

Aim for more safety and reliable implantation as an orthodontic anchorage

~ Usefulness of New type Rotational torque in mini-screw implantation~

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Regarding Dual-Top Anchor Screw

The situational fixation materials in clinical orthodontics is a critical factor highly affecting the treatment result. So far, there have been various approaches to obtain proper fixation materials like internal oral fixation or external oral fixation, however these trials accompany patient's inconvenience and even though the practice is performed with patient's agreement, it is not always true that adequate fixation materials can be acquired.

Recently, the use of screw type implant simply applicable for implanting of mini screws in any dental place has been spread rapidly as a robust fixation materials and there are a set of product classified as Multi Bracket System as well as single product called as Temporary Anchorage Device (TAD) in the mini implant. As TAD was employed for orthodontics, the implanting of the mini screws in various regions of maxilla and mandible was achieved and this is considered as a novel treatment in modern orthodontics because of the advantage accurately determining the moving direction of the tooth in three dimension. In addition, because the fixation materials employed for orthodontics is only temporarily required during treatment period, there has been a need of applicable materials accompanying less danger and ease in implanting or removal process rather than having fixation materials demanding surgery when performing implanting of mini screws or removing it.

The orthodontic screw satisfying these requirements is constituted of Titanium alloy which is not harmful to human body and it contains a processed cutting

blade on the tip for Self Drilling. The Self Drilling Screw makes possible to have direct implanting of mini screws on gingiva or mucosa without using Guide Drill before implanting of mini screws. Accordingly, it results in easy implanting of mini screws and their removal without big emotional burden of patients and operators. Moreover, because it is made of Titanium Alloy materials, there is no concern in biocompatibility. Unlike Dental Implant employing Osseointegration, Self drilling screw functions with using mechanical cohesion ability between a bone and screw because of no surface treatment process undergone. If the screw can tolerate the load caused by the weight up to 1kg which is the orthodontic ability needed for moving a tooth, it is believed to be satisfying fixation materials. Consequently, only the concern by medical operators is whether the screw would be fallen off or not in the operation process.

To achieve high success rate

The success rate in implanting of mini screws on dental channel at maxilla exceeds 90% in the department of orthodontics, University of Hiroshima and this is appreciated as a noteworthy result because the data has been acquired from operators with no experience to operators with adequate experience among all individual medical staffs.

It has been reported that the dominant factor determining the safety of Mini-Screw is the rotational torque utilized in implanting of mini screws according to the investigation results obtained from animal tests as well as clinical tests. Although the factors controlling the rotational torque can be deliberated in patient's condition and the operator's technique (mainly implanting technique with mini screws), the discussion in patient's condition will be left for the future.

In this paper, "appropriate method for implanting of mini screws via adjusting the rotational torque in implanting of mini screws" is discussed among various topics related to operator's technique, based on animal test results and clinical study results.

Discussions in animal tests

Materials & Methods

Test animals: Around 15 weeks old male rat from Winstar

Implanting Region with mini screws : dental area in maxilla

Mini-Screw: Diameter 1.6 mm, Length 6.0 mm

Rotational torque: 5~10Ncm, 15~20Ncm

Drilling: Pre-Drilling, Self-Drilling

Stability period after implanting with mini screws: 0, 7, 28, 56 days

Stability evaluation method:

- Tensile strength (Figure 1)
- The area of contact between Screw and Bone
(Bone-Implant contact ratio, and B/I ratio) (Figure 2)

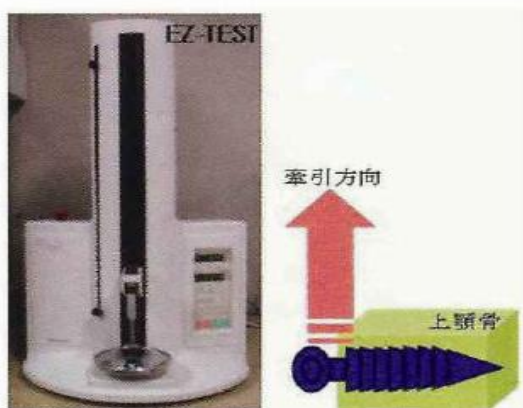


Fig. 1. Tensile strength tester (left) and measurement of tensile strength (right)



Fig. 2. B/I ratio

Calculated by subtracting total surface contact extent (yellow line) between Bone and Screw from Screw's circumference.

Result Summary

The results indicated that the screw used for implanting with 5~10Ncm rotational torque has the largest tensile strength and large B/I ratio (Fig. 3) as

well as high value after 56 days of time lapse (Fig. 4) regardless of drilling. In addition, the screw applied with 15~20Ncm rotational torque value showed lower tensile strength and B/I ratio when compared to the one applied with 5~10Ncm and there is no enhancement during 56 days of the stability period.

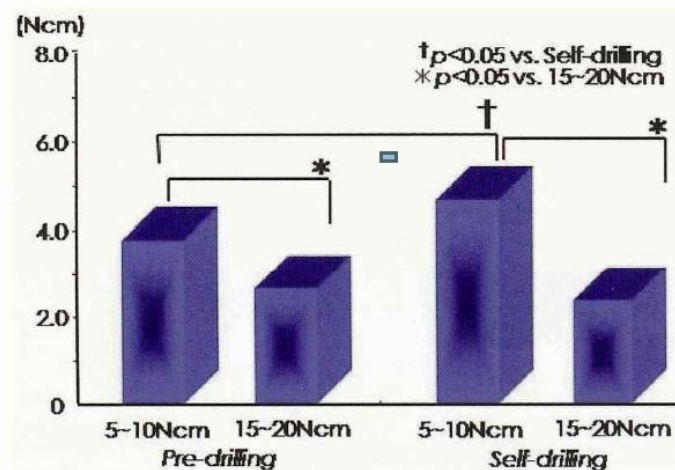


Fig. 3. Testing Result for Tensile Strength

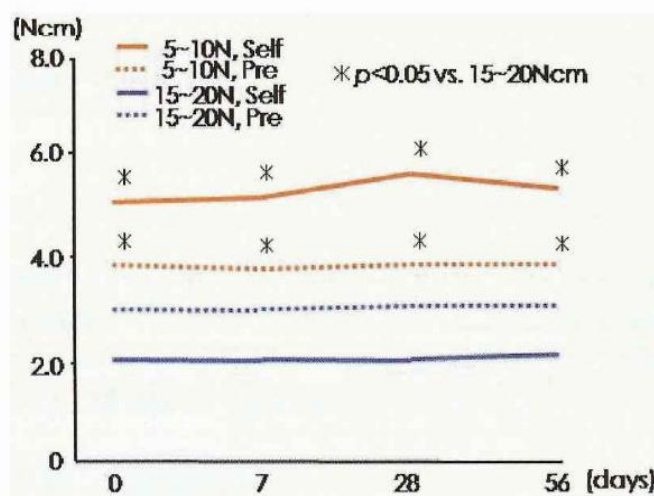


Fig. 4. Tensile Strength comparison during stability period

Conclusion

- ① Regardless of drilling, it was thought that the screw applied with 5~10Ncm rotational torque in implanting process has larger tensile strength than 4Ncm and adequate B/I ratio.
- ② The result indicated that there was no change in B/I ratio during the stability period showing no relation with the rotational torque applied in implanting of mini screws.

It was revealed that when 5~10Ncm rotational torque is employed for implanting of mini screws, destroying excessive cortical bone is prevented, and it is possible to achieve higher safety. Based on these results, it is thought that the way of the approach in implanting of mini screws should be considered in adjusting the rotational torque in further study.

Moreover, because the thickness of human cortical bone at buccal aspect on dental area in maxilla is about 1.0mm~1.4mm and this is thicker than the one in Rats (about 1.0mm), the rotational torque applied in implanting of mini screws should be allowed up to the range bigger than 5~10Ncm obtained from animal tests (around maximum 15Ncm)

Discussion in clinical study results

Experimental Methods

Experiment place: Department of Orthodontics in hospital in Hiroshima University

Experiment period: January, 2007~ December, 2007

Implanting region with mini screws: Maxilla in between 2nd premolar and 1st molar

Mini Screw: Diameter 1.6mm, Length 6.0mm (n(numbers)=62)

Experiment: **Rotational torque in Implant mini screws**

Industrial rotational torque is used for the measurement in the final stage of implant mini screw, a screw base is to be adjacent to gingiva (Fig. 5).

Failure rate

The screws failed within 3 months and disturbed after 3months were counted as failure.



Fig. 5. Industrial rotational torque (left)

Magnified picture on the measurement reading (right)

Result Summary

Generally, the screw is implanted in the range of 4.8Ncm~17.3Ncm of the rotational torque and when the used rotational torque is below 5Ncm or above 16Ncm, the failure rate appears higher (Fig. 6). Therefore, it can be assumed that when a Duel-Top Anchor screw, diameter 1.6mm, length 6.0mm sized, is implanted at buccal aspect on dental area in maxilla, the adjustment of the rotational torque to 5Ncm~15Ncm reduces the failure rate and results in acquiring higher early safety as predicted in animal test results.

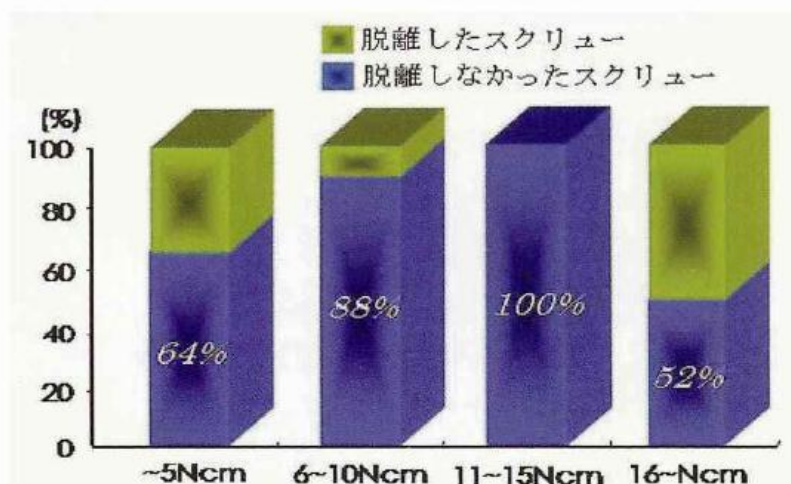


Fig. 6. Failure rate in rotational torque increase

From these results, we slightly modified previous method using implant mini screws and the following 3 implant mini screw techniques were adopted in our study.

① Prevent generating rotational torque more than 5Ncm.

According to clinical study, it is thought that the rotational torque in implant mini screw should not stay below 5Ncm because when rotational torque is so small in implant mini screw, the frequency of screw failure increases. Thus, when implanting mini screws at buccal aspect on dental area in maxilla, if it is case which is difficult to apply the rotational torque higher than 5Ncm, the consideration of movement of the region applied for implant mini screw toward palate in good condition for the ossein is worthwhile.

Also, drilling process performed before implanting mini screws was ceased because it was very difficult to predict patient's ossein or bone quantity. The

reason for this is because if pre-drilling is performed on fragile cortical bone, it causes no increment of the rotational torque to appropriate range and the lack of the support in cortical bone surrounding the screw(the force generated when the screw is inserted by pressing and widening the cortical bone = the force the cortical bone supports TAD), therefore accompanying the risk was avoided.

② **Prevent generating the rotational torque more than 15Ncm.**

When self-drilling method is employed for the implant mini screw, the increment of the rotational torque should be controlled(measured) during the process to complete implanting of mini screws in the condition which does not exceed the rotational torque more than 15Ncm.

Duel-Top Anchor Screw is composed of a cutting blade on the tip, half of cylinder type body on the screw, half of taper type on backside and the taper type portion should be recognized by the cortical bone region contacted(Fig. 7). Consequently, when the cutting blade on the tip is inserted into a bone in the process of implanting of a mini screw, firstly the rotational torque increases rapidly and when the rest of portion of screw is inserted to bone, the increase of rotational torque is re-occurred. If the structural characteristics is understood, it can be easily inferred when half of screw body is implanted into the bone, more than 10~12Ncm rotational torque occurrence is expected and eventually the rotational torque exceeding 15Ncm is generated in the later implanting of mini screws.

In this case, the screw was carefully pulled off by reverse rotation, and the rotational torque was decreased by drilling implanting region of mini screws with Drilling-Bar.

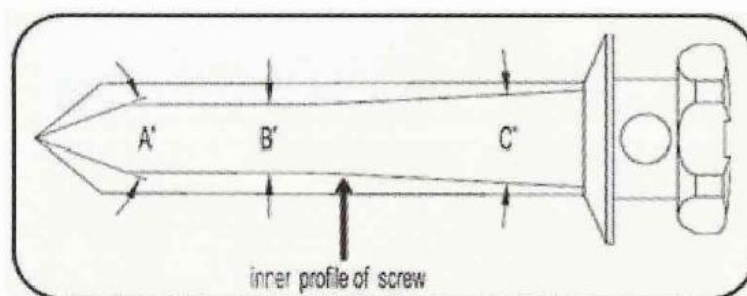


Fig. 7. Structure of Duel-Top Anchor Screw

③ Regarding the time of load

Since it is believed that the early safety of the screw is not associated with the stability period based on the animal test results and the screw implanted in optimal rotational torque on the implanting region of mini screws was admitted in its high safety, it was immediately pulled.

Development of a new type torque driver

There was no way other than measuring by an industrial torque driver after eliminating the dedicated driver to measure the rotational torque during implanting of mini screws. However, this method has drawbacks since it causes swaying the screw easily in terms of clinical view point and the industrial driver cannot be possessed by pharmacists, which hampers wide prevalence. Owing to these, the new type torque driver which is possible to set up the rotational torque value in the implanting process of mini screws is developed with assistance by Jeil medical(Fig. 8)

The new type torque driver has the characteristics the hand driver runs idle when attained to the set torque value, and this brings the operator to prevent the generation of excessive torque value as setting up maximum rotational torque value(below maximum rotational torque) in the range of optimal rotational torque value appropriate for patients or implanting region of mini screws prior to performing implanting process. Furthermore, this new type torque driver does not require changing of driver to measure the rotational torque during the implanting process of mini screws, so the operator can manipulate this easily. This new type torque driver has been approved for pharmacists in Japan.



Fig. 8. New type torque driver

The implanting method of mini screws using Duel-Top Anchor Screw is proposed to perform implanting of mini screws without big damage to cortical bone of implanting region by introducing the driver with limited function. The steps are as follows.

- ① Sterilize implanting region of a mini screw
- ② Perform Surface Anesthesia and local infiltration
- ③ Set up the aimed value of rotational torque for the torque driver
- ④ Install Driver Shaft on the torque driver
- ⑤ Screw Pick-up
- ⑥ Initiate the implanting of mini screws using Self-Drilling method
- ⑦-1

If the driver does not make idle running when the screw of about 1/2~2/3 is inserted into the bone, continue implanting of mini screws in optimal torque range.

⑦-2

If the torque driver runs idle, it is the case bigger rotational torque than torque in optimal range. In this case, take out screw and have drilling using a Drilling Bar, then redo implanting of mini screws on the same region.

- ⑧ If the head of the screw is implanted to the region closer to gingival mucosa, implant up to the end as exchanging with a cross shaft.

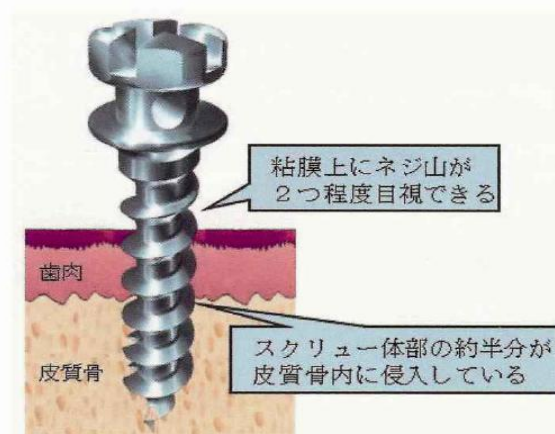


Fig.9. Feature of an implanted mini screw when the rotational torque is identified

Results obtained from the implanting of mini screws using the new type torque driver

Experimental methods

Experiment place: Department of Orthodontics in hospital in Hiroshima University

Experiment period: January, 2008~ August, 2008

Implanting Region with mini screws : Maxilla in between 2nd premolar and 1st molar

Screw: Diameter 1.6mm, Length 6.0mm (n(numbers)=52)

Implanting method with mini screws: Follow the method described above

Time for pull: Immediate pull after implanting of mini screws(Fig. 10)

Set value for the maximum rotational torque: 12Ncm (Fig. 11)

Experiment: Failure rate and the rate of Drilling performed



Fig.10. Oral picture after implanting mini screws. Initiating the pull right after implanting mini screws for giving the load to the screw



Fig.11. Maximum magnified picture.
Set a maximum rotational torque value

using a dedicated wrench.

Result Summary

It was shown that the ones the rotational torque value was less than 5Ncm were 2 each, the ones the rotational torque value between 5~10Ncm were 12 each, and the ones the rotational torque value between 10~15Ncm were 38 each among the 52 screws, conclusively more than half of screws employed for implanting mini screws had 10~15Ncm rotational torque values(Fig. 12). Also, when Drilling was performed to the patients having the rotational torque exceeding 10Ncm, the rotational torque values obtained from all the implanted mini screws were under 15Ncm. 2 screws implanted with mini screws with less than 5Ncm was removed 1 month later and re-implanted on the palate site. Among 12 screws implanted with 5~10Ncm rotational torque, 10 of them were implanted by Self Drilling method, and 2 rest of them was re-implanted after drilling. In addition, 26 of them among 38 screws implanted with 10~15Ncm were implanted by Self-Drilling method, 12 rest of them was re-implanted after drilling in the middle of implanting process. In other words, the percentage drilling was performed was 20% in the screws implanted with 5~10Ncm rotational torque, the percentage of the screws undergone for drilling was 46.1% in the ones implanted with 10~15Ncm rotational torque and the drilling rate was higher in the patients shown for bigger rotational torque in the implanting process of mini screws. As the result, whereas the rate of success in screws implanted by common methods after 3 months of the implanting of mini screws is closer to 96.2%, the rate of success in the screws implanted with 5~10Ncm rotational torque attains to 100%.

Rotational Torque Details

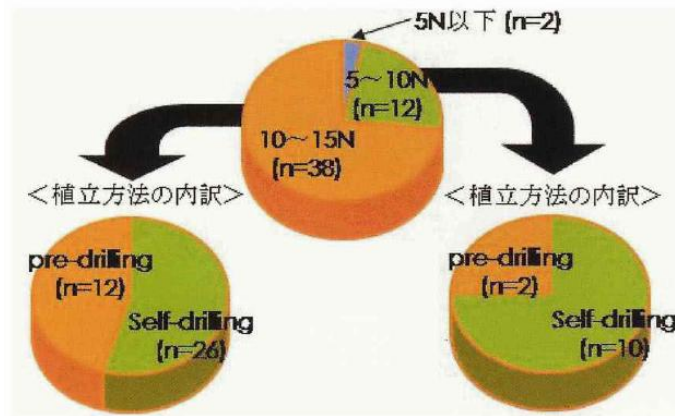


Fig.12. Experiment Result Depending on the Rotational Torque

Summary

Based on the results obtained from animal tests as well as clinical studies by now, it is concluded that the Duel-Top anchor Screw designed for self drilling Type with Titanium Alloy highly provides early safety as controlling the rotational torque occurring in the implanting process of mini screws in an optimal condition(5~15Ncm at buccal aspect on dental area in maxilla) on the implanting region. Moreover, Self Drilling Type Screw is recognized as an exceptionally effective mean for preventing failure in the way of the rotational torque control by drilling.

The utilization of the new type torque driver makes possible to avoid damaging cortical bone caused in implanting of the mini screws as well as to prevent screw fracture, consequently higher safety can be achieved. Besides, it is believed to be a useful tool to prevent the possibility of the rotational torque increase due to the speed and pressure in implanting of mini screws (the force pressing bone surface with screws) by operators in implanting of mini screws.

Acknowledgment

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