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Rationale and design for efficacy and safety evaluation of Bone-Anchored Maxillary Protraction (BAMP) for patients with unilateral cleft lip and palate with skeletal anterior crossbite: a single-arm, open-label, non-randomised prospective study protocol

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ABSTRACT

Introduction Bone-anchored maxillary protraction (BAMP) was devised recently as a method of direct maxillary protraction using anchor plates implanted in the maxilla and mandible without involving the teeth. Although several reports have described orthognathic effects of BAMP on patients with cleft lip and palate (CLP) with skeletal crossbite, none has described a study of Japanese patients with CLP or of BAMP treatment effects on speech in patients with CLP. This study, by performing BAMP treatment, and by evaluating speech function and skeletal and soft tissues, is intended to clarify BAMP efficacy and safety for patients with unilateral CLP (UCLP) who have skeletal crossbite.

Methods and analysis This single-arm, open-label, non-randomised prospective study examines 20 patients with UCLP with skeletal crossbite (Wits appraisal ≤−5.0 mm). These 10–15 year-old participants had already undergone cheiloplasty, palatoplasty and bone grafting. The anchor plates are implanted in the zygomatic process in the maxilla and in the anterior part of the mandible. Two weeks after anchor plate implantation, maxillary protraction is started using elastics. Protraction is performed at 150 g per side at the start of protraction, 200 g per side from 1 month after the start of protraction and 250 g per side from 3 months after the start of protraction. The treatment period will be approximately 1½ years. Pretreatment and post-treatment, cephalometric analysis, speech evaluation, nasopharyngeal closure function evaluation and facial soft tissue evaluation will be performed to ascertain the effects of BAMP on patients with UCLP.

Ethics and dissemination Ethical approval for this study has been received from Tohoku Certificated Review Board of Tohoku University, Japan, CRB2200003. The approval number is 2021-34-2. The results of this research shall be presented at domestic and international academic conferences, and be published to peer-reviewed journals.

Trial registration number jRCTs022210007.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Assessment of nasopharyngeal closure and articulation can be used to evaluate bone-anchored maxillary protraction (BAMP)-induced functional changes in patients with unilateral cleft lip and palate.
⇒ Incorporation of three-dimensional imaging evaluation allows assessment of BAMP-induced changes in facial soft tissue.
⇒ A limitation of this study is that it is a single-arm study comparing pre-BAMP and post-BAMP treatment and not a randomised controlled trial.

INTRODUCTION

Background and rationale

Conventional orthodontic treatment for patients with cleft lip and palate with skeletal anterior crossbite

Cleft lip and palate (CLP), the most frequently occurring congenital anomaly, is a congenital disorder caused by various genetic and environmental factors. It causes clefts in the lip, alveolar ridge and palate. After birth, the cleft can be closed by cheiloplasty and palatoplasty, but postoperative scarring often results in growth restriction of the maxilla.[1] These outcomes can engender a relative anterior crossbite. Many medical facilities use a facemask with or without rapid expansion for maxillary protraction during the deciduous to mixed dentition to improve skeletal disharmony.[2 3] Although this treatment improves the anterior crossbite,[4] protraction of the maxilla through the teeth causes tooth movement. Moreover, it does not allow for the full forward movement of the maxilla that should be expected. Downward movement of

the maxilla has the side effect of clockwise rotation of the mandible, which increases the height of the lower face.[5 6] For that reason, careful attention is warranted when applying the treatment to long face cases. In addition, the facemask is an extraoral orthodontic appliance. For adolescents who are beginning to be concerned about their facial appearance, it is a device that is likely to cause considerable social and psychological resistance. Therefore, conventional facemask therapy used between the mixed dentition and the end of adolescent growth is not always the best treatment for patients with skeletal crossbite. If the degree of skeletal malocclusion is severe, then surgical procedures such as Le Fort I osteotomy or anterior maxillary distraction osteogenesis[7] are useful to correct the skeletal disharmony after completion of adolescent growth. In recent years, the number of cases showing marked growth suppression of the maxilla has decreased because of surgical technique improvement. However, in Japan, one in four to five patients with unilateral CLP (UCLP) undergoes orthognathic surgery after growth is complete.[8] A more effective orthodontic treatment for use during adolescent growth must be developed.

Bone-anchored maxillary protraction

In recent years, methods have been devised using anchor plates for direct protraction of the maxilla without the teeth.[9 10] One method of protraction of the maxilla using elastics and anchor plates implanted in the maxilla and mandibular (figure 1) is designated as bone-anchored maxillary protraction (BAMP).[11] Actually, BAMP requires no extraoral orthodontic appliance such as a facemask. Therefore, it poses less psychosocial stress while garnering better patient cooperation. Because the maxilla is protracted directly through the anchor plates, skeletal disharmony can be improved with little dental movement.[12] Moreover, BAMP treatment has no effect on the alveolar bone graft status.[13] Although slight changes occur in the airway and temporomandibular joint,[14 15] no severe harmful effect has been reported. If future surgery can be avoided, then physical and economic burdens on patients can be reduced, which will engender improvement of their quality of life (QOL).

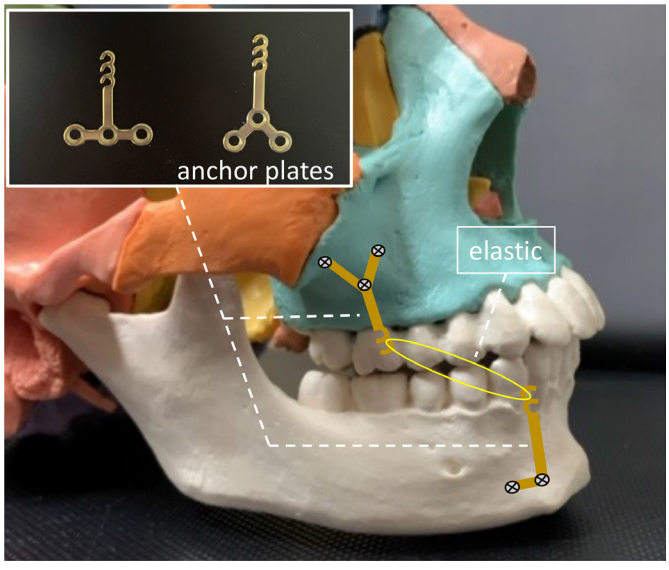

Figure 1 Schematic diagram of bone-anchored maxillary protraction and anchor plates: Y-shaped (right) and T-shaped (left) type. This figure was created by the author (ES) of this paper and was not taken or downloaded from any other literatures or internet sites. The author provides the permission for publishing it.

No clinical study of BAMP has been conducted in Japan. Moreover, most earlier studies have evaluated only the morphological effects of BAMP on the maxilla and mandibular.[11–13 15–21] Effects of BAMP on the nasopharyngeal closure function and articulation, which are mainly related to the QOL of the patients with CLP, remain unclear.

Objectives

For this study, patients with UCLP with skeletal crossbite because of maxillary undergrowth will be treated with BAMP. In addition, cephalometric analysis, evaluation of facial soft tissue, of nasopharyngeal closure function and of speech will be performed. The aim of this study is to compare the skeletal, soft tissue and functional changes which occur before and after BAMP treatment, and to clarify the efficacy and safety of BAMP for patients with UCLP.

METHODS AND ANALYSIS

Trial design

For this study, patients with UCLP with skeletal anterior crossbite because of maxillary undergrowth will be treated with BAMP. Treatment effects will be investigated by comparing the pretreatment and post-treatment skeletal changes.

Methods: participants, interventions and outcomes

Study setting

Patient recruitment and orthodontic treatment will be performed at the Department of Orthodontics and Speech Therapy for Craniofacial Anomalies, Tohoku University Hospital. Anchor plate implantation will be performed by surgeons at the Department of Oral and Maxillofacial Surgery, Tohoku University Hospital. The registration period is from March 2021 through August 2023. About 40 patients with CLP from various places in the Tohoku region come to the Department of Orthodontics and Speech Therapy for Craniofacial Anomalies, Tohoku University Hospital, as new patients every year. Therefore, we are in an environment where subjects of a sufficient number are accessible.

Eligibility criteria

Inclusion criteria

1. Patients with UCLP with skeletal anterior crossbite (Wits appraisal ≤−5.0 mm) being treated at the

Department of Orthodontics and Speech Therapy for Craniofacial Anomalies, Tohoku University Hospital.
2. Patients who have had cheiloplasty, palatoplasty and alveolar bone graft.
3. Male and female patients of 10–15 years of age who have had their carpal bones evaluated and determined as being just past the peak of adolescent growth.

Maxillary protraction is usually applied from primary dentition to the completion of permanent tooth eruption. Earlier studies using facemasks and anchor plates for maxillary protraction have demonstrated that even immediately after peak adolescent growth, Wits appraisal improved by 8.1–12.2 mm in skeletal Class III cases and by 11.9 mm in a skeletal Class III case with cleft palate.[10 22]

Exclusion criteria

1. Patient with bilateral CLP, cleft lip, cleft palate, cleft lip or alveolus.
2. Patients with congenital diseases that affect jaw and mouth morphology, except CLP.

Who will provide informed consent?

One dentist who performed the recruiting will obtain the patient's informed consent. Because the potential subjects are 10–15 years old, informed consent will be obtained from a parent of each subject. For children under 16 years of age, in addition to informed consent by a parent, informed assent should be obtained according to the subject's own comprehension. A version of the explanatory document for informed assent is created for elementary school upper grades. After the explanation, the willingness of the subject to participate in the research will be confirmed. If the subject agrees, the signatures of the dentist who gave the explanation and the subject, the date of explanation and the date of consent will be written in the informed assent document. The explanatory document for the informed assent and a copy of the informed assent document signed by the dentist and subject will be delivered to the subject or to the parent. The original documents of the informed consent and informed assent will be kept at Department of Orthodontics and Speech Therapy for Craniofacial Anomalies, Tohoku University Hospital.

Additional consent provisions for collection and use of participant data and biological specimens

Not applicable: No participant data require additional consent.

Interventions

Explanation for the choice of comparators

Not applicable: Because this is a single-arm study, no control group is used.

Intervention description

The anchor plates used for this study are the Y-shaped and T-shaped types of Ortho Anchor (J Morita, Japan) (figure 1). The Y-shaped type anchor plates are attached to the maxilla. The T-shaped type anchor plates are cut and attached to the mandible as an L-shape. The hook part of the Ortho Anchor is adjusted to be positioned on the first molar in the maxilla and between the lateral incisor and canine in the mandible. The Ortho Anchor should be placed in an area where there is at least 2.0 mm of cortical bone on the outside bone surface of the maxillary and mandibular bones, thereby avoiding the alveolar region. In the maxilla, the Ortho Anchors are placed in the zygomatic process. In the mandible, they are placed in the anterior part of the mandibular body. Two weeks after Ortho Anchor implantation, their fixation is confirmed. Maxillary protraction is started. Elastics (JM Ortho, Japan) will be placed on the hooks of the Ortho Anchors in the maxilla and mandible. The load setting is 150 g per side at the start of maxillary protraction, 200 g per side from 1 month after and 250 g per side from 3 months after, referring to a report by Cevidanes *et al*.[16] The elastics should be used 24 hours a day, except for eating and brushing. The treatment period should be approximately 1 year and 6 months.

Criteria for discontinuing or modifying allocated interventions

If the dentist in charge determines that continued treatment is difficult because of marked inflammation of the anchor plate implantation site, or if the patient does not cooperate sufficiently, the intervention should be discontinued.

Strategies to improve adherence to interventions

Before the intervention, patients with UCLP will be given a thorough treatment explanation and instructions. After the start of the treatment, they will be asked to fill in the elastics usage time chart every day to keep them motivated to continue the treatment.

Relevant concomitant care permitted or prohibited during the trial

Regular general dental care by a family dentist or orthodontic treatment other than BAMP is permitted.

Provision for post-trial care

After the study, the plates should be removed as soon as possible, the condition of the plate implantation site after removal should be observed. Appropriate treatment should be administered if infection or other difficulty occurs.

Outcomes

Primary outcome

The primary outcome will be the change in Wits appraisal (figure 2), one of the cephalometric parameters, between pretreatment (T0) and 1 year and 6 months post-treatment (T1) (figure 3). Wits appraisal is the distance between AO and BO, which are the intersection points of the vertical lines descending from point A and point B to the occlusal plane. It is used to evaluate the positional relation between the maxilla and mandible.[23] Wits appraisal ≤−5.0 mm is considered mandibular protrusion, −5.0 mm<Wits appraisal<0 mm is considered normal skeleton and Wits appraisal ≥0 mm is considered maxillary protrusion.

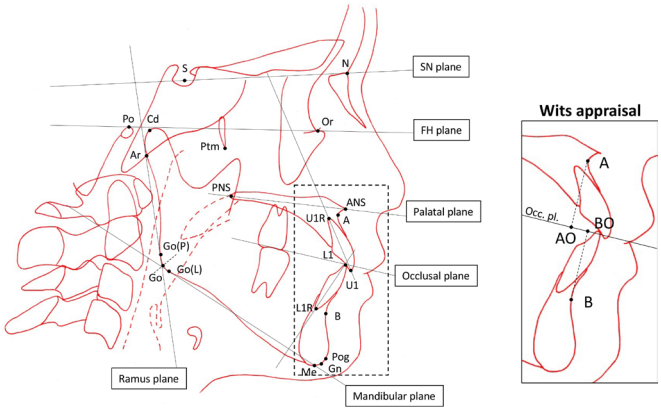

Figure 2 Cephalometric landmarks and planes. The SN plane consists of S and N. The FH plane consists of Or and Po. The palatal plane consists of ANS and PNS. The occlusal plane includes the midpoint of U1 and L1, and the centre point of the intercuspation of the upper and lower first molars. The mandibular plane consists of Me and Go(L). The ramus plane consists of Ar and Go(P). A, point A; Ar, articulare; ANS, anterior nasal spine; AO, point at the intersection of perpendicular line dropped from point A with occlusal plane; A', point at the intersection of perpendicular line dropped from point A with palatal plane; B, point B; BO, point at the intersection of perpendicular line dropped from point A with occlusal planes; B', point at the intersection of perpendicular line dropped from point B with palatal plane; Cd, condyle; Gn, gnathion; Go, gonion; Go(P), posterior gonion; Go(L), lower gonion; L1, lower 1; L1R, lower 1 root; Me, menton; N, nasion; Or, orbitale; PNS, posterior nasal spine; Po, porion; Pog, pogonion; Pog', point at the intersection of perpendicular line dropped from point Pog with mandibular plane; Ptm, pterygomaxillary fissure; S, sella; U1, upper 1; U1R, upper 1 root.

Secondary outcomes

Secondary outcomes will be used to assess the change between pretreatment (T0) and 1 year and 6 months post-treatment (T1) for the following assessments (figure 3).

1. Cephalometric analysis—The following analysis items other than Wits appraisal will be examined: SNA, anteroposterior position of the maxilla relative to the cranial base; SNB, anteroposterior position of the mandible relative to the cranial base; ANB, CdGn-CdA, anteroposterior relation of the maxilla and mandible; Mand. plane. to SN, inclination of the mandibular plane to the cranial base; U1 to SN, inclination of maxillary central incisor to the cranial base; occlusal plane to SN, inclination of the occlusal plane to the cranial base; L1 to mandibular plane, inclination of the mandibular central incisor to the mandibular plane; gonial angle, angle of mandible; FMIA, inclination of mandibular central incisor to the upper face; FMA, inclination of the mandibular plane to FH; Overjet, anteroposterior distance between the incisal edges of the maxillary and mandibular central incisors; Overbite, vertical distance between the incisal edges of the maxillary and mandibular central incisors; A'-Ptm', anteroposterior size of maxilla; Pog'-Go, length of the body of mandible; Cd-Go, length of ramus of mandible; Gn-Cd, overall length of mandible; FH-occlusal Plane, inclination of occlusal plane to FH.
2. Evaluation of facial soft tissue—The VECTRA Handy (Canfield Scientific, USA) is used to scan facial soft tissue and to construct three-dimensional images.
   The origin is found as the midpoint between the medial ocular angles. The XZ plane is that plane which passes through the origin, and parallel to the plane approximated by left and upper right edge of the auricles and distal ocular angles. The XY plane is the plane perpendicular to the XZ plane passing through the origin. The YZ plane is the plane perpendicular to the XY plane passing through the origin.[24] Measurement points are the tip of the nose, labialis superior (Cupid's bow vertex), left and right cheilion (left and right side of the mouth) and the amount of change in the XYZ axis pre and post BAMP will be compared.
3. Evaluation of nasopharyngeal closure function—The nasalance score (%), which is the ratio of the sound pressure from the nasal cavity to that from the oral cavity will be measured (Nasometer Model 6500; Pentax of America, USA). The pretreatment and post-treatment nasalance scores will be compared with BAMP to assess the effects of BAMP on the nasopharyngeal closure function.
4. Evaluation of speech—Speech evaluation will be made by a speech therapist. Any consistent dysarthria of even one sound, either monosyllable or speech (palatalised articulation, lateralised articulation, glottal rupture, pharyngeal friction, pharyngeal rupture, nasopharyngeal articulation, consonant distortion because of expiratory nasal leakage) is considered an articulation disorder. The presence or absence of pretreatment and post-treatment dysarthria will be examined in each subject with BAMP.

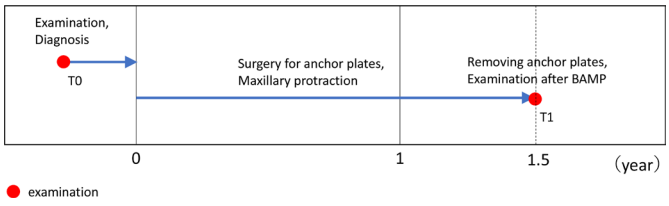

Figure 3 Schedule of BAMP examination. BAMP, bone-anchored maxillary protraction.

Participant timeline

See table 1.

Sample size

Because this study is a single-arm protocol, and because pre/post comparisons of the same persons in a group will be made, a corresponding t-test will be used. Faco *et al* treated 23 patients with UCLP with BAMP and improved their Wits appraisal from −7.53 mm to −5.04 mm.[20] Referring to a report describing that the mean value of the change in Wits appraisal of pretreatment and

Table 1 Schedule of research

	−8 weeks (T_0)	−4 weeks	−2 weeks	0 week	2 weeks	4 weeks	8 weeks	12 weeks	16 weeks	Every 8 weeks	72 weeks (T_1)
Background, clinical history	•										
Gaining consent, registration	•										
Examination	•										•
Diagnosis		•									
Implanting anchor plates			•								
Maxillary protraction				•	•	•	•	•	•	•	
Removing anchor plates											•

post-treatment was 2.49 mm with a SD of 3.22 mm, we infer significance at the 5% level and infer power of 80%. The necessary number of patients with UCLP was calculated as 16. In addition, the number of ineligible cases was estimated as 20%. The number of patients with UCLP is set as 20.

In the registry, the sample size is set to 70, which is the number of subjects including 50 in the control group. For this study, the sample size is set to 20 because the main purpose is comparison of pretreatment and post-treatment as a single arm.

Recruitment

When recruiting patients, recruitment will be done by a dentist other than the dentist in charge of the study to avoid putting pressure on patients or on family members to participate in the study. Patients will be fully informed that if they choose not to participate in this study, or that if they do participate but choose not to receive treatment with the anchor plates, their subsequent treatment will not be adversely affected.

Assessment of interventions: allocation

Sequence generation

No randomisation is performed.

Concealment mechanism

Not applicable: Because this study will not be randomised, there is no need for concealment.

Implementation

Not applicable: Because this study will not be randomised, no patient assignment will be made.

Assignment of interventions: blinding

Who will be blinded

Because the anchor plates are implanted in the maxilla and mandible of the patients in this study, neither the patients nor their dentists can be blinded. However, when performing cephalometric analysis, one dentist will give cephalometric radiographs of the patients to other dentists in charge of evaluation for tracing and analysis. Therefore, the dentists performing the cephalometric analysis are blinded: they do not know which patients are being analysed. A dentist who randomly distributes standardised cephalometric radiographs is not an evaluator.

Data collection and management

Plans for assessment and collection of outcomes

Because tracing and analysis of cephalometric radiographs are performed by multiple evaluators, some variation will exist among them. Therefore, the interclass correlation coefficient is used to guarantee consistency among the evaluators in advance.

Soft tissue evaluation is performed by multiple evaluators, so the interclass correlation coefficient ensures in advance that there is little variation in the evaluation. Evaluation of the nasopharyngeal closure function and dysarthria will be performed by a skilled speech therapist.

Plans to promote participant retention and complete follow-up

During the study, the orthodontist will monitor the treatment progress regularly, checking the condition of the tissues surrounding the anchor plates and the continued use of the device, so that the patients can continue to participate in the study. After the study, the patients will continue to be monitored; additional orthodontic treatment will be administered if necessary.

Data management

During the research period, information other than medical records on paper media should be stored in a lockable locker. Electronic media information should be stored on a computer that is not connected to a network. The files will be password-protected. The storage period will be 5 years after the completion of the research.

Confidentiality

All data will be fully anonymised. Data including the personal information of the patients to be collected in this study will have personal information removed when transcribed from the electronic medical record to the case report form. These data will be assigned a patient identification code for research purposes.

Statistical methods

Statistical methods for primary and secondary outcomes

Primary outcome

Cephalometric analysis will be used to assess changes occurring before and after BAMP treatment (evaluation criterion: Wits appraisal). The statistical method will apply a corresponding t-test. However, patients who do not consent to BAMP treatment but who agree to participate in the study itself will be defined as the control group and will be monitored for growth until the next orthodontic treatment. In this case, the control group will be matched with age, gender and Wits appraisal (−5.0 mm to −11.5 mm) at pretreatment examination, as reported by Faco *et al*. Then comparison will be made between the BAMP group and the control group.[20] When making comparisons between groups, no correspondence t-test will be applied.

Secondary outcomes

The following evaluation of changes before and after BAMP treatment will be performed: cephalometric analysis (evaluation criteria: SNA, SNB, ANB, CdGn-CdA, Mand. plane to SN, U1 to SN, Occlusal plane to SN, L1 to Mand. plane, Gonial angle, FMIA, FMA, Overjet, Overbite, A'-Ptm', Pog'-Go, Cd-Go, Gn-Cd), and evaluations of facial soft tissue, nasopharyngeal closure function and speech. The statistical method used will be a corresponding t-test. As with the primary outcome, comparison between the BAMP group and the control group will be made after matching with age, gender and Wits appraisal (−5.0 mm to −11.5 mm) at pretreatment examination, as reported by Faco *et al*.[20] When making comparisons between groups, no correspondence t-test will be used.

Analytical methods to handle protocol non-adherence and statistical methods to handle missing data

Per-protocol analysis will be conducted for the outcome measures in this study.

Plans to give access to the full protocol, participant level-data and statistical methods to handle missing data

The research outline and results of this study will be registered in the Japan Registry of Clinical Trials (jRCT) maintained by the Ministry of Health, Labour and Welfare, and will be made public in the jRCT by submitting an implementation plan to the Minister of Health, Labour and Welfare. If any change occurs in the content, then the jRCT will be revised. The changes will be notified to the Minister of Health, Labour and Welfare with the approval of Tohoku Certificated Review Board of Tohoku University. In addition, the information will be updated at least every year in accordance with the law. If the patient requests access, the research protocol and other related materials might be accessed to the extent that the rights of the patient and rights of the medical institution are unaffected.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee

The principal investigator of this study is KI, who designed the study. KI is primarily responsible for overseeing the study and managing BAMP-eligible patients. The project groups for this study are HK, ES, TT and KY. HK and ES will perform orthodontic treatment using BAMP and analyse data. TT and KY perform anchor plate surgery and management.

Composition of the data monitoring committee, its role and reporting structure

The principal investigator will request monitoring by a monitoring officer to confirm that the study is being conducted safely and in accordance with the research protocol. The monitoring officer will also confirm that data are being collected accurately.

Adverse event reporting and harms

For all adverse events, record the name of the event (diagnosis), date of onset, course of the event, severity, causality, predictability, outcome and date of determination of outcome.

An efficacy and safety evaluation committee, consisting of experts independent of the study, will be established for this study. The efficacy and safety evaluation committee will evaluate the study progress, safety data and key endpoints, and make recommendations or advise the principal investigator on the continuation, suspension or discontinuation of the study, or on changes to the study plan.

Plans for communicating important protocol amendments to relevant parties (eg, trial participants, ethical committees)

When changes are made to the plan for implementation, the changes must be approved by the Tohoku Certificated Review Board of Tohoku University. After approval, the notification will be submitted to the Minister of Health, Labour and Welfare after obtaining approval from the administrator of the implementing medical institution. If the changes are likely to have a marked effect on the benefit or safety of the patients, then a full explanation should be provided.

Ethics and dissemination

Tohoku Certificated Review Board of Tohoku University CRB2200003. Approval number is 2021-34-2. The results obtained from this study shall be presented at domestic and international conferences. Additionally, publication in international journals related to dentistry is planned.

Patient and public involvement

There is no patient or public involvement in this study.

DISCUSSION

Patients with CLP tend to have skeletal crossbite because of growth inhibition of the maxilla caused by scarring after palatoplasty performed in infancy.[1] To improve skeletal crossbite in patients with CLP, orthodontic treatment has mainly involved maxillary protraction through the teeth during the deciduous to mixed dentition period.[2 3] For cases in which this has been unsuccessful, or for those in which the patient has severe skeletal crossbite that cannot be corrected by conventional maxillary protraction, surgical procedures have been used to improve skeletal crossbite by moving the maxilla forward after completion of adolescent growth. However, the adolescent growth period is a sensitive period. The impossibility of improving facial appearance through orthodontic treatment during this period is a great shortcoming for patients with CLP with skeletal crossbite. If it can be demonstrated that BAMP is able to improve skeletal crossbite in patients with CLP before the end of adolescent growth in this study, this earlier timing might represent an important reduction in the psychological burden for patients with CLP. Furthermore, if surgery can be avoided after growth is complete, then the physical and financial burdens of undergoing surgery can be reduced. Although several reports have described clinical trials using BAMP in patients with skeletal crossbite including patients with CLP,[11–21] the only reported study investigating BAMP in Japan is an animal study conducted by Ito *et al*.[25] This study is therefore expected to be the first clinical efficacy study of BAMP for patients with CLP in Japan.

In patients with CLP, the acquisition and maintenance of normal articulation is an extremely important treatment goal, as is the improvement of skeletal crossbite. In fact, patients with CLP are more prone to nasopharyngeal insufficiency because of a shorter soft palate and less elevation than those of healthy subjects.[26] This difficulty cannot be ignored because it causes articulation disorders such as hypernasality. Maxillary protraction with BAMP using bone as a fixed source might enlarge the pharynx and affect the nasopharyngeal closure function to a greater or lesser extent. In a study for which anchor plates were implanted in the maxilla and maxillary protraction was conducted with a facemask on patients with CLP, extensive expansion of the pharyngeal region across the upper to middle pharynx was observed.[27] Nevertheless, no description is made of changes in articulation because of pharyngeal enlargement. No report in the relevant literature has yet described the effects of maxillary protraction by BAMP on articulation.

This report is the first describing evaluation of the effects of BAMP on nasopharyngeal closure and articulation in patients with CLP: a subject of great clinical importance. Considering the results to be obtained from this study, BAMP can be a useful treatment for patients with CLP with skeletal crossbite if it can be improved appropriately for adolescents.

Trial status

Protocol V.1.4 (1 January 2022). The study started in October 2021. It is currently recruiting.

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Contributors KI, the Chief Investigator, conceived the study. ES and HK contributed to the study design and to development of the proposal. ES, HK, and KI were responsible for data collection, orthodontic treatment and data analyses. KY and TT were responsible for setting anchor plates. KN was the lead trial methodologist. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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