

# Validation of measurements of mandibular protrusion in the treatment of obstructive sleep apnoea and snoring with a mandibular protruding device

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**SUMMARY** The aims of this study were to compare the maximum range of protrusion determined with a ruler with measurements made using a George Gauge<sup>®</sup> (GG) and to validate the methods of measurement (ruler and GG) of the advancement established by mandibular protruding devices (MPDs), using cephalograms as the gold standard. The study comprised 77 patients (63 males, 14 females, mean age 54 years, range 31–73 years) with obstructive sleep apnoea (OSA) ( $n = 50$ ) or complaints of snoring ( $n = 27$ ). After a medical examination that included an overnight somnographic registration and a dental and stomatognathic examination, each patient was given a MPD. Measurements of the maximum range of protrusion with the GG and a ruler were compared. Pairs of upright cephalograms were taken with and without the MPD. The position of the mandible on the cephalograms was compared with ruler measurements of the device-induced protrusion in the incisor and premolar regions, the vertical opening in the anterior region, and GG construction bite registration.

The maximum range of protrusion was significantly greater with GG than ruler measurements, on average +1.2 mm ( $P < 0.001$ ). The mandibular position as measured in the incisor or premolar region with a ruler or on the cephalogram was not significantly different. GG values, however, were higher and differed significantly from ruler and cephalometric measurements ( $P < 0.001$ ). The degree of anterior mandibular advancement with a MPD measured with a ruler in the incisor or premolar regions compared well with corresponding cephalometric measurements. The ruler and cephalometric measurements of the vertical opening with the MPD coincided well in the incisor region. The GG overestimated the maximum range of protrusion compared with ruler measurements.

## Introduction

Mandibular protruding devices (MPDs) have become popular because of their effectiveness in treating sleep-disordered breathing (Bonham *et al.*, 1988; Marklund *et al.*, 1998a,b; Wilhelmsson *et al.*, 1999). A survey (Lowe, 2000) described more than 55 different devices currently on the market for dentists in the USA and Canada, with oral monobloc devices being used most frequently (Marklund *et al.*, 1998c; Fransson *et al.*, 2001). Clark *et al.* (1993) recommended that MPDs should be constructed to position the mandible forward by 75 per cent of the maximum range of protrusion. In a number of studies, the degree of maximal mandibular advancement has varied (Clark *et al.*, 1993; Ferguson *et al.*, 1996, 1997; Tegelberg *et al.*, 1999; Yoshida, 2000; Gavish *et al.*, 2001), but details of how this measurement was determined were not reported. Marklund *et al.* (2001) measured the degree of mandibular repositioning on initial plaster casts made from wax construction bites and Battagel *et al.* (1999) carried out measurements on

cephalograms taken while wax wafers maintained the mandible in the correct position. The anterior mandibular advancement and the vertical distance between the maxilla and mandible (bite opening) obtained with MPDs have been reported in several studies (Ferguson *et al.*, 1997; Tegelberg *et al.*, 1999; Lowe, 2000; Gavish *et al.*, 2001). The vertical distance between the edges of the incisors is described (Schmidt-Nowara *et al.*, 1991; Ferguson *et al.*, 1996; George, 2001), but not the individual vertical overbite.

The most critical step in the construction of a MPD is bite registration (George, 1996). The most common bite registration material is wax in a protruded position used for orthodontic activators. This has also been used for constructing the index for MPDs. The George Gauge<sup>®</sup> (GG) (George, 1992, 1996, 2001) was developed and introduced as an aid in determining the amount of protrusion needed in MPD construction (Bondemark, 1999; Lowe, 1999; Bondemark and Lindman, 2000; Gale *et al.*, 2000).

According to L'Estrange *et al.* (1996), who reported that the airway lumen decreased with increased vertical opening, measurements of the total vertical opening are necessary. To date, no standards have been established so that comparisons between the positions of the appliances can be adequately undertaken. The aims of the study were, therefore, to compare the maximum range of protrusion determined with a ruler with measurements made using a GG and to validate these two methods of measurement of mandibular advancement established by MPDs, using cephalograms as the gold standard.

### Subjects and methods

The study population comprised 77 patients (63 males and 14 females, mean age 54 years, range 31–73 years), referred for treatment from Örebro University Hospital to the Department of Stomatognathic Physiology at the Postgraduate Dental Education Centre. The inclusion criteria were a diagnosis of obstructive sleep apnoea (OSA) ( $n = 50$ ) or complaints of snoring ( $n = 27$ ) and a sufficient number of teeth to retain the MPD. The exclusion criteria were a mandibular protrusion ability of less than 6 mm measured with the GG, and a severe cariogenic or periodontally compromised dentition. All patients included in the investigation had undergone a somnographic registration before MPD treatment. A detailed description of the overnight somnographic monitoring technique has been reported previously (Fransson *et al.*, 2001).

All patients signed an informed consent form and agreed to participate in the present study, which was approved by the Ethics Committee of Örebro County Council.

Following a medical examination that included an overnight somnographic registration, the patients underwent a dental and stomatognathic examination. At the baseline examination the mean sagittal distance between the retruded position (RP) and intercuspal position (IP) was measured with a millimetre graduated steel ruler in the right first premolar region. A baseline measurement of the maximum range of protrusion was determined using both a ruler (in the premolar and incisor regions) and the GG. The intention was to protrude the mandible with the MPD 75 per cent of the patient's maximum range of protrusion. In subjects with a limited range of protrusion and when the advancement is measured with the GG, the construction bite should be at least 5 mm, i.e. in these patients more than 75 per cent of the maximum range of protrusion was established. A MPD was then fabricated using the GG index, i.e. the index determined the degree of mandibular protrusion as well as the degree of established vertical opening. Two cephalograms were then taken, one with and one without the MPD in place. In conjunction with

the cephalometric examination, a ruler measurement of the MPD-guided protrusion was made.

### MPD

The MPD was constructed as a monobloc of heat-cured methyl methacrylate (Microdent®, Forshaga, Sweden). The upper and lower portions provided full occlusal coverage of the teeth. To increase the retention of the device, four Adams clasps were placed on the maxillary and mandibular first molars.

### Ruler measurement of mandibular movement

At baseline, with the patient biting together in a normal manner (IP), the horizontal overjet was measured as the distance from the buccal side of the lower right incisor to the buccal side of the upper right incisor edge with a ruler. For measurements of the total range of protrusion, the patient was asked to protrude his or her mandible from the IP as far anteriorly as possible, and the distance from the buccal surface of the upper right incisor to the buccal side of the lower right incisor edge was then recorded. The total range of protrusion included the horizontal overjet. The vertical overbite was measured in the right incisor region. The projection of the edge of the upper incisor on the buccal surface of the lower incisor was marked with a 0.4 mm felt pen. The distance from this mark to the edge of the lower incisor was determined as the vertical overbite. Measurements were made to the nearest 0.5 mm.

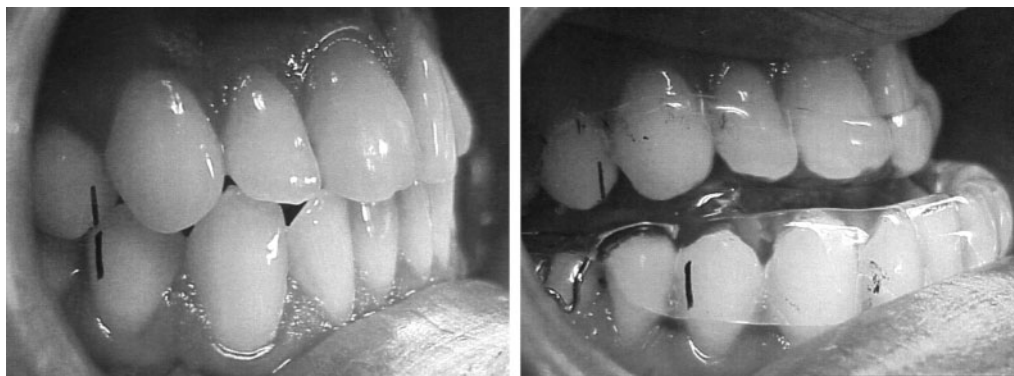
### Ruler measurements of MPD-guided mandibular protrusion

After the MPD was fabricated, vertical lines were drawn over the first right premolars to indicate the IP (Figure 1). The horizontal overjet and vertical overbite were also re-checked. The MPD was then inserted in the mouth and the degree of protrusion was determined both on the vertical premolar lines (through the acrylic) as well as in the right incisor region. The distance from the buccal surface of the upper right incisor to the buccal surface of the lower right incisor plus the horizontal overjet was measured with a ruler, which determined the total mandibular protrusion induced by the MPD.

The vertical opening with the MPD was measured in the right incisor region and comprised the distance from the edge of the upper right incisor to the edge of the lower right incisor plus the vertical overbite.

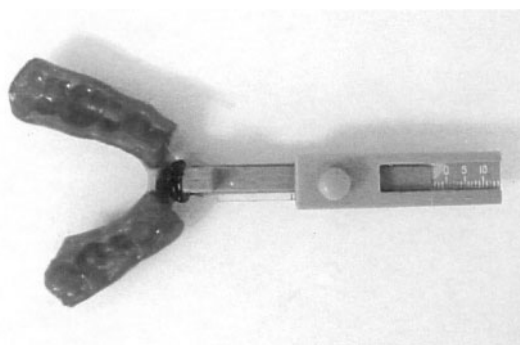
### GG measurement

The GG was primarily designed for use in registrations of the mandibular bite and also measurement of the



**Figure 1** Lateral view of the mandibular protruding device with the vertical lines marked on the right first upper and lower premolars.

maximum range of protrusion (George, 1996) (Figure 2). After the moveable incisal notches of the GG were set, they were stabilized with a thermoplastic impression material (Kerr®, UK Ltd, Salerno, Italy) to ensure a firm grip on the incisors. The maximum range of protrusion (from the RP to the maximum protruded position) was then determined using the millimetre scale of the GG (George, 1992). A heated base plate wax (Tenax®, SS White, Gloucester, UK) was then placed around the prongs of the bitefork to support the posterior teeth, thus creating the bite index used in the construction of the MPD.

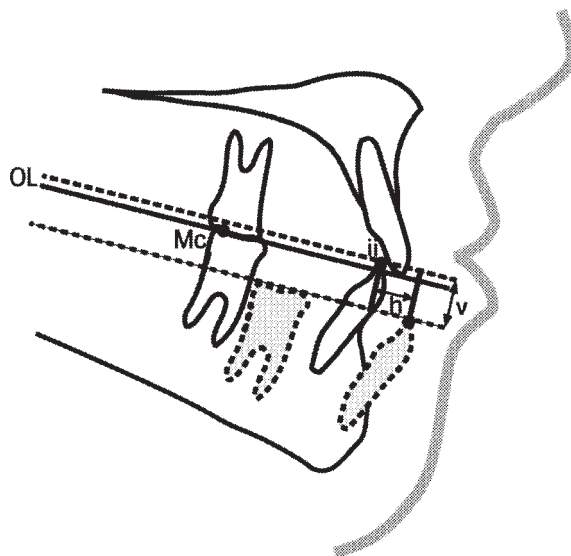


**Figure 2** The George Gauge® bite registration index.

#### *Lateral cephalometric radiography*

Two upright cephalograms, the first without the MPD and the second with the MPD, were obtained by supporting the patient's head with a cephalostat (Iikubo *et al.*, 1975) with the head orientated according to the Frankfort horizontal plane. The patient was instructed to bite in an IP when the cephalogram was taken without the MPD.

To enable the measurement of mandibular advancement with the MPD, an acetate film was placed over the cephalogram taken when the patient was wearing the MPD and the lower incisor was outlined. The acetate was then placed over the cephalogram taken when the patient was not wearing the MPD and the lower incisor was again traced. Sella, nasion, and the upper incisors were marked or outlined with a thin pencil and used as reference points for the placement of the acetate (Athanasίου *et al.*, 1994). The numerical values in millimetres of the mandibular advancement (mandibular movement along the occlusal line) and the increase in vertical height (mandibular movement perpendicular to the occlusal line) were then obtained (Figure 3). The enlargement factor was 1.07 (7 per cent). The measurements were corrected for enlargement and converted to a 1:1 scale. The cephalograms were



**Figure 3** Cephalometric landmarks and reference lines for the measurement of the mandibular advancement induced by the mandibular protruding device. h, horizontal movement along the occlusal line (OL); v, vertical movement perpendicular to the OL; Mc, distobuccal cusp of the maxillary first permanent molar; ii, incisal tip of the most prominent mandibular incisor. Reprinted from Sleep and Breathing 2002 6: 55–68, Fransson *et al.*, with permission from Thieme New York.

registered using a digitizer tablet (Scriptel RDT, Dentofacial™ Software Inc., Toronto, Canada) connected to a computer and the cephalometric tracing program PCDIG (Centre for Dental Technology and Biomaterials, Karolinska Institute, Stockholm, Sweden) was used. A detailed description of the cephalometric analysis has been reported (Fransson *et al.*, 2002).

#### Method error and reliability

The consistency of a single examiner was evaluated. Twenty consecutive patients wearing a MPD were clinically measured twice with a ruler to determine the amount of anterior and vertical mandibular advancement. Duplicate readings of randomly selected cephalograms from 20 patients were made. To calculate the consistency between readings, Dahlberg's formula for measuring method error ( $S$ ) was used:  $S = \sqrt{(\Sigma d^2/2n)}$  (Dahlberg, 1948). The importance of the method error was assessed by calculating the error variance ( $C$ ):  $C = S \times 100/\text{mean}_{1+2}$ .

#### Statistics

The arithmetic mean and standard deviation (SD) were calculated for each variable. Tests for the statistical significance of the differences between the methods of measurement were performed with a paired sample Student's  $t$ -test. The 95 per cent confidence interval (95% CI) was calculated for each variable.  $P$  values less than 0.05 were considered significant.

#### Results

At the baseline examination, the mean sagittal distance between the RP and the IP was 0.26 mm (range 0–2, SD 0.5, 95% CI 0.16–0.37,  $n = 76$ ).

#### Range of protrusion

The range of protrusion measured with a ruler in the incisor region was a mean of 9.5 mm (range 4.5–15.0, SD 2.1, 95% CI 9.1–10.0,  $n = 77$ ) and with the GG a

mean of 10.7 mm (range 6.0–16.0, SD 2.3, 95% CI 10.1–11.2,  $n = 70$ ). The mean GG measurement was significantly larger, +1.2 mm (95% CI<sub>d</sub> +0.7 – +1.6,  $n = 70$ ) ( $P < 0.001$ ), than the mean ruler measurement.

#### Anterior mandibular advancement with the MPD

Measurements of anterior mandibular advancement with the MPD *in situ* as determined with a ruler, the GG, and on cephalograms are shown in Tables 1 and 2. The differences in the number of patients are due to missing data. There were significant differences between the measurements of the advancement with the GG and a ruler in the incisor region, a mean of +1.1 mm (95% CI<sub>d</sub> 0.7–1.4,  $n = 65$ ) ( $P < 0.001$ ), and with the GG and a ruler in the premolar region, a mean of +1.3 mm (95% CI<sub>d</sub> 0.9–1.6,  $n = 73$ ) ( $P < 0.001$ ).

The cephalometric and GG measurements ( $n = 73$ ) differed significantly by a mean of 1.3 mm (SD 1.9,  $P < 0.001$ ). However, only small insignificant differences were seen between cephalometric and ruler measurements, means of 0.3 mm (incisor region) and 0.1 mm (premolar region) (Table 2).

#### Vertical opening with the MPD

At the right incisors, differences in measurements of the vertical opening with the MPD in place made with a ruler were, on average 6.9 mm (range 3.0–13.0, SD 2.2, 95% CI 6.4–7.4,  $n = 77$ ), and on cephalograms, on average 6.9 mm (range 2.4–12.1, SD 2.1, 95% CI 6.4–7.4,  $n = 77$ ), which were insignificant.

#### Method error

The method errors for the ruler measurement with the MPD in place were 0.3 and 0.5 mm for anterior mandibular advancement and 0.6 mm for vertical opening of the mandible. Corresponding coefficients of variation ranged from 4.6 to 8.8 per cent. The method error on the cephalograms was 0.7 mm for anterior mandibular advancement with the MPD and 1.0 mm for vertical opening of the mandible with the MPD.

**Table 1** Descriptive statistics of different methods of measurement of the anterior mandibular advancement with the mandibular protruding device inserted.

Method	Mandibular advancement (mm)			
	Mean	Range	Standard deviation	95% confidence interval
Ruler, incisor region ( $n = 67$ )	6.7	3.0–10.5	1.6	6.3–7.1
Ruler, premolar region ( $n = 77$ )	6.5	3.5–11.0	1.6	6.2–6.9
George Gauge® ( $n = 73$ )	7.8	5.0–14.0	1.9	7.4–8.3
Cephalometric, incisor region ( $n = 77$ )	6.4	2.3–11.2	2.1	6.0–6.9



**Table 2** Mean differences in comparing the cephalometric measurements versus the ruler and George Gauge® with the mandibular protruding device *in situ*.

	Ruler, incisor region ( <i>n</i> = 67)					Ruler, premolar region ( <i>n</i> = 77)					George Gauge® ( <i>n</i> = 73)				
	<i>d</i>	95% CI <sub><i>d</i></sub>	SD <sub><i>d</i></sub>	<i>P</i>		<i>d</i>	95% CI <sub><i>d</i></sub>	SD <sub><i>d</i></sub>	<i>P</i>		<i>d</i>	95% CI <sub><i>d</i></sub>	SD <sub><i>d</i></sub>	<i>P</i>	
Cephalometric measurement	0.3	-0.1 – +0.7	1.8	0.189		0.1	-0.3 – +0.5	1.7	0.606		1.3	+0.9 – +1.8	1.9	<0.001	

Paired sample Student's *t*-test.

*d*, mean differences between the techniques; 95% CI<sub>*d*</sub>, 95 per cent confidence interval; SD, standard deviation.

Corresponding coefficients of variation were 10.5 and 14.3 per cent (Fransson *et al.*, 2002). No systematic errors were detected.

## Discussion

It was found that measurement of the advancement established by the MPD with a ruler in the incisor or premolar region and the cephalometric measurement (the 'gold standard') coincided well. It was also found that vertical opening with the MPD measured with a ruler in the region of the incisors compared well with measurements made on cephalograms. The ruler measurements of anterior mandibular advancement with the MPD in the region of the incisors or the premolars were equal. The range of protrusion measured in the incisor region with a ruler was significantly lower than that with the GG. Consequently, the values obtained with the GG for anterior mandibular advancement with the MPD in place were larger. The reason for this difference compared with the other methods is the endpoint of the mandible. When the GG is used the instrument creates a larger vertical opening and thereby the mandible will be positioned more posteriorly. One explanation could be that with the GG, the range of protrusion increased because measurements were made from a more mandibular retruded position instead of from the IP, as with the ruler and the cephalogram. In this study the RP–IP distance was on average 0.3 mm, which is in accordance with Tegelberg and Kopp (1987), who reported the same mean sagittal distance between the RP and IP in a control group. However, even if the RP–IP distance was included in the GG measurement, the range of protrusion was larger than that measured with the ruler. The GG, instead of positioning the mandible further forward, in the desired direction, allowed the mandible to be even more retruded.

The construction of the MPD must permit the lower incisors to pass the upper ones without interference. L'Estrange *et al.* (1996) reported that a minimum vertical height was necessary to prevent posterior rotation of the mandible, which is in agreement with a

previous study (Fransson *et al.*, 2002). Many authors have reported the vertical distance measured at the edges of the incisors but did not add the individual vertical overbite (Schmidt-Nowara *et al.*, 1991; Ferguson *et al.*, 1996; Menn *et al.*, 1996; Hans *et al.*, 1997; Marklund *et al.*, 1998 a,c; Bondemark and Lindman, 2000; Johnston *et al.*, 2001). According to the above, the total vertical mandibular opening with the MPD *in situ* should be measured, but none has reported this measurement. Several studies, however, have reported cephalometric measurements of the advanced mandibular position with the MPD *in situ* (Bonham *et al.*, 1988; Battagel *et al.*, 1999; Gale *et al.*, 2000; Liu *et al.*, 2000a,b). The GG is a useful aid when making a bite registration. The ability to fix the incisors in the incisal notches in the advanced position makes it easier for the patient to maintain the correct advancement during bite registration. The GG overestimated the maximum range of protrusion compared with the ruler measurements, and therefore significantly underestimates the construction bite, which could negatively influence treatment results if no compensation is made for this. According to the present results, the advancement must be greater if the mandible is to reach the planned advanced position from the IP than when a ruler is used. It is recommended that the advancement be checked when the MPD is delivered and inserted in the mouth. Kato *et al.* (2000) found that the degree of mandibular protrusion influences treatment results. A 2 mm increase in the advancement of the mandible improved the somnographic variables by 20 per cent. In prolongation, when it is found in the somnographic follow-up that the position of the MPD needs to be altered, the baseline measurements can be used to determine if it is possible to alter the mandibular position or if another therapy must be chosen instead.

Cephalometry was used in the present study as the gold standard as this method has been regarded as reliable. However, the results of this study show that the cephalometric measurement variability in the incisor area was greater than ruler measurements. However, cephalometry is advantageous in determining

the position/changes in other parts of the jaw/pharyngeal area where ruler measurements are impossible to carry out.

## Conclusion

Measurements of anterior mandibular advancement with a MPD in place made with a ruler in the incisor or premolar regions compared well with those on cephalograms. The ruler and the cephalometric measurements of the vertical opening with the MPD coincided well. The GG overestimated the maximum range of protrusion compared with the ruler measurements.

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