Original Article

Twenty-year follow-up of functional treatment with a bionator appliance (part 2): a retrospective cephalometric analysis of skeletal and dentoskeletal changes

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ABSTRACT

Objectives: To investigate skeletal and dentoskeletal changes 20 years after bionator treatment.

Materials and Methods: Analog lateral cephalograms of 18 subjects treated with a bionator appliance during growth were digitized with a transmitted light scanner. Inclusion criteria were: increased overjet ($\geq$4 mm), skeletal Class II, available lateral cephalograms before (T0), after (T1), and 20 years after (T2) treatment with only a Bionator. To assess standard cephalometric parameters, the software ivoris analyze was used. Data were analyzed using Friedman's two-way analysis of variance by ranks followed by Dunn's post hoc tests ($P \leq .05$).

Results: During therapy (T0–T1), ANB decreased significantly by 1.9° and remained unchanged long term. SNA slightly decreased (–0.6°) during treatment, SNB and SNPg increased (+1.4°, +1.7°). All three parameters showed a significant increase at T2 (+1.2°, +1.6°, +1.6°). Vertical measurements (ML-NL, ML-NSL, NL-NSL) remained almost unchanged during therapy. NL-NSL also was unchanged during the long-term interval; ML-NSL and ML-NL decreased significantly (–3.4°, –4.9°). During treatment, the maxillary incisors retroclined (OK1-NL: –1.6°, OK1-NA: –0.6°), the mandibular incisors proclined (UK1-ML: +3.5°, UK1-NB: +4.9°), neither significantly. Long term, there was a nonsignificant tendency toward proclination of upper (OK1-NL: +0.1°, OK1-NA: +0.7°) and retroclination of lower incisors (UK1-ML: –1.5°, UK1-NB: –5°).

Conclusions: Changes of ANB after bionator treatment without additional fixed appliances remained stable after 20 years. The observed long-term changes are probably consequences of well-known physiological and age-related processes. (*Angle Orthod.* 2023;93:269–274.)

KEY WORDS: Functional treatment; Cephalometric analysis; Bionator; Long-term follow-up

INTRODUCTION

Class II division 1 malocclusion is a common reason for undergoing orthodontic treatment.[1,2] Removable functional orthopedic appliances, allowing bite decoupling, offer the ability to treat Class II division 1 malocclusion as a first step of treatment in growing patients irrespective of the dentition period if patients have a favorable mandibular growth potential and direction.[3,4] These appliances are also commonly used to eliminate orofacial dysfunction that impedes dentoalveolar development.[3] The generally positive effect of two-phase treatment is the possible reduction of fixed appliance treatment time if a Class I occlusion can already be achieved beforehand. This might reduce the risk of white spot lesion development, which is related to treatment duration with fixed appliances.[5,6] One of these appliances is the bionator, which is an appliance that can cause skeletal mandibular adaptation during puberty and mainly dentoalveolar effects during pre-

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puberty.[7–10] One of the expected side effects mainly during prepubertal treatment is protrusion of the lower incisors, which was the reason for Ascher to modify the original Balter's bionator with an acrylic covering of the lower incisors to prevent protrusion.[3,11] Stable inclination of the lower incisors, considering morphological and functional criteria related to narrow biological limits and the musculature surrounding the stomatognathic system, is crucial for long-term stability.[3,12] In general, the knowledge of long-term changes regarding physiological aging processes and differentiation to relapse is also important. There are many publications reporting positive effects after functional orthopedic treatment, mostly followed by multibracket appliance treatment for the correction of incorrect tooth positions.[13–15] However, only limited data have been published on the long-term stability (>15 years) of the skeletal and dentoskeletal parameters after treatment solely with removable functional appliances. Therefore, it was the aim of the present study to investigate long-term stability 20 years after treatment with a bionator appliance not followed by fixed appliance treatment.

MATERIALS AND METHODS

Study Design

Lateral cephalograms (LCs) of patients treated with a Balter's bionator modified by Ascher (A-Bionator) were collected retrospectively from the archive of the Department of Orthodontics, University Medical Center Munich, Germany. Treatment was performed by one experienced orthodontist (IR). To be included in this study, the following criteria had to be fulfilled: (a) treatment with an A-Bionator, (b) no treatment with fixed appliances, (c) LCs before (T0), after (T1), and ≥20 years after treatment (T2), (d) no space closure, opening, extraction therapy, (e) skeletal Class II according to the Hasund/Segner analysis,[16] (f) overjet ≥4 mm, and (g) no craniofacial syndromes. All participants were part of a long-term investigation for which the ethical approval had been obtained from the ethics committee of the University of Munich (77/97). Written consent of the participants for the data collection at T2 was obtained.

Detailed information on the A-Bionator treatment protocol has been described previously.[17] From T1 to T2, patients received no orthodontic treatment or retention.

Analysis of Lateral Cephalograms

First, existing analog LCs were digitized using a transmitted light scanner (Epson Perfection V850 pro, Epson, Suwa, Japan). For LC analysis the software ivoris analyze (Computer konkret, Falkenstein, Germany) was used. One investigator performed all measurements (RJ). All outcome variables are presented in Figure 1.

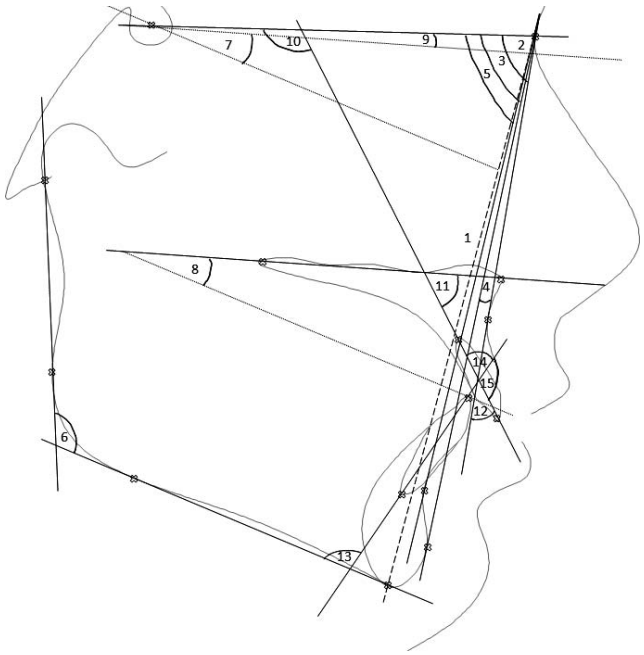

Figure 1. Illustration of the cephalometric variables measured. 1: Index (defined as ratio between middle and lower face height: N-Sp'/Sp'-Gn, where Sp' is the intersection of the maxillary base and the Nasion-Gnathion line), 2: SNA, 3: SNB, 4: ANB, 5: SN-Pg, 6: ArGoMe, 7: ML-NSL, 8: ML-NL, 9: NL-NSL, 10: U1-NSL, 11: U1-NL, 12: U1-NA, 13: L1-ML, 14: L1-NB, 15: U1-L1.

Reliability of Measurements

Twenty randomly selected LCs were reanalyzed by the same investigator (RJ) after 4 weeks, and by a second investigator (NB) to assess the casual and systematic error of measurements using Dahlberg's formula and the intraclass correlation coefficient (ICC, two-way mixed, absolute agreement).

Statistical Analysis

Due to the explorative character of the investigation, no sample size calculation was performed. IBM SPSS Statistics 28 (IBM, Armonk, NY, USA) was used for analysis. The mean (M), standard deviation (SD), median (MD), and interquartile range (IQR) were calculated as descriptive statistics. According to the Shapiro-Wilk-test and visual assessment of histograms, more than 5% of the variables were not normally distributed. Therefore, a nonparametric Friedman's two-way analysis of variance by ranks was performed and pairwise comparisons calculated with Dunn's post hoc tests. P values of ≤.05 were considered statistically significant. The effect size

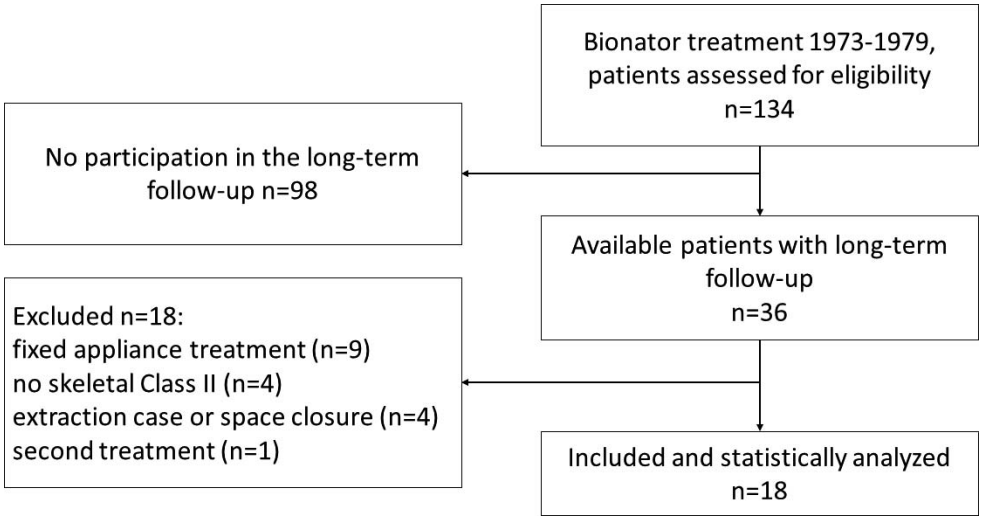

Figure 2. Flow chart demonstrating the retrospective patient sample collection.

was calculated as Pearson's r and interpreted in accordance with Cohen.[18]

RESULTS

A total of 18 patients (nine females, nine males) could be included (Figure 2). Before treatment they were on average 9.8 ± 1.5 years old; after treatment, 13.3 ± 1.9 years old; and, at long-term follow-up, 33.3 ± 2.3 years old. The mean treatment duration was 3.5 ± 1.4 years. At baseline, the patients had the following characteristics: overjet: 5.5 ± 2.1 mm, overbite: 3.8 ± 1.2 mm, peer assessment rating (PAR) index: 19.9 ± 9.9, and a sagittal occlusal relationship of 0.6 premolar widths at the first molars.

During treatment (T0–T1), SNA slightly decreased (–0.6°) and the Index remained unchanged (–0.2%). SNB and SNPg increased (+1.4°, +1.7°), and the pairwise comparison revealed a significant reduction of ANB (–1.9°). The vertical measurements (ML-NSL, ML-NL, NL-NSL) remained unchanged (–0.1°, +0.1°, +0.1°). The inclination of upper incisors decreased according to all three measurements (U1-NSL: –2.5°, U1-NL: –1.6°, U1-NA: –0.6°) but not significantly. There was a nonsignificant increase in the inclination of the lower incisors to the mandibular plane (+3.5°) and the NB line (+4.9°). The angle between the upper and lower incisors showed a decrease of –2.5° (Table 1).

During the long-term follow-up, the Index slightly decreased (–1.1%). SNA, SNB, and SNPg showed a significant increase (+1.2°, +1.6°, +1.6) and ANB remained stable (+0°). ArGoMe decreased (–1.5°), ML-NSL and ML-NSL both significantly decreased during the follow-up (–3.4°, –4.9°), NL-NSL remained stable (+0.1°). The inclination of the upper incisors increased slightly (U1-NSL: +2.5°, U1-NL: +0.1°, U1-NA: +0.7°) while that of the lower incisors decreased (L1-ML: –1.5°, L1-NB: –5°). The angle between the upper and lower incisors was reduced (–0.9°) (Table 1).

The ICC was good to excellent and ranged between 0.902–0.982 for the intrarater and 0.804–0.980 for interrater reliability. The method error was between 0.6–2.5 and 0.8–3.2, respectively.

DISCUSSION

The aim of this retrospective long-term follow-up was to analyze the treatment effects and the long-term changes of the cephalometric parameters after functional treatment with a bionator appliance modified by Ascher without any further fixed appliance treatment. LCs before, after, and 20 years after treatment were analyzed.

ANB decreased significantly, combined with a slight decrease of SNA and an increase of SNB (+1.4°). In accordance, Francisconi et al. found a significant reduction of ANB, a minor decrease of SNA, but a significant increase of SNB of +1.7°.[14] This could be attributed to the adjunctive fixed appliance treatment and the later treatment start in terms of chronological age of participants by almost 2 years. Another study[19] using only a bionator for treatment also found a slight reduction of SNA, a significant decrease of ANB, but also a significant increase of SNB. These patients differed only slightly in chronological and skeletal age compared with the present study. Both age groups with a mean age at baseline of 9.9 and 9.8 years, respectively, can be classified as prepubescent.[20] In the present investigation, all participants were still before the pubertal growth stage at the end of treatment. In the study by Kochel et al.,[19] treatment ended later at 13.8 years, so an interval of pubertal

Table 1. Descriptive and Analytical Statistics of Measured Outcome Parameters of the Cephalometric Analysis Before (T0), After (T1), and 20 Years After (T2) Bionator Treatment

		T0				T1				T2				Global Friedman ANOVA	Dunn's Post Hoc Tests		
														Adjusted *P* Value			
Variables	N	M	SD	MD	IQR	M	SD	MD	IQR	M	SD	MD	IQR	*P* Value	T0–T1 (r)	T1–T2 (r)	T0–T2 (r)
Index (%)	18	81.4	6.0	80.3	9.0	81.7	6.6	80.1	8.3	80.2	7.4	79.0	12.3	.250	-	-	-
SNA (°)	18	80.1	2.7	79.6	3.1	78.7	2.3	79.0	4.2	80.2	3.0	80.2	5.7	.013*	.073	.018* (.20)	1.000
SNB (°)	18	75.2	2.5	74.9	3.5	75.6	2.2	76.3	3.3	77.5	3.0	77.9	5.2	<.001***	1.000	.003** (.20)	.001** (.21)
ANB (°)	18	4.9	1.0	4.7	1.5	3.1	1.5	2.8	2.5	2.7	1.6	2.8	2.8	<.001***	.005** (.20)	.287	<.001*** (.27)
ArGoMe (°)	18	128.5	7.7	126.7	13.6	126.9	8.6	125.6	14.7	123.8	7.8	124.1	10.7	.002**	.401	.137	.001** (.20)
ML-NSL (°)	18	35.4	4.8	35.4	4.9	35.2	4.7	35.3	5.6	32.4	6.0	31.9	8.4	<.001***	1.000	.005** (.20)	.003** (.20)
ML-NL (°)	18	27.6	5.0	28.6	8.1	27.1	5.6	28.7	9.1	24.4	6.7	23.8	11.2	<.001***	.952	.008** (.20)	<.001*** (.22)
NL-NSL (°)	18	7.8	3.2	7.4	5.3	8.1	3.9	7.5	5.7	8.0	3.4	7.6	6.0	.946	-	-	-
SN-Pg (°)	18	76.2	2.8	75.3	3.2	76.7	2.5	77.0	4.5	78.9	3.4	78.6	5.4	<.001***	1.000	.005** (.20)	.001** (.20)
U1-NSL (°)	18	102.2	9.2	103.5	12.3	101.9	7.2	101.0	9.0	103.7	7.1	103.5	10.4	.311	-	-	-
U1-NL (°)	18	70.1	7.9	70.0	10.6	70.1	7.3	68.4	12.5	68.3	6.6	68.5	10.1	.678	-	-	-
U1-NA (°)	18	22.1	8.5	23.7	12.5	23.2	6.9	23.1	10.5	23.5	6.5	23.8	9.4	.678	-	-	-
L1-ML (°)	18	92.5	6.3	93.5	10.7	95.2	6.7	97.0	6.5	93.8	6.7	95.5	13.0	.476	-	-	-
L1-NB (°)	18	23.0	5.6	23.1	7.7	26.0	5.3	28.0	8.4	23.7	5.6	23.0	9.5	.115	-	-	-
U1-L1 (°)	18	130.0	11.2	131.9	13.8	127.7	8.0	129.4	14.5	130.1	9.9	128.5	16.9	.607	-	-	-

[a] IQR indicates interquartile range; M, mean; MD, median; N, numbers analyzed; SD, standard deviation; T0, before treatment; T1, end of treatment; T2, 20 years after treatment.

[b] Global changes were tested with a nonparametric Friedman's two-way analysis of variance by ranks and pairwise comparisons calculated by Dunn's post hoc tests.

* $P < .05$; ** $P < .01$; *** $P < .001$; r: effect size calculated as Pearson's correlation coefficient (<0.3 small effect, 0.3–0.5 medium effect, >0.5 large effect).

growth may have been included, which could be a reason for the significant increase of SNB.

During the follow-up period, a significant increase of SNA, SNB, and also SNPg occurred, while ANB remained stable. Francisconi et al.[17] also found an increase of SNA and SNB after treatment, although not significant. The long-term interval in their investigation started at the age of 15.4 and ended at 25.0 years, whereas the interval of the present study started at the age of 13.3 until 33.3 years, which is almost twice as long. Nevertheless, the results are to some extent comparable as from the early to mid-20s on to the mid-40s, those skeletal parameters are likely to only decrease slightly and remain stable,[21,22] possibly with exception of SNB in men.[22] However, it is to be expected that most changes found in both investigations occurred before the mid-20s and, therefore, included in both groups. The amount of SNA and SNB increase in the present study might be more pronounced, as the long-term interval started earlier at the age of 13.3 years, including a phase of more pubertal growth compared to the other study. In general, it needs to be considered that, in terms of skeletal growth and especially late and residual growth, there might be gender differences[21,22] that make comparison among different studies even more complicated.

The vertical parameters (ML-NSL, ML-NL, NL-NSL) remained unchanged during treatment, in agreement with another study[8] where only minor changes in the vertical measurement during treatment with a bionator and subsequent fixed appliances were found, showing no significant differences compared to an untreated control group. Pancherz et al.[23] found the ML-NSL angle remained stable during treatment, but significantly decreased in the long term, which was in agreement with the present findings as both ML-NSL and ML-NL decreased significantly. According to the literature, there seems to be a relationship between sex and rotation of the mandible.[24] Long-term investigations of untreated samples revealed controversial results regarding mandibular rotation. Some did report posterior rotation in females[25,26] or in both sexes,[27] or anterior rotation in males.[26] In the present study, all patients had favorable sagittal and anterior growth potential as a requirement for bionator treatment, so that the change of the mandibular rotation is no surprise. Anterior rotation of the mandible long term was also found in untreated Class II individuals.[28]

Considering the dentoskeletal changes during treatment, the lower incisors protruded, depending on the measurement, by 3.5° (ML) or 4.9° (NB-line). Although the change in incisor inclination was not significant in the present investigation, the median amount of protrusion is still of clinical importance, especially when patients already have proclined lower incisors before treatment. In general, measurements to the mandibular plane according to Tweed, but also to the NB-line, are accepted as very reliable.[29] Nevertheless, a change in the sagittal position of the mandible is

likely to have an influence on inclination values when measured in relation to the NB-line.[29] This could be the reason why the increase in protrusion in relation to the NB line was greater than to ML in the present study. In general, protrusive movement of the lower incisors is an undesirable effect of appliances for mandibular advancement and is in agreement with the literature, even if functional appliances with capping of the lower incisors to prevent them from protruding are used.[8,19,30]

During the follow-up period, the lower incisors uprighted almost to their original inclination. This finding was in agreement with the long-term effects 32 years after fixed functional treatment with a Herbst appliance.[23,31] Proclination of the mandibular incisors, depending on the amount, is known to be very likely to recover after treatment unless lifelong retention is planned.[31–33] In contrast, lower incisors of untreated Class II individuals tend to protrude long term instead.[28] In the first part of this investigation evaluating the dental casts of the study patients, a significant increase in mandibular incisor crowding was obvious; that might have been caused by a decrease in intercanine width[17] but also by uprighting of the incisors. However, after treatment with only functional appliances during prepuberty without subsequent treatment with fixed appliances, fixed retainers are not indicated before the end of mandibular growth because there is a very high risk of developing a forced bite with a dorsal direction if the incisors cannot upright again.

Upper incisors were slightly retroclined during treatment. Concerning the different measurements to NSL, NL, and NA lines, it needs to be considered that measurements relative to adjacent structures (NL and NA) seem to be preferable.[34] In contrast to these results, Francisconi et al.[14] and Kochel et al.[19] reported a significant reduction of upper incisor proclination during bionator treatment. The reason could be the fact that their patients started with more proclined upper incisors than those in the present study (108.4°[19] vs 103.5° to NSL; 63.8[19] vs 70.0° to NL, 31.9°[14] vs 23.7° to NA).

In the long term, the upper incisors remained stable or proclined slightly depending on the measurement, which was in agreement with Francisconi et al.[14]

The intent of this study was not to show that treatment solely with a bionator can replace a combination of functional removable and subsequent fixed appliances followed by retainers. In a previous investigation of changes on dental casts,[17] it was obvious that the reduction of the PAR index was remarkably less during treatment and the increase during follow-up was higher compared to other studies including patients with subsequent fixed appliance treatment and retention during the follow-up.[14,17,35] Rather, the results of this study show that, if chosen for the appropriate patient, removable functional appliance treatment as part of a two-phase treatment can already achieve very stable treatment results in a sagittal Class I occlusion. This may shorten the time required for treatment with fixed appliances and possibly reduce the risk of white spot lesion development.[5,36]

Being a retrospective long-term investigation, there are several limitations to consider. Most importantly there is no matching control group, which is mainly due to ethical reasons and, therefore, an unavoidable problem. Consequently, results need to be interpreted with caution, considering the natural processes related to development and aging. The only possible solution could be matching with a historical control group, but this can also cause serious bias, resulting in a limited benefit.[37] A further source of bias is the fact that, in a long-term follow-up investigation, it is almost impossible to include all former study patients. This leads to a limited number of subjects, which is unavoidable in this kind of study. To increase the generalizability of this investigation, strict inclusion criteria were applied to include a homogenous sample and, therefore, reduce the risk of bias.

CONCLUSIONS

- After treatment with a bionator, the ANB angle was significantly reduced. This treatment result remained stable during the long-term follow-up of 20 years.
- Significant long-term changes of SNA, SNB, SNPg, ML-NSL, and ML-NSL are most likely due to natural processes related to growth and aging.

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