The use of the Hanks Herbst vs Twin-block in Class II malocclusion: A randomized controlled trial

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Introduction: This 2-arm parallel study aimed to compare and evaluate the efficiency of Hanks Herbst (HH) and Twin-block (TB) functional appliances in treating adolescents with Class II malocclusion. **Methods:** A parallel-group randomized controlled trial was undertaken in a single United Kingdom hospital. Eighty participants were recruited and randomized in a 1:1 ratio to receive either the HH or TB appliance. Eligibility criteria included children aged 10-14 years with an overjet of ≥7 mm without dental anomalies. The primary outcome was the time (in months) required to reduce overjet to normal limits (<4 mm). Secondary outcomes included treatment failure rates, complications and their impact on oral health–related quality of life (OHRQOL). Randomization was accomplished using electronic software with allocation concealed using sequentially numbered, opaque, and sealed envelopes. Blinding was only applicable for outcome assessment. Data were analyzed using descriptive statistics and regression analyses to detect between-group differences, including Cox regression for time to treatment success. **Results:** HH was significantly faster than TB in reducing the overjet to within normal limits (95% confidence interval [CI], −3.00 to −0.03; $P = 0.046$). Mean overjet reduction was more efficient with the HH than the TB appliance (ß = 1.3; 95% CI, 0.04-2.40; $P = 0.04$). Fifteen (37.5%) of the participants in the TB group and 7 (17.5%) in the HH group failed to complete the treatment (hazard ratio = 0.54; 95% CI, 0.32-0.91, $P = 0.02$). However, TB was associated with fewer routine (incidence rate ratio = 0.81; 95% CI, 0.7-0.9; $P = 0.004$) and emergency (incidence rate ratio = 0.1; 95% CI, 0.1-0.3; $P = 0.001$) visits. Chairside time was greater with the HH (ß = 2.7; 95% CI, 1.8-3.6, $P = 0.001$). Participants in both groups experienced complications with similar frequency. A greater deterioration in OHRQOL was found during treatment with the TB. **Conclusions:** Treatment with HH resulted in more efficient and predictable overjet reduction than TB. More treatment discontinuation and greater deterioration in OHRQOL were observed with the TB. However, HH was associated with more routine and emergency visits. **Registration:** ISRCTN11717011. **Protocol:** The protocol was not published before trial commencement. **Funding:** No specific external or internal funding was provided. Treatment for participants was provided as part of routine orthodontic treatment in the hospital. (Am J Orthod Dentofacial Orthop 2023;■:■-■)

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Both removable and fixed functional appliances have proven to successfully correct Class II Division 1 malocclusion by producing a combination of dental and skeletal effects.[1] However, although fixed functional appliances may lead to more efficient overjet correction[2] and are more popular in the United States and mainland Europe,[3] the removable Twin-block (TB) appliance continues to be preferred in other countries, such as the United Kingdom.[4]

Few studies have been designed to differentiate between removable and fixed functional appliance designs.[2,5] The available literature is largely retrospective,[2,5-7] and lacks patient-centered data.[8] Furthermore, it is increasingly

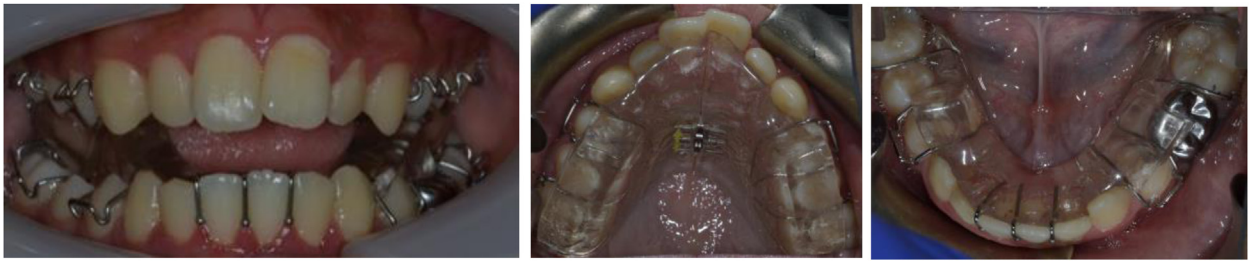

Fig 1. TB design. *TB*, Twin-block.

accepted that orthodontic research tends to be overly focused on clinician-centered outcomes rather than those that matter more to patients, with an increasing agreement that to investigate the effectiveness of orthodontic interventions, both patient- and clinician-centered outcomes are required.[9]

A previous systematic review concluded that all types of functional appliances, including removable designs, can be associated with adverse events and complications (eg, breakages) that negatively impact oral health–related quality of life (OHRQOL) and treatment discontinuation.[10] Specifically, 34% and 69% of included participants reported complications with hybrid (removable-fixed design) and fixed designs, respectively. It is accepted that successful orthodontic treatment relies on patient acceptance and adaptation,[11] and their adherence to the treatment protocol.[12] Negative patient experiences may culminate in treatment discontinuation, depriving children of essential treatment during a critical active growth period. Unsurprisingly, it has, therefore, been highlighted that removable designs can be associated with particularly high noncompletion rates of up to 34%.[10]

Specific objectives

We aimed to compare the effectiveness of the fixed Hanks Herbst (HH) and the removable TB appliance in terms of time (in months) required to reduce the overjet to within normal values (<4 mm). We further aimed to explore treatment failure, complications, patient experiences, and impact on OHRQOL.

MATERIAL AND METHODS

Trial design and any changes after commencement

A parallel-group 2-arm randomized controlled trial with a 1:1 allocation ratio was undertaken with the protocol registered before commencement (ISRCTN11717011). Although there were no planned deviations from the registered protocol, the study was initially planned for 2 United Kingdom centers; however, because of logistical challenges, the second center was withdrawn, and the study was conducted in 1 site only (Institute of Dentistry, Queen Mary University of London). Ethical approval was obtained from the Health Research Authority in the United Kingdom (IRAS project ID: 208408) along with local approval by Research and Development Department, which was given on 18th January 2017 to commence the trial (reference no. 011417).

Participants, eligibility criteria, and setting

Participants were recruited at the Institute of Dentistry (Queen Mary University of London) from February 2017 to September 2019. Treatment was carried out by 1 specialist orthodontist (M.M.P.) applying the following selection criteria: (1) Class II Division 1 incisor relationship, (2) overjet of ≥7 mm, and (3) children aged 10-14 years. Those with previous orthodontic treatment, missing teeth, relevant medical conditions, and/or hyperdivergent facial type (MP/NSP >40°) were excluded.

Interventions

A modified Clark TB appliance was used with the bite registration taken in maximum protrusion incorporating the following features: (1) Adam's clasps on all first premolars (or first deciduous molars) and first permanent molars, (2) ball-ended clasps on the mandibular incisors, (3) midline expansion screw in the maxillary component, (4) blocks intersecting at 70°, with a height of 6 mm in the first premolar region (Fig 1). Participants were instructed to wear the appliance full-time, except for eating, and during contact or water sports. In the comparison group, HH (American Orthodontics, Sheboygan, Wis) was constructed from stainless steel Rollo bands on the first permanent molars, with buccally-positioned threaded attachments, connecting a lingual arch in the mandible and transpalatal arch or rapid maxillary expander in the maxilla (cantilever design; Fig 2). This was cemented using a light-cured glass ionomer material. The HH was activated by advancing the mandible incrementally using crimpable shims, as indicated.

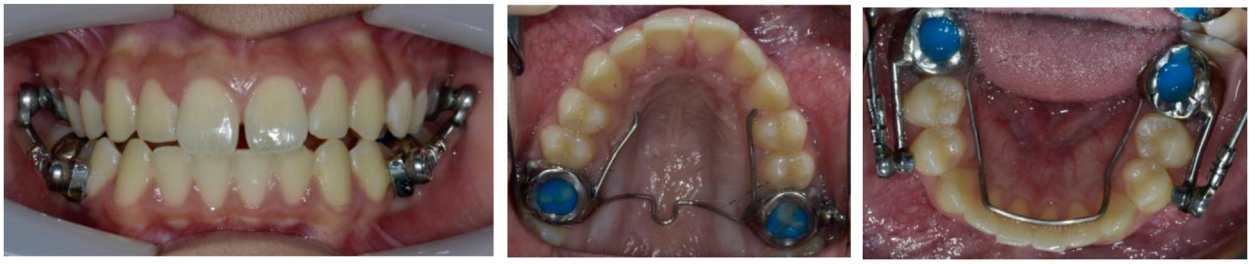

Fig 2. HH appliance. *HH*, Hanks Herbst.

For both groups, detailed instructions and leaflets about appliance care and oral hygiene requirements were provided. Treatment was undertaken with standard recall intervals of 6-8 weeks. Participants who did not attend an appointment were contacted to arrange a further appointment. All participants were free to withdraw from the study at any stage. Once the overjet was considered clinically corrected (<4 mm) and stable, the appliance was removed, and the treatment was deemed complete. A participant was classified as noncompliant (treatment failure) if the overjet was not reduced by at least 10% within a consecutive 6-month period or if it did not achieve a normal overjet (<4 mm) after 12 months of active treatment. Breakage of the appliance more than 3 times over the initial 6-month period and/or persistent poor oral hygiene with associated harms hindering treatment progress was also regarded as a failure. No participant in the trial was allowed to switch between appliances (eg, from TB to HH or vice versa).

Outcomes

The primary outcome was the time taken to reduce the overjet to within normal limits (<4 mm). Secondary outcomes included the failure of treatment rates, number of routine and emergency visits, chairside time, number and nature of complications and the impact of both appliances on OHRQOL.

Overjet and occlusal measurements were taken from study models at the start of the study (T0) and immediately after the functional appliance (T1) withdrawal. Study model measurements were recorded by 1 examiner (M.S.). The reliability of overjet scores was evaluated, with repeat measures undertaken on 20 randomly selected study models with an intervening period of 2 weeks.

Details of adverse events (complications) in both groups, including breakages and harms reported during routine or emergency visits, were collected from participants' notes using a bespoke data collection sheet and categorized according to their nature and severity using a previously published novel classification system[10] (Supplementary Table I).

The impact of both appliances on OHRQOL, including oral symptoms, functional limitations, and emotional and social impacts, was evaluated using validated questionnaires.[13-16] The following questionnaires were completed at T0 and T1: Childhood Experience Questionnaire (CEQ),[13] Child Oral Health Impact Profile (COHIP),[14] and Malocclusion Impact Questionnaire (MIQ).[15] In addition, the Orthodontic Experience Questionnaire (OEQ)[16] was completed to assess patients' experiences and their perceptions during treatment, at least 3 months after the initial fitting of the appliance. Participants were asked to complete the questionnaires independently when attending their appointments to remove any possible parental influence, and 1 examiner (M.M.P.) helped the participants with difficulties in reading or comprehension.

The CEQ, COHIP, and MIQ were scored using a Likert system. A high overall score indicated an unsatisfactory or negative impact on OHRQOL. Regarding the OEQ score determination, questions related to each item were added to give a single score and percentage. The last item in the OEQ was an open question (What would you say to someone about to have a brace?), which was evaluated qualitatively by 2 examiners (M.M.P. and A.J.), each ranking the participant's answers into either positive or negative comments, with disagreement resolved by discussion. Furthermore, data derived from both MIQ and OEQ, which related to specific negative impact domains for the participant as a result of wearing the appliance (eg, impact on eating, impact on appearance, getting bullied or teased, pain and soreness, etc), were additionally combined and analyzed to give a single score or percentage for each topic.

All participant data, including responses to open questions, were reported in bespoke data collection sheets using the unique ID number of participants.

Sample size calculation

The sample size was calculated on the basis of a previous study, which indicated that a 4-month (standard deviation = 4.6) difference in treatment duration

between fixed and removable appliances was clinically significant.[2] Thus, a sample size of 40 participants per group was determined, which allowed for a noncompliance rate of 30%, with a power of 85% and a significance level of 0.05.

Interim analysis and stopping guidelines

No interim analysis was performed during this study. However, during the protocol stage, it was agreed that the trial would be stopped prematurely if it became clear that any intervention was significantly more effective than the other or if frequent and severe harm occurred because of the wear of the appliance.

Randomization (random number generation, allocation concealment, implementation)

Participants were recruited from patients attending new patient clinics, with those fulfilling the selection criteria invited to participate. Information leaflets were provided to both participants and their parents or guardians. Those agreeing to participate were rebooked for the informed consent process, including consent and assent forms for parents or guardians and participants. Baseline records, including impressions and x-rays, were also collected. Each participant was then randomly allocated to the TB or HH group on the basis of electronic randomization, stratified for gender, and performed by an independent statistician. Allocation was concealed from the participant and treating clinician using sequentially numbered, opaque, and sealed envelopes. The number on the sequenced envelope of allocation was used as the study ID number for each participant and attached to all documents related to the trial.

Blinding

The visibility of the functional appliances precluded the blinding of either the clinician or the participants to the allocated arm during treatment. However, all used participants' data were coded and anonymized to ensure that assessors and statisticians were blinded to the group allocation.

Statistical analysis

Descriptive statistics were used to assess demographic and clinical data at baseline. The reliability of overjet scores was evaluated using the intraclass correlation coefficient. Internal consistency for the used questionnaires was assessed by calculating Cronbach α.[17]

Regression analyses were used to detect between-groups differences, including Cox regression for time to treatment success, linear regression (for continuous outcomes [eg, overjet reduction, chairside time and questionnaire scores]), logistic regression (for binary outcomes [eg, frequency of complications]), negative binomial regression (for count outcomes [eg, number of routine and emergency visits]) and Kaplan-Meier survival estimate to evaluate the failure of treatment. For categorical data with contingency tables, Fisher exact test was used, and the odds ratio (OR) was calculated (eg, questionnaires data). In addition, other regression analyses of covariance tests were performed to detect factors (eg, sex and age) that might have influenced the failure of treatment or the number of emergency visits. Statistical analyses were performed using Stata software (version 17.0; StataCorp, College Station, Tex) with the level of statistical significance predefined at $P < 0.05$. The data were analyzed on an intention-to-treat basis, and all participants' records, if available, were included according to their original allocation, regardless of the treatment outcome.

RESULTS

Participant flow

Overall, 127 participants were assessed for eligibility. Of these, 47 were excluded for various reasons (Fig 3). Eighty participants were randomized between the 2 groups, with equal distribution of males and females. Two participants from the TB group failed to reduce their overjet score after 6 months of treatment and were lost to follow-up after that. A further 13 participants in the TB group also failed to have full overjet reduction (<4 mm), increasing the total number of failures in the TB group to 15 (37.5%). In the HH group, no dropouts were reported. However, 7 (17.5%) participants discontinued their treatment because of poor oral hygiene, frequent breakages and/or complications.

Baseline data

Baseline demographic and clinical characteristics (age, gender, ethnicity, initial overjet, Peer Assessment Rating score, and psychosocial assessment [using questionnaire data]) were tabulated with no meaningful clinical differences observed between the groups (Table I).

Reliability and error tests

The intraclass correlation coefficient test showed excellent agreement for overjet scores from study models (>0.91). Internal consistency for the OHRQOL questionnaires using Cronbach α test was found to be in the range of 0.76 to 0.78, 0.82 to 0.88 and 0.94 to 0.98 for CEQ, COHIP, and MIQ, respectively, indicating satisfactory internal reliability.

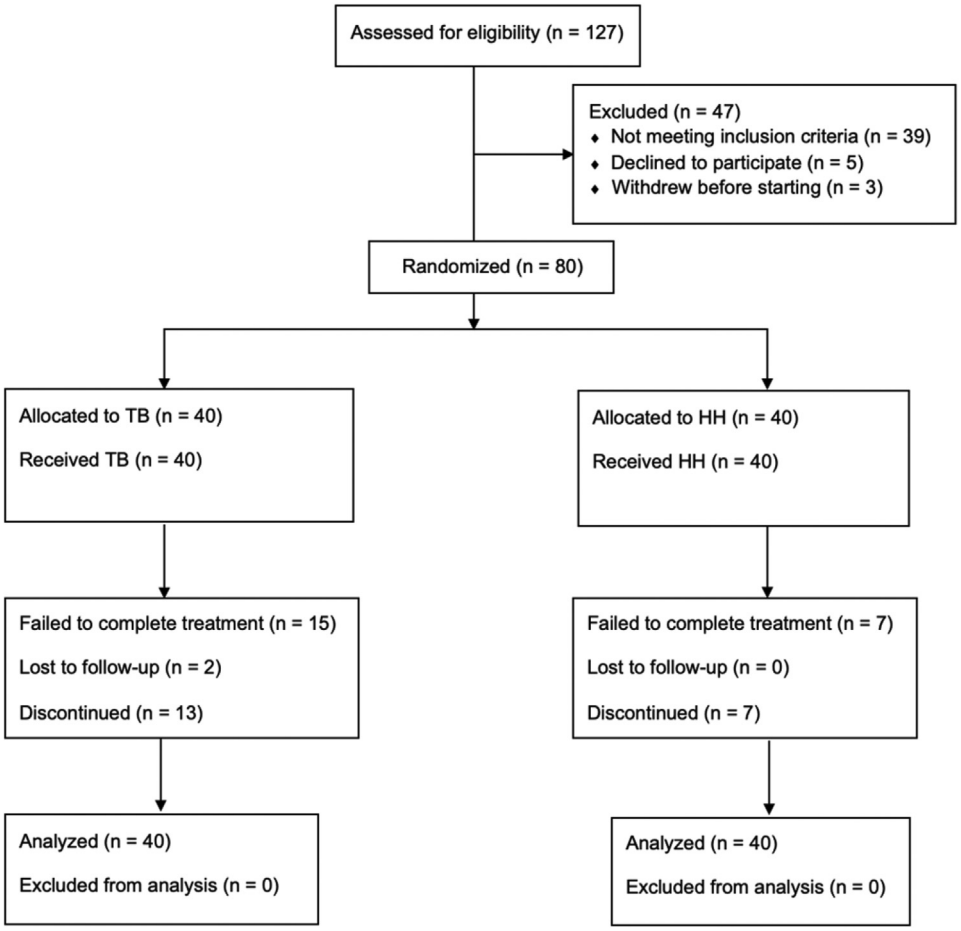

Fig 3. Consolidated Standards of Reporting Trials (CONSORT) flowchart of participants in the study. *TB*, Twin-block; *HH*, Hanks Herbst.

Table I. Comparison of participant characteristics at T0

Variable	*TB group (n = 40)*	*HH group (n = 40)*
Gender		
Female	20	20
Male	20	20
Age range (y)	10-14	10-14
Mean age (y)	12.8 ± 1.3	12.7 ± 1.2
Ethnicity		
South Asian	21 (52.5)	25 (62.5)
White	14 (35)	10 (25)
Afro-Caribbean	5 (12.5)	5 (12.5)
Overjet (mm)	10.3 ± 2.1	10.4 ± 2.3
PAR score	39.6 ± 8.6	39.9 ± 6.4
CEQ score	29 ± 10.9	30 ± 8.6
COHIP score	23.9 ± 11.4	23.9 ± 11.3
MIQ score	12.8 ± 7.8	10.6 ± 7.4

Note. Values are presented as mean ± standard deviation or n (%). *TB*, Twin-block; *HH*, Hanks Herbst; *PAR*, Peer Assessment Rating; *CEQ*, Childhood Experience Questionnaire; *COHIP*, Child Oral Health Impact Profile; *MIQ*, Malocclusion Impact Questionnaire.

Numbers analyzed for each outcome, estimation and precision, subgroup analyses

The results from all participants, regardless of whether the treatment was completed, were included in the final analysis according to their original intervention (40 in each TB and HH group).

Participants in the TB group required 1.5 months longer to complete the functional phase than those in the HH group, which was statistically significant (95% confidence interval [CI], −3.00 to −0.03; $P = 0.046$). The difference in mean overjet reduction with the HH (−7.1 mm) compared with the TB (−5.8 mm) appliance was statistically significant (ß = 1.3; 95% CI, 0.04-2.4; $P = 0.04$; Table II). The slopes in the plot diagram were steeper for the HH group, demonstrating more consistent and predictable overjet reduction over the treatment time with the HH than the TB appliance (Fig 4).

Table II. Comparison of the results of the outcomes

Outcome	*HH (n = 40)*	*TB (n = 40)*	*Type of analysis*	P *value*
Linear regression, β (95% CI)				
Treatment duration (mo)	8.8 ± 2.9	10.3 ± 3.7	−1.5 (−3.00 to −0.03)	0.046
Overjet reduction in mm (study models)	−7.1 ± 2.5	−5.8 ± 3.4	1.3 (0.04-2.40)	0.04
Chairside time (h)	7.6 ± 2.5	4.9 ± 1.3	2.7 (1.8-3.6)	0.001
Negative binomial regression, IRR (95% CI)				
No. of routine visits	10.0 ± 2.8	8.1 ± 2.2	0.81 (0.7-0.9)	0.004
No. of emergency visits	2.7 ± 3.4	0.3 ± 0.9	0.12 (0.06-0.26)	0.001
Logistic regression, OR (95% CI)				
Frequency of overall complications	25 (63)	24 (60)	1.1 (0.5-2.7)	0.8
Frequency of minor complications	15 (38)	13 (33)	1.3 (0.5-3.1)	0.6
Frequency of moderate complications	11 (28)	10 (25)	1.1 (0.4-3.1)	0.8
Frequency of severe complications	14 (35)	11 (28)	1.4 (0.5-3.7)	0.5

Note. Data are presented as mean ± standard deviation or n (%). Estimates, 95% CIs and P values for the effect of treatment.
TB, Twin-block; *HH*, Hanks Herbst.

Fifteen (37.5%) of the participants in the TB group and 7 (17.5%) in the HH group failed to successfully correct their overjet to within normal values (<4 mm), and hence, functional treatment was discontinued. Survival analysis indicated that the hazard ratio (HR) of completing treatment was lower for the TB than the HH appliance (HR, 0.54; 95% CI, 0.32-0.91; $P = 0.02$, Fig 5). However, regression analysis concluded that other factors, such as gender and age, were insignificantly correlated to treatment failure (β = 0.60; 95% CI, 0.22-1.63; $P = 0.32$; and β = 0.83; 95% CI, 0.56-1.23; $P = 0.36$, respectively).

Chairside time was significantly greater with the HH than with the TB appliance (ß = 2.7, 95% CI, 1.8 to 3.6, $P = 0.001$). The TB appliance was associated with a lower number of routine visits (incidence rate ratio [IRR] = 0.81; 95% CI, 0.7-0.9; $P = 0.004$) and additional appointments to deal with emergencies, such as breakages or complications (IRR = 0.12; 95% CI, 0.06-0.26; $P = 0.001$; Table II). Regression analysis suggested that male participants were more likely to experience an emergency visit regardless of the appliance type (IRR = 2.1; 95% CI, 0.96-4.40; $P = 0.06$).

Adverse events and complications

Overall, both appliances were associated with a similar frequency of complications and adverse events, including minor, moderate and severe categories (Tables II and III). TB complications were mainly related to crib fractures (19%), oral irritation (12%) and loose fit (8%), which did not affect the function of the appliance. Severe complications included catastrophic fracture of the acrylic component (14%) and appliance loss (8%), which required refabrication. Participants in the HH group suffered mainly from mucosal irritation (21%) and telescopic arm detachment (21%), which were readily repaired at the chairside. Fractures of the HH were observed in 4 participants (7%). The mandibular lingual arch became embedded in the lingual mucosa (26%). Similar problems were reported with the transpalatal arch but with lower frequency (7%).

Impact of wearing the appliance on OHRQOL

There were no significant differences between TB and HH groups in the overall scores for CEQ, COHIP, and MIQ responses (Table IV). With regard to MIQ, a higher proportion in the TB group reported more negative perceptions of appliance wear: (1) I don't feel very happy (OR = 3.6; 95% CI, 1.2-11.5; $P = 0.03$), (2) I don't feel very good looking (OR = 2.8; 95% CI, 1.1-7.4; $P = 0.05$), and (3) I feel sad (OR = 2.7; 95% CI, 1-7; $P = 0.05$) (Table V). Data from OEQ (Table VI) showed that the HH was 4 times more likely to produce problems with eating (OR = 4; 95% CI, 1.2-13.6; $P = 0.03$). In contrast, feeling embarrassed was 4-fold more likely with the TB than HH appliance (OR = 4; 95% CI, 1.4-11.4; $P = 0.01$). The vast majority of participants in both groups reported similar problems related to appliance cleaning, pain and soreness, as well as problems in their schoolwork. A smaller proportion suffered from the appearance of the appliance and bullying, regardless of the appliance type (Table VI).

Responses to open questions were categorized as either positive (eg, The brace works amazingly, and it's worth getting the brace) or negative (eg, It really hurts at the start, and the brace is a hassle and prevents talking), which suggested greater negative experience during TB (44%) than HH (38%) treatment (further examples are reported in Supplementary Table II).

DISCUSSION

Only 4 prospective studies have previously compared the effects of removable and fixed functional

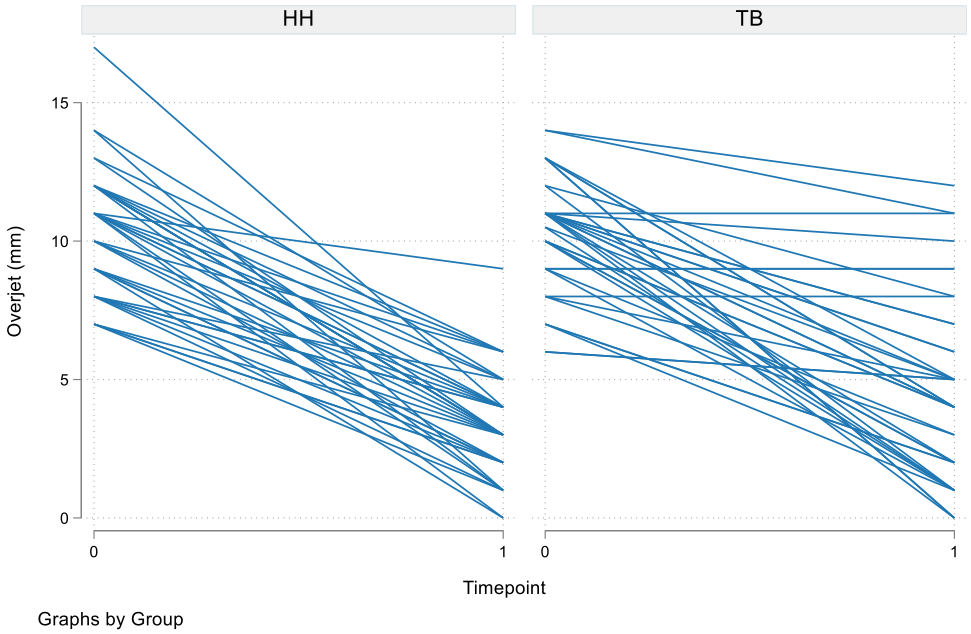

Fig 4. Plot diagram of slopes for each participant in respect of overjet reduction over time with TB and HH appliances. *TB*, Twin-block; *HH*, Hanks Herbst.

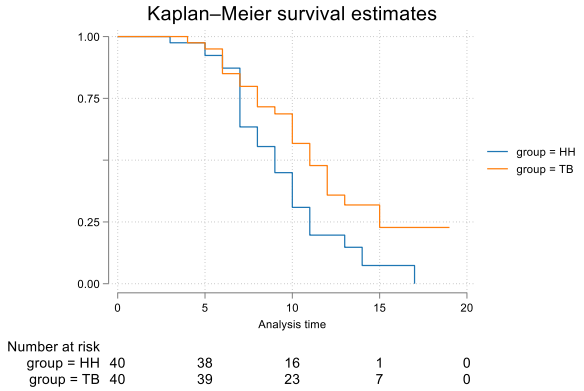

Fig 5. Kaplan-Meier survival estimate of successful treatments (overjet reduction of <4 mm) with the TB and HH. *TB*, Twin-block; *HH*, Hanks Herbst.

appliances.[2,7-9] However, the present study appears to be the first randomized controlled trial considering both clinician-based measures and patient perceptions and opinions, with only the study by O'Brien et al,[2] presenting limited comparable data in this respect.

Treatment with the HH was clinically faster than TB (8.8 vs 10.3 months, respectively) as well as more efficient in reducing the overjet (absolute mean overjet reduction is −7.1 vs −5.8 mm, respectively), most likely because of the enforced nature of full-time wear, leading to adaptation and acceptance of the appliance sooner than might be the case with the TB appliance. However, compared with the multicenter study by O'Brien et al,[2] the treatment duration was longer. This study was carried out in a relatively lower socioeconomic background which has been linked to extended treatment duration and higher failure rate,[18] which might explain the extended duration with HH in this study, although further work may be required to confirm this. Notwithstanding this, the observed treatment duration for TB compares favorably with some allied research.[19,20]

A significantly greater number of routine visits was required with the HH compared with the TB appliance. The chairside time was also commensurately longer, reflecting the more complex fitting procedure with the HH, considering the additional visits and time required (eg, for placing separators). Although the HH was found to be more efficient and associated with better compliance, a key disadvantage was the need for additional visits to deal with emergencies and complications, which might conceivably hinder its wider adoption.

In this study, we found that both appliances partially or completely reduced the overjet to within normal values (<4 mm), in broad agreement with previous prospective studies.[2,6,7] However, our results confirmed the impact of appliance type (removable vs fixed) and suggested a strong association between using the TB and treatment discontinuation (15 failures in TB vs 7 in

Table III. Distribution and description of complications according to nature and severity

Severity of complication	*No. of complications*	*Nature of complication*	*n (%)*
TB			
Minor	23	Crib fracture without discontinuation	19 (39)
		Mouth irritation/rubbing without discontinuation	4 (8)
Moderate	11	A component fracture resulting in temporary discontinuation	5 (10)
		Poor retention and fit (dentition changes, screw-over opening) resulting in temporary discontinuation	4 (8)
		Mouth irritation/rubbing caused temporary discontinuation	2 (4)
Severe	15	A component fracture requires remaking the appliance	7 (14)
		Poor fit and retention require remaking the appliance	4 (8)
		Appliance loss	4 (8)
Total	49		49 (100)
HH			
Minor	28	Rollo band dislodgement requiring re-cementation	10 (17)
		Mouth irritation because of metal component rubbing adjusted at chairside	12 (21)
		Mandibular arch embedded in the mucosa but addressed chairside	4 (7)
		Transpalatal arch embedded in mucosa but adjusted chairside	2 (3)
Moderate	12	Telescopic arm detached, causing functional impairment but addressed chairside	12 (21)
Severe	18	Fracture of the weld point between metal components of the appliance requiring remake	4 (7)
		The mandibular arch component of Herbst is completely buried in the mucosa requiring removal under local anesthesia and remake	11 (19)
		Transpalatal arch embedded in the palate needs removal and remake	2 (3)
		The buccal bar of the lower component is buried in buccal mucosa and needs removal	1 (2)
Total	58		58 (100)

TB, Twin-block; *HH*, Hanks Herbst.

Table IV. Overall questionnaire scores for TB and HH groups at T0 and T1

		HH (n = 40)		*TB (n = 38)*			
Questionnaire	*Domains and possible scale*	*T0*	*T1*	*T0*	*T1*	*β (95% CI)*	P *value*
CEQ	Overall Score (0-80)	29.1 ± 10.8	26.9 ± 9.6	30 ± 8.6	30.2 ± 8.0	2.8 (−0.3 to 5.8)	0.07[†]
COHIP	Overall Score (0-76)	23.9 ± 11.3	24.7 ± 11.7	23.9 ± 11.4	24.7 ± 13	0.3 (−4.4 to 5.0)	0.9[†]
MIQ	Overall Score (0-34)	10.5 ± 7.4	8.7 ± 8.1	12.7 ± 7.8	10.7 ± 7.9	−0.1 (−3.9 to 3.6)	0.9[‡]

TB, Twin-block; *HH*, Hanks Herbst; *CEQ*, Childhood Experience Questionnaire; *COHIP*, Child Oral Health Impact Profile; *MIQ*, Malocclusion Impact Questionnaire.
[†]Linear regression for CEQ and COHIP using β (95% CI); [‡]Median regression for MIQ.

HH: HR, 0.54; 95% CI, 0.32-0.91; $P = 0.02$), which was again in agreement with allied research.[10] The higher preponderance of outright failure in TB was a major contributor to this group distinction. Possible reasons for this high discontinuation rate in the TB group are its ease of removal, level of discomfort, and problems associated with speech. It is also worth acknowledging a greater disturbance in eating was reported in relation to HH treatment. However, participants in the TB were instructed to remove their appliances for eating, which may account for the observed difference. In contrast, despite the HH being cemented in situ, a relatively high chance of treatment discontinuation was observed, with the main reasons being persistent poor oral hygiene and complications involving the frequent fracture of its components or impingement against the mucosa.

Both appliances had similar complication rates and severity according to the classification system used.[10] However, although not statistically significant, the regression model suggested that male participants were twice as likely to experience emergency visits regardless of the appliance design, which might be another reason for treatment failure.

Although it has not been evaluated before, minor emergencies with the TB appliance were relatively common, with fracture of Adam's clasps, discomfort because of appliance loosening, reduced mandibular range of motion and ulceration resulting in temporary or permanent discontinuation of appliance wear. Furthermore, severe complications were observed, such as catastrophic breakages and appliance loss, resulting in the need to refabricate the appliance or treatment failure. Regarding the HH,

Table V. Percentage of participants with MIQ who believed that each item had got very, a bit, or a lot worse during treatment with TB and HH

Item	*HH*	*TB*	*OR (95% CI)*	P *value*[†]
I don't feel very happy	5 (13%)	13 (34%)	3.6 (1.2-11.5)	0.03
I don't feel very good looking	9 (23%)	17 (45%)	2.8 (1.1-7.4)	0.05
I don't feel very confident	8 (20%)	71 (8%)	0.9 (0.3-2.8)	1
I don't feel very normal	3 (8%)	4 (11%)	1.5 (0.3-7)	0.7
I feel sad	10 (25%)	18 (47%)	2.7 (1-7)	0.05
I feel nervous	15 (38%)	17 (45%)	1.4 (0.6-3.3)	0.6
I feel shy	19 (48%)	19 (50%)	1.1 (0.5-2.7)	1
Smiling bothers me	21 (53%)	24 (63%)	1.6 (0.6-3.8)	0.3
Laughing bothers me	14 (35%)	19 (50%)	1.9 (0.8-4.6)	0.3
Seeing photographs of myself bothers me	23 (58%)	23 (61%)	1.1 (0.5-2.8)	0.8
Talking in public bothers me	13 (33%)	16 (42%)	1.5 (0.6-3.8)	0.5
I worry about other people having nicer teeth than me	15 (38%)	18 (47%)	1.5 (0.6-3.7)	0.5
I worry about being bullied	10 (25%)	11 (29%)	1.2 (0.5-3.3)	0.8
I worry about making friends	5 (13%)	6 (16%)	1.3 (0.4-4.7)	0.8
I worry about fitting in with friends	6 (15%)	5 (13%)	0.9 (0.2-3.1)	1
I cover my teeth with my hands when I smile	15 (38%)	17 (45%)	1.4 (0.6-3.3)	0.6
I have a problem biting some foods	20 (50%)	14 (37%)	0.6 (0.2-1.4)	0.3

Note. Values are presented as n (%).
TB, Twin-block; *HH*, Hanks Herbst.
[†]Fisher exact with OR (95% CI) was used.

Table VI. Percentage of participants with the OEQ who believed that each item had got worse during treatment with TB and HH

Factor	*HH*	*TB*	*OR (95% CI)*	P *value*[†]
Problems with cleaning the appliance	26 (65)	23 (62)	0.9 (0.4-2.2)	0.8
Problems with eating with appliance	13 (33)	4 (11)	4.0 (1.2-13.6)	0.03
Problems with the appearance of the appliance	2 (5)	5 (14)	0.30 (0.06-1.90)	0.3
Bullying with appliance	5 (14)	6 (18)	1.4 (0.4-5.2)	0.7
Soreness and pain with appliance	36 (90)	31 (84)	0.6 (0.2-2.2)	0.5
Embarrassment with appliance	7 (18)	17 (46)	4.0 (1.4-11.4)	0.01
Schoolwork impact	33 (85)	26 (72)	0.5 (0.2-1.5)	0.3
Friends and family impact	21 (53)	9 (56)	1.2 (0.5-2.9)	0.8
Hobbies impact	4 (44)	9 (53)	0.7 (0.1-3.6)	1

Note. Values are presented as n (%).
TB, Twin-block; *HH*, Hanks Herbst.
[†]Fisher exact with OR (95% CI) was used.

although most reported complications were mild or moderate, being repairable at the chairside, severe complications were about 1.5 times higher than TB treatment. For example, instances in which the mandibular lingual arch became embedded in the lingual mucosa with the need to remove it under local anesthesia. A similar complication was reported in a previous study with the Dynamax appliance,[21] which also incorporates the lingual arch, highlighting the need to ensure an optimal level of oral hygiene and close clinical monitoring.

In this study, we used 4 different questionnaires to provide a better understanding of the impact of functional appliance wear on the OHRQOL, which could be somewhat burdensome for the participants. However, we aimed to use the triangulation protocol in collecting qualitative data, which might have helped develop a comprehensive understanding of the problems with wearing functional appliances.[22] A greater deterioration in the generic domains of OHRQOL was identified during TB treatment, with a significantly higher proportion of participants in this group reporting problems related to self-confidence and self-esteem. These findings were in keeping with O'Brien et al,[2] who applied a nonvalidated single scale and reported that participants with TB experienced more embarrassment and more problems that influenced their schoolwork resulting in treatment discontinuation. With respect to the open question in the OEQ, replies suggested that factors, such as pain

and discomfort and impairment in quality of life, could have played an important role as barriers to treatment, promoting rejection of the appliance. However, these findings should be interpreted with caution and further evaluation; adopting a qualitative study approach would be of added value.

Limitations

This randomized controlled trial was conducted in relatively high social deprivation, perhaps explaining the high drop-out in TB compared with the HH group. It has been suggested that social deprivation can result in poor attendance[23] and more breakages,[18] which might lead to treatment discontinuation. Notwithstanding this, an appropriate allowance for drop-out was considered during the sample size calculation, suggesting that the statistical inferences remain robust.

The current paper did not report the outcomes related to dental, skeletal, and soft-tissue changes, which will be published in separate articles. Furthermore, we acknowledge that although the primary endpoint of the current study is the "end of functional appliance treatment," the vast majority of participants proceed to a second phase with multibracket appliances to detail the occlusion. Therefore, the present study provides a valid measure to evaluate the effects of functional appliances in isolation, which can be difficult to differentiate at the end of the multibracket appliance phase. A further publication will report findings at the end of the overall treatment.

We were unable to assess the cost-effectiveness of these appliances. It is acknowledged that the HH appliance incurs additional costs in terms of time, materials, and laboratory fees. Nevertheless, from a clinical perspective, the observed increased risk of discontinuation coupled with the lack of predictability of overjet reduction with the TB appliance vs the relative impact of more routine and emergency visits with the HH highlight the need for economic analysis of both alternatives.

Generalizability

The generalizability of these results might be limited because this research was undertaken in a single-center hospital in an area of relatively high deprivation. Furthermore, the treatment was carried out by a single clinician, albeit experienced in both appliances. Therefore, the findings might not be generalizable.

CONCLUSIONS

Treatment with HH resulted in more efficient and predictable overjet reduction than TB. A significantly higher treatment discontinuation rate and greater deterioration in OHRQOL were observed with the TB during treatment. HH was, however, associated with more routine and emergency visits and several significant complications involving the need occasionally for local anesthesia.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.ajodo.2023.06.002.

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Supplementary Table I. Classifications of complications (with examples) according to their severity with TB and HH appliances

Severity of complication	*TB*	*HH*
Minor	Loosening or crib fracture, in which retention and stability of the appliance were still acceptable and did not compromise appliance wear	Band decementation
	Soft-tissue irritation because of rubbing or sharp edges	Soft-tissue irritation because of rubbing or sharp edges
Moderate	Loss of appliance retention and stability compromising the use of the appliance but can be addressed at the same appointment	Detachment, distortion or loss of the appliance can be repaired or replaced at the same appointment
Severe	Fracture of acrylic component that requires laboratory repair	Component impinging/embedded on the mucosal tissue to the degree that removal followed by replacement after healing or refabrication is required.
	Loss of the appliance	Fracture of key components

Supplementary Table II. Examples of positive and negative comments from the OEQ

Positive comments	*Negative comments*
The brace works amazingly. I am happy to get them	You cannot eat anything hard, chew sticky food
It is very good experience and it makes your teeth better	It really hurts at the start, but it gets better
It's worth getting the brace. It makes a huge difference	I would say it may be difficult and annoying but worth it
Be confident because it can make huge difference	Do not eat hard food because the metal fragile and can break
I would highly recommend it as it moves you nice	Uncomfortable but will settle down soon
It might hurt at first but will 100% help your appearance	It is hard to wear it all the time because it is hard to speak
The pain is worth the gain. It wasn't that bad	If there is a pain, you should have a medicine
At first weak difficult to eat but with time get easier to eat	Do not use the brace that is not fixed in your mouth because you will take them of as I did
I may advise not too scary at all	Don't lose them. Be careful when they are out so they don't break
Go for it because you won't regret it	I become getting bullied when I take out
This brace has changed my life a lot in a good way	Brace is a hassle and prevent talking. Very uncomfortable