An evaluation of patient experiences, success rates and complications with mid-palatal temporary skeletal anchorage devices

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Declaration

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Abstract

Background

Mid-palatal placement of temporary skeletal anchorage devices (TSADs) has become increasingly popular among clinicians. There is however limited patient data in relation to associated experiences and impacts, success rates and complications associated with these orthodontic adjuncts.

Methods

A two-part study was undertaken involving a survey and retrospective evaluation. A survey of patients undergoing mid-palatal TSAD insertion was carried out using a 27-item bespoke questionnaire. Questionnaires were distributed using both electronic and surface mail with a 3-month period allowed for response. Pain experience; the use of analgesia; requirement for additional visits; impacts on hygiene, speech, eating, and hobbies; and social impacts were assessed. Reponses involved the use of a Visual Analogue Scale as well as binary information.

A retrospective analysis was undertaken in a specialist practice setting (Traben-Trarbach, Germany) over a 16-year period. A range of demographic and clinical variables associated with success were considered including gender, age, incisor relationship, vertical skeletal pattern, oral hygiene levels, attendance and the indication for TSAD use. Complications and days to TSAD failure were also reported. Data analysis consisted of descriptive and inferential statistics including logistical regression analysis.

Results

Overall, 152 responses (a response rate of 28%) were obtained from the survey, with 87.5% describing experience of TSAD insertion either "as expected" or "better". Procedural pain was reported as mild in 62.5%. Local post-operative pain was scored as moderate in 21.1%. Some functional impairment was reported with 63.2% attributing difficulty with speech and 67.8% difficulty with eating due to the implant. However, these functional impairments

were generally considered mild (by 68.1% and 60.2%, respectively) and most were very likely to recommend this treatment to others, with 65.1% (n = 99) scoring 8 or above out of 10.

Based on the retrospective analysis of success rates and complications, ten TSAD failures were noted from a total of 451 patients representing a 2.2% failure at the patient level. Overall, 13 out of 902 individual TSADs failed reflecting a 1.44% TSAD failure rate. Based on logistical regression analysis, vertical skeletal relationship and TSAD indication may influence the rate of failure with no association noted between failure and either gender, age, malocclusion type and attendance.

Conclusions

Appreciable levels of pain, discomfort and functional impairment were noted with the use of mid-palatal TSADs. However, any unpleasant experiences were generally regarded as mild with most highly likely to recommend mid-palatal TSADs to prospective patients.

Excellent success rates were found with mid-palatal placement of temporary skeletal anchorage devices (TSADs) with failure rates of 1.44% and 2.2% at the implant and patient level, respectively. Complications were also rare with loosening of the mid-palatal TSAD associated with failure.

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Table of contents

List of Tables

Glossary of Terms

TSAD	Temporary Skeletal Anchorage Device
OMI	Orthodontic Mini-Implant
MI	Mini-Implant
VAS	Visual Analogue Scale
FMPA	Frankfort-mandibular Plane Angle
TPA	Trans-palatal Arch
PREM	Patient Related Experience Measure
PROM	Patient Related Outcome Measure
OH	Oral Hygiene
OS	Oral Surgeon
RCT	Randomised Control Trial.

1. Chapter 1: Literature review

1.1 Means of Anchorage Management

Anchorage is defined as the resistance to unwanted tooth movement (Proffit and Fields, 2013). According to Newton's Third Law "for every action, there is an equal and opposite reaction". To avoid the effects of unwanted reciprocal forces, anchorage is key to successful orthodontic treatment. Mechanics that provide anchorage support can also be adapted to introduce traction in the form of anterior-posterior movement (chiefly molar mesial and distal movement), vertical movement (intrusion and extrusion), as well as tooth-bone, bone-borne or hybrid forms of expansion.

These effects can be mediated intra-orally from teeth, bone and soft tissue and extra-orally from the neck, head and face. Many of these mechanisms are constrained either by a reliance of patient adherence or uncertain extent of anchorage support.

In recent years, temporary skeletal anchorage devices (TSADs) have emerged as a viable means of providing both absolute anchorage with less onus on patient input. Moreover, TSADs also offer the possibility of providing positive traction including but not limited to molar distal movement, intrusion and extrusion.

1.1.1 Intra-oral: Dentition – intra-arch

A fundamental source of anchorage is the dentition itself and occlusal interferences. These aspects encompass both tooth type and location as well as root length, bone levels and the impact of the occlusion (Table 1.1).

Table 1.1 Intra-oral anchorage: dentition - intra-arch.

Theory	**Description**	**Key Findings**	**References**
Differential Force Theory	The rate of tooth movement is related to the force per unit area of the root surface in the bone.	An animal study showed that the ratio of tooth movement is not the same as tooth surface area. No significant difference in mesial movement of anchorage units in different force groups (50, 100, 200g). Increasing force levels does not increase the rate of tooth movement, thus placing a bigger strain on anchorage.	Begg and Kesling, 1977; Hixon *et al.,* 1970; *Pilon et al*., 1996; Quinn and Yoshikawa, 1985
Optimal Force Levels	The relationship between applied force and tooth movement is not fully understood.	Forces between 50-100g may be optimal for orthodontic tooth movement and patient comfort with fewer side effects.	Ren *et al*., 2003; Theodorou *et al.,* 2019
Occlusal Interferences	A theoretical reinforcement of anchorage created by specific extraction patterns.	In Class II cases, extracting upper first permanent premolars and lower second permanent premolars creates an interlocking occlusion that resists posterior anchorage loss. Greater mesial movement of molars and less resolution of anterior crowding was seen with the extraction of second	Saelens and De Smit, 1998

		permanent premolars rather than first permanent premolars.	

Appliances involving bilateral placement on the molar dentition including lingual or palatal arches, or lip bumpers can also be used to reinforce anchorage, however there is limited evidence concerning clinical effectiveness (Table 1.2).

Table 1.2 Intra-oral anchorage: appliances - intra-arch.

Appliance	**Clinical Effectiveness**	**Purpose**	**Limitations/Findings**	**References**
Lingual Arch	Limited evidence	To hold the Leeway Space and prevent anchorage loss after deciduous molar exfoliation in the lower arch.	Helps reduce arch perimeter loss, at the expense of proclination of lower incisors.	Rebellato *et al.,* 1997
Trans-palatal Arch (TPA)	Limited evidence	To hold upper molars in three dimensions during extraction-based treatment.	Does not have a significant effect on vertical or anteroposterior anchorage. Should not be used alone for maximum anchorage in extraction cases.	Zablocki *et al.,* 2008; Diar-Bakirly *et al.,* 2017

Space Maintainers and Regainers	Limited evidence	To preserve arch length and prevent crowding in the mixed dentition.	Often at the expense of lower incisor proclination.	Khalaf *et al.,* 2022

Andrews (1979) described a pre-adjusted bracket design to control tooth movement in three dimensions which required fewer bends, hence reducing chairside time. Roth introduced further modifications to reduce the bracket inventory required (Talapaneni *et al.,* 2012). Preadjusted edgewise bracket prescriptions can be modified to enhance anchorage. By using different systems, employing local bracket variations and artistic placement of brackets, the anchorage value can be altered by adjustment of second and third order values (Table 1.3).

Table 1.3 Intra-oral anchorage: appliance prescription – intra-arch.

Appliance	**Features**	**Intended Effect**	**Findings**	**References**
Preadjusted Edgewise Bracket, Lawrence Andrews (1979)	Control tooth movement in three dimensions, reducing the need for wire bends.	Required fewer bends.	Reduction in chairside time.	Andrews, 1979
Roth Prescription	Added distal crown tip in lower buccal segments (-1 degree).	To increase anchorage value.	Aims to reduce bracket inventory.	Talapaneni *et al.,* 2012

MBT (MacLaughlin, Bennet, and Trevisi 1998) Appliance	Reduced anterior tip from Andrews and Roth to values closer to Andrews' original data. Reduced posterior tip in upper buccal segments.	To reduce strain on molar anchorage and reduce anchorage demands.	MBT prescription effectively addresses anchorage management inadequacies of the Roth system.	Talapaneni *et al.,* 2012
Local Bracket Variations	Transposing lower canine brackets (changing mesial tip to distal).	To reduce the strain on anchorage in Class III camouflage cases.	Reduction in anchorage loss.	Thickett, Taylor and Hodge, 2007
Lacebacks	0.009" stainless steel ligature fixing the arch length between canines and molars, theoretically limiting incisor proclination during alignment.	Thought to alter anchorage.	RCT found no advantage in their use for altering anchorage balances.	Usmani *et al.,* 2002

1.1.2 Intra-oral: dentition - inter-arch

Intermaxillary traction is commonly used to transfer anchorage from one arch to another (Table 1.4). However, Class II elastics may be associated with unwanted side effects include extrusion and mesial tipping of the lower molars, and proclination of the lower labial segment. Class III elastics may also induce extrusion and mesial tipping of the upper molars, and proclination of the upper labial segment. It is recommended that the use of a rectangular stainless steel archwire, use of tip-back, step-down and toe-in bends would reduce the risks of these side effects (Farret, 2023). Notwithstanding, inter-arch mechanics may be inappropriate in certain circumstances with potential implications on prospective stability, periodontal support and dental aesthetics.

Table 1.4 Intra-oral anchorage: dentition – inter-arch.

Type of Intermaxillary Traction	**Feature**	**Purpose**	**References**
Class II Correction	Elastic extended from the upper cuspid to the lower molar.	To use the lower arch to reinforce upper posterior anchorage when reducing overjet.	McSherry and Bradley, 2000; Farret, 2023)
Class III Correction	Elastics extended from the upper molar to the lower cuspid.	To use the upper arch to reinforce lower posterior anchorage and retract the lower labial segment.	Singh *et al.,* 2012

1.1.3 Intra-oral: Soft tissue appliances and auxiliaries

The oro-facial muscles and the palatal vault has also been advocated as a source of anchorage (Table 1.5). The lip bumper attaches to the dentition by molar bands and utilises forces from the musculature via an acrylic pad in the lingual sulcus. The Nance appliance utilises the palatal vault via an acrylic button bracing the palatal vault from arms extending distally to banded molars. Repelling magnets anchored to a modified Nance appliance cemented to the premolars were described to distalise the maxillary molars (Gianelly *et al.,* 1989).

Table 1.5 Intra-oral anchorage: soft tissue appliances.

Anchorage Source	**Key Findings**	**Effectiveness**	**References**
Lip Bumper	Thought to distalize the lower buccal segment and reinforce anchorage. Can lead to lower incisor proclination due to removing resting lip pressure.	Literature regarding effectiveness is poor.	Proffit, 1978; Cetlin and Ten Hoeve, 1983; Khalaf *et al.,* 2022
Nance Appliance	The inclination of the palate correlates with anchorage value; steeper palates show less mesial movement of premolars.	No clinically significant difference in anchorage loss compared to Headgear and TSADs.	Metin-Gursoy and Tortop, 2022; Sandler *et al.,* 2014
Magnets	Rare earth-coated magnets showed good biocompatibility, but uncoated magnets showed cytotoxicity.	Forces decrease with the reciprocal square of the separation distance. Intra-arch NiTi coils were more efficient.	Bondemark, Kurol and Wennberg, 1994; Bondemark, Kurol and Bernhold, 1994

1.1.4 Intra-oral: Skeletal

There is moderate quality evidence suggesting that Orthodontic Mini-Implants (OMIs) are clinically and statistically more effective in preserving anchorage than conventional anchorage methods (Alharbi *et al*., 2019). Robust clinical evidence surrounding other forms of skeletal anchorage including the use of cortical bone plates and the effect of bone density is limited (Table 1.6).

Table 1.6 Intra-oral anchorage: skeletal.

Anchorage Source	**Description**	**Key Findings**	**References**
Cortical Bone	Torquing upper molar roots buccally has been suggested to reinforce anchorage.	Cortical bone is resistant to resorption than medullary bone. Has the potential for root resorption and periodontal issues.	Bartley *et al.,* 2011
Bone Density and Quality	Classified using systems like Linkow's (Class I, II, III) or Misch's (D1-D5, based on Hounsfield units).	OMIs in D1 and D2 regions show greater stability. OMIs in D4 regions are associated with higher failure rates. Mandibular teeth have a higher anchorage value than maxillary teeth due to root morphology, bone density, and cortical thickness.	Linkow and Cherchève, 1970; Misch, 1999; Kravitz and Kusnoto, 2007
Temporary Skeletal Anchorage	Devices inserted into the bone for maximum anchorage.	Moderate quality evidence suggests they are clinically and statistically more effective in preserving	Alharbi, Almuzian and Bearn, 2019;

Devices (TSADs)		anchorage than conventional methods. Robust clinical evidence is limited, but a 2025 Delphi study provided consensus statements from experts.	Franchi *et al.,* 2025

1.1.5 Extra-oral

Historically, headgear was preferred as a means of providing maximum anchorage. The appropriate direction of pull (high pull from an occipital anchoring unit, low pull from a cervical neck strap, or straight pull which is a combination of both) is determined by the pre-treatment malocclusion, vertical dimensions and treatment goals. The force required to provide anchorage is 200-250g with wear time of 10-12 hours per day (Littlewood and Mitchell, 2019).

Headgear relies heavily on compliance and has fallen out of favour given the potential risks associated with its use (Samuels and Jones, 1994;Table 1.7).

Table 1.7 Extra-oral anchorage.

Risk	Description	Key Findings	References
Injuries, & Safety	Disengagement during sleep/play can lead to severe ocular injuries, penetrating skin injuries, and abscesses.	Up to 230 injuries reported over a 14-year period in a 1975 survey, with some involving the eyes. Multiple reports of ocular injuries leading to blindness. Safety mechanisms (at least two) are	Samuels and Jones, 1994; Chaushu, Chaushu and Weinberger, 1997; Blum-Hareuveni, Rehany and Rumelt, 2006; Shaver, Gilberg and McCluskey, 2000; Zamir, Hemo and Zauberman, 1999;

		recommended to prevent disengagement and recoil.	Booth-Mason and Birnie, 1988; Holland *et al.,* 1985; Stafford, Caputo and Turley, 1998; Postlethwaite, 1989
Dermatological Risks	Associated with skin irritation from facial masks and alopecia from occipital strap pressure.	Contact dermatitis and atopic eczema have been reported, caution is needed for patients with dermatological conditions.	Leonardi *et al.,* 2008; Premkumar and Vidya, 2013; Liu, Abbas and Seehra, 2019; Brooks and Curzon, 1991; Lowey, 1993; Burden and Eedy, 1991; McComb and King, 1992
Compliance	Patient wear time is critical for successful outcomes.	Compliance is poor and decreases with age. Can be improved by self-monitoring or with active monitoring devices (e.g., electronic module timers, temperature monitors). Patients often overreport wear time, especially when aware of a recording device. Younger patients	Gratsia *et al.,* 2024; Cureton, Regennitter and Yancey, 1993b, 1993a; Northcutt, 1974; Kyriacou and Jones, 1997; Shah, 2017; Al-Moghrabi *et al.,* 2017

		are more compliant than older patients.	

1.2 Mini-implants in Orthodontics

1.2.1 History of TSADs in Orthodontics

Temporary Skeletal Anchorage Devices (TSADs) are also known as Orthodontic Mini-Implants (OMIs) or mini-screws. TSADs provide skeletal anchorage during orthodontic treatment. They are placed for a limited time when skeletal anchorage is required during treatment before being removed. They have an obvious advantage over other methods of anchorage as they do not rely on patient compliance. Higher cooperation with orthodontic treatment has been shown to be associated with higher levels of patient motivation (Daniels *et al.*, 2009).

As defined by Cope (2005), a TSAD is “a device that is temporarily fixed to the bone to enhance orthodontic anchorage either by supporting the teeth of the reactive unit or by obviating the need for the reactive unit altogether and which is subsequently removed after use”. The idea for TSADs was derived from restorative dental implants and maxillofacial surgical plating screws and plates. TSADs are smaller than restorative dental implants, ranging in diameter from 1mm to 3mm, and in length from 5mm to 15mm. The surface of a TSAD is smooth and polished compared to dental implants. At the University of Iowa, Gainsforth and Higley (1945), first proposed the idea of skeletal anchorage using Vitallium screws in animal models to distalise. They placed a Vitallium screw in the mandibular ramus to distalise a canine; however, all screws failed in 16 to 31 days (Costello *et al.,* 2010). Linkow (1969) first reported a patient treatment with the use of osseointegrated implant or both restorative and orthodontic purposes. The implant was first used for Class II elastics while retracting maxillary incisors and later used as a bridge abutment. The first clinical report of the use of TSADs was by Creekmore and Eklund (1983), who treated a deep overbite by placing a TSAD for intrusion made of surgical vitallium just below the anterior nasal spine.

Costa *et al*. (1998) produced a preliminary report discussing the possible solutions suggested in the literature for deficient anchorage situations. Kanomi (1997), suggested the use of titanium implants for orthodontic anchorage with a 1.2mm diameter and a 6mm length. These were not suitable for skeletal anchorage but provided stability for orthodontic movement.

Traditional dental implants rely on osseointegration for retention, as TSADs are temporary in nature, osseointegration is not desired and would make removal difficult (Branemark, 1985). TSADs rely on mechanical retention (Cope, 2005). However, studies have shown that a variable level of osseointegration could occur (10-58%) (Prabhu and Cousley, 2006; Melsen and Costa, 2000). Orthodontic implants are made of titanium alloy grade 5 and are not surface-treated. Surface treatment of dental implants increases roughness and osseointegration. The surface roughness of dental implants governs cell interactions and osteoblastic cells adhere well to rough metal surfaces. Surface treatment of orthodontic implants increases the torque needed when removing the implant which is not wanted (Ikeda *et al.,* 2011).

Chen *et al.,* (2007), carried out a retrospective analysis of 359 OMIs in 129 patients. Three different types of TSADs were compared (miniplates, OMIs and micro-screws). Type of implant, the mandibular arch and age were the only statistically significant factors found. Mini-plates had greater stability, however, require a periodontal surgery for insertion and removal and so would be least favoured clinically. Younger age was associated with higher failure rates; however, participant demographic varied greatly, with the majority of the sample being female (25 males, 104 females) and ages ranged from 12 to 55 (mean 24.5 years). Operator experience or proficiency which may influence success rates was also not reported.

1.2.2 Classification of TSADs

There has been much in the literature regarding the classification of TSADs; however, there is no standardised terminology or classification system for TSADs. A number of key characteristics are outlined in Table 1.8.

Table 1.8 TSADs classification.

Classification Basis	**Sub-type**	**Examples**
Morphology	Screw type	Mini screw implant, micro implant, Aarhus implant, spider screw
	Disc type	Onplant
	Plate type	Mini-plate implant, zygoma anchorage system
Head Exposure	Open	-
	Closed	-
Surface Texture	Threaded	-
	Non-threaded	-
	Porous	-
	Non Porous	-
Location	Alveolar	Buccal shelf, palatal intraarticular
	Extra-alveolar	Palatal, infra-zygomatic, retromolar

1.2.3 Components of Orthodontic Mini-Implants (OMI)

Elias *et al.,* (2012) described a range of OMI components in a review article designed to update orthodontic practitioners on current OMI concepts outlined in Table 1.9.

Table 1.9 OMI components.

Component	Design Variations
Head Design	Smooth button, bracket-type, through-hole
Diameter	1mm to 3mm
Length	5mm to 15mm
Body Design	Tapered or cylindric
Transmucosal Collar Thickness	0mm to 3mm
Intraosseous Thread & Insertion Technique	Self-tapping or self-drilling
Thread Orientation	Left or right
Material	Titanium alloy or stainless steel

1.2.3.1 Extra-osseous Components

The extra-osseous component of the mini-implant allows the orthodontists to apply mechanics directly and indirectly from. There are a range of considerations including the head, neck and transmucosal collar.

1.2.3.1.1 Head

The component of the mini-implant that resides in the oral cavity and is available for orthodontists to apply mechanics directly and indirectly from. It also engages the mini-implant driver for placement. Heads come in different designs for different purposes, smooth button, bracket-type and through-hole head.

1.2.3.1.2 Neck

This component of the mini-implant is a short cylindrical area joining the head to the transmucosal collar. This is narrower in diameter than the head or the transmucosal collar. It serves a purpose as an undercut area. It may or may not contain a through-hole (approx. 0.8mm in diameter), which the orthodontist can apply mechanics such as steel ligatures, NiTi coils and elastomeric chain.

1.2.3.1.3 Transmucosal collar

This component is a smooth cylindrical area passing through the soft tissue, it also provides a stop once it encounters bone. It is smooth in design to reduce the risk of soft tissue inflammation, plaque accumulation and infection. The length differs depending on the location of the intended implant. Short transmucosal collars lend themselves to buccal areas where the attached mucosa is thin, whereas long transmucosal collars are better suited to the placement in thick mucosa such as the palate.

1.2.3.2 Intra-osseous Components

A range of features of the intra-osseous component of the mini implant that is situated within bone, underneath soft tissues are possible. These are outlined in Table 1.10.

Table 1.10 Intra-osseous OMI components.

Component	Feature	Key Findings	References
Form	Conical vs. Cylindrical	Conical implants provide higher initial stability and require higher insertion torque, but may cause more bone compression.	Martinez *et al.,* 2001; O'Sullivan, Sennerby and Meredith, 2004; Kim *et al.,* 2008
Length		Maxillary implants should be longer and wider than mandibular ones due to more cancellous bone. Increasing length does not affect	Crismani *et al.,* 2010; Pithon, Figueiredo and Oliveira, 2013;

		fracture/flexural strength but may increase primary stability.	Mortensen *et al.,* 2009
Diameter		Chosen based on location and bone consistency. Torsional strength is proportional to the cube of the core diameter. Wider implants are preferred in areas with more cancellous bone and thinner cortex. Diameters of 1.0mm or less are associated with mobility and failure.	Wu, Kuang and Wu, 2009; Miyawaki *et al.,* 2003; Wiechmann, Meyer and Büchter, 2007; Morarend *et al.,* 2009; Crismani *et al.,* 2010; Romanec, Panaite and Zetu, 2025
Intraosseous Thread	Thread type	Provides mechanical retention. Double-thread mini screws have a significantly higher success rate than single-thread mini screws (97.8% vs. 86.7%).	Chen, Shin and Kyung, 2008; Merati *et al.,* 2024
	Screw pitch	High pitch threads are far apart and are inserted quickly. More dense threads show increased stability.	Nausheer *et al.,* 2020; Jedliński *et al.,* 2022
	Thread depth & core dimension	Greater thread depth correlates with greater pull-out strength. A greater core dimension and a tapered core design can reduce stress concentration.	Chang *et al.,* 2012; Walter *et al.,* 2013; Jedliński *et al.,* 2022
Material	Pure Titanium,	No significant difference in mechanical stability or	Brown *et al.,* 2014; Bollero *et*

	Titanium Alloy vs. Stainless Steel	histological responses between stainless steel and titanium alloy OMIs. Material is not a major factor in success, and stainless steel is a good, low-cost option. Titanium alloy is the most commonly used material in the UK and Australia.	*al.,* 2018; Chang, Lin and Roberts, 2019; Mecenas *et al.,* 2020; Woolley, Wright and Meade, 2024

1.2.3.3 Surface Morphology and Modifications in OMI

An RCT of 62 OMIs in 31 patients in 2021 looked at the effect of sandblasting versus acid etching the surface of OMI. The survival rate of the sandblasted group was 90.3% and the acid-etched was 83.9%, this difference was not statistically significant. However, the torque required for removal was higher in the sandblasted group (Moghaddam *et al*., 2021). This study did not mention blinding, and did not provide a power analysis to state if the size was sufficient to confirm statistically significant differences. A systematic review in 2022 showed similar results, analysing 14 articles. Surface treatment of OMI with sandblasting or acid etching improves primary stability and is associated with higher removal torque values (Al-Thomali, Basha and Mohamed, 2022). However, there was heterogeneity among the included studies with animal models also considered.

An RCT based in India investigated if surface treating OMIs would have an effect on the success rates, and on the insertion and removal torque of OMIs. The surface treatment consisted of sandblasting with large alumina particles and acid etching with hydrochloric acid and sulfuric acid. It was shown that removal torque was higher in the surface-treated group, and there was no significant differences in the insertion torque or failure rate between surface treated and non-treated OMIs. However this may be interpreted with caution due to the very small sample size of 7 patients with 32 OMIs (Ravi *et al.,* 2023). Participants were also treated exclusively by postgraduate students.

A recent systematic review and meta-analysis by van den Braak *et al., (*2024) based on six studies investigated the effect of surface roughening on OMI success. Low quality evidence that there was no statistically significant effect of surface roughening on OMI success was observed. The lack of prospective data from homogeneous well-controlled primary studies was also noted.

1.2.4 Mini-implant placement

After analysing the malocclusion and planning treatment and anchorage, the placement site of the OMI should be evaluated for suitability. Soft tissue examination should include: the presence of a frenum, soft tissue phenotype, the location of the attached non-attached junction for buccal shelf OMIs and the thickness of the gingiva. Roots of teeth can be located in two-dimensional radiography, with an orthopantomogram, although small field Cone Beam Computed Tomography (CBCT) may offer additional information. After confirming the location of the OMI, topical anaesthetic can be applied to the mucosa. Infiltration of local anaesthetic at the site is a preferred method of anaesthetic over topical alone (Valieri *et al.,* 2014).

1.2.4.1 Guides and Appliance Fabrication

A guide can aid implant placement, increasing the accuracy of placement and potentially reducing the failure rate of OMI (Jedliński *et al.,* 2021). This systematic review included 9 studies, 3 RCTs and 6 non-randomised control trials in human studies only, comparing 3D guided placement to other methods. Meta-analysis was performed on 3 comparisons, 3D guide versus no guide (220 OMIs), 3D versus wire guide (285 OMIs), 3D tooth-borne versus mucosa-borne. Guides supported by the dentition had increased accuracy compared to mucosa-borne guides. This was a large review with large heterogeneity.

A systematic review based on 92 articles in 2023 showed that OMI placed in the interradicular spaces with the use of an image-guided-based guide was more accurate than free-hand conventional placement (Mihit Mihit *et al.,* 2023). However, this review has a large limitation, only *in vitro* trials were included, and *in vitro* models do not accurately replicate the clinical environment.

Computer-aided design along with a CBCT can be used to design and print a precise guide for implantation that achieves more accurate positioning, thus giving higher success rates (Zhu *et al.,* 2023). Limitations of this study include; it's lack of control group, it's small sample size, and that it is based on cadaver heads which may not replicate an *in vivo* environment.

1.2.4.2 Self-tapping and Self-drilling

Self-tapping OMIs require a pilot hole to be placed in the bone. The pilot hole should be 0.3mm narrower than the screw diameter. Self-drilling OMIs have a sharp tip which do not require a pilot hole to be drilled out of the bone. They have sharp flutes that allow them to be driven into bone. A drawback for self-drilling OMIs is that there may be a lack of tactile sensitivity, bone compression and patient discomfort when placing the OMI. Son *et al.,* (2014), carried out an RCT in which they directly compared self-drilling and self-tapping OMIs, they found that more mobility was seen with self-drilling OMIs that were in contact with roots. However lack of blinding of the operator must be considered with the results.

1.2.4.3 Insertion angle and technique

Implants placed closer to the line of applied force the greater the stability and greater the resistance to failure (Pickard *et al.,* 2010). However, it has also been shown that insertion at 90 degrees to the cortical plate is the ideal angle for retention and stability, insertion at oblique angles reduces retention (Petrey *et al.,* 2010). Root perforation is more likely with a perpendicular insertion, as with an oblique insertion slippage is likely to occur instead of penetration into the root (Lee, 2007). For this reason, the OMI is first placed at 90 degrees and insertion is started. Once the cortical bone has been penetrated 1-1.5mm, the implant is withdrawn and the insertion angle is changed from 90 degrees to an oblique angle of 60 to 70 degrees to engage more of the cortical bone and reduce the risk of root perforation (Wilmes *et al*., 2008). Care must be taken to ensure excessive force is not put on the OMI when being inserted. A nail would be inserted into a wall with vertical force or pushing, whereas, a screw is inserted employing rotation, not by an excessive vertical force. Having said that, an RCT found no statistically significant effects of an insertion angle of 90 degrees versus 45 degrees on the survival rate of the OMI, however the generalisability may be questioned as this study had a small sample being based on a single operator (Golshah *et al*., 2021).

1.2.4.4 Insertion Torque

Early studies on OMI placement torque highlighted that increased torque during placement was associated with a higher rate of failure (Motoyoshi *et al.,* 2006). Insertion torque is an indicator for the primary stability of OMIs. It has been shown that insertion torques of higher than 10Ncm have a higher failure rate than of 8Ncm (Motoyoshi *et al.,* 2007). Predrilling of the cortical bone was done in both of these studies.

In 2012, a systematic review looked at insertion torque values on the success rates of orthodontic mini implants. They analysed the difference between recommended maximum insertion torque values of 5 to 10Ncm compared to insertion torque values exceeding this range. At the time the quality of the literature was low and they concluded that no evidence indicated a specific maximum torque value and success rates (Meursinge Reynders *et al.,* 2012). A more recent systematic review by the same author on insertion torque and diagnosis of root contact showed that higher torque values are seen with root contact. In animal and cadaver studies it was shown that higher torque values are also seen with self-drilling compared to pre-drilling OMIs (Meursinge Reynders *et al.,* 2016b).

In keeping with previous literature, Lim *et al.,* (2008) concluded that torque was influenced by OMI diameter, length and shape. Cho and Baek (2012) advocated predrilling of thick cortical bone to overcome the risk of microdamage to the bone. However, this was an *in-vitro* study using artificial bone limiting the clinical relevance of the findings.

1.2.4.5 Cortical Thickness and Engagement

The quantity and quality of bone has an effect on the success rates of OMIs (Wilmes *et al.,* 2006; Leo *et al.,* 2016). Motoyoshi *et al.,* (2007) recommended cortical thickness of OMI site should be at least 1mm thick as in their trial higher success rates were seen in patients with thicker cortical bone. Cortical thickness is a decisive parameter for the stability of OMIs. Thinner cortical bone increases the dependence on the Young's modulus of the cancellous bone with mobility. The greatest stresses and strain can be seen when Young's modulus of cancellous bone is low and the cortical bone is thin (Stahl *et al.,* 2009).

A cross-sectional CBCT study in 2011 has shown that the cortical plates are significantly thicker in adults than adolescents, except in the infrazygomatic crest, the mandibular buccal first molar and the posterior palate (Farnsworth *et al.,* 2011). However, longitudinal data would be of benefit. A retrospective study on 123 CBCT scans measured the thickness of the cortical bone in the buccal and palatal inter-radicular spaces, mesial to the first permanent molars for subjects between 12 and 30 years old. It was shown that cortical bone thickness increased with age and therefore the authors concluded that there would be better primary stability of OMI in older patients (Centeno *et al.,* 2022). It has also been observed that bone density may increase around OMIs after 3 months of loading (Al Maaitah, Safi and Abdelhafez, 2012).

A systematic review in 2021 also looked at cortical thickness and bone density with OMIs and their success rates. Cortical bone density had minimal effect on the success; however, cancellous bone density had a strong effect on the success of OMI. This differed depending on the insertion sites, in the maxilla cancellous bone density had a strong effect on the success. Whereas, in the mandible, it was shown to have a moderately negative effect on the success rates. The authors of this study also highlighted a high level of clinical heterogeneity and that further studies with larger sample sizes were needed in this area (Lee *et al.,* 2021).

1.2.5 Indications, Contraindications and Application of Mini-implants

Three recent survey studies focused on exploring current practices, usage and clinical preferences with OMI among different cohorts; UK and Australia, and two based in Romania (Woolley *et al*., 2024; Bungău *et al.,* 2024; Panaite *et al.,* 2024).

Molar protraction was reported as the most common indication for TSAD use in the UK and Australia. Loosening, infection, soft tissue overgrowth and ulceration were cited as common complications. “Confidence” and “insufficient postgraduate training” were barriers to use. There was a low response rate, with voluntary survey studies liable to inclusion bias (Woolley, Wright and Meade, 2024). A survey in Romania of 105 participants found that the interradicular area most common placement site (60%) with higher success rates reported with infrazygomatic crest site. Complications noted were; mobility and soft tissue damage, with the mid-palatal area associated with a higher rate of complications. OMI usage frequency increased with more clinical years of experience, practitioners with more than 10 years of experience were more likely to place OMIs than with less than 3 years of experience. A limitation of this self-reported study is that it is subject to inclusion bias, also as it is cross-sectional in design no long-term data is available so we cannot see trends in OMI use over time (Bungău *et al.,* 2024).

Another survey study in Romania consisting of 159 orthodontists with a response rate of 64% found that over half had less than 5 years of experience.

Clinicians with less than 5 years of experience completed training that was mostly theoretical, while clinicians with over 11 years of experience completed training that also had practical components. Most common motivation for usage was the potential to offer more efficient treatment. Titanium OMIs were most commonly used >60%. However this study was subject to recall bias and social desirability bias (Panaite *et al.,* 2024). These studies highlight the need for further education on placement of OMIs and complications that arise with their use in order to increase their usage in practice.

Ashton *et al.,* (2023) carried out an international survey study in 2023, this included 256 orthodontists with a 10% response rate. Respondents were asked questions on the last 6 TSADs they had placed. The most common reasons given were closing extraction spaces, followed by intrusion of posterior teeth. However orthodontists from South America reported distalising the posterior segment as the most frequent use of TSADs. Interestingly, 15% of respondents had never placed a TSAD before, and half of respondents did not place a TSAD during training programme. Angulation of TSAD insertion differs internationally with North American orthodontists electing for a more perpendicular placement, whereas orthodontists from elsewhere report a more oblique angulation utilising more cortical bone contact. The most reported complication was mobility/loss (88.9%) followed by root contact (26.9%). A limitation is although the study is international the survey was only undertaken in English, and the answers were limited to the last six TSADs, which may therefore fail to provide a representative assessment of TAD practice.

1.2.6 Factors influencing success of OMIs

1.2.6.1 Patient-related factors

1.2.6.1.1 Age

There is conflicting evidence in the literature regarding age and success of OMI. Some studies show no difference in survival rates due to age (Thean *et al.,* 2018; Umeh *et al.,* 2023). A recent systematic review and meta-analysis based on 15 studies concluded no substantial influence of age on OMI failure (Valeri *et al.,* 2024). A strength of this review was it included only *in vivo* human models. Other studies state that younger patients show reduced survival rates, potentially due to bone thickness (Moghaddam *et al*., 2021; Chen *et al.,* 2007).

1.2.6.1.2 Soft Tissue

Poor oral hygiene has been implicated in OMI failure (Aly *et al.,* 2018; Miyawaki *et al.,* 2003; Kravitz and Kusnoto, 2007). In a retrospective study based in an orthodontic department, soft tissue infections were noted between 6.3% and 33.3% of cases (Gurdan and Szalma, 2018). OMIs placed in non-keratinised gingiva has been shown to have higher failure rates due to persistent inflammation (Cheng *et al.,* 2004; Miyawaki *et al.,* 2003). OMI placed in the attached mucosa show higher success rates (Topouzelis and Tsaousoglou, 2012). A multicentre cephalometric retrospective study consisting of 218 patients looked at mini-plates in Class III malocclusion patients. One of the three centres gave oral antibiotics (amoxicillin clavulanic acid or clindamycin). Less failure was seen when the miniplate was placed in attached mucosa and post-operative antibiotics were given (Van Hevele *et al.,* 2018).

1.2.6.2 Procedure-related factors

1.2.6.2.1 Location of OMI

A systematic review of risk factors and survival of OMI found site of OMI placement to be a big contributor to success. The observed midpalate failure rate was 1.3%, with zygomatic buttress failure rate of 16.4%, mandibular buccal sites of 13.5%, and inter-radicular of 9.9% (Mohammed *et al.,* 2018).

A recent systematic review and meta-analysis by Valeri *et al.,* (2024) showed that there is significant differences in failure rates based on location. Of the 15 studies in the review, 5 were excluded as they only referred to a single jaw, of the 10 that were analysed, 9 found maxillary sites had higher failure rates, with only one showing higher failure in the mandible. A strength of this review was it included only *in vivo* human models.

1.2.6.2.2 Immediate Loading and Orthodontic Forces

Orthodontic forces of up to 400 grams can be applied to skeletal TSADs (Janssen *et al.,* 2008). A clinical trial investigated the failure rates of immediately loaded OMI for orthodontic anchorage. They found that the maxilla had a higher failure rate of 12.2% while the mandible had 8%. The results were similar to the available literature at the time suggesting immediate loading with light forces should not be considered a risk factor (Luzi, Verna and Melsen, 2007).

1.2.7 Success and Failure Rates

The literature shows promising results for the success of OMI with very high success rates being reported. An initial scoping review based on 103 articles by Jaramillo-Bedoya *et al.,* (2022) showed 47.6% of the studies had success rates over 90%. A clinical trial based on 87 patients and 227 OMIs of four different types in 2006 found an overall success rate of OMI to be 91.6% (Park, Jeong and Kwon, 2006). The authors concluded that inflammation had a significant effect on success rates. If OMIs were loosened they were considered failures, however if they remained in bone until the end of treatment or until treatment objectives were met, regardless of mobility they were considered successful. All OMIs were placed by a single operator potentially limiting the generalisability of the findings.

Failure rates of different TSADs were investigated in a systematic review in 2009. The analysis was based on 27 studies with observed failure of 7.3% for miniplates, 10.5% for palatal implants and 16.4 % for OMIs (Schätzle *et al.,* 2009). However, this study is now 16 years old and does not reflect current clinical practice. They do not outline an explicit definition for success or failure. Another limitation is the high heterogeneity among the 27 studies. A more recent systematic review involving a very large sample size of 4,987 OMIs among 2,281 patients considered the failure rates and associated risk factors noting an overall failure rate of 13.5% (Papageorgiou *et al*., 2012). However, similar to the study above, an explicit definition of failure was not delineated with a range of disparate primary studies included.

Another systematic review done in 2018 included 16 RCT's and 30 prospective cohort studies. The overall OMI failure rate was also shown to be 13.5% (Alharbi, Almuzian and Bearn, 2018). The large sample of 3250 OMIs, comprehensive search and clearly outlined success criteria are strengths; however, methodological and clinical heterogeneity among the primary studies was again noted.

1.2.8 Risks and Complications

Several risks and complications associated with the use of OMI have been reported in the literature (Kravitz and Kusnoto, 2007; Giudice *et al.,* 2021).

1.2.8.1 Root Contact

Root proximity and contact is a common complication of OMI insertion and has been shown to be an influential factor contributing to the success of OMI (Gintautaitė and Gaidytė, 2017; Montasser and Scribante, 2022). While the root does have some capacity to repair, the quality of repair is dependent on the extent of contact or perforation (Inchingolo *et al.,* 2023). If damage is limited to the PDL, cementum or dentine, healing and repair of the periodontium is more likely to occur (Alves *et al.,* 2013).

Ghanbarzadeh *et al.,* (2017) placed OMIs in 14 patients who were planned for extraction of the first premolars. The roots of these teeth were injured using self-drilling and self-tapping OMIs. 8 weeks were allowed for any repair of the roots before being extracted and examined. In all teeth, normal responses to vitality tests were seen. No difference between the self-drilling and self-tapping was seen. 75.4% of teeth extracted had formed reparative cementum while 24.5% showed no repair.

Root perforation is a risk associated with OMIs and root treatment may be required if a tooth loses vitality to restore it. Ankylosis is at risk of occurring if more than 4mm of the root is damaged (Hwang and Hwang, 2011). A small sample clinical trial looked into roots that came in contact with OMI. The results showed root repair within a few weeks after the removal of the OMI screw or the orthodontic force (Kadioglu *et al.,* 2008).

A systematic review suggests recording certain parameters during insertion could provide immediate information and diagnosis of root contact as the insertion torque increases when OMI contacts roots (Meursinge Reynders *et al.,* 2016b).

1.2.8.2 Displacement

Although OMIs can provide absolute anchorage during orthodontic treatment, they do not remain absolutely stable throughout treatment. The displacement of OMIs was assed using cone beam computed tomography. It was found that on average 0.78mm of displacement was seen for buccal, palatal and mid-palatal OMIs but this is of limited clinical relevance (Alves, Baratieri and Nojima, 2011). It has been suggested in the literature that this displacement could be attributed to a higher rate of bone turnover and active remodelling (Zhao, Jia and Wang, 2023).

To minimise the risk of damage to adjacent structures it has been recommended a 2mm clearance between the OMI and dental roots, or placing the OMI in an extra alveolar site, free of any vital structures (Liou, Pai and Lin, 2004).

1.2.8.3 Failure

Investigation in the survival of OMI found the risk of failure is highest immediately post-placement. This risk reduced over time, the authors suggesting that this is perhaps due to gradual osseointegration of the OMI (Lee *et al.,* 2010). A more recent study in Nigeria in 2023 also showed that TSAD failure in orthodontic patients was highest within one month of placement (Umeh *et al.,* 2023).

1.2.8.4 Contraindications

Table 1.11 OMI contraindications.

Category of Contraindication	**Specific Contraindication**
General	Complex medical history
	Immunocompromised patients
Hard Tissue	Systemic bone disease
	Local factor - bone remodeling (e.g., extraction site, exfoliation of a primary tooth)
Soft Tissue	Active periodontal disease
	Poor oral hygiene
Attitude-related	Lack of commitment or motivation for complex treatment

1.3 Palatal Mini-implants

1.3.1 History and Development of palatal Mini-Implants

Palatal placement of OMI offers many advantages over buccal and interradicular placement. The extra alveolar location ensures reduced risk of root contact or periodontal ligament damage. The thick cortical bone and increased depth of palatal vertical bone height provide good stability. However, there is a tradeoff between good stability and a potential increase in risk of fracture as the density of the bone increases. The nature of OMI means treatment does not rely on patient compliance for anchorage, which we know is poor (Schlegel, Kinner and Schlegel, 2002). This poor compliance risks compromised results and makes it more difficult to achieve our treatment aims and objectives.

Palatal implant trials were first described by Block and Hoffman (1995), who carried out canine and monkey trials using "onplants". A disc 2mm high and 10mm in diameter, coated on one side by 75 μm thick layer of hydroxyapatite with an internal thread on the other side was placed on the palatal bone and after integration was connected to the teeth for anchorage. The purpose of the canine study was to determine the ability of the onplant to remain stable once integrated. The purpose of the monkey study was to investigate the ability of the onplant to remain stable during retraction of the anterior dentition. Although this study contained a small sample size and is an animal trial it did confirm that palatal implants could provide absolute anchorage.

Palatal implants for orthodontic anchorage in humans were first described by Wehrbein *et al.,* (1996). The extraction of maxillary first premolars with retraction of the upper labial segment under maximum anchorage conditions was described. The Orthosystem by Straumann was used. A pure titanium surface-treated, screw-shaped endosseous implant of 3.3mm diameter and lengths of 4mm and 6mm were used. The surface treatment consisted of a grit sand-blasting with 0.125-0.25mm size particles and then acid etching with hydrochloric and sulfuric acid, followed by heat treatment. The self-tapping fixture was placed in the mid-palatal area after a mucosal punch had been taken. It was inserted at a 60-degree angle to the occlusal plane at the level of the first premolars. The maxillary first premolars were extracted 10 weeks after the insertion of the implant. 12 weeks after insertion an impression was taken and a trans-palatal arch was fabricated. This was fitted and active orthodontic treatment started in the same session. After 9 months of treatment no anchorage loss was noted. The extraction sites had all closed. Radiographic examination showed the implants in the same position, the premolars had moved mesially by approx. 0.5mm, and the canines and incisors had been retracted by 8mm. A small mesial movement of the molars was seen, however the authors attribute this to possible deformation of the TPA.

In 1997 the same authors carried out another canine study looking at shorter titanium screw implants in mid palatal region with a relatively short unloaded healing period. The length of the titanium screws was 6mm with diameter 4mm. The healing period in this study was 8 weeks, at which time orthodontic force was applied for 26 weeks. This study showed that these short titanium screw implants retain their stability during orthodontic loading (Wehrbein, Glatzmaier and Yildirim, 1997).

In 1996 an *in vitro* study and a pilot clinical trial of implants was undertaken with a biodegradable component to obviate the need for a second surgery to recover the implant. Although the *in vitro* results seemed promising these implants failed to achieve suitable stability for orthodontic treatment (Glatzmaier, Wehrbein and Diedrich, 1996).

1.3.2 Popularity of mid-palatal TSADs

Markic *et al.,* (2014) carried out a survey among Swiss orthodontists asking case-specific and general questions, with a response rate of 24.4% (108 responses). The case was an adult female with Class II div 2 malocclusion complicated by a deep bite, upper labial segment crowding and a history of fixed orthodontic treatment with four premolar extractions. 75.1% of responders suggested treatment with maxillary TSADs and distalisation, 3.7% suggested TSADs or headgear with Class II mechanics and surgery. 70.6% of responders would have used palatal TSADs, followed by 22.4% using buccal OMIs, the least popular choice being infrazygomatic mini-plates (7%). A limitation of this study is it’s very low response rate, it is self-reported in nature, hence being subject to reporting, recall and non-response bias.

A survey carried out in Germany by Bock and Ruf, (2015) was also seeking information about how common skeletal anchorage was within the German-based orthodontists, and in what clinical situations was it being used. In 2013, 2,459 members of the German Orthodontic Society were posted questionnaires, a response rate of 48% was seen. 62% of responders indicated using skeletal anchorage, however, most were using them infrequently. Reasons for choosing not to use skeletal anchorage were scepticism over the success and failure rates, and complex and lengthy procedure for placement. This study had a higher response; however, it remains subject to reporting, recall and non-response bias.

1.3.3 Anatomical considerations

1.3.3.1 Mid palatal suture ossification

The mid-palatal suture is a high-density site when ossified, making it a good location for OMI. If the suture has not been ossified, placement of an OMI could interfere negatively with growth (Asscherickx *et al.,* 2005). Ferrillo *et al.,* (2024) carried out a cross-sectional study analysing 201 subjects CBCT scans and lateral cephalograms and the mid-palatal suture maturation. Age, gender, and vertical skeletal patterns were the parameters being examined. As age increased, the chance of belonging to a higher maturation stage increased. No correlation between vertical skeletal patterns and maturation was seen. The authors concluded that chronological age is associated with maturation, and this occurred later in males.

In view of the age-related changes at the mid-palatal suture, para-median placement is now favoured. Wilmes *et al.,* (2016) therefore proposed the use of: The T-Zone. The authors discussed the advantages and disadvantages of the median or paramedian sites for OMI placement. Median sites are less likely to damage incisor roots and have more available bone, however, this location for placement also runs a higher risk if damage to the incisive canal. Although it has been proposed by Asscherickx *et al.,* (2010), that median placement may interrupt growth at the suture, the authors have not experienced this unwanted effect. The paramedian sites are less likely to penetrate the incisive canal or interfere with the suture but the risk of root damage is higher. They also advocated the use of two implants to be used in tandem to prevent any tipping or rotational issues secondary to the development of couples.

1.3.3.2 Palatal Bone vertical thickness/height

It is difficult to directly compare studies quantifying the thickness of structures in the oral cavity due to different methodologies. Studies differ as they measure from the dentition, the mid palatal suture, or the palatal rugae. Considering anatomical variation, crowding and displacement of teeth makes this difficult for comparison. Baumgaertel (2009), suggested the area that is most favourable for TSAD placement in the palate is at the level of the first and second premolars. It was found that bone depth decreased with increasing distance from the midsagittal plane, and from anterior to posterior. Cortical thickness also decreased from anterior to posterior.

Palatal OMI bicortical engagement reduces OMI fracture, improves stability and expansion, and creates a more parallel expansion in bone-borne devices. Although bicortical engagement itself improves stability, the depth of engagement is not significant (Lee, Moon and Hong, 2017).

Farnsworth *et al.,* (2011), compared cortical bone thickness at various intraoral sites for OMIs. 26 adolescents and 26 adults CBCTs were examined in this study. It was found that for palatal sites 3mm lateral to the incisive foramen and at 3mm, 6mm and 9mm dorsal to the incisive foramen. It was found that the cortical bone was significantly thicker at the 3mm site than at the 6mm and 9mm sites. This thickness ranged from 0.2 to 1.8mm in adolescents and 0.5 to 1.8mm in adults.

Gracco *et al.,* (2008), investigated the palatal bone thickness in 162 patients based on CT scans. This sample was divided into three groups based on age, 10-15 years, 15-20 years, 20-44 years. The area with the greatest depth was found in the anterior palate at the suture and in the paramedian areas. This was between 4-8mm thick. The authors found no statistical differences between the groups except between the 10-15 years and 20-44 years groups at the 16mm paracoronal site 6mm from the midline.

A systematic review in 2014 looked at the literature available at the time to give recommendations of where to place mid-palatal TSADs. They found because of the heterogeneity of the studies so far, comparison was difficult. However, their compilation of the data suggested that 3mm behind the incisive foramen, 3 to 9mm lateral to the mid-palatal suture would contain adequate palatal bone height for placement of OMI (Winsauer *et al.,* 2014).

It has been shown that lateral cephalograms underestimate the amount of available vertical bone in the mid-palatal, middle and anterior maxillary regions by about 2mm (Wehrbein, Merz and Diedrich, 1999). Hourfar *et al.,* (2015a), were the first to investigate bone thickness and vertical heights based on soft tissue locations. As it was seen in the literature that the palatal rugae stayed stable throughout growth this location was chosen to investigate (Kim *et al.,* 2012). Plaster model scans were superimposed on lateral cephalometric radiographs pre-treatment and post-treatment, bone height was measured at the first, second and third palatal rugae in an oblique and vertical orientation. They found an adequate level of bone availability at the level of the third rugae on average 9.9mm. OMI of 8mm length and 1.6mm diameter were placed 1-2mm lateral to the mid-palatal suture at the level of the third rugae in an oblique orientation.

Considering, distance to the central incisor apex, available bone height and potential for movement of the incisor during treatment, the position of the most distal (third) rugae was seen as a stable and identifiable landmark for mid-palatal OMI placement (Hourfar *et al.,* 2015a).

The authors then went on to investigate using three-dimensional radiography. This study confirmed their previous findings and showed that the level of the third rugae is a stable and clinically identifiable landmark. They also found that the bone height reduces the more posterior you go. Bone availability was highest between the contact points of the canines and first premolars at the level of the second rugae 90 degrees to the bone, it ranged from 9.74mm to 13.86mm. Cortical thickness along this line ranged from 1.4 to 1.65mm. The level of the third rugae between the contact points of the first and second premolar cortical level was found to be on average 1.08mm (Hourfar *et al.,* 2015b).

Lyu *et al.,* (2020), recommended gender and age specific sites for mid-palatal TSAD placement. This was based on a small sample for 15 adult and 15 adolescent patient CBCT scans. In keeping with previous literature, it was found that the palatal thickness decreased from anterior to posterior and from medial to lateral in a V-shaped pattern.

A retrospective CBCT study based on 36 subjects (mean age 17.1 +/- 4.1 years) using the third palatal ruga as a reference looked at the anatomical characteristics and found that the area with maximum bone depth (9.7mm) was 2mm posterior to the third ruga and 4mm lateral to the mid-palatal suture (Nucera *et al.,* 2022)

A prospective clinical study looking at the morphology of the palate was undertaken investigating its influence on TSAD placement accuracy. This was the first of its kind in the literature. 24 subjects were divided into three groups based on the morphology of the palate (medium, steep/high vaulted or low/flat). A computer guided navigation system Navident was used. Intraoral scans and CBCT pre and post placement along with virtually planned positions were superimposed and examined in two dimensions and three dimensions. The authors concluded that high or steep palatal vaults are associated with lower accuracy and angulation of the OMIs (Brilli, Cauli and Cassetta, 2024).

1.3.3.3 Bone Density

Increasing bone density has a positive effect on the success rates of OMI. CBCT scans of 71 patients who received 127 OMI were evaluated. As the cancellous bone density increased, so too did the success rate of the OMIs. Cortical bone density did not have a significant effect on the success rates (Lee *et al.,* 2016).

CT scans of 30 patients were evaluated to investigate the density of the palatal bone for implant placement. 15 males and 15 females, aged between 23-54 with a mean age of 27 years. It was shown that the density of the palate was greatest in the mid-palatal area and within 3mm of the midsagittal suture. Similar to vertical bone height thicknesses, density of the palatal bone decreased laterally and posteriorly (Moon *et al.,* 2010).

A cadaver study investigated the effect of density of the palatal bone and the stability of OMI; this was measured by recording the maximal insertion torque. They found that the stability of OMI in the palate is affected by bone quality and quantity and that the highest primary stability was found anterior to the second premolars (Bourassa *et al.,* 2018).

1.3.3.4 Epithelial Thickness

OMIs have a higher failure rate when placed in unattached mucosa (Cheng *et al.,* 2004). The whole palatal mucosa is keratinized. Selecting an OMI with a transmucosal collar that is suitable for the thickness of the mucosa may increase the success rates. Measurement of thickness of the palatal mucosa can be carried out by CT scans, CBCT scans, ultrasonic devices or manually probing down to bone. Several authors found similar trends with palatal mucosa, increasing thickness with age and increasing in thickness from median to lateral and from posterior to anterior (Marquezan *et al.,* 2012; Gibas-Stanek *et al.,* 2023; Poorsattar-Bejeh Mir *et al.,* 2017). There is coincident evidence between genders, showing that males have thicker palatal mucosa (Gupta *et* *al.,* 2014; Parmar *et al.,* 2016; Cha *et al.,* 2008). When in doubt about palatal mucosa thickness it has been recommended to choose OMIs with longer transmucosal necks to avoid gingival overgrowth (Ziebura, Flieger and Wiechmann, 2012). Nucera *et al.,* (2022), suggest a transmucosal collar of 2-2.5mm for optimal mucosa adaption. Song *et al.,* (2008) analysed 100 CT scans and found the overall thickness of the palatal mucosa is 3.83 +/- 0.58mm.

1.3.3.5 Nerves and Blood supply to the Palate

1.3.3.5.1 Greater Palatine Foramen

The greater palatine foramen is the oral opening of the greater palatine canal and houses the innervation and blood supply of the hard and soft palate. There is a low risk of damage to these vessels when placing palatal OMI but their location is essential to every clinician. It is a bilateral oval-shaped hole located at the level of the third molar most commonly in men and women (Yilmaz, Boke and Ayali, 2015). It has also been noted that it is commonly found between the second and third molars (Fu *et al.,* 2011; Oduncuoğlu *et al.,* 2023). Its diameter ranges from 2.7mm to 4.9mm (Methathrathip *et al.,* 2005). It is most commonly found approximately 15mm from the mid-palatal suture coursing anteriorly close to the alveolar ridge (Tomaszewska *et al.,* 2014; Kim *et al.,* 2023).

1.3.3.5.2 Nasopalatine Nerve

The opening of the nasopalatine canal is called the incisive foramen. It is found 5-6mm posterior to the maxillary central incisor roots (Cho *et al.,* 2016). In a CBCT study looking at the vertical bone heights and locations of structures that could potentially be damaged by mid-palatal implants, the risk of damage to the nasopalatine nerve is highest 3mm anterior to the level of the first premolars and in the midsagittal area. The more posterior, the less risk for potential damage to the nasopalatine nerve (Kawa *et al.,* 2017). Morphological assessments of the nasopalatine canal in children revealed many different configurations with most having a single canal, but double and even up for 4 separate canals were also seen. In this study the mean width of the incisive foramen was found to be 2.53mm (Sekerci, Buyuk and Cantekin, 2014). Another CBCT study focusing on an adult population for the mean incisive foramen diameter to be 4.49 +/- 1.71mm (Friedrich *et al.,* 2015).

Tilen *et al.,* (2017) analysed 298 CBCT scans retrospectively for relationships between the nasopalatine canal, skeletal vertical dimensions, and palatal bone height at various locations. The mean vertical bone height at the first and second premolar interproximal area was seen to be 5.22mm and was seen to be at low risk for neuro-sensory impairment. The nasopalatine canal morphology was negatively correlated with vertical skeletal relationships. The authors suggest that in high-angle patients a more distal or paramedian placement of the palatal TSAD should be considered.

1.3.3.6 Nasal Cavity

Minimal complications with maxillary sinus perforations with OMIs have been reported (Costa, Raffainl and Melsen, 1998). Nasal cavity perforation was studied on cadaver maxillae. Lateral cephalograms and low-dose CT scans were obtained from the maxillae and implants placed based on these. A second lateral cephalogram was taken post-implant insertion and superimposed on the original, 20% of implants projecting into the nasal cavity were false-positive records (Crismani *et al.,* 2005).

1.3.4 Palatal OMI Placement

The digital workflow protocol and placement procedure of mid-palatal TSADs has been described in the literature (Maino *et al.,* 2016; Cassetta *et al.,* 2018). The procedure requires an intraoral scan and a radiograph in the form of a lateral cephalogram, although for complex malocclusions a CBCT may be justified. 3D planning software to accurately plan position of the TSADs and fabrication of a surgical guide. A benefit of intraoral scanning, digital planning and guided techniques have been a reduction in risks and allow for precise controlled placement of mid-palatal TSADs.

Based on a prospective cohort study, if two mid-palatal TSADs are being placed, a one-visit protocol is sufficient (Pozzan *et al.,* 2022). However, if four mid-palatal TSADs are being placed, more accuracy is required, and a two-visit approach should be undertaken. This study looked at the influence each step of the digital workflow had on the planned and final positioning of TSADs and the accuracy between them. It was a small sample study, and the accuracy measured is dependent on the quality of the scans and radiographs and how these are interpreted which may lead to bias.

Another recent study by Ronsivalle *et al.,* (2023) looked at the accuracy of digital workflow based on orthodontic 3D analysis and planning software versus restorative dentistry generic open licensed systems (Blue Sky Plan versus Dolphin Imaging Software). The accuracy was based on angular deviations. No significant differences were noted between the two software systems. Interestingly, although a significant difference was not noted between the two software's, there was a statistically significant difference noted between the left and right-side accuracies (1 degree difference). This study suggests that generic implant planning software is adequate for planning the placement of mid-palatal TSADs rather than expensive orthodontic specific software. The limitations of this study are its small sample size (of 20 patients), both operators who were right-handed and its measurements were only based on the intraoral portion of the TSADs and did not examine the intra-osseous portion of the TSAD. Clinicians should be mindful of software that is not compatible with certain intraoral scanners and types of digital files.

The differences in accuracies between conventionally manufactured surgical guides versus 3D printed guides, with five different materials were investigated. It was concluded that whilst 3D printed surgical guides may be used in clinical practice, conventionally made surgical guide (Pattern Resin LS by GC) represents the gold standard with the highest transfer accuracy for insertion of mid-palatal TSADs (Mang de la Rosa *et al.,* 2023). 3D-printed guide made of

IMPRIMO LC Splint, and conventionally made Memosil 2 presented with the largest angular and linear deviations. This study was based on 96 mid-palatal TSADs, placed on two different patient models, using five different material guides.

A recent study by Al-Gazzawi *et al.,* (2024) analysed the accuracy of digital planning and surgical placement of mid-palatal TSADs using resin guides. Very promising results were seen with errors of less than 1mm in both vertical and horizontal planes recorded with surgical guided placement of mid-palatal TSADs.

Jung *et al.,* (2011) looked at the quantity of bone found on lateral radiographs versus 3D CBCT scans to see if 3D scans were necessary for paramedian OMI insertion treatment planning. The authors concluded that the vertical bone seen on a lateral radiograph represented the minimum bone height in the median plane. They advocate that a 3D radiograph is only necessary if an insufficient quantity of bone is seen on the lateral radiograph. Möhlhenrich *et al.,* (2021) compared vertical bone heights measured from lateral cephalograms and CBCT of 30 fresh cadaver heads. It was found that the bone height measured on the lateral cephalogram was accurate for mid-palatal but slightly less for para-median sites. Therefore, lateral cephalograms are adequate for treatment planning OMI insertion in the mid-palatal region. A limitation of this study is the age range of cadavers was between 66 and 84 years old. A recent systematic review and meta-analysis by Haude *et al.,* (2025) investigated the literature in relation to two-dimensional and three-dimensional radiography for clinical orthodontics. 41 articles were included for analysis. The results confirm that two-dimensional radiography is sufficient for OMI placement planning.

Therefore, when measuring the vertical bone height for planning palatal OMI placement, a lateral cephalogram is justified, if insufficient bone is seen on the lateral cephalogram a CBCT scan is justified for bone height measurement (Jung *et al.,* 2011).

1.3.5 Indications and Applications

Mid-palatal TSADs can be used in many different treatment modalities, for anteroposterior anchorage, vertical anchorage, and transverse expansion.

1.3.5.1 Retraction

The first report of an RCT looked at comparing mid-palatal implants with headgear for absolute anchorage took place in the United Kingdom and was published in 2007. The sample consisted of patients with Class II div 1 malocclusions who required absolute anchorage while retracting anterior incisors. The results show that there was more posterior movement of the maxillary incisors (mean 2.1mm) in the implant group than in the headgear group (mean 0.7mm). There was also more mesial movement of the maxillary molars in the headgear group (mean 3.0mm) compared to the implant group (mean 1.5mm) (Benson *et al.,* 2007).

Anchorage for en-masse retraction was evaluated in a systematic review by palate by Becker *et al.,* (2018). In this study they analysed the effect of OMI use compared to conventional methods for anchorage in patients who required retraction of the upper labial segment. With indirect anchorage some anchorage loss is seen, whereas, maximum anchorage is associated with direct anchorage and the ideal location is the palate.

1.3.5.2 Distalisation

Palatal TSADs can be used to distalise the posterior dentition. This can be done with a pendulum appliance or a lingual arch type appliance. Pendulum type appliances can distalise the upper molars but also have an effect of distal tipping and intrusion that is not seen with the lingual arch type appliances (Mah *et al.,* 2016).

A systematic review in 2024 compared distalisation of maxillary molars with the use of TSADs based on their placement location: palatal, buccal and zygomatic, number and appliance design. Only 4 studies were identified in the literature for analysis. Distalisation of the maxillary molars was not seen to be significantly greater by palatal and zygomatic than by buccal TSADs. The authors suggest further studies in this area would provide more clinical evidence (Ceratti *et al.,* 2024)

Anchorage can be direct or indirect. To use palatal TSADs directly, lingual fixed appliances would be required. Torque control of the upper labial segment is difficult with lingual appliances (Liang *et al.,* 2009). Controlled retraction of upper labial segment has been shown to be effective without anchorage loss or torque control loss with the use of mid-palatal TSADs (Hong, Heo and Ha, 2005).

1.3.5.3 Intrusion

Intrusion forces on the palate, will cause palatal tipping of dentition. A TPA is needed to counter these forces. Hong *et al.,* (2013) described a case report in which a 31-year-old female patient with a gummy smile was treated over 18 months with intrusion of the entire maxillary arch.

A similar case report of a 26-year-old female was published in 2017, with 22 months of active treatment, differential intrusion of anterior and posterior teeth was accomplished with a single mid-palatal TSAD, TPA, extraction of upper and lower first premolars, accentuated and curve of Spee on the maxillary and reverse curve of Spee on the mandibular archwires (Paik, Park and Ahn, 2017).

1.3.5.4 Expansion

The first report of lateral maxillary expansion by separation of the maxilla was in January 1860 by Emerson Colon Angell. Angell described a 14-year-old patient who he had treated with an ectopic left lateral incisor and premolars in crossbite was corrected using a unique appliance with contrarotating screws relying on pressure from the screw to push against the necks of the teeth. Angell claimed that by turning this screw the maxilla separated laterally in 2 weeks correcting the malocclusion and creating a midline diastema (Timms, 1999).

Rapid maxillary expansion (RME) hybrid expanders consist of two palatal implants connected to an expansion screw and to the first permanent molars via orthodontic bands. Walter *et al.,* (2017) compared three different bone-borne RME hybrid expanders. They compared single and double arm force transmitting systems, the authors suggest that double wire arms should be mandatory in adults and late adolescents as double wire arms or using a greater diameter wire may provide greater stability and withstanding force.

A prospective RCT comparing rapid palatal expansion (RPE) with micro-implant assisted rapid palatal expansion (MARPE) on skeletal and dental effects found that mid-palatal suture separation occurred 90% in the RPE group and 95% in the MARPE group. The authors concluded that the reinforcement of the RPE with OMIs helps to maintain the basal bone during consolidation (Chun *et al.,* 2022).

A study published in 2023 compared the results of MARPE in adults and later adolescents. Evaluated of CBCT scans revealed that as age and maturation stage increased, the effectiveness of the MARPE treatment decreased (Nie *et al.,* 2023).

A recent study assessed 17 adult patients who underwent bone-born maxillary expansion to assess the dental and skeletal effects. CBCT scans were evaluated pre-treatment and post-treatment. Expansion was seen at a rate of 0.17mm/day. Mid-palatal suture opening was seen in 100% of patients. Expansion was seen in a pyramidal pattern with the posterior nasal spine opening was 61% of anterior nasal spine opening (Ponna *et al.,* 2024).

The Delphi study by Franchi *et al.,* (2025) concluded that bone-borne expansion produces less buccal inclination of the teeth then tooth borne.

1.3.6 Success and failure rates

1.3.6.1 Success-related Factors for Palatal TSADs:

A range of patient, procedural and TSAD specific features have been implicated in the success of para-median TADs. These include the following:

TSAD Morphology: (Wu, Kuang and Wu, 2009), (Männchen and Schätzle, 2008) (Ichinohe *et al.,* 2019)

- Length
- Diameter
- Thread
- Shape
-

Patient-related factors:

- Age (Kim *et al.,* 2010)
- Medical history and wound healing (Jung *et al.,* 2012)
- Oral hygiene (Wu, Kuang and Wu, 2009)
- Hard tissue factors: (Ichinohe *et al.,* 2019) (Gedrange *et al.,* 2005)
    - Bone quality and quantity
    - divergence of roots
- Soft tissue factors:
    - Inflammation
    - Morphology of palatal mucosa

Procedure-related factors:

- location/insertion site (Kim *et al.,* 2010) (Mohammed *et al.,* 2018) (Hourfar *et al.,* 2017)
- technique sensitive/difficulty
- immediately loaded or healing period
- magnitude and direction of force
- number of OMI (Kim *et al.,* 2010)

Clinician-related factors: (Karagkiolidou *et al.,* 2013)

- operator experience
- placement on the left or right-hand side

Surgeons experience and operating skills have been seen to positively affect the success rate of mid-palatal TSADs (Crismani *et al.,* 2010; Lim *et al.,* 2011; Kim *et al.,* 2010). Jung *et al.,* (2012) carried out a retrospective analysis involving 239 palatal implants placed between January 1998 and 2007. Data analysed included: age, gender, vertical bone height, surgeons experience and implant type. The authors attributed "surgeons experience" as the cornerstone of palatal implant success.

Baumgaertel *et al.,* (2020) carried out a retrospective analysis of 109 OMIs placed during orthodontic residency programs over a 10-year period from 2006 to 2016. The anterior palate had the highest success rate. The authors found a success rate of 83.9% and therefore advocate for this location when beginner clinicians are placing skeletal anchorage. They also found that OMI's used indirectly had a higher success rate than direct anchorage but highlight that further research in this area is needed to clarify why.

1.3.6.2 Success Rate

Implant success has been defined as fulfilling "anchorage objectives with or without mobility or even with displacement" (Reynders, Ronchi and Bipat, 2009).

Asscherickx *et al.,* (2010) found a 91% success rate for palatal implants. 33 palatal implants were placed, with a success rate 88.8% in the adult group (mid-palatal placement) and 92% in the adolescent group (paramedian placement).

Hourfar *et al.,* (2017) carried out a retrospective cohort study on 239 patients who had skeletal anchorage loaded with a force greater than 2 Newtons. The authors found very promising success rates of 98.4% for OMI placed in the anterior palatal at the level of the third ruga. There was a statistically significant difference in the success rate of palatal OMI compared to buccal interradicular OMI. A success rate of 71% was seen for buccal interradicular OMIs.

Mohammed *et al.,* (2018) carried out a systematic review and meta-analysis on the role of anatomical site and correlated risk factors for the survival of OMI. For palatal OMI the failure rates were catagorised based on the placement location: mid-palatal, paramedian, and parapalatal. Although there was very low to low quality evidence for mid-palatal locations, they had promising failure rates of only 1.3%. Failure rates for OMIs in paramedian sites and parapalatal sites were 4.8% and 5.5%, respectively.

1.3.7 Complications

A range of complications have been associated with TAD placement and removal. A retrospective analysis involving 101 implantations and 44 explantations of palatal implants in 146 patients who received orthodontic treatment in a university setting between 1999 and 2010 were evaluated (Fäh and Schätzle, 2014) (Table 1.12 and 1.13).

Table 1.12 Palatal implantation complications.

Complication	**Associated Percentage**
No primary stability	6.70%
Prolonged pain	6.70%
Secondary bleeding	5.80%
Perforation of nasal floor	1.90%
Necrotic mucosa	1.90%
Sensory impairment	1%

Table 1.13 Palatal explantation complications.

Complication	Associated Percentage
Disturbed wound healing	6.80%
Perforation of nasal floor	2.30%
Secondary bleeding	2.30%
Fracture of the implant	2.30%

1.4 Patient Experience

1.4.1 PREMS and PROMs

To gain a better understanding of our treatments and strive to provide patient-centred care, we must understand the outcomes related to the patient and their experiences (Kingsley and Patel, 2017). This concept can be thought of as Patient-Related Outcome Measures (PROM) and (PREM) Patient-Related Experience Measures. These are important in assessing quality of care (Coulter, 2017). Orthodontic treatment research regarding PROMs and PREMs is increasing (Tsichlaki and O'Brien, 2014). However, no research has looked at PREMs and mid-palatal TSADs.

Young people experience physical, practical and emotional effects of orthodontic treatment (Kettle *et al.,* 2020). Some complications with fixed appliances include sore mouth, breakages, gingivitis, with greater effects in relation to pain, speech and eating. However even with these negative effects, the literature shows that 87% would have treatment again, with 91% recommending treatment to a friend (Bradley *et al.,* 2020).

1.4.2 Patient Experiences and Orthodontic Treatment

1.4.2.1 Orthodontic Treatment and Pain Experience

McCaffery, (1968) stated that “pain is what the person says it is and exists whenever he or she says it does”. Pain is subjective and multidimensional which makes it very difficult to objectively measure (Katz and Melzack, 1999; Consuelo *et al.,* 2023). There have been many complex attempts at quantifying pain and discomfort with orthodontics in a multidimensional way in the literature (Wideman *et al.,* 2019). A unidimensional method considers only one factor or characteristic of pain. A common unidimensional method is with a Visual Analogue Scale (VAS) is a simple, valid, quick and effective tool in quantifying subjective phenomenon (Maxwell, 1978; Price *et al.,* 1983). Pain varies based on age, gender, personality, culture, previous experience and expectations (Breivik *et al.,* 2008; Reed and Van Nostran, 2014).

In 2020 the International Association for the Study of Pain (IASP) revised its definition of pain as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage". Pain is a common side effect of orthodontic treatment (Bergius, Kiliaridis and Berggren, 2000). Pain from orthodontic appliance placement is felt after 2 to 4 hours, peaks at 19 to 24 hours, decreases by day 3 and continues to decline until day 7 (Erdinç and Dinçer, 2004; Salmassian *et al.,* 2009; Abed Al Jawad *et al.,* 2012; Inauen *et al.,* 2023). Other studies show that it peaks at 12-14 hours post-placement (Bernhardt *et al.,* 2001). There have been reports of younger patients reporting less pain, more pain being felt in the morning and pain being felt still after 7 days (Firestone *et al*., 1999; Inauen *et al.,* 2023).

1.4.2.2 Orthodontic Treatment and Functional Impairments

Orthodontics is associated with functional impairments such as difficulty with chewing. Studies have shown that diet does change due difficulties with alterations in chewing, pain, and also as a response to instructions from the orthodontist (Abed Al Jawad *et al.,* 2012). Physical problems while eating such as taking longer and being messy also restricts food choices (Carter *et al.,* 2015). It has been reported that adults are more affected by functional impairments such as mastication and potentially weight loss (Negruțiu *et al.,* 2024).

1.4.3 Patient Experiences with TSADs

Extraction of a tooth has been shown to be more unpleasant than a dental implant placement (AlQutub, 2021). A systematic review has shown that pain expectation was greater than actual pain experiences due to the placement of interradicular OMI and pain was almost non-existent after 7 days (de Paiva *et al.,* 2023). Pain during some OMI procedures has been reported to be caused by the infiltration of anaesthetic itself (Gündüz *et al.,* 2004).

Studies have looked at buccal interradicular OMI placement with local anaesthetic infiltration or topical only. Patients prefer infiltration of local anaesthetic rather than topical alone. Topical had more failures, and gave less predictable, less comfortable and inadequate levels of anaesthesia (Lamberton *et al.,* 2016) The pressure felt during placement was the most unpleasant sensation, if great pain was reported infiltration of anaesthetic was given (Valieri *et al.,* 2014).

Mousa *et al.,* (2023) carried out a systematic review on PROMs with TSADs. This systematic review included three randomised control trials, a prospective cohort study, and a retrospective cohort study. Pain, discomfort, swelling and functional impairment were analysed. However, the papers included in this systematic review were all at a high risk of bias. Meta-analysis could not be done because of the heterogeneity of methodologies. The authors concluded that the highest pain levels were associate with all forms of TSADs (OMI, onplants or mini-plates) compared to other anchorage methods, these levels decreased over the course of a week, and reduced to mild or no pain by 1 month (Mousa, Al-Sibaie and Hajeer, 2023; Sandler *et al.,* 2014; Feldmann, List and Bondemark, 2012; Lee *et al.,* 2008; Kuroda *et al.,* 2007).

While the above studies provide an indication of patient impacts and pain, they failed to account for analgesic consumption and soft tissue impingement such as cheek irritation.

1.4.3.1 Patient Experiences with mid-palatal TSADs

The literature regarding PREMs and PROMs with mid-palatal TSADs is limited. Gündüz *et al.,* (2004) carried out a questionnaire study carried out in 2 Austrian clinics looking at the acceptance rate of palatal implants. Eighty-five patients between 10 and 59 years (mean age 28) were given questionnaires before they completed their orthodontic treatment. The surgical protocol was not explicit although an oral surgeon was involved with the osseointegrated implant unloaded for 3 months. The results showed that 95% of patients were satisfied with treatment and adapted within 2 weeks. The most unpleasant stage of treatment was the injection. Discomfort with function such as speaking and eating was comparable to a trans-palatal arch. Once traction was applied to the palatal implant, some patients felt pressure, but most felt little or no pain.

Kawaguchi *et al.,* (2014) carried out a questionnaire-based study involving 64 patients in Japan comparing discomfort and pain after buccal and palatal OMIs and mini-plates. The miniplate was associated with more pain and discomfort. Palatal OMI showed prolonged discomfort levels. At 12 hours analgesics were taken in 95% of miniplate, 50% in OMI and 26.7% in palatal OMI groups. After 3 days analgesics were used in 35% of miniplate group, 7.1% in OMI and 0% of palatal OMI groups. Interestingly, 10% of patients from the palatal group noted a dull pain from the entire maxilla from the time of insertion that was different from the pain caused by the insertion.

Sreenivasagan *et al.,* (2021) carried out a cross-sectional questionnaire-based survey looking at pain perception associated with OMI. The study consisted on 244 (156 females, 88 males with a mean age of 23.9 +/- 6.4 years) subjects receiving 625 OMIs ranging from 1.2mm to 2mm diameter and 8 to 14mm length, these were inter-radicular, buccal shelf, infrazygomatic and palatal

OMIs. A questionnaire based on patient experience was given to the patients for self-reporting. Results showed that females gave higher pain scores. Palatal OMI caused greatest pain and caused greatest discomfort during speech and eating. Functional impairment from buccal TSADs related to highest scores for difficulty with laughing followed by IZC. In this study 155 orthodontists were also questioned on their protocols for patient management and adverse effects. Most common cause of pain as reported by practitioners was at the site of insertion, this was followed by ulceration caused by implant. The authors conclude by advocating for the prescription of analgesics when placing OMI's. A limitation for this study was the questionnaire was not given at a set time point following the procedure risking recall bias.

2 Chapter Two: Aims and Objectives

2.1 Aim

The aim of this two-part study is to evaluate patient experiences, success rates and complications with mid-palatal temporary skeletal anchorage devices (TSADs).

2.2 Objectives

2.2.1 Part 1: Patient experiences and discomfort associated with mid-palatal TSADs:

- To assess patient intraoperative experiences and discomfort associated with mid-palatal temporary skeletal anchorage devices (TSADs) using a bespoke questionnaire.
- To assess patient postoperative recovery experiences and discomfort associated with mid-palatal temporary skeletal anchorage devices (TSADs) using a bespoke questionnaire.
- To assess experiences and discomfort associated with mid-palatal temporary skeletal anchorage devices (TSADs) via Visual Analogue Scales (VAS), ordinal and binary scales.
- To use quantitative analysis and descriptive statistics to describe the experiences and discomfort associated with mid-palatal temporary skeletal anchorage devices (TSADs).

2.2.2 Part 2: Success rates and complications with mid-palatal TSADs:

- To evaluate retrospectively the rate of failure with mid-palatal temporary skeletal anchorage devices (TSADs) in a cohort.

- To evaluate retrospectively any complications with mid-palatal temporary skeletal anchorage devices (TSADs) in a cohort.
- To evaluate any associations between independent variables and failure or complications with mid-palatal temporary skeletal anchorage devices (TSADs) in a cohort.

3 Chapter Three: Materials and Methods

3.1 Ethical Approval

Ethical approval for this two-part study was obtained both from The School of Dental Science Research Ethical Committee, Trinity College Dublin (DSREC2023-05) and from Landesärztekammer Rheinland-Pfalz ethics committee (17095).

3.2 Participants and Recruitment

Data concerning palatal mini-implant insertion performed in a specialist practice setting (Traben-Trarbach Germany) was evaluated. All procedures were undertaken by a single experienced operator (B.L.).

Participants for Part 1 and Part 2 were derived from the same parent sample involving 743 patients. Consecutive analysis of TSADs placed over a 16-year period was carried out with the most recent insertion in August 2023.

3.3 Selection Criteria

3.3.1 Part 1: Patient experiences and discomfort associated with mid-palatal TSADs:

Inclusion criteria:

- Aged 10 to 21 years
- Non-smokers, with no allergies or medications
- No history of previous orthodontic treatment
- Willingness to participate in the study
- Patients receiving at least one mid-palatal TSAD

Exclusion criteria:

- Patients aged under 10 or over 21 years
- History of orthodontic treatment

3.3.2 Part 2: Success rates and complications with mid-palatal TSADs:

Inclusion criteria:

- Aged 10 to 21 years
- Non-smokers, with no allergies or medications
- No history of previous orthodontic treatment
- Willingness to participate in the study
- Patients receiving two mid-palatal TSADs

Exclusion criteria:

- Patients aged under 10 or over 21 years
- History of orthodontic treatment

3.4 Clinical Procedures

Demographic data and date of implant placement were recorded. All participants had TSAD placement according to the same protocol involving the use of 0.2ml to 0.5ml of local anaesthesia with insertion involving a guided stent and two 8mm x 1.7mm TSADs (OrthoEasy Pal, Forestadent, Pforzheim, Germany). All TSADs were placed para-median, 1-2mm lateral to the mid-palatal suture at the level of the third rugae, perpendicular to the palatal bone surface, at a speed of 60rpm, with unlimited insertion torque up to 50Ncm, using a Dentsply Sirona (Charlotte, USA) implant handpiece (1:20). Pre-drilling was not carried out. All clinical procedures were performed by the same experienced orthodontist (B.L.). The supra-structures were connected with the same type of abutment, attached with fixation screws to the inner thread of the TSAD (Forestadent, Pforzheim, Germany). An impression or scan was taken the day of placement, and an appliance was fitted within one week. The oral hygiene and TSAD status was monitored at each clinical visit.

3.5 Data Collection

3.5.1 Part 1: Patient experiences and discomfort associated with mid-palatal TSADs:

All data collection was undertaken in Germany. Patient names and addresses were recorded for the surveys to be posted. Patient date of birth and date of implant placement were recorded in order to meet our inclusion criteria of aged 10 to 21 years on the procedure date. Patient data was then anonymised in Germany. Anonymised data analysis and interpretation of results was undertaken on a password protected device with encryption in Ireland.

For **Part 1**, a 27-item bespoke questionnaire concerning intra-operative experience and post-operative recovery following the insertion of mid-palatal TSADs was developed (**Appendix 1**), based on previous orthodontic questionnaire literature (Patel *et al.,* 2016; Benson *et al.,* 2016; Valieri *et al.,* 2014). Overall experience; pain experience and the use of analgesia; requirement for additional visits; impacts on hygiene, speech, eating, sport and other hobbies including music; and social impacts were assessed.

Reponses involved the use of a 10-point VAS (Visual Analogue Scale) as well as ordinal (Much better/Better/As expected/Worse/Much worse) and binary scales (Yes/No). Pain was described as mild, moderate or severe with a score 0-4 is classified as mild, 5-6 moderate, and 7-10 indicative of severe pain (Jensen *et al.,* 2017; Serlin *et al.,* 1995).

To guarantee the integrity and cross-cultural applicability of the questionnaire, we implemented a robust translation and back-translation protocol (**Appendix 1**). The original English version served as the foundational document. For the initial forward translation into German, we engaged a highly proficient English-speaking German colleague. Their expertise was instrumental in ensuring that the translated content accurately conveyed the original meaning while also being culturally appropriate and naturally sounding for German speakers. Following this, a back-translation step was undertaken. This involved a fluent German-speaking Irish colleague translating the German version back into English. This back-translation phase actively accounted for potential cultural differences, ensuring that the concepts and questions remained universally understood and interpreted as intended across both linguistic and cultural landscapes.

After applying the inclusion criteria, questionnaires were sent to 550 participants in January 2024. A window of 3 months was allowed for responses with one reminder sent to non-responders. Responses were received via post.

3.5.2 Part 2: Success rates and complications with mid-palatal TSADs:

Part 2 involved retrospective analysis of patient records. Participants were derived from the same parent sample involving 743 patients with those receiving paired mid-palatal TSADs examined in this study. From a cohort of 743 patients in which the ages ranged from 6 to 59 years, 451 participants aged 10 to 21 having two mid-palatal TSADs each (902 TSADs overall) were included in the analysis.

The following demographic and clinical variables were recorded:

- Gender: male, female.
- Age: from 10 to 21 years.
- Incisor relationship: Class I, Class II (division 1 and 2 combined), Class III.
- Frankfurt-mandibular planes angle (FMPA): in degrees.
- Oral hygiene status: positive, negative, variable.
- Attendance: good, intermediate, poor.

- TSAD function/indication: Maximum AP anchorage (TPA), transverse expansion, molar distalization, molar intrusion, molar protraction, molar re- and protraction.

Any associated complications and days to failure were recorded. If both mid-palatal TSADs remained *in situ* for the time period for which it was required and treatment objectives had been met, it was deemed successful. If one or both were lost prematurely this was deemed a failure.

3.6 Data Management

3.6.1 Part 1: Patient experiences and discomfort associated with mid-palatal TSADs:

For **Part 1,** a structured two-stage approach was adopted for data management and statistical analysis. Initially, all returned questionnaires were processed, with the raw data systematically collected and organized within Microsoft Excel TM 2021.

3.6.2 Part 2: Success rates and complications with mid-palatal TSADs:

For **Part 2**, as above, Microsoft Excel TM 2021 was used to collect and analyse data.

3.7 Statistical Analysis

3.7.1 Part 1: Patient experiences and discomfort associated with mid-palatal TSADs:

For **Part 1**, descriptive statistics were used to present the findings.

3.7.2 Part 2: Success rates and complications with mid-palatal TSADs:

For **Part 2**, statistical analysis was undertaken using STATA® version 17 software (Stata Corporation, College Station, TX, USA). Statistical significance was set at $p<0.05$. Data analysis included descriptive and inferential statistics including use of the chi-square test to evaluate the rate of TSAD failure. Logistical regression analysis was used to evaluate the association between independent variables including vertical relationships, oral hygiene level, and TSAD function/indication with failure and complications.

4 Chapter Four: Results

4.1 Patient experiences and discomfort associated with mid-palatal TSADs (Part 1)

After applying the inclusion criteria, questionnaires were sent to 550 participants in January 2024. These included 319 females (58%) with 63.5% (n= 349) aged 11-14 years and just 2% (n= 11) above 18 years.

A total of 152 responses were received with a response rate of 28%. Overall, 87.5% described experience of TSAD insertion “as expected” or “better”, with pain during the procedure being reported as mild in 62.5% (Table 4.1). Local post-operative palatal pain over the first 3 days following placement was scored as moderate in 21.1%, necessitating the use of painkillers among 33.6% over this period. More prolonged use of painkillers was required among 14.5% (Table 4.2).

Table 4.1 Experience of TSAD insertion.

Experience	N = 152	%
Much Better	30	19.7%
Better	55	36.2%
As expected	48	31.6%
Worse	14	9.2%
Much Worse	5	3.3%

Some associated burden was noted with 62.5% noted increased time required for hygiene. Over the course of the orthodontic treatment 50.7% felt the TSAD caused more pain on teeth, although the level of discomfort was mild in 57.1%. Similarly, 64.5% and 37.5%, respectively, attributed palatal pain and pain due to rubbing during treatment to the TSAD. Again, however, associated issues were mild in 53.6% and 73.7% respectively (Tables 4.2 & 4.3). 66.5% required no painkillers over the first week, and 85.5% did not require painkillers at any other time during treatment. Additional visits for emergencies were only required in 8.6%, while antibiotic use was only required in 1.3%.

Table 4.2 Subjective experiences associated with mid-palatal TSAD placement.

	Yes	**No**	**Total**
Painkillers required over first week			
N (%)	51 (33.6%)	101 (66.5%)	152 (100%)
Painkillers required at any other time during treatment			
N (%)	22 (14.5%)	130 (85.5%)	152 (100%)
Antibiotics required for any issues during TSAD treatment			
N (%)	2 (1.3%)	150 (98.7%)	152 (100%)
Emergency visits required due to TSAD			
N (%)	13 (8.6%)	139 (91.5%)	152 (100%)
Over the course of treatment, subjectively the TSAD lead to:			
An increase in cleaning time			
N (%)	95 (62.5%)	57 (37.5%)	152 (100%)
An increase in pain on teeth			
N (%)	77 (50.7%)	75 (49.3%)	152 (100%)
An increase in pain on palate			
N (%)	98 (64.5%)	54 (35.5%)	152 (100%)
Soreness from rubbing			
N (%)	57 (37.5%)	95 (62.5%)	152 (100%)
Difficulty with speech			
N (%)	96 (63.2%)	56 (36.8%)	152 (100%)
Difficulty with eating			
N (%)	103 (67.8%)	49 (32.2%)	152 (100%)
A feeling of embarrassment			
N (%)	26 (17.1%)	126 (82.9%)	152 (100%)
Adverse effect on musical hobby			
N (%)	37 (24.3%)	115 (75.7%)	152 (100%)

Adverse effect on sporting hobby			
N (%)	32 (21%)	120 (79%)	152 (100%)

Table 4.3 Subjective experiences associated with mid-palatal TSAD.

Scale	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Total**
Pain experienced during TSAD placement											
N (%)	24 (15.)	22 (14.5)	27 (17.8)	22 (14.5)	15 (9.9)	15 (9.9)	9 (5.9)	11 (7.2)	2 (1.3)	5 (3.3)	152 (100)
Grade		Mild 95 (62.5%)		Moderate 30 (19.7%)			Severe 27 (17.8%)				
Pain experienced over first 3 days											
N (%)	19 (12.5)	25 (16.5)	26 (17.1)	14 (9.2)	15 (9.9)	17 (11.2)	7 (4.6)	14 (9.2)	6 (4%)	9 (5.9)	152 (100)
Grade		Mild 84 (55.3%)		Moderate 32 (21.1%)			Severe 36 (23.7%)				
Over the course of treatment the TSAD caused:											
Pain experienced on teeth (50.66%)											
N (%)	13 (16.9)	10 (13)	12 (15.6)	9 (11.7)	12 (15.6)	10 (13)	6 (7.8)	3 (3.9)	1 (1.3)	1 (1.3)	77 (100)
Grade		Mild 44 (57.1%)		Moderate 22 (28.6%)			Severe 11 (14.3%)				
Pain experienced on the palate (64.47%)											
N (%)	14 (14.4)	8 (8.3)	18 (18.6)	12 (12.4)	16 (16.)	14 (14.4)	3 (3.1)	9 (9.3)	0 (0)	3 (3.1)	97 (100)
Grade		Mild 52 (53.6%)		Moderate 30 (30.9%)			Severe 15 (15.5%)				
Soreness from rubbing (37.50%)											

N (%)	19 (33.3)	5 (8.8)	11 (19.3)	7 (12.3)	9 (15.8)	1 (1.8)	4 (7)	1 (1.8)	0 (0)	0 (0)	57 (100)
Grade		Mild 42 (73.7%)		Moderate 10 (17.5%)			Severe 5 (8.8%)			
Difficulties with speech (63.16%)										
N (%)	12 (12.8)	14 (14.9)	16 (17)	22 (23.4)	10 (10.6)	8 (8.5)	8 (8.5)	2 (2.1)	1 (1.1)	1 (1.1)	94 (100)
Grade		Mild 64 (68.1%)		Moderate 18 (19.2%)			Severe 12 (12.8%)			
Difficulties with eating (67.76%)										
N (%)	13 (12.6)	11 (10.7)	22 (21.4)	16 (15.5)	13 (12.6)	9 (8.7)	10 (9.7)	6 (5.8)	1 (1)	2 (1.9)	103 (100)
Grade		Mild 62 (60.2%)		Moderate 22 (21.4%)			Severe 19 (18.5%)			
Adverse effects on musical hobby (24.34%)										
N (%)	22 (61.1)	3 (8.3)	3 (8.3)	3 (8.3)	2 (5.7)	0 (0)	3 (8.3)	0 (0)	0 (0)	0 (0)	36 (100)
Grade		Mild 31 (86.1%)		Moderate 2 (5.6%)			Severe 3 (8.3%)			
Adverse effect on sporting hobby (21.05%)										
N (%)	25 (78.1)	3 (9.4)	3 (9.4)	1 (3.1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	32 (100)
Grade		Mild 32 (100%)		Moderate 0 (0%)			Severe 0 (0%)			

In terms of functional impairment, 63.2% of patients felt the TSAD caused difficulty with speech, while 67.8% alluded to difficulty with eating. However, these impairments were reported as mild in 68.1% and 60.2% respectively. A smaller proportion (17.1%) noted feelings of embarrassment, with this generally ascribed to speech (44%) and eating (32%) issues, while appearance (16%) and hygiene (8%) implications were less frequently cited. A significant proportion (24.34%) felt that the TSAD had an impact on ability to perform music, while fewer (21.1%) cited an impact on sports, again being reported as mild in 86.1% and 100% respectively (Table 4.3).

Overall, participants were very likely to recommend this treatment to others with 65.1% (n= 99) scoring this 8 or above (Table 4.4).

Table 4.4 Responses concerning likelihood to recommend mid-palatal TSADs to other prospective patients (n=152).

Response	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Total**
N (%)	6 (4)	1 (0.7)	2 (1.3)	3 (2)	13 (8.6)	11 (7.2)	17 (11.2)	31 (20.4)	19 (12.5)	49 (32.2)	152 (100%)

4.2 Success rates and complications with mid-palatal TSAD (Part 2)

From a cohort of 743 patients in which the ages ranged from 6 to 59 years, 451 participants having two mid-palatal TSADs each (902 TSADs overall) were included in the analysis. Of these, 263 patients were female (58.5%), 188 were male (41.5%). The average age was 12.9 (+/- 2.3 years) with 78.5% of the sample aged 10 to 14 years old. All malocclusion types were represented: Class I (20.8%), Class II division 1 (33%), Class II division 2 (7.8%) and Class III (38.4%). The Frankfort mandibular plane angle (FMPA) ranged from 8.4 to 43.8 degrees with an average of 23.1 (+/- 6.1) degrees.

From a total of included 451 patients, only 10 failures noted, all of which were associated with complications, reflecting a failure rate of 2.2%. The occurrence of failure based on demographic and clinical characteristics is presented in Table 4.5. Of the 10 failures, 9 were associated with TAD loosening while a further TSAD presented with significant local inflammation. The mean time to failure was 163.6 days (Range: 59 – 341; Table 4.6).

Table 4.5 TSAD failure rate based on demographic and clinical variables.

Variables	(n)	(%)	Failure (n)	Failure (%)	Total	Total	P value *
Gender							
Female	258	57.2%	6	1.3%	264	58.5%	0.903
Male	183	40.6%	4	0.9%	187	41.5%	
Incisor Relationship							
Class I	94	20.8%	0	0.0%	94	20.8%	0.184
Class II	180	39.9%	4	0.9%	184	40.8%	
Class III	167	37.0%	6	1.3%	173	38.4%	
TSAD Function/Indication[$]							
Maximum AP anchorage (TPA)	22	4.9%	0	0.0%	22	4.9%	-
Molar distalization	110	24.4%	1	0.2%	111	24.6%	
Molar intrusion	20	4.4%	0	0.0%	20	4.4%	
Molar protraction	90	20.0%	0	0.0%	90	20.0%	
Molar re- and protraction	3	0.7%	0	0.0%	3	0.7%	
Transverse Expansion	196	43.5%	9	2.0%	205	45.5%	
Oral Hygiene							
Negative	67	14.9%	3	0.7%	70	15.5%	0.099
Variable	51	11.3%	2	0.4%	53	11.8%	
Positive	323	71.6%	5	1.1%	328	72.7%	
Attendance							
Good	425	94.2%	9	2.0%	434	96.2%	0.329

Poor	5	1.1%		0.0%	5	1.1%	
Intermediate	11	2.4%	1	0.2%	12	2.7%	

*Based on Pearson's Chi-squared test

[$]Chi-squared could not be performed in view of low numbers of failures

Table 4.6 Characteristics of TSAD failures (n= 10).

n	Gender	Age	Incisor Rel.	FMPA (Degr.)	TAD Indic.	OH	Attendance	Complication	Days to Failure
1	F	13	II div. 2	10	Molar distalization	neg./pos.	good	Loosening	120
2	F	11	III	14.9	T. Expansion	pos.	good	Loosening	138
3	M	17	II div. 1	19.2	T. Expansion	pos.	good	Loosening	126
4	M	14	III	20.1	T. Expansion	pos.	good	Loosening	84
5	F	13	III	12.4	T. Expansion	neg.	good	Gingivitis	128
6	M	16	III	14.3	T. Expansion	pos./neg.	intermediate	Loosening	146
7	F	13	III	31.9	T. Expansion	pos.	good	Loosening	187
8	F	11	II div. 1	18.8	T. Expansion	neg.	good	Loosening	307
9	F	13	II div. 1	22.7	T. Expansion	neg.	good	Loosening	341
10	M	12	III	27.8	T. Expansion	pos.	good	Loosening	59

In terms of failure, 57.2% of the failure group were female. While 38.4% of the overall sample had Class III malocclusion, 60% of the failure group had Class III malocclusion and 90% of the failure group were good attenders. However, based on the univariate analysis, no associated between TSAD failure and gender, malocclusion type, or attendance was observed (Table 4.5).

71.6% of the total group had positive oral hygiene for the whole duration of treatment, 28.4% had negative oral hygiene at some point during the duration of treatment. No association between poor oral hygiene and failure was noted (p =

0.099). Failures occurred in subjects aged 11 to 17 years old with the mean age at failure being 13.3 years (+/- 1.9). Logistic regression analysis was used to further evaluate the effect of age, gender, FMPA, oral hygiene, and TSAD function/indication on failure (Table 4.7). Multivariate logistic regression analysis showed that age was not associated with failure (p-value = .955).

In terms of vertical dimension, the mean FMPA in those experiencing TSAD failure was 19.2 (+/- 6.5) degrees. Based on logistic regression analysis, higher FMPA was associated with lower failure rates (p-value = .025; Table 4.7). Failure was observed only in cases in which TSADs were used either for transverse expansion (n= 9) or molar distalization (n= 1). A significant association between TSAD failure with use for transverse expansion was noted using Chi-square test of association (p-value = .003).

Among the ten failures, the mean number of days to failure was 163.6 (+/- 91.5 days). Cox regression analysis showed that time to failure was not significantly affected by other variables (p > .10).

Table 4.7 Logistical regression analysis evaluating association between clinical and demographic variables and TSAD failure.

Demographic Variables						
	B	S.E.	Sig.	Exp(B)	Exp(B) 95% C.I.	
					Lower	Upper
Age at Insertion	.009	.153	.955	1.009	.747	1.362
Gender	-.473	.677	.485	.623	.165	2.348
FMPA	-.139	.062	.025	.870	.771	.983
Incisor Rel. II	17.149	4032.25	.997	.997	-	-
Incisor Rel. III	18.205	4032.25	.996	.996	-	-

Oral Hygiene	-1.113	.675	.099	.099	.329	.088

5 Chapter Five: Discussion

5.1 Barriers to mid-palatal TSAD usage

While the use of TSADs is now increasingly commonplace, lack of appropriate training, costs, fear of risk factors and scepticism about additional benefits have been considered as barriers by more than 50% of orthodontic clinicians (Meursinge Reynders *et al.,* 2016). A further barrier may relate to the dearth of patient-focussed information particularly patient experiences. This is particularly pertinent as orthodontic patients and their relatives may have associated reservations regarding mid-palatal TSAD placement as this does involve a minor surgical procedure (Uribe *et al.,* 2014). This study serves to increase knowledge on risks and complications and to increase mid-palatal TSAD usage in orthodontics. It is noteworthy that mid-palatal TAD placement is routinely provided within this practice setting potentially limiting associated anxiety and translating into a high level of operator proficiency.

5.2 Patient Experiences

In this study the pain experienced during the procedure of TSAD placement was relatively low, being reported as mild in 62.5%. It is accepted that young people experience physical, practical and emotional effects of orthodontic treatment (Kettle *et al.,* 2020). Some complications with fixed appliances include sore mouth, breakages, gingivitis, with greater effects in relation to pain, speech and eating. However even with these negative effects, the literature shows that 87% would have treatment again, with 91% recommending treatment to a friend (Bradley *et al.,* 2020). These findings correlate with the present study with 65.1% highly likely (8-10/10) to recommend mid-palatal TSAD insertion to a prospective patient.

Pain is subjective and multidimensional complicating objective measurement (Katz and Melzack, 1999; Consuelo *et al.,* 2023). A common method used for recording orthodontic pain is a Visual Analogue Scale (VAS) which represents a simple, valid, quick and effective tool (Maxwell, 1978; Price *et al.,* 1983). Orthodontic pain following appliance placement is felt after 2 to 4 hours, peaking at 19 to 24 hours, decreasing by day 3 and continues to decline until day 7 (Erdinç and Dinçer, 2004; Salmassian *et al.,* 2009; Abed Al Jawad *et al.,* 2012; Inauen *et al.,* 2023). In our study pain in the palate over the first 3 days following placement was moderate in 21.1% with 33.6% requiring analgesia mirroring discomfort and analgesic use associated with routine therapy not involving the use of TSADs (Erdinç and Dinçer, 2004; Abed Al Jawad *et al.,* 2012). In an allied study involving patients undergoing intra-alveolar buccal TSAD insertion in the maxillary second premolar to first molar region, (Pithon *et al.,* 2015) highlighted discomfort during placement, although this was low. The benefits of OMI placement were also acknowledged with up to 94.8% of participants willing to undergo treatment with OMI again (Pithon *et al.,* 2015). The latter study, however, involved adults aged 30 to 50 years with TSADs inserted manually using a hand-driver while the present study included younger participants.

5.3 Procedure Experiences

Pain during TSAD procedures has been attributed to the infiltration of anaesthetic itself (Gündüz *et al.,* 2004). Based on previous research, patients may prefer local anaesthetic infiltration rather than the use of topical in isolation. Topical use has been linked to higher rates of failure while producing less predictable anaesthesia (Lamberton *et al.,* 2016). Sparing amounts of palatal infiltration were used in the present study with this likely to have accounted for some of the intra-operative pain reported. It is noteworthy that Pithon *et al.,* (2015) also used a sparing amount of local anaesthesia (one-quarter cartridge), although this involved a buccal infiltration, which is typically less painful that palatal administration.

There is limited available data on patient experiences between different modalities of TSADs. Kawaguchi *et al.,* (2014) carried out a prospective cohort questionnaire study in Japan comparing discomfort and pain after buccal and palatal TSADs, as well as mini-plates with the miniplate associated with more pain and discomfort. Palatal TSADs necessitated analgesic use at 12 hours in 95% with miniplate, 50% buccal and 26.7% palatal insertions, respectively. No analgesics were needed with palatal TSADs after 3 days. In a further questionnaire-based survey, Sreenivasagan *et al.,* (2021) involving inter-radicular, buccal shelf, infra-zygomatic and palatal TSADs, palatal mini-implants caused highest levels of pain and caused greatest discomfort during speech and eating. These studies mirror the results of the present study with reports of more functional impairment than with alternatives, and appreciable post-operative pain although limited analgesic use was reported 3 days after insertion.

In our study, all TSADs were placed transmucosally by a single experienced orthodontist. Kuroda *et al.,* (2007) investigated the PREMs of interradicular OMI placed transmucosally by an orthodontist compared to oral surgeon (OS) placed OMI or mini-plates with reflected mucogingival flaps. The OMI placed by the orthodontist transmucosally was associated with the least discomfort and by day 7 no pain was reported in this group. Compared to 10% of the mini-plate and OS placed OMI with mucogingival flaps still reporting pain at day 14. The authors suggest that the OMI placed with the orthodontist was associated with least discomfort due to the lack of gingival trauma and swelling. These findings correlate with our own findings, with just 33.6% of patients requiring analgesic use over the first week.

Although we did not investigate differences in pain in relation to other treatments such as extractions, it is noteworthy to see in the literature how the pain levels correspond to each other in order to better inform and consent our patients. An RCT in the public dental service in Sweden also considered pain and discomfort following placement of skeletal anchorage. This RCT was carried out on 120 patients (mean age group A 14, B 14.6, C 14.2), requiring 2 unit maxillary extractions. Significantly less pain was seen with OMI insertion than with onplant or extraction groups. No significant differences with functional impairments was seen in the OMI or onplant groups (Feldmann *et al.,* 2007).

Similarly, a prospective cohort study carried out in Hong Kong University placement by Lee *et al.,* (2008) considered pain during orthodontic treatment including with separators, extractions, alignment and OMI placement. In keeping with our study, a questionnaire based on a Visual Analogue Scale (VAS) was used. This was given for 7 days after each procedure. One month after OMI placement patients were asked to rate their acceptance of the OMI. Similar to our results in which 97.5% described the experience of TSAD insertion “as expected” or “better”, Lee *et al.,* (2008) showed that patients expected to experience a significantly higher level of pain than they did for each procedure. The expected level of pain for OMI placement was similar to extraction. The expected level of pain for OMI placement was seen to be more than separator placement and orthodontic alignment. Overall, 76% of patients were satisfied with OMI treatment and 78% would recommend to a friend or family member. These findings again corresponded to our own findings with 65.1% highly likely to recommend this treatment to a friend.

A smaller questionnaire study similar to our own on TSADs, comparing patient experience was carried out in Bahia University. Pithon *et al.,* (2015) consisted of 58 patients aged between 30 to 50 years, receiving 132 self-drilling OMIs (1.6mm diameter 8mm length). These were placed with a manual handriver after ¼ cartridge of local anaesthetic between the maxillary second premolar and first molar. A questionnaire was VAS relating to pain during placement and during treatment, difficulty with eating and cleaning, any unesthetic appearance and perceived benefits was given. The most negative aspect was discomfort during placement, although this was low. This mirrors our own findings of 62.5% rating the pain during TSAD placement as mild. The least negative was difficulty with eating. Interestingly, our finding of difficulty with eating was 67.8% and this was mild in 62% and our least negative finding was soreness from rubbing in 37.5%, with 73.7% being reported as mild. The benefits of OMI placement with orthodontic treatment score was high. Good patient satisfaction was reported. Mirroring our own findings, 94.8% of participants were willing to undergo treatment with OMI again.

Although our study focused solely on TSAD experiences, to better inform and consent our patients an understanding of the hierarchy of approaches to anchorage management and how patient experiences differ is crucial. Sandler *et al.,* (2014) carried out a 3-arm multicentre RCT. The participants required maximum anchorage and could not afford any mesial movement of the molars. 78 adolescent participants between the ages of 12 to 18 years (mean age 14.2) were randomly assigned into three treatment groups involving: American Orthodontic TSADs (8mm length, 1.6mm diameter), Nance palatal arch and headgear. No difference in effectiveness of anchorage with the three methods was seen. This mirrors previous literature in which little significant differences between different anchorage methods were noted between TPA, headgear and TSADs (Feldmann, List and Bondemark, 2012). More problems were associated with Nance palatal arch and headgear than TSADs. This correlates with our findings of only 8.6% requiring additional visits due to the TSAD. Questionnaires about comfort/discomfort levels were given over week following placement and removal of all appliances. Comfort levels for placement of TSAD and Nance were similar. Quality of treatment was deemed to be better with TSADs. The failure rate of TSADs was 2.8%, approximating our own failure rate of 2.2%.

Another questionnaire-based study looking at the hierarchy of anchorage and how patient experiences differ is an RCT in 2023, which compared pain and discomfort levels between treatment with a TPA and 2-step retraction, and treatment with a TSAD and *en-masse* retraction (Mousa, Al-Sibaie and Hajeer, 2023). The study consisted of 38 patients (29 females, 9 males) with an average age of 21.7. Participants were given questionnaires to complete at 5 time points: after 24 hrs, 3 days, 1 week, 2 weeks and 1 month rating perception of pain and swelling, functional impairments with eating talking and cleaning using a 4-point Likert scale (1: not at all; 2: little; 3: much; 4: very much). Pain after 24 hours was 79% moderate to severe in the TSAD group compared to 94.7% mild or no pain in the TPA group. The pain experience with the TSAD group is similar to our own findings of moderate-severe pain in 44.8% over the first 3 days. Although we did not investigate swelling, we noted pain on the palate over the course of treatment among 64.5%. In this study, swelling was seen as mild 73.68% of the TSAD group compared to 31.58% mild in the TPA group. These results showed that there was more pain and swelling associated with TSAD treatment, and these were statistically significant differences. Interestingly there were statistically insignificant differences for functional difficulties like talking and eating. A limitation of this study is that the questionnaires were filled out in the dental chair which may lead to bias.

5.4 Functional Impairments

Orthodontics is associated with functional impairments including difficulty with chewing. Diet can be affected due to masticatory issues, pain, and also in response to dietary instructions (Abed Al Jawad *et al.,* 2012). Physical problems while eating may also restrict food choices (Carter *et al.,* 2015). It has been reported that adults are more affected by functional impairments such as mastication and potentially weight loss (Negruțiu *et al.,* 2024). These findings are mirrored in the present study with 63.2% reporting speech impairment and 67.8% citing a minor degree of difficulty with eating. Feelings of embarrassment were elicited from 17.1% of patients with this typically stemming from functional impairment due to speech or eating difficulty. These observations are in keeping with experiences associated with more routine appliance therapy with Kettle *et al.,* (2020) identifying physical, practical and emotional impacts associated with fixed and removable appliances.

In our present study, there were mainly mild side effects reported, and complications with TSADs were associated with loosening. It has been shown by one study looking at compliance rates and orthodontic treatment that 8% discontinued treatment due to pain (Patel, 1992). In our study, no patient expressed an interest to discontinue treatment. Therefore it is of great value to know that TSADs lead to mild functional impairments and with difficulty with speech in 63.16% and difficulty with eating in 67.76%, both being reported as mild in 68.15% and 60.2% respectively.

Ganzer *et al*., (2016) in an RCT based in the Dental Public service in Sweden, compared pain, discomfort and functional impairment with premolar extractions and buccal OMIs using extraction pain as a reference. Eighty patients were divided into 2 groups, Group A OMI miniscrews; Group B premolar extractions. Previous literature shows that extractions and OMI placement are similar (Feldmann *et al.,* 2007). Pain and discomfort levels the evening post-OMI and 1/52 were less than extraction group figures. Interestingly to note, patients report significantly more issues after extractions with function such as drinking and eating compared to OMI. Pain and discomfort levels during extraction and OMI placement procedures were insignificant. These findings enable orthodontists to make informed clinical decisions and more effectively inform and consent patients.

In our study we investigated patient perception and experience of the mid-palatal TSAD placement and treatment. In a similar study by Cornelis *et al.,* (2008) patient perceptions and experiences with OMIs were investigated in two university settings with a mixture of experienced and inexperienced operators. A success rate of 92.5% was seen with 82% revealing that their surgical experience was better than they expected with little or no pain and 72% did not mind having the implant. We noted 87.5% with an experience of mid-palatal TSAD insertion as “better” or “as expected”. The most frequent problem reported was post-surgical swelling which lasted on average 5 days, and cheek irritation. This irritation was considered severe in one patient necessitating removal.

5.5 Success rates of mid-palatal TSADs

Based on this retrospective analysis, the failure rate associated with mid-palatal TSADs may be extremely low with this site appearing to offer greater predictability than other sites in either maxillary or mandibular arches (Alharbi *et al*., 2019). Coupled with previous patient-centered data based on this patient cohort, the suitability of mid-palatal sites appears to be clear (Barry *et al.,* 2025).

Orthodontic mini-implant (OMI) success in the literature has been defined by fulfilling “anchorage objectives with or without mobility or even with displacement” (Reynders, Ronchi and Bipat, 2009). Other studies have defined success as if it is “maintained for more than six months” (Wu, Kuang and Wu, 2009). In our study we used a more holistic definition based on both TSADs remaining in situ for which it was required ensuring that treatment objectives were made. It is felt that this definition best reflects the success rather than mere survival of the adjunct.

In this study a 97.8% success rate across patients was observed. In terms of individual TSADs, only 13 out of 902 failed reflecting a 1.44% failure rate at the TSAD level. Previous research by Asscherickx *et al.,* (2010) reported a 91% success rate for palatal implants. Although a smaller sample study, 33 palatal implants were investigated, with a success rate of 88.8% in the adult group (mid-palatal placement) and 92% in the adolescent group (paramedian placement). Hourfar *et al.,* (2017) also carried out a similar retrospective cohort study comparing palatal OMIs to buccal interradicular OMIs. In this study, 239 patients who had skeletal anchorage loaded with a force greater than 2 Newtons finding similar success rates of 98.4% for OMI placed in the anterior palatal at the level of the third rugae compared to 71% for buccal interradicular sites.

Mohammed *et al.,* (2018) carried out a systematic review and meta-analysis on the role of anatomical site and correlated risk factors for the survival of OMI. For palatal OMI the failure rates were categorised based on the placement location: mid-palatal, paramedian, and parapalatal. Although there was very low to low quality evidence for mid-palatal locations, promising failure rates of only 1.3% were noted. Failure rates for paramedian sites and parapalatal sites were 4.8% and 5.5%, respectively. In our study, para-median placement was considered with lower success rates observed. It is conceivable that these lower rates may relate to the experience and expertise of the operator. Notwithstanding this, it does appear that para-median sites offer a suitable and predictable location for TSAD insertion.

5.6 Patient-Related Factors

In our study no association between gender and failure was observed. We used had the same protocol for all patients, regardless of gender. However, palatal bone thickness has been shown to be greater in males (Yadav *et al.,* 2018; Kang *et al.,* 2007; Manni *et al.,* 2011). Yadav *et al.,* (2018) carried out retrospective analysis on CBCT scans of 359 growing and non-growing males and females. The authors concluded that the thickness of the palatal bone is higher in males than females, although they do not recommend tailored procedures based on gender. This is in keeping with other literature stating female patients have statistically significant less vertical bone height; however, it was not clinically significant and authors suggest the lack of need for gender-specific recommendations (Kawa *et al.,* 2017).

In our study, all TSADs were placed para-median, 1-2mm lateral to the mid-palatal suture, at the level of the third rugae, perpendicular to the palatal bone surface. Chang *et al.,* (2020) assessed 43 CBCT scans (22 adults with a mean age of 23, and 21 adolescents with a mean age of 14) and found that the area with the greatest thickness of palatal bone was 3mm distal to the incisive foramen and 4-8mm lateral to the mid-palatal suture. However, the authors noted that for adolescent patients requiring skeletal anchorage the area 6mm posterior to the incisive canal and 2-8mm lateral to the mid-palatal suture contained adequate palatal bone thickness as well as being away from the incisor roots. Our patient demographic contained patients aged 10 to 21 years, however 63.5% were aged 11 to 14 years, and so our protocol of 1-2mm lateral to the mid-palatal suture ensured adequate bone for TSAD placement.

Failures were confined to those aged 11 to 17 years with the average age of failure being 13.3 (+/- 1.9) years. While no statistical association between age and failure rates were noted, higher success has previously been reported in the literature with mid-palatal TSADs in older patients (Kim *et al.,* 2010). In our study, the same protocol was applied for adolescents and adults. However, data derived from CBCT has illustrated thinner palatal bone in younger patients (Ryu *et al.,* 2012). This study compared CBCT scans of 118 patients divided into three groups based on age and dentition status, early mixed, late mixed, and permanent dentition (group 1 38 subjects with mean age 8.03 +/- 0.93 years, group 2 40 subjects with mean age 11.51 +/- 0.92 years, and group 3 40 subjects with mean age 20.92 +/- 1.17 years). As to be expected, there was significantly lower bone thickness in the early mixed dentition group. No significant differences were seen between the late mixed and permanent dentition groups.

In our study, based on the vertical dimension, the mean FMPA in those experiencing TSAD failure was 19.2 (+/- 6.5) degrees. Based on logistic regression analysis, higher FMPA was associated with lower failure rates (p-value = .025). Sato *et al.* (2005) reported higher density of cortical bone in low-angle cases. Our findings confirm that different growth patterns can affect the outcomes of mid-palatal TSADs, potentially based on bone thickness and density variations (Nucera *et al.,* 2022). Moon *et al.* (2010) investigated a potential relationship between vertical skeletal pattern and OMI. This involved 778 self-drilling OMIs of 1.6mm diameter and 8mm length in 306 patients, 70 to 80 degrees to the long axis of the tooth. In contrast to our findings, average angle patients had a higher success rate than low or high-angled. The lack of observed difference may therefore relate to the low number of recorded failures, although high levels of success were found irrespective of vertical skeletal pattern.

5.7 Procedural Factors

In our study the placement protocol remained the same for every patient. This involved insertion involving a guided stent and two 8mm x 1.7mm TSADs (OrthoEasy Pal, Forestadent, Pforzheim, Germany). A systematic review and meta-analysis based on 11 studies looked primarily at safety during interradicular OMI placement; root contact or damage, comparing freehand placement, radiographic guided placement and placement with computer-assisted 3D planning software guides. This study concluded that 3D computer-assisted guided placement results in reduced risk of root damage compared to radiographic guides or freehand placement (Santmartí-Oliver *et al.,* 2024).

In our study, all TSADs were placed para-median, 1-2mm lateral to the mid-palatal suture at the level of the third rugae, perpendicular to the palatal bone surface, at a speed of 60rpm, with unlimited insertion torque up to 50Ncm, using a Dentsply Sirona implant handpiece 1:20. In 2018, a study using porcine tiba bones (1.5mm thick) inserted OMI using a torque limiting hand screwdriver set at 12 Ncm, 18 Ncm and 24 Ncm. It was found that at 24 Ncm, complete insertion was found for all OMI, whereas, for the lower torque values partial insertion or failure to insert completely was seen. OMI's inserted at 24 Ncm also produced more microdamage in the bone, theoretically increasing the osteoclastic resorptive activity and having a detrimental effect on the stability of the OMI (Nguyen *et al.,* 2018). Wilmes *et al.,* (2006) advocated for 5 to 10 Ncm as the ideal range for insertion torque; however, this seems to be achievable only when cortical bone is between 0.5mm and 1mm thick. Therefore a higher torque value is needed to overcome the friction of insertion through the cortical bone (Nguyen *et al.,* 2018).

In our study, pre-drilling was not carried out. Kim, Ahn and Chang, (2005) inserted 32 orthodontic implants in two dogs in a spilt-mouth study of drilling before implant placement versus no drilling. It was shown that drill-free implants had greater anchorage value and stability. An in-vitro study done in Italy showed that self-drilling miniscrews had a greater resistance to dislocation (Tepedino, Masedu and Chimenti, 2017). A systematic review and meta-analysis by Yi *et al.,* (2017) comparing self-tapping miniscrew success to self-drilling showed similar success rates, however, when contacting a tooth root self-drilling miniscrews showed a higher risk of failure.

In our study, bicortical engagement involving the inferior oral cortex and the superior nasal cortex was planned. The first report of bicortical engagement for increasing stability in screws for orthodontic anchorage was by Freudenthaler, Haas and Bantleon, (2001). Brettin *et al.,* (2008) in Iowa University used human cadaver maxillae and mandible specimens comparing monocortical OMI placement versus bicortical placement to test force resistance and stability. Based on finite-element analysis, greater cortical stress can be seen with monocortical skeletal anchorage. Some benefits can be seen in monocortical engagement as it reduces the risk of damage to adjacent structures such as periodontal ligaments (Lemieux *et al.,* 2011). However, bicortical engagement of OMIs is biomechanically more stable. In monocortical engagement, the OMI is fixed in the cortical bone, but potentially could be subject to levering effects with the body of the implant in cancellous bone. Bicortical engagement eliminates this risk as the implant is stabilised at the apex of the implant and at the cervical region (Holberg *et al.,* 2014).

5.8 Clinician-Related Factors

All clinical procedures in our study were performed by the same orthodontist. Operator experience and dominant hand preference has been shown to affect the outcomes of TSADs. Previous literature states that the left side has lower failure rates as access is difficult on the patient's right-hand side for right-handed operators (Wu, Kuang and Wu, 2009; Park, Jeong and Kwon, 2006). A recent systematic review and meta-analysis confirmed this as the authors concluded higher failure rates were associated with the patients right side (Valeri *et al.,* 2024). This study also highlights operator experience and its inverse relationship with failure rates. Another study highlighting the importance of operator experience looked at 407 OMI, it was seen that more experienced clinicians had a 3.6-fold higher success rate compared to OMI placed by less experienced clinicians (Lim *et al.,* 2011). This may have influenced the high levels of success noted in the present evaluation.

5.9 TSAD-Indication Related Factors

In our study most of the TSAD failures (90%) arose in those having transverse expansion. While the sample size is low, it could be speculated that the failures may relate to TAD loading with mid-palatal sutural separation reliant on direct loading and high initial force levels, in particular. Previous research has alluded to lower success rates with direct loading between implants (Baumgaertel *et al.,* 2020). A recent finite element modelling analysis by Panaite *et al.,* (2025a) investigated the optimal forces used in conjunction with TSADs and the force range in which risk of failure increases. It was shown that the structural integrity of the TSAD is maintained when forces are maintained within an optimal range of around 2 Newtons. However, when the load reaches 10 Newtons, the risk of failure increases significantly. This study only 12mm long titanium alloy TSADs. Future research into differing lengths and available TSAD materials is required.

It is further noteworthy that TSAD-borne expansion often involves the use of four or more TADs in an effort to mitigate this issue while also limiting the direct application of forces to the dentition in order to minimise unwanted dento-alveolar effects. Notwithstanding, additional information concerning the relative impact of two or four TSAD based approaches would be welcome.

5.10 Complications

In terms of complications associated with failing TSADs in our study, 90% involved “loosening” with one instance of significant inflammation of the palatal tissues. No complications noted in the successful TSADs. Previous research has shown that other complications have been associated with palatal TSAD placement such as perforation of the nasal floor, sensory impairment and prolonged pain (Fäh and Schätzle, 2014). No case reports of paraesthesia to the nasopalatine nerve related to orthodontic treatment were found in the literature. Fäh and Schätzle, (2014) evaluating complications and adverse reactions associated with palatal implants looked retrospectively at 146 subjects between 1999 to 2010. Of these 146, only 101 implantation met the inclusion criteria. Of this sample a single (1%) report of sensory impairment was noted. However, based on our research, although patients may experience functional impairments and pain following placement, these unpleasant experiences did not deter a clear majority from recommending mid-palatal TSADs to others (Barry *et al.,* 2025).

5.11 Future Research

Although complication rates are low, there is little in the literature regarding increasing stability or addressing mobility associated with TSAD use. Panaite *et al.,* (2025b) used finite element modelling to evaluate the advantages of stabilisation discs surrounding TSADs. A 4mm disc made out of a titanium alloy with 4mm depth prongs through which a TSAD is placed was investigated using geometric modelling software. The rationale for this is to provide support for the TSAD and improve force distribution. Forces of 10 Newtons were placed at an angle of 30 degrees. The authors concluded that these stabilisation discs reduced displacement of the TSADs by 41% and stresses were more evenly distributed through the TSAD. This study does have limitations as inherently finite element modelling does not account for biocompatibility, potential damage to soft tissue by the prongs of the disc and patient related factors such as pain and experience. The long-term effects of the stabilisation discs were not evaluated.

Nishioka-Sakamoto *et al.,* (2023) described a novel approach to address loose or failing TSADs in a rodent model in Japan. The group placed 20 (3mm x 1.2mm) TSADs in 1.6mm pilot holes in 11-week old male Wistar rats. These TSADs were allowed to heal for 4 weeks. After this time the TSAD was loosened and the sample was separated between control group and study groups, 100g nickel-titanium coil spring was attached and orthodontic force was applied in the control group. In the study group, after the TSAD was loosened, beta-tricalcium phosphate was placed around the loosened TSAD and the mucosa was sutured. Traction was applied for 4 weeks before evaluation of results. Micro-CT scans allowed analysis using superimposition. Histological analysis of the bone was undertaken after euthanisation of the rodents. At 2 weeks in the control group, fibrous tissue was seen around the TSAD, and at 4 weeks fibrous tissue reduced and partially localised new bone-like tissue was seen. At 2 weeks in the beta-tricalcium phosphate study group, a thin layer of regenerated new bone was seen around the beta-tricalcium phosphate granules. And at 4 weeks there was an increase in the amount of bone-like tissue. Within the limitations of the animal model, this points to possible benefit to placing a material such as beta-tricalcium phosphate around a loosened TSAD.

There are multiple outstanding gaps in the literature with regard to mid-palatal TSADs and their success in the treatment of specific malocclusions. Further research would be required to draw conclusions on their benefit in Class I, Class II division 1, Class II division 2 and Class III malocclusion treatment. Perhaps treatment with mid-palatal TSADs could affect the number of cases requiring orthognathic intervention and expand the scope of non-surgical treatment options.

5.12 Limitations

Based on qualitative research, young patients do tend to adapt to functional issues attenuating any associated challenges during appliance therapy (Kettle *et al.,* 2020). While we did examine the short-term impacts of TSADs in relation to pain experience, in particular, the longitudinal impacts of TSADs were not fully elucidated in the present study. Patient experiences are multidimensional and a questionnaire developed in one language for a population may not be appropriate for others. We therefore developed a bespoke questionnaire and implemented forward translation by bilingual experts along with back translation, accounting for cultural context in order to limit any associated bias.

The response rate of 28% must be considered when interpreting these results. There is a potential for response bias when considering this response rate. The patient demographics including healthy non-smokers, between 10 and 21 years old may been seen as narrow; however, this reflects a typical cohort undergoing orthodontic treatment.

Our research is retrospective and although cost-effective does have inherent limitations that may compromise validity and reliability of the findings. Those of which include quality of data over 16 years, recall and selection bias.

TSADs were placed by a single trained, high-volume operator in the present study. It would be intuitive to expect that surgical experience may affect the success rate of mid-palatal TADs (Jung *et al.,* 2012). Baumgaertel *et al.,* (2020) reported a success rate of 83.9% for supervised TSAD placement during a residency programme with the highest success rate again noted in the anterior palate. The authors therefore advocate the use of this location for relative novices. Nevertheless, given that the data was collected from a single experienced clinician, the success rates may not be representative of a wider body of clinicians.

In addition, although a large sample size was included, the low number of failures meant that few statistical associations were found. Similarly, it was not possible to consider success rates of secondary placement of mid-palatal TSADs. The literature shows that secondary placement is associated with lower success rates (Uesugi *et al.,* 2018). Similarly, complications with explantation of mid-palatal TSADs are mentioned in the literature but were not investigated in this study (Fäh and Schätzle, 2014).

6 Chapter Six: Conclusions

6.1 Patient experiences and discomfort associated with mid-palatal TSAD

Some pain, discomfort and functional impairment were noted with the use of mid-palatal TSADs. Functional impairments chiefly included speech and eating issues, although levels of associated disability were limited. Overall, unpleasant experiences were generally considered to be low with a clear majority of patients highly likely to recommend TSADs to prospective patients.

6.2 Success rates and complications with mid-palatal TSAD

Based on this analysis of TSAD placement undertaken by an experienced operator, excellent success rates with mid-palatal placement of temporary skeletal anchorage devices (TSADs) are possible with failure rates of just 1.44% and 2.2% at the implant and patient level observed, respectively. Complications were also rare with loosening of the mid-palatal TSAD associated with failure. A possible association between failure and use during skeletal expansion was noted, although this should be interpreted with caution in view of the low overall failure rate.

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8 Appendices

Appendix 1. Questionnaire.

Palatal Mini-Implants/Temporary Anchorage Device (TAD): Patient Experiences

1. Relative to your expectation, was your experience of TAD placement?

Much better ☐ Better☐ As expected☐ Worse☐ Much worse ☐

2. On a scale of 1-10, how painful did you find the procedure to place the TAD?

1	2	3	4	5	6	7	8	9	10

3. On a scale of 1-10, how painful was the area over the first 3 days following placement?

1	2	3	4	5	6	7	8	9	10

4. Did you require painkillers to deal with the pain over the first week after placement?

   Yes ☐ No ☐

5. Were painkillers needed to deal with the pain related to the TAD at any other point of your treatment?

   Yes ☐ No ☐

6. Were antibiotics needed to deal with issues related to the TAD at any point of your treatment?

Yes ☐ No ☐

7. Did you have any extra emergency visits to the clinic because your TADs?

   Yes ☐ No ☐

8. Over the course of your orthodontic treatment, do you feel that the TAD led to?

a. Increased cleaning time Yes ☐ No ☐

b. More pain on the teeth Yes ☐ No ☐

   If yes, please rate on a scale of 1-10;

1	2	3	4	5	6	7	8	9	10

c. Pain on the roof of your mouth Yes ☐ No ☐

   If yes, please rate on a scale of 1-10;

1	2	3	4	5	6	7	8	9	10

d. Soreness from rubbing Yes ☐ No ☐

   If yes, please rate on a scale of 1-10;

1	2	3	4	5	6	7	8	9	10

e. Difficulty with speech Yes ☐ No ☐

   If yes, please rate on a scale of 1-10;

1	2	3	4	5	6	7	8	9	10

f. Difficulty with eating Yes ☐ No ☐

   If yes, please rate on a scale of 1-10;

1	2	3	4	5	6	7	8	9	10

g. Feeling embarrassed Yes ☐ No ☐

If yes, please explain ….

h. Adverse effects on hobbies/interests:

1. Music Yes ☐ No ☐

If yes, please rate on a scale of 1-10;

1	2	3	4	5	6	7	8	9	10

2. Sport Yes ☐ No ☐

If yes, please rate on a scale of 1-10;

1	2	3	4	5	6	7	8	9	10

8. Based upon YOUR experience of the palatal TAD, how likely would you be to recommend this to other patients? Please rate on a scale of 1-10;

1	2	3	4	5	6	7	8	9	10

Please explain ….

9. What would YOU say to someone who was about to have a palatal TAD placed?

Appendix 2. Ethical Approval

Landesärztekammer Rheinland-Pfalz
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Deutschhausplatz 3 · 55116 Mainz
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Bitte geben Sie bei jedem Schriftwechsel die Antragsnummer an!

Mainz, den 18.08.2023 / BJ

Antragstitel: Evaluation von Patientenerfahrungen und Komplikationen mit mittlerer palatinaler temporärer Verankerung bei jugendlichen Patienten: Eine retrospektive Studie
Antragsnummer: 2023-17095-retrospektiv

Sehr geehrte Frau Knode,

da zwischenzeitlich bestätigt wurde, dass im Rahmen der o.g. Studie retrospektiv ausschließlich anonymisierte Daten ausgewertet werden, ist keine weitere Beratung durch die hiesige Ethik-Kommission erforderlich.

Bitte nehmen Sie folgenden Hinweis zur Kenntnis:

Es wurde am 06.08.2023 zwar ein korrigiertes Antragsformular nachgereicht, allerdings ist die Unterschrift des Praxisinhabers auf der letzten Seite noch auf den 30.05.2023 datiert. Diese Unstimmigkeit sollte bereinigt werden. Bitte reichen Sie der Vollständigkeit halber das korrigierte und unterschriebene Antragsformular mit aktuellem Datum nach.

Entsprechend Satzung und Geschäftsordnung der Ethik-Kommission wurde der Vorgang außerhalb einer Sitzung entschieden.

Mit freundlichen Grüßen

Dr. Andrea Wagner
Geschäftsführende Ärztin

Deutsche Apotheker- und Ärztebank – IBAN DE07 3006 0601 0001 2997 35 – BIC DAAEDEDDXXX
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Appendix 3. Abstract of peer-reviewed publication in Progress in Orthodontics.

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Progress in Orthodontics

RESEARCH Open Access

Patient experiences and discomfort associated with mid-palatal temporary skeletal anchorage devices

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Abstract

Background Mid-palatal placement of temporary skeletal anchorage devices (TSADs) has become increasingly popular among clinicians due to high success rates, low associated risk and streamlining and enhanced customization of associated supra-structures. There is however limited patient data in relation to associated experiences and impacts.

Methods A survey of patients undergoing mid-palatal TSAD insertion was undertaken using a 27-item bespoke questionnaire. Questionnaires were sent using both electronic and surface mail with a 3-month period allowed for response. Pain experience; the use of analgesia; requirement for additional visits; impacts on hygiene, speech, eating, and hobbies; and social impacts were assessed. Reponses involved the use of a Visual Analogue Scale as well as binary information.

Results Overall, 152 responses were obtained with 87.5% describing experience of TSAD insertion either "as expected" or "better". Procedural pain was reported as mild in 62.5%. Local post-operative pain was scored as moderate in 21.1%. Some functional impairment was reported with 63.2% attributing difficulty with speech and 67.8% difficulty with eating due to the implant. However, these functional impairments were generally considered mild (by 68.1% and 60.2%, respectively) and most were very likely to recommend this treatment to others, with 65.1% (n = 99) scoring 8 or above out of 10.

Conclusions Appreciable levels of pain, discomfort and functional impairment were noted with the use of mid-palatal TSADs. However, any unpleasant experiences were generally regarded as mild with most highly likely to recommend mid-palatal TSADs to prospective patients.

Keywords Patient experience, Patient reported outcomes, Mid-palatal, Anchorage, TSAD (Temporary skeletal anchorage device), MI (Mini-implant), OMI (Orthodontic mini-implant), Orthodontics, VAS (Visual analogue scale), Questionnaire

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Appendix 4. American Journal of Orthodontics & Dentofacial Orthopedics Submission for peer-reviewed publication.