Early Healing Events Following Placement of a Palatal Subperiosteal Orthodontic Anchor: A Pilot Study

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Purpose: *The aim of this report was to describe the initial 8-month healing events of 8 consecutive cases of placement of an onplant device for orthodontic anchorage and to report the results of a questionnaire evaluating subjective patient experience.* ***Methods:*** *At 2 weeks and at 4 and 8 months after placement of the device, presence or absence of exposure of the device, mobility using gentle finger palpation, and signs of possible inflammation were evaluated. At 8 months, the inflammatory status of the tissue-abutment interface was determined from presence or absence of bleeding and/or suppuration on probing. Patients' experience of pain, discomfort, and acceptance of the treatment were evaluated by the use of visual analog scales.* ***Results:*** *In 7 of the 8 patients, the device became stable and could be used for orthodontic anchorage. In 1 case, infection occurred, and the device was removed. At the 8-month time point, none of the 7 successful devices showed any plaque or any bleeding or suppuration on stimulation with a periodontal probe. Most patients reported little pain/discomfort from the various treatment procedures and indicated that they felt that opting for the onplant treatment had been the right choice.* ***Conclusion:*** *The results of this pilot study suggest that placement of the onplant can lead to uneventful healing and stability of the device. Further studies with larger numbers of subjects are necessary to substantiate these findings and to determine the usefulness of this device for orthodontic anchorage.* Int J Oral Maxillofac Implants 2006;21:623–628

Key words: *absolute anchorage, onplants, orthodontic anchorage*

In patients having protruded and/or crowded teeth in the anterior maxilla and requiring premolar extraction prior to the start of orthodontic treatment, some type of anchorage is necessary to the posterior teeth in place while the anterior teeth are retracted into the extraction positions.

To obtain this anchorage, different types of extra- and intraoral devices have been tried. The extraoral devices have a number of disadvantages: the inconvenience of wearing them, the risk of injury to the patient, and the high degree of dependence on patient compliance.[1–9] Traditional intraoral devices sometimes fail to deliver an adequate amount of retention, and their use often leads to a tipping movement of the anterior teeth.[9–12]

To avoid these problems, short implants have been placed in the median ridge area of the palate and used for orthodontic anchorage. It has been shown histologically that osseointegration of these implants takes place and that they are clinically stable and withstand the orthodontic forces applied.[13–19] One potential disadvantage of the placement of these implants is the surgical risk of perforating the nasal floor. Also, there must be a sufficient amount of bone for placement.

A method has been developed to accomplish orthodontic anchorage using a hydroxyapatite-coated disk known as an onplant that is placed subperiosteally in the midpalatal area. It has been shown in dogs and monkeys that onplants can become

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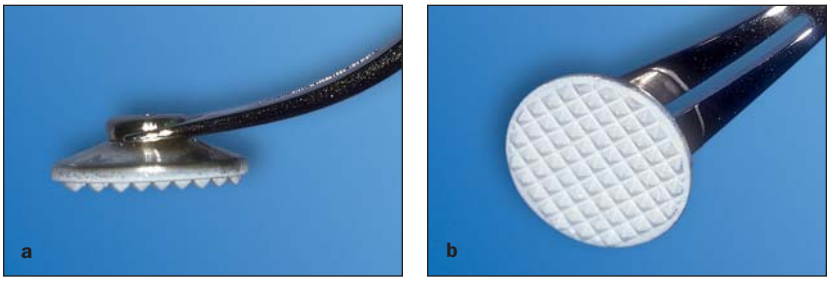


Fig 1 OnPlant device with inserter. *(a)* Lateral view; *(b)* hydroxyapatite-coated surface.

osseointegrated and provide sufficient stability to withstand orthodontic forces.[20] The feasibility of using an onplant as an orthodontic device in humans has also been demonstrated.[21,22] The use of this device should reduce the invasiveness of the surgical procedure and also the danger of perforating the palate.[23]

This report describes the healing events for the first 8 months postplacement of the first 8 consecutive cases of placement of onplants at the Advanced Periodontics Clinic at Loma Linda University School of Dentistry. In addition, it presents the results of a questionnaire evaluating subjective patient experience. The results of the orthodontic outcomes will be presented separately.

MATERIALS AND METHODS

Subjects

Subjects were selected from patients referred to the Graduate Orthodontics Clinic at Loma Linda University School of Dentistry. To be eligible to participate in the study, patients were required to:

- Be systemically healthy
- Be ≥15 years of age
- Demonstrate evidence of completed skeletal growth, as defined by absence of change in sella-nasion relation in cephalograms taken 6 months apart and/or radiographic confirmation of the closure of the metacarpal epiphyseal growth plate
- Present with absence of destructive periodontal disease and evidence of good oral hygiene performance
- Present with Angle class I or class II malocclusion
- Present with protrusion of maxillary dentition measuring at least 4 mm beyond the mandibular incisor position or maxillary crowding amounting to at least 4 mm
- Be in need of an orthodontic treatment plan requiring extraction of maxillary premolars

Pregnancy was considered an exclusion criterion. Patients that satisfied the criteria were asked about their willingness to participate in the study. Approval for the study was granted by the institutional review board at Loma Linda University. Signed consent to participate in this study was given by the patients or their assigned guardians.

The OnPlant Device

The onplant used was OnPlant (Nobel Biocare USA, Yorba Linda, CA), a disk with a textured bone-interfacing surface coated with a 75-μm-thick layer of hydroxyapatite. It is available in a round or oval shape (diameters or lengths, respectively, of 7.7 mm or 9.8 mm). The device has an internal threaded hole in its center into which a cover screw can be placed during the healing phase. The cover screw can subsequently be replaced by an orthodontic abutment. The peripheral edges are rounded to reduce the risk of development of soft tissue dehiscence around them (Figs 1a and 1b). Further details about the OnPlant can be obtained from the manufacturers' technique manual.[24]

Treatment

All of the surgical procedures placing the onplant were carried out at the Advanced Periodontics Clinic of Loma Linda University School of Dentistry. The surgeries for the 8 patients took place over a total time period of 13 months. The procedures were performed using specially designed instruments provided by the manufacturer.

After the patient's medical history had been reviewed, local anesthesia was delivered to the planned recipient site in the palate. The desired placement site on the median palatal ridge was predetermined by the treating orthodontist using a diagnostic cast. To transfer this location to the patient, a vacuum-formed palatal template with a circular hole in the position of the desired location was used. The template was fitted on the patient, and the palatal mucosa underneath the circular hole was stained with a tissue marker (Fig 2a).

A semilunar incision about 15 to 20 mm in width was made perpendicular to the median ridge, posterior to the incisal foramen and around 10 to 15 mm anterior to the position marked for the onplant. A

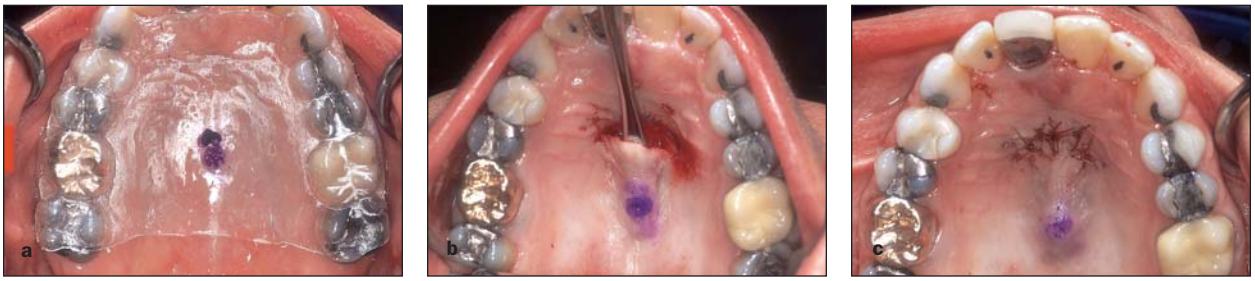


Fig 2 Onplant placement. *(a)* Surgical template in place; *(b)* creation of the subperiosteal tunnel; *(c)* the device in place.

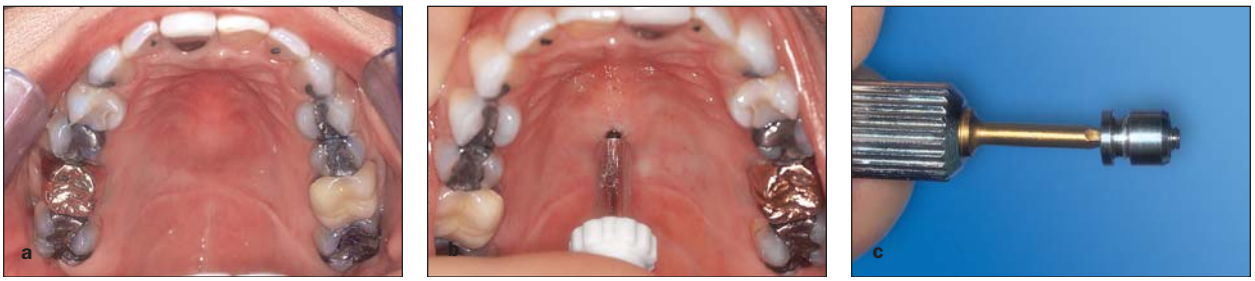


Fig 3 Uncovering surgery. *(a)* The location of the onplant (easily detected by the bulkiness of the tissue); *(b)* the tissue punch in place; *(c)* anchor abutment with screwdriver (note the circular groove for placement of a palatal bar above the lower portion of the abutment).

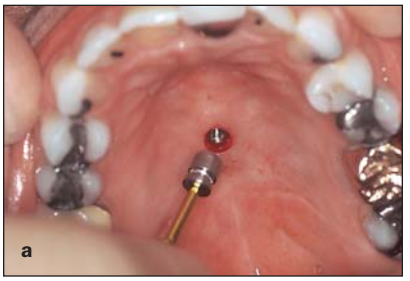
subperiosteal tunnel was created from this incision to the area of the onplant recipient position by blunt dissection of a full-thickness flap using a curved periosteal elevator (Fig 2b). Care was taken to limit the width of the tunnel to ensure sufficient initial stability of the device after placement. A flat osseous bed was created for the placement of the device through the use of a bone file with a curved shaft, allowing close adaptation of the onplant. The onplant was removed from its sterile container and carried with an inserter to the recipient site with its cover screw in place (Fig 1b). Retracting the inserter from the device, manual verification that the onplant did not "rock" was obtained. In addition, the stability was checked by finger palpation on the mucosa overlying the onplant.

The incision was closed with 4-0 chromic gut resorbable sutures (Fig 2c). The surgical site was placed under slight pressure for 5 minutes using sterile gauze.

An individually fitted acrylic resin cover with a raised area over the onplant was placed in the palate to provide protection for the device. The cover was relined using a soft lining material prior to positioning. Patients were advised to wear the cover continuously until uncovering 4 months following placement and to remove it only to perform oral hygiene procedures. Patients were placed on amoxicillin 500 mg 3 times daily for 10 days and 0.1% chlorhexidine rinse 10 mL twice daily for 3 weeks as a supplement to their mechanical oral hygiene procedures. Postoperative checks were performed after 1 and 2 weeks.

At the 4-month interval, the cover screw was exposed (Fig 3). First, a 1- to 2-mm-wide incision was made through the soft tissue over the central part of the device to find the location of the central hole of the cover screw. A tissue punch, guided by this central hole, was then used to remove the tissue overlying the cover screw (Fig 3b). Any remaining tissue over the cover screw was removed using a number 15 surgical blade. Subsequently, the cover screw was replaced by an anchor abutment (Fig 3c). The height of the anchor abutment used was determined by measuring the soft tissue height with a periodontal probe. An abutment was then selected that would then protrude 1 to 1.5 mm above the level of the surrounding tissue (Figs 4a and 4b). At the completion of this visit, the patients received instruction on how to clean the abutment with a toothbrush.

After 2 to 3 weeks of healing, the patients were seen at the orthodontic clinic. At this time, the anchor abutment was removed and replaced by an orthodontic abutment. A transpalatal bar was placed, connecting the orthodontic abutment of the onplant to orthodontic bands placed on the first molars. The bar was positioned to allow for 1 to 1.5 mm of clearance from the palatal soft tissue (Fig 5).



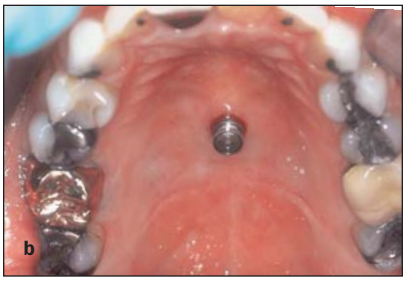


Fig 4 *(a)* Placement of the anchor abutment during uncovering surgery; *(b)* the anchor abutment in final position.

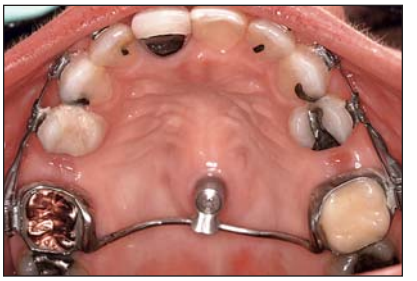


Fig 5 Orthodontic abutment, transpalatal bar, and orthodontic appliance in place 3 months after start of orthodontic treatment.

Measurements

The healing response following placement of the onplant device was monitored at 2 weeks and at 4 and 8 months postoperatively. Exposure of the device, mobility using gentle finger palpation, and signs of possible infection were evaluated. At 8 months, the inflammatory status of the tissue-abutment interface was determined by recording the presence or absence of bleeding and/or suppuration on probing. Presence or absence of bacterial plaque around the onplant was also recorded at the 8-month follow-up.

The degree of pain and discomfort experienced by the patients from the various procedures was evaluated using a questionnaire. A 100-mm visual analog scale where 0 indicated "no pain" and 100 indicated "intolerable pain," and one where 0 indicated "no discomfort" and 100 indicated "extreme discomfort," were used for 6 questions. A final seventh question evaluated the patients' opinion about the choice of the onplant method using endpoints 0 (definitely right) and 100 (definitely wrong).

RESULTS

Healing Events

Patient characteristics and healing events are presented in Table 1. In 7 of 8 cases healing was uneventful. Surgery to uncover the cover screw was performed after 4 months as scheduled for 7 of the 8 patients.

Patient 2 called after 3 months complaining about pain in the area of the onplant. A small fistula could be found above the center of the onplant. Exudate was evident on finger palpation. The area was drained by surgical exposure, and amoxicillin 500 mg 3 times daily was prescribed for 10 days together with 0.1% chlorhexidine rinses twice daily. On the day of second-stage surgery, the onplant was stable, and the cover screw could be uncovered. Two weeks later the patient called again, complaining about suppuration from the onplant area. This was confirmed by inspection, which also disclosed that the onplant was mobile. After consulting the treating orthodontist, it was decided to remove the onplant and to use a different appliance for orthodontic anchorage.

In patient 3, the device appeared stable when palpated before the start of the uncovering surgery, but was found to be mobile during the attempts to locate the central hole of the cover screw. The incision was closed with a 4-0 chromic gut suture, and uncovering was postponed for another 4 weeks. At this point the onplant was stable and was successfully uncovered. No further complications appeared during the remaining observation period.

At the 8-month time point, none of the 7 successful devices showed any plaque or any bleeding or suppuration on stimulation with a periodontal probe.

Questionnaire

A questionnaire used to evaluate the degree of pain, discomfort, and acceptance together with the results are presented in Table 2.

With the following exceptions, only mild pain or discomfort was reported by the subjects from the various procedures: 2 patients rated pain during the first surgery as 36 and 49, respectively.

The same 2 patients and an additional patient reported moderate to severe postoperative pain following the first surgery (scores of 45, 56, and 79). Connecting the device to the orthodontic bands was experienced as uncomfortable by 1 patient only (VAS 66 mm). This patient was 1 of those who reported pain during the first surgery and postoperatively.

When asked whether onplant treatment had been the right choice, 7 patients' VAS scores indicated that they felt it was. One patient gave a VAS score of 51.

Table 1 Healing Events for the First 8 Months for 8 Consecutive Cases Treated with an Onplant Orthodontic Anchoring Device

			0 to 8 months			8 months		
Patient	Age	Sex	Exposure	Fistulation	Mobility	Plaque	Bleeding	Suppuration
1	22	M	—	—	—	—	—	—
2	25	F	—	3 mo	4.5 mo*	NA	NA	NA
3	21	F	—	—	4 mo†	—	—	—
4	48	F	—	—	—	—	—	—
5	35	F	—	—	—	—	—	—
6	58	F	—	—	—	—	—	—
7	18	M	—	—	—	—	—	—
8	14	F	—	—	—	—	—	—

In cases where an event occurred, the time point at which the event occurred is shown.
NA = not applicable.
*Onplant was removed at this point of time.
†Second surgery exposing the device was postponed for 4 weeks; the OnPlant regained stability. Thus, the 8-month follow-up actually took place at 9 months.

Table 2 Questionnaire Used to Evaluate the Degree of Pain, Discomfort, and Acceptance Associated with the Treatment

	Response		
Question	Average	Median	Range
1. How painful was the first surgery when the device was placed in your palate? (No pain to intolerable pain)	18.4	13	3 to 49
2. Did you experience any pain after the first surgery? (No pain to intolerable pain)	30.6	12	5 to 79
3. Was it uncomfortable to wear the stent? (No discomfort to extremely uncomfortable)	12.6	6	2 to 34
4. How painful was the second surgery to expose the device? (No pain to intolerable pain)	10.9	9	4 to 25
5. Did you experience any pain after the second surgery? (No pain to intolerable pain)	9.9	9	3 to 22
6. Was the device uncomfortable after the orthodontist connected it to the teeth? (No discomfort to extremely uncomfortable)	15.4	6	1 to 66
7. Given the knowledge about the other treatment options that were offered to you, do you think opting for the OnPlant treatment was the right choice? (Definitely right to definitely wrong)	11.7	6	1 to 51

Results from 100-mm VAS scales are shown.

DISCUSSION

The manufacturer's surgical manual suggests placement of the initial incision 3 to 5 mm away from the gingival margin in the right or left premolar region.[24] Access to the site of onplant placement from this incision location seemed difficult because of the curvature of the palate, especially in patients with deep palates. Therefore, the surgical procedure was modified by placing the initial incision perpendicular to the median ridge in the incisor area, posterior to the incisal foramen. This approach allowed for easier access to the site of onplant placement, while still leaving enough tissue above the device to establish initial stability.

In 7 of 8 patients, the onplant device became stable and could be used for orthodontic anchorage as planned. In 1 case the device appeared to be stable when palpated before the start of the surgery to uncover it, but was later found to be mobile. Interestingly, after only 4 additional weeks, the device was stable and could be used as an orthodontic anchor. A possible explanation for this lack of stability would be that the cover was not relined correctly after the first surgery and thus placed undue pressure on the device during the initial 4-month healing period. A more likely explanation would be that while trying to locate the central hole of the cover screw, undue force exerted in an unfavorable plane with the guiding tip of the tissue punch made the device detach

from the bone. This explanation would clarify why stability was achieved after only 4 additional weeks; if this was the case, only repair of the already-formed tissue under the onplant was needed.

In the case in which the onplant finally had to be removed, fistulization was observed 4 weeks before the uncovering surgery. No apparent reason could be found for occurrence after 3 months of uneventful healing. After surgical drainage and amoxicillin for 10 days, the suppuration disappeared but emerged again 6 weeks later, 2 weeks after the uncovering, without apparent cause.

Most patients reported only minor pain or discomfort from the various procedures. The higher pain and/or discomfort reported by some patients could be the result of differences in individual pain thresholds or individual differences in events during the various procedures. Furthermore, the questionnaire indicated that almost all of the patients were satisfied with their treatment.

In conclusion, this pilot study suggests that placement of the onplant can lead to uneventful healing and stability of the device. Further studies with larger numbers of subjects are necessary to substantiate these findings and to determine the usefulness of this device for orthodontic anchorage.

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