CHAPTER 3: METHODOLOGY

This was a clinical prospective study in TMD. The methodology was summarized in a flow chart in Figure 3.1. The scope of the study was as follows:

1. The demographic data, dentition characteristics, functional overloading, signs and symptoms of the TMD patients were recorded.
2. The postural and maximum clenching EMG activities of the anterior temporal and masseter muscles were recorded before insertion of the soft splint.
3. The postural and maximum clenching EMG activities of the anterior temporal and masseter muscles were recorded again 15 minutes after insertion of the soft splint.
4. The patients were instructed to wear the soft splint to sleep at night for a period of six weeks. They were also prescribed with analgesics together with patient education and self-care.
5. After 6 weeks of conservative treatment, the same EMG test was repeated.
6. The patients were reviewed for the signs and symptoms of TMD after six weeks. Patient's comment towards splints was taken down. Patients were also noted down whether they currently did resume their routine oral function without pain. Then the collected data was analyzed.

For the healthy subjects, splint was only used for the sack of the EMG test. They went through the same EMG test as in the TMD patients but only once. They were not asked to wear the splint to sleep due to ethical concern. There was no follow-up for the healthy subjects after the EMG test.

This study was carried out with the approval of the ethics committee, Faculty of Dentistry, University of Malaya (Ethics approval no.: DF OP0304/0016(P)). Patient information sheet was given to all cases selected for this study (Appendix1). Consent was also obtained for all cases (Appendix 2). For minors, consent was obtained from the guardian (Appendix 3).

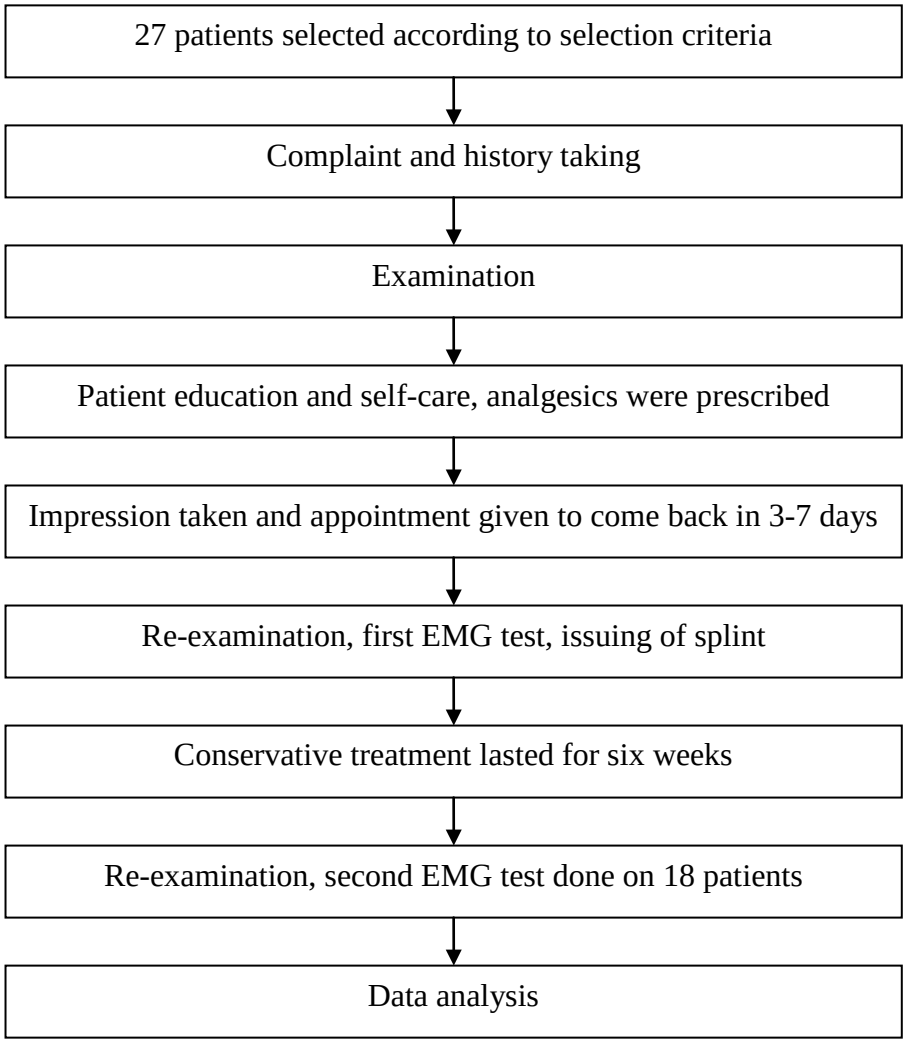


Figure 3. Flow chart of methodology.

3.1. Sampling

Two groups of subjects were recruited for this study. The experimental group was recruited to study the effect of the soft splint on the EMG activities of the masseter and the anterior temporal muscles in TMD patients. The TMD patients were studied because it was generally thought that splint would reduce both the postural and clenching EMG activities of the masseter and the anterior temporal muscles. The healthy subjects were also recruited as a control group to see whether the splint would cause different effect on them as compared to the TMD patients. The study was also extended to see whether the splint would cause any different effect on the TMD patients after six weeks of conservative treatment.

3.1.1. Selection of the experimental subjects

3.1.1.1. Inclusion criteria

The experimental subjects were selected from those patients who attended the Oral Medicine Clinic of the Department of Oral Pathology, Oral Medicine and Periodontology, Faculty of Dentistry, University of Malaya. The Oral Medicine Clinic is a referral centre and also the main Oral Medicine centre in the country. The inclusion criteria were:

1. Patients complained of pain of the masticatory system and the pain should still exist on the day of EMG test.
2. They were diagnosed having myofascial pain or/ and arthralgia with disc displacement.
3. They had at least 20 teeth with at least one molar contact for each quadrant of dentition, either on natural teeth or on fixed prostheses.

4. Their age should be above 12 years old which was assumed to be able to comprehend the basic study procedure, and below 60 years old which was assumed still physically fit to undergoing the study.
5. They should complete the full course of study until the second EMG test.

3.1.1.2. Exclusion criteria

The following patients were excluded:

1. Patients who had existing dentures or orthodontic appliances.
2. Patients who had previous treatment with any kind of splint for TMD.
3. Patients who had underlying medical conditions namely rheumatoid arthritis, osteoarthritis and other autoimmune disorders affecting the joints.

3.1.1.3. Experimental group

There were 18 patients with the age range of 14-55 years, mean=28.9 years, SD $\pm$10.9 years, 14 of them were female, aged 14-42 years, mean=27.6 years, SD$\pm$8.8 years; and 4 were male, aged 15-55 years, mean=33.3 years, SD$\pm$17.6 years, that were selected for this study. Out of these 18 TMD patients, 8 (2 male and 6 females) were diagnosed as having myofascial pain only, 4 (1 males and 3 females) were diagnosed as having arthralgia with disc displacement only, and 6 (1 males and 5 females) were diagnosed as having myofascial pain and arthralgia with disc displacement together.

These subjects were selected over duration of eight months. There were 45 TMD patients that were approached by the researcher, 27 of them consented to participate and 18 of them completed the full course of study. These patients did not represent the total TMD patients that had attended the Oral Medicine Clinic.

Some of the patients were referred directly to a specific dental officer and some of them preferred to be taking care only by the specific officer. Due to the ethical requirement, patients had the right not to participate the study and could be not giving any reason. Even after they consented to take part in the study, they also had the right to quit at any point of time and could be not giving any reason, and they were still be treated like usual as under normal circumstances. Some of the patient did not participate in this study because they felt that EMG test did not contribute to the treatment of their disorders. Some of the patients who did not participate gave ambiguous reasons such as busy at their own work, thought of feeling uncomfortable towards EMG test, thought of feeling tire because the testing time is long or just failed to attend the follow-up visit. Most of the patients, who did not complete the course of study, did so because they did not feel the need of repeating the EMG test which they thought did not contribute directly to their treatment.

3.1.2. Selection of the control subjects and the control group

There were 10 healthy subjects with the age range of 24-32 years, mean=26.9 years, SD $\pm$2.9 years, 7 of them were female, aged 24-32 years, mean=27.9 years, SD$\pm$3.0 years; and 3 were male, aged 24-25 years, mean=24.7 years, SD$\pm$0.6 years. They had no history of having TMD currently or in the past. The subjects were also screened to be free from having any sign of TMD including TMJ clicking, jaw deviation on mouth-opening, limited mouth-opening, limited lateral excursion and muscle tenderness. They should meet all the others inclusion and exclusion criteria as in the experimental group except the first, second and fifth inclusion criteria. This control groups were mainly recruited through acquaintance. They were not age or sex matched with the experimental group.

3.2. Examination and treatment

3.2.1. Complaint and history taking

A detailed history-taking were carried out for all selected cases. The complaint of the patient was recorded. The detailed descriptions of the pain were taken from the patient. The severity of the current pain was noted on a ten-point scale to facilitate follow-up of the symptom. However the determination of the treatment outcome of the conservative treatment was only based on either there was “pain” or “no pain” in performing their routine oral function. The basic demographic data was also obtained from the patients.

3.2.2. Examination

Clinical examination was carried out. Extraoral examination would include assessment of the TMJ for pain and joint sounds, assessment of the muscles of mastication for tenderness, and assessment of the range of mandibular movement. Intraoral examination would include appraisal of the dentition and occlusion. The examination was carried out using a standard patient examination form (Appendix 4). Plain radiographs of orthopantomograph (Figure 3.2.2(a)) and transcranial views of TMJ at open and close positions (Figure 3.2.2(b)) would be obtained for each case.

For all confirmed cases, impressions of the upper dentition were taken for construction of upper soft occlusal splints. Patients were first prescribed with analgesics together with patient education and self-care. They were then arranged for appointments to come back as soon as possible in 3 to 7 days for EMG test and for splint issuing. Prior to first EMG test at following visit, the examination would be repeated again especially for the assessment of current pain and the measurements of jaw movements. Any data changes obtained in this visit would overwrite the data of the first visit. Patients who had the pain resolved before the first EMG test would be excluded from the study.

After six weeks of conservative treatment, examination would be repeated again to follow up the signs and symptoms of the patients.

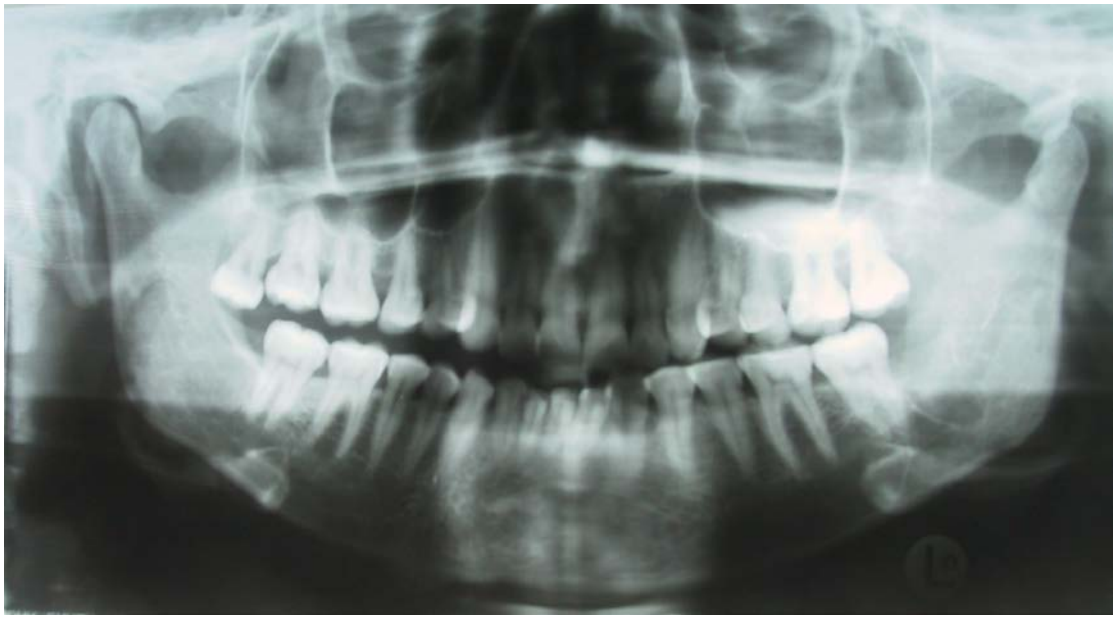


Figure 3.2.2(a) Orthopantomograph showing the dentition, maxilla and mandible.

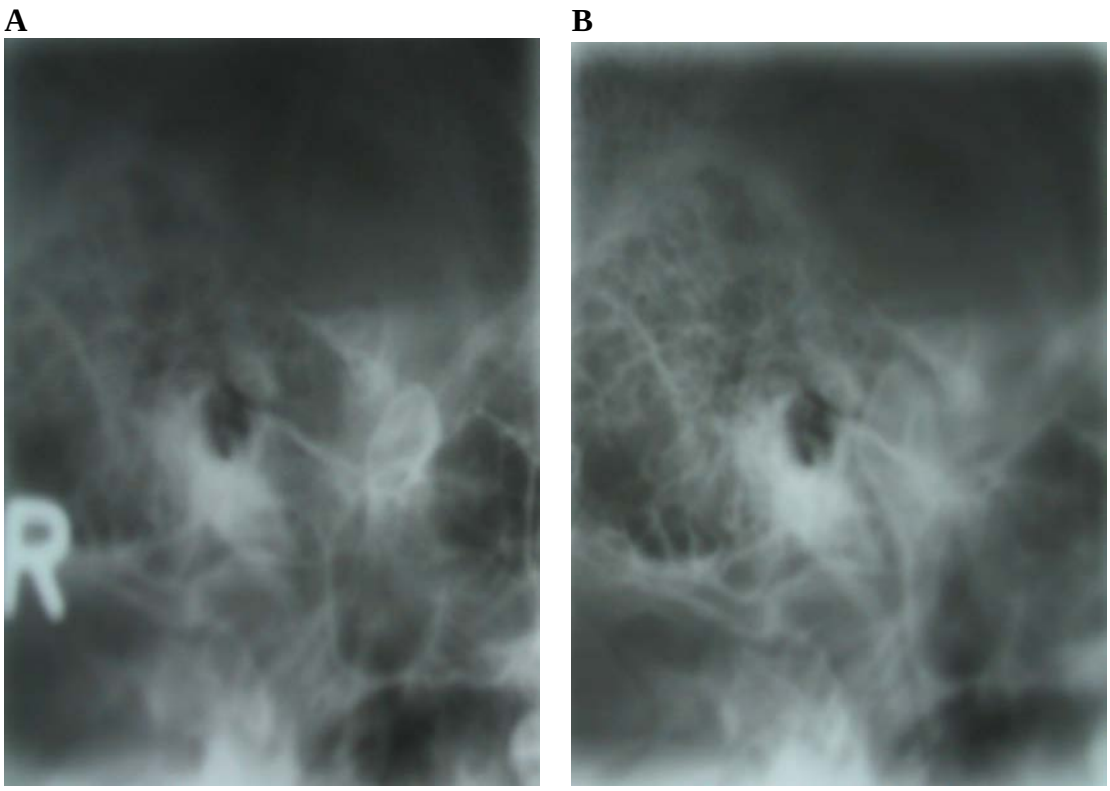


Figure 3.2.2(b) Standard transcranial oblique lateral radiograph at open and closed positions of the TMJ. A, open position; B, closed position.

3.2.3. Treatment for subjects

Subjects was provided with conservative treatment included patient education and self-care, analgesics, and soft occlusal splint. Patient was advice to take the analgesics when necessary especially during acute pain period, except one day before EMG tests and clinical assessment. Patient education and self-care mainly included promoting self awareness of functional overloading, reversal of parafunctional habit and adverse usage of masticatory system, and voluntary limitation of mandibular function. Soft occlusal splint was given and patients were asked to wear the splint to sleep at night. These conservative treatments lasted for six weeks.

Soft occlusal splint was assessed in this study because at the research centre of this study, the splint of choice was normally soft splint (Figure 3.2.3). Meanwhile, the effectiveness of hard splint in the treatment of TMD was still not confirmed through systematic reviews of randomized controlled trial (Forssell et al, 1999; Al-Ani et al, 2004). The studies by Al-Quran and Lyons (1999), and Okeson (1987) were also not conclusive to prove that hard splint was superior to soft splint.

A B

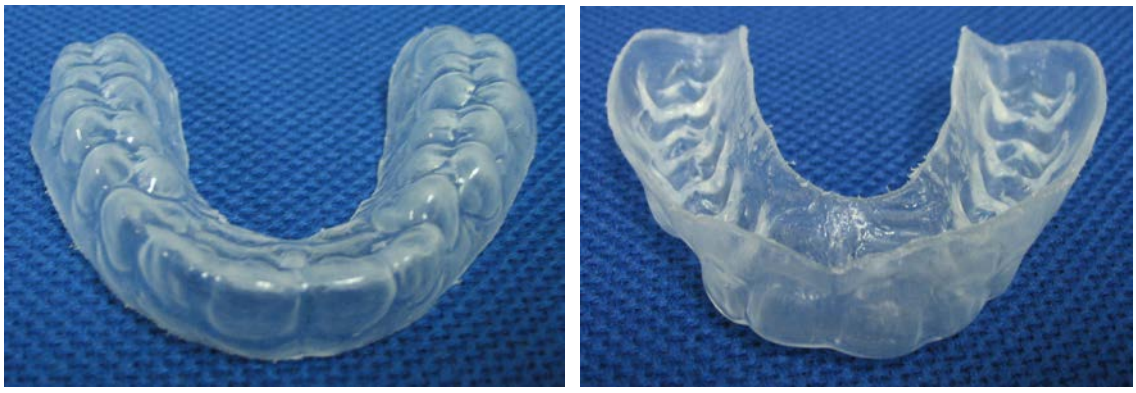


Figure 3.2.3 Soft splint made of polyvinyl with uniform thickness, made by vacuum forming technique. A, external view; B, internal view.

3.3. EMG Instrumentation

3.3.1. EMG machine and acquisition setup

The EMG equipment that was used in this study is a five-channel system, Medelec Synergy N series, manufactured by Oxford Instruments Medical, surrey, United Kingdom. (Figure 3.3.1(a), (b)). The electrical activity was amplified by an amplifier with a bandwidth of 0.1-10 kHz. In this study, the low-pass filter was set as 20 Hz to suppress the movement artifacts (Soderberg, 1992). The high-pass filter was set as 1000 Hz (Donegan et al., 1990; Cram et al., 1998) to reduced noise (Brinkworth &Turker, 2003).

The EMG signal was sampled sequentially with sweep duration of 1 second each sample. The signal was full-wave rectified and integrated. The mean amplitude of the integrated signal was obtained as microvolts, μV. (Figure 3.3.1(c), (d)). All the data acquisition were done simultaneously through a notebook computer (Figure 3.3.1(e), (f)). The amplitude of the integrated signal can be multiplied by the sweep duration to obtain the dynamic EMG activity as microvolt-millisecond, μVms. The unit could then be converted to microvolt-second, μVs. The dynamic EMG activity can be expressed by cumulative energy within a time limit, which was represented also by the area under the graph line in electromyograph tracing (Shi & Wang, 1989). The magnitude of dynamic EMG activity with sweep duration of one second was equivalence to the magnitude of mean static EMG activity for sweep duration of one second.

3.3.1.1. Electrode placement

The electrode placement was one of the most significant factors causing the variability of the EMG readings during recording. The variability was least if the readings were collected within same setting of electrode placement and most if the readings were

collected between days. As reported by Soderberg (1992), measurements made during one day and one setting was considered to be far more superior to other settings. Therefore in this study, the paired EMG readings were recorded within the same setting.

The procedure of electrode placement had been described by Ferrario et al. (1991) (Figure 3.4(a)). Circular disc electrode was used in their study. In this study, square bar electrode was used instead. Little modification to their electrode placement procedure was needed because generally the principle of electrode placement was the same except the shape, size and length of electrode was looked different. The electrodes that were used in both of this study were prefabricated in pairs with the advantage that the distance between the paired electrodes would be more identical. This would avoid investigator's variability in placing the electrodes apart in certain distance.

3.3.1.2. EMG recording duration

In this study, the postural EMG activity was recorded 10 times continuously for duration of 1000 ms each. These 10 readings were then averaged out to give rise to a single value. Meanwhile the maximum clenching EMG activity was recorded 3 times continuously for duration of 1000 ms each. These 3 readings were then also averaged out to give rise to a single value. Both of these single values would be for duration of 1000 ms each and this would facilitate comparison between the postural EMG activity and the clenching EMG activity. On the other hand, by means of continuing recording it would allow notification of any irregular or spurious traces among the EMG signals. Occasionally, these might be observed randomly in this study. To monitor the reliability, each section of EMG recording was repeated once to compare again for irregularity or spuriousness. The readings acquired from the first and the second sections were averaged out respectively to give rise to one set of final readings.

Figure 3.3.1(a) Five-channel system EMG equipment (Medelec Synergy N series, Oxford Instruments Medical, surrey, U.K.).

A B

Figure 3.3.1(b) Two of the major components of EMG equipment. A, Control panel; B, five-channel amplifier.

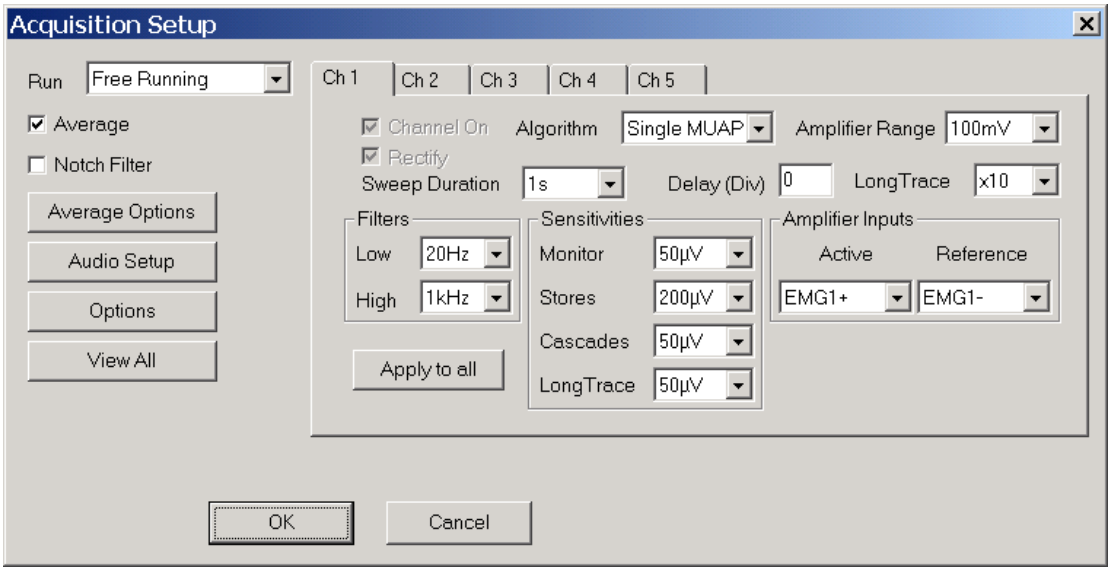


Figure 3.3.1(c) Acquisition setup of Channel 1.

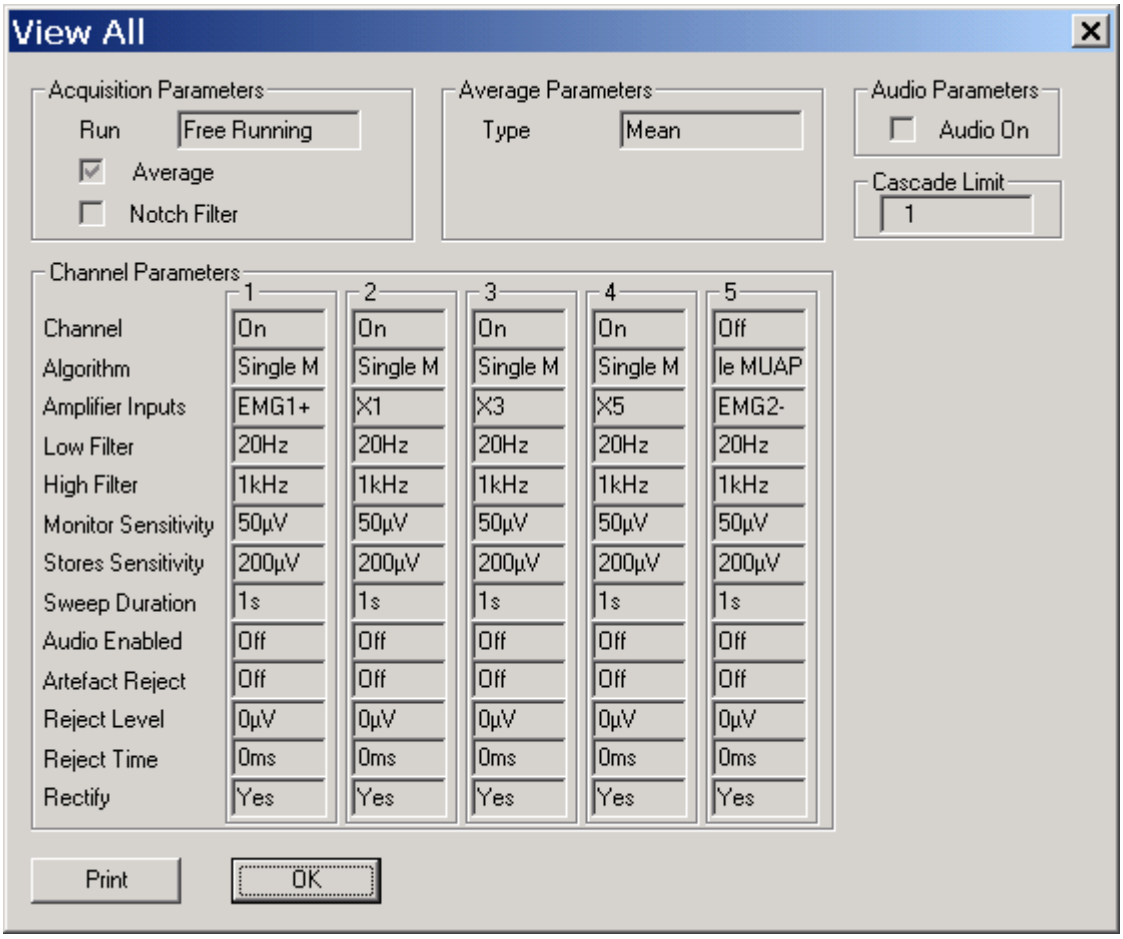


Figure 3.3.1(d) Summary of acquisition settings of all 4 channels.

Figure 3.3.1(e) The plinth under the notebook is a central data acquisition unit that links together the computer, amplifier and control panel.

Figure 3.3.1(f) Acquisition of data through notebook computer.

3.3.1.3. Calibration of EMG measurements

The EMG machine was well-maintained and calibrated regularly in the Neurology Unit of University Malaya Medical Centre. In this study, single investigator was responsible for the electrode placement and the EMG recording therefore excluded the need of inter-investigator calibration. There was also no intra-investigator calibration in this study.

3.3.2. Electrode and cable

Disposable self-adhesive surface silver/silver chloride gel electrodes (Teca, Oxford Instruments Medical, surrey, U.K.) were used in this study to be applied on the subjects. Lead cables were used to connect the electrodes to the EMG machine (Figure 3.3.2(a)). The paired bipolar electrodes were made off two individual electrodes. Each individual electrode was 14.0± 0.5mm times 12.5± 0.5mm in dimension. The paired electrodes were distanced in 21.0mm± 0.5mm edge-to-edge. The ground electrode was 25.5± 0.5mm times 36.5 ± 0.5mm in dimension. Lead cables were used to connect the electrodes to the EMG machine (Figure 3.3.2(b)).

A B

Figure 3.3.2(a) A, disposable electrodes; B, lead cable.

A B

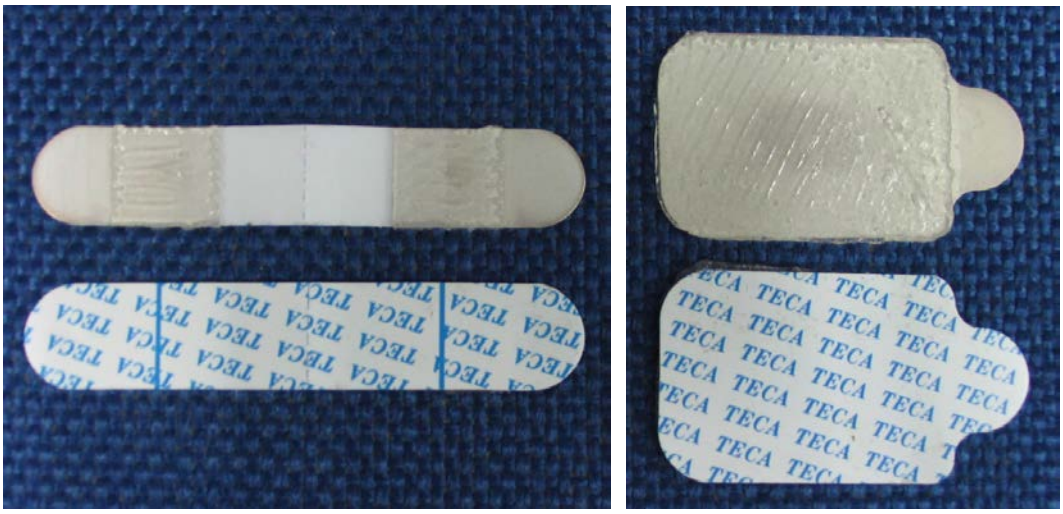


Figure 3.3.2(b) A, bipolar electrodes with the front and back view; B, ground electrodes with the front and back view.

3.4. Step-by-step EMG measurement procedure

1. The subject was given with careful instruction and explanations about the tests and EMG apparatus.

2. The overlying skin of anterior temporal and masseter muscles of both left and right side were cleansed using alcohol scrub.

3. Surface marking of anterior temporal and masseter muscles, and the electrode placement were done as follows:

   A. Anterior temporalis: the most anterior border of the anterior temporalis was palpated as subject asked to clench. A vertical line was drawn to mark down the border. Then the superior border of the zygomatic arch was again palpated and second horizontal line was marked down accordingly. The disposable self-adhesive paired bipolar electrode will be place parallel to the vertical line just behind it and just above the horizontal line. The Bipolar electrodes were place on the muscle parallel to muscular fibres (Ferrario et al.,1991).

   B. Masseter: The angle of the mandible was palpated and a vertical line was drawn from external canthus of the eye to the angle of mandible. Another horizontal line was drawn from the tragus of the ear to the angle of the mouth. The paired bipolar electrode will be placed along the vertical line with the centre of upper electrode at the junction of these two lines.

   C. The ground electrode was place at the centre of the forehead (neutral zone) (Macaluso & Laat, 1995).

4. Lead cables were then attached to the electrodes and secured with adhesive micropole tape. The other ends of the cables were connected to the EMG machine (Figure 3.4 (b)).

5. Subject was asked to sit upright, comfortably in a chair with arm rest. The ankle and knee angle were both about 90 degree, and the feet was putting flat on the floor (Figure 3.4(c)). Subject was asked to maintain natural erect position without head rest and with the eye closed to avoid eye blinking movement (Holmgren et al.,1985).

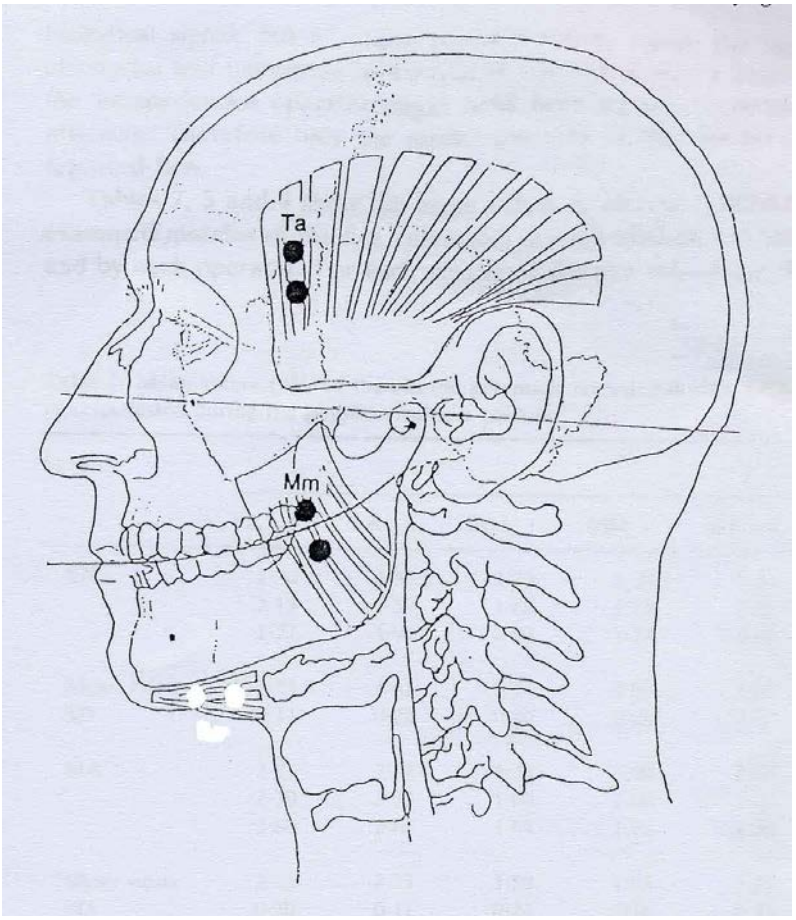
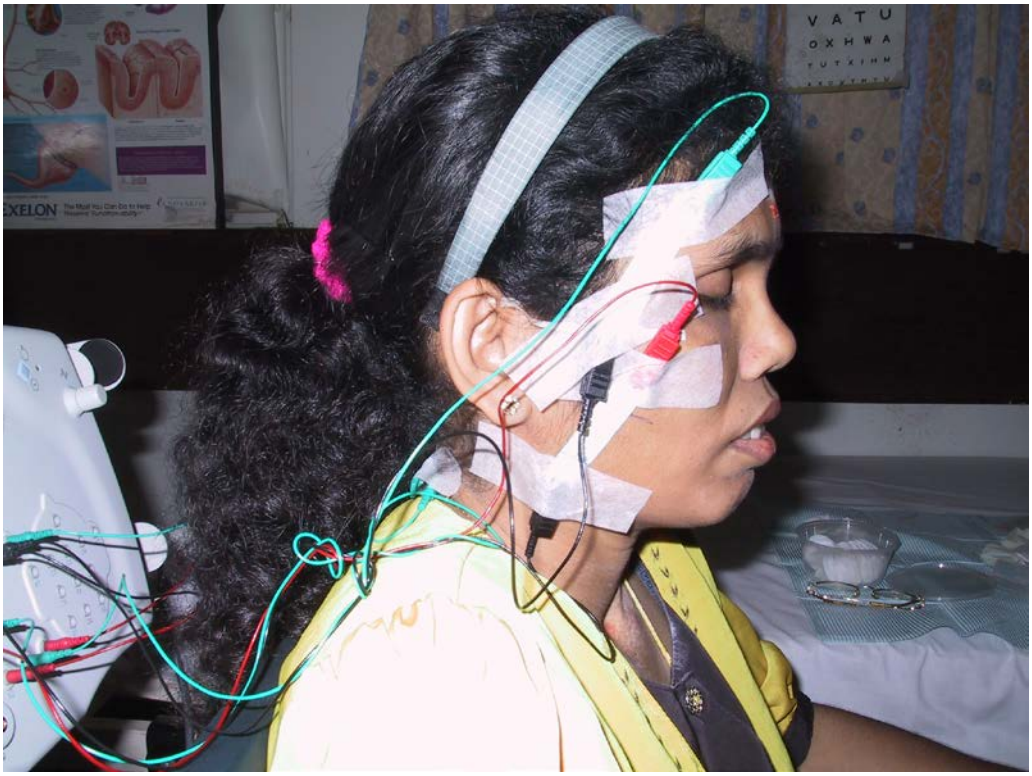


Figure 3.4(a) Scheme showing the position of the double electrodes on the analyzed muscles in the study by Ferrario et al. (1991): Ta, anterior temporalis; Mm, masseter.

A



B

Figure 3.4(b) Electrodes placement and the cables connection to the EMG machine at the side and frontal views. A, Side view; B, frontal view.

Figure 3.4(c) Positioning of the subject. Subject sit upright, comfortably in a chair with arm rest. The ankle and knee angle are both at about 90 degree, and the feet are placed flat on the floor. Subject is asked to maintain natural erect position without head rest and with the eyes closed.

6. The electrode impedance was checked to be less than 10 kohm (Macaluso & Laat, 1995). Five minutes was allowed after placement of electrode, in order for the gel to moisten the skin (Ferrario et al., 2002).

7. Meantime, subject was asked to relax (about 2 minutes before recording) (Ferrario et al.,1993).

8. Subject was asked to gently swallow the saliva for the last time before the recording. Subject was then asked to relax and sit in still. Postural activity usually referred to the resting stage of the masticatory muscle whereby there was no occlusal contact of the teeth.

9. Ten continuous recordings of 1000ms duration each were made for postural muscle activity (Figure 3.4(d)). Irregular or spurious traces were omitted. Whenever necessary, the recordings were repeated.

10. Subject was then asked to clench as fast and as hard as possible and maintain it for 4 second until the next instruction was given to stop. 4 continuous recordings of 1000ms duration each were made. Recording was started immediately after the instructions were given to the subject. However the first 1000ms reading was discarded to compensate for the delay in subject response time (Figure 3.4(e)). To avoid muscle fatigue, the subject was asked to rest for 15 minutes (Kawazoe et al., 1980). Second measurement of maximum voluntary clenching was then performed again. All the EMG tests were performed without changing the electrodes or moving the cables.

11. The readings from the above 2 measurements were then compared for irregularity or spuriousness. Measurement would be repeated if necessary.

12. Subject was asked to wear the splint and relax for 15 minutes (Holmgren et al., 1985).

13. Steps 8 to 12 were repeated similarly but with the soft splint in place.

14. The total session was about 75 minutes.

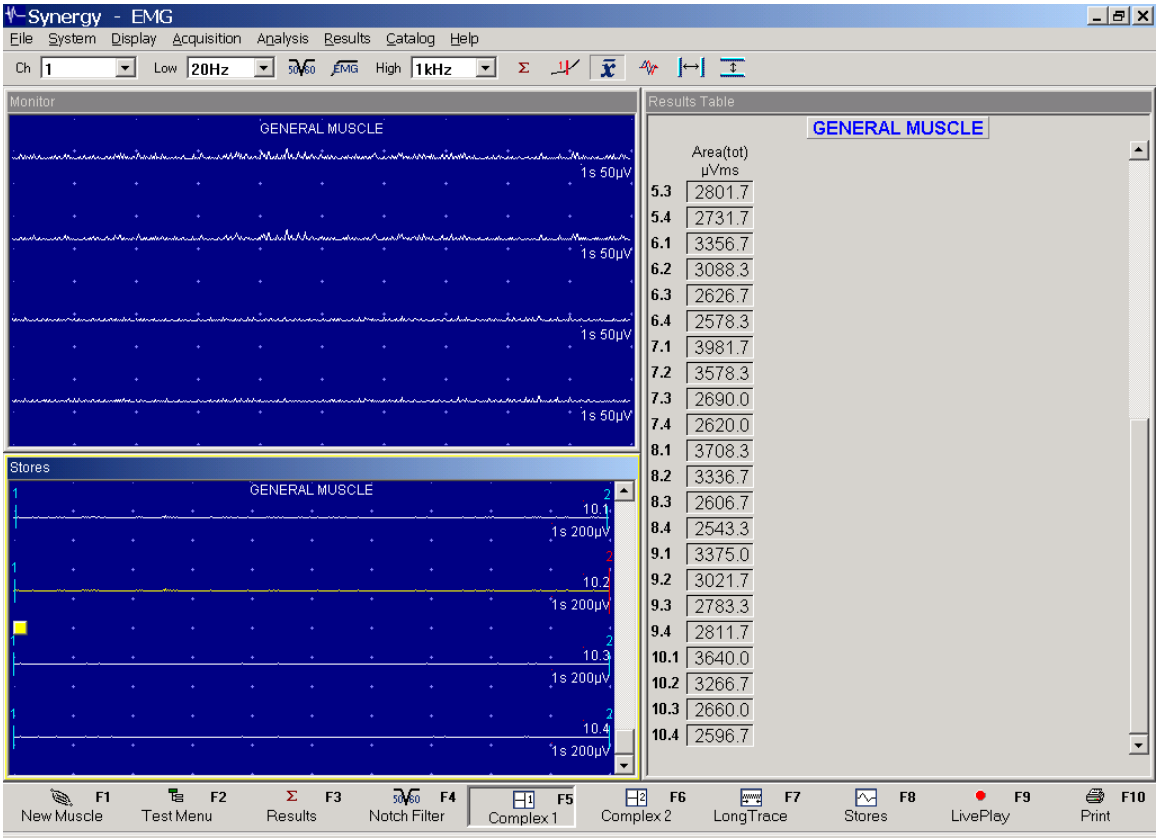


Figure 3.4(d) Recording of postural muscle activity showing 10 continuous recordings of 1000 ms duration each.

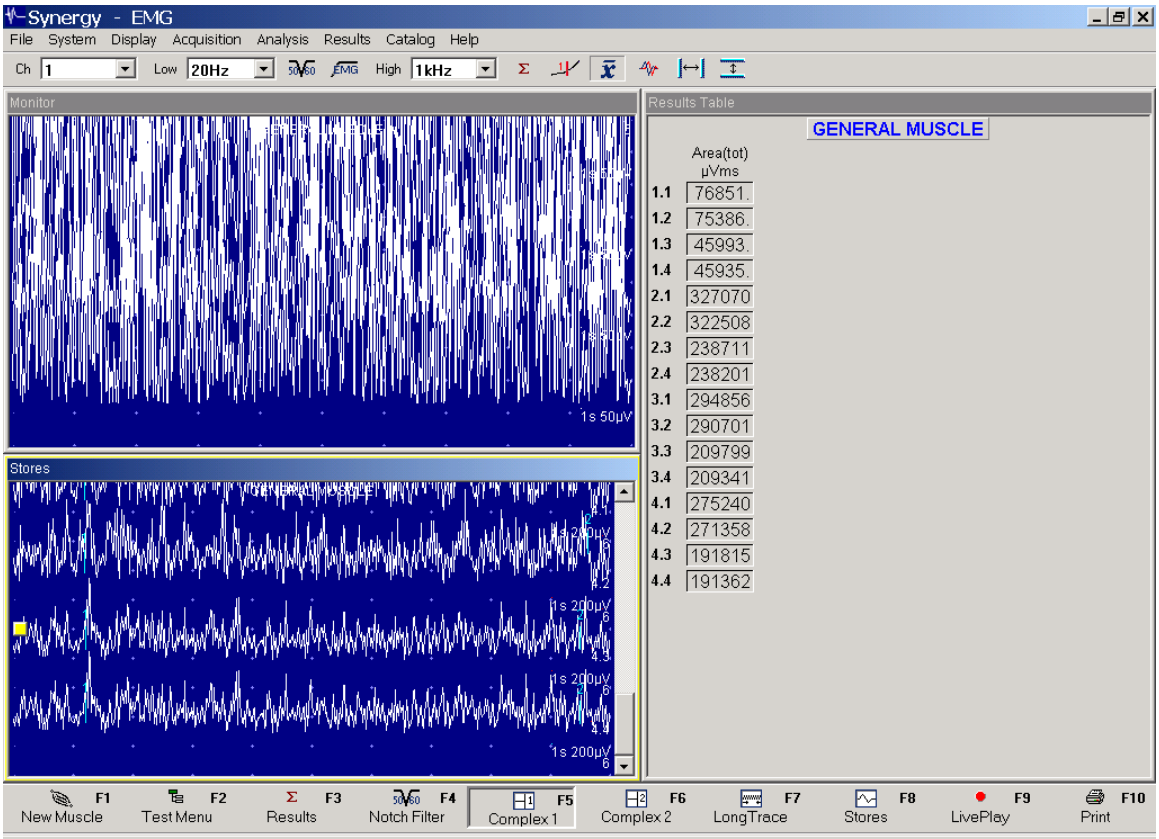


Figure 3.4(e) Recording of clenching muscle activity showing 4 continuous recordings of 1000 ms duration each.

3.5. Data analysis

3.5.1. EMG test analysis before conservative treatment

3.5.1.1. Analysis for experimental group

The postural and maximum clenching EMG activities of the masseter and temporal muscles before and after insertion of splint would be analyzed for any significant difference.

Prior to the analysis, the data was sorted out and paired up accordingly. The two types of EMG activity readings of the masseter muscles before and after insertion of splint were paired accordingly for each of the left side and the right side. The same was applied to the temporal muscles. Each type of EMG activities before and after insertion of splint for each muscle on each side would be paired up to make up for one set of data. For examples, the postural EMG activities before and after insertion of splint for the masseter muscle on the left side would make up for one set of data, while the postural EMG activities for the masseter muscle on the right side would make up for another set of data, and so on. It was worth to mention that the analysis would be individualised to each set of these data and there would not be any analysis across the muscle on the left and right side.

The data was first tested for normality using Kolmogorov-Smirnov test. Kolmogorov-Smirnov test was used to test whether obtained distribution of scores in the data is normal. The tests of normality actually overlay a normal curve on actual data to assess the fit. If the test is not significant; the data would fit the normal curve well. For normal data, means were compared for any significant difference with Student paired t-test; while for non-normal data, medians were compared for any significant difference

with non- parametric Wilcoxan signed-rank test. Two-tailed probability is used for either test that would be used. The statistical significance level was set as $P<0.05$ to reject the null hypothesis.

In this study, it was found that the data was normally distributed by using Kolmogorov-Smirnov test. Therefore Student paired t-test was used in this study. The electromyographic activity samples before and after insertion of splint was analyzed for any significant difference with paired t-test, using Microsoft Excel 2002. The analysis tool that was employed in this study was the T-test of Paired Two Sample for Means. The two-tailed t-test was used to consider differences in both directions.

3.5.1.2. Analysis for control group

Since this study also took consideration that the splint might cause different effect on TMD patients as compared to normal subjects, a control group was therefore recruited. The control group was analyzed similarly as in the experimental group.

3.5.2. EMG test analysis after six weeks of conservative treatment

3.5.2.1. Analysis for experimental group after six weeks of conservative treatment

In this study, all of the TMD patients were prescribed with six weeks of conservative treatment. In order to see whether the splint would still cause the same effect on the TMD patient after six weeks of conservative treatment, the same analysis was repeated on experimental group after six weeks of conservative treatment.

3.5.2.2. Analysis for TMD patients with resolved and unresolved pain after six weeks of conservative treatment

One of the inclusion criteria for this study was that the patient must have pain of masticatory system. For all TMD patient that were recruited in this study, one of the main reason that they came to seek for treatment was pain in performing their routine oral function. In order to see whether TMD patients with resolved pain after treatment would behave similar to healthy subjects that the splint caused no significant difference in the maximum clenching muscle activity, the experimental group was analyzed by dividing it into 2 subgroups which were the subjects with resolved pain and subjects with unresolved pain, after six weeks of conservative treatment. This would also allow us to compare these two subgroups in term of their response towards the soft splint. The data was analyzed similarly as described previously.

3.5.2.3. Analysis for TMD patients with resolved and unresolved pain before conservative treatment

Since the experimental group was divided into two subgroups after six weeks of conservative treatment, the experimental group before the conservative treatment was also divided retrospectively into two subgroups accordingly. This was to monitor if there was a real progressive change in these two subgroups respectively. The data was also analyzed similarly as described previously.

3.5.3. Analysis for effectiveness of conservative treatment

The sign and symptoms of the TMD patients before and after the conservative treatment were sorted out into two tables respectively, and then compared for any improvement. Patient's comments on the usefulness of splint and the effectiveness of conservative treatment were also tabulated. The effectiveness of conservative treatment was only based on whether there was pain remission in performing all their routine oral function which included eating, drinking, talking, laughing and brushing teeth. The measurement of treatment outcome effectiveness was according to the 2-points answer of either there was "pain" or "no pain". The effectiveness of conservative treatments was calculated as percentage of subjects that had reported resumption of all their routine oral function without pain.

3.5.4. Analysis for demographic data, dentition characteristic and functional overloading

The patients' demographic data was tabulated according to sex, race and age to see their distributions. The patients' dentition characteristic was also tabulated, including incisor relationship, anterior guidance, deep overbite, deviated occlusal plane, crowding, and interference on lateral excursion.

Patients were identified for any functional overloading caused by parafunctional habits and adverse usage of the masticatory system. Parafunctional habits includes clenching, grinding, tongue thrusting, cheek and lip biting, finger sucking, resting the jaw on the hand, biting on pencils, pin, or nails, and phone bracing. Adverse usage of masticatory system includes heavy mastication, gum chewing, wide yawning and yelling, prolonged mouth-opening and singing, sleeping on the stomach, playing some musical instruments, and biting on the mouthpiece during diving.