group (N=100) was 0.55mm. The means of the two groups were compared with a one sided T test, and the result was a mean difference of -.15mm ($p<.001$, one sided CI -.09). Our hypothesis that the CNC Prototype could prepare teeth for crowns with an accuracy that was as good or better than the Prosthodontists was found to be true. The finding was consistent with the findings of previous studies that compared the accuracy of CNC fabricated implant frameworks and crowns to frameworks and crowns made with traditional casting techniques. Katsoulis *et al.* (2015) performed found the experimental CAD/CAM groups and the titanium control made via CAD/CAM had equivalent accuracy (ZrO-L (median 14 μm; 95% CI 10–26 μm), ZrO-M (18 μm; 12–27 μm) and TIT-L (15 μm; 6–18 μm)), and were statistically superior to the traditional cast method frameworks (236 μm; 181–301 μm, ($P < 0.001$)). In essence, the CAD/CAM methods delivered results that were an order of magnitude more accurate than the traditional casting technique.[19] Lee *et al.* (2015) found that the marginal gaps for the three test groups (all CNC milled) were equivalent to the marginal gaps of the control (MCG crown). The marginal gaps were 87.2 (22.8) μm for Lava, 58.5 (17.6) μm for Cercon, and 72.3 (30.8) μm for CEREC. The control group, MCG, had a marginal gap of 70.5 (34.4) μm.[18] In a controlled, bench top study, Ortorp *et al.* (2003) found an overall distortion for CNC milled frameworks that was 5 microns (0.005mm) and overall distortion of cast gold frameworks was 53 microns (0.053mm). The results were statistically significant.[15] Our results, intriguingly, stand in the 400 micron range, whereas the literature shows results in the tens of microns. Rockler® lists its Shark® CNC router as having an accuracy of 12.7 microns on a full step setting and 1.59 microns on a 1/8 step setting.[14] Based on the consistency of our results, casting doubt on the abilities of the Shark® to perform would seem unjust to Rockler®. Theoretically, we should have been able to perform on the tens of microns or even on the single micron level. Our best performance from the prototype, as seen in Appendix A Table 2 Raw Data, does not bring RMSE to below the 100 micron level. Speculation as to the cause would include the length of the arm (approximately 45 cm) and the degree to which the arm was flexible. It is not a far leap to suspect that incorporating a 45cm arm made of hundreds of Lego® bricks, no matter how carefully designed for rigidity, could result in distortion. Another source of error would be our initial design. Our protocol involved scanning combined with some subjective design work in Geomagic Design, leaving open the door for artistic license and, inevitably, inaccuracies.

The primary hypothesis hinged on a presupposition that the Prosthodontists would be a reasonably cohesive group against which a comparison could be drawn definitively. Had the prosthodontists exhibited extreme differences in performance, the validity of the study could have been called into question on the grounds that our control group needed tighter exclusion criteria and perhaps redesign. To confirm that it was valid to group the prosthodontists as a homogenous group with one arithmetic mean RMSE a One Way ANOVA was performed. The Prosthodontist 1 had an arithmetic mean RMSE of 0.59mm, Prosthodontist 2 an arithmetic mean RMSE of 0.50mm, Prosthodontist 3 an arithmetic mean RMSE of 0.58mm, Prosthodontist 4 an arithmetic mean RMSE of 0.52mm, and Prosthodontist 5 an arithmetic mean of 0.59mm. The group arithmetic mean RMSE for the Prosthodontists was 0.55mm. The result of the One Way ANOVA (F stat <1, $F=.526$, p=.717) indicated that we could not reject the null hypothesis that the means were representative of a single population mean, and thus it was valid to treat the prosthodontists as a single group for our comparison. This finding of homogeneity among the faculty members was expected. Annerstedt *et al.* (1996) accumulated 127 dies from dental students, and 351 dies from dentists. Results indicated a total occlusal convergence range of -2 degrees to 51 for dental students, and 0 degrees to 70 degrees for dentists. The results were statistically significant. The ideal referenced by Annerstedt *et al.* (1996) was 4 to 6 degrees of total occlusal convergeance.[8] Nordlander *et al.* (1988) obtained 88 dies by 8 residents and 120 dies by two prosthodontists. A photograph was taken of the faciolingual and mesiodistal views and enlarged with a projector. The angle of convergence was measured. Results indicated total occlusal convergence ranged from 13.3 to 30.4 degrees. The results were statistically significant. No statistically significant differences were found between the two groups. The ideal total occlusal convergence cited by Nordlander *et al.* (1988) was 2 to 10 degrees of total occlusal convergence.[6] Nordlander *et al.* (1988) obtained 88 dies by 8 residents and 120 dies by two prosthodontists. Results indicated total occlusal convergence ranged from 13.3 to 30.4 degrees. The results were statistically significant. No statistically significant differences were found between the two groups.[6] Shillingburg *et al.* (1988) saved 418 dies over 12 years. Photographs were taken of the buccal and the mesial. Photographic enlargement was performed. The results indicated an average total occlusal convergence that ranged from 13.4 degrees to 15.8 degrees.[7] Ghafoor and Siddiqui (2011) gathered 197 dies, collected randomly from Aga Khan University Hospital, dental section. The Mean Total Occlusal Convergence was reported as 23.7degrees +/- 8.9 degrees. The results were statistically significant. There was no statistically significant difference found between residents and specialists who had been practicing for more than five years post residency.[9] Ultimately the literature had already suggested that across a wide range of dentists a limit of ability existed, and through experience once that limit was reached the individual was reasonably similar to the wider cohort of experienced practitioners. This would intuitively make sense.

We tested the hypothesis that the Prototype would experience a statistically significant increase in RMSE with burs that had been used a higher number of times. This hypothesis was evaluated for the Prototype (N=100), and a Spearman correlation was performed to evaluate the number of times a bur was put into use (possible values 1 through 5) against RMSE recorded for that tooth. The prototype showed a weak but significant rise in RMSE with higher bur use numbers ($\rho = .36$, $p<.001$). We expected this outcome. CNC moves a tool along a path. Our prototype did not have any feedback mechanism to relay actual bur position for comparison against theoretical bur position. A dull bur with poor cutting efficiency will not be given any additional time or cutting power from the CNC, and it would be reasonable to expect that less material would be removed, creating a disconnect between where the prototype believes the reduction to be in x, y, and z coordinates and where the reduction has actually occurred, leading to higher RMSE. Rotating cutting instruments also develop eccentricities as they wear, leading to wobbles, uneven reduction, and often a wider range of motion of the cutting surface through the material than the intended long axis of the cutter would specify.[1]

It was hypothesized that the Prototype would maintain consistent accuracy (RMSE values) throughout the 100 preparations. This hypothesis was evaluated for the Prototype (N=100). A Spearman correlation was performed for the Prototype to evaluate the order of the tooth (possible values 1 through 100) against RMSE recorded for that tooth. The prototype showed no significant RMSE vs Order correlation ($\rho = .1$, $p=.334$), CNC systems are designed for high volume work and are robustly built. A sample of one hundred preparations was unlikely to lead to significant decalibration of the system, especially because a passive load monitor was incorporated into the design. Excessive forces which might otherwise distort the axial components or geometric integrity of the gantry could not be applied to the Prototype because the protective passive load monitor would disengage from the applied force when it reached a threshold level.

Mirror study questions regarding the accuracy of the prosthodontists with bur use and with progression through their assigned set of preparations proved more complex to evaluate because the homogeneity of the prosthodontists held only for their mean RMSE and not for trends within their samples. As such, the prosthodontists were evaluated individually.

For each prosthodontist individually (N=20), a Spearman correlation was performed to evaluate the order of the tooth (possible values 1 through 20) against RMSE recorded for that tooth. It was predicted that the prosthodontists would develop better accuracy (a decrease in RMSE) with a greater number of teeth completed. This expectation of improvement was related to our speculation of a limit that was approached with practice and experience. Presumably, because the teeth were plastic there would be a learning curve of working in plastic. Ten practice teeth were provided to mitigate unfamiliarity as a confounder, and the Prototype was only allowed ten practice teeth as well, preventing the operator from having unfair home field advantage in materials. Prosthodontist 4 showed a moderate and decrease in RMSE with higher order number ($\rho=-.54$, $p= .015$). Prosthodontist 5 showed a moderate and significant rise in RMSE with higher order numbers ($\rho= .58$, $p =$

.022). Prosthodontist 3 (ρ=.16, p=.498), Prosthodontist 2 (ρ=-.069, p=.772), and Prosthodontist 1 (ρ=-.08, p=.741) showed no significant monotonic correlation between RMSE and order number. See Table 1 for a summary of the findings and Figure 4.1-4.5 showing a scatterplot of the RMSE vs. Order data for the prosthodontists. Thus our prediction that the prosthodontists would develop better accuracy with a greater number of teeth completed was true for Prosthodontist 4, but false for Prosthodontists 5,3,2, and 1. It may be that the sample sizes were too small (N=20) to fully appreciate statistically significant correlation. Individual differences in mindset – a desire to finish strong, ennui, or simply a fluid concept of the intended outcome that was more artistic than machined could also explain why a statistically significant curve of improvement was found in only one of the five prosthodontists.

It was also predicted that the individual prosthodontists (N=20) would develop poorer accuracy with a greater number of bur uses. Prosthodontist 5 showed a moderate and significant rise in RMSE with higher bur use numbers (ρ= .51, p = .007) and Prosthodontist 2 showed a moderate and significant rise in RMSE with higher bur numbers (ρ=.46, p= .040). Prosthodontist 4 (ρ=-.07, p=.758), Prosthodontist 3 (ρ=.18, p=.445), and Prosthodontist 1 (ρ=.43, p=.059) showed no significant monotonic correlation between RMSE and bur use. See Table 1 for a summary of the findings. We did not find development of poorer accuracy with an increase in bur use among three of the prosthodontists, but we did find the development of poorer accuracy with an increase in bur use with two of the five prosthodontists. Here it would be important to note that the Prosthodontists, individually or as a group, did not hold lower RMSE values for higher bur uses, but simply showed less consistent directionality of deviation of already high RMSE values. One of the large advantages that the Prosthodontists had was being able to self adjust their work as they progressed. By its nature, the CNC Prototype in this iteration lacked the ability to alter or modify its work as it moved through its rasters. It is reasonable to assume that a practitioner might compensate for a duller, more eccentric bur by slowing down and applying corrective measures. Likewise, a practitioner with a new, sharp cutting bur may move more swiftly, increasing RMSE through haste.

Despite the success of the research aims, many limitations exist in the study that would prevent the question of man vs. machine from being put to rest so quickly. The study was performed in clinical simulation on manikins. A real oral environment, replete with movement, pain, and a personality, would place far greater performance demands on the Prototype. From a mechanical standpoint, the next logical iteration of the Prototype should incorporate additional degrees of freedom of motion and active feedback mechanisms to ensure position can be maintained in a dynamic environment. In considering how to do this, it would be apt to note that although the arch may move, the tooth does not move relative to the arch. The equivalent of finger rests or mirrored movement could be used to achieve this goal. Another area to investigate would be the emotional response of patients to the presence of the Prototype. A study might be designed that evaluated willingness to undergo treatment by a machine and emotions felt with knowing that a non-human entity was acting of its own volition in executing a treatment. An interesting second experimental group would be to test for the same parameters if a person, such as an assistant, were present in the treatment room alongside the Prototype. The astuteness (highly capable to inept) and temperament (friendly to abrasive or disinterested) of the assistant could be varied to assess patient response.

What initially seemed to be a limitation, a paucity of revenue for equipment and supplies, may have actually increased the relevance of this study. The study was financed through a small (less than $2500) research budget from Tufts University and hard won savings across five years by Nicholas Bello (cumulatively about $20,000). Nearly every element of design had to be taken back to the drawing board and re-conceived to work on minimal resources. Considerable cross department and cross institution borrowing occurred. In future pursuit of CNC dental surgical systems, a focus on conventional, off the shelf components may lead to a low cost system that can be brought to the public. An initiative that may encourage collaboration and grass roots research may be an annual or biannual contest between the local Boston colleges with designs being made public and prizes awarded in the form of tuition waivers.

What we should not do is wait. As our colleagues in medicine have found with the DaVinci and ZEUS systems, if rigorous randomized controlled trials are not performed in adequate numbers, policy makers will deem the level of evidence unsatisfactory and discourage further advancement on the grounds of futility.

Conclusion

This study demonstrated that CNC, an automated approach to dentistry, can achieve superior results in clinical simulation compared to prosthodontists, within the limits of the study, achieving the primary aim. Several of our secondary hypotheses, specifically tied to predicting human accuracy performance with higher number of bur use and higher number of completed samples were shown to be incorrect. We concluded that human performance in accuracy may be more complex than a simple correlation between practice and performance or bur and performance. The study also demonstrated that a successful outcome can be attained on a modest budget with a modest level of research support. Robotic surgical systems such as Da Vinci or Zeus offer lessons for the development of dental surgical systems and for the need for rigorous randomized controlled trials. Work should continue on the next iteration of a prototype to address some of the limitations of movement, feedback, and emotional acceptance of a machine performing treatment from the perspective of a patient.

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Appendix A: Tables

Table 1: All Results

Test	Variables	Outcome	P Value	Insight
One-Sided Independent Samples T Test with one sided CI (90%)	Mean RMSE Prototype = .40mm, (N=100) Mean RMSE Prosthodontists=.55mm, (N=100)	Mean Dif =-.15 CI Upper Bound =-.09	<0.001	Machine beat man by a mean difference of .15mm, and the results were significant
One-Way ANOVA	Mean RMSE in mm Group = 0.55, (N=100) Prosthodontist 1=.59, (N=20) Prosthodontist 2=.50, (N=20) Prosthodontist 3=.58, (N=20) Prosthodontist 4=.52, (N=20) Prosthodontist 5=.58, (N=20)	F<1 F= .53	.717	There was no significant difference in RMSE among the five prosthodontists.
Spearman Correlation	RMSE Prototype vs Run Order Number 1-100, (N=100)	ρ = .10	.334	There was no significant correlation
Spearman Correlation	RMSE Prototype Vs Bur Use 1-5, (N=100)	ρ = .36	<0.001	There was a weak but significant rise of RMSE with higher bur use
Spearman Correlation	RMSE Prosthodontist 5 vs Order Number 1-20, (N=20)	ρ =.51	.022	There was a moderate and significant rise of RMSE with higher order number
Spearman Correlation	RMSE Prosthodontist 5 vs Bur Use 1-5 (N=20)	ρ =.58	.007	There was a moderate and significant rise of RMSE with higher bur use
Spearman Correlation	RMSE Prosthodontist 4 vs Order Number 1-20 (N=20)	ρ =-.54	.015	There was a moderate and significant decrease of RMSE with higher order number
Spearman Correlation	RMSE Prosthodontist 4 vs Bur Use 1-5 (N=20)	ρ =-.07	.758	There was no significant correlation
Spearman Correlation	RMSE Prosthodontist 3 vs Order Number 1-20 (N=20)	ρ =.16	.498	There was no significant correlation
Spearman Correlation	RMSE Prosthodontist 3 vs Bur Use 1-5 (N=20)	ρ =.18	.445	There was no significant correlation
Spearman Correlation	RMSE Prosthodontist 2 vs Order Number 1-20 (N=20)	ρ =.07	.772	There was no significant correlation
Spearman Correlation	RMSE Prosthodontists 2 vs Bur Use 1-5 (N=20)	ρ =.46	.040	There was a moderate and significant rise of RMSE with higher bur use
Spearman Correlation	RMSE Prosthodontist 1 vs Order Number 1-20 (N=20)	ρ =-.08	.741	There was no significant correlation
Spearman Correlation	RMSE Prosthodontist 1 vs Bur Use 1-5 (N=20)	ρ =.43	.059	There was no significant correlation

Table 1: Shows the outcome of testing the Primary Hypothesis: that the Prototype was as good or better than the Prosthodontists (True), and it also shows the outcome of testing the secondary hypotheses, that the Prototype would show poorer accuracy with higher order number (false) and poorer accuracy with higher bur use (true); that the Prosthodontists would show better accuracy with higher order number (1 true, 4 false), and that the Prosthodontists would show poorer accuracy with higher bur use (2 true, 3 false).

Table 2: Raw Data; Yellow = Prosthodontists, Blue = Prototype

Serial Number	Order	RMSE	Bur Use	Prosthodontist	Serial Number	RMSE	Use of Bur
0	0	0	N/A	N/A	0	0	N/A
1001	1	0.68	1	1	1	0.36	1
1002	2	0.29	2	1	2	0.27	2
1003	3	0.8	3	1	3	0.58	3
1004	4	0.3	4	1	4	0.2	1
1005	5	1.48	5	1	5	0.21	2
1006	6	0.23	1	1	6	1.25	3
1007	7	0.5	2	1	7	0.32	1
1008	8	0.51	3	1	8	0.36	2
1009	9	1.61	4	1	9	0.5	3
1010	10	0.53	5	1	10	0.49	1
1011	11	0.35	1	1	11	0.24	1
1012	12	0.32	2	1	12	0.27	1
1014	13	0.32	3	1	13	0.23	2
1015	14	1.13	4	1	14	0.38	3
1016	15	0.48	5	1	15	0.54	1
1017	16	0.45	1	1	16	0.22	1
1018	17	0.31	2	1	17	0.51	1
1020	18	0.3	3	1	18	0.16	1
1021	19	0.75	4	1	19	0.2	2
1022	20	0.36	5	1	20	0.36	3
1033	1	0.34	1	2	21	0.14	1
1035	2	0.53	2	2	22	0.4	2
1037	3	1.27	3	2	23	0.43	3
1038	4	0.46	1	2	24	0.17	1
1040	5	0.41	2	2	25	0.24	2
1041	6	0.51	3	2	26	1.02	1
1042	7	0.38	1	2	27	0.3	1
1043	8	0.33	1	2	28	0.38	2
1044	9	0.38	1	2	29	0.42	1
1046	10	0.43	1	2	30	0.3	2
1048	11	0.35	2	2	31	0.4	3
1049	12	0.53	3	2	32	0.2	4
1050	13	0.51	4	2	33	0.66	5
1052	14	0.43	1	2	34	0.2	1
1053	15	0.46	2	2	35	0.43	2
1054	16	0.45	3	2	36	0.28	3
1055	17	0.3	1	2	37	0.15	4

1056	18	0.89	1	2	38	0.35	5
1058	19	0.39	1	2	39	0.26	1
1059	20	0.57	1	2	40	0.4	2
1061	1	0.63	1	3	41	0.43	3
1062	2	0.25	2	3	42	0.32	4
1063	3	0.37	3	3	43	0.41	5
1065	4	0.48	4	3	44	0.46	1
1066	5	0.77	5	3	45	0.5	2
1067	6	0.45	1	3	46	1.18	3
1068	7	0.34	2	3	47	0.17	1
1069	8	0.4	3	3	48	0.71	2
1070	9	0.84	4	3	49	0.49	1
1071	10	1.1	5	3	50	0.57	2
1072	11	0.56	1	3	51	0.32	1
1080	12	0.75	2	3	52	0.71	2
1081	13	0.58	3	3	53	0.33	1
1082	14	0.38	4	3	54	0.28	1
1083	15	0.58	5	3	55	0.14	1
1084	16	0.97	1	3	56	0.32	2
1085	17	0.36	2	3	57	0.43	3
1088	18	0.74	3	3	58	0.55	4
1089	19	0.6	4	3	59	0.52	5
1090	20	0.38	5	3	60	0.42	1
1091	1	0.94	1	4	61	0.44	2
1092	2	0.64	2	4	62	0.38	3
1095	3	0.42	3	4	63	0.16	1
1096	4	0.55	4	4	64	0.42	2
1097	5	0.56	5	4	65	0.27	1
1101	6	0.39	1	4	66	0.3	1
1104	7	0.5	2	4	67	0.8	2
1105	8	0.62	3	4	68	0.39	3
1106	9	0.8	4	4	69	0.17	1
1107	10	0.4	5	4	70	0.16	2
1108	11	0.76	1	4	71	0.5	3
1109	12	0.38	2	4	72	0.9	1
1110	13	0.47	3	4	73	0.6	1
1111	14	0.59	4	4	74	0.18	1
1112	15	0.49	5	4	75	0.37	2
1113	16	0.41	1	4	76	0.45	3
1116	17	0.32	2	4	77	0.14	1
1118	18	0.41	3	4	78	0.15	2

1119	19	0.48	4	4	79	0.19	3
1120	20	0.31	5	4	80	0.51	4
1131	1	0.39	1	5	81	0.36	1
1132	2	0.45	2	5	82	0.21	1
1133	3	0.5	3	5	83	0.23	2
1134	4	0.36	1	5	84	0.46	3
1135	5	0.6	2	5	85	1.12	4
1136	6	0.39	1	5	86	0.34	1
1137	7	0.76	2	5	87	0.38	2
1138	8	0.62	3	5	88	0.44	3
1139	9	0.73	4	5	89	0.27	1
1140	10	0.46	1	5	90	0.45	2
1141	11	0.52	2	5	91	0.54	3
1142	12	0.5	3	5	92	0.23	1
1143	13	0.72	4	5	93	0.8	2
1144	14	0.55	1	5	94	0.34	1
1145	15	0.72	2	5	95	0.76	2
1146	16	0.69	3	5	96	0.51	1
1147	17	0.54	1	5	97	0.5	2
1148	18	0.63	2	5	98	0.47	3
1149	19	0.49	1	5	99	0.12	1
1150	20	0.97	2	5	100	0.35	2
Mean		0.55			Mean	0.40	
Standard Dev.		0.25			S.Dev.	0.22	

Table 2 Shows all raw data for the Prosthodontists (Yellow) and the Prototype (Blue). Root Mean Squared Error (RMSE) data is given in millimeters. If a tooth was prepared with a bur and it was the first use of the bur the event was recorded as a 1 under bur use. If a tooth was prepared with a bur and it was the second use of the bur the event was recorded as a 2 under bur use. So went the numbering of bur use through 5, which was the highest permissible number of times to use a bur in this study. Prosthodontists were labeled with a numerical replacement identity, numbers 1 through 5.