COMPARING THE CLINICAL ACCEPTABILITY OF INNOVATEDLY MADE TRANSPALATAL ARCH (TPA) FROM 3D RECONSTRUCTED MODEL AND CONVENTIONALLY-MADE TPA

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COMPARING THE CLINICAL ACCEPTABILITY OF INNOVATEDLY-MADE TRANSPALATAL ARCH (TPA) FROM 3D RECONSTRUCTED MODEL AND CONVENTIONALLY-MADE TPA

ABSTRACT

Introduction: Digital workflow have been widely implemented in dental clinics for easier data management and reduction of physical storage of dental records. However, the need for physical model supersedes the sophistication of virtual model in dental appliances fabrication. Thus, there is a need to investigate whether the 3D reconstructed model is clinically applicable for the construction of orthodontic appliances. **Aim and objectives:** The study aimed to investigate whether transpalatal arch (TPA) directly fabricated from 3D reconstructed model is a feasible alternative to conventionally constructed TPA for clinical practice, by assessing the patients' oral health related quality of life (OHRQoL), pain level and clinicians' preferences. **Materials and methods:** This is a two-part study comprising quantitative and qualitative methods. Part 1 comprised of a parallel group randomized clinical trial study on 52 subjects who were recruited from patients receiving orthodontic fixed appliances treatment at Faculty of Dentistry, University of Malaya. Twenty-six subjects were allocated into two groups each (CG and 3DG) by block randomization. TPAs (0.9mm stainless steel with midpalatal semi loop) were constructed on conventional stone model and 3D reconstructed model (ABS material printed by UP! Plus 3D Printer). Two outcomes were measured: (1) self-administered questionnaire of the modified short version of Malaysian Oral Health Impact Profile-14 (OHIP-14[M]) to assess the oral health related quality of life (OHRQoL). (2) self-administered pain level by visual analogue score. Data were collected at baseline (T0), and one week (T1), one month (T2) and three months (T3)

after insertion of TPA. Part 2 is a qualitative study involving a Focus Group Discussion (FGD) among five clinicians who treated all the subjects to explore clinicians' preference of clinical application. **Result:** All 52 subjects were analysed and there was no drop out in this study. Severity of OHRQoL among the patients was highest at first week insertion of TPA (10.08; S.D. 6.69) and improved after one month (8.37; S.D. 5.85) and three months (7.56; S.D. 4.97) of wear. There was no significant difference in OHRQoL between the two types of TPA *($p>0.05$)* at all measured time points (T0, T1, T2 and T3). The most affected domain after wearing TPA was psychological discomfort and the least was social disability. There was no significant difference in pain level between the two types of TPA (*$p>0.05$)* at all measured time points (T1, T2 and T3). Four out of five clinicians preferred the TPA fabricated on 3D reconstructed model than the conventional TPA with three emerged themes (1) time factor, (2) molar band selection (3) cost factor. **Conclusion:** There was no significant difference of OHRQoL and pain level between the two types of TPA. Majority of clinicians preferred the TPA fabricated on 3D reconstructed model rather than the conventional TPA. The 3D reconstructed models are clinically acceptable as working models in replacing conventional stone models for TPA fabrication.

Keywords: Transpalatal Arch (TPA), 3D printing, Oral Health Related Quality of Life (OHRQoL, orthodontic pain, focus group discussion (FGD)

PERBANDINGAN KEBOLEHTERIMAAN KLINIKAL ANTARA 'TRANSPALATAL ARCH' (TPA) YANG DIHASILKAN DARI MODEL YANG DIIMBAS DAN DICETAK SEMULA MELAUI KAEDAH TIGA DIMENSI (3D) DAN TPA KONVENSIONAL: SATU KAJIAN KLINIKAL RAWAK

ABSTRAK

Pengenalan: Aliran kerja digital telah banyak dilaksanakan di klinik pergigian untuk pengurusan data yang lebih mudah dan pengurangan penyimpanan secara fizikal rekod pergigian. Walau bagaimanapun, keperluan untuk model fizikal mengatasi kecanggihan model digital dalam fabrikasi peralatan pergigian. Oleh itu, terdapat keperluan untuk mengkaji sama ada model 3D yang dibina semula secara klinikal digunakan untuk pembinaan peralatan ortodontik. **Matlamat dan objektif:** Kajian ini bertujuan untuk mengkaji sama ada TPA yang direka secara langsung daripada model yang dibina semula secara 3D adalah alternatif yang sesuai untuk TPA yang dibuat secara konvensional untuk diguna secara klinikal, dengan menilai tahap kesihatan mulut (OHRQoL), tahap kesakitan yang dialami oleh pesakit dan kecenderungan pilihan di kalangan perawat. **Bahan dan kaedah:** Ini adalah kajian dua bahagian yang terdiri daripada kaedah kuantitatif dan kualitatif. Bahagian 1 terdiri daripada kajian percubaan klinikal rawak kumpulan selari pada 52 subjek yang direkrut dari pesakit yang menerima rawatan peralatan tetap ortodontik di Fakulti Pergigian, Universiti Malaya. Dua puluh enam subjek diperuntukkan kepada dua kumpulan masing-masing (CG dan 3DG) oleh rawak blok. TPAs (keluli tahan karat 0.9mm dengan separa di pertengahan lelangit) telah dibina pada model kajian konvensional dan model 3D yang dibina semula (bahan ABS dicetak oleh UP! Plus 3D Printer). Dua ulasan telah diambil: (1) OHRQoL dengan menggunakan borang soal selidik yang ditadbir sendiri versi pendek Profil Kesihatan 14 (OHIP-14 [M]) (2) Tahap kesakitan dengan menggunakan skor analog visual (VAS) yang termasuk

dalam borang soal selidik OHIP-14[M] yang diubahsuai. Data dikumpulkan sebelum pemasangan TPA (T0), seminggu (T1), sebulan (T2) dan tiga bulan (T3) selepas pemasangan TPA. Bahagian 2 adalah kajian kualitatif yang melibatkan Perbincangan Kumpulan Fokus (FGD) di kalangan lima orang doktor yang merawat semua subjek untuk menilai kecenderungan keutamaan aplikasi klinikal. **Keputusan:** Semua 52 subjek dianalisis dan tidak ada subjek yang digugurkan dalam kajian ini. Tahap OHRQoL di kalangan pesakit paling terjejas pada minggu pertama pemasangan TPA (10.08; S.D. 6.69) dan bertambah baik selepas sebulan (8.37; S.D. 5.85) dan tiga bulan (7.56; S.D. 4.97). Tidak terdapat perbezaan yang signifikan dalam OHRQoL antara kedua-dua jenis TPA ($p > 0.05$) di semua titik masa yang diukur (T0, T1, T2 dan T3). Domain yang paling terjejas selepas pemasangan TPA adalah ketidakselesaan psikologi dan paling rendah adalah kecacatan sosial. Tidak terdapat perbezaan yang signifikan dalam tahap kesakitan di antara kedua-dua jenis TPA ($p > 0.05$) di semua titik masa yang diukur (T1, T2 dan T3). Empat daripada lima perawat lebih menyukai TPA yang dibuat pada model 3D yang dicetak semula daripada TPA konvensional dengan tiga tema berbangkit iaitu (1) faktor masa, (2) pemilihan gegelung besi gigi geraham dan (3) faktor kos. **Kesimpulan:** Tidak terdapat perbezaan yang signifikan OHRQoL dan tahap kesakitan di antara kedua-dua jenis TPA dan majoriti perawat memilih TPA yang direka bentuk pada model 3D yang dibina semula daripada TPA konvensional. Model yang dircetak semula secara 3D boleh digunakan secara klinikal dalam menggantikan model konvensional dalam pembuatan TPA.

Kata kunci: Transpalatal Arch (TPA), percetakan 3D, Kualiti Kehidupan Berkaitan Kesihatan Kehidupan (OHRQoL), kesakitan ortodontik, perbincangan fokus kumpulan (FGD).

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LIST OF SYMBOLS AND ABBREVIATIONS

3D	:	Three-dimensional
3DG	:	Three-dimensional group
ABS	:	Acrylonitrile-Butadine-Styrene
AM	:	Additive manufacturing
ANOVA	:	Analysis of variance
ASTM	:	American Society for Testing and Materials
CAD	:	Computer aided design
CAM	:	Computer aided manufacturing
CBMTI	:	Centre for Biomedical and Technology Integration CBMTI
CG	:	Conventional Group
CONSORT	:	Consolidated Standards of Reporting Trials
DLP	:	Digital Light Processing
DMFT	:	Decay, Missing, Filled Teeth
DSA	:	Dental surgical assistant
EBM	:	Electron Beam Melting
FDM	:	Fused Deposition Modelling
FGD	:	Focus group discussion
IASP	:	International Association for the Study of Pain
L-OHIP[M]	:	Oral Health Impact Profile Malaysian version
LOM	:	Laminated Object Manufacturing
NPA	:	Nance palatal arch
NRS	:	Numerical Rating Scale
OHIP	:	Oral health impact profile

PDC	:	Palatally displaced canines
PPP	:	PolyJet Photopolymerization
QOL	:	Quality of life
RCT	:	Randomized clinical trial
RMANOVA	:	Repeated Measure ANOVA
SLA	:	Stereolithography
SLM	:	Selective Laser Melting
SLS	:	Selective Laser Sintering
S-OHIP[M]		Short version Oral Health Impact Profile Malaysian version
SOP	:	Standard operating procedure
SPSS	:	Statistical Package for Social Science
STL	:	Standard tessellation language
T0	:	Baseline (During treatment planning visit)
T1	:	One-week post cementation of TPA
T2	:	One-month post cementation of TPA
T3	:	Three months post cementation of TPA
TAD	:	Temporary Anchorage Device
TBA	:	Twin-Block Appliance
TPA	:	Transpalatal arch
UM	:	University of Malaya
VAS	:	Visual analogue score
VRS	:	Verbal Rating Scale

List of Appendices

CHAPTER 1: INTRODUCTION

In the conventional and contemporary fixed appliance system, orthodontists have been using various means of intraoral and extraoral auxiliary devices for anchorage control. Many inventions of appliance appeared and underwent series of developmental improvement to optimize the anchorage value during the space closure stage. It started in the year 1923 when the concept of orthodontic anchorage was fully understood and clearly defined as "The base against which orthodontic force or reaction of orthodontic force is applied" (Ottofy, 1923). Following the Newton's third law, which states that for every action there is an equal and opposite reaction, every attempt to move teeth orthodontically in one direction will be counteracted by an equal force in the opposing direction. Nowadays, the more comprehensible and frequently used term for orthodontic anchorage is "Resistance to unwanted tooth movement" (Daskalogiannakis J, 2000).

Transpalatal arch (TPA) is one of the most widely used intraoral appliance for anchorage reinforcement. Although it is said that usage of TPA in isolation does not provide sufficient anchorage during *en masse* or for two-step retraction in extraction cases when maximum anchorage is sought (Diar-Bakirly, Feres, Saltaji, Flores-Mir, & El-Bialy, 2017), TPA still remained as the popular choice of certain orthodontists due to its versatility. In the United Kingdom, a survey among specialist orthodontists regarding the use of anchorage adjunct in fixed appliance system revealed that TPA is the most popular device with 24.6% of use. It is followed by Nance palatal arch (21.1%), lingual arch (15.1%) and the least is utilization of implants with only (0.2%) featured response (Odondi *et al*., 2010), (Figure 1.1).

	Transpalatal arch	Nance arch	Lingual arch	Implant	Quadhelix	Rapid maxillary expansion	Removable biteplane	Fixed biteplane	Torquing auxiliary
Hospital	25.7	23.9	11.1	0.4	33.6	11.9	20.4	6.6	2.7
Practice (all)	22.9	18.5	14.4	0.0	30.9	3.8	43.8	7.1	3.2
NHS only	31.5	24.1	16.7	0.0	29.6	0.0	44.4	1.8	1.8
Private only	23.1	3.8	19.2	0.0	23.1	7.7	30.8	3.8	0.0
Community	27.6	20.7	31.0	0.0	41.4	0.0	37.9	3.5	17.2
Qualified <10 years	29.1	19.2	12.7	0.0	35.2	5.6	49.3	10.3	1.4
Qualified 11–20 years	23.3	19.3	14.2	0.0	35.2	4.0	30.7	6.2	2.3
Qualified 21–30 years	21.0	28.3	15.9	0.0	26.7	3.4	24.4	2.8	4.0
Qualified 30+ years	20.0	21.4	18.6	1.4	34.3	1.4	32.9	4.3	8.6
North	26.9	36.6	10.6	1.0	40.4	3.8	33.0	9.6	0.0
South	24.5	17.8	15.7	0.0	37.0	5.0	34.5	7.1	2.8
Midlands	33.3	28.2	25.6	0.0	33.3	10.3	69.2	10.2	12.8
Wales	33.3	4.8	19.0	0.0	33.3	0.0	33.3	4.8	4.8
Scotland	33.3	23.5	25.5	0.0	25.5	7.8	43.1	3.9	2.0
Northern Ireland	14.3	3.6	3.6	0.0	21.4	3.6	57.1	0.0	0.0
All	24.6	21.1	15.1	0.2	34.3	4.8	37.2	6.6	3.6

Figure 1.1 Percentage routine uses of commonest fixed appliance adjunct

Source: (Odondi *et al*., 2010)

The fabrication of TPA, like other intraoral orthodontic devices are conventionally made on stone-based working models. It involves meticulous clinical steps that starts with insertion of elastomeric separators on the mesial and distal interproximal surfaces of the maxillary permanent first molar teeth. Approximately five days to a week later (Tallman, Santner, & Miller, 2006), separators are removed and a series of molar bands selection or 'try in' sessions are carried out to get the correct band size that fits the molar teeth. The drawbacks of this procedure are that the previously 'tried-in' molar bands, if not properly decontaminated with an enzymatic cleaning and properly sterilized using autoclave may constitute a cross-infection hazard (Fulford, Ireland, & Main, 2003). An ultrasonic cleaning for 15 minutes itself reported to be inadequate in eliminating the salivary protein (amylase) from the 'used' molar bands (Benson & Douglas, 2007) . Furthermore, it has to be carried out with care as the metal stainless steel molar bands are small in size and has the possibility of accidental swallowing. Although not many, there is a report on accidental ingestion of molar band (Naragond, Kenganal, Rajasigamani, & Kumar, 2013) (Figure 1.2) and various other dental apparatus such as endodontic files, orthodontic

expansion activation key, archwire and retainer have been documented (Goultschin & Heling, 1971), (Monini, Maia, Jacob, & Gandini, 2011), (Umesan, Ahmad, & Balakrishnan, 2012), (Hinkle, 1987). Besides the countless clinical complications such as risk of bacteremia as well as accidental ingestion, this sort of incidence may lead to inevitable litigation and the best way to avoid such situation is by prevention, potentially through a technique that can avoid patients from undergoing molar band selection intra-orally. The next step is an upper arch impression with molar bands taken *in situ* and sent to the dental laboratory for fabrication of the TPA followed by reinsertion of separators between the molar teeth. Usually, an adequate interdental space has been created between the upper first maxillary molars and the adjacent teeth during the first elastomeric insertion thus in some circumstances, the consecutive elastomeric insertion might fail due to looseness. If the elastomeric separators get dislodged, the space created may close back resulting in failure of TPA insertion and cementation. A new appointment has to be arranged for the replacement of lost elastomeric separators. This will add extra workload to the clinician and more appointments to the patient. Furthermore, the clinician has to spend a long chair side time for molar bands selection that is carried out intra-orally.

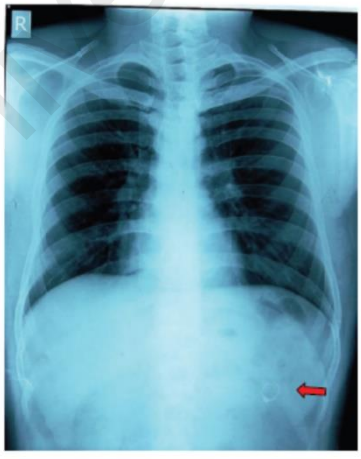


FIGURE 1: X-ray showing evidence of molar band.

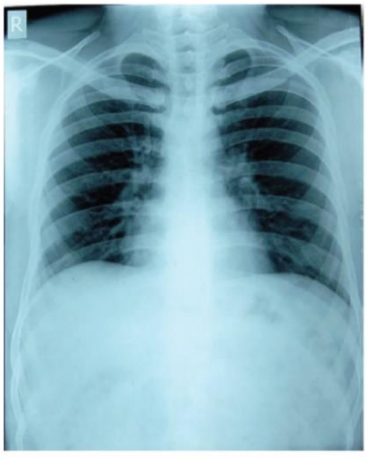


FIGURE 2: X-ray showing no evidence of molar band.

FIGURE 3: Retrieved molar band.

Figure 1.2 Accidental swallowing of metal molar band

Source : A case report by (Naragond *et al.*, 2013)

Currently at the Department of Pediatric and Orthodontics, Faculty of Dentistry, University of Malaya (UM), there are seven orthodontic dental technicians to cater for 10 Orthodontists, 16 postgraduate students and requests from clinicians of other departments. All seven technicians also provide service to maintain the dental chair for the faculty while one of the technicians is primarily assigned to assist clinical operative teaching at Balai Ungku Aziz. Such workload and other commitments places heavy burden on them to complete orthodontic cases on time. Thus, any methods to help reduce their workload may help increase efficiency of patient management. To relate back to TPA, to date, there is no international standard operating procedure (SOP) for the average time taken for TPA construction. It is solely depending on the institutional set up and it may vary around the globe. At UM, the SOP for TPA fabrication is separator placement that is left *in situ* for five to seven days, followed by a subsequent visit for molar band selection and upper arch impression with the molar bands *in situ* is sent to the laboratory. The TPA would be then be ready after seven days for insertion on the patient. This means that patients, on average, could only receive the TPA after weeks from the separator placement appointment.

To address the problems faced at UM, we proposed to innovate the method of TPA fabrication with the assistance of three-dimensional (3D) technology. Our proposed method involved construction of 3D printed working models from modified digitalized study models, followed by molar band selection on the 3D printed working models. The TPA is then fabricated by the technician. We anticipated that our proposed methods have few advantages: (1) The risks of contaminated and accidental ingestion of molar bands can be prevented if the molar band selection is carried out extra orally. (2) The time taken for TPA construction can be reduced to less than one week and reduction of 1 appointment. This is because molar band selection can be done on the 3D printed working model without requiring the patient to be present as an alternative to taking impressions with the bands *in situ.* Patients do not have to undergo two episodes of elastomeric separator placements between the maxillary first molar teeth. In a study comparing four types of orthodontic treatment procedures, which were upper alginate impression, separator placement, band placement and adjustment of arch wire, placement of separator was shown to cause significant bacteremia (Lucas, Omar, Vieira, & Roberts, 2002). In this study, intervention group (3D), will undergo one elastomeric separator placement whilst in the conventional group, they have to undergo 2 times separator placements thus increasing the of bacteremia. By reducing the number of appointments required for TPA fabrication, clinicians' time could be utilized to see other cases.

Nowadays, the availability of an intraoral digital scanning technology has provided orthodontists an alternative to eliminate the unpleasant procedure of impressions. Eliminating traditional impressions and stone models not only reduces clutter and storage requirements in the office, but enhances practice efficiency, improves appliance fit, allows model reuse, and results in more satisfied patients and staff members (Groth, Kravitz, Jones, Graham, & Redmond, 2014) . The next paradigm shift in orthodontics will come with the development of three-dimensional printers, working in conjunction

with intraoral scanners. Although 3D printing has not become a routine in orthodontic practice, it is expected to follow a similar path with intraoral digital scanners. With the availability of a 3D printer, the orthodontist can achieve a complete digital workflow. In addition, automated model-fabrication with the 3D printer significantly reduces construction times and exponentially increases the output per technician. Thus by transitioning to a complete digital process, there is no mass storage of bulky physical models and the digital data is available as long as it is needed (Mahamood, Khader, & Ali, 2016).

1.1 Aim and objectives

1.1.1 Aim

To investigate whether TPA directly fabricated from 3D reconstructed model is a feasible alternative to conventionally constructed TPA for clinical practice.

1.1.2 Objectives

1. To compare the oral health related quality of life of patients before wearing TPA and after 3 months of appliance wear.

2. To compare the oral health related quality of life of patients wearing TPA fabricated from 3D reconstructed model and conventionally produced TPA up to treatment duration of 3 months.

3. To compare pain levels of patients wearing TPA fabricated from 3D reconstructed model and conventionally produced TPA up to treatment duration of 3 months.

4. To assess clinicians' preference for using TPA fabricated from 3D reconstructed model and conventionally produced TPA.

1.1.3 Null Hypothesis

1. There is no difference in severity of impact on the oral health related quality of life among patients before and after wearing TPA up to three months' time.

2. There is no difference in severity of impacts on the oral health related quality of life between patients wearing TPA fabricated from 3D reconstructed model and conventionally produced TPA up to three months' time.

3. There is no difference in pain levels between patients TPA made from 3D reconstructed model and TPA produced from conventional plaster dental cast.

CHAPTER 2: LITERATURE REVIEW

2.1 Anchorage in orthodontic treatment

The term 'Orthodontics' derived from the Greek language with the word 'Orth(o)' means straight and Odontic is defined as teeth. As the name implies, orthodontics is one of the many branches in dentistry that involved with teeth straightening treatment. In order to straighten the teeth, spaces are required and teeth need to be bodily moved in three planes of direction which are anteroposteriorly, vertically and in transverse manner. Moving the teeth into the desired position requires certain amount of force and according to the Newton's third Law, every force has an equal but opposite reactionary force, thus every attempt made to move certain teeth into certain direction will have a contradictory effect to the opposing teeth. In order to resist the unwanted force resulting from the Newton's third Law, a good anchorage system must be created and planned earlier prior to commencement of the treatment. Orthodontic anchorage is simply defined as '"resistance to unwanted tooth movement" (Daskalogiannakis J, 2000) and it is paramount in orthodontic treatment especially if the force is totally applied to the teeth for three important reasons (Higley, 1960). Firstly, it indicates the resistance necessary to arrest undesired tooth movement while allowing the desired movement. Secondly, it is an indication of the type of resistance the tooth or teeth will offer and indicating the type of movement that may be expected. Thirdly it will determine the type of appliance that must be utilized in order to produce the type desired tooth movement. Orthodontic anchorage can be obtained from two main sources which are intraorally and extraorally.

2.1.1 Intra-oral anchorage

Intraoral anchorage is an anchorage provided from the intraoral structures, either from the teeth, oral mucosa and its underlying bones or devices such as an implants (Roberts-Harry & Sandy, 2004). It can be further subdivided into the following: -

2.1.1.1 Intra-oral anchorage from the teeth

As the term implies, anchorage from the teeth utilize the teeth present intra-orally as the anchorage means. It can be subcategorized into simple, compound, reciprocal and stationary anchorage, depending how many teeth are used and the type of movement desired.

(a) ***Simple***

Simple anchorage consists of one tooth as an anchorage against one tooth that is planned to be moved. The anchorage tooth has to be a tooth with larger root surface area as according to (Hixon, Atikian, Callow, McDonald, & Tacy, 1969), teeth with larger root surface area will have higher resistance to tooth movement thus they have a higher anchorage value.

(b) ***Compound***

Compound anchorage includes more than 1-unit tooth as an anchorage system. The anchorage supplied by the teeth can be derived from the same arch as the teeth that are being moved, also known as intramaxillary anchorage or from the opposing arch that is intermaxillary anchorage.

(c) ***Intramaxillary***

In compound anchorage, the more teeth that are included into an anchorage block, there will be less occurring of unwanted tooth movement. In the fixed appliances system, the more teeth that are bracketed, banded and tied up together, the greater will be the anchorage resistance. The same concept implies if the removable appliance is used, the more teeth incorporated and in contact with the acrylic baseplate and retention clasps, the more anchorage value can be created.

2.2 The Transpalatal Arch (TPA)

Transpalatal Arch (TPA) is an adjunctive orthodontic device that comprises of 0.9mm or 1.25mm stainless wire with presence of semi-loop in the centre that is attached to molar bands of upper first permanent molars (Almuzian, Alharbi, Chung, & McIntyre, 2015) (Figure 2.1)

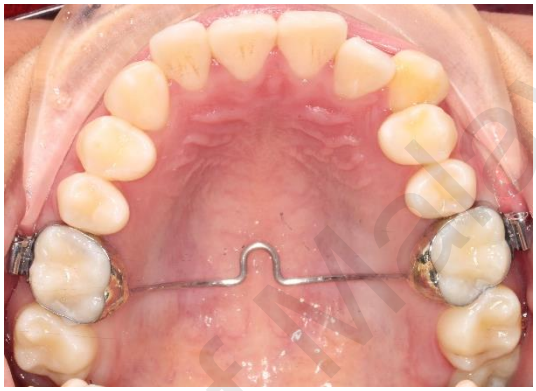


Figure 2.1 Transpalatal Arch

Source: From authors collection in this study

Commonly, it is used as an active or passive anchorage means to control the position of maxillary molars in three planes of direction in extraction of upper premolar cases (Almuzian *et al*., 2015). Figure 2.2 shows the passive type of TPA that is permanently soldered at the molar bands, the active types usually involved modifications such as removable palatal bar that can allow molar movements such as derotation. Being a versatile appliance, with modification in the design and material used, TPA can also be utilized in other ways to facilitate orthodontic tooth movement such as the in the interceptive treatment of palatally displaced canines (PDC). It has been shown in a clinical trial (Baccetti, Sigler, & McNamara, 2011) with the combination RME. Another alternative recently used is the combination of TPA and temporary anchorage devices (TADs) to correct anterior open bites (Cousley, 2010).

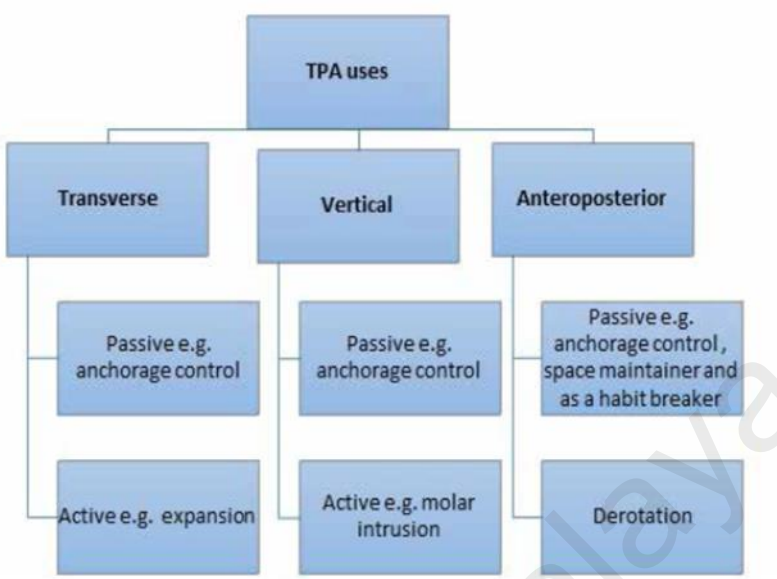


Figure 2.2 Uses of TPA

Source: (Almuzian *et al*., 2015)

2.2.1 History of the development of TPA

TPA was invented by Dr. Robert Ara Goshgarian, a renowned orthodontist from Waukegan, Illinois in the year 1972 (Gore *et al*., 1998) . Goshgarian TPA itself is a modification of palatal bar that comprised of arch wire that is soldered to the upper molar bands, which served as a fixed and non-adjustable device. The original design of Goshgarian TPA consisted of 0.036-inch stainless steel wire with a U-shaped loop facing distally in the center of arch. Both ends were bent and compressed flat to be inserted manually into the lingual slots that are soldered at the palatal surface of the upper molar bands. It was a removable appliance that allows adjustment, expansion, contraction, intrusion and torqueing of the upper first permanent molar (Figure 2.3)

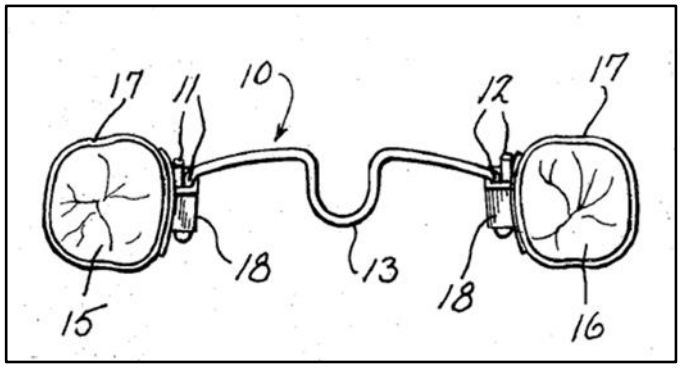


Figure 2.3 Goshgarian TPA

Source: (Gore *et al*., 1998)

2.2.2 Variations in the design of TPA

Throughout the years, TPA has been widely used and various modifications have been made to customize the usage of TPA for specific purposes. To date, a minimum of 28 variations of the design are recorded and discussed in the literature (Singh & Singh, 2018), (Almuzian *et al*., 2015).

From the year 1980 – 1989

1981: Burstone lingual arch.

In the year 1981, Burstone and Koenig introduced transpalatal lingual arch in order to bring molar corrections in first, second and third order movements (Burstone & Koenig, 1981) (Figure 2.4) shows definitive tying in place with wire size of 0.036 inch with the folded terminal ends are soldered to allow better fit in the lingual sheaths.

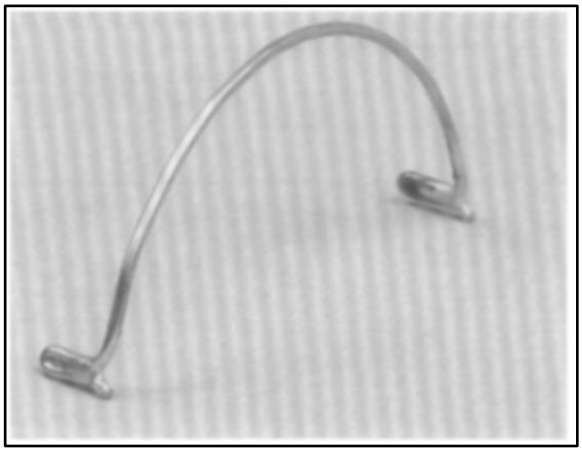


Figure 2.4 Transpalatal lingual arch

Source, (Burstone & Koenig, 1981)

2.2.2.1 From the year 1990 - 1999

1997: Zachrisson type transpalatal bar (ZTPB)

Figure 2.5 shows an occlusal representation of Zachrisson-type transpalatal bar which was introduced in 1997. It was made of 0.036-inch (0.9 mm) Blue Eligiloy wire, and formed of three loops, on either side two small, distally directed loops and a larger and longer mesially directed central loop. There is less or no reactivation is required due to lower load deflection rate. This modification of TPA had lower horizontal contractive forces in comparison to Goshgarian TPA (Zachrisson 1997).

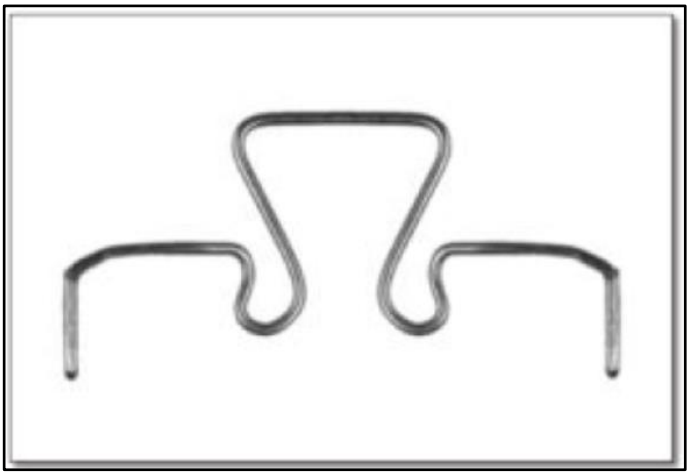


Figure 2.5 Zachrisson type transpalatal bar (ZTPB)

Source: (Zachrisson 1997)

1998: Wallis &Vasir modification of TPA

Wallis & Vasir invented a simple method of attachment for Transpalatal Arch in the year 1998, (Figure 2.6) shows the TPA by passing the wire distal to the most posterior molar which enters the headgear tube mesially. It wasclaimed to be more flexible than its standard counterpart produced lighter forces and couples thus enabling greater precision for horizontal expansion and molar angulation (Wallis, Vasir, & Waters, 1998).

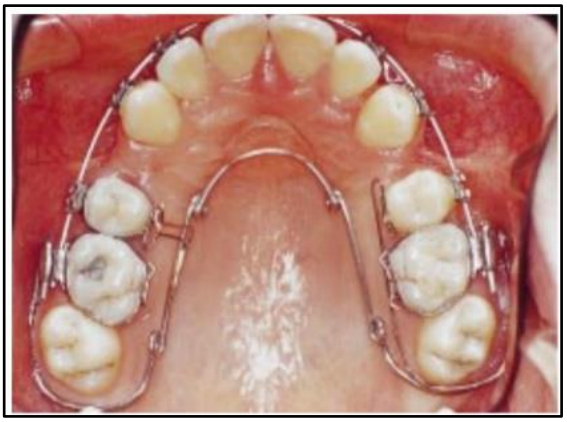


Figure 2.6 Modification of quad helix and TPA insertion

Source: (Wallis, Vasir & Waters 1998)

1998: Combination of Goshgarian arch & Nance button

J.M Cobo in the year 1998 introduced one of the more commonly utilized modified TPA other than Nance Palatal Arch (NPA), that is the combination of the two appliances, the TPA and NPA (Figure 2.7).

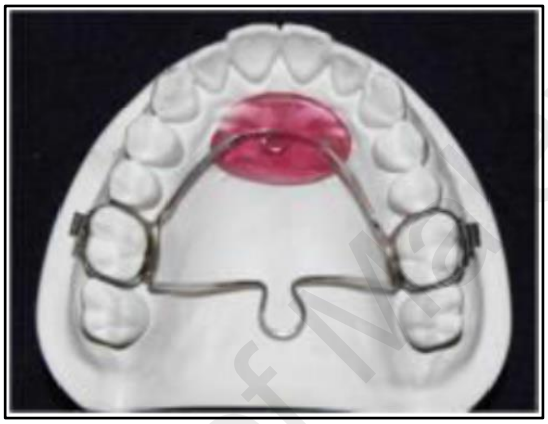


Figure 2.7 Combination of Goshgarian arch and Nance button

Source: (J.M. Cobo *et al* in 1998)

2.2.2.2 From the year 2000 – 2009

2000: Tongue friendly TPA

Michael Hudson in 2000 invented a simple modification yet practicable tongue friendly transpalatal arch (Figure 2.8). He simply filled the loop with acrylic to prevent deep marks leaving on patients' tongue. It was made for cases requiring vertical anchorage preparation, (low level TPA) where TPA is placed 5-6mm away from palate, to facilitate molar intrusion.

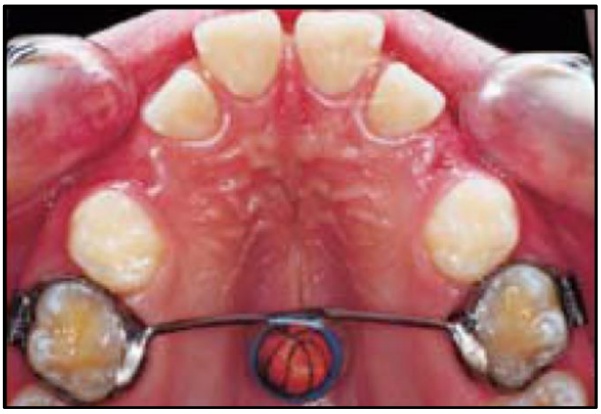


Figure 2.8 Tongue friendly TPA

Source: (Hudson, 2000).

2001: TPA for Asymmetric distalization of molars

In 2001, Massimiliano Mandurino and Laura Balducci introduced TPA that can be inserted from two different directions, distal into tube of the maxillary molar used as anchorage and from mesial into tube of the maxillary molar that has to be distalized. It was fabricated from TMA wire for asymmetric distalization of molars. The activation of the TPA applies mesiobuccal rotation to anchor molar and distally directed force to the opposite molar (Figure 2.9).

Figure 2.9 TPA for asymmetric distalization of molars

Source: (Massimiliano Mandurino and Laura Balducci in 2001)

2002: TPA with helices

In 2002 Horacio Garcia-Rojas Guerra introduced modified transpalatal with two additional helices incorporated adjacent to the omega loop, claiming the appliance can correct molar rotations while providing anchorage and torque control (Figure 2.10) The incorporated two helices increase flexibility and working range of transpalatal arch (Garcia-Rojas Guerra 2002).

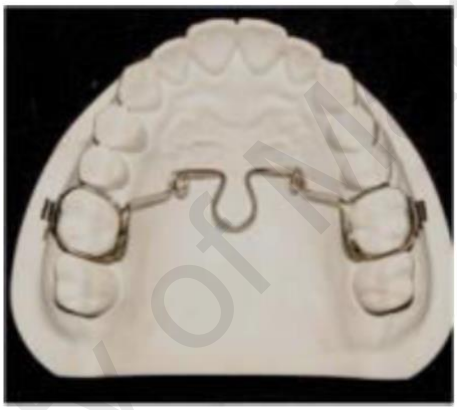


Figure 2.10 TPA with helices

Source: (Garcia-Rojas Guerra 2002)

2003: Keles TPA

An easy, effective, and precise method of correcting molar rotation was introduced by Ahmed Keles in 2003.This TPA was fabricated with square beta-titanium alloy wires (TMA; Ormco) instead of round stainless-steel wires and hinge cup attachments were used instead of palatal sheath (Figure 2.11).

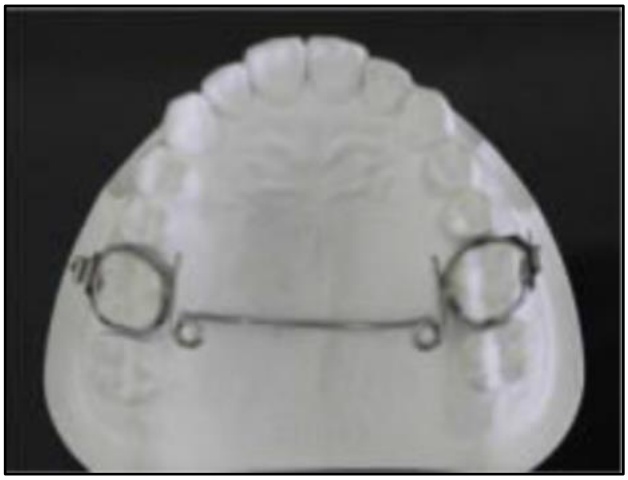


Figure 2.11 Keles TPA

2004: Bonded TPA

Garri Tsibel, Mladen M. Kuftinec, introduced bonded instead of banded TPA in the year 2004. Fabrication was done by sending the patient's cast in laboratory for construction of bondable pads (Figure 2.12). These pads must be closely adapted to the palatal surfaces, micro etched and wide enough molar pads it has to be– all of which contribute to optimal retention and bond strength (Tsibel G, Kuftinec M. 2004).

Figure 2.12 Bonded TPA

Source: (Tsibel G, Kuftinec M. 2004)

2006: Miniscrew-Assisted TPA

Hyun Sang Park introduced Miniscrew-Assisted Transpalatal Arch in 2006 in conjunction with the use of Lingual Orthodontics (to improve anchorage control for retraction of the upper anterior teeth, using single mini screw).The posterior arrangement of palatal mini-screw allows minor tip back or distal crown movements on molars ((Singh & Singh, 2018).

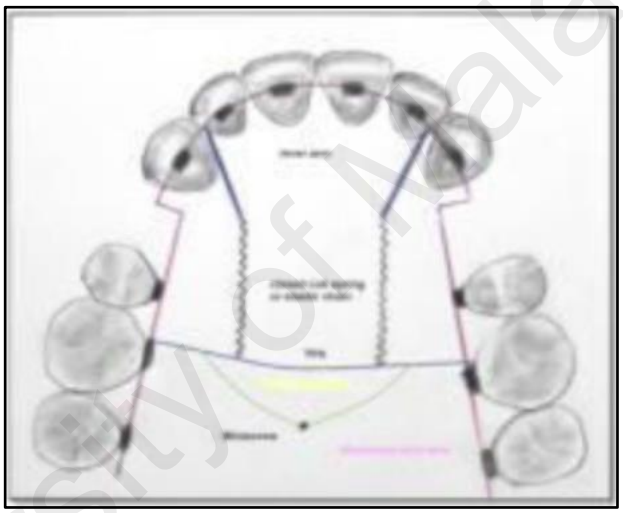


Figure 2.13 Miniscrew assisted TPA

Source: (Singh & Singh, 2018)

2009: Atraumatic Transpalatal arch

In 2009 Valentin Moutaftchie, Alexander Moutaftchiev introduced individually prepared atraumatic Transpalatal arches. This type of TPA considers the position of the palatal tubes thus avoids the need for molar bands removal and placing them in a plaster model (Moutaftchiev & Moutaftchiev, 2009) (Figure 2.14).

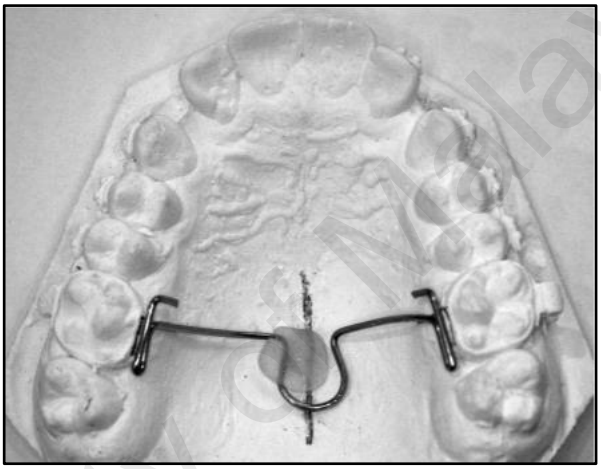


Figure 2.14 Atraumatic Transpalatal Arch

Source: (Moutaftchiev & Moutaftchiev 2009)

2.2.2.3 From the year 2010– 2019

2010: Fibre reinforced composite TPA

Pizzoni in 2010 fabricated a fibre reinforced composite TPA (Figure 2.15) for aesthetic demanding patients. The TPA was bonded to molars and premolars to orthodontically align impacted maxillary canine using a palatal cantilever (Pizzoni, 2010).

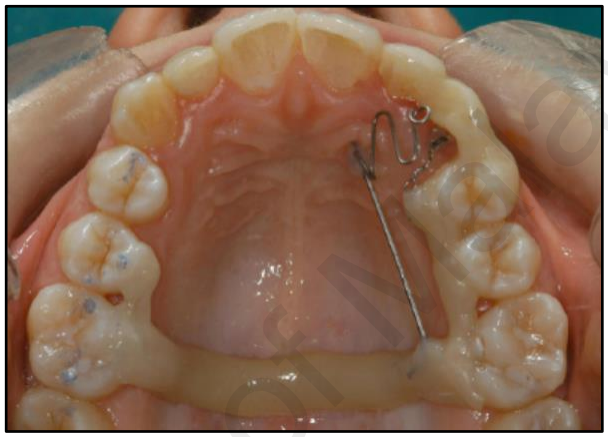


Figure 2.15 Fibre reinforced composite TPA

Source, (Pizzoni, 2010)

2011: M-TPA with customized bonding base

M. Fujisawa & A. Komori modified TPA (MTPA) was introduced in 2011, by customizing the bonding base. It can be directly bonded using resin-reinforced glass ionomer cement (Figure 2.16). MTPA has larger contacts area and provides a tight fit. The labial fixed appliances was not disturbed as MTPA can be removed as it is bonded on lingual side (Fujisawa & Komori, 2011).

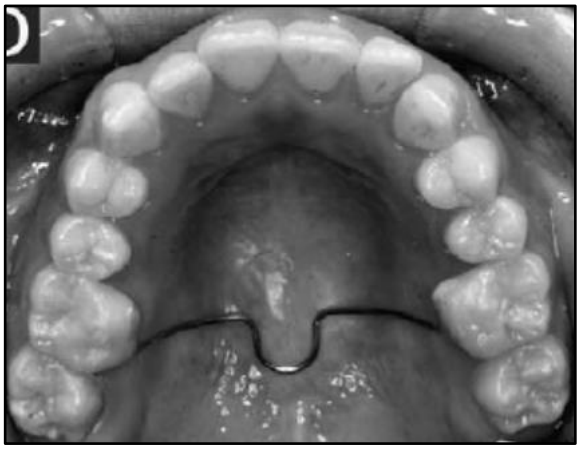


Figure 2.16 M-TPA with customized bonding base

Source: (Fujisawa & Komori, 2011)

2.2.2.4 Current usage of TPA

The most recent modification reported is the combination of TPA with Twin-Block Appliance (TBA). The modification was simple and innovative by merging the free end of transpalatal arch into the acrylic used as bite blocks in fixed twin block appliance (Figure 2.17). It give an additional retention as well as prevents the possibility of accidental ingestion of the twin block appliance (Shetty, Vigneshwaran, & Kumar, 2019).

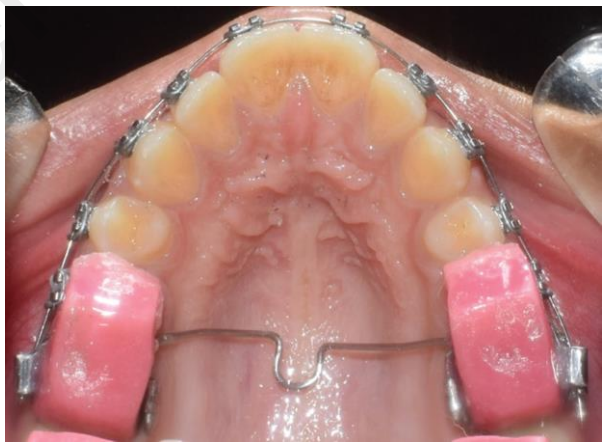


Figure 2.17 Twin-block appliance with modified TPA cemented

Source: (Shetty et al., 2019)

2.3 Three-dimensional (3D) Printing

Three-dimensional (3D) printing or referred as additive manufacturing (AM), is a fabrication technique in which objects were prepared by the fusion or deposition of various selected materials to produce a 3D object based on a 3D designed file. The official definition of Additive Manufacturing (AM) is given by American Society for Testing and Materials (ASTM) F2792 as "process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies" Historically, the concept of 3D printing was introduced by Chuck Hull in 1984, while he was working on ultraviolet light to cure the table top coatings. Two years later, in the year 1986, Hull established a company named the 3D Systems, to market the first ever 3D printer machine for rapid prototyping, which he called stereolithography (SLA). He patented it as an apparatus for building three dimensional objects with sheets (Gabriel & Hull, 1984). Not long after that, in 1988, Scott Crump developed another method of 3D printing called fused deposition modelling (FDM), which was commercialized by Stratasys in 1990. In 1998, another different printing process named PolyJet photopolymer (PPP) printing was founded by Objet Geometries (Groth *et al*., 2014).

From the mechanical aspect of view, 3D printer is conceptually a simple robotic device that utilize the computer aided design (CAD) software to produce 3D objects through a computer aided manufacturing (CAM) technique or known as CAD/CAM technology. The success of 3D printing is much dependent on the development of the computer technology and software applications (Dawood, Marti, Sauret-Jackson, & Darwood, 2015). Since the first development of the 3D printer, there are many modifications have been made and to date there are many types of 3D printers available in the market. Although they differ in the printing techniques and the types of material used, the principal behind the digital workflow is the same (Figure 2.18).

The first step is an acquisition of the digital model, either from 3D scanning of physical model or any existing digital model using CAD software. Secondly, the CAD file or image is converted to the standard tessellation language (STL) format. STL, is a file format developed for 3D Systems in 1987 for use by its stereolithography apparatus (SLA) machines. Thirdly, any virtual remodeling can be carried out using the software prior to the printing process. Users can designate the size and orientation of the objects before sending it to the connected machine. Fourthly, the machine set up, each printer has its own requirements and procedures on how to prepare for a new print job. This includes refilling the raw materials such as polymers, binders and other consumables the printer will use. Post printing, refinement of the end products is made manually depending on the type of materials printed, for example, users have to brush off any remaining powder or washing the printed object to remove debris from the water-soluble supports.

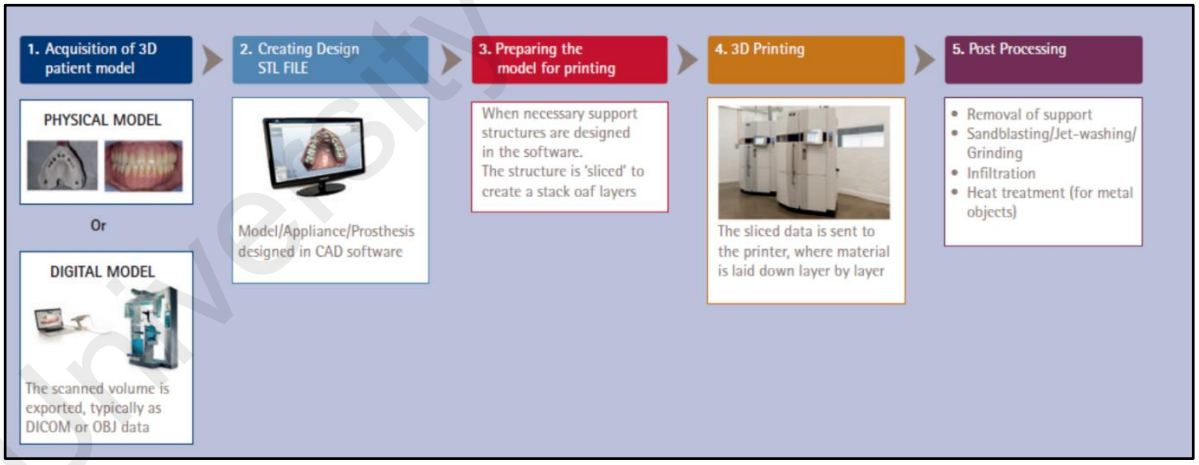


Figure 2.18 Digital workflow of 3D printing

Source (Dawood *et al.*, 2015)

2.3.1 Types of 3D printer

2.3.1.1 Stereolithography (SLA)

3D Systems company is still the largest producer of SLA printers; however, many other similar models are available in the market. The SLA build tray printer is immersed in curable liquid resin that can be cured by concentrated ultraviolet laser light (Figure 2.19). Each layer was formed by cross-section drawn by the laser, every time after each layer is cured, the tray will descend by similar distance to the layer thickness, allowing the uncured resin to cover the previously deposited layer. This procedure is repeated to hundreds of times as the printed object takes shape. Contradictory to other types of 3D printers, SLA printers are generally slower because the laser can cure only a small area at a time .

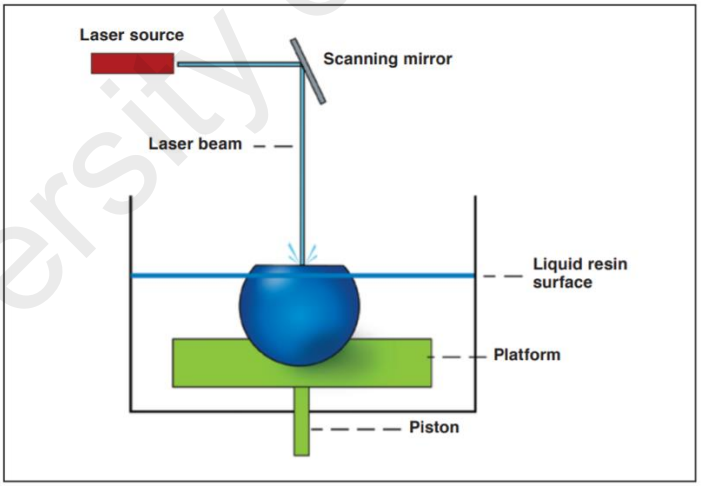


Figure 2.19 Stereolithography (SLA) Printer

2.3.1.2 Fused Deposition Modelling Printer (FDM)

FDM printer differs from SLA in a sense that it extrudes a resin that has been heated just beyond its melting point, depositing it layer by layer (Figure 2.20), instead of curing the deposited layer of liquid resin with projected light, Once heated, the material will then harden immediately after being extruded, thus reducing inaccuracies. The most common material used are polylactic acid and acrylonitrile butadiene styrene (ABS), these type of can easily be changed as necessary and the materials usually come on multi colored spools.

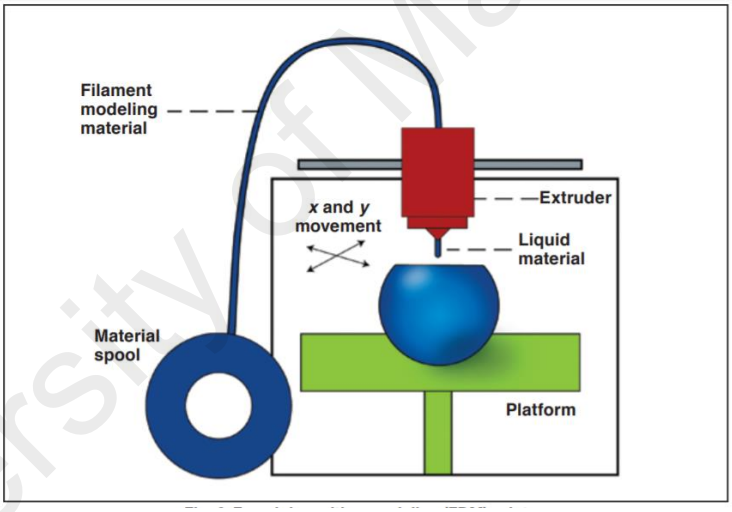


Figure 2.20 Fused Deposition Modeling (FDM) Printer

2.3.1.3 Digital Light Processing (DLP)

Similar to SLA, DLP utilize the same method except for the light source: instead of laser, a projector is used to cure an entire layer at a time (Figure 2.21). Comparing it to the difference between stamping and drawing an object, DLP is significantly faster print times. It was also known as a digital micromirror device as it has a chip that contains hundreds of thousands of tiny mirrors that are able to move in two directions, on and off, thousands of times per second. DLP making the finish quality the best of all 3D printing as the printer builds a model in voxels rather than layers so there are no visible steps in the printed objects.

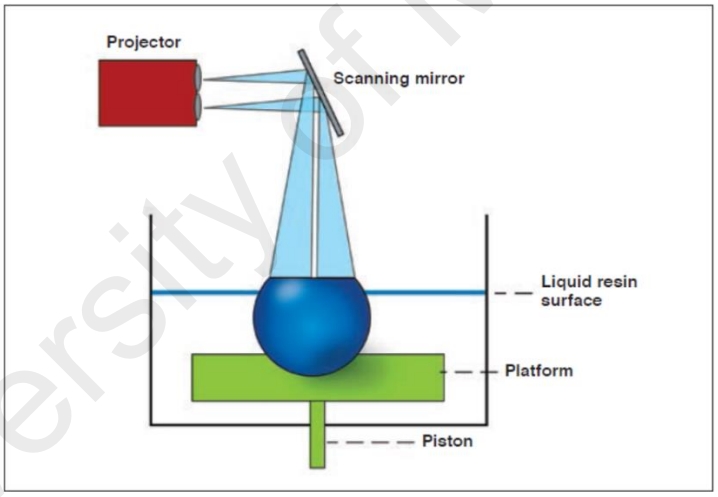


Figure 2.21 Digital Light Processing (DLP)

2.3.1.4 PolyJet Photopolymerization (PPP)

Currently, Stratasys and 3D Systems are the only manufacturers of PPP printers, which utilize the similar basic technology in three dimensions (the standard inkjet conventional office printer). Liquid resin is jetted out of hundreds of nozzles and immediately cured with ultraviolet light in PPP (Figure 2.22). The build platform moves in vertical direction to harbor the subsequent layers. This type mechanism also leaves layer lines on the model; however, the stratifications can be as thin as 16 microns, which portrays excellent quality finish of PPP. The higher-end PPP printers have the capability to print multiple materials on a single model with wide selection of media from rubber-like compounds to materials designed to operate at high temperatures. The drawbacks are, it has more wastes than other technologies as the excess material need to be removed to ensure dimensional accuracy. Although the volume of waste at any one time is minimal, constant use can add up the amount.

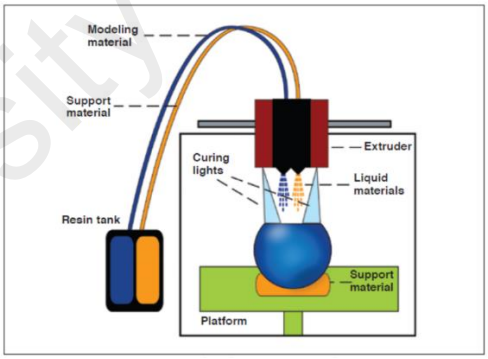


Figure 2.22 Polyjet Photopolymer (PPP) printer

2.3.1.5 Selective Laser Melting (SLM) and Selective Laser Sintering (SLS)

Laser based additive manufacturing, such as selective laser melting (SLM) and selective laser sintering (SLS), uses power in the form of a high energy laser beam directed by scanning mirrors to build three-dimensional objects by melting metallic powder and fusing the fine particles together. The laser energy is strong enough to allow full welding/melting of the particles to create a solid part. The process which can include partial and full melting or liquid phase sintering is recurring layer after layer until the object is completed. The technology is commonly utilized due to its ability to form parts with complex geometries with very thin walls and hidden channels or voids directly from digital CAD data. Compared to other types of 3D printing, SLM/SLS have very high productivity and can build objects from a relatively big selection of commercial powder materials. These include polyamides, polycaprolac- tone, hydroxyapatite, ultra-high molecular weight polyethylene, polyethylene, ceramic, glass, stainless steel, titanium, and Co/Cr alloys. Although most of the initial applications of the laser based technologies were for manufacture of lightweight aerospace parts, the SLM/SLS have found an acceptance for production of orthopedic and dental implants, dental crowns and bridges, partial denture frameworks, and bone analogues (Di Giacomo, Silva, Martines, & Ajzen, 2014).

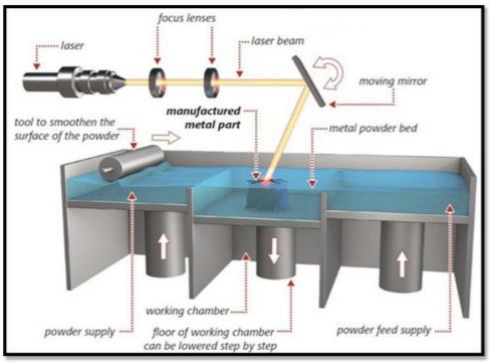


Figure 2.23 Selective Laser Sintering (SLS) Printer

Source: (empa.ch)

2.3.1.6 Electron Beam Melting (EBM)

Another type of additive manufacturing is known as Electron beam melting (EBM). As opposed to a laser, the EBM technology utilizes the energy source of an electron beam. Fully melted metal powder utilizing a computer-controlled electron beam in a high vacuum were used to manufacture objects by layer. The technology functions at a very high temperatures of up to 1000 °C, which could result in differences of the phases formed through solidification. EBM has the ability to form extremely porous mesh or foam structures with different types of alloys including stainless steel, titanium, and copper. This technology is commonly applied in orthopedic and oral and maxillofacial surgery for fabricating customized implants as their structure allows the ingrowth of bone, offer better fixation and helps to prevent stress shielding (Van Noort, 2012).

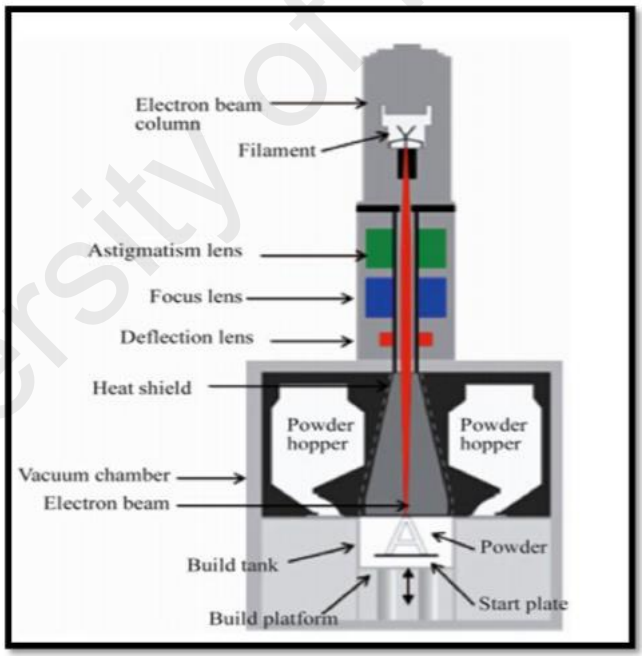


Figure 2.24 Electron Beam Melting (EBM) printer

Source: (arcam.com)

2.3.1.7 Laminated Object Manufacturing (LOM)

Laminated object manufacturing (LOM) utilizes a slightly different technology from other existing 3D printers. It applies the process that combines both; additive and subtractive techniques to print out an object. It operates by successively layering sheets of material one on top of another and binding them together using adhesive, pressure, and heat application. After the completion of the process, printed objects are cut to desired dimensions using various methods including knife, laser or modified drilling machine. Since no chemical reaction involved, the technology is able to produce relatively large parts. Plastics, paper, ceramics, composites, and metals are the most common materials used in LOM which are widely available and yield comparatively inexpensive 3D printing method. Furthermore, LOM allows mixture of materials in various layers throughout the printing process giving more flexibility in the final outcome of the printed objects, however, the surface accuracy is slightly inferior to selective laser sintering. Commonly, LOM systems are used in architectural applications.

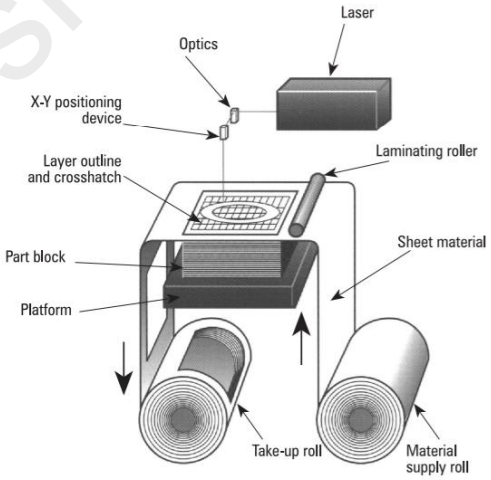


Figure 2.25 Laminated Object Manufacturing (LOM)

Source: (Park, Tari, & Hahn, 2002)

3D Printer	Materials	Potential application in dentistry
Fused Deposition Modeling (FDM)	Thermoplastic polymers such as polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), polycarbonate (PC), polyether ether ketone (PEEK), etc.	In-house production of basic proof-of-concept models, low-cost prototyping of simple anatomical parts
Stereolithography (SLA)	A variety of resins for photopolymerization, ceramic filled resins, etc.	Dental models, surgical guides and splints, orthodontic devices (aligners and retainers), castable crowns, and bridges.
Selective Laser Sintering (SLS)	Powder such as alumide, polyamide, glass-particle filled polyamide, rubber-like polyurethane, etc.	Hospital set up for metal crowns, copings and bridges, metal or resin partial denture frameworks
Polyjet printing	A variety of photopolymers	Hospital set-up manufacturing of craniomaxillofacial implants, sophisticated anatomical models, drilling and cutting guides, facial prosthesis (ear, nose, eye)
Bioprinter	Cell-loaded gels and inks based on collagen, photopolymer resins, agarose, alginate, hyaluronan, chitosan, etc.	Cell-laden scaffolds for hard and soft tissue printing

Figure 2.26 Different types of 3D printers and their potential dental application

Source: (Oberoi et al., 2018)

2.3.2 Applications of 3D printing in Orthodontics

Additive manufacturing is likely to continue rapid growth in conjunction with intraoral scanning technology as a more effective system for orthodontic practices and laboratories for automatic fabrication of high-resolution study models, retainers, metal appliances, aligners, and indirect bonding, accelerating the production time and increasing the capability (Groth *et al*., 2014).

2.3.2.1 Study Models

Despite various TPA modifications, to date, no TPA constructed on 3D printed model has been reported. 3D imaging and printing has become a phenomenon throughout the world for the past two decades. Numerous 3D related studies had been carried out to investigate the usage and outcomes of various software, techniques and materials used pertaining to digitization. The ability of manipulating and printing images three dimensionally has shifted the world industries including Orthodontics to a new paradigm. Comparisons of different aspect between plaster and digital model had been done repeatedly and resulted with similar conclusion that 3D printed model yield the same properties as conventional study models. Measurements of arch length and width are accurate and reproducible on digital models when compared to direct caliper measurement on stone dental cast (Sousa, Vasconcelos, Janson, Garib, & Pinzan, 2012). Either by direct intra oral scanning or cone-beam computed tomography (CBCT) scans of the alginate impressions, the measurements of digital models for diagnostic purposes have shown to be valid, reliable and reproducible (van der Meer, Tutein Nolthenius, Engelbrecht, Wiranto, & Ren, 2012). 3D printed model had proven to be acceptable substitute to plaster dental cast due to its accuracy in linear measurements (Hayasaki, Martins, Gandini, Saitoh, & Nonaka, 2005), (El-Beialy *et al*., 2010).

2.3.2.2 3D printed appliance

The most sophisticated method in materializing innovations are carried out by application of Computer –aided design/additive manufacturing (CAD/CAM) system in conjunction with three-dimensional (3D) imaging and printing (Al Mortadi, Jones, Eggbeer, Lewis, & Williams, 2015). Recent studies by (Al Mortadi *et al*., 2015) demonstrated the possibility of fabrication of Hawley retainer using digital technology even without the presence of analogue impression. Thus, application of 3D imaging and printing method are considered in the innovation of this TPA.

2.4 Oral Health Related Quality of Life (OHRQoL)

WHO defines oral health as "a state of being free from chronic mouth and facial pain, oral and throat cancer, oral infection and sores, periodontal (gum) disease, tooth decay, tooth loss, and other diseases and disorders that limit an individual's capacity in biting, chewing, smiling, speaking, and psychosocial wellbeing." (OMS, 2003). Oral health–related quality of life (OHRQoL) is an assessment of quality of life (QOL) that is related to orofacial concern. In spite of the fact that malocclusion itself is not a life-threatening disease, people seek orthodontic treatment as the aesthetic impairment has an impact on the QoL issue (Shaw, Rees, Dawe, & Charles, n.d.). Patients who underwent orthodontic procedures have proven to achieve a better OHRQoL after the completion of treatment (Feu, Miguel, Celeste, & Oliveira, 2013), (M., D.-W., & L.-P., 2010) however, during the treatment itself, OHRQoL seem to be deteriorated (Bernabé, Sheiham, & De Oliveira, 2008), (Liu, McGrath, & Hägg, 2011), (Johal, Alyaqoobi, Patel, & Cox, 2015). Most of the articles discussed the impact of removable and fixed orthodontic appliances in general, to date there is no report regarding the usage of TPA alone may affect OHRQoL.

2.4.1 Oral Health Impact Profile

The Oral Health Impact Profile (OHIP) is one of the instruments that measures people's perception of the social impact of oral disorders on their well-being. It was developed with the aim of providing a comprehensive measure of self-reported dysfunction, discomfort and disability attributed to oral conditions (Slade, 1997). OHIP was originally developed in Australia by Slade and Spencer and contains 49 unique questions that were extracted from 535 statements obtained from interviews with 64 patients. The questions were grouped into seven domains drawn from Locker's model and cover a wide range of possible oral health problems that may influence quality of life. These domains aim to describe the negative impacts of oral health conditions. The domains are;

1. Functional limitation
2. Physical pain
3. Psychological discomfort
4. Physical disability
5. Psychological disability
6. Social disability
7. Handicap

The functional limitation domain includes items that is related to oral function limitations such as speech and mastication with the use of any intraoral appliance such as difficulties in chewing foods, trouble in pronouncing words and loose intra oral appliance. For physical pain, the pain aspect that is directly and indirectly caused by oral appliance were asked such as toothache, gum pain, jaw pain or whether the appliance cause any ulceration that leads to pain. Psychological discomfort evaluates the psychological aspect such as stressful feeling, worried, discomfort and embarrassment due to the wearing of intraoral appliance. As for the physical disability, assessment on whether the oral condition or existing appliance caused unclear speech, interrupted meals or avoidance in smiling were included. The fifth domain, psychological disability assessed the disturbance in psychological aspect including disturbed sleep, loss of concentration depressed and loss of appetite. Social disability domain includes problems in carrying out daily activities, being less tolerant and easy irritability. The seventh domain, handicap assessed whether subjects had inability to work at full capacity, felt unwell, less confident, less satisfied with life and had to spend a lot of money relate to the oral condition.

The Malaysian version of OHIP, which is called L-OHIP(M) and contains 45 items grouped into the same seven domains as the original version. The short version of the OHIP(M) was developed following the cross-cultural adaptation of the long form of OHIP. The original English-language OHIP was translated into the Malay language using a forward–backward technique (Saub & Locker, 2006). The original version of OHIP questionnaire contained 49 questions which was later considered time consuming to complete by the subjects thus a shorter version with 14 items was developed from the original (OHIP-19). The new version (OHIP-14) consisted a subset of two questions each under the seven domains. In this study, the validated short version of Malaysian Oral Health Impact Profile (S-OHIP-[M]) among Malaysian adult population was used. Although the S-OHIP(M) was developed to be used as a descriptive and discriminative measure in population oral health surveys, it may also be appropriate for use in clinical trials and in clinical practice as an evaluative measure. OHIP has been widely used in orthodontic studies as it was recognized that the impacts of malocclusion, the motivating factors behind seeking care, and the outcomes from orthodontic care are related to quality of life issues (Cunningham & Hunt, 2001). OHRQoL measures capture both improvements and declines in oral health status, thereby providing the opportunity to conceptualize and analyse change longitudinally.

In this study, there are two types of questionnaire used, the short version Oral Health Impact Profile Malaysian version (S-OHIP[M]) and the modified version adapted from (S-OHIP[M]) for specific usage of patients wearing TPA. Oral Health Impact Profile Malaysian version (L-OHIP[M]) with 45 items is an adaptation of the original version developed by Slade and Spencer (1994) that consisted of 49 items. The short version (S-OHIP[M]) contains only 14 items under seven domains.

(S-OHIP[M])) was developed to be used as a descriptive and discriminative measure in population oral health surveys, it may also be appropriate for use in clinical trials and in clinical practice as an evaluative measure. Both questionnaires were made available in English and Malay language. It can be divided into four parts, A, B, C and D with utilization of Likert scale scoring system which is coded as below:

0 = Never,

1 = Seldom,

2 = Sometimes,

3 = Quite often

4 = Very often

5= Don't know

The scoring methods for OHIP can be carried out in three aspect, the prevalence if impact, severity of impact and the extend of impact. The prevalence of impact can be done by calculating the percentage of participants reporting one or more impacts "very often" or "often". Secondly, severity of impact or known as Additive (ADD score), it can be calculated by adding up the response code for each item. The ADD score could range from 0 to 180 for the he L-OHIP(M) and 0 to 56 for the S-OHIP[M). The extend of impact is carried out by applying simple count (SC score); calculated by summing the number of items reported as "very often" and "often" with score 0 to 14. (Saub, Locker, 2006). In this study, the method of severity of impact was applied, with higher score as an indication of poor OHRQoL.

2.5 Pain in orthodontic treatment

International Association for the Study of Pain (IASP) 1979 defined pain as"An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." (Treede, 2018). In orthodontic treatment, presence of intraoral appliance that consists of foreign material such as metal, acrylic and elastomeric chains may cause friction with mucosal tissue resulting in discomfort, pain and even trauma such as an ulceration. The application of force through arch wires and brackets to move teeth through the alveolar bone is accepted as nociceptive input and activates the pain and inflammatory receptors (Polat, 2007). Patients receiving orthodontic treatment encounter a varying degree of pain and discomfort along the procedure. It is reported that 70% of patients experienced pain regardless the type of appliance wear whether it is a removable or fixed appliance and it is the worst thing about appliance wear besides the other undesirable side effects such as appearance, function and maintenance aspect (Oliver & Knapman, 2014).The orthodontist should never ignore and neglect the pain aspect as it is proven to be one of the main reason for discontinuation of treatment (Brown & Moerenhout, 1991),(Haynes, 1967). In addition, orthodontists should inform and explain to the patient about the common side-effects of treatment, especially before inserting an appliance that will cause pain and discomfort. In most cases, the level of explanations prior to the treatment seems to be generally satisfactory, however it is reported that many people were not been well-informed (Oliver and Knapman, 1985). Except for a marked influence on the consistency of food consumed, the insertion of fixed appliances was reported to have only a transient and minor effect on the patients' daily lives (Scheurer, Firestone, & Bürgin, 1996). In comparison to the modified version that is Nance Palatal Arch (NPA), TPA is found to cause slightly reduced discomfort between the two. To date, there is no study to assess the pain level among patients wearing TPA alone.

2.6 Rationale of the study

In the coming years, with the availability and more options of cheaper intra-oral scanners, 3D software and 3D printer, there will be a paradigm shift from conventional to digital workflow. The dental records including study models will be digitized in order to overcome the burden of physical storage. The virtually kept data of study models allowed the disposal of conventional stone models as it can be printed out whenever needed. Various studies had shown the accuracy and reliability of the digital models in comparison to the stone models and agreed on the clinical acceptability (Wan Hassan et al., 2016), (TOMITA et al., 2018). However reported studies of an appliance fabrication on 3D printed model is scarce.

Thus, this study is carried out as an effort to reduce the storage's physical burden by evaluating the clinical applicability of 3D printed model for orthodontic appliance fabrication. Being one of the mostly fabricated adjuncts in fixed orthodontics appliance treatment, (Odondi et al., 2010), TPA was selected and the clinical acceptance was assessed on how it affect patients' quality of life as well as clinicians' preferences'.

CHAPTER 3: RESEARCH METHODOLOGY

This study was divided into two parts; Part 1, a randomized clinical trial involving a prospective single blinded study and Part 2, a qualitative study involving a focus group discussion.

3.1 Part 1: Randomized Clinical Trial

3.1.1 Ethical Approval and Permission to conduct the study:

Ethical approval was obtained from the Medical Ethics Committee, Faculty of Dentistry, University of Malaya and valid from 11th July 2016 to 31st May 2019 (DF CD1607/0057(P)).

3.1.2 Trial design

This was a parallel arm prospective randomized clinical trial with a 1:1 allocation ratio. This study was conducted at the Postgraduate Orthodontic Clinic, Faculty of Dentistry, University of Malaya. Data collection was carried out from July 2017 until January 2019. This study was funded by UM Dental Postgraduate research grant (Grant No. PPPC/C1-2016/DGD/12) with a value of RM 17,085.00.

3.1.2.1 Trial Registration

The study was registered with ClinicalTrials.gov (Ref. No.: NCT03755622).

3.1.3 Participants

3.1.3.1 Eligibility Criteria

(a) ***Other inclusion criteria***

1. Age 18 and above
2. Requiring upper premolar extractions
3. Patients do not have previous orthodontic treatment before

(b) ***Exclusion criteria***

1. Patient requiring lingual arch, modified TPA, Nance Palatal Arc
2. Non extraction upper arch treatment
3. Patients requiring upper arch expansion
4. Requiring upper first permanent molar extraction
5. Presence of dento-facial anomalies.
6. Patients requiring orthognathic surgery

Patients requiring TPA in conjunction with upper and lower fixed appliance were included and assessed for eligibility. Consent were taken and all patients were given oral and written information sheets concerning the study.

3.1.3.2 Settings and locations

Patients registered in the waiting list and in the queue to be treated with fixed appliance therapy by orthodontics postgraduates at the Postgraduate Orthodontics Clinic, Faculty of Dentistry, University of Malaya were recruited in this study. All the potential subjects were screened based on the need of TPA as an adjunct to the fixed appliance therapy and fulfilled the inclusion as well as the exclusion criteria.

Once participants agreed to participate, the researcher (ANMAF) gave a full verbal explanation of the conduct of the study and supplemented the details with a written patient information sheet that was available in both Malay and English language. Once the nature and flow of the study were fully understood, participants gave their written consent.

3.1.4 Interventions

There were two interventional groups: the conventional group (CG) where the TPA was fabricated using conventional method on stone working models and the 3D group (3DG) where the TPA was fabricated on 3D printed working model. They are differentiated by the mode by which the working models were acquired.

3.1.4.1 Work flow for the conventional group

In the conventional group, subjects had to attend three clinical appointments in comparison to the 3DG where the number of appointments were only two.

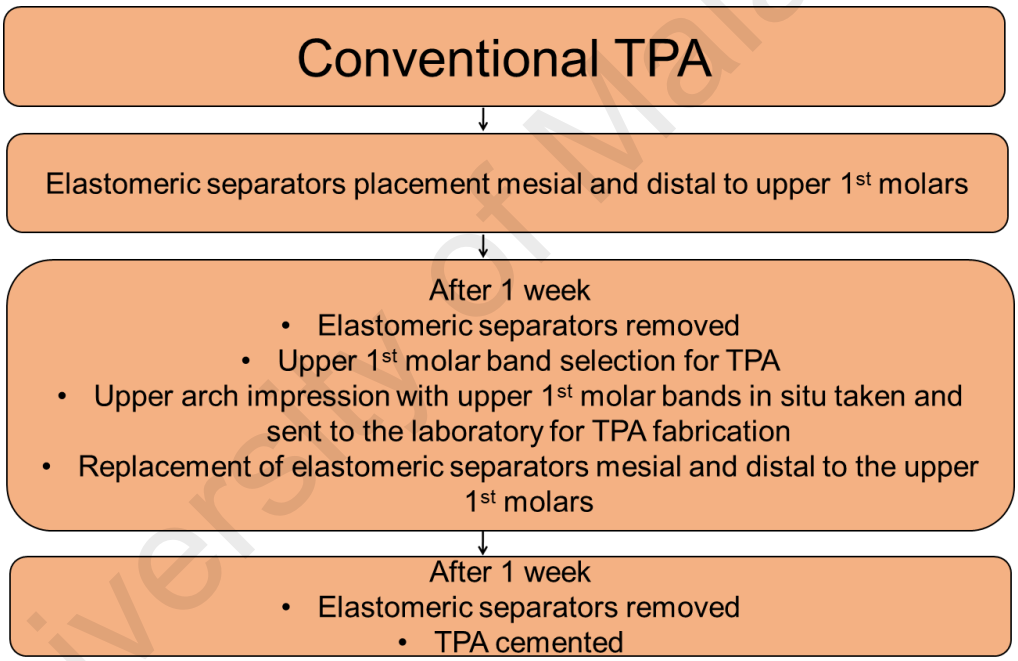


Figure 3.1 Workflow for the conventional group

(a) ***First patient visit***

During the first visit, four elastomeric separators (3M Unitek Alastik Radiopaque Separators (SX) made in United State of America) were inserted between the mesial and distal surfaces of upper right and left first molar teeth using separator holder by the clinician. Patients were informed that the elastomeric separators were placed in order to

create an adequate space for the metal band insertion and there were possibilities of some amount of discomfort. Patients were also instructed not to intentionally extract out the separators due to the adverse outcomes. They were reminded to inform the researcher if the separators were dislodged before the given date of consecutive appointment as the created space may closed and the molar band selection procedure cannot be carried out. Patients were given a consecutive appointment one week later for the molar band selections procedure.

(b) ***Second patient visit***

For the CG, molar bands selections were carried out intraorally to determine the correct size by clinicians and followed by an upper arch impression with molar bands (stainless steel molar band, 3M Unitek brand made in United States with Pat No. 5.322.436) *in situ* (Figure 3.2) The impression material used was alginate powder (Aroma Fine Plus Normal Set by GC, made in Tokyo Japan).

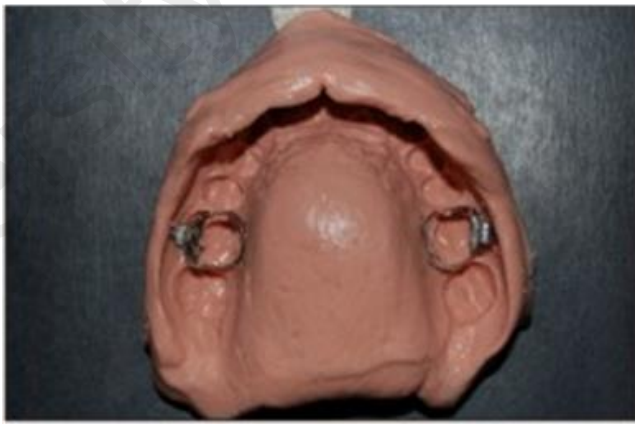


Figure 3.2 Upper arch impression using alginate with upper molar bands in situ

Source : (Gupta, 2014)

(c) ***Prior to the patient's third visit***

i *Working model casting and TPA construction*

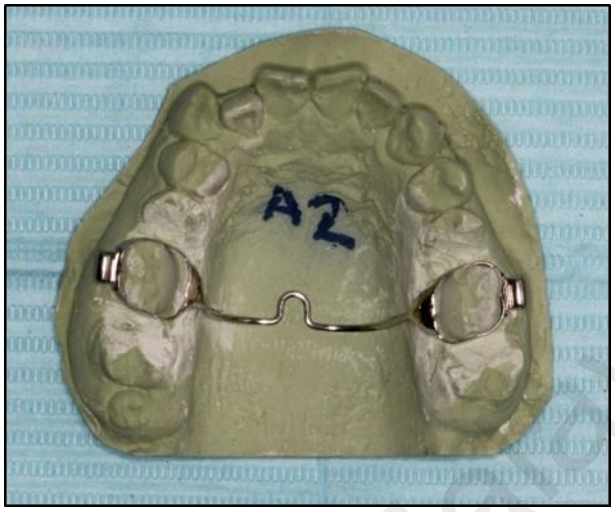


Figure 3.3 TPA construction on conventional model

The impression with the molar bands were sent to the orthodontic laboratory and casted with dental stone (SHERA Werkstoff-Technologie GmbH & Co, made in Germany). The conventional TPA were fabricated on the plaster model as shown below (Figure 3.3).

All TPAs from CG and 3DG were constructed by the same technician (MNMI), using the same type of metal Molar Bands (3M Unitek brand made in United States with Pat No. 5.322.436), 0.9 stainless steel wire and the same design.

(d) ***Third patient visit***

At the third visit, the inserted elastomeric separators were removed using Probe Number nine dental explorer by the clinician and patients were asked to rinse for

removal of remaining debris in between the teeth. The TPA were inserted and adapted to the upper molar teeth with band seater and pusher. It was then removed by molar band remover and cemented to the teeth with glass ionomer cement (3M Unitek Multi-Cure Glass Ionomer Orthodontic Band Cement, made in USA) and liquid (3M Unitek Multicure Glass Ionomer Orthodontic Band Cement made in Germany)

3.1.4.2 Work flow for the 3D group

For the 3DG, the clinical appointments were cut down by one visit in comparison to the CG. The steps include acquisition of the digital model, followed by 3D printing of the working model prior to molar band selection, extra-orally (Figure 3.4).

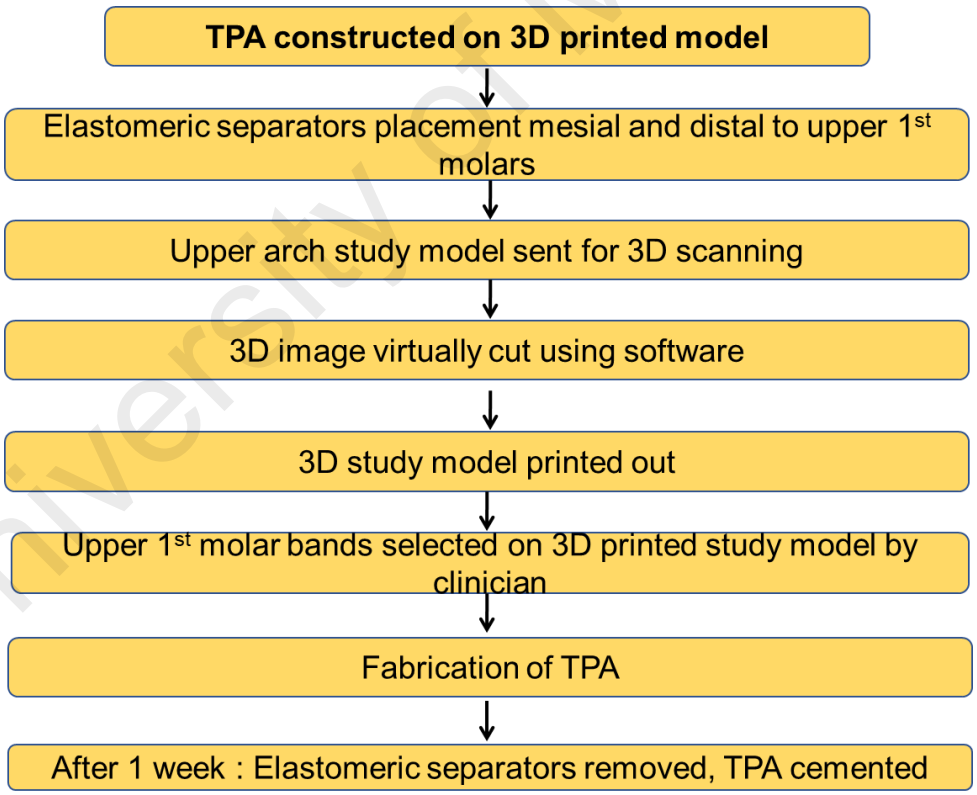


Figure 3.4 Workflow of TPA constructed on 3D printed model

(a) ***First patient visit***

Similar procedures of CG group were applied to the subjects in the 3DG during the first visit. During the first visit, four elastomeric separators (3M Unitek Alastik Radiopaque Separators (SX) made in United State of America) were inserted between the mesial and distal surfaces of upper right and left first molar teeth using separator holder by the clinician. Patients were informed that the elastomeric separators were placed in order to create an adequate space for the metal band insertion and there were possibilities of some amount of discomfort. Patients were also instructed not to intentionally extract out the separators due to the adverse outcomes. They were reminded to inform the researcher if the separators were dislodged before the given date of consecutive appointment as the created space may closed and the molar band selection procedure cannot be carried out. Patients were given a consecutive appointment one week later for the molar band selections procedure.

(b) ***Prior to the patient's second visit***

i *Acquisition of the working digital model:*

Since the institution of the study location does not have an intra-oral scanner, digital model had to be acquired indirectly by scanning patients' study models. Existing stone study models of the participants were sent to the Centre for Biomedical and Technology Integration (CBMTI), located at Institute of Postgraduate Studies, University of Malaya for digitization.

The three-dimensional scanner used is Geomagic Capture Manufacturer (by 3D System, made in USA) (Figure 3.5) and the procedure was carried out by two trained design engineers (MAS and MFB) working in the office. Captured images are automatically processed by the Geomagic Design X (XOR) (by 3D System, made in

USA) (Figure 3.6) to produce a full arched 3D digital working model, which comprised all dentition from the last standing tooth (second or third molars, depending on the case) to the contralateral last standing tooth (second or third molars, depending on the case) and included the palatal vault and sulcular (buccal and labial) areas.

The working model to fabricate the TPA required for the bands to be seated on the first permanent molars and thus the digital model needed to be remodeled prior to TPA construction. It also cut down the printing cost by removing the unwanted part of the models that is not required in TPA construction.

The digital model was virtually remodeled by the researcher (ANMAF) with assistance from the same personnel whom carried out the 3D scanning procedure using Geomagic Design X (XOR) softwire (by 3D System, made in USA). Total resection of the upper right and left second premolars (UR5, UL5) and upper right and left second molars (UR7, UL7) were carried out digitally. The virtual cutting was carefully carried out to ensure that the anatomical structure of upper first molars were not jeopardized.

Figure 3.5 Geomagic Capture 3D Scanner

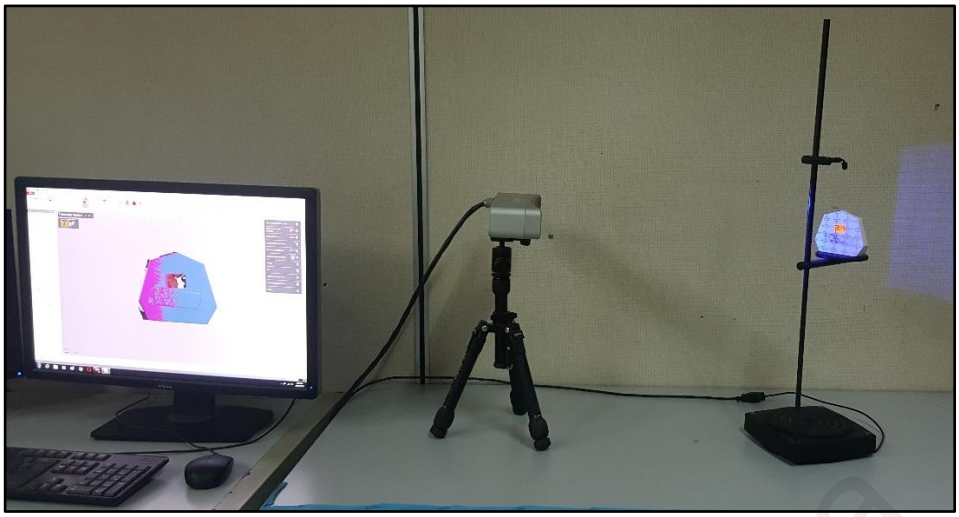


Figure 3.6 Geomagic Design X (XOR) 3D software

Table 3.1 Technical Specification of Geomagic Capture 3D Scanner

Property	Capture
Dimensions (L x W x H)	276 x 74 x 49 mm 155 x
Weight	1.35 kg
Depth of Field	180 mm
Stand-off Distance	300 mm
Field of View	124 x 120 mm (near) 190 x 175 mm (far)
Data Capture Rate	985,000 points/scan (0.3 sec per scan)
Accuracy	0.060 mm
Resolution	0.110 mm at 300 mm; 0.180 mm at 480 mm
Computer Requirements	Gigabit Ethernet interface, 4 GB Memory or greater, 512 MB Video Card or better

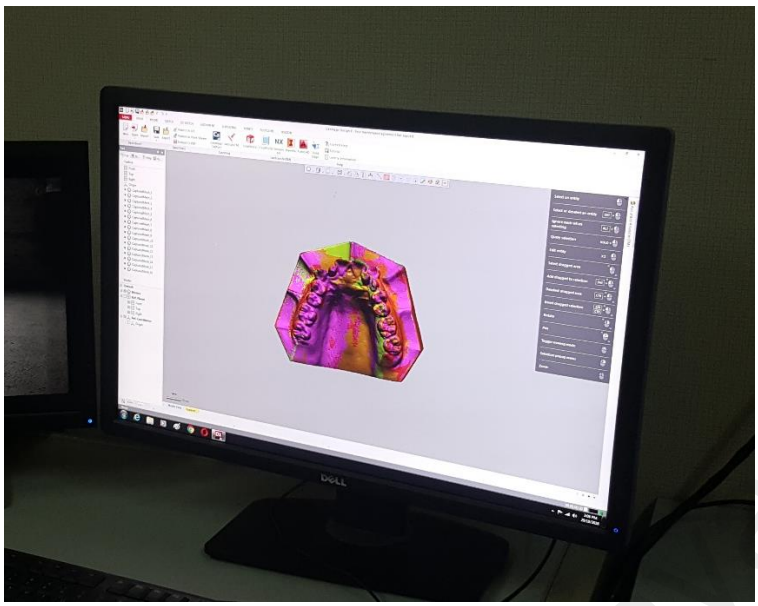


Figure 3.7 Geomagic Design X (XOR) 3D software

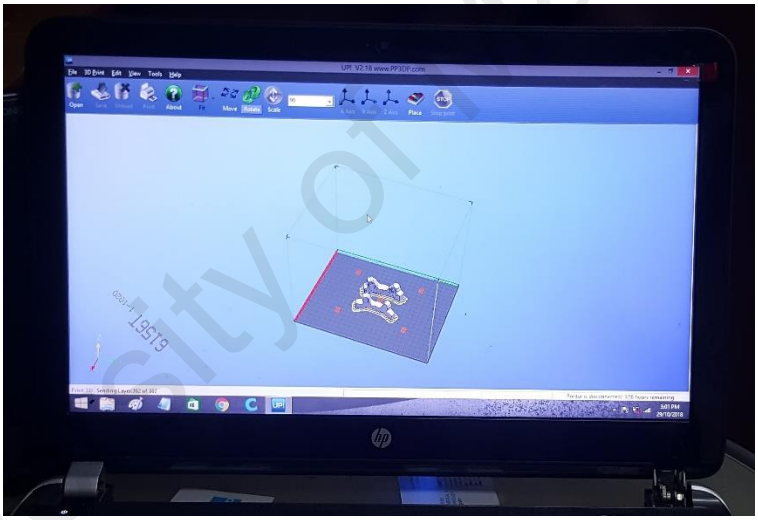


Figure 3.8 Geomagic Design X (XOR) 3D software

Table 3.2 Technical Specification of Geomagic Software

Geomagic® Design X™ Features
Direct 3D scanner control tools for the widest range of the most popular devices
Full integration with Geomagic Capture Scanners
Supports import of over 60 file formats including polygons, point clouds and CAD
Expertly handles massive mesh and point cloud data alignment, processing and refining, mesh construction
Easy-to-use mesh repair tools deliver rapid hole filling, smoothing, optimizing, re-wrapping and polishing tools such as Smart Brush
Automatic, feature-based solid and surface extraction direct from 3D scans
Rapidly creates solids or surfaces like you would in CAD
Automated Accuracy Analyzer™ tools compare and validate surfaces, solids and sketches against original scan data
Live Transfer™ supports the output of data to the industry's leading CAD systems
Industry-leading "Exact" surface creation converts organic shapes to precise CAD models
Supports comprehensive export of neutral CAD or polygon files
Instantly create stunning renderings of your designs in Keyshot

ii Acquisition of 3D printed working model:

Modified 3D dental model was printed out with Acrylonitrile-Butadine-Styrene (ABS) (TierTime Company, manufactured in China) material using a Fused Deposition Modelling (FDM) type 3D printer (UP Plus 2, TierTime Company, manufactured in China) as shown in (Figure 3.9) and (Figure 3.10).

Figure 3.9 "UP Plus 2" 3D Printer

Figure 3.10 "UP Plus 2" 3D Printer

Table 3.3 Technical Specification 3D Printer

Printing	Properties
Printing Technology	Melted Extrusion Manufacturing (MEM)
Build Volume	255 x 205 x 205 mm (W x H x D) 10" x 8" x 8"
Print Head	Single, modularize for easy installation
Layer Thickness	0.1/0.15/0.20/0.25/0.30/0.35/0.40mm
Supporting Structure	Smart Support Technology: automatically generated, easy to remove and fine—tunable.
Platform Levelling	Fully automatic levelling with integrated levelling probe
Print Surface	Heated, Perforated Print Board or UP flex print board
Untethered Printing	Yes
Average Operational Noise	51.7dB
Advanced Features	Closed Working Chamber, Air Filtration, Light-pulse functional LED.

iii Band selection and TPA construction

Contradictory to the CG, molar bands selection in the 3D group were carried out extra-orally without the presence of patients. The clinicians selected the correct molar bands for their own patients. They selected the appropriate size of the molar bands based on the 3D printed model (Figure 3.11) before sending them off to the technician for TPA construction. Similar to the CG, the TPAs for 3D groups were constructed by the same technician (MNMI), using the same type of metal Molar Bands (3M Unitek), 0.9 stainless steel wire with the same appliance design.

(c) ***Second patient visit***

In contrast to the CG, 3DG subjects received their TPA at the second visit, the molar band selections were already carried out by the clinicians on the 3D printed models and directly sent to the dental laboratory for TPA construction. The existing separators were removed in between the teeth and the TPA were inserted for try in and adaptation prior to cementation with the same material used for the CG group (3M Unitek Multi-Cure Glass Ionomer Orthodontic Band Cement, made in USA) and liquid (3M Unitek Multicure Glass Ionomer Orthodontic Band Cement made in Germany)

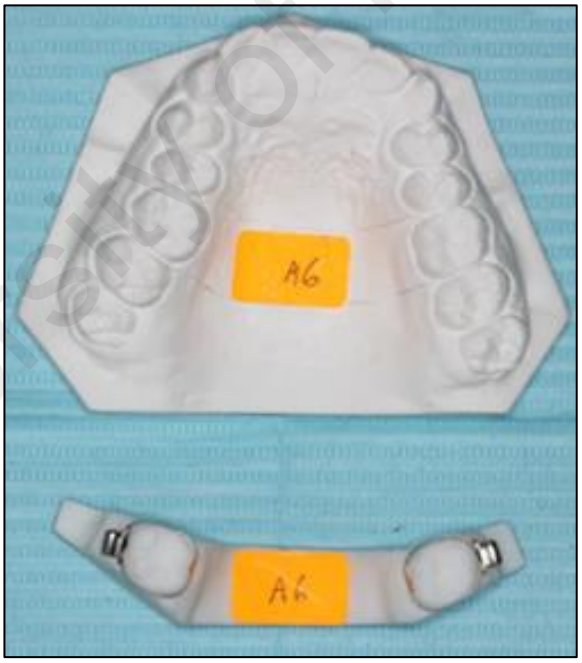


Figure 3.11 Molar bands selection on 3D printed working model

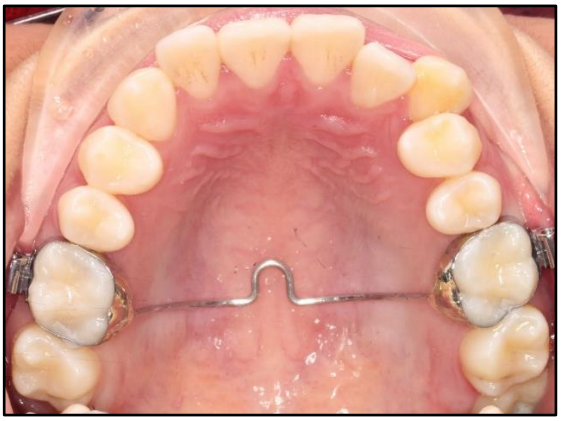


Figure 3.12 Cemented TPA intraorally

3.1.5 Outcomes

3.1.5.1 Primary outcome measure

The primary outcome measure was the impact of the TPA on the patients OHRQoL. OHRQoL was measured using a modified version of the Oral Health Impact Profile (OHIP-14) adapted from (Saub & Locker, 2006). This instrument was selected as it is widely used in OHRQoL studies in the orthodontic field. It focused on the impact of oral health on quality of life via seven domains: “functional limitation”, “physical pain”, “psychological discomfort”, “physical disability”, “psychological disability”, “social disability” and “handicap”. For each item, the responses were scored on a Likert scale measure as follows: 0=Never, 1=Seldom, 2=Sometimes, 3=Quite often, 4=Very often and 5=Don’t know.

For this study, the modified OHIP-14[M] was pre-tested and evaluate for the face validity. The pre-test was carried out among ten existing patients with TPA to ensure the content validity of the modified OHIP-14[M]. All questions items in the seven domains were relevant and fully understood by the pilot patients. The selected domains were described in the (Table 3.4).

3.1.5.2 Secondary outcome measure

(a) ***Pain assessment***

The second primary outcome was to measure the patients' pain experience by the TPA. The respondents are asked to answer on a five-point frequency Likert scale (very often, quite often, sometimes, once a while, and never). For the presence and intensity of the pain, the data was analyzed by Chi-square/fisher exact test. For the severity of the pain, it analyzed by Independent T Test and repeated measure ANOVA (RMANOVA). Face validation was carried out in a pilot study among ten existing patients with TPA to ensure the content validity.

3.1.5.3 Questionnaire

Both primary and secondary outcomes were measured using a questionnaire. A self-administered questionnaire was prepared and utilized to obtain patients information of sociodemographic backgrounds and their oral health related quality of life at baseline and after wearing TPA.

The baseline questionnaire (administered at T0) comprises of three parts: (A) OHIP-14[M], (B) Pain assessment and (C) Demographics, measuring the age, gender, ethnicity and education level of the subjects and. The subsequent questionnaire (administered at 1 week (T1), one month (T2) and 3 months (T3) after TPA insertion) comprises only two parts which were OHIP-14 and Pain assessment.

Prior to commencement of any treatment, all participants filled in the first baseline OHIP-14[M] questionnaire (T0). This is to record the patient's demographic information and the existing level of OHRQoL before any intervention is carried out. Upon completion of the questionnaire, elastomeric separators were placed between the right and left upper molar teeth.

After one week, one month and three months, participants were seen again and they were given the relevant questionnaires. The study was completed after administration of the final questionnaire and the patient proceeded to continue with their orthodontic treatment.

3.1.5.4 Other measures

(a) ***DMFT***

The DMFT status of all subjects were recorded at baseline, this was carried out as high DMFT scores may influence the OHRQoL of the subjects. A study on relationship between oral health and its impact on quality of life among adolescents aged 15 to 17 in Brazilian population by (Biazevic, Rissotto, Edgard, Mendes, & Mendes, 2008) found that that participants with a higher average of intact teeth presented less impact on the performance of their daily activities and the largest impact on the performance of daily activities was related to the number of decayed teeth and a higher DMFT. Another study by (De Vasconcellos Rocha Maia, Mendes, & Normando, 2018) also confirmed that dental caries and periodontal disease negatively impact oral health-related quality of life. Thus, DMFT baseline status was included in this study as having an affected OHRQoL at the beginning of the study may affect the consecutive assessment and may contribute as confounding factor of high OHIP scores.

i Calibration of the operators for DMFT assessment

Intra and inter operator calibrations training were carried out for all the six clinicians with gold standard (RS). Four subjects were involved in the training. The calibration was carried out two times, the second part was done two weeks after the first calibration procedure. Intraclass correlation coefficient (ICC) scores of all clinicians (Examiner A to F) were excellent for the inter and intra-operator measurements with all scores above ICC value of 0.80 (Table 3.5). Thus, all clinicians were standardized to conduct the RCT.

Table 3.4 Calibration of DMFT

Average Measure	Intraclass Correlation	Interclass Correlation
Examiner A	0.807	0.889
Examiner B	0.856	0.927
Examiner C	0.930	0.908
Examiner D	0.896	0.891
Examiner E	0.837	0.871
Examiner F	0.943	0.889
Mean	0.878	0.896

ii DMFT assessment

DMFT assessments were carried out at T0, prior to the insertion of elastomeric separators. Subjects with decayed teeth were sent for restorative treatment prior to the commencement of the TPA.

3.1.6 Sample Size

Sample size calculation was based on comparative literature by (Johal *et al*., 2014) and calculated using G Power version 3.1.92 software. It was estimated that a sample size of 46 subjects was needed to demonstrate a significant change in OHRQoL, with an 80 per cent probability power at the 5% level of significance. The sample size was inflated by a 10% margin to allow for loss to follow-up and drop outs; thus, the total sample size was a minimum of 52.

3.1.7 Randomization

Randomization was conducted by a statistician (NN), the study involved 52 subjects and six clinicians. Thus, the randomization was done in two parts: First was to randomize the allocation of the subjects into the interventions. Second was to randomize the clinicians who would receive the block randomization groups.

3.1.7.1 Sequence generation

(a) ***Sequence generation for the participants***

The statistician used an online software to create the block randomization (https://www.randomizer.org/). Six groups were required for six clinicians. However, due to the imbalanced number of patients per operator, the patients were divided such that four operators would have nine patients each while the other two operators would have eight patients each. The sequence for a blocking size of eight was generated for the initial 48 subjects. The block randomization was carried out six times for the six clinicians. Odd numbers were assigned to the CG and the even numbers were for 3DG. For the remaining four subjects, a randomization with a block of four was carried out (Table 3.6) and (Table 3.7).

Table 3.5 Block randomization of eight in determining CG and 3DG treatment group

First Stage Randomization: Block of Eight						
Order	**Block 1**	**Block 2**	**Block 3**	**Block 4**	**Block 5**	**Block 6**
1	2	1	1	1	2	1
2	2	1	1	2	1	1
3	2	2	2	1	1	2
4	2	2	1	1	1	1
5	1	1	1	2	1	2
6	1	1	2	2	2	2
7	1	2	2	2	2	1
8	1	2	2	1	2	2

*1=CG, 2=3DG

Table 3.6 Block randomization of four in determining CG and 3DG treatment group

Order	**Second Stage Randomization: Block of Four**
1	2
2	1
3	2
4	1

*1=CG, 2=3DG

(b) ***Sequence generation for the clinicians***

The statistician used an online software (https://www.randomizer.org/) to determine which clinician would have the eight or nine sample group. The six lists of the block of eight and the list with the block of four were randomized again to the six clinicians (Table 3.8).

Table 3.7 Randomization in determining allocation of block randomizations to clinicians

Randomization Block	**1**	**2**	**3**	**4**	**5**	**6**
Clinicians	E	F	B	D	C	A

3.1.7.2 Allocation Concealment

The statistician then prepared an envelope for each subject with a piece of paper with allocated group written on it. The opaque envelopes were sealed with initials written on it. For clinician A, the initial A1, A2, A3, A4, A6, A7 and A8 were written on the envelopes. After the subjects gave their written consent, the DSA was charged with opening the sealed envelope and to follow the sequence written on it. The content was not known to all the clinicians, DSAs and the patients.

3.1.7.3 Implementation

Once the patient gave their written consent, the dental surgical assistant (DSA) opened the opaque envelope to inform the clinician the assigned group of the patient. CG group underwent normal clinical and laboratory procedure of conventional TPA while for Group 3D followed a new workflow procedure.

3.1.7.4 Blinding

In this study, blinding was not possible. The clinicians, technicians and patients involved were directly exposed to the different methods and procedures in the intervention groups. For clinicians, they carried out the molar bands' selection intra orally in the CG and extra orally in the 3DG. All procedures were documented in the patients' folder where they have access to while treating the patients. It was also impossible to blind the technician as the fabrication of TPA was carried out on two different type of working models. For the patients, the procedure of the CG and 3DG required three and two visits respectively. The 3DG also did not require to have impressions with the molar bands in situ, which the CG had to undergo.

3.1.7.5 Statistical Method

Statistical analysis involved Statistical Package for Social sciences (SPSS version 22.0.0.0) software.

(a) ***Analysis for the primary and secondary outcomes***

The primary and the secondary outcomes for OHIO-[M] and pain scores were analyzed with Independent T-Test, Paired T-Test and Repeated Measure ANOVA (RMANOVA) with further post-hoc Bonferroni analysis.

(b) ***Analysis for the demographics***

For the demographics, the data was analyzed with Independent T-Test, Chi-square and Fisher exact tests.

(c) ***Analysis for the DMFT***

The DMFT between the two groups was compared with Mann Whitney U test.

3.2 Part 2 (Qualitative study): Focus group discussion (FGD)

Focus group interview is a "carefully planned discussion designed to obtain perceptions in a defined area of interest in a permissive, nonthreatening environment" (Krueger, 1988). It was intended to promote self-disclosure among participants. A thorough discussion most likely to happen when the participants perceive that they are alike in some important way and when the environment is non-judgmental. It is usually carried out with six to ten participants and facilitated by one moderator.

3.2.1 Setting

The FGD was carried out in a closed room with an oval table that accommodate eight chairs. All the subjects were randomly allocated to their sitting arrangement with the moderator at the head of the table. The transcriber (SW) of the FGD was present during the procedure as an observer. The entire conversation was tape in a recorder by the transcriber. The discussion continued until saturation point reached (saturation is the point at which no new information emerges).

3.2.2 Study subjects

There researcher (ANMAF) facilitated the discussion as the moderator. Five clinicians were invited to participate in the FGD. They consisted of two male and three female clinicians aged from 31-35 years old. Two of them are Malay and three of them are Chinese. All subjects had a minimum of three years working experience in orthodontic field.

3.2.3 Transcription process

The recorded discussion was sent in the form of soft copy to the hired transcriber (SW) for the transcription process. SW transcribed the audio discussion in a text form and emailed it to the researcher.

3.2.4 Themes

The text form of the FGD was analyzed using NVivo software. Themes of the FGD can be autogenerated by the software or manually carried out. In this study, the emerged themes were manually extracted from the NVivo software based on the frequencies of the mostly discussed matter. The emerged themes were agreed through discussions and meetings with two experts (RS) and (WNWH).

CHAPTER 4: RESULTS

4.1 Randomized control trial

4.1.1 Participant flow

Figure 4.1 shows the CONSORT flow chart. Initially, 80 patients were assessed for eligibility in this study. Of these, 28 patients were excluded as they did not meet the inclusion and exclusion criteria. None of the patients declined participation. The remaining 52 eligible participants were randomized into two groups. An equal number of 26 samples were allocated into each group (CG and 3DG). All 52 participants received the intended treatment at all four interval times (T0, T1, T2 and T3) and there was no drop out participant at follow up until completion of the study. The primary outcome measure using the OHIP-14[M] was measured at all time points (T0, T1, T2 and T3). All subjects were analyzed for the primary and secondary outcomes.

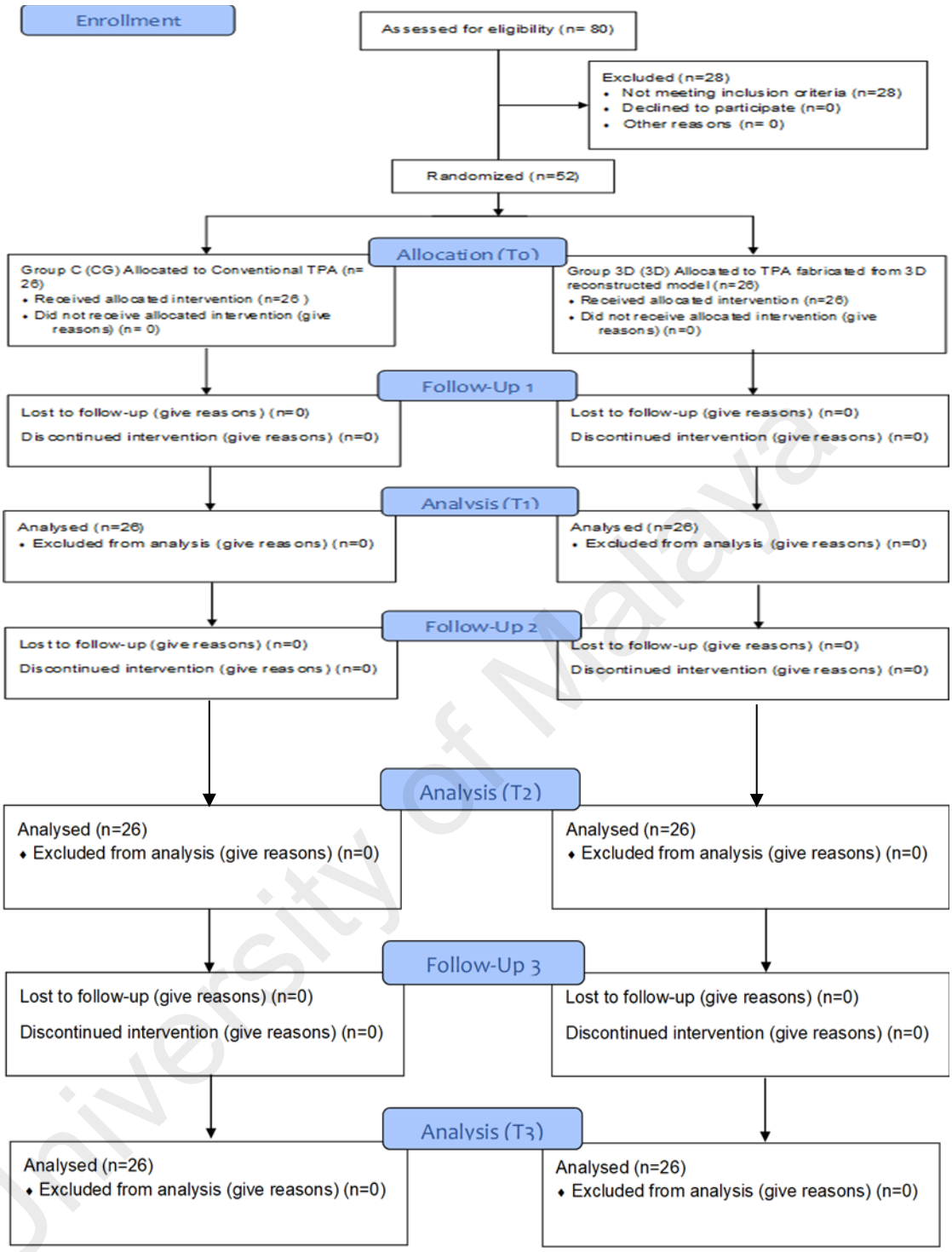


Figure 4.1 CONSORT flow chart

Legend: Conventional (TPA fabricated by conventional method) group (CG);

Interventional (TPA fabricated by using 3D working model) group (3DG)

4.1.2 Recruitment

Recruitment of the first participants was carried out in March 2017 and the last participant was recruited in October 2018. The first follow up was in March 2017 and the last follow up of the last participant ended in January 2019. The trial ended upon completion of follow up of the last participant at three months of wearing TPA.

4.1.3 Baseline data

The baseline data included demographic information and clinical characteristic of all 52 samples. The clinical characteristic comprises of decayed, missing and filled teeth (DMFT) scores. The patient reported outcome was measured using OHIP-14[M]. All data were obtained at the baseline (T0), prior to commencement of the TPA fabrication.

4.1.3.1 Sample demographic data

Table 4.1 shows the distribution of study samples according to the sociodemographic details of all the study samples (N=52) at baseline (T0), which includes gender, ethnicity, highest education level and age.

Table 4.1 Demographic data of study samples (N=52) at baseline (T0)

Characteristics	Distribution			*P Value*
	Total (N=52)	**CG (N=26)**	**3DG (N=26)**	
	N (%)	**n (%)**	**n (%)**	
Gender				
Male	19 (36.5)	9 (34.6)	10 (38.5)	*0.910[a]*
Female	33 (63.5)	17(65.4)	16 (61.5)	
Ethnicity				
Malay	27 (51.9)	12 (46.2)	15 (57.7)	*0.426[b]*
Chinese	21 (40.4)	12 (46.2)	9 (34.6)	
Indian	3 (5.8)	2 (7.7)	1 (3.8)	
Others	1 (1.9)	0 (0)	1 (3.8)	
Highest Education Level				
University	42 (80.8)	20 (76.9)	22 (84.6)	*0.815[b]*
Secondary	6 (11.5)	4 (15.4)	2 (7.7)	
Others	4 (7.7)	2 (7.7)	2 (7.7)	
Age	**Mean (S.D)**	**Mean (S.D)**	**Mean (S.D)**	***P Value***
	23.94 (5.72)	24.27 (7.43)	23.62 (3.36)	*0.921[c]*

**p<0.05 [a]Chi-square, [b]Fisher exact test, [c]Independent T-Test*

(CG): Conventional (TPA fabricated by conventional method) group

(3DG) Interventional (TPA fabricated by using 3D working model) group

(a) ***Gender***

Overall, majority of the subjects were female (n=33; 63.5%) while male comprised about 36.5% of the sample (n=19). Both groups had more female subjects than male subjects. In the CG, there was 17 (65.4%) female subjects and 9 (36.5%) male subjects. In the 3DG, 16 (61.5%) subjects were female and 10 (38.5%) subjects were male. However, chi-square tests showed that there was no significant difference in the gender characteristic between the two groups with $p>0.05$.

(b) ***Ethnicity***

Overall, Malay ethnicity was the highest with 27 (51.9%) subjects followed by Chinese 21 (40.4%), Indian 3 (5.8) and 1 (1.9%) from 'other' category, who was of a Sabah Bumiputra race. In the CG, there was equal number of Malay and Chinese ethnicities with 12 (46.2%) subjects for each ethnicity followed by two Indians (7.7%) subjects. In the 3DG, Malay was the highest ethnicity with 15 (57.7%) subjects, followed by Chinese 9 (34.6%) and 1 Indian, 1 other ethnicity that contributed to 3.8% each to the group. There was no significant difference $p>0.05$ in terms of ethnic distribution among CG and 3DG from the fisher exact test.

(c) ***Highest education level***

The highest education level of all subject (N=52) was documented at three levels; university, secondary and others with 'others' included other different qualification than university and secondary school. Overall, 42 subjects had the highest educational qualification up to the university level which contributed 80.8%. This was followed by secondary schools' qualifiers with 6 (11.5%) subjects and 4 (7.7%) from others. Similar result for the CG and 3DG with 20 (76.9%) and 22 (84.6%) subjects had university qualification respectively. They were followed by secondary schools' qualifiers, 4 (15.4%) in CG and 2 (7.7%) in 3DG and equal distribution of other highest education level with 2 (7.7%) subjects each. Fisher exact test test showed there was no difference in the highest educational level between CG and 3DG with *(p>0.05).*

(d) ***Age***

The overall mean age for all subjects (N=52) was 23.94 (S.D 5.72). In the CG, the mean age was 24.27 years old (S.D 7.43) and for the 3DG, the mean age was 23.62 years old (S.D 3.36). Independent T-Test showed that there was no difference in the mean age between the two groups with *(p>0.05).*

4.1.3.2 Clinical characteristic: Decayed, Missing and Filled Teeth (DMFT) scores

(a) ***DMFT of participants pre-treatment***

Almost half of the subjects had 0 DMFT scores and three subjects had a high DMFT ranged from 12 to 14, the high scores were due to presence of filling. Subjects with decayed teeth were sent for restorative treatment prior to the commencement of the TPA.

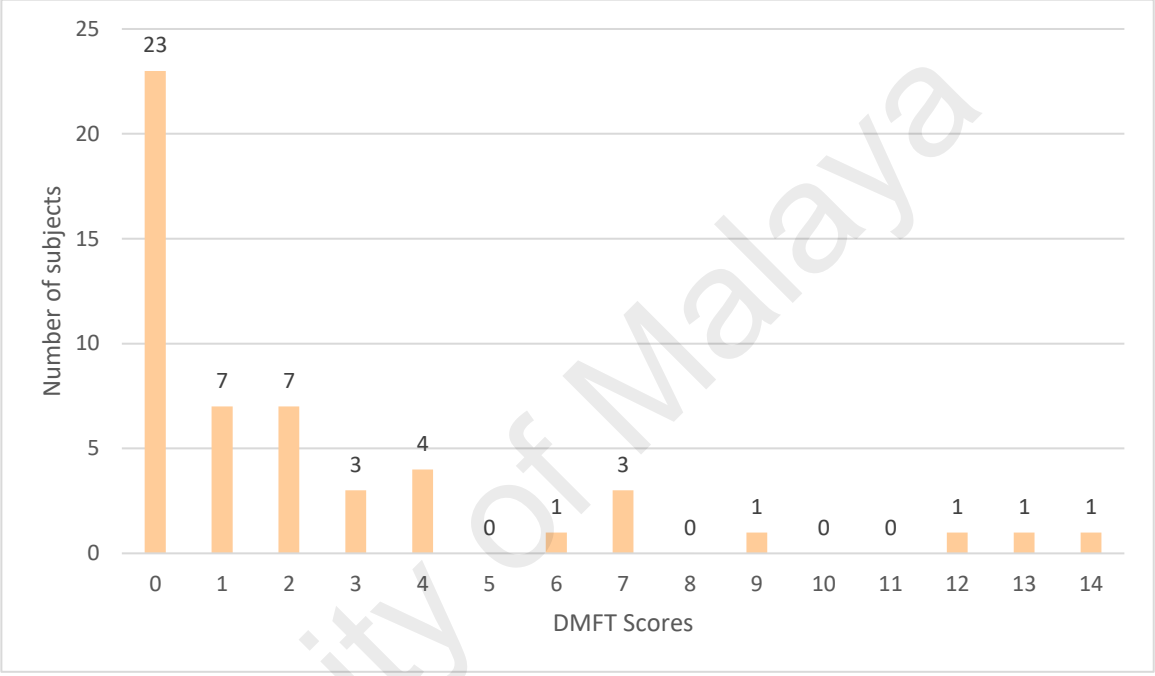


Figure 4.2 DMFT scores of all subjects (N=52) at baseline (T0)

Figure 4.2 shows DMFT scores of all subjects (N=52) in both groups at baseline (T0), before the cementation of the TPAs. The minimum DMFT scores was 0 for 23 subjects which comprised 44% of all samples. The maximum score was 14 for 1 subject with 1.92% of overall percentage. 44 subjects (84.6%) had DMFT score less than 5 while 8 subjects (15.4%) scored more than 5. Out of 8 subjects who scored more than 5, 3 subjects had DMFT scores more than 10 and 1 subject each had DMFT scores of 12, 23 and 14.

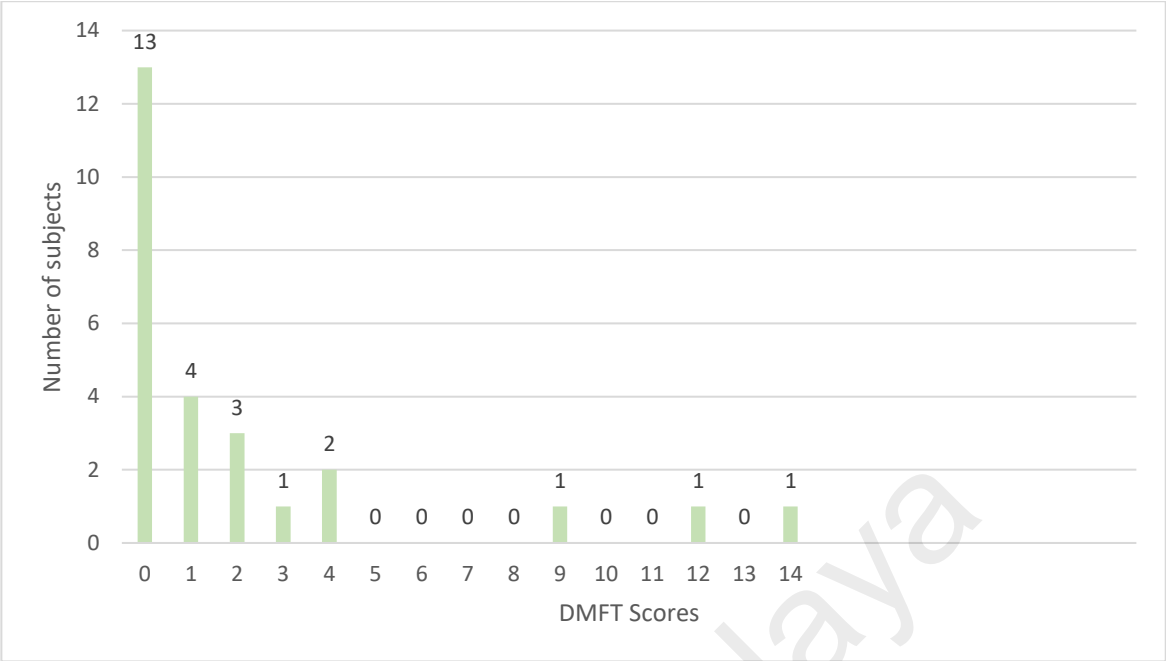


Figure 4.3 DMFT score of Conventional Groups (CG) of all subject (n=26) at baseline (T0)

Figure 4.3 shows DMFT scores of the subjects (n=26) in the CG. 13 subjects (50%) had the minimum score of 0 and 1 subject (3.8%) had the maximum score of 14. 23 (88.5%) subjects in the CG had DMFT scores less than 5 while 3 subjects (11.5%) had DMFT scores more than 5.

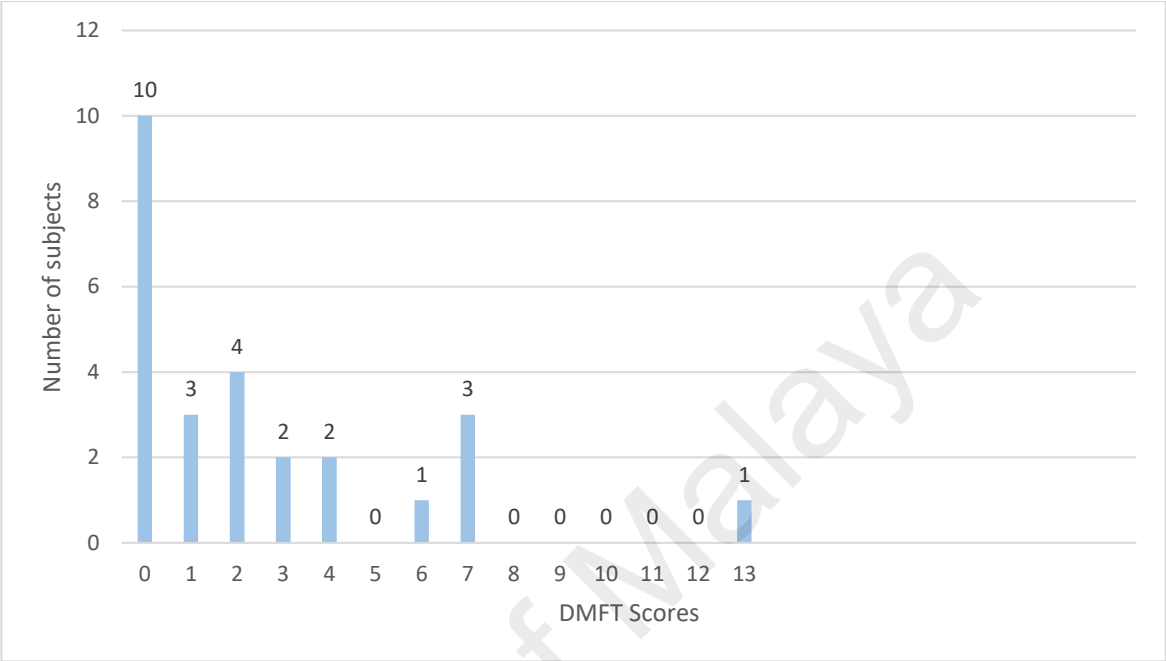
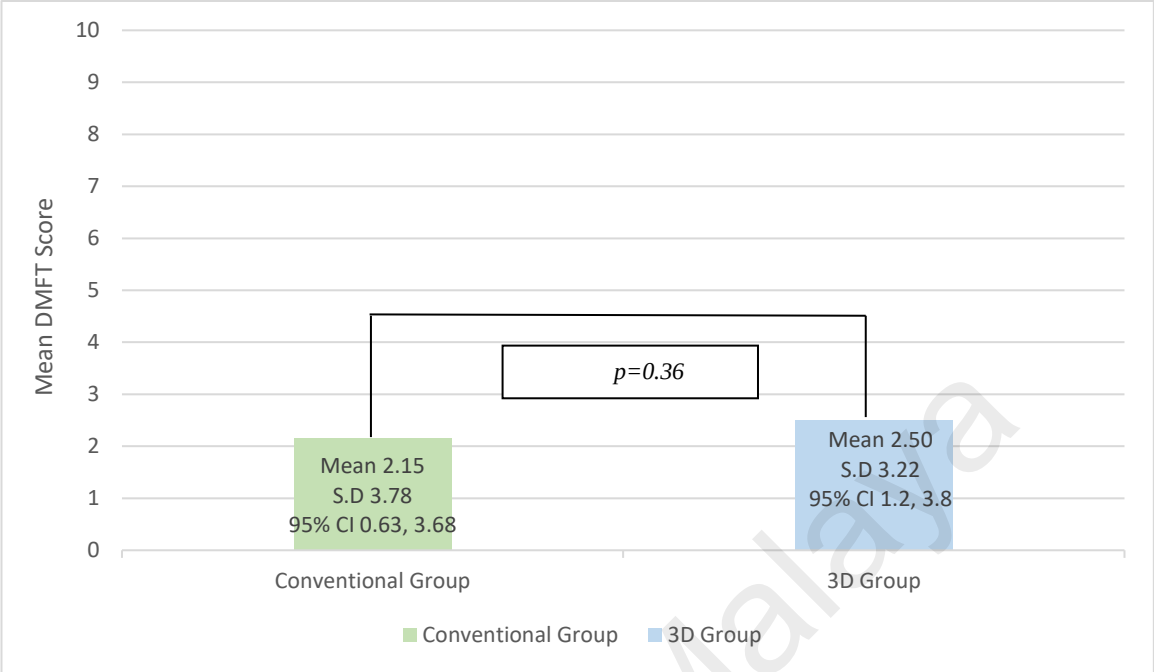


Figure 4.4 DMFT score of 3D Groups (n=26) at baseline (T0)

Figure 4.4 shows DMFT scores of the subjects (n=26) in the CG. Ten subjects (38%) had the minimum DMFT scores of 0 and one subject (1.9%) had the maximum score of 13. 21 subjects (80.8%) had DMFT scores less than 5 while 5 subjects (19.2%) scored more than 5.



p<0.05

Figure 4.5 Mean DMFT scores for all subject (N=52) of CG and 3DG at baseline (T0)

Figure 4.5 shows the mean DMFT score for all subjects (N=52) in CG and 3DG. The mean DMFT score for CG (n=26) was 2.15 (S.D 3.78) while for 3DG (n=26), the mean score was 2.50 (S.D 3.22). Mann Whitney U test showed there was no significant difference between the mean score of the two groups with the mean difference of 0.35 and (*p>0.05).*

4.1.3.3 Baseline OHIP-14[M]

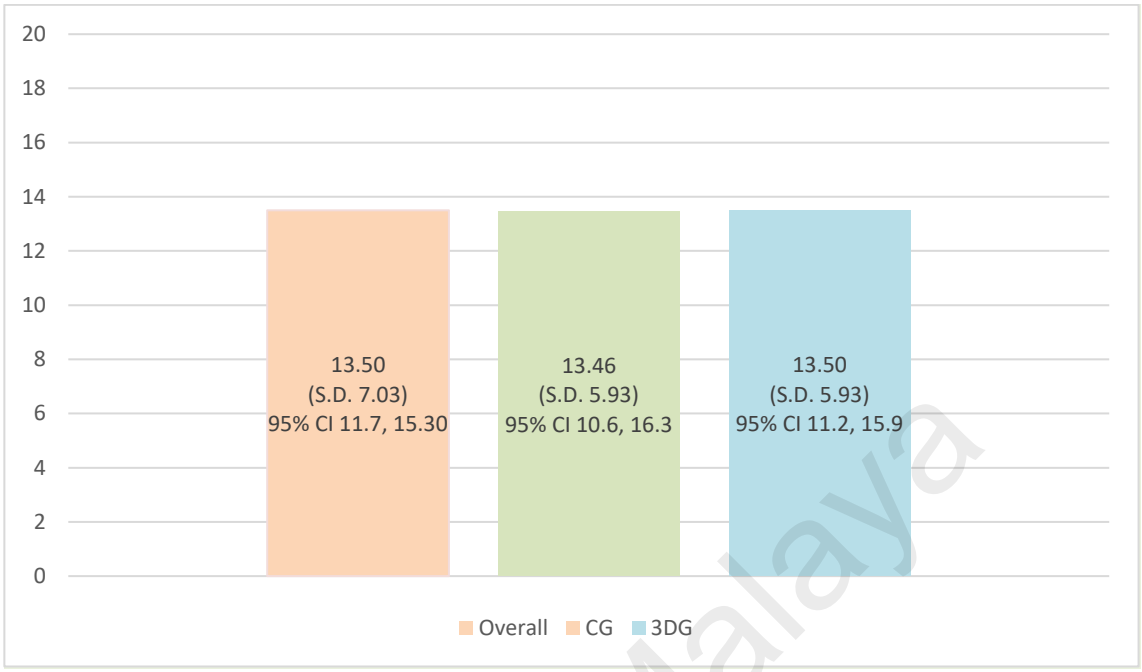


Figure 4.6 Severity of OHIP-14[M] score at baseline for all subjects (N=52) and by group CG (n=26) and 3DG (n=26)

Figure 4.6 shows the severity of OHIP-14[M] scores at baseline. Overall for the 52 subjects, the baseline the score was 13.50. The score was also 13.50 (N=26). In CG, the score was 13.46. Independent t-test showed that the baseline OHIP was not significant between the CG and 3DG ($p>0.05$).

4.1.4 Numbers analyzed

There were no drop outs during the study. All 52 subjects were included and analyzed from T0, T1, T2 and T3.

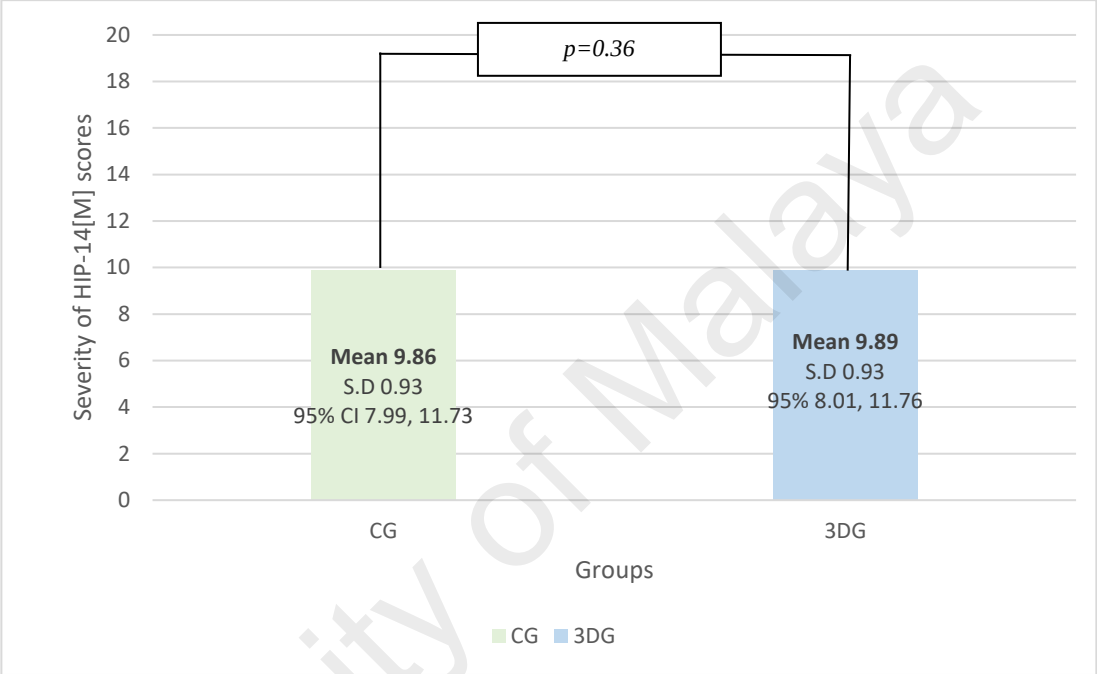
4.1.5 Outcomes and estimation

4.1.5.1 Primary outcome

The primary outcome in this study was assessment of OHRQoL for all subjects in the CG and 3DG at baseline (T0) and interventions at T1, T2 and T3.

(a) ***Assessment of the OHRQoL of all subject (N=52)***

i *Severity of OHIP Score between the CG and 3D Groups regardless the time.*

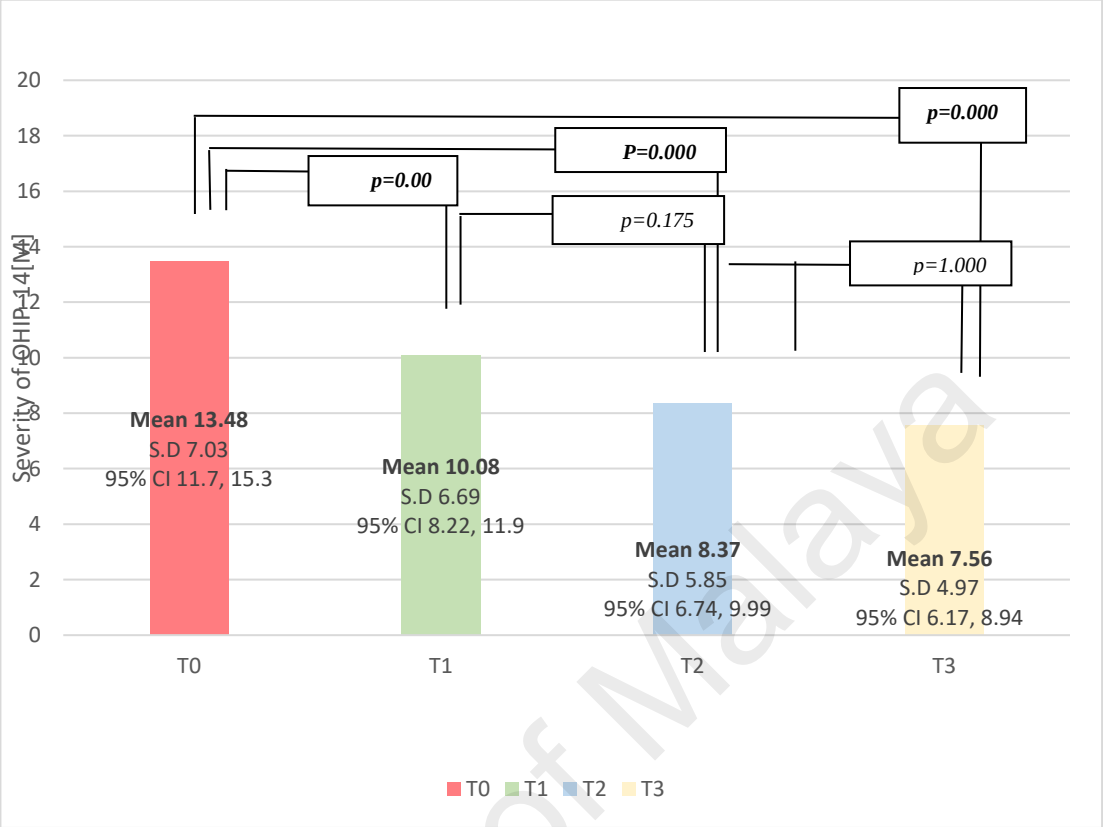


**p<0.05*

Figure 4.7 Severity of OHIP-14[M] scores for all subject (N=52) between the CG and 3DG regardless of the time.

Figure 4.7 shows the severity of OHIP-14[M] scores for all subjects in CG and 3DG regardless of the time. The mean score for CG was 9.86 (S.D 0.93) and 9.89 (S.D 0.93) for 3DG. Overall there was no significant difference in the overall mean score of OHIP-14[M] between the two group regardless of time with *(p>0.05).*

Severity of OHIP score before (T0) and after wearing TPA (T1, T2 and T3) regardless of the group



**p<0.05 RMANOVA*

Figure 4.8: Mean of OHIP-14[M] scores of all subject (N=52) before (T0) and after wearing TPA (T1, T2 and T3) regardless of the group

Figure 4.8 shows the severity of OHIP-14[M] scores for all subject (N=52) regardless the group at four different times, before (T0) and after wearing TPA at (T1, T2 and T3). The mean score at T0 was 13.48 (S.D. 7.03), followed by 10.08 (S.D. 6.69) at T1, 8.37 (S.D. 5.85) at T2 and score of 7.56 (S.D. 4.97) at T3. Repeated Measure ANOVA (RMANOVA) showed that the difference between time were significant between the times. Post hoc analysis using the Bonferroni correction shows that the OHIP-[M] scores significantly different between T0 and T1 *(p=0.002)*, T0 and T2 (*p=0.000)* and T0 and T3 *(p=0.000)*. The OHIP-[M] scores were not significantly different at T1 and T2 *(p=0.175)* and T2 and T3 *(p=1.000)*.

(b) ***Assessment of the severity of OHIP-14[M] scores for all subject (N=52) between the groups at four different times (T0, T1, T2 and T3)***

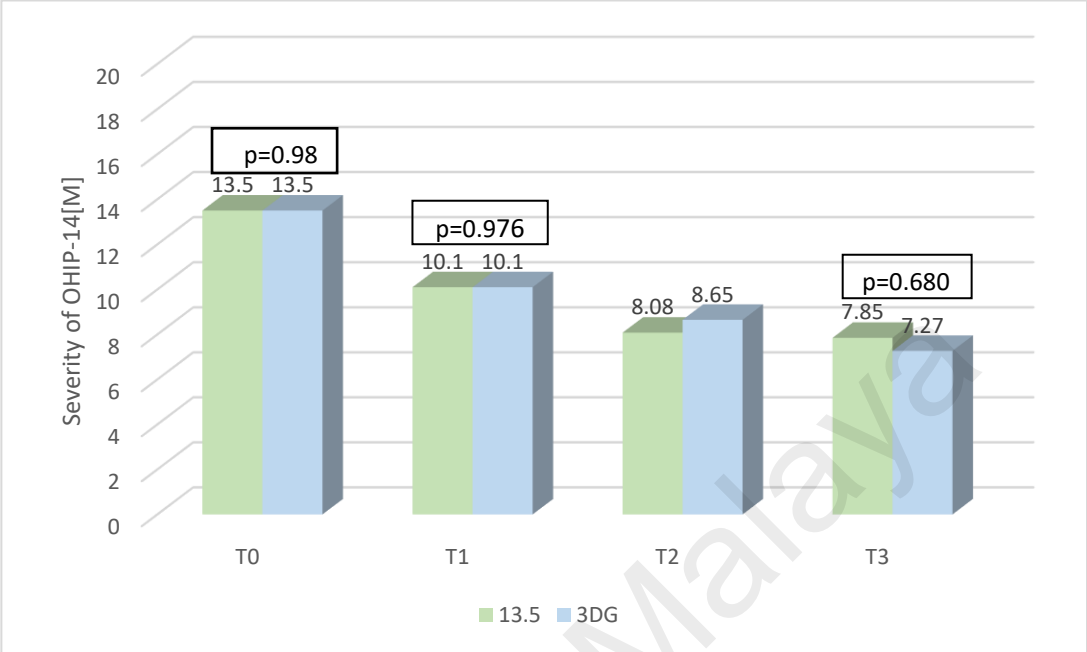


Figure 4.9 Severity of OHIP-14[M] scores for all subjects in CG and 3DG at (T0) and after wearing TPA (T1, T2 and T3)

Figure 4.9 shows the mean score of severity of impact OHIP-14[M] for all subject (N=52) according to groups at four different times T0, T1, T2 and T3. Both groups, CG and 3DG showed a decrease in mean scores from T0 to T3. For CG, the mean scores were 13.5 (T0), 10.1 (T1), 8.08 (T2) and 7.85 (T3) while in 3DG, the mean scores were 13.5 (T0), 10.1 (T1), 8.65 (T2) and 7.27 (T3). There was no significant difference between groups at four intervals with ($p<0.05$).

(c) ***Assessment of the severity of OHIP-[M] scores for all subject (N=52) by domain at four different times (T0, T1, T2 and T3)***

Table 4.3 shows the severity of the impacts based on the OHIP domains for the 52 subjects at all time intervals. At all intervals, psychological discomfort was the domain with the highest severity and the social disability was the least affected domain. RMANOVA shows that there was significant difference between the time points for four domains, psychological discomfort, psychological disability, physical disability and handicap.

Post hoc analysis using the Bonferroni correction found significant difference between four time points. The significant difference occurred between T0 to T1 (for psychological discomfort, psychological disability, and handicap), between T0 to T2 (for psychological discomfort and handicap), between T0 to T3 (psychological discomfort, psychological disability, physical disability and handicap) and between T1 to T2 (handicap).

(d) ***Assessment of the severity of OHIP-[M] scores for CG (N=26) by domain at four different times (T0, T1, T2 and T3)***

Table 4.4 shows the severity of the impacts based on the OHIP domains for the 26 subjects in CG at all time intervals. Similar to overall findings, at all intervals, psychological discomfort was the domain with the highest severity and the social disability was the least affected domain. RMANOVA shows that there was significant difference between the time points for four domains, psychological discomfort, psychological disability, physical disability and handicap.

Post hoc analysis using the Bonferroni correction found significant difference between four time points. The significant difference occurred between T0 to T1 (for psychological discomfort and handicap), between T0 to T2 (for psychological discomfort and handicap), between T0 to T3 (psychological discomfort and handicap) and between T1 to T2 (handicap).

(e) ***Assessment of the severity of OHIP-14[M] scores for 3DG (N=26) by domain at four different times (T0, T1, T2 and T3)***

Table 4.5 shows the severity of the impacts based on the OHIP domains for the 26 subjects in 3DG at all time intervals. Similar to overall findings, at all intervals, psychological discomfort was the domain with the highest severity and the social disability was the least affected domain. RMANOVA shows that there was significant difference between the time points for four domains, psychological discomfort, psychological disability, physical disability and handicap.

Post hoc analysis using the Bonferroni correction found significant difference between four time points. The significant difference occurred between T0 to T1 and T0 to T2 (for psychological discomfort and handicap), between T0 to T3 (for psychological discomfort, psychological disability, physical disability and handicap) and between T1 to T2 (psychological discomfort).

(f) ***Assessment of the severity of OHIP-[M] scores for all subject (N=52) by domain at four different times (T0, T1, T2 and T3)***

Table 4.6 shows the severity of the impacts based on the OHIP domains for the 52 subjects by group, CG and 3DG at T0, T1, T2 and T3 intervals. Overall, independent t-test showed that there was no difference in the severity of OHIP scores by domain between the groups at all time intervals except at two times; T1 for psychological disability domain and T3 physical disability domain with ($p<0.05$).

4.1.5.2 Secondary outcome

Pain was measured in terms of the presence of pain, extent of pain and severity of pain. The duration of pain was measured. The intensity of pain was measured relative to the experience of separator placement.

(a) ***Presence of pain***

i *Presence of pain for all subjects (N=52) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement regardless of groups.*

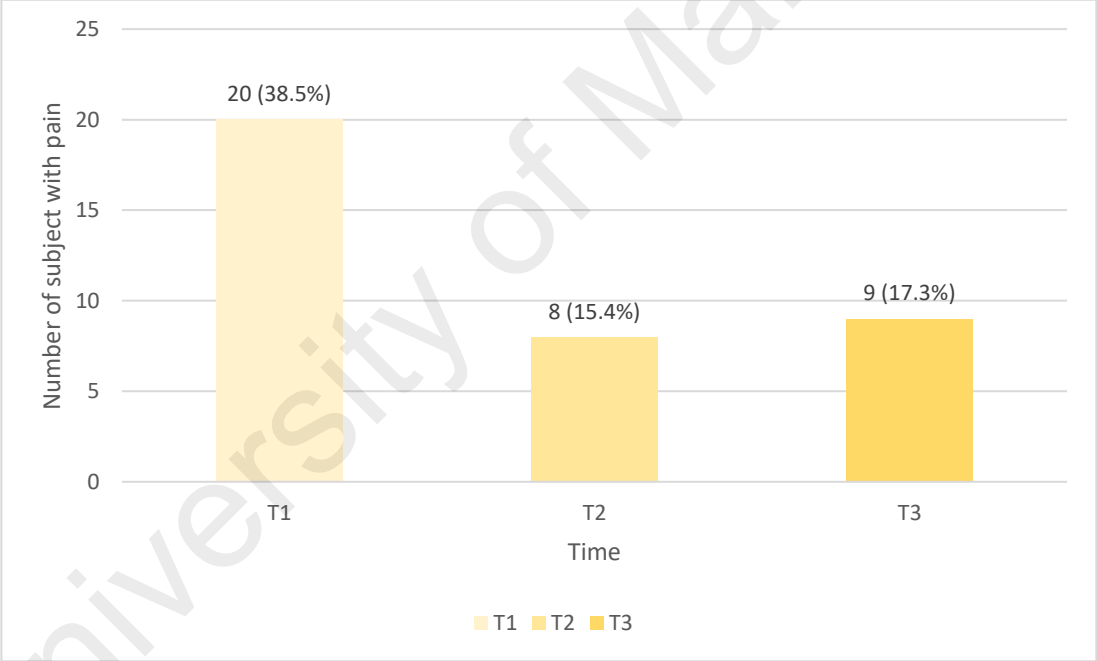


Figure 4.10 Presence of pain for all subjects (N=52) at T1 (1 week), T2 (1 month) and T3 (3 months) phase after TPA placement

Figure 4.10 shows the presence of pain of all 52 subjects regardless the type of TPA received. At T1, 20 (38.5%) subjects have pain and at T2, number of subjects with pain reduced to 8 (15.4%). At three months of TPA insertion, 9 subjects or 17.3% subjects experienced pain.

ii Presence of pain for CG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.

Figure 4.11 Presence of pain for CG (N=26) at T1 (1 week), T2 (1 month) and T3 (3months) phase after TPA placement

Figure 4.11 shows the presence of pain in 26 subjects in CG. At T1, it shows similar result to overall with 11 (42.3%) subjects experienced pain at T1 and reduced to six (23.1%) and five (19.2%) subjects at T2 and T3 respectively.

iii Presence of pain for 3DG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.

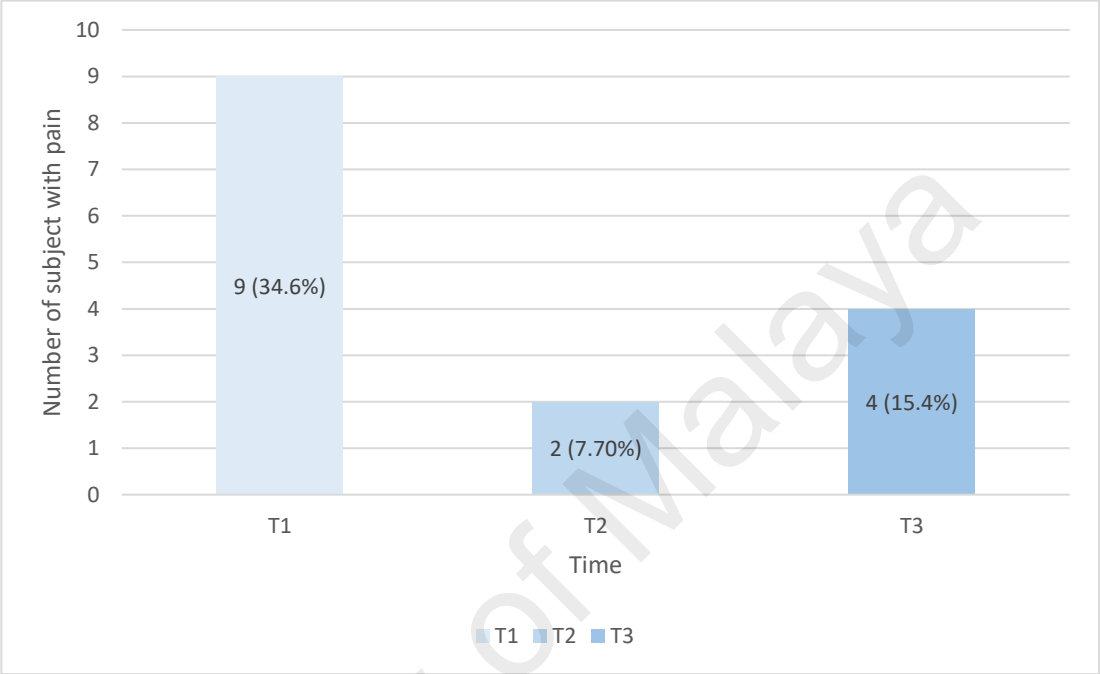


Figure 4.12 Presence of pain for 3DG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.

Figure 4.12 shows at T1 9 (34.6%) subjects had pain and the number dropped down to two (7.7%) at T2 and slightly increased to four (15.4%) at T3.

(b) ***Intensity of pain***

i *Intensity of pain for all subjects (N=52) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement regardless of groups*

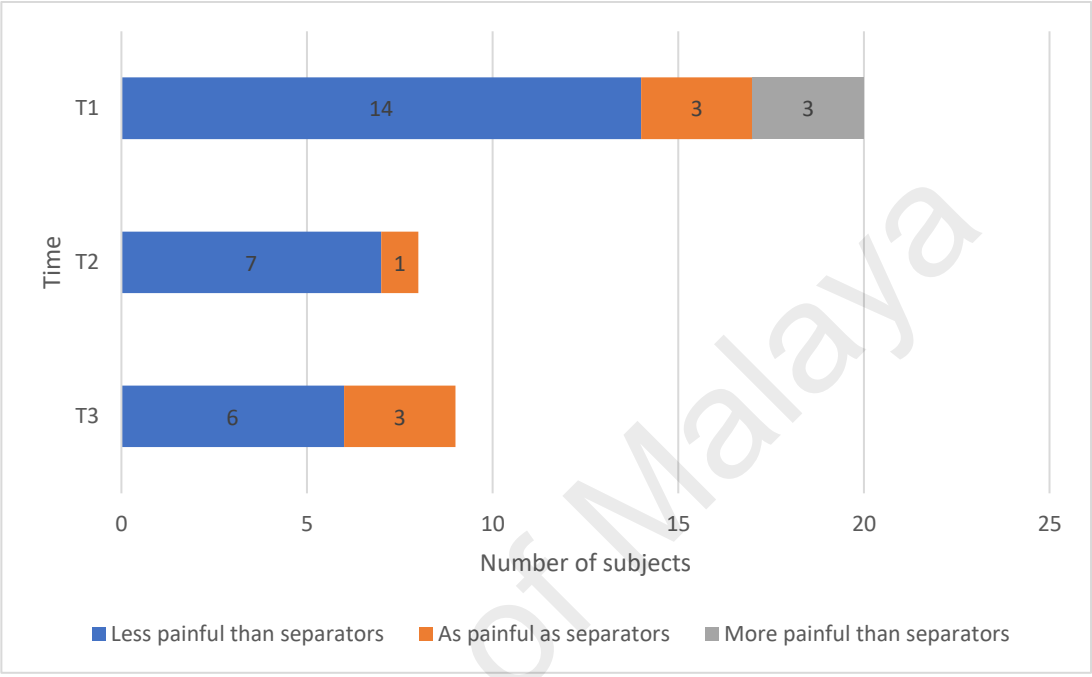


Figure 4.13 Intensity of pain for all subjects (N=52) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement

Figure 4.13 shows at T1, T2 and T3 majority of the subjects claimed that the pain intensity of TPA placement is less than separators placement with 14, 7 and six subjects at T1, T2 and T3 respectively. At T1, three subjects felt the pain intensity is more than separator placement.There were only one and three subjects had pain intensity similar to separator placement at T2 and T3 and no subject felt that the pain is more intense the separator placement.

ii *Intensity of pain for CG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.*

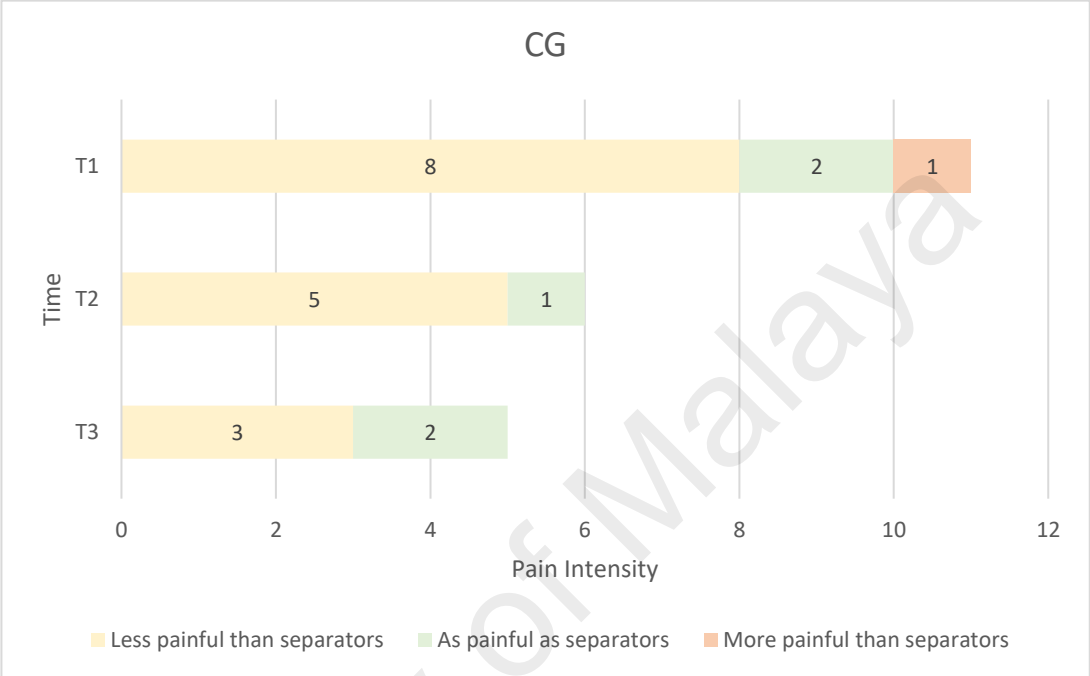


Figure 4.14 Intensity of pain for CG (N=26) at T1 (1 week), T2(1 month) and T3 (3 months) of TPA placement

Figure 4.14 shows at T1, 8 subjects had pain intensity less than separator placement, two subjects with similar pain and one subject with more pain in comparison to separator placement. At T2 and T3, five and three subjects had pain less than separator respectively. There was one subject had pain as painful as separator placement at T2 and two subjects at T3.

iii Intensity of pain for 3DG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.

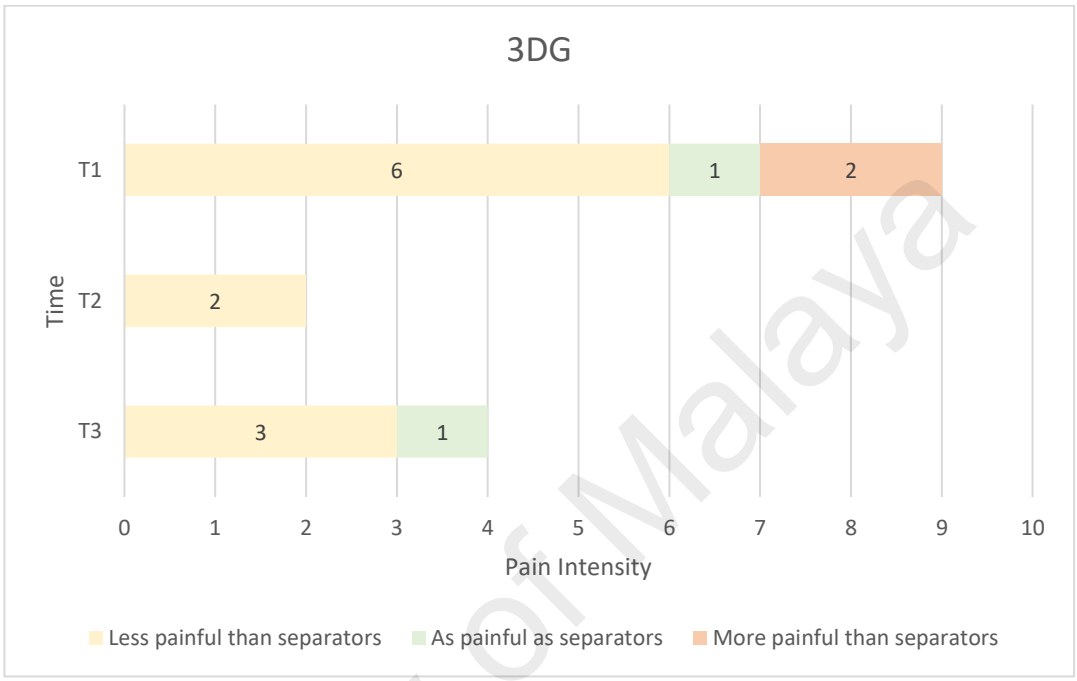
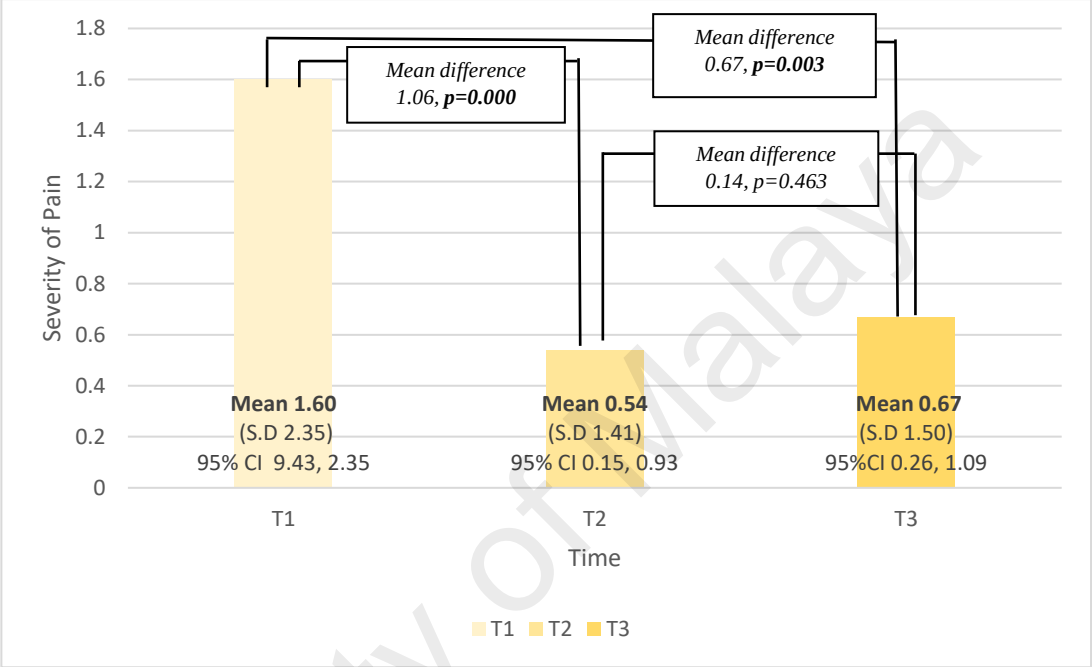


Figure 4.15 Intensity of pain for 3DG (N=26) at T1 (1 week), T2(1 month) and T3 (3 months) of TPA placement

Figure 4.15 shows at T1, T2 and T3 there were six, two and three subjects had pain intensity less than separator placement respectively. At T1 and T3, there was two and three subjects respectively had pain similar to separator placement and at T1 there was one subject had pain more than separator placement.

(c) ***Severity of pain***

Severity of pain for all subjects (N=52) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement regardless of groups.

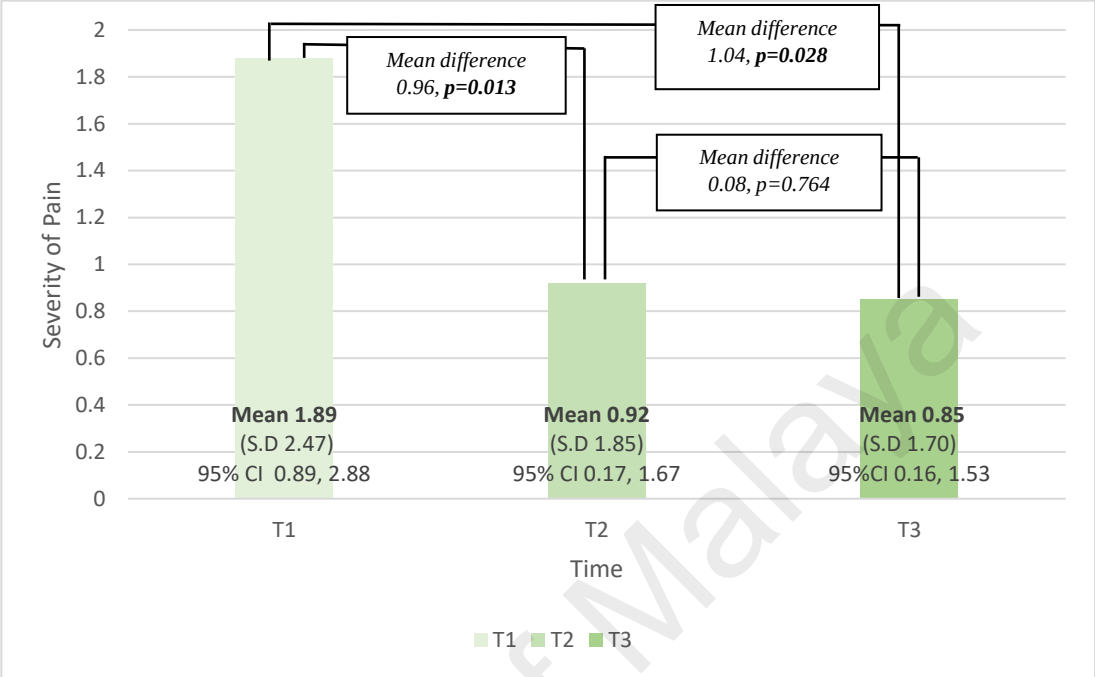


p<0.005

Figure 4.16 Severity of pain for all subjects (N=52) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement regardless of groups.

Figure 4.16 shows at T1 the mean severity of pain was 1.60 (S.D. 2.35) and declined to 0.58 (S.D. 1.41) at T2. There was a slight increase of the pain severity from T2 to T3 with 0.68 (S.D. 1.50) score and mean difference of 0.14. Overall, there was significant pain severity from T1 to T2 and T3 with *(p<0.05).*

i Severity of pain for CG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.

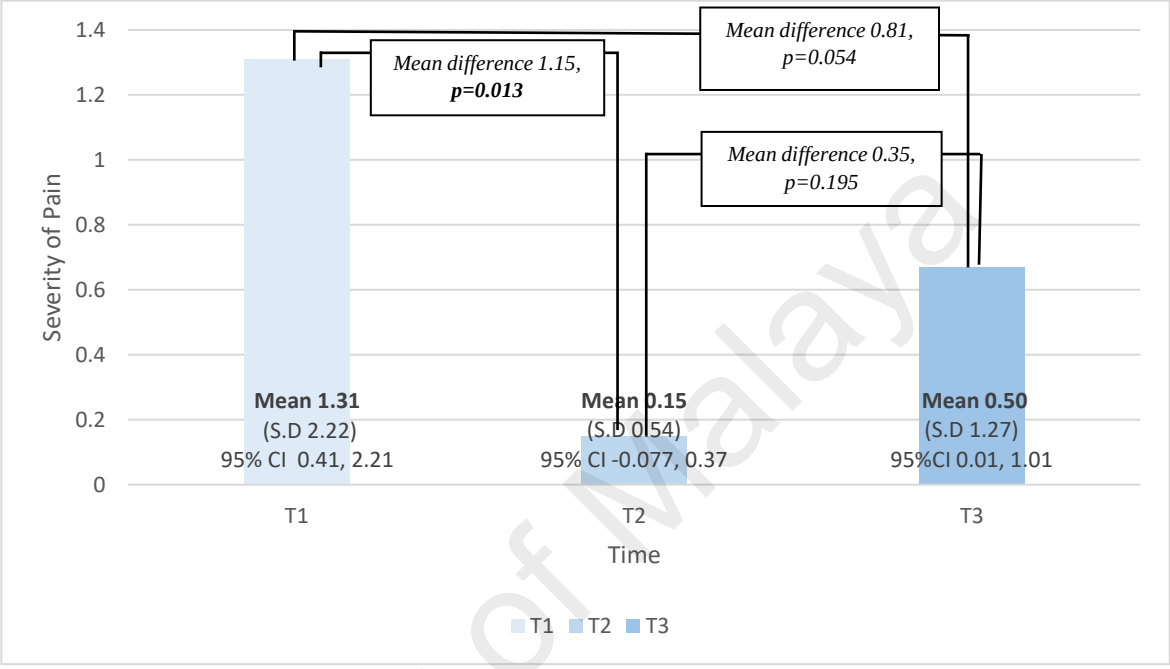


p<0.05

Figure 4.17 Severity of pain for CG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.

Figure 4.17 shows pain severity of 1.89 (S.D. 2.47) at T1 and decreased to 0.92 (S.D 1.85) at T2 with mean difference of 0.96, the difference was significant with *(p<0.05).* The pain severity decreased slightly from T2 to T3 with score of 0.85 (S.D 1.70), mean difference of 0.08 and no significant difference with *(p>0.05).* There was also significant difference observed from T1 to T3 with (p<0.05)

ii Severity of pain for 3DG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.



p<0.05

Figure 4.18 Severity of pain for 3DG (N=26) at T1 (1 week), T2 (1 month) and T3 (3 months) after TPA placement.

Figure 4.18 shows at T1 the pain severity was 1.31 (S.D 2.22) and decreased significantly to T2 with score of 0.15 (S.D. 0.54) and ($p<0.05$). At T3, the severity slightly increased with score of 0.50 (S.D. 1.27). There was no significant difference from T1 to T3 and T2 to T3 with ($p<0.05$).

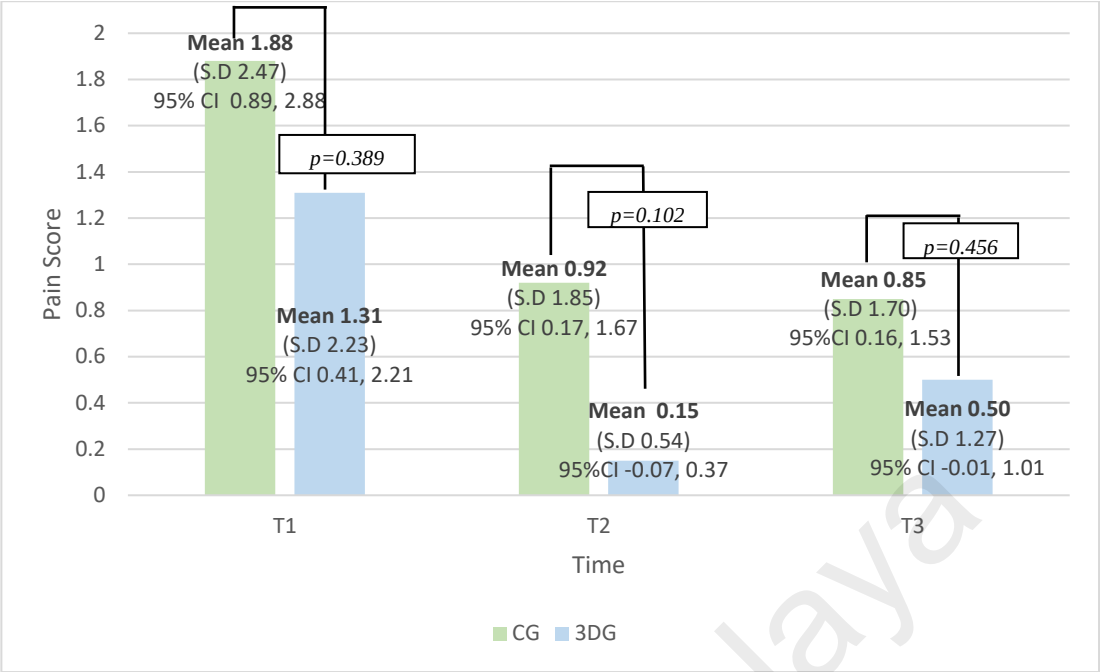


Figure 4.19 Pain level mean scores of all subject (N=52) between group at three different times (T1, T2 and T3).

Figure 4.19 shows mean scores of pain level for all subject (N=52) between group at three different times (T0, T1, T2 and T3). For CG, the mean score of pain decreased from 1.88 (T1) to 0.92 (T2) and 0.85 at T3. 3DG also showed the same decreasing manner of pain level with score of 1.31 (T1), 0.92 (T2) and 0.85 (T2). Overall, there were no significant difference in the mean score of pain level between the two groups at T1, T2 and T3 with *(p>0.05).*

4.1.6 Harm

There were no harms reported during the conduct of the study.

4.2 Part 2 (Qualitative study): Focus group discussion (FGD)

4.2.1 Subject demographics

Table 4.2 Age, gender and working experience of the participants

Respondents	Age	Gender	Work Experience (Years)	Conventional TPA Issued	3D TPA Issued
ESX	31	Female	8	5	4
AJ	34	Female	10	4	4
MSH	34	Male	10	4	5
TNHK	35	Female	10	4	4
LM	34	Male	9	4	5

Table 4.6 shows five clinicians were interviewed at the FGD. The subjects consisted of 3 females and 2 males aged from 31 to 35 years old with 8 to 10 years of working experience. All the clinicians had a minimum three years working in orthodontic field.

4.2.2 Emerged Themes

In this study, the three emerged themes from the conducted FGD were time factor, molar band selection issue and the cost factor.

4.2.2.1 Time factor

Many clinicians stated that TPA constructed from 3D printed models are more time saving than the conventional TPA as one of the appointments in the conventional procedure can be skipped or cut down.

'Ar, 3D TPA actually it saves time because I only need one session for the separator placement and the next visit, I can straight away issue the print, the the fabricated TPA whereas the conventional one I need one more visit for band urm selection.'

(Female, age 31).

'It saves time.'

(Female, age 31).

'It saves chair site time, so it saves a lot of appointment time.'

(Female, age 31).

The above statement was agreed by 4 another clinician.

'*I don't like to take extra, I don't have to take extra impressions also.'*

(Female, age 34).

'Yes, I agree ar the pro about this 3D ar 3D TPA is ar time saving.'

(Male, age 34).

'I think both serve the same function but for 3D printed model is more save time. Time saving for the patient.'

(Female, age 34).

'Ya, definitely, having it, it saves me quite a lot of chair site time and patients are much happier to take impression', 'I would definitely go with this 3D printed TPA, saves me a lot of chair site time.'

(Male, age 35).

The time saving factor was assumed to be more beneficial and liked by patients as it was indirectly related to cost savings for both for clinicians as well as the patients.

'Which is also the patients like it better.'

(Female, age 35).

'*Because it saves chair site time and it's more comfortable for the patient I feel, so when you save chair site time, you actually you helping the patient to save their cost as well, not only your cost.'*

(Female, age 34).

'The time taken from work you know.'

(Male, age 35).

Other participant added that it did not only save the clinicians' but also the other supporting staff's time.

'And also, you save your assistant from you know sterilizing another set of impression material, things like that. You actually save a lot of things.'

(Female, age 31).

Provided that there is no problem related to the molar band size selection, one participant agreed that the innovated TPA was more time saving than the traditional one.

'Yes, definitely, but provided I mean the band selection is done correctly, yes'.

(Male, age 35)

When asked regarding their preferences, one participant stated that they favored the 3D TPA in comparison to the conventional one due to time saving factor.

'*We have considered a lot of things, (can't hear as someone is coughing in the background) clinicians' factor and patient factor and then in term of appointment, intervals, if let say the 3D give more benefit, so better go for 3D in term of cost, we save in term of alginate materials and if let say the 3D are more accurate, it is better to go for, if I, if it was me, I will go for 3D.'*

(Female, age 34).

'*Yes, because less hassle for me and also for the patients, patient don't need to come for many visits.'*

(Female, age 34).

'Because it saves chair site time and ar it's more comfortable for the patient I feel. So, when you save chair site time, you actually you helping the patient to save their cost as well, not only your cost.'

(Female, age 34).

One participant added with less appointment, it saved patients time taken from work.

'*The time taken from work you know.'*

(Female, age 34).

4.2.2.2 Molar bands selection issue

Besides the time saving factor favored in the 3D group, the other mostly discussed theme was the band selection procedure.

Few participants said that they preferred the 3D version as they can omit one appointment for the molar band selection.

'Ar, 3D TPA actually it saves time because I only need one session for the separator placement and the next visit, I can straight away issue the print, the the fabricated TPA whereas the conventional one I need one more visit for band urm selection.'

(Female, age 31).

'*I can straight away issue the print, the 3D fabricated TPA whereas the conventional one I need one more visit for band selection.'*

(Female, age 31).

'I don't like to take extra, I don't have to take extra impressions also.'

(Female, age 34).

One participant assumed that less impression taking was favored by the patient.

'*Yes, I don't like to take extra, I don't have to take extra impressions also', 'Which is also the patients like it better.'*

(Male, age 35)

However, not all participants preferred the innovated way of molar bands selection. One participant claimed that he had difficulty and did not the like molar band selection procedure to be carried out on the 3D printed working model as he felt that the 3D printed model is not as accurate as the conventional stone model.

'Yes, I agree ar the pro about this 3D ar 3D TPA is ar time saving, ar however there is a few things that I don't like to use the 3D TPA. Ar, because first um, ar we not sure, there is not, I I feel that the the the model that we that we are took by the by the the model the snap model we took is not accurate as the conventional way we take the ar...'

(Male, age 34).

He also claimed that, with the conventional plaster model, he was able to select the correct size of molar bands but with the 3D printed models, he estimates the wrong size of the molar bands.

'Yes, the because I can see there is a difference when we choose the band, I always choose the estimate the right size of the molar. However, with this inaccurate I think, inaccurate of the 3D from the 3D printer.'

(Male, age 34).

His statement on the wrong size molar band selection that is due to the inaccurate 3D printed working model was supported by few other clinicians.

'Yes, I agree because we have a half size band so, the fit has to be quite, the accuracy of the study model has to be quite quite accurate and we can get correctly fitted bands, all I just want to say I agree with you have that problem also sometime.'

(Male, age 35).

The clinicians added that, they ended up choosing bigger size molar bands on the 3D printed working model and when they inserted it intraorally, it does not fit well due to the excess in the metal molar band sizes.

'Then it cannot fit the mould the band in so you have to eventually select the one size larger and when comes to the fitting session it will be too large.'

(Female, age 31).

'In order to fit the study model but then the bigger size bands don't fit in your mouth.'

(Male, age 35).

Some other clinicians claimed they had no problems with the molar band selection method and if they were blinded between the two types of TPA, they cannot differentiate which one was fabricated in the traditional manner and which was constructed via the innovated way.

'Isn't it the same, the difference is just the size of the band bu I don't have any problems between both, both I can look at the shouldering of the of the wire to the bands is equally the same to me.'

(Male, age 35).

'For me, I didn't face any problems and if you were to buy for me and then after that ask me to differentiate between these two, I wouldn't be able to tell'.

(Female, age 34).

This statement is agreed by another clinician.

'I agree'.

(Female, age 31).

'Ya, ya because because with smaller bands because if we select the bands although it's another extra appointment but we can make sure that the bands kind of fit on the molar teeth so they shouldn't be technically they shouldn't be any problems with the fit of the bands unless there is problem when you transfer the bands from impression to lab and somewhere the bands get dislodge or the technician er doesn't hold them properly and cement in er solder them in the wrong position then we have a fitting problem. Other than that, ar, I don't think so.

(Male, age 35).

When asked the most disliked thing about TPA, with absence of wrong molar band size selection, there was nothing unfavourable about 3D TPA.

'No. Just that the cut has to be accurate, otherwise the that will be a problem for band selection'.

(Female, age 31).

'Ar, for me based on my experience using both ways, the methods of both TPA, ar I feel like the conventional way is more ar more accurate and more I much more confident with the conventional way. However, ar I still, I do think that I will improve my skill in term of the selection of size for band ar by time and...

(Male, age 34).

Participants preferred the 3D TPA provided the molar band selections were correct.

'*Ya, definitely. But provided I mean the band selection is done correctly. Ya.'*

(Male, age 35).

One participant added he will choose 3D TPA in the future after mastering the molar bands selection skill on the 3D reconstructed model.

'In future I would probably like the 3D TPA but for now I would prefer the conventional TPA.'

(Male, age 34).

4.2.2.3 Cost factor

All participants stated that the innovated TPAs were more beneficial to patients due to the cutting down of one appointment visit that involved molar bands selection and upper arch impression. It was not only convenient to the clinician but also beneficial to the patients in the cost aspect. With the reduction of one appointment visit, many participants claimed that it was more convenient to patients as it will indirectly save the cost of attending the visit as well as less time taken from work.

'Have to look at the cost benefit of it, I mean my patients do like it, I also do like it that where I can just straightaway get my TPA and issue instead of just having to give another appointment.'

(Male, age 35).

'Yes, because less hassle for me and also for the patients, patient don't need to come for many visits.

(Female, age 34).

'Because it saves chair site time and it's more comfortable for the patient I feel, so when you save chair site time, you actually you helping the patient to save their cost as well, not only your cost.'

(Female, age 34).

'Because you have to count a lot of things, patient cost in terms of parking.'

(Female, age 34).

Few participants claimed that with less one appointment visit, 3D TPA saved more dental material.

'Saves impression material'.

(Female, age 34).

'And also, you you you save urm the your assistant from you know urm sterilizing another set of impression material, things like that. You actually save a lot of things (overlapping speech with P2). Ya, um'.

(Female, age 31).

If the cost of fabricating 3D TPA is not an issue in comparison to the traditional one, many participants would prefer the 3D TPA.

'Have to look at the cost benefit of it. I mean my patients do like it ar, I also do like it that where I can just straightaway get my TPA and issue instead of just having to give another appointment but I have to, it depends on the cost actually if it's too expensive, I don't think I will'.

(Male, age 35).

'If, cost is not an issue, I will choose 3D. If cost is an issue definitely then the conventional one'.

(Female, age 31).

'We have considered a lot of things, (can't hear as someone is coughing in the background) clinicians' factor and patient factor and then in term of appointment, intervals, if let say the 3D give more benefit, so better go for 3D in term of cost, we save in term of alginate materials and if let say the 3D are more accurate, it is better to go for, if I, if it was me, I will go for 3D'.

(Female, age 34).

'Urm, ya, definitely, I would definitely go with this 3D printed TPA, saves me a lot of chair site time but again, have to whether the cost of this extra service is actually enough to outweighs the benefits I got from chair site time saving'.

(Female, age 34).

4.2.3 Other reported issues

During the metal band size selections procedure was carried out on the upper first molar teeth on the 3D reconstructed model, 2 clinicians reported of issues with the fit of the TPA. They realized that they selected a bigger size of bands for one participant each in the 3DG. They were able to fit both TPAs but they had to do some chairside adjustment of the molar bands by contouring the bands prior to insertion and cementation. Both participants did not report any problem and both TPAs were intact until the third follow up at T3.

CHAPTER 5: DISCUSSION

5.1 Parallel-group study design

A parallel design or known as parallel group study (PGS) is one of the classifications in RCT study design. Principally, it compares two or more treatments with one control group or placebo group included. Samples in this study were randomly allocated into the groups to receive the standard treatment (control group) or interventions. Since this study involved the same type of appliance that only differ in terms of fabrication, the crossover design is not selected. Crossover study design (CSD) is another type of RCT study design that consist of samples who receive all the interventions involved in the study at different allocated times and sequence (Ofori-Asenso & Adom Agyeman, 2015).

Although the crossover study design has a higher statistical power in comparison to the parallel design, it is not suitable to be implemented in this particular research. In this study, the PGS was selected as TPA is a type of device that is permanently cemented throughout the fixed appliance orthodontic treatment. The presence of tubes at the buccal surfaces were meant for the insertion of arch wires utilized in the fixed appliance therapy. If CSD is applied, it will interfere with the treatment as the permanently cemented TPA need to be removed. The design of this study does not allow each participant to receive more than one intervention and therefore effects from a previous intervention cannot be carried over to another. Secondly, considering the fact that the interventions are given at the same time enables preparation of interventions to be done simultaneously which makes the study fairly easy to manage, contradict to CSD where each crossover will require a new set of randomizations rendering to exhaustion. The absence of wash over period also contributes to a shorter duration of study which will result in possibility of low dropout rates. Furthermore, the results from PGS are less complicated to analyse and presents with a straight forward interpretation as well. On the other aspect, PGS presents with some limitations with the major one is the influence of inter-patient variability on

estimated values which may result in less precise values compared with intra-patient variability (Ofori-Asenso & Adom Agyeman, 2015).

5.1.1 Interval time between trial

All samples were reviewed after one week (T1), one month (T2) and three month (T3) of appliance wear. One week follow up was selected as it was carried out prior to extraction of teeth and commencement of the upper and lower fixed orthodontic appliances. Thus, the OHRQoL and pain aspect were assessed while patients have TPA alone intraorally. If it is carried out at similar time of extraction and fixed appliance cementation, it may be a cofounding factor that indirectly affect the OHRQoL and pain aspect. A study by (M. *et al*., 2010) that evaluated the impact of fixed appliance therapy on OHRQoL found that overall the impact was greatest at one week of appliance wear with the reported effects on physical pain, psychological discomfort and physical disability. It was found that prevalence, intensity, frequency, and duration of pain was much higher for patients after insertion of an arch wire than after a dental extraction. Although it varies among individual, some patients experienced pain which peak up on the second or third day and may lasted up to one week (Jones & Chan, 1992), (Stewart, Kerr, & Taylor, 1997). At one-month post insertion, patients had passed three weeks' time of extraction and fixed appliance cementation and adapted to the new intra oral environment thus TPA can be assessed. At three months interval, averagely most patients are still in the aligning and levelling stage whether the conventional or self-ligating brackets were used (Megat Abdul Wahab, Idris, Yacob, & Zainal Ariffin, 2012). The OHRQol and pain aspect were again assessed at the same stage of contemporary orthodontic procedures. Proceeding to a later time of interval may vary the stages of treatment received by the patients such as overbite correction and space closure. Mechanotherapy utilized in the later stages may vary and have an indirect effect on the OHRQoL and pain aspect for example usage of Niti coil springs and power chains.

5.1.2 Blinding

This was not a blinded study as the patients know the different procedures between the two groups. It was impossible to apply blinding among clinicians and technician involved as they were directly exposed to the different methods and procedures in the intervention groups. For clinicians, they carried out the molar bands' selection intra orally in the CG and extra orally in the 3DG. All procedures were documented in the patients' folder where they have access to while treating the patients. It was also impossible to blind the technician as the fabrication of TPA was carried out on two different type of working models.

5.2 Accuracy and reliability of study methodology

5.2.1 Reliability of 3D scanning and printing

Studies on comparisons of the conventional models and 3D printed models by digital scanning show that the digital models obtained from plaster dental model scanning and dental impression scanning showed high accuracy and reliability (Gül Amuk, Karsli, & Kurt, 2019), (Fowler et al., 2019). Another report in a study comparing 3D printed study models and stone models found that the volume of the ABS models was significantly smaller compared to the stone model by 0.96% ($p=0.001$). However, when the ABS based working model made from the same printer was used to construct VFR, there was no difference with the conventionally made VFR in terms of stability and patients perception (impact) based on OHIP (Mohd Tahir, Wan Hassan, & Saub, 2018)

Many studies have proof that digitally printed model is equivalent to the conventional plaster model in various aspects. A systematic review by (Fleming & Marinho, 2011) reported that, overall, the absolute mean differences between direct and indirect measurements on plaster and digital models were minor and clinically insignificant. They concluded that orthodontic measurements with digital models were comparable to those

derived from plaster models. Although the evidence identified in the review is of variable quality, the use of digital models as an alternative to conventional measurement on plaster was recommended.

5.3 Oral Health Related Quality of Life (OHRQoL)

5.3.1 Overall severity of the OHRQoL

The primary outcome measure was the impact of the TPA on the patients OHRQoL. Since the TPA for both CG and 3DG had similar design and function, clinically the effectiveness of the function was assumed to be the same. Thus, they were not likely to quantitatively show clinically meaningful differences on the effectiveness as anchorage device. However, since the fabrication process was different between the two groups, it was not known how the TPA would affect the patient, in particular on their OHRQoL. For example, there might be differences in the fitting or comfort. Thus, the OHIP-14 was used as it is a valid (Saub & Locker, 2006) patient reported outcome instrument to measure based on patients' experience.

Originally, OHIP and OHIP-14 were developed to evaluate the OHRQoL among elderly (Slade, 1997), however both were recognized as a valid and reliable instruments to be used in assessing OHRQoL among adolescents and young adults (Feu, De Oliveira, De Oliveira Almeida, Kiyak, & Miguel, 2010), (Hassan & Amin, 2010). In orthodontics, many studies have been carried out to evaluate its relation to OHRQoL, a systematic review and meta-analysis by (Sun, HM, & CP, 2017) stated that untreated malocclusion was significantly associated with OHRQoL. They found out, the more severe the malocclusion, the worse was the impact on some physical domains and all psychosocial domains of OHRQoL. Although malocclusion was known to have a negative impact on OHRQoL, it could be improved with orthodontic treatment (D., J.A.M., R.K., & B.H., 2013). However, undergoing fixed orthodontic therapy itself had a negative impact on the

overall OHRQoL during the first three months of treatment, which then improved to pre-treatment scores (Johal *et al*., 2015).

Although there is no specific study that evaluate the impact of TPA in isolation to OHRQoL, it is proven that both, removable and fixed orthodontic appliance have an impact on quality of life (Bernabé *et al*., 2008). This study was carried out to evaluate OHRQoL at baseline, one week, one month and three months after the insertion of TPA appliance. The mean scores for each domain and item of OHIP-14[M] was compared prior to insertion of TPA and one week, one month and three months after the fixation of TPA. In this study, baseline OHIP- [14] had the highest scores among all four interval times. After the intervention, one-week post insertion had the highest scores which gradually decreased at one month and third months' of TPA wearing. This finding is similar to studies by (Liu *et al*., 2011) and (Johal *et al*., 2015) that show similar changes in OHRQoL occurred during fixed orthodontic appliance therapy. The greatest deterioration in OHRQoL occurs in the early phase of treatment, with ongoing treatment, the detrimental effects to OHRQoL are reduced. This is in line with other studies that reported the most OHIP domains were significantly higher 24 hours after the insertion of fixed orthodontic appliances (Jawaid & Qadeer, 2019), (Othman, Saub, & Mansor, 2013)

5.3.2 Severity of the OHRQoL by domain

In this study, the most affected domain of all subject with mean age of 23.94 years old (S.D. 5.72) at four interval times was psychological discomfort (i.e. 'felt uncomfortable' and 'shy') and the least affected was social disability (i.e. 'avoided going out' and 'problems carrying out daily activities). These findings were similar to a previous study that evaluated the OHRQoL of Malaysian adult populations by (Saub & Locker, 2006) where, the younger adult (18-39 years old) and middle adult (40-59 years old) scored the highest of psychological discomfort domain due to poor oral health and the least was

social disability. In this study, overall at baseline (T0), the mean score of the psychological discomfort was 3.85 (S.D. 1.91) and 0.42 (S.D. 0.7) for social disability. This is much the same as another Malaysian study that assessed the impact of malocclusion on the OHRQoL among patients aged 12-35 years, without orthodontic treatment by (Ashari & Mohamed, 2016), they had had the same findings of psychological discomfort as mostly affected domain with mean of 3.71 (S.D. 2.0) and the least being social disability domain with mean value of 0.60 (S.D. 1.2).

A systematic review on the impact of malocclusion on the OHRQoL by (Liu, McGrath, & Hagg, 2009) suggested that that there is an association (albeit modest) between orthodontic treatment need and poor OHRQoL, and that they coexist in the same population. Another study by (Liu *et al*., 2011) that looked into changes in oral health-related quality of life during fixed orthodontic appliance therapy among adult Chinese population also revealed the same outcomes of psychological discomfort as the most affected domain and social disability as the least. This demonstrated that the presence of malocclusion itself may affect the OHRQoL in the same manner while undergoing orthodontic treatment. However, the study by (Zheng *et al*., 2015) found that the impact of comprehensive orthodontic treatment on patients' OHRQoL do not follow the same pattern among patients with different malocclusion. With respect to psychological discomfort and psychological disability domains, Class II patients benefit the most from the stage of space closure, while Class I patients benefits in the first stage (alignment and levelling) during treatment.

5.3.3 Comparing OHRQoL between the CG and 3D TPAs

Overall, in this study there was no significant difference in OHRQoL of all subjects aged 23.94 years old (S.D. 5.72) between the CG and 3DG with the mean of OHIP-14[M] score of 9.86 (S.D. 0.93) in the CG and 9.89 (S.D. 0.93) in the 3DG. The score was almost

similar most probably because the TPA design was the same. To date, there is no published study that evaluate and discussed the OHRQoL status of patients wearing TPA alone. A randomized clinical trial carried out by (Stivaros, Lowe, Dandy, Doherty, & Mandall, 2010) that compared TPA and Nance palatal arch (NPA) found that there was a significant slight reduced patient discomfort with the NPA in comparison to the TPA. The study however measured patient discomfort by using seven-point Likert scale where score of one indicated no pain and a score of seven as severe pain, the however this finding is similar to a crossover randomized clinical study comparing retainers constructed on conventional stone models and on 3D printed models by (Mohd Tahir et al., 2018), which revealed that OHIP-14[M] scores between the two retainers were not significantly different.

5.3.3.1 Within subjects in CG and 3D group, between time interval

There was an improvement in the OHRQoL for all subjects in CG and 3DG from T0 to T3. The improvement was significant prior to TPA insertion from T0 to T1, T0 to T2 and T0 to T3. Interestingly, the baseline OHRQoL scores were the highest at baseline and gradually decreased to the third months of TPA insertion, it was initially expected that the score would increase from baseline to T1.

Overall, after the TPA insertion, the OHRQoL improved from T1 to T2 and from T2 and T3, although there was no significant difference between the above time intervals , most likely the improvement occurred due to the patients' adaptation to the appliance. In contrast to the active fixed appliance treatment, TPA is passive in nature, thus it is expected that there is no significant changes.

Similar pattern of OHRQol scores was seen in the CG and 3DG, an improvement from T1 to T2 and from T2 to T3. This is expected as all subjects in both groups received the same appliance that only differ in the sense of methods of fabrication.

5.3.3.2 Between CG and 3DG at the same interval T1, T2, and T3

Overall, in this study there was no significant difference in the severity of OHRQoL between subjects in CG and 3DG except for T1 and T2. For psychological disability domain, there was a significant difference with p=0.044 and mean difference of 0.423 between the CG and 3DG at T1. At T3 there was a significant difference between the CG and 3DG in physical disability domain with mean difference of 0.462 and p=0.040. The mean difference ranged from -0.038 to 0.462 between the CG and 3DG at four-time intervals. Looking at the overall scores and the mean difference, it is safe to say that although it was statistically significant, clinically there was significant difference between the two groups.

This outcome is expected as all subjects received the same TPA appliance fabricated with same design, materials and prepared by the same individual, therefore their OHRQoL should not differ at all time intervals. Since the pattern of improvement and deterioration in both groups are similar and not significant, we can safely conclude that the subjects are not affected to the type of TPA appliance. Therefore, 3D printed models used in the fabrication of TPA appliance are clinically acceptable and comparable to the conventional stone model and can be used as working model in other intraoral appliance fabrications. Similar findings were found in the study by (Mohd Tahir et al., 2018) that compares VFR made on conventional stone models and 3VFR fabricated on 3D reconstructed model.

5.4 Pain assessment

In this study, pain was assessed in terms of presence of pain, intensity of pain in relation to elastomeric separator placements and severity of pain through visual analogue score (VAS) method.

5.4.1 Presence of pain

Pain is a subjective matter and evaluation of an individual's perception on pain factor is difficult to measure. Several studies have described patients' responses pertaining to pain while undergoing removable and fixed orthodontic appliances (Brown & Moerenhout, 1991),(Jones & Chan, 1992), (Polat, 2007), (Zhang, Mcgrath, & Ha, 2007). A study by (Krukemeyer, Arruda, & Inglehart, 2009) on 116 subjects found that 59% (mean 3.6/ S.D. 1.13) of the subjects agree and strongly agree that they have pain for a few days after orthodontic appointment.

5.4.1.1 Within subjects in CG and 3D group, between time interval

In this study, overall, 20 (38.5%) subjects had pain at one-week TPA placement and reduced to 8 (15.4 %) subjects and 9 (17.3%) subjects at one month and three months post insertion respectively. This is similar to study by (Al-Ma'ani, 2014) who found that 90.2% out of 276 orthodontic patients had pain from braces and the highest ratio of the patients reported pain was on same day of bonding, followed by gradual decrease in ratio over the successive days. Study by (AN, 2005) revealed that discomfort started two to six hours after initial archwire placement in fixed orthodontic appliance treatment with peak discomfort generally occurring at 24 hours. Another study by (Erdinç & Dinçer, 2014) investigated the initial time pain reported after insertion of two initial archwires in different sizes and found that in bigger archwires, 25 (44.6%) out of 109 subjects had pain at sixth hours and reduced to 9 (33.9%) at day seven.

In this study, CG and 3DG have similar trend of pain presence in comparison to the overall group with the highest subjects had pain at T1 and the frequencies gradually decreased to T2 and T3. This is due to the same type of TPA with similar design and material of fabrication given to all subjects in both groups. To date there is no reported study that compares the pain aspect of orthodontic appliance made on conventional model and fabricated on 3D reconstructed model. A randomized crossover clinical study by (Mohd Tahir *et al*., 2018) looked into OHRQoL to compare retainers constructed on conventional stone models versus 3D printed model and found that there was no significant difference in physical pain domain between the two groups**.**

5.4.1.2 Between CG and 3DG at the same interval, T1, T2, and T3

Results of this study revealed that at three interval times, one week, one month and three months of TPA insertion, CG had slightly more subjects with pain in comparison to the 3D groups. CG had 2, 4 and 1 patient more than 3DG at T1, T2 and T3 respectively. At one-week TPA insertion presence of pain is the most probably due to adaptation, being at palatal surface of the mouth it interferes with speech and mastication. A study by (Stewart *et al*., 1997) had similar findings that the first 4 to 7 days are the most critical for the patient in terms of general discomfort and difficulty in performing normal oral functions with an appliance in situ. Being a passive adjunct in orthodontic treatment, the presence of pain might be different in comparison to an active fixed orthodontic appliance treatment. A prospective randomized clinical trial on 70 subjects (mean age ± SD, 16.1 ± 2.3 years) that compares perceived peak pain levels after engaging the initial aligning archwire between active and passive self-ligating brackets until 24 hours after the procedure and then gradually reduce by the third day and pain is minimal by the seventh day (Ackerman & Thornton, 2011).

5.4.2 Visual Analogue Score (VAS) pain score

Pain is a known subjective matter; pain intensity and severity as sole measures may be insufficient for an adequate understanding of pain perception. Thus, many instruments were developed in attempt to understand the pain aspect. Among the most commonly used tools for general pain assessment are Visual Analogue Scale (VAS), the Verbal Rating Scale (VRS) and the Numerical Rating Scale (NRS) (Williamson & Mbbs, 2005). Although for simplicity purposes, patients prefer the VRS, it lacks sensitivity and the data it produces can be misunderstood. Since the pain assessment was included as part of the modified OHIP-[M] questionnaire, it is easy for patient to mark down the pain score and recorded as valid data.

5.4.2.1 Within subjects in CG and 3D group, between time interval

Pain severity reduced from T1 to T3 for overall subjects, there was a significant difference from one-week TPA insertion to one month and three months of wear with highest pain severity at T1. This is expected as being a fixed intraoral appliance that is adapted to the palate, patients may experience some amount of pain as the appliance interfere with speech and mastication. The pain severity reduced with times as patients were more tolerant with the presence of TPA intraorally. At one month and three months of wear, the pain severity was not significant anymore.

Subjects in CG and 3DG show similar pattern of pain reduction as the overall outcomes. Pain was most severe at one-week TPA insertion and reduced at one month and three months of wear. The severity was not statistically significant at one month and three months of TPA wearing. The same outcomes in findings was postulated between the two groups as all subjects in the CG and 3DG received the same TPA.

5.4.2.2 Between CG and 3DG at the same interval, T1, T2, and T3

Overall, there was no significant difference found in pain severity between subjects in CG and 3DG at the same time interval, T1, T2, and T3. We can safely conclude that there is no clinical and statistical difference between conventional TPA and TPA fabricated on 3D reconstructed TPA in terms of pain severity. Therefore, 3D printed models used in the fabrication of TPA appliance are clinically acceptable and comparable to the conventional stone model and can be used as working model in other intraoral appliance fabrications.

5.5 Focus Group Discussion

The purpose of the present study was to investigate which clinical application between the CG and 3DG was preferred by five clinicians who were involved in the clinical part of TPA fabrications. Qualitative method research with FGD was chosen due to its ability to generate data based on the synergy of the group interaction (Green, Draper, & Dowler, 2003). It also provides information about a range of ideas and feelings that individuals have about certain issues, as well as illuminating the differences in perspective between groups of individuals. This study focused on the opinion of clinicians; a different outcome might be expected if the similar topic was discussed among the dental technicians. The technician was limited due to only one technician was involved for quality control of the RCT. As for patients, their feedback was measured by the patient reported outcome measure who were involved in the laboratory works as well as the end users; the patients. In addition, in this study, fabrication of all TPAs was assigned to one technician for quality control of the RCT. As for the patients, their feedback was assessed by the patient reported outcome measure.

The current FGD consisted of five orthodontic postgraduates with comparable age range of being in the early thirties i.e. between 31 years old to 35 years old. They are qualified dentists and under training to be orthodontic specialists. They are of the same batch i.e. the 2015/16 intake of a four-year orthodontic programme and had undergone the programme for approximately 40 months by the FGD session. Therefore, it is safe to say that they familiar with each other and able to work together. The sixth orthodontic postgraduate of this batch, 39 years old, was the moderator of the FGD. The moderator and the subjects of the FGD all had been trained together as the operators of this study from the beginning to be familiar with both TPA modes i.e. CG and 3DG. Thus, they all had the similar level of experience with regards to both TPA modes. This is concurrent with suggestion by Krueger RA 1994 who recommended valuable data can only be

obtained if participants share similar characteristics: gender group, age-range, ethnic and social class background. According to (Rabiee, 2005) the members of the FGD should feel comfortable to engage with the discussion thus the chosen method was suitable. In an individual interview, the researcher usually dominates the discussion while in FGD, it is the participants who tend to take the initiative of further conversations, it is important as in this study we are looking into the clinician's preferences between two methods and implementing an individual interview may have the possibility that lead to bias. This method is particularly useful as we want to explore the degree of consensus on a given topic.

5.5.1 Identified themes

Three themes were identified from the analysis. These were time, molar band selection issue and cost factors.

5.5.1.1 Time factor

Time saving factor in 3DG was agreed to be directly and indirectly beneficial to both, treatment providers and patients due to elimination of one appointment that involved molar bands selection and upper arch impression. As there was no previous data exist in this area, we decided to carefully explore and identify the correlation of other orthodontic experiences to the withdrawal one visit appointment in time factor theme.

In a qualitative study that utilized FGD method by (Bennett & Tulloch, 1999), they discovered that among the negative factors about orthodontic treatment were 'uncomfortable impression', 'impression taste bad', 'treatment takes so long' and 'the appointments were too long'. Besides saving time, the new digital workflow removed the negative aspects of orthodontic treatment that was unfavoured by patients. In the article of digital workflow in contemporary orthodontics, (Christensen, 2017) agreed that intraoral scanning was not only giving us the ability to produce more complex appliance

with high precision but it benefitted the patients in many manners such as eliminated appointments for separator placement and repeated appointments for retainer impression. According to Christensen (2017 for the last two and half years of adhering to the digital workflow, they came across of only one patient who preferred the alginate impression.

About three decades ago, a study by (Alger, 1988) that looked into the relation of frequency versus treatment time in orthodontics concluded that current armamentariums was the possible factors to change the length of appointment intervals commonly used without lengthening the overall treatment time. Thus, it is agreed that the modifications of equipment's used in service delivery may alter the interval times and duration of orthodontic treatment.

5.5.1.2 Molar band selection issue

During the metal band size selections were carried out on the upper first molar teeth on the 3D reconstructed model, two clinicians reported of issues with the fit of the TPA. They realized that they selected a bigger size of bands for one participant each in the 3DG. They were able to fit both TPAs but they had to do some chairside adjustment of the molar bands by contouring the bands prior to insertion and cementation. Both participants did not report any problem and both TPAs were intact until the third follow up at T3. This however may lead to a potential problem as the amendment made may alter the expression of prescribed torque, tip and in out value, the changes may not express the initial intended value.

In the 3DG clinical workflow of TPA fabrication, molar band selections were carried out extra-orally on the 3D reconstructed working model. This is favored by four out of the five clinicians as they had a direct vision for the procedure. The single clinician who preferred the conventional way of intra-oral molar band selection because he felt that the 3D reconstructed model was not as accurate as the traditional stone models and ended up choosing a bigger size of molar bands which needed some adjustment and contouring upon cementation of the TPA. Many studies had been carried out to compare orthodontic measurements of 3D printed models and conventional stone models (Keating, Knox, Bibb, & Zhurov, 2008), (Wan Hassan et al., 2016), (TOMITA et al., 2018) and found that digital linear measurements demonstrate high accuracy, and may be suitable for clinical applications.

Another reported study found that measurement of teeth sizes superimposed between the arch forms on plaster and digital models were considered accurate, and the differences were not clinically significant, with the exception of the second molar area (Camardella, 2019). The molar band selections on 3D reconstructed model in this study were carried out on upper first molar teeth thus there was no significant difference in the size of the teeth involved. A study that compared conventional vacuum formed retainers (VFR) to VFR fabricated on 3D reconstructed model found no differences in terms stability and patients' OHRQoL (Mohd Tahir *et al*., 2018).

In contrast, a study that compares the trueness and precision of models of fixed dental prostheses fabricated by digital and conventional workflows found that the accuracy of the complete arch and trueness of the preparations of 3D printed models were inferior to those of the stone models. It was concluded that the 3D printed model cannot completely replace conventional stone models until further improvements are made (Sim *et al*., 2019). Molar bands selection in TPA fabrication differ in a sense that it did not require

hundred percent precision of the template as indicated in fixed prosthesis fixation. Molar bands that are slightly less well-fitted like having a bigger size of molar bands was found to be acceptable and still clinically applicable. The clinicians were still able to proceed with the orthodontic treatment without having to replace the TPA. In finishing the case the TPA can be removed and the archwires can be bent to achieve the desired position of the upper molar teeth in terms of first second or third order position.

On the other hand, extra-oral molar bands selection has other benefits. The process eliminates 'reuse' of contaminated molar bands that have been 'tried in' intra-orally. It also avoids the risk of accidental swallowing if carried out intra-orally. A survey among orthodontist in the United Kingdom on molar band 're-use' and decontamination revealed that majority of them are re-using orthodontic bands that have been tried-in the mouth, but not used for treatment. It was also found that they were carrying out decontamination procedures with great diversity (Dowsing & Benson, 2006). (Benson & Douglas, 2007) carried out a study to measure the effectiveness of ultrasonic cleaning for decontaminating orthodontic molar bands following size determination using a quantitative antibody capture assay technique. They found out that by applying ultrasonic cleaning for 15 minutes reduces, but does not always eliminate, salivary proteins (amylase) from tried in bands and it is less effective at removing serum protein (albumin). They concluded that there is a need, therefore, to investigate effective means of cleaning organic material from orthodontic bands if they are to be adequately sterilized and reused. In this study, since the procedure was carried out extra-orally, it eliminates the chance of contaminating the bands no matter what sterilizing protocols used.

Although not many, there has been reported hazard involving dental devices including molar bands ingestion among patients (Naragond *et al*., 2013), (Mahto, Rana, & Kharbanda, 2019). By carrying out the band size selection extra-orally like in the 3DG of

this study, the probability of an accidental swallowing is of the try-in procedure is reduced to nil.

5.5.1.3 Cost factor

Cost factor was discussed in two aspects in this study, firstly the cutting down of direct and indirect cost with digital workflow by eliminating one appointment time and secondly the related cost of the 3D workflow itself.

Reducing one appointment is beneficial to the service provider and patients by cutting down the cost of many things. For the provider (clinicians and supporting staff), elimination of molar bands selection appointment reduced the cost of clinical procedures such as alginate impression materials, re-placement of elastomeric separators, utilization of disposable materials and cleaning and sterilization of used instruments.

As for the patients, besides not taking more time off from work, there is less expenditure for another dental visit that include cost of travelling, petrol, toll, public transportation and parking fees, it would be more significant if they live far from the dental clinic. More arrangement has to be made if it involves patient with children or underaged patients who need to be accompanied by their parents or caregivers.

To date, there was no comparative literature that compared the exact cost between conventional orthodontic treatment and digital orthodontics. In this study, the cost of 3D printed models using ABS material for the TPA fabrication was RM24, excluding the charge of 3D scanning and virtual modification with the 3D software. The cost for 3D printing was also reduced by cutting down the parts of the cast that was not required for TPA construction. The conventional stone models ranged from RM50 to RM60 per arch and most of the local dental laboratories had similar average price. At the start of the study, the printing of the digital model was assisted and carried out by a third-party who

had no competition in the local vicinity. In the future, with emergence of more 3D laboratories and the cutting down of 3D related equipment and materials, the price can be further reduced.

5.5.2 Limitation

This FGD includes orthodontic postgraduates in Faculty of Dentistry only which may not reflect the general population. Although the transcription of the discussion was carried out by an independent party, the researcher involved in this study played a role as the moderator in the FGD, that would lead to potential bias. Currently, there's no clinician had a formal training on how to conduct a proper FGD in the department. Due to the time constraint in finding a suitable candidate, the decision was made for the researcher to become the moderator as she was trained by an expert (RS). Besides the time factor, there was also a financial constraint to hire the freelance moderator. In addition, the moderator must have an orthodontic clinical background as layman would not understand the dental terms, other clinicians were not familiar with and understand the process of TPA fabrication as the procedure is only common in orthodontics. Thus the FGD should have been facilitated by clinician with an orthodontic background who was not involved in the study.

5.5.3 Generalizability

Since focused discussion is qualitative in nature, we are unable to make a broad generalization of these data. Although the aim of the discussion was to evaluate the clinicians' preferences between the two method, FGD was designed to uncover and identify ideas in certain topic of previously unidentified issue. The output from the five clinicians had provided a diverse information that would be useful basic framework for further studies and allowing new theories to be formulated and tested (Bennett & Tulloch, 1999). Overall, the qualitative part of this research has provided us the issues of

importance in clinical application between the conventional and digital workflow of TPA fabrication. This information can be used to develop a clinician-based measure questionnaire to evaluate clinicians' perceptions towards clinical application of traditional versus digital workflow. The FGD had identified items that were not foreseen to be measured at the start of the RCT especially since the 3DG is an innovative method and was not tried before this, through the FGD we did not lose important information.

CHAPTER 6: CONCLUSION AND RECOMMENDATION

6.1 Conclusions

1. Oral Health Quality of Life (OHRQoL) improved from baseline up to three months after TPA wearing, the severity of OHRQoL among all the participants in the two groups was high at one-week after cementation of TPA and gradually improved at one month and third months of wear.
2. For both groups, the most affected domain in OHRQoL was psychological discomfort and the least was social disability.
3. Transpalatal Arch (TPA) fabricated from 3D reconstructed model demonstrate the same Oral Health Quality of Life (OHRQoL) as the TPA made on conventional stone model up to three months of wear.
4. Visual Analogue Score (VAS) of pain among participants in the two groups revealed that there is no significant difference in the pain level of patients wearing conventional TPA and TPA fabricated on 3D reconstructed model up to three months of wear.
5. Majority of clinicians who treated the subjects prefer the clinical application of TPA fabricated on 3D reconstructed model than the conventional TPA.
6. 3D reconstructed models with ABS material produced by UP!2 Plus 3D printer are clinically applicable and have the potential to replace the conventional stone models in TPA fabrication. The conventional study models can be scanned three dimensionally by Geomagic Capture and virtually modified with Geomagic Design X (XOR) software prior to printing.

6.2 Recommendation

i. Study on clinical application of more complex orthodontic appliance fabricated on 3D reconstructed model such as Quadhelix or Twin Blocks Appliance.

ii. Study on comparison of 3D models constructed from digital data acquired from direct intra-oral scanning, 3D scanning of the impressions and scanning of the conventional study models.

REFERENCES

Ackerman, M. B., & Thornton, B. (2011). Scientific Innovation, 22–28. https://doi.org/10.11607/ortho.856

Al-Ma'ani, M. (2014). Pain Perception in Orthodontic Patients Treated by Fixed Orthodontic Appliances and It's Effect on Their Quality of Life. *Journal of the Royal Medical Services*, *21*(2), 36–48. https://doi.org/10.12816/0004540

Al Mortadi, N., Jones, Q., Eggbeer, D., Lewis, J., & Williams, R. J. (2015). Fabrication of a resin appliance with alloy components using digital technology without an analog impression. *American Journal of Orthodontics and Dentofacial Orthopedics*, *148*(5), 862–867. https://doi.org/10.1016/j.ajodo.2015.06.014

Alger, D. W. (1988). Appointment frequency versus treatment time. *American Journal of Orthodontics and Dentofacial Orthopedics*, *94*(5), 436–439. https://doi.org/10.1016/0889-5406(88)90135-7

Almuzian, M., Alharbi, F., Chung, L. L.-K., & McIntyre, G. (2015). Transpalatal, nance and lingual arch appliances: clinical tips and applications. *Orthodontic Update*, *8*(3), 92–100. https://doi.org/10.12968/ortu.2015.8.3.92

AN, Y. (2005). An evaluation of preemptive valdecoxib therapy on discomfort caused by initial archwire placement in adult orthodontic patients. *Texas Dental Journal*, *122*(7), 673. Retrieved from http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/196/CN-00524196/frame.html

Ashari, A., & Mohamed, A. M. (2016). Relationship of the Dental Aesthetic Index to the oral health-related quality of life. *Angle Orthodontist*, *86*(2), 337–342. https://doi.org/10.2319/121014-896.1

Baccetti, T., Sigler, L. M., & McNamara, J. A. (2011). An RCT on treatment of palatally displaced canines with RME and/or a transpalatal arch. *European Journal of Orthodontics*, *33*(6), 601–607. https://doi.org/10.1093/ejo/cjq139

Bennett, M. E., & Tulloch, J. F. (1999). Understanding orthodontic treatment satisfaction from the patients' perspective: a qualitative approach. *Clinical Orthodontics and Research*, *2*(2), 53–61. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/10534980

Benson, P. E., & Douglas, C. W. I. (2007). Decontamination of orthodontic bands following size determination and cleaning. *Journal of Orthodontics*, *34*(1), 18–24. https://doi.org/10.1179/146531207225021879

Bernabé, E., Sheiham, A., & De Oliveira, C. M. (2008). Impacts on daily performances related to wearing orthodontic appliances. *Angle Orthodontist*, *78*(3), 482–486. https://doi.org/10.2319/050207-212.1

Biazevic, M. G. H., Rissotto, R. R., Edgard, M.-C., Mendes, L. A., & Mendes, M. O. A.

(2008). Relationship between oral health and its impact on quality of life among adolescents Post-Doctoral Student; Undergraduate Student. *Epidemiology Braz Oral Res Mendes MOA Braz Oral Res*, *2222*(11), 36–4236. Retrieved from http://www.scielo.br/pdf/bor/v22n1/a07v22n1.pdf

Brown, D. F., & Moerenhout, R. G. (1991). The pain experience and psychological adjustment to orthodontic treatment of preadolescents, adolescents, and adults. *American Journal of Orthodontics and Dentofacial Orthopedics*, *100*(4), 349–356. https://doi.org/10.1016/0889-5406(91)70073-6

Burstone, C. J., & Koenig, H. A. (1981). Precision adjustment of the transpalatal lingual arch: Computer arch form predetermination. *American Journal of Orthodontics*, *79*(2), 115–133. https://doi.org/10.1016/0002-9416(81)90310-9

Christensen, L. (2017). Digital workflows in contemporary orthodontics. *APOS Trends in Orthodontics*, *7*(1), 12. https://doi.org/10.4103/2321-1407.199180

Cousley, R. R. J. (2010). A clinical strategy for maxillary molar intrusion using orthodontic mini-implants and a customized palatal arch. *Journal of Orthodontics*, *37*(3), 202–208. https://doi.org/10.1179/14653121043101

Cunningham, S. J., & Hunt, N. P. (2001). Quality of life and its importance in orthodontics. *Journal of Orthodontics*, *28*(2), 152–158. https://doi.org/10.1093/ortho/28.2.152

D., F., J.A.M., M., R.K., C., & B.H., O. (2013). Effect of orthodontic treatment on oral health-related quality of life. *Angle Orthodontist*, *83*(5), 892–898. https://doi.org/10.2319/100412-781.1

Dawood, A., Marti, B. M., Sauret-Jackson, V., & Darwood, A. (2015). 3D printing in dentistry. *British Dental Journal*, *219*(11), 521–529. https://doi.org/10.1038/sj.bdj.2015.914

De Vasconcellos Rocha Maia, C., Mendes, F. M., & Normando, D. (2018). The impact of oral health on quality of life of urban and riverine populations of the Amazon: A multilevel analysis. *PLoS ONE*, *13*(11), 1–11. https://doi.org/10.1371/journal.pone.0208096

Di Giacomo, G., Silva, J., Martines, R., & Ajzen, S. (2014). Computer-designed selective laser sintering surgical guide and immediate loading dental implants with definitive prosthesis in edentulous patient: A preliminary method. *European Journal of Dentistry*, *8*(1), 100–106. https://doi.org/10.4103/1305-7456.126257

Diar-Bakirly, S., Feres, M. F. N., Saltaji, H., Flores-Mir, C., & El-Bialy, T. (2017). Effectiveness of the transpalatal arch in controlling orthodontic anchorage in maxillary premolar extraction cases: A systematic review and meta-analysis. *Angle Orthodontist*, *87*(1), 147–158. https://doi.org/10.2319/021216-120.1

DIGITAL TECHNOLOGY IN ORTHODONTICS : Digital model acquisition , digital planning. (2019).

Dowsing, P., & Benson, P. E. (2006). Molar Band Re-use and Decontamination: a survey

of specialists. *Journal of Orthodontics*, *33*(1), 30–37. https://doi.org/10.1179/146531205225021366

El-Beialy, A. R., Abou El-Ezz, A. M., Attia, K. H., El-Bialy, A. R., Mostafa, Y. A., & El-Zanaty, H. M. (2010). Three-dimensional dental measurements: An alternative to plaster models. *American Journal of Orthodontics and Dentofacial Orthopedics*, *137*(2), 259–265. https://doi.org/10.1016/j.ajodo.2008.04.030

Erdinç, A. M. E., & Dinçer, B. (2014). Perception of pain during orthodontic treatment. *European Journal of Orthodontics*, *26*(1), 79–85. https://doi.org/10.1093/ejo/26.1.79

Feu, D., De Oliveira, B. H., De Oliveira Almeida, M. A., Kiyak, H. A., & Miguel, J. A. M. (2010). Oral health-related quality of life and orthodontic treatment seeking. *American Journal of Orthodontics and Dentofacial Orthopedics*, *138*(2), 152–159. https://doi.org/10.1016/j.ajodo.2008.09.033

Feu, D., Miguel, J. A. M., Celeste, R. K., & Oliveira, B. H. (2013). Effect of orthodontic treatment on oral health-related quality of life. *Angle Orthodontist*, *83*(5), 892–898. https://doi.org/10.2319/100412-781.1

Fleming, P. S., & Marinho, V. (2011). Orthodontic measurements on digital study models compared with plaster models : a systematic review, (1), 1–16. https://doi.org/10.1111/j.1601-6343.2010.01503.x

Fowler, P., Bellardie, H., Shaw, B., Eyres, P., Semb, G., & Thompson, J. (2019). Reliability of a Categorical Scale (GOSLON) and a Continuous Scale (10-cm Visual Analog Scale) for Assessing Dental Arch Relationships Using Conventional Plaster and 3D Digital Orthodontic Study Models of Children With Complete Unilateral Cleft Lip and Pa. *The Cleft Palate-Craniofacial Journal : Official Publication of the American Cleft Palate-Craniofacial Association*, *56*(1), 84–89. https://doi.org/10.1177/1055665618770054

Fujisawa, M., & Komori, A. (2011). A modified transpalatal arch with customized bonding base. *Orthodontic Waves*, *70*(1), 39–42. https://doi.org/10.1016/j.odw.2010.06.002

Fulford, M. R., Ireland, A. J., & Main, B. G. (2003). Decontamination of tried-in orthodontic molar bands. *European Journal of Orthodontics*, *25*(6), 621–622. https://doi.org/10.1093/ejo/25.6.621

Gabriel, S., & Hull, C. W. (1984). United States Patent (19), (19). https://doi.org/US005485919A

Gore, I. G. E., Branch, N., Roman, T., Orange, E., Wayne, K., & Gore, R. A. (1998). United States Patent (19), (19). https://doi.org/US005485919A

Goultschin, J., & Heling, B. (1971). Accidental swallowing of an endodontic instrument. *Oral Surgery, Oral Medicine, Oral Pathology*, *32*(4), 621–622. https://doi.org/10.1016/0030-4220(71)90329-X

Green, J. M., Draper, A. K., & Dowler, E. A. (2003). Short cuts to safety: Risk and "rules

of thumb" in accounts of food choice. *Health, Risk and Society*, *5*(1), 33–52. https://doi.org/10.1080/1369857031000065998

Groth, C., Kravitz, N. D., Jones, P. E., Graham, J. W., & Redmond, W. R. (2014). Three-dimensional printing technology. *Journal of Clinical Orthodontics : JCO*, *48*(8), 475–485. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/25226040

Gül Amuk, N., Karsli, E., & Kurt, G. (2019). Comparison of dental measurements between conventional plaster models, digital models obtained by impression scanning and plaster model scanning. *International Orthodontics*, *17*(1), 151–158. https://doi.org/10.1016/j.ortho.2019.01.014

Gupta, R. (2014). of Dental Sciences. *Indian Journal of Dental Sciences*, (1), 122–124. Retrieved from http://www.ijds.in/article-pdf-GP._CAPT._SATISH_KUMAR_GUPTA_WG._CDR_SHASHI-618.pdf

Hassan, A. H., & Amin, H. E. S. (2010). Association of orthodontic treatment needs and oral health-related quality of life in young adults. *American Journal of Orthodontics and Dentofacial Orthopedics*, *137*(1), 42–47. https://doi.org/10.1016/j.ajodo.2008.02.024

Hayasaki, H., Martins, R. P., Gandini, L. G., Saitoh, I., & Nonaka, K. (2005). A new way of analyzing occlusion 3 dimensionally. *American Journal of Orthodontics and Dentofacial Orthopedics*, *128*(1), 128–132. https://doi.org/10.1016/j.ajodo.2004.07.039

Haynes, S. (1967). Discontinuation of orthodontic relative to patient age Orthodontic.

Higley, L. B. (1960). Anchorage in orthodontics. *American Journal of Orthodontics*, *46*(6), 456–465. https://doi.org/10.1016/0002-9416(60)90071-3

Hinkle, F. G. (1987). Ingested retainer :

Hixon, E. H., Atikian, H., Callow, G. E., McDonald, H. W., & Tacy, R. J. (1969). Optimal force, differential force, and anchorage. *American Journal of Orthodontics*, *55*(5), 437–457. https://doi.org/10.1016/0002-9416(69)90083-9

Hudson, J. M. (2000). Tongue-friendly transpalatal arches. *J Clin Orthod*, *34*(11), 671.

Jawaid, M., & Qadeer, T. A. (n.d.). Assessment of the changes in the oral health related quality of life 24 hours following insertion of fixed orthodontic appliance components — An observational cross-sectional study conducted at Bahria University Medical and, 677–683.

Johal, A., Alyaqoobi, I., Patel, R., & Cox, S. (2015). The impact of orthodontic treatment on quality of life and self-esteem in adult patients. *European Journal of Orthodontics*, *37*(3), 233–237. https://doi.org/10.1093/ejo/cju047

Jones, M., & Chan, C. (1992). The pain and discomfort experienced during orthodntic treatment: A randomized controlled clinical trial of two intial aligning arch wires. *American Journal of Orthodontics and Dentofacial Orthopedics*, *102*(4), 373–381. https://doi.org/10.1016/0889-5406(92)70054-E

Keating, A. P., Knox, J., Bibb, R., & Zhurov, A. I. (2008). A comparison of plaster, digital and reconstructed study model accuracy. *Journal of Orthodontics*, *35*(3), 191–201. https://doi.org/10.1179/146531207225022626

Krukemeyer, A. M., Arruda, A. O., & Inglehart, M. R. (2009). Pain and Orthodontic Treatment Patient Experiences and Provider Assessments. *Angle Orthodontist*, *79*(6), 1175–1181. https://doi.org/10.2319/121308-632.1

Liu, Z., McGrath, C., & Hagg, U. (2009). The impact of malocclusion/orthodontic treatment need on the quality of life a systematic review. *Angle Orthodontist*, *79*(3), 585–591. https://doi.org/10.2319/042108-224.1

Liu, Z., McGrath, C., & Hägg, U. (2011). Changes in oral health-related quality of life during fixed orthodontic appliance therapy: An 18-month prospective longitudinal study. *American Journal of Orthodontics and Dentofacial Orthopedics*, *139*(2), 214–219. https://doi.org/10.1016/j.ajodo.2009.08.029

Lucas, V. S., Omar, J., Vieira, A., & Roberts, G. J. (2002). The relationship between odontogenic bacteraemia and orthodontic treatment procedures. *European Journal of Orthodontics*, *24*(3), 293–301. https://doi.org/10.1093/ejo/24.3.293

M., C., D.-W., W., & L.-P., W. (2010). Fixed orthodontic appliance therapy and its impact on oral health-related quality of life in Chinese patients. *Angle Orthodontist*, *80*(1), 49–53. https://doi.org/10.2319/010509-9.1

Mahamood, S., Khader, M. A., & Ali, H. (2016). Applications of 3-D Printing in Orthodontics : A Review, *3*(11), 267–270. https://doi.org/10.17354/ijss/2016/99

Mahto, R. K., Rana, S. S., & Kharbanda, O. P. (2019). Accidental Swallowing of a Molar Band. *Turkish Journal of Orthodontics*, (January 2018), 3–6. https://doi.org/10.5152/turkjorthod.2019.18001

Megat Abdul Wahab, R., Idris, H., Yacob, H., & Zainal Ariffin, S. H. (2012). Comparison of self- and conventional-ligating brackets in the alignment stage. *European Journal of Orthodontics*, *34*(2), 176–181. https://doi.org/10.1093/ejo/cjq179

Mohd Tahir, N., Wan Hassan, W. N., & Saub, R. (2018). Comparing retainers constructed on conventional stone models and on 3D printed models: a randomized crossover clinical study. *European Journal of Orthodontics*, *02866617*, 1–11. https://doi.org/10.1093/ejo/cjy063

Monini, A. D. C., Maia, L. G. M., Jacob, H. B., & Gandini, L. G. (2011). Accidental swallowing of orthodontic expansion appliance key. *American Journal of Orthodontics and Dentofacial Orthopedics*, *140*(2), 266–268. https://doi.org/10.1016/j.ajodo.2011.05.009

Moutaftchiev, V., & Moutaftchiev, A. (n.d.). the Fabrication of Individual Tpa, 13–16.

Naragond, A., Kenganal, S., Rajasigamani, K., & Kumar, N. S. (2013). Accidental Ingestion of Molar Band and Its Management: Maintenance Is Better than Management. *Case Reports in Dentistry*, *2013*, 1–3. https://doi.org/10.1155/2013/891304

Oberoi, G., Nitsch, S., Edelmayer, M., Janjić, K., Müller, A. S., & Agis, H. (2018). 3D Printing—Encompassing the Facets of Dentistry. *Frontiers in Bioengineering and Biotechnology*, *6*(November), 1–13. https://doi.org/10.3389/fbioe.2018.00172

Odondi, L., Elton, V., Jones, Y., Banks, P., Derwent, S., & Rice, P. (2010). The use of fixed appliances in the UK: a survey of specialist orthodontists. *Journal of Orthodontics*, *37*(1), 43–55. https://doi.org/10.1179/14653121042867

Ofori-Asenso, R., & Adom Agyeman, A. (2015). Understanding Cross Over and Parallel group studies in Drug Research. *Precision Medicine*, (July), e1046. https://doi.org/10.14800/pm.1046

Oliver, R. G., & Knapman, Y. M. (2014). Attitudes to Orthodontic Treatment. *British Journal of Orthodontics*, *12*(4), 179–188. https://doi.org/10.1179/bjo.12.4.179

OMS. (2003). The World Oral Health Report 2003. *World Health Organization*, 45.

Othman, S., Saub, R., & Mansor, N. (2013). Changes in the oral health-related quality of life 24 h following insertion of fixed orthodontic appliances. *Journal of Orthodontic Science*, *1*(4), 98. https://doi.org/10.4103/2278-0203.105880

Park, J., Tari, M. J., & Hahn, H. T. (2002). Characterization of the laminated object manufacturing (LOM) process. *Rapid Prototyping Journal*, *6*(1), 36–50. https://doi.org/10.1108/13552540010309868

Pizzoni, L. (2010). Fibre reinforced composite transpalatal arch in impacted canine orthodontic treatment. *Progress in Orthodontics*, *11*(1), 83–85. https://doi.org/10.1016/j.pio.2010.04.011

Polat, Ö. (2007). Pain and Discomfort After Orthodontic Appointments. *Seminars in Orthodontics*, *13*(4), 292–300. https://doi.org/10.1053/j.sodo.2007.08.010

Rabiee, F. (2005). Focus-group interview and data analysis. *Proceedings of the Nutrition Society*, *63*(04), 655–660. https://doi.org/10.1079/pns2004399

Roberts-Harry, D., & Sandy, J. (2004). Orthodontics. Part 9: Anchorage control and distal movement. *British Dental Journal*, *196*(5), 255–263. https://doi.org/10.1038/sj.bdj.4811031

Saub, R., & Locker, D. (2006). The impact of oral conditions on the quality of life of the Malaysian adult population: Preliminary results. *Medical Journal of Malaysia*, *61*(4), 438–446.

Scheurer, P. A., Firestone, A. R., & Bürgin, W. B. (1996). Perception of pain as a result of orthodontic treatment with fixed appliances. *European Journal of Orthodontics*, *18*(4), 349–357. https://doi.org/10.1093/ejo/18.4.349

Shaw, W. C., Rees, G., Dawe, M., & Charles, C. R. (n.d.). the Influence of Dentofacial Appearanceon the Social Attractiveness.Pdf.

Shetty, S., Vigneshwaran, Ar., & Kumar, Ym. (2019). Modification in transpalatal arch used in conjunction with a fixed twin block. *Journal of Indian Orthodontic Society*,

53(1), 81. https://doi.org/10.4103/jios.jios_214_17

Sim, J. Y., Jang, Y., Kim, W. C., Kim, H. Y., Lee, D. H., & Kim, J. H. (2019). Comparing the accuracy (trueness and precision) of models of fixed dental prostheses fabricated by digital and conventional workflows. *Journal of Prosthodontic Research*, *63*(1), 25–30. https://doi.org/10.1016/j.jpor.2018.02.002

Singh, J., & Singh, S. (2018). Mucosal copper and zinc levels in oral submucous fibrosis patients. *Journal of Advanced Medical and Dental Sciences Research |Vol. 6|Issue*, *3*(2), 26–32. https://doi.org/10.21276/jamdsr

Slade, G. D. (1997). Slade GD, Spencer AJ. Development and evaluation of the oral health impact profile. *Community Dentistry and Oral Epidemiology*, *25*(4), 284–290. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/9332805

Sousa, M. V. S., Vasconcelos, E. C., Janson, G., Garib, D., & Pinzan, A. (2012). Accuracy and reproducibility of 3-dimensional digital model measurements. *American Journal of Orthodontics and Dentofacial Orthopedics*, *142*(2), 269–273. https://doi.org/10.1016/j.ajodo.2011.12.028

Stewart, F. N., Kerr, W. J. S., & Taylor, P. J. S. (1997). Appliance wear : the patient ' s point of view, *19*, 377–382.

Stivaros, N., Lowe, C., Dandy, N., Doherty, B., & Mandall, N. A. (2010). A randomized clinical trial to compare the Goshgarian and Nance palatal arch. *European Journal of Orthodontics*, *32*(2), 171–176. https://doi.org/10.1093/ejo/cjp075

Sun, L., HM, W., & CP, M. (2017). Relationship Between the Severity of Malocclusion and Oral Health Related Quality of Life: A Systematic Review and Meta-analysis. *Oral Health & Preventive Dentistry*, *15*(6), 1–15. https://doi.org/10.3290/j.ohpd.a38994

Tallman, M. J., Santner, C., & Miller, R. B. (2006). (12) United states patent, *1*(12). https://doi.org/10.1038/incomms1464

TOMITA, Y., UECHI, J., KONNO, M., SASAMOTO, S., IIJIMA, M., & MIZOGUCHI, I. (2018). Accuracy of digital models generated by conventional impression/plaster-model methods and intraoral scanning. *Dental Materials Journal*, *37*(4), 628–633. https://doi.org/10.4012/dmj.2017-208

Treede, R.-D. (2018). The International Association for the Study of Pain definition of pain: as valid in 2018 as in 1979, but in need of regularly updated footnotes. *Pain Reports*, *3*(2), e643. https://doi.org/10.1097/PR9.0000000000000643

Umesan, U. K., Ahmad, W., & Balakrishnan, P. (2012). Laryngeal impaction of an archwire segment after accidental ingestion during orthodontic adjustment. *American Journal of Orthodontics and Dentofacial Orthopedics*, *142*(2), 264–268. https://doi.org/10.1016/j.ajodo.2011.05.025

van der Meer, W. J., Tutein Nolthenius, H. E., Engelbrecht, W. P., Wiranto, M. G., & Ren, Y. (2012). Validity, reliability, and reproducibility of linear measurements on digital models obtained from intraoral and cone-beam computed tomography scans

of alginate impressions. *American Journal of Orthodontics and Dentofacial Orthopedics*, *143*(1), 140–147. https://doi.org/10.1016/j.ajodo.2012.06.018

Van Noort, R. (2012). The future of dental devices is digital. *Dental Materials*, *28*(1), 3–12. https://doi.org/10.1016/j.dental.2011.10.014

Wallis, C., Vasir, N. S., & Waters, N. E. (1998). A simplified method of attachment for the quadhelix and transpalatal arch. *British Journal of Orthodontics*, *25*(4), 263–267. https://doi.org/10.1093/ortho/25.4.263

Wan Hassan, W. N., Othman, S. A., Chan, C. S., Ahmad, R., Ali, S. N. A., & Abd Rohim, A. (2016). Assessing agreement in measurements of orthodontic study models: Digital caliper on plaster models vs 3-dimensional software on models scanned by structured-light scanner. *American Journal of Orthodontics and Dentofacial Orthopedics*, *150*(5), 886–895. https://doi.org/10.1016/j.ajodo.2016.04.021

Williamson, A., & Mbbs, B. H. (2005). ISSUES IN CLINICAL NURSING Pain: a review of three commonly used pain rating scales. *Journal of Clinical Nursing*, *14*(Spence 2000), 798–804.

Zhang, M., Mcgrath, C., & Ha, U. (2007). Patients' Expectations and Experiences of Impact on Quality of Life. *Angle Orthod*, *77*(2), 318–322. https://doi.org/10.2319/121905-447

Zheng, D. H., Wang, X. X., Su, Y. R., Zhao, S. Y., Xu, C., Kong, C., & Zhang, J. (2015). Assessing changes in quality of life using the Oral Health Impact Profile (OHIP) in patients with different classifications of malocclusion during comprehensive orthodontic treatment. *BMC Oral Health*, *15*(1), 1–8. https://doi.org/10.1186/s12903-015-0130-7