Accuracy of Digitally Produced Stabilization Splints

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ABSTRACT

Stabilization splints are one of the most commonly used treatments for temporomandibular disorders. Digital scanning has been introduced as a method for registration of intraoral conditions and to produce prosthetic constructions.

The aim of this study was to investigate the accuracy and comfort of digitally produced stabilization splints after intermaxillary registration in centric occlusion (CO) or in the planned construction position (CP) of the appliance.

15 consecutive patients who needed an occlusal appliance were included in the study. A digital intraoral scanner (TRIOS®3Shape) was used to register the upper and lower jaw. The patients were randomly divided for either CO or CP group. Comparison of the intermaxillary contact pattern of the planned digital appliance (in vitro) and the actually contact pattern (in vivo) was done with 3 different methods. Registration of the patient's experience of comfort and dentist's assessment of the splint was done.

All splints had good accuracy and fit to the teeth. The adjustment time to the opposite jaw was significant longer in the CP group. The clinical- and patient judgement showed a satisfactory and acceptable result with no significant difference between the two groups.

In the CP group, there was a tendency for more contacts in the front part of the splint, compared with the CO group with more contacts posteriorly. Clinical experience indicates that adjustment of primary contact in the front takes more time compared to posteriorly contacts. The increased adjustment time for the CP group may be explained by this.
INTRODUCTION

Temporomandibular disorders

Temporomandibular disorder (TMD) is an umbrella term for symptoms and signs of musculoskeletal disorders of the temporomandibular joint (TMJ) and related muscles. Pain and dysfunction are the two most common symptoms associated with TMD. Characteristic symptoms of TMJ are decrease in the range of mandibular movement, locking of the jaw, TMD sounds such as clicking or crepitation during jaw movement, and pain in the jaw-facial area and associated headache (Okeson, 2012). The most common reason for demanding TMD treatment is chronic pain (List and Jensen, 2017). TMD is commonly associated with co-morbid conditions that affect patient’s quality of life such as depression, impaired general health or other psychological disabilities (List and Jensen, 2017). A meta-analysis of studies evaluating treatment need owing to TMD (Al-Jundi et al., 2008) found that the median value of treatment need was 16 % and that the min–max values varied between 1 and 30 %. This observation may be related to different definitions, criteria and age. A 2-year prospective study showed that some deviations in the dental occlusion and self-reported bruxism were significantly related to incidence and persistence of TMJ symptoms (Marklund and Wänman, 2010). Women seem to have a higher risk to develop TMD signs and symptoms compared to men (Hirsch et al., 2006; Yekkalam and Wänman, 2014) Analysis of performed treatment owing to TMD indicates that approximately 0.5-1 % of the Swedish adult population receives such treatment (Wänman and Wigren, 1995; Socialstyrelsen, 2012). The results thus indicate under-treatment of TMD within dentistry.

Treatment of temporomandibular disorders

A conservative treatment approach to TMD is recommended as the first line of management, usually with a stabilization splint (Alencar and Becker, 2009). This may produce an optimal stabilization and unload for the TMJ and the jaw muscles, and may lead to a reduced abnormal muscle activity (Al-Ani et al., 2004). A multimodal and multidisciplinary treatment may be needed for those who suffer from more severe TMD (Al-Ani et al., 2005). Education program, including reassurance and information about the pain and disorders and how to behave can be a successful way for the individual patient to enhance self-care and awareness. This can also involve exercise program, in
order to reduce eventual parafunctional behaviors. (Michelotti et al., 2012).

Treatment of TMD as well as protection of dental wear with the aid of an occlusal appliance is quite common in dentistry. The number of occlusal appliances made in dental health care has increased significantly between 2008 and 2016 (Personal communication with Barbro Hjärpe, TLV, 2017). There are different types of occlusal appliances where the hard resin stabilization splint is the most common and recommended in the treatment of TMD. The aim is to reduce pain, increase functional ability (Socialstyrelsen, 2012; Al-Obeidi and Baza, 2015).

**Stabilization splints**

Stabilizations splints are usually produced conventionally by dental technicians with many steps which may induce several sources of error. Alginate impressions of each jaw and a wax index to depict the intermaxillary relationship are sent to a dental technician to make plasters models, to mount them in an articulator, to mold and produce the splint and finally polish it. The accuracy of manually produced occlusal appliances varies and cause variations in time needed for adjustments. It would therefore be beneficial to find a method to improve the quality of the splint to increase the comfort and to reduce the time needed for adjustment. The registration between the jaws is done in centric occlusion which is the occlusion of opposing teeth when the mandible is in centric relation (Glossary of prosthodontic terms, 2005). According to national guidelines for dentistry, treatment with stabilization splints has received high priority for TMD conditions. The guidelines are based on the scientific evidence, expected outcome, cost-benefit, low risk of complications (Socialstyrelsen, 2012).

**Digital technology**

The digital development with intraoral scanning and production of prosthetic restoratives with the aid of CAD/CAM technology has many advantages. Instead of an alginate impression, an intraoral scanner is used to register the jaws and the relationship between the jaws. The scanned image is sent to a computer where a software program is used to design the appliance in a virtually 3D view. The occlusal appliance is designed with the software program where an articulator can do the articulation movements and the contact
pattern is shown on the splint. Every splint can then be individually designed even though there are also standard settings available in the software. *Trios 3Shape™* is an intra oral scanner that has been used mostly to produce models for prosthetic restorations. However, it is possible to use the scan for stabilization splints although it is less thoroughly tested (3Shape, 2011). It is stated that patients prefer intra oral scanning instead of conventional impressions because of the increased comfort and short chair time (Chalmers et.al., 2016.). By using intra oral scanning the reliability of the impression is increased compared to indirect digital and to plaster models (Chalmers et.al., 2016.).

**3D printing**

The digital development, has made it possible to use production methods such as milling and 3D printing. The latter method in regard to accuracy of occlusal appliances is not studied and more knowledge is needed before it can be implemented on a broad front.

Additive manufacturing is a modern technology recently utilized in dentistry. The manufacture by milling has been introduced to dentistry many years ago but additive processes has not been available until recently. Even though research of additive processes with different plastic materials has been done since the early 1980’s, they have only been used in dental technology for the last years. The reasons behind this are the high requirements on precision and the specific qualities of the materials. If the constructions should be placed in the patient's mouth the material needs to fulfil the requirements of class 1 medical products. Advantages with 3D-printing is the low consumption of material and fast manufacturing time. Varseo (BEGO GmbH & Co. KG) is a 3D-printer that uses stereolithography (SL) as manufacturing process. SL is the oldest CAM process and the objects are polymerized from a light-curing-plastic bath where the product is built layer by layer. BEGO Varseo is working with a precision of 25 to 50 μm. With SL it is not the physical parameters that is the limiting factor, but the technical machine implementation (von See and Meindorfer, 2015).

**Preceding studies**

A clinical pilot study showed that occlusal appliances produced with SL has good accuracy and the patients found the splints comfortable to use. It also reduced their
symptoms of muscle tension (Salmi et al., 2013).

**Study aim**
The first aim of this study was to investigate the accuracy of digitally produced splints with intermaxillary registration in centric occlusion or in the planned inter-maxillary position of the splint. That is, to evaluate if intermaxillary registration in the planned bite-splint position (construction position) lead to a more optimal occlusion of the splint and shorter the adjustment time compared to registration in centric occlusion. The second aim was to analyze if there was any difference in time needed to adjust the appliances. The third aim was to evaluate the patient’s values of the appliance.

**Hypotheses**
An intermaxillary registration in the construction position will produce an occlusal stabilization splint with more optimal occlusion than an intermaxillary registration in the centric occlusion. The second hypothesis was that the adjustment time would differ between the two registration types. The third hypothesis was that patient’s opinion of the appliance would not differ between the two registrations methods.

**MATERIAL AND METHODS**
PubMed database was searched for articles related to digitally produced bite splints. Initially we did a free search on “scanned bite splints”, got two hits and found one publication. There were not so many published articles in our topic and therefore we have also used other search strategies such as websites where the software, scanner and 3D printer come from. Some references are the same as used in a previous master thesis that we got from our tutor since the subject is similar.

**Study-population**
15 consecutive patients (10 men and 5 women) between 22 and 70 years old at a private dental clinic were included in the study. Some of the test subjects had previous experience of bite splint treatment. All subjects had an indication to be treated with a bite splint and their dental arch should involve at least the first molar, for the bite splint to cover. The splint was placed in the upper or lower jaw according to individual conditions. Subjects
with horizontal overjet > 6 mm were excluded.

**Ethical considerations**
Since the study was done in a private dental clinic with ongoing activity, it could cause a slightly lower revenue for the private dental clinic. The risk that the patients would suffer damage was assessed as very low, because the treatment with a splint was indicated for the patient. All test subjects were informed about the study and signed information and consent. The study was reviewed and approved for by an ethical committee at Umeå University, Sweden.

**Clinical operator and dental technician**
The entire clinical process was conducted at a private dental clinic where an experienced dentist performed all steps including scanning, design, manufacturing and adjustments.

**Scanning**
A digital image with an intraoral scanner was produced with TRIOS® 3Shape in the upper and lower jaw. The test subjects were randomly divided into two groups based on inter-maxillary registration method; in centric occlusion (CO) or in the planned position of the splint, construction position (CP). The group registered in CP was instructed to bite on a wooden spatula with alminax wax in the incisor region, adjusted so that it was about 2-2.5 mm in the center of the model. A recording was scanned in that position on both sides (Fig 1.). In the other group the index recording was scanned on both sides in the CO.

**Computer aided design and manufacturing**
The scanning was sent to a computer with the software, 3Shape Dental System, to design the splints. In the CP-group, the design was made according to the CR. In the CO-group the jaw-opening was adjusted virtually in the software about 3.0 mm between the incisors. The splints were designed with the articulator Kavo Protar Evo® using settings with 30 degrees condylar guidance and 10 degrees of Bennet angle. All test subjects in the study received their splint in the upper jaw after an individually evaluation. The splints were 3D-printed with Varseo 3D-printer from BEGO and the material VarseoWax Splint.
Evaluation of the splints

The splints were evaluated before any adjustment was done. One splint with a mediotrusive contact had to be adjusted before the index and contact pattern were made. After the evaluation, the splints were adjusted and the adjustment times were registered. The evaluation of the splints consisted of three parts described below:

Protocol

By using a protocol the splints were evaluated by both the dentist and the patient. Clinical measurements and the test subjects’ comments was registered. The clinical criteria were the same as used in the study "Precision of Digitally Produced stabilizations splints" (Al-Obeidi and Baza, 2015)

During extradition of the bite splint, all the patients answered on following questions. Answering alternatives included “YES” or “NO”.

- “Do the bite splint have any tension?”
- “Do you feel smoothen contacts to the bite splint, with the teeth in the opposite jaw?”
- “Do you feel an acceptable fit of the bite splint to the teeth in the actual jaw?”
- “If you have had a bite splint before, is this one better than your old one?”

The splint was after that rated according to fit the maxillary teeth. This evaluation was done by the dentist. The different values were as follows:

- “Insufficient retention” - The splint has no retention or comes off too easily.
- “Fits with tension” - The splint gives a sensation of pressing against one or more teeth too hard.
- “Wiggles” - Uneven retention that gives unstable splints. Tilts when pressed in different areas.
- “Impeded retention” - The splint does not go in place. A double-contour, or space between teeth and splint, is visible.
- “Acceptable retention” - The splint goes in place, is stable, and only comes off when intended to.

More than one option could be selected.
Contact Pattern I – Occlusion Foil
The contact pattern was analyzed by using occlusion foil (Trolldental 0,08 mm thickness) in retruded position (RP). A photo of the splint and contact pattern were taken for further comparison with the CAD design and Optic Bite analyze (fig 2).

Contact pattern II - Optic Bite Registration
An index with Beauty Pink Wax (Moyco Union Broach/A Division of Moyco Technologies Inc) was formed and put on the splint where the registration in RCP was done. Optic Bite is a program that measures light transmittance through a wax sheet to determine the thickness of specific areas in the sheet. The analyze program is based on the Beer-Lambert law.

Statistic method
All data were collected and processed using Microsoft Excel and SPSS v21. Mean values and standard deviation (SD) were calculated. Comparison of adjustment time for the stabilization splints manufactured after an index in CO or in CP was analyzed with Student t-test since Q-Q Plot showed that the outcome variable was normally distributed. Analyzes of difference in registered contact patterns, clinical- and patient judgement was done with a Fisher Exact test. A P-value < 0.05 was considered statistically significant.

RESULTS
Accuracy of the splints
When comparing contact patterns between the splints with the two types of index, CP and CO, there were no significant difference between the groups. Three splints registered in CP had contacts in the front of the splint compared to one in CO group (Table 1). The dentist’s clinical judgment of the fit of the stabilization splints did not differ significantly depending on jaw registration in CP or in CO. All splints had good fit to the teeth that the splint was placed on. A few splints fitted with some minor tension at the canines but it was so marginal that it was rated as good fit, and a good retention of the rail.
**Adjustment time**
The time for adjusting the splints were significant shorter in the CO group compared to splints with CP index (P =0.03). The adjustment time was approximately twice as long in the CP group compared to the CO group (Table 2). Three test subjects had bite splints with optimal contact pattern at the first try-out.

**Patient’s value**
All patients, except two, expressed that the stabilization splint had an acceptable fit. Two experienced the splint clumsy. Three weeks later, when all the patients were contacted in regard to re-describe the fit, 93 % were satisfied with the design and fit and were able to use it during the night. One patient (7 %) had difficulties to use the splint due to unacceptable fit and size.

**Re-examination**
All patients came for follow up of their splint after approximately two weeks. At an early stage, most patients had no comments that the splint did not work, except that it needed to be adjusted slightly in contacts or against the teeth. After a few weeks five of the patients who participated in the study reported that the splint was broken, cracked or that small pieces had loosened. This caused the dental clinic to recall all splints. A letter was sent to all patients, even those who had not participated in the study, with information that the splints should not be used due to the risk of inhalation at night and that the splints must be submitted to the dental clinic to be sent to the material manufacturer. All patients were also called by telephone for the same information.
DISCUSSION

The study indicates that type of inter-maxillary registration may influence the splint’s contact patterns on the antagonistic jaw. The first hypothesis that an inter-maxillary registration in the construction position will produce an occlusal stabilization splint with more optimal occlusion was thus rejected. The second hypothesis was that the adjustment time differs between the two registration types was accepted. The tendency of more contacts in the front part of the splint in the CP group and more posteriorly located contacts in the CO group may be related to differences in adjustment time. Clinical experience suggests that adjustment of primary contact in the front generally takes more time compared to adjustment of contact posteriorly. The number of included test patients was low which may affect the interpretation. All splints had good accuracy to the teeth that the splint was placed on and there was no difference between the groups. By taking the index in the construction position, we thought that the distance between the jaws would be as similar as possible and conform when the patient got the stabilization splint in reality.

The technique used for registration in the CP group may have been too unreliable and thus affected the result. When the patients were asked to bite on the wax placed on a wooden spatula it may have involved some difficulties to keep the bite stable completely still during the scanning of the inter-maxillary relationship. An index method that provides a more stable position may produce a more accurate registration. One way could be to take a double alminax wax index and let the patient bite through it. The index is then cut it apart in the middle and just half of the index is insert on one side of the jaw, while scanning the opposite side. This may perhaps produce a more stable position during the scan.

The third hypothesis was that patient’s opinion of the appliance would not differ between the two registrations methods. The result showed that all patients had a positive experience of the treatment and accepted the splint well except for two. This outcome was not attributed to which index method that had been used. Some complaints were related to the fact that the splint had too much tense and one of the test subjects had experience of the treatment and thought the new splint felt worse than the previously.
There was no significance between the groups due to their judgement.

A digital production and process has many advantages both for the patient, therapists and technicians. It is easier to complete the scan with a digital impression than conventional. There are fewer steps and operations that contain sources of error and uncertainty. A digital impression is also more hygienic and can be saved as a file and used for documentation in the patient’s records. The manufacturing process of stabilization splints with 3D printing is very new in dentistry. There is little knowledge and studies on the resin and the long-term studies of the printed products. More research is needed in this area to provide a greater knowledge. It is although an attractive way to produce bite splints since it only takes about three hours to print a splint with this technology. The first two splints were printed with the supports placed on the occlusal plane which results in rough surface when these grounds off before trying in the mouth. This could have affected the contact pattern on the bite splint. The remaining splints were printed out at the height and the supports were placed buccal which eliminate this potential source of error.

A strength in the study is that the same operator performed all steps and had routines and ability to see the whole chain in the entire process.

The fact that the adjustment time varied so much in the CO group corresponds quite well with clinical experience. Some splints fit directly, while other take longer time to adjust. What it depends on is not known. The CP group has a higher mean value but a lower standard deviation. The time for correcting the splints in the CP group were generally higher and varies less. The aim for this study was an attempt to find an index registration method that would reduce the time for adjusting the splints and see if it received a more similar result in terms of time to adjust the splints. Our results show that making the index registration in the planned inter-maxillary position of the splint does not lead to a more optimal occlusion and it is therefore preferable to continue with registration in CO until some other method proves otherwise.
The 3D-printing material is a resin that is cured layer by layer. A bottle of this resin costs 4000 Swedish crowns and is sufficient for about 20 splints. It is about twice as expensive as producing with milling. In addition to that cost, wear of tools must be added. Each splint took about 30 minutes to design for the dentist who performed it. The dentist's clinical time may be higher and compared to sending a dental lab, it is a higher cost to produce everything at the clinic.

The fact that the material in the 3D-printed splints is not good enough became a clear result of this study. The material manufacturers at BEGO were contacted and for the dental clinic where the study was done, this became a lot of additional work. The material does not exist on the market now and it is not yet resolved how to proceed. The patients that need their stabilization splint are now under treatment with conventional splints until further notice.

ACKNOWLEDGEMENTS

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http://www.socialstyrelsen.se/tandvardsriktlinjer/centralarekommendationer/bettfysiologi on 2017-02-03


Table 1. Adjustment time in seconds (sec), clinical - and patient judgment and the contact pattern to the opposite jaw for 8 stabilization splints with intermaxillary registration in a construct position (CP) and 7 registered in centric occlusion (CO). All registrations were done with TRIOS® 3Shape and the splints were 3D-printed with BEGO Varseo 3D-printer and the material VarseoWax Splint.

<table>
<thead>
<tr>
<th>Index</th>
<th>Subject</th>
<th>Time for adapting of the splint (sec)</th>
<th>Fit judgment</th>
<th>Clinical judgment</th>
<th>Fit judgment</th>
<th>Patient’s judgment</th>
<th>Contact pattern</th>
</tr>
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<tbody>
<tr>
<td>CP 1</td>
<td>843</td>
<td>Fit’s with tension</td>
<td>Satisfactory</td>
<td>Posterior</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP 3</td>
<td>822</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Frontal</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>CP 4</td>
<td>548</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Optimal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP 6</td>
<td>817</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Unilateral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP 8</td>
<td>551</td>
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<td>Satisfactory</td>
<td>Frontal</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>CP 12</td>
<td>785</td>
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<td>Deficient</td>
<td>Frontal</td>
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<td></td>
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<tr>
<td>CP 14</td>
<td>645</td>
<td>Fit’s with tension</td>
<td>Satisfactory</td>
<td>Optimal</td>
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<td></td>
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<td>CP 15</td>
<td>1265</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Unilateral</td>
<td></td>
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<td></td>
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<td>CO 2</td>
<td>124</td>
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<td>Satisfactory</td>
<td>Frontal</td>
<td></td>
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<td>CO 5</td>
<td>372</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Posterior</td>
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<tr>
<td>CO 7</td>
<td>49</td>
<td>Acceptable</td>
<td>Deficient</td>
<td>Optimal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CO 9</td>
<td>693</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Posterior</td>
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<tr>
<td>CO 10</td>
<td>580</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Unilateral</td>
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<tr>
<td>CO 11</td>
<td>255</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Posterior</td>
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<tr>
<td>CO 13</td>
<td>932</td>
<td>Acceptable</td>
<td>Satisfactory</td>
<td>Unilateral</td>
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</tbody>
</table>
Table 2. Mean value and standard deviation (SD) in seconds for adjusting the stabilization splints after registration of intermaxillary relationship in a construction position (CP) and in centric occlusion (CO), respectively.

<table>
<thead>
<tr>
<th>Splint group</th>
<th>Mean value (sec)</th>
<th>SD</th>
<th>P-value</th>
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<tr>
<td>CP (n=8)</td>
<td>784.5</td>
<td>229</td>
<td>0.03 (Student T-test)</td>
</tr>
<tr>
<td>CO (n=7)</td>
<td>429.3</td>
<td>321</td>
<td></td>
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</table>
Figure 1. Index used in the CP group. Alminax was on a wooden spatula that was placed in the incisor region so that it was about 2-2.5 mm in the molar region.
Figure 2. The figure shows the CAD sketch of planned splint in the software, the registration of clinical contacts with occlusal foil and the Optic bite registration.