A digital process for additive manufacturing of occlusal splints: a clinical pilot study

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The aim of this study was to develop and evaluate a digital process for manufacturing of occlusal splints. An alginate impression was taken from the upper and lower jaws of a patient with temporomandibular disorder owing to cross bite and wear of the teeth, and then digitized using a table laser scanner. The scanned model was repaired using the 3DATA EXPERT software, and a splint was designed with the VISCAM RP software. A splint was manufactured from a biocompatible liquid photopolymer by stereolithography. The system employed in the process was SLA 350. The splint was worn nightly for six months. The patient adapted to the splint well and found it comfortable to use. The splint relieved tension in the patient’s bite muscles. No sign of tooth wear or significant splint wear was detected after six months of testing. Modern digital technology enables us to manufacture clinically functional occlusal splints, which might reduce costs, dental technician working time and chair-side time. Maximum-dimensional errors of approximately 1 mm were found at thin walls and sharp corners of the splint when compared with the digital model.

1. Introduction

Temporomandibular disorder (TMD) is a common clinical entity [1,2]. The prevalence of TMD in the adult population ranges from 25 to 50 per cent [3]. There is an increased risk for TMD in patients suffering from malocclusion, such as cross bite, open bite or crowding [4,5], deep bite or mandibular retrognatia [6]. Also bruxism, significant teeth wear, temporomandibular joint (TMJ) problems or facial traumas may lead to TMD [7,8]. Traditionally, TMD treatment starts with an occlusal splint. Usually, if there is no response during the first one to six months, there is a need for additional examination and treatment [9]. The conventional process to produce an occlusal splint comprises inter-occlusal wax bite registration and alginate impressions of the upper and lower dentition to make working models. The manufacturing process when performed by a dental technician is labour intensive. Digital manufacturing processes are suggested as an alternative to a hand-made occlusal splint. Additive manufacturing (AM, Rapid Prototyping, Layer Manufacturing, Freeform Fabrication) is a process where parts are manufactured directly from a digital three-dimensional model by adding material, usually on a layer-by-layer basis as opposed to subtractive manufacturing methodologies, such as traditional machining [10]. One of the advantages of an automated AM process comes from the ability to print a large number of individual splints in a short time period.

Indirect AM has been used for clear and hard tooth aligners by digitizing teeth, virtually straightening them and fabricating a pattern for vacuum heat process by AM [11]. A combination of computed tomography and rapid prototyping has been used to produce a physical copy of unusual tooth root anatomy.
A computer-assisted method for design and fabrication of hard occlusal splints was developed by scanning for stone casts and milling for manufacturing [13]. AM has been used for rapid tooling to create soft oral appliances by moulding [14]. There are commercially available hard clear aligners, which are made by digitizing dentition, virtual straightening, fabricating a mould by AM, vacuum forming and finishing [15]. The accuracy of wax patterns for facial prostheses produced by AM has been found to be better than conventional duplication [16]. An AM model has been used as a mock-up for manufacturing obturator prosthesis from acrylic polymethyl methacrylate [17]. Laser surface digitizing with computer-aided design (CAD)/computer-aided manufacturing (CAM) techniques has been used for developing facial prostheses and for casting prosthetic parts [18,19]. Optical three-dimensional imaging and CAD/CAM systems have been deployed in designing and fabricating facial prostheses more precisely than by conventional manual sculpturing techniques [20]. The accuracy of the photographic three-dimensional imaging system has been found sufficient for clinical description of the mid-face structures and may be potentially useful for AM of facial prostheses [21]. Direct AM applications in the medical field are still rather rare. There are case studies on custom-made implants [22–25] and dental crowns and bridges [26] made by these technologies. Direct AM has been suggested as an effective methodology also for patient- and operation-specific instruments [27]. Dental splints for orthognathic surgery have been manufactured, using additive manufacturing and three-dimensional reconstruction from computed tomography images as a template [28].

The aim of this study was to develop a digital method for producing custom-made occlusal splints by AM. The approach selected combined CAD, AM and digitization of the patient’s dental arches. The secondary aim was to obtain information regarding patient adaptation, i.e. convenience, tolerance and its effect to bite muscle pain, and to study the side effects of this oral appliance.

2. Material and methods

Our approach to an occlusal splint was to use three-dimensional digitizing to create a three-dimensional model from the patient’s upper and lower teeth and to use the model as a basis for AM from an appropriate material. A flow chart of the process is demonstrated in figure 1.

2.1. Patient

The process started with dental examination of the patient with cross bite on the right- and left-hand sides, severe teeth wear and bite muscle pain. The patient was a generally healthy 27-year-old male, with no allergies or medications. He had not received any orthodontic treatment and had no history of facial traumas or snoring. The periodontal tissues were clinically healthy. His profile was straight, with an orthognathic maxilla and a slightly prognatic mandible. The horizontal overjet was 4 mm, the vertical overbite was −1 mm and the molar relationship was cusp to cusp on the right-hand side and AI on the left-hand side. The maximal opening of the mandible was 55 mm, and its lateral movement was 10 mm to the right and 7 mm to the left. The protrusion of the mandible was 7 mm. The patient had minor bite muscle tension, but no TMJ clicking, crepitation or pain on palpation. The patient’s dentition is shown in figure 2.

2.2. Scanning

Teeth can be scanned straight from the mouth, using an intraoral scanner, or indirectly by taking a plaster model and scanning it. The indirect method was selected because currently intraoral scanners are usually designed only for scanning a single tooth or a few teeth for crowns and bridges. Plaster models from the patient were taken and digitized using the 3Shape D710 Multi Die Scanning table laser scanner (3Shape A/S, Denmark) and the SCANServer v. 1.0.4.3 software (3Shape A/S, Denmark). The scanner comprises a laser, two cameras with 1.3 megapixel (Mpx) resolution and three-axis motion. Scanning the plaster model took approximately 60 s. The accuracy of the D710 Multi Die Scanning is 20 μm. All teeth were selected in focus in order to achieve maximal accuracy on every surface of the teeth. The format used for surface was STL (Stereolithography/Standard Tessellation Language), which describes a triangulated surface by the unit normal and vertices. The scanned model had a few holes and triangulating errors but those were easily repaired using manual and automatic repair tools. The STL file was repaired using 3DATA EXPERT v. 9.1 (DeskArtes Oy, Finland).

2.3. Three-dimensional design

The splint was designed with the Viscam RP v. 4.0 software (Marcam Engineering GmbH, Germany), which is an engineering software package for preparation of CAD/CAM data for AM. The scanned and repaired three-dimensional model of upper teeth was used as a starting point. First, all tooth surfaces
in the three-dimensional model were extruded to a thickness of 2.0 mm. This can be done with the software’s extrude surface or offset commands. Thereafter, the extruded surfaces were cut off from the three-dimensional model, using a Boolean operation to obtain a cover for teeth for a rough three-dimensional model of the splint. At this stage, it is important to cut the edges so that the splint will not touch the gingivae, but still has enough contact with the teeth. Finally, the rough three-dimensional model of the splint was cut to the desired shape using the trim and cut tool. The smoothing command was used to achieve good surface quality for the three-dimensional model. Smoothing, which removes sharp corners and self-locking forms, was also used to remove too tight fitting to the teeth. The absolute minimum wall thickness for laser-based AM systems would be the width of a single cured line and this is related to the diameter of laser beam and the cure depth [29]. Therefore, the slight residual roughness of the three-dimensional model tends to be smoothed in AM, and very small errors have only insignificant influence to the end product. The three-dimensional model of the designed occlusal splint is shown in figure 3.

2.4. Manufacturing

AM is a material-adding fabrication process, which suits manufacturing complex geometries for either one piece or small series production. The parts are produced automatically according to a digital three-dimensional model. The selected additive process for manufacturing was stereolithography (SL, SLA) because of its good accuracy and availability of suitable materials. Stereolithography is a process where laser hardens curable photopolymer resin layer by layer. Parts are manufactured on the building platform, which is located in liquid resin. After a layer is cured, the build platform descends by one layer thickness, and a new layer of resin is spread over the previous one. This procedure is repeated until the parts are completely built. The machine employed was SLA 350 (3D Systems, USA). For the material, Somos WaterShed XC 11122 (DSM Functional Materials, USA) was selected because it complies with the ISO 10993-5 Cytotoxicity, ISO 10993-10 Sensitization and ISO 10993-10 Irritation regulations. It also has USP Class VI approval. The SLA 350 laser beam diameter is 100 μm, and features smaller than that disappear. The layer thickness of the current process was 0.05 mm. After the manufacturing phase, the splint was soaked in pure isopropanol for 20 min, and clean towels were used to scrub off any excess resin. Dry, compressed air was used to blow excess solvent from the surface of the splint. The splint was placed in a post-cure apparatus for 60 min after cleaning. The manufacturing can be done automatically overnight, and the current cost of manufacturing one splint is approximately 60 euros.

2.5. Clinical testing

The patient was asked to note his impressions regarding the appliance use. This phase of the process and patient reporting started with a standard dentist visit, where the occlusal splint was trimmed to fit to the upper dental arch and to get optimal contact with the lower dental arch. The patient was advised to use the appliance every night, as is done with a conventional bite splint, and to report on his own observations. The appliance was cleaned every morning with water and toothbrush and once a week with Corega Tabs (GlaxoSmithKline plc, UK).

After one, three and six months, the splint was examined for possible wear and other changes. The final occlusal splint in use is shown in figure 4.

2.6. Evaluation

Dimensional accuracy of stereolithography in medical model production has been found to be better than 1 per cent when compared with a three-dimensional model and manufactured model [30,31]. The accuracy of medical models varies between different materials, AM technologies and the machine used [32]. After six months of splint use, the GOM ATOS II Triple scan 3D scanner (GOM mbH, Germany) was used to capture a virtual three-dimensional model of the product used. The scanner employs structured light and cameras to record three-dimensional surfaces. The accuracy of the measurement was not less than 0.02 mm. A mixture of titanium oxide and alcohol was sprayed over the splint before measuring to gain better response for the optical scanner. The geometry of the splint after use was compared with the geometry of the three-dimensional design using GOM Inspet V7 SR2 (GOM mbH, Germany), since the accuracy of the stereolithography process is well known, and it can still be estimated after use from the appliance’s surroundings where there is no wear or trimming.

3. Results

The digitally manufactured occlusal splint was used for six months nightly as would a conventional one made by a dental technician. After 5 days, the splint was trimmed, since signs of slight pressure on the upper right canine and pressure between the upper and lower right premolars were noted. The patient felt the splint to be tight after a couple of minutes from the beginning of every usage, which is typical also with a conventional splint. No other problems were detected, and the patient adapted to the splint well and found it comfortable to use. It also relieved his bite muscle tension. No sign of tooth wear or significant splint wear was detected after the six-month test period. The splint after a test period of six months is shown in figure 5.

Figure 6 compares the splint, after six months of use, with the three-dimensional model. The overall accuracy of the described system can be estimated from those areas with no wear or trimming. The maximum trim needed was approximately 1 mm. Wear can be estimated to be smaller than 0.2 mm. When comparing the physical model with the three-dimensional design, dimensional errors of approximately 1 mm were found at thin walls and sharp corners. The accuracy in other areas seems to be better than 0.3 mm.

4. Discussion

Oral appliances are frequently suggested as a treatment option in the management of obstructive sleep apnoea,
TMD and for teeth protection in bruxism. The prevalence of TMD in adult population ranges from 25 to 50 per cent [3]. Therefore, an increasing number of occlusal splints are currently manufactured for these purposes, using traditional labour intensive process. This warranted us to design a novel method to produce these appliances more rapidly and with reduced costs. This study describes the process of designing and manufacturing a novel occlusal splint and also the first subjectively reported experiences of its use. As in case of a conventional splint, the patient reported the present occlusal splint being slightly tight when first put in place but after a few minutes it felt comfortable. This may occur due to absorption of oral fluid to the splint material or because of simple teeth adjusting.

The aim of the present study was to describe the multi-disciplinary process that is needed to develop and evaluate a novel digital process for manufacturing occlusal splints. So far, the evidence of clinical applicability of this occlusal splint is limited to a single patient, and testing in a patient series is needed before considering commercial production. However, production of a physical prototype and individual testing usually lead to further developing phases of the process and the product before further clinical experience is obtained.

A commonly used and well-known CAD/CAM technology for manufacturing of ceramic inlays in odontology is Cerec (Siemens, Germany) [33]. It has been pointed out that AM is the next revolution in dental device manufacturing [34]. By using and developing this kind of technology, there is a possibility to use milling to manufacture occlusal splints from a solid block. Also, oral sleep apnoea appliances could be partly or fully manufactured using digital...
technology and AM technologies. Scanning or the software used could track occlusion and movement of jaws. Thereby, movement of the device and interface to the teeth could be more accurate.

Traditionally, an occlusal splint is hand-made in a dental laboratory. Therefore, the costs are fairly high, and the lead time is approximately one week before the patient is able to use it. Modern digital technology, including three-dimensional scanning and AM, opens up a possibility to manufacture these splints more efficiently and to achieve shorter lead times. Digital technology may also improve the accuracy of the final occlusal splint. This improved accuracy and also the more advanced design may reduce the time needed for the dentist to trim the splint. Our aim is to validate the feasibility of the presented methodology in a case series. Currently, another patient (the second one) has reported his full satisfaction after four months use of an occlusal splint made by this technology.

Three-dimensional design of occlusion splint is a quite straightforward process: extruding or offsetting teeth surfaces and then cutting the edges so that there is no contact to the gingivae but enough contact to the teeth. Every splint has different geometry in terms of teeth contact, but other parts are similar. Working with scanned data usually produces small ‘craters or spikes’ when the surface is extruded. At the current stage, modelling is done manually, but also semi- or fully-automated modelling can be considered. Cases where some teeth are missing may need more manual work. The material used in the current study seemed suitable for occlusal splint manufacturing. The consistency seemed rather optimal. Also, mechanical properties could stand the forces from teeth and jaws. The material was biocompatible with low water absorption. Further, the accumulation of dental plaque on various splint materials used in the AM process should be investigated. We noted only minimal plaque deposits on the tested splint after six months.

The fast development of AM processes and materials potentially offers more and more direct applications in medicine. Possibilities of AM have not been used sufficiently as this requires multidisciplinary processes. In the future, new materials and technologies offer the medical and dental professions new treatment options, and therefore provide faster and more cost-efficient solutions to improve patient quality of life.

## 5. Conclusion

We provide proof-of-concept experiments to manufacture clinically functional occlusal splints by using modern digital technology without manual working phases in a dental laboratory. In future, this might reduce costs, dental technician working time and chair-side time. Accuracy can also be improved, since manual work phases are reduced. In this experiment, splint fit was found as good as in the best conventional splints and the accuracy of the method was excellent.

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