

Long-Term Prospective Study of an Orthodontic Bone Anchor

Maurice Y. Mommaerts, MD, DMD, PhD¹/Valerie Nols, MSc²/Guy De Pauw, DDS, PhD³

Purpose: (1) To determine whether immediate loading of orthodontic bone anchors (OBAs) generates more failures than delayed loading and (2) to evaluate the impact of different variables on the success rate of the use of OBAs as temporary anchorage devices in orthodontic treatment. **Materials and Methods:** In a prospective registry, consecutive patients were treated with OBAs by one experienced maxillofacial surgeon. An independent evaluator compared and analyzed different prospectively determined parameters: gender, age (young [< 16 years] versus mature [≥ 16 years]), time of loading (delayed versus immediate), jaw, location, fixation screw length, complications, and orthodontic indications. Success with the OBA was defined as the capacity to maintain anchorage throughout treatment. Premature removal of an OBA because of infection, serious mobility, or persistent pain was considered a failure. Fisher exact tests for analysis of associations between the categorical variables, with the patient as independent variable, were performed. Success and complications were evaluated using multivariate logistic regression. **Results:** Sixty-one patients (37 male, 24 female) were treated with 106 OBAs over a 5-year period (2001 to 2006). The reported success rate in this study was 88.3%. In seven patients (11.7%) an OBA was removed prematurely. Age, gender, time of loading, jaw, and location did not influence the failure rate. In 25% of patients, at least one screw failure was noted. A statistically higher screw failure rate was noted in female patients, and the younger group presented more complications than the mature group. **Conclusion:** According to the results of this study, OBAs are a reliable means to obtain absolute orthodontic anchorage. Immediate loading of an OBA did not generate more failures than delayed loading. Age, jaw, and position did not seem to play important roles in success. Age and gender were important parameters in fixation screw failure rate. *INT J ORAL MAXILLOFAC IMPLANTS* 2014;29:419–426. doi: 10.11607/jomi.2378

Key words: delayed loading, immediate loading, longitudinal study, orthodontic anchorage procedures, orthodontic bone anchor, prospective study

Anchorage is an important factor in obtaining stable treatment results in orthodontics. Therefore, skeletal anchorage is a field that has seen strong development in orthodontics over the last 15 years, although it has been studied for more than 60 years.^{1–3} Since the introduction of implants for orthodontic anchorage, different types of implant devices and ap-

plication mechanics have been explored.¹ Orthodontic bone anchors (OBAs) are derived from the small titanium osteosynthesis plates used in craniomaxillofacial surgery for fracture repair or segment fixation in orthognathic surgery, which were first introduced by Michelet et al in 1973.⁴ By 1985, Jenner and Fitzpatrick were using these “miniplates” for orthodontic anchorage.⁵ Interest in this plate-type implant concept arose after a number of innovations in design, mainly with the addition of common orthodontic tools.^{6,7} OBAs can be placed anywhere on the buccal bony surface, provided the cortex has a minimum thickness to hold the screws; areas such as the symphysis, the posterior body and ramus of the mandible, the zygomaticomaxillary buttress, and the piriform buttress are usually sufficient.⁸

To date, no long-term prospective studies with a large patient sample have evaluated a series of different variables in relation to the success of OBAs.^{9–11} Therefore, this long-term prospective registry exam-

¹Professor and Head, European Face Centre, Universitair Ziekenhuis Brussel, Brussels, Belgium.

²Resident, Orthodontic Department, University Hospital Ghent, Belgium.

³Professor and Head, Orthodontic Department University Ghent, University Hospital Ghent, Ghent, Belgium.

Correspondence to: Guy De Pauw, Orthodontic Department University Ghent, University Hospital Ghent De Pintelaan 185 P8, B-9000 Ghent, Belgium. Fax: +32-9-3323851. Email: guy.depauw@ugent.be

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Fig 1 OBA with hook. The baseplate is 0.5 mm thick and has been sandblasted and acid-etched.



Fig 2 OBA with tube as orthodontic force application tool.



Fig 3 OBA with bracket as orthodontic force application tool.

ined a large sample to determine whether immediate loading of an OBA results in more failures than delayed loading. Another aim was to evaluate the effect of different variables on the success rate of OBAs in orthodontic treatment.

MATERIALS AND METHODS

Sixty-one consecutive patients (24 male and 37 female) with ages ranging from 11.3 to 46.3 years (mean age 20 years, standard deviation 11.3 years) requiring skeletal anchorage for orthodontic purposes were included in this prospective registry. In this study, 106 OBAs of one brand (Surgi-Tec NV) were placed by a single experienced maxillofacial surgeon (MYM) over a time span of 5 years (2001 to 2006). An independent evaluator (VN) compared and analyzed the different parameters, which were determined prior to the start of the observation period (prospective case series study).

The titanium OBA consists of a sandblasted and acid-etched baseplate (0.6 mm thick) that is rectangular or triangular and stabilized with self-tapping monocortical screws (diameter 2.3 mm and length 5, 7, or 10 mm). The machine-polished flat connection bar, which is wider than it is thick, projects through the mucosa into the oral cavity. The connection bar is short in variants used in the retromolar area and longer in the tree stem-shaped variants that allow tooth migration along the OBA. Its coronal portion has a hook to facilitate tools for orthodontic force application such as nickel-titanium coil springs or rubber elastics. Some varieties also include a bracketlike slot or a tube (Figs 1 to 3).

Placement of the anchor was carried out under local infiltration anesthesia. A hockey stick-type incision was made with the horizontal leg preferably in

the attached gingiva, and a mucoperiosteal flap was elevated. The anchor plate length was selected according to the distance between the implant site and the dentition. Then, the selected OBA was contoured to fit the bony surface and the connection bar curved into a bayonet shape to reduce the circumference of the portion piercing the gingiva and facilitate cleaning of the posterior portion of the connection bar. Pilot holes were drilled, and the self-tapping monocortical fixation screws were inserted to firmly attach the baseplate to the bony surface. The choice of a specific length of screws was based on a clinical estimate by the operator before placement. The emergence of the connection bar should be located at the mucogingival junction or within the attached gingiva. The wound was closed and sutured with absorbable material (Vicryl Rapide 4-0, Ethicon). Brushing instructions for the transmucosal part of the OBA were given to the patient, along with an antiseptic gel (Corsodyl Gel 1%, GSK Consumer Healthcare) to prevent and control infections. A cold pack was provided for postoperative comfort. Except for mild facial swelling, postoperative discomfort was usually minimal.

The sample was divided into two groups: the immediate loading (IL) group (33 patients with 52 OBAs) and the delayed loading (DL) group (28 patients with 54 OBAs). The choice of loading time depended on the presence or absence of fixed appliances. The OBA was immediately loaded with a nickel-titanium coil spring or a rubber elastic (1 N) if the patient already had fixed appliances. In the DL group, a latency period of 2 months was allowed to elapse before any orthodontic force was applied (Fig 4).

Different parameters were examined: demographic details (age, gender); location of OBA (mandible, maxilla, anterior, posterior); time of force application (IL and DL); dates of placement and removal of the OBA;

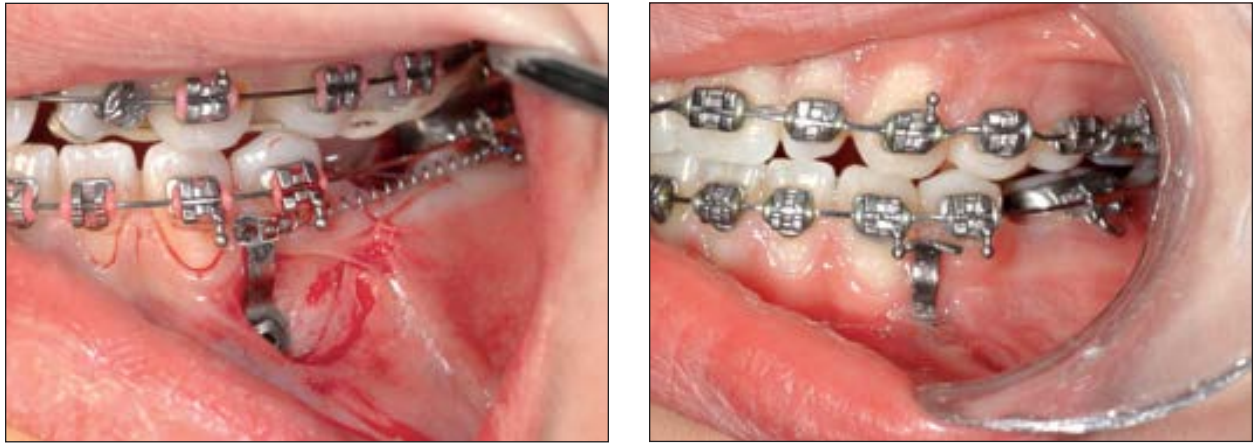


Fig 4 Intraoral view of immediate loading after an initial phase of tooth alignment before and after closure of the diastema.

orthodontic indication for placement of an OBA (closing and opening diastemas, proclination or retroclination of the dental arch, intrusion, uprighting of molars); screw length (5, 7, or 10 mm); type of connection bar (short, medium, long); type of force application tool (hook, tube, or bracket); reason for removal of the OBA (end of treatment, persistent severe inflammation, severe mobility of the bone anchor); and orthodontic result (Tables 1 to 3). Furthermore, at the time of removal of the bone anchor, a clinical examination was carried out with emphasis on mobility of the plate and/or fixation screws, bony overgrowth on the plate and/or fixation screws, infection of surrounding tissues or bone, and any changes in the surrounding tissues such as gingival recession.

In case of missing data in the registry, including the orthodontic result, the file of the patient in question was consulted and the treating orthodontist was contacted. All data of these prospectively determined parameters were tabulated.

Success of the OBAs in the patient sample was defined as sustained function of anchorage throughout the course of orthodontic treatment without persistent infection or severe mobility of the OBA. An OBA was classified as a failure when a persistent infection did not subside after local cleaning and antibiotic treatment or when the OBA was unable to resist the orthodontic force because of significant mobility, which resulted in the premature removal of the anchorage device. Fixation screw failure, observed at the time of removal as one of the complications, was defined as a loose screw of the miniplate.

For the statistical analyses, the patients were subdivided into two groups for better understanding of the failures. A young age group (< 16 years) including 39 patients and a mature age group (\geq 16 years) including 22 patients were defined according to growth potential.

Statistical analysis was performed using SPSS version 18 (SPSS Inc). The Fisher exact test was used to analyze associations between categorical variables. Success of the anchorage system and success of the fixation screws were analyzed using binary logistic regression. The significance level was set at $\alpha = .05$.

RESULTS

In 61 consecutive patients, 106 OBAs were placed. Only 7 OBAs in seven different patients were removed prematurely, representing a success rate of 88.3% in the patient sample. Taking into account the number of successful OBAs, 98 of the 106 OBAs (93.3%) showed good stability. Data on success were unavailable for one OBA. The apparent reasons for removal were persistent infection without mobility in three cases and persistent infection in combination with severe mobility of the anchorage device in two cases. There was no sign of infection in the remaining two cases; increased mobility of the OBA was the only symptom.

The failure rate of the OBAs was statistically significantly higher in the mandible ($P = .024$), although most failures were hypothetically expected to occur in the maxilla. The time of loading (immediate or delayed) did not influence the failure rate.

Logistic regression analyses showed no correlation between success and different patient-related parameters. However, the young female group exhibited more failures: six of the seven failed OBAs were placed in six young female patients (< 16 years).

The clinical observations at the time of removal of the bone anchor revealed mild to moderate infection of the surrounding tissues in four OBAs, of which only three had to be removed early. A combination of infection and plate mobility was detected in six OBAs,

Table 1 Demographic and OBA Details

	No.	%
Patients		
Total	61	
Mean age (y) (range)	20.0 (11.3–46.3)	
Female/male	37/24	60.7/39.3
Young age group (< 16 y)	39	65.1
Mature age group (≥ 16 y)	22	34.9
Delayed/immediate loading	28/33	45.9/54.1
No. of OBA/patient		
1	23	37.7
2	32	52.5
3	3	4.9
4	3	4.9
Other OBA data		
Total	106	
Location (mand/max)	66/40	62.3/37.7
Position (ant/post)	82/24	77.4/22.6
Immediate loading	52	49.1
Delayed loading	54	50.9
Connection bar (short/medium/long)	19/81/6	18/76/6
Fixation screw length (mm)		
5-5-5	30	28.3
7-7-7	14	13.2
7-7-5	35	33.0
5-5-7	15	14.2
Two fixation screws	4	3.8
Other combinations	3	2.8
Missing data	5	4.7
Force application tool (hook/bracket/tube)	57/26/23	53.8/24.5/21.7

of which only two failed. Mobility of the anchor without infection was observed in four cases, of which two had to be removed prematurely (Table 2). Gingival recession uncovering one or two fixation screws was a rare clinical complication seen in five cases (4.8%). A remarkable phenomenon at the time of removal was bone overgrowth in 10 cases (9.5%), which covered the bone plate and/or fixation screws in the apical region; it was always seen in the mandible and only in the young age group. In 76 OBAs (72.4%), none of the previously stated clinical observations were detected.

With respect to failure of the fixation screws, in 25% (n = 15) of the patients, one or more screw failures were noted. A statistically significantly higher screw failure rate was noted in female patients ($P = .044$), and the young age group presented more complications ($P = .016$) than the mature age group. Five loose screws were detected in the maxilla and 19 in the mandible. Screw failure was found more often in the mandible of

Table 2 Success and Failure of OBAs and Fixation Screws*

	No.	%
Success/failure	53/7	88.3/11.7
Screw success/failure	45/15	75/25
Reasons for removal of OBA		
End of orthodontic application	98	92.5
Infection	3	2.8
Mobility	2	1.9
Mobility + infection	2	1.9
Unknown	1	0.9
Orthodontic result after OBA treatment		
Satisfactory	96	90.6
Compromise	8	7.5
Unknown	2	1.9

*Data missing for one patient.

the younger patients. Loosening of all fixation screws occurred in 28.6% of all screw failures, leading to the loss of four OBAs. The coronal fixation screw showed more failures (43%) than the middle screw (21.4%) or the apical screw (not significant).

Logistic regression analyses showed a clear correlation between failure rate of the fixation screws and the patient-related parameters age and gender. The young female patients showed the most failures of the fixation screws.

None of the other variables, such as complications, time of loading, screw length, jaw, or anteroposterior position, presented any statistical correlation. No statistical correlations were found between orthodontic indication and complications or between orthodontic indication and success. The main orthodontic indication in this study was closing diastemas (64.2%), followed by proclination, retroclination, and intrusion (Table 3).

In 96 (90.6%) of 106 OBAs, the predetermined orthodontic tooth movement was achieved and a satisfactory orthodontic result was reported. In eight cases, a compromise for the final orthodontic result had to be considered (7.5%), of which four were a result of premature removal of the OBA. The orthodontic result remained unknown in two cases.

DISCUSSION

Control of anchorage is fundamental for successful orthodontic treatment of malocclusions. The ideal absolute anchorage is total resistance to unwanted reciprocal tooth movements and is independent of patient compliance.¹² Temporary anchorage devices

Table 3 Orthodontic Indications for 106 OBAs in Relation to the Orthodontic Force Application Tools

Orthodontic indication	Total		Hook		Bracket		Tube	
	No.	%	No.	%	No.	%	No.	%
Closing diastemas	68	64.2	48	70.6	13	19.1	7	10.3
Opening diastemas	5	5.7	–	–	2	40	3	60
Proclination of the dental arch	9	8.5	5	55.6	–	–	4	44.4
Retroclination of the dental arch	10	9.4	2	20	4	40	4	40
Intrusion (bite opening)	10	6.6	2	28.6	3	42.8	2	28.6
Uprighting of molars	4	3.8	–	–	4	100	–	–
Complex	2	1.9	–	–	–	–	2	100

(TADs) such as OBAs allow orthodontic movements that were previously thought to be difficult or even impossible.^{13–15} A variety of problems encountered by the orthodontist on a regular basis, such as missing permanent teeth, loss or absence of anchor teeth, and noncompliance with extraoral traction, are now more efficiently treated with skeletal anchorage as an adjunct to traditional mechanics, leading to a reduction in unwanted side effects.⁹ In this study, the orthodontists reported a 90.6% rate of perfectly satisfactory orthodontic results using OBAs in a series of 61 consecutively treated patients. There were no data available on orthodontic results for two patients. In only eight patients did a compromise for the predetermined orthodontic goal have to be considered. Premature removal of the OBA because of infection of the soft tissues or mobility of the OBA, noncompliance with orthodontic treatment, poor oral hygiene, or the orthodontist's inexperience regarding this treatment modality have been mentioned as possible reasons for failing to achieve a satisfactory orthodontic treatment result. Contraindications for TADs include problems in healing, a compromised immune system, bleeding disorders, or inadequate oral hygiene.^{16,17}

A recent systematic review of Schätzle et al stated an average success rate of 92.7% based on seven clinical studies with a total of 586 plate-type anchorage devices and 406 patients.¹⁸ Cornelis et al described, in their prospective study of a large patient sample with 200 OBAs, a success rate of 92.5%.¹¹ Currently, the literature provides few long-term prospective studies with a large patient sample evaluating a series of different variables in relation to the success of OBAs.^{9–11} A direct comparison of the failure rates of different studies is difficult because of the differences in study design, screw and/or plate design, and insertion technique.

The 2-year outcome audit of Mommaerts et al in 2005,⁹ a prospective clinical registry, reported a failure rate of 8.6% for 23 OBAs, but this was too small a sample to provide full evidence-based conclusions. In

attempts to decrease the number of failures, several changes in the hardware were introduced.⁹ The base-plate was roughened by etching and sandblasting, since motion seems to appear beneath smooth plates under relatively low physiologic loads.^{19,20} Reductions of the height of the pentagon-shaped screw heads to prevent piercing of the soft tissues and bending of the neck of the connection bar into a bayonet shape were also introduced to reduce the circumference of the portion piercing the gingiva and to facilitate cleaning of the posterior part of the connection bar. That prospective registry reported on 53 patients, some with multiple OBAs, with no problems. Of the 106 placed OBAs in the present study, 98 were successful. Seven OBAs in seven patients were removed prematurely. The reasons for premature removal of the TAD were persistent infection without mobility in three cases, persistent infection in combination with severe mobility of the anchorage device in three cases, and increased mobility of the OBA prior to orthodontic loading, without infection, in two cases. According to Veziroglu et al, the stability of plate-type anchorage devices depends on the stresses and strains imposed on the plate by the screw heads.²¹ If the bone under the plate or around the screws resorbs over time because of improper plate adaptation or inhibition of blood flow in the cortical bone through excessive compression of the rib surface of the plate, too much force may be exerted on the bone around the screws. This may cause loosening of the screw(s), in addition to cortical bone resorption induced by excessive pressure and/or the rotation of the other screw(s), both of which impair the stability of the plate.^{21,22} Thus, to ensure good primary stability of the TAD, overtightening of the fixation screws should be avoided, and excellent passive adaptation of the plate to the anatomical bony structure is necessary to avoid excessive force on the bone.²³ Chen et al stated that it is probably more likely that the miniscrew-bone interface, rather than the miniplates themselves, would undergo critical failure.²⁴

An important question in the use of skeletal anchorage is when to begin loading. In the present study, the time of loading—immediate or delayed—did not influence the success rate of the OBAs. The literature reports mostly relatively short healing periods ranging from 6 weeks to immediate loading.^{25–28} De Clerck et al indicated a healing period of 2 to 4 weeks before orthodontic loading to allow the soft tissues to heal.²⁹ Chen et al concluded from their study that the duration of healing is a significant factor in the success of a TAD.³⁰ Avoidance of loading until after 3 weeks of healing, when primary stability of the TAD is being established, cannot be overemphasized, although osseointegration is not required. However, these results are in contrast with the outcomes of other studies. The timing of loading was not related to the success rate according to Kuroda et al.³¹ Moreover, Miyawaki et al claimed that the number of days from implant placement to force application was not associated with stability and that immediate loading of a screw-type implant anchor is possible if the applied force is less than 2 N.³² Miniscrews do not osseointegrate; their anchorage stability results from mechanical interlocking, which eliminates the need for a waiting period before force application and permits easy removal.^{25,33–35} On the other hand, because miniscrews are not osseointegrated, their anchorage potential is most likely influenced by the quality and quantity of bone into which they are placed.³⁶

In the present study, the young age group exhibited significantly more failures of the fixation screws ($P = .016$). Six of the seven failed OBAs were placed in young patients (< 16 years). In addition, screw failures occurred more often in the mandible of the younger patients. Loosening of all fixation screws occurred in 28.6% of all screw failures, leading to the loss of four OBAs. Although most studies reported that age was not a significant variable,^{10,31,32} Cornelis et al mentioned a higher failure rate because of mobility in growing patients than in adults.¹¹ Although their surgeons were always instructed to place the attachment arm to penetrate the tissue at the mucogingival junction, this might be more difficult in younger patients, when alveolar height tends to be shallow, width of the attached gingiva is less, and access is restricted. Another study confirmed the current findings suggesting that TADs placed in young patients were at a significantly greater risk of failure as a result of the lower bone density and thinner cortical bone.¹⁶ When analyzing the literature, the question that applies to all types of skeletal anchorage is the point of insertion with adequate bone potential, a factor of particular relevance in the cortical area.^{37–39} The best approach to ensure biomechanical strength is actual contact with mature lamellar bone.^{38,40} In young patients, maturity has not yet

been reached, which might explain the higher failure rate in this group.

In this study, a higher failure rate, although not significant, of coronal fixation screws (43%) in comparison to the middle (21.4%) or the apical screws was noticed. Veziroglu et al explained that stress can directly affect the screws, especially the screw that is closest to the force application unit, and may impair screw stability.²¹

None of the other variables, such as complications, screw length, type of force application tool, jaw, or anteroposterior position, presented any statistical correlation. The diameter of the fixation screws in this study was 2.3 mm. The literature confirms that an increase in the failure rate by approximately twofold was identified for miniscrews with a diameter of 1.2 mm compared with miniscrews with a diameter of 2 mm or more.^{18,32} No statistical correlations were found between orthodontic indication and complications or between orthodontic indication and success. The main orthodontic indication in this study was closing diastemas (64.2%), followed by proclination, retroclination, and intrusion.

The clinical observations at time of removal of the bone anchor revealed mild to moderate infection of the surrounding tissues in four OBAs, of which only three had to be removed before the end of orthodontic treatment. A combination of infection and plate mobility was detected in six OBAs, of which only two failed. Mobility of the anchor without infection was observed in four OBAs, of which two had to be removed prematurely. Several studies reported that, although the soft tissues surrounding the miniplates at the transmucosal area showed slight inflammatory changes, most miniplates used for orthodontic anchorage remained stable throughout their use.^{41,42} In addition, some miniplates showed increased mobility without infection but remained stationary throughout orthodontic loading, which was also observed by Choi et al.⁴³ The most frequently cited cause of loss was infection.^{27,32,44} Sugawara and Nishimura reported that infection occurred in about 10% of patients.⁴⁴ Positioning of anchorage elements outside the dental arch fairly often leads to discomfort and more difficult care.⁴¹ Mild infection can be controlled with antiseptic mouthwash and careful brushing techniques. In general, the literature insists on the extreme importance of oral hygiene in higher success rates with TADs. Sato et al⁴⁵ suggested that the environment in crevices around titanium orthodontic anchor plates is anaerobic and supports anaerobic growth of bacteria, which may trigger inflammation in the tissues around the plates. Therefore, orthodontic treatment with titanium anchor plates requires strict self-care and regular professional plaque control to prevent infection.⁴⁵

Gingival recession uncovering one or two fixation screws was a rare clinical complication seen in five patients. This recession probably derived from soft tissue irritation resulting from emergence of the connection arm through nonkeratinized gingiva and/or poor oral hygiene. A remarkable phenomenon at the time of removal was bone overgrowth in 10 patients (9.5%) covering the bone plate and/or fixation screws in the apical region; this was seen only in the mandible and only in the young age group (Fig 5). This might have complicated removal of the TAD, but for the most part the bone was easily chipped off. Cornelis et al also mentioned this phenomenon.⁴² In their study, bone covering 25% or more of the plate was reported for more than 1 in 10 patients, but it did not seem to be correlated with the location of the miniplate or with the age of the patient. In the current study there seemed to be a correlation with the location and the age of the patient, although this was not significant. The reason why this phenomenon occurs unequally in patients is unknown. A possible reason for the bone overgrowth in the young age group is a high level of bone remodeling because of the patients' high growth potential. In 72.4% of the OBAs, none of the previously stated clinical observations were detected.

CONCLUSION

According to the results of this study, the use of orthodontic bone anchors is a reliable treatment modality to obtain absolute orthodontic anchorage. Immediate loading of an orthodontic bone anchor did not generate more failures than delayed loading. Age and gender seemed to play roles in the failure of the fixation screws.

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Fig 5 Bone overgrowth is clearly visible on the fixation plate of the OBA. In this case, removal of the miniplate was difficult, which explains the breakage of the plate through torsional force and the imprints of a removal instrument on the OBA.

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