ASSOCIATION BETWEEN INSERTION TORQUE AND THE SUCCESS OF MINI-SCREWS USED AS ORTHODONTIC ANCHORAGE

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ASSOCIATION BETWEEN INSERTION TORQUE AND THE SUCCESS OF MINI-SCREWS USED AS ORTHODONTIC ANCHORAGE

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ABSTRACT

The purposes of this study were - (1) to investigate the association of the insertion torque and the success of mini-screws used as orthodontic anchorage., (2) to determine the optimal insertion torque range., (3) to examine the success rate of mini-screws., and (4) to identify other factors associated with the success of the mini-screws. Forty two mini-screws (1.4 x 7 mm) were placed in 25 patients (6 male, 15 female; mean age 25.6 years). The digital torque gauge was used to measure the maximum insertion torque. Mini-screws were loaded immediately after insertion with a force of 100-150 g. Each patient received a questionnaire with a visual analogue scale (VAS) concerning the pain caused by the surgical procedure. The result implicated that there was no statistically significant association between the insertion torque and the success of mini-screws. The optimal insertion torque could not be defined but there was a tendency that the mini-screws with an insertion torque in the range of 4-8 Ncm showed a higher success rate than those of insertion torque < 4 Ncm (P = 0.096). The 3-month success rate of mini-screws was 73.8%. There was no statistically significant association between the clinical variables of host factors (age, gender, jaw, side, bone density, tightness when driving the mini-screws, skeletal and dental relationship), procedure factors (operator, method of insertion, and path of insertion) and success rate. The pain caused by mini-screw insertion is about 1-1.7 on the 10-point and the pain is reduced to near zero 1 week after insertion.

KEY WORDS: MINI-SCREW/ INSERTION TORQUE/ SUCCESS/ ANCHORAGE

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ความสัมพันธ์ระหว่างแรงบิดที่ใช้ในการขันสกรูและความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟัน
(ASSOCIATION BETWEEN INSERTION TORQUE AND THE SUCCESS OF MINI-SCREWS USED AS ORTHODONTIC ANCHORAGE)

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บทคัดย่อ

วัตถุประสงค์ของการศึกษาครั้งนี้เพื่อ (1) ศึกษาความสัมพันธ์ระหว่างแรงบิดที่ใช้ในการขันสกรูและความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟัน (2) กำหนดช่วงของแรงบิดที่เหมาะสม (3) สำรวจอัตราความสำเร็จของสกรูและ (4) ค้นหาปัจจัยอื่นที่เกี่ยวข้องกับความสำเร็จของสกรู ผู้ป่วยจำนวน 25 คน เป็นผู้ชาย 9 คน และผู้หญิง 15 คน อายุเฉลี่ย 25.6 ปี ได้รับการปักสกรูจำนวน 42 ตัว ขนาดเส้นผ่านศูนย์กลาง 1.4 มม. ยาว 7 มม. วัดค่าแรงบิดในการขันสกรูด้วยเครื่องวัดแรงบิดที่แสดงค่าเป็นตัวเลข จากนั้นให้แรงเคลื่อนฟันในช่วง 100 ถึง 150 กรัมกับสกรูทันทีหลังปัก ผู้ป่วยให้คะแนนความเจ็บปวดที่เกิดขึ้นตามมาตรอุปมาจากการมองเห็นหลังปักสกรู ผลการศึกษาพบว่าไม่มีความสัมพันธ์กันอย่างมีนัยสำคัญทางสถิติ ระหว่างแรงบิดที่ใช้ในการขันสกรูและความสำเร็จของสกรู ไม่สามารถกำหนดช่วงของแรงบิดที่เหมาะสมได้ แต่มีแนวโน้มว่าสกรูที่ใช้แรงบิดในช่วง 4-8 Ncm มีอัตราความสำเร็จมากกว่าสกรูที่ใช้แรงบิดน้อยกว่า 4 Ncm (P= 0.096) อัตราความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟันช่วงเวลา 3 เดือนเท่ากับร้อยละ 73.8 และพบว่าไม่มีความสัมพันธ์ระหว่างความสำเร็จของสกรูและตัวแปรทางคลินิกเกี่ยวกับปัจจัยของผู้ป่วย ได้แก่ อายุ เพศ ขากรรไกร ความหนาแน่นกระดูก ความรู้สึกแน่นขณะขันสกรู ความสัมพันธ์เกี่ยวกับโครงสร้างกระดูกและฟัน และตัวแปรเกี่ยวกับขบวนการปักสกรูได้แก่ ผู้ทำการปักสกรู วิธีในการปักและแนวในการปักสกรู ค่าความรู้สึกเจ็บปวดระหว่างการปักสกรูประมาณ 1-1.7 จากคะแนนเต็มสิบ และค่าความรู้สึกเจ็บปวดจะลดลงจนเหลือเกือบศูนย์ใน 1 สัปดาห์หลังทำการปัก

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CHAPTER I
INTRODUCTION

One of the most important determinants in successful orthodontic treatment is optimal anchorage control. Orthodontic anchorage is defined as "resistance to unwanted tooth movement"(1). Orthodontists use appliances to produce certain desired tooth movements. According to Newton's third law of motion, every action has an equal and opposite reaction. This means that, inevitably, reaction forces can move other teeth if the appliance contacts them. Absolute anchorage is the term used to describe the anchorage unit that remains stationary under orthodontic force. Therefore it is impossible to achieve absolute anchorage with intraoral anchorage. Extraoral appliances require cooperation of the patient but many patients reject headgear wear because of social and esthetic concerns (2).

When there is no adequate dentition for orthodontic anchorage, or when extraoral devices are impractical, implants are alternatives to traditional orthodontic anchorage management. In recent years, the use of dental implants for orthodontic anchorage has increased in popularity. However, conventional implants can be placed only in retromolar (3, 4) and edentulous areas (5, 6). In addition, severity of surgery, delay loading for several months, the high cost especially when the implant cannot be used as part of the post-treatment reconstruction, direction of force application and intervention for removal unusable implants at the end of treatment limit the use of this type of implant for anchorage only. The onplant (7) also has the same disadvantages as the conventional implants with respect to cost and delay loading but requiring less bone depth for placement and easier to remove.

The skeletal anchorage system (SAS) consists of titanium miniplates and monocortical screws. Miniplates are frequently used in orthognathic surgery for osteotomy fixation or fixing segments of fractured bone. The effectiveness of SAS as absolute orthodontic anchorage was reported (8, 9). The advantages of this system are minimally invasive surgical procedure, does not interfere with tooth movement and little risk of damaging tooth roots because all portion of the anchor plates and screws are placed outside the maxillary and mandibular dentition(9). But the necessity of flap reflection, removal of the plates and delay loading until the wound is healed are their disadvantages.

Mini-implants (10, 11), mini-screws (12, 13), micro-implants (14, 15), micro-screws (16) are referred to the group of implants that are 2.5 mm. or less in diameter(17). In this study, “mini-screws” will be used referring to this group of implant. Mini-screws are small enough to place in any surface of alveolar bone , even in the interradicular regions. The placement and removal is simple and can be performed by orthodontists (10-16). These mini-screws do not require osseointegration, only rely on mechanical retention between mini-screws and bone. They can be loaded immediately (18, 19) or wait for 2 weeks after insertion allow healing of the gingiva (12, 14, 16, 18).

There are many studies investigated factors related to failure of mini-screws. Miyawaki et al (20) reported the mini-screw less than 1 mm in diameter and patients with high MP-SN angle (i.e., thin cortical bone) were associated to the failure. Mini-screws placed in the mandible showed higher failure rate than in the maxilla (21-23). Placing the mini-screws in nonkeratinized mucosa causes tissue irritation and inflammation which leads to mobility (24). Kuroda et al (23) studied the relationship between mini-screws position and dental roots from periapical radiographs. They found a high failure rate of mini-screws in proximity with roots. The success rate of mini-screws placed in the younger patient (less than 20 years old) was lower than the older group (25, 26). Motoyoshi et al (27) preoperatively investigated the cortical bone thickness with computerized tomographs. The higher failure rate was observed in the mini-screws placed in prepared site with cortical bone thickness less than 1 mm.

Initial stability after mini-screw placement is considered to play an essential role in successful immediate loading. It depends on bone quality and quantity, implant geometry and surgical procedure (28-30). An implant placed in compact dense bone is more likely to ensure initial stability and better able to sustain such immediate forces than an implant placed in open trabecular network. Implants inserted in low bone density and limited bone volumes show high failure rate, which associated with poor implant-bone interface (31). Lekholm and Zarb (32) classified jaw bone density into 4 groups, D1: homogenous compact bone, D2: thick cortical bone with dense trabecular core, D3: thin cortical bone with dense trabecular core, and D4: thin cortical bone with low density trabecular core. Their bone quality assessment is based on the radiograph and subjective feeling of the operator when drilling the bone. Friberg et al (33) found statistically significant correlation between maximum insertion torque and bone density and suggested that the method with cutting resistance measurement for evaluation of bone quality seems to be reliable.

Factors affecting the maximum insertion torque are related to local bone, mini-screw and procedure factors. Mini-screw inserted in a high bone density area and thicker cortical bone has significant higher maximum insertion torque than those in the low density bone and thinner cortex (34, 35). Longer and larger external diameter mini-screws have higher insertion torque. Tapered shape mini-screw had significantly more insertion torque value than the cylindrical mini-screw. Among the tapered form screw, mini-screws with more degree of taper has higher insertion torque value (34). Motoyoshi et al (36) reported the optimal insertion torque range of tapered 1.6 x 8-mm mini-screw anchors. The success rate for mini-screw with a torque within the range from 5-10 Ncm was significantly higher than that for mini-screws with torque 5 Ncm or less, and more than 10 Ncm.

The aims of this study were to investigate the relationship between insertion torque and the success mini-screws anchors, the optimal insertion torque value, and to identify other risk factors for their failure.

CHAPTER II
OBJECTIVES

Objectives of the study

1. To examine the association between insertion torque and the success of mini-screws used as orthodontic anchorage.
2. To determine the optimal range of the insertion torque value.
3. To examine the success rate of mini-screws used as orthodontic anchorage.
4. To identify other factors associated with the failure of mini-screws used as orthodontic anchorage.

Hypothesis

1. There is no statistical significant association between insertion torque and the success of mini-screws used as orthodontic anchorage.
2. There is no statistical significant association between 14 variables and the success of mini-screws used as orthodontic anchorage.

Expected benefits

1. To know the association between insertion torque and the success of mini-screws used as orthodontics anchorage.
2. To know the optimal range of the insertion torque value.
3. To know the factors responsible for the failure of mini-screws anchorage.

CHAPTER III
LITERATURE REVIEW

Definition of Orthodontic Anchorage

The term *orthodontic anchorage* is defined as “resistance to unwanted tooth movement” (1). Orthodontists use appliances to produce certain desired tooth movements. According to Newton’s third law of motion, every action has an equal and opposite reaction. This means that, inevitably, reaction forces can move other teeth if the appliance contacts them. Anchorage, then, is the resistance to reaction forces that are provided by other teeth, or by the palate, head or neck (via extraoral force), or implants in bone. An important aspect of treatment is to maximize desirable tooth movement, while minimizing undesirable side effects. Absolute anchorage is the term used to describe the anchorage unit that remains stationary under orthodontic force. Therefore it is impossible to achieve absolute anchorage with intraoral anchorage while extraoral appliances require cooperation of the patient (2).

Osseointegration

Osseointegration, according to Brånemark (37), is defined as a direct structural and functional connection between ordered, living bone and the surface of a load-carrying implant on the light microscopic level (Fig. 1) This concept is based on long-termed in vivo studies, in the early 1960s, of microcirculation of the rabbit fibula bone marrow via implanted titanium chambers containing an optical system for translumination with a screw-shaped design. These studies strongly suggested the possibility of osseointegration since the optical chamber could not be removed from the surrounding bone once they had healed. The titanium framework had become completely incorporated in the bone, and mineralized tissue completely congruent with micro irregularities of the titanium surface. The clinical applications of osseointegrated implants to support prostheses have been reported with high success rate (38-41).

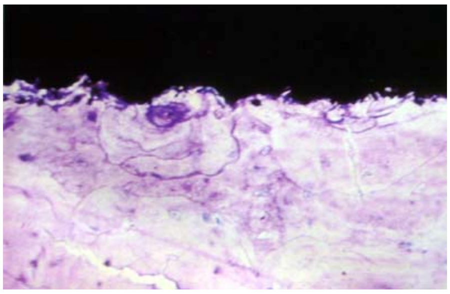

Figure 1 Close physical approximation between the surface of a dental implant and vital bone is a key structural characteristic of osseointegration (42).

Implant Materials

The implant must be nontoxic and biocompatibility, possess excellent mechanical properties, and provide resistance to stress, strain, and corrosion. Commonly used materials can be divided into 3 categories (43): biotolerant (stainless steel, chromium-cobalt alloy), bioinert (titanium, carbon), and bioactive (hydroxyapatite, ceramic oxidized aluminum). Because of titanium's characteristics (no allergic and immunological reactions and no neoplasm formation), it is considered an ideal material and is widely used. Bone grows along the titanium oxide surface, which is formed after contact with air or tissue fluid. However, pure titanium has less fatigue strength than titanium alloy. A titanium alloy (Ti-6Al-4V) is used to overcome this disadvantage

Healing of peri-implant bone (44)

In term of the host response, exogenous materials are not the only foreign bodies; endogenous substances can also elicit the host response. Both exogenous and endogenous foreign bodies elicit phagocytic activity and reactive inflammation. Such reactions continue until the foreign body is in some way either removed or rendered harmless. Following implantation of titanium, aluminum oxide or calcium phosphate ceramics into bone, healing can occur via bone apposition or by connective tissue encapsulation.

Foreign Body (Biomaterial) → Chronic Inflammation (Foreign Body Reaction) → Soft Tissue → Connective Tissue Encapsulation

Foreign Body (Biomaterial) → Chronic Inflammation (Foreign Body Reaction) → Osseous Tissue → Bone Healing

Osseous healing-Early phase

The osseous healing of an implant is preceded by hemorrhage and the information and the formation of a blood clot. This coagulum consists of fibrin and imbedded blood cells, and represents the scaffold for reparative tissue (granulation tissue). Therefore, attachment of the blood clot to the surface of an implant is important for osseous healing.

The coagulum begins to organize with the ingrowth of capillaries and pre-osteoblasts (centripetal bone growth)**.** During this early stage, in addition to new bone formation, the organism recognizes the foreign body, and macrophages as well as multinucleated giant cells appear. As bone formation is initiated at the implant surface, the number of multinucleated cells is reduced. However, the alternating relationships between host tissue and implant material as this early stage of healing are difficult to evaluate, as acute inflammation and proliferative wound healing processes are superimposed.

Osseous healing-Late stage

Depending upon the width of the gap between the implant surface and the osseous bed, direct filling of the space can occur up to about 0.2 mm by means of concentric bony apposition. Wider spaces will usually be filled within 14 days by a network of new woven bone, which will be remodeled in about 2 months into lamellar bone; remnants of the early woven bone may persist centrally.

Complete coverage of the surface by bone does not occur with any implant. Direct bony contact with the implant surface ranges from 56-85% with screw-type implants. Areas of the implant surface not covered with bone will manifest adipose cells without an intervening fibrous layer.

A lack of stability during the healing phase is the major reason for connective tissue accumulation around biomaterial in osseous beds. Movement of the implant inhibits the ingrowth of capillaries from the osseous bed, and also affects the differentiation of the peri-implants cells into fibroblasts or osteoblasts. The absolute requirements for all types of bone growth are mechanical stability and adequate blood supply.

A role of strain on bone physiology (45)

Loads on bone cause bone strains that generate signals that some cells can detect and to which they or other cells can respond. Without such strains, disuse-mode remodeling tends to remove a callus while modeling tends to stay off, so bone healing can retard or fail. Excessive strains (gross motion) can usually prevent bony union. The naturally permissible strains might lie in the 100-2000 microstrain span; about 2 MPa-40 MPa (Table 1). One thousand microstrain equals a 0.1 %stretch or shortening.

Table 1 Set point values for bone's thresholds and ultimate strength (in Microstrain, stress and unit-load terms)

MESr, 50-100 microstrain; ~ 1-2 MPa, or ~0.1 kg/mm2
MESm, 1000- 1500 microstrain; ~ 20 MPa, or ~2 kg/mm2
MESp , ~ 3000 microstrain; ~ 60 MPa, or ~6 kg/mm2; This also approximately equals bone's yield point.
Fx, ~ 25,000 microstrain; ~120 MPa or ~12 kg/mm2 in healthy young adult mammals.

MESr, bone's genetically determined disuse-mode threshold strain range, below which the maximum disuse-mode activity occurs and above which it deigns to declined or turn off.

MESm, bone's genetically determined modeling threshold range strain, in and above which modeling usually turns on to strengthen a bone.

MESp, bone's genetically determined operational microscopic damage in bone threshold strain range, in and above which unrepaired microscopic damage can begin to accumulate.

Fx, a bone's fracture strength or ultimate strength.

The updated bone physiology suggests that the design of load-bearing endoprotheses should keep typical peak strains in the bone supporting implants below the bone's microscopic damage threshold but let those strains exceed bone' MESr, and perhaps exceed its MESm but much less than its MESp. This strain makes modeling strengthen the supporting bone but help to keep disuse-mode remodeling from removing it. When the strains exceed MESp, then bone's microdamage damage accumulation would usually occur and lead to nontraumatic and stress fractures.

Osseointegrated Implants as Orthodontic Anchorage

The ability of osseointegrated implants supported prostheses to withstand and remain stable under occlusal loading has led orthodontists to use them as an alternative to traditional orthodontic anchorage methodologies. Many animal and human studies using osseointegrated implants as anchorage have been reported.

Roberts and colleagues (46) investigated the rigidity of titanium implants placed in the femurs of 3- to 6-month old rabbits. The force of 100 gm. applied, after 6, 8, 12 of healing, by stretching a stainless steel spring between the implants for 4 to 8 weeks (Fig. 2). All but one of twenty loaded implants remained rigid. They found that 6 weeks of healing in rabbits, which they concluded that was equivalent to 5-6 months in man, was the earliest an implant should loaded after placement. They also suggested that endosseous implants have potential as a source of firm skeletal anchorage for orthodontics and dentofacial orthopedics.

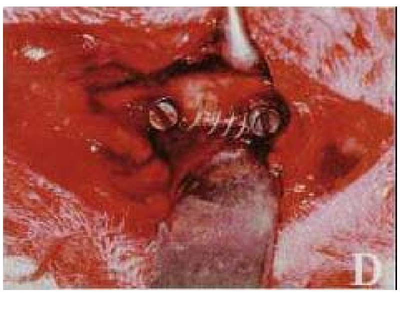

Figure 2 The stretching spring was placed between the implants.

Another study by Turley et al (47) placed two-stage titanium implants, 4.75 mm in diameter and 6.0 mm long, in the mandibular alveolar ridge for orthodontic retraction in dogs. All implants remained stable through the loading period. Radiographic examination revealed the alveolar bone level at the top of the screw thread and no radiolucency between bone and implant (Fig. 3). Histological examination revealed osseous growth into the threads and lamellar compaction in the implant.

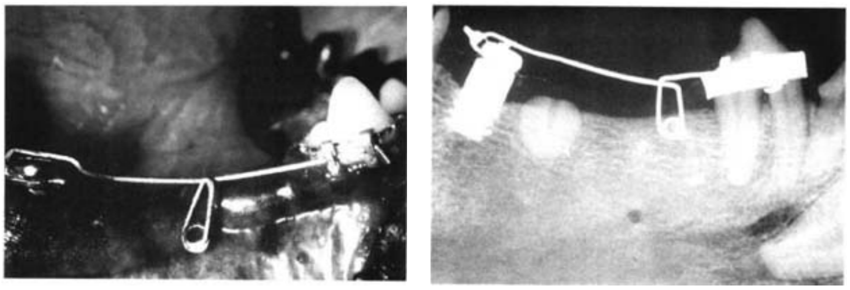

Figure 3 A segmental archwire used to retract the second premolar toward the implant.

Roberts et al (3, 4) reported the successes of conventional two-stage dental implants in retromolar area to help reinforce anchorage while protracting molars to close lower first molar extraction sites (Fig. 4)

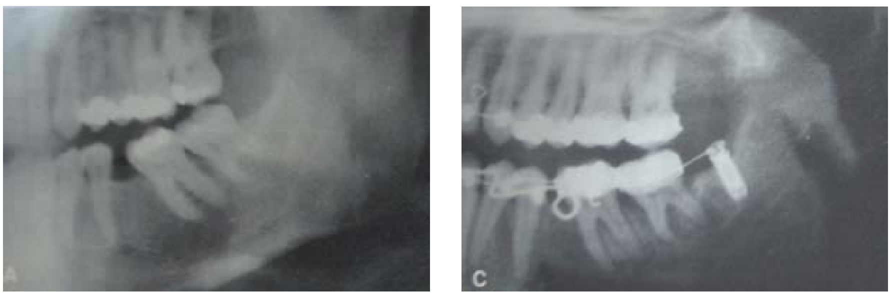

Figure 4 The use of retromolar implant as anchorage to protract the molars. Left, patient before treatment. Right, molars translated mesially without distal movement of the premolars.

In 1994, Ödman et al (5) reported the use of osseointegrated implants as orthodontic anchorage in 9 partially edentulous adult patients to perform various types of orthodontic tooth movements. All of them remained stable during the orthodontic treatment and the fixtures can also be used as abutments for permanent prosthetic constructions.

Conventional endosseous implants proved to be efficiently used as orthodontic anchorage. However, they can be placed in limited areas such as retromolar region, edentulous ridge. The application of endosseous implants in orthodontics didn’t widely spread since most of orthodontic patients have full dentitions. Other disadvantages of this type of skeletal anchorage are severity of surgery, delayed healing period, high cost and surgical removal after termination of orthodontic treatment.

Alternatives to Endosseous Implants

Several alternatives to cope with the limitations of endosseous implants as orthodontic anchorage have been developed and know in the term of temporary anchorage devices. A temporary anchorage device (TAD) is a device that is temporarily fixed to bone for the purpose of enhancing orthodontic anchorage, and which is subsequently removed after use (17). They can be fixed to bone either by mechanical interlock or osseointegration. The TADs includes a modification of a dental implant, palatal implant, mini-screw with plate and freestanding mini-screws.

Palatal Implants

In 1995, Block and Hoffman developed a 2-stage hydroxyapatite-coated titanium subperiosteal implant (Onplant, Nobel Biocare, Göteborg, Sweden) to provide absolute anchorage for tooth movement in dog and monkey models(7). The Onplant is a thin titanium alloy disc (2mm. thick and 10mm. in diameter), with textured and coated with hydroxyapatite on the side facing bone. The side facing soft tissue is smooth titanium alloy with a threaded hole in the center into which abutments are placed (Fig. 5).

Onplants are placed subperiosteally on the palatal bone and allowed 10-12 weeks for healing before applied orthodontic forces. After osseointegration achieved, soft tissue punch is made to expose the disc. A ball-shaped abutment is connected, to which orthodontic devices will be attached. The canine study found that the premolars attached to the onplant abutment move toward the onplant while the onplant remained in place (Fig. 6). In monkey study used the onplant to stabilize molars during retraction anterior dentition. The anchored molars move 1.2 ± 0.2 mm. toward the central incisors, however, the non anchored molars moved an average of 4.1 ± 1.4 mm. toward the central incisors (Fig. 6). They concluded that the onplant can provide sufficient anchorage to molars to prevent anterior migration when in situation requiring maximum anchorage.

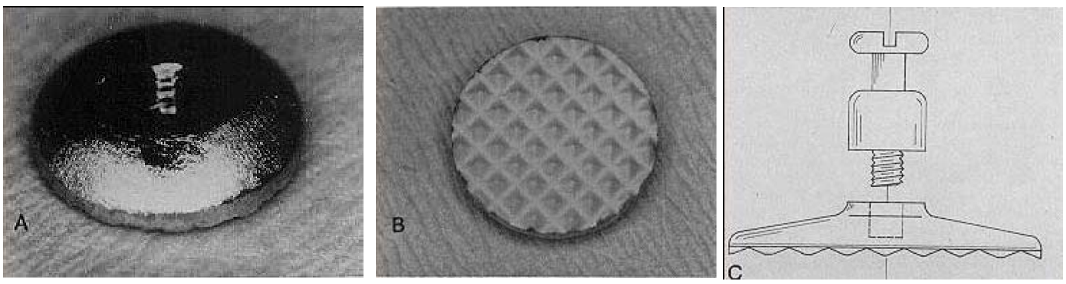

Figure 5 A, Superior smooth surface of onplant with internal thread for placement of transgingival abutment. **B**, Textured, HA coated surface of onplant that is placed against bone for biointegration. **C**, Diagram of onplant and abutment.

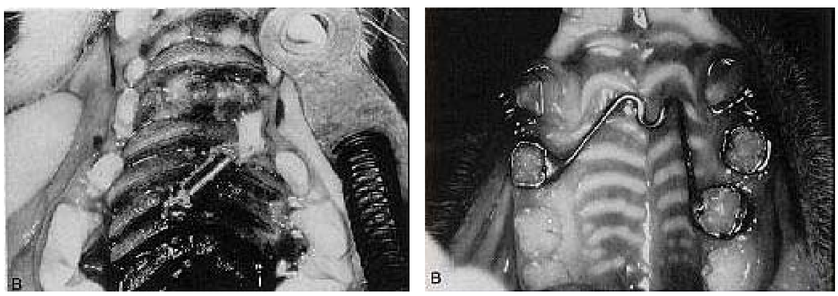

Figure 6 Onplants used as orthodontic anchorage in dog (left) and monkey (right) models.

The advantages are that it requires less bone depth for placement compared with endosseous implants and can be loaded after shorter healing period. But removal of a large portion of soft tissue when removal of the onplant, could be uncomfortable for a patient.

Janssens et al (48) used the onplant for palatal anchorage to extrude the unerupted horizontally maxillary first molars in a 12-year–old white girl with tooth aplasia and secondary cleft palate. After a healing period of 21 weeks, the onplant remained stable under indirect elastic tension of approximately 100 g. applied for 17 weeks, and the maxillary first molars were successfully extruded.

In 1996, Wehrbein and collegues (49) presented a 1-stage orthodontic implant for palatal anchorage (Orthosystem, Straumann, and Basel, Switzerland). It is pure titanium with a sandblasted and acid-etch screw fixture inserted to the bone by self-tapping procedure. The Orthosystem implant (Fig. 7) has a diameter of 3.3 mm and endosseous length of 4 or 6 mm. Above the polished transmucosal neck follows an abutment where transpalatal bars made of rigid orthodontic wire (0.032 x 0.032 inch) are fixed by means of a clamp-cap. Their pilot study using the Orthosystem in midsagittal region of the palate after 3 months of healing for stabilization the posterior anchorage while retracting the anterior teeth in first premolars extraction cases (Fig.8). The result found that the anterior teeth were retracted by 8 mm. and no implant mobility and no marked movement of the implant supported teeth, observed by the lateral cephalograms superimposition. They also mentioned the possibility use of the Orthosystem in retromolar region.

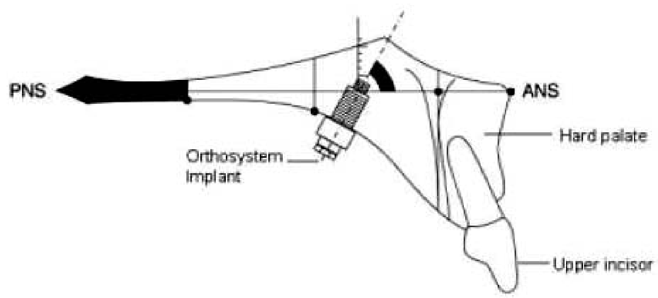

Figure 7 Schematic representation of an Orthosystem implant (50).

Figure 8 The use of Orthosystem as anchorage for retraction of anterior teeth in first premolars extraction case (50).

The disadvantages are that the implantation processes required a surgeon, delayed healing after osseointegration is achieved, and removal require a trephine.

Miniplates

An alternative approach using implantable device in orthodontic treatment as absolute anchorage has been the use of titanium miniplates. Umemori and Sugawara et al (9) developed the skeletal anchorage system (SAS) to correct the open-bite by intrusion of the lower molars. They used surgical L-shaped titanium miniplates and fixed with bone screws (length 5 or 7 mm.) in buccal cortical bone around the apical region of the lower first and second molars on both right and left sides (Fig. 9). The intrusive forces were generated by an elastic thread that was tied between the archwire and the miniplates (Fig. 10). There are three features of the SAS placement that must be controlled to prevent movement of the miniplates : bite force, bone alignment, and implantation technique (51). Sugawara et al (8) also use the SAS to move molar distally for correction of anterior crossbites, maxillary dental protrusion, crowding, and dental asymmetry without premolar extraction.

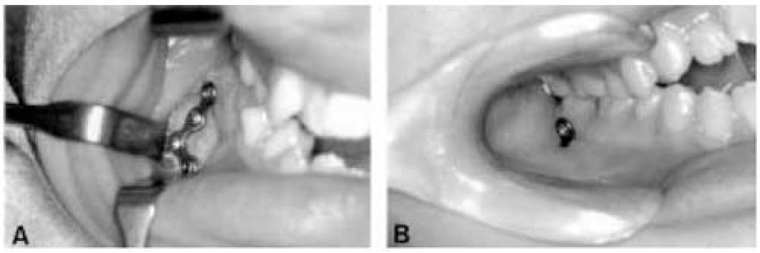

Figure 9 Implantation of a titanium miniplate. A, Surgical procedure, B, after healing

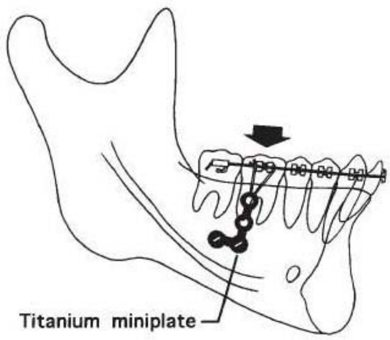

Figure 10 Scheme of the treatment mechanics for open-bite correction with SAS.

In the case report by Chung and colleagues (52), they used the miniplate with a hook soldered to one end. The authors called this device the C-tube (Fig. 11), which was designed instead of a rectangular slot to minimize torque in the archwire. In their case report was the 10-year-old female with severely crowed, narrow and tapered with the canines block out and superiorly positioned. A miniplate with C-tube was fixed in each quadrant with titanium screws. In the maxilla, C-tubes were placed between the second premolar and first molars, and between the first and second molars in the mandible. They reported good results in retraction of anterior teeth and leveling the occlusal plane (Fig. 12). Only one C-tube of the four loosened by the end of the sixth month of treatment due to inflammation of tissue around the C-tube.

Figure 11 C-tube and surgical procedure.

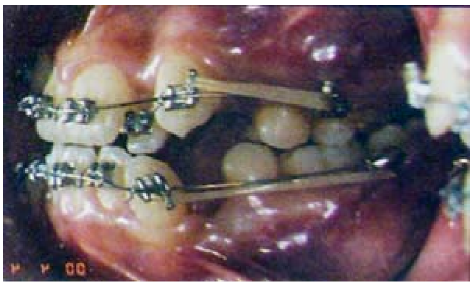

Figure 12 Initial canine retraction with elastic to the C-Tube.

The disadvantages of this system are that the placement required a surgeon, swelling and pain after surgery.

Mini-screws

This is referred to the group of implants includes titanium implants that are less 2.5 mm. in diameter (17) . The unique characteristic is their small size and can be placed anywhere of the alveolar bone, even in the interradicular regions. The placement and removal can be performed by orthodontist. The orthodontic load can be applied immediately after placement because its primary stability gained from mechanical retention between mini-implants and bone, not osseointegration.

Kanomi used 1.2 mm diameter and 6 mm. long titanium mini-implants placed in the alveolar bone between the root apices of lower incisors, in a self-tapping fashion, for intruding these teeth to correct the deep bite (10) (Fig. 13). After four months, the mandibular incisors had been intruded 6 mm. Neither root resorption nor periodontal pathology was evident.

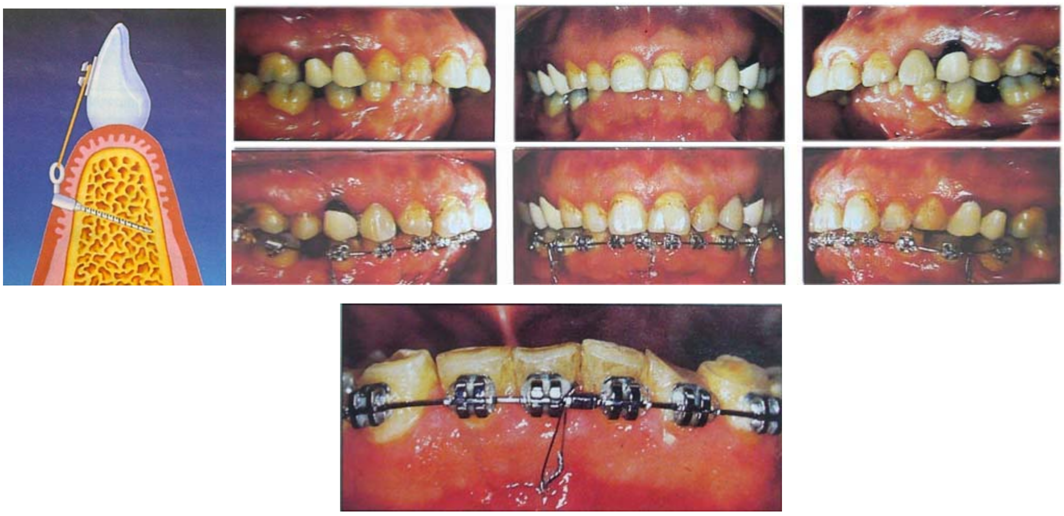

Figure 13 The use of 1.2 mm mini-implants for anchorage to intrude lower anterior teeth.

Costa and colleagues (13) used titanium mini-screws, 2mm. in diameter and the length of 9 mm., in their cases report. The surgical procedure involved a pilot hole of 1.5 mm. diameter was drilled with slow-speed handpiece with irrigation and the mini-screws was inserted manually with a screw driver and was loaded immediately. They reported to be useful in both the maxilla and mandible in the locations as follow:

inferior surface of the anterior nasal spine, midpalatal suture, infrazygomatic crest, retromolar region, edentulous areas of the alveolar process, laterally in the molar and premolar region, and the symphysis. Two of the 16 miniscrews used in clinical trial were loosened and lost before the treatment finished. They said that when the screws were loaded so that a moment unscrewing the mini-screw was generated, a loosening becomes occurred.

Melsen and Costa (18) reported the use of titanium vanadium screws called Aarhus Screw in monkey. The mini-screws inserted into the infrazygomatic crest and symphyseal region. Orthodontic loading 25-50 g of forces were applied with sentalloy spring extending to the canines (Fig. 14). Follow an observation period of 1, 2, 4 and 6 months, the screws and the surrounding bone were removed. Histological examination (Fig. 15) found osseointegration even the mini-screws were loaded immediately and the degree of osseointegration increase with time.

Figure 14 Aarhus screw inserted into the infrazygomatic crest of the mokey, used as anchorage retracting the canine.

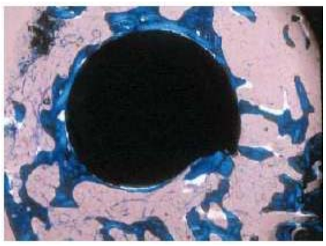

Figure 15 Microphotograph shows degree of osseointegration.

Ohmae et al (11) reported the clinical and histological results of titanium mini-implants (1mm. in diameter and 4 mm. in length) used as anchors for intrusion in the beagle dog. After 6 weeks of healing the 150 g intrusive force was applied between the mini-implant to the crowns of the third premolars via closed coil springs. After 12 to 18 weeks of force application, all the mini-implants remained stable without any mobility or displacement. They also mentioned that a low amount of osseointegration, about 25% in this study, does not necessarily indicate a negative finding because the mini-implant must be removed after the orthodontic treatment. If the mini-implant integrated bone completely, it would not be able to be removed easily.

A case reported by Park and co-workers (14), using the micro-implants (1.2 mm in diameter and 6 mm in length) as anchorage for treatment of skeletal class I bialveolar protrusion(Fig. 16). The micro-implants inserted into the buccal alveolar between the maxillary second premolar and first molar and the mandibular first and second molars. None of the micro-implants loosened during the treatment period and successfully used as anchorage to retract the six anterior teeth *en masse*.

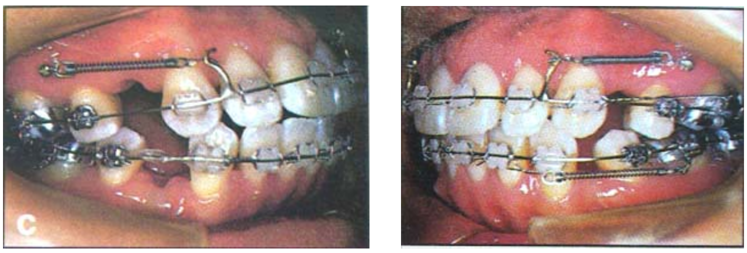

Figure 16 En masse anterior retraction using micro-implants to correct bialveolar protrusion.

Park et al (16) reported the use of micro-screws to correct the open bite malocclusion. The maxillary micro-screws (8 mm long, 1.2 mm in diameter) were placed into interradicular bone between the maxillary second premolar and the first molars, and mandibular implants (6 mm long, 1.2 mm. in diameter). Two weeks after insertion the micro-screws were loaded with 150 g of force to intrude maxillary posterior teeth and bodily move mandibular posterior teeth mesially. The micro-screws did not loosen during treatment and were removed by unscrewing them.

Mini-screw is a stable anchorage for tooth movement but does not remain absolutely stationary throughout orthodontic loading. Liou et al (53) examined the position of mini-screws by superimposition of cephalometric tracings. On average, the mini-screws tipped forward by 0.4 mm at the screw head. They recommended that there should be 2 mm safety clearance between the mini-screw and dental root.

Possible sites for mini-screws placement

Possible insertion sites include, in the maxilla: the area below the nasal spine, the palate, the alveolar process, the infrazygomatic crest and the maxillary tuberosities (Fig. 17). Possible sites in the mandible include the alveolar process, the retromolar area, and the symphysis (Fig. 18) (54).

Figure 17 Maxillary mini-screw locations. A. Below nasal spine. B. In the palate. C. Infrazygomatic crest.

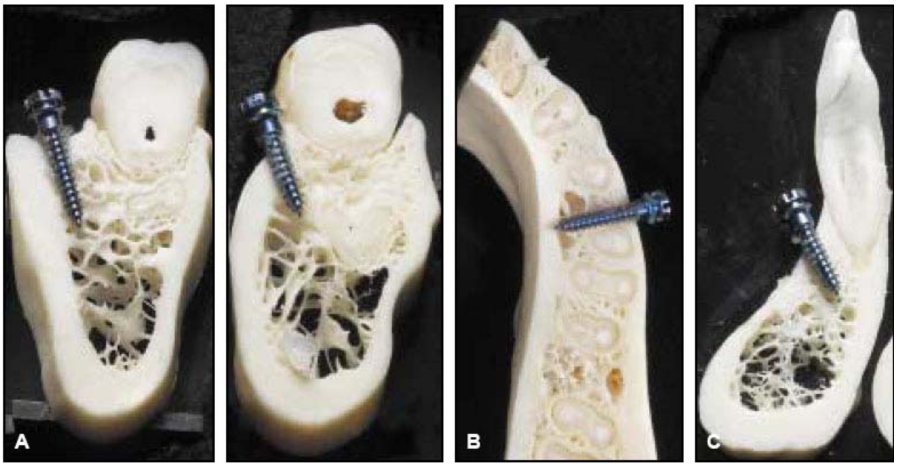

Figure 18 Mandibular mini-screw locations. A. Retromolar area and molar region. B. Alveolar process. C. Symphysis.

The study of Poggio et al (55) using the volumetric tomographic images to provide an anatomic map to assist the clinician in mini-screw placement between dental roots. In the maxilla, the greatest amount of mesiodistal bone was on the palatal side between the second premolar and the first molar. The least amount of bone was in the tuberosity. The greatest thickness of bone in the buccopalatal dimension was between the first and second molars, whereas the least was found in the tuberosity. In the mandible, the greatest amount of mesiodistal dimension was between first and second premolar. The least amount of bone was between the first premolar and the canine. In the buccolingual dimension, the greatest thickness was between first and second molars. The least amount of bone was between first premolar and the canine (Fig. 19).

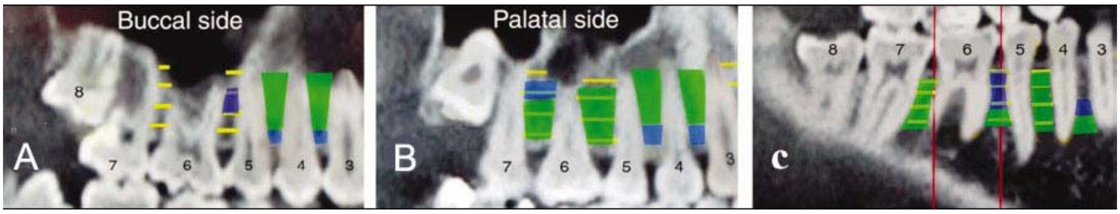

Figure 19 A. Maxillary buccal and B. palatal side, and C. mandible images. In green are the zones with a mesiodistal measure over 3.1 mm. In blue are the zonea with mesiodistal measure between 2.9-3.1 mm.

The available bone volume in the hard palate for orthodontic mini-screw anchorage was investigated using dental CT (Fig. 20) (56). The mean available bone height was found to be best at 6 mm, dorsally from the incisive canal, with a mean height of 6.17±2.81 mm. The region 3 to 6 mm posterior to the incisive foramen, the paramedian region offered a better bone volume than the median region, whereas the 9 to 12 mm median region was only slightly superior (Fig. 21).

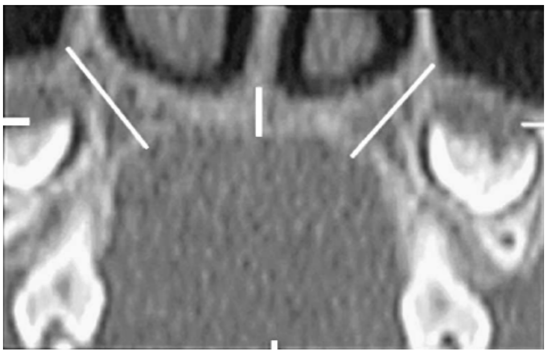

Figure 20 Paracoronal reconstruction of the palate with paramedian and median measurement site.

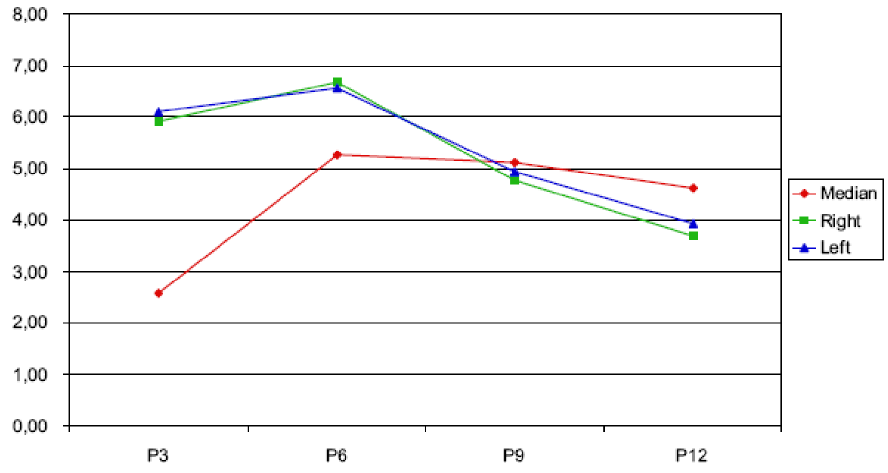

Figure 21 Graph demonstrating the mean bone thickness (mm) in the median (median) and both paramedian (right and left) regions for all patients and each of the four paracoronal planes (P3–P12). The highest bone volume is found 6mm dorsally from the incisive canal (P6).

Primary Stability and Immediate Loading

Osseointegration can be achieved if fixtures are inserted with delicate surgical technique and are allowed to heal without load for periods of not less than 3-4 months in maxilla and 5-6 months in mandible. This was because premature loading caused micromovement may induce fibrous formation, leading to implant failure (37). Immediate loading is the term defined as a situation which loading occurs within 2 weeks after surgery (57). Immediate loading found not to be detrimental to osseointegration. There is a critical threshold of micromotion, which is not zero as generally interpreted, between 50 and 150 µm that does not deleterious the osseointegration (58). Babbush et al (59) reported a cumulative success rate of 88 % up to 8 years of function of 1,739 immediate loaded titanium plasma-sprayed screw implants. Subsequently, many studies regarding immediately loaded implants have been reported.

Implant stability immediately after insertion is called primary stability. An implant gains secondary stability after healing phase and osseointegration. The key to the success of immediate loaded implants is achieving primary stability which is influence by the local bone quality, implant-related factors and surgery-related factors (28-30).

Bone Quality

Bone Quality is depended on bone density and bone quantity.

Lekholm and Zarb classified bone density into 4 types (Fig. 22, 23):

D1: Homogeneous cortical bone

D2: Thick cortical bone with dense trabecular core

D3: Thinner cortical bone with dense trabecular core

D4: Thin cortical bone with low density trabecular core

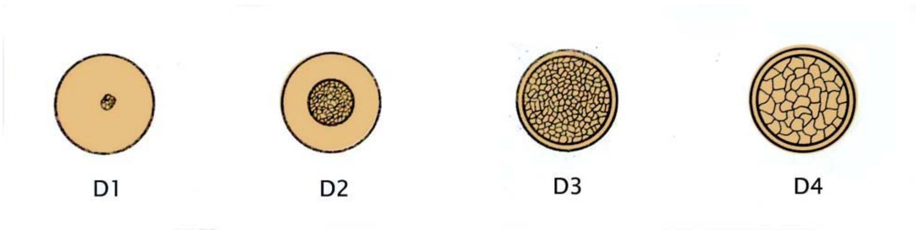

Figure 22 Lekholm and Zarb bone density classification (32)

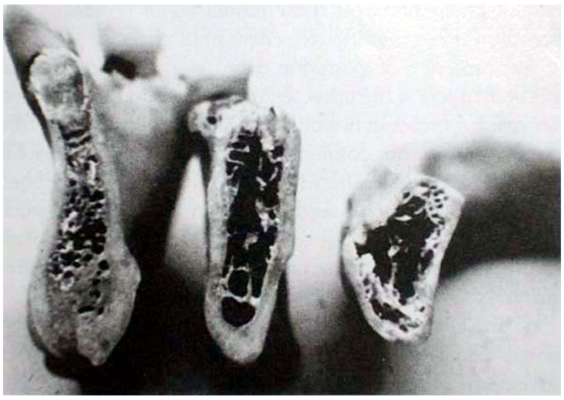

Figure 23 Crown sections of three mandibles exhibiting three different densities, from left to right, D2, D3, and D4 (60).

Misch classified bone density based on tactile sense compared to materials of varying densities. Drilling and placing implants into D1 bone is similar to drilling into oak or maple wood. D2 bone is similar to the tactile sensation of drilling into white pine or spruce. D3 bone is similar to drilling into balsa wood. D4 bone is similar to drilling into Styrofoam (60).

Bone density plays an important role in determining the predictability of the immediate implant loading success. An implant placed in compact dense bone is more likely to ensure initial stability and better able to sustain such immediate forces than an implant placed in open trabecular network. Jaffin and Berman (31) reported that 90% of 1,054 implants were inserted in type I, II, III bone. Only 3% of these fixtures were lost; of the 10% of the fixtures placed in Type IV bone, 35% failed. This is because implant-bone interface is much less in type IV bone.

A review of literature by Misch (60) found the location of different bone densities may be superimposed with the different regions of the mouth (Table 2) D1 bone is almost never observed in maxilla. In the mandible, D1 bone is observed twice as often in the anterior region compared with the posterior region. The bone density D2 is the most common bone density observed in the mandible. The maxilla presents D2 bone less often than the mandible. Bone density D3 is very common in the maxilla. Almost half of the posterior mandible also presents with D3 bone. The softest bone, D4, is most often found in the posterior maxillae (approximately 40%), especially in the molar regions. The mandible presents with D4 bone less than 3% of the patients. In conclusion, the anterior maxilla is usually D3 bone, the posterior maxilla is D4 bone, the anterior mandible is D2 bone, and the posterior mandible is D3 bone.

Table 2 Usual anatomic location of bone density type (% occurrence)

Bone	**Anterior Maxilla**	**Posterior Maxilla**	**Anterior Mandible**	**Posterior Mandible**
D1	0	0	6	3
D2	25	10	66	50
D3	65	50	25	46
D4	10	40	3	1

Friberg et al (33) applied the cutting resistance measurements to access bone quality during implantation confirmed this bone density locations distribution. The measurement of cutting resistance values during low-speed tapping in autopsy specimens were higher in mandible compared with maxilla, and there was tendency towards greater value in the incisos regions than in the premolar regions in both jaws because posterior regions tends to have a thinner, more porous cortex and fine trabeculae (61).

Norton and Gamble (62) demonstrated that an objective scale of bone density based on the Houndsfiled unit is strongly correlated with subjective quality score and also correlated with the region of the mouth (Table 3). Houndsfiled scale is the X-ray attenuation unit that is mostly used in computed tomographic scanning and characterizes the relative density of a substance. Each pixel is assigned a value between -1 and 1k. The value of zero equals water, and soft tissue such as muscle tissue equals +40, air (-1000) and bone (+50 to +2500) (63).

Table 3 Correlation between subjective quality classification, objective scale of bone density, and region of the mouth.

Bone Quality (Lekholm and Zarb)	**Bone density range (HU) (Norton and Gamble)**	**Region of interest**
Q1	> +850	Anterior mandible
Q2/3	+500 to +850	Posterior mandible Anterior maxilla
Q4	0 to +500	Posterior maxilla

Bone quantity refers to bone thickness. Cortical bone in the mandible is thicker surrounding the implant than in the maxilla. Miyamoto et al (64) found that the initial stability at the time of implant placement depend largely upon the cortical bone thickness. Interestingly, the application of longer implants is not effective to increase primary implant stability in their study.

Deguchi et al (65) quantitatively evaluated cortical bone thickness in various locations in the maxilla and mandible with computed tomographic scanning for orthodontic implants. They found that less cortical bone thickness was observed at buccal region distal to the second molar compared with other areas in the maxilla and more cortical bone was observed on the lingual side of the second molar compared with the buccal side. In the mandible, mesial and distal to the second molar, significantly more cortical bone was observed compared with the maxilla. Cortical bone thickness resulted in approximately 1.5 times as much at 30^{o} compared with 90^{o}.

Implant-related factors

Threaded implants design present advantages compared with cylinder implants for immediate load protocols, because their design features do not require osseointegration to resist loads and they also have greater surface area to resist occlusal forces (66). The thread shape can be divided in to 3 types V-shape, reverse buttress and square (67) (Fig. 24). The V-thread design is called a “fixture” in conventional engineering applications and is primarily used for the fixation of the metal parts together because the 30 degree incline of the V-thread design cause the male component of the screw to stretch during preload, which decreases the incidence of screw loosening. The original Branemark implant system had a V-thread pattern in order to place in a threaded osteotomy (68). The reverse buttress thread shape is flat on the top and is optimized for pullout loads. The square thread provides an optimized surface area for intrusive and compressive load transmission (67). Bone is strongest in compression and weakest in shear loading. For V-shaped thread design, a 10 times greater shear force is applied to the bone compared with a square thread shape. The shear component per unit length of a reverse buttress thread design is similar to a V-thread when subject to occlusal loads. Hence, the square thread design may provide some benefit for immediate load protocols (66).

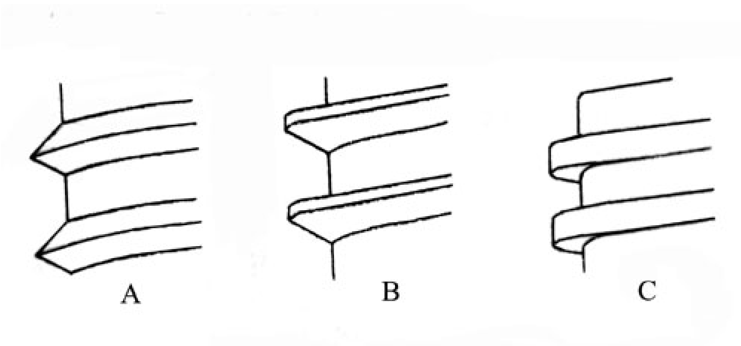

Figure 24 Thread shape may be a V-shape (A), reverse buttress (B) or square (C) (67).

Thread pitch is defined as the distance between adjacent threads, or the number of threads per unit length. The finer (or smaller) the pitch, the more threads on the implant body for a given unit length and the greater surface area per unit length of the implant.The thread depth refers to the distance between the major and minor diameter of the thread. The greater the thread depth, the greater the surface area (67).

Rough implants surfaces increase bone-to-implant contact area. An implant surface with hydroxyapatite coating (69) or sandblasting (70) or acid-etching (71) gained higher primary stability compared with a smooth surface implant.

Surgery-related factors

Excessive surgical trauma and thermal injury may lead to bone necrosis and result in fibrous capsulation of the implant. Heat generating during drilling without adequate cooling is associated to bone damage. It has been shown that a temperature over 47^{o}C for 1 minute causes heat necrosis in the bone (72). The undersize preparation approach, i.e. smaller drilling diameter than that of the implant, for implant installation also influences the primary stability (71). There is marked local compression of the bone when an implant is inserted. These stresses are enhancing the primary stability of an implant, but if they reach a sufficiently high level, resulting in necrosis and local ischemia of the bone at the implant-tissue interface would occur, and then the bone regeneration surrounding the implant thread may be aggravated (30). Heidemann et al (73) reported that the pilot hole size should not greater than 85% of the mini-screw external diameter, otherwise the holding power of the mini-screw will rapidly decrease.

Many studies reported the use of dental implant for prosthetic abutments with the success rate more than 95% (38-41), but those of the mini-screw anchors have been reported with lower values, 83.9-91.6% (20, 21, 24, 74). Factors that may influence the success of dental implant, including local bone quality and quantity, implant design and surgical technique as mentioned above. However, there are important different conditions between the use of dental implant and mini-implant anchors to consider. Prosthetic forces are multidirection, interrupted heavy forces; orthodontic forces generally are unidirectional, continuous and much lighter. Most of orthodontic patients are younger and have relatively high bone density. Therefore, factors affecting with the stability of implant might not be associated with the stability of mini-screw anchors.

Past clinical studies related to factors affecting failures of mini-screw anchors

Miyawaki et al (20) studied the factors associated with the stability of 134 titanium screws of 3 types, and 17 miniplates in buccal alveolar bone of posterior region of 51 patients with malocclusion. The diameters of mini-screws were 1, 1.5 and 2.4 mm, and theirs length were 6, 11 and 14 mm. The 1-year success rates were 83.9-96.4%. All of the mini-screws with 1-mm diameter loosed. Risk factors associated to mobility of mini-screws were the diameter of mini-screws of 1 mm or less, inflammation of the peri-implant tissue and thin cortical bone.

Cheng et al (24) placed 140 mini-screws in 44 patients, including 48 miniplates and 92 freestanding mini-screws, in various areas of the mouth. The mini-screws were 2 mm in diameter and 5 to 15 mm long, and were placed in a self-tapping fashion. The observation period was about 2 years 9 months. The overall success rate was 89%. The mobility or complete exfoliation was found for 15 mini-screws. Four of them failed before the application of orthodontic load, and 6 mini-screws were lost after loading of less that 1 month. The remaining 5 failed mini-screws were loaded for 3 to 12 months before failure. An anatomical location of mini-screws and the character of soft tissue at the implant emergence site have significant influences on the mini-screws outcome. Mini-screws in the posterior mandible and those surrounded by the non-keratinized mucosa were prone to failure. Absence of keratinized mucosa around mini-screws significantly increased the risk of infection. In addition to the lack of sufficient masticatory mucosa, bone in the posterior mandible is dense and overheating is more likely to occur during mini-screw placement, especially in the self-tapping manner.

Tseng et al (74) applied the 45 mini-screws for skeletal anchorage in 25 patients. The diameter of mini-screws was 2 mm and theirs length were 8, 10, 12 and 14 mm. The drill procedure was directly through the cortical bone without any incision or flap operation. The overall success rate was 91.1% and risk factors for the failure were the location of mini-screws placement at anterior ramus. Two of the mini-screws that failed in this area were 8 mm long and had only locked in the bone about 3-4 mm due to very thick surrounding mucosa. But the other 3 mini-screws that were 10 mm long and inserted into the bone at least 6 mm remained stable under the orthodontic loading. They suggest the recommended depth being at least 6 mm.

Park et al (21) studied the factors affecting the clinical success of 227 mini-screw of 4 type in 87 patients. The mini-screws were 1.2 and 2 mm in diameter and 4 to 15 mm long. The mini-screws were placed with a self-tapping method. Success rate during a 15-month period of force application was 91.6%. Risk factors for mini-screw loosening were mobility of mini-screws, right side of the jaw, the mandible and the inflammation of tissue surrounded the mini-screw. The left side had higher success rate than the right. The might be explained by better hygiene on the left side of the dental arch by right-handed patients. The manbidle has a thicker and denser cortical bone than the maxilla. The overheating of bone during drilling can cause bone damage. Local inflammation can be exaggerated by oral hygiene and weak non-keratinzed soft tissue at the implant emergence site.

Kuroda et al (23) reported the use of 216 mini-screws for orthodontic anchorage in 110 patients. The diameter of mini-screws was 1.3 and 1.5 mm and theirs length were 6, 7, 8, 9, 10, 12 mm. The mini-screws were placed with a self-tapping method. The screws had a high success rate—above 80%. Screws placed in the maxilla had a significantly higher success rate than those in the mandible. There was a significant correlation between success rate and root proximity. The post-implantation periapical radiographs were classified into 3 categories depending on the distance between the screw and the root (Fig. 25): category I, the screw was absolutely separate from the root; category II, the apex of screw appeared to touch the lamina dura; category III, the body of the screw overlaid the lamina dura. There were significant differences in the success rates between categories I and II, I and III, and II and III. The proximity of a miniscrew to the root is a major risk factor for the failure of screw anchorage.

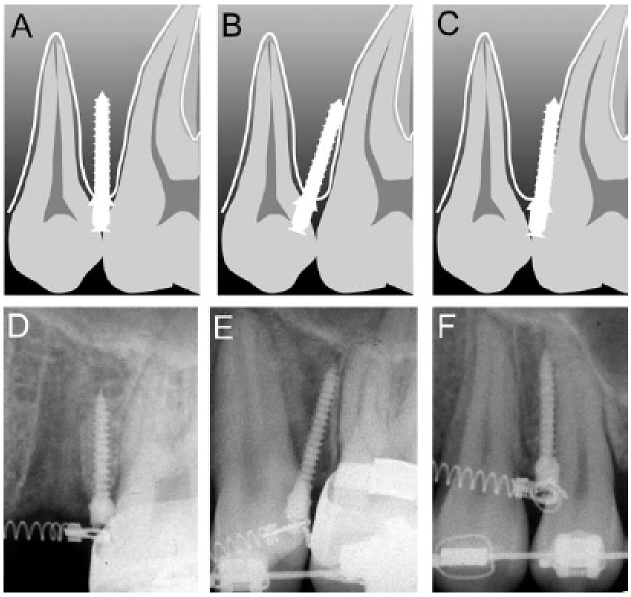

Figure 25 Schematic illustrations (*A*-*C*) and dental radiographs (*D*-*F*) of category classifications. **A** and **D**, Screw was absolutely separate from root; **B** and **E**, apex of screw appeared to touch lamina dura; **C** and **F**, body of screw overlaid lamina dura.

Noninvasive method to measure primary implant stability (30, 63, 75)

Percussion test

The aim of this test was to determine the resonances and damping of an implant from the audible ringing produced by tapping an implant with a metallic instrument. However, such a test is relatively insensitive to changes in implant stability for 2 reasons: first, the ear is insufficiently sensitive to discriminate the resonance frequency, damping and amplitude of the tone produced, and second, tapping the implant and abutment is a simplification of what is essentially a complex system. A simple tap with a mirror handle will not transfer sufficient energy to the implant to enable accurate measurements.

Radiographic methods

The objective of radiograghs is to identify peri-implant radiolucencies. Radiographic methods are probably the most widely used clinical technique not only for preoperative assessment prior to implant placement, but also for the evaluation of osseointegration and the assessment of abutment fit. The use of radiographs is criticized because they are two-dimensional and difficult to standardize.

Periotest®

Periotest® is an electronic instrument originally designed to perform quantitative measurements of the damping characteristic of the periodontal ligament surrounding the tooth, thereby establishing a value for its mobility (75). The Periotest® instrument comprises a hand piece containing a metal slug that is accelerated towards a tooth by an eletro-magnet. The contact duration of the slug on the tooth is measured by an accelerometer. The software in the instrument is designed to relate contact time as a function of tooth mobility. The result is displayed digitally and audibly as Periotest® values (PTVs) on a scale of -8 (low mobility) to +50 (high mobility). The technique has also been used to determine implant mobility, and typical values obtained were defined as ranging from -5 to+5, thus representing a narrower range over the scale of the instrument than for tooth mobility measurements. A stable implant will exhibit different stiffness characteristics compared with those of teeth that are connected by periodontal ligament. While the single PTV measurement has been shown to correlate with the ordinal bone density classification, an implant placed in D1 bone has lower PTV, but there is as yet no evidence that it provides valid means to define primary stability (63). The variables that may influence the PTV: the vertical measuring point on the implant abutment, the hand piece angulation, and the horizontal distance of the hand piece from the implant (30).

Resonance frequency analysis (RFA)

RFA was first proposed by Meredith et al (76).The technique uses changes in an L-shaped transducer designed as a simple offset cantilever beam that is screwed onto an implant. The transducer has two piezoceramic elements attached. The transducer is vibrated by exciting one of the elements with a signal which is a sine wave typically varying in frequency from 5 to 15 kHz with peak amplitude of 1 V. The second element measures the response of the beam, and the signal generated is amplified and compared with the original signal frequency by the Osstell® machine. The captured data are displayed as a RF versus amplitude graph. The RF values, calculated from the peak amplitude, are represented in a quantitative unit called implant stability quotient (ISQ) on a scale from 1 to 100. ISQ values are derived from the stiffness (N μm^{-1}) of the transducer/implant/bone system and the calibration parameters of the transducer. A high ISQ value indicates high stability, whereas low values indicate low implant stability. The RFA results in a reproducible and highly repeatable system. The RF value correlated with the computerized tomography unit and also insertion torque value for implant placement (77, 78). Suzuki and Suzuki found that the RFA of failed mini-screws revealed significant lower values compared to the successful mini-screws (79).

Insertion torque measurement

The use of cutting resistance measurements to assess bone density during implant surgery was first described by Johansson and Strid (80). The technique involved the measurement of torque created when cutting a thread in a hole in bone as determined by the current drawn by an electric motor. A computer connected to the motor unit was used for registrations of torque values. The measured torque consisted of two parts: the true cutting resistance and the friction. By using special computer software to subtract friction, so that only the true cutting resistance was registered. High correlation (r =0.77) between insertion torque values and computerized tomography values (81), and between the RF values and insertion torque values were observed (r =0.89) (77). A study by Ottoni et al (82) showed a statistically significant increase in implant success for the immediate-loaded implants if the insertion torque was higher than 20 Ncm.

Factors affecting the maximum insertion torque of mini-screws.

Insertion torque is influenced by local bone, mini-screw and procedure factors. For local bone factor, bone density measured by computerized tomography (CT) was related to maximum insertion torque value (81, 83). Mini-screw inserted in the high bone density area has significant higher maximum insertion torque than mini-screw placed in the low density bone. Cortical bone thickness also influences the maximum insertion torque. As the thickness of cortical bone increases the maximum insertion torque increases (34, 35).

Diagram of mini-screw features is shown in Fig.26. Thread pitch is defined as the distance between adjacent threads. Thread depth is the difference between external diameter and core diameter of the screw. Length of the unthreaded shank is the distance between the screw run-out and the screw neck. External diameter of the mini-screw is the most influencing in determining the insertion torque (35), it could predict 80% of maximum insertion torque (84). Mini-screws with larger external diameter have higher insertion torque. Longer mini-screws required more torque to tighten them, especially the cylindrical screw. During insertion of the screw, the insertion path in cortical bone is formed so that when the diameter in the cortical bone reaches the maximum diameter of the screw, the increase in torque is mainly affected by the insertion depth in the medullary bone (34). Tapered shape mini-screw had significantly more insertion torque value than the cylindrical mini-screw. The part of the mini-screw that makes contact with cortical bone affects insertion torque value the most. The contact area with the cortical bone of the cylindrical shaped mini-screw is not as wide as the tapered form screw, therefore the insertion torque value in the tapered screw is greater than the cylindrical group. Among the tapered form screw, mini-screws with more degree of taper has higher insertion torque value (34). Thread pitch also influences the insertion torque value. You et al (84) found that the intermediate pitch value yielded the highest maximum insertion torque values, which is about 0.8-0.9 mm for 2 mm diameter screw. Thread pitch length more or less than this value decreased the maximum insertion torque. For 2 mm screw, the maximum insertion torque value decreases as the unthreaded shank increased. However, the screws with 1.5 mm or smaller diameter, the variations in the unthreaded shank and pitch lengths did not seem to greatly affect the insertion torque. Thread depth and core diameter did not affect the insertion torque significantly. Lim et al (35) studied the factors affecting the maximum insertion torque of orthodontic mini-screws. Summary of the mini-screws used in their study was shown in Table4. The insertion torque was affected by external diameter, length and shape in that order. The screw with long cutting flutes are easier to insert and having higher insertion torque (85).

The insertion torque for screws with an asymmetric progressive thread, the threads changed gradually from square at the neck of the screw to V-shape type at the screw tip, were significantly greater than the traditional V-thread design (86). The V-shape threads help cutting and grooving the bone while the square threads at the neck of the screw increases contact area with the cortical bone.

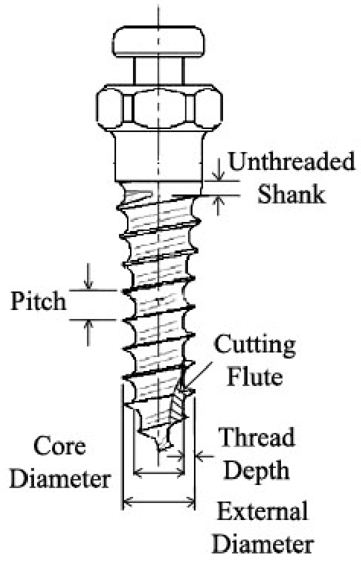

Figure 26 Diagram of mini-screw features.

Table 4 Summary of mini-screws used in the study of Lim et al (35).

1. Shape : Cylindrical and Taper
2. External diameter : 1.15, 1.45, 1.75, 2.00 and 2.45 mm
3. Core diameter : 0.80, 1.00, 1.20 and 1.65 mm
4. Length : 6, 7, 8 and 9 mm
5. Pitch : 0.50, 0.70, 0.75 and 0.80 mm
6. Taper length : 1.51 and 1.94 mm

According to the procedure factor, there are two methods for mini-screw insertion, self drilling and self tapping methods. The self tapping method, mini-screws were inserted into bone after drilling a pilot hole, has disadvantages such as thermal necrosis of the bone (72), more instruments and time required. The pilot hole size also affects the holding power of mini-screw, which should not exceeds 85% of external diameter of the screw otherwise the holding power will decrease rapidly (73). Self drilling screw, which enables the mini-screw to insert without drilling, was developed to avoid these problems (87). The self-drilling method has higher insertion torque, more bone-screw contact (87, 88).

Past studies related to insertion torque used for tightening the mini-screw anchors

Motoyoshi et al (36) studied the insertion torque used for tightening 124 mini-screws in 41 orthodontic patients. The diameters of mini-screws were 1.6 mm and 8 mm long (Fig.27). The mini-screws were all placed in the self-tapping method, into the buccal alveolar bone of the posterior region. The peak insertion torque value was recorded at the terminal turning when the taper-shaped screw was tightened into the bone by a torque screw driver (Fig.28). The 6-month success rate was 85.5%. The mean insertion torque ranged from 7.2 to 13.5 Ncm, depended on the location of the mini-screws. The success rate for mini-screws with an insertion torque value ranged from 5 to 10 Ncm was significantly higher than that for implants with insertion torque 5 Ncm or less, and more than 10 Ncm.

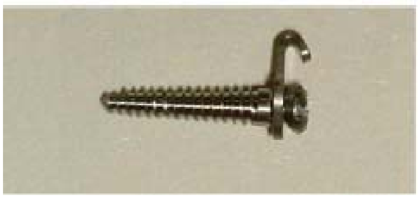

Figure 27 A commercially tapered mini-screws with 1.6 mm diameter (spearhead diameter 1.3 mm) and 8 mm length (ISA orthodontic implants, Biodent Co. Ltd, Japan)

Figure 28 Torque screw driver (N2DPSK, Nakamura MFG Co. Ltd) used to record the placement torque of the mini-screw. This device has a round dial gauge with a pointer to read the peak value.

Anka (89) reported the ideal torque value at the end of implantation is between 15 Ncm and 20 Ncm. The torque value should not less than 10 Ncm otherwise the mini-screw will not be able to resist immediate loading. Sites with dense bone, where the final torque value can be above 20 Ncm, should be pre-drilled to avoid fracturing the mini-screw.

Orthodontic Department, Mahidol University evaluated the clinical success rate of mini-screws used for orthodontic anchorage for 12 months (unpublished study). Data collected between December 2004 and May 2006. In 55 patients (15 males, 40 females; mean age 27.3$\pm$11.7 years) with 126 mini-screws were examined (Table 5). Two types of mini-screws were used with 73 from Absoanchor, Dentos, Korea (1.3, 1.4 mm in diameter and 6, 7 and 8 mm in length) and 53 from Dual Top, Jeil Medical Corp., Korea (1.6 mm in diameter, 6 and 8 mm in length). The mini-screws placement were limited by 2 operators. A small vertical stab incision was made through the mucosa and small indentation was made initially using 1 mm round bur under saline irrigation when necessary. Logistic regression analysis was used to examine the relationship between 21 clinical variables and the failure of mini-screw anchorage. The overall success rate was 74.6%. There was no significant association between the success rate and the following variables: age, gender, smoking, incision made, method of insertion (drill or no drill), soft tissue characteristic at insertion site (attached gingiva, movable mucosa and junction between attached and movable mucosa), jaw in which mini-screw was placed, position (buccal or lingual/palatal), mini-screw type (Absoanchor or Dual Top), mini-screw diameter, path of insertion (perpendicular or diagonal to bone surface), method of force application (early or delay loading), anteroposterior skeletal relationship, vertical skeletal and dental relationship, transverse skeletal and dental relationship. A mini-screw with a length less than or equal to 7 mm, D3 and D4 type bone, loose feeling when driving mini-screw in to the bone and Angle's class II malocclusion were found significantly related to the failure (Table 6).

Table 5 Summary of the study of Orthodontic department, Mahidol University (n=126)

1. Mini-screws used:	Absoanchor, Dentos, Korea Dual Top, Jeil Medical Corp., Korea
2. Diameter : 1.3, 1.4, 1.6 mm	
3. Length : 6, 7, 8 mm	
4. Observation period : 12 months	
5. Insertion Method : pre-drill and no pre-drill	
6. Force application : immediate and delayed	

Table 6 Success rate and number of mini-screws (n=126) according to mini-screw length, bone quality, tightness and Angle's classification.

Clinical variable	**Success (n)**	**Failure (n)**	**Total (n)**	**Success rate**	**p value**
Mini-screw length					
≤7 mm	58	26	84	69%	0.048
>7 mm	36	6	42	85.7%	
Bone density					
D1-D2	74	14	88	84.1%	
D3-D4	20	18	38	52.6%	0.000
Tightness					
Tight	85	22	107	79.4%	
Loose	9	10	19	47.4%	0.005
Angle's classification					
Class I	27	5	32	84.4%	
Class II	49	26	75	65.3%	0.04
Class III	17	1	18	94.4%	

After the previous study, we increased the sample size to 232 mini-screws in 136 patients (Table 7). Data collected between December 2004 between December 2006, the clinical success rate for mini-screws used as orthodontic anchorage for 6 months was evaluated. In 136 patients, 35 were males and 101 were females with mean age 27.5 year and standard deviation of 11.2 year. Four types of mini-screws were used with 141 from Absoanchor, Dentos, Korea, 64 from Dual Top, Jeil Medical Corp., Korea, 17 from Re-mark Orthoplant Anchor, Renew Biocare, Sweden and 10 from Orlus, Ortholution, Korea. The overall success rate was 75.9%. Insertion method and management protocol was the same as previous study. Among the same 21 variables examined, patients with age under 20 years old, D3-D4 bone and loose feeling when driving the screw were found to be related to the failure (Table 8).

Table 7 Summary of the study of Orthodontic department, Mahidol University (n=232)

1. Mini-screws used:	Absoanchor, Dentos, Korea Dual Top, Jeil Medical Corp., Korea Re-mark Orthoplant Anchor, Renew Biocare, Sweden Orlus, Ortholution, Korea
2. Diameter : 1.3, 1.4, 1.6 mm	
3. Length : 6, 7, 8 mm	
4. Observation period : 6 months	
5. Insertion Method : pre-drill and no pre-drill	
6. Force application : immediate and delayed	

From these studies showed that age of patient and local bone density at insertion site is related to mini-screw anchorage success. Bone classification by Lekholm and Zarb (32) using the radiographic image and tactile sensation when cutting the bone is commonly used to determine the bone quality in dental implantology. However this method is subjective and difficult to standardize. The insertion torque is a reliable method to evaluate the bone density (33). In this study insertion torque value was examined if associate to the mini-screw failure. The optimal torque range, the possibly use of insertion torque as a clinical predictor for mini-screw success was explored. The other factors were studied if it associate with success and failure of mini-screw anchorage.

Table 8 Success rate and number of mini-screws (n=232) according to age, bone quality and tightness.

Clinical variable	Success (n)	Failure (n)	Total (n)	Success rate	p value
Age					
≤19	34	15	49	69.4%	0.025
20-39	98	33	131	74.8%	
≥40	44	8	52	84.6%	
Bone density					
D1-D2	7	2	158	82.3%	
D3-D4	24	9	74	62.2%	0.001
Tightness					
Tight	160	42	202	79.2%	
Loose	30	14	30	53.3%	0.003

CHAPTER IV
MATERIALS AND METHODS

This research was designed to be a clinical prospective study and had been approved by the committee on human rights related to human experimentation of Mahidol University before starting the study. The documentary proof of ethic clearance is shown in appendix A.

Samples

A total of 42 mini-screws in 25 patients with malocclusion who received mini-screws for skeletal anchorage in orthodontic treatment at faculty of dentistry Mahidol University, Bangkok, Thailand between August 2007 and November 2007. Of the 25 patients, 6 were men and 19 were female. The ages ranged from 14 to 51 years, with a mean age of 25.6 years and SD 9.6 years. All patients and his or her parents were informed of the advantages, disadvantages, surgical techniques of the procedure and the possibilities of failure, irritation or local inflammation during orthodontic treatment. The document explained about this study[*] was given to each patient.

Each patient was received the questionnaire to fill in, with information as follow: name, gender, occupation, age, systemic disease, history of hospitalization, current medication used, allergy, history of dental treatment, amount and frequency of tobacco and alcohol consuming. After informed consent [†]was obtained, the mini-screw was placed.

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[*] See appendix B

[†] See appendix B

The inclusion criteria are as followed:

1. All patients were healthy with no systemic diseases and no smoking.
2. All patients and his or her parents, in case under 18-year of age, were informed about the details and willing to participate in this study.
3. All patients signed the consent form.
4. The mini-screws were placed by two senior orthodontists[‡] of orthodontic department, faculty of dentistry, Mahidol University.
5. Type of mini-screws were Absoanchor (Dentos, Korea), small head type, with diameter of 1.4 mm and 7 mm in length (SH 1413-07).
6. The mini-screws that placed in the buccal alveolar bone of posterior region of the first premolar to the second molar of the maxilla and/or the mandible.

Materials

1. Mini-screws (Absoanchor, Dentos, Korea) (Fig. 29)
   Forty two mini-screws with 1.4 mm in diameter and 7 mm in length.
2. Hand screw driver (Absoanchor, Dentos, Korea) (Fig. 30)
3. The pilot drill (Orlus, Ortholution, Korea) (Fig. 31)
   The diameter of the drill is 1 mm and 4 mm in length. For manual pre-drilling through the cortical bone.
4. Digital torque gauge (MGT 50Z model, Mark-10 Corp.,USA) (Fig. 32)
   This torque gauge can display the peak value of torque and the capacity range from 0 to 35 Ncm with the resolution of 0.05 Ncm.

Figure 29 Mini-screw with 1.4 mm in diameter and 7 mm in length

[‡] Chaiwat P and Santiwong P

Figure 30 Hand screw driver used in this study.

Figure 31 The pilot drill with a hand driver handle.

Figure 32 Digital torque gauge with a chuck grips the hand driver tip.

Methods

In this study, we calibrated the tactile sense while driving the mini-screw between 2 operators by insertion the mini-screws into different materials classified by Misch (60). Drilling mini-screw into D1, D2, D3 and D4 bone is similar to the tactile sensation of drilling into oak, white pine, balsa wood and styrofoam respectively**.**

1. All patients underwent a pretreatment examination, including facial and intraoral photograph, dental model analysis, panoramic radiography, lateral and posteroanterior cephalograph, and full mouth periapical radiography.
2. Evaluation the site before mini-screw placement by periapical radiograph.
3. Disinfection the mucosa at implantation site with 0.2% chorhexidine.
4. Injection the local anesthesia limited to the gingiva of implantation site.
5. In some case manual pre-drilling with the pilot drill at the cortical bone level with no incision.
6. The mini-screw was inserted in the pilot hole with a hand screw driver or directly through the attached gingiva, in case of no pre-drilling.
7. Screwing the mini-screw ¼ turn and pause for 5 seconds then screwing in the same pattern to the terminal turning, at this point peak insertion torque was measured by a digital torque gauge, which a chuck grip the hand screw driver. The value was recorded in Ncm. Irrigating the mini-screw and bone with normal saline solution at the time of implantation to prevent overheating.
8. Evaluation the location of mini-screw after placement by periapical radiograph.
9. The mini-screw was immediately loaded with a NiTi coil spring or an elastic chain with a force magnitude of 100 to 150 g.
10. Each patient received a retrospective questionnaire with 10-point visual analog scale (VAS) concerning pain caused by the surgical procedure. The VAS was a 10-cm line with anchors at each end of line that read “no

pain" (0 cm) and "pain as much as possible" (10 cm). The pain experience was asked as it occurred during insertion, 1 day and 7 days.

11. The patient was instructed to clean the teeth and the exposed mini-screw with a tooth brush.

All information was recorded in the mini-screws operation sheet§.

Clinical variables

The 15 variables examined were divided into 2 categories:

1. **Host factors**
   - Age
   - Gender
   - Jaw in which the screws were placed: maxilla or mandible
   - Side of screw placement: right or left
   - Bone density: D1, D2, D3, D4
   - Tightness while driving: required drilling, dense, loose, very loose
   - Insertion torque value
   - Skeletal relationship:
     Sagittal: skeletal type 1, type2 , type3
     MP to Sella-Nasion angle : high, average, low
     Transversal: symmetry, asymmetry
   - Dental relationship:
     Vertical: normal, deepbite, openbite
     Transversal: symmetry, asymmetry
2. **Procedure factors**
   - Operator: Chaiwat P or Santiwong P
   - Method of insertion: drilling or no drilling
   - Path of insertion: diagonal or perpendicular

Criteria for the success

Mini-screws that maintained in the bone under the orthodontic force for at least 3 months were considered successful. If the mini-screws loose, they were considered as failure.

Statistical analysis

Mann-Whitney U test or Kruskal Wallis test was used to compare the insertion torque values according to clinical variables.

A logistic regression analysis was performed to estimate the influence of each factor on failure when the other factors were controlled.

P values less than .05 was considered statistically significant. These analyses were performed with a statistical analysis program (SPSS 14 for Windows).

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§ See appendix C

CHAPTER V
RESULTS

From data in appendix D, we analyzed the result with statistic analysis. The success rate of mini-screws anchor examined in this study was 73.8%. There was no significant association between the success rate and all the variables investigated (Table 9). In order to classified the insertion torque range, we used the formula given by Sturges (90). It is a guidance to decide how many class intervals are needs. This formula gives

$$k = 1+3.322(\log n)$$

where *k* stands for the number of class intervals and *n* is the number of values in the data set. The width of the class interval (*w*) may be determined by dividing the range by *k*. Symbolically, the class interval width is given by

$$w = \frac{R}{k}$$

where R (range) is the difference between the maximum and minimum values in the data set. We applied Sturges' rule to obtain the number of class intervals.

$$k = 1+3.322(\log 42)$$
$$= 1+3.322(1.623)$$
$$\simeq 6$$

In order to determine the class interval width

$$w = \frac{R}{k} = \frac{16 - 0.5}{6} = \frac{15.5}{6} = 2.583$$

It is apparent that a class interval width of 3 was more convenient to use. According to this information, we constructed the insertion torque interval as shown in Table 10.

Table 9 Success rate and number of mini-screws according to clinical variables.

Clinical variable	Success (n)	Total (n)	Success rate(%)	P	Odds ratio	95% CI of Odds ratio
Age						
<20	8	12	66.67	0.508	1.643	0.378-7.134
≥20	23	30	76.67			Ref. group
Gender						
Male	7	9	77.78			Ref. group
Female	24	33	72.72	0.760	1.312	0.228-7.540
Jaw of placement						
Maxilla	25	32	78.13			Ref. group
Mandible	6	10	60	0.263	2.381	0.522-10.860
Side of placement						
Right	10	13	76.92			Ref. group
Left	21	29	72.41	0.759	1.270	0.276-5.839
Method of insertion						
Drill	22	32	68.75	0.209	4.091	0.455-36.812
No-drill	9	10	90			Ref. group
Operator						
PC	13	18	72.22	0.839	1.154	0.289-4.608
PS	18	24	75			Ref. group
Bone density						
D1-D2	11	13	84.62			Ref. group
D3-D4	20	29	68.97	0.296	2.475	0.452-13.543
Tightness when driving						
Req drilling-dense	19	23	82.61			Ref. group
Loose	12	19	63.16	0.161	2.771	0.666-11.524
AP skeletal relationship						
Class I	16	23	69.57	0.493	1.641	0.398-6.761
Class II	15	19	78.95			Ref. group
MP-SN angle						
Normal	6	11	54.55	0.061	4.538	0.930-22.585
Low	3	5	60	0.221	3.667	0.457-29.419
High	22	26	84.62			Ref. group
Transverse skeletal relationship						
Symmetry	22	28	78.57			Ref. group
Asymmetry	9	14	64.29	0.325	2.037	0.493-8.408
Vertical dental relationship						
Normal	12	18	66.67	0.999	8.077	Not calculated
Deepbite	17	22	77.27	0.999	4.751	Not calculated
Openbite	2	2	100			Ref. group
Trans. dental relationship						
Symmetry	14	19	73.68	0.987	1.012	0.254-4.029
Asymmetry	17	23	73.91			Ref. group
Total	**31**	**42**	**73.81**			

Table 10 Number of mini-screws according to insertion torque range classified from Sturges' rule

Max. insertion torque (Ncm)	Success (n)	Failure (n)	Total (n)
$\leq$ 2.99	8	6	14
3-5.99	12	2	14
6-8.99	6	1	7
9-11.99	4	1	5
12-14.99	0	1	1
$\geq$ 15	1	0	1
Total	**31**	**11**	**42**

From Table 10, the number of mini-screws in some class intervals were small and seem to be insufficient statistically analyzed. The distribution of insertion torque value was shown in Figure 33. Sample number 26 (raw data was shown in an appendix D) is an outlier with an insertion torque of 16 Ncm. Thus, the minimum and maximum value we used to classify the torque range is 0.5 and 12.3 respectively. According to the previous studies related to optimal insertion torque of mini-screws (26, 27, 36), they classified the torque range in to 3 groups. Therefore, the insertion torque was divided in to 3 groups with and interval of 4 Ncm in this study. Table 11 showed the success rate where the subjects were divided into 3 groups according to the maximum insertion torque. The success rate in the group with an insertion torque of 4-8 Ncm (87.5%) was higher than the < 4 Ncm group (61.11%) or the $\geq$ 8 Ncm group (75%), but there was no statistically significant difference. The average time in the bone before screws failure was 35.4$\pm$19.9 days with 1 and 69 day as minimum and maximum value respectively.

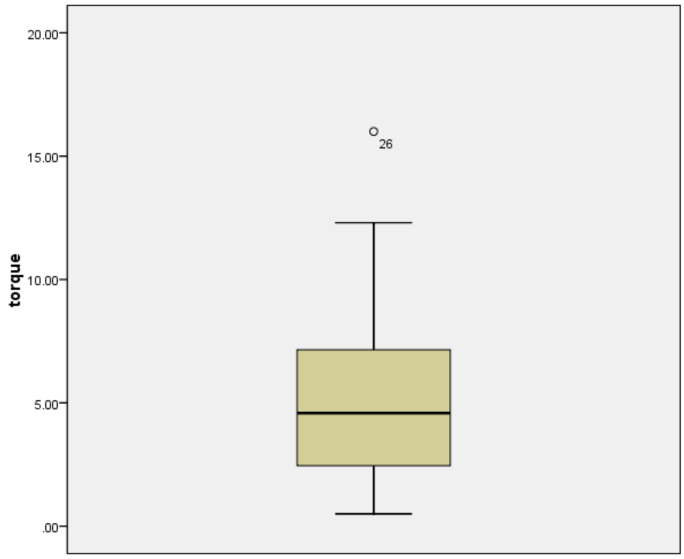

Figure 33 Box plot represent the tests of normality of maximum insertion torque

Insertion torque in this study was distributed in a range of 0.5-16 Ncm. Because the maximum insertion torque value was not normally distributed, Mann-Whtiney U test or Kruskal Wallis test was used to compare the maximum insertion torque values according to clinical variables. There was no significant difference in maximum insertion torque according to age, gender, left or right side, MP to SN angle and method of insertion (Table 12). There was no significant difference in the maximum insertion torque between maxilla and mandible, and success and failure group (Table 13). Only one mini-screw was inserted perpendicular to the bone surface in this study, so the path of insertion was not included in the statistical analysis. There was statistically significant correlation between maximum insertion torque value and bone density D1-D4 ($P < 0.001$, $r = -0.77$, $r^2 = 0.593$) (Fig. 34). Maximum insertion torque in D1 and D2 type bone was significant greater than D3 and D4 bone ($P < 0.05$) (Table 14). The require drilling and tight feeling when driving the mini-screw had significantly more insertion torque value than the loose feeling group (Table 15).

Table 11 Success rate according to maximum insertion torque.

Max. insertion torque (Ncm)	Success (n)	Total (n)	Success rate(%)	P	Odds ratio	95% CI of Odds ratio
< 4	11	18	61.11	0.096	4.455	0.767-25.859
4 - 8	14	16	87.5			Ref. group
≥ 8	6	8	75	0.446	2.333	0.264-20.659
Total	**31**	**42**	**73.81**			

Table 12 Maximum insertion torque according to clinical variables

	Max. Insertion torque (Ncm)		
Clinical variable	**Mean**	**SD**	**P**
Age			0.743
<20	4.89	3.08	
≥20	5.59	4.1	
Gender			0.203
Male	3.61	1.27	
Female	5.71	3.93	
Jaw of placement			0.871
Maxilla	5.02	3.12	
Mandible	6.03	5.03	
Side of placement			0.522
Right	6.1	4.64	
Left	4.88	3.08	
Method of insertion			0.701
Drill	5.38	3.7	
No-drill	4.88	3.52	
MP-SN angle			0.175
Normal	6.19	3.11	
Low	6.29	3.68	
High	4.67	3.81	

Table13 Maximum insertion torque of the success and failure groups according to jaw

	Total	Maxilla	Mandible
Success (n=31)			
Mean	5.50 (0.5-16)	5.12	7.08
SD	3.55	2.9	5.61
Failure (n=11)			
Mean	4.58 (1-12.3)	4.62	4.46
SD	3.91	4.06	4.23
Total (n=42)			
Mean	5.26 (0.5-16)	5.02	6.03
SD	3.62	3.12	5.03

Parentheses (minimum value-maximum value)

No significant difference between maxilla and mandible, and success and failure group.

Table 14 Maximum insertion torque and bone density grades according to Lekholm and Zarb (1985).

	No. of mini-screws	Max. insertion torque (Ncm)	
D1	3	12.20	*
D2	12	7.74	
D3	20	3.89	
D4	7	1.94	

*A significant difference was detected between the grades ($P < 0.05$)

Table 15 Maximum insertion torque and tactile sensation while mini-screws drilling.

	No. of mini-screws	Max. insertion torque (Ncm)	
Require drilling	2	13.30	*
Dense	22	7.10	
Loose	19	2.40	

*A significant difference was detected for maximum insertion torque between the groups of tactile sensation ($P < 0.05$).

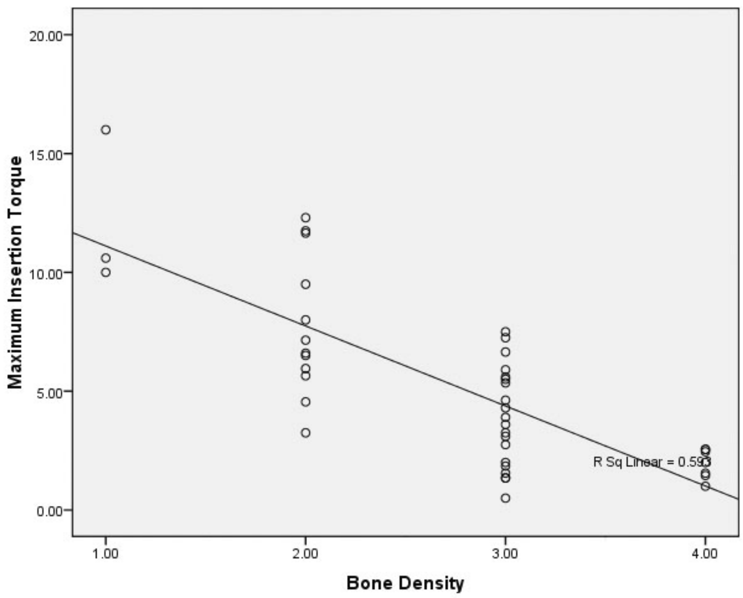

Figure 34 Scatter plot of maximum insertion torque values versus bone density.

The average pain intensity reported by the patients assessed by VAS during mini-screw placement was 0.99. The VAS assessments 1 and 7 days after insertion were 1.74 and 0.45 respectively (Table 16). There was no significant difference of VAS between the success and the failure group in all 3 groups of time observed, although the success group had low pain level than the failure group (Table 17, Fig. 34).

Table 16 The VAS pain score of mini-screw placement during-operative, 1 day post-operative and 7 day post operative pain.

	VAS	
Timing	**Mean**	**S.D.**
During-op. pain	0.99	1.37
1 day post-op. pain	1.74	1.11
7 day post-op. pain	0.45	2.75

Table 17 The VAS pain score of mini-screw placement in success and failure group during-operative, 1 day post-operative and 7 day post operative pain.

	VAS			
	Success		**Failure**	
Timing	**Mean**	**S.D.**	**Mean**	**S.D.**
During-op. pain	0.82	1.17	1.49	1.78
1 day post-op. pain	1.34	2.09	2.87	3.99
7 day post-op. pain	0.23	0.52	1.07	1.92

No significant difference of VAS between the success and the failure group in all 3 groups of time observed.

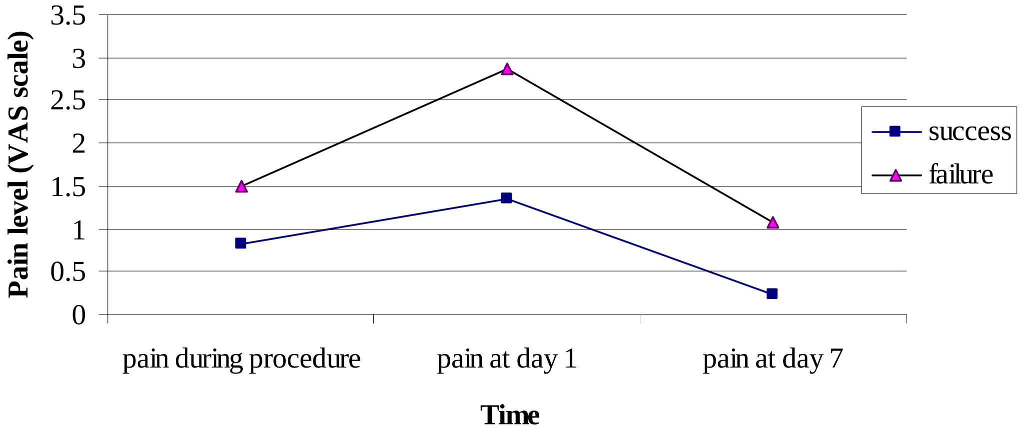

Figure 35 Mean pain intensity of mini-screw insertion in success and failure group.

CHAPTER VI
DISCUSSION

Initial stability after mini-screw placement is considered to play an essential role in successful immediate loading. It depends on mechanical retention between bone and the mini-screw which is related to the local bone quality and quantity, type of screw and placement technique used (28-30). Friberg et al (33) found significant relationship between implant placement resistance and bone density. They suggested that the insertion torque is a reliable method to evaluate the bone density (91). This study used digital torque gauge to measure the maximum insertion torque when driving the mini-screw into the bone. The mean maximum insertion torque examined in this study ranged from 4.62-7.08 Ncm according to the jaw of placement and the mean insertion torque for 42 mini-screws was 5.26 Ncm. Motoyoshi et al (36) reported the mean insertion torque ranged from 7.2-13.5 Ncm according to the placement location. Other studies reported the peak insertion torque of mini-screw range form 7.7-9.2 Ncm according to age of patient and placement location (26, 27). These values were higher than those in this study because the difference in screw diameter, length and shape. In this study, we used the mini-screw with 1.4 mm in diameter and 7 mm long, the 1.6 x 8 mm mini-screws with more degree of taper were used in the previous studies (26, 27, 36).

Motoyoshi et al (36) found the success rate of 1.6 x 8 mm tapered shape mini-screws with insertion torque within the range 5-10 Ncm was significantly higher than that for mini-screws with insertion torque more or less than this range. They reported 2 more studies related to insertion torque and the success rate of mini-screws. Another study by Motoyoshi et al (27) found the optimal insertion torque range of 8-10 Ncm. However they could not define the optimal insertion torque in the study using mini-screws as orthodontic anchorage in adolescents. The mini-screws with insertion torque range 5-10 Ncm had significant higher success rate only in early-load group of adolescent in the maxilla, but was not found to have higher success rate in the combined results (26). Although the mini-screws used in these 3 studies had the same shape, size, diameter, insertion procedure and same torque gauge used. The summary of the studies of Motoyoshi et al (26, 27, 36) and this study was shown in Table 18. From the results of these studies, we hypothesized that the optimal torque range exists. In this study the mini-screws were divided into 3 groups based on maximum insertion torque. The success rate of mini-screws with maximum insertion of 4-8 Ncm was higher than the $<$ 4 Ncm group or the $\geq$ 8 Ncm group. Although there was no statistically significant difference, but the odds ratio in Table 9 indicates that there are 4.45 and 2.33 greater probability of failure for the insertion torque $<$ 4 Ncm group and $\geq$ 8 Ncm group than for the 4-8 Ncm group respectively. The odds is the ratio between the number of events relative to the number of nonevents. The odds ratio is the ratio between the odds of the treated group and the odds of the control group. The odds ratio takes values between zero to infinity. One is the null value and means that there is no difference between the groups compared; close to zero or infinity means a large difference (92). Within the limits of this study, the optimal torque range could not be defined. But there was a tendency that the mini-screws with an insertion torque $<$ 4 Ncm had a greater chance for failure compared with the 4-8 Ncm group ($P=0.096$, odds ratio = 4.45). This tendency needs further investigation to confirm with larger sample size.

We calibrated the tactile sense while driving the mini-screw between 2 operators by insertion the mini-screws into different materials classified by Misch (60). Subjective assessments seem to have a limited value when trying to differentiate among bone density, it can distinguish in extreme categories (D1 and D4) but poor to tell the difference in moderate categories (D2 and D3) (93). In this study an insertion torque was significant related to the subjective bone density and tightness when driving the mini-screw, which similar to the previous study (93). We suggest using the insertion torque measurement to evaluate the bone density at mini-screw placement site.

Table 18 Summary of the studies of Motoyoshi et al (26, 27, 36) and this study.

	Motoyoshi et al (36)	**Motoyoshi et al (27)**	**Motoyoshi et al (26)**			**This study**		
			Adult early load	Adolescent early load	Adolescent late load	Age <20	Age ≥20	Total
No. of mini- screws	114	87	86	47	36	30	12	42
No. of patients	41	32	27	15	15	7	18	25
(male, female)	(4,37)	(4,28)	(3,24)	(6,24)		(3,4)	(3,15)	(6,19)
Age (year)	24.9±6.5	24.4±6.5	26.2±5.6	15.9±1.9	16±2.4	15.9±1.5	29.4±8.6	25.6 ±9.6
(range)	(13.3-42.8)	(14.6-42.8)	(20.4-36.1)	(11.7-18.9)		(14-18)	(21-51)	14-51
Insertion method	Self	Self	Self tapping			Self drilling, Partial self tapping		
Size of drill (mm)	1.3x8	1.3x8	1.3-1.4x8			1x4 if partial self tapping		
Site of placement	Buccal alveolar bone of posterior teeth							
Mini-screw size	1.6x8	1.6x8	1.6x8			1.4x7		
Latent period	Immediate	Immediate	2-4 wk	2-4 wk	> 3m	Immediate		
Force applied	Less than 200g					100-150 g		
Observation time	6m	6m	6m			3m		
Success rate	85.5%	87.4%	91.9%	63.8%	97.2%	66.7%	76.7%	73.8%
Mean torque	7.2-13.5	8.28-10.11	7.6-9.2			4.53	5.55	4.62-7.08
Optimal torque range	5-10	8-10	Undefined			Undefined		

The mandible has thicker cortex and more bone tissue. Therefore insertion torque value expected to be higher in mandibles than in maxillae, which is confirmed by many studies (27, 33, 36). In this study, insertion torque value in the mandible was greater than in the maxilla, however, there was no significant difference. This finding is similar to the previous study (26). The possible reasons for this finding might be explained by wide range of bone density distributed in this group of patient and small sample size.

In this study, mini-screws inserted after the pilot drill was made showed no insertion torque difference from mini-screws inserted directly into the bone. Previous studies showed higher insertion torque value in the no pre-drill group (87, 88). However, in these studies the pilot hole depth was the same as screw length. In this study, the depth of drilling only limited at cortical bone level, not involved the full length of the mini-screw. Therefore, this may be the reason why the insertion torque of the pre-drill group was not significant difference from the no pre-drill group.

There were many studies examined the success rate of mini-screws, which reported in range of 63.8-91.6% (21, 24, 26, 74, 94). Wide range of these rates might be explained by wide range of patients' age and facial types, various types of the mini-screws, difference surgical procedures and varying management protocols. So, the success rate might not be directly compared. In this study showed 73.8 % success rate which similar to our previous studies of 74.6% and 75.9% (unpublished data) and considered a moderate rate.

In 1985, Lekholm and Zarb described a classification method to assess bone density preoperatively base on radiographs and hand-felt perception of the drilling resistance. Jaffin and Berman (31) found a high failure rate (35%) in D4 bone. This finding is also observed in the study of Herrmann et al (95). They investigated 487 implants and found a higher failure rate in D4 (24.5%) bone than in D1-D3 bone (4.5 - 11.1%). Trisi and Rao (96) found a significant correlation between Lekholm and Zarb bone density and histomorphometric bone density which was expressed as percentage of bone trabeculae over the total bone plus marrow area. Histologic micrographs of the D1-D4 bone biopsies were shown in Fig. 36. Initial stability depends on mechanical interlock between bone and mini-screw. Mini-screws inserted in low bone density have less bone contact compared with those inserted in denser bone. Thus they may not withstand the immediate loaded force and leads to excessive mobility and higher failure rate. In this study, the success rate of mini-screws inserted in D1 and D2 bone was higher than those inserted in D3 and D4 bone but there was no significant difference. The perception of require drilling and dense when inserted the mini-screws had more success rate compared with the loose sensation group, but there were not significant difference. The possible reasons of this result may be explained by a small sample size and distribution of data in each category investigated.

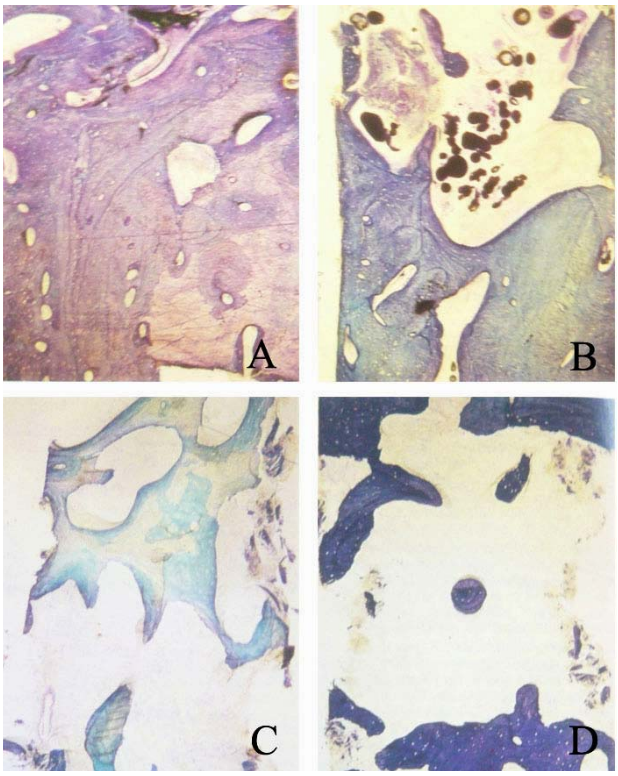

Figure 36 Histologic micrograph of bone biopsies; A, B, C and D is D1, D2, D3 and D4 bone density respectively (96).

There was no significant difference in the success rate of mini-screw anchors with respect to age, though the success rate in patients less than 20 years old (66.67%) was lower than patients more than 20 years old (76.67%). This finding was similar to previous studies (20, 21, 94). Motoyoshi et al (26) used 169 mini-screws in 57 orthodontic patients. The higher failure rate of mini-screw was observed in adolescent group (mean age 15.9 $\pm$ 1.9 years) compared with the adult group (mean age 26.2 $\pm$ 5.6 years). The success rate of adolescent group and adult group were 63.8% and

91.9% respectively. They recommended waiting for 3 months healing period to improve the success rate in the adolescent group. Chen et al (25) inserted 359 miniplates and mini-screws in 129 patients with a mean age of 24.5 $\pm$ 7.1 years. They found that the success rate in patients less than 20 years old (69.8%) was significantly lower than in those more than 20 years old (81.2-93.2%). The possible reason for higher failure rate in young patient is more bone remodeling (97). Bone remodeling is the process which follows an activation, resorption and formation sequence. Bone is remodeled by teams of cells which are called the basic multicellular unit (BMU). Insertion the mini-screws into the bone cause bone damage, remodeling removes the damaged tissue and then replaced by new bone tissue. If damage accumulates faster than the tissue can be repaired, larger microcracks may develop and propagate to form a stress fracture (98). There are more resorptive spaces per unit of cortical bone area in children than in adults (97). Thus the immediate loading of mini-screws inserted in children may cause excessive mobility and leads to failure. The difference between the results of this study and the studies reported by Motoyoshi et al (26) and Miyawaki et al (25) might be explained by the difference in age distribution and small sample size.

The mini-screws placed in the mandible show lower success rate than those inserted in the maxilla (21, 23-25). The possible reasons might be related to overheating from drilling because all these studies inserted the mini-screws in the self tapping fashion. The posterior mandible has less attached gingiva which increases the risk of peri-implant infection, tissue destruction and loosening of the mini-screw. In this study, the success rate of mini-screws inserted in mandible was lower than in maxilla but there was no significant difference. This finding is similar to previous studies (20, 36). This can be explained by the insertion method used in this study. In order to decrease the heat from drilling we used the self drilling method to insert the mini-screws. When the pre-drilling was required we used the manual pre-drilling method rather than drilling with a handpiece. Moreover, all mini-screws in this study were inserted through attached gingiva to reduce the chance of inflammation. For these reasons, there was no significant relationship was found between success rate in the maxilla and the mandible.

Four of the failed mini-screws showed inflammation of soft tissue around the mini-screw heads. Peri-implantitis is an important factor in dental implant failure.

There were observed that soft tissue inflammation followed with the progressive breakdown of the peri-implant bone cause the implant became unstable and were lost (99, 100). This finding was also observed in the mini-screw anchors. Miyawaki et al (20) reported the inflammation of peri-implant tissue was associated with the failure of mini-screw placed in the buccal alveolar region for orthodontic anchorage. Oral hygiene and the presence of keratinized mucosa at the implantation site also associated with inflammation. The absence of adequate keratinized mucosa around dental implants was associated higher plaque accumulation and peri-implant tissue destruction (101, 102). Similar finding was found in mini-screws inserted in the area surrounded by non-keratinized mucosa, especially in posterior mandible, which was reported that they were prone to infection and failure (24). It is important to control the infection around the mini-screw. Trejo et al (103) compared the effect of mechanical therapy alone or combined with chlorhexidine irrigation on peri-implant mucositis lesion. There was no difference between the two methods, they concluded the mechanical effect alone is sufficient to achieve clinical and histologic resolution of mucositis lesion. All patients in this study were instructed to clean the mini-screw with a tooth brush for plaque control.

There are two procedures for mini-screw insertion, self drilling and self tapping methods. The self tapping method, mini-screws were inserted into bone after drilling a pilot hole, has disadvantages such as thermal necrosis of the bone (72), more instruments and time required. The pilot hole size also affects the holding power of mini-screw, which should not exceeds 85% of external diameter of the screw otherwise the holding power will decrease rapidly (73). Self drilling screw, which enables the mini-screw to insert without drilling, was developed to avoid these problems (87). In this study the success rate of the no drilling group (90%) was higher than the drilling group (68.75%) but there was no significant difference. Kim et al (104) used an animal model to evaluate the effects of the drilling procedure on the stability of the mini-screw under early 200-300 g orthodontic loading. Eleven weeks under loading period found that mini-screws in the drill-free group showed more success rate, less mobility, and more bone-to-metal contact compared with the drilling group. The difference between the results of this study and the study of Kim et al

(104) may be explained by small sample size and distribution of the data, only 10 mini-screws was inserted without drilling.

Miyawaki et al (20) reported a significant relationship between high mandibular angle and the failure of mini-screw anchorage. The recent studies of the computed tomograms from dry skulls showed thinner buccal cortical bone of the posterior region in subjects with high mandibular plane angle (1.5-2.7 mm) than those with low angle (2.3-3.7mm)(105, 106). The cortical bone thickness of posterior region seems to be influence by masticatory function. Masseter muscle thickness was positively correlated with the alveolar process thickness and negatively correlated with mandibular plane angle (107). In this study an insertion torque in high mandibular plane angle was lower than the normal and low angle groups but there was no significant difference. Because the stability of mini-screw depends on mechanical interlock to the bone, therefore the sufficient cortical bone thickness is related to the success which is confirmed by the study of Motoyoshi et al (27). But this present study, we found no association between the high mandibular plane angle and the failure of mini-screw anchorage. The possible reason may be explained by small sample size and uneven distribution of mini-screws in each group.

The interradicular spaces of the buccal posterior region from tomographic images have been reported (65). There was at least 1.5 mm of distance between the roots in both the maxilla and mandible. Therefore, the mini-screws with diameter less than 1.5 mm can avoid damaging the roots in both jaws. Kuroda et al (23) used mini-screws with 1.3 and 1.5 mm in diameter for orthodontic anchorage and found high success rate of 90.4% and 85.7% respectively, which was not significantly different between these two sizes. The safest length for mini-screw placed on buccal posterior region would be about 5 mm to avoid damaging roots based on thickness of soft tissue (1-1.5 mm) (108) and cortical bone (2 mm) and the distance from the interradicular bone to root surface (2 mm) (65). But from the unpublished study, regarding factors for failure of mini-screw anchors of Department of Orthodontic, Mahidol University found that there was an association between failure and the length less than 7 mm. According to these anatomical and clinical studies, the mini-screw with diameter of 1.4 mm and 7 mm long was used in this study.

Table 19 Summary of past clinical studies of mini-screw anchors

	Success rate (%)	No. of mini-screw	Age of patients (y)	Mini-screw diameter (mm)	Mini-screw length (mm)	Latent period	Force applied(g)	Observation time
Miyawaki et al(20)	0	10	21.8±7.8	1	6	NA	<200	1 y
	83.9	101		1.5	11			
	85	23		2.3	14			
Cheng et al (24)	89	92	29±8.9	2	5-15	2-4 wks	100-200	>2 y
Tseng et al (74)	91.1	45	29.9	2	8,10,12,14	2 wks	100-200	16 m
Park et al (21)	91.6	227	15.5±8.3	1.2, 2	4-15	NA	<200	15 m
Chen et al (22)	84.7	59	29.8	1.2	6, 8	2 wks	200	20 m
Kuroda et al (94)	> 80	116	21.8±8.2	1.3, 2, 3	6-12	0-12 wks	50-200	1 y
Motoyoshi et al (36)	87.4	114	24.9±6.5	1.6	8	Immediate	< 200	6 m
This study	73.8	42	25.6±9.6	1.4	7	Immediate	100-150	3m

Frost's hypothesis stated that bone functions within an optimum strain range. If the strain in bone is too low, disuse mode of bone occurs and remodeling results in net loss of bone. If strain exceeds a threshold that the bone can withstand, fatigue failure can occur (45). According to this hypothesis, low intensity immediate loading on the healing bone shortens healing rather than prolongs it. Animal experimental studies showed that immediate loading of 100-250 g on mini-screws showed significantly indifferent in bone-to-metal contact ratio among immediate loading group, unloading control group and up to 12 weeks healing groups (109, 110). Clinical studies also reported high success rate (>80%) of mini-screw anchors under 200 g force loaded immediately after placement (26, 36). But the mini-screws used in this study (1.4x7 mm) were smaller than those previous studies (1.6x8 mm). Therefore, immediate loading of 100-150 g force was used in this study. Data of force magnitude used in past clinical studies of mini-screw anchors was shown in Table 19.

Interestingly, the mini-screw with lowest torque value in this study (0.5 Ncm) showed no failure. After one month of 100 g immediate loading this screw had slight mobility and soft tissue inflammation. But under the same amount of force applied for a next one month there was no clinically detectable mobility and the inflammation decreased. This may be implied that the insertion torque can not be used as the single clinically predictor for mini-screw success. The important factor that clinicians must be considered is individual bone response of the patient.

Pain cause by the mini-screw placement is very important because the use of mini-screw is an additional procedure from conventional orthodontic treatment. Patients might have fear and anxiety. In this study, the average pain intensity assessed by VAS were 0.99, 1.74 and 0.45 during mini-screw placement, 1 day and 7 day after insertion respectively. This result supported the data studied by Manopatanakul et al (111) which reported the pain intensity after mini-screw placement assessed by VAS during mini-screw insertion, 1 and 7 days after insertion were 1.69, 1.53 and 0.29 respectively. Kuroda et al (94) reported the average pain intensity immediately after insertion to 14 days after insertion of mini-screw with 1.3 mm in diameter and 7 mm long. The VAS scale were less than 1 in every observation times except 1 hour after insertion which average pain intensity reached 1.95. The result from this study will help orthodontists to communicate with the patients, which will reduce the level of patient's anxiety. Pain caused by mini-screw insertion is about 1-1.7 on the 10-point and the pain is reduced to near zero 1 week after insertion.

Within limit of time of the present study, the evaluation period of orthodontic force applied to the mini-screws was 3 months. Two thirds of the failures was noted before loading or within the first month after orthodontic loading in the study of Cheng et al (24). A study of Orthodontic department, Mahidol University about the success rate of mini-screw anchors for 18 months (unpublished study) found most of the failure occurred within 3 months after insertion. In this study, the average time of the failed screws inserted in the bone before loosening was 36.4 day. In human cortical bone, it would take approximately 20 days to initiate and increase the size of resorptive cavity by the osteoclasts, follow by the 10 days of relative quiescence, and finally, 90 days of deposition of bone matrix by the osteoblast teams (98). This may be an explanation why most mini-screws loosening occurred within the first month after insertion. Three months observation period in this study might be too short but it seems to cover the critical period for the failure of mini-screws used as orthodontic anchorage.

This study was performed to investigate the relationship between insertion torque and the success of mini-screw used as orthodontic anchorage, and to investigate other factors that could affect the failure of mini-screws. The sample was collected prospectively. With time limitation, the sample size was small which was a major problem in this study. This small sample size when categorized according to clinical variables seems to be insufficient to statistically evaluate the effect of each factor to failure. In order to investigate the effect of insertion torque on the success of mini-screws, the study design needs to control many factors that could affect an insertion torque. In this study we used one type of mini-screw to eliminate the mini-screw factor on an insertion torque. The insertion method should be the same for whole sample. Mini-screw inserted after pre-drilling the bone was reported to have lower insertion torque than those with no prior drilling (87, 88). Age of the patients should be considered because modulus of elasticity of bone increases with age (112). An insertion torque in adult group should be higher than that of younger patients. In case of an insertion torque was not difference between the groups, patients with age under 20 years old have higher bone remodeling (97). This group of patient was reported to have higher failure rate of mini-screws immediately loaded compared with the $\geq$ 20 years old group (26). We recommend collecting sample in patients with age more than 20 years old to eliminate the effect of bone physiology in further study. Mini-screws contacted the roots showed higher insertion torque than those without contact. More failure rate was observed among those contacting adjacent roots (113) and those with root proximity (23). The study design should confirm the position of mini-screws after placement by radiographs using shift tube technique or computed tomography for more precise localization. The association between insertion torque and success of mini-screws used as orthodontic anchorage can not be found due to the limitation of this study.

CHAPTER VII
CONCLUSION

1. There was no statistically significant association between insertion torque and the success of mini-screw used as orthodontic anchorage.

2. The optimal insertion torque could not be defined but there was a tendency that mini-screws with an insertion torque in the range of 4-8 Ncm showed higher success rate than those of insertion torque < 4 Ncm (P = 0.096).

3. The results of this study indicate that the mini-screws can be immediately loaded with 100-150 g forces. The overall success rate was 73.8% with an observation time of 3 months.

4. There was no statistically significant association between the success of mini-screw anchors and any variables observed. But there was a tendency that mini-screws placed in mandible, pre drilling method, D3 and D4 bone density and loose tactile sensation had greater chance for failure (P = 0.263, 0.209, 0.296 and 0.161 respectively).

5. The maximum insertion torque of D1 and D2 bone density was statistically significantly higher than that of D3 and D4 bone group.

6. The maximum insertion torque of require drilling and dense perception when driving the mini-screw was statistically significantly higher than that of loose perception group.

7. Pain caused by mini-screw insertion is about 1-1.7 on the 10-point and the pain is reduced to near zero 1 week after insertion.

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APPENDICES

APPENDIX A

No. MU 2007-061

Documentary Proof of Ethical Clearance
The Committee on Human Rights Related to
Human Experimentation
Mahidol University, Bangkok

Title of Project: Association between Insertion Torque and the Success of Mini-Screws used as Orthodontic Anchorage

Principle Investigator: Assistant Professor Passiri Nisalak

Name of Institution: Faculty of Dentistry

Approved by the Committee on Human Rights Related to Human Experimentation

Signature of Chairman: ....
(Professor Dr.Srisin Khusmith)

Signature of Head of the Institute: (for) ....
(Professor Dr.Pornchai Matangkasombut)

Date of Approval: 29 MAR 2007

Date of Expiration: 28 MAR 2008

APPENDIX B

เอกสารคำอธิบายโครงการวิจัยแก่ผู้เข้าร่วมโครงการวิจัย

การวิจัยเรื่อง ความสัมพันธ์ระหว่างแรงบิดและความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟัน

วัตถุประสงค์

เพื่อประเมินความสัมพันธ์ระหว่างปริมาณของแรงที่ใช้ในการขันสกรูและความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟัน

วิธีการวิจัย

ทำการวิจัยเมื่อได้รับความยินยอมจากทั้งตัวผู้เข้าร่วมโครงการและผู้ปกครอง (กรณีอายุไม่ถึง 18 ปี)

ขั้นตอนตามปกติในการรักษาทางทันตกรรมจัดฟันที่ต้องปักสกรูเพื่อเป็นหลักยึด

1. ได้รับการถ่ายภาพรังสี พิมพ์ปาก และถ่ายรูป เพื่อการวินิจฉัย
2. ติดเครื่องมือทางทันตกรรมจัดฟัน
3. ปักสกรูเพื่อเป็นหลักยึดในทางทันตกรรมจัดฟัน
4. เคลื่อนฟันให้ชิดกันมีการสบฟันถูกต้องสวยงามตามหลักวิชาชีพทางทันตกรรมจัดฟัน

ขั้นตอนที่เพิ่มเติมเพื่อการวิจัย

1. วัดแรงบิดที่ใช้ในการขันสกรู

เหตุผลที่เชิญชวนท่านเข้าร่วมโครงการวิจัย

อัตราความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟัน เกิดจากปัจจัยหลายอย่างที่เกี่ยวข้อง จำเป็นต้องอาศัยข้อมูลจากการศึกษาในมนุษย์ของงานวิจัยเพื่ออธิบายถึงปัจจัยที่เกี่ยวข้องกับความสำเร็จได้อย่างชัดเจน อันจะเป็นประโยชน์อย่างยิ่งต่อการพัฒนาการรักษาทางทัน-ตกรรมจัดฟันโดยการใช้สกรูเป็นหลักยึดให้เกิดผลสำเร็จดียิ่งขึ้น การวิจัยนี้เป็นการศึกษาถึงค่าของแรงบิดที่ใช้ในการขันสกรูว่ามีความสัมพันธ์กับความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟันหรือไม่ เพื่อนำไปเป็นตัวบ่งชี้ในทางคลินิกต่อไป

ระยะเวลาในการวิจัย

ขั้นตอนการปักสกรูและการบันทึกข้อมูลแต่ละครั้งจะใช้เวลาประมาณ 30-45 นาที/1ตัว

ประโยชน์ที่คาดว่าจะเกิดขึ้นต่อตัวท่านและต่อผู้อื่น

ทำให้ทราบถึงค่าแรงบิดที่ใช้ในการขันสกรูและความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟันว่ามีความสัมพันธ์กันหรือไม่ ทราบช่วงของแรงบิดที่เหมาะสมในการไขสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟัน ซึ่งจะสามารถนำค่าแรงบิดนี้มาใช้ในการทำนายความสำเร็จทางคลินิกและปรับปรุงมาตรการการใช้สกรูเป็นหลักยึดในทางทันตกรรมจัดฟันให้มีประสิทธิภาพมากยิ่งขึ้น

ข้อเสี่ยงที่อาจเกิดขึ้น และการแก้ไขป้องกัน

การวิจัยนี้ศึกษาในผู้ป่วยที่จำเป็นต้องรับการปักสกรูเพื่อเป็นหลักยึดในการรักษาทางทันตกรรมจัดฟันอยู่แล้ว เพียงนำเครื่องมือมาวัดแรงบิดที่ใช้ในการขันสกรู จึงไม่ก่อให้เกิดความเสี่ยงใดๆนอกเหนือจากความเสี่ยงที่อาจเกิดขึ้นจากการปักสกรู

การดูแลรักษาความลับ

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเกี่ยวกับผู้เข้าร่วมโครงการเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับผู้เข้าร่วมโครงการต่อหน่วยงานต่างๆที่เกี่ยวข้องกระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น หากจะต้องเปิดเผยข้อมูลต้องได้รับความยินยอมจากผู้เข้าร่วมโครงการก่อน

สิทธิของผู้เข้าร่วมโครงการวิจัย

ผู้เข้าร่วมโครงการมีสิทธิที่จะถอนตัวออกจากโครงการได้ทุกเมื่อ โดยไม่กระทบต่อการดูแลรักษาที่พึงได้รับตามปกติ

ชื่อผู้วิจัย

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2. ทพญ. พรทิพย์ วีรยางกูร
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4. ทพญ. ชนิกานต์ ศรีนอก

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ที่อยู่ถาวร 32/547 ม.การบินไทย ซ.แจ้งวัฒนะ-ปากเกร็ด 43 ถ.แจ้งวัฒนะ ต.คลองเกลือ อ.ปากเกร็ด จ.นนทบุรี 11120

ในกรณีที่เกิดปัญหากับอาสาสมัคร สามารถติดต่อ ทพญ. ชนิกานต์ ศรีนอก ได้ตลอด 24 ชั่วโมง เบอร์โทรศัพท์ 08-9967-4943

ข้อพิจารณาด้านจริยธรรม (Ethical Consideration)

ผู้วิจัยตระหนักถึงประเด็นด้านจริยธรรม ซึ่งวิธีการวิจัยไม่ทำให้เกิดอันตรายต่อผู้เข้าร่วมโครงการ และได้ปฏิบัติตามหลักการวิจัยของเฮลซิงกิ

ใบยินยอม

การวิจัยเรื่อง ความสัมพันธ์ระหว่างแรงบิดที่ใช้ในการขันสกรูและความสำเร็จของสกรูที่ใช้เป็นหลักยึดในทางทันตกรรมจัดฟัน

Association between insertion torque and the success of mini-screws used as orthodontic anchorage

วันให้คำยินยอม วันที่ .... เดือน .... พ.ศ. ....

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย อันตราย หรืออาการที่อาจเกิดขึ้นจากการวิจัยหรือจากยาที่ใช้รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจ ไม่ปิดบังซ่อนเร้น จนข้าพเจ้าพอใจ

ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้ และเข้าร่วมโครงการวิจัยนี้โดยสมัครใจและการบอกเลิกการเข้าร่วมการวิจัยนี้ จะไม่มีผลต่อการรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ผู้วิจัยรับรองว่าหากมีข้อมูลเพิ่มเติมที่ส่งผลกระทบต่อการวิจัย ข้าพเจ้าจะได้รับการแจ้งให้ทราบโดยไม่ปิดบังซ่อนเร้น

ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม..(ผู้ยินยอม)

ลงนาม..(พยาน)

ลงนาม..(พยาน)

ในกรณีที่ผู้ยินยอมตนให้ทำการวิจัยไม่สามารถอ่านและเขียนหนังสือได้ จะต้องได้รับการยินยอมในขณะที่ยังมีสติสัมปชัญญะ และระบุข้อความไว้ตามนี้ ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนาม หรือประทับลายนิ้วหัวแม่มือของข้าพเจ้าในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม..(ผู้ยินยอม)
(หรือประทับลายนิ้วหัวแม่มือ)

ลงนาม..(พยาน)

ลงนาม..(พยาน)

ในกรณีที่ผู้ยินยอมตนให้ทำการวิจัยยังไม่บรรลุนิติภาวะ จะต้องได้รับการยินยอมจากผู้ปกครอง หรือผู้อุปการะโดยชอบด้วยกฎหมาย

ลงนาม..ผู้ปกครอง
/ผู้อุปการะโดยชอบด้วยกฎหมาย

ลงนาม..(พยาน)

ลงนาม..(พยาน)

ในกรณีที่ผู้ยินยอมตนให้ทำการวิจัยไม่สามารถตัดสินใจเองได้ (เช่น กรณีผู้ยินยอมตนให้ทำการวิจัยอยู่ในภาวะหมดสติ) ให้ผู้แทนโดยชอบด้วยกฎหมาย หรือผู้ปกครอง หรือ ญาติที่ใกล้ชิดที่สุดเป็นผู้ลงนามยินยอม

ลงนาม..ผู้แทน
ผู้ปกครอง/ญาติ

ลงนาม..(พยาน)

ลงนาม..(พยาน)

APPENDIX C

Record Sheet for Mini-screw Operation

Operator Name__________________________ ☐ Oral Surgeon ☐ Periodontist ☐ Orthodontist ☐ Others

Name of Orthodontist : __________________________

Patient Record No : ____________________________

Address : ____

Tel : _________________________ _**Fax** : ____________________ **E-mail** : ___________________________

Date of operation ___________ y ___________ m __________d

Age : ______________ **Sex** : ☐ Male ☐ Female **Smoking** : ☐ Yes ☐ No

Screw Company : ☐ Absoanchor ☐ Orlus ☐ Remark ☐ Jeil ☐ Hans

Site of insertion : ☐ Attached gingiva ☐ Movable mucosa ☐ Junction betw attached gingiva and movable mucosa

Screw size : Ø ________ mm Length __________ mm

Path of insertion : ☐ Diagonal ☐ Perpendicular

Please mark the location of screw

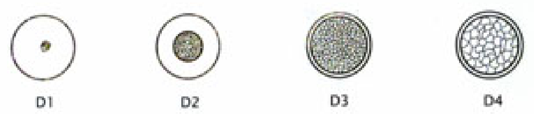
Bone quality: ☐ D1 ☐ D2 ☐ D3 ☐ D4

Tightness : ☐ require drilling ☐ dense ☐ loose ☐ very loose

Insertion torque _____________ Ncm

Drill : ☐ Yes ☐ No (self drilling)

Bone Quality



D1 : mainly cortical bone
D2 : dense cortex & cancellous bone
D3 : thinner cortex & less dense cancellous
D4 : very thin cortex & sparse bone trabeculae

If Yes :

Company of drill : ☐ Dentos ☐ Absoanchor ☐ Orlus ☐ Remark ☐ Jeil ☐ Hans

Drill size : Ø ____________ mm Length __________ mm

Drilling depth : ☐ Cortical bone only ☐ Full length

Drill Speed : _____________ RPM

Surgical Incision : ☐ No ☐ Yes

Medication : ☐ No ☐ Yes ; specify: ☐ Pre-med with ______________________________

☐ Post-med with ______________________________

Date of initial force application : ___________ y ___________ m __________d (_______wks)

Magnitude of force : _____________ gms

Date of failure : ___________ y ___________ m __________d Site : __________________________

Reason of failure (* must be specified) ____

Date of removal ___________ y ___________ m __________d (_______months)

Removal torque : ____________ Ncm

อาการปวด

กรุณาให้คะแนนความรู้สึกเจ็บ โดยขีดเส้นลงบนเส้นที่ให้ไว้ คะแนนศูนย์หมายถึงเจ็บน้อยหรือไม่เจ็บเลย คะแนนเต็ม 10 หมายถึงเจ็บมากจนทนไม่ได้

- อาการปวดระหว่างติดสกรู

0 10

เจ็บน้อยหรือไม่เจ็บเลย เจ็บมากจนทนไม่ได้

- อาการปวดหลังติดสกรู 1 วัน

0 10

เจ็บน้อยหรือไม่เจ็บเลย เจ็บมากจนทนไม่ได้

- อาการปวดหลังติดสกรู 7 วัน

0 10

เจ็บน้อยหรือไม่เจ็บเลย เจ็บมากจนทนไม่ได้

มีอาการเจ็บที่บริเวณ...

เวลาที่ใช้ในการปรับตัวไม่ให้รู้สึกว่าสกรูเป็นสิ่งแปลกปลอมในช่องปาก.................................วัน

APPENDIX D

Raw data of this study

no	Subject ID	Result	Age	Sex	Operator	Drill	Jaw	Side	Path	Density
1	SSO	2	14	2	1	1	1	1	1	2
2	SSO	1	14	2	1	1	1	2	1	3
3	SSO	1	14	2	1	1	1	2	1	4
4	VB	2	34	2	1	1	1	2	1	4
5	NB	2	21	2	2	1	2	2	1	3
6	NB	1	21	2	2	1	1	2	1	4
7	NB	2	21	2	2	1	1	2	2	1
8	PY	2	16	1	2	1	1	1	1	2
9	PY	2	16	1	2	1	1	2	1	2
10	SSI	1	51	1	2	1	1	2	1	4
11	VT	2	26	2	1	2	1	2	1	3
12	NN	1	21	2	2	1	1	1	1	2
13	SSA	2	45	1	2	1	1	2	1	3
14	ST	1	25	2	1	1	1	2	1	3
15	ST	2	25	2	2	1	1	2	1	3
16	SL	2	24	2	2	2	2	2	1	3
17	SV	2	17	2	1	1	1	2	1	3
18	SC	1	24	2	1	1	1	1	1	4
19	SC	2	24	2	1	1	1	2	1	2
20	VV	2	23	1	1	1	1	2	1	3
21	JL	2	37	2	1	1	1	2	1	3
22	JL	2	37	2	1	1	2	2	1	2
23	OS	2	37	2	2	1	1	1	1	4
24	OS	2	37	2	2	1	1	2	1	4
25	OS	2	37	2	2	1	2	2	1	2
26	OS	2	37	2	2	1	2	1	1	1
27	AP	1	35	2	2	1	2	1	1	1
28	AP	1	35	2	2	1	2	2	1	3
29	VL	2	23	2	1	1	1	1	1	2
30	VL	2	23	2	1	1	1	2	1	3
31	VLN	2	18	1	1	1	2	1	1	2
32	VLN	1	18	1	2	1	2	2	1	3
33	SP	2	16	2	2	2	1	2	1	3
34	MD	1	16	2	1	2	2	2	1	3
35	APU	2	14	1	2	1	1	1	1	3
36	APU	2	14	1	2	2	1	2	1	3
37	OO	2	30	2	1	2	1	1	1	3
38	OO	2	30	2	1	1	1	2	1	3
39	CHK	2	22	2	2	2	1	1	1	2
40	MS	2	25	2	2	2	1	2	1	2
41	SR	2	27	2	2	2	1	1	1	3
42	SR	2	27	2	2	2	1	2	1	2

The failed mini-screws were marked in red.

Raw data of this study (cont.)

no	Subject ID	Tightness	Torque (Ncm)	Skeletal relationship			Dental relationship	
				Sagittal	NS-MP	Trans.	Vertical	Trans.
1	SSO	2	8	2	1	1	2	1
2	SSO	2	7.25	2	1	1	2	1
3	SSO	3	2.55	2	1	1	2	2
4	VB	3	2.55	2	3	1	2	2
5	NB	3	1.55	1	3	2	1	2
6	NB	3	1	1	3	2	1	1
7	NB	2	10	1	3	2	1	2
8	PY	2	3.25	1	3	1	1	2
9	PY	2	5.65	1	3	1	1	2
10	SSI	3	2.45	1	2	1	1	2
11	VT	2	5.6	1	2	1	1	2
12	NN	2	12.3	1	2	1	2	2
13	SSA	2	4.62	1	2	1	2	2
14	ST	2	5.5	1	1	1	1	1
15	ST	2	6.65	1	1	1	1	1
16	SL	2	2.75	2	3	1	2	2
17	SV	2	5.9	2	1	1	2	2
18	SC	3	1.45	2	3	2	2	1
19	SC	2	9.5	2	3	2	2	1
20	VV	3	3.6	2	1	2	2	2
21	JL	3	5.35	1	3	1	3	2
22	JL	2	5.95	1	3	1	3	2
23	OS	3	1.55	2	3	2	2	1
24	OS	3	2	2	3	2	2	1
25	OS	2	11.65	2	3	2	2	1
26	OS	1	16	2	3	2	2	1
27	AP	1	10.6	1	1	2	1	2
28	AP	3	2	1	1	2	1	2
29	VL	2	6.6	2	3	1	1	1
30	VL	3	3.25	2	3	1	1	1
31	VLN	2	4.55	1	3	1	1	1
32	VLN	3	3.9	1	3	2	1	1
33	SP	2	7.5	1	3	1	1	2
34	MD	3	1.35	2	3	1	2	2
35	APU	3	3.1	2	3	1	2	2
36	APU	3	1.35	2	3	1	2	2
37	OO	3	0.5	1	3	1	1	1
38	OO	3	1.85	1	3	1	1	1
39	CHK	2	7.15	2	3	2	2	1
40	MS	2	6.5	1	2	1	2	1
41	SR	3	4.3	1	1	1	2	2
42	SR	2	11.75	1	1	1	2	2

The failed mini-screws were marked in red.

Raw data of this study (cont.)

no	Subject ID	VAS pain score			Time before failure (day)
		during-op	1d post op	7d post op	
1	SSO	1.35	0.6	0.3	
2	SSO	1.1	0.35	0.15	43
3	SSO	0.7	0	0	19
4	VB	0	0.75	0	
5	NB	2.2	3.2	0.95	
6	NB	0.6	1.4	0	28
7	NB	0.6	1.35	0	
8	PY	0.6	3.7	0.5	
9	PY	0.6	3.45	0.5	
10	SSI	0.65	0	0	1
11	VT	0	0	0	
12	NN	0	0	0	69
13	SSA	0	0	0	
14	ST	0.25	0.15	0	17
15	ST	0.45	0	0	
16	SL	0	0	0	
17	SV	1.15	0	0	
18	SC	6.45	3.9	2.15	19
19	SC	5.95	4.85	2.55	
20	VV	0.15	0	0	
21	JL	0	1.75	0	
22	JL	1.5	1.6	0	
23	OS	1.1	0	0	
24	OS	0.7	0.1	0	
25	OS	2.15	0	0	
26	OS	1.1	0	0	
27	AP	0.9	10	5	39
28	AP	2.35	10	4.45	39
29	VL	0	0	0	
30	VL	0.3	0.1	0.1	
31	VLN	1	7.85	0	
32	VLN	1.75	5.75	0.1	59
33	SP	0.1	0.2	0	
34	MD	1.6	0	0	61
35	APU	0	0	0	
36	APU	0	0	0	
37	OO	2	0	0	
38	OO	1.4	1.75	0.95	
39	CHK	0	2.05	0.9	
40	MS	0.9	7.1	0.45	
41	SR	0	0.6	0	
42	SR	0	0.8	0	

The failed mini-screws were marked in red.

Code description of variables

Variable	Code 1	2	3	4
Sex	Male	Female		
Result	Failure	Success		
Operator	Chaiwat P	Santiwong P		
Drill	Drill	No drill		
Jaw	Maxilla	Mandible		
Side	Right	Left		
Path	Diagonal	Perpendicular		
Density	D1	D2	D3	D4
Tightness	Require drilling	Dense	Loose	Very loose
Skeletal relationship				
Sagittal	Skeltal typeI	Skeletal typeII	Skeltal typeIII	
MP-SN	Normal	Low	High	
Transverse	Symmetry	Asymmetry		
Dental relationship				
Vertical	Normal bite	Deep bite	Open bite	
Transverse	Symmetry	Asymmetry		

BIOGRAPHY

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