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Arbitrary versus exact mounting procedure during fabrication of intraoral splints: an exploratory randomised controlled clinical trial

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The present study examined possible advantages of a kinematical determination of hinge axis points over arbitrary axis points in the fabrication of occlusal splints for CMD treatment.

The single blinded prospective randomised trial was performed in a general dental practice. A total of 14 consecutive patients presenting for CMD treatment were considered for participation and declared informed consent, and 12 patients (average age about 40 years) eventually participated. These patients were randomly assigned to either fabrication method and were not informed about how their individual splint was constructed. Condylography, required for the kinematical hinge axis determination, was therefore performed in both groups. Patients were recalled after 1, 2, 4, 14 and 28 days, and splints were selectively ground in order to achieve full occlusal contact in 12 points. The required number of corrective grindings was recorded, as was the clinical course of the patients.

Kinematical splint construction yielded the desired result – mandibular repositioning as reflected by the full number of occlusal contact points – faster and more completely than the employment of an arbitrary hinge axis, and substantially (about 50%) less corrective grinding was required. The difference was statistically significant despite the rather small sample size. Clinically, both methods appeared to be equally effective.

The greater initial effort required by kinematical determination of the individual hinge axis seems to be at least partially outweighed by a lower amount of corrective grinding required achieving the desired splint effect. Which method has the superior cost-benefit ratio remains to be determined.

Keywords: Intraoral splints, arbitrary facebow, hinge axis location, hinge axis transfer, splint adjustment, splint equilibration

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Introduction

By their very nature, diseases like CMD whose diagnosis is significantly dependent on the patient's subjective information are such that it is difficult to provide specific data concerning their prevalence. However, based on large epidemiological studies one may assume that approximately 50% of the population in developed countries suffers from symptoms of a CMD [1, 6, 8, 16, 25, 36]. The principal reason for the markedly lower prevalence data reported thus far [31] appears to be the fact that only a rather small number of patients associate their own symptoms with the temporomandibular joint. CMD symptoms were detected in one half of the investigated persons, but only 2.7% perceived these as signs of dysfunction of the temporomandibular joint [25]. Other investigatiors concluded that only 15–20% of adults suffer from CMD requiring treatment [5, 43].

CMDs have become even more significant because of their now established relationship with the entire human organism. In the last few years there has been an increasing tendency to view spinal pain syndromes from a systemic point of view. Amongst many systems, the stomatognathic system plays a central role in these syndromes [19, 20]. Back pain, in turn, is one of the most common health impairments in general. In Germany and throughout the world, it is one of the leading causes of the inability to work [59]. Approximately 10% of patients affected by this condition are unable to return to work within 3 months. In particular, chronic back pain is responsible for significant overall costs in terms of public health.

CMDs have been treated with intraoral splints for more than 100 years now [48]. Increasingly complex systems for the purpose of positioning the mandible have been developed during this time [4, 12, 14, 15, 23, 32–34, 41, 42, 53].

Given the diversity of systems used, it is very difficult to draw final conclusions about the effectiveness of splint therapy. One of the reasons is that scientific evidence of the efficacy of a therapeutic procedure always requires a control treatment, a so-called placebo, which is convincingly similar to the

test treatment as far as the patient is concerned. This is quite difficult with regard to splint treatment because any device introduced into the oral cavity influences the neuromuscular control circuits of balance and mobility in the temporomandibular joint. Besides, the placebo effect is especially pronounced in diseases whose pathogenesis includes a psychic component, because the fact of human attention itself has a therapeutic effect in this setting. Therefore, with reference to splint treatment one may always raise the following question, irrespective of the specific procedure used: Is the observed effect an obvious consequence of the splint or an "elaborated placebo effect" [34]?

A distinction may be made between the numbers of basic intraoral splint constructions:

⇒ Relaxation splints which are essentially derived from the so-called Michigan splint [50].
⇒ Anterior devices [17, 29, 51] which cover 6–8 maxillary front teeth and thus unload bite forces on the posterior teeth.
⇒ Mini-anterior devices (derived from the so-called Lucia jig [40]) which are based on a similar concept and cover only 2–4 teeth. Today we have highly diverse and complex concepts derived from these.
⇒ Anterior repositioning devices which shift the mandible forward by the application of a "ramp" on the anterior portion of the maxillary splint and can be traced back to Farrar [18].
⇒ Neuromuscular splints [13] whose purpose is to achieve ideal positioning of the mandible in relation to the maxilla by means of functional interventions in the musculature of the temporomandibular joints.
⇒ Mandibular repositioning splints which alter the vertical dimension and whose purpose is also to achieve the ideal position [24].
⇒ Pivot splints which consist of a complete mandibular or maxillary splint and as far posterior individual occlusal contacts as possible in every quadrant. Their purpose is to reduce intra-articular pressure [50].

Accordingly, the effectiveness of splint treatment is controversially discussed in the published literature. As a large number of individual investigations have yielded positive results, one can hardly dispute the fact that splint treatment has a marked and sustained symptomatic effect. Besides, in the majority of patients the treatment can be performed easily and effectively even in the office of a general physician [57].

However, in recent overviews doubts have been raised about the degree of evidence of the existing studies [4, 21, 22, 35, 37, 39]. In general the majority of systems seem to affect acute symptoms of CMD, whereas the long-term curative effect appears to be doubtful at the present time [4, 15, 21, 22, 34, 53]. On the other hand, the protective effect of occlusal splints with regard to abrasions appears to be useful in patients with bruxism [30].

Independent of the scientific discussion and in view of the paucity of non-invasive alternatives with a more favourable ratio of desired and undesired effects, according to the most recent recommendations of German scientific societies, treatment with occlusal splints is the dental method of choice for the treatment of a CMD [2, 3].

Derivation of the question

The starting point of the present study is to assess the precision of a centric splint for the mandible, manufactured by various procedures, for patients undergoing treatment in the office of the general physician.

The aim of the investigation is to determine whether a splint produced with a kinematic facebow and a registrate in unforced retral physiological borderline position requires fewer grinding measures after its alignment than a splint produced with an arbitrary facebow and a centric registrate. The discrepancy between hinge axis and arbitrary axis was investigated [56].

Hypothesis

A splint produced by the use of a kinematic arch (K) requires fewer grinding measures (ES) for the purpose of adjustment after its alignment than a splint produced by the use of an arbitrary facebow (A).

$$H_A: ES_{(K)} < ES_{(A)}$$

Alternative hypothesis

A splint produced using a kinematic arch requires an equal number of grinding measures immediately after its alignment compared to a splint produced with an arbitrary facebow.

$$H_0: ES_{(K)} < ES_{(A)}$$

Randomisation procedure

The selected patients were randomised into Group K (kinematic adjustment based on the hinge axis) and Group A (arbitrary adjustment). For this purpose we prepared 12 envelopes, of which 6 contained a note saying "Group A" and the other 6 contained a note saying "Group K". The patients were assigned to the groups on the basis of their condylography, which was performed as a routine investigation in all subjects. Thus the hinge axis was localised in all study participants but was used only in those who had been assigned to Group A. The patients were not informed as to which of the two splints had been used in their individual case.

Material and method

The patients were recruited at the office of a dentist in Hamburg. Inclusion and exclusion criteria are listed in Tab. 1. In all 14 patients who fulfilled these prerequisites were screened. All of them were suitable for inclusion in the study. The patients were informed verbally about the procedure of splint production and the subject of the Master's thesis, and provided their voluntary informed consent. Of 14 patients who were initially included in the study, 2 dropped out prior to randomisation for the following reasons (Fig. 1): one patient could not attend the follow-up investigations because of preoccupation at work whilst one patient had to be hospitalised during the treatment. The patients were between 21 and 73 years of age (mean, 39.6±17.8 years) and 58.3% of them

Tab. 1: Inclusion/exclusion criteria

Older than 18
At least one of the following symptoms
• bruxism
• loss of molar support
• posterior interferences
• muscle spasm in the neck/head
• pain in the jaw joints and/or in the ears
• jaw joint noices
The patients had these symptoms at least since 4 weeks

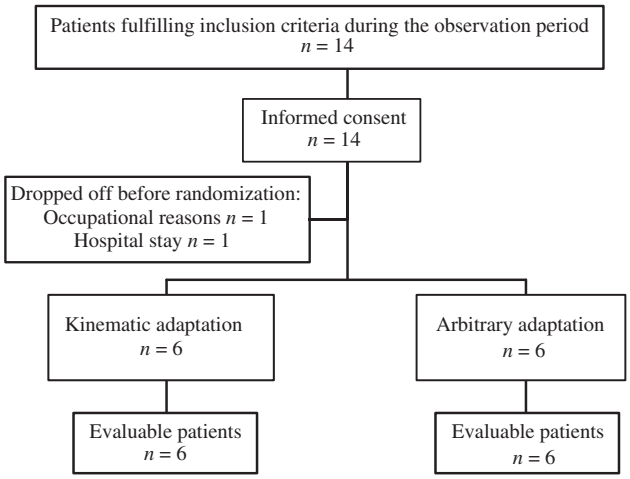

Fig. 1: Patient recruitment and patient flow

Tab. 2: Demographics

	Kinematic adaptation	Arbitrary adaptation
Age (mean ± standard deviation)	37.3 ± 16.9 years	41.8 ± 20.1 years
Sex (*n*, %)		
female	3 (50.0%)	2 (33.3%)
male	3 (50.0%)	4 (66.7%)

were women. Age and gender distributions were similar in the two groups (Tab. 2).

Procedure for mounting the models of the temporomandibular joints

The models were mounted in centric position in the articulator. One exact model of the maxilla and two models of the mandible were prepared for every patient. In order to transfer the mandibular relationship and check the accuracy and reproducibility, a second centric bite registration was prepared for all patients.

The following was performed for all the 6 patients

⇒ instrumental functional analysis with the aid of kinematic facebow transfer and
⇒ arbitrary facebow transfer.

The models of the temporomandibular joint were inserted into the articulator according to criteria that took the skull and the joint into account; a split-cast (control base) was used for this purpose.

Production of splints

Characteristics of splints in the articulator in the region of the lateral teeth were as follows:

⇒ punctiform contacts of the palatine cusps of the maxilla on the splint in the mandible
⇒ no guidance contacts
⇒ no interferences
⇒ protection from retrusion.

Characteristics in the region of the front teeth:

⇒ punctiform contacts (fewer than those in the region of the lateral teeth; the occlusion foil was not fixed)
⇒ all guidance contacts; (front) canine guidance had to be as flat as possible and as steep as necessary
⇒ no interferences.

Grinding procedure

Control and grinding of the splint were performed on day 1 after alignment and on days 2, 4, 14 and 28 after alignment. All of the 12 palatine contacts from the canine to the mesiopalatinal cusp of the second molar of the maxilla on the mandibular splint were checked. In contrast to routine clinical therapy, we tried to establish all 12 desired palatine contact points by the use of grinding measures. This was necessary in order to render the groups objectively comparable. It resulted in the fact that a rather large number of grinding measures were used in the present study, even in cases of a primarily well-positioned splint. Furthermore, a grinding protocol was used on the respective day. The quantities of grinding and, at the end of the session, the number of actual contact points on the splint were noted.

The aim was to have a red contact point on the splint at all contact points of the upper palatine cusps from the canine to the mesiopalatinal cusp of the upper second molar. The front was still supposed to be in slight contact. The foil had to be such that it could be pulled out against mild resistance.

We divided the following regions into sub-groups: molar contacts with 6 contact points, pre-molar contacts with 4 contact points, canine contacts with 2 contact points and front characteristics (the occlusion foil had no/mild/strong contact).

To compare the probability of occurrence of an undesirable effect, the χ^2 test was used in both groups. For further exemplification the odds ratio was determined with a 95% confidence interval. The level of significance was uniformly set to $p < 0.05$.

Results

On day 1, patients with a kinematic splint were only marginally different from those who received an arbitrarily adjusted splint. On day 2, however, a marked difference was noted; the difference clearly persisted until day 14 and remained until the end of the observation period (Fig. 2).

Patients with kinematic splint adjustment do not routinely require fewer corrections – as demonstrated by the patient with the largest number of grinding measures on day 2 – but do *tend* to require markedly fewer corrections. This was especially evident on day 4: on this day the largest number of grinding measures required in group K was 11 whilst the least number required in group A was 13.

The differences in mean values were – given identical baseline conditions – quite marked and were significant on day 4 despite the small total number of 12 patients (U-test; $p = 0.0039$). The number of grinding measures required after kinematic adjustment was consistent during the entire observation period and constituted only 50% of the grinding measures needed in patients who had undergone arbitrary adjustment (Fig. 3).

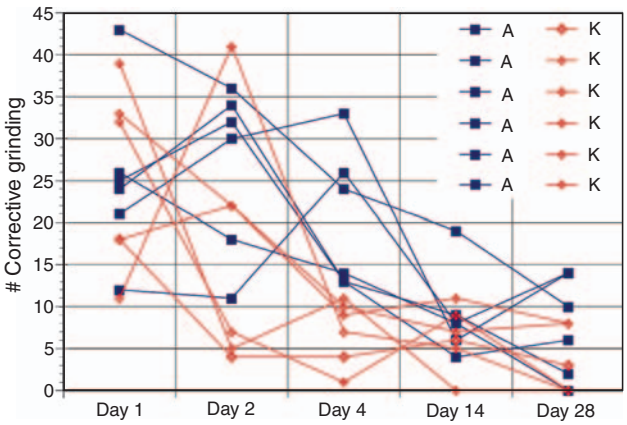

Fig. 2: Number of Equilibration needed on Day 1, 2, 4, 14 and 28. All recruited patients are presented. The data are presented in a descriptive form without statistical test

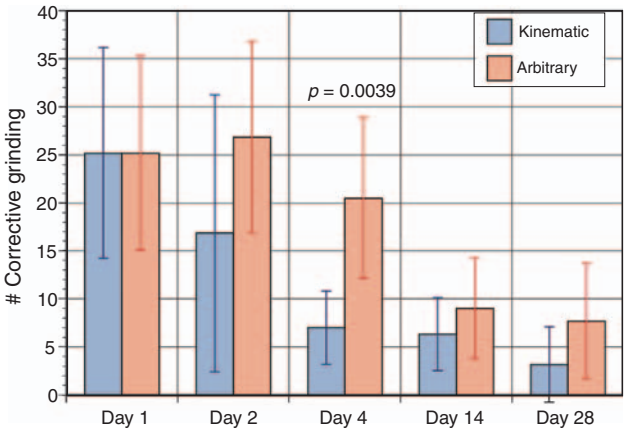

Fig. 3: Number of Equilibration needed on Day 1, 2, 4, 14 and 28 (mean and standard deviation). Statistical significant difference on D4 ($p < 0.01$, U-test)

The number of achieved desired contacts from the beginning to the end of the observation period was markedly higher after kinematic adjustment of the splint. From day 4 onward, assessments of individual patients revealed 10 contacts or less only in those who had undergone arbitrary adjustment (Fig. 4).

The mean values also confirmed a marked and consistent difference in favour of kinematic splint adjustment. Despite the slight quantitative differences and the small random sample, the difference was significant at two time points (day 1 and 14) and was only marginally non-significant on day 4 and 28 at a significant level of $p < 0.1$ (Fig. 5).

Undesired contacts were sporadic and their numbers did not differ between the groups. More than one such contact per day of investigation was only observed in 2 patients (one each in Group A and K).

Also with regard to the desired initial effect, the outcome was markedly more favourable after kinematic adjustment: it was achieved in 4 of 6 patients who had undergone kinematic

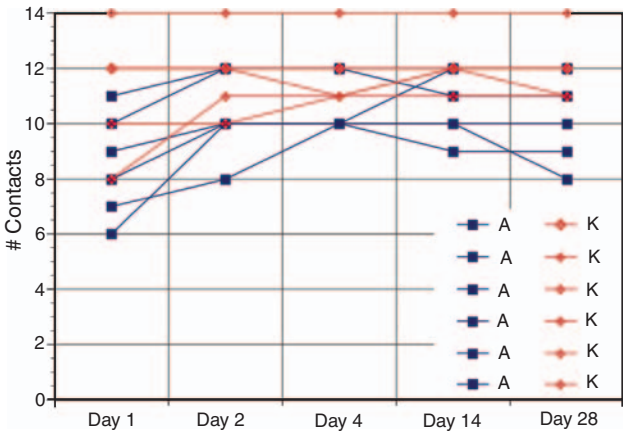

Fig. 4: Number of desired contacts on Day 1, 2, 4, 14 and 28. All recruited patients are presented. The data are presented in a descriptive form without statistical test

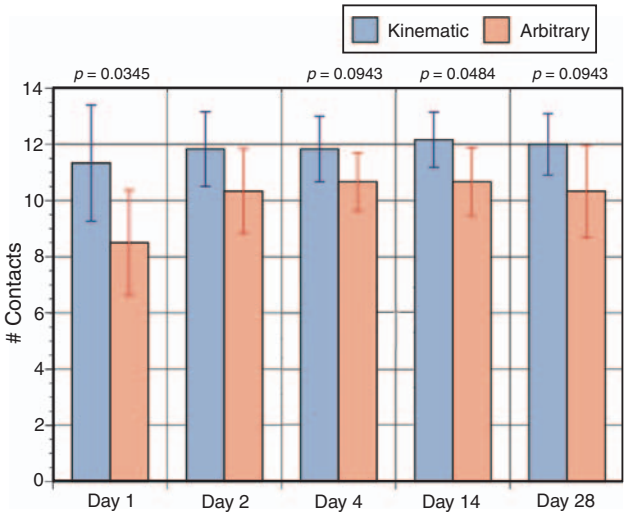

Fig. 5: Number of desired contacts on Day 1, 2, 4, 14 and 28 (mean and standard deviation). Statistical significant difference on D1 and D14 ($p < 0.05$, U-test)

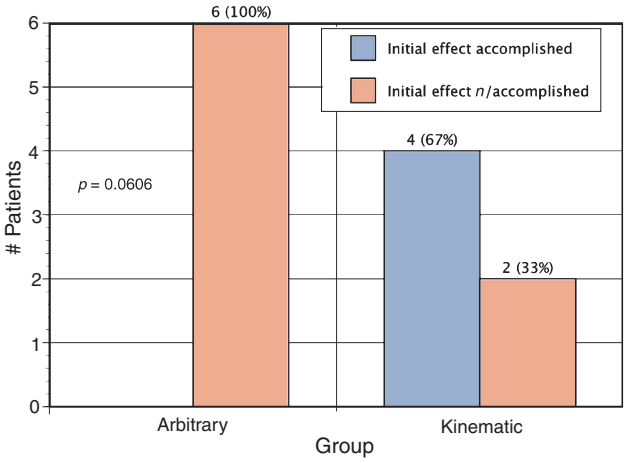

Fig. 6: Reaching the aspired initial effect (see text). χ^2-test, difference marginal above the statistical significant level of $p = 0.05$

adjustment, but in none of those who had undergone arbitrary adjustment (Fig. 6). The odds ratio could not be calculated because of division by zero (no initial effect in cases of arbitrary adjustment), but the difference is only marginally non-significant.

Significant difficulties in becoming habituated to and wearing the splints were rarely encountered. The single patient who had persistent compliance difficulties had received kinematic adjustment. Thus, arbitrary adjustment is obviously not associated with any major disadvantage in this regard.

Discussion

The present investigation showed an apparent and marked quantitative effect of kinematic adjustment: its use permitted the desired number of 12 occlusal contacts on the splint to be achieved much faster and more comprehensively, and the splint had to be ground much less frequently during the treatment. Given the identical baseline situation on the first day, in the subsequent course of treatment patients who had undergone kinematic adjustment required half as many grinding measures as did patients who had undergone arbitrary adjustment.

However, even after arbitrary adjustment, we were able to produce comfortably fixed and patient-friendly splints for the treatment of CMD. These splints are equally well tolerated by patients but their production requires much more grinding measures to produce the complete number of 12 contact points.

Thus, the greater effort involved in producing splints by kinematic adjustment is balanced if one takes a comprehensive look at the issue. Besides, according to the present author's clinical and practical experience, kinematic adjustment is associated with further advantages, especially with regard to correction of the position of the mandible. For instance, anterior shifting by 1–2 millimetres or even elevations of bite can be achieved much more simply and accurately.

A subsidiary finding of the present investigation is that it confirms a largely undisputed fact in the published literature: splint treatment frequently reduces acute symptoms of CMD. As the clinical course of complaints was not really a part of the issue investigated in the present study, it was not registered on a systematic basis. However, 4 patients reported marked improvement even during the brief observation period of 4 weeks. Of these 4 patients, 2 each had received arbitrary and kinematic adjustment, respectively. This fact confirms the above-mentioned conclusion: fully adequate splints can be also produced by arbitrary adjustment.

In principle, axiography is a very reliable procedure when used with the system employed in the present study [10, 11, 47, 52, 55, 58]. This is basically due to an arbitrary baseline position as well [7]. In a comparative investigation of different systems [27], this system (along with 2 others) yielded the best reproducibility of results; this is a weak point in some electronic systems [45].

The method of evaluation by detection of occlusal contact points is basically prone to error. First the thickness of the foil exerts an influence [9]. Second, the procedure is strongly investigator-dependent. Both of these sources of error were eliminated in the present study by the fact that all measurements were performed with identical material and personally by the author of the report.

Likewise, we avoided the potential falsification of results reported in the literature, arising from differences between articulators – even those of the same type [28]. The method of (double) centric registration also corresponds to the standard in terms of method and is highly reliable when used as described here [54]. Thus, the results of the present study may generally be regarded as valid from the viewpoint of method.

The results of our investigation are clearly contradictory to the conclusion drawn by [44]. According to the latter authors, kinematic adjustment of occlusal splints provides no advantage compared to arbitrary adjustment. The authors compared the two procedures in a random sample of 57 asymptomatic voluntary probands and found vertical errors of more than 500 µm only in 1% of cases after arbitrary adjustment. Although this method of evaluation cannot be directly compared with the method used in the present study, the results are highly contradictory. This may be for several reasons:

⇒ A marked increase of error could be observed, when the opening of the mouth was extreme. Therefore, changes in joints, such as those in patients with CMD (as in the present investigation) may magnify the error in the case of arbitrary adjustment [44].
⇒ The method of kinematic determination of the axis point was markedly different from that used in the present study; possibly the method was less accurate. The fact that the registration system may exert a significant impact has been demonstrated in an investigation performed by [27].
⇒ The criterion ">500 µm" is obviously too generous. According to a study performed by [46], even inaccuracies of a magnitude of 100 µm may necessitate extensive grinding measures.

A similar approach as used in the present study was used before [26]. However, the authors of this study did not compare different axis points but the production of splints in centric relation and in maximal intercuspidation. In the latter

study the authors compared two different positions of the mandible, whereas splint construction in the present study was based on two different positions of the maxilla.

With regard to the clinical course and the results of electromyography and electrognathography after splint treatment, no significant differences were registered between groups in the latter study. The positive effect of splint treatment was equally marked and significant in both groups. This is in conformity with our findings: all splints were prepared in centric relation but with different adjustment procedures (axis point or arbitrary) and we also registered a marked clinical effect [26] also reported corrective grinding measures but did not evaluate these in quantitative terms.

In general it would be meaningful to analyse not only the effort of splint adjustment but also the entire effort of treatment required when the two procedures are compared [49] compared 5 facebows and their study revealed that the apparently more costly measure may well be economical in the final analysis if it helps to reduce the total effort involved.

Conclusion

Conclusions derived from the present study and the published literature must be viewed as a snapshot statement because the technology of splint production and adjustment is undergoing constant changes. Fully computer-assisted systems [38] may necessitate re-evaluation once they have proved their value in the clinical setting.

Under this premise, the present investigation gives rise to the following consequences:

⇒ Repositioning of the mandible, which is the aim of splint treatment, can be achieved more rapidly and comprehensively with the aid of kinematic localisation of the axis point than with the aid of arbitrary adjustment.
⇒ Even arbitrary adjustment permits the production of well-tolerated and therapeutically effective occlusal splints.
⇒ In the subsequent course of treatment the initially greater effort of kinematic adjustment is balanced by the fact that much fewer (the magnitude is about 50%) occlusal contact points need to be ground.

It would be desirable to make cost-benefit analyses of the entire course of treatment in order to work out a rational recommendation in favour of, or against, kinematic adjustment.

Conflict of interest

The authors declare that there is no conflict of interest.

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