# MEASUREMENT OF APPLIED FORCE TO DISLODGE ORTHODONTIC TEMPORARY ANCHORAGE DEVICES

By

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## ABSTRACT

**Aims:** To measure the force required to dislodge three different orthodontic temporary anchorage devices (TADs) from artificial test blocks and to investigate whether varying the cortical thickness of the test block will affect these forces.

**Materials and Method:** The TADs were embedded into test blocks consisting of polyurethane foam, laminated with either 2mm or 3mm short-fibre-filled epoxy sheets and a horizontal dislodging force applied, using an Instron universal testing machine. The maximum force applied before the TAD was fully dislodged was recorded. Three TADs were tested: Infinitas™, Ancor Pro™ and Ortho Implant™. 150 of each design were tested in the 2mm thickness test block and a further 150 of each were tested in the 3mm thickness test block.

**Results:** The mean force required was 468N (standard error = 3N) in the 2mm test blocks and 567N (standard error = 3N) in the 3mm test blocks. No significant difference was observed between the Infinitas™ and Ancor Pro™ TADs, however there was a significant difference ($P>0.05$) between both of these TADs and the Ortho Implant™. The force required in the 3mm test blocks was significantly higher than the force required in the 2mm test blocks.

**Conclusion:** All of the TADs were functionally acceptable, in terms of resistance to dislodgement forces. The Ortho Implant™ required a significantly higher force to be dislodged from both the 2mm and 3mm test blocks. The thickness of the test block had a significant effect on the force required to dislodge each of the TADs.

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# Chapter One

## LITERATURE REVIEW AND AIMS OF STUDY

## 1.1 Introduction

Orthodontic temporary anchorage devices (TADs) are small titanium alloy or stainless steel surgical bone screws. They are placed in order to create a source of rigid, bone-supported, intra-oral anchorage and are increasingly being used as an alternative form of anchorage reinforcement. Their attachment to bone is mechanical, with no intent to either encourage or establish osseointegration with the surrounding bone. Once they have served their purpose, they are removed.

## 1.2 Definitions

There has been little conformity on the nomenclature of TADs[1] and to date there is no universally accepted definition[2]. Cope[3] defines a TAD as 'a device that is temporarily fixed to bone for the purpose of enhancing 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'. There are currently numerous terms in use to describe such fixtures as are temporarily inserted into bone to provide skeletal or absolute anchorage. (Table 1.1)

Implants and mini-implants refer to systems that imply the need for osseointegration prior to loading. On the other hand, screws and self-tapping devices may be used without the condition of osseointegration[4]. The prefixes *mini-* and *micro-* are currently used without differentiation[5], however the Greek word *micro* relates to units in the order of $10^{-6}$. The term 'temporary anchorage devices' or 'TADs' will be used

throughout this study to describe those devices that are temporarily fixed to bone to provide skeletal anchorage without the need for osseointegration.

**Table 1.1 Nomenclature of TADs**

| Available Terms in the Published Literature |
|---|
| Implants |
| Mini-implants |
| Mini-screws |
| Micro-implants |
| Micro-screws |
| Intraoral Extra-dental Anchorage Systems[6] |
| Temporary Anchorage Devices[3] |

## 1.3 Anchorage

Orthodontic anchorage may be defined as resistance to reactionary forces during treatment.[7] Anchorage therefore resists those forces resulting from Newton's 3rd Law, namely that 'every force has an equal and opposite reactionary force'. The careful management of anchorage helps to control these unwanted forces and is a prerequisite for the successful completion of orthodontic treatment. Even a relatively small reactive force can cause unwanted tooth movements and it is therefore important to attain absolute anchorage to avoid them.[8,9,10] This 'absolute' anchorage is defined as no movement of the anchorage unit (zero anchorage loss) as a consequence to the reactionary forces applied to move teeth.[11] Such anchorage is difficult to achieve and may traditionally be attained by using ankylosed teeth or dental implants as anchors: both relying on bone to inhibit movement.[12] Surgical procedures have been described since 1945, to provide more definite anchorage points.[13] These procedures include the

use of osseointegrated dental implants that can provide much greater resistance to unwanted tooth movement, following a period of osseointegration. The ability of orthodontic TADs to provide absolute anchorage was demonstrated in a study by Thiruvenkatachari *et al*.,[14] who compared canine retraction anchorage loss with the use of TADs, to conventional molar anchorage.

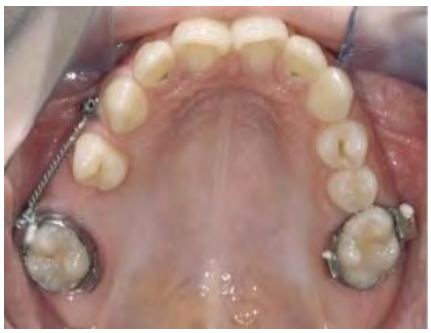
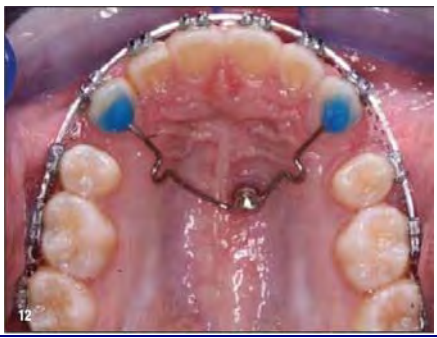
Conventionally, anchorage has been provided by other teeth, the palate, alveolar ridges, circum-oral musculature and the head and neck (via extra-oral appliances). Intraoral anchorage can be supplemented by securing teeth together by means of metal wires, such as trans-palatal arches, nance buttons or lingual arches. Anchorage may also be supplemented by using elastic traction to the opposing arch - intermaxillary anchorage.[15] None of these methods provide 'absolute anchorage' however, as orthodontic forces can still cause unintended, iatrogenic movement of these teeth. The classical concept of anchorage has been built on the principle that more teeth will provide anchorage for the displacement of fewer teeth. This has, however, no biological support, since small forces of only a few Newtons are capable of moving a tooth.

A common method of reinforcing anchorage in the maxillary arch is to use extra oral headgear attached to the first molars. Unfortunately this appliance is not popular with patients and is frequently not worn as prescribed, leading to poor treatment results.[17] The dangers of headgear wear are also well documented[18] with the most severe being permanent damage to the eyes.[19] In an interesting randomised clinical trial comparing headgear and TAD use with the MBT[20,21] system,[22] it was found that, during treatment for bimaxillary protrusion, the use of TADs rather than headgear may result in more

retraction and intrusion of the maxillary incisors, more lingual inclination of the mandibular incisors and may also counteract clockwise rotation of the mandibular and occlusal planes.

TADs can provide 2 different types of anchorage - direct and indirect. When used for indirect anchorage, they are connected through bars or wires to the reactive unit. When used for direct anchorage, they directly receive the reactive forces by acting as an anchor unit. (Figure 1.1)

**Figure 1.1 Direct and indirect anchorage**

| Direct Anchorage | Indirect Anchorage |
|---|---|
|  |  |
| A TAD in situ distal to the upper right canine. The TAD is providing direct anchorage for the distalisation of the upper right molar. | A TAD in situ in the palate. The TAD is providing indirect anchorage to the upper canines, through a trans-palatal bar. |

## 1.4 History of TADs

In 1945, Gainsforth and Higley proposed the possibility of gaining orthodontic anchorage in basal bone, using vitallium screws in the ascending rami of 6 dogs, to retract the canines.[13] The first clinical use reported in the literature came in 1983, when Creekmore and Eklund[23] used a vitallium bone screw inserted in the anterior

nasal spine to treat a patient with a deep overbite and excessive gingival show. However, the use of such devices was not immediately embraced. Thereafter, a number of papers focused on the use of other means to obtain skeletal anchorage, including dental implants,[24-26] onplants[27] and palatal implants.[28] One example of how techniques have changed with time is the palatal onplant, which was designed to rest on the bone under the palatal mucosa, rather than being placed within the bone.[27] This was initially considered to be an innovative means of achieving anchorage in the maxilla, however, there were early reports of failures[29] and the technique has not achieved widespread use.

Early work on surgical anchorage reinforcement was carried out with implants that osseointegrate with the surrounding bone. This followed Brånemark's reports of their successful use when replacing teeth that had been previously lost.[30] The first implant fixtures were relatively large diameter (3 to 4 mm) pre-prosthetic implants made of titanium and placed using established and tested surgical techniques. Research in animal models and human subjects showed that successful bone healing and remodelling could be maintained when the implant was subjected to the continuous and low magnitudinal forces applied during orthodontic treatment.[31]

These endosseous implants have features to promote both functional and structural integration (osseointegration) at the implant - bone interface and require an unloaded latency period of up to 6 months.[32] In 1984, Roberts *et al*.[33] investigated the tissue response to orthodontic forces applied to restorative implants and concluded that continuously loaded implants remained stable with 100g force after a 6 week healing period. In a follow-up study, osseointegration was found in 94% of the implants placed in dog mandibles and it was concluded that less than 10% of endosseous

surface area contact with bone was needed to resist forces of up to 300g for 13 weeks.[25] Subsequently, several manufacturers modified restorative implant designs to produce customized orthodontic fixtures. Clinical studies on the use of osseointegrated implants for orthodontic anchorage have reported a success rate of 86-100%.[34-37] The retromolar implants,[26] Onplant™, Straumann Orthosystem™ and Mid-plant system™ are examples of these osseointegrating bone anchorage devices (BADs).

In 1997, Kanomi[38] described a mini-implant specifically made for orthodontic use and in 1998 Costa *et al.*[39] presented a screw with a head resembling an orthodontic bracket. Several other variations have since been introduced using various alloys, diameters of the threaded portions, length of implant and head design. Furthermore, in recent years other means of bone anchorage have been proposed, including zygomatic anchors,[40] wires[41] and miniplates.[42,43]

## 1.5 Classification

Skeletal anchorage devices may be classified into 2 main categories, based on their origin.[44] The first category has its origin in osseointegrated dental implants and includes the orthodontic TADs, the retromolar implants and the palatal implants. The second category has its origin in the surgical mini-implants, such as the ones described by Kanomi[38] and Costal *et al.*[39] The main difference between the 2 categories is that the devices in the second category are smaller in diameter, have smooth surfaces and are designed to be loaded shortly after insertion.[44]

A useful classification system described by Labanauskaite *et al.*[45] suggests classifying orthodontic TADs according to 3 criteria. (Table 1.2)

**Table 1.2 A useful classification system for TADs**

| Shape and Size | Implant Bone Contact | Application |
|---|---|---|
| • Conical (cylindrical)<br>- miniscrew implants<br>- palatal implants<br>- prosthodontic implants<br>• Miniplate implants<br>• Disc implants (onplants) | • Osseointegrated<br>• Non-osseointegrated | • Orthodontic purposes only<br>• Prosthetic and Orthodontic purposes |

## 1.6 Orthodontic Use of TADs

Traditional osseointegrated dental implants, such as those described by Brånemark,[46] may be used as an anchor source in certain instances.[26] This method is indicated in cases where there is limited available anchorage for orthodontic tooth movement and a need for post-orthodontic restoration of edentulous spaces. Several articles have described protocols for the accurate placement of these implants prior to the completion of orthodontic treatment, thus enabling the implant to be used for both orthodontic anchorage and subsequent tooth replacement.[47-49] In these cases, the implant requires 3 to 6 months of osseointegration prior loading. These traditional dental implants have a number of inherent disadvantages namely, multiple procedures for their placement, the use of a large diameter implant, a time-consuming laboratory protocol (if used as a permanent implant[50,51]), a third invasive surgical procedure to

remove (if used as a temporary device), additional expense and sufficient time to allow for their osseointegration with the surrounding bone.

In contrast, TADs are retained by mechanical interlocking of the cortical bone around the implant and do not rely on osseointegration. They offer the advantage of lower cost, a single surgical placement procedure, smaller size with potential for more placement sites, no additional laboratory work, a simple removal procedure and no waiting period to allow for osseointegration.[52] The fundamental question therefore must be asked – how strong is this mechanical interlocking of the cortical bone? This is one of the questions that will be investigated in this study.

TADs may be particularly useful in cases where the conventional anchorage support is compromised. This may include patients with a reduced level of periodontal support or in partially edentulous patients. An absolute indication for their use is the requirement for minimum undesired reactive forces.[53] The suggested cases for their use include anchorage for tooth movements that would otherwise be very difficult to achieve without causing unwanted side-effects. Such cases include:

- Patients with insufficient teeth for the application of conventional anchorage
- Cases where the forces on the reactive unit would generate adverse side effects
- Patients with a need for asymmetrical tooth movements in all planes of space
- In some cases, as an alternative to orthognathic surgical procedures[44]

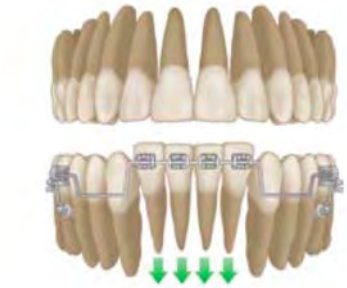
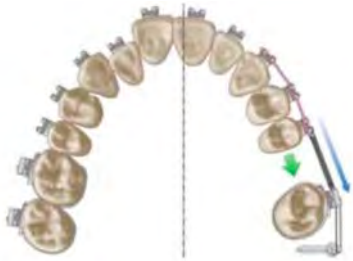
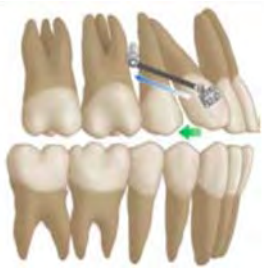
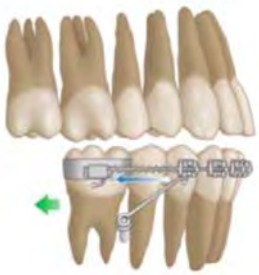
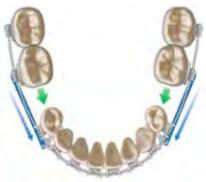
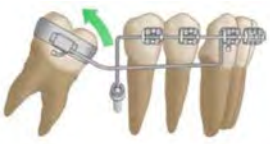
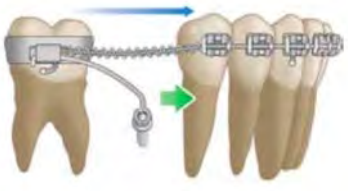
In recent years, the application of TADs has been expanded and now includes the following:

- Closure of extraction spaces[54-56]

- Correction of a canted occlusal plane[57]
- Extrusion of impacted canines[58]
- Extrusion and uprighting of impacted molars[59-61]
- Molar intrusion [54-62]
- Intermaxillary alignment for the correction of sagittal discrepancies[63,64]
- Correction of vertical skeletal discrepancies that would otherwise require orthognathic surgery[65,66]
- Forced eruption
- Correction of posterior buccal crossbite[1]

Some clinical examples of the use of TADs in Orthodontic practice are given in Figure 1.2.

**Figure 1.2 Clinical applications of TADs**

| Correction of Deep Over Bites[23,57, 67] | Alignment of Dental Midlines[57] |
|---|---|
|  |  |
| **Distalisation of Maxillary Teeth[68]** | **Distalisation of Mandibular Teeth[63,66]** |
|  |  |
| **Molar Mesialisation[70,71]** | |
|    | |
| **Molar Uprighting[57]** | **Mesialisation of Mandibular Premolars[70]** |
|  |  |

## 1.7 Sites for Placement of TADs

The biggest challenge in TAD insertion is insuring their accurate placement, thus avoiding adjacent root structures.[72] Numerous anatomical sites for application have been proposed,[58,71,73] including the symphysis or parasymphysis, the alveolar process (between the roots) and the retromolar region.[44,57] In the maxilla, possible sites are the sub-nasal spine, the palate (in the median or paramedian area), the infra-zygomatic crest, the maxillary tuberosities and the alveolar process (between the roots, either buccally or palatally).[57]

A volumetric CT study of 20 patients to assess the hard and soft tissue depths required for TAD insertion, indicated that 10 mm length screws could be placed in the symphysis and retro-molar regions and 4 mm lengths were preferable in the mid-palate area, incisive and canine fossae.[74]

Kanomi[38] and Costa *et al.*[39] implanted TADs (1.2 mm and 2mm in diameter) into the basal bone below the roots of the teeth, to prevent root damage. As the implanted TADs were positioned so high, the applied force for applying vertical vectors was limited. Hence Park *et al.*[54] and Park[75] implanted TADs (1.2 mm in diameter) into the alveolar bone between the roots of the posterior teeth and thereby increased the horizontal component of the applied force.

Park[76] studied images from 21 patients and provided anatomic data to assist implantation of TADs, in the alveolar region. A greater amount of bone tissue was found to be present in the inter-radicular spaces between the second premolar root and

first molar root in the upper arch and between the first molar root and the second molar root in the lower arch.

Even when the TAD has been placed in an area of sufficient bone, it is questionable whether the TAD remains stationary throughout its full period of loading. Liou *et al.*[77] found that TADs inserted in the zygomatic buttress move when orthodontic forces are applied. When loaded over a period, these fixtures were displaced by up to 1.5 mm in the direction of the applied force. The authors conclude that it is therefore prudent to allow 2mm of safety clearance between the TAD and roots of adjacent teeth.

Since the width of a given site varies between patients and the TAD is not absolutely stationary during treatment[77,78] it is necessary to calculate the clearance between the TAD and the root for each separate case. For example, if a 2.0mm diameter TAD is being used, the clinician needs to consider the thickness of the adjacent periodontal ligament and allow for the potential displacement under loading of the TAD (=1.5mm[77]). So if the thickness of the periodontal ligament is 0.25mm, then the necessary clearance is 0.25mm + 2.0mm + 1.5mm + 1.5mm + 0.25mm = 5.5mm. For this patient, therefore, 5.5 mm is the distance that should exist to safely accommodate the 2.0mm diameter TAD.[76]

Poggio *et al.*[79] found that in the maxilla, the safest insertion sites for TADs are in the anterior and apical areas. The least amount of bone was found to be in the tuberosity, making this an unsuitable placement site. In the mandible, the safest sites were found to be between the first and second molars and between the first and second premolars, irrespective of the length of TAD used. They used 25 volumetric tomographic images of the maxilla and mandible to assess the interproximal alveolar sites in terms of the

vertical insertion levels. They found that, in both the maxilla and mandible, insertion in the buccal inter-premolar areas, between 5mm and 11mm from the alveolar crest, would avoid damage to roots. The mean mesio-distal width of interproximal bone available was 3.5mm in maxilla and 4.9mm in mandible. In the maxilla, maximum bone width was available on the palatal aspect of the alveolus; however, in the molar region, insertion more than 8mm from the alveolar crest should be avoided because of proximity to the maxillary sinus. Table 1.3 lists the inter-radicular insertion sites considered to be safe, in the areas of the posterior maxilla and mandible.

**Table 1.3 Order of the safer sites available in the inter-radicular spaces**

| ORDER | POSTERIOR MAXILLA | POSTERIOR MANDIBLE |
|---|---|---|
| **1** | On the palatal side, the inter-radicular space between the maxillary first molar and second premolar, 2-8 mm from the alveolar crest. | Inter-radicular spaces between the second and first molar. |
| **2** | On the palatal side, the inter-radicular space between the maxillary second and first molars, 2-5mm from the alveolar crest. | Inter-radicular spaces between the second and first premolar. |
| **3** | Both on buccal or palatal side between the second and first premolar, 5-11mm from the alveolar crest. | Inter-radicular spaces between the first molar and second premolar at 11mm from alveolar crest. |
| **4** | Both on buccal or palatal side between the first premolar and canine, 5-11mm from the alveolar crest. | Inter-radicular spaces between the first premolar and canine at 11mm from the alveolar crest. |
| **5** | On the buccal side, in the inter-radicular space between the first molar and second premolar, 5-8 mm from the alveolar crest. | |

So the choice of site for placement of the TAD is important, in order to avoid contact with adjacent structures and also to insure that the correct force vectors may be applied, to achieve efficacy in orthodontic tooth movement. The site is also important for insuring the stability (and hence success) of the TAD. As discussed previously, the mechanical interlocking of the TAD with the surrounding bone is paramount to the primary stability of the TAD. It is the forces that need to be applied, in order to

disrupt this mechanical interlocking, that will be investigated in this study.

Kuroda *et al.*[80] noted that, in the maxilla, it can be difficult to obtain sufficient mechanical interdigitation between the TAD and the alveolar bone, owing to the thinner cortical bone in this region. An earlier study by Deguchi *et al.*[81] showed that maxillary implants in dogs had less bone-implant contact than mandibular implants. In addition, oral hygiene control is sometimes poor in the posterior maxilla, which may potentially add to the risk of peri-implant inflammation in that region. Cheng *et al.*[82] also reported that TADs in the posterior mandible exhibited a lower success rate.

Studies have shown that there is sufficient bony support in the palatal midline, for the insertion of small TADs (I.E. 4mm to 6mm).[83-85] An alternative palatal site that offers a better bone support was found to be located 6mm to 9mm posterior to the incisive foramen and 3mm to 6mm paramedian. This site may be considered when TADs larger than 4mm length are to be used.[34] Its worth bearing in mind that if initial alignment is carried out prior to TAD insertion, then a greater number of potential sites may become available, as the operator may intentionally move adjacent roots into a divergent relationship.[85]

Careful assessment of the available bone needs to be carried out, prior to the insertion of TADs, in long-term edentulous areas. In such areas, significant alveolar resorption is likely, which increases the risk of damage to nearby structures, such as the inferior alveolar canal in the mandible and the maxillary sinus in the maxilla.

## 1.8 Insertion of TADs

### 1.8.1 Radiography

As with any surgical procedure, planning is paramount. The planning stage includes the process of gaining informed consent, selection of a suitable TAD and selection of an appropriate site for placement. Accurate study casts assist in identifying potential insertion areas and in the prescription of a surgical stent, should it be required. Bone depth, proximity of adjacent structures and confirmation of the final position post operatively, may be assessed using various radiographic techniques (I.E. panoramic radiography, periapical radiography, lateral cephalostat radiography). Computerised tomography (CT scan) successfully yields very accurate information in this regard,[87] however Prabhu and Cousley[88] argue that, given the costs, radiation exposure and accuracy of alternative radiographical modalities, routine CT investigation is difficult to justify in clinical practice.

### 1.8.2 Surgical Stent

A number of authors[88-91] advocate the use of removable stents manufactured at the planning stage, in order to transfer the pre-surgical prescription to the surgical stage. These 3-D removable stents require an additional laboratory stage, however they facilitate the accuracy of subsequent TAD placement. For many users, the reduced chair-side time and purported patient morbidity outweigh the disadvantage of additional laboratory input. This is especially true when different clinicians are responsible for planning and placement, or for those inexperienced in insertion techniques.[92]

Others currently recommend an 'indirect planning technique', whereby a brass separating wire or a custom-made wire guide is placed between adjacent teeth and over the insertion site. The wire may also be attached to an adjacent fixed appliance bracket.[93] These wire markers are then radiographed in situ, in order to relate them to the proposed insertion site and adjacent dental roots.[66,71,94] These wire markers can provide indirect topographical and angulation information, but offer no guidance on the appropriate inclination for the TAD insertion.

### 1.8.3 Pilot Hole

The method employed in the placement of a TAD will largely be defined by the system being used. The TADs may either be self-drilling (E.G. Aarhus Anchorage System™, AbsoAnchor System™) or non-self-drilling (E.G. Miniscrew Anchorage System™, IMTEC Mini Ortho Implant™). The self-drilling systems do not require the formation of a pilot hole prior to the insertion of the TAD. In cases where the cortical bone is greater than 2mm thick however, a pilot hole may be required by the self-drilling TADs to avoid blunting and bending of the fine screw tip. The pilot hole should be 0.3 mm thinner than the TAD and should be between 2mm and 3mm deep.[44,57] Heidemann *et al.*[95] proposed that the critical size of the pilot hole should be approximately 80% of the external diameter of the TAD. If this critical point is exceeded, the stability is reduced. Some authors suggest the increased failure rate of TADs placed in the mandible may be, to some degree, attributable to over-heating of the bone during pilot hole formation.[96-98]As previously discussed, close contact between the bone and the TAD is critical for stability and Kim *et al.*[99] have found that self-drilling TADs have better bone-to-TAD contact than TADs requiring a pilot hole.

### 1.8.4 Operator

So who is best positioned to place these TADs? Melsen[44] advises that the insertion of TADs should be performed by surgical colleagues, especially when using the non-self-drilling types. McGuire *et al.*[100] argue that periodontists' knowledge of hard and soft tissue anatomy and their ability to manage soft tissue, position them well to collaborate with orthodontists in the placement of TADs.

### 1.8.5 Surgical Procedure

Some TADs require the creation of a mucoperiosteal flap, which clearly makes the procedure more invasive. It is not clear whether this is an efficacy or safety issue.[2] A recent review of the available research concludes that at comparable success rates, the flapless method should be chosen because it is less invasive and causes less patient discomfort.[101]

The clinical procedure for the correct placement of TADs is available in the respective product brochures. However, the following are general principles:

(1) Local anaesthetic is usually placed in the insertion site to anaesthetise the soft tissues.[71] Some operators advocate the use of topical anaesthetic only.

(2) In cases where a pilot hole is necessary, this should be performed under surgical conditions. Soft tissue overlying the insertion site is removed using a scalpel or trephine. The pilot hole is then drilled. This should be done with the drill rotating at less than 1000 rpm. The TAD is subsequently screwed into position using an appropriate screwdriver.

(3) In the case of self-drilling TADs, no soft tissue removal or pilot hole is necessary. Infection control is similar to that for an extraction procedure.

### 1.8.6 Operative Time

Two case series have reported on the operative time for insertion of TADs. The procedure times ranged from 5 to 8 minutes in one series[107] and from 10 to 15 minutes in the other.[102]

### 1.8.7 Insertion Torque

The TAD placement torque (PT) is a measure of resistance to fixture insertion. It has been found that the PT is higher in the mandible than the maxilla and that the failure rate in the mandible increases when high torque values are encountered during insertion. Motoyoshi *et al*.[103] attributed such failures to excessive stress created in the dense bone immediately surrounding the TAD. This stress may potentially result in local ischaemia and resultant bone necrosis. Therefore, it would appear that while a low PT may indicate bone deficiency and subsequent poor initial stability, a high torque value may be associated with bone degeneration. Motoyoshi *et al*. recommend PT values within the range of 5-10 Ncm (when inserting 1.6mm diameter TADs). They also suggest the use of a relatively larger pilot drill for the mandible than the maxilla. Although their conclusions are limited to pre-drilled TADs, it is likely that the general TAD placement torque principles also apply to the self-drilling design.

The TAD placement torque has been identified as a risk factor for early failure and loss. PT values below or above a certain threshold have been associated with up to 12

times higher risk for early failure. To overcome this problem, some TAD manufacturers offer torque-limiting devices to control the placement-torque during TAD insertion. Schätzle *et al.*[72] investigated the accuracy of four such torque-limiting gauges and noted significant variations between individual devices, at all times. The torque output of each individual device deviated, in varying degrees, from the target torque values. Furthermore, the torque output was influenced, again in varying degrees, by the sterilisation process over time.

### 1.8.8 Angle of Placement of TADs

The inherent variations in anatomical sites, coupled with the desired biomechanics, mean there can be no absolute 'ideal' angle at which to place a TAD. Wilmes *et al*. suggest that an insertion angle of about $25^0$ provides the highest torque values, for self-drilling TADS.[104]

Carano *et al.*[57] suggest an angulation of between $30^0$ and $45^0$ in the maxilla, with a more perpendicular angulation in the area of the maxillary sinus, to reduce the risk of perforation. Poggio *et al.*[79] have suggested that, in interproximal sites, TADs should be angled at $30^0$ to $40^0$ to the vertical axis of teeth. This will facilitate the insertion of longer TADs in the available three-dimensional bone trough. Melsen[44] recommends the placement of TADs at an oblique angle towards the apex in the maxilla and as parallel to the roots of teeth (if present) in the mandible. Kyung *et al.*[73] suggest placing the TADs at $30^0$ to $40^0$ to the long axes of the maxillary teeth and at $10^0$ to $20^0$ in the mandible.

## 1.9 Removal of TADs

A significant advantage of TADs is that they are, in theory, easy to remove. To date, however, no data are currently available on the success of their removal.[2] Nonetheless numerous case reports would suggest that their removal and the subsequent healing is normally uneventful. The removal procedure can be performed without the use of anaesthesia[105] however the use of local or topical anaesthesia is advocated in those cases where gingival hypertrophy partially or completely covers the head of the TAD.[106] The TAD is removed using the corresponding screwdriver. Gelgor *et al.*[107] reported that primary wound healing was achieved in 100% of patients, within 14 months of TAD removal.

In the event that the TAD cannot be removed, it is advisable to wait 3 to 7 days after the initial unsuccessful attempt. It has been reported that this time-period will allow for loosening of the device, probably due to bone remodelling or micro-fractures, as a result of the initial removal attempt.[106]

## 1.10 Loading of TADs

In contrast to osseointegrating dental implants, orthodontic TADs are usually loaded immediately and most researchers suggest the application of light forces initially.[39,57,96,106,108] Some authors suggest that it may, however, be beneficial to wait until after the initial inflammatory response has subsided.[15] Early excessive force is likely to cause bony micro-fractures and mobility of the device[109]. Kuroda *et al.*[80]

have found on the other hand that the timing of loading was not related to the success rate.

Two animal studies examined the reaction of surrounding tissues to immediate loading of TADs and would suggest that immediate loading can be performed without complications.[110,111] Büchter *et al.*[110] confirmed that TADs can be immediately loaded by continuous forces not exceeding a tipping-moment (force x lever arm) of 9 Nmm. This study showed good success rates, however the study was conducted on pigs' mandibles and may not necessarily translate directly to human subjects.

Dalstra *et al.*[112] used finite element analysis to show that the immediate loading force should be limited to 50cN (for a 2mm TAD). Miyawaki *et al.*[113] conducted a study on 51 patients, in which 134 TADs of various diameters (1.0mm, 1.5mm and 2.0mm) were immediately loaded and found no significant association between success rates and immediate loading. They concluded that immediate loading of TADs is possible if the applied force is less than 2N. Cheng *et al.*[82] suggest that the application of light initial forces does not directly influence failure rates.

Romanos *et al.*[114] showed that immediate loading increased the ossification of the alveolar bone around the implant. Therefore, immediate loading may contribute to a more favourable prognosis.

Duyck *et al.*[115] demonstrated that the loading of an orthodontic TAD with a constant force, such as that used to effect tooth movements in orthodontics, lead to the deposition of dense cortical lamellar bone around the device. This is advantageous for

stability. In contrast, a variable force produced crater-like marginal bone defects with resorption, which could lead to device failure.

## 1.11 Complications

### 1.11.1 Choice of Site

All surgical procedures carry an inherent risk of iatrogenic damage to local structures. Cases of TADs coming into contact with adjacent structures such as roots, periodontal ligament, nerves and blood vessels.[105,106,116] have been reported. In such cases, the patient will usually feel discomfort at the time of insertion, as the amount of anaesthetic used (if any) is usually minimal. Pain on percussion or mastication may indicate damage to the periodontal ligament and sensitivity to hot and cold may indicate root injury. In such cases, it is advisable to remove the TAD.[106]

In the mandible, the insertion of TADs in the premolar region may cause damage to the mental nerve. In the retromolar area, the insertion may be complicated by limited access and can potentially lead to damage of the inferior alveolar nerve, lingual nerve or even the nerve to the mylohyoid. This is particularly true in cases where significant alveolar resorption has occurred. Placement in the lingual aspect of the mandible should be avoided posterior to the second molar because of the proximity to the lingual nerve.

In the palate, shorter implants should be used, due to the reduced height of bone available. Alternatively, placement of the fixture higher in the vestibule may be

necessary to engage thicker bone, to gain stability. The zygomatic buttress offers good quality bone and is an excellent location when strong, intrusive forces on maxillary posterior teeth are anticipated.[52] Bone turnover rates in the palate are slower than those in the tooth-supporting alveolus, therefore healing may be prolonged and in pre-adolescent patients there is the possibility of damage to the midline suture; an important centre of appositional bone growth.[109] There have also been reported technical difficulties with attachments to TADs failing or distorting.[83,89] Maxillary sinus perforation is possible and can lead to pneumatisation, especially in cases of tooth loss with subsequent alveolar resorption. Extension of titanium screws into the sinus occurs frequently with the use of rigid fixation in trauma and orthognathic surgery without sequelae.[52] Although quoted success rates for palatal TADs are relatively high,[117] the sample sizes reported to date have been small.

If there is inadequate thickness of cortical bone to secure the device, it is likely to fail.[106] Numerous investigators have found that the cortical plate is the principle source of primary stability.[103,104,108,118-120] In the event of insufficient cortical bone thickness, it is recommended that the device be removed and re-inserted at a more appropriate site.

Finally, Miyawaki *et al*.[113] found an association between TAD failure rates and patients with high mandibular plane angles. They attribute this finding to the possibility of thinner cortical bone in these patients.

### 1.11.2 Inflammation and Infection

Inflammation or infection may occur around the TAD, although with aseptic surgical technique, this is not a common occurrence.[44,106] Meticulous oral hygiene is essential and the use of a 0.2% w/v chlorhexidine gluconate mouthwash is advisable as an adjunct to careful oral hygiene procedures.[5,44] Miyawaki *et al.*[113] found that the success rate in patients with tissue inflammation at the site of implantation was lower (54%) than in patients without inflammation (87%).

Where infection does occur, the prescription of an appropriate antibiotic is indicated and consideration must be given to the removal of the source of infection.[105] To date, no studies have demonstrated a need for the routine use of prophylactic antibiotics during the placement of TADs.[93]

### 1.11.3 Mucosa Type

In order to reduce the amount of inflammation and trauma during function, TADs should be placed in keratinized tissue, where possible.[44,105] Fraenal and muscle tissue should be avoided.[113,116] In those rare cases where it is not possible to place the TAD in keratinized tissue, it has been recommended that a healing cap abutment be placed at the time of insertion of the TAD.[105] Design modifications of TADs may be necessary in the future, to overcome this problem and decrease soft tissue irritation.[121] In reality however, it would be prudent to re-consider conventional forms of anchorage in these instances.

### 1.11.4 Root Contact

Iatrogenic root damage during TAD insertion is an important clinical complication.[122] There is always the potential for TADs to come into contact with adjacent roots and cause damage. Potential complications of such root injury include loss of tooth vitality, osteosclerosis and ankylosis.

The prognosis in these cases will be dependant largely on whether there has been injury to the dental pulp.[106] In an animal experimental study, histological examination of the roots of 3 teeth that had been damaged by TAD placement demonstrated complete healing of the periodontal structures in a period of 12 weeks following removal of the devices.[123]

When a TAD has made contact with a root surface, it has been suggested that the offending TAD be removed immediately and replaced. If, however, the TAD is left in place, varying responses can be expected. The tooth root may resorb away from the TAD thread, with cementum healing occurring in most instances after 12 weeks. When the TAD thread is left in contact with the root surface, mostly due to high force and severe trauma to the root during TAD placement, no healing will occur. When the conditions are not optimal, resorption and repair do not occur. The damage is irreversible when the TAD ruptures through thicker areas of dentin and into pulp tissue.

Interestingly, Kim and Kim[122] found that when a TAD was placed less than 1mm from the adjacent periodontal ligament, external root resorption occurred – even though no direct contact was made and there was bone remaining between the TAD

and the root. They therefore recommend that at least a 1 mm space should be left between the TAD and the root surface.

### 1.11.5 TAD Diameter

The choice of TAD diameter will largely be determined by radiographic assessment of the bone width at the insertion site. In principle, a smaller diameter TAD should be used in tooth-bearing areas, to minimise the chances of any contact with the tooth roots. Similarly, TADs with a greater diameter should be used in non-tooth bearing areas, to utilize the greater surface area available for mechanical interlocking.

A number of studies have pointed to an increased fracture rate in diameters of less than 1.2mm,[112,113,124,125] so to avoid this complication it is advised that TADs with a diameter of 2mm or more be used.[116] In contrast, the risk of contact with the adjacent tooth roots seems to increase with TAD diameters of 2mm and greater.[125] Most of the commercially available systems recommend a 2mm diameter TAD.

Some systems recommend and provide an 'emergency anchor' for use in those cases where there is a perceived increased risk of the primary TAD failing. For example, in the LOMAS™ system, a 2mm diameter screw plays the role of emergency anchor for the 1.5mm diameter screw and a 2.3mm diameter screw is used for the 2mm diameter screws.[126]

### 1.11.6 Pilot Hole

There are potential inherent complications in the production of a pilot hole. Vibrations or movement by the operator or patient may result in an enlarged hole, which has

been shown to adversely affect the stability of the TAD.[112] Overheating, caused by high drill speeds and inadequate irrigation may, in severe cases, lead to a localised osteonecrosis.[124] Heidemann *et al.*[127] demonstrated that drill-free insertion of TADs produced little bone debris and less thermal damage than a drilling method. Drilling into a dental root may also occur. It has been suggested by Lin *et al.*[128] that the increased chair-time necessary for the production of a pilot hole, coupled with the invasive nature of the procedure, can lead to an increase in psychological stress for both the patient and operator.

### 1.11.7 Pain and Discomfort

While the potential for intra-operative and post-operative discomfort can never be completed removed, there is little evidence to suggest that discomfort is a common finding, either during placement of a TAD or while under loading. The most likely source of pain during TAD insertion is proximity to or contact with adjacent structures. Post-operatively, pain is most likely to be related to whether a mucoperiosteal flap was raised.

Vogel *et al.*[129] showed that 50% of patients who received periodontal flap surgery reported severe or moderate pain after the procedure. Curtis *et al.*[130] showed that mucogingival surgery was significantly related to pain and was 3.5 times more likely to cause pain than osseous surgery. Al-Ansari *et al.*[131] showed that the placement of conventional dental implants without an incision or flap could reduce both the intensity and the duration of pain after surgery. So the effects of raising a mucoperiosteal flap, in terms of pain and discomfort, are well documented.

In contrast to the mucoperiosteal procedures above, Kuroda *et al*.[80] have shown that TADs placed without a mucoperiosteal incision or flap surgery significantly reduced the patient's pain and discomfort after implantation. They conclude that flap surgery during TAD insertion should be avoided in order to minimize pain for patients.

## 1.12 Contraindications

Manufacturers of TADs suggest a number of contraindications to the placement of TADs (Table 1.4) although there is no implicit evidence presented in any of the brochures that TAD insertion under these conditions would be either less successful or disadvantageous to the patient. The manufacturers seem unanimous that these products should not be placed in children under 13 years of age, except in very select cases and advise that special care must be taken to avoid developing teeth. A number of manufacturers also recommend the use of powder-free gloves when inserting TADs.

**Table 1.4 Suggested contraindications for the insertion of TADs**

| ABSOLUTE CONTRAINDICATIONS | RELATIVE CONTRAINDICATIONS |
|---|---|
| History of metal hypersensitivity | Use of drugs, tobacco, alcohol |
| History of bisphosphonates | Oral mucosal pathologies |
| Titanium allergy | Poor oral hygiene |
| Bone pathology/metabolic disorders | Inadequate dexterity |
| Poor bone healing | Para-functional habits |
| Cardiovascular disease | Poor patient compliance |
| Psychosomatic disease | Insufficient inter-radicular space |
| Uncontrolled active Periodontitis | Insufficient intra-radicular space |
| Undergoing radiation therapy | Reduced mouth opening |
| Unsuitable for surgical procedures | Gingivitis and periodontitis |
| Active, intra oral infection | |
| Inadequate bone quantity or quality | |

## 1.13 Success and Failure

Unlike osseointegrating dental implants, which have been robustly investigated and reported on in the literature,[132] the reported success rates of orthodontic TADs has been slightly more clouded. This is, in large part, due to the analyses of success rates for TADs being complicated by the various definitions of primary outcomes, different timings of success assessment, poor methodologies and lack of clarity in many studies.[1]

Park *et al.*[132] examined a series of 87 patients fitted with 227 TADs and followed them up for 15 months. They reported that there was no statistically significant difference in the success rates for four different TAD designs (success rates = 80-94%). They did find a significant difference, however, between TADs inserted in the maxilla (96%) and those inserted in the mandible (86%). Finally, mobility, the patient's right side, the placement sites for the TADs and inflammation were all factors that influenced the failure rate of TADs.

Park *et al.*[30] reported a 93% success rate at 18 months and a 66% success rate at 3 months. Results from a second study by Park *et al.*[16] reported a 90% success rate over a mean of just over 1 year and a 100% success when the lost TADs were replaced without complication. Most of the TADs evaluated were 1.2mm diameter and the lengths varied from between 6 and 15mm.

Cheng *et al.*[82] loaded 140 TADs (48 for miniplates and 92 freestanding) in vivo and reported a cumulative success rate of 89%. They report that most of the failures

occurred within 1 month of orthodontic loading. In this study, all failures were attributable to mobility.

Barnhart *et al.*[133] placed 21 TADs in the palate (21 subjects) and reported a loss of 4 after loading (due to inflammation at the insertion site) and a success rate of 84.8% at 22 months. On the other hand Wehrbein *et al.*[117] placed 9 TADs in the palate (9 subjects) and reported no failures over a loading period of 11 months.

Tseng *et al.*[134] reported on 45 TADs (25 subjects) used for the purposes of intermaxillary fixation. The overall success rate, after a mean follow-up period of 16 months, was 91%. The placement site of the TAD was found to be the only significant risk factor for failure, with those TADs placed in the ramus having the highest failure rate. The length of the TAD was found to be related to the success rate, with the longer TADs exhibiting the highest success rates.

Luzi *et al.*[135] reported an overall success rate of 84%, in a prospective clinical trial of 140 TADs used for orthodontic anchorage.

The latest report of the ongoing audit of the British Orthodontic Society into the use of TADs by UK orthodontists has examined the data from 130 centres, with placement of 499 TADs in year 1 and 997 TADs in year 2. The data so far would seem to indicate that success is associated with longer TADs, use of a bur to place a pilot hole, placement of TADS in the maxilla and delayed loading.[136]

## 1.14 Consent

As a result of the high success rate and the relatively few complications when using TADS, patients' acceptance of the procedure is generally good.[137] The consent process is straightforward and Echarri *et al.*[138] have suggest the following proforma reproduced in Figure 1.3.

**Figure 1.3 Example of a consent form for use with TADs**

I _____ accept the treatment plan proposed by Dr. _____ which includes the use of temporary devices as an aid to position my teeth.
I understand that Dr. _____ will use these devices as anchorage units because number, position or state of my teeth does not allow their use as anchorage to achieve an effective movement of the teeth that should be repositioned. It was explained to me that ____ devices will be inserted into my mouth in appropriate position in my palate or between my upper or lower teeth.
Dr. _____ explained to me that devices will be inserted with local anaesthesia.
He also explained to me the insertion procedure, and I understand that the absolute success of all these devices cannot be guaranteed. Some risks that can occur are:
1. Discomfort or mild pain in the area.
2. Infection or inflammation of the insertion site.
3. Mobility or loss of micro implant during the treatment.
4. Fracture of micro implant.
5. Damage of the dental roots or other structures adjacent to insertion site.

Name of the patient _____
Date _____

## 1.15 Design Features and materials

### 1.15.1 General Characteristics

Orthodontic TADs are self-tapping screws, consisting of a body that inserts into bone, a neck that protrudes through the mucosa and a head suitable for connection to orthodontic loading systems. Papadopoulos and Tarawneh[5] suggest some properties for an ideal orthodontic TAD. (Table 1.5)

**Table 1.5 Ideal properties of an orthodontic TAD**

- Biocompatible
- Available in different diameter calibres
- Available in different lengths and sizes
- Available with various head designs (E.G. button, bracket)
- Easy to insert
- Self-tapping or self-drilling
- Capable of immediate loading
- Easy to remove without accessory equipment
- Robust
- Cost effective

There are a rapidly growing number of commercially available TADs for orthodontic use currently available on the market. Some examples are illustrated in Table 1.6. The differences between the various devices relate mainly to the following design aspects:

- The metal or alloy used in their fabrication
- The length of the device
- The diameter of the threaded portion
- The platform design
- The head design

**Table 1.6 Currently available TAD systems**

| | Year | Manufacturer | Designer | Material | Length (mm) | Diameter (mm) | Head Design | Insertion Method | Pilot Drill Diameter (mm) | Loading Force (g) | Immediate Loading |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Orthoanchor K-1 System** | 1997 | Densply-Sankin, Japan | Kanomi R (Japan) | C-P Titanium | 4/6/8 | 1.0/1.2 | Button-like head with small plate | Self-tapping | 0.8/1.0 | - | No (6 months healing) |
| **Aarhus Anchorage System** | 1998 | Medicon, Germany | Costa A Melsen B (Italy/Denmark) | Ti-6-A1-4V Alloy | 9/11 | 1.5/2.0 | 0.022x0.028" slot | Self tapping/self drilling | 1.2/1.7 | 50 | Yes |
| **Lin/Liou Orthodontic Mini Anchorage System (LOMAS)** | 2002 | Dentaurum, Germany | Lin J, Liou E (Taiwan) | Ti-6-A1-4V Alloy | 7/9/11 | 1.5/2.0/ 2.3 | Hook/Quattro 22x28ml slot; Rectangular tube | Self tapping/Self drilling | 1.0/1.5/2.0 | 200-600 | Yes |
| **Spider Screw Anchorage System** | 2003 | HDC, Italy | Maine BG *et al.* (Italy) | Ti-6-A1-4V Alloy | 6/8/10 7/9/11 | 1.5/2.0 | 0.021x0.025" slot; 0.025" round hole | Self Tapping | 1.2/1.5 | 50-300 | Yes |
| **Miniscrew Anchorage System (MAS)** | 2005 | Micerium, Italy | Carano A *et al.* (Italy) | C-P Titanium (Grade 5) | 9/11 | 1.3/1.5 | 2 fused spheres 0.6mm round hole | Self tapping | 0.9/1.1 | 50-250 | Yes |
| **VectorTAS** | 2005 | Ormco,, Netherlands | Graham, J *et al.* (USA) | Ti-6-A1-4V Alloy | 6/8/10/ 12 | 1.4/2.0 | Double delta | Self tapping/self drilling | - | - | Yes |

| | Year | Manufacturer | Designer | Material | Length (mm) | Diameter (mm) | Head Design | Insertion Method | Pilot drill Diameter (mm) | Loading Force (g) | Immediate Loading |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **OrthoEasy T.I.T.A.N.** | 2007 | Forestadent (UK) | Bister, D (Germany) | Titanium (Grade 5) | 6/8/10 | 1.6/1.7 | Octangular head | Self-tapping | - | - | Yes |
| **Infinitas** | 2007 | DB Orthodontics (UK) | Cousley, R (UK) | Ti-6-A1-4V Alloy | 6/9 | 1.5/2.0 | Universal head | Self drilling | - | - | Yes |
| **Abso-anchor** | 2003 | Dentos (Korea) | Kyng, Park, Bae *et al.* | Ti-6-A1-4V Alloy | 5/6/7/8/ 10/12 | 1.2-2.0 | Multiple heads (7 designs) | Self drilling/self tapping | - | - | Yes |
| **Orthodontic Mini Implant (OMI)** | - | Leone S.p.A (Italy) | - | Ti-6-A1-4V Alloy | 6/8/10/ 12 | 1.5/2.0 | High head/low head | Self drilling/self tapping | 1.1-1.7 | - | Yes |
| **Ancor Pro** | 2007 | Ortho Organizers (USA) | - | Ti-6-A1-4V Alloy | 6/8/10 | 1.6 | Button/0.022” hole | Self drilling/self tapping | 0.1-2.4 | - | Yes |
| **IMTEC Mini Ortho Implant** | 2005 | IMTEC, USA | Cope JB (USA) | Ti-6-A1-4V Alloy | 6/8/10 | 1.8 | Ball head with 0.7mm round holes (2 holes) | Self tapping | 1.1 | - | Yes |
| **MIA** | 2001 | Dentos, Korea | Park HY, Kyung HS *et al.* (Korea) | C-P Titanium to Ti-6-A1-4V Alloy | 4-12 (9 sizes) | 1.2 -1.8 (7 sizes) | 7 types | Self tapping/self drilling | 0.9/1.0/1.1/1.2 | 300-450 | Yes |

### 1.15.2 Surface Characteristics

TADs used in orthodontics must be removable with minimal effort in order to cause the least amount of iatrogenic damage to the area. For this reason, osseointegration of these devices is a disadvantage. Most of the devices are therefore manufactured with a smooth surface that minimizes the development of bone in-growth and promotes soft tissue attachment at ordinary conditions and in the absence of special surface treatment regiemes.[4,96,97] Animal studies have, however, demonstrated that a limited and variable level of (10-58%) of osseointegration can occur.[96] Thus, the TADs are sufficiently anchored for orthodontic purposes but may still be removed manually.

### 1.15.3 Materials

Generally, two material types are used: commercially pure titanium (C-P titanium) and titanium alloy (Ti-6-A1-4V). Titanium has proven properties of biocompatibility, is lightweight, has excellent resistance to stress, fracture and corrosion and is subsequently considered to be the material of choice. Table 1.7 compares the properties of Ti-6Al-4V and commercially pure titanium. Surgical grade stainless steel has also been used (E.G. Leone mini-implants™) and is used in several systems to fabricate supra-implant attachments (E.G. IMTEC™ mini-implant). As osseointegration in undesirable, TADs are manufactured with a smooth endosseous surface or additional surface treatments (E.G. TOMAS™ system) to actively discourage osseointegration and therefore simplify their removal. The commercially pure titanium is ranked from grade 1 to grade 5, according to its property hardness. The titanium alloy is harder than the pure titanium and is most often used in the manufacture of TADs. (Table 1.7)

From a clinical viewpoint, the main difference between the two materials is the insertion technique. When using TADs manufactured from C-P titanium, a pilot hole may be necessary, particularly in sites where there is a high bone density. Their softer nature means they run the risk of distorting or indeed fracturing on insertion. This softness must also be borne in mind when applying heavy orthodontic loads to the devices.[128] As the Ti-6A1-4V alloy is relatively denser, the risk of bending or breakages is reduced. When inserting these TADs into areas of less dense bone, the manufacturers do not generally recommend the creation of a pilot hole.

Overall, it appears that the harder titanium alloy design is advantageous, owing to its better mechanical retention and its reduced risk of breakages. It seems likely that TADs of this alloy will form the mainstream in the future and for this reason, the three different designs of TADs used in this study were manufactured from titanium alloy.

### 1.15.4 Diameter & Length

TADs are available in various lengths and diameters, to accommodate placement at different sites in the jaws. Most commercially available TADs have a length of between 4 and 12mm, however some systems manufacture TADs up to 21mm.[126]

The diameter of TADs varies according to manufacturer and ranges from 1mm to 2.3mm. Most TADs, however, have a thread diameter ranging from 1.2mm to 2mm. The diameter refers to the widest part of the body, which is the distance between 2 thread tips.

**Table 1.7 Properties of titanium alloy and commercially pure titanium**

| COMPOSITION | Ti-6Al-4V | C-P TITANIUM |
|---|---|---|
| | | |
| C | <0.08% | <0.08% |
| Fe | <0.25% | <0.03% |
| $N_2$ | <0.05% | <0.03% |
| $O_2$ | <0.2% | <0.18% |
| Al | 5.5-6.76% | - |
| V | 3.5-4.5% | - |
| $H_2$(sheet) | <0.015% | <0.0125% |
| $H_2$(bar) | <0.0125% | - |
| $H_2$(billet) | <0.01% | - |
| Ti | Balance | 99.67 |
| **PHYSICAL PROPERTIES** | | |
| Density g/cm$^3$ | 4.42 | 4.54 |
| Melting Range $^oC$+/-15$^oC$ | 1649 | 1668 |
| Specific Heat J/Kg.$^oC$ | 560 | 528 |
| Volume Electrical Resistivity ohm-cm | 170 | 0.0000554 |
| Thermal Conductivity $Wm^{-1}k^{-1}$ | 7.2 | 22 |
| **MECHANICAL PROPERTIES** | | |
| Yield Strength MPa | 825-869 | 485 |
| Ultimate Strength MPa | 895-930 | 550 |
| Elongation Over 2 Inches % | 18 | 20-40 |
| Reduction in Area % | 20+ | 45-65 |
| Young's Modulus GPa | 110-114 | 104 |
| Ultimate Strain % | 6-10 | 15 |
| Poissons Ratio | 0.33 | 0.32 |

### 1.15.5 Collar

The main purpose of the collar design is to prevent irritation of the surrounding gingival tissues from the attachments to the head. Suppression of the gingival tissues can keep the head exposed, permit easy access to the orthodontic accessories and aid in patient comfort. Having a smooth, polished platform will also aid in this endeavour. It is suggested that the platform height should be 1 to 2mm thicker than the soft tissue into which it is embedded.[128]

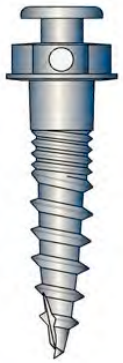
### 1.15.6 Thread Body

*Self-drilling* TADs have a sharp, pointed end and do not require preliminary drilling for insertion. Some such screws have an additional notch or groove at their tip, which adds to the bone-cutting capability. These self-drilling screws are sometimes referred to as 'self-cutting'. The additional bone-cutting notch has previously been considered by some authors to increase the chance of fracture of the screw tip, but with current designs this is not a well-supported concern. The additional cutting power is designed to ease screw insertion, particularly in areas of more dense bone in the jaws such as the retromolar area.

*Self-tapping* TADs require no separate tapping of a thread, whether or not they are self-drilling and so all currently available TADs are self-tapping.

Finally, the thread body may be either conical or parallel. The parallel design tapers only at the very tip of the infra bony section. (Figure 1.4)

**Figure 1.4 Conical and parallel thread design**

| Conical thread design | Parallel thread design |
|---|---|
|  |  |
| E.G. IMTEC Ortho Implant™<br>Infinitas™<br>AnchorPro™<br>Aarhus Anchorage System™<br>AbsoAnchor™<br>Miniscrew Anchorage System™ | E.G. Orthodontic Mini Implant™ |

### 1.15.7 Head Design

Many of the currently available TADs are manufactured with a variety of head designs, to accommodate various clinical scenarios (Table 1.8). The most common head design is either hexagonal or spherical in shape, with a button-like appearance. This design is mainly used for direct anchorage, with the attachment of auxiliaries through a hole in either the head the neck, usually 0.8mm in diameter. However this design has the following inherent disadvantages:

- Difficulty when hooking more than 2 coil springs
- The commercially available coil springs can slip off the head, particularly when the TAD is placed at an acute angle
- Movement is limited to 2 dimensions

A bracket design head is also available and may be used for either direct or indirect anchorage. This design has the following inherent disadvantages:

- The bracket-like head is not a true Edgewise design, which can lead to difficulties in wire-ligation
- The slot size is limited and so it may not be compatible with Edgewise systems
- As the hole is round, the torque normally achieved through the use of a rectangular wire in a rectangular slot, cannot be expressed

Finally, a further hook design is used by the TOMAS™ product.

**Table 1.8 Various head designs for TADs**

| Button-like head design | Bracket-like head design |
|---|---|
| Anchor Pro™<br>IMTEC Ortho Implant™<br>AbsoAnchor System™<br>Dual Top Anchor System™<br>Aarhus Anchorage System™<br>Orthoanchor K1 System™<br>Spider Screw™ Implant System. | Infinitas™<br>Aarhus Anchorage System™<br>AbsoAnchor System™<br>Dual Top Anchor System™<br>Spider Screw Implant System™<br>Temporary Mini Orthodontic Anchorage System™ |

## 1.16 Summary

In 2007, the Interventional Procedures Programme Specialist Advisers of the National Institute of Health and Clinical Excellence considered the key efficacy outcomes of the use of TADs.[2] They concluded that TADs provided:

- Effective anchorage and intended tooth movement
- Acceptable failure rates
- Good patient acceptance
- A reduction in extraction rate requirement for external headgear

To date, much of the evidence relating to TADs has been anecdotal.[2] A Cochrane systematic review in 2007 commented: "In view of the fact that this is a dynamic area of orthodontic practice we feel there is a need for high quality, randomised controlled trials." Of course there are financial restrictions in running trials of this nature. A clinical randomized controlled trial is currently underway in Chesterfield, UK.

The growth in popularity of TADs is largely attributable to their ease of insertion and removal, wide range of insertion sites, low cost, low patient morbidity and discomfort, and early/immediate loading. They are also considered to be clinician-friendly, since orthodontists can easily insert them as a routine procedure. Although they have been shown to displace under loading,[62] they can be safely placed in most interproximal areas. Their main limitations are dependence on adequate bone quality/depth for stability, adjacent soft tissue inflammation and a small risk of fracture during insertion or removal.

It has been more than 70 years since the concept of skeletal anchorage was first described. Improvements in technology and technique now suggest that its application is not just feasible, but predictable, safe and reliable. With reported success rates of 70 to 100% the clinical application of this form of anchorage would certainly seem acceptable.[137] With some authors anticipating the development of resorbable TADs in the future[139] they are certainly here to stay.

## 1.17 Aims of Study

Many of the current *in vitro* studies have described the primary stability of orthodontic TADs in terms of the insertion and removal torque. There is, however, little data available on the external forces required to dislodge the TADs once they have been placed.

It is unclear at this time whether the direction of the extrusive force will affect TAD success *in vivo*. This study will examine the *in vitro* affects of placing a force on the TADs using force vectors that one would normally associate with routine orthodontic tooth movements. The aims of this study are therefore:

(i) To measure the force required to dislodge orthodontic TADs of varying designs, from an artificial bone substitute.

(ii) To compare the 3 different designs of TADs in terms of the forces required to dislodge them from an artificial bone substitute.

(iii) To investigate whether varying the cortical thickness of the test block will affect the forces required to dislodge the TADs.

The null hypotheses state that:

(i) There is no significant difference between the 3 designs of TADs, in terms of the applied force required to dislodge them.

(ii) The thickness of the cortical portion of the test block will have no affect on the forces required to dislodge the TADs.

# Chapter Two

# MATERIALS

## 2.1 Temporary Anchorage Devices (TADs)

It seems likely that TADs manufactured from titanium alloy (as opposed to commercially pure titanium) will form the design mainstream in the future and for this reason the TADs chosen for this study were manufactured from this alloy. Three contrasting designs of TAD were used and in order to ensure experimental consistency, each of the three TADs had the same thread-portion dimensions and conical thread design. (Figure 2.1)

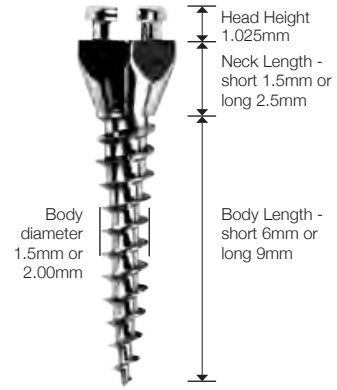
**Figure 2.1 Testing was carried out on 3 Temporary Anchorage Devices**

| Infinitas™ | Anchor Pro™ | Ortho Implant™ |
|---|---|---|
|  |  |  |
| Conical thread design<br>Bracket-like head design<br>Diameter: 2mm<br>Length: 6mm | Conical tread design<br>Button-like head design<br>Diameter: 2mm<br>Length: 6mm | Conical tread design<br>Button-like head design<br>Diameter: 2mm<br>Length: 6mm |

### 2.1.1 Infinitas™

The Infinitas Temporary Anchorage Device is fabricated from grade 5 titanium alloy (Ti-6Al-4V). The head design combines cross-slots and both external and internal undercuts on a single vertical plane. In contrast to conventional TAD head designs, the Infinitas head has a low profile that still allows direct attachment of various types of auxiliaries and archwires, with dimensions up to 0.021" x 0.025". It is claimed that the low profile head not only improves patients' comfort but also reduces the risk of undesirable tipping moments, by limiting the ratio of the head and neck length to the body length.[113] (Figure 2.2)

**Figure 2.2 The Infinitas™ Temporary Anchorage Device**

<table>
<tr><th colspan="3">Infinitas™ TAD</th></tr>
<tr><td colspan="3"> 
</td></tr>
<tr><th>Head</th><th>Transmucosal Neck</th><th>Self Drilling Thread</th></tr>
<tr><td>  </td><td> 
</td><td>  </td></tr>
<tr><td>The Infinitas head is designed to facilitate appliance placement (elastomeric chains/wire springs). Two intercepting slots can accept wire up to 0.021” x 0.025”.</td><td>1.5mm neck for areas of thin mucosa and 2.5mm neck for areas of thick mucosa</td><td>All Infinitas TADs are self-drilling</td></tr>
</table>

The coronal part of the Infinitas neck has a pentagonal shape that closely matches the internal contours of the insertion screwdriver. As the screw head is small, the screwdriver engages only the neck, which serves to minimise breakages. The apical part of the neck is tapered to enable insertion at both perpendicular and oblique angles to the cortical plate, with a reported minimal compression of adjacent mucosa.

The Infinitas TAD is available in two neck lengths (1.5mm and 2.5mm) to accommodate typical buccal and palatal mucosal depths, respectively.[140] In this study, the 2.5mm neck design was used. Although buccal insertions are routinely performed

with a direct transmucosal technique, a customised, reusable circular mucotome is available to remove loose or thick mucosa, especially at palatal insertion sites, should it be required.

The Infinitas body comes in diameters of 1.5mm and 2.0mm and lengths of 6mm and 9mm, for four size combinations. With the two neck lengths and universal head design, there are five different configurations for all alveolar and palatal insertions.[92]

(Table 2.1)

All the Infinitas™ TAD variations are self-drilling, with asymmetrical, modified buttress threads and tips.[99,146]

**Table 2.1 Infinitas™ configurations and insertion sites**

| DIAMETER (mm) | BODY LENGTH (mm) | NECK LENGTH | TYPICAL INSERTION SITES |
|---|---|---|---|
| | | | |
| 1.5 | 9 | Short | Maxilla (Buccal) |
| 1.5 | 6 | Short | Mandible, anterior Maxilla |
| 1.5 | 9 | Long | Maxilla (Palatal) |
| 2.0 | 6 | Long | Mid-Palate |
| 2.0 | 9 | Long | Edentulous areas, temporary abutments |
| | | | |

Engagement of the cortical plate is maximised by two specific Infinitas design features. Firstly, the thread continues to the coronal end of the body, which provides full seating in the bone. Secondly, the 1.5mm diameter body version widens coronally, beginning 1.5mm from the head, with the thread diameter (and body-core) gradually reaching 2mm at the junction with the neck. This results in an increased torque during the final stage of insertion. While the additional torque may improve primary stability,[119] the extra screw width at the coronal section is claimed to enhance the strength in this area,

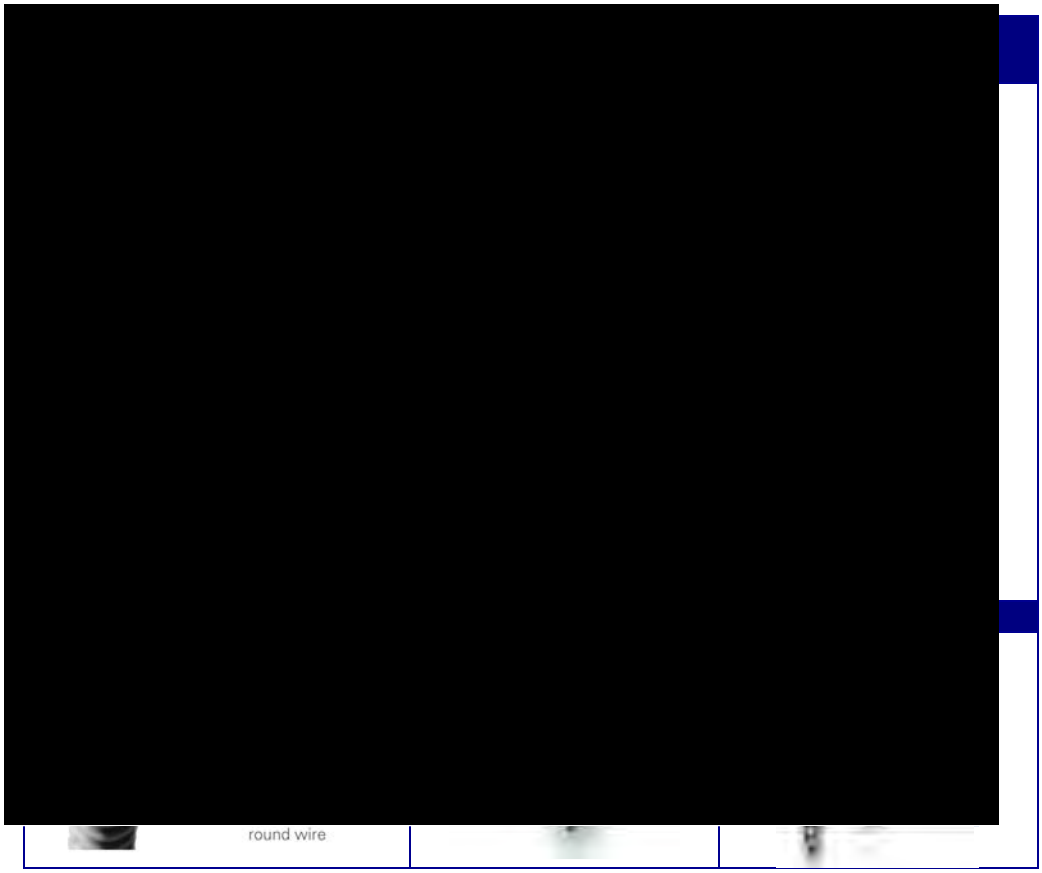
considering that a 0.2mm increase in diameter of a screw can increase its strength by 50%.

The Infinitas system includes a cortical bone punch to perforates dense cortical bone up to a maximum depth of 2mm. The manufacturers recommend the use of this device for all mandibular and mid-palatal insertion sites. The punch may also be used to notch the cortex and thus prevent TAD slippage during oblique insertion.[92]

### 2.1.2 Ancor Pro™

The Ancor Pro TAD is manufactured from titanium alloy (Ti-6Al-4V) and features a multi-functional single head for the attachment of elastic chains, coil springs and archwires up to 0.022". The sharp tip and threads of the anchor allow for self-drilling and self-tapping. These TADs are available in 1.6mm diameter and multiple lengths of 6mm, 8mm and 10mm. (Figure 2.3)

**igure 2.3 The Ancor Pro™ Temporary Anchorage Device**

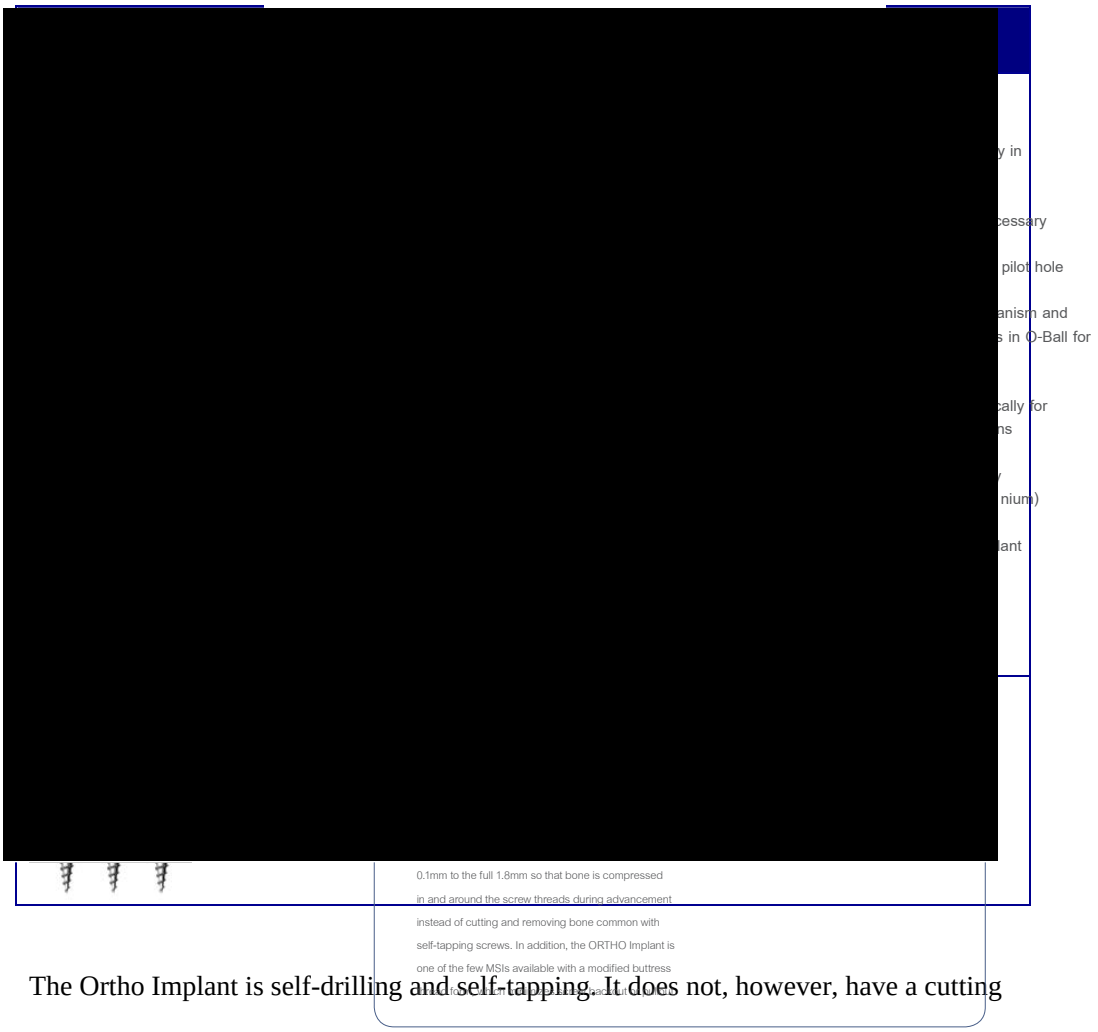



### 2.1.3 IMTEC Ortho Implant™

The Ortho Implant was developed from IMTEC's already established TAD system called 'Sendax Mini Dental Implant'. The Sendax MDI was modified at the head to provide orthodontic force systems the benefit of a hole to which an appliance may be attached. The Ortho Implant is 1.8mm in outer diameter and 1.6mm core diameter at the head and tapers. There is a 0.7mm diameter hole in the ball head of the implant and a second 0.76mm hole in the square hex of the implant oriented at 90° to the first hole. (Figure 2.4)

The holes provide a mechanism for attachment of a variety of orthodontic auxiliaries. These TADs are available in 6mm, 8mm and 10mm lengths and are manufactured from titanium alloy (Ti-6Al-4V).

**Figure 2.4 The IMTEC Ortho Implant™**




The Ortho Implant is self-drilling and self-tapping. It does not, however, have a cutting flute at the apex to cut the bone. In lieu of a thread-cutting flute the apical 4mm is tapered from 0.1mm to the full 1.8mm. The manufacturers claim that this causes compression in the bone adjacent to the tip, as the TAD is advanced. This is in contrast

to cutting tips, where bone is removed at the advancing tip. The manufacturers claim that the modified buttress thread form resists dislodgement of the TAD.

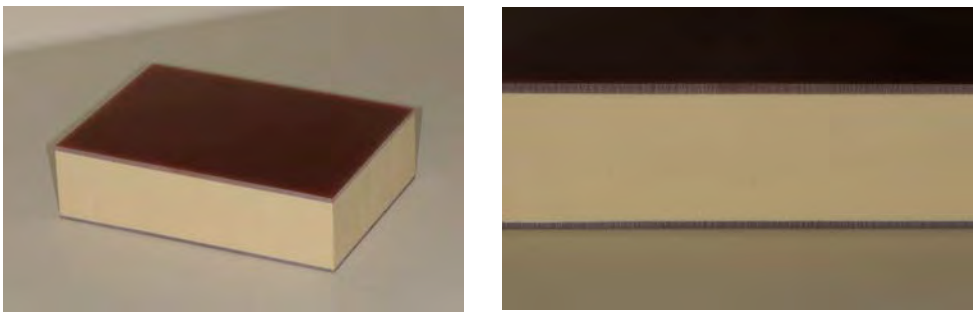
The Ortho Implant kit includes a soft tissue punch to aid in placement of the implant, a variety of different sized drivers, a 1.1mm pilot drill, and a healing cap abutment that is not necessary in every case. The healing cap can be used to ligate an appliance, elastomeric or ligature to the implant.[105]

## 2.2 Artificial Bone Substitute

An artificial bone substitute was used as a substrate for insertion of the TADs. This was manufactured from solid, rigid, polyurethane foam with similar mechanical characteristics to cancellous bone. The polyurethane foam was laminated with either 2mm or 3mm thick short-fibre-filled epoxy sheets, using acrylate bond. (Figure 2.5)

**Figure 2.5 Laminated test blocks as artificial bone substitute**

**Artificial Bone Substitute**



**'Sawbones' - Pacific Research Laboratories Inc., Vashon Island, WA, USA**

Short-fibre-filled epoxy sheets are primarily used as an alternative test medium to human cortical bone. These fourth-generation epoxy sheets are a mixture of short glass fibres and epoxy resin that has been pressure moulded into a thin sheet. (Table 2.2)

**Table 2.2 Properties of short-fibre-filled epoxy sheets**

| DENSITY | COMPRESSIVE | | TENSILE | | |
|---|---|---|---|---|---|
| | STRENGTH | MODULUS | STRENGTH | MODULUS | STRAIN |
| $g/cm^3$ | MPa | GPa | MPa | GPa | % |
| 1.64 | 157 | 16.7 | 106 | 16 | 0.80 |

The foam has a closed cell content ranging from 96.0 to 99.9% and a coefficient of thermal expansion (CTE) of 6.3x10-5 $K^{-1}$ (from -46 to +93 °C). Its water absorption ranges from 0.301 to 0.0 $kg/m^2$. It is available in a range of sizes and densities, from 0.16 to 0.80 grams per cubic centimetre. (Table 2.3)

**Table 2.3 Properties of solid, rigid polyurethane foam**

| DENSITY | COMPRESSIVE | | TENSILE | | SHEER | |
|---|---|---|---|---|---|---|
| | STRENGTH | MODULUS | STRENGTH | MODULUS | STRENGTH | MODULUS |
| $g/cm^3$ | MPa | MPa | MPa | MPa | MPa | MPa |
| 0.08 | 0.6 | 16 | 1.0 | 32 | 0.59 | 7.1 |
| 0.16 | 2.2 | 58 | 2.1 | 86 | 1.6 | 19 |
| 0.24 | 4.9 | 123 | 3.7 | 173 | 2.8 | 33 |
| 0.32 | 8.4 | 210 | 5.6 | 284 | 4.3 | 49 |
| 0.28 | 18 | 445 | 12 | 592 | 7.6 | 87 |
| 0.64 | 31 | 759 | 19 | 1000 | 11 | 130 |
| 0.80 | 48 | 1148 | 27 | 1469 | 16 | 178 |

## 2.3 Embedding material

The laminated test blocks were sectioned and embedded in Crystacal R (BPB Formula, Newark Works, Nottinghamshire, UK). This is a high strength hemihydrate plaster ($CaSO_4.^1/_2\ H_2O$) produced from high purity gypsum mineral. It has a dry-set density of approximately 1670 $kg/m^3$.

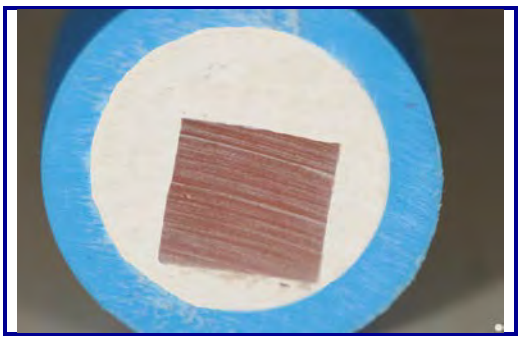
# Chapter Three

## METHOD

## 3.1 Apparatus Setup

The artificial bone substitute was sectioned into individual test blocks measuring 144mm$^2$, by means of a jig-saw. These test blocks were then mounted in rigid plastic tubing with an external diameter of 22.5mm and an internal diameter of 19mm. The test blocks were mounted by embedding in Crystacal R. This setup was repeated a total of 300 times - 150 times for the 2mm thickness test blocks and 150 times for the 3mm thickness test blocks. (Figure 3.1)

**Figure 3.1 Laminated test block embedded in Crystacal R**



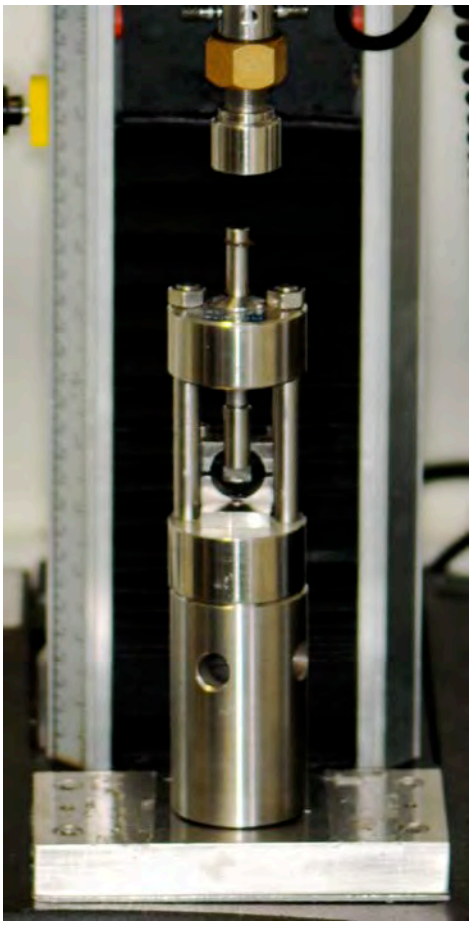
100 of each type of TAD were inserted into the artificial bone substitute, according to each manufacturer's instructions. A modified stent system[92] was used to ensure that each TAD was inserted at $90^0$ to the surface of the test material. 50 of each TAD were inserted into the 2mm thickness test block and 50 into the 3mm thickness test block. (Figure 3.2)

**Figure 3.2 TADs inserted into test blocks**


Testing was performed on an Instron servo-hydraulic universal testing machine (Model 5544, Instron Ltd., High Wycombe, Buckinghamshire, UK). The embedded TADs were mounted on the Instron by means of a bespoke jig (Bencor Multi-T, Bencor, Calgary, Alberta). (Figure 3.3)

**Figure 3.3 The Bencor Multi-T jig attached to the Instron testing machine**

**The Bencor Multi-T Jig**

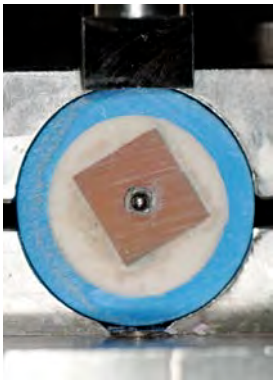


The Instron was operated via a PC with relevant Merlin software (Version 5.41; Instron, Darmstadt, Germany). Figure 3.4 [a] shows the final setup, with force being applied to an IMTEC Ortho Implant™.

**Figure 3.4 The final setup just prior to testing**

**[a] Apparatus Setup**


**[b] Force application to TAD using Instron and Jig**



The traction force was 2.54 mm/min, in line with similar tests. The applied force (load) was measured as a function of screw displacement in the substrate. The TADs

were loaded until they lost their hold in the test material and the maximum force applied (peak load) was then recorded. The Instron was set up to move in increments of 0.2mm (Figure 3.4 [b]) and the maximum force reading was recorded from the Instron computer. The data was recorded in Microsoft Excel and subsequently analysed using PASW Statistics 18 (SPSS, Hong Kong).

# Chapter Four

## RESULTS

## 4.1 Univariate Analysis of Variants

**Table 4.1 Analytical identifiers**

| VARIABLE | IDENTIFIER |
|---|---|
| Infinitas™ | 1 |
| Ortho Implant™ | 2 |
| Anchor Pro™ | 3 |
| Mandible (3mm laminate) | 4 |
| Maxilla (2mm laminate) | 5 |

**Table 4.2 Between-subject factors**

| | | N |
|---|---|---|
| TAD IDENTIFIER | 1 | 100 |
| | 2 | 100 |
| | 3 | 100 |
| SUBSTRATE IDENTIFIER | 4 | 150 |
| | 5 | 150 |

The ANOVA (Table 4.3) clearly demonstrates that the interaction between the TADs and the substrates is not significant I.E. P>0.05 (0.591).

**Table 4.3 ANOVA summary table**

Dependent Variable: FORCE

| Source | Type III Sum of Squares | Df[1] | Mean Square[2] | F[3] | Significance |
|---|---|---|---|---|---|
| Corrected Model | 7.727E5 | 5 | 154547.530 | 114.296 | .000 |
| Intercept | 8.041E7 | 1 | 8.041E7 | 59467.543 | .000 |
| TAD IDENTIFIER | 40084.407 | 2 | 20042.203 | 14.822 | .000 |
| SUBSTRATE IDENTIFIER | 731229.635 | 1 | 731229.635 | 540.781 | .000 |
| TAD IDENTIFIER * SUBSTRATE IDENTIFIER | 1423.609 | 2 | 711.804 | .526 | .591 |
| Error | 397539.313 | 294 | 1352.175 | | |
| Total | 8.158E7 | 300 | | | |
| Corrected Total | 1.170E6 | 299 | | | |

a. R Squared = .660 (Adjusted R Squared = .655)

**df[1]** (Degrees of freedom)
5 degrees used up for 3 TADs and 2 substrates
1 degree used for Intercept
294 (300-6) remaining for estimating the within-group variants

**Mean Square[2]** Estimates of the variants within the model

**F[3]** Ratios between the variants estimates

* Tad Identifier X substrate Identifier.
Describes the interaction between the TAD variable and the substrate variable.

## 4.2 Marginal Means

**Table 4.4 Overall mean force for both substrates**

Dependent Variable: FORCE

| Mean | Std. Error | 95% Confidence Interval | |
|---|---|---|---|
| | | Lower Bound | Upper Bound |
| 517.72 | 2.12 | 513.54 | 521.90 |

**Table 4.5 TAD identifier**

Dependent Variable: FORCE

| TAD IDENTIFIER | Mean | Std. Error | 95% Confidence Interval | |
|---|---|---|---|---|
| | | | Lower Bound | Upper Bound |
| 1 | 512.977 | 3.677 | 505.740 | 520.214 |
| 2 | 533.641 | 3.677 | 526.404 | 540.878 |
| 3 | 506.545 | 3.677 | 499.308 | 513.782 |

Table 4.6 shows that substrate 4 gives a significantly higher score than substrate 5.

**Table 4.6 Substrate identifier**

Dependent Variable: FORCE

| SUBSTRATE IDENTIFIER | Mean | Std. Error | 95% Confidence Interval | |
|---|---|---|---|---|
| | | | Lower Bound | Upper Bound |
| 4 | 567.091 | 3.002 | 561.182 | 573.000 |
| 5 | 468.351 | 3.002 | 462.442 | 474.260 |

## 4.3 Post Hoc Tests

It can be seen from Table 4.7 that TADs 1 and 2 (Infinitas™ and Ortho Implant™) differ significantly from each other.

Similarly, TADs 2 and 3 (Ortho Implant™ and Anchor Pro™) differ significantly from each other.

However, no significant difference exists between TADs 1 and 3 (Infinitas™ and Anchor Pro™).

**Table 4.7 TAD identifier – multiple comparisons**

FORCE

Tukey HSD

| (I) TAD IDENTIFIER | (J) TAD IDENTIFIER | Mean Difference (I-J) | Std. Error | Sig. | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| 1 | 2 | -20.6639* | 5.20034 | .000 | -32.9140 | -8.4137 |
| | 3 | 6.4317 | 5.20034 | .432 | -5.8184 | 18.6818 |
| 2 | 1 | 20.6639* | 5.20034 | .000 | 8.4137 | 32.9140 |
| | 3 | 27.0956* | 5.20034 | .000 | 14.8454 | 39.3457 |
| 3 | 1 | -6.4317 | 5.20034 | .432 | -18.6818 | 5.8184 |
| | 2 | -27.0956* | 5.20034 | .000 | -39.3457 | -14.8454 |

Based on observed means

The error term is Mean Square (Error) = 1352.175

* The mean difference is significant at the .05 level

**Table 4.8 Homogeneous subsets**

**FORCE**

Tukey HSD[a,,b]

| IMPLANT IDENTIFIER | N | Subset 1 | Subset 2 |
|---|---|---|---|
| 3 | 100 | 506.5452 | |
| 1 | 100 | 512.9769 | |
| 2 | 100 | | 533.6408 |
| Sig. | | .432 | 1.000 |

Means for groups in homogeneous subsets are displayed.
Based on observed means.
The error term is Mean Square(Error) = 1352.175.
a. Uses Harmonic Mean Sample Size = 100.000.
b. Alpha = .05.

## 4.4 Summary of Findings

The data from this experiment confirm that there was no significant difference observed between the Infinitas™ and Ancor Pro™ TADs, however there was a significant difference between both of these TADs and the Ortho Implant™ – The Ortho Implant™ requires a significantly higher force to be dislodged from both the 3mm laminated test block and the 2mm laminated test block.

The force required to dislodge the TADs from the 3mm laminated test blocks is significantly higher than the force required to dislodge the TADs from the 2mm laminated test blocks.

# Chapter Five

# DISCUSSION

## 5.1 Experimental Design

Research has indicated that there are many factors working to influence the success of TADs *in vivo*. The success or failure can depend on the operator's experience, the site of implantation, local bone density, force vectors applied to the TAD, level of oral hygiene, insertion torque, angle of placement, the TAD material and the TAD design. This study was designed with the aim of standardising as many of these variables as possible, in order that the specific effect of the threaded portion of the TADs could be ascertained in different media.

### 5.1.1 TADs

The TADs used in this study were selected because they each exhibited different design features. To ensure accurate comparability of the results, they were each made from the same titanium alloy (Ti-6Al-4V) and they each exhibited the same length (6mm) and diameter (2mm). They each featured a conical thread design and are commercially available for use in mainstream orthodontic practice. There is little price variation between the TADs.

### 5.1.2 Artificial Bone Substitute

A prerequisite for retention of a TAD is optimum primary stability, which is related to the contact area between the bone and the TAD. This is influenced by the thickness and density of bone, the insertion torque and whether a pilot hole is drilled before the TAD is placed. The density of bone into which the TAD is placed, is influenced by

many factors, including but not limited to patient's age, nutritional status, presence of underlying systemic conditions, hormonal influences and presence or absence of teeth in the area and length of time the teeth have been absent. In order to eliminate these variables, an artificial human bone substitute was used, in preference to cadaverous, porcine or murine bone used in similar studies.

Ono *et al.*[141] examined human cortical bone thickness from 1 to 15 mm below the alveolar crest at 1mm intervals. They found the average cortical bone thicknesses ranged from 1.09 to 2.12 mm in the maxilla and 1.59 to 3.03 mm in the mandible. In another study, Schwartz-Dabney *et al.*[142] found that mandibular cortical bone density differed among sites. Variability in the mean density throughout most sites was small, ranging between 1.85 –2.00g/cm$^3$. The 2mm thick, short-fibre-filled epoxy sheets thus closely replicated the cortical bone found in human maxillae, while the 3mm sheets closely replicated the mandibular cortex.

Solid rigid polyurethane foam is primarily used as an alternative test medium for human cancellous bone. It provides a consistent and uniform material with properties in the range of human cancellous bone. The American Society for Testing and Materials states that "The uniformity and consistent properties of rigid polyurethane foam make it an ideal material for comparative testing of bone screws and other medical devices and instruments".[143]

### 5.1.3 Insertion of TADs

A number of authors advocate the use of removable stents, to increase the accuracy of placement. The anecdotal evidence[47,89] would suggest that this is sound clinical practice and so a stent was used to ensure that each TAD was inserted at right angles to the test material. The stent was manufactured using vacuformed Essix C+® plastic material, at 1mm thickness (Dentsply, Raintree Essix).

This setup ensured that each TAD was inserted at the same angulation in the test material (I.E. $90^0$). This is important as it ensured uniformity of the applied force to each TAD (I.E. the applied force vector acted at $180^0$ to the surface of the test material and hence at $90^0$ to the long axis of each TAD.

The manufacturer's instructions were strictly adhered to, when inserting the TADs into the test material. The Infinitas™ system includes a cortical bone punch that perforates dense cortical bone and mucosa, using a slow manual clockwise rotation, up to a maximum depth of 2mm. The manufacturers recommend the use of this device for all mandibular sites and so this was used when inserting the Infinitas™ TADs into the 3mm test blocks. Neither the Anchor Pro™ system nor the IMTEC Ortho Implant™ routinely recommended this procedure and so these TADs were inserted directly.

As the manufacturers do not advocate the routine use of a torque-measuring or torque-limiting gauge, no such devices were used. In any case, as this study involves the use of self-drilling TADs into uniform artificial bone substitute, such devices are not necessary. Therefore, each of the TADs was inserted by hand, using the

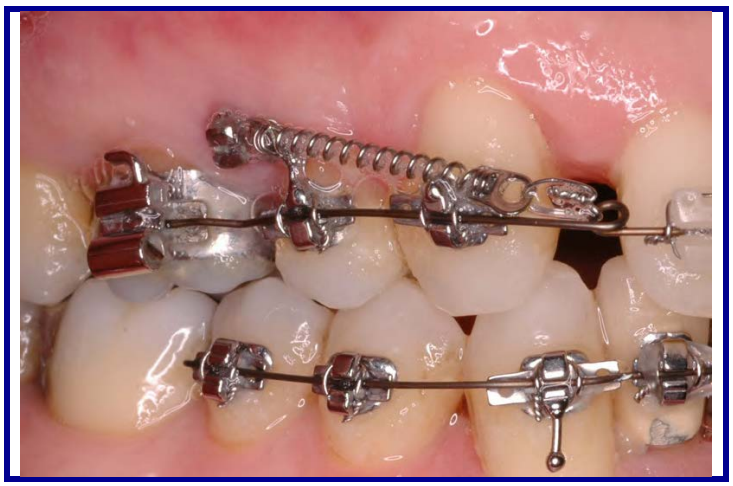
corresponding screwdriver and by the same operator.

During insertion of the TADs and indeed throughout testing, no TAD fractures were observed and no deformation was apparent. While this is reassuring, it is hardly surprising, given the mechanical properties of the titanium alloy (Table 1.7). It does however raise the question of the need for and efficacy of a pilot hole. An interesting follow-up study could examine 2 groups of identical TADs, following insertion and subsequent force application – one group inserted with a pilot hole and one without a pilot hole.

### 5.1.4 Instron Universal Testing Machine

Numerous *in vitro* studies have examined the effects of applying a force along the long axis of a TAD (I.E. the applied force acts at $180^0$, termed 'pullout' force). In the clinical setting however, it is much more likely that the applied force will act closer to $90^0$ to the TAD, as illustrated in figure 5.1.

**Figure 5.1 Clinical example of a force being applied to a TAD**

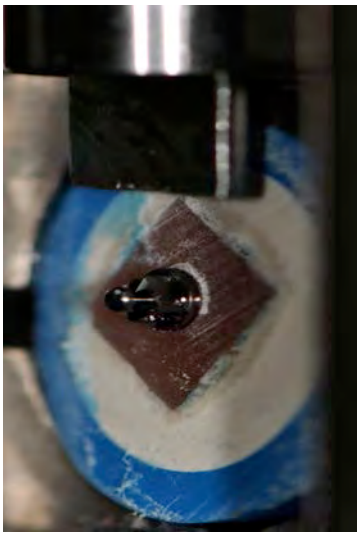


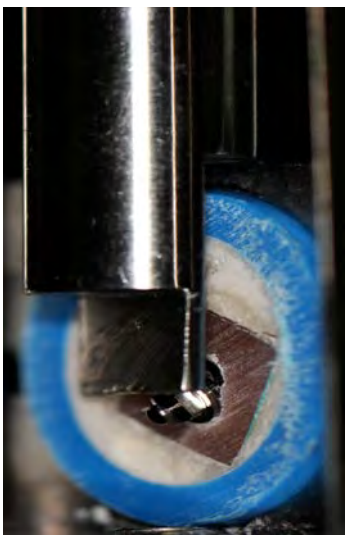
The setup of the Instron Universal Testing Machine with Bencor Multi-T jig was described in section 3.1 and this setup aimed to generate the force application in a more clinically relevant direction.

The magnitude of force remains the same, regardless of the direction of that force, because it is generated by the Instron Testing Machine. Therefore regardless of whether the TAD is being pulled (as is the case clinically) or pushed (as is the case in this study), the force magnitude will be the same. When testing pulling forces, the elasticity of the pulling wire joining the Instron and TAD may lead to inaccuracies. A better approach was to employ a pushing force, as can be seen in Figure 5.2. While this setup negates the necessity to allow for the elasticity of any wires, the additional friction between the jig arm and the test block needs to be overcome. This may have lead to a small systematic error in the force results.

**Figure 5.2 The jig arm in contact with the test block as it moves**

**The force generated by the Inston was applied by means of a jig-arm and thus the TADs were pushed. The use of wires, to pull the TADs, would potentially introduce measurements errors, due to the elasticity of the wire.**
**The setup employed had the disadvantage of introducing friction to the system. Thus, the force exerted by the jig arm includes that component necessary to overcome the friction between the jig arm and the test block. (Anchor Pro™ demonstrated)**





## 5.2 Results

The results indicate that the potential interaction between the substrate variable (I.E. either 2 or 3mm test blocks) and the 3 TAD variables is not significant. This can therefore be discounted and the statistical tests examine the effects of using different TADs and the effects of using different test blocks.

The means for the TADs (Table 4.5) were found to differ significantly from each other ($P<0.05$) and this highlights differences in the 3 TAD designs, in terms of their ability to resist displacing forces. While the Infinitas™ and Ancor Pro™ TADs performed equally, the Ortho Implant™ required a significantly higher force to be dislodged from both the 3mm laminated test block and from the 2mm laminated test block.

A likely explanation for this observed variation may be differences in design of the threaded portion of the TADs. More specifically, the tip of the Infinitas™ and Ancor Pro™ both have a cutting flute at the apex, allowing them to cut through bone as the TAD is advanced and so bone is removed at the advancing tip. Conversely, the Ortho Implant's™ modified buttress thread form, in lieu of a thread-cutting flute, has an apical 4mm that tapers from 0.1mm to the full 1.8mm. The manufacturers claim that, as the tip is advanced, the adjacent bone is compressed and this compressed bone makes the TAD more resistant to dislodgement forces.

The means for the substrates (Table 4.6) shows the two groups differ significantly from each other ($P<0.05$) confirming that the force required to dislodge the TADs from the 3mm test blocks is higher than the force required to dislodge the TADs from

the 2mm test blocks. This finding is in agreement with other studies[32,76] and confirms that the mechanical interlocking of the TAD with the surrounding bone is paramount to the primary stability of the TAD.

The mean force required to dislodge the TADs from the test block was found to be 567N in the 3mm test block and 468N in the 2mm test block. Unfortunately, the current body of literature does not make it possible to perform a meta-analysis of the relationship between force magnitude and rate of tooth movement. As a result, no evidence-based force level can be recommended for the optimal efficiency in clinical orthodontics.[144] None-the-less Proffit[147] offers some suggested optimum forces, which are generally acceptable to the Orthodontic Profession (Table 5.1), although he does not state from where these data have been derived.

It is immediately apparent that the applied force required to dislodge each TAD in this study far exceeds the forces routinely applied in clinical orthodontic tooth movement. This is an important finding, as it suggests that in the clinical scenario, the operator could feel free to choose a TAD system based on factors other than stability, such as collar design to minimise inflammation, head design to maximise potential for attachments, emergence profile to minimise patient discomfort and cost-effectiveness. However, caution should always be exercised when extrapolating the findings of *in vitro* testing to the clinical situation. It would appear however that in the clinical setting, failure is less likely to be due to the choice of TAD and more likely to be resultant from some other influence, such as those discussed in section 1.11.

**Table 5.1 Suggested optimum forces for orthodontic tooth movement**

| Type of Movement | Force (N) |
|---|---|
| Tipping | 0.34-0.59 |
| Bodily Movement (translation) | 0.69-1.17 |
| Root Uprighting | 0.49-0.98 |
| Rotation | 0.34-0.59 |
| Extrusion | 0.34-0.59 |
| Intrusion | 0.10-0.20 |

# Chapter Six

# CONCLUSIONS

## 6.1 Conclusions

(1) The mean forces required to dislodge the 3 groups of TADs from the artificial bone substitute were as follows:

- 2mm laminate bone substitute: 468N (Range: 576N – 368N)
- 3mm laminate bone substitute: 567N (Range: 451N - 754N)

These forces far exceed those routinely applied in clinical orthodontic practice, suggesting that each of the TADs is functionally acceptable in terms of resistance to dislodgement forces.

(2) The Infinitas™ and Ancor Pro™ TADs required similar forces to dislodge them from both the 2mm and 3mm laminate bone substitutes.

(3) The Ortho Implant™ required a significantly higher force to be dislodged from both the 2mm and 3mm laminate bone substitute, thus the null hypothesis (I.E. that there is no significant difference between the 3 designs of TADs, in terms of the applied force required to dislodge them) is to be rejected.

(4) The thickness of the laminate, representing 2 and 3mm cortical bone thickness, has a significant effect on the force required to dislodge each of the TADs. The null hypothesis (I.E. that the thickness of the cortical portion of the test block will have no affect on the forces required to dislodge the TADs) is therefore rejected. In clinical terms, great care should be taken in assessing the cortical thickness prior to placement of a TAD.

(5) The use of a plastic stent was found to be a useful adjunct in the placement of TADs.

(6) The question of which TAD system to use is multifactorial. It would appear that each of the TADs studied was acceptable in terms of resistance to dislodgement forces and choice may be based on personal preferences, such as extra mucosal design features.

(7) Caution must be exercised in extrapolating the findings of this *in vitro* study to the *in vivo* situation.

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# APPENDICES

## Appendix 1: Raw Data for Anchor Pro™ TAD in 3mm Laminate

| ANCHOR PRO™ MANDIBLE | |
|---|---|
| **SAMPLE** | **FORCE (N)** |
| 1 | 568.90 |
| 2 | 578.87 |
| 3 | 623.02 |
| 4 | 553.34 |
| 5 | 547.65 |
| 6 | 519.81 |
| 7 | 579.62 |
| 8 | 538.41 |
| 9 | 503.34 |
| 10 | 529.59 |
| 11 | 579.54 |
| 12 | 579.51 |
| 13 | 588.61 |
| 14 | 578.01 |
| 15 | 579.50 |
| 16 | 573.42 |
| 17 | 576.49 |
| 18 | 508.43 |
| 19 | 579.54 |
| 20 | 584.64 |
| 21 | 583.57 |
| 22 | 587.19 |
| 23 | 538.36 |
| 24 | 588.67 |
| 25 | 577.21 |
| 26 | 603.43 |
| 27 | 586.98 |
| 28 | 501.12 |
| 29 | 513.43 |
| 30 | 598.99 |
| 31 | 498.02 |
| 32 | 587.56 |
| 33 | 534.76 |
| 34 | 554.54 |
| 35 | 578.32 |
| 36 | 587.98 |
| 37 | 529.47 |
| 38 | 481.23 |
| 39 | 545.98 |
| 40 | 565.89 |
| 41 | 512.54 |
| 42 | 504.34 |
| 43 | 576.54 |
| 44 | 589.54 |
| 45 | 512.54 |
| 46 | 587.54 |
| 47 | 569.43 |
| 48 | 576.54 |
| 49 | 519.98 |
| 50 | 587.87 |

## Appendix 2: Raw Data for Anchor Pro™ TAD in 2mm Laminate

| ANCHOR PRO™ MAXILLA | |
|---|---|
| **SAMPLE** | **FORCE (N)** |
| 1 | 450.34 |
| 2 | 444.25 |
| 3 | 502.43 |
| 4 | 506.34 |
| 5 | 455.12 |
| 6 | 481.45 |
| 7 | 499.65 |
| 8 | 476.12 |
| 9 | 423.90 |
| 10 | 461.01 |
| 11 | 431.13 |
| 12 | 446.65 |
| 13 | 481.90 |
| 14 | 424.91 |
| 15 | 413.26 |
| 16 | 434.44 |
| 17 | 502.12 |
| 18 | 462.00 |
| 19 | 435.34 |
| 20 | 564.33 |
| 21 | 412.44 |
| 22 | 436.74 |
| 23 | 461.01 |
| 24 | 411.33 |
| 25 | 433.56 |
| 26 | 441.67 |
| 27 | 471.32 |
| 28 | 422.43 |
| 29 | 413.44 |
| 30 | 443.21 |
| 31 | 512.21 |
| 32 | 463.23 |
| 33 | 412.00 |
| 34 | 439.56 |
| 35 | 477.12 |
| 36 | 413.33 |
| 37 | 453.86 |
| 38 | 461.04 |
| 39 | 402.33 |
| 40 | 434.66 |
| 41 | 473.44 |
| 42 | 461.33 |
| 43 | 454.12 |
| 44 | 433.85 |
| 45 | 438.54 |
| 46 | 576.86 |
| 47 | 435.39 |
| 48 | 413.33 |
| 49 | 453.65 |
| 50 | 451.03 |

## Appendix 3: Raw Data for Infinitas™ TAD in 3mm Laminate

| INFINITAS™ MANDIBLE | |
|---|---|
| **SAMPLE** | **FORCE (N)** |
| 1 | 531.11 |
| 2 | 552.63 |
| 3 | 581.43 |
| 4 | 754.45 |
| 5 | 472.32 |
| 6 | 467.89 |
| 7 | 622.45 |
| 8 | 451.54 |
| 9 | 507.54 |
| 10 | 451.45 |
| 11 | 507.36 |
| 12 | 548.45 |
| 13 | 605.56 |
| 14 | 576.78 |
| 15 | 465.76 |
| 16 | 612.43 |
| 17 | 545.09 |
| 18 | 630.01 |
| 19 | 598.76 |
| 20 | 536.54 |
| 21 | 487.76 |
| 22 | 567.54 |
| 23 | 631.87 |
| 24 | 584.75 |
| 25 | 538.65 |
| 26 | 537.34 |
| 27 | 539.09 |
| 28 | 548.45 |
| 29 | 514.43 |
| 30 | 612.43 |
| 31 | 598.76 |
| 32 | 598.34 |
| 33 | 523.50 |
| 34 | 632.54 |
| 35 | 598.00 |
| 36 | 513.94 |
| 37 | 587.98 |
| 38 | 567.12 |
| 39 | 561.98 |
| 40 | 572.78 |
| 41 | 509.90 |
| 42 | 599.60 |
| 43 | 578.65 |
| 44 | 609.54 |
| 45 | 589.09 |
| 46 | 574.45 |
| 47 | 562.43 |
| 48 | 578.54 |
| 49 | 533.55 |
| 50 | 569.53 |

## Appendix 4: Raw Data for Infinitas™ TAD in 2mm Laminate

| INFINITAS™ MAXILLA | |
|---|---|
| **SAMPLE** | **FORCE (N)** |
| 1 | 367.54 |
| 2 | 476.99 |
| 3 | 401.54 |
| 4 | 409.67 |
| 5 | 476.56 |
| 6 | 479.99 |
| 7 | 467.24 |
| 8 | 487.57 |
| 9 | 499.13 |
| 10 | 389.21 |
| 11 | 457.58 |
| 12 | 509.35 |
| 13 | 478.54 |
| 14 | 479.25 |
| 15 | 466.55 |
| 16 | 484.36 |
| 17 | 475.54 |
| 18 | 488.58 |
| 19 | 484.46 |
| 20 | 471.94 |
| 21 | 502.45 |
| 22 | 474.11 |
| 23 | 490.04 |
| 24 | 478.90 |
| 25 | 473.54 |
| 26 | 414.34 |
| 27 | 421.91 |
| 28 | 465.44 |
| 29 | 467.65 |
| 30 | 402.38 |
| 31 | 490.34 |
| 32 | 442.57 |
| 33 | 488.57 |
| 34 | 466.76 |
| 35 | 476.77 |
| 36 | 423.54 |
| 37 | 387.89 |
| 38 | 479.75 |
| 39 | 465.66 |
| 40 | 490.18 |
| 41 | 471.03 |
| 42 | 494.08 |
| 43 | 465.48 |
| 44 | 497.47 |
| 45 | 501.47 |
| 46 | 470.30 |
| 47 | 450.17 |
| 48 | 489.56 |
| 49 | 479.77 |
| 50 | 481.90 |

## Appendix 5: Raw Data for Ortho Implant™ TAD in 3mm Laminate

| ORTHO IMPLANT™ MANDIBLE | |
|---|---|
| **SAMPLE** | **FORCE (N)** |
| 1 | 580.03 |
| 2 | 560.43 |
| 3 | 565.87 |
| 4 | 604.68 |
| 5 | 608.34 |
| 6 | 577.98 |
| 7 | 587.89 |
| 8 | 599.87 |
| 9 | 623.54 |
| 10 | 601.00 |
| 11 | 635.45 |
| 12 | 598.65 |
| 13 | 576.01 |
| 14 | 548.56 |
| 15 | 584.56 |
| 16 | 552.45 |
| 17 | 587.65 |
| 18 | 598.93 |
| 19 | 578.58 |
| 20 | 577.13 |
| 21 | 698.65 |
| 22 | 576.79 |
| 23 | 524.67 |
| 24 | 594.58 |
| 25 | 556.67 |
| 26 | 574.00 |
| 27 | 577.36 |
| 28 | 623.54 |
| 29 | 547.65 |
| 30 | 599.07 |
| 31 | 578.65 |
| 32 | 578.98 |
| 33 | 601.54 |
| 34 | 564.35 |
| 35 | 567.55 |
| 36 | 597.33 |
| 37 | 509.61 |
| 38 | 597.59 |
| 39 | 508.77 |
| 40 | 589.99 |
| 41 | 571.55 |
| 42 | 587.58 |
| 43 | 599.31 |
| 44 | 535.08 |
| 45 | 588.69 |
| 46 | 577.79 |
| 47 | 572.47 |
| 48 | 598.61 |
| 49 | 554.78 |
| 50 | 571.02 |

## Appendix 6: Raw Data for Ortho Implant™ TAD in 2mm Laminate

| ORTHO IMPLANT™ MAXILLA | |
|---|---|
| **SAMPLE** | **FORCE (N)** |
| 1 | 534.43 |
| 2 | 512.43 |
| 3 | 490.54 |
| 4 | 502.45 |
| 5 | 476.48 |
| 6 | 499.00 |
| 7 | 512.09 |
| 8 | 491.58 |
| 9 | 490.13 |
| 10 | 486.43 |
| 11 | 498.60 |
| 12 | 489.98 |
| 13 | 475.55 |
| 14 | 503.87 |
| 15 | 489.34 |
| 16 | 509.90 |
| 17 | 498.37 |
| 18 | 498.68 |
| 19 | 461.80 |
| 20 | 511.34 |
| 21 | 478.54 |
| 22 | 490.42 |
| 23 | 465.90 |
| 24 | 480.26 |
| 25 | 486.59 |
| 26 | 454.58 |
| 27 | 490.53 |
| 28 | 531.06 |
| 29 | 499.45 |
| 30 | 473.57 |
| 31 | 486.34 |
| 32 | 476.56 |
| 33 | 496.69 |
| 34 | 455.08 |
| 35 | 496.49 |
| 36 | 486.44 |
| 37 | 470.15 |
| 38 | 481.49 |
| 39 | 408.45 |
| 40 | 488.90 |
| 41 | 413.55 |
| 42 | 480.22 |
| 43 | 507.10 |
| 44 | 491.98 |
| 45 | 470.31 |
| 46 | 478.34 |
| 47 | 469.49 |
| 48 | 491.53 |
| 49 | 488.14 |
| 50 | 471.12 |