

Orthodontic treatment measures

GUTACHTEN

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List of abbreviations

abbreviation	explanation
(C) OHIP	(Child) Oral Health Impact Profile
(C) OIDP	(Child) Oral Impacts on Daily Performances
AWMF	Association of Scientific Medical Societies
BEL II	Federal Uniform Bid document
BEMA-Z	Uniform assessment scale for dental services
BMG	Federal Ministry of Health
BZÄK	German Dental Association
CBCT	Cone Beam computer tomography
CENTRAL	Cochrane Central Register of Controlled Trials
COHQoL	Child Oral Health Quality of Life
CPI	Community Periodontal Index
CPQ	Child Perception Questionnaire
CT	Computer tomography
DAI	Dental Aesthetic Index
DMFS	Decayed Missing Filled Surfaces Index
DMFT	Decayed Missing Filled Teeth Index
EARR	External Apical root resorption
GI	Gingival index
SHI	Statutory health insurance
GOHAI	General Oral Health Assessment Index
GOZ	Fees for Dentists
GSROH	Global Self-Rating of Oral Health

abbreviation	explanation
ICON	Index of Complexity Outcome
ICTRP	World Health Organization International Clinical Trials Registry Platform
IOTN	Index of Orthodontic Treatment Need
IQWiG	Institute for Quality and Efficiency in Public Health
Orthodontic	orthodontics
Orthodontic RL	Guidelines for orthodontic treatment
KI	confidence interval
KIG	Orthodontic indication groups
KZBV	Kassenzahnärztliche Confederation
LCR	Lateral Cephalometric Radiography
OASIS	Oral Aesthetic Subjective Impact Score
OHRQoL	Oral Health Related Quality of Life
GRANDPA	Overall proportion of Agreement
PAR	Peer Assessment Rating Index
PD	Probing Depth (probing depth)
PI	Plaque Index
PSI	Periodontal Screening Index
RCT	Randomized Controlled Trial
RME	Rapid Maxillary Expansion
SIGN	Scottish Intercollegiate Guidelines Network
TAD	Temporary Anchorage Device
TSVG	Terminservice- and Supply Act
YQoL	Youth Quality of Life

Summary

In orthodontics (orthodontic) accounted for in 2016 about 1,103 million € (almost 8%) of the total expenditure for dental treatments in the amount of 13,793 million €. Given this output volume, a test was initiated by the federal court of auditors, the result raises the question of whether a sufficient scientific basis of clinical benefit and cost-effectiveness of orthodontic care is. From previous studies, which essentially are based on routine data of individual health insurance or interviews, references are emerging on pensionable deficits in orthodontics. These include too long average duration of treatment or routine conduct not necessarily domestic dizierten diagnostic radiology.

Against this background, on behalf of the Federal Ministry of Health (BMG) (tendency EVI) to the existing reports based on scientific evidence three questions:

Question 1: What are the long-term effects of the most important orthodontics
Indian treatments on oral health? Question 2: What are the financial costs of
statutory health
insurance and self-pay patients for orthodontic services? Question 3: What are the
future research needs to the evidence and the
determine benefits of orthodontic treatment measures, and to what expected time
horizon further studies could be carried out?

To answer the questions referred to three separate Registry searches were carried out.

Ad Question 1

The "relevant interventions" those diagnostic and therapeutic measures have been understood, which account for 80% of all completed orthodontic rule performance in statutory health insurance. The evidence base was overall severed after the two types of measures (a) diagnosis and (b) therapy Siert analyzed.

Ad Question 1

The goal of diagnostic procedures in orthodontics is the treatment planning. therefore as relevant endpoint the impact of diagnostic interventions to treatment planning has been defined in this report. In the evidence-based analysis of diagnostic orthodontic measures a total of nine studies found entrance. is essential statement of most of these studies that the nature and extent of diagnostic measures largely on the degree of

are dependent malocclusion. The analyzed studies were very heterogeneous in terms of both the evaluated methods as well as with regard to the study methodology. Because of this, no final assessment can be taken, the influence of individual diagnostic measures on treatment planning and for what (additional) insights they contribute superiors.

Ad Question 1b

Therapeutic measures have been as common practice, valued at their medical rule benefit and harm for patients. In particular, the morbidity and health (oral) quality of life were in the foreground.

A total of 18 studies were included in the evidence-based analysis for orthodontic treatment rule. The focus of most studies was on the comparison of different intraoral or extraoral orthodontic devices. One-third of the studies looked orthodontic treatments overall gegenüber no intervention. In addition, studies were identified that faced early treatment in children with mixed dentition of a control treatment in adolescents with permanent dentition.

Three quarters of the studies on orthodontic treatment (13 studies) reported indices on the extent of treatment effect. Consistently showed this improvement of the respective malocclusion after completion of silicic ferorthopädischen treatment.

Parameters for oral health were only serving reports of four of the 18 study programs. In the case used indices is Surrogatpa- parameters, which affect the morbidity of patients and patient with th orthodontic treatment can only be approximated. In the included studies, no significant differences between different orthodontic appliances or orthodontic treatment regimens were used for the indices vs. advertising of non-treatment found the. Long-term patient-relevant outcomes such as tooth loss, tooth mobility and pain were reported in any of the included studies. Likewise in four of the 18 studies included oral quality of life has been detected. It is to be stated that across studies for patients with orthodontic treatment high oral quality of life is reported. However, persons treated, depending on their underlying indication and then indexed treatment different improvements in the quality of life appear to have oral. As with the consideration of the diagnostic studies is also reflected in the therapy studies, a high heterogeneity serving design regarding study methodology, study programs and being investigated. In addition, the inkludi- differ

vacate Erten studies in the applied interventions and the observa-. Since a total of only a few studies on oral health were identified, which also mainly based on surrogate endpoints, this can make any definitive assessment of whether and what long- term effects of the applied orthodontic treatment regimen to oral health.

Ad Question 2

In the analysis of SHI expenditures for orthodontic care wur- the ten included statistics and analysis of various stakeholders in the health care system as well as a retrospective observational study. The analog analysis of the available data shows that have the costs incurred for the statutory health insurance as part of orthodontic care, have increased over the past years continuously and reached for the year 2017 of € 1,115 million, a new record. This is development fell mainly due to an increased number of treatment due. And at the level of the insured and members of an increase in the average cost was observed - with a simultaneous decline in primarily relevant for orthodontic services insured population. Spending itself largely through again acknowl- rare or materials, laboratory practice of our own laboratories causes, which together for more than 90% of expenditure are the cause.

Ad Question 3

In this report, the current scientific evidence for the benefit and effectiveness zusammenge- wear orthodontic intervention. Although a large number of studies and documents in the Recher- chen was found that identified material is, however, only suitable to answer the questions to-grunde lying.

With the aim of generating evidence for the benefit of orthodontic loading action measures to promote in the foreseeable future, implemented oriented epidemiological studies should already used in the future to a greater extent to advertising to evaluate the long-term results of orthodontic measures. To-the should complete primary and / or secondary studies advertising implements, advertising so long achieved a significant improvement of the evidence the can. Registry documents that are taught with such studies should, in particular, it can be used to establish standards in diagnosis and treatment of malocclusions in the form of guidelines.

1. background

Orthodontics (KFO) is a specialty of dentistry that the improvement of the function and aesthetics, as well as the prevention of dental caries and periodontal diseases as a goal has [1]. It is concerned [2] with the diagnosis, prevention and treatment of morphological and functional differences in the area of the orofacial system.

In 2004, the dentists and Krankenkassen - the performances were by the federal Committee seen in the Directive for orthodontic treatment (orthodontic RL) type and scope set whose costs the statutory health insurance (GKV) contributes [3]. Basically, these services are designed to ensure a sufficient, even expedient and economical contract dental care. It solvency then apply only such examination and treatment methods, their diagnostic and therapeutic value is sufficiently secured. [3] According orthodontic RL [3] an orthodontic intervention, belongs to contract dental treatment then if the functions of biting, chewing, the articulation of speech, breathing through the nose, the mouth end, or the joint function is significantly affected by misalignments of the jaw or teeth or impairment is to be expected. The need for treatment is made on the basis of diagnosis-related orthodontic indication groups (KIG). For the assumption of costs by the SHI a need for treatment of at least 3 is required. The span of the KIG is 1 to 5 (positions congenital malformation of the overall face and jaw, skeletal Dysgathien and injury-related Kieferfehl-) With the exception of serious jaw anomalies must also treatment before Vollendung of 18 years for a reimbursement begun have been [3]. Treated people orthodontic treatment are therefore primarily children and young people.

Orthodontic treatment is usually carried out with removable plate apparatuses or functional appliances to the jaw position correction, fixed braces for correcting a malocclusion, palatal arch or a combination of removable and fixed braces [4]. Measures that are purely cosmetic will not be reimbursed by health insurance [3].

Treatment measures orthodontics are expensive. So in 2016 accounted for about 1,103 million € (almost 8%) of the total of 13,793 million € for dental loading negotiations on orthodontics. In the same year desvereinigung (KZBV) were charged 7.916 million treatment cases, according to cash Dental federal [5]. Because of the high spending an audit was initiated by the Federal Court, the result raises the question of whether a sufficient scientific basis of clinical benefit and cost-effectiveness of orthodontic care is rule [6]. From previous studies, the surfaces essentially restricted routine data of individual health insurance or are based on surveys,

there are indications emerging to supply deficits in orthodontics. These include too long average duration of treatment or routine implementing a not necessarily indexed X-ray diagnosis [7]. Given the discrepancy between routine care of SHI insureds with orthodontic services and the previously outstanding demonstration of the benefit of coming to apply orthodontic treatments, the Federal Ministry of Health (BMG) commissioned the upstream lying report, which based on scientific evidence (evidence) answered, have orthodontic treatment which medical benefits. Also a consideration of SHI expenditures, as well as co-payments by the insured for services of orthodontic done. the report is supplemented by the identification of evidence gaps and took the presentation of possible measures that can act to close it.

Second issues

As part of the opinion, the following three scientific questionnaires are settings evidence-based answers:

- What long-term effects the most important rule orthodontic treatments on oral health (Question 1)?
- What is the financial expenses of the statutory health insurance are insurance and self-pay patients for orthodontic services (questionnaire position 2)?
- What are the further research needs to determine the evidence and benefits of orthodontic treatment measures, and to what expected time horizon further studies could be carried out (question 3)?

The following are the objectives of the individual issues and the measures taken with regard to basic requirements are described in detail.

2.1 Use and effectiveness of orthodontic treatment measures (Question 1)

Objective of this analysis is to systematically identify and workup of the existing scientific literature on the effectiveness and the tongue-zen orthodontic treatment. One benefit of medical interventions is in accordance with the Institute for Quality and Efficiency in Health Care (IQWiG) present when it was demonstrated that the use of these interventions has causally positive effects on patient-relevant outcomes. In patient-relevant outcomes is disease- and requiring treatment-related changes in terms of mortality, morbidity and health-related quality of life of the person treated [8]. The focus of the present study, the effects had to be on oral health. This is after the FDI World Dental Federation defined as follows: "Oral health is diverse and includes the ability to speak, to smile, to smell, to taste, to touch, chew, schluck- and emotions through facial expressions with confidence and without to transmit pain or discomfort and without disease of kraniofazialen complex. "This reflects in particular the physiological aspects (morbidity) and the social and psychological factors contradict that affect the oral health related / oral quality of life (oral Health-related quality of life - OHRQoL) have [9].

Basis for the evaluation of the benefits of medical interventions constitute systematic literature searches, which together carry the current state of scientific evidence and reappraise the results structured. This require the transfer of the-made question 1, using the PICO-schema, in an adequate, clinically relevant key issue.

The specification of the scientific evidence is performed taking into account the population (P), intervention (I), comparator (C) and the outcomes (O). When defining the parameters, the stipulations of the German legal framework and orthodontic care context were used.

population

When the focus of attention population to Question 1 is by law insured persons who are entitled to orthodontic loading action. The basis for the treatment claim § 29 SGB V and the Orthodontic RL, which entered into force on 01.01.2004. These controls depending diagnosis-related orthodontic indication groups (KIG) which patient tinnen and patients from the perspective of the SHI orthodontic treatment re- quire. Required is at least one treatment required degree KIG 3. Furthermore, be distinguished under the orthodontic RL the people treated by the age and the severity of the jaw anomaly. Basically three Populatio- can be differentiated nen:

- Population A: children up to age 18, after 2nd Phase of the dentition (late mixed dentition) with a treatment degree of the demand \geq 3rd
- Population B: patients with severe malocclusions requiring orosurgical and -orthopädische treatment (. Eg thien congenital deformities of the face and jaw, skeletal Dysgna-, injury-related Kieferfehlstellungen) and a treatment degree of the demand A5, D4, M4, have O5, B4, K4.
- Population C: Children and adolescents before the second phase of the dentition (late mixed dentition) with a need for treatment degree D5, M4, M5, O4, O5, B4, K3, K4, P3.

Figure 1 provides an overview of the ISCC stages 3-5 and includes a FAR bige identification of populations A to C.

Children and adolescents up to 18 years in which an ISCC level 1 or 2 is present, and adults without a heavy jaw anomaly (population B) have not been report- included in the present scientific investigation, as these are not for orthodontic treatment at the expense SHI eligible.

In the international context, the KIG find direct application. Only the description of the population within studies allows a conclusion on the KIG according to German standards. Due to the definition of all relevant population supplementary indexes were used, with which the orthodontic treatment is needed may be determined.

Figure. 1: Overview KIG stages including identification of populations A to C

KIG-STUFEN	BEFUND - ZAHNFEHLSTELLUNG										
	D Überbiss	M Vorbiss	O Offener Biss	T Tiefer Biss	B Bukkal-/Lingual-okklusion	K Kopfbiss/Kreuzbiss	E Engstand	P Platzmangel	A Kiefer-Gaumen-Anomalien	U Zahnunterzahl	S Durchbruchstörung
	 Obere Schneidezähne stehen vor	 Untere Schneidezähne stehen vor	 Schneidezahnkanten stehen ab	 Schneidezahnkanten überlappen	bukkal lingual normal normal 	Kopfbiss: Kreuzbiss: Schneidezähne stehen Kante auf Kante	 Kontaktpunktabweichung frontal	 Die Lücke (blau) ist zu klein, um einen weiteren noch durchbrechenden Zahn aufzunehmen	 Lippen-Kiefer-Gaumenspalte und andere Entwicklungsstörungen im Kopfbereich	 Zahn nicht angelegt	 Durchbruchstörung
KIG 3			2 bis 4 mm	über 3 mm mit traumatischem Zahnfleischkontakt		beidseitiger Kreuzbiss	3 bis 5 mm	3 bis 4 mm			
KIG 4	6 bis 9 mm	0 bis 3 mm	über 4 mm offener Biss durch schlechte Angewohnheit		Bukkal-/Lingual-okklusion	einseitiger Kreuzbiss	über 5 mm	über 4 mm		Unterzahl	Einschluss (außer 8er)
KIG 5	über 9 mm (bei Habit)	über 3 mm	über 4 mm angeborener offener Biss						komplexe Fehlbildungen		Verlagerung im Kiefer (außer 8er)

Source: IGES - Modified representation after dental Wiki [10]

Annotation: Green: A population, Orange: population B, Red: Population C

This is the one about the "Peer Assessment Rating" index (PAR Index PAR). This was fundamentally designed to evaluate the success of treatment, but is simultaneously also used in the measurement of deviations from the normal or ideal tooth position [11]. In validation studies it could be demonstrated that the PAR index has a good predictive value relative to the treatment need. The individual components of the index may be weighted to reflect country-specific views (z. B. Expertenmeinungen) [12]. According to Firestone et al. (2002a) [13] is given ≥ 17 an indication to an orthodontic treatment from a PAR. Furthermore, the "Index of Complexity, Outcome and Need" (ICON) as an instrument used to assess the need for treatment, the complexity of a case and the treatment of treatment success. A Behandlungsindikation if the ICON value is > 43 is. Treatment is considered successful if an ICON value is achieved < 31 [14].

A direct comparison between the CIC and the indices PAR or ICON is not possible. Therefore, both the CIC and the PAR index and the ICON were purchased switched according to the above limits for the definition of the population.

According to the common methodical procedure [8] the inclusion criterion was considered the population to be met if at least 80% of the Studienstiftung population corresponded to the above-described treatment indications. there were no information about the severity or even the type of malocclusion, the study in question was not included in the report.

intervention

In the underlying issue is principally spoken of orthodontic treatment measures. As part of the report were defined relevant interventions as therapeutic and diagnostic measures, which account for 80% of all completed orthodontic services at GKV-insured parties.

The basis for the identification of these services, the Abrechnungsstatistiken orthodontic services, which are published annually in the Yearbook of KZBV. The settlement orthodontic services between service providers and the individual statutory health insurance is performed via the Uniform Value Scale for dental services (BEMA-Z, hereinafter referred to as BEMA). If during the course of treatment additional dental services development necessary invoicing shall be performed on the Uniform Federal Specification II (BEL II). The services invoiced are evaluated annually by the KZBV and published. On the basis of the Yearbook 2017, settled with the primary and substitute funds in 2016 BEMA positions for orthodontic-specific services were analyzed for the present report. The most common services invoiced were differentiated by diagnostic and therapeutic services.

diagnostic measures in orthodontic medical history and diagnostic findings include elevation (general findings, extraoral- and intraoral findings, functional status). In addition, imaging techniques such as X-ray photography and are used to loading the tooth status, periodontium and the bone structures judging [2].

Most common measures of clinical diagnostics and consulting services are coded (eg. As BEMA position 01 "Thorough examination to DETERMI- of teeth, mouth and jaw diseases, including advice"), which are quietly zwin- necessary to the way to estimate the extent of further orthodontic treatment. These basic services were not entered into the present evidence-based analysis. The billing data showed that are used in addition to the basic services, in particular imaging in the framework of treatment planning and follow-up [15]. The following diagnostic services could be identified based on the number of billed BEMA positions, which account for 80% of the volume of services and were therefore analyzed within the report [16]:

- Photography, profile or en-face photograph (BEMA position 116)
- Impression, bite registration in habitual occlusion for creating three- dimensional models of the oriented upper and lower jaws (BEMA-PO sition 7a)
- Receiving part of the skull, panoramic (layer) recording (BEMA-position Ä 935)
- Cephalometric analysis (BEMA position 118)
- Recording of the skull (also cephalogram) (BEMA-position Ä 934)

therapeutic measures in orthodontic applications comprise essentially the extension of extra- and intra-oral devices. These have the aim lungs- a tissue remodeling or Zahnstel- means dosed force effects on the periodontium and bite position change to bring about [1]. Depending on the type and severity of the anomaly different orthodontic appliances are used. Due to the often complex therapeutic applications, the combination of equipment in the course of treatment and the long-term duration of therapy exist primarily undifferentiated settlement items, which are as partly also to upfront payments or extension is [15]. That is why a specific identification of the most commonly performed therapeutic treatment measures is only possible with the help of publicly available data, as they do not allow doubt to draw conclusions about the services individual services.

Due to the resulting lack of opportunity, the most common measures adopted to identify unequivocally therapeutic jaw-orthopedic interventions were intra- and extra-oral devices defined as relevant.

comparison intervention

The correct scientific approach provides in principle for the definition of a comparator / a comparator intervention. In the scope of the present question was tet dispense with the determination of a comparison intervention, as in the use of diagnostic and therapeutic treatment measures in the Orthodontic no validated gold standard depends exist on the degree of malocclusion. Thus, both studies were included in which the comparison intervention was no orthodontic treatment, as also studies the action types to compare different orthodontic loading the object.

outcomes

As explained were the focus of the investigation, the long-term effects of orthodontic treatment measures on the patient-tenrelevanten endpoints. Since the diagnostic and therapeutic interventions nen fundamentally different objectives within the framework of the treatment cycle followed comparable, different endpoints were defined.

diagnostic interventions develop their benefit or harm significantly by the subsequent therapeutic measures [8]. In the field of orthodontics relevant to the question of diagnostic procedures substantially at- tributable [17] are used to represent the anatomy of the patient and perform morphological measurements.

The goal of diagnostic procedures in orthodontics, therefore, the treatment is planning. As relevant endpoint because of its tersuchung in the present UN, the effect has been defined on the treatment planning.

therapeutic interventions are, as already described, valued at their me- dizinischen benefit and harm for the treated person. Much as the patient feels, how it can perceive its functions and activities, or whether he survived. For Both the intended and unintended effects of interventions into account [8]. In terms of orthodontic treatment and the present investigation particularly morbidity and health (oral) quality of life, the focus was. In previous studies the specifics of orthodontics in terms of the collection of patient-relevant end points were discussed. The primary goal of orthodontic treatment, the correc- tion of misalignments, leads only to a patient-relevant benefit if the long-term oral health is improved [4]. Therefore, in conducting studies ostensibly surrogate parameters are used to measure the short-term results.

To carry both the study and practice the criteria of evidence-based medicine in this study account both common surrogate parameters and patient-related clinical endpoints were defined as relevant endpoints.

In terms of morbidity, these are to:

- Patient-relevant endpoints
 - Caries
 - gingivitis
 - periodontitis
 - tooth loss
 - loosening of teeth
 - pain
 - root resorption
 - Unwanted events
- surrogate
 - Probing depth (Probing depth - PD)
 - Attachment level
 - Plaque Index (PI)
 - Gingival index (GI)
 - DMF-T-Index
 - DMF-S index
 - Community Periodontal Index (CPI)
 - Periodontal Screening Index (PSI)

Further, various indices were validated considered which allow an objective evaluation of the deformity and collection of a person's need for treatment. Using these indices, the results of a therapeutic, orthodontic intervention can be measured and be scientifically comparable orthopedic loading discoveries. These focus in particular malocclusion and their effects on dental health, but also include aesthetic and social components. The following indices were defined as part of the investigation as endpoints:

- Index of Orthodontic Treatment Need (IOTN)
- Index of Complexity Outcome and Need (ICON)
- Peer Assessment Rating Index (PAR)
- Dental Aesthetic Index (DAI)

Patient-relevant endpoints that quality of life, the oral health related or oral LE (Oral Health Related Quality of Life - OHRQoL) capture were considered only if they have been mapped using valid measurement instruments. The instruments vary depending on the population. For example, there for children and youth specifically adapted Befra- supply instruments.

The following instruments have been considered for the collection of OHRQoL:

- (Child) Oral Health Impact Profile (C) (OHIP)
- (Child) Oral Impacts on Daily Performances (C) (OIDP)
- Child Perception Questionnaire (CPQ)
- WHO Oral Health Questionnaire (Adults, Children)
- General Oral Health Assessment Index (GOHAI)
- UK Oral Health Related Quality of Life measure (OHQoL-UK)
- Global Self-Rating of Oral Health (GSROH)

As part of this opinion, the goal was only included studies that have collected the relevant endpoints after treatment because the appraisers followed to assess the long-term effects of orthodontic treatment [18]. End of treatment was defined as:

- Apparent completion of all treatment measures, including the retention period based on the study methodology or
- Identification of the survey timing in the study as the end of treatment or a specified period after the end of treatment.

The representation of the endpoints collected in the trials is due to its exclusively to T0 (baseline) and T1 (end of treatment).

study characteristics

In the investigation to question 1 find the criteria of evidence based medicine application. This is accompanied by the establishment of methodological inclusion criteria to be met by the included studies. In terms of research methodology, only studies the level of evidence Ia found to III into account [19]. This is specifically to:

- Ia: Systematic review of studies of evidence level Ib
- Ib: Randomized clinical trials (RCTs)
- IIa: Systematic review of studies of evidence level IIb
- IIb: Prospective comparative cohort studies
- III: retrospective comparative studies.

Studies with lower level of evidence, such as case series or expert opinion, were excluded.

One limitation of the publication period of the studies did not take place. In the report only studies were received, including a full publication existed which have been published in a scientific journal and were written in German or English. Abstracts, conference publications, study reports, dissertations, preliminary versions of publications and unpublished register data were not included. Such authority publications, quantitative, extractable and evaluable data were included also only contained.

2.2 Financial expenses of SHI and the legally insured parties (Question 2)

In Germany to date (date of July 1 2018) are approximately 72.8 million persons with statutory health insurance. [20] The conditions for the provision, the fielding scope of services and reimbursement of orthodontic measures for Versichertenpo- are pulation since 2004 explicitly defined by the Directive for orthodontic loading action. § 29 SGB V the insured described therein (Figure 1) only have the right to the conditions established by the dentist or dental diagnostic and therapeutic benefits. The scope of services is defined in the SHI and the BEMA BEL II. Objective of the above issue 2 is an illustration of the expenditure of the SHI obligations for orthodontic performance that are provided in accordance with § 29 SGB V.

Furthermore, to be analyzed, the degree to which take Insured benefits in claim, which go beyond the level of a sufficient, convenient and economic contract dental care. This must always be financed by the treated person himself. The billing of these diagnostic and therapeutic treatment measures via the fees for dentists (GOZ).

Basis for the analysis of monetary expenses of SHI and insured made publicly available statistics, fragungsstudien health economic studies, loading and routine data analysis. Since there was an issue with no international element was omitted research in international scientific databases. Instead websites of the German health system stakeholders and relevant Internetsuch- were machines used for research. Overlooking the legal basis for orthodontic care publications were included only contain data with reference year 2004 (entry into force of the orthodontic RL). It wur- the only documents in German or English language into account Untitled containing quantitative, extractable and evaluable data.

2.3 Research requirements (question 3)

After the current evidence and data regarding silicic ferorthopädischen care were treated in questions 1 and 2, the need for further Beforschung the subject to be evaluated afterwards. The basis for answering the question 3, the findings from the research processes and the identified studies on the previous analyzes of the benefits and the costs of orthodontics. Since this is a major concerns in statements to research requirements to qualitative information, the methodology of systematic text analysis Mayring [21] was applied.

Table 1: Summary of the basic requirements to issue 1 and 2

	Question 1	Question 2
population	<ul style="list-style-type: none"> Population A: children up to age 18, after the second phase of the dentition (late mixed dentition) with a need for treatment grade \geq 3rd Population B: patients anomalies with severe jaw, a orosurgical and -orthopädische treatment-requiring (eg congenital malformations of the overall brow and the jaw, skeletal malocclusions, injury-related Kieferfehlstellungen.) And a treatment degree of the demand A5, have D4, M4, O5, B4, K4. Population C: Children and adolescents before the second phase of the dentition (late mixed dentition) with a need for treatment degree D5, M4, M5, O4, O5, B4, K3, K4, P3. 	<ul style="list-style-type: none"> Population A: children up to age 18, after the second phase of the dentition (late mixed dentition) with a need for treatment grade \geq 3rd Population B: patients anomalies with severe jaw, a orosurgical and -orthopädische treatment-requiring (eg congenital malformations of the overall brow and the jaw, skeletal malocclusions, injury-related Kieferfehlstellungen.) And a treatment degree of the demand A5, have D4, M4, O5, B4, K4. Population C: Children and adolescents before the second phase of the dentition (late mixed dentition) with a need for treatment degree D5, M4, M5, O4, O5, B4, K3, K4, P3. take self-pay benefits in claim statutory health insured.
intervention	<ul style="list-style-type: none"> diagnostic measures <ul style="list-style-type: none"> O Photography, profile or en-face photograph (BEMA position 116) O Impression, bite registration in habitual occlusion for the Creating three-dimensionally oriented models of the upper and lower jaw (MA BE-position 7a) O Receiving part of the skull, panoramic (layer) uptake (BEMA-position Ä 935) O Cephalometric analysis (BEMA position 118) O Recording of the skull (also cephalogram) (BEMA-position Ä 934) therapeutic measures <ul style="list-style-type: none"> O Intra- and extra-oral devices 	<ul style="list-style-type: none"> SHI benefits under Bema and BEL II Self-pay services

Question 1		Question 2
comparison intervention		No restriction
endpoints	<p><u>morbidity</u></p> <ul style="list-style-type: none"> • Patient-relevant endpoints <ul style="list-style-type: none"> <input type="radio"/> Caries <input type="radio"/> gingivitis <input type="radio"/> periodontitis <input type="radio"/> tooth loss <input type="radio"/> loosening of teeth <input type="radio"/> pain <input type="radio"/> root resorption <input type="radio"/> Unwanted events • surrogate <ul style="list-style-type: none"> <input type="radio"/> Probing depth (PD) <input type="radio"/> Attachment level <input type="radio"/> Plaque Index (PI) <input type="radio"/> Gingival index (GI) <input type="radio"/> DMF-T-Index <input type="radio"/> DMF-S index <input type="radio"/> Community Periodontal Index (CPI) <input type="radio"/> Periodontal Screening Index (PSI) • need for treatment <ul style="list-style-type: none"> <input type="radio"/> Index of Orthodontic Treatment Need (IOTN) <input type="radio"/> Index of Complexity Outcome and Need (ICON) <input type="radio"/> Peer Assessment Rating Index (PAR) <input type="radio"/> Dental Aesthetic Index (DAI) 	Expenditure (€)

Question 1		Question 2
	<p><u>OHRQoL</u></p> <ul style="list-style-type: none"> • (Child) Oral Health Impact Profile (C) (OHIP) • (Child) Oral Impacts on Daily Performances (C) (OIDP) • Child Perception Questionnaire (CPQ) • WHO Oral Health Questionnaire (Adults, Children) • General Oral Health Assessment Index (GOHAI) • UK Oral Health Related Quality of Life measure (OHQoL-UK) • Global Self-Rating of Oral Health (GSROH) 	
study types	<ul style="list-style-type: none"> • Ia: Systematic review of studies of evidence-stage Ib • Ib: Randomized clinical trials (RCTs) • IIa: Systematic review of studies of evidence-stage IIb • IIb: Prospective comparative cohort studies • III: retrospective comparative studies 	<ul style="list-style-type: none"> • Publicly available statistics • Health economic studies • survey studies • Routine data analysis
Publication period	No restriction	
study language	German English	
Document type	Full publications in national and international journals	Full publications, study reports, PowerPoint presentations, statistics (Excel, PDF)

Source: IGES - Compiled

Third Methods of treatment

It was gistern a systematic review of the scientific literature using systematic literature searches in bibliographic databases and Studienre- and structured hand research conducted. The choice of metal thodik occurred (Table 2) in response to the questions previously defined.

Table 2: Overview of the applied research methodology per question

	Question 1	Question 2	Question 3
systematic search	x		Deriving from profit Nissen the Recher- chen for Fragestel- Lung 1 and 2
Structured manual search	x	x	

Source: IGES - Compiled

3.1 The actual search

3.1.1 bibliographic research

The aim of the systematic literature search in scientific databases and registers is the identification of internationally published literature, study-related. The recommendations of internationally recognized institutions arrival found application (eg. B. Cochrane Collaboration). The documentation of the methodological procedure was performed according to the specifications of the "Preferred Reporting Items for Systematic Reviews and Meta-Analyzes" - PRISMA statement [22]. A systematic search was conducted for the question first To ensure adequate mapping of the criteria described in Section 2.1 to warranty th, for the identification of evidence for diagnostic and therapeutic measures separate searches were carried out.

The systematic search to identify studies was according to the recom- mendations "Cochrane Handbook for Systematic Reviews nen to interventions" in the following bibliographic databases performed:

- MEDLINE,
- EMBASE and
- Cochrane Central Register of Controlled Trials (CENTRAL) [23]. Taking into

account the population, intervention defined (s) and end points developed a search strategy. were used for both preamble handles (MeSH terms and Emtree-term) and free text terms. These were imple- mented in OVID, which allowed access to all three bibliographic databases. The search strategies used are detailed, including the

Search terms used and the number of identified publications, documented in Table 14 to Table 16 in Appendix A1.

3.1.2 register Search

following trials register have been searched, environmentally grasp the dental studies:

- US National Institutes of Health Ongoing Trials Registry (ClinicalTrials.gov)
- World Health Organization International Clinical Trials Registry Platform (IC TRP)

The Cochrane Oral Health's Trials Register could not be searched as part of this report, since access to this exclusive Au- factors of Cochrane reviews is granted that are currently involved in the creation of a Cochrane review.

3.1.3 Manual search

Question 1

The hand search was conducted to run to identify scientific studies that

- have been published in international journals, which are not listed in the searched bibliographic databases, or
- which were published exclusively in German-speaking countries and published in national orthodontic journals. Furthermore, as part of the manual search individual studies were analyzed when:
 - were part of a systematic review, did not satisfy the inclusion and exclusion criteria used in the vorliegen- the certificate, or
 - were reported as the relevant literature in of register entries. Regarding the efficiency and benefits of orthodontic treatment measures including diagnostic measures were Literaturver- tories of identified through systematic research relevant study programs searched serving. In addition, a search in the following international and national journals. International Trade Journal:

- Seminars in Orthodontics
- Australian Orthodontic Journal

National scientific journal:

- Progress of orthodontics / Journal of Orofacial Orthopedics (organ of the German Society of Orthodontics)
- Dentistry up2date
- IOC - Information & of Orthodontics Orthodontics
- DZZ - German Dental Journal
- ZWR - The German Zahnärzteblatt
- zm - Dental Releases

For the following journals due to the lack of structured search capabilities of available online surfaces (eg no use of Boolean operators.) No search could be carried out:

- Clinical Orthodontics and Research
- Dental Magazine
- Oral Prophylaxis & Pediatric Dentistry (organ of the German Society of Pediatric Dentistry - DGKiZ)

this German and English keyword combinations were used depending on the research source. The strategies (Annex A2) listed were in accordance with the available search options on the home pages of magazines and publishing houses (eg. B. Use Boolean Operato- ren) adjusted.

Question 2

The hand search at the expense of the statutory health insurance and self-pay for kieferorthopädische services found using search engines instead of relevant (Google, Google Scholar). To research the advanced search interface of the platforms was used.

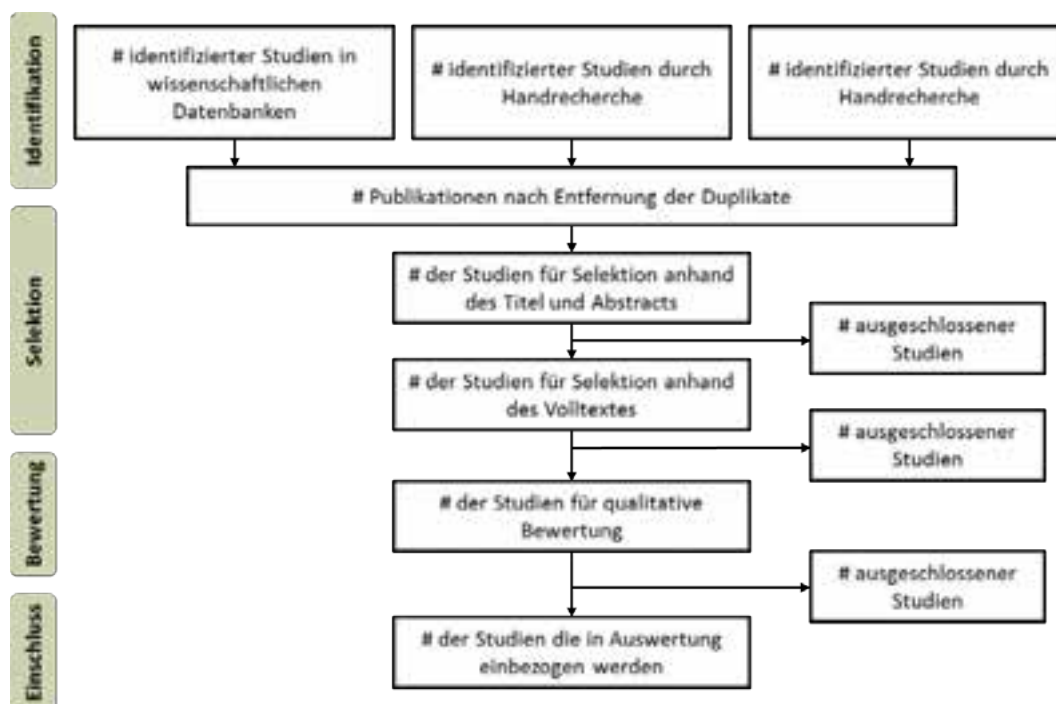
In addition, individual websites of stakeholders of the German health care system have been searched, associated with the orthodontic pensionable (z. B. BMG, KZBV, German Dental Association).

3.2 Selection of relevant studies

Identified in the bibliographic research, registry search and manual search studies on Question 1 were criteria taking into account the inputs and Ausschlusskri- previously defined in terms of their relevance to the issues examined independently by two people. The Studienselek- tion was carried out in two steps.

In the first step (Filter 1) first title and abstract of the study (filter 2) were tet gesich-, in the second step, the studies were based on the full-text is selected (Figure 2). In the case of discrepancies in the evaluation a third per- son was called in for decision.

Figure 2: Procedure for selection study



Source: IGES to PRISMA Statement [22]

For studies that were excluded due to the full text, specifying the reason for exclusion based on a predefined categorization (A1 done - population not met, A2 - does not fulfill intervention, A3 - not met Outcome, A4 - not met study type, A5 - No collection of endpoints after the end of treatment, A6 - publication language does not apply A7 - publication type does not apply (no full text), A8 - multiple publication, A9 - animal experiments hiring studies, A10 -No extractable results).

For Question 2, the selection of studies by a person carried. In the case of uncertainties in evaluating a second independent person was involved.

3.3 Assessment of study quality

The after the sighting of the full text (Filter 2) included studies were then evaluated using standardized checklists regarding their study quality. The selection of evaluation instruments were dependent on the level of evidence. the checklists of the Scottish Intercollegiate Guidelines Network (SIGN) were preferred as they are available for a wide range of Study- pen.

So exist SIGN checklists:

- Systematic reviews and meta-analysis
- Randomized controlled trials
- Cohort studies
- Case-control studies
- Diagnostic studies
- Economic studies (Scottish Intercollegiate Guidelines Network 2018).

The assessment of the studies was carried out by two people independently. A high risk of bias did not lead to the exclusion of a study, but was taken into account in the assessment.

3.4 data extraction

After the methodical assessment of study quality, the Datenextraktion was performed using standardized extraction forms. To extracting data environmentally grasp both important aspects of the study (population, intervention, study duration, inclusion and exclusion criteria, etc.) and the results in terms of the outcomes that were considered during the investigation. is also integral part of the data extraction, the identification of research needs (question 3). From the identified studies on the issues 1 and 2, the notes and statements were extracted to open research question and worked structured.

Data extraction was performed by one person. The extracted data were checked by a second person examined are and quality assured. Possible discrepancies were resolved through dialogue.

4th Results

The result presentation is differentiated by the underlying questioning settings. The systematic search in the three bibliographic databases took place on September 11 2018th The results for question 1, set the value and impact of orthodontic treatments DAR are explained ER separately for diagnostic and therapeutic measures.

4.1 Use and effectiveness of orthodontic treatment measures (Question 1)

4.1.1 diagnostics

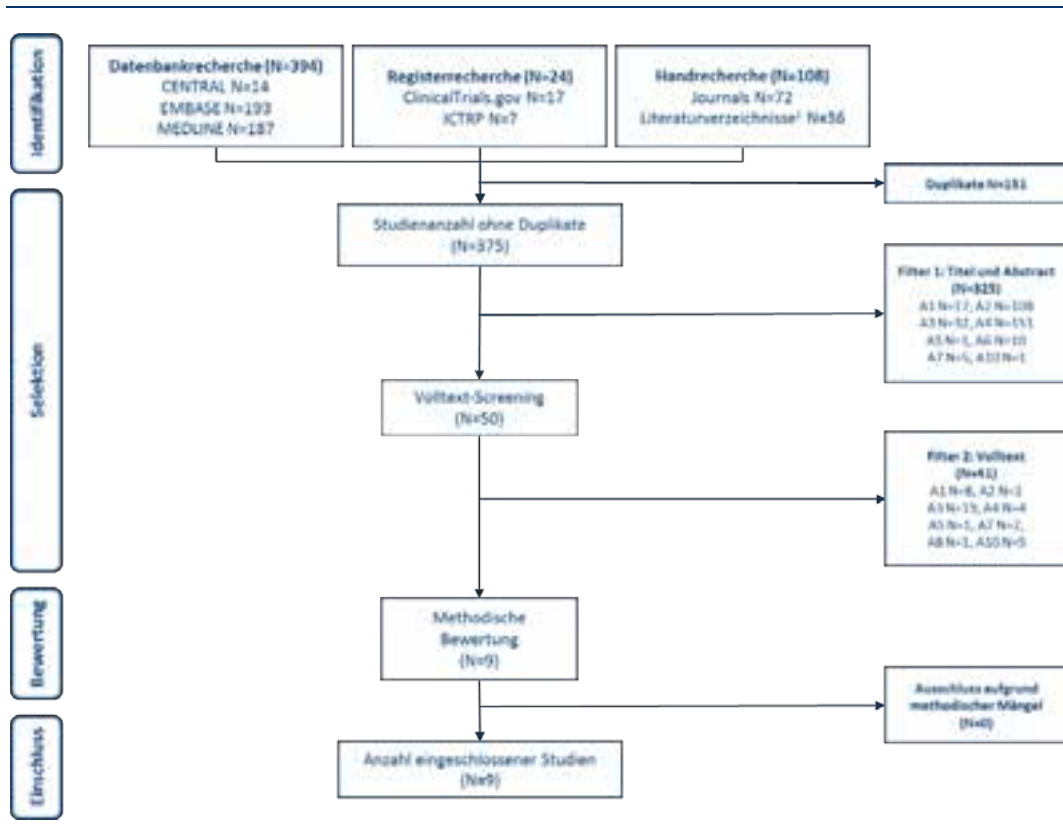
As part of the bibliographic research and the Registrar and Handrecher- che total of 526 references were identified. After removing the duplicates remaining 375 posts that went through the selection process. After screening the titles and abstracts (Filter 1) were evaluated 50 publications as potentially relevant. These were based on the full text appraised (Filter 2). Based on the predefined inclusion criteria as nine studies for the Fragestel- development could be relevant identified. These were subjected to a methodological assessment to determine the risk of bias. It was ruled no study up fundamentally poor quality. Instead, the findings were concerning. Study quality input into the discussion of the study results. The results of the selection process are shown in Figure 3 according to the specifications of the PRISMA statement.

Regarding the effects of diagnostic measures on the treatment planning a different operationalization showed over the nine included studies. In five of the studies, the compliance of orthodontists and orthodontists was respect.

the

Treatment decisions expressed as a percentage [24-28]. In one of these five studies, the indication of the kappa coefficient was additionally as a statistical measure of agreement for therapeutic approach [26]. In one study [29] the "Overall proportion of Agreement '(OPA) has been reported as a measure of fit. Rheude et al. (2005) [30] found changes in the treatment regimen, depending on the use of various diagnostic procedures [30]. In the study by Pae et al. (2001) [31] were asked the Working people involved at different times, different types of diagnostic images available against which they had pieplan from prescribed treatment options to create a THERA-. The results presented in the studies on the effects on the treatment planning are described in detail below. Further, Ta beauty can 3 shows an overview of the study results are taken.

Figure 3: PRISMA scheme - men Diagnostic orthodontic measures



Source: IGES - Compiled

Annotation: [†] Bibliographies of included in filters 1 systematic review and references in registry entries.

Exclusion criteria: - not fulfilled intervention, A3 - not fulfilled A1 -Population, A2 outcome is not met, A4 - not met study type, A5 - No collection of endpoints after the end of treatment, A6 - Publication language does not apply A7 - Publication type not applicable (no full-text), A8 - cation Mehrfachpubli-, A9 - animal studies A10 - No extractable results

Bjerklin and Ericson (2006) [27] analyzed the orthodontic Therapiepla- with planning and without the use of computed tomography (CT) in 80 children impacted with 113 or ectopic canines. In 39 children also was present root resorption on the incisors. T1 to the diagnosis and treatment planning was based on, inter alia, intra- and extra-oral photographs, pull the trigger dental, plain radiographs, panoramic radiographs, domestic traoralen radiographs and, if available, of Fernröntgenseitenbil- countries rather than through an investigator. At T2, about ten to twelve months later, the same doctor created a new treatment plan based on the original diag nostischen documents and additional CT scans. The addition of CT-education led in 35 people with 43 impacted canines, ie in 43.7% of cases, a change in the treatment plan. In patients that had a root resorption at the cutting teeth (n = 39), found at 21 people

(53.8%) a change in the treatment plan instead. For those individuals without additional root resorption treatment in 14 cases (34.1%) has been adjusted. Based on these results, the authors come to the conclusion that the CT investigation in this population an important tool in the creation of the treatment plan [27].

In a survey study by Botticelli et al. (2011) [24], NEN on the Kieferorthopädin-, orthodontist or dental personnel participating in orthodontic training, was evaluated how differences in the diagnostic benefits between two-dimensional and computer tomography by cone beam Com- (CBCT) are three-dimensional images produced. The aim was to evaluate the treatment decisions by eight Examine gutters and examiner for the same collective exercise on the basis of different Bilde-. were considered 27 people with Disturbed eruption of the canines, with a total of 39 dogs were evaluated by each examiner. All Examine gutters and investigators have obtained both the 2D and the 3D shots. In total, be assessed subjects rated 312 records for the 39 canines. With regard to the two-dimensional and three-dimensional images, a significant correlation ($p = 0.008$) of 70% with respect to the planned therapeutic procedure showed. Systematic differences were due to the fact that a two-dimensional representation e- unto conservative decisions (incl. Observation period) resulted. however, three-dimensional representations seemed to be associated with less conservative treatment decisions. A decision in favor of the ex-traction of the permanent canine and oral surgical treatment was hit more frequently based on the CBCT images. The study concludes that the use of 3D technology nen more interventions and less follow-up observations and non treatments led [24]. Durao et al. (2015) [25] examined the influence of the additional use of a lateral cephalometric radiograph (lateral cephalometric radio- graphy; LCR) development planning with regard to the diagnosis and subsequent treatment. The diagnostic records of 43 individuals with indication for orthodontic treatment were to happen to existing those selected from a pool. Ten orthodontists and orthodontists with un- differently long experience (range: 5 to 24 years) examined the diagnostic records and gave their decisions regarding the treatments in a questionnaire. For the first measurement time (T1) was (dellen illustration of Zahnmo-, panoramic radiographs, seven intra- and extra-oral four shots) assessing the diagnostic images without LCR. For the second Messzeitpunt (T2), the diagnostic material was added from T1 to the LCR, and there was a reassessment. coupling methods in relation to the treatment approved the investigating people agree in 64% of cases. Here, it was observed that those with the longest experience concord an over 80% achieved and a change in treatment planning to

T2 was made only in eight cases. Examine gutters and investigation cher, the other hand, had ten years of experience, achieved a compliance of 37%; a change in the treatment planning to T2 was performed in 26 cases. the authors conclude the study that most Kieferorthopäden- nen and consider orthodontist in the sample examined the LCR as important for the development of a therapeutic plan, this but apparently has no significant influence on orthodontic treatment planning [25]. In a study by Han et al. (1991) [28] evaluated the relevance verschiedener diagnostischer Studien auf orthodontische Behandlungsentscheidungen. For this purpose, tion process medical records of 57 individuals with a malocclusion Angle- class II / 1 were applied by means of a stratified randomized selectivity and evaluated by five female and male orthodontics. The persons to be treated had different stages der Zahnentwicklung: each 20 persons had a late mixed dentition or early permanent dentition and 17 had a permanent set of teeth. Folgende diagnostische Methoden wurden eingesetzt: study models or Zahnab- press (S), extraoral photographs (F), panoramic radiographs (P), laterales Cephalogramm (C) und Tracings der Cephalogramme (T). five combinations of these diagnostic records were submitted to a total of five orthodontists and orthodontists in the following sequences:

- 1. Sequence: S
- 2. Sequence: S + F
- 3. Sequence: S + F + P
- 4. Sequence: S + F + P + C
- 5. Sequence: S + F + P + C + T

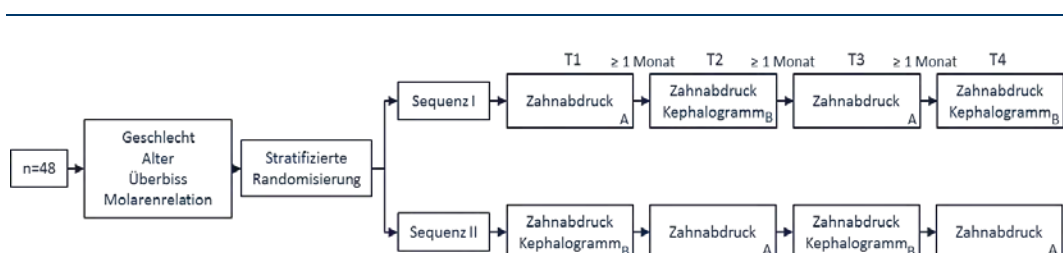
The fifth sequence and the simultaneous use of all diagnostic methods described was by Han et al. (1991) defined as "diagnostic standard". one session per sequence was scheduled for diagnosis and treatment planning for each assessor, which was a period of about a month between each assessment. was determined by the engrossing persons the rate per sequence, in which the combinations of diagnostic information sufficient to meet the "standard diagnostic". The following rates were determined: S = 54.9%, S + F = 54.2%, S + F + P = 60.9%, S + F + P + C = 59.9%. In respect of conformity with the "standard diagnostic" thus presented in 54.9% of cases the individual dental impression or the study model already adequate information for treatment planning. The supplement other diagnostic findings resulted in only slight differences. [28]

In the study of Manosudprasit et al. (2017) [26] was held a comparison of diagnostic and treatment decisions based on different diagnostischer Methoden. On the one hand, were of the conducting the study per-

sonen defined as a standard diagnostic images (including intra- and extra-oral photographs, dental impression, panoramic radiographs, cephalometri- specific x-rays) are considered, and the other three-dimensional dentofacial photogrammetric records were created. This was done in the course of treatment of 20 people. The diagnosis and treatment planning took the time T1 to twelve Examine gutters and investigators, and they were made available to the diagnostic standard material. Based on this, the diagnosis and treatment planning took place through a questionnaire. After four to six weeks, the same material was again, however, examined in conjunction with the 3D recordings. The average Liche match between the standard material and the 3D pictures was on average 72.1% in terms of treatment planning. Looking at the individual components of treatment planning, surrendered different matching rates and coefficients: In view of the need egg ner extraction compliance was 80.4% ($\kappa = 0.58$); When asked WEL cher tooth should be extracted, this was ($\kappa = 0.49$) at 67.8%. With respect to the desired position incisor in the maxilla or mandible congruences yielded 60% ($\kappa = 0.35$) and 59.6% ($\kappa = 0.34$). In the need for a surgical procedure, a percentage match of 87.5% ($\kappa = 0.63$) has been reported. The authors conclude that the necessity is for the use of 3D images depending on the severity of the Malokklu- sion. At low degrees of malocclusion 3D images do not appear to add extra value for the diagnosis and treatment planning to have [26]. Nijkamp et al. (2008) [29] conducted a randomized cross-over study on the influence of cephalometric radiography to the individual therapy planning by (Figure 4). In the examination, the diagnostic Aufzeichnungun- (6 mm inter alia overbite in Sagitta ler level of mind.) Went toward of 48 individuals with a malocclusion of class 2, which randomized stratified one of two diagnostic sequences have been assigned. The sequences differed in the type of diagnostic information that was examined points to the respective Erhebungszeit-. At any time formulated 14 investigators, including ten postgraduate orthodontic trained people and four silicic ferorthopädinnen and orthodontists, treatment plans using the available diagnostic data.

Figure 4:

Study design Nijkamp et al. (2008)



Source:

IGES according Nijkamp et al. (2008) [29]

The aim was firstly to evaluate the influence of the order of the expert appraisal of diagnostic images and other possible consequences in the treatment planning. Regarding the importance of the order of Betrach- of diagnostic images tung came Nijkamp et al. (2008) concluded that this had no effect on the results. With regard to the therapy plan were to be assessed physicians dichotomous three treatment options: functional treatment device (FUNC), rapid expansion of the maxillary fers (Rapid Expansion Maxillary; RME) and extraction (EXTR). The combination DIE ser dichotomous decisions (FUNC + RME + EXTR) formed the basis for the end point measurement. The treatment decision from the blocks A and B the wur- compared to T1 and T2. Only when the decision to Blö- blocks A and B for all three treatment modalities were identical, it was considered a concordance. The match each patient or patient was calculated as "Overall proportion of Agreement '(OPA). Thus, a means of OPA 0.5, that half of the examiner did not change the treatment plan based on the extended diagnostics. orthopaedists for the ten post-graduate orthodontists and maxillo the median OPA between the blocks A and B was 0.60, and had a span of 0.1-1 on. päden for the four orthodontists and Kieferortho- the median OPA was between Block A and B to 0.50 with a span of 0-1. Due to conclude Nijkamp et al. [29] that the additional use of cephalometric x-rays no influence on the change in the treatment planning for adolescents with malocclusion of class II [29].

In a study of Rheude et al. (2005) [30] the benefits of digital dental models compared with prints in plaster in terms of diagnosis and therapy planning compared. 30 people randomly selected with an indication for orthodontic treatment from a pool. In order to take into account the professional experience of the investigators as a possible factor, wur- the seven doctors divided into two groups. The first group were conces- shares with at least 15 years of professional experience investigator with less than 15 years of experience, the second group investigated person. At the time T1 to be assessed persons were the respective crane kenakten (medical, dental history, panoramic radiograph, kepha- lometrische radiography, extra- and intraoral photography) and digital dental models provided. Furthermore, they were given a standardized questionnaire for the diagnosis and were asked to provide a description of the topics rapieplanung based on digital dental models deliver. For assessment time T2, which took place within 30 minutes after T1, the investigators received the plaster casts in addition to the diagnostic material from T1. Arrival hand which was re-assessing and responding to the same ques- instead gebogens. A total of 49 treatment plans were created by the seven investigators. over

All investigators away were three from
49 treatment plans changed after the plaster casts were also evaluated. Overall, therefore, changed by adding the plaster models 6% of treatment plans. [30]

Pae et al. (2001) [31] investigated the role of lateral cephalometric images in the assessment of the difficulty of orthodontic cases. For this purpose, 80 medical records of previously treated individuals with un- terschiedlicher indication for orthodontic treatment (malocclusion Angle Class III malocclusion Angle Class II / 1, crowding, open bite and bimaxillary protrusion) of 16 orthodontists and orthodontists were at the ROWA , For the first time (T1) received the examined persons only dental impressions. For the second measurement time (T2) (at least one week later) were against it puts teeth marks and lateral cephalometric shots superiors. The Examine gutters and investigators were able to choose between different preset treatment options. Came several treatment plans into consideration, the orthodontist or the orthodontist for ER- folgversprechendste option should decide. The study author noted that T1 and T2 were significant differences in the group with bimaxillary protrusion (group 1) and persons with malocclusion Angle Class II / 1 (group 2) between the times. (67 vs. n = T2: T1 n = 127) in the first group, the extraction of premolars became T2 significantly more often selected. (N = 34 vs. T2: T1 n = 17) in the second group on the other hand to T2 significantly less for extraction of premolars, it was decided. From these results conclude Pae et al. (2001) that the use of a Kephalogramms in ER- supplement to a dental impression treatment planning significantly in relation to the extraction of teeth, depending on the indication influenced [31].

In the study of Whetten et al. (2006) [32] was analyzed how the use of digital dental models and conventional plaster models ged terschieden regarding the treatment decision. Surgical procedures, extractions and the use of auxiliary equipment leads. To this end, ten files of persons with malocclusion Angle class II were used. The diagnostic data included study models, extraoral images, Panoramaschichtauf- took and lateral cephalometric shots and were the kieferor- thopädischen Examine gutters and investigators submitted for evaluation. In the study, two groups of people be assessed were formed, an ex perimentalgruppe (n = 20) and a control group (n = 11). In the experimental group only orthodontists and orthodontists been entered in closed, who had no experience with digital dental models. had orthodontic medical staff development planning already has experience in the treatment of digital models, the control group zugewie- sen. The plaster models in conjunction with the other materials have been accepted as standard gold, should be compared against the digital models. Examine all gutters and investigators, a decision tree for encryption addition was made, were in which three treatment categories set out: sur- gery vs. no surgery; Extraction vs. No extraction and auxiliary equipment vs. no auxiliary equipment. To be assessed people in the experimental group were provided in the first session and digital models in the second session Gipsmo- delle. The control group received to the first and second session

only plaster models. At each meeting, which took place least at a distance of at one month developed the orthodontists and silicic ferorthopäden a treatment plan based on the decision tree. Overall, in the experimental group 400 assessments (200 per session) and in the control group 220 assessments were performed (110 per session). Regarding the matches of the treatment decisions between the two sessions were reported the following results for the experimental group: For the surgical procedures ($\kappa = 0.55$; $p = 1.000$; consensus: 0.775) for extractions ($\kappa = 0.57$; $p = 0.36$; match: 0.785) and for the use of Hilfsap- repairs ($\tilde{y} = 0.54$; $p = 1.000$; match: 0.870) extends showed no significant differences. , Extractions ($\tilde{y} = 0.626$; $p = 1.000$; Match: in the control group also no statistically significant changes in surgical procedures showed (0.836 accordance $\tilde{y} = 0.671$; $p = 1.000$):

0.818) and auxiliary equipment ($\tilde{y} = 0.672$; $p = 1.000$; Match: 0.873). The general common agreement in the experimental group (digital model vs. plaster model) was from 0.777 to 0.870; in the control group (plaster model vs. gypsum model) from 0.818 to 0.873. Based on the results attracted Whetten et al. (2006) that digital models had the résumé no significant effect on treatment planning.

Quick Facts

The focus of the investigation into the diagnostic orthodontic measures men the question of how the diagnostic applications have an impact on treatment planning was. In the evidence-based analysis of a total found studies including nine input. It was noticeable that in particular the CBCT standard- as three-dimensional imaging and digital dental models in the focus of the investigation and the established two-dimensional diagnostic methods were compared. is essential statement of a variety of studies that the nature and extent of diagnostic measures are largely dependent on the degree of malocclusion. So three-dimensional images with patients, for example, with breakthrough disorders of corner teeth represent for treatment planning [24, 27] an important study, whereas at low degrees of malocclusion the production of kephalo- metric recordings in addition to dental impressions does not significantly affect the treatment planning [25, 28, 29]. The analyzed studies were very heterogeneous in terms of both the evaluated methods as well as with regard to the Studienmetho- dik. Because of this, no final assessment can follow ER, the influence of individual diagnostic measures on the loading action planning and to what (additional) insights lead them.

Table 3: Overview of diagnostic orthodontic studies

Author, Year	study characteristics		outcomes	
	Study Setting / population	methodology		
Bjerklin et al., 2006 [27]	<ul style="list-style-type: none"> Number of persons / samples in the study: 80 Number of investigated person: 1 Diagnostic equipment: for CT: Siemens Somatome Plus CT scanner (Siemens AG, Erlangen, Germany) Instrument the outcome levying: k. A. Age [MW (SD)]: O Diagnosis 11.7 years (2.1 years); O Baseline 12.7 Years (2.6 years) Gender (m / f): 31/49 Indications for treatment: reticulo-defined and ectopic canines Diagnosis: O 39 people with Wurzelresorption of cutting teeth; while 57 dogs affected <ul style="list-style-type: none"> Palatal: n = 24 Buccal n = 17 	<p><u>diagnostic set 1</u></p> <ul style="list-style-type: none"> Intra- and extra-oral Bildaufnah- men working models + + + crane kenakte conventional X-ray panoramic and intraoral genaufnahmen + Röntgenaufnah- men + lateral Schädelauf- exception (if available) <p><u>diagnostic set 2</u></p> <p>Intra- and extra-oral image acquisition + Working models + Medical Record + radiographs + panoramic and intraoral radiographs + lateral Schädelauf- exception (if available) + CT-men Aufnah-</p>	<p><u>Diagnostic Method 1</u></p> <p><u>Individuals with root resorption of cutting teeth (n = 39)</u></p> <ul style="list-style-type: none"> Extraction of the two upper teeth: n = 6 No extraction: n = 9 Extraction of the first premolar ren: n = 6 	<p><u>Diagnostic Method 2</u></p> <p><u>Individuals with root resorption of cutting teeth (n = 39)</u></p> <ul style="list-style-type: none"> No extraction: n = 2 A canine and a lateral incisor removed: n = 2 A lateral incisor corresponds removed: n = 1 Premolars removed: n = 1 Extraction of the two lateral incisors: n = 6; Extraction of the two lateral incisors: n = 3 Extraction of the two lateral incisors: n = 2 a canine removed: n = 2 Extraction of the second premolar ren: n = 2 Extracting a canine and premolar three n = 1

Author, Year	study characteristics		outcomes	
	Study Setting / population	methodology		
	<ul style="list-style-type: none"> Central n = 16 <p>O 41 persons without Wurzelresorption of cutting teeth; while 56 canines affected</p> <ul style="list-style-type: none"> Palatal n = 24 Buccal n = 27 Central n = 5 <p>O 113 canines affected overall</p> <p>velvet</p> <ul style="list-style-type: none"> Palatal n = 48 Buccal n = 44 Central n = 21 		<p><u>Persons without root resorption of incisors (N = 41)</u></p> <ul style="list-style-type: none"> Extraction of the two upper incisors: n = 7 Extracting one of the upper incisors: n = 4 Extraction of both the upper first premolar: n = 2 Extraction of the first premolar ren: n = 1 	<p><u>Persons without root resorption of incisors (N = 41)</u></p> <ul style="list-style-type: none"> No extraction: n = 4 Extraction of the first premolar ren: n = 3 No extraction: n = 2 Extraction of the first premolar ren: n = 2 No extraction: n = 2 Extraction of a canine and premolar three: n = 1
Botticelli et al., 2011 [24]	<ul style="list-style-type: none"> Number of persons / samples in the study: <ul style="list-style-type: none"> O Persons n = 27 O Canines n = 39 O Data sets n = 312 Number of investigated person: 8 Diagnostic equipment: <ul style="list-style-type: none"> O 2D: DPT with Digora Optime System (Soredex, Tusuula, Finland) O 3D: CBCT with New Tom 3G Scanner (Quantitative radio logy srl, Verona, Italy); Instrument of the outcome levying Questionnaire Age [MW] = 11.8 Gender (m / f): 10/17 	<p><u>diagnostic set 1</u></p> <ul style="list-style-type: none"> each canine (n = 39): 2D Aufnahmen (panoramic radiograph, lateral skull uptake and periapical recording with different projections) <p><u>diagnostic set 2</u></p> <ul style="list-style-type: none"> 3D Cone Beam Computertomography (CBCT) 	<p><u>Compliance of the treatment decision</u> (2D vs. 3D) 70%, p = 0.008, significantly</p>	<p><u>Diagnostic Method 1</u></p> <p><u>Treatment decisions 2D</u></p> <ul style="list-style-type: none"> Extraction of the primary Eckzah- nes: n = 26 Observation, no treatment, n = 63 Extraction of the permanent canine: n = 6 Kieferchirurgische- / orthodontic treatment: n = 211 Surgical transplantation of the canine: n = 6 <p><u>Diagnostic Method 2</u></p> <p><u>3D treatment decisions</u></p> <ul style="list-style-type: none"> Extraction of the primary Eckzah- nes: n = 12 Observation, no treatment, n = 50 Extraction of permanent corner tooth: n = 15 Kieferchirurgische- / orthodontics sized treatment: n = 230 Surgical transplantation of the canine: n = 5

Author, Year	study characteristics		outcomes	
	Study Setting / population	methodology		
	<ul style="list-style-type: none"> Indications for treatment: breakthrough failure of the canines; Tion indicators for 3D evaluation 		<ul style="list-style-type: none"> Conformity of of assessment of the severity of the case: 46%; $P \leq 0.05$, significantly 	<ul style="list-style-type: none"> Conformity of the assessment of the severity of the case: 46%; $P \leq 0.05$, significantly
Durao et al., 2015 [25]	<ul style="list-style-type: none"> Number of persons / samples in the study: 43 Number of investigated person: 10, differences in experience (of professional experience: 5 to 24 years) Diagnostic equipment: k. A Instrument of the outcome levying Questionnaire Age [range]: 10-42 years Gender (m / f): 19/24 Indications for treatment: k. A. 	<p><u>diagnostic set 1</u></p> <ul style="list-style-type: none"> Evaluation of diagnostic images without Ke lateral phalometrie (LCR) <p><u>diagnostic set 2</u></p> <ul style="list-style-type: none"> Evaluation of diagnostic images included lateral cephalometric (LCR) 	<p><u>Match / change in treatment decision</u></p> <ul style="list-style-type: none"> Changing the treatment decision: 36% of cases Investigators with the most experience (24 years): 80% conformity Investigator with 10 years experience: 37% compliance <p><u>Compliance of the treatment decision on the question.</u></p> <ul style="list-style-type: none"> F 4: "The following treatment is carried out: Orthopedic growth tumorsmodifikation, orthognathic surgery or dentoalveoläre COMPENSATION" = 64% F 6: "Would you consider the patient's teeth, if so, what?" = 56% F 7: "Would you expand the upper arch?" = 58% F 8: "Would you anchor in the upper or lower jaw anbrin- gen"; maxillary = 58%; mandibular = 67% Q 9: "Do you expect during treatment complications?" = 65% 	
Han et al., 1991 [28]	<ul style="list-style-type: none"> Number of persons / samples in the study: 57 Number Investigator: pädinnen 5 Kieferortho- and odontologists Diagnostic equipment: k. A. Instrument of the outcome levying: Decision Tree Age: k. A. Gender (m / f): k. A. Indications for treatment: NEN personnel with Class II, Division 1 	<p><u>5 combinations of the diagnostic data</u></p> <ul style="list-style-type: none"> 1) S 2.) S + F 3.) S + F + P 4) S + F + P + C 5.) S + F + P + C + T (down as a diagnostic standard) 	<p><u>Reaching the diagnostic standards (rate)</u></p> <ul style="list-style-type: none"> S: 54.9% S + F: 54.2% S + F + P: 60.9% S + F + P + C: 59.9% <p><u>Percent agreement between sessions</u></p> <p>(All investigators MW all groups):</p> <ul style="list-style-type: none"> Session I: 55% Session II: 55% Session III: 65% 	

Author, Year	study characteristics		outcomes
	Study Setting / population	methodology	
	malocclusion; 3 groups after use bit status: <ul style="list-style-type: none"> (A) late mixed dentition (n = 20) (B) early permanent dentition (n = 20) (C) Adult teeth (n = 17) <ul style="list-style-type: none"> diagnostic data <ul style="list-style-type: none"> O Record 1: Study Models (S) O Record 2: extraoral Photo recordings (F) O Record 3: Panoramaröntgenaufnahme (P) O Record 4: lateral Zephalometrie (C) O Record 5: Tracing (T) 	Time interval between the sequences ca. 1 month	<ul style="list-style-type: none"> Session IV: 60%
Manosud-Prasit et al., 2017 [26]	<ul style="list-style-type: none"> Number of persons / samples in the study: 20 Number examiner: 12 <ul style="list-style-type: none"> O Member of the orthodontic's department: n = 6 O Completion of at least 18 months long assistance medical program: n = 6 Diagnostic equipment: <ul style="list-style-type: none"> O 3D images extraorally: Vectra M3 imaging system 	<p><u>diagnostic set 1</u></p> <ul style="list-style-type: none"> Standard receptacles (intra- and extra-oral photographs, dental impression, Panoramaröntgenaufnahme, cephalometri- specific X-ray with ordered cing) <p><u>2 diagnostic set (after 4-6 weeks)</u></p> <ul style="list-style-type: none"> Standard recordings + 3D up measures 	<p><u>Percent agreement treatment decisions</u></p> <p>(Standard vs. 3D): MD = 72.06%</p> <p><u>individual questions</u></p> <ul style="list-style-type: none"> "If a tooth extraction necessary?" = 80.42% (κ = 0.578) "Which tooth has to be pulled?" = 67.8%, (κ = 0.489) "Target for incisor position in the upper jaw" = 60%, (κ = 0.353) "Target for incisor position in the lower jaw" = 59.58% (κ = 0.341) "Is surgery necessary?" = 87.5%, (κ = 0.633) "Treatment time (less or more than one year)" = 77.08% (κ = 0.457)

Author, Year	study characteristics		outcomes
	Study Setting / population	methodology	
	<p>(Canfield Imaging Systems, Fairfield, NJ)</p> <p>O 3D images dental: Ortho</p> <p>insight scanner (Motion View software, Chattanooga TN)</p> <ul style="list-style-type: none"> Instrument of the outcome levying Questionnaire Age: k. A. Gender (m / f): k. A. Indications for treatment: k. A. 		
Nijkamp et al., 2008 [29]	<ul style="list-style-type: none"> Number of persons / samples in the study: 48 Number of study: 14 O Postgraduate orthodontics Dinside / orthodontist: n = 10 O Orthodontists / maxillary orthopedist: n = 4 Diagnostic equipment: Zephalomet- rie was digitized from usage-view box © 1.9 Software (dhal Kifissia, Greece) Instrument of the outcome levying Questionnaire Age [range]: 11-14 years Gender (m / f): 24/24 Indications for treatment: <ul style="list-style-type: none"> Bilateral Class II buccal segment relationship of more 	<p><u>diagnostic set 1</u></p> <ul style="list-style-type: none"> dental impression <p><u>diagnostic set 2</u></p> <ul style="list-style-type: none"> Dental impression + + cephalometric cephalometric analysis 	<p><u>Overall proportion of agreement (OPA)</u></p> <ul style="list-style-type: none"> OPA AB postgraduate = 0.60 [Min 0.10; Max 1], not significant OPA AB orthodontist / orthodontist = 0.50 [Min 0; Max 1], not significant

Author, Year	study characteristics		outcomes
	Study Setting / population	methodology	
	<p>wide than half a hump when the primary lower second molars were still present)</p> <ul style="list-style-type: none"> ○ Bilateral Class II buccal segment relationship of at least half a cusp width when the permanent teeth had erupted in the lateral segment elements ○ Overbite of 6 mm or more ○ No kranofazialen or dental malformations and no loss of teeth • Data collection: 2 sequences: <ul style="list-style-type: none"> ○ I. T 1 (A), T 2 (B), T 3 (A) 4 T Z (B) ○ II. T 1 (B), T 2 (A) T 3 (B), T 4 (A) <p>(1 period between T1, T2, T3, T4 respectively min. A month) (Figure 4)</p>		

Author, Year	study characteristics		outcomes
	Study Setting / population	methodology	
Pae et al., 2001 [31]	<ul style="list-style-type: none"> Number of persons / samples in the study: 80 files Number examiner: 16 Kieferorthopäden / orthodontist O Experience [MW; Range; Median]: 11.4 years; 1-35 years; 7 years Diagnostic equipment: k. A. Instrument the outcome levying: k. A. Age [MW (SD)]: 16.4 ± 6.16 years Gender (m / f): 61/39 Indications for treatment: <u>5 subgroups</u> <ol style="list-style-type: none"> Class I malocclusion with crowding light (n = 14) Second Class II malocclusion loading rich 2 (n = 17) Third Class III malocclusion (n = 16) Open bite (n = 18) Bimaxillary protrusion (n = 15) 	<p><u>diagnostic set 1</u></p> <ul style="list-style-type: none"> models <p><u>diagnostic set 2</u></p> <ul style="list-style-type: none"> Models + lateral Cephalometrie + Assessment "severity" = degree of deviation from standards malocclusion and "difficulty" = to reach a malocclusion standards, the probability; <p>minimum time interval between 1 and diagnostic set diagnostic set. 2 a WO-che</p>	<p>Significant differences:</p> <p><u>Subgroup 2: Class II area 2</u></p> <ul style="list-style-type: none"> Decision for "4-premolar" Extraction: O DIAGNOSTIC 1: n = 34 O DIAGNOSTIC 2: n = 17 Decision for non extraction: O DIAGNOSTIC 1: n = 45 O DIAGNOSTIC 2: n = 51 <p><u>Subgroup 5: Bimaxillary protrusion</u></p> <ul style="list-style-type: none"> Decision for "4-premolar" Extraction: O DIAGNOSTIC 1: n = 62 O Diagnostic set 2: n = 127 Decision for non extraction: O DIAGNOSTIC: n = 126 O DIAGNOSTIC 2: n = 80
Rheude et al., 2005 [30]	<ul style="list-style-type: none"> Number of persons / samples in the study: 30 randomly selected cases, of which 7 are selected for loading gutach device (by the American Board of Orthodontics case record criteria) by investigated person 	<p><u>diagnostic set 1</u></p> <ul style="list-style-type: none"> Act (medical, dental history, panoramic X receptive, cephalometric radiograph, extra- and intraoral photography) + digital models 	<p><u>Change the treatment plan</u></p> <ul style="list-style-type: none"> Difference between diagnostic set 1 and diagnostic set 2 (p = 0.05) Difference in n = 3 (the same case concerning) <p><u>Change the proposed mechanical method of treatment</u></p> <ul style="list-style-type: none"> Difference between diagnostic set 1 and diagnostic set 2 (p = 0.05)

Author, Year	study characteristics		outcomes
	Study Setting / population	methodology	
	<ul style="list-style-type: none"> Number of investigated person: 7; divided by the experience of the examiner O Group 1: <15 years of experience O Group 2: ≥ 15 years Berufser- experience Diagnostic equipment: creating the digital model with geo digmy Instrument of the outcome levying Questionnaire Age: k. A. Gender (m / f): k. A. Indications for treatment: k. A. action plans 49 loading: Number of persons in Analysis 	<p><u>diagnostic set 2</u></p> <ul style="list-style-type: none"> Medical Record + digital models + Plaster models 	<ul style="list-style-type: none"> Difference in n = 6 (by 3 investigators / s) <p><u>Group differences between examiner groups</u></p> <ul style="list-style-type: none"> No statistically significant differences (p = 0.05) rule for the number of changes of the treatment plan and the treatment method proposed mechanical

Author, Year	study characteristics		outcomes	
	Study Setting / population	methodology		
Whetten et al., 2006 [32]	<ul style="list-style-type: none"> Number of persons / samples in the study: 10 files Number examiner: 2 groups <ul style="list-style-type: none"> Intervention group: n = 20; Inclusion criteria: no experience with digital Models Control group: n = 11; experience stanchions with digital model len Diagnostic equipment: digital Model: Geodigm Corporation Instrument of the outcome levying Questionnaire Age: k. A. 	<p><u>intervention group</u></p> <ul style="list-style-type: none"> Session 1: Digital Models Session 2: plaster models <p><u>control group</u></p> <ul style="list-style-type: none"> Session 1: plaster models Session 2: plaster models <p>Time interval between sessions: at least 1 month.</p>	<p><u>Diagnostic Method 1</u></p> <p><u>intervention group</u></p> <ul style="list-style-type: none"> Surgical procedure: not significantly (p = 1.00, κ = 0.549, = 0.775 accordance) Extraction (p = 0.360, κ = 0.570; Match = 0.785) Braces (p = 1.00, κ = 0.539; Match = 0.870) 	<p><u>Diagnostic Method 2</u></p> <p><u>control group</u></p> <ul style="list-style-type: none"> Surgical procedure: not significantly (p = 1.00, κ = 0.671, = 0.836 accordance) Extraction (p = 1.00, κ = 0.626, = 0.818 accordance) Braces (p = 0.791, κ = 0.672, = 0.873 accordance)

Author, Year	study characteristics		outcomes
	Study Setting / population	methodology	
	<ul style="list-style-type: none"> Gender (m / f): k. A. Indications for treatment: class II malocclusion Number of people in analysis: Intervention group: n = 400 assessments (200 per session) control group n = 220 assessments (110 per session) . Standard recordings regarding diagnostics market tik: files including working models, late-rare cephalometric, tracing, ramaröntgenaufnahme pan-, intra- and extra-oral photography. 2 evaluation sessions: O Baseline (T0): Standard recordings + digital model or plaster model O 1 month after the start of the study (T1): Standradaufnahmen + digital model or Gipsmo- dell (opposite of T1) 		<ul style="list-style-type: none"> Overall compliance 0.777 to 0.870 for digital vs. gypsum model Overall Accord 0.818 to 0.873 for plaster model vs. plaster model

Source: IGES - Compiled

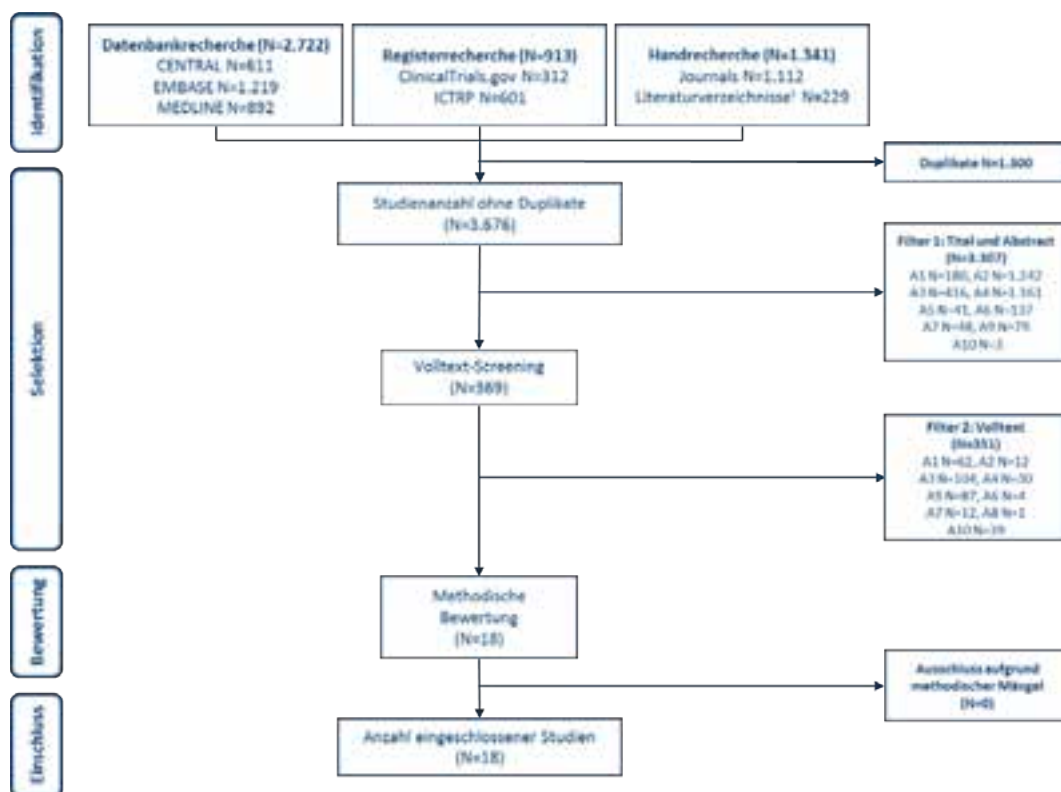
4.1.2 therapy

Total could regarding orthodontic treatment procedures with the bibliographic database search, register research and manual search

4976 references are identified. After removal of 1,300 duplicates loading up the hit resulted in 3,676 publications.

As part of the selection of the 3676 hit based on the title and abstracts (Filter 1) were evaluated 369 publications as potentially relevant. these 369 publications were less on step in the second filter based on the full text. 18 studies were ultimately included in the present report. This was followed by a review of these publications in terms of methodological quality. A high risk of bias did not lead to the exclusion of a study, but was taken into account when interpreting the results. According to the methodological guidelines of the PRISMA statement is found in Figure 5 an overview of the selection process for the therapeutic orthodontic interventions.

Figure 5: PRISMA scheme - Therapeutic orthodontic measures



Source: IGES - Compiled

Annotation: ¹ Bibliographies of included in filters 1 systematic review and references in registry entries.

Exclusion criteria: - not fulfilled intervention, A3 - not fulfilled A1 -Population, A2 outcome is not met, A4 - not met study type, A5 - No collection of endpoints after the end of treatment, A6 - Publication language does not apply A7 - Publication type not applicable (no full-text), A8 - cation Mehrfachpubli-, A9 - animal studies A10 - No extractable results

In seven of the 18 identified studies it was intervention studies in which various intraoral or extraoral orthodontic devices to treat a malocclusion were compared [33-39]. In four studies [40-43], the focus on the comparison of early treatment was development, beginning in childhood with mixed dentition and with a later treatment in adolescents with permanent dentition. Six of the included publications considered both a treated and a non-treated population [44-49]. For all other studies either both the Inter- were Preventions- and the control group treated immediately with a temperature orthodontic on apparatus, or it was the methodology of the waiting group [38, 39, 43] applies reasonable.

The presentation of the results are measured according studies investigated the parameters of the oral health, and those which inquired oral quality of life or determined the success of treatment using various indices. A detailed overview of the studies in terms of their methodology and the expertise relevant results in Table 4 can be removed.

4.1.2.1 oral health

Four parameters detected by 18 included in the report publications related to oral health [34, 40, 45, 50]. This is a major indices that capture the oral health and periodontal disease. These include the gingival index (GI), probing depth (probing depth PD), plaque index (PI), the Decayed-Missing Filled Teeth-index (DMFT), the Decayed-Missing-Filled- Surfaces index (DMFS) and information on the extent of external apical root resorption and Inziden- zen to dental injuries.

Under an RCT Atik and Ciger led (2014) [34] a comparison of two treatment systems, the Roth-bracket system and the Damon 3MX system, through. A total of 33 female patients were aged 13 to 17 annual reindeer in part with moderate crowding in the upper and lower jaws in the investigation. 17 persons of the group were zugwiesen with Roth-bracket system and 16 persons of the group with Damon 3MX system. The study participants with Roth-bracket system had a median crowding in the upper jaw of 3.5 mm (2.4 to 6.0 mm) and in the lower jaw of 3.4mm (2.3 to 4.6 mm), while patien - tinnen with Damon 3MX bracket system for baseline a median crowding in the upper jaw of 3.5 mm (2.4 to 6.2 mm) and in the lower jaw of 3.9 mm (2,3-

5.5 mm) exhibited, which corresponds to a KIG stage. 3 collected the three fol-

constricting clinical variables at baseline and at the end of treatment: GI, PI and PD. For the group with Roth system, the median treatment duration was 15.3 lung (10.0 to 23.0) and for the group with Damon 3MX System 13.2 (10.0 to 22.0) months. After the end of treatment, the average mean change in GI for patients that have been punched with the behan- with Roth-bracket system with MW = -0.08 (SD: 0.62), the mean change of the PI at MW = 0 , 23 (SD: 0.52) and the average change in PD during MW = 0.25 (SD 0.35). For patients who received treatment with the Damon 3MX system, the corresponding values were for the GI with MW = 0.16 (SD 0.39) for the PI in MW = 0.17 (SD 0.45) and for the PD at MW = 0.12 (SD 0.27). In terms of periodontal parameters No significant differences were be- tween the two treatment systems are found. Atik and Ciger (2014) conclude that the Damon 3MX System and the Roth-Bracket- system divorced only in terms of the achieved inclination of the upper molars lower [34].

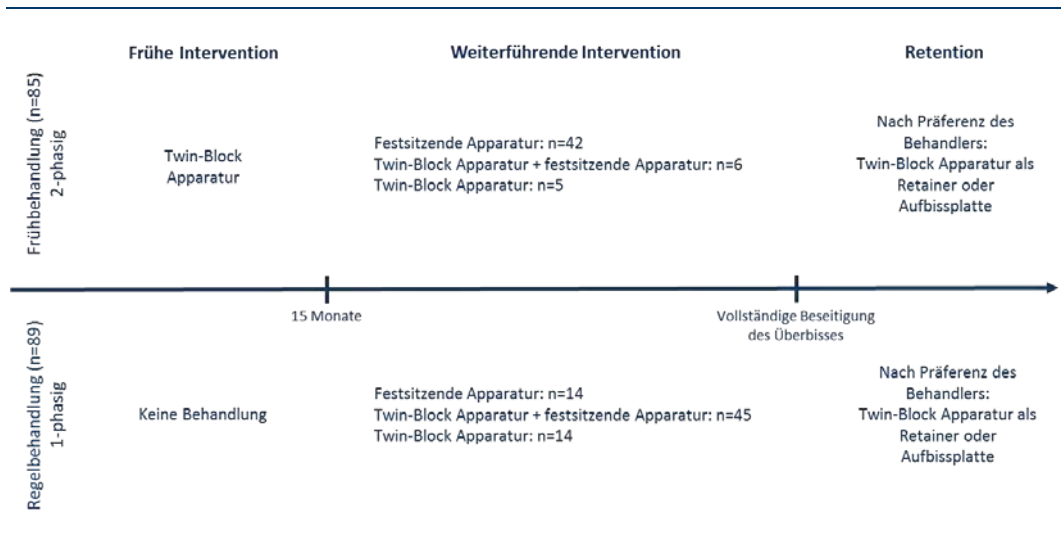
Bonde Mark et al. (1998) [45] conducted a prospective, controlled study over a period of five years. The interest for the report flat fees chargeable parameters were indices for caries prevalence (DMFT, DMFS) at the end of treatment. At the beginning of 40 people were included in the study. Groups of 20 young people have been assigned to a group with orthodontic and a group without orthodontic treatment (control group). The person-intervention group had baseline a lack of space between

3.0 mm and 5.5 mm (ISCC stage 3) and a frontal overbite in the vertical plane (MW: 5.6 mm, SD: 1.26 mm, KIG stage 2/3) and were on average MW = 14.3 (SD: 2.0) years old. The study participants and study participants in the control group had no development indication for orthodontic treatment and were on average MW = 14.3 (SD: 1.9) years old. At baseline the DMFT and DMFS of the intervention group were at a MW = 3.8 (SD: 3.1) or in a MW = 0.5 (SD 1.2). For the control group, however, the DMFT and DMFS were at a MW = 3.3 (SD: 3.4) or a MW = 0.7 (SD: 1.2). The differences between the two groups were not significant at baseline. The follow-up of 5 years, the intervention group had a DMFT of the MW = 4.4 to (SD: 3.4) and a DMFS of the MW = 0.8 (1.9 SD). The corresponding values to the control group amounted to DMFT on average 3.9 (SD 2.9) and for DMFS in the central 1.1 (SD 1.2). At the end of the study, no significant differences between the two groups could be detected [51]. The investigation is based on medical records of Brin et al. (2003) [40] inkludi- erte patients who had previously participated in an RCT for orthodontic treatment and completed a treatment phase with fixed appliances. In the first group, consisting of 54 children's the age of 11.95 ± 1.12 years (mean \pm SD) and an overbite in the sagittal plane springs (mean \pm SD: 8.94 ± 1.84 mm, KIG stage 4) a single-stage treatment was carried out with fixed braces. In the second group was a two-step protocol

-stage treatment with headgear, and then fixed braces BE DONE (n = 50 men children, age mean \pm SD: 12.14 ± 1.08 years; overbite in the sagittal plane: MW \pm SD: 7.81 ± 2.48 mm, KIG -Level 4). In the third group of treatment was development phase with a fixed appliance, treatment with a Bionator upstream (n = 41; age mean \pm SD: 12.21 ± 0.96 years; overbite in the sagittal plane: MW \pm SD: 5.38 ± 2.67 mm). The aim of the study was to investigate the Association of predisposing factors such as the treatment plan and later external apical root application (External Apical root resorption, EARR) at central and lateral incisors. In the case of persons who were originally treated single stage with fixed braces (Group 1, n = 49) had 22% of the incisors no EARR, 60% mild and 19% EARR a moderate to severe EARR. In individuals in Group 2 (n = 49) were treated with a fixed appliance with headgear and data to, 15% of the incisors had no EARR, 72% mild EARR and 13% of a moderate to severe EARR on. The patient reports that paratur in advance of the fixed Ap Bionator a given (Group 3, n = 40) had 28% no EARR IH rer incisors, 78% mild EARR and 5% a moderate to severe on EARR, The authors conclude that the treatment regimen has by no nen direct impact on the extent of root resorption. The RCT by O'Brien et al. (2009) [50] compared a premature and a Regelbehand- development in terms of dental trauma occur. Under investigation were 174 children on average at baseline in the early treatment group

9.7 (SD: 0.98) and in the waiting control group 9.8 (SD: 0.9) were years old. It wur- the 48 boys and 41 girls in the group with early treatment, and 46 boys and 39 girls studied in the control group. All Studienteilnehmerinnen and study participants had to have an overbite of at least 7 mm, which corresponds to a KIG stage. 4 Both groups received as intraoral les device for correcting the misaligned teeth, a twin-block apparatus. The youth union of the control group received this therapy only 15 months after study programs serving onset (Figure 6).

Figure 6: Study Design O'Brien et al. (2009)



Source: IGES by O'Brien et al. (2009) [50]

Ten years after baseline 8% of the participants reported the early treatment group new dental injuries (z. B. damaging the enamel), in the waiting control group 14%. The difference between the two groups was not statistically significant ($p = 0.36$). O'Brien et al. (2009) came to the conclusion that early treatment is not time effects to significant long against the rule treatment results. Furthermore, a two-phase treatment with serious hardship was associated, such as increased costs, a longer duration of treatment and a worse final occlusal result [50].

None of the included studies long-term patient-relevant end points were as tooth loss, tooth mobility, pain or oral health-related quality of life captured.

4.1.2.2 Oral quality of life

Among the 18 included studies were four studies in which oral LE was investigated quality of life. In these studies, a [33, 44] or two [46, 49] validated questionnaires were used. To measure the quality of life mundgesundheitsbe- covered various measuring instruments were used. In a prospective cohort study of Agou et al. (2011) [44] participated 199 children's between 11 to 14 years, was indicated for orthodontic treatment. The intervention group of 98 people (baseline) was kieferor- thopädisch treated (including 44.2% due to debilitating malocclusion, 25.7% with severe malocclusion, 23.9% with a significant malocclusion and

6.2% with mild malocclusion). Children who have not started treatment, served as controls ($n = 101$ at baseline). Quality of life was detected from the developed specifically for children and young people CPQ11-14.

For this, the participants in the intervention group were ten GeBE, at baseline (T0) and at the time of the first inspection appointment after treatment (T1) to answer the questions of CPQ11-14. The data of the control group were collected at comparable times. It also charged at both times also the psychological well-being based egg ner subscale of the questionnaire. Total follow-up data were available for 118 children from (74 children in the intervention group and 44 children in the control group). The evaluation for children with values at both time points showed for the group of children treated a significant improvement in quality of life: At the time T0 the children in the intervention group reported an overall average score of 21.63 (SD: 14.19) on the time T1 was the score at 16.16 (SD: 10.99). The difference was statistically significant ($p < 0.01$). however, the difference in quality of life scores in the group of children who were not yet orthodontic treatment, was not significant (T0: 24.07 (SD: 16.5) vs. T1:

23.14 (SD: 17.97). The present results on quality of life were of Agou et al. (2011) as a function assessed by the mental well-being. DA by this assume that children with higher mental well-being find basically report a better quality of life, regardless of their orthodontic treatment status [44].

In another prospective cohort study by Antoun et al. (2015) [33] wur- the patients to their quality of life before (T0) and after orthodontic or surgical intervention (T1) based on the OHIP-14 loading asks. The cohort consisted of 83 consecutive individuals were assigned depending on the indication of one of the following three intervention groups: Intervention Group 1: severe malocclusion and orthodontic treatment (30 persons, mean age 14.5 years), Intervention Group 2: Heavy skeletal Diskre - Panzen and orthodontic / -chirurgische therapy (29 people, average age 19 years), intervention group 3: cleft lip / cleft palate / lip and palate and orthodontic treatment (24 people, average age

12.6 years). For patients in the intervention group 2 O was compared HIP-14 score at baseline for most of the items about twice as high with the other two intervention groups and significantly different ($p < 0.05$). MW 19.52 (SD: MW: For these individuals, the quality of life improved after the intervention ($p < 0.01$) compared with the baseline values for all the items most clearly (T0 9.62) vs. T1 2, 03 (SD: 3.13)). For the group of "standard person" (Group 1) Whole also resulted in a significant improvement of the mean OHIP-14 scores of 11.60 (SD: 10.93) at baseline compared to 3.83 (SD: 5.04) treatment at the time after the loading ($p < 0.01$). Regarding the individual items that improvements in the following areas were significant: "physical pain" ($p < 0.05$), "Handicap" ($p < 0.05$), "psychological discomfort" ($p < 0.01$) as well as "mental impairment" ($p < 0.01$). Antoun et al. (2015) conclude that patients and paper tienten receiving an orthodontic treatment in combination with an ortho gnatischen operation, compared with relatively poor output values

Standard persons or patients with cleft lip and / or palate benefit most from the treatment [33].

To what extent malocclusion and their treatment have an impact on oral quality of life, examined Taylor et al. (2009) [49] based on a cohort of 293 children aged 11 to 14 years. The following groups were compared: Intervention Group 1: people who have completed domestic orthodontic treatment, intervention group 2: people in need, but not yet successful orthodontic treatment and a control group, which consisted of children who have not completed, ongoing or planned orthodontic treatment. The children of all the groups were asked to answer two questionnaires for oral quality of life, on the one hand the COHQoL, on the other hand the YQoL. From the latter questionnaire that was used to assess the overall quality of life, two of the 40 questions were deleted since they were the eingeschlossene adolescents with no relevance for the age group in the study. The answers to the questionnaires carried out either prior to the start of treatment (group 2), on completion of orthodontic treatment (group 1) or in front of a dental routine examination (control group). As a result, no differences between the groups of the cohort showed quality of life either in terms of the general nor the oral of life. Overall, Taylor et al. (2009) stated a high quality of life in the study participants and study participants [49]. A cohort of 1,675 randomly selected students aged between 15 and 16 years was questioned quality of life for its mouth-related life by de Oliveira and Sheiham (2004) [46]. The subjects were classified according to their orthodontic treatment status of the following three groups: Intervention Group 1: completed orthodontic treatment (15.5%), Intervention Group 2: current orthodontic treatment (21.3%), control group: no orthodontic treatment (63.3%). The measurement of the quality of life oral was done once by means of the two survey instruments OHIP-14 and ODIP. When analyzing the relationship of the reported in ODIP daily activities and orthodontic treatment, significant differences among the three groups for the parameters "lack of confidence" and "Show of teeth without shame" ($p < 0.001$) showed statistically. The analysis for the link between the general-oral health (OHIP-14) and of the orthodontic treatment resulted in 12 of 14 daily activities significant differences between the three groups ($p < 0.001$ and $p < 0.05$). Adolescents who have completed orthodontic treatment reported fewer restrictions oral quality of life than those who are currently in treatment or those who have never had orthodontic treatment. Oliveira and Sheiham (2004) conclude that an orthodontic intervention leads to reduction of oral health-related impairments, although during treatment negative effects on the quality of life. [46].

4.1.2.3 treatment effect

Of the 18 publications included 14 studies reported the indices that measure the extent of treatment outcome. The PAR index was raised in eleven studies [35-39, 41-43, 47, 48, 50]. ICON gave two study programs serving at [42, 49]. SGI also provided two studies [33, 44], where it was used in a publication solely to determine the need for treatment degree at the beginning of the study [33].

In a prospective cohort study of Agou et al. (2011) [44], which is described in Chapter oral quality of life closer, was on both observations of DAI-up time points collected in order to assess the clinical severity of Malokklus- sion. Here, a DAI lower defining a better occlusion. The assessment was based on study models at the times T0 and T1. The DAI was chosen because it takes into account the view of the engrossing persons in contrast to other indices to assess the treatment needs and the overall societal acceptance of children with regard to their oral appearance. The DAI is shown for the intervention group was a significant difference ($p < 0.01$) between the values at baseline (MW 34.21; SD: 8.18) and the average index value at the time after the treatment (22,49; SD : 2.86). An interpretation of the results of the DAI was carried out by Agou et al. (2011) is not [44].

In an RCT of King et al. (2003) [41] 276 children were enrolled with a malocclusion class II and compared the results of different treatment regimens in terms of dentoalveolar effects. The patients and patient th were stratified randomly assigned to one of three groups assigned net: 1-phase control treatment, 2-phase treatment with application of a Biona- tors during early treatment, or 2-phase treatment with a headgear / bite plate in the early phase of therapy , Furthermore, the per- were sonen the 2-phase regime with regard to the implementation of a Retentionsbe- randomized treatment. The single-stage treatment in adolescence has not been specified with regard Lich therapy applied. The PAR indices were determined from the study models before the first treatment phase and before and after the second phase. Before starting the first treatment phase, the single-stage treatment group had a mean PAR index of 21.9 (SD: 6.4) on the two-stage treatment group Bionator of 20.5 (SD: 6.0) and the two-stage treatment group with headgear of 21.5 (SD 6.6). There was no significant difference between the groups ($p = 0.418$). The first phase of the two-stage treatment regimen were terminated when two persons examined are agreed independently that a satisfactory corrective structure of malocclusion has been reached, or two lung had passed since the beginning of the treatment. A total of 208 people completed the study, 70 in the one-step treatment group, 66 in the two-stage treatment group Bionator and 72 in the two-stage treatment group with headgear. After all groups orthodontic treatment was completed, for the one-step treatment group PAR index (in MW = 6.0 SD:

4.4) corresponding to an average percentage improvement of 69.3% (SD: 25.9) reported for the two-stage treatment group Bionator for a mean PAR index of 6.0 (SD: 5.0) is equivalent to an average percent improvement of 67% (SD 32.5) and for the two-stage treatment group with a headgear PAR index of 5.3 on average (SD: 4.5) corresponding to an average percent improvement of 72.9% (SD: 25.4). The UN differences between the groups were not significant ($p = 0.424$). Due to the study results, the authors could not confirm the hypothesis that the treatment regimen had an effect on the dentoalveolar effects in the Patients and Patients with malocclusion class II.

King et al. (2012) [42] examined in an RCT 170 children who either received an interceptive treatment (group 1) followed by an observation period, or was in which first performed the observation followed by a conventional orthodontic treatment (group 2). The total study duration was 48 months. 86 children were in the group of intervention of the first and assigned to 84 children the second group. In the group with home interceptive treatment the PAR index was at baseline at a mean of

30.6 (SD: 8.2) while the PAR index in the conventional treatment group a mean of 31.4: having (SD 9.0). The group difference was not significant ($p = 0.56$). In addition, at the beginning of the investigation of the ICON with a mean of 75.1 reported for the conventional treatment group (SD: 16.1) for the interceptive and 73.5 (14.9 SD). End of the study the dropout rate for Group 1 was approximately 24% for Group 2 and about 18%. For the remaining patients in group 1, the mean PAR index was baseline to 21.0 (SD: 12.6). The conventional treatment group had DA against the investigation end an average PAR index of on average

13.1 (SD: 12.9). The group difference was in favor of the second therapy group was significantly ($p = 0.001$). Both groups had with respect to the PAR index compared to baseline also a significant reduction ($p < 0.001$). Comparable results were also seen for the ICON. This was the end of the loading action on average for the group 1 40.7 (SD: 21.0), for the Group 2 average 23.8 (SD 18.9). Again, the group difference was in favor of conventional treatment ($p = 0.001$). ICON also showed each opinion within the groups a significant improvement compared to the baseline ($p < 0.001$). King et al. (2012) come to the conclusion that both treatments are effective, the interceptive treatment but less serious than the continuous Liche treatment [42].

In a multicenter, single-blind RCT of Mandall et al. (2012) [47] the effectiveness of early treatment of Class III malocclusion using facial mask at 35 children under ten years of age (mean age 8.7 years, SD: 0.9) was investigated. The 38 children who were randomized to the control group were assigned, received no treatment and were 9.0 years (SD: 0.8) in the middle age. In all patients was an indication for treatment due to a cross bite in three to four incisors and a skeletal deformity of the

Class III before. With the study, the hypothesis should be tested that differences in early treatment of Class III malocclusion using facial mask sub hang with no treatment in terms skeletal and dental cooperation, provide the psychosocial well-being as well as a temporomandibular dys- function. At baseline, at 15 months and at the time of the 3-year follow-up made a cephalometric diagnosis by X-ray and an investigation into signs and symptoms of temporomandibulä- ren dysfunction. PAR weighted scores were calculated for all three times by an investigator. In addition, the children were asked to complete a questionnaire for self-esteem (Piers-Harris Children's Self-Concept Scale) and (Oral aesthetic Subjective Impact Score, OASIS) used for subjective aesthetic perception. In the analysis of data were received from a total of 63 people. For the 33 children in the intervention group, the analysis showed a difference of the weighted PAR Index by almost 30% between the Inter-Preventions- and the control group. In children who were is sawn with a face mask, the weighted PAR improved from baseline (MW 34.1 SD: 8.5) to a weighted PAR of 27.0 (SD 12.0) at the time of 3 annual follow-up. This improvement by 21% was statistically significantly (regression $p = 0.02$). In contrast, the mean PAR index in the Middle deteriorating in the 30 considered for the evaluation of children in the control group

8.4% of 31.0 (SD: 10.6) at baseline to 33.6 (SD: 10.6) after three years. Mandall et al. (2012), by presenting its results established that early, orthopedic Class III treatment for patients under ten years is an effective option in terms of skeletal parameters and leads to an improvement of the PAR [47].

O'Brien et al. (2003a) [43] conducted a multicentre RCT by the efficacy of early orthodontic treatment with a twin block apparatus. In the reported outcomes in this publication is the outcome of the first treatment phase of the study programs described in Section 4.1.2.1 of O'Brien et al. (2009) [50]. The reported endpoints based on the analog analysis of the same collective. The PAR values were weighted for Great Britain. Thus, the group pointed with early intervention an average PAR index of 31.15 (95% CI: 29.03 to 32.26) and the control group, a PAR-index (mean 32.72 95% CI 30, 91 to 34.55) at baseline. corresponding to an average percentage reduction of 42% (SD: 29.3): After 15 months, a PAR-Index of on average showed 18.04 (16.24 to 19.84 95% CI) in the early treatment group and in the wait control group, an average PAR index of 35.70 (95% CI: 33.9 to 37.5) corresponding to a mean percent increase of 9% (SD 21.1). The difference between groups was significant ($p = 0.001$). This can be attributed to the fact that the waiting room control group in this time no treatment has been subjected. [43]

In another of O'Brien et al. (2003b) [35] conducted multicenter RCT with a collective of a total of 215 children aged between 11 and

14 and a sagittal overbite of at least 7 mm (ISCC step 4) were to treat the patient with either a Herbst appliance ($n = 105$) or with a modified Twin Block apparatus ($n = 110$). At the beginning of the treatment, the subjects had in group 1 (Herbst appliance) a medium-sized PAR index (weighted for the UK) of 31.1 (95% CI 28.92 to 33.36) and the people in group 2 (Twin block apparatus) a PAR-Index of on average 34 (95% CI: 31.74 to 36.25). Once the overbite was completely reduced, the Herbst appliance was removed and the treatment ended when a satisfactory occlusion was achieved. With respect to the second group corresponds the treated and treated persons eliminated after complete reduction-of overbite whether a second phase of treatment should be performed at a fixed apparatus. If the patient or the patient it does not wish the treatment was stopped. In group 1, 82 out of 98 remaining subjects ($n = 7$ lost to follow-up) completed the treatment. In the group with twin block unit closed 69 of 85 remained feeding patients and patient th ($n = 25$ lost to follow-up) from the treatment. After the orthodontic treatment rule, the group had with Herbst appliance a PAR index of the co-tel 7.3 (95% CI: 5.9 to 8.7) corresponding to an average reduction of 39% (SD:

21.1) and the group with twin-block devices an average PAR index of 10.6 (95% CI: 7.9 to 13.3) corresponding to an average reduction of 40% (SD 29.3) on. A p value was not reported. O'Brien et al. (2003b) came in reducing the overbite to the conclusion that the Herbst appliance was more effective in the initial phase of treatment, this does not *samtbehandlungsdauer* was accompanied by a reduction in the overall because after a longer connection points inside was made treatment with a fixed appliance [35].

In a multicenter, randomized controlled trial (RCT) of O'Brien et al. (2009) [50] was an early orthodontic treatment ($n = 89$ persons) with a wait control group ($n = 85$ persons) compared (Detailed loading write-in section 4.1.2.1). Both groups received intra-oral appliances for the correction of malocclusion. Patients early on phase of intervention identified at the beginning of the study a mean PAR index of 31.9 in (SD: 9.1), and people in the waiting control group of 32.5 (7.9 SD). At the end of any treatment measures (10 years after the start of the study) had the Pati- entinnen and patients of the group with early treatment a PAR index of on average 10.3 (SD: 10.7) and people in the waiting control group a mean PAR index of 6 , 3 (SD: 6.2) to. The difference between groups was significantly ($p = 0.002$). This result was attributed by the authors treatment phase to the significantly reduced adherence of the early intervention group in the second loading ($p < 0.001$), as these significantly longer THERA- piedauer opposite usually treatment had ($p < 0.001$) [50]. An RCT of Pavlov et al. (2008) [48] was aimed to investigate the effect of early loading action on the stability of occlusion in sufferers with Class II Malokklusi- ones. A total of 325 persons (no age given) were with

Class II malocclusions randomized to one of three groups assigned net: Group 1 - Application of a bionator (109 persons), Group 2 - treatment with a headgear / bite plate (113 persons), Group 3 - control group, no treatment (103 persons). The patients were treated in one or two phases. The therapy consisted of three phases: Phase 1 was the Class II early treatment or observation and follow-up, in Phase 2, a comprehensive treatment, in Phase 3, the follow-up took place. Loading zugleich the PAR index could merinnen the end of the active treatment for 208 participants and participant in the study, the following averages are reported: in the Bionator group was the average of 7.4 (SD: 3.5), in the group with head- gear / biteplate 7.1 (SD: 3.5) and in the control group 7.7 (SD: 3.7). Pavlov et al. (2008) note that the PAR at the end of treatment, the period since the end of treatment and the PAR index at the start of Phase 2 a signifikan- th impact on the PAR index after treatment have [48]. A multi-center RCT of Penning et al. (2017) [36] examined the difference between the customized Insignia™ system and the conventional Damon® system for effectiveness. At baseline, the individuals with Insignia™ (n = 90) had an average of 14.6 (SD: 4.1) years old and had a PAR index of on average 23.3 (SD: 9.2) to European Ge - weightings on. The group consisted of 36 boys and 54 girls. The patient tinnen and patients who were treated with the Damon® system (n = 90) wa-, reindeer baseline average of 13.7 (SD: 1.3) years old and had a mean PAR index of 21, 8 (SD: 7.9) according to European weights. The gender distribution was 41 to 49 for boys and girls. After detachment of the brackets, the subjects received a fixed retainer. 174 of 180 people initially completed the respective treatment. The group pointed to the end of treatment with domestic signia™ system a PAR index of on average 5.4 (SD: 3.8) corresponding to an improvement of 78.9% and the group with Damon® system a PAR index of on average 5.9 (SD 3.6) in accordance with an improvement of 73.3% to. The difference between the groups was not significant ($p > 0.05$). Thus, the study authors concluded that the use of the customized system, the duration of treatment did not significantly reduce and Therapieeff- fect between the systems were comparable. Furthermore, it was reported that the use of insignia system took significantly more time for the treatment plan in claim wa- and more visits to the doctor due to loose brackets necessary ren [36].

In a multicenter RCT of Sandler et al. (2014) [37] were compared three different intra- and extra-oral devices at 78 persons each other, the required maximum anchorage of the respective apparatus for its orthodontic treatment. The study participants and study participants wa- reindeer on average 14.2 (SD: 1.5) years old. The study had three points of measurement on T1 as initial treatment phase in which the gain of the anchor has been applied; T2 when this was no longer necessary; T3 at the end of kieferor-

thopädischen treatment. With 27 people temporary anchorage device (TAD - Temporary Anchorage Device) were placed under local anesthesia. 26 patients received a Nance apparatus with Palatinalbö- gene and 25 individuals were treated with a headgear. At the beginning of the investi- gation the persons treated headgear group had a PAR Index of on average 33.13 (SD: 13.40), the participants with Nance appliance an average PAR index of 36, 92 (SD: 12.52) and the personnel NEN a PAR index of the means 34,86 with TADs: on (SD 13.39). Information on significant differences were not reported to the baseline. The addition of the anchor was not continued when space in the upper dental arch was pine achieved sufficient to complete the correction of malocclusion. At this time the headgear treatment have been completed and the TADs and Nance appliance removed. The end of treatment 22 people remaining in the original headgear group nor 23 persons in the group with Nance- apparatus 26 persons and in the group which TADs were used. With respect to the PAR index in the end of the active treatment reported folic constricting mean values: in the headgear of the middle group was worth 11.91 (SD 7.39) in the group with Nance appliance 11.38 (SD: 5.73) and in the TAD group 8.27 (SD 4.13). The corresponding reductions in the PAR-in dex were thus in the middle 21.26 (SD: 10.61), 25.69 (SD: 11.47) and

26.59 (SD: 13.82). In a linear regression model to estimate the loading effects of action by means of the PAR values after treatment revealed for the TAD-group compared to the headgear group a significant improvement ($p = 0.05$). Sandler et al. conclude (2014) that with respect to the effectiveness of the apparatus, no differences are present [37].

Taylor et al. (2009), in addition to the ICON tersucht in their study for oral quality of life (Details on the study s. Chapter "oral quality of life") (total and aesthetically) un-. The scores were averaged from the values of two independent persons be examined. The comparison of the post-ICON showed ducks have completed orthodontic treatment, a significant Verbesserung ICON both for patients and Pati-, both total and aesthetic ($p < 0.0001$) [49]. In an RCT of Tulloch et al. (1998) [38], the effects of various loading treatment regime to the treatment of individuals with a Class II malocclusion examined. The therapy consisted basically of two phases, the early and usually treatment. The 166 children at an average age of 9.9 years (range 7.7 to 12.4 years), with an overbite in the sagittal plane of more than 7 mm (KIG Level 4), were for the first phase two intervention and a control group assigned. The intervention involved either treating with egg ner functional apparatus or a headgear. In this phase, which extended over a period of 15 months, the people of jewei- time intervention have undergone or not treated. The first treatment phase was completed by all patients. Thereafter, the remaining 147 children were re-randomized in response to the treatment group in phase 1, and for the control treatment a treating of four

Persons assigned. The individuals were then treated by the person deemed necessary therapy (non-specified treatment protocols). After the first phase, a median PAR index of about 27 was reported for patients of headgear group, a median PAR index of about 24, and for the control group without treatment, median for children with a functional-equipment PAR index of about 33 (values Figure taken). After completion of the second therapy phase, the median PAR values amounted to about 5 for the prevention headgear group for the functional inter- to about 6, and for the group that received no treatment initially loading in the first phase,

to about 4.5.

An indication of p-values for

Group differences were not made. Tulloch et al. (1998) note that the PAR indices after treatment for all groups were similar in approximately in patients with class II malocclusion, regardless of whether early treatment has taken place or not [38].

Tulloch et al. (2004) [39] examined in an RCT the success of treatment of two treatment strategies (2-phase 1-phase versus therapy) in patients with Class II malocclusion. Details on the study are already at Tulloch et al. [38] (1998). In the publication of 2004 on the study are nisse the second treatment period shown. were included children with an overbite in the sagittal plane of more than 7 mm without previous jaw orthopedic treatment (ISCC step 4). The participants were stratified randomly assigned to three groups: A total of 180 people for the first phase were allocated to two intervention and a control group. The intervention involved either treatment with a functional apparatus or a headgear. In this phase, which extended over a period of 15 months, the patients of the intervention were subjected or not treated. The first treatment phase was completed by 166 people. Thereafter, the remaining 145 subjects were again depending on the treatment group in Phase 1, RAN domisiert and allocated for the control treatment one of four orthodontists and orthodontists. The patients then received the deemed by the treating person as necessary therapy (not specific graded treatment protocols). A total of 139 people completed the second phase, of which 137 patients were included for analysis. (SD: 5.7) after the end of the second phase, an average PAR index of 7.2 was used for people in the headgear group, which have passed through both the phases, given presence, for persons having a functional apparatus, an average PAR Index of 8.4 (SD: 7.7) and for the control group without treatment, a mean PAR index of 9.3 (SD: 8.1). The changes from baseline were not significant. Tulloch et al. (2004) note that the PAR indices tinnen with patient and patient with malocclusion Class II who received early treatment, some were better [39].

Quick Facts

A total of 18 studies were included in the evidence-based analysis for orthodontic treatment rule. Focus of most studies was on the comparison of different councils intraoral or extraoral orthodontic overall. One-third of the studies looked at orthodontic treatment Compared with no intervention. In addition, studies were identified that faced early treatment in children with mixed dentition of a control treatment in youth union with permanent dentition.

Three quarters of the studies on orthodontic treatment (13 studies) reported indices on the extent of treatment effect, particularly on the basis of the PAR index, followed by the ICON and DAI. Consistently showed this improvement of the respective malocclusion after completion of orthodontics Indian treatment, but were mostly independent of the applied intra- and extra-oral appliances. In comparison of early vs. Control treatments were two [38, 41] of five studies to evaluate the treatment effects no benefits of early treatment report. Another study [47] was able to show positive effects of early treatment compared to a untreated control group th. Accordingly, the authors of another study reported better treatment effects for patients and paper tienteen with an early treatment compared to a control treatment [39]. In another study, the authors conclude that early treatment is not associated with significant long-term effects and ten with increased cost, einher- prolonged treatment and poorer occlusion is [50].

Parameters for oral health were only serving reports of four of the 18 study programs. Here were made information on relevant indices such as the GI, PI, DMFT and DMFS index and probing depth. Under investigation were likewise the extent of external apical root resorption and associated with orthodontics Indian treatments dental injuries. The used index is a surrogate endpoints, which impact on the morbidity of patients with orthodontic treatment can only be approximated. In the included studies, no significant differences between different orthodontic appliances or orthodontic treatments were for-called indices vs. no treatments (GI, PD, PI, DMFT, DMFS index) are found [34, 50]. As regards the external apical root resorption various loading schemes seem to act (z. B. step treatment vs. two-stage treatment) to have by no NEN effect [40]. Also regarding the incidence of dental trauma as adverse events, no significant difference between early treatment and a control treatment could be found [50]. Long-term patient-relevant outcomes such as tooth loss, tooth mobility and pain wur- the reports in any of the included studies. This can be attributed to the fact that these endpoints can be detected only after lengthy periods of observation after working termination of therapy. A measurement of these endpoints

also takes in combination with the collection of health behavior (ER- nutrition, oral hygiene) associated. This would enable the identification of influencing factors and thus allow a conclusion about causality between jaw-orthopedic treatment and patient-relevant outcomes. In four of the 18 studies included oral quality of life has been detected. It should be noted that in this case different measuring instruments used were the direct comparison and thus is not possible. It can be noted that across studies for patients with orthodontic treatment high oral quality of life is reported. Children or adolescents whose treatment is completed, report doing a higher oral quality of life than those who are currently in treatment or have never received treatment [46]. However, there is a high correlation between the overall quality of life and psychological well-being and the quality of life of oral, there were no significant differences between treated and untreated [44, 49]. Further indicated for the inquiry indicates that patients depending on their underlying indication and then indexed treatment improvements have different oral quality of life. To view individuals with cleft lip and / or cleft palate after orthodontic treatment, a significantly lower oral quality of life compared to patients with malocclusion and orthodontic treatment or people with severe skeletal discrepancies and orthodontic / -chirurgischer therapy [33].

development measures Looking at the different studies, orthodontic treatment itself shows a high heterogeneity regarding the Studienmethode, the study design and the studied indications. Moreover, this distinction in the applied interventions and measures to Beobachtungszeitraum. The study methodology regarding the studies on orthodontic rule therapy was assessed using standardized checklists independently by two people to be moderate overall. Shortcomings of the study methodology environmentally preconceived missing comparisons of patients, intention-to-treat analysis and explanation of drop-outs. Because few studies have been identified for oral health, which also primarily end points on surrogate based, this can make any final assessment of whether and what long-term effects of the orthodontic treatments used on oral health.

Table 4: Overview of therapeutic orthodontic studies

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
Agou et al., 2011 [44]	<ul style="list-style-type: none"> Study Type: prospective cohort study Study duration: k. A. Data collection: start of treatment (T0), first check-up after the end of treatment (T1) Number of persons (baseline / Followup): 199/118 Intervention group: Orthodontic treatment Control group: No treatment Indications for treatment: patients with indication for orthodontic treatment 	<p>total group</p> <ul style="list-style-type: none"> Number of persons (baseline / Followup): 199/118 Age [MW (SD)]: 12.9 (0.98) Gender (m / f): 59/59 Indications for treatment: <ul style="list-style-type: none"> O Interfering Malokklusion: 44.2% O Severe malocclusion: 25.7% O Significant malocclusion: 23.9% O Slight malocclusion: 6.2% <p>intervention group</p> <ul style="list-style-type: none"> Number of persons (baseline / Followup): 98/74 <p>control group</p> <ul style="list-style-type: none"> Number of persons (baseline / Followup): 101/44 	<p>DAI</p> <p>Baseline ITT (T0) (n = 98) [MW (SD)]: 34.21 (8.18) Baseline (T0) (n = 74) [MW (SD)]: 33.72 (7.78)</p> <p>Follow -up (T1) [MW (SD)]:</p> <p>22.49 (2.86) difference T1-T0 significant (p <0.01)</p> <p>CPQ11-14</p> <p>Baseline ITT (T0) (n = 98) [MW (SD)]: 21.05 (15.09) baseline (T0) (n = 74) [MW (SD)]: 21.63 (14.19) Follow-up (T1) [MW (SD)]: 16,16 (10,99) difference T1-T0 significant (p <0.01)</p>	<p>DAI</p> <p>Baseline ITT (T0) (n = 101) [MW (SD)]: 36.53 (8.89) Baseline (T0) (n = 44) [MW (SD)]: 36.25 (7.25)</p> <p>Follow -up (T1) [MW (SD)]:</p> <p>33.56 (7.14) difference T1-T0 not significant</p> <p>CPQ11-14</p> <p>Baseline ITT (T0) (n = 101) [MW (SD)]: 24.07 (16.15) baseline (T0) (n = 44) [MW (SD)]: 24.07 (16.15) Follow-up (T1) [MW (SD)]: 23.14 (17.97) difference T1-T0 not significant</p>
Antoun et al., 2015 [33]	<ul style="list-style-type: none"> Study Type: prospective cohort study Study duration: k. A. Data Collection: Before treatment (T0), after treatment (T1) Number of persons: 83 	<p>Intervention Group 1</p> <ul style="list-style-type: none"> Number of persons: 30 Age [MW (SD)]: 14.5 [1.9] Gender (m / f): 17/13 Indications for treatment: severe malocclusion 	<p>OHIP-14 Intervention Group 1</p> <p>Baseline (T0) [MW (SD)]: 11.60 (10.93) Follow-up (T1) [MW (SD)]: 3.63 (5.04)</p>	<p>OHIP-14 Intervention Group 2</p> <p>Baseline (T0) [MW (SD)]: 19.52 (9.62) Follow-up (T1) [MW (SD)]: 2.03 (3.13)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<ul style="list-style-type: none"> Indications for treatment: patients with severe malocclusion (DAI > 32), orofacial cleft Intervention group 1: patients with severe malocclusion and orthodontic treatment Intervention group 2: patients with severe skeletal discrepancies and orthodontic / -chirurgischer therapy Intervention Group 3: Non-symptomatic patients with cleft lip, cleft palate or cleft lip and palate and orthodontic treatment 	<p>O DAI baseline (T0) [MW (SD)]: 45.5 (9.0)</p> <p><u>Intervention Group 2</u></p> <ul style="list-style-type: none"> Number of persons: 29 Age [MW (SD)]: 19.0 [4.3] Gender (m / f): 15/14 Indications for treatment: severe skeletal discrepancies <p>O DAI baseline (T0) [MW (SD)]: 56.6 (12.8)</p> <p><u>Intervention Group 3</u></p> <ul style="list-style-type: none"> Number of persons: 24 Age [MW (SD)]: 12.6 (2.8) Gender (m / f): 14/10 Indications for treatment: cleft lip, cleft palate, lip and palate <p>O DAI baseline (T0) [MW (SD)]: 45.4 (13.4)</p>	<p>Difference T1-T0 significant (p < 0.01)</p>	<p>Difference T1-T0 significant (p < 0.01)</p> <p><u>Intervention Group 3</u></p> <p>Baseline (T0) [MW (SD)]: 10.50 (10.80) Follow-up (T1) [MW (SD)]: 7.25 (7.28) difference T1-T0 ns</p>
Atik & Ciger., 2014 [34]	<ul style="list-style-type: none"> Study Type: RCT Study duration: k. A. Data collection: start of treatment (T0), the end of treatment (T1) Number of persons: 33 	<p><u>intervention group</u></p> <ul style="list-style-type: none"> Number of persons: 17 Age [MW (SD)]: 14.5 (1.2) Gender (m / f): 0/17 Indications for treatment: 	<p><u>gingival</u></p> <p>Baseline [MW (SD)]: k. A. Mean change (T0-T1) [MW (SD)]: (-) 0.08 (0.62); [Group difference ns]</p>	<p><u>gingival</u></p> <p>Baseline [MW (SD)]: k. A. Mean change (T0-T1) [MW (SD)]: 0.16 (0.39); [Group difference ns]</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<ul style="list-style-type: none"> Indications for treatment: crowding in the lower and / or upper jaw Intervention group: 0022-inch Damon 3MX appliance system (Ormco / A Company, San Diego, California) Control group: 0022-inch Roth bracket system (Forestadent, Pforzheim, Germany) 	<p>Crowding in the mandible (3,4 mm; 2,3 4.6 mm) p = 0.094 [Group difference ns]; Crowding in the upper jaw (3.5 mm; from 2.4 to 6.0 mm) p = 0.763 [Group difference ns]</p> <p>control group</p> <ul style="list-style-type: none"> Number of persons: 16 Age [MW (SD)]: 14.8 (1.0) Gender (m / f): 0/16 Indications for treatment: crowding (in the lower jaw 3.9 mm; 2,3 5.5 mm); Crowding in the upper jaw (3.5 mm; from 2.4 to 6.2 mm) 	<p>probing depth</p> <p>Baseline [MW (SD)]: k. A. Mean change (T0-T1) [MW (SD)]: 0.25 (0.35) [Group difference ns]</p>	<p>probing depth</p> <p>Baseline [MW (SD)]: k. A. Mean change (T0-T1) [MW (SD)]: 0.12 (0.27); [Group difference ns]</p>
			<p>plaque Index</p> <p>Baseline: k. A. Mean change (T0-T1): [MW (SD)] 0.23 (0.43) [Group difference ns]</p>	<p>plaque Index</p> <p>Baseline: k. A. Mean change (T0-T1): [MW (SD)] 0.45 (0.37) [Group difference ns]</p>
Bonde Mark et al., 1998 [45]	<ul style="list-style-type: none"> Study Type: prospective controlled trial Study duration: k. A. Data collection: start of treatment (T0); after 2.8 years (T1); End of the 5-year study period (T2) Number of persons: 40 Intervention group: Treatment Control group: no treatment 	<p>intervention group</p> <ul style="list-style-type: none"> Number of persons: 20 Age [MW (SD)]: 14.3 (2.03) Gender (m / w): 5.15 Indications for treatment: lack of space zw 3.0 mm - 5.5 mm, vertical overbite (MW (SD)). 5.6 mm (1.26 mm) <p>control group</p> <ul style="list-style-type: none"> Number of persons: 20 Age [MW (SD)]: 14.3 (1.99) Gender (m / w): 5.15 Indications for treatment: absence 	<p>DMFT</p> <p>Baseline [MW (SD)]: 3.8 (3.07) Follow-up (T2) [MW (SD)]: 4.4 (3.38) [Group difference n. s.]</p>	<p>DMFT</p> <p>Baseline [MW (SD)]: 3.3 (3.42) [groups by dental health gematched] Follow-up (T2): 3.9 (2.95) [Group difference ns]</p>
			<p>DMFS index</p> <p>Baseline [MW (SD)]: 0.5 (1.15) Follow-up (T2) [MW (SD)]: 0.8 (1.86) [Group difference n. s.]</p>	<p>DMFS index</p> <p>Baseline [MW (SD)]: 0.7 (1.21) [groups by dental health gematched] Follow-up (T2) [MW (SD)]: 1.1 (1.15) [Group difference ns]</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
Brin et al., 2003 [40]	<ul style="list-style-type: none"> Type of study: retrospective analysis of medical records Study duration: k. A. Data collection: k. A. Number of people: 138 children (equivalent to 532 incisors, go to the results of only 512 incisors a) Intervention Group 1: 2-phaisge treatment with headgear (mixed dentition) Intervention Group 2: 2-phase treatment with Bionator during phase 1 and fixed devices during Phase 2 Control group: 1-phase treatment with fixed equipment (permanent dentition) 	<p><u>Intervention Group 1</u></p> <ul style="list-style-type: none"> Number of persons: 49 Age [MW (SD)]: 9.84 (1.07) Gender (m / f): 57% / 43% Indications for treatment: Horizontal overbite [MW (SD)]: 9.45 mm (2.07 mm) <p><u>Intervention Group 2</u></p> <ul style="list-style-type: none"> Number of persons: 49 Age [MW (SD)]: 9.98 (0.92) Gender (m / f): 55% / 45% Indications for treatment: Horizontal overbite [MW (SD)]: 9.18 mm (2.18 mm) <p><u>control group</u></p> <ul style="list-style-type: none"> Number of persons: 40 Age [MW (SD)]: 9.77 (0.99) Gender (m / w): 59.2% / 40.8% Indications for treatment: Horizontal overbite [MW (SD)]: 9.10 mm (1.49 mm) 	<p><u>EARR intervention group 1</u></p> <p>Values were read and apply to central and lateral incisors:</p> <p>O No: 15%</p> <p>O Mild: 72%</p> <p>O Moderate Severity: 13%</p> <p><u>Intervention Group 2</u></p> <p>Values were read and apply to central and lateral incisors:</p> <p>O No: 28%</p> <p>O Mild: 78%</p> <p>O Moderate: 5%</p>	<p><u>EARR</u></p> <p>Values were read and apply to central and lateral incisors:</p> <p>O No: 22%</p> <p>O Mild: 60%</p> <p>O Moderate Severity: 19%</p>
De Oliveira et al., 2004 [46]	<ul style="list-style-type: none"> Study Type: case-control study Study duration: k. A. Data collection: k. A. Persons: 1,675 	<p><u>Total:</u></p> <ul style="list-style-type: none"> Persons: 1,675 Age: 15-16 years Gender (m / f): 724/951 	<p><u>OIDP</u></p> <p>"Laughter" significant difference parameters (p <0.001)</p>	<p><u>OIDP</u></p> <p>"Laughter" significant difference parameters (p <0.001)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<ul style="list-style-type: none"> Intervention group 1: Completed orthodontic treatment Intervention Group 2: Ongoing orthodontic treatment Control group: non-orthodontic treatment 	<ul style="list-style-type: none"> Indications for treatment after IOTN: <ul style="list-style-type: none"> O Grade 1, 2 1031 O Grade 3: 351 O Grade 4, 5: 293 Orthodontic treatment status: <ul style="list-style-type: none"> O Completed Treatment: 15.8% O No treatment: 63.3% O Ongoing treatment: 21.3% 	<p><u>Intervention Group 1 [n (MW (Rank))]</u></p> <p>Laughing: 258 (768.17)</p> <p><u>Intervention Group 2 [n (MW (Rank))]</u></p> <p>Laughter: 357 (830.70)</p>	<p><u>Control group 1 [n (MW (Rank))]</u></p> <p>Laughter: 1060 (857.46)</p>
			<p><u>OHIP-14</u></p> <p>Group differences in 14.12 daily activities significantly (p <0.001 and p <0.05)</p>	
King et al., 2003 [41]	<ul style="list-style-type: none"> Study Type: RCT Study duration: k. A. Data collection: k. A. Number of people who completed the study: 208 Indications for treatment: malocclusion Angle class II Intervention Group 1: 2-phase treatment (early and control treatment) O Phase 1: Bionator <ul style="list-style-type: none"> O Phase 2: Retention vs. none retention treatment Intervention Group 2: 2-phase treatment (early and control treatment) 	<p><u>Total population *</u></p> <ul style="list-style-type: none"> Age [median (range)]: 9.5 (7.0 to 12.6) Gender (m / f): 123/85 <p>* Population at the end of the study</p> <p><u>Intervention Group 1</u></p> <ul style="list-style-type: none"> Number of those who completed the trial: 66 Treatment: After the first phase patient retention treatment were re-randomized to respect.. When wearing the retention bionator at night. 	<p><u>PAR Index Intervention Group 1</u></p> <p>Baseline [MW (SD)]: 20.5 (6.0) ITT [MW (SD)]: 6.0 (4.4) Total Change [MW (SD)]: 69.3 (25.9)</p> <p><u>Intervention Group 2</u></p> <p>Baseline [MW (SD)]: 21.5 (6.6) ITT [MW (SD)]: 5.3 (4.5) Total Change [MW (SD)]: 72.9 (25.4) [ns]</p>	<p><u>PAR Index</u></p> <p>Baseline [MW (SD)]: 21.9 (6.4) ITT [MW (SD)]: 6.0 (5.0) Total Change [MW (SD)]: 67.0 (32.5)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<p>O Phase 1: Headgear / occlusal plate</p> <p>O Phase 2: Retention vs. none retention treatment</p> <ul style="list-style-type: none"> Control group: 1-phase treatment in adolescence (control treatment) 	<p><u>Intervention Group 2</u></p> <ul style="list-style-type: none"> Number of those who completed the trial: 72 Treatment: After the first phase patient retention treatment were re-randomized to respect.. In Retention full-time wearing the bite plate or overnight headgear. <p><u>control group</u></p> <ul style="list-style-type: none"> Number of those who completed the trial: 70 		
King et al., 2012 [42]	<ul style="list-style-type: none"> Study Type: RCT Study duration: 4 years Data Collection: Assessment after 48 months Number of people: 170 children 	<p><u>intervention group</u></p> <ul style="list-style-type: none"> Persons: 86; 65 were considered in the analysis Age [MW (SD)]: 9.4 (1.3) Gender (m / f): 42/44 Indications for treatment: PAR index and ICON 	<p><u>PAR Index</u></p> <p>Baseline [MW (SD)]: 30.6 (8.2) follow-up [MW (SD)]: 21.0 (12.6) significant reduction from baseline (p <0.001)</p>	<p><u>PAR Index</u></p> <p>Baseline [MW (SD)]: 31.4 (9.0) [ns] Follow-up [MW (SD)]: 13.1 (12.9) significant reduction from baseline (p <0.001)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<ul style="list-style-type: none"> Intervention group: Interceptive orthodontics (IO, early treatment), followed by observation (OBS) Control group: Observation (OBS), followed by regular exemplary (comprehensive) Orthodontics (CO, control treatment) 	<p><u>control group</u></p> <ul style="list-style-type: none"> Persons: 84; 69 were considered in the analysis Age [MW (SD)]: 9.2 (1.2) Gender (m / f): 40/44 Indications for treatment: PAR index and ICON 	<p><u>ICON</u></p> <p>Baseline [MW (SD)]: 75.1 (16.1)</p> <p>Follow-up [MW (SD)]: 13.1 (12.9) group difference = 7.9; significant (p <0.001)</p>	<p><u>ICON</u></p> <p>Baseline [MW (SD)]: 73.5 (14.9) follow-up [MW (SD)]: 8.3 (18.9) group difference, Diff = 12.5; significant (p <0.001)</p>
Mandall et al., 2012 [47]	<ul style="list-style-type: none"> Type of study: Multicentric RCT Study duration: 3 years Data collection: baseline (T1), after 15 months (T2), after 3 years (T2) Number of persons (baseline / Followup): 73/63 Intervention group: face mask Control group: No treatment 	<p><u>intervention group</u></p> <ul style="list-style-type: none"> Number of persons (baseline / Followup): 35/30 Age [MW (SD)]: 8.7 (0.9) * Gender (m / f): 15/15 Indications for treatment: cross bite at three - four incisors, skeletal deformity Class III <p><u>Control group *</u></p> <ul style="list-style-type: none"> Number of persons (baseline / Followup): 38/33 Age [MW (SD)]: 9.0 (0.8) * Gender (m / f): 15/18 Indications for treatment: cross bite at three - four incisors, skeletal deformity Class III <p>* Values come from the publication of Mandall et al. (2010) [52]</p>	<p><u>PAR Index</u></p> <p>Baseline (T0) [MW (SD)]: 34.1 (8.5) Follow-up (T2) [MW (SD)]: 27.0 (12.0) difference T2-T0 [MW (SD)]: 7.1 (14.3)</p>	<p><u>PAR Index</u></p> <p>Baseline (T0) [MW (SD)]: 31.0 (10.6) Follow-up (T2) [MW (SD)]: 33.6 (10.6) difference T2-T0 [MW (SD)]: -2.6 (10.2) Group difference significant (p = 0.02)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
O'Brien et al., 2003a [43]	<ul style="list-style-type: none"> Type of study: Multicentric RCT Study duration: 15 months Data collection: baseline (T1), after 15 months (T2) Persons: 174 Children Intervention group: Early orthodontic treatment during the transition set of teeth (early treatment) Control group: Wait control group (delayed treatment, the patients were able to start treatment after a minimum of 15 months, usually treatment) 	<p><u>intervention group</u></p> <ul style="list-style-type: none"> Number of persons: 89 Age [MW (SD)]: 9.7 (0.98) Gender (m / f): 48/41 Indications for treatment: malocclusion Angle class II / 1 Treatment: All patients were instructed to wear the device 24 hours a day (including food, exceptions. Contact Spot types, swimming). After complete reduction of horizontal overbite apparatus was wearing a retainer at night or adapted retainer with strong bite surface, depending on the preference of the person treated. <p><u>control group</u></p> <ul style="list-style-type: none"> Persons: 85; 84 people at follow-up Age [MW (SD)]: 9.8 (0.94) Gender (m / f): 46/39 Indications for treatment: malocclusion Angle Class II / 1 	<p><u>PAR index (UK-weighting)</u></p> <p>Baseline [MW (95% CI)]: 31.15 (95% CI 29.03 to 32.26)</p> <p>Follow-up [MW (SD)]: 18.04 (29.3); 95% CI: 16.24 to 19.84</p> <p>There were no baseline PAR values due to faulty models. These data were imputed.</p>	<p><u>PAR index (UK-weighting)</u></p> <p>Baseline [MW (95% CI)]: 32.72 (95% CI 30.91 to 34.55)</p> <p>Follow-up [MW (SD)]: 35.70 (21.1); (95% CI: 33.95 to 37.46) (p = 0.001) between the groups</p> <p>There were no baseline PAR values due to faulty models. These data were imputed.</p>
O'Brien et al., 2003b [35]	<ul style="list-style-type: none"> Type of study: Multicentric RCT Duration of study: was up treatment stops 	<p><u>intervention group</u></p> <ul style="list-style-type: none"> Persons: 105; were analyzed 98 	<p><u>PAR index (UK-weighting)</u></p> <p>Baseline [MW (95% CI)]: 31.14 (95% CI 28.92 to 33.36)</p>	<p><u>PAR index (UK-weighting)</u></p> <p>Baseline [MW (95% CI)]: 34 (95% CI 31.74 to 36.25)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<ul style="list-style-type: none"> Data collection: baseline (T1), the end of treatment (T2) Number of persons: 215 Intervention group: Herbst appliance Control group: Twin-block apparatus 	<ul style="list-style-type: none"> Age [MW (95% CI)]: 12.74 (95% CI 12.48-12.99) Gender (m / f): 50/55 Indications for treatment: Malokklussion, Angle Class II / 1 <p>control group</p> <ul style="list-style-type: none"> Persons: 110; were analyzed 85 Age [MW (95% CI)]: 12.41 (12.17-12.63) Gender (m / f): 48/62 Indications for treatment: malocclusion, Angle Class II / 1 	Follow-up [MW (95% CI)]: 7.28 (21.1); (95% CI: 5.87 to 8.70)	Follow-up [MW (95% CI)]: 10.57 (29.3); (95% CI: 7.86-13,28)
O'Brien et al., 2009 [50]	<ul style="list-style-type: none"> Study Type: Multicenter RCT Study duration: 10 years Data collection: study entry (T1); Removal of the apparatus (T2) Number of persons: 174 Intervention group: 2-phase treatment (early treatment) with Twin Block apparatus Control group: 1-phase treatment, 15 months waiting time after entry into the study, control treatment with functional or fixed apparatus 	<p>intervention group</p> <ul style="list-style-type: none"> Number of persons: Phase 1: 89; Phase 2: 54 Age [MW (SD)]: Phase 1: 9.7 years (0.98); Phase 2: 12:41 year (1.16) Gender (m / f): 48/41 Indications for treatment: malocclusion Angle Class II / 1 Treatment: All patients were instructed to wear the device 24 hours a day (including food, exceptions. Contact Spot types, swimming). 	<p>PAR Index</p> <p>Baseline (n = 63) [MW (SD)]: 31.91 (9.13) Follow-up (n = 63) [MW (SD)]: 10.25 (10.67) was significantly higher at the end of treatment (p = 0.002)</p> <p>dental trauma</p> <p>n = 4 (8%) [Group difference ns]</p>	<p>PAR Index</p> <p>Baseline (n = 70) [MW (SD)]: 32.55 (7.85) Follow-up (n = 70) [MW (SD)]: 6.30 (6.17)</p> <p>dental trauma</p> <p>n = 7 (14%) [Group difference ns]</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
		<p><u>control group</u></p> <ul style="list-style-type: none"> Number of persons: Phase 1: 85; 2nd phase: 73 Age [MW (SD)]: Phase 1: 9.8 years (0.94); 2nd stage: 12.1 years (1.0) Gender (m / f): 46/39 Indications for treatment: malocclusion Angle Class II / 1 Treatment: All patients were instructed to wear the device 24 hours a day (including food, exceptions. Contact Spot types, swimming). 		
Pavlov et al., 2008 [48]	<ul style="list-style-type: none"> Study Type: RCT Study duration: k. A. Data collection: start of treatment (T0), the start of the second treatment period (T1), the end of treatment (T2) Persons: 325; 174 treatment have ended Intervention group 1: <ul style="list-style-type: none"> O Phase 1: Bionator O Phase 2: Control treatment Intervention Group 2: <ul style="list-style-type: none"> O Phase 1: Headgear / biteplate O Phase 2: Control treatment Control group: 	<p><u>Intervention Group 1</u></p> <ul style="list-style-type: none"> Number of persons (baseline / Followup): 109/59 Age [MW (SD)]: k. A. Gender (follow-up population) (m / f): 34/24 Indications for treatment: <ul style="list-style-type: none"> O High Severity: 48% O Medium severity: 26% O Low Severity: 26% <p><u>Intervention Group 2</u></p> <ul style="list-style-type: none"> Number of persons (baseline / Followup): 113/61 	<p><u>PAR Index Intervention</u></p> <p><u>Group 1</u></p> <p>Baseline (T0) [MW (SD)]: 21.1 (5.9) Follow-up (T2) [MW (SD)]: 7.4 (3.5)</p> <p><u>Intervention Group 2</u></p> <p>Baseline (T0) [MW (SD)]: 20.7 (6.5) Follow-up (T2) [MW (SD)]: 7.1 (3.5)</p>	<p><u>PAR Index</u></p> <p>Baseline (T0) [MW (SD)]: 22.3 (6.0) Follow-up (T2) [MW (SD)]: 7.7 (3.7)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<p>O Phase 1: no treatment</p> <p>O Phase 2: Control treatment</p>	<ul style="list-style-type: none"> Age [MW (SD)]: k. A. Gender (follow-up population) (m / f): 30/28 Indications for treatment: <ul style="list-style-type: none"> O High Severity: 41% O Medium severity: 28% O Low Severity: 31% <p>control group</p> <ul style="list-style-type: none"> Number of persons (baseline / Followup): 103/57 Age [MW (SD)]: k. A. Gender (follow-up population) (m / f): 38/19 Indications for treatment: <ul style="list-style-type: none"> O High Severity: 49% O Medium severity: 25% O Low Severity: 26% 		
Penning et al., 2017 [36]	<ul style="list-style-type: none"> Type of study: Multicentric RCT Study duration: k. A. Data collection: start of treatment (T0), the end of treatment (T1) Number of persons (baseline / Followup): 180/174 Intervention group: insignia system (self-ligating brackets) Control group: Damon Q system (self-ligating brackets) 	<p>intervention group</p> <ul style="list-style-type: none"> Number of persons: 85 Age [MW (SD)]: 14,55 (4,11) Gender (m / f): 36/54 Indications for treatment: <ul style="list-style-type: none"> O Malocclusion Angle class I: 47.8% O Malocclusion Angle class II: 44.4% 	<p>PAR index (European weighting)</p> <p>Baseline [MW (SD)]: 23.32 (9.15)</p> <p>follow-up [MW (SD)]: 5.38 (3.75)</p> <p>(improvement in 78.9% of individuals)</p> <p>[group difference ns]</p>	<p>PAR index (European weighting)</p> <p>Baseline [MW (SD)]: 21.84 (7.95)</p> <p>follow-up [MW (SD)]: 5.93 (3.58)</p> <p>(improvement in 73.3% of individuals)</p> <p>[group difference ns]</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
		<p>O Malocclusion Angle class III: 7.8%</p> <ul style="list-style-type: none"> Treatment: The brackets were bonded indirectly with the aid of bracket positioning devices <p><u>control group</u></p> <ul style="list-style-type: none"> Number of persons: 89 Age [MW (SD)]: 13.66 (1.34) Gender (m / f): 41/49 Indications for treatment: <ul style="list-style-type: none"> O Malocclusion Angle class I: 56.7% O Malocclusion Angle class II: 43.3% O Malocclusion Angle class III: - Treatment: The brackets were glued directly 		

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
Sandler et al., 2014 [37]	<ul style="list-style-type: none"> Type of study: Multicentric RCT Duration of study: was up treatment stops Data Collection: Initial treatment phase (T1), reinforcing the anchoring (T2), Distance anchorage (T3), the end of treatment (T4) Number of persons: 78 Intervention Group 1: Temporary anchoring devices (temporary anchorage devices; TADS) for reinforcing the anchoring Intervention Group 2: Nance palatal apparatus with Control group: Headgear 	<p><u>Intervention Group 1</u></p> <ul style="list-style-type: none"> Number of persons (baseline / ITT): 27/22 Age [MW (SD)]: 14,15 (1,25) Gender (m / f): 11/16 Indications for treatment: requirement of a maximum anchoring in orthodontic treatment Treatment: fixed devices in the upper and lower jaws were placed for the TAD patients and -Patients. For the sides, which had an anchorage reinforcement 8 x 1.6mm TADS were placed under local anesthesia. <p><u>Intervention Group 2</u></p> <ul style="list-style-type: none"> Number of persons (baseline / ITT): 26/26 Age [MW (SD)]: 14.14 (1.48) Gender (m / w): 7.19 	<p><u>PAR Index Intervention</u></p> <p><u>Group 1</u></p> <p>Baseline (T1) [MW (SD)]: 34.86 (13.39) Follow-up (T3) [MW (SD)]: 8.27 (4.13); Reduction of 26.59 (13.82)</p> <p>[The TAD group showed in comparison to the headgear group a significant improvement (p = 0.05)]</p> <p><u>Intervention Group 2</u></p> <p>Baseline (T1) [MW (SD)]: 36.92 (12.52) Follow-up (T3) [MW (SD)]: 11.38 (5.73), reduction of 25.69 (11.47)</p>	<p><u>PAR Index</u></p> <p>Baseline (T1) [MW (SD)]: 33,13 (13,40) Follow-up (T3) [MW (SD)]: 11.91 (7.39); reduction of 21.26 (10.61)</p> <p><u>Serious adverse events</u></p> <p>none</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
		<ul style="list-style-type: none"> Indications for treatment: requirement of a maximum anchoring in orthodontic treatment Treatment: Nance apparatus with a 1.0 mm stainless steel palatal <p><u>control group</u></p> <ul style="list-style-type: none"> Persons: 25; ITT: 23 Age [MW (SD)]: 14.38 (1.67) Gender (m / f): 11/14 Indications for treatment: requirement of a maximum anchoring in orthodontic treatment Treatment: There were adjusted to each side of the headgear bow 250 g. It is desired that the headgear was worn at least 100 hours of the treated person was. 	<p><u>Serious adverse events</u></p> <p><u>Intervention Group 1</u></p> <p>None</p> <p><u>Intervention Group 2</u></p> <p>none</p>	
Taylor et al., 2009 [49]	<ul style="list-style-type: none"> Type of study: cohort study Study duration: k. A. Data Collection: Once Number of persons: 107 Intervention group 1: patients who have completed interceptive orthodontic treatment were 	<p><u>Intervention Group 1</u></p> <ul style="list-style-type: none"> Number of persons: 44 Age [MW (SD)]: 12.6 (1.1) Gender (m / f): 23/11 Indications for treatment: <ul style="list-style-type: none"> ICON total [MW (SD)]: 79.0 (20.1) ICON aesthetically [MW (SD)]: 7.8 (1.8) 	<p><u>COHQoL intervention group 1</u></p> <p>Total [MW (SD)]: 19.00 (12.73)</p> <p><u>Intervention Group 2</u></p> <p>Total [MW (SD)]: 18.08 (11.83)</p> <p><u>YQoL intervention group 1</u></p>	<p><u>COHQoL</u></p> <p>Total [MW (SD)]: 19.97 (11.07)</p> <p><u>YQoL</u></p> <p>Total [MW (SD)]: 82.18 (12.26)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<ul style="list-style-type: none"> Intervention group 2: patients who were not subjected to any orthodontic treatment rule Control group: children without completed, ongoing or planned orthodontic treatment 	<p><u>Intervention Group 2</u></p> <ul style="list-style-type: none"> Number of persons: 93 Age [MW (SD)]: 12.6 (1.1) Gender (m / f): 48/45 Indications for treatment: <ul style="list-style-type: none"> ICON total [MW (SD)]: 69.0 (21.5) ICON aesthetically [MW (SD)]: 6.6 (2.2) <p><u>control group</u></p> <ul style="list-style-type: none"> Number of persons: 156 Age [MW (SD)]: 12.9 (1.1) Gender (m / f): 80/76 Indications for treatment: <ul style="list-style-type: none"> ICON total [MW (SD)]: k. A. ICON aesthetically [MW (SD)]: 4.0 (1.9) 	<p>Total [MW (SD)]: 82.33 (12.71)</p> <p><u>Intervention Group 2</u></p> <p>Total [MW (SD)]: 82.59 (12.80)</p> <p><u>Post-intervention group</u></p> <p><u>ICON 1</u></p> <p>ICON total [MW (SD)]: 48.9 (21.4) ICON aesthetically [MW (SD)]: 4.6 (2.2) Pre-post comparison was statistically significant ($p < 0.0001$)</p>	
Tulloch et al., 1998 [38]	<ul style="list-style-type: none"> Study Type: RCT Study duration: k. A. Data collection: k. A. Number of persons: 107 Intervention group 1: O Phase 1: Headgear 	<p><u>Intervention Group 1</u></p> <ul style="list-style-type: none"> Persons: k. A. Age [MW (SD)]: k. A. Gender (m / f): k. A. Indications for treatment: k. A. <p><u>Intervention Group 2</u></p> <ul style="list-style-type: none"> Persons: k. A. Age [MW (SD)]: k. A. 	<p><u>PAR Index Intervention</u></p> <p><u>Group 1</u></p> <p>After phase 1 [median] of about 27, after phase 2 [median]: 5</p> <p>Readings were taken from figure.</p> <p><u>Intervention Group 2</u></p>	<p><u>PAR Index</u></p> <p>After Phase 1 [median]: about 33 to Phase 2 [median] 4,5</p> <p>Readings were taken from figure.</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<p>O Phase 2: the physician's discretion (Z. B. fixed device, the expansion device, lip bumper, headgear or partial harness)</p> <ul style="list-style-type: none"> Intervention Group 2: <p>O Phase 1: Funktionskieferorthopädie</p> <p>O Phase 2: the discretion of the Ärztin / the doctor</p> <ul style="list-style-type: none"> Control group: <p>O Phase 1: No treatment</p> <p>O Phase 2: the discretion discretion of the Doctor / the doctor</p>	<ul style="list-style-type: none"> Gender (m / f): k. A. Indications for treatment: k. A. <p>control group</p> <ul style="list-style-type: none"> Persons: k. A. Age [MW (SD)]: k. A. Gender (m / f): k. A. Indications for treatment: k. A. 	<p>After Phase 1 [median]: ca.24 After phase 2 [median]: about 6 readings were taken from figure.</p>	
Tulloch et al., 2004 [39]	<ul style="list-style-type: none"> Study Type: RCT Study duration: 10 years Data collection: baseline (T0), the end of Phase 2 (T1) Number of persons (baseline / Followup): 180/139 2-fold randomization. 1. randomization prior to Phase 1, Phase 1 again after the end of randomization with respect weiterbehandelndem doctor (AC) Intervention group 1: <p>O Phase 1: Headgear;</p> <p>O Phase 2: the discretion of the Ärztin / doctor (z. B. fixed overall</p>	<p>Attending physician / A woman doctor</p> <ul style="list-style-type: none"> Number of persons: 40 Age baseline [MW (SD)]: 9.76 (1.06) Gender (m / f): 17/23 Indications for treatment: overbite ≥ 7 mm <p>Patients Distribution:</p> <ul style="list-style-type: none"> Intervention group 1: 35.0% Intervention Group 2: 25.0% Control group: 40.0% <p>Attending physician / doctor B</p> <ul style="list-style-type: none"> Number of persons: 18 Age [MW (SD)]: 10.32 (0.86) Gender (m / w): 8.10 	<p>PAR intervention group 1</p> <p>Baseline (T0) [MW (SD)]: 32.3 (7.5) Follow-up (T1) [MW (SD)]: 7.2 (5.7)</p> <p>Intervention Group 2</p> <p>Baseline (T0) [MW (SD)]: 30.4 (8.7) follow-up (T1) [MW (SD)]: 8.4 (7.7)</p>	<p>PAR</p> <p>Baseline (T0) [MW (SD)]: 32.5 (6.9) Follow-up (T1) [MW (SD)]: 9.3 (8.1)</p>

Author, Year	study characteristics		outcomes	
	study setting	Description of the population	intervention group	control group
	<p>councils, expansion device, lip bumper, headgear or partial harness)</p> <ul style="list-style-type: none"> Intervention Group 2: <ul style="list-style-type: none"> ○ Phase 1: Funktionskieferorthopädie ○ Phase 2: the physician's discretion Control group: <ul style="list-style-type: none"> ○ Phase 1: No treatment ○ Phase 2: the physician's discretion 	<ul style="list-style-type: none"> Indications for treatment: overbite ≥ 7 mm Patients Distribution: <ul style="list-style-type: none"> ○ Intervention group 1: 44.4% ○ Intervention Group 2: 27.8% ○ Control group: 27.8% <p><u>Attending physician / doctor C</u></p> <ul style="list-style-type: none"> Number of persons: 36 Age [MW (SD)]: 9.66 (0.94) Gender (m / f): 24/12 Indications for treatment: overbite ≥ 7 mm Patients Distribution: <ul style="list-style-type: none"> ○ Intervention group 1: 30.6% ○ Intervention Group 2: 33.3% ○ Control group: 26.1% <p><u>Attending physician / doctor D</u></p> <ul style="list-style-type: none"> Number of persons: 43 Age [MW (SD)]: 9.81 (0.98) Gender (m / f): 29/14 Indications for treatment: overbite ≥ 7 mm <p>patient distribution:</p> <ul style="list-style-type: none"> ○ Intervention group 1: 32.5% ○ Intervention Group 2: 28.0% ○ Control group: 39.5% 		

Source:

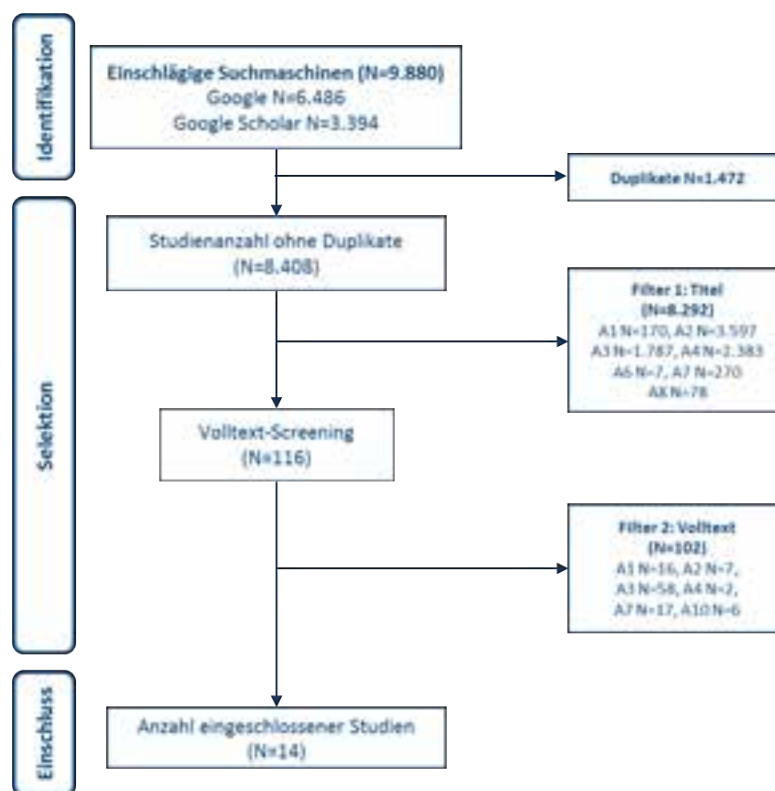
IGES - Compiled

4.2 Analysis of the financial cost of orthodontic treatment-specific measures (Question 2)

Basis for the identification of relevant data on the costs related to the jaw-orthopedic care in Germany were gen scientific investigations, publicly available statistics, secondary data analyzes and studies of questioning. These were identified by an internet search with the aid of relevant search engines.

The results of the searches were screened both by title and the full texts. Of the 8,408 identified documents 14 national formations included the SHI expenditures or cost of the statutory health insurance for orthodontic services (Figure 7).

Figure 7: PRISMA scheme - spending GKV and cost of SHI insureds



Source: IGES - Compiled

Annotation: Exclusion criteria: A1 - not met population, A2 - does not fulfill intervention, A3 - Outcome not met, A4 - not met study type, A5 - No collection of endpoints after the end of treatment, A6 - Publication language does not apply A7 - Publication type not applicable (no full-text), A8 - cation Mehrfachpubli-, A9 - animal studies A10 - No extractable results

In the report included documents specifically generated had to include extractable bare, numeric figures for expenditure to go In order to limit in the analysis. Web pages without giving any sources and no discernible scientific background were excluded. Further documents were excluded, the formatted data only from publicly available statistics zi- and reported no own surveys and calculations.

4.2.1 Spending by the statutory health insurance

Ten of the identified studies and annual statistics contained information on the SHI expenditures for orthodontic services. It was a retrospective observational study published internationally and nine analysis of accounting data by public institutions of the German health as the BMG, the KZBV and selected health insurance (Table 5).

Table 5: Overview of included studies in the analysis of SHI expenditures

Author, Year	title	database	raised parameters
Barmer, 2018 [53]	Dental Report 2018. Series for Health Analysis	<ul style="list-style-type: none"> Assured the Barmer 	<ul style="list-style-type: none"> Utilization rates <i>Average expenditure per insured treated</i> <i>Cost per orthodontic power range</i>
Barmer, 2017 [54]	Dental Report 2017. Series for Health Analysis	<ul style="list-style-type: none"> Assured the Barmer 	<ul style="list-style-type: none"> Utilization rates <i>Average expenditure per insured treated</i> <i>Cost per orthodontic power range</i>
BMG, 2005-2018 [55-68]	Final accounting results of the statutory health insurance (KJ1)	<ul style="list-style-type: none"> GKV-insured 	<ul style="list-style-type: none"> <i>Revenue and expenditure of the SHI absolutely</i> <i>Revenue and expenditure per person insured / rate of change to the previous year</i>
BMG, 2004-2018 [20, 69-82]	SHI-insured by age and place of residence (GKV statistics KM6)	<ul style="list-style-type: none"> GKV-insured 	<ul style="list-style-type: none"> <i>Number of duty members</i> <i>Number of family members</i> <i>Members and family members together</i>
HKK, 2018 [7]	Health Report: Orthodontic treatment of children and adolescents in the mirror of routine data (2012-2017)	<ul style="list-style-type: none"> Assured the HKK, which KfOBehandlung has been approved by the HKK or previous health insurance with a cash exchange in 2016 and since then are in treatment. 	<ul style="list-style-type: none"> Type of treatment (early, usually treatment, diagnosis phase) Diagnostic procedures Treatment Technology <i>Type and amount of settled until the end of 2017 costs (ZA fees, escort services, cost of services in their own or other laboratory)</i>

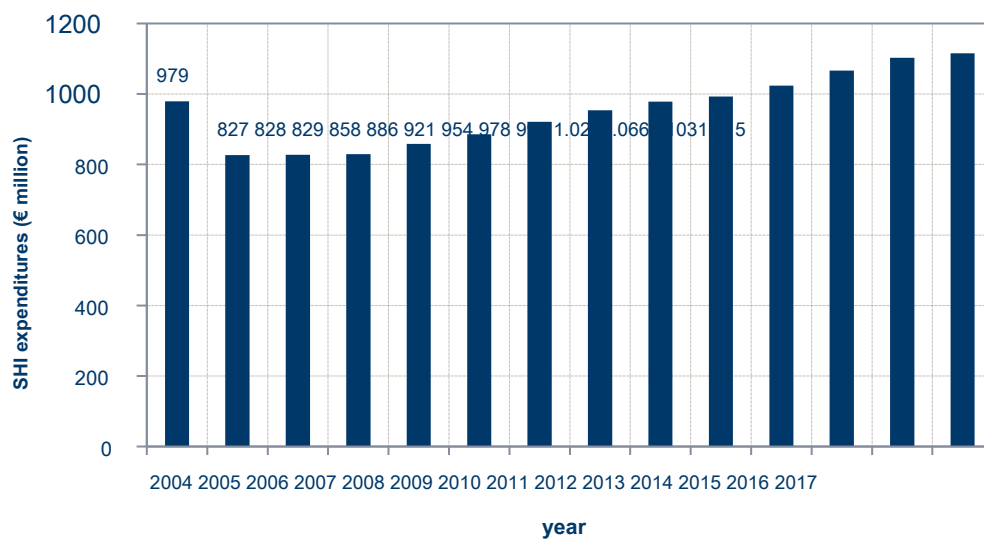
Author, Year	title	database	raised parameters
KZBV, 2014-2017 [15, 16, 83, 84]	Yearbook 2017. Basic statistics for contract dental care	• Data of KZVen	<ul style="list-style-type: none"> • <i>Total expenditure in absolute terms for orthodontic services</i> • <i>Total expenditure on orthodontic services, change rate to the previous year</i> • <i>Spending on orthodontic services for each Member</i> • <i>Spending on orthodontic services per member, change rate to the previous year</i>
	Yearbook 2016. Basic statistics for contract dental care		<ul style="list-style-type: none"> • <i>Development of the amount of power</i> • <i>About the KZVen with your primary and backup cash settlement amounts</i>
	Yearbook 2015. Basic statistics for contract dental care		
	Yearbook 2014. Basic statistics for contract dental care		<ul style="list-style-type: none"> • <i>About the KZVen with your primary and backup cash-settled cases</i> • <i>About the KZVen with your primary and backup cash-settled BEMA points - amount of power</i> • <i>About the KZVen with your primary and backup cash settlement amounts Annual rates of change</i> • <i>About the KZVen with your primary and backup cash-settled cases Annual rates of change</i> • <i>About the KZVen with your primary and backup cash-settled BEMA points - amount of power Annual rates of change</i> • <i>billed to the primary and substitute funds BEMA positions</i>
Bremen et al., 2017 [85]	Changes in orthodontic care at a university clinic over a period of 20 years	• Medical records orthodontic treated, public insurance patients from 1992 to 2012	<ul style="list-style-type: none"> • Patient characteristics • Duration of treatment • Treatment Outcome • <i>costs</i>

Source: IGES - Compiled

Basically, the SHI expenditures for orthodontic services since 2004, only the costs for legally insured persons who have a right according to § 29 SGB V. This amounted to in 2017

€ 1,115 million (Figure 8) and had a continuous increase to [68] since of 2005.

Figure 8: Total expenditure of the SHI for orthodontic services, 2004-2017

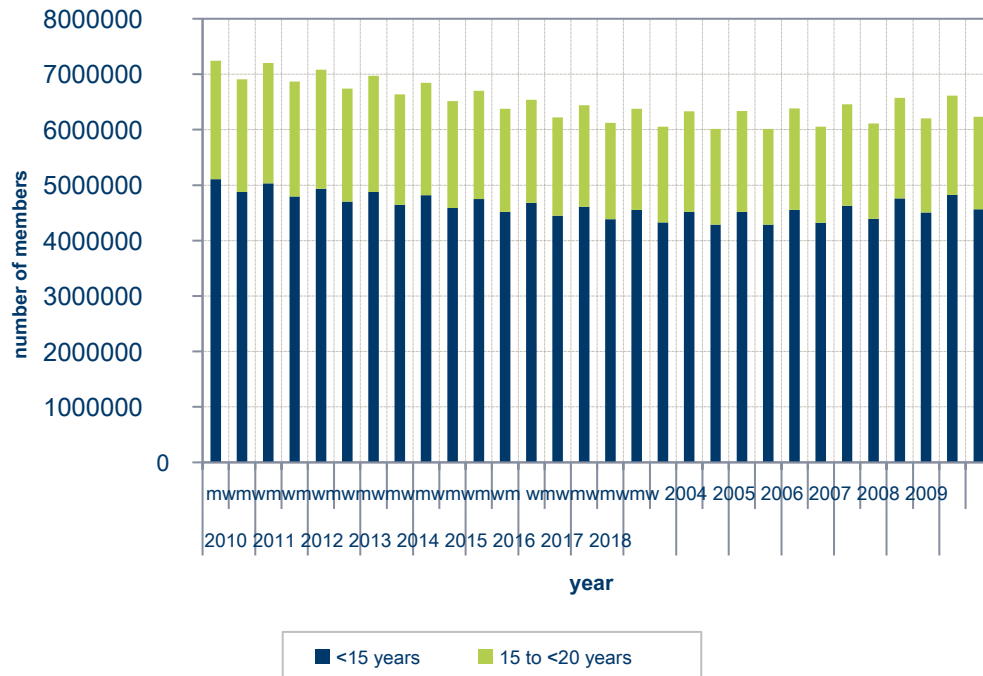


Source: BMG (2005-2018 KJ1) [55-68]

Because of the age-dependent and degree of deformity Erstattungsregelun- (Chapter 2.1 - population) gen in the field of orthodontics provide children and young people who meet the criterion of started before age 18 treatment, the treatment group primarily of interest represents Therefore, in Abbil. - making 9, the numerical development of this age group within the GKV shown since of 2004. The numbers are thereby shown separately excluded for both sexes. be applied to orthodontic treatment measures mainly into diesel ser insured population, shows an analysis of the statement of account data of the Barmer GEK-insured from the year 2016. The highest utilization rates have children and young people aged from 10 to to under 15 years. In this age group, almost 50% of female and 40% received the male insured orthodontic services that are part of the

3. part of the BEMA are. With age, the use of statutory health services in the field of orthodontics [53] decreases.

Figure 9: Development of the statutory health insurance (members and Familienange- hearing together) to <20 years, from 2004 to 2018



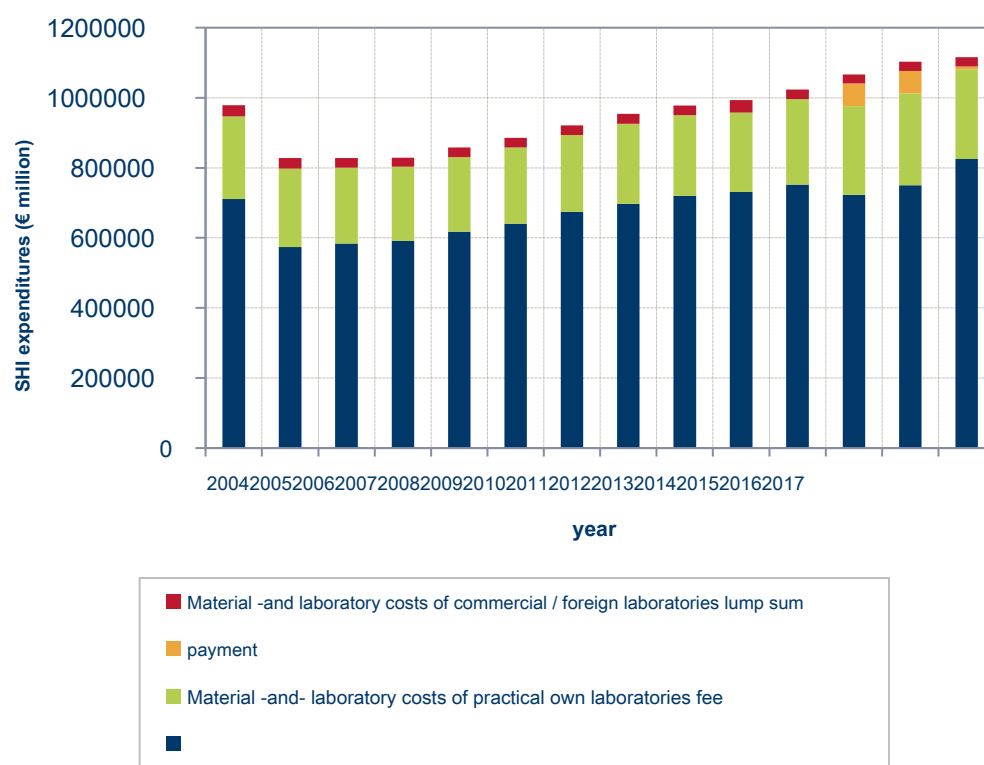
Source: BMG (2004-2018 KM6) [20, 69-82]

In terms of significant relevant insured population can be found that these winds, unlike the SHI expenditures for orthodontic corresponds decline. Thus, the population of children and adolescents under 20 years decreased from 14.1 million in 2004 to 12.8 million in 2018. The development of SHI expenditures is broken down by activity type to consider. Fundamentally is in orthodontic care to fol- constricting three and distinguished by four types of benefits since 2015:

- fee
- Material and labor costs of commercial / foreign laboratories
- Materials, laboratory practice of our own laboratories
- Lump sum payment (since 2015)

These are relevant for settlement services have developed differently in recent years, as Figure 10 can be seen.

Figure 10: SHI expenditures for orthodontics by activity type, 2004-2017



Source: BMG (2005-2018 KJ1) [55-68]

The bulk of the spending is thopäden to the fee of orthodontists / Kieferor- or due dentists / dentists that be- tween depending on the year 68% and 74% (2017: approximately € 825 million; 74%) of the total expenditure of - makes. The second-largest block form materials, laboratory practice of our own laboratories whose shares between 23% and 27% lower (2017: approximately € 256 million; 23%). Only marginal importance to the issues of practical foreign laboratories. Your cost share is about 2% to 4% (2017: 26 million €;

2.4%) (own calculations by BMG 2005-2018 KJ1, [55-68]). The differentiation in another activity, the lump sum payment was held for the first time, 2015. This is about, negotiated at country level between health insurers and KZVen, annual lump-sum payments based on quality orthodontic treaties. These represent framework agreements, which provide for higher quality orthodontic encryption supply by far not taken into sichtigte benefits are financed by the respective health insurance company in the SHI reimbursement canon. An example

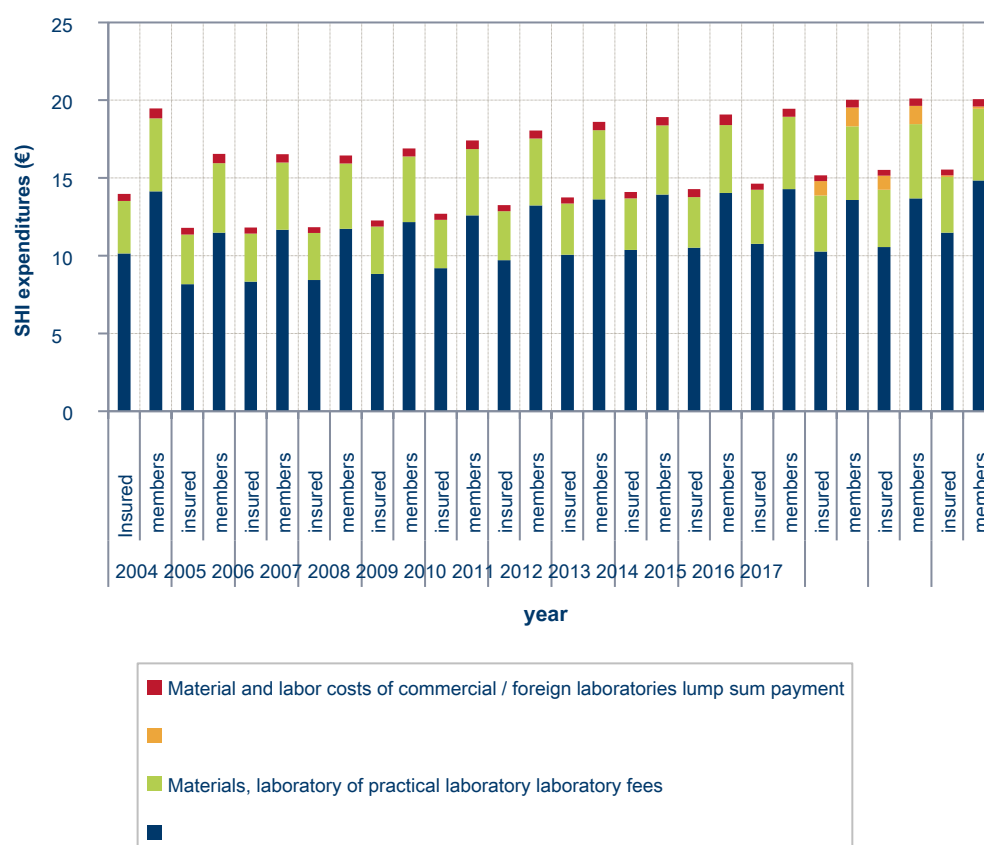
the 2010 came into effect the framework agreement between the dentists' association in Bavaria and the BKK Bavarian Association, which the insured an additional cost free supply of various special brackets or highly elastic, tooth caring nickel-titanium wires enables light [86]. The proportion of expenditure, however, has since 2015, due to termination conditions of these contracts, steadily decreased [87]. So this amounted to in 2017

0.68% of the total expenditure for orthodontics (own calculations by BMG 2006-2018 KJ1, [55-68]).

The individual costs of orthodontic care in Germany to insured and members of the SHI level are presented below (Figure 11). When members is dues-paying compulsorily-assured and voluntary contributors. This was in 2018 to 56.58 million people in Germany. Among insured members as well as the contribution free of statutory health insurance are subsumed. Overall, this figure was in 2018

72,810,000 people [20].

Figure 11: SHI expenditures by activity type and per insured member, 2004-2017



Source:

IGES - Compiled using BMG KM6 2004-2018 [20, 69- 82] and BMG 2005-2018 KJ1 [55-68]

Figure 11 shows that in particular the professional fees since 2005 have risen steadily and in 2017 an average of € 11.49 per insured member and amount to € 14.48 per member. An output increase is also recorded in the materials, laboratory practice their own laboratories. Since 2013, these have risen steadily to 2016 inclusive; in 2017 it fell for the first time.

A comparison of the rates of change per person insured in terms of total expenditure in the orthodontic and dental care without dentures (not shown here), shows a similar development.

In connection with the development of expenditure of the SHI for orthodontic services must also developments in the number of cases considered advertising to. These are shown for the years 2004-2016 in Table 6 below. The KZBV reported that the amount of power from 2,005 to 2,016 per member has 1.5% pa conces- taken.

Table 6: Development of the settled cases in the field of orthodontics, 2004-2016

year	Case number in thousands. (ALTERATION per member,%)	year	Case number in thousands. (ALTERATION per member,%)
2004	7266.5 (-9.6)	2011	7533.3 (+1.2)
2005	6783.5 (-6.2)	2012	7564.9 (-0.4)
2006	6661.2 (-1.9)	2013	7636.1 (+0.2)
2007	6710.7 (+0.2)	2014	7742.3 (+0.3)
2008	6957.0 (+3.0)	2015	7803.3 (-0.4)
2009	7214.8 (+3.4)	2016	7915.9 (-1.4)

Source: KZBV (2017) [15]

The development of billed SHI services in orthodontics the years 2013 to 2016 which basically takes place via the BEMA positions, was attached to the notes A3 due to the circumference. Here, too, a continuous increase shows. Sun accounted for 11.5% of the total in 2016 abgerechne- th BEMA points volume of dental treatments (without dentures) to the orthodontic [15].

Individual health insurance companies have carried out targeted analysis in the field of dentistry and orthodontic care in recent years. The focus is on the utilization rate and the spending per comparison were secured according to individual service areas in orthodontics. The Barmer evaluated both 2017 and 2018, the data of its 8.5 million insured parties in respect to the contractual dental care. This reflects the loading action happened of 12.0% and 11.8% of the statutory health insurance resist. The initial evaluations in the field of orthodontics comprising data 2015 and 2016 and all directly billed during this period with the insured Barmer power ratings [53, 54]. reported both the utilization rates kieferortho- pädischer treatment measures and the average treatment costs (Table 7).

Table 7: Listing of the average orthodontic treatment costs and average use per treated Barmer insured persons by age and sex

insured group	average Inan- entitlement transfer (%)		Average Orthodontic treatment costs (€)	
	2015	2016	2015	2016
total	4.4	4.5	108.44	108.28
Men	4.1	4.1	116.67	114.91
women	4.7	4.8	100.44	101.82
Total <20 years	18.11	18.13	252.18	255.22
Men <20 years	16.41	16.43	255.05	257.33
Women <20 years	19.95	19.97	249.10	252.94
Total 10 - <15 years	k. A.	k. A.	450.00	460.00
Boys 10 - <15 years	~ 40	~ 40	k. A.	k. A.
Girls 10 - <15 years	~ 50	~ 50	k. A.	k. A.
Total > 20 years	k. A.	k. A.	~ 100	~ 100
Total > 60 years	k. A.	k. A.	<50 €	<50 €

Source: Barmer tooth Report (2017, 2018) [53, 54]

The data show a minimal increase in the use and cost. In terms of cost, the Barmer dental Report 2018, the distribution to the various service areas within the orthodontic represents (Table 8).

Table 8: National average of the average expenditure per treated insureds <20 years for all services of the BEMA part 3 performance processing areas

year	Expenditure (€)			
	total	Orthodontic	laboratory	accompanying services
2015	252.2	137.7	63.0	51.1
2016	255.2	138.9	64.0	52.3

Source: Barmer tooth Report (2017, 2018) [53, 54]

Although these are among the Barmer tooth reports a series of publications, JE include but previous reports no special evaluation for the power range of orthodontics. Therefore the derivation of a trend from this data is not possible.

In addition to the Barmer the HKK 2018 was an evaluation of their Abrechnungsda- th carry and focused while the orthodontic treatment of children and adolescents. Database represented the routine data for the years 2012-2017. As part of the evaluation of two insured populations were seeks loading. Firstly, Brown and Spassov analyzed (2018) [7] of the data

4,288 insured ¹ (46.6% male, 53.4% female), which the previous health insurance an orthodontic-specific treatment has been approved based on the ISCC levels in 2016 by the HKK or cash changers. On the other were insured in the focus of evaluation that had been completed from 2012 to 2016 the treatment. To advertising included in the study to which children and young people had to be insured for the entire period in the HKK. This was true for 5,535 people. Information KIG- classification did not exist for these insured. th based on the available DA were differentiated evaluations with respect to the type of treatment (early, usually treatment, diagnosis phase), conducted diagnostic and the- peutic measures and are created to the type and amount of billed costs. As part of this opinion, the reported utilization rates and the costs are only differentiated by the two insured populations reported, as these are crucial for moving grunde lying question.

With regard to the use, it became apparent that the majority of insured parties a rule undergo treatment, ie the treatment is carried out only after the start of the second phase of the dentition. Early treatment, which denotes the orthodontic intervention in the early stage of development Gebissent- (milk teeth), should only take place in exceptional cases to. Other types of treatment are the extension and the empty quarter. An extension of the treatment can be applied when action is required on the fourth year and beyond. Empty quarters are characterized by the lack of settlement of payments, which can be performed in spite of treatment measures (z. B. Use / repair of Apparatu- ren) (Table 9).

Table 9: Number of patients per treatment type

population	usually treatment	Early treatment extension	empty quarter	
Current treatment (n = 4,288)	2543	644	k. A.	k. A.
Completed treatment (n = 5.535)	4520	912	426	3426

Source: Brown and Spassov (2018) [7]

¹ The information on KIG classification was present in 4,123 of the 4,288 insured.

In the population of children and adolescents in whom treatment has been completed, it was found that several types of treatment have been demanding in the presence. Sun received 386 of the 4,520 patients both an early and a control treatment, and at 305 insured the control treatment was prolonged.

The cost of billed orthodontic treatment measures, depending on the activity and distinguishes between the two analyzed groups have also been reported (Table 10). action cases regarding completed loading the average costs reported were shown from 2012 to 2017. In children and adolescents, where the loading action was approved in 2016, the data related to the accounting period 2016-2017.

Table 10: Cost of orthodontic treatment (current vs. off connected Falls) to brown and Spassov (2018)

activity	population	Minimum amount per case (€)	Maxima ler amount per case (€)	Total of all felling amount (€)	Throughput schnittskos- ten per admission (€)
Dentist charge	Active cases	13.14	3,098.74	2223060	727.44
	enclosed. cases	11.39	3,322.22	6,674,892.61	1,227.45
own laboratory	Active cases	1.10	2,606.55	929,993.55	299.51
	enclosed. cases	0.98	2,520.68	2,328,913.30	431.84
External laboratory	Active cases	12,63	1,724.63	140,901.88	310.36
	enclosed. cases	20.33	1,857.39	408,419.12	406.39
incidental benefit	Active cases	0.55	963.20	622,190.04	198.91
	enclosed. cases	0.55	1,237.29	1,513,877.93	278.39
Total (average cost per case)	Active cases				1,536.22
	enclosed. cases				2,344.07

Source: Brown and Spassov (2018) [7]

Brown and Spassov (2018) [7] come to the conclusion that the cost profiles of individuals with KIG classification who were in treatment and those de- ren treatment had been completed, are similar. The highest costs in the areas of dental fees as well as practice their own laboratory, the laboratory costs in early treatment due to frequent Einsat- zes removable appliance fail highest.

In addition to the reported national statistics and analysis of billing data of individual health insurance could advertising identified based on medical records as part of the research, a retrospective observational study to. Bremen et al. (2017) [85] analyzed data from 3,210 patients who were treated orthodontically in a university hospital in the period from 1992 to 2012, and had health insurance law. Due to the extensive time horizon found in the analysis of both data before the introduction of KIG-stage (1992-2002: 1273) and after (2002-2012:

1,937) input. In terms of cost or reimbursement of treatment by the public health insurance 300 medical records were selected at random. In this case, it was 100 in the ISCC stages 3, 4 and 5 (treatment period: 2004-2012). Thus, no comparison of the cost found before and after the Systemumstel- development instead. The evaluations showed that costs of € 2,183.95 per patient for the material and laboratory expenses were reimbursed by the GKV in the median. An overview of the median reimbursed by the statutory health insurance costs and the reimbursement amounts per treatment schedule is shown in Table 11 below.

Table 11: By SHI reimbursed costs of orthodontic care, and each appointment to Bremen et al. (2017)

	KIG 3	KIG 4	KIG 5
Refund per date (€)	74.27	76.93	68.07
Refund entire treatment (€)	2,097.52	2,155.55	2,332.00

Source: Bremen et al. (2017) [85]

These results show that the reimbursed medical costs are not necessarily the severity of malocclusion in context. Bremen et al. [85] point out that the reimbursement situation in Universitätsklinikum to ken is different from that in private practices.

Quick Facts

In the analysis of SHI expenditures for orthodontic care wur- the ten included statistics and analysis of various stakeholders in the health care system as well as a retrospective observational study. The analog analysis of the available data shows that the costs incurred for the statutory health insurance as part of orthodontic care, away steadily increased over the past years and have achieved for the year 2017 of € 1,115 million, a new record. This is development fell mainly due to an increased number of treatment due. And at the level of the insured and members of an increase in the average cost was observed. In contrast to the primarily relevant for orthodontic services insurance took chertenpopulation - children and young people aged between 10 and 20 years - in the same period from. Spending even caused largely by fees and materials, laboratory practice of our own laboratories, which together

are the cause of more than 90% of expenditure. The data presented are up due to the populations the evaluations underlying only partially comparable. Thus, the Germany-wide data only from the expenditure incurred monetary expenses for the total population of the statutory health insurance. The de- tailed case and cost data that can be drawn from the evaluations of the individual health insurance companies, however, are only a certain insurance chertenpopulation. On the basis of the data can not be judged, therefore, that the expenditure in orthodontic care to the criteria satisfy the cost-effectiveness.

4.2.2 Private expenditure by statutory insurance

As part of the orthodontic plan exists for statutory health insurance the chance to take diagnostic or therapeutic treatment measures claim that is not an integral part of the § 29 Abs. 1 SGB V included performances of SHI. Basis for the settlement of obligations Privateis- is a written agreement between the Vertragszahnärz- tin / contract dentist and the publicly insured (Mehrkostenverein- barung). These services are invoiced to the insured on fees for dentists (GOZ). The use of Zusatzleistun- gen and the associated private liquidation is allowed only if the comparison secured express the desire or the desire for a Privatbehand- development expressed [88]. In § 128 SGB V continues specifying that "independent physicians who demand illegal payments or accept or insured demanding acceptance for Inan- influence of private medical care instead of their rightful power of public health insurance, failed to meet their contractual ethical obligations". wur- Against the background of this tension the identified studies as part of this report and evaluated who had the use of private services and so STE Henden in connection costs by SHI insured the subject. A total of four relevant articles were identified. This was to survey studies, one carried out by telephone and three writing. Initiators of the interviews were legal and private medical insurance companies. The objectives and populations surveyed differed significantly between the surveys.

The HKK (2012) [89] interviewed children and young people whose orthodontic treatment was completed. The aim was to identify the motives circum- stances, results and outcomes of orthodontic care. Furthermore, the parents were included in the survey in order to bring knowledge to the level of private co-payments or of household income in experience. To participate in the survey 1,309 insured were asked their treatment in 2010 was completed. The response rate was 33.2%, meaning that 435 questionnaires were included in the evaluation. was due to the structural data

assesses the group of respondents to be representative of the population of HKK-insureds. The average age of respondents was 16 years. In 56% of patients it was girls, 44% were boys [89]. In the survey of DAK Health (2015) [90] were insured When integrated whose children currently one rule treatment undergone. Background of the survey were the issues as it is with the orthodontic advice and treatment in Germany, how satisfied the insured within the framework of which are and to what extent arise for this cost. In total, 8,900 questionnaires were sent to the insured of the DAK health. In the evaluation of 3,500 responses were received, representing a response rate of 39%, respectively [90].

Part of the Barmer GEK Health Monitor 2016 was also a by Spassov et al. 2016 [91] initiated survey of children in whom the period of questioning orthodontic therapeutic interventions have been applied (children's group) and adolescents whose treatment has been completed (youth group). This should examine evidence on the role of children, adolescents and their parents in the decision-making process (eg. As consulting services, processes and results) and the nature and the scope of services as part of orthodontic care. were used more, partially validated questionnaires, which were supplemented "with their own goal-oriented questions". In the group of children (10-14 years) 2,991 questionnaires were sent out, of which 865 (29%) responded. In the youth group (15-17 years), the response rate was 25%, so that by 3015 Ask arches 750 input found in the evaluation. The evaluation of the issues did not take place on a group basis [91]. The performed with a different focus each year representative population survey of private health insurance Continentale a. 2017 G. examined how self- and co-payments of statutory health insurance. In co-payments is set out in § 61 SGB V monetary amounts which have applied SHI insured in the use of services. Self services were in the study obligations as private spending on Gesundheitsleis- (z. B. medical practitioner,

IGeL services) defined. total:

1,365 people over the age of 25 years, interviewed by telephone. Approximately 87% (1,195) had health insurance law. The addressed in this survey population does not correspond largely affected by the directive orthodontic patients.

Table 12: Overview of included studies in analysis at cost of statutory health insurance

Author, Year	study characteristics			Results
	study setting	Description of the population	raised parameters	Results in terms of the relevant th Paramater
HKK, 2012 [89]	<ul style="list-style-type: none"> Type of study: survey Of survey: Written Survey period: unknown Population: <ul style="list-style-type: none"> O Insurance portfolio of HKK O Children and youth, deren treatment in 2012 was completed, and their parents Number initially interviewed people: 1309 Response rate: 33.2% (435) Survey Instrument: Standardized, elfseitiger questionnaire 	<ul style="list-style-type: none"> Age (min-max (Ø)): 8-38 years (16 years) <ul style="list-style-type: none"> O 8-13 years: 23.9% O 14-17 years 47.8% O ≥ 18 years: 28.4% Gender (m / f): 244/191 	<ul style="list-style-type: none"> Frame data for use Motives, reasons, reasons for orthodontic treatment Importance and satisfaction Unwanted events Long-term effects 	<ul style="list-style-type: none"> % share of parents and children who get offered at least one additional service or have used: 75.2% co-payment amount: <ul style="list-style-type: none"> O ≤ 500 €: 50% O 500-1000 €: 32% O > 1000-2000 € 15% O > € 2,000: 3%

Author, Year	study characteristics		Results	
	study setting	Description of the population	raised parameters	Results in terms of the relevant th Paramater
DAK Health, 2015 [90]	<ul style="list-style-type: none"> Type of study: survey Of survey: Written Survey period: June 2015 Population: <ul style="list-style-type: none"> O Insurance portfolio of DAK health O Insured whose children are in a current control treatment already for almost a year Number initially interviewed people: 8900 Response rate: 39% (3500) Survey Instrument: Questionnaire (type unknown) 	k. A.	<ul style="list-style-type: none"> Counseling and treatment in orthodontic care insured satisfaction <i>additional costs</i> 	<ul style="list-style-type: none"> % share of families who received the offer of an additional payment-free treatment: 74.9% % share of families who have received a cost estimate: 88.3% Planned costs <ul style="list-style-type: none"> O 500 €: 13% O > 500-1000 € 28% O > 1000: 45% O Not known: 14% % share of the families who pay a flat monthly rate: 70% Nationwide, average cost of DAK health per case: 3100 €

Author, Year	study characteristics		Results	
	study setting	Description of the population	raised parameters	Results in terms of the relevant th Paramater
Spasov et al., 2016 [91]	<ul style="list-style-type: none"> Type of study: survey Of survey: Written Survey period: unknown Population: insurance portfolio of Barmer GEK Number initially interviewed people: 6006 Response rate: 27% (1,615) Survey Instruments: Questionnaires <p>O C-OLDP</p> <p>O QPQ 11-14</p> <p>O KINDL Questionnaire</p> <p>O Instruments of the studies have been adapted and enriched with their own goal-oriented questions</p>	<p><u>children's group</u></p> <ul style="list-style-type: none"> Respondents: children with their parents Number initially interviewed people: 2991 Response rate: 29% (865) Age: 10-14 years Gender (m / f): 415/450 started treatment within the last three to six months prior to the survey <p><u>youth group</u></p> <ul style="list-style-type: none"> Respondents: Teenagers with their parents Number initially interviewed people: 3015 Response rate: 25% (750) Age: 15-17 years Gender (m / f): 352/398 completed treatment with a fixed appliance within the year prior to the survey 	<ul style="list-style-type: none"> Satisfaction with treatment as well as information and advice to young patients and their parents What or who caused an orthodontic treatment? Important aspects of the treatment of children and young Processes and results of completed orthodontic treatment <i>additional costs</i> 	<ul style="list-style-type: none"> Frequency addition undrawn and privately paid non-contractual benefits: 85% level of private co-payments for additional services over the entire duration of treatment: <ul style="list-style-type: none"> < 500 €: 24% > 500-1000 €: 38% > 1000-2000 €: 29% > 2.000 € 9% Average private supply payment: 1200 € Obtaining additional Leisun-gen did not significantly on treatment satisfaction

Author, Year	study characteristics		Results	
	study setting	Description of the population	raised parameters	Results in terms of the relevant th Paramater
Continentale crane kenversicherung, 2017 [92]	<ul style="list-style-type: none"> Type of study: survey Of survey: Telephone Survey period: unknown Population: People aged 25 and over Number initially interviewed people: 1365 Response rate: - Survey instrument: Questionnaire 	<ul style="list-style-type: none"> Age: <ul style="list-style-type: none"> O 25-39 years: 21% O 40-49 years: 21% O 50-59 years: 22% O > 60 years: 37% Gender (m / f): 660/705 Insurance status (GKV / PKV): 1195/170 	<ul style="list-style-type: none"> <i>Self- and co-payments by Activity Type</i> 	<ul style="list-style-type: none"> % share of persons who have made an additional payment in the field of orthodontics in the last 12 months: 15%

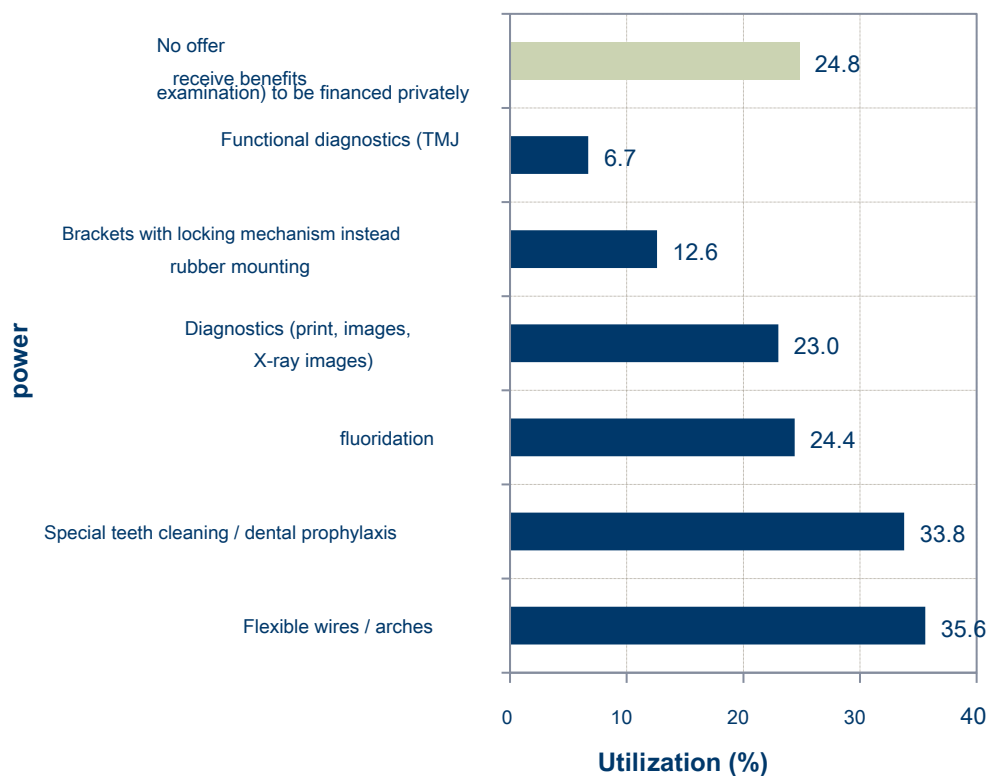
Source: IGES - Compiled

Annotation: In italics parameters is levied within the study relevant parameters for the underly- constricting Question 2 of the report

Use and type of services

Privately financed services were different processing often taken depending on the type of performance to complete and paid. The survey of HKK (2012) [89] resulted in that 24.8% of parents a free loading was offered treatment without private services (Figure 12) [89]. The DAK Health (2015) [90] inquired whether the insured an additional payment-free loading treatment was offered. This affirmed 74.9% of the insured. A list of the frequency of the claimed benefits included the study reports the HKK [89] and the Barmer [53]. In particular services in connection with fixed appliances such as special wires or bows and measures to promote oral health (dental cleaning / dental prophylaxis, fluoridation) were at the focus.

Figure 12: Utilized and privately funded services in the perception of parents



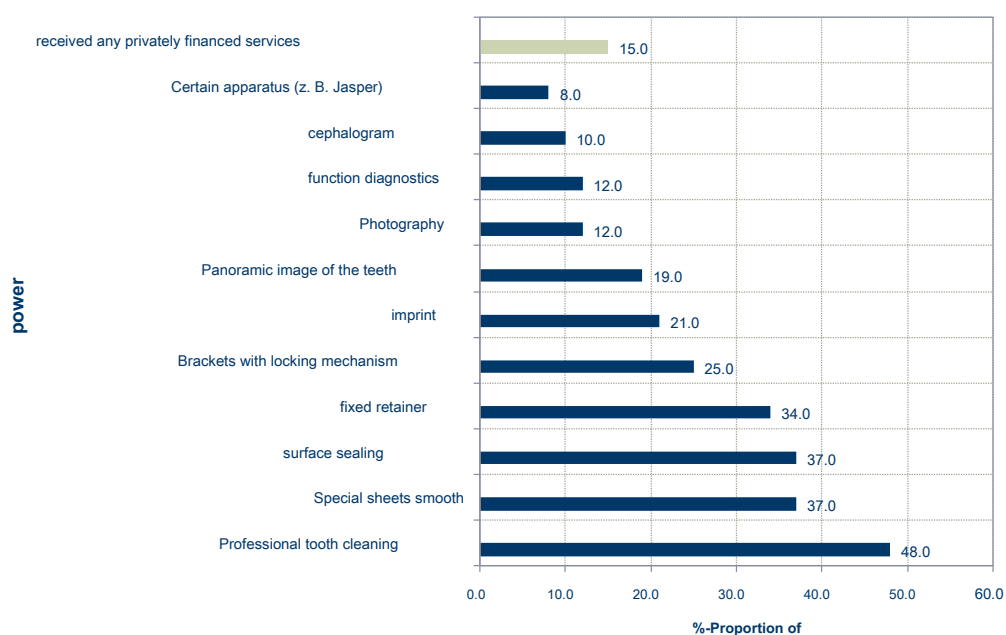
Source: HKK (2012) [89]

Annotation: Multiple answers were possible

The nature and categorization of the interviews are addressed in treatment measures differ in this case between the reports of HKK [89]

and Spassov et al. [91] (Figure 13). Furthermore, the surveyed ten populations differ, so that only a limited degree of comparability is given between the survey results.

Figure 13: Use orthodontic private services



Source: Spassov et al. (2016) [91]

The reported use of private services within the past 12 months for orthodontic services was in the Continentale study 15% [92].

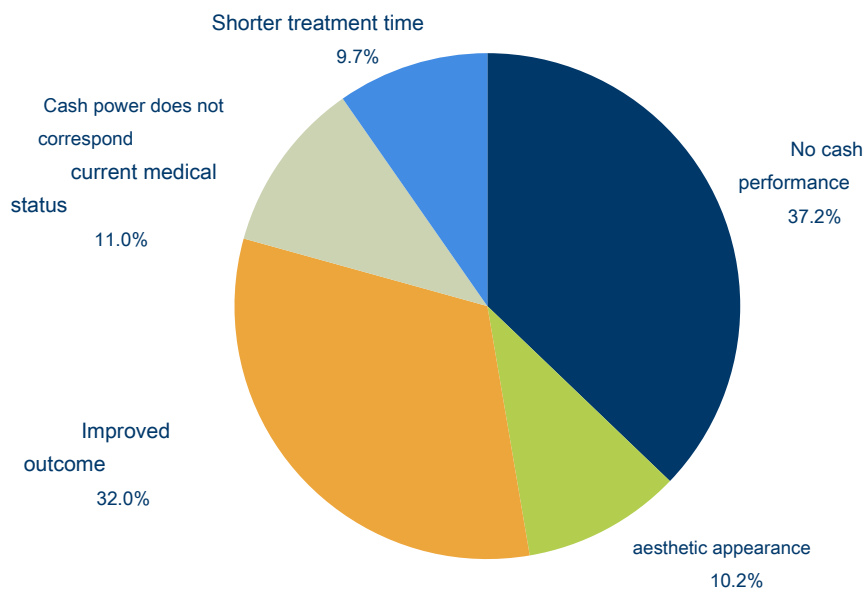
Basically, items need to be considered co-payments under the rule orthodontic care in light of the provisions of the SGB V advertising to. According to § 29 para. 2 SGB V have insured a contribution of 20% ² the costs are borne. This will be refunded to the insured by health insurance to-if the "determined by the medical treatment plan ER- ford variable" services have been completed. Because of this, not abzuschät- frontiers in how far it is at the given numbers to self-payments for orthodontic services outside the SHI benefits catalog or payment payments as part of the equity share.

As part of the survey of HKK was also charged with what justification the private services dung policyholders were offered (Figure 14). Most often, the argument is that it is a measure

² For the second and each subsequent child, the own contribution amounts to 10%.

which is not part of the statutory health insurance benefit package. Furthermore, the treatment plays an important role development success.

Figure 14: Reason for the provision of private services

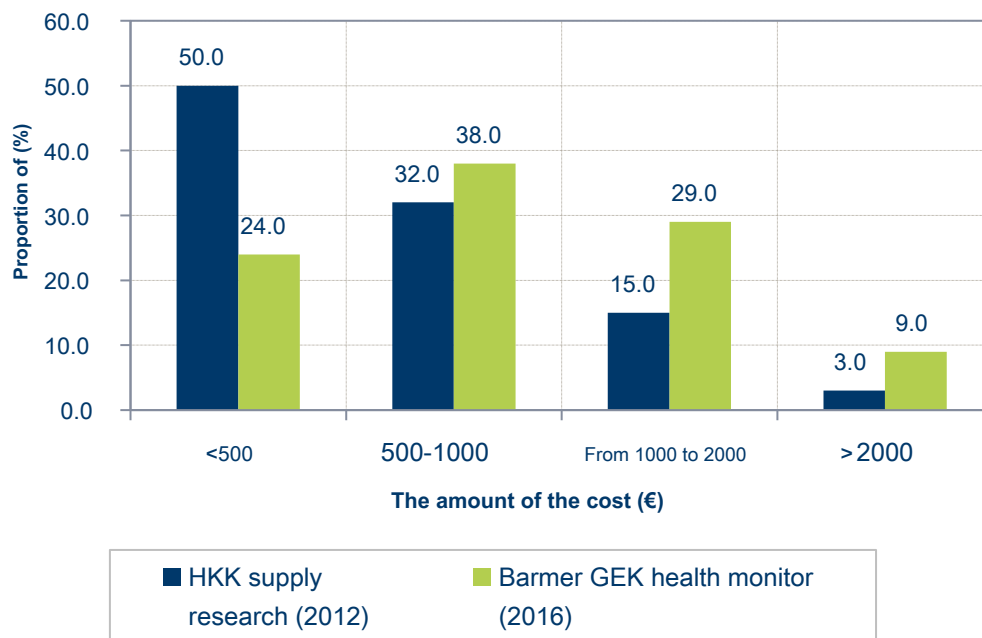


Source: IGES - Compiled by HKK (2012) [89]

prime costs

As part of the survey by the HKK (2012) [89] was raised, how high the cost of the insured for orthodontic care were. Since the treatment of children and adolescents had been completed, advance payments have already been recorded here. Also charged Spassov et al. (2016) [91], the additional costs of the treatment. However, both parents were interviewed, whose children had already completed the treatment, as well as children who were still active treatment (Figure 15). regarding a separate presentation. the work already done and anticipated financial expenses did not take place there.

Figure 15: the amount of the cost in the context of orthodontic comparison supply



Source: HKK (2012) [89] and Spassov et al. (2016) [91]

The Continentale study inquired about the amount of payments. In terms of Orthodontic respondents [92] indicated that they have an average of 777 € spent.

Quick Facts

Health insurance approved in principle able to take as part of the orthodontic benefits in the claim that are not integral part of the SHI benefits catalog. These costs are not wearing overall by the SHI, but must be financed privately by the insured. The use and in related monetary up walls were analyzed in four survey studies found their way into the report. The studies were initiated by various health insurance companies and subsequently hand the respective insured population conducted. According Befragungsergebnissen take 75 to 85% of insured private benefits. These are, in particular, treatment measures for oral hygiene so-as the supply of special sheets and wires. Regarding the reasons for seeking additional services, for example, gave the HKK-insureds that was conveyed to them by the doctors that the desired performance tung was not part of the SHI benefits catalog or additional service to faster treatment success lead [89]. costs regarding the level of self- showed the interviews that the majority of the insured costs up to 1000 € recovered or has already applied that amount. Basically, must be considered in connection with the costs that insured

carry a cost of 20%, the supply them after successful termination of orthodontic treatment is refunded. It can at this point be possible to assess the questionnaires used behaves this property in the form of an explanation, or the formulation of the question addressed ha-ben. Overall, it must be considered in the interpretation that the comparability of the reported data is very limited. First, the respondents merely reflect the insured clientele single large health insurance companies. Secondly, the children and adolescents (current vs. completed treatment) were in terms of silicic ferorthopädische care in different stages of treatment. Furthermore, the reports did only WE nige information on the survey methodology and not indicated that of validated questionnaires were used. An independent analysis of the carried by the statutory health insurance cost in the course of orthodontic treatment could not be identified in the research.

4.3 Research requirements (question 3)

In this report, the current scientific evidence on the benefits and effectiveness of orthodontic treatment measures were so-so as the related costs for orthodontic encryption supply in Germany compiled. Although a high number of study programs could serve and documents found in the research; the identified studies, however, are only suitable to answer the underlying questions. Because of this will be explained below, which insights on the current state missing and what specific research needs DA out to be derived. Furthermore, the first steps are formulated as identified ed research needs could be addressed in the future.

4.3.1 Use and effectiveness of orthodontic treatment measures

treatment measures research and analysis of existing literature on orthodontic loading has also shown addition to the reported findings that in terms of the generation of studies and supply data in the orthodontic some methodological peculiarities must be upheld. This particularly concerns the use of standardized interventions and measuring patient-relevant outcomes. These methodological limitations described in more detail below lead to consequences in deriving evidence-based guidelines. Because of the research needs derived here do not correspond consistently with the generally known and recognized presence sayings of evidence-based medicine.

generate evidence through clinical trials - Prevention randomization, Vergleichsinter- and time horizon as obstacles

The medical effect, as well as the benefit of therapeutic interventions to be detected according to the standards of evidence based medicine by RCTs. The focus of these studies collecting patient-relevant end points should be that to express what long-term impact of the application of each method. took overlooking the diagnostic measures, the patient-relevant benefit reflects only when the patient-relevant outcomes are positively influenced by adequate treatment planning. Diagnostic measures, for example, their tongue-zen thus develop to help prevent risky or complication-prone interventions or improving the effectiveness of therapeutic measures allow [8].

As part of the actions undertaken in this report research long-term patient-relevant outcomes were identified in relation to the therapeutic measures RCTs, but only len In individual have raised. Relevant are patients in orthodontic context especially the oral health, schwerwie- constricting periodontal disease, tooth loss and the mundgesundheitsbe-

solid quality of life. In terms of diagnosis, none of the ten studies included evaluated both the derivation of the treatment plan on the basis of the various diagnostic measures and the resulting therapeutic measures. Consequently, it can be assessed currently neither relevant in the context of the report therapeutic nor diagnostic orthodontic policy measures, which patient-relevant benefit they have.

To answer this question, the throughput would basically guide a clinical study in the form of RCTs with a long observation period aftertreatment necessary as the gold standard. In connection with this, however, comparable different methodological aspects need to be considered. It is in particular the definition of the comparison intervention and the willingness of patients to randomization. According to the principle of a classic intervention study and in the context of the proposed evidence of the benefits of orthodontic treatment to a non-treatment, the comparison intervention would be the omission of orthodontic care. This would, strictly speaking, however, mean for the patients in the control group that they are denied benefits of orthodontic supply, SGB V entitled after § 29th In addition, the patients could not decide whether it ever comes into consideration for them to forego treatment because of the randomization provided for this purpose.

Another major challenge in the acquisition of these endpoints is the survey period. So come periodontal disease and tooth loss, if necessary, only after years or decades; a correspondingly long loading would observation period thus needed. Among the mentioned aspects, the conduct of such studies will not look realistic. Because DES and orthodontic interventions are for the evaluation controlled, non-randomized, clinical trials suggested that various diagnostic measures based on treatment planning (z. B. fixed vs. removable appliances, early vs. usually treatment) as well as relevant patient-relevant endpoints after therapy. However, the problem of long observation period is maintained even in a cohort study setting; it is inevitable, hard clinical endpoints to be recorded.

Pull secondary data analyzes to assess the long-term effects in loading cost

In order to map the long-term endpoints regardless of a clinical study, a retrospective analysis of the accounting data of the German health insurance companies would be conceivable. For a proper representation of the population this analysis would have to include diagnostic data. The KIG-stage part of the treatment and cost plan are to be expanded. On the basis of such data pools patients could be tracked with already completed orthodontic treatment, and

Connection diagnoses such as dental caries, periodontal disease or tooth loss may be applicable. However, such an investigation would methodological

Limitations subject. That is why, for example, socio-economic factors are not considered, and the mapping of oral health-related quality of life would also be impossible. These two variables could be collected exclusively by means of supplementary survey.

develop standardized clinical pathways depending on the nature and extent of the malocclusion

As part of the research and the analysis of studies on the therapeutic orthodontic intervention no standardized recommendations could be identified that would indicate a treatment regimen depending on the diagnosis. Such diagnostic and therapeutic pathways are usually based on study findings and have already been implemented in other medical specialties. Model could be the existing provisions in the area of the denture. There by the G-BA specified diagnoses that are associated with the indexed for their supply zahnärztl- against payment [93].

implement projects through the use of already implemented study advanced insights

To further evidence in relation to the orthodontic care reindeer to generie-, making use of existing structures, the expansion would tion of the survey of the German Oral Health Study possible. In this case, it Han delt is a population representative survey dental and social science parameters in selected cohorts. A group to young people. As part of the social science survey they are also asked to determine whether a tooth or jaw regulation has been or is currently being carried out [94]. It is likely that even adults surveyed have received orthodontic treatment and generally can provide information on the type. Thus, an expansion would tion of the Oral Health Study to the aspect of the orthodontic encryption supply possible and could contribute to an increased gain of knowledge with regard to the number of orthodontic treatment Germans and their long-term oral oral health.

Furthermore, could the NAKO Health Study, be used as a long-term population study with a duration of 20 to 30 years, to investigate orthodontic treatments and their long-term effects. The study aims to explore the development of common diseases. The selection of personnel nen is random. To ensure representativeness, the selection of study participants and study participants will be randomly are based on data rend the registration offices. The investigations carried resulted in the study are divided into various levels. Level 1 includes baseline studies, Level 2 Additional studies. can be complemented

by MRI and biological samples. Currently includes Level 2 (Zusatzuntersu- deviations) a dental investigation, which includes the Erfas- solution of the dental status as well as the determination of caries, gum disease and tooth loss are [95]. Like the German Oral Health Study supplemental information may be subject to treatment measures already taken place to orthodontic loading here.

fix lack of evidence-based guidelines for orthodontic care

Apart from the aspect of the benefit was found during the research that study authors point out frequently that no recommendations with regard to the nature and extent of diagnostic measures, depending on the indicators were formulated tion area [25, 28, 29]. Basically, there are only a few national and international guidelines in the field of orthodontic care. With respect to the use of diagnostic measures may be mentioned as an example, the guideline of British Orthodontic Society (2015) [96], formulated the recommendations for the use of radiological methods. At the national level there is only the S2K guideline for dental volume tomography [97], which is not handy for orthodontic routine diagnosis in children and youth is suitable and not part of the contract dental care. In terms of therapeutic orthodontic treatment no guidelines could be identified that would broach the management of various Malokklu- emissions. The American Academy of Pediatric Dentistry medicine published in 2014 a guideline that fundamentally gen the Zahnfehlstellun- and addressed their treatment [98]. To what extent these guidelines in the light of the German KIG levels and the SHI benefit package is transferable to the German supply situation would be examined. Basically, however, the development should be aimed at the German supply system of adapted guidelines national. To this end, should the standards of the Arbeitsgemeinschaft of the Scientific Medical Societies (AWMF) serve as a basis.

4.3.2 Expenses for orthodontic treatments

expand Existing analytical methods for total insured: SHI expenditures

The SHI expenditures are processed annually in Germany and also in loading train documented in detail to the orthodontic care. Supplemented by the evaluations of the billing data for individual health insurance could thus the question 2 of this report analyzed in detail the advertising. Based on the available data, however, no conclusion on the exact average cost per case and therefore no judgment to be made whether the current orthodontic care to legal claims will meet at a sufficient, appropriate and efficient care.

The secondary data analysis of Brown and Spassov (2018) [7] is basically constitutes an appropriate approach tinnen extensive analyzes to supply the patient and carry patients and the billed costs. However, it represents only the care given in the insured population of a single health insurance with a relatively short time horizon.

Based on the methodology used a more comprehensive analysis of the accounting data relative to the entire population insured leads could be carried. One could also imagine a supplement such Sekundärdaten- analysis to primary data from surveys of insured.

In combination with the above approaches in Section 4.3.1 a holistic view of orthodontic supplies would thus be in the long term including the assessment of a cost-benefit ratio possible and to be applied aspire.

take advantage of opportunities independent investigations of the privately-dental care events already: cost of statutory health insurance

Regarding the cost of the statutory health insurance no independent, science-based investigation could be identified. Exclusively survey studies using non-validated questionnaires could be included in the evaluation. Thus, no evidence-based statement regarding the scope and adequacy of self-pay services can be made in the orthodontic area.

However, an analysis of the cost of the statutory health insurance is basically possible in Germany. Private services are paid according to the scale of fees for dentists (GOZ) and made available to the insured person into account. To track the pri- vatzahnärztliche supply situation in Germany, the German Dental Association (BZÄK) that KZBV and the Institute of the German dental have the project physicians already initiated in 2013/2014 "GOZ Analysis". This captures the DA th of 3,000 randomly selected German dental practices. An annual evaluation will be published in the Yearbook of BZÄK. The Standardaus- evaluation of the data, however, is currently comprised exclusively privately insured patient tinnen and patients. the personenidentifizierbaren DA are recorded according BZÄK th of patients and patient as well as dentists and dentists, which are supplemented by calculations essential information of all private dental accounting [15, 99]. This includes the insurance status of the patient / of patent tienten (private / statutory). Currently is exclusively an analysis of data from privately insured people. Since orthodontic services over the exhaust section G of the GOZ are settled, representation of Versorgungsgesche- hens in this field is possible. It can be assumed that such evaluations for members of statutory health insurance are possible. Thus could be done both retrospectively and prospectively a data-based analysis of the self-pay costs in the orthodontic area.

Addressing ambiguity with regard to private payments for statutory health insurance benefits

Both the report of the HKK (2012) [89] and in interviewing Spassov et al. (2016) [91] specified by the insured that the offered and unused portfolio of the private services includes treatment measures orthodontic loading, the part of the BEMA and thus are subject to the principle of payment in kind SHI. This is on the one hand diagnostic measures, such as impressions of the teeth and imaging methods, and on the other the use of special additions of apparatuses (special sheets, wires or brackets). More details on this issue has not been raised within the survey. When interpreting these results, the settlement rules of BEMA should be considered in relation to individual performances into consideration. Table 13 shows examples of some BEMA services and related billing requirements and notes the KZBV. Based on the available data, no assessment can be made as to whether the additional measures are medically indicated and on what grounds the insured principle of service catalog of the GKV included orthodontic treatment as private services are offered.

Information facilities for insured structured expand

As part of the research for the report was found that in contrast to many other medical indications in the field of kieferortho- pädischen supply tale few independent knowledge-based information portal exist for patients. Only the website www.kostenfalle-zahn.de, a sumer funded by the Federal Ministry of Justice and encryption offer the Consumer, provides inter alia information available for orthodontic care. In this Internet site, however, particularly the cost of care in the foreground without would be represented comprehensively and transparently, there are development options which treatment and whether there is evidence from scientific studies on this stand.

With respect to the domain name of this website also criticism from the KZBV was expressed that trust relationship the negative colored designation as disturbing for the comparison evaluates between doctor and patient [100]. In the same context, refer to the websites of KZBV and BZÄK which also nen infor- provide for patients. A review of these sites, however, has shown that orthodontic treatment is there content not in focus [101, 102]. Due to an extension of the existing the offer and in connection with the bundling of information should be considered, so that the majority of patients and patient th in connection with the orthodontic care is being promoted.

Table 13: Exemplary overview of the accounting regulations and notices of individual statutory health insurance benefits

Bema position	performance designation	Settlement rules, instructions
116	Photography (profile or en-face photography)	In the course of orthodontic treatment up to four times billable.
7a	Preparatory measures: Impression taking, bite took	Orthodontic Treatment 3: <ul style="list-style-type: none"> up to three times during the course of billable Combined orthodontic / -chirurgische treatment: up to four times in the course of billable Provided that such power must be provided over four times, this is not a SHI benefits.
Ä 934a	A recording of the skull (also cephalometric reception)	Most twice, three times maximum billable in justified cases in the course of orthodontic treatment rule. If more than three shots in the treatment are necessary, they do not represent SHI benefits.
Ä 935	Member receiving the skull (also in special projection)	Belongs to contract dental care when clinical examination for diagnosis is not sufficient or specific treatment steps require. May be carried out only if this is necessary for dental indications. 4
IP 4	Local fluoridation of the teeth	Each calendar half-year once billable.

³ Billing instructions do not apply to early treatment of cleft lip, cleft palate or other craniofacial anomalies, a skeletal-open bite, a progeny or Injury Kieferfehlstellungen.

⁴ Insured afford to orthodontic treatment a share of 20 per cent of the cost of the contract dentist / dental contract. This does not apply for services rendered in connection with orthodontic treatment preservative-surgical and x-ray services.

Bema position	performance designation	Settlement rules, instructions
120	Measures for adjustment of the lower jaw bite into the control in the sagittal or lateral direction including retention	<p>All subsequent treatment products and systems are inefficient in general and not required (§ 12 Abs. 1 SGB V).</p> <ol style="list-style-type: none"> 1. Malu system 2. Tubular Jumper 3. Jasper Jumper 4th Magnetic molar Distalization System 5. Pendulum Springs 6. deleted 7th BioPendig appliance 8th. Bite Jumping Appliance 9. Ribbondretainer 10. retainer 11. Eurekafeder 12th Adjustable Bite Corrector 13. Essix retainers 14 positioner 15. Elasto devices 16. Flex-Developer <p>A pure autumn hinge is exceptionally billable under the following conditions:</p> <ol style="list-style-type: none"> a) later start of treatment (planned date!), growth climax must be exceeded b) bite correction can not be achieved with alternative conventional measures c) measure must be individual cases justifiable taking into account the economic requirements <p>As a non-compliance alternative, a fall hinge is never billable.</p>
126a	Incorporate a bracket or ATTACH ments, including materials, laboratory ceramics or gold, sapphire or plastic brackets represent no contract dental performance.	

Source: KZBV (2018) [103]

5th conclusion

With this report the results of an analysis of the pensionable state of knowledge of medical and health economic aspects are orthodontic care provided. The findings resultier- th of a systematic research and processing of existing international and national environment literature.

To illustrate both the benefits of diagnostic and therapeutic kieferor- thopädischen measures separate searches were carried out. This was necessary to take account of the different interventions and outcomes.

Overlooking the orthodontic diagnosis, the five most frequently billed in Germany interventions were examined. This was in order imaging tests (photography, panoramic radiograph, remote radiography), called their evaluation (cephalometric) and Modellabformun-. These are used to determine the extent of malocclusion and are intrinsic to the derivation of necessary treatment measures. nine studies tions the importance of that investigation were evaluated studied in the treatment planning. These studies were highly heterogeneous in terms of both the evaluated methods and study conduct. Because of this, no recommendations can be made in this opinion for or against the application of certain diagnostic measures adopted.

However, the large number of studies suggest that the number and the type of diagnostic methods to be employed on the nature and extent of the malocclusion depend. Thus, it in which sub-populations which orthodontic diagnostic tests are necessary to treatment planning to carry out an adequate and appropriate loading and countries to prevent unnecessary action seems sensible to examine future. It should be noted that the diagnostic value usually only becomes manifest that instituted as a result of diagnosis therapeutic interventions to take effect with significant latency. To evaluate the appropriate long-term, high-quality studies to be carried out, because according to German standards of the methods review "information about management changes alone [...] not be used for proof of benefit, as long as no information on the patient-relevant effects of such changes are present" can [8th]. Therefore, must be evaluated properly as an evidence-based derivation of diagnostic procedures in orthodontics can be created. As part of the research into the medical benefits and effectiveness jaw-orthopedic interventions to treat misalignments of the teeth 18 studies were identified. This raised by means of different

Parameters, the effects of treatment with fixed and removable appliances cash on oral health, oral quality of life and the effects in terms of tooth position. Here, too, it was found that the studies are very heterogeneous both in their study design and in terms of population, the orthodontics Indian intervention as well as the collection of endpoints. It is notable that long-term patient-relevant outcomes such as tooth loss, periodontal disease and other complications have been raised in any of the studies. Most commonly, treatment effects were evaluated using indexes, the correction of malocclusion and their effects are charged with whose help. Independent of the used indices showed here by the use of orthodontic appliances improvements. When interpreting these results, however, important to note that it merely Surrogatpara- meter is that give no indication of whether the treatment dität the Morbi or has relevant influences the quality of life of patients. The oral quality of life was also collected using validated instruments in egg Nigen studies. This showed that patients with a completed orthodontic treatment reported a higher quality of life than non-treated study participants or patients undergoing orthodontic treatment currently. These measurements, however, were carried out with different survey instruments, so that a comparison at this point is not given.

Overall, the identified studies do not allow any conclusion on a patient-relevant benefit in terms of the diagnostic and therapeutic orthodontic treatment. This is particularly due to the heterogeneity of the studies in terms of the observed populations functions the applied intervention and the study design and to the fact that morbidity tätsrelevante endpoints such as tooth loss, tooth decay or periodontal disease and periodontal tose usually several years after treatment occur and thus require very long observation times.

With the aim to promote the generation of evidence for the benefit of orthodontic treatment measures in the near future, already imple- mented epidemiological studies should be used in the future to a greater extent to evaluate long-term results of orthodontic measures. In addition, comprehensive primary and / or secondary studies should be implemented so that in the long term a significant improvement of the evidence in Germany can be achieved. Registry documents that are taught with such studies should, in particular, it can be used to establish standards in the diagnosis and treatment of malocclusions in the form of guidelines.

Another focus of the report was to analyze the costs that connexion in supply caused by the orthodontic treatment. The majority of the financial expenses is thereby obtained on the part of SHI. Since 2005, expenditures increased steadily and amounted in 2017 to € 1,115 million. He-

supplemented these men by spending on additional services that the insured au- ßerhalb the reimbursement framework for SHI services by Kieferorthopädin- and orthodontists are offered. Surveys health insurance have shown that was specified for 75 to 80% of the insured to have tens taken Any artwork such performance in claim. Not scientifically studied economically is the need and nature of these services and the extent to which they are provided.

As part of the development of the statutory health insurance coverage in Germany of the first draft of the Terminservice- und Versorgungsgesetz (TSVG) was introduced in September 2018th This also addresses measures regarding the CRG, in particular with a view to promoting transparency. The amendment provides for the creation of a catalog containing the invoice timing as agreed and capable Additional services in orthodontics. In addition, this should be also apparent indication of which services are not covered by the statutory health insurance and are therefore fully financed by the insured. This is to orthodontic measures that differ particularly from those contained in BEMA services. Furthermore, the skilled already in orthodontic practice, the additional cost regulation in the SGB V is integrated. The additional costs associated with services that go beyond the one shown in the BEMA and thus funded by the statutory health care must wear Insured continue as in the past her own. the patients have to pay financially for the difference between the selected treatment and supported by the statutory health treatment. The written form requirement in relation to the additional costs will be emphasized in the draft bill by amendment of §§ 630c, 630e BGB [104]. They are promoting the transparent demarcation between statutory health services and self-pay services in orthodontic encryption supply and also by the BZÄK and KZBV welcomes [105, 106]. In addition to these new regulations, the implementation of a central information platform is desirable for patients. This should include a clear and easily understandable treatment which are diagnostischen and therapeutic orthodontic interventions available, which are considered by the SHI as appropriate and are funded and what excess or extra services are available. Particularly in view of the additional services study data on the medical efficacy, the side effects should and the additional costs are shown on a platform, so-that patients can check sufficient and be empowered to mature to make decisions.

6th attachment

**A1 Search strategy bibliographic research A2 Keyword
combinations of the manual search A3 Development billed
BEMA positions**

A1 Search strategy bibliographic research

Table 14: Search strategy for therapeutic treatment measures in MEDLINE¹ via OVID
(as of 6/9/2018)

#	keyword	hits
1	exp orthodontics /	50411
2	orthodontic * .ti, from, kf.	34841
3	exp malocclusion /	32159
4	malocclusion.ti, from, kf.	9508
5	Or / 1-4	76026
6	exp orthodontic appliances /	21801
7	orthodontic applianc * .ti, from, kf.	2431
8th	exp Braces /	5161
9	exp Orthodontic brackets /	3887
10	exp Orthodontic Wires /	3309
11	appliance * .ti, from, kf.	16311
12	intraoral.ti, from, kf.	11281
13	intra-oral.ti, from, kf.	2782
14	Intra oral.ti, from, kf.	2782
15	extraoral.ti, from, kf.	2252
16	extra oral.ti, from, kf.	886
17	Extra oral.ti, from, kf.	886
18	* fix .ti, from, kf.	360812
19	remov * .ti, from, kf.	572702
20	* extract .ti, from, kf.	709484
21	function * .ti, from, kf.	3287244
22	Or / 6-21	4672325
23	exp dental caries /	43043
24	"Tooth decay" .ti, from, kf.	1113
25	caries.ti, from, kf.	40165
26	exp periodontal diseases /	81957
27	periodont * .ti, from, kf.	70193

#	keyword	hits
28	exp Chronic periodontitis /	2600
29	exp periodontitis /	28191
30	exp Tooth Extraction /	19063
31	exp tooth loss /	3549
32	tooth loss.ti, from, kf.	3677
33	exp gingival diseases /	25904
34	exp gingivitis /	10956
35	gingiv * .ti, from, kf.	46936
36	"Attachment loss" .ti, from, kf.	2585
37	exp PERIODONTAL ATTACHMENT LOSS /	3382
38	"Tooth pain" .ti, from, kf.	244
39	exp toothache /	2685
40	toothache.ti, from, kf.	1131
41	exp Dental Health surveys /	21378
42	"Dental health" .ti, from, kf.	7932
43	exp Oral Health /	14148
44	"Oral health" .ti, from, kf.	22308
45	"Oral health related quality of life" .ti, from, kf.	1835
46	OHRQoL.ti, from, kf.	978
47	"Index of Complexity Outcome and Need" .ti, from, kf.	72
48	exp "Index of Orthodontic Treatment Need" /	161
49	"Peer assessment rating index" .ti, from, kf.	51
50	"Dental Aesthetic Index" .ti, from, kf.	235
51	"Periodontal Index" .ti, from, kf.	987
52	"Community Periodontal Index" .ti, from, kf.	756
53	"Periodontal screening index" .ti, from, kf.	37
54	"Periodontal Screening and Recording" .ti, from, kf.	42
55	exp DMF Index /	9022
56	(DMF * .ti decreases. AND index.ti, from, kf.)	2341
57	"Oral health impact profile" .ti, from, kf.	1119

#	keyword	hits
58	"Oral impacts on daily performance" .ti, from, kf.	78
59	"Child perception questionnaire" .ti, from, kf.	41
60	"Oral health questionnaire" .ti, from, kf.	44
61	"Oral health assessment" .ti, from, kf.	402
62	Or / 23-61	211330
63	5 and 22 and 62	8669
64	randomized controlled trial.pt.	468035
65	randomized.mp.	754277
66	placebo.mp.	197944
67	Or / 64-66	813447
68	meta analysis.mp, pt.	148734
69	review.pt.	2427041
70	search * .tw.	384897
71	Or / 68-70	2706151
72	67 or 71	3375376
73	63 and 72	1212

Annotation: 1 Ovid MEDLINE (R) and Epub ahead of print, in-process & Other Non-Indexed Citations and Daily
1946 to 4 September 2018

Table 15: Search strategy for therapeutic treatment measures CENTRAL 1 via OVID
(as of 6/9/2018)

#	keyword	hits
1	exp orthodontics /	2440
2	orthodontic * .ti decreases.	2120
3	exp malocclusion /	779
4	malocclusion.ti decreases.	424
5	Or / 1-4	3772
6	exp orthodontic appliances /	1507
7	orthodontic applianc * .ti decreases.	313
8th	exp Braces /	373
9	exp Orthodontic brackets /	550

#	keyword	hits
10	exp Orthodontic Wires /	210
11	appliance * .ti decreases.	1750
12	intraoral.ti decreases.	802
13	intra-oral.ti decreases.	296
14	Intra oral.ti decreases.	296
15	extraoral.ti decreases.	119
16	extra oral.ti decreases.	58
17	Extra oral.ti decreases.	58
18	* fix .ti decreases.	22301
19	remov * .ti decreases.	22609
20	* extract .ti decreases.	20635
21	function * .ti decreases.	164499
22	Or / 6-19	220617
23	exp dental caries /	2111
24	"Tooth decay" .ti decreases.	69
25	caries.ti decreases.	3554
26	exp periodontal diseases /	5364
27	periodont * .ti decreases.	5698
28	exp Chronic periodontitis /	666
29	exp periodontitis /	2533
30	exp Tooth Extraction /	1607
31	exp tooth loss /	99
32	tooth loss.ti decreases.	122
33	exp gingival diseases /	2330
34	exp gingivitis /	1207
35	gingiv * .ti decreases.	5360
36	"Attachment loss" .ti decreases.	305
37	exp PERIODONTAL ATTACHMENT LOSS /	793
38	"Tooth pain" .ti decreases.	33
39	exp toothache /	216

#	keyword	hits
40	toothache.ti decreases.	62
41	exp Dental Health surveys /	2953
42	"Dental health" .ti decreases.	303
43	exp Oral Health /	330
44	"Oral health" .ti decreases.	1329
45	"Oral health related quality of life" .ti decreases.	199
46	OHRQoL.ti decreases.	92
47	"Index of Complexity Outcome and Need" .ti decreases.	5
48	exp "Index of Orthodontic Treatment Need" /	3
49	"Peer assessment rating index" .ti decreases.	6
50	"Dental Aesthetic Index" .ti decreases.	2
51	"Periodontal Index" .ti decreases.	37
52	"Community Periodontal Index" .ti decreases.	21
53	"Periodontal screening index" .ti decreases.	3
54	"Periodontal Screening and Recording" .ti decreases.	5
55	exp DMF Index /	526
56	(DMF * .ti decreases. AND index.ti decreases.)	129
57	"Oral health impact profile" .ti decreases.	178
58	"Oral impacts on daily performance" .ti decreases.	6
59	"Child perception questionnaire" .ti decreases.	1
60	"Oral health questionnaire" .ti decreases.	4
61	"Oral health assessment" .ti decreases.	32
62	Or / 23-61	16526
63	5 and 22 and 61	712
64	randomized controlled trial.pt.	457121
65	randomized.mp.	591226
66	placebo.mp.	230564
67	Or / 64-66	839478
68	meta analysis.mp, pt.	7172
69	review.pt.	3098

#	keyword	hits
70	search * .tw.	8452
71	Or / 68-70	16224
72	67 or 71	842243
73	63 and 72	529

Annotation: 1 Cochrane Central Register of Controlled Trials August 2018

Table 16: Search strategy for therapeutic treatment measures in EM BASE 1 via OVID
(as of 6/9/2018)

#	keyword	hits
1	exp orthodontics /	28716
2	orthodontic * .ti decreases.	30337
3	exp malocclusion /	25368
4	malocclusion.ti decreases.	7975
5	Or / 1-4	56274
6	exp orthodontic appliances /	18411
7	orthodontic applianc * .ti decreases.	2042
8th	exp Braces /	10072
9	exp Orthodontic brackets /	1314
10	exp Orthodontic Wires /	954
11	appliance * .ti decreases.	15103
12	intraoral.ti decreases.	11067
13	intra-oral.ti decreases.	2835
14	Intra oral.ti decreases.	2835
15	extraoral.ti decreases.	2135
16	extra oral.ti decreases.	912
17	Extra oral.ti decreases.	912
18	* fix .ti decreases.	423587
19	remov * .ti decreases.	709098
20	* extract .ti decreases.	882503
21	function * .ti decreases.	3951825
22	Or / 6-19	5629102

#	keyword	hits
23	exp dental caries /	42417
24	"Tooth decay" .ti decreases.	1176
25	caries.ti decreases.	34048
26	exp periodontal diseases /	87691
27	periodont * .ti decreases.	64226
28	exp Chronic periodontitis /	3511
29	exp periodontitis /	37206
30	exp Tooth Extraction /	19939
31	exp tooth loss /	87691
32	tooth loss.ti decreases.	3665
33	exp gingival diseases /	31189
34	exp gingivitis /	14321
35	gingiv * .ti decreases.	44667
36	"Attachment loss" .ti decreases.	2461
37	exp PERIODONTAL ATTACHMENT LOSS /	87691
38	"Tooth pain" .ti decreases.	236
39	exp toothache /	6427
40	toothache.ti decreases.	1302
41	exp Dental Health surveys /	2215
42	"Dental health" .ti decreases.	6997
43	exp Oral Health /	601698
44	"Oral health" .ti decreases.	21173
45	"Oral health related quality of life" .ti decreases.	1671
46	OHRQoL.ti decreases.	879
47	"Index of Complexity Outcome and Need" .ti decreases.	63
48	exp "Index of Orthodontic Treatment Need" /	53
49	"Peer assessment rating index" .ti decreases.	41
50	"Dental Aesthetic Index" .ti decreases.	204
51	"Periodontal Index" .ti decreases.	897
52	"Community Periodontal Index" .ti decreases.	712

#	keyword	hits
53	"Periodontal screening index" .ti decreases.	43
54	"Periodontal Screening and Recording" .ti decreases.	46
55	exp DMF Index /	561
56	(DMF * .ti decreases. AND index.ti decreases.)	2463
57	"Oral health impact profile" .ti decreases.	1045
58	"Oral impacts on daily performance" .ti decreases.	69
59	"Child perception questionnaire" .ti decreases.	35
60	"Oral health questionnaire" .ti decreases.	44
61	"Oral health assessment" .ti decreases.	389
62	Or / 23-61	783935
63	5 and 22 and 61	9668
64	random * .tw.	1322313
65	placebo * .mp.	416361
66	double-blind * .tw.	189500
67	Or / 64-66	1563532
68	meta analysis * .mp.	225118
69	search * .tw.	476520
70	review.pt.	2345134
71	Or / 68-70	2787198
72	67 or 71	4106365
73	63 and 72	1492

Annotation: 1 EMBASE 1974 to 2018 September 5

A2 Keyword combinations of manual search

Question 1 - research in national and international journals

- German
 - ☐ Orthodontics AND benefits
 - ☐ Orthodontics AND effectiveness
 - ☐ Orthodontics AND damage
 - ☐ Orthodontics AND side effects
 - ☐ Orthodontics AND Registry
 - ☐ Orthodontics AND STUDY
 - ☐ Orthodontics AND Investigation
- English
 - ☐ Orthodontic AND Benefit
 - ☐ Orthodontic AND Effectiveness
 - ☐ Orthodontic AND Efficacy
 - ☐ Orthodontic AND Harm
 - ☐ Orthodontic AND Adverse Events
 - ☐ Orthodontic AND Evidence
 - ☐ Orthodontic AND Study
 - ☐ Orthodontic AND Analysis

Question 2 - research on Google and Google Scholar using German and English keywords

- German
 - ☐ Orthodontics study costs
 - ☐ Orthodontics study payment
 - ☐ Orthodontics study bill
 - ☐ Orthodontics investigation costs
 - ☐ Orthodontics study payment
 - ☐ Orthodontics investigation bill
 - ☐ Orthodontics survey costs
 - ☐ Orthodontics survey Payment
 - ☐ Orthodontics private costs
- English
 - ☐ Orthodontic study cost German
 - ☐ Orthodontic study German invoice
 - ☐ Orthodontic study German account
 - ☐ Orthodontic study German payment
 - ☐ Orthodontic survey cost German
 - ☐ Orthodontic survey invoice German
 - ☐ Orthodontic survey account German
 - ☐ Orthodontic survey payment German

A3 Development billed BEMA positions

Table 17: Changes in the number settled BEMA positions 2013-2016

BEMA position	Abridged name	2013	2014	2015	2016
116	Photography, profile or en-face photograph with diagnostic evaluation	1,410.8	1,443.4	1,480.5	1,507.4
117	Model analysis, additional application of methods for the analysis of jaw models (three-dimensional analysis, graphic or parametric analysis, graphs) depending no. 7a	1,147.6	1,164.8	1,174.0	1,180.8
118	cephalometric analysis	714.9	722.8	725.9	725.5
119a-d	Measures for forming a jaw including retention	8,690.0	8,809.8	8,853.2	8,937.9
120a-d	Measures for adjustment of the lower jaw bite into the control ler or Sagitta in the lateral direction including retention	3,912.5	3,987.8	4,029.8	4,087.8
121	Elimination of Habits in a habitual distoclusion or a habitual open bite	23.6	22.3	20.3	19.0
122a-c	Orthodontic chores as the sole power	34.1	34.2	33.5	31.2
123a-b	Orthodontic measures with removable devices for keeping open gaps as a result of premature milk tooth loss	266.0	275.5	285.3	294.0
124	Grinding of primary teeth with cross or forced bite	4.0	4.0	3.7	3.5
125	dereinfügen measures to restore treating agents incl. How-	148.9	143.3	133.0	128.8

BEMA position Abridged name		2013	2014	2015	2016
126a-d	Integration / rehabilitation / removal of a bracket, ATTACH ment or band including materials, laboratory	16,959.7	17,415.3	17,696.2	17,818.7
127a-b	Integration / outsourcing partial sheets including materials, laboratory	545.4	565.4	588.9	601.7
128a-c	Inclusion of a ready-made / customized full arc, spin-off of full arches, including materials, laboratory	8,211.7	8,530.9	8,715.6	8,847.8
129	Reintegration of a full or partial arc	445.1	447.2	447.9	447.4
130	Inclusion of additional fixed appliances (palatal or Transversalbogen, quad helix, lingual, lip bumper, headgear via two anchor bands), including materials, laboratory	158.4	158.9	158.0	155.1
131a-c	Integration and outsourcing a Gaumennahterweiterungsappa- temperature	34.9	36.4	36.1	37.4
Ä 925a-d	X-ray diagnostics of the teeth, up to two shots	6.6	5.9	5.3	4.8
Ä 928	X-ray of hand	23.8	22.5	21.1	19.2
Ä 934a-b	Recording of the skull (also cephalogram)	709.9	711.3	721.9	721.5
Ä 935a-d	Receiving part of the skull (also in special projection) also Nebenhöh- len, mandible, panoramic image of the teeth of a jaw and the teeth of the maxilla and mandible same side	1,127.4	1,147.8	1,162.5	1,173.0
Ä 1	Advising a patient, even by telephone	1,605.5	1,626.50	1,676.1	1,693.2
01	Depth investigation for the detection of teeth, mouth and jaw diseases, including advice	2,044.5	2,095.50	2,142.8	2,164.2

BEMA position Abridged name		2013	2014	2015	2016
01k	Orthodontic investigation to clarify the indication and the time point orthodontic treatment measures	1,040.3	1,071.70	1,089.1	1,123.8
5	Extraction of cellular material from the oral cavity and preparation for zy tologischen investigation, including material costs	413.8	418.20	418.7	422.2
7a	Preparatory measures: impressions, bite registration in habitual occlusal for creating three-dimensional oriented models of the upper and lower jaw for diagnostic evaluation and planning as well as written resignation	1,153.8	1,170.70	1,179.8	1,186.1
12	Special measures during preparation or filling (separation, aeration side disturbing gums, applying rubber dam, stilling excessive Papillenblutung)	1,136.5	1,147.40	1,147.1	1143.5
IP1	Oral hygiene status	469.1	463.30	448.7	449.4
IP2	Oral health education for children and adolescents	499.9	495.80	481.2	483.5
IP4	Local fluoridation of the teeth	529.7	526.60	509.8	506.5
IP5	Sealing of caries-free pits and fissures of the permanent molars (teeth 6 and 7) with thermosetting plastics	7.7	8.30	7.1	6.6
FU	Dental Screening for a child of 30 to 72 months of age	1.2	1.10	1.1	1.2
IP cases		715.4	712.70	685.5	684.4

Source: BEMA

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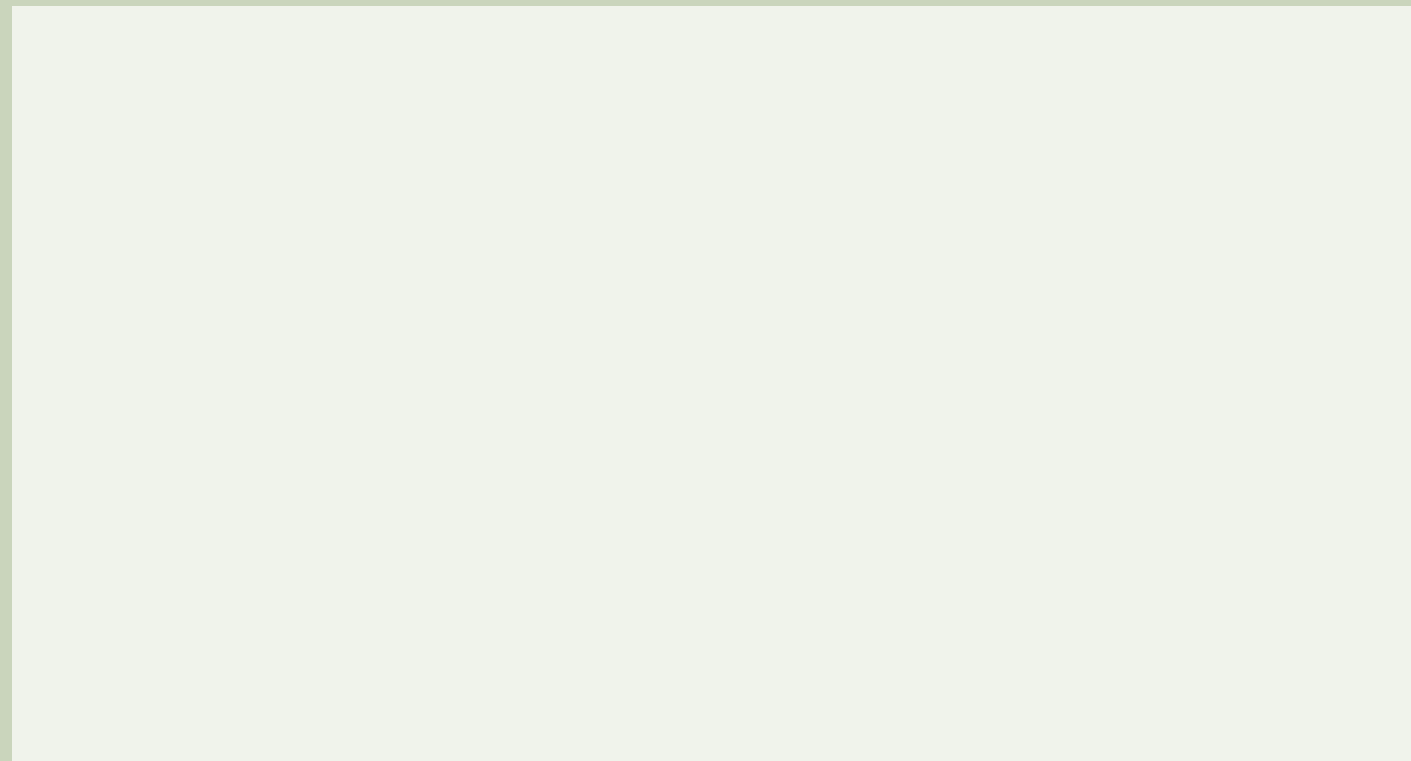
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