EFFECTIVENESS OF REPOSITIONING SPLINTS AND STABILIZATION SPLINTS IN THE TREATMENT OF SYMPTOMATIC TEMPOROMANDIBULAR JOINT DISK DISPLACEMENT WITH REDUCTION

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ประสิทธิผลของเฝือกสบฟันจัดตำแหน่งและเฝือกสบฟันเสถียรในการรักษาอาการของแผ่นรองข้อต่อขากรรไกรเคลื่อนชนิดเข้าที่ได้เอง

นาง พนมพร วานิชชานนท์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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สถานที่ทำการทดลอง: คลินิกบัณฑิตศึกษาทันตกรรมบดเคี้ยว คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

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ระเบียบวิธีวิจัย : จัดผู้ป่วยทั้ง 34 คนเข้าการศึกษาด้วยวิธีการสุ่มอย่างง่าย กลุ่มหนึ่งได้รับเฝือกสบฟันจัดตำแหน่ง อีกกลุ่มได้รับเฝือกสบฟันเสถียร ก่อนการรักษาให้ผู้ป่วยประเมินอาการของตนเอง ด้วยสเกลวิชวลแอนะล็อก ทั้งอาการปวดข้อต่อขากรรไกรโดยเฉลี่ย และปัญหาการทำกิจกรรมที่ต้องใช้ขากรรไกร 3 อย่าง ซึ่งภายหลังนำมาเฉลี่ยเป็นคะแนนการใช้ขากรรไกรโดยรวม รวมทั้งตรวจอาการแสดงทางคลินิก ให้ผู้ป่วยใส่เฝือกสบฟันเฉพาะตอนกลางคืน ประเมินผลที่ระยะเวลา 10 สัปดาห์ ด้วยวิธีเดียวกับก่อนการรักษา หากคะแนนอาการปวดโดยเฉลี่ยและคะแนนการใช้ขากรรไกรลดลงเท่ากับหรือมากกว่าร้อยละ 50 จากคะแนนก่อนการรักษา ถือว่าอาการดีขึ้นเด่นชัด

ผลการศึกษา : ที่ระยะเวลา 10 สัปดาห์ กลุ่มที่รักษาด้วยเฝือกสบฟันจัดตำแหน่งมีจำนวนผู้ป่วยที่มีอาการปวดและปัญหาการใช้ขากรรไกรดีขึ้นเด่นชัด (7 ใน 17 หรือ ร้อยละ 41) มากกว่ากลุ่มที่รักษาด้วยเฝือกสบฟันเสถียร(4 ใน 17 หรือร้อยละ 23) แต่ไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ (การทดสอบไค-สแควร์, p=0.271)

สรุปการศึกษา : เฝือกสบฟันจัดตำแหน่งใส่เฉพาะกลางคืนมีแนวโน้มให้ผลทางคลินิกในการรักษาอาการแผ่นรองข้อต่อขากรรไกรเคลื่อนชนิดเข้าที่ได้เองดีกว่าเฝือกสบฟันเสถียร แต่ประสิทธิผลของเฝือกสบฟันทั้งสองชนิดไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ

ลายมือชื่อนิสิต.....

สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่ออาจารย์ที่ปรึกษา.....

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KEY WORD: OCCLUSAL SPLINTS / TMJ DISK DISPLACEMENT WITH REDUCTION / TREATMENT OUTCOME / RANDOMIZED CONTROLLED TRIAL

PHANOMPORN VANICHANON : EFFECTIVENESS OF REPOSITIONING SPLINTS AND STABILIZATION SPLINTS IN THE TREATMENT OF SYMPTOMATIC TEMPOROMANDIBULAR JOINT DISK DISPLACEMENT WITH REDUCTION. THESIS ADVISOR : ASST. PROF. MONTCHAI CHALAPRAWAT, M.D., M.Sc., 81 pp. ISBN 974-17-4878-7

Objectives : To evaluate the effectiveness of nighttime use of repositioning splints (ARS) with that of stabilization splints (SS) in the treatment of symptomatic temporomandibular joint disk displacement with reduction

Design : Randomized controlled trial

Setting : Graduate Clinic, Department of Occlusion, Faculty of Dentistry, Chulalongkorn University

Participants : 34 patients with TMJ disk displacement with reduction (DDR) who fulfilled the eligibility criteria

Methodology : Patients were randomly assigned to one of the two groups: anterior repositioning splint group or stabilization splint group using simple randomization. Before treatment, by using visual analog scales, patients assessed their pain VAS and functional VAS on 3 activities which were averaged for composite functional scores. They were also examined for clinical signs. Patients wore their assigned splints only nighttime. After 10 weeks of treatment, evaluation was performed using the same method as the pretreatment. Those who demonstrated at least 50% reduction of both pain and functional scores were counted as important improvement.

Results : At 10-week appointment, the ARS group demonstrated higher number of patients with important improvement (7 of 17, 41%) than did the SS group (4 of 17, 23%). However, no significant difference was found between groups (Chi-square test, p=0.271).

Conclusion The nighttime use of ARS tends to provide better clinical outcome in the treatment of symptomatic TMJ DDR than that of the SS., but no statistical significant difference is demonstrated between these two treatment groups.

Student's signature.....

Field of study Health Development Advisor's signature.....

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CHAPTER 1

BACKGROUND AND RATIONALE

Significance of the Problem

Temporomandibular joint (TMJ) disk displacement with reduction (DDR) is a condition that a disk is displaced from its original position between a mandibular condyle and its eminence, but reduces on full opening, usually resulting in a noise (1). Patients with DDR usually demonstrate TMJ noise, i.e., clicking on mouth opening and closing at different positions or so-called reciprocal clicks (2, 3).

TMJ clicking is a common clinical finding and subjective report in epidemiologic investigations as well as in clinical series of temporomandibular disorders (TMD) patients. While TMJ clicking can occur from various mechanisms (4), clicking due to disk displacement appears to be the most prevalent sound (5). A diagnosis of TMJ DDR confirmed by magnetic resonance image (MRI) was found in 30% of asymptomatic volunteers and 40% of symptomatic TMD patients (6). However, data on the prevalence of DDR assessed by MRI has not yet been reported in Thailand. By means of clinical examination, TMJ clicking has been demonstrated in 32% of selected non-TMD Thai samples (7).

Not only clicking sounds that could bother the patient to some extents, TMJ pain, episodic and momentary catching of smooth jaw movement may also be associated symptoms of DDR (8). Nonetheless, not all patients with TMJ clicking require treatment. Only those with painful joint noise or evidence of progression of the joint dysfunction should receive some kinds of treatment (9).

Treatment of patients with painful TMJ DDR includes medication, occlusal splints, physical therapy, and surgery. However, there is evidence that reciprocal clicking does not usually progress to locking (10, 11). Therefore, it is widely accepted that every therapeutic effort should firstly be focused on non-surgical management. Among various types of conservative treatment, occlusal splint therapy has received much popularity since 1970's.

Among many types of occlusal splints, a stabilization splint (SS) and an anterior repositioning splint (ARS) have frequently been used in the treatment of DDR. However, the rationale for each splint differs greatly. The SS aims to create the best condition for tissue recovery without concerning disk position (12). The ARS, on the other hand, has originally been designed to recapture the displaced disk by positioning the mandible anteriorly during wearing (13, 14).

In short-term studies (15-17), a full-time (24-hour) wearing of ARS seems to provide favorable results in the management of DDR than those of the SS. However, posterior open bites are a frequent consequence of a continually full-time wearing of ARS (18-20). This occurrence may need either continued splint wear or bite closure by equilibration, prosthetics, or orthodontics which would cause additional expense to patients.

In order to avoid the unwanted occlusal changes related to the ARS therapy, the philosophy of an ARS in view of academicians has been recently changed to part-time use (19, 21, 22). They recommended using an ARS at nighttime or only 8-10 hours a day. In addition, the ARS should be used after unsuccessful pain reduction from the SS therapy (19). This suggestion indirectly reflects the belief in the superiority of the ARS over the SS in the management of DDR symptoms.

However, the effectiveness of ARS could be compromised by the pattern of splint usage. As shown in the study by Davies et al. (23), a 24-hour wearing provides the best result (88% improvers) over a 3-month period of treatment, followed by nighttime use (65%) and daytime use (52%). In addition, the effectiveness of ARS in the treatment of TMJ DDR in part-time use in comparison with those of the SS in a randomized controlled trial has never been reported. Therefore, the potential benefits of part-time use of an ARS are still subject of much debate.

When well-designed clinical trials are lacking, it is difficult to establish standard of care for symptomatic DDR patients. It is difficult to decide which type of splints should be provided for those patients to maximize a clinically meaningful outcome. Thus, there is a need for a randomized clinical trial in order to investigate the effectiveness of nighttime use of an ARS and a SS in the treatment of symptomatic TMJ DDR.

The primary intention of this study is to determine the success rate of nighttime use of the ARS in comparison with that of the SS in a short-term follow-up. At present, there is no uniform of treatment outcome measures for patients with DDR. Thus, this study would concentrate on patient-oriented outcome measures, i.e., the evaluation of the important improvement ($\geq$50% reduction) of average pain intensity and composite functional score measured in visual analog scales.

The result of this study will help establishing a standard practice in the management of symptomatic DDR patients. It is interesting to note that all dental schools in Thailand are still reluctant to include an ARS therapy in the undergraduate curriculum. The SS therapy has only been taught for the reason that it is more conservative and easy to fabricate. If nighttime use of ARS has been proved to yield better treatment outcome with no complication, then it could be introduced into a practice guideline and later into the revision of undergraduate dental curriculum.

CHAPTER 2

REVIEW OF LITERATURE

Definition of TMJ Disk Displacement with Reduction

Temporomandibular joint (TMJ) disk displacement with reduction (DDR) is a kind of TMJ disk interference disorders, or so-called internal derangement of the TMJ **(24)**. It is considered to be one of a subgroup of temporomandibular disorders (TMD) **(1)**. Internal derangement refers to any abnormality within the joint, shown by an abnormal relationship of the disk to the mandibular condyle and articular eminence. In disk displacement with reduction the disk is displaced anteriorly or anteromedially to the condyle in the closed position. During opening, the condyle slides over the posterior band of the disk. Finally, normalization of condyle disk relationship can occur, i.e., the condyle articulates against the thin intermediate zone of the disk. During closing the condyle then slips posterior and rests on the retrodiskal tissue with the disk returning to the anterior or anteromedially displaced position **(24)**.(Figure 2.1)

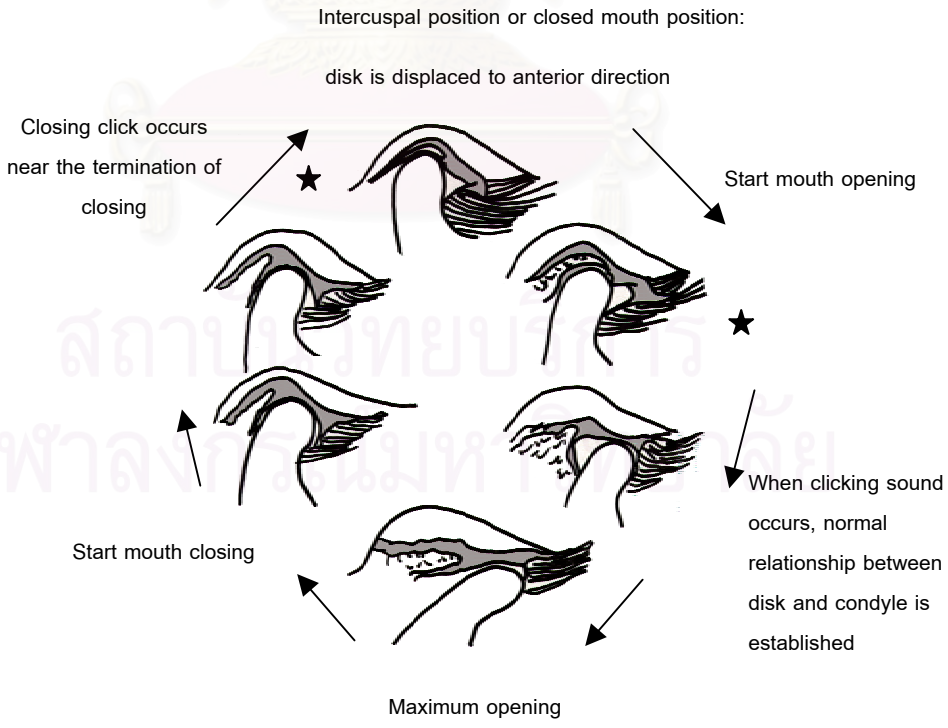


Figure 2.1 Relationship between TMJ disk and mandibular condyle in disk displacement with reduction, sagittal view

Although disk displacement may be either rotational displacement or sideway displacement or combination of both, the disk is often displaced in an anteromedial or anterior direction. Rotational disk displacements were observed in 53% of the anterior disk displacements with reduction group (25). Therefore, rotational displacement was the most likely a characteristic of DDR (26).

Clinical Presentations of Disk Displacement with Reduction

Disk displacement with reduction is usually presented as clicking on mouth opening and closing at different positions or so-called reciprocal clicks (3). The opening click is usually louder than the closing click. It is generally accepted that reciprocal clicking is considered to be pathognomonic for the first stage of TMJ disk displacement (24).

In addition, during mouth opening jaw deviation to the affected side can be observed. Until the click occurs, mandible then returns to midline after the click. Thus, patients often report a limited range of opening until the disk is reduced (opening click occurs), thereafter a range of mandibular movement becomes normal. Not only a normal range of jaw motion during mouth opening, patients frequently show a normal range of eccentric movements. When keeping the mandible in a slightly protruded position after recapturing the disk, catching sensation could be eliminated. Patients often present without any pain. Thus, deviation is considered another characteristic finding of anterior DDR but pain is not a characteristic of this condition (8).

Some patients present with reciprocal clicking with intermittent locking. These patients usually complain about the jaw becomes locked associated with some pain over the affected joint. Some kinds of maneuver such as applying the pressure over the affected joint or shifting the jaw side to side may be needed to unlocked the joint. Reciprocal clicking with intermittent locking is considered as the second stage of disk displacement (14).

DDR can impair masticatory function to some extent. Occlusal contact area, bite force, and masticatory efficiency of the patients with anterior disk displacement with reduction (ADDR) were significantly smaller than those measured in the controls (27). Nonetheless, there is no report related to quality of life of patients with DDR.

Whereas pain is not a characteristic of DDR, it is widely accepted that any treatment should be provided only for those patients with pain associated or jaw dysfunction that interfere daily life activities (19).

Natural Courses of Disk Displacement with Reduction

Originally, it has been hypothesized that disk displacement is presented as a continuum, progressing from clicking to clicking with intermittent locking to closed lock and finally disk perforation (28). Then, every therapeutic method should be focused on correcting this condition in order to prevent disease progression.

However, most patients do not show symptom progression through these stages of derangement. At present, there is much evidence to support that DDR is not necessarily progressive. Clicking tends to remain but not progress to locking in most patients. Joint sounds come and go and are often unrelated to major masticatory symptoms (29, 30). Several studies reported that only 4% to 9% of the patients with TMJ sounds developed to advance stage, i.e., disk displacement without reduction or locking (11, 12, 29). Neither TMJ osteoarthrosis nor radiographically visible degenerative changes develops 30 years after nonsurgical treatment of DDR (31). In addition, the prevalence of clicking and nonreducing disk displacement does not increase with age (32, 33). Therefore, asymptomatic joint sounds become less clinical significance than the previously belief.

Nevertheless, progression to closed lock seems to be more likely (as high as 20%) in patients with pronounced joint pain and disturbed joint function, temporally locking, and a deep anterior recess of the lower joint compartment (34). At present, it is still a difficult task for clinicians to predict whether that particular patient will develop to the advance stages.

Diagnosis of Disk Displacement with Reduction

Clinicians often use a common sign “reciprocal click” as a key to a diagnosis of DDR. According to the research diagnostic criteria for temporomandibular disorders (RDC/TMD) (1), disk displacement with reduction has been defined as:

“either:

- reciprocal clicking in TMJ (click on both vertical opening and closing that occurs at a point at least 5 mm greater interincisal distance on opening than on closing and is eliminated on protrusive opening), reproducible on two of three consecutive trials; or
- click in the TMJ on both vertical range of motion (either opening or closing), reproducible on two of three consecutive trials, and click during lateral excursion or protrusion, reproducible on two of three consecutive trials.”

Although this operational definition for the diagnosis of TMJ DDR has been proposed by the group leader in the field, the validity of the criteria has recently been challenged. Slater et al (35) recorded the condylar movement of 30 participants with a unilateral anterior DDR. The opening clicks were found over a broad range of the opening movement, while all the closing clicks occurred just before the condyle reached its terminal position in the fossa. They concluded that the 5-mm criterion of the RDC is not characteristic of all anterior disk displacements with reduction (35). Thus, the use of RDC/TMD was insufficient reliable for determination of DDR. It is also doubtful that the human ear can distinguish the reciprocal click associated with DDR from clicks due to deviation in form (36). However, when clinical examination was accompanied by the additional tests, anterior DDR can be diagnosed with high accuracy (90%). Those additional tests were whether the clicking is eliminated at a protrusive position, and whether the clicking become louder when manipulates the mandible toward the eminences (37). Caution is needed when any diagnostic assignment includes joint sounds as an essential criterion. It has been reported that 40% of patients with anterior disk displacement without reduction demonstrated clicking during mouth opening (38).

Nowadays, the magnetic resonance imaging (MRI) of TMJ becomes a gold standard in making a diagnosis of TMJ DDR. When standardized classification criteria are used, moderate to substantial observer agreement across all defined categories of disk status may be achieved (39). When the validity of the RDC/TMD was compared with the magnetic resonance findings, the positive predictive value for disk

displacement with reduction ranged from 44% (40) to 65% (41). The overall diagnostic agreement for DDR was 47.6% (40). Therefore, clinical findings alone may not be correctly indicates the exact status of the disk-condyle relationship (40, 42). While MRI can help determining the functional 'disk-condyle relationship', it is considered an expensive diagnostic method. It should be preserved for surgical planning and in difficult cases to diagnose pathological condition of the TMJ. Until now, an operational definition of DDR proposed in the RDC/TMD is still used for research purposes. However, ones should be aware of its limitation.

Prevalence of Disk Displacement with Reduction

Epidemiologic studies have used “clicking” as a signs of TMJ internal derangement. The study methods frequently used are clinical examination and /or using questionnaire or interviewing. Clicking is common in general population as well as in patient population, but the symptomatic patients present with TMJ clicking of higher prevalence than that of general population (21).

In western countries, TMJ clicking was found in an average of one-third of the people examined with a wide range between 8% to nearly 80% (43). The reported prevalence varies among studies. The difference in findings may be due to the differences in study samples, methods of study, methods of clinical examination, and the operational criteria. Using the research diagnostic criteria for TMD (RDC/TMD), DDR was found 10% in Singapore (44), 33% in Sweden and approximately 20% in the US. (45). In Thailand, data on the prevalence of DDR based on the RDC/TMD were not existed. However, Vanichanon et al. reported 32.6% of non-TMD patient subjects aged 20-60 years demonstrated TMJ clicking as determined by clinical examination (7).

Since 1990’s, the MRI has become increasingly used in TMJ research. Asymptomatic disk displacement is also common in MRI studies. Larheim et al. reported 21.8% of asymptomatic volunteers demonstrated TMJ DDR revealed by MRI (46). Prevalence of TMJ DDR in patient population may vary depending on the study samples. In 58 patients with pain and jaw dysfunction, 22.6% were found to have partial disk displacement (46). In a specific group of patients with TMJ disorders, 68% revealed anterior DDR (47). There was no statistically significant difference in the

distribution of disorders on a unilateral or bilateral basis or in the prevalence of disorders in right versus left joints (42).

Etiology of Disk Displacement with Reduction

It is difficult to determine the exact cause of TMJ DDR that is often multifactorial. However, some major causes are more likely to be involved. Those include macrotrauma and microtrauma such as bruxism. Non-MVA (motor vehicle accidents) trauma was found the major defining feature of the temporomandibular joint intracapsular disorders (48).

The association between occlusal variables and DDR is still inconclusive. However, using a multifactorial analysis patients with DDR are most characterized by unilateral posterior crossbite and longer RCP-ICP slides (49).

TMJ morphology has been studied for a predisposing factor for TMJ internal derangement with inconsistent results. Disk displacement is less likely to be found in joints with a shallow articular eminence (50). In other words, a steeper posterior slope and higher articular tubercle are predisposing factors for the development of DDR (51). However, a study by Gokalp et al. found that there was no correlation between movements of the disk-condyle assembly and the steepness of the articular eminence in the DDR group (52). There is evidence that posterior movement in ipsilateral excursion of the condyle could be a high risk factor for developing the clicking conditions (53).

Management

While reciprocal clicking does not usually progress to locking, every therapeutic effort should firstly be focused on non-surgical management (19). Non-surgical options that should be considered for treatment of patients with symptomatic TMJ DDR include patient education, physical therapy, occlusal splint therapy, and pharmacotherapy (19, 21).

Patient education is very important. Those included a brief description of the mechanism of disk displacement, an instruction to eat softer food, the disorder natural course and treatment options so that reasonable expectation can be met. A well informed patient could play a vital role in the treatment since the patient will use the

jaw more carefully. Thus, patient education can help modifying the patient's behavior and will benefit for patients (21). For ethical reason, patient information should be given to every patient. However, it could affect the treatment outcome evaluation in clinical trials provided that it was given to the subjects unequally in control group and experimental group.

Physical therapy includes different modalities such as hot moist towels, ice cubes, or jaw exercises etc. Although various modalities are widely used, the effectiveness of physical therapy in the treatment of DDR has not been widely substantiated by a randomized controlled clinical trial. Recently, therapeutic jaw exercise for clicking due to DDR has been introduced in a randomized controlled trial and demonstrated moderate success rate (62%) (54).

The most commonly used medications for TMJ pain are the non-steroidal anti-inflammatory agents (19). In the absence of pain, it is unnecessary to prescribe any medication for treating disk displacement with reduction. Therefore, pharmacotherapy should be used only when moderate to severe pain involved.

Occlusal Splints Therapy

Stabilization splints and anterior repositioning splints

Occlusal splints whether designed as stabilization splints (occlusal appliances) or anterior repositioning splints are served to be more conservative therapies for patients with symptomatic DDR than surgical repositioning or resection of the articular disk. However, the rationale for each splint differs greatly.

Stabilization Splints (SS)

The design frequently used is a hard, clear, heat-cured acrylic splint or so-called "stabilization splint". It covers all of the teeth in the dental arch and has flat occlusal centric stops with simultaneous tooth contact for all of the opposing teeth. In addition, it has a mild gradual canine rise starting 0.5 mm from the centric occlusion. This canine rise helps preventing non-working interferences and protrusive interferences during mandibular excursive movements (18). It can be fabricated for either upper or lower dental arch. Carlsson and Magnusson suggested that it should be placed in the jaw that could provide the best occlusal stability, i.e., the jaw with the

least number of remaining teeth (21). A maxillary splint usually preferred for the reason that it is usually more stable, more retentive and less likely to break (19). A detailed manual of fabrication and adjustment of stabilization splints has been provided in a number of textbooks and will not be included here. Ramfjord and Ash suggested that if the patient has reciprocal click close to the intercuspal position, the thickness of the splint should be raised beyond the click (18). However, this suggestion has never been evaluated for its beneficial via clinical trials.

Stabilization splints are widely used in the treatment of temporomandibular disorders (TMD). By using the SS, a more favorable distribution of the loading of the masticatory system could be obtained. In addition, the SS can reduce muscle activity. These possible mechanisms could lead to a decrease in the signs and symptoms of TMD (21). However, the available evidence suggests that the SS do not recapture the displaced disk (55). The SS sometimes reduce the clicking but not cured. TMJ clicking is the least responsive to treatment (56). In a long-term study of clicking status, about one third of patients reported unchanged and the other two-third reported cessation or improvement (12). In terms of its effectiveness, the SS demonstrated significantly reduced TMJ pain symptoms in comparison with those of the control splints in a randomized controlled trial (57). Nevertheless, the study by Kurita et al.(58) suggested that the presence of displaced disk significantly reduced the effectiveness of the SS.

The proponents think that TMJ symptoms can effectively be resolved without taking into consideration the disk position. Therefore, the SS aim to create the best condition for tissue recovery and TMJ remodeling by using centric relation (CR) as a therapeutic position. The flat surface design helps increasing the stability between the maxilla and the mandible. In consequence, the affected TMJ could be able to perform its function even without an optimum condylar position (12).

Anterior Repositioning Splints (ARS)

Like the SS, the ARS may be fabricated for either upper or lower dental arch. The fabrication of ARS has been well described by Clark (59). By its design, definite occlusal indentations or a guide ramp helps the mandible protruding into a new forward position in a period of time. Then, a normal relationship of the disk to the

condyle and eminence could be maintained when the splint is worn. These splints often provide quick relief from pain. Then, ARS have been described as a suitable treatment for patients suffering from DDR in order to decrease adverse joint loading, decrease pain and decrease joint clicking (56, 59, 60).

The representatives of ARS originally believe that DDR is progressive. Thus, every click is considered as pathological symptoms. Consequently, ARS aim to recapture the displaced disk by positioning the mandible anteriorly, and thus could reduce the clinical problems that are thought to be caused by its dislocation (14). Many clinicians, for example, Lundh et al.(17) suggested that the final therapeutic position, obtained at the end of the ARS therapy, must be stabilized by means of permanent rehabilitation. This approach certainly increases the cost of treatment to the patients.

Comparison between Two Splints

In early short-term studies (not more than 6-month duration), ARS seemed to provide favorable results in reducing TMJ symptoms than those of the SS (15-17). The followings are three original clinical trials that are most cited regarding the comparison between two splints.

Anderson et al (15) compared an ARS to a maxillary SS with 20 patients. Inclusion criteria included 1). Reciprocal clicking of the TMJ 2). elimination of reciprocal clicking by repositioning the mandible in a protrusive position, and 3). subjective and objective evidence of joint and muscle pain. The patients were randomly assigned to one of the two treatment groups.

Patients in the SS group were instructed to wear a maxillary SS on a full-time basis (24 hr per day for 12 weeks). Those in the ARS group were instructed to wear a mandibular splint 24 hr per day for 6 weeks. At the end of week 6th, a mandibular Gelb-type appliance were given for them. So the last 6 weeks, they wore the ARS at nighttime and the Gelb-type appliance during the day.

Subjective data collected included the Helkimo Anamnestic Index (Ai) and objective data included Helkimo's Clinical Dysfunction Index (Di) and Helkimo's Occlusal Index. All evaluation were conducted by an independent examiner.

At posttreatment, there was no change in the SS group relative to the Ai, while 60% of the patients in the ARS group improved. This finding was significant at a p value of 0.01. Objectively, in the SS group 10% improved, 70% no change, and 20% got worse. No significant change was found in the Di. In the ARS group 70% showed an improvement in Di and 30% had no change. This finding in the ARS group was significant at a p value of 0.01. During treatment, 2 patients (20%) in the SS developed to a clinical diagnosis of closed lock whereas non in the ARS group. The authors concluded that ARS therapy provided significant improvements in these patients relative to the SS.

Lundh et al. (16) conducted a clinical trial in which they randomly assigned patients among ARS therapy, maxillary SS therapy, and a no-treatment group. After screening 568 patients, only 70 patients (12.3%) met their inclusion criteria and enrolled in the study.

Patients in the SS group were instructed to wear SS at nighttime for 6 weeks; then its use was gradually decreased during the following 2 weeks until it was no longer used. Those in the ARS group were instructed to wear a maxillary splint 24 hr per day for 6 weeks. Its use was gradually reduced during the following 2 weeks until it was no longer used.

Patients were clinically examined for objective data. In addition, pain at rest, during chewing, and during protrusion was recorded by the patient on a 100-mm VAS. The same procedure was accomplished before treatment and at 6, 17, and 52 weeks.

They found that at the 6th week the ARS group had a superior outcome than the no-treatment control group. When the SS group was compared to the control group, both groups showed a significant reduction in pain but not reciprocal clicking. When the ARS was compared to the SS, the only significant difference was that there was a decrease in reciprocal clicking in the ARS group as compared to the SS group. However, the apparent effects of the splints were not maintained.

Three years later Lundh et al (17) published another RCT comparing patients who had anterior repositioning of their mandible using disk-reposition onlays versus a SS or no treatment. This study involved 63 patients. Single-contrast lower compartment arthrgraphy was preformed for all symptomatic joints to verify the diagnosis. Patients in

the SS group were instructed to wear SS at nighttime for 6 months. Those in the onlay group were instructed to use the cemented onlay for 6 months.

Clinical examination and questionnaires were conducted before and after 6 months of treatment. In all clinical findings, the onlay group had significantly better results than the controls. In comparing the onlay group relative to the SS group, no significant differences were found between pain during chewing and pain during protrusion. However, reciprocal clicking was significantly decreased in the onlay group as compared to the SS group and the control group.

These studies lead the profession to believe that repositioning the disk was an essential part of treatment. However, TMJ symptoms particularly clicking sounds have usually returned when patients stop wearing it.

In long-term studies (9, 29, 61) the success rates of ARS were much lower; and relapse rates of clicking were relatively high. In a 2.5-year study (9), 66% of the patients still demonstrated joint sounds but only 25% experiencing pain problems. When the presence of asymptomatic joint sounds is not a rationale for treatment failure, the success rate for ARS rises to 75 %.

In a meta-analysis study, full-time use of ARS has been suggested to be more effective in the resolution of the articular click and of the pain in the treatment of disk displacement with reduction (62). However, those original studies (15-17) did not fulfill the rules of clinical trials suggested by Guyatt et al. (63). Recently in a systematic review, the original studies by Anderson et al. (15) and Lundh et al.(16) demonstrated relatively low quality score of RCT (0.39 and 0.44, respectively) (64, 65). Therefore, the potential benefits of ARS are still subject of much debate.

Frequently, it has been suggested to wear ARS for a full-time basis for maximum benefit. However, a long term full-time wearing (24-hour use) of ARS could lead to posterior open-bite. Then recommendation for ARS now is to reduce the time the splint is being worn. Okeson (19) as well as Carlsson and Magnusson (21), in their textbooks, have recommended using ARS for 8 to 10 hours during sleep to minimize adverse occlusal changes. Actually, wearing an ARS for 24 hours per day provides better outcome than part-time use. Anyhow, nighttime use yields better results than daytime use (23). Although ARS have been used for more than 20 years, surprisingly,

the effectiveness of the ARS in part-time use has never been published in a randomized controlled trial.

Recently, the efficacy of ARS has been studied by using MRI. With the insertion of the splint, corrected disk position has been demonstrated in more than 50% of the anterior DDR patients (66-68). However, the ARS appear much less effective in cases with TMJ disk displacement without reduction (66). The possibility for disk recapture depends on the disk-condyle position and disk configuration, the integrity of the posterior attachment, and the degree of degenerative changes of the intra-articular structures, such as osteophytosis, condylar erosion, or flattening of the articular disk (66).

Treatment Outcome Measurement

According to LeResche, reliable physical and behavioral outcome measures are available for assessing the following: clinical signs and symptoms of temporomandibular disorders; pain intensity; affective aspects of pain; pain-related coping; pain behaviors, including expressive behaviors, activity limitation and use of health services; as well as pain-related disability and life interference (69).

Regarding the evaluation of occlusal splint therapy in the treatment of temporomandibular disorders, various treatment outcome measures have been used. Those includes subjective evaluation such as pain measurement on visual analog scale (17, 57, 70, 71), composite pain index (72), improvement of overall subjective symptoms (57), jaw function difficulties (71, 73, 74), and quality of life (70). Clinical signs and symptoms have also frequently been used (for example: maximum mouth opening, TMJ sounds, pain on movement, pain on palpation)(16, 17, 57). Some studies have used some kinds of validated symptom measurement system such as TMJ scale (75), Helkimo clinical index (57) or Craniomandibular index (CMI)(72, 76).

None of them is considered the best outcome measures. Most studies applied different set of variables to demonstrate the effectiveness of the splints. Therefore, it is difficult to make a comparison among studies. Table 2.1 shows different outcome measures in the previous studies regarding the treatment of TMJ DDR.

Table 2.1 Outcome measures used in previous clinical studies on use of occlusal splints for treatment of DDR.

Study	Outcome measures	Variables / Criteria
Anderson et al.(15)	Number of patients with improvement, no change, exacerbation	Helkimo anamestic index (Ai) Helkimo clinical dysfunction index Helkimo occlusal index
Lundh et al. (16, 17)	1. Changes in pain VAS	Pain during chewing, protrusion (VAS) and disturbed joint function (VAS)
	2. Number of patients with clinical findings	Reciprocal clicking Tenderness to muscle palpation
Moloney & Howard (61)	Number of success cases	criteria for success for ARS therapy: 1. free of pain 2. no longer wear ARS 3. free of clicking and locking
Okeson (9)	Number of success cases with various criteria of success	various criteria of success 1. free of pain, clicking, locking, no ARS 2. free of pain, locking, no ARS 3. free of pain, no ARS 4. patients' subjective evaluation
Davies and Gray (23)	Number of improvers	Criteria for improvers 1. improved or resolve of symptoms 2. objective improvement of range of motion, joint noises, and of the muscles

Recently in 2003, there was a consensus that in conducting chronic pain clinical trials, six core domains: 1) pain, 2) physical functioning, 3) emotional functioning, 4) participant ratings of improvement and satisfaction with treatment, 5) symptoms and adverse events, 6) participant disposition, should be assessed (77).

While VAS pain scores have widely been used in the field of temporomandibular disorders, the functional scores are lesser used. This may be due to no parameters of odontostomatognathic disability have been established (78). Those include problems with mastication, deglutition, digestion, speech, facial expression, respiration, sexual

activity, appearance and posture. Some studies applied daily activity limitation scores in the assessment of treatment outcome (73, 74, 79). The number of item questionnaires varies among studies. A functional index based on multiple VAS (10 jaw activities) was used in Freund et al.'s studies (73, 74) who evaluated the effectiveness of botulinum toxin for the treatment of temporomandibular disorders.

The use of important improvement (relevant change, significant improvement) as a treatment outcome has become increasingly used in many clinical trials particularly in medical field. Significant improvement generally means improvement higher than 50%. The magnitude of improvement of patients' initial symptoms can be evaluated by a lot of means such as using a numeric rating scale (69) or direct measuring in VAS. In the field of temporomandibular disorders, Linde et al. have used similar outcome measure (>50% VAS pain reduction) in their study to compare the effectiveness of occlusal splints and transcutaneous electrical nerve stimulations (TENs) in the treatment of disk displacement without reduction (80). A study by Forouzanfar et al. suggested that relative pain reduction of 50% or more and an absolute pain reduction of at least 3 cm on the VAS are accurate in predicting a successful pain reduction after a given treatment (81).

CHAPTER 3

RESEARCH METHODOLOGY

Research Questions

A. Primary question:

Does nighttime use of anterior repositioning splints provide 35% more patients with ≥50% reduction in pain and functional VAS scores than that of stabilization splints in the treatment of symptomatic TMJ disk displacement with reduction in a short-term follow-up?

B. Secondary questions:

1. Does nighttime use of anterior repositioning splints provide better outcome in overall symptoms self-assessed by patients than that of stabilization splints?

2. Does nighttime use of anterior repositioning splints provide better outcome in reducing TMJ clicking than that of stabilization splints?

3. Does a posterior open bite occur as a result of nighttime use of anterior repositioning splints?

Research Objectives

A. Primary objective

To determine the effectiveness of nighttime use of anterior repositioning splints in the treatment of symptomatic TMJ DDR in comparison with that of stabilization splints in terms of important improvement.

B. Secondary objectives

1. To determine overall symptom improvement in patients with TMJ DDR treated by anterior repositioning splints and stabilization splints.

2. To evaluate the effectiveness of anterior repositioning splints compare with those of stabilization splints in the reduction of TMJ clicking.

3. To assess the incidence of posterior open bite associated with nighttime use of anterior repositioning splints.

Research Hypothesis

A. Research hypothesis

Nighttime use of anterior repositioning splints provides more patients with important improvement in the treatment of symptomatic TMJ DDR than that of stabilization splints in a short-term follow-up at the effect size of 35%.

B. Statistical hypothesis

Null hypothesis: $P_{ARA} = P_{SA}$

Alternative hypothesis : $P_{ARA} \neq P_{SA}$

P_{ARA} : proportion of patients whose TMJ symptoms are important improvement by an ARS therapy

P_{SA}: proportion of patients whose TMJ symptoms are important improvement by a SS therapy

Keywords

occlusal splints, randomized controlled trial, TMJ disk displacement with reduction, treatment outcome

Conceptual Framework

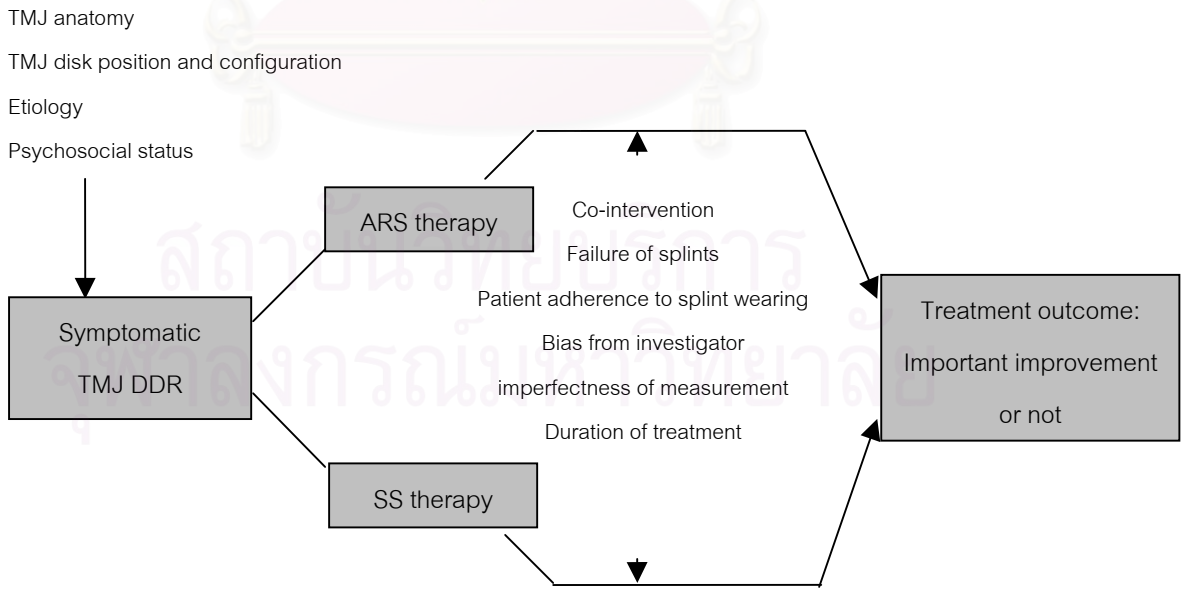


Figure 3.1 Conceptual framework

Operational Definitions

1. Disk placement with reduction: either

1.1 reciprocal clicking in TMJ (click on both vertical opening and closing that occurs at a point at least 5 mm greater interincisal distance on opening than on closing and is eliminated on protrusive opening), reproducible on two of three consecutive trials; or

1.2 click in the TMJ on both vertical range of motion (either opening or closing), reproducible on two of three consecutive trials, and click during lateral excursion or protrusion, reproducible on two of three consecutive trials **(1)**.

2. TMJ Clicking: A single distinct snapping, popping or cracking sound of short duration emanating from the TMJ during movement that was audible to or palpable by the examiner.

3. TMJ pain: Pain localized in TMJ region either at rest or during jaw movements.

4. Symptomatic TMJ disk displacement with reduction: Disk displacement with reduction associated with average TMJ pain and/or functional problem of greater than 2 in 10 of VAS for at least two months.

5. Patients with important improvement: Patients who demonstrate at least 50% reduction in the pre-treatment pain score and the composite functional score. In case only one problem exists, at least 50% reduction in the pre-treatment score of that particular problem is needed in order to constitute for important improvement.

6. Posterior open bite: no posterior tooth contact in the maximum intercuspation (intercuspal position, ICP) determined by shim stock foil despite the present of opposing posterior teeth.

Research Design

This study was carried out in a randomized controlled clinical trial. All eligible patients were randomly assigned to one of the two groups: ARS or SS. A research assistant operated the process of simple randomization.

One faculty staff in the Department of Occlusion (investigator 1) completed the screening for cases, comprehensive history and clinical examination process as well as evaluation after treatment. This person was blinded to the treatment group. Another

faculty staff in the same department (investigator 2) only delivered and readjusted the splints without any other involvement in the treatment. However, patients were not fully blinded to the splint they received.

Research Methodology

A. Population and Sample

Population:

Patients with TMJ disk displacement with reduction (DDR)

Target population:

Patients with symptomatic TMJ DDR.

Study population:

Patients with symptomatic TMJ DDR at the graduate clinic, Department of Occlusion, Faculty of Dentistry, Chulalongkorn University

Sample population:

Patients with symptomatic TMJ DDR at the graduate clinic, Department of Occlusion, Faculty of Dentistry, Chulalongkorn University who fulfill the eligible criteria

B. Eligible Criteria

1. Inclusion criteria

a. Age between 15-65 years

b. Patients who fit to the operational criteria for TMJ DDR

c. TMJ pain or dysfunctional problems of grater than 2 in 10 VAS

d. Pain or jaw dysfunctional problems occurred at least two months

e. Elimination of reciprocal clicking by repositioning the mandible in a protrusive position

f. Patient was able to return to clinic for at least 6 months follow-up

2. Exclusion criteria:

a. Asymptomatic clicking / popping

b. Pain diffusely spread in the masticatory muscles

c. Previous treatment with occlusal splints

d. A history of psychiatric disorders or symptoms associated with pain from other sources in orofacial area.

e. Acute TMJ pain requiring pharmacologic management

f. Patients with upper and/or lower full denture or those who cannot wear a splint

C. Sampling Method

Subjects in this study were recruited from patients referred for treatment of temporomandibular disorders (TMD) at the graduate clinic, Department of Occlusion, Faculty of Dentistry, Chulalongkorn University during March 2001-October 2003. After screening examination and brief history, only those who fulfilled the eligible selection criteria and already signed informed consent were enrolled in the study.

D. Allocation and Concealment

All eligible patients were randomly assigned to one of the two groups: ARS group or SS group. A research assistant undertook a process of simple randomization using a table of random number. This person kept a randomization list and assigned intervention for the randomization scheme. After an assistant had recorded a treatment assignment sequence, the assigned interventions were kept sequentially numbered in opaque, sealed envelopes.

The treatment allocation for each patient was not revealed until the patient had been signed the consent form entering into the study. The allocation sequence was kept separately. Only a dental assistant who wrote the prescription of occlusal splints for a dental technician was allowed to open those envelopes.

E. Blinding

One faculty member in the Department of Occlusion (investigator 1) performed the screening, history-taking, and clinical examination as well as post-treatment evaluation. This person had no information as to which group the patient belonged. Another faculty member in the same department (investigator 2) only delivered and adjusted the splint without any other involvement in the information gathering.

The patients were not told as to which arm of randomized grouping they were in. However, due to the difference in splint design, thus, it is not possible to fully blind the subjects to which type of splint they received.

All the codes were revealed at the time of analysis. No attempt was made to blind the investigator to treatment results.

F. Intervention

Patients received either an ARS or a SS according to the treatment assigned. Patients in the SS group got a stabilization splint. The stabilization splint was designed to be similar to that advocated by Ramfjord and Ash (82). With a flat and smooth surface, the SS covered all teeth in the arch with the opposing teeth in contact in the centric relation position. A canine rise helps to prevent posterior teeth contact during excursion and protrusion. Therapeutic position for the SS is centric relation.

Patients in the ARS group received an anterior repositioning splint. The splint, placing on the maxillary teeth, was designed to keep the mandible in the anterior position. This anterior position was maintained through an anterior reverse incline at the anterior teeth. Contact of the anterior reverse incline with the lingual surfaces of the mandibular anterior teeth guided the mandible into the protrusive treatment position. Therefore, during construction of the splint, the patient was instructed to open and close in a protrusive end-to-end anterior relationship. This treatment position must eliminate the TMJ clicking to indicate reduction of the anteriorly displaced articular disk. This maxillary splint design followed that of suggested by Clark (59). It had a smooth surface with all opposing teeth in contact at the protruded position with 1 mm cuspal imprints for the mandibular posterior teeth.

Both types of splints were placed on the maxillary teeth. Except those whose lower jaw had less number of the remaining teeth, the mandibular splint would be fabricated in order to enhance occlusal stability. Patient in both groups were instructed to use the splints during the night at least 8 hours per night for 10 weeks.

For ethical reason, all patients received patient-education and self-care instructions at the first visit. They were told that no other treatments were allowed.

G. Exit from Protocol

The patients would exit the study in one of the following situations:

1. Upon completion of the protocol.

2. The patient had severe pain and/or dysfunction and wanted to stop wearing a splint

3. The patient decided to withdraw from the study

H. Sample Size

Concerning the evaluation of pain reduction, it is estimated that 65 % of the patients treated by nighttime wearing of ARS response successfully **(23)** and approximately 30 % of the patients treated by SS showed successful response **(62)**.

The suitable formula for sample size calculation for this hypothesis testing is

$$n/group = [Z_{\alpha/2}\sqrt{2P_0Q_0}+Z_{\beta}\sqrt{P_tQ_t+P_cQ_c)}]^2/(P_t-P_c)^2 \quad (83)$$

$P_0 = (P_c+P_t)/2$, $Q_{0:}1-P_0$

Using $\alpha = 0.05$, power of the test = 80 %, $\beta = 0.20$

P_c: proportion of success by SS = 0.30

P_t: proportion of success by ARS = 0.65

Therefore, sample size in each group will be 36.

It is expected to have 5 % drop out and carry out an intention-to-treat analysis. Hence, sample size needed for each treatment group has been computed by the following formula **(84)**:

$n/(1-R)^2$; R=0.05 (drop out rate);

then 40 patients are needed for each treatment group after adjusted for drop out rate and for an intention-to-treat analysis.

I. Control of Co-intervention

Before randomization, patients were introduced about the basic anatomy and function of the temporomandibular joint, mechanisms of clicking, and possible causes of pain as well as the nature of the disk displacement with reduction. All patients were instructed to rest the joint and to avoid hard food and no other treatment was allowed during this study period.

The investigator also asked the patients in every visit whether they had used any medication or other treatment modalities besides an occlusal splint. In case patient received any other treatments or medications, it would be reported in a concomitant treatment report form.

Instruments

For patient enrollment visit:

1. Oral examination set (a mouth mirror, an explorer no.5, a cotton plier)
2. Articulating papers, Shim stock foil and Miller's forceps
3. A ruler in millimeter
4. A case record form
5. A pretreatment self-administered questionnaire (Appendix 1)
6. A clinical examination record form (Appendix 2)

For fabrication of occlusal splint:

1. Dental impression trays (upper and lower)
2. Impression material (Alginate)
3. Plaster bowl and plaster spatula
4. Pink baseplate wax and wax knife
5. Alcohol lamp
6. Stone plaster
7. A semi-adjustable articulator
8. A randomization envelope

For occlusal splint delivery visit

1. Oral examination set (same as above)
2. Articulating papers
3. Carbide bur, Rubber burs
4. An occlusal splint (either SS or ARS)
5. Occlusal splint instruction sheet

For follow-up and evaluation visit

1. Same as the patient enrollment visit and splint delivery visit.

2. A post treatment self-administered questionnaire.

Method

A. Pretreatment Subjective Pain and Functional Assessment

After patients had been orally informed about the detail of the study, they were asked to read patient information sheet (Appendix 3) and signed a consent form (Appendix 4). They were informed as follows: "Both types of splints have been used widely in the treatment of TMJ DDR for more than 20 years. This study, we only want to know which one is better in solving patients' symptoms on the condition that only nighttime is used".

Patients were instructed how to use the VAS prior to completion of a self-administered questionnaire regarding detail of the symptoms. They were asked to place a mark on the 10 cm VAS where "0" is no pain and "10" is the unbearable pain. Regarding pain scores, a pretreatment questionnaire comprised maximum pain VAS, average pain VAS, and pain VAS at the time of answering the questionnaire.

Subjective functional assessments were also performed using VAS. The scales represented chewing, yawning, eating hard food, smiling/ laughing and talking. Patients were asked to place a mark on a line between "0" and "10" where "0" is "no limitation" and "10" is "extreme limitation" which meant patient was unable to perform that particular activity at all due to their TMJ problems. Only 3 additional VASs from chewing, yawning and eating hard food which were usually the most troublesome to patients were averaged to produce a composite functional score.

B. Clinical Examination Method

After completing the questionnaire, one faculty member (investigator 1) performed comprehensive clinical examination and history-taking. Each patient was clinically examined for jaw muscle tenderness, temporomandibular joint tenderness, characteristics of TMJ clicks, range of motion, pain on movement. In addition, patient's occlusion was examined and recorded for the presence of posterior tooth contact in the intercuspal position. The method of clinical examination followed the recommendation for the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) **(1)**.

The degree of tenderness was evaluated according to a 4-point scale: 0 =no tenderness, 1=mild tenderness reported by patient, 2=moderate tenderness with palpebral reflex, 3=severe tenderness with a defense reaction. All data were recorded in the case record form.

C. Treatment Method

After clinical examination, dental impressions were taken for splint fabrication. Subsequently, two bite registrations were performed. One was a centric relation (CR) wax bite, the other was a protrusive wax bite (position that can eliminate TMJ clicks). However, only one type of bite registration was used according to randomly assigned treatment, i.e. CR wax bite for a SS and protrusive wax bite for an ARS.

Later, a dental assistant opened the sealed envelope and wrote down the assigned treatment in the lab prescription form. The dental technician then fabricated the splint as prescribed. After the appliance was returned, the assistant rechecked for the correctness of the splint type before splint delivery. As stated in section F (Intervention), the SS group received stabilization splints (Figure 3.2.1) while the ARS group got anterior repositioning splints (Figure 3.2.2).

At the second visit, a splint was delivered and carefully adjusted by the other faculty member (investigator 2). Before giving the splints to patients, final criteria for the SS and ARS as suggested by Okeson **(19)** had to be met (Appendix 5). In addition, every patient received oral instructions and an additional information sheet regarding insertion and removal of the splint and its proper care. All patients were instructed to wear the splint only at night for at least 8 hours per night.

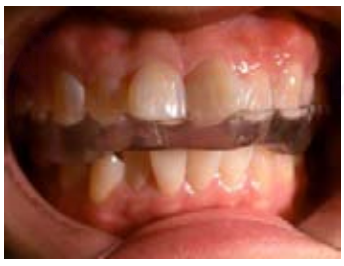


Figure 3.2.1. a stabilization splint

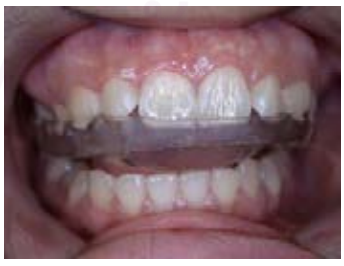


Figure 3.2.2. an anterior repositioning splint

Figure 3.2 occlusal splints

Patients were scheduled for adjustment of the splint two weeks later. No further adjustment was performed during the following eight weeks, except for those who had discomfort or unwanted symptoms would need additional appointments. Subsequent appointments were scheduled 8 weeks later. The total time for follow-up period was 10 weeks. In case a patient was unable to wear the splint during the first two weeks, the time of follow-up would start from the day that patient could wear the splint comfortably.

D. Evaluation Method

After 10 weeks of wearing occlusal splints, patients were scheduled for evaluation of treatment outcome. Patients were asked to assess their pain and jaw function ability using a follow-up questionnaire with the same format as the pre-treatment assessment. Patients' initial scores were shown to them in order to avoid problems with memory of pain and jaw function on the VAS **(85)**. Moreover, patients also assess their overall symptoms and their clicking symptoms (cured or resolved, much better, better, same, worse, much worse). These questions were related to patient's perception of the treatment they received.

After completion of the post-treatment self-administered questionnaires, the patients were clinically examined for evaluation of clinical signs and symptoms. Clinical examination was conducted by the same operator as the first examination (investigator 1). Occlusal examination was assessed particularly for the occurrence of posterior open bite. All data were kept in a case record form.

The period of 10-week follow-up was selected based on the evidence that TMJ pain could be reduced in the time frame **(57)**. Study sequence has been shown in Figure 3.3.

Measurement

A. Variables

1. Independent variable

The independent variable is the intervention given, i.e., the SS splint or the ARS splint.

2. Dependent variable

The dependent variable is the number of patients with important improvement at a 10-week follow-up.

B. Primary Outcome Measurements

The primary outcome is the number of important improvement cases, i.e., number of patients in each treatment group who have at least 50% reduction of pain and dysfunctional scores. Since patient's chief complaints, i.e., pain and dysfunctions are of their major concern, therefore, the outcome measures focus on a combination of the clinical improvement in pain and jaw function.

C. Secondary Outcome Measurements

1. Overall changes in symptom severity assessed by patients according to a 6-point scale.

2. Changes in clicking

2.1 The number of patients who demonstrated no clicking during the examination

2.2 Changes in clicking sound assessed by patients according to a 6-point scale

3. The number of patients who demonstrate posterior open bite related to nighttime use of anterior repositioning splints.

D. Data Collection

Before randomization:

1. Demographic data: age, gender, marital status and education level were recorded in a case record form

2. Self-administered questionnaire:

2.1 Although pain VAS were measured in 3 aspects: maximal pain, average pain and pain at the time of answering the questionnaire. Only average pain VAS was used for further analysis. The assistant measured the distance form 0 to the mark and wrote down in a case record form.

2.2 Subjective functional assessment is also based on a VAS with the endpoint "0" is "no limitation" and "10" is "extreme limitation". Patients have to evaluate their

own jaw functional ability for each of the following activity: chewing, yawning, smiling/laughing, eating hard food, and talking. These VAS scores were summed up and averaged for a composite functional score.

2.3 Other background data include duration of pre-treatment pain, duration of pre-treatment clicking, history of direct trauma to the face and jaw, previous orthodontic treatment, and awareness of bruxism.

3. **Clinical examination**

Before treatment: Clinical examination includes registration of TMJ sounds, lateral and posterior tenderness of TMJ, masticatory muscle palpation tenderness, measurement of jaw mobility, and registration of opening pattern. In addition, patient's static and functional occlusion were examined and recorded.

The degree of tenderness will be evaluated according to a 4-point scale: 0 = no tenderness, 1=mild tenderness, 2 = moderate tenderness with palpebral reflex, 3 = severe tenderness with a defense reaction.

After 10 weeks of treatment: The patients were clinically examined and were asked to re-assess their TMJ pain and their jaw function on the VAS in the self-administered questionnaires.

Subsequently, patients were asked to evaluate their overall changes in symptom severity and changes in their clicking sounds according to a 6-point scale: 0 = symptom-free, 1 = much better, 2= better, 3 = unchanged, 4 = worse, 5 = much worse.

Ethical Consideration

Before starting the study, one investigator thoroughly explained the study objectives and the protocol to the patient or the parents. Every patient had to read the patient information sheet and signed his/her permission to participate in the study in the consent form (Appendix 3 and Appendix 4). The informed consent stated the risks and

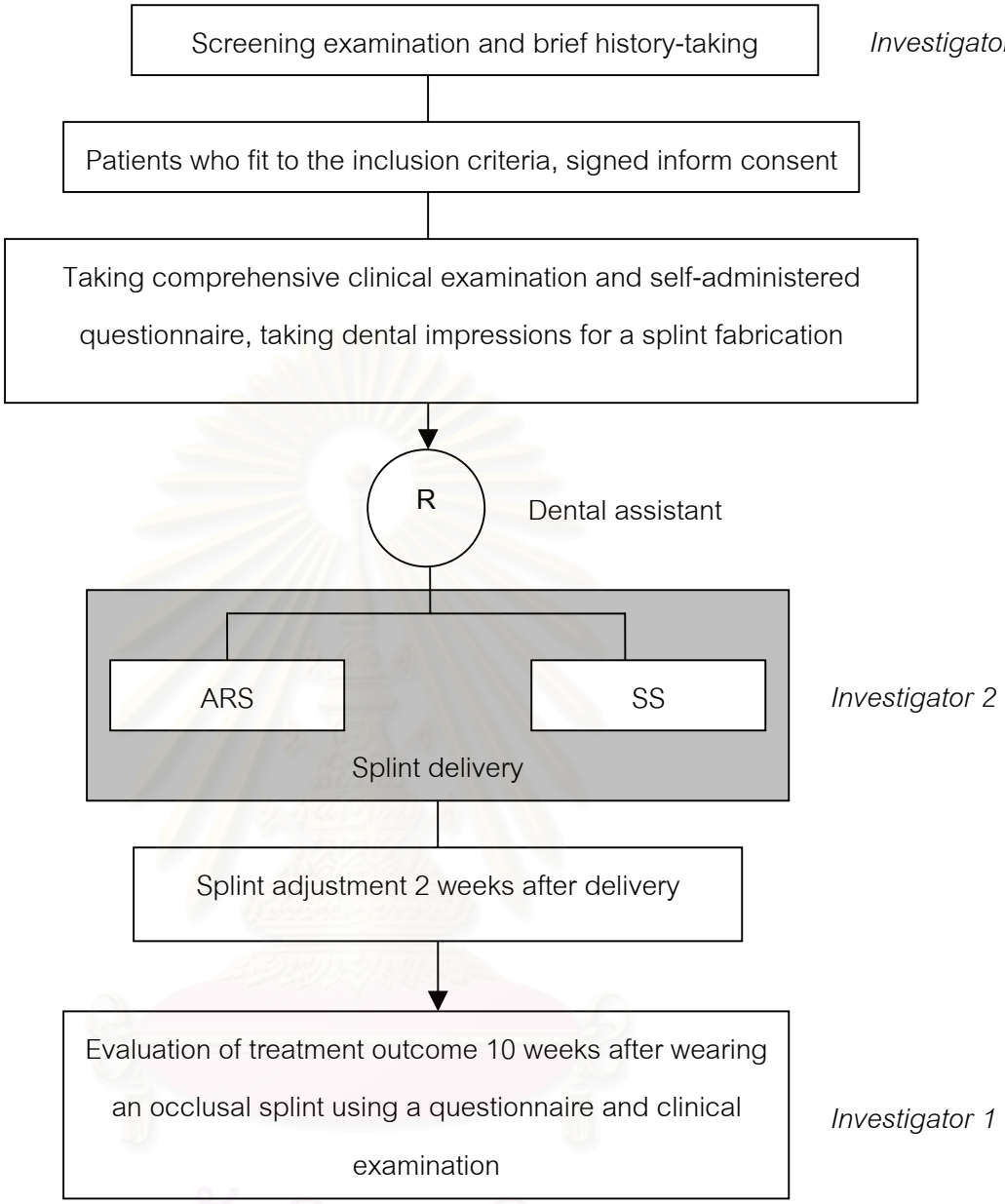


Figure 3.3 Diagram of study sequence

benefits of enrolling the study, and patients could withdraw from the study at any time they want to without affecting the quality of care.

Although full-time use of ARS could cause changing in occlusion, there was no report on the adverse effect of a part-time use of ARS.

In case severe pain occurred during the study, patient would receive medication for relieving pain. Patients were informed that removal of splint would be of necessary in case wearing the splint increased pain or dysfunction to level of intolerable.

The protocol and details of the study were submitted to the Human Ethics Committee of the Faculty of Medicine, Chulalongkorn University. The study protocol was approved with the number of study protocol approval form 167/2001.

Statistical analysis

Statistical analyses were done on an intention-to-treat basis **(86, 87)**. In case of protocol violations such as acute pain needed for medication or in need of splint removal, that particular patient was continually observed. He or she would be included in the further analysis in the group to which he/she was randomized. All tests are two-tailed; statistical significance is set at $p<0.05$.

All statistical analyses were performed by using a statistical software package; (Statistical Package for the Social Sciences, version 11.5, SPSS Inc. and Intercooled STATA 6.0, Stata Corporation, TA, U.S.A.).

A. Baseline Demographic Data and Background Data were analyzed by using descriptive statistics. Continuous data were reported in mean and standard deviation whereas categorical data were reported in proportion and percentages as shown in Table 3.1.

B. Outcome Variables

Primary outcome: The primary objective of this study is to determine whether nighttime use of anterior repositioning splints provide more patients with important improvement than that of stabilization splints in the treatment of symptomatic TMJ disk displacement with reduction in a short-term follow-up.

Upon completion of the study, the average pain VAS reduction and composite functional VAS score reduction were calculated. If the VAS scores reduction (pain and

dysfunction) demonstrated 50% or greater, that particular patient would be grouped into an “important improvement”. The number of patients with important improvement in each treatment group was presented by descriptive statistics in percentage. The chi-square test or the proportional Z test was used to test the difference between two independent groups (the proportion of patients with important improvement in the ARS and the SS groups) for these dichotomous data. In addition, 95% confidence interval for the difference in proportions with successful outcomes was also reported.

Table 3.1 Baseline demographic, background variables and statistics used

Variables	Type of variables	Statistics
Age	Continuous	Mean, S.D.
Sex	Categorical	Percentage, ratio
Duration of TMJ clicking	Categorical (less than 1 month, between 1-5 months, between 6-11 months, between 1-2 years, between 3-5 years, >6 years)	Percentage
Duration of TMJ pain	Categorical (same as duration of TMJ clicking)	Percentage
Awareness of bruxism	Categorical	Percentage
History of orthodontic treatment	Categorical	Percentage
History of facial or jaw trauma	Categorical	Percentage

Secondary outcomes:

1. The number of patients who assessed their overall changes in symptom severity according to a 6-point scale were tabulated and reported in percentages for each treatment group. Comparison of global improvement between the two treatment groups was analyzed by a Mann Whitney U test.

2.1 The number of patients who had no clicking during the examination were tabulated and presented in percentage. Comparison between groups was analyzed by a Chi-square test.

2.2 Patients' self-assessment of their changes in clicking sounds according to a 6-point scale were tabulated and presented in percentage. Comparison of patients' self-assessed in changes in clicking sound between the two treatment groups was analyzed by a Mann Whitney U test.

3. The number of patients who demonstrate adverse occlusal changes related to nighttime use of anterior repositioning splints was described in percentage.

The details of the statistical analysis are presented in Table 3.2.

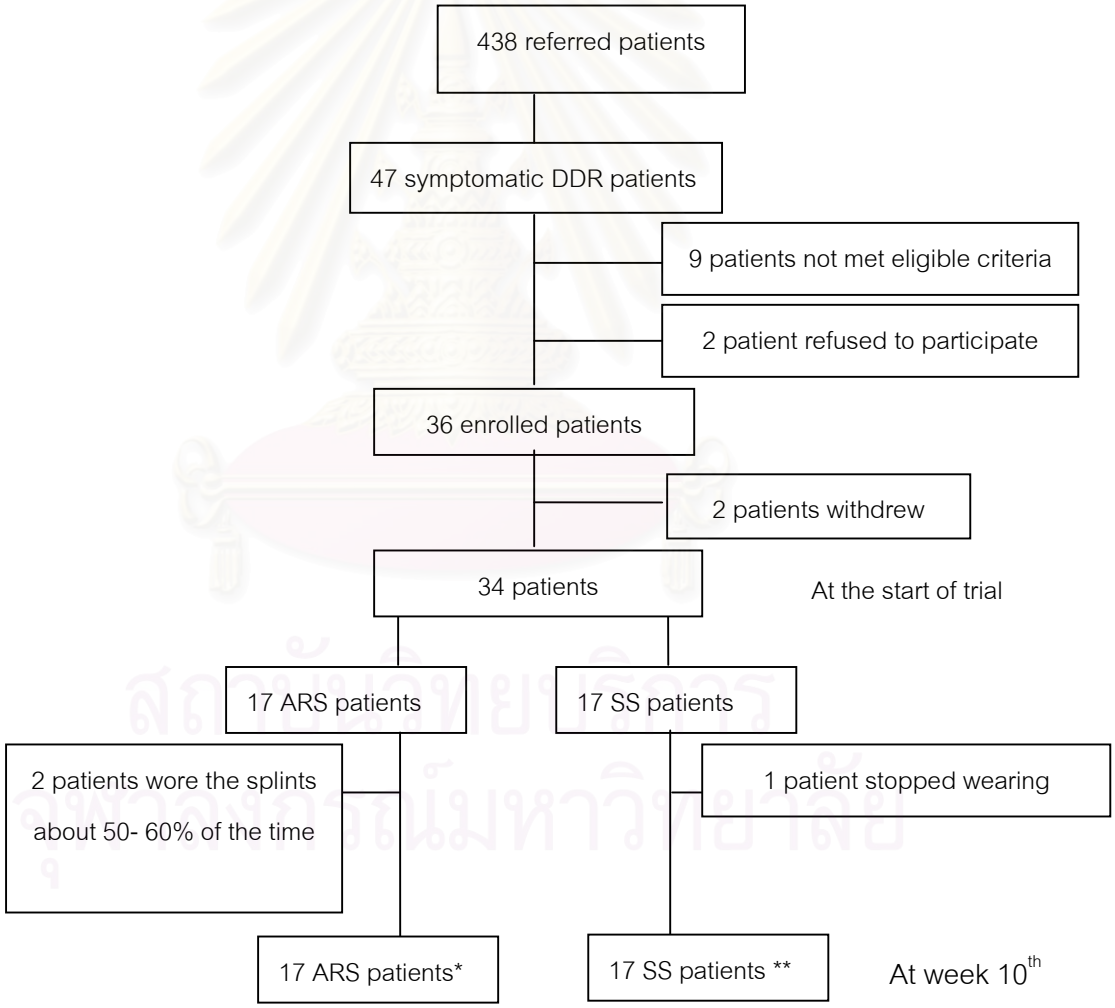
Table 3.2 Outcome variables and statistics used

Variables	Type of variables	Statistics
Response to treatment	Dichotomous (important improvement or not)	Percentage Chi-square test with 95% CI for difference
Overall change in symptom severity	Ordinal (symptom free, much better, better, unchanged, worse, much worse)	Percentage Mann Whitney U test
Presence of clicking (by clinical examination)	Dichotomous (presence or absence)	Percentage Chi-square test
Changes in clicking sound (patient assessment)	Ordinal (symptom free, much better, better, unchanged, worse, much worse)	Percentage Mann Whitney U test
Adverse occlusal changes	Dichotomous (presence or absence)	Percentage

CHAPTER 4

RESULTS

The total of 438 patients were referred to the Graduate Occlusion Clinic, Faculty of Dentistry, Chulalongkorn University for treatment of temporomandibular disorders (TMD), during March 2001 to-October 2003,. All patients were clinically screened; out of 438 patients, 47 patients had symptomatic TMJ clicking, 9 patients were excluded because they did not fulfill the inclusion criteria, and 2 refused to participate in the study. At the start of treatment, 2 patients withdrew from the study, thus 34 patients were left for further analysis (Figure 4.1).



(* 2 patients had closed lock and symptoms resolved** 1 patient developed closed lock and symptoms got worse)

Figure 4.1 Summary of patient flow

Before Treatment

Baseline characteristics

The patients comprised 26 females (76.5%) and 8 males (23.5%). The mean age at the start of the study was 26.4 ± 8.7 years. Table 4.1 shows the demographic data of the patients.

Table 4.1 Demographic data of the 34 symptomatic TMJ DDR patients before treatment, percentage in parenthesis

		SS group (n=17)	ARS group (n=17)
Gender	Females	13 (76.5)	13 (76.5)
	Males	4 (23.5)	4 (23.5)
Age	Mean (yrs)	26.8 ±10.5	26.0 ± 6.4
Duration of pre-treatment clicking	< 1 year	7 (45.2)	8 (47.1)
	1-2 years	6 (35.3)	4 (23.5)
	3-5 years	3 (17.6)	4 (23.5)
	> 5 years	1 (5.9)	1 (5.9)
Duration of TMJ pain	< 1 year	9 (52.9)	10 (58.9)
	1-2 years	1 (5.9)	3 (17.6)
	3-5 years	5 (29.4)	3 (17.6)
	> 5 years	2 (11.8)	1 (5.9)
Presence of bruxism	Aware of bruxing	5 (29.4)	6 (35.5)
	Not bruxing	8 (47.1)	9 (52.9)
	Not sure/don't know	4 (23.5)	2 (11.8)
History of orthodontic treatment	No	16 (94.1)	14 (82.4)
	Yes	1(5.9)	3 (17.6)
History of facial or jaw trauma	No	12 (70.6)	12 (70.6)
	Yes	4 (23.5)	4 (23.5)
	Cannot remember	1 (5.9)	1 (5.9)

SS group = stabilization splint group, ARS group = anterior repositioning splint group

Pain VAS scores and functional scores

As pain VAS scores revealed large variability among patients, then the median scores were calculated. A dispersion of each data set was demonstrated by an interquartile range. Figure 4.2 summarizes all VAS scores before treatment via box-and-whisker plots. Pain VAS scores comprised maximal pain, average pain, and pain at the time of examination. Functional VAS included scores from 3 activities (chewing food, wide mouth opening, and eating hard or tough food) and composite functional scores.

Due to chronic condition of the symptoms, only average pain scores were used for further analysis. One patient reported no pain, but she had difficulty with jaw activities. So only her composite functional score was used as the pretreatment data.

Clinical examination: baseline data

As shown in Table 4.2, clinical examination revealed average maximal mouth opening in each group was within normal limit (SS = 46.9±4.9 mm, ARS = 47.0±5.1mm). The majority of the patients presented with mild TMJ and jaw muscle tenderness as indicated by low tenderness scores (Table 4.2). In addition, bilateral posterior tooth contact in the intercuspal position was shown in every patient.

After Treatment

At the first follow-up visit, i.e., 2 weeks after wearing the splint. One patient in the SS group complained about the feeling of jaw locking and pain level increase. He wanted to stop wearing the splint since then. This patient was scheduled for evaluation as regular patients. There were two patients in the ARS group and one patient in the SS group who developed closed lock. All received jaw manipulation with TMJ distraction. One patient in each group received medication (Ibuprofen 400 mg t.i.d for two weeks).

Two patients in the ARS group reported that they were able to wear the splint for only 50-60% of the time instructed (Figure 4.1). Although one patient made an effort to wear the splint, she felt it interfered with her job duty. The other complained about pain on her tongue while wearing the splint, so she reduced the time of wearing. After adjusted the splint, she could wear the splint as usual.

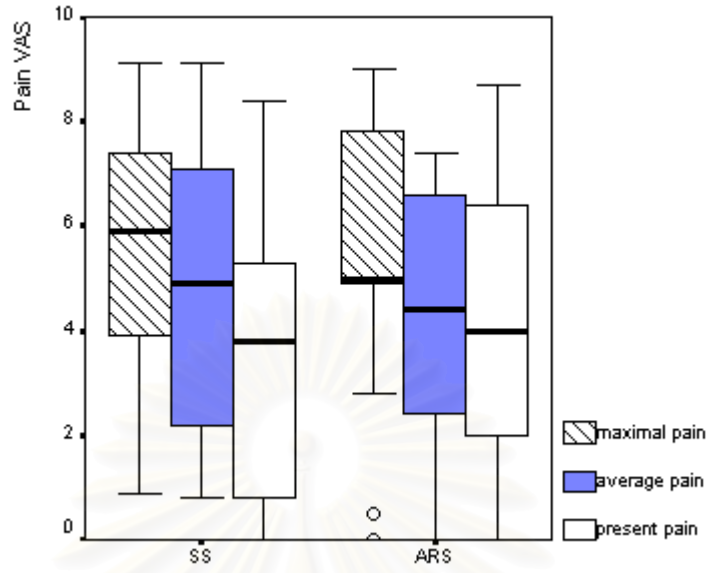


Figure 4.2.1 Pain VAS scores before treatment

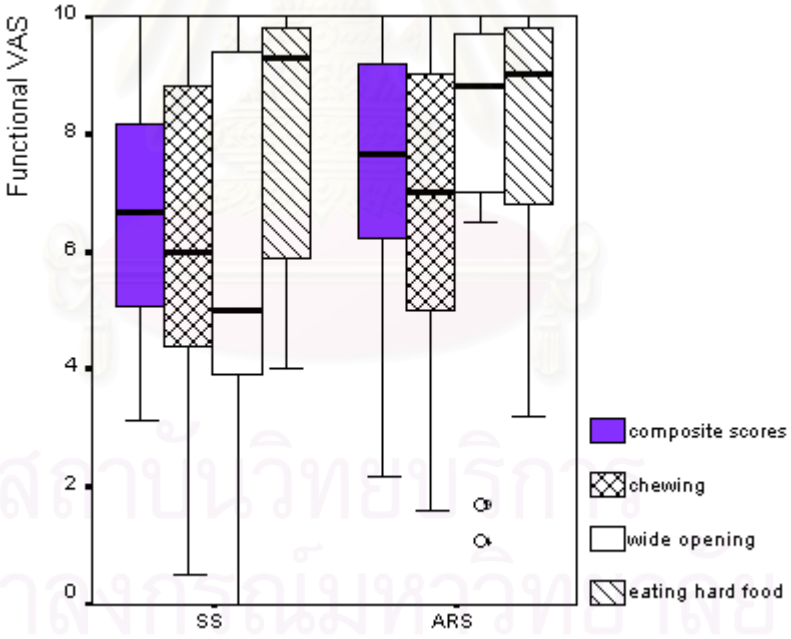


Figure. 4.2.2 Functional VAS scores before treatment

Figure 4.2 Box-and-whisker plot of the pain VAS and functional VAS data, showing the 2.5, 25, 50, 75, and 97.5% cumulative relative frequencies

Fourteen patients (82%) in the ARS group and 15 patients (88%) in the SS group reported to use the splint several nights a week or every night. All patients came for evaluation at the 10-week follow-up. Data were analyzed based on an intention–to-treat basis.

Table 4.2 Number of patients with clinical signs before and after treatment with splints in the two treatment groups.

	Before				After			
	SS group		ARS group		SS group		ARS group	
	n=17	%	N=17	%	n=17	%	n=17	%
Masticatory muscle tenderness score (max=60)								
0	5	29.4	5	29.4	10	58.8	12	70.6
1-3	5	29.4	7	41.2	5	29.4	3	17.6
≥4-12	7	41.2	5	29.4	2	11.8	2	11.8
TMJ tenderness score (max=12)								
0	8	47.1	10	58.8	14	82.4	13	76.5
1-3	8	47.1	7	41.2	3	17.6	3	17.6
≥4-6	1	5.9	0	0	0	0	1	5.9
Maximal opening <40 mm.	1	5.9	2	11.8	1	5.9	2	11.8

Pain VAS scores and functional VAS scores

After 10 weeks of treatment with occlusal splint, the majority of patients demonstrated various degree of improvement. Details of the median pain VAS scores and functional scores after treatment in comparison with those of pre-treatment are shown in Table 4.3.

Table 4.3 Median VAS pain scores and functional scores before and after treatment, interquartile range in parenthesis

Symptom severity	Before		After	
	SS group	ARS group	SS group	ARS group
	n=17	n=17	n=17	n=17
Pain VAS :median (IQR)				
Worst	5.9(3.9)	5.0(3.0)	3.6(5.2)	2.6(4.1)
Average	4.9(5.4)	4.4(5.2)	2.7(3.7)	1.0(2.0)
In the time of examination	3.8(4.8)	4.0(5.1)	1.7(3.5)	1.0(2.3)
Functional VAS :median (IQR)				
Chewing	6.0(4.8)	7.0(4.2)	3.1(4.2)	3.5(3.6)
Wide mouth opening	5.0(6.8)	8.8(2.8)	3.7(4.5)	3.3(3.0)
Eating hard/tough food	9.3(4.4)	9.0(3.2)	5.3(3.7)	4.0(4.2)
Composite functional scores	6.7(3.8)	7.7(3.4)	4.2(3.0)	3.8(3.3)

Primary Outcome Analysis

After 10 weeks of splint therapy, pain and functional VAS was re-evaluated.

Average pain VAS scores

Regarding average pain VAS, 15 patients (88.2%) in the SS group demonstrated pain decrease and 2 patients (11.8%) reported pain increase. In the ARS group, 15 patients (88.2%) also reported pain decrease and 1 patient (5.9%) got worse. Another patient in the ARS group who had no pain at the start of treatment was still in pain free condition. Only 7 patients (41.2%) in the SS group and 11 in the ARS group of patients (64.7%) demonstrated $\geq$ 50% pain reduction (Table 4.4).

Composite functional scores

All except one patient in the SS group reported better jaw functions after 10 weeks of treatment. Nevertheless only 5 patients (29.4%) in the SS group and 8 patients (50%) in the ARS group showed greater than 50% reduction in functional scores (Table 4.4).

Table 4.4 Details of subjective response to pain and composite functional scores in each treatment group, percentage shown in parenthesis

		Improve		Worse
Variable	group	>50%	<50%	
Average pain	SS	7	8	2
		(41.2%)	(47.0%)	(11.8%)
	ARS*	11	4	1
		(64.7%)	(23.5%)	(5.9%)
Composite functional score	SS	5	11	1
		(29.4%)	(64.7%)	(5.9%)
	ARS	8	9	0
		(47.0%)	(53.0%)	(0%)

* 1 patient in the ARS had no pain at the start of the study

When the criteria for important improvement were applied, only 4 patients (23.5%) in the SS group and 7 patients (41.2%) in the ARS group fulfilled the operational definition. Thirteen patients (76.5%) in the SS group and 10 patients (58.8%) in the ARS group demonstrated not important improvement (Table 4.5).

Using a chi-square test with 95% significant level, the proportion of patients with important improvement in the ARS group was not significantly different from those in the SS group ($\chi^2 = 1.21$, $p=0.27$). The treatment effect was 18% with 95%CI ranged from -0.13 to 0.48. This means it is 95% sure that the effect size could range between 13% worse to 48% better. Details of different responses to criteria for important improvement are shown in Table 4.5.

Clinical examination

After 10 weeks of treatment, an average maximal mouth opening was still within normal limit (47.3±5.5 mm for the SS group and 46.2±5.4 mm for the ARS group). No obvious changes in vertical mouth opening could be observed. With regards to jaw

muscle and TMJ palpation, both treatment groups presented more patients with no jaw muscle and TMJ tenderness (tenderness scores = 0) than those of before treatment (Table 4.2).

Table 4.5 Number of DDR patients with different responses based on the criteria for important improvement

Outcome		Types of splints	
		SS	ARS
Important improvement	≥ 50%reduction (pain and composite function VAS scores)	*4(23.5%)	*7(41.2%)
Not important improvement	≤ 50% reduction (both pain and composite function VAS scores)	9 (53.0%)	4(23.5%)
	Only pain VAS score ≥50% reduction	3(17.6%)	5(29.4%)
	Only composite function score ≥50% reduction	1(5.9%)	1(5.9%)

*$\chi 2$ =1.21, p=0.27, 95%CI:-0.13-0.48

Secondary Outcome Analysis

Outcome assessment for overall symptoms

Fourteen patients (82%) in each group reported symptom improvement (some improvement and much improvement). One patient in the SS group reported symptoms got worse after treatment. However, there was no report of symptoms resolved or much worse (Table 4.6). No significant difference between overall symptoms assessment could be demonstrated using Mann Whitney U test at 95% significant level (p=0.562).

Table 4.6 Overall symptoms assessment after 10 weeks of treatment

	SS group (n=17)	ARS group (n=17)
Excellent / symptoms resolved	0 (0%)	0 (0%)
Much improvement	7 (41.2%)	9 (53.0%)
Some improvement	7 (41.2%)	5 (29.4%)
Same/no change	2 (11.8%)	3 (17.6%)
Worse	1 (5.9%)	0 (0%)

Mann-Whitney U= 129.0, P=0.562, no significant difference by Mann Whitney U test

Outcome assessment for TMJ clicking

Objectively, clinical examination showed that 3 patients (17.6%) in the SS group and 8 patients (47.0%) in the ARS group demonstrated no click. Although there were more patients in the ARS group with absent clicking sounds, a statistical significant difference between two treatment groups could not be established using a Chi-square test (Chi-square =3.36, p=0.06, 95%CI=-0.4%-59%).

Subjectively, when patients self assessed their clicking in response to treatment, 12 patients (70.6%) in the ARS group stated that they felt at least some improvement in reduction of clicking symptoms. The remaining reported much improvement (23.5%) and clicking resolved (5.9%). On the contrary, 41.2% of the patients in the SS group noted that their clicking was the same or no change. Table 4.7 demonstrates the result from patient assessment of their clicking symptoms. By using a Mann-Whitney U test, there was a significant difference in patient response to clicking between the ARS and the SS group (Mann-Whitney U = 86.5, p=0.027).

Table 4.7 Patient assessment for their clicking symptoms after 10-week of treatment

	SS group (n=17)	ARS group (n=17)
Excellent / symptoms resolved	1 (5.9%)	1 (5.9%)
Much improvement	2 (11.8%)	4 (23.5%)
Some improvement	7 (41.2%)	12 (70.6%)
Same/no change	7 (41.2%)	0 (0%)
Worse	0 (0%)	0 (0%)
Much worse	0 (0%)	0 (0%)

Mann-Whitney U=86.5, p=0.027*, significant difference by Mann-Whitney U test

Adverse occlusal changes and other findings

In the ARS group, three patients demonstrated mild changes in their occlusion. One patient reported that his posterior teeth did not fit as before, but he preferred this position for his symptoms got better. The other patient reported difficulty biting on the posterior teeth. The anterior teeth were found to make heavier contacts than did the posterior teeth. However, when attempt was made to bring the jaw backwards, posterior tooth contact was resumed. In another patient, heavier occlusal contacts were found on the anterior teeth than the posterior teeth but this patient was not aware of these changes. No patient demanded for further treatment regarding these occlusal changes.

One patient developed acute closed lock while eating hard food after 2 weeks of wearing. Jaw manipulation with TMJ distraction was provided. The patient continued wearing the splint as before, her symptoms showed a lot of improvement after that event.

Another patient also developed closed lock in the morning after 5 weeks of treatment. She received jaw manipulation and TMJ distraction in combination with Ibruprofen and muscle relaxants for two weeks. Symptoms got better and then resolved. She was able to open her mouth as usual. During the period of locking she discontinued wearing the splint for 1 week.

In the SS group, no patient reported occlusal changes. However, two patients reported unwanted symptoms. One patient did have difficulty wide opening after 2 weeks of treatment in combination with the feeling of jaw tightness. Feeling the symptoms getting worse, this patient asked for stop wearing the splint. The other patient developed intermittent locking at the two-week follow-up and symptoms turned to acute closed lock in 4 weeks. Limited moth opening and severe TMJ pain was reported. This patient received medication (NSAID and muscle relaxants) for treating acute and severe TMJ pain. Patient did continue wearing the splint but the symptoms persisted.

CHAPTER 5

DISCUSSION

Research regarding the effectiveness of the ARS and the SS in the treatment of TMJ disk displacement with reduction is not relatively new. There is some evidence that in short-term follow-up, a 24-hr wearing of ARS provide favorable results in reducing symptoms of disk displacement with reduction than those of the SS (15, 16) and the untreated control group (16). However, a full-time wearing could lead to adverse change in occlusion. Then, a part-time usage has been suggested (19, 21, 22). Thus, this study helps further the knowledge of whether nighttime use of ARS provides more effectiveness than that of the SS by using important improvement as an outcome measure.

This study suggests that both SS and ARS therapy can reduce the symptoms of TMJ DDR to some extent. Although nighttime use of ARS revealed more patients with important improvement (7 patients or 41.2%) than that of SS (4 patients or 23.5%), the results were not statistically significant (p=0.27). Therefore, the null hypothesis of this randomized clinical trial performed on symptomatic TMJ DDR patients could not be rejected.

In a clinical point of view, significant difference between the effectiveness of two splints should come from true treatment effect. However, many factors tend to deviate the results away from the truth, resulting in underestimation or exaggeration of the effects of an intervention. Thus, when the outcome of the study revealed no significant difference between groups, related factors should also be discussed.

As shown in the conceptual framework (Figure 3.1), before randomization, patients could be different in many aspects. Those included gender, age, TMJ anatomy, TMJ disk position, disk configuration, symptom severity, etiologic factors such as trauma, psychological factors, and so on.

Gender and age were found unrelated to the treatment except young age patients usually fail to wear the splint 24 hrs (61). Severity of disk displacement may affect the treatment outcome. Kurita et al. (88) have reported that a deformed disk and

severe disk displacement may account for the failure in recapture the disk with the ARS. Psychological factors also play a vital role for chronicity and patient response to treatment outcome (89, 90). With the use of proper randomization, it was expected that study groups were as similar as possible at the outset. In addition, the unknown prognostic factors at baseline could be balanced. When those factors were controlled, the effect of the splints would be easily to quantify. This was shown by comparable baseline data.

In a randomized controlled trial, biases are major sources of systematic errors (91). Prevention of selection bias in this study was conducted with randomization process and allocation concealment. Furthermore, no patients were excluded after randomization.

However, knowledge of which splint each patient is receiving could lead to ascertainment bias which can systemically distorted the data. Although this type of bias could be prevented by blinding (91), this study confronted with the problem of double-blinding.

While the features of two splints were different, it was difficult to blind the patient to which type of splint they received. However, the quality of the study could be improved by blinding the examiner or the investigator. This study tried to blind the investigator 1 who conducted clinical examination as much as it could be. However, for practical reason the blinding process could only be completed for 10 patients. Due to the fact that the primary outcome measures were based on patients' assessment of their VAS pain and function. Therefore, non-blinded investigator may not seriously compromise the primary outcome in this study. No attempt had been made to have investigators blind to study results. Nevertheless, the investigator would only view the results when all patients had completed the study.

In consequence, co-intervention may occur when blinding process is lacking (91). However, all patients received no other treatment except one in each treatment group who developed acute closed lock. Both patients received NSAIDs and muscle relaxants for about 2 weeks. At the start of treatment, for ethical reasons, all participants received patient education and self-care instructions. Therefore, the study groups did not differ on the use of co-interventions.

In occlusal splint therapy, a splint will be effective only if patient wears it. Hence, patient adherence to splint wearing plays a major role in affecting treatment outcome. As reported in the study by Davies et al. (23), reduction time of ARS wearing could lower the success rate. Theoretically, the nighttime splint should be worn every night for at least 8-10 hours per night (19). Fourteen (14) patients (82%) in the ARS group and 15 patients (88%) in the SS group reported to have used the splint several nights a week or every night. In fact, it is extremely difficult to monitor patient adherence to splint usage along the 10-week of study particularly the hours of wearing each night. However, this study presented with good patient adherence to appointment schedules as there was no patient loss to follow-up at the 10-week period (Figure 4.1).

It may be argued that splints per se could lead to failure of treatment. Regarding the construction of splints, the ARS seems to be more technique sensitive than the SS. While the ARS has to reposition the mandible in a forward position, the SS only stabilizes the mandible at the centric relation position. Then, failure of ARS could easily come from over adjustment of the anterior ramps leading to losing the repositioned relationship in the joint causing the clicking symptoms to return (59). However, after splint insertion, all patients were scheduled for 2-week follow-up. They were checked whether the TMJ was click-free during opening and closing movements while wearing an ARS. Should any problem related to splint design occurs, it would be corrected until patients were able to wear the splint comfortably without rocking motion and interferences during movement. At the 2-week appointment, 2 patients in the ARS group were shown to have non-working side interferences during wearing the splints. These findings were corrected promptly in that visit.

In terms of outcome measures, quality of measurement tool could contribute to the study results. This study applied visual analog scales (VAS) to measure pain and jaw function. As shown in the literature review by Forssell et al. (64, 65), pain VAS scores were frequently used as outcome measures in many randomized controlled trials on the use of occlusal splints for treatment of temporomandibular disorders. Those VAS have been demonstrated to be a valid tool in pain research (92). However, imperfectness of the use of VAS could happen.

Scott and Huskisson (85) reported that in using VAS, patients tended to overestimate their pain severity when previous scores were not available. They suggested that initial scores should be made available when serial measurements of pain are made in long-term experiments. This study has been planned to be a long-term follow-up. Therefore, patients' initial scores were shown to them at 10-week follow-up.

In this study, average pain VAS scores were selected for outcome analysis for the reason that all the patients have symptoms for longer than 2 months. Therefore, it would be suitable to use average pain for a chronic pain condition instead of maximal pain or pain at the time of examination. However, VAS scores only provide the magnitude of pain intensity. Other aspects of pain such as pain frequency and pain duration should also be evaluated. The use of overall symptom assessment in this study could help evaluating other aspects of symptoms that have not been pointed out, though not as clear as one specified.

In previous RCTs, no study has used functional scores as a sole treatment outcome. Assessment of activities of daily living are often included in a set of outcome measures in many studies (71, 73). A functional index based on multiple VAS (10 activities) has been used in the study on the use of botulinum toxin for the treatment of temporomandibular disorders (73). Raphel et al. (71) applied functional VAS outcome based partly on 12 activities. Patients were asked to indicate how much the facial pain interfered with their daily activities, in the last 2 weeks, using a 10-point scale (71). In their results, chewing, eating hard food, and yawning were three activities most disturbed by facial pain. As in the present study, those three activities were shown to be the most troublesome to patients. In consequence, patients were asked to score their perceived functional limitation on those three activities by use of VAS. Therefore, the reliability of the data depended solely on patient response.

It is still a question whether each type of splints affects jaw activities differently. If it does, composite functional VAS which is the average score may not demonstrate the difference between groups. In this study, wide mouth opening demonstrated a lot of improvement in the ARS group while it was the least response in the SS group (Table 4.3). Until now, there is no report on this issue. Further investigation is needed.

The primary outcome variable, i.e., important improvement, defined as >or= 50% reduction of pain VAS becomes widely used in recent pain research. However, a standard definition of clinically important improvement in clinical trials of occlusal splint therapy is absent. Therefore, this arbitrary number of 50% was set to demonstrate the magnitude of improvement and help determining the success outcome. It may not be similar to patient self-assessment. The reliability of this outcome measure depends on the ability of the patients to correctly use the VAS which had not been tested in this study. However, the results demonstrated the number of patients with important improvement was in line with those of patient self-assessment (Table 4.5-4.6). Patients tended to report more favorable outcome in overall symptom assessment. Clearly, developing a standard outcome across TMD studies would greatly enhance the comparability, validity, and clinical applicability of the studies.

An adequate follow-up period is another point to be mentioned. Treatment time should be long enough to demonstrate the effectiveness of occlusal splints. In a study by Ekberg et al., a 10-week period was long enough to manage TMJ pain via occlusal splints (57). However, it is not known whether it would be long enough to treat TMJ clicking. As suggested by Clark (56), the ARS should be worn 24 hours for 6-8 months. Therefore, a 10-week period of study should be appropriate for TMJ pain reduction but may be too short for reducing clicking.

Therefore, when related factors were considered, a “not significant difference” result could mainly come from the true effect of interventions in combination with some unavoidable errors found in the study.

In a statistical point of view, this non-significant finding could come from two possible reasons: 1) small treatment effect size and 2) the effect of small sample size (Type II error)(87).

It is likely that nighttime use could reduce the effectiveness of ARS to some extent. As reported by Davies et al (23) that 24-hour of wearing the ARS provided more improvers (88%) than that of nighttime use (65%) and daytime use (52%). As stated in Chapter 3, 35% effect size was expected. However, in the present study, only 41% of the patients in ARS group and 23% in the SS group revealed important improvement. This means the observed effect size is 18%. Clearly, the effect size is smaller than that

stated in the primary research question and sample size calculation. The smaller the effect size, the larger is the sample size required providing that the significant level and the power are fixed.

It is important to stress that a non-significant result most likely comes from a smaller number of patients than the prior estimate of sample size. These small group sizes (17 of each group) can fail to detect a reasonable effect size. While this study only includes patients demanding treatment for TMJ disk displacement with reduction, it is difficult to enroll a number of patients to the study within this time constraint period. Although more than 400 patients were clinically screened, only 10% of those fitted to eligible criteria. This small sample size could lead to the major flaw of the study result and lead to the reduction of power of the test.

Using the data obtained from this study, 17 patients would yield a power of 19%. This means that only 19 times out of 100 the alternative hypothesis is correct based on this sample size (n=17).

When an effect size (18%) is used for sample size calculation, it would need about 110 patients per group in order to obtain power of the test = 80%. Figure 5.1 demonstrates power curve fixing alpha=0.05 and power of the test = 80% (calculated by StatXact with Cytel Studio, version 6.0, Cytel Software Corporation).

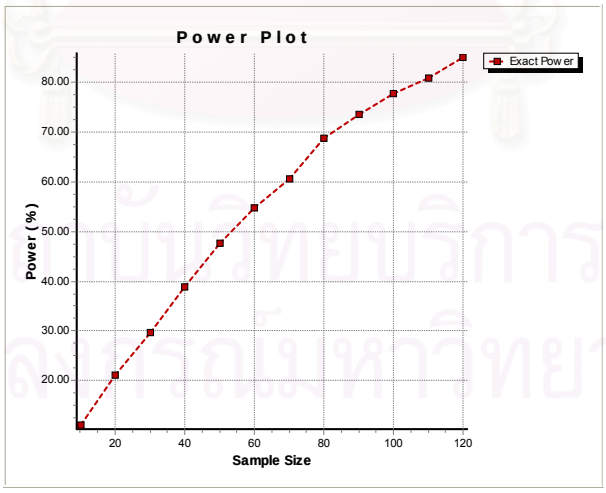


Figure 5.1 Power curve for the observed effect size, alpha = 0.05

If such a large number of patients was required to demonstrate the difference between two splints, these two splints (ARS and SS) would be “no clinical different” in treating symptomatic DDR in a short-term basis.

It is interesting to note that if only average pain scores were used for success, 64.7% of the ARS group demonstrated at least 50% improvement and 41% of the SS group. These 65% success were comparable to the previous studies (23). Therefore, the success rate based on multiple parameters could lower the success rate in this study.

Results from overall assessment and clinical examination on clicking were in line with those of primary outcome measure. More patients in the ARS group demonstrated more favorable outcome than those of the SS group. This finding was in concordance with earlier studies by Anderson et al.(15) and Lundh et al.(16). However, statistical significant difference in treatment response between the two groups could not be obtained.

It is of importance to ask the patients to evaluate their joint noises in addition to clinical examination. TMJ clicks may not be detected at the time of examination but still be present during function, or the quality of click has been changed after treatment.

Concerning patients' self-assessment on their clicking, the ARS group yielded more patients with at least some improvement than did the SS group. The SS group, on the other hand, had more patients with no change in TMJ clicking. The result suggested that the ARS seems to improve clicking sound to some extent in 10-week follow-up. The SS appeared to play no major role in treating clicking in most patients. This study also supports the earlier studies on the effectiveness of ARS in reducing TMJ clicks (15, 16). However, it is not known whether the clicking would return in the long-term follow-up.

Relatively mild occlusal changes during the use of a nighttime ARS have been found. Anterior teeth made heavier contact than the posterior teeth in 2 of 17 cases particularly in the morning. No obvious posterior open bite has been observed. The result suggests that nighttime use of ARS does not cause posterior open bite that requires additional treatments and causes no patient concern. Therefore, nighttime wearing of ARS can be safely used within a 10-week period.

As stated in the results, two patients in each group developed signs of locking. These unwanted events also happened in the past studies (15, 16) which were most likely to occur in the stabilization splint group (15, 16) and the control group (16). It is possible that acute closed lock could occur by chance and may not related to the

treatment. This is due to the patients' history of frequent intermittent locking. In order to test this assumption, a negative control group should be added.

When locking had occurred, the ARS seemed to help relieving patient's symptoms better than the SS. After manual manipulation and joint distraction, patients in the ARS group could wear the ARS and symptoms resolved. On the other hand, one patient who developed locking in the SS group got worse after manual manipulation and continual wearing the SS. The other patient in the SS group, after manipulation without wearing the SS his symptoms got better.

In the treatment of symptomatic DDR with the ARS, patient improvement may be due to specific effect of splint and a variety of factors. Objectively, the efficacy of ARS can be demonstrated by MRI (58, 66, 67, 88). At the best response reported in the earlier studies, about 83% of displaced disks can be recaptured to the normal position (66). If we assumed that there are no errors in the methodology (for example, patient using of VAS, improper splint design, and patient compliance), the possibility of disk recapture depends on the stage of the TMJ disease. According to Eberhard et al. (66), it was not possible to achieve a normal disk-condyle relationship using an ARS in the non-reducing disk or the later stages of the TMJ internal derangement. In addition, the ARS seems much less effective in cases with a transverse disk displacement (67). In this study, it is not possible to determine the extent to which the stage of the TMJ disease contributed to the treatment outcome due to the lack of MRI.

Alternatively, the SS appears to have no direct effect on TMJ clicking mechanisms. Patient improvement may due in part to a reduction in muscle splinting with the use of SS. This could help reduction in clicking in some patients. A shown in a long-term study by Greene and Laskin (12), without repositioning the mandibles, 30% of the 190 individuals had no click and 33% improved.

However, improvement of subjective symptoms such as pain status could arrive from other factors such as non-specific effects of treatment ('placebo effects'); or regression to the mean (93). These factors can mislead the results to some extent.

Placebo effects have been demonstrated in a study by Dao et al. (70). They found that gradual reduction in pain and unpleasantness of myofascial pain, as well as

the improvement of quality of life during their study, was non-specific and not related to the type of splints.

Hawthorne effect has been acknowledged as “the awareness of being under observation can alter the way in which a person behaves was significant for psychological dimensions” (94) and is capable of invalidating results (95). The natural course effect could also be accounted for the success of treatment (95). The majority of patients with DDR were found symptom improvement within the period of two years. In a study by Sato et al., tenderness of masticatory muscles tended to be lessen, but reciprocal clicking and TMJ pain tended to remain (11).

In a methodological point of view, the selection of treatment outcome measures may affect the result of the study. It is generally accepted that the pain VAS scores can be treated as the continuous data. For the outcome measures, the changes in VAS scores are relatively more sensitive than the categorical or the dichotomous data. It is possible that the use of dichotomous data such as “important improvement or not” may reduce the sensitivity of the measurement. In addition, the sensitivity of the outcome measures (important improvement) depends on the cut off point or the criteria for success. It is of interest to perform a sensitivity analysis of the treatment outcome by varying the criteria of success (such as from 10% to 90% pain reduction). As stated before, the issue of treatment outcome measures needs to be addressed in the future TMD research.

Another concern on the methodological viewpoint is that the outcome of this study arrived from a trial of small sample size. Thus, this study could be considered as an interim analysis. While the results supported clinical significance of nighttime use of ARS, no statistically significant difference between the effectiveness of two treatment groups was demonstrated in terms of important improvement. This leads to the question whether it is appropriate to continue the study. The decision to stop or alter the study should be based on medial ethics, the statistical evidence and practical aspects of therapy (96).

Theoretically, it may be unethical to provide a treatment known to be inferior to any patient in the trial (96). In addition, early interim results shown to investigators or other practitioners could change their outlook. They may hesitate to refer the patients to

the trial. Moreover, if the interim results were exposed to the society, it would be difficult to obtain informed patient consent and to randomize the next patient.

However, if the sample size is so small, it would be unwise to stop the trial since the difference is likely to occur by chance (96). Pocock suggested to adopt $p<0.01$ as the criterion for stopping the trial provided that one anticipates no more than 10 interim analyses and there is one main response variable (96). The $p<0.01$ is set for the prevention of type I error in the sequential of interim analyses. While the secondary outcome variables such as patients' perception to the changes in clicking sound demonstrated significant difference between groups. Therefore, this small sample size may not be appropriate to find the difference of pain and functional improvement but may be adequate for detecting the difference between patients' self-assessment on clicking sounds.

In addition, while the patient recruitment is difficult, it would need about 6 years to reach the adequate sample size. By that time, the research question may no longer be interesting. So, the study may not worth conducting in such a long period of time.

Finally, the results of this study only shed some light on a short-term follow-up. It is not known whether the same outcome would be demonstrated in a long-term basis. A future study should be planned to give insight into the long-term effectiveness of these two splints.

CHAPTER 6

CONCLUSION

The primary outcome of this study was the important improvement determined by ≥50% reduction in an average pain VAS and a composite functional VAS. The results tended to demonstrate more patients with important improvement in the ARS group (41%) than those in the SS group (23%). However, within the limitation of this study, no significant difference was demonstrated between these two groups. This non-significant result was mainly due to a problem of small sample size. The small observed effect size than expected led to the need of more patient recruitment in the future study.

In addition, concerning the secondary outcomes, no significant differences were found in the overall symptoms self-assessed by patient and the presence of clicking determined by clinical examination. Nevertheless, patients in the ARS group perceived better clicking improvement than those of the SS. No serious occlusal changes were associated with nighttime use of the ARS.

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APPENDICES

APPENDIX 1

Self-administered questionnaire

คำชี้แจงในการตอบแบบสอบถาม

แบบสอบถามจัดทำขึ้นเพื่อรวบรวมรายละเอียดเกี่ยวกับปัญหาที่เกี่ยวกับกล้ามเนื้อและ/หรือข้อต่อขากรรไกรของคุณ โปรดอ่านคำถามแต่ละข้ออย่างรอบคอบ และกรุณาทำเครื่องหมาย (/) หรือ (X) ในช่องที่ตรงกับคำตอบของคุณ ตามความเป็นจริงให้มากที่สุด

ขอบคุณในความร่วมมือ

ผู้ช่วยศาสตราจารย์ ทันตแพทย์หญิงพนมพร วานิชชานนท์

ชื่อ-สกุลผู้ป่วย: .....

วัน-เดือน-ปีที่ตอบแบบสอบถาม: ☐☐-☐☐-☐☐ **ลำดับที่**: ☐☐☐

การวินิจฉัย:

(เฉพาะเจ้าหน้าที่)

ตอนที่ 1 ข้อมูลส่วนตัวของผู้ป่วย

คำแนะนำ: ให้ทำเครื่องหมาย (/) หรือ (X) ลงในช่อง ☐ ที่ตรงกับคำตอบของคุณ

1. เพศ	1. ☐ ชาย 2. ☐ หญิง
2. วัน-เดือน-ปีพ.ศ.เกิด	☐☐ - ☐☐ - ☐☐☐☐ วันที่ เดือน ปี พ.ศ.
3. สถานภาพสมรส	1. ☐ โสด 2. ☐ แต่งงาน 3. ☐ หม้าย 4. ☐ หย่า / แยกกันอยู่ 5. ☐ อื่นๆ คือ.....
4. ระดับการศึกษา	1. ☐ ระดับประถม 2. ☐ ระดับมัธยมต้น 3. ☐ ระดับมัธยมปลาย 4. ☐ ระดับปริญญาตรี 5. ☐ อื่นๆ ระบุ.....
5. อาชีพ	1. ☐ นักเรียน นิสิต นักศึกษา 2. ☐ แม่บ้าน 3. ☐ ธุรกิจ 4. ☐ ลูกจ้าง 5. ☐ ข้าราชการ 6. ☐ เกษตรกร 7. ☐ ไม่ได้ประกอบอาชีพ 8. ☐ อื่นๆ ระบุ .....
6. รายได้(บาท)ต่อเดือน	1. ☐ น้อยกว่าหรือเท่ากับ 2,000 บาท 2. ☐ 2,001-5,000 บาท 3. ☐ 5,001-10,000 บาท 4. ☐ 10,001-30,000 บาท 5. ☐ มากกว่า 30,000 บาท

ตอนที่ 2 รายละเอียดเกี่ยวกับอาการที่กล้ามเนื้อ / ข้อต่อขากรรไกร

คำแนะนำ: ให้ทำเครื่องหมาย (/) หรือ (X) ลงในช่อง ☐ ที่ตรงกับคำตอบของคุณ

1. **คุณมีอาการหรือปัญหา อย่างไรบ้าง ? ในรอบหนึ่งเดือนที่ผ่านมา (อาจมีมากกว่าหนึ่งข้อ)**

☐ 1. ปวดส่วนใดส่วนหนึ่งต่อไปนี้ เช่น ใบหน้า ขากรรไกร ในช่องปาก หรือ ปวดศีรษะ เป็นต้น

☐ 2.ขากรรไกรทำงานไม่ปรกติ เช่น อ้าปากได้น้อย, อ้าปากขัด, มีเสียงที่ข้อต่อขากรรไกร, อ้าปากแล้วเบี้ยว หรือตวัด, อ้าปากค้าง

☐ 3.อื่นๆ ระบุ----------

ถ้าตอบหลายข้อ ปัญหาที่สำคัญที่สุดคือ ข้อ _____ ☐

2. **คุณคิดว่าคุณนอนกัดฟัน หรือชอบกัดถูฟัน หรือกัดเน้นฟัน หรือไม่ ?**

☐ 1.ไม่

☐ 2.ใช่

☐ 3.ไม่ทราบ/ไม่แน่ใจ ☐

3. **คุณเคยจัดฟันหรือไม่ ?**

☐ 1.ไม่เคย

☐ 2.เคย ☐

4. **คุณเคยถูกกระแทก หรือมีอุบัติเหตุรุนแรงที่ศีรษะ ใบหน้า หรือขากรรไกร หรือไม่ ?**

☐ 1.ไม่เคย

☐ 2.เคย

☐ 3.จำไม่ได้ / ไม่ทราบ ☐

หากมีอาการปวด ให้ตอบข้อ 5-11 ด้วย

5. **บริเวณที่ปวดคือ (ดูรูปประกอบ)**

☐ 1. หน้าหู /ข้อต่อขากรรไกร

☐ 2. แก้ม

☐ 3. ขมับ

☐ 4. โหนกแก้ม

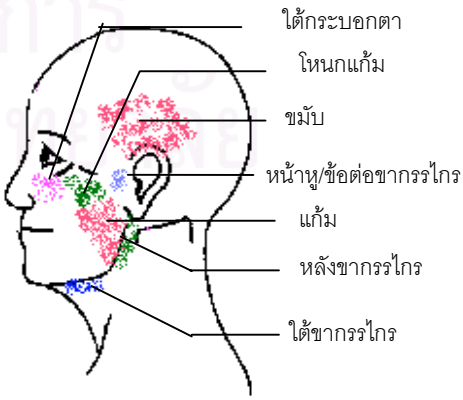
☐ 5. หลังขากรรไกร

☐ 6. ใต้ขากรรไกร

☐ 7. ในช่องปาก เช่น เหงือก,ฟัน,ลิ้น,กระพุ้งแก้ม

☐ 8. ศีรษะ

☐ 9. บริเวณอื่นๆ ระบุ----------



6. **หากมีการปวดหลายตำแหน่ง** บริเวณ หรือตำแหน่งที่**ปวดมากที่สุด** คือ บริเวณหมายเลข _____
บริเวณ หรือตำแหน่งที่**ปวดรองลงมา**คือ บริเวณหมายเลข _____

7. **อาการปวดมีลักษณะอย่างไร?**

☐ 1.ปวดตื้อ
☐ 2.ปวดแปล๊บ / ปวดจี๊ด
☐ 3.ปวดตุ้บๆ
☐ 4.ปวดลักษณะอื่น คือ_____ ☐

8. **อาการปวดเกิดขึ้น บ่อยมากน้อยเพียงใด?**

☐ 1.ปวดทุกวัน
☐ 2.ปวดประมาณ 2-4 ครั้ง/สัปดาห์
☐ 3.ปวดหนึ่งครั้งหรือน้อยกว่าหนึ่งครั้งต่อสัปดาห์ ☐

9. **อาการปวดของคุณเกิดขึ้นอย่างไร?**

☐ 1.อยู่เฉยๆก็ปวด
☐ 2.ปวดเฉพาะเวลาอ้าปากกว้าง
☐ 3.ปวดเฉพาะเวลาเคี้ยว
☐ 4.ปวดหลังจากใช้ขากรรไกร เช่น หลังการเคี้ยวอาหาร หรือ หลังการพูดมากๆเท่านั้น
☐ 5.ไม่แน่นอน
☐ 6.อื่นๆ ระบุ_____ ☐

10. **ลักษณะอาการปวดของคุณ เกิดขึ้นเป็นช่วงนานแค่ไหน?**

☐ 1.ปวดข้ามวัน ปวดตลอดเวลา
☐ 2.ปวดเป็นวัน
☐ 3.ปวดเป็นชั่วโมง
☐ 4.ปวดเป็นนาที
☐ 5.ปวดเป็นวินาที ปวดแป๊บเดียว ☐

11. **อาการปวดของคุณเป็นมานานแค่ไหน ก่อนมารับการรักษา?**

☐ 1.น้อยกว่า 1 เดือน
☐ 2.ระหว่าง 1-5 เดือน
☐ 3.ระหว่าง 6-11 เดือน
☐ 4.ระหว่าง 1-2 ปี
☐ 5.ระหว่าง 3-5 ปี
☐ 6.มากกว่า 5 ปี ☐

ถ้าคุณมีปัญหาขากรรไกรทำงานไม่ปรกติ ให้ตอบข้อ 12-16 ด้วย

12. ปัญหาการทำงานของขากรรไกรที่คุณมีอยู่คืออะไรบ้าง ? (อาจมีมากกว่าหนึ่งข้อ)

☐ 1. อ้าปากไม่ขึ้น

☐ 2. อ้าปากขัด หรือ ต้องขยับขากรรไกรไปมาก่อนที่จะอ้าปากได้ หรือ รู้สึกเหมือนข้อต่อขากรรไกรไม่เข้าที่

☐ 3. มีเสียงที่ข้อต่อขากรรไกร (เช่น เสียงคลิก, เสียงแกร็กๆ, เสียงกึก เป็นต้น)

☐ 4. อ้าปากแล้วขากรรไกรเบี้ยว หรือตวัด

☐ 5. ปัญหาอื่นๆได้แก่ _____ ☐

13. หากมีปัญหาหลายอย่าง, ปัญหาที่สำคัญ หรือ กังวล มากที่สุด คือ หมายเลข_____

ปัญหาที่สำคัญรองลงมา คือ หมายเลข_____

14. อาการสำคัญที่สุดที่เกี่ยวกับปัญหาขากรรไกรทำงานไม่เป็นปกติ ตามที่ตอบในข้อ 13 เกิดขึ้นถี่มากน้อยเพียงใด?

☐ 1.มีปัญหาทุกวัน / ทุกครั้งที่ทำกิจกรรม

☐ 2.มีปัญหาประมาณ 2-4 ครั้ง/สัปดาห์

☐ 3.มีปัญหาหนึ่งครั้งหรือน้อยกว่าหนึ่งครั้งต่อสัปดาห์ ☐

15. ปัญหาขากรรไกรทำงานไม่ปกติในข้อ 13 เกิดขึ้นมานานแค่ไหน ก่อนมารับการรักษา?

☐ 1.น้อยกว่า 1 เดือน

☐ 2.ระหว่าง 1-5 เดือน

☐ 3.ระหว่าง 6-11 เดือน

☐ 4.ระหว่าง 1-2 ปี

☐ 5.ระหว่าง 3-5 ปี

☐ 6. มากกว่า 5 ปี ☐

16. ในกรณีที่คุณ<u>มีเสียงที่ข้อต่อขากรรไกร</u> เสียงนี้เกิดขึ้นมานานแค่ไหน ก่อนมารับการตรวจ-รักษาครั้งนี้?

☐ 1.น้อยกว่า 1 เดือน

☐ 2.ระหว่าง 1-5 เดือน

☐ 3.ระหว่าง 6-11 เดือน

☐ 4.ระหว่าง 1-2 ปี

☐ 5.ระหว่าง 3-5 ปี

☐ 6. มากกว่า 5 ปี ☐

ตอนที่ 3 อาการปวดและปัญหาการทำงานของขากรรไกรก่อนการรักษา

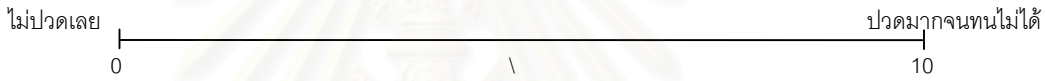
3.1 อาการปวดใบหน้า-ขากรรไกรมีมากน้อยเพียงใด?

3.1.1 ในขณะนี้ (ตอนนี้) อาการปวดใบหน้า-ขากรรไกรของคุณมีมากน้อยเพียงใด?

คำแนะนำ: ให้ขีดเส้นตรง (I) ขวางบนเส้นตรงข้างใต้ เพื่อบอกระดับอาการปวดขากรรไกรของคุณ.ในขณะนี้

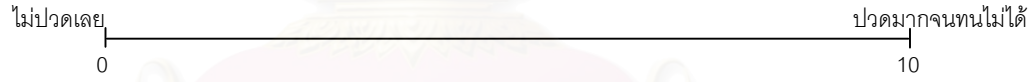
3.1.2 ช่วงสองเดือนที่ผ่านมา ขณะที่ปวดมากที่สุด อาการปวดใบหน้า-ขากรรไกรของคุณรุนแรงมากน้อยเพียงใด?

คำแนะนำ: ให้ขีดเส้นตรง (I) ขวางบนเส้นตรงข้างใต้ เพื่อบอกระดับอาการปวดใบหน้า-ขากรรไกร ในขณะที่คุณปวดมากที่สุด



3.1.3 ช่วงสองเดือนที่ผ่านมา โดยเฉลี่ย อาการปวดใบหน้า-ขากรรไกรของคุณมีมากน้อยเพียงใด?

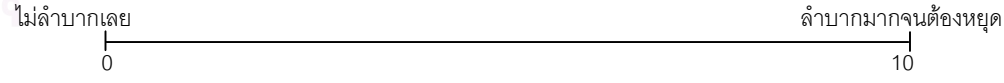
คำแนะนำ: ให้ขีดเส้นตรง (I) ขวางบนเส้นตรงข้างใต้ เพื่อบอกระดับอาการปวดขากรรไกรของคุณโดยเฉลี่ย



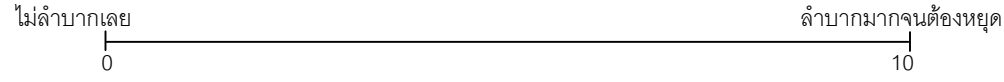
3.2 ช่วงสองเดือนที่ผ่านมา อาการปวดใบหน้า-ขากรรไกรหรือปัญหาที่ขากรรไกรทำให้คุณมีความลำบากในขณะทำกิจกรรมต่อไปนี้หรือไม่? อย่างไร?

คำแนะนำ: ให้ขีดเส้นตรง (I) ขวางบนเส้นตรงข้างใต้ เพื่อบอกว่าคุณมีความลำบากในการทำกิจกรรมต่างๆมากน้อยเพียงใด?

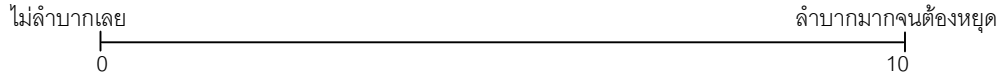
3.4.1 ขณะเคี้ยวอาหาร



3.4.2 ขณะพูด



3.4.3 ขณะอ้าปากกว้าง เช่น ตะโกน หรือ อ้าปากหาว หรือ อ้าปากรับประทานอาหารคำโต ๆ



3.4.4 ขณะยิ้มหรือหัวเราะ

3.4.5 ขณะกัดอาหารแข็งหรือเหนียว เช่น หมูทอด กระยาสารท ปลาหมึกย่าง หรืออ้อย เป็นต้น

APPENDIX 2

CLINICAL EXAMINATION RECORD FORM..... (Page 1 of 2)

Examination date☐☐-☐☐-☐☐ D M Y	**Case number:**☐☐☐

TMJ SOUNDS	**Right**	**Left**
Open click	☐	☐
Close click	☐	☐
Reciprocal click	☐	☐
Right lateral excursive click	☐	☐
Left lateral excursive click	☐	☐
Protrusive click	☐	☐
Position of opening click	Early click☐ Late click ☐	Early click☐ Late click ☐
Crepitus	☐	☐
Popping	☐	☐

TMJ TENDERNESS	**Right**	**Left**
Lateral aspect	0 1 2 3	0 1 2 3
Posterior attachment	0 1 2 3	0 1 2 3

MUSCLE TENDERNESS	**Right**	**Left**
Temporalis muscles		
Anterior	0 1 2 3	0 1 2 3
Middle	0 1 2 3	0 1 2 3
Posterior	0 1 2 3	0 1 2 3
Masseter muscle		
Origin	0 1 2 3	0 1 2 3
Body	0 1 2 3	0 1 2 3
Insertion	0 1 2 3	0 1 2 3
Posterior mandibular region	0 1 2 3	0 1 2 3
Submandibular region	0 1 2 3	0 1 2 3
Lateral pterygoid area	0 1 2 3	0 1 2 3
Tendon of temporalis	0 1 2 3	0 1 2 3

TOOTH RELATION	**mm**	**RANGE OF MOTION**	**mm**	**OPENING PATTERN**
Vertical overlap		Maximum unassisted opening		☐ straight
Horizontal overlap		Unassisted opening without pain		☐ corrected deviation
Midline deviation		Assisted opening		☐ right lateral deviation
	R L	Right lateral excursion		☐ left lateral deviation
		Left lateral excursion		☐ other type
		Protrusion		

CLINICAL EXAMINATION RECORD FORM (PAGE 2 of 2)

Examination date☐☐-☐☐-☐☐ **Case number:**☐☐☐
D M Y
Pre-treatment ☐ Post-treatment ☐ at…….weeks/months

OCCLUSION	**Right**	**Left**
Molar occlusion	☐ cl I ☐ cl II ☐ cl III	☐ cl I ☐ cl II ☐ cl III
Canine occlusion	☐ cl I ☐ cl II ☐ cl III	☐ cl I ☐ cl II ☐ cl III
Posterior crossbite	☐ no ☐ yes specify…….	☐ no ☐ yes specify……
Anterior crossbite	☐ no ☐ yes specify……..	☐ no ☐ yes specify……
Anterior openbite	☐ no ☐ yes	☐ no ☐ yes
Loss of molars	☐ no ☐ yes specify……..	☐ no ☐ yes specify……
Posterior tooth contact in ICP	☐ no ☐ yes	☐ no ☐ yes
Working side relationship	☐ guidance☐ interference specify……	☐ guidance☐ interference specify……
Non-working side relationship	☐ guidance☐ interference specify……	☐ guidance☐ interference specify……
Protrusive relationship	☐ guidance☐ interference specify……	
CR discrepancy ≥2 mm V	☐ no ☐ yes	
CR discrepancy ≥2 mm H	☐ no ☐ yes	
CR discrepancy ≥2 mm A-P	☐ no ☐ yes	

SOFT TISSUES	**Right**	**Left**
Tongue ridging	☐ no ☐ yes	☐ no ☐ yes
Buccal scalloping	☐ no ☐ yes	☐ no ☐ yes

Note:_____

_____

_____

_____

_____

_____

_____

_____

_____

APPENDIX 3

ข้อมูลที่ผู้ป่วยควรทราบ (Patient Information Sheet)

ชื่อโครงการวิจัย ประสิทธิผลของเฝือกสบฟันจัดตำแหน่งและเฝือกสบฟันเสถียรในการรักษาอาการของแผ่นรองข้อต่อขากรรไกรเคลื่อนชนิดเข้าที่ได้เอง

วัตถุประสงค์ของการวิจัย ต้องการทราบว่าระหว่างเฝือกสบฟันชนิดจัดตำแหน่งขากรรไกรกับชนิดเสถียร เฝือกสบฟันชนิดใดที่ให้ประสิทธิผลสูงกว่าในการรักษาอาการของแผ่นรองข้อต่อขากรรไกรเคลื่อนชนิดเข้าที่ได้เอง

สถานที่ทำการวิจัย คลินิกบัณฑิตศึกษา สาขาทันตกรรมบดเคี้ยว คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

ผู้ทำการวิจัย ผู้ช่วยศาสตราจารย์ ทันตแพทย์หญิงพนมพร วานิชชานนท์

ผู้ทำวิจัยร่วม อาจารย์ ทันตแพทย์หญิงอตินุช ลัดพลี

อาจารย์ที่ปรึกษา ผู้ช่วยศาสตราจารย์ นายแพทย์มนต์ชัย ชาลาประวรรตน์

ข้อมูลทั่วไป ปัญหาแผ่นรองข้อต่อขากรรไกรเคลื่อนผิดตำแหน่งชนิดเข้าที่ได้เอง มักทำให้เกิดเสียงคลิกที่ข้อต่อขากรรไกร อาจมีอาการปวด และ/หรือมีอาการติดขัดที่ข้อต่อขากรรไกรในขณะที่ใช้ขากรรไกรในการทำหน้าที่ หลักการรักษาอาการผิดปกติที่ข้อต่อขากรรไกรชนิดนี้ใช้วิธีการรักษาแบบอนุรักษ์เป็นขั้นแรก โดยวิธีการรักษาที่ใช้กันในปัจจุบันยังเป็นการใช้เฝือกสบฟันซึ่งเป็นเครื่องมือที่ทำด้วยเรซินแข็งใส เฝือกสบฟันที่ได้รับความนิยมมากมีสองลักษณะคือ เฝือกสบฟันชนิดเสถียรหรือชนิดเรียบ และชนิดจัดตำแหน่งขากรรไกรไปด้านหน้า

ข้อมูลของโครงการ การศึกษาในโครงการวิจัยนี้ เป็นการเปรียบเทียบประสิทธิภาพการรักษาอาการของแผ่นรองข้อต่อขากรรไกรเคลื่อนผิดตำแหน่งชนิดเข้าที่ได้เองด้วยเฝือกสบฟันสองชนิด ได้แก่ เฝือกสบฟันชนิดเสถียรหรือชนิดเรียบ และชนิดจัดตำแหน่งขากรรไกรไปด้านหน้า โดยให้ใส่เฝือกสบฟันเฉพาะตอนกลางคืน ใช้กลุ่มตัวอย่างที่เป็นผู้ป่วยที่มีปัญหาดังกล่าวที่มาขอรับการรักษาที่คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ประมาณ 80 คน โดยมีขั้นตอนดังต่อไปนี้

1. การตรวจทางคลินิก ร่วมกับการใช้แบบสอบถามเกี่ยวกับอาการของผู้ป่วย
2. การให้การรักษาด้วยการใช้เฝือกสบฟันชนิดใดชนิดหนึ่งโดยวิธีการสุ่ม โดยที่เฝือกสบฟันทั้งสองชนิดได้เป็นที่ยอมรับมานานกว่า 20 ปี ในการช่วยบำบัดอาการของกล้ามเนื้อและข้อต่อขากรรไกร
3. การประเมินผลการรักษา ในแง่ ความเจ็บปวด การทำงานของขากรรไกร การกดเจ็บที่ข้อต่อขากรรไกร เป็นระยะๆ โดยการศึกษาครั้งนี้จะวิเคราะห์ผลเมื่อเวลา 10 อาทิตย์หลังจากใส่เครื่องมือ

ความไม่สะดวกที่อาจเกิดจากการศึกษาวิจัย

การศึกษานี้อาศัยการซักประวัติ การสัมภาษณ์ การตรวจระบบบดเคี้ยว การให้คำแนะนำผู้ป่วย และการให้การรักษาด้วยเฝือกสบฟันแก่ผู้ป่วยซึ่งเป็นสิ่งที่ทันตแพทย์ทันตกรรมบดเคี้ยวปฏิบัติอยู่ตามปกติในการดูแลผู้ป่วย ส่วนการตอบแบบสอบถามกระทำเพื่อให้ได้ข้อมูลเกี่ยวกับอาการปวด การทำหน้าที่ของขากรรไกร และรายละเอียดเกี่ยวกับประวัติอาการ ทั้งก่อนและหลังรักษา เพื่อใช้ช่วยประเมินผลการรักษาในภายหลัง

ทันตแพทย์และผู้ป่วยจำเป็นต้องใช้เวลาในการให้ข้อมูลที่ละเอียดและถูกต้อง ผู้ป่วยจำเป็นต้องสามารถมาตามเวลานัดได้เป็นระยะๆ และต้องใส่เฝือกสบฟันตามคำแนะนำ ซึ่ง ผู้ป่วยอาจมีความรำคาญ รู้สึกตึงๆที่ซี่ฟัน เมื่อถอดเฝือกสบฟันในตอนเช้าอาจรู้สึกแปลกๆคล้ายฟันเคลื่อน อาจมีน้ำลายไหลมากขึ้น ซึ่งอาการเหล่านี้จะเกิดขึ้นในระยะ 3-4 วันแรกเท่านั้น แต่ไม่มีรายงานปัญหาร้ายแรงใดๆจากการใส่เฝือกสบฟัน ในกรณีที่เป็นเฝือกสบฟันชนิดจัดตำแหน่งที่ผู้ป่วยใส่ตลอด 24 ชั่วโมงเป็นเวลาหลายเดือนถึงเป็นปีอาจพบมีการเปลี่ยนแปลงการสบฟันหลังได้ในผู้ป่วยบางราย

ประโยชน์ที่ได้รับจากการวิจัย

ข้อมูลที่ได้จากการวิจัยนี้จะเป็นข้อมูลให้กับทันตแพทย์ และนิสิตทันตแพทย์ในการเลือกใช้เฝือกสบฟันที่จะให้ประสิทธิผลในการรักษาสูงสุด และจะเป็นข้อมูลในการปรับปรุงหลักสูตรรายวิชาทันตกรรมบดเคี้ยวให้แก่นิสิตระดับปริญญาบัณฑิต

ทั้งนี้ข้อมูลที่ได้จากผู้ป่วยจะใช้สำหรับวัตถุประสงค์ทางวิชาการเท่านั้น ข้อมูลต่างๆจะเปิดเผยเฉพาะในรูปของผลการวิจัย และขอรับรองว่าจะไม่มีการเปิดเผยชื่อของท่านตามกฎหมาย

ท่านจำเป็นต้องเข้าร่วมการศึกษาครั้งนี้หรือไม่?

ขึ้นกับตัวท่านเอง การเข้าร่วมเป็นอาสาสมัครในโครงการวิจัยนี้ ขอให้เป็นไปโดยความสมัครใจของท่านเอง อาจารย์จะดูแลท่านอย่างดีที่สุด ไม่ว่าท่านจะเข้าร่วมการศึกษานี้หรือไม่? และท่านสามารถถอนตัวจากการศึกษาได้ทุกเวลา โดยไม่ทำให้คุณภาพการรักษาที่ท่านจะได้รับด้อยลงไป

หากท่านตัดสินใจที่จะเข้าร่วมการศึกษาวิจัยนี้ จะมีข้อปฏิบัติร่วมดังต่อไปนี้

1. ท่านจะได้รับการถ่ายภาพรังสีข้อต่อขากรรไกร 1 ภาพ โดยไม่ต้องเสียค่าใช้จ่าย
2. ท่านจะได้รับการตรวจระบบบดเคี้ยว รวมถึงการสบฟันอย่างละเอียด
3. ท่านจะได้รับการรักษาด้วยเฝือกสบฟันในราคาพิเศษ (500 บาท) โดยไม่ต้องเสียค่าใช้จ่ายสำหรับค่าเครื่องมือ และไม่ต้องเสียค่าใช้จ่ายในการนัดติดตามผลทุกครั้ง แต่ไม่รวมถึงการรักษาทางทันตกรรมอื่นๆในกรณีที่จำเป็น เช่น อุดฟัน ขูดหินปูน ถอนฟัน ฯลฯ
4. ท่านจะได้รับเงินตอบแทนค่าเดินทางในการมาติดตามผลเมื่อครบ 10 อาทิตย์ ในอัตราครั้งละ 200 บาท
5. ระหว่างการศึกษาขอให้ท่านมาตามนัดเป็นระยะๆ
6. ท่านต้องดูแลการใช้เฝือกสบฟันเป็นอย่างดี ในกรณีที่สูญหายหรือแตกหักจากการเก็บรักษาที่ไม่ระมัดระวัง ท่านจำเป็นต้องเสียค่าใช้จ่ายสำหรับการทำเฝือกสบฟันใหม่เอง (1,000 บาท) แต่ถ้า

เครื่องมือแตกหักจากการใช้งาน ท่านไม่ต้องเสียค่าใช้จ่ายเพิ่มเติมแต่ขอให้นำเครื่องมือที่แตกหักมาด้วย

ทันตแพทย์ผู้ที่ท่านสามารถติดต่อได้

หากท่านมีปัญหา หรือข้อสงสัยประการใด สามารถสอบถามรายละเอียดเพิ่มเติมได้จาก ผู้ช่วยศาสตราจารย์
ทันตแพทย์หญิง พนมพร วานิชชานนท์ ใบประกอบวิชาชีพทันตกรรมเลขที่ 2471 หมายเลขโทรศัพท์ที่ติดต่อได้ 02-218-8529 หรือ 02-218-8766 ขอขอบคุณในความร่วมมือมา ณ โอกาสนี้

ทันตแพทย์หญิงพนมพร วานิชชานนท์

APPENDIX 4

ใบยินยอมเข้าร่วมการวิจัย (Consent form)

ผู้ป่วยเลขที่.....**(สำหรับเจ้าหน้าที่)**

ชื่อและนามสกุล.....

ชื่อโครงการวิจัย ประสิทธิผลของเฝือกสบฟันจัดตำแหน่งและเฝือกสบฟันเสถียรในการรักษาอาการของแผ่นรองข้อต่อขากรรไกรเคลื่อนชนิดเข้าที่ได้เอง

ข้าพเจ้าได้รับทราบจากทันตแพทย์ผู้รักษา ซึ่งได้ลงนามด้านท้ายของหนังสือนี้ ถึงวัตถุประสงค์ ลักษณะและแนวทางการศึกษาของเฝือกสบฟันทั้งสองชนิด รวมทั้งทราบผลดี ผลข้างเคียง และความเสี่ยงที่อาจเกิดขึ้น ข้าพเจ้าได้ซักถาม ทำความเข้าใจเกี่ยวกับการศึกษาดังกล่าวนี้ เป็นที่เรียบร้อยแล้ว

ข้าพเจ้ายินดีเข้าร่วมการศึกษานี้โดยสมัครใจ และยอมรับสิ่งไม่พึงประสงค์ที่อาจเกิดขึ้น และจะปฏิบัติตัวตามคำแนะนำของทันตแพทย์ผู้รักษาทุกประการ และอาจถอนตัวจากการเข้าร่วมศึกษานี้เมื่อใดก็ได้ และการบอกเลิกการเข้าร่วมวิจัยนี้ จะไม่มีผลต่อการรักษาที่ข้าพเจ้าจะพึงได้รับต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆที่เกี่ยวข้องทำได้เฉพาะกรณีจำเป็น ด้วยเหตุผลทางวิชาการเท่านั้น

ข้าพเจ้าได้รับทราบจากทันตแพทย์ผู้รักษาว่า หากข้าพเจ้าได้รับความผิดปกติเนื่องจากการศึกษา ข้าพเจ้าจะได้รับการคุ้มครองตามกฎหมาย และหากข้าพเจ้ารับการรักษาด้วยวิธีการอย่างอื่นโดยมิได้ปรึกษาทันตแพทย์ผู้รับผิดชอบการศึกษานี้ และมิแจ้งให้ทันตแพทย์ทราบทันทีเกี่ยวกับความผิดปกติของร่างกายที่เกิดขึ้น จะถือว่าข้าพเจ้าทำให้การคุ้มครองความปลอดภัยเป็นโมฆะ (ตามที่กฎหมายกำหนด)

ข้าพเจ้ายินดีให้ข้อมูลของข้าพเจ้าแก่ทันตแพทย์ผู้รักษา เพื่อเป็นประโยชน์ในการศึกษาวิจัยครั้งนี้

สุดท้ายนี้ ข้าพเจ้ายินดีเข้าร่วมโครงการวิจัยนี้ด้วยความเต็มใจ ภายใต้เงื่อนไขที่ได้ระบุไว้แล้วข้างต้น

ลงนาม.....ผู้ยินยอม (.....) ...../...../.....	ลงนาม.....ผู้วิจัย (.....) ...../...../.....	ลงนาม.....พยาน (.....) ...../...../.....
ในกรณีที่ผู้ป่วยยังไม่บรรลุนิติภาวะ จะต้องได้รับการยินยอมจากผู้ปกครอง หรือผู้อุปการะโดยชอบด้วยกฎหมาย		
ลงนาม..... (ผู้ปกครอง/ผู้อุปการะโดยชอบด้วยกฎหมาย) (.....) ...../...../.....	ลงนาม.....ผู้วิจัย (.....) ...../...../.....	ลงนาม.....พยาน (.....) ...../...../.....

APPENDIX 5

Final Criteria for occlusal appliances

Final criteria for the anterior repositioning appliance (19)

1. It should accurately fit the maxillary teeth, with total stability and retention when in contact with the mandibular teeth and when checked by digital palpation. In the established forward position all the mandibular teeth should contact it with even force.
2. The forward position established by the appliance should eliminate the joint symptoms during opening and closing to and from that position
3. In the retruded range of movement the lingual retrusive guidance ramp should contact and on closure direct the mandibular into the established forward position
4. The appliance should be smoothly polished and compatible with adjacent soft tissue structures.

Finial criteria for the stabilization appliance (19)

1. The appliance must accurately fit the maxillary teeth, with total stability and retention when contacting the mandibular teeth and when checked by digital palpation
2. In centric relation all posterior mandibular buccal cusps must contact on flat surfaces with even force.
3. During protrusive movement the mandibular canines must contact the appliance with even force. The mandibular incisors may also contact the appliance but not with more force than the canines
4. In any lateral movement only the mandibular canines should exhibit laterotrusive contact on the appliance.
5. The mandibular posterior teeth must contact the appliance only in the centric relation closure.
6. In the alert feeding position the posterior teeth must contact the appliance more prominently than the anterior teeth.
7. The occlusal surface of the appliance should be as flat as possible with no imprints for mandibular cusps
8. The occlusal appliance is polished so that it does not irritate any adjacent soft tissues.

VITAE

Phanomporn Vanichanon was born in September 1961. She did her Doctor of Dental Surgery (D.D.S.) degree with a second class honor at the Faculty of Dentistry, Mahidol University in 1984. After graduation, she furthered her studies at the Faculty of Dentistry, Mahidol University and received a certificate in Pediatric Dentistry in 1986. After working as an adjunct lecturer at Mahidol University for one year, she continued her studies at the University of Michigan, Ann Arbor, U.S.A. In 1991, she received a Master of Science in Restorative Dentistry-Occlusion. After returning to Thailand, she joined the Faculty of Dentistry, Chulalongkorn University as a fulltime faculty member at the Department of Occlusion until present. In 2000, she decided to continue her studies again in Health Development program at the Faculty of Medicine, Chulalongkorn University.