Development of a surgical procedure for biointegration of a newly designed orthodontic onplant

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Aim: An onplant is an orthodontic anchorage device fixed to the bone surface with osseointegration. Compared with implants, the onplant has fewer limitations regarding placement and is less invasive. The purpose of this study was to clarify the effect of bone-surface treatment and the fixing method of a newly designed smaller-sized onplant and establish a prospective surgical procedure for placement of the onplant. Methods: Thirty-eight onplants were placed in six beagle dogs. The bone surface was planed where the cortical bone was thick and reducible (bone-planed). Where the cortical bone was thin and uneven, a filling was inserted in the space between the onplant and bone (filled). The onplant was fixed to the bone in one of two ways: using a membrane that covered the onplant and fixing the membrane with titanium pins (membrane-fixed) or fixing the onplant directly to the bone using the same titanium pins (pin-fixed). Results: Twelve weeks later, all the onplants were osseointegrated. The bone-planed group showed significantly (P < .05) larger shear stress than the filled groups. In the bone-planed group, the pin-fixed group showed significantly (P < .05) larger shear stress than the membrane-fixed group. The shear stresses were considered strong enough to function in orthodontic treatment. Conclusion: The effect of the bone-surface treatment and the onplant-fixing method on the shear stress was clarified, and the findings in the present study may be useful for the improvement of surgical procedures for orthodontic onplants. ORTHODONTICS (CHIC) 2012;13:216–225.

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Many rigid intraoral devices for orthodontic anchorage have been developed.¹⁻¹⁴ Mini-implants have become increasingly common in clinical orthodontics,¹¹,¹² and osseointegrated dental implants¹⁻¹⁰ and miniplates¹³,¹⁴ have also been used in orthodontic treatment. When placed in bone, osseointegrated dental implants require an appropriate insertion site and a highly invasive surgical procedure for insertion and removal. On the
other hand, miniplates and mini-implants are fixed to the alveolar or jaw bone with screws. They can be placed and used more quickly than osseointegrated implants but still have spatial limitations.

Developed by Block and Hoffman, onplants are titanium disks 8 or 10 mm in diameter coated with hydroxyapatite fixed to the bone surface by biointegration. The onplant is reported to have a similar bonding strength to bone as a dental implant, with fewer limitations regarding placement. It is less invasive and can be clinically applied. However, the effects of surgical procedures of the onplant on the bonding strength between onplants and bone have yet to be clarified.

The purpose of this study was to investigate the effect of bone surface treatment and fixing method on the bonding strength and to establish a prospective surgical procedure for placement of onplants with an improved fit to the bone surface.

METHODS

Onplant design
The onplant used in this study was a disk made of pure titanium, 7.0 mm in diameter and 1.8 mm thick. The surface facing the bone had three pits, 0.8 mm in diameter and 1.0 mm deep. It was plasma-spray coated with highly crystallized recrystallized hydroxyapatite (coating thickness, 38.5 μm; Advance). The hydroxyapatite coating was about 50% thinner than that of the onplant used by Block and Hoffman. The newly designed onplant used in this study is referred to as modified onplant (Fig 1).

Animals and their management
Six healthy male beagle dogs, 1.5 to 2.5 years old, weighing 10 to 14 kg, were used in this study. Before surgery, their teeth and oral cavities were thoroughly cleaned. They were fed normal dry food before the surgery and soft meals after the surgery.

All the surgical procedures were performed under systemic anesthesia with intravenous injection of pentobarbiturate (nembutal, Dainippon Pharmaceutical) (25 mg/kg), following muscular injection of atropine sulfate (Tanabe Seiyaku) (0.01 mg/kg). During the operation, 1.0 g of cefazolin sodium (cephalosporin antibiotic, Cefamezin, Fujisawa Pharmaceutical) and 80 mg of methylprednisolone sodium succinate (adrenocortical hormones, Solu-Medrol, Pharmacia & Upjohn)
were given intravenously. After the surgery, 0.5 g of cefazolin sodium and 40 mg of methylprednisolone sodium succinate were given intravenously twice a day, for 5 days. At the same time, the mouths of the dogs were rinsed with povidone-iodine (Isodine Gargle, Meiji Seika). All dogs were in good health.

This study followed the guidelines for animal experiments of Tokyo Medical and Dental University and was approved by the Committee of Ethics of Animal Experiments of the institution.

Flap elevation
The surgical site was anesthetized locally with 1/80,000 epinephrine added 2% lidocaine hydrochloride (Xylocaine Cartridge for Dental Use, Fujisawa Pharmaceutical) after sterilization. Mucoperiosteal flaps were raised to expose the bone surface. In the pin-fixed group (described later), a 15- to 20-mm incision was made peripheral to the onplant insertion site. A minimized mucoperiosteal flap was then elevated in the shape of a tunnel.

Treatment of bone surface
To stabilize the onplant, the bone surface was flattened. On the buccal side of the mandible where the cortical bone was thick and reducible, the bone surface was planed with an exclusive bur (bone-planed group [Fig 2a]). On the buccal and palatal sides of the maxilla where the cortical bone was thin and uneven, one of two kinds of fillings was inserted in the space between the onplant and bone. The fillings were hydroxyapatite granules (Boneject, Koken) (hydroxyapatite-filled group) or atelocollagen sponge (Teruplug, Terumo) (atelocollagen sponge–filled group [Fig 2b]).

Fixation of onplant
The screw holes on the modified onplant were filled with thermoplastic resin to prevent infiltration of soft tissue before fixation. The onplant was fixed.
to the bone in one of two ways. In one method, the onplant was covered with a nonresorbable membrane (Gore-Tex Regenerative Material, Japan Gore-Tex), and the periphery of the membrane was fixed by three or four titanium pins (0.5 mm in diameter and 1.5 mm long, FRIOS Membrane Tacks, Friadent) (membrane-fixed group). In the other method, the onplant was fixed directly to the bone with three or four titanium pins (pin-fixed group) (Fig 3). The number of onplants in each experimental group is shown in Table 1.

Radiographic and bonding strength evaluation
After insertion and fixation of the onplant, the mucoperiosteal flap was sutured, and a radiograph was taken parallel to the bone surface. Twelve weeks later, the dogs were euthanized by an overdose of intravenously injected nembutal (50 to 70 mg/kg). The onplant, bone, and surrounding tissue were removed en bloc and radiographs were taken as described before.
The bone where the onplant was inserted was removed with a reciprocating saw (Command 2 microsystem, Stryker), and the mucosa was exposed to macroscopically evaluate the situation around the onplant.

The shear stress test was chosen for evaluation of the bonding strength of the onplant to bone, considering the direction of orthodontic force applied to the onplant. The pins and membrane were removed, and the testing screw (Fig 1b) was inserted. Shear stress was measured using a handy load measure (Digital Push-Pull Gauge model 9550B, Aikoh Engineering). The onplant was pulled slowly away from the screw in a direction parallel to the bone surface. From the measurement of the force (N and kgf) and the area of the onplant (m²), shear stress per unit area (MPa = N/m²) was calculated.

Histologic analysis
Some of the membrane-fixed onplants with bone and surrounding soft tissue were immersed en bloc in 10% neutrally buffered formalin, fixed for 48 hours at 4°C, embedded in resin (HistoDur, Leica) following the conventional method, and made into nondecalcified polished specimens 40 μm thick. Followed by staining with toluidine blue, the specimens were observed histologically.

Statistical analysis
The values of shear stress are represented as the mean ± standard error of the mean (SEM). Comparisons between the groups were performed with the Kruskal-Wallis test using Statview 5.0 (SAS Institute). The level of significance was set at .05.

RESULTS

Macroscopic observation
Twelve weeks later, no infection was present around the onplants. Neither mobility nor spontaneous separation of the onplant was observed. Macroscopic observation around the onplant after exfoliation of soft tissue showed that fibrous tissue covered the onplant directly under the membrane (membrane-fixed group). Some of the pin-fixed onplants were partially covered with bone-like structure. No radiographic penetration was observed between the onplant and the bone (Fig 4).
Shear stress
In the mandible, the mean shear stress 12 weeks after insertion of the onplants of the bone-planed and pin-fixed group (5.3 MPa, 23.0 kgf) was significantly higher than that of the bone-planed and membrane-fixed group (3.5 MPa, 15.1 kgf) (Fig 5).

In the maxilla, there was no significant difference between the shear stress of the atelocollagen sponge–filled and pin-fixed groups (1.5 MPa, 5.9 kgf) and that of the hydroxyapatite-filled and membrane-fixed group (1.4 MPa, 5.6 kgf). Onplants in the mandible showed significantly higher resistance to the shear stress than those in the maxilla.

Histologic findings
In the bone-planed and membrane-fixed groups, new bone and osteoid were formed right under the onplant. There was a microscopic bond between the newly formed bone and recrystallized hydroxyapatite that coated the titanium, and neither inflammation nor bone resorption was observed (Fig 6a).

In the hydroxyapatite-filled group, bone was newly formed in the matrix of hydroxyapatite granules. However, newly formed bone did not reach the onplant surface in places where there was more than 1 mm of space between onplant and bone (Fig 6b).

*P < .05, **P < .01.

“Onplants in the mandible showed significantly higher resistance to the shear stress than those in the maxilla.”
DISCUSSION

Our modified onplant with plasma-sprayed coating of recrystallized hydroxyapatite exhibited so-called biointegration,\textsuperscript{31,32} which is a chemical bond between bone and hydroxyapatite. Because titanium is bioinert, it shows adaptive osseointegration, which is a contact between the implant surface and bone with no intervention of soft tissue at the light microscopic level.\textsuperscript{33} Hydroxyapatite would be favorable for quick bonding, because hydroxyapatite assimilates with bone faster than titanium.\textsuperscript{34–40} Compared with the conventional apatite coating layer,\textsuperscript{28–30} we succeeded in making a markedly pure hydroxyapatite layer with the plasma-spray coating method using recrystallized hydroxyapatite. With this method, we managed to overcome a weakness of hydroxyapatite coating, degradation and exfoliation of the coating layer.

A preliminary study in our laboratory showed weak shear bond strength when the onplant was placed on an uneven bone surface without any treatment. To achieve stable osseointegration, it was necessary to eliminate the stress concentration and minute agitation of onplants.\textsuperscript{41–44} Either a planed bone surface or fillings on an uneven bone surface enabled close contact of bone and the onplant, resulting in mechanical stabilization.

When the initial fixation of an implant is inadequate, minute agitation occurs in the implant, which triggers the phenomenon of foreign substance exclusion of a living body, and fibrous tissue is formed between the implant and bone. This means failure of osseointegration, and in some cases, bone resorption occurs.\textsuperscript{41–44} Sufficient blood supply is required for bone formation.\textsuperscript{45,46} The good results seen in the bone-planed group were also due to the fact that bone planing caused abundant blood supply, which activated the wound recovery process required for bone formation. Furthermore, compared with the hydroxyapatite- and atelocollagen sponge-filled groups, the planed bone surface had closer contact with the recrystallized hydroxyapatite–coated surface of the onplant. This reduced the amount of bone formation required for osseointegration and was therefore advantageous for the bone-planed group.

\*Fig 6* Histologic findings in nondecalcified polished specimens stained with toluidine blue. (a) In the bone-planed and membrane-fixed groups, new bone and osteoid (NB) were formed right under the onplant and membrane (M). There was microscopic adhesion between the newly formed bone and the recrystallized hydroxyapatite coating under onplant (O). Neither inflammation nor bone resorption was observed. (b) In the hydroxyapatite-filled group, bone was newly formed (NB) in the matrix of hydroxyapatite granules (HA) and right under the onplant (O). Bar, 1 mm.
Among the two fixing methods, the pin-fixed group showed higher shear bond strength than the membrane-fixed group, despite the fact that the guided tissue regeneration method was applied in the membrane-fixed group to achieve more new bone formation. Direct fixation of onplants by pins required less elevation of the periosteal flap and less agitation compared with the indirect fixation of onplants by membrane, which would result in more certain and stronger fixation.

It has been reported that the shear bond strength of bone surface and biomaterials such as titanium or hydroxyapatite is between 0.1 and 4.0 MPa. The bond strengths of onplant to bone surface in the present study showed similar values, and osseointegration was therefore considered to be achieved. The bond strengths of onplant to bone in the pin-fixed groups were 23.0 kgf in the mandible and 5.9 kgf in the maxilla. Since the magnitude of orthodontic force is considered to be less than a few hundred grams, these results indicate that the modified onplant could be applied as orthodontic anchorage. In the case of the maxilla, because of the irregularity of the bone surface, it would take longer for the bone formation to fill the gap between the onplant and alveolar bone. Thus, it might be necessary to delay the time to start functioning in the maxilla to increase the amount of newly formed bone. Using bone-inducing material such as bone morphogenetic protein or preparing the bone-contact surface of the onplant to conform to the shape of the bone surface could reduce the waiting period.

Three surgeries are necessary for the placement of an onplant: insertion of the onplant, removing pins and fixing the suprastructure, and removing the onplant. This is the same number of surgical procedures as implants with the two-stage method, which requires surgeries for insertion, fixing the suprastructure, and removal. Compared with those developed by Block and Hoffman, our modified onplant was designed to be 30% smaller in diameter and 10% thinner, with almost the same shear strength as the originally designed onplant. One of the reasons might be the coating of hydroxyapatite on the titanium onplant, which was improved with higher crystallized hydroxyapatite. Moreover, the results of this study suggest that the bone surface treatment and fixing method were appropriate. The improved onplant may be useful as an orthodontic fixation device in the future.

Because the onplant does not need as much bone thickness as an implant, it can be placed where an implant is difficult to apply. Prospectively, it may be possible to apply the onplant in orthodontics as a fixation apparatus, as well as in clinical medicine—for example, as support for prostheses in craniofacial reconstruction.

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