A systematic review of the relationship between overjet size and traumatic dental injuries

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SUMMARY The aim of this study was to aggregate the risk of traumatic dental injury due to overjet using several published papers and performing a meta-analysis on the results. The 11 articles involved in this investigation were identified by a literature search of Medline (1966–1996) and Exerpta Medica (1985–1996) databases using predetermined keywords, and inclusion and exclusion criteria.

In order to assess the quality of each paper, a methodological checklist for observational studies was developed resulting in a score between 0 and 100. The relative risk of overjet, compared with a reference, was expressed as an Odds Ratio (OR). For each study, the OR was computed using the data presented and, subsequently, these ORs were pooled across studies. The effect of confounders (i.e. age, gender), which could bias the relationship between overjet and dental injury was taken into account. Furthermore, the influence of quality of the study on the pooled OR was addressed.

The average methodological score was 41. From the results, it can be concluded that children with an overjet larger than 3 mm are approximately twice as much at risk of injury to anterior teeth than children with an overjet smaller than 3 mm. The effect of overjet on the risk of dental injury is less for boys than for girls in the same overjet group. In addition, risk of injury of anterior teeth tends to increase with increasing overjet size. Furthermore, the pooled OR does not seem to be affected by the quality of the studies.

Introduction

In order to determine a patient's need for orthodontic treatment, there are many assessment indices available, e.g. the Treatment Priority Index, TPI (Grainger, 1967), the Handicapping Malocclusion Assessment Record, HMAR (Salzmann, 1968), Summers' Occlusal Index, OI (Summers, 1971), and the Index of Orthodontic Treatment Need, IOTN (Brook and Shaw, 1991). These indices consist of several malocclusion items, such as overjet, overbite, crossbite, crowding, etc. However, the reason why a particular item is included in these assessment systems is not always explained. In the area of evidence-based medicine, however, there is a need to justify the incorporation of an item of malocclusion in the orthodontic treatment need indices with empirical evidence. In an attempt to identify those measurements most closely related to a clinical assessment of the need for orthodontic treatment, Kowalski and Prahl-Andersen (1976) identified six dento-alveolar measurements. Of these six measurements overjet was considered to be the most important predictor.

The possible effects of overjet have been investigated by several authors as to periodontal destruction (Alexander and Tipnis, 1970; Geiger et al., 1973; Geiger and Wasserman, 1976; Davis et al., 1988; Helm and Petersen, 1989; Bjørnaas et al., 1994), wearing of teeth (Ritchard et al., 1992; Silness et al., 1993), TMJ problems (Riolo et al., 1987; Pullinger and Seligman, 1991; Pullinger et al., 1993; Keeling et al., 1994), speech (Stansell, 1970; Laine et al., 1985), and aesthetic and/or psychological problems (Shaw et al., 1980; Helm et al., 1985; Kilpelainen et al., 1993). The relationship between overjet and traumatic dental injury has also been investigated. However,

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the results of the studies vary considerably. No significant difference in the means of overjet sizes between the injury group and the control group was found in the study of Stokes *et al.* (1995). Petti and Tarsitani (1996) reported that individuals with an overjet greater than 3 mm were two and a half times more at risk compared with individuals who had a normal overjet. It is an interesting question as to why the results of these studies differ so much. The investigated populations, the sample sizes, the methods of measurement, examiner reliability, etc., differed from study to study. In other words, the quality of the study itself could also be a factor contributing to the variations in results.

In this systematic literature review, metaanalysis was used to pool the results of the available studies concerning the relationship between overjet and traumatic dental injury. Furthermore, in order to assess the quality of the studies and thus the validity of their results, a methodological assessment list was developed. By doing this, the relationship between the quality of the studies and the results could also be investigated. Subsequently, the possible confounders biasing the relationship of overjet and trauma were explored. In summary, the aims of this systematic literature review were:

- The development of a methodological checklist.
- Aggregating information on the risk of injury on anterior teeth in relation to different degrees of overjet using several published papers and performing a meta-analysis.
- 3. Exploring confounders that may bias the pooled results.

Materials and methods

Selected studies

With Medline and Exerpta Medica databases, a literature search was conducted for the period from January 1966 to December 1996 and from January 1985 to December 1996, respectively. The following keywords and their combinations were used: malocclusion, overjet, trauma, fractured teeth, injuries, epidemiology. In addition,

the references given in the selected papers were examined, irrespective of the publication year.

In total, 26 articles were identified. Included were studies concerning the relationship between overjet sizes, scored in millimetres, and traumatic injury of anterior teeth. Studies with missing data (four) and those concerning the prevalence of incisor injuries only (eight) were excluded. Also excluded were those in which only the inclination of incisors (two) or the position of the lips (one) was examined. No attempt was made to correspond with the authors. Eleven studies remained after this selection procedure.

Methodological quality assessment

In order to assess the methodological quality of the selected studies, a quality assessment list was developed (Appendix 1). The items incorporated are generally accepted methodological criteria and the scoring allows a quantitative assessment of the reported investigations. To facilitate its use and to standardize the scoring procedure, a 'directions for use' of the checklist was made (Appendix 2), with a maximal score of 100. Based on the definitions, these criteria were divided into two categories: internal and external validity. External validity is important when one wishes to extrapolate the study result and internal validity refers to the soundness of the study itself.

Two reviewers (QN and PB) independently scored the methodological quality of each study, according to this assessment list. Subsequently, disagreements between the examiners, which were small, were discussed to reach consensus.

Statistical procedure

Using the available data reported, a reconstruction of 2×2 tables relating determinant and outcome, in this case overjet sizes and trauma, of each study was made. Odds ratios (OR) were used to compare the risk of trauma between categories of overjet sizes. Furthermore, the 95 per cent confidence interval (CI) of these ORs was calculated. Subsequently, the ORs were pooled according to Whitehead and Whitehead (1991).

To address the statistical validity of the aggregation the ORs were tested on homogeneity, according to Whitehead and Whitehead (1991). In addition, to look for outliers the OR of each study was graphically displayed. In case of heterogeneity, the effect of confounders (i.e. age, gender) biasing the relationship between overjet and traumatic dental injury was analysed. The methodological quality of studies was addressed by separate analyses for studies scoring above the average. For this purpose, the total methodological score, as well as the internal validity score (part of the checklist) was used.

In this study, an OR of 2 was assumed to be clinically relevant (Pullinger *et al.*, 1993). For the validation of the incorporation of overjet into orthodontic indices, the OR would need to be larger than 2.

Results

Quality assessment

Table 1 shows the quality scores of each study after the consensus meeting. The two categories of quality of a study, external and internal validity, are reported separately. To assess the relationship between overjet and dental injury, only the data of overjet sizes and incidences of injuries given in each study were required. For this purpose, the internal validity category of the methodological assessment list was most relevant, since these items concern the type of study, methods of measurement, interand intraexaminer reliability, blind measurement, etc. The outcome scores of the internal validity ranged from 13 to 27 (maximum 62).

To address the validity of the pooled result for the general population the total methodological score was also applied. The average total score was 41 with a range of 33 to 51 points.

Pooling

It is only possible to pool the results of the available studies when the data are presented in the same manner. The data of overjet were mostly given in several categories with a cut-off point differing from study to study. The most

commonly used cut-off points were 3 and 6 mm. Roder and Arend (1971), and Petti and Tarsitani (1996) reported a cut-off point of 3.2 and 3.5 mm, respectively. It was assumed, therefore, that these authors practically applied 3 mm. Data from the investigations of Hunter *et al.* (1990) and Holland *et al.* (1988) were excluded since they used 5 mm as cut-off point. Using 3 and 6 mm as cut-off points, the data given in the papers were grouped into three categories: 3 mm and less, more than 3 mm and 6 mm and more.

Overjet of 3 mm and less versus more than 3 mm. Table 2 and Figure 1 show the pooled result for the overjet group of 3 mm and less compared with the one of more than 3 mm, regardless of methodological quality of the study and age. The pooled OR was 2.30 (CI = 2.04–2.58). The homogeneity test was significant (P < 0.001), which means that the ORs were heterogeneous. In order to find an explanation for the heterogeneity of the ORs the following analyses were performed.

The study of Otuyemi (1994) was excluded for further analysis since its OR differed considerably from other studies. A possible explanation for this deviation is that its data were collected only for a single age (12 years). The pooled OR of the remaining investigations was therefore 2.16 (CI = 1.91-2.44). The ORs were still heterogeneous (0.01 < P < 0.02) and shown in Table 2.

Only pooling results of studies with an internal validity score above average (19), Table 2, resulted in a pooled OR of 2.17 (CI = 1.81–2.59). The homogeneity test remained significant (0.02 < P < 0.05). When the average of the total methodological score was used (score 41), the pooled OR of the studies scoring above this average remained almost unchanged, 2.17 (CI = 1.87–2.51). However, the homogeneity test was no longer significant (0.1 < P < 0.2), which indicates no evident heterogeneity (Table 2).

Finally, the studies were stratified by gender, regardless of the methodological quality (Table 3 and Figure 2). The pooled ORs were 2.90 (CI = 2.33-3.76) and 1.77 (CI = 1.41-2.20) for girls and boys, respectively, with no significant heterogeneity (0.1 < P < 0.2 for girls and 0.05 < P < 0.1 for boys).

 Table 1
 Methodological score after consensus meeting.

	Exte	External validity	validit	y.							Inte	ernal v	Internal validity								
Item label Max. score ^a	4 4	9 4	O 4	D 6	2 2	H 2	J 4	O 9	R 6	Subtotal 38	Ŧ 4	G 10	I 8) 9	A 4	M 6	2 9	O 12	P 6	Subtotal 62	Total 100
Petti and Tarsitani, 1996	4	2		9				8	8	18	4	2	9					∞	9	26	4
Stokes et al., 1995	4	4	4	4				9		22		9						4	\vdash	11	33
Burden, 1995		4	4	4			2	3		17	4	2	4			2		12	3	27	4
Otuyemi, 1994	4	4	4	4			2	9	9	30	4	2	9			2		4	3	21	51
Forsberg and Tedestam, 1993	4	4	4	9				9	3	27	4	2	8					4	9	24	51
Hunter et al., 1990		4	4	4		2	2	Э	3	22	4	2				2		4	2	14	36
Holland et al., 1988		4		ε			4	9	3	20	4	2	2		3	4		4	3	22	42
Garcia-Godoy et al., 1982	4	4		ε				9	3	20	0	2	4					4	3	13	33
Järvinen, 1978	4		4	ε				9	3	20	4	2	2					4	3	15	35
Roder and Arend, 1971	4	2		ε			2	8	9	20	4	2	2			2		4	3	17	37
Lewis, 1959	4	4	4	ε				9	9	27	4	2	4					4	2	16	43
Average										22										19	41

^a The maximum possible score of each item is mentioned beneath its label (A-R: see appendices 1 and 2).

Table 2 Pooling of overjet group 3 mm and less versus more than 3 mm with separate analysis: for all ages, for age group 6 to 18, for studies scored higher than averages of internal validity score and total methodological score.

		≤ 3 mm versus >	3 mm		
Reference	OR ^a (CI 95%) ^b	Method ^c score: all Age: all	Method score: all Age: 6–18	Intern ^d score >19 Age: 6–18	Method score >41 Age: 6–18
Petti and Tarsitani, 1996	2.57 (1.28–3.64)	✓	✓	✓	✓
Stokes et al., 1995	0.89 (0.33-2.36)	✓	✓		
Burden, 1995	2.77 (1.98–3.88)	✓		✓	✓
Otuyemi, 1994	4.47 (2.75–6.69)	✓			
Forsberg and Tedestam, 1993	1.70 (1.30–2.21)	✓	✓	✓	✓
Garcia-Godoy et al., 1982	2.90 (1.83-4.55)	✓	✓		
Järvinen, 1978	2.80 (2.13–3.67)	✓	✓		
Roder and Arend, 1971	1.62 (1.25–2.10)	✓	✓		
Lewis, 1959	2.50 (1.41-4.36)	✓	✓		✓
Homogeneity test		heterogeneous $(P < 0.001)$	heterogeneous $(0.01 < P < 0.02)$	heterogeneous $(0.02 < P < 0.05)$	homogeneous $(0.1 < P < 0.2)$
Pooled OR		2.30 (2.03–2.50)	2.16 (1.91–2.44)	2.17 (1.81–2.59)	2.17 (1.87–2.51)

^aOR: odds ratio.

Overjet 3 mm and less versus more than 6 mm. For this analysis only three studies were available (Table 4 and Figure 3). The age group was from 6 to 18 years. The pooled OR was 2.63 (CI = 2.03-3.29) and the results incorporated in this analysis were heterogeneous (0.01 < P < 0.02).

Discussion

In order to assess the methodological soundness of a study several checklists are available. Most of these were developed to assess the quality of randomized clinical trials, but so far there is no assessment list available for observational studies. To judge the methodological quality of investigations in dentistry, where most of the published studies are observational, a checklist was developed. The items incorporated in this checklist included generally accepted criteria (Chalmers *et al.*, 1981; Moher *et al.*, 1995) and were grouped into two categories: external and internal validity.

Some striking methodological aspects of the papers included in this study are:

- 1. The sample sizes differed considerably, varying from 36 individuals in the study of Stokes *et al.* (1995) to more than 2300 children for each age in that conducted by Holland *et al.* (1988). Moreover, pre-investigation estimation of sample sizes were never performed and/or reported by the authors. When the sample size is too small, a clinically relevant effect could be overlooked and when it is too large any effect could be statistically significant, relevant or not.
- 2. The cause of injury on anterior teeth is multi-factorial. Except for the central determinant, i.e. the overjet, there are several other factors, called confounders, which could affect the relationship between overjet and traumatic dental injury. These possible confounders are listed in Table 5. Mostly, marginal

^bCI 95%: 95% confidence interval.

^cMethod: methodological.

dIntern: internal validity.

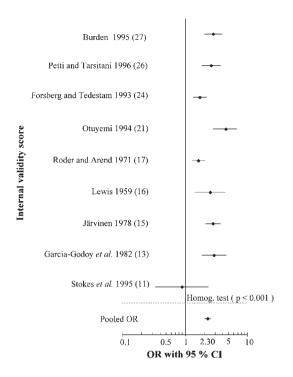


Figure 1 Graphic illustration of pooling for overjet categories ≤ 3 versus > 3 mm. All selected studies are included. Y-axis: internal validity score of each study presented between brackets and in hierarchical order. The pooled OR is presented beneath the dotted line. X-axis: OR with 95 per cent confidence interval. OR = 1 means no risk of trauma. OR > 1 means overjet increases risk of trauma and OR < 1 means overjet lowers the risk. Homog. test = homogeneity test.

- comparative techniques (*t*-test, Chi²-test) were applied. The disadvantage of these techniques is that they do not take into account the interrelations between confounders, for instance, overjet size and the position of the lip (Haynes, 1975). So when confounders may affect the relationship between overjet and dental trauma the statistical method of choice is model analysis, especially, multiple regression analysis.
- 3. The intra- and/or inter-reliability were not always clearly stated. The level of agreement, if reported, was given in percentages without correction for chance. Intra- and interreliability reflects the soundness of the method of measurement. Consequently, it indicates the trustworthiness of the reported data.
- 4. Blind measurement was not considered in any of the selected papers. Normally, blind measurement means that examination of injury on anterior teeth and measurement of overjet should not be performed by the same examiner. When only one examiner is available, the examination of trauma and measurement of overjet should not be carried out at the same time. Avoidance of information bias is the reason why blind measurement is important.

Turning to the relationship between overjet and traumatic dental injury, and the influences of several confounders, the following may be

Table 3 Pooling of overjet group 3 mm and less versus more than 3 mm stratified for boys and girls.

	≤ 3 mm versus > 3 mm	
Reference	Method. score : all Age: 6–18 Sex: female OR (CI 95%)	Method. score : all Age: 6–18 Sex: male OR (CI 95%)
Garcia et al., 1982	4.08 (2.18–7.53)	2.13 (1.07–4.18)
Järvinen, 1978	3.54 (2.29–5.40)	2.34 (1.67–3.28)
Roder and Arend, 1971	2.00 (1.30–3.14)	1.26 (0.90–1.80)
Lewis, 1959	2.75 (1.21–6.18)	2.30 (1.85–2.84)
Homogeneity test	homogeneous $(0.1 < P < 0.2)$	homogeneous $(0.05 < P < 0.1)$
Pooled OR	2.90 (2.33–3.76)	1.77 (1.41–2.20)

For abbreviations see Table 2.

Homog.test (0.01)

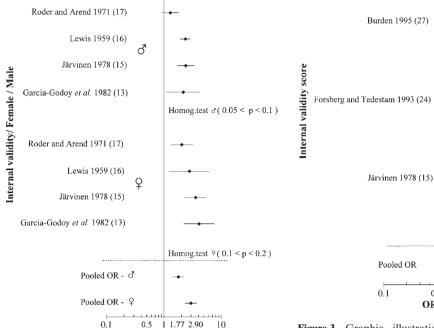


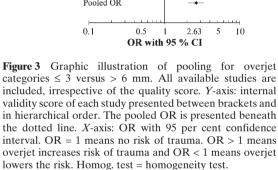
Figure 2 Graphic illustration of pooling for overjet categories ≤ 3 versus > 3 mm stratified for gender, irrespective of study quality. *Y*-axis: internal validity score of each study presented between brackets and in hierarchical order. The pooled OR is presented beneath the dotted line. *X*-axis: OR with 95 per cent confidence interval. OR = 1 means no risk of trauma. OR > 1 means overjet increases risk of trauma and OR < 1 means overjet lowers the risk. Homog. test = homogeneity test.

OR with 95 % CI

Table 4 Pooling of overjet group 3 mm and less versus 6 mm and more.

Reference	≤ 3mm versus ≥ 6mm Method. score : all Age: 6–18 OR (CI 95%)
Burden, 1995	3.28 (2.05–5.25)
Forsberg and Tedestam, 1993	1.79 (1.26-2.50)
Järvinen, 1978	3.81 (2.56–5.68)
Homogeneity test	heterogeneous $(0.01 < P < 0.02)$
Pooled OR	2.63 (2.03–3.29)

For abbreviation see Table 2.



noted: Table 5 shows the possible confounders investigated. Investigators who have included the recording of confounders in their studies have used different methods of measurements, and/or different methods of data collection and presentation, and therefore, except for gender, it was not possible to incorporate the remaining confounders into the present analysis. Moreover, some of these confounders were only investigated by one or two authors.

Lip posture was investigated by Otuyemi (1994), Forsberg and Tedestam (1993), Burden (1995), Petti and Tarsitani (1996). Otuyemi (1994) delivered data both of the upper and lower lip. Forsberg and Tedestam (1993) only collected data of the upper lip, but reported it together with inter-labial gap. Burden (1995) reported his data unclearly. Petti and Tarsitani (1996) presented the data of the upper lip only.

Table 5 Inventory of the investigated confounders identified per author.

	Possible	Possible confounders	,s							
Reference	Age	Age	Gender	Gender Overjet (mm) ^a	Molar	Lip	Molar Lip Inter	Accid.	Mode Sport	Sport
	lange	group(s)		0 1 2 3 4 5 6 7 8 9	OCCIUSION	posture	iau, gap	ргопе	U catil	
Petti and Tarsitani, 1996	6–11	9	ć.	_	Š	upper		`		`
Stokes et al., 1995	7–18	1	٠							
Burden, 1995	11–12	1	٠	_		٠.				
Otuyemi, 1994	12	1	;	_		upper + lower	wer			
Forsberg and Tedestam, 1993	7–15	1	M/F	- - - - -	`	upper	close/open		`	`
Hunter et al., 1990	11–12	1	M/F	_						
Holland et al., 1988	8,12,15	3	M/F	_						
Garcia-Godoy et al., 1982	3–14	2	M/F	_						
Järvinen, 1978	7–16	1	M/F	_						
Roder and Arend, 1971	6–16	1	M/F	_						
Lewis, 1959	8–13	1	M/F	_						

^aVertical lines present the overjet categories in millimetres.

^bVertical distance between the lip and the edge of the incisor of the corresponding jaw reported in proportion of total crown height (1/3, 2/3, 1).

^cInterlabial gap.

^dTendency to accidents.

^eMode of breathing.

^fConfounder investigated.

The age range of the sample also differed from paper to paper with Otuyemi (1994) selecting only one single age. Furthermore, data of overjet and dental trauma were collected and analysed together in this predetermined age range without distinguishing each year. As a result, pooling for certain ages was impossible and it was also impossible to calculate the age when risk of dental injury due to overjet was greatest. It is important to note that, although the incidence decreases after a certain age (Andreasen and Ravn, 1972; Järvinen, 1979; Forsberg and Tedestam, 1990), the prevalence of traumatic dental injury increases with age. Thus, by choosing a certain age range one definitely influences the calculated risk.

The same is true for overjet. Although overjet is continuous, most authors report it into categories. The advantage of this approach is a simple analysis and presentation. However, an important disadvantage is loss of information. As a consequence, it is impossible to determine an empirically based cut-off point of overjet size at which the highest increase in risk of dental injury occurs. Finally, when the chosen cut-off points differ from study to study comprehensive pooling can be hindered.

In literature research, especially when using meta-analysis, the availability of papers is of the utmost importance. Unfortunately, there are only a few papers concerning the relationship between overjet and traumatic dental injury. Twenty-six articles were identified with the search method mentioned above. Eventually, only 11 studies remained for further analysis. Moreover, we were compelled to select the studies having the same cut-off points of overjet to undertake the pooling procedure. Using 3 and 6 mm as cut-off points, the following comparisons were made:

(a) When the overjet group of 3 mm and less was compared with that of more than 3 mm, regardless of the methodological quality and age, the pooled OR was 2.30 which is highly significant, but the ORs were heterogeneous which indicates differences among study results. Except for age, the pooled OR (2.16) seems not to be affected by the studies of higher quality. It does not make

much difference whether internal validity score or total methodological score was applied to select the better studies for the calculation of the pooled OR. On the contrary, heterogeneity among the selected studies disappeared when the latter was used. This implies that in order to draw a conclusion for a general population concerning the risk of overjet on traumatic dental injury, the entire checklist should be used.

The risk of trauma due to overjet is apparently different for boys and girls. This study shows that within the same overjet group, the effect of overjet is less for boys than for girls. This seems to be controversial at first glance since Forsberg and Tedestam (1990); Ravn (1974); Hedegard and Stalhane (1973) have reported that boys have higher injury frequency than girls. The explanation for this finding may be that, because of their behaviour and/or their involvement in specific types of sports, boys are more prone to receive trauma regardless of their overjet. Moreover, it was noticeable that heterogeneity of ORs could be explained by not distinguishing boys and girls (Table 3).

(b) Comparing the overjet groups of 3 mm and less with that of more than 6 mm, the pooled OR indicates that the risk of trauma can increase with increasing overjet size. However, neither this assumption nor the heterogeneity among the ORs could be tested in view of the limited data.

Generally, systematic reviews are hampered by two main problems: publication bias, generally resulting in too strong relationships and dissimilar studies (as to populations and methods), resulting in heterogeneity of results. The first problem has to do with the tendency of investigators and editors not to publish 'negative results'. However, it was assumed that publication bias was modest in this literature review. The second problem is clearly present in this study. Perhaps the large range of publication years is one of the causes. By pooling in several ways it is found that especially gender is the source of heterogeneity, and thus boys and girls should be considered separately. Although the pooled OR is not considerably affected, differences in the quality of studies seem to matter for heterogeneity of results.

Conclusions

Although the possibility of publication-bias cannot be excluded, it can be concluded from this study that children with an overiet larger than 3 mm are approximately twice as much at risk of traumatic dental injury on anterior teeth than those with an overjet less than 3 mm. The effect of overjet is less for boys than for girls in the same overiet group. In addition, risk of an injury to anterior teeth tends to increase with increasing overjet size. Surprisingly, the pooled OR does not seem to be affected by the quality of the studies. In this investigation, comprehensive pooling was not possible because of differences in the method of measurement, reporting of data, confounders involved in the study and the chosen categories of overjet size. Nevertheless, the incorporation of overjet as a malocclusion item into orthodontic treatment indices seems to be valid since the overall odds ratio is larger than 2. Although this threshold is, in fact, arbitrary, it is commonly accepted that an odds ratio of 2 is a plausible limit for occlusal abnormalities (Pullinger et al., 1993).

Concerning orthodontic treatment indices, however, many aspects regarding the relationship between overjet and traumatic dental injury still remain obscure. What is the empirically best cut-off point of overjet related to the risk? What is the risk of trauma given a certain overjet size when different ages are taken into account? What is the minimal risk at which treatment should be indicated? Should the indication for treatment be different for boys and girls? To answer these questions more studies are needed. The recommendations for the design of future studies include avoidance of changing continuous data into categorical data. Furthermore, it has to be borne in mind that age is an important factor. Concerning the sample size, power analysis can be performed preceded by determination of the clinically relevant effect of overjet to be detected (Cohen, 1992; Hallahan and Rosenthal, 1996) and finally, due to the multifactorial character of trauma, model-analysis is the statistical technique of choice.

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Acknowledgements

We would like to acknowledge the contribution of Dr M. A. A. Blom, for her assistance in the preparation of this manuscript, and Dr P. Assendelft for his helpful comments on the methodological checklist.

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Appendix 1: Methodological assessment list

Methodological Criteria

I. S	Study design	Score
A.	Objective description	4
В.	Description of population	4
C.	Selection criteria	4
D.	Description of potential confounders	6
E.	Pre-investigation sample size estimation	n 2
F.	Sample size	4
G.	Type of study (maximum score $= 10$;	
	items cannot be randomly combined	l)
	Longitudinal	6
	Mixed-longitudinal	4
	Case-control	2
	Cross-sectional	2
	Follow-up time	4
	Subgroup comparability	4
II.	Study conduct	
H.	Mentioning of dropouts	2
I.	Method of measurement described	8
J.	Blind measurement	6
K.	Number of examiners	4
L.	Intra- and inter-examiner reliability	
	described	4
M.	Level of agreement intra- and inter-	
	examiner	6
Ш	. Statistical analysis	
	Dropouts included in data analysis	6
O.	Statistical method correct	12
P.	Confounders analysed	6
Q.	Presentation of data	6
IV.	Conclusion	
R.	Statement referred to statistical proceed	lure
	used and appriopriate to objective	6
Ma	aximum score	100

Appendix 2: Directions for use of the methodological criteria

- A. Objective clearly formulated: 4 pts
- B. Positive if study population is clearly described (2 pts) and considered adequate (2 pts)
- C. Inclusion and exclusion criteria are clearly described (2 pts) and considered adequate (2 pts)
- D. Positive if confounders are mentioned; one point for each determinant, including central determinant(s): e.g. overjet, gender, age, lip

- coverage, contact sport, and others. Maximum score: 6 pts
- E. Positive if sample size has been estimated before collection of data: 2 pts
- F. Positive if sample size has been considered as adequate (not too small or too large regarding objective and statistical method used): 4 pts
- G. Longitudinal study (6 pts), mixedlongitudinal study (4 pts), case-control study (2 pts), cross-sectional study (2 pts)
 - (i) Additional score for follow-up time in case of (mixed-)longitudinal study or retrospective time in case of case-control study: 0–2 years, 0 pt; 2–4 years, 1 pt; 4–6 years, 2 pts; 6–10 years, 3 pts; more than 10 years, 4 pts
 - (ii) In case of case-control study, if subgroup comparability is considered as adequate: 4 pts
- H. In case of mentioning of dropouts: 2 pts
- I. Positive if the methods of measurement are clearly described and considered appropriate to the objective. Measurement of overjet, trauma, lip coverage, and others: 2 pts each item. In case of unclear description and/or considered as less adequate to the objective, 1 pt for each item mentioned
- J. Positive if blind measurement procedure has been mentioned and carried out: 6 pts
- K. Maximal score 4 points if there are more than two examiners, 3 points for two examiners and 0 point for one examiner (per individual)
- L. Positive if intra- and inter-examiner reliability is mentioned: 2 pts each. In case of unclear description: 1 pt
- M. Level of agreement of intra- and interexaminer—Kappa value more than 80%, 3 pts each; 60–80%, 2 pts; less than 60%, 0 pt each
- N. Positive if dropouts included in data analysis: 6 pts
- O. Positive if statistical methods are considered appropriate for data; maximal score 12 points for model analysis relating outcome variable to determinants; 8 pts for combined subgroup analysis (for example: Mantel–Haenszel method); 4 pts for only marginal comparision (for example, Chi²-test, *t*-test)

- P. Maximal score if confounders are included in the analysis, 1 point for each item mentioned in D
- Q. Positive if data are clearly presented: 6 pts. In case of unclear and/or incomplete presented: 3 pts
- R. Positive if statements refer to statisticalprocedure used and considered as appropriate to objective: 6 pts. In case of unclear or uncomplete reported: 3 pts