Occlusal Force Diagnostic System – A Device for Clinical Application in Orthognathic Surgery

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Abstract:
This research project was designed to apply several, newly developed and more sophisticated methods of measuring muscle structure and function to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach, as is the case with orthognathic surgery.
The masseter muscle displays a penniform structure typically characterized by the presence of alternating muscular/aponeurotic layers. The anatomical sections and the MRI section in the same plane allowed the appearance of the intra-muscular aponeurotic layers on the MRI to be defined. Given these characteristics, the masseter muscle was chosen in preference to the medial pterygoid muscle.
A prototype device called the Occlusal Force Diagnostic System accompanied by a second prototype device called the Bite Training Machine were constructed to measure patients' occlusal force. This system was applied in a repeatability test with 30 patients that attend the combined orthodontic/orthognathic surgery outpatient clinic of Clitrofa - Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal.
KEY-WORDS
Occlusal Force Measurement; Orthognathic Surgery;Clinical Application

I. INTRODUCTION

One of the main purposes of orthognathic treatment in patients with a dentofacial deformity is to improve masticatory function as well as aesthetics. Numerous studies have documented masticatory function, for example:bite force, occlusal contact and masticatory efficiency, in patients with mandibular prognathism before and after orthognathic surgery [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13]; but few reports compared the results with those in controls with normal occlusion [1, 3, 6, 7, 8, 9, 12, 13]. There have also been few studies that involved

evaluation of these parameters at the initial medical consultation for patients undergoing orthognathic surgery [14, 15]. No reports were found that simultaneously evaluated the relationships between bite force, occlusal contact and masticatory efficiency in patients with mandibular prognathism and in controls with normal occlusion.

Previously, changes in bite force and occlusal contact before and after orthognathic surgery were investigated and presented using the T-Scan system™ (Tekscan, USA) [3]. This system is convenient and simple but is poor in regard to reproducibility and quantification.

Another method for occlusal analysis, the Dental Prescale™ system (Fuji Photo Film Co., Japan), has been developed. This is a computerized system intended to assist occlusal analysis by providing information as to the magnitude of the bite force and the distribution of occlusal contacts. The system is capable of simultaneously measuring these parameters for teeth separated by less than 10mm and has potential for research in centric occlusion. It is a horseshoe-shaped thin film that consists of two layers: a layer of microcapsules containing colour-forming materials and a layer of colour-developing materials. The colour-developing materials, producing a red colour in the contact area when a force is generated, absorb the released colour-forming materials. The Dental Prescale™ system has already been used for analysing occlusion in dentures [16, 17] dental implants [18] and orthognathic surgery [2, 8].

Many methods for the quantitative measurement of masticatory efficiency have been introduced, but none stands out as ideal. Spectrophotometric methods for the evaluation of masticatory efficiency have been reported, involving measurement of the absorbance of adenosine triphosphate (ATP) granules [6, 7, 12]. This technique shows both accuracy and reproductibility, but it has an high cost and an high complexity. Achewing-gum system has been developed for the estimation of masticatory function by the Meiji Chewing Gum Corporation. It utilizes a phloxine–sodium bicarbonate reaction and measures a chromatic coordinate as an indicator. This low-adhesive colourdeveloping chewing-gum system has already been used for analyzing the masticatory function of dental implants [19] and dentures [20], but it does not allow quantitative determination[21].

OCCLUSAL FORCE DIAGNOSTIC SYSTEM
1. SENSORS

The FS Series sensors provide precise reliable force sensing performance in a compact commercial grade package. The sensor features a proven sensing technology that uses a specialized piezoresistive micromachined silicon sensing element. The low power, unamplified, uncompensated wheatstone bridge circuit design provides inherently stable mV outputs over the force range[22].

Force sensors operate on the principle that the resistance of silicon-implanted piezoresistors will increase when the resistors flex under any applied force. The sensor concentrates force from the applications, through the stainless-steel ball, directly to the silicon-sensing element. The amount of resistance changes in proportion to the amount of force being applied. This change in circuit resistance results in a corresponding mV output level change[22].

The stainless-steel ball provides mechanical stability and is adaptable to a variety of applications. The FSS sensor delivered 20 million operations in Mean Cycles to Failure (MCTF) reliability testing at 50°C [122°F]. This test determines the number of possible sensor operations at full scale until failure. Various electric interconnects can accept prewired connectors, printed circuit board mounting, and surface mountings. The sensor design also provides a variety of mounting options that include mounting brackets, as well as application specific mounting requirements.

The typical applications of this sensors are: medical infusion pumps, ambulatory non-invasive pump pressure, occlusion detection, kidney dialysis machines, load and compression sensing, variable tensions control, robotic end-effectors and wire bonding equipment [22].

2. SENSOR CIRCUIT
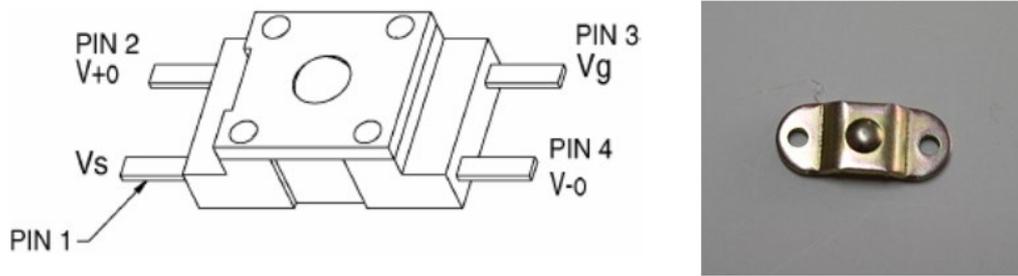
Fig. 1 - Schematic illustration of Sensor Circuit. 1- Sensor terminals (pins): Pin 1 = Supply VS (+), Pin 2 = Output VO (+), Pin 3 = Ground Vg (-) Pin 4 = Output VO (-). 2 - The force sensor may be powered by voltage or current. Maximum supply voltage is not to exceed 12 volts. Maximum supply current is not to exceed 1.6 mA. Power is applied across Pin 1 and Pin 3.3- The sensor output should be measured as a differential voltage across Pin 2 and Pin 4 (VO = V2 - V4). The output is ratiometric to the supply voltage. Shifts in supply voltage will cause shifts in output. Neither Pin 2 nor Pin 4 should be tied to ground or voltage supply.

3. SENSORS DISTRIBUTION

The first idea was to place seven sensors distributed by the dental arch in a horseshoe-shaped form designated by bite force, but because of the sensors dimensions was decided to place only five. One sensor was for the anterior teeth (central and lateral incisors), two sensors for the canine and first pre-molar and another two sensors for the second pre-molar and first molar. The objective of this sensor's distribution was to make measurements of occlusal contact areas and occlusal pressures individually and in total. The sensors were connected between them, and the cables connected to a transducer that shows the digital reading in kilograms.

During the process of development was felt interesting to have the five sensors reading at the same time, and to achieve this several changes were introduced, namely the inclusion of five digital screens, each one corresponding to one sensor, the construction of a portable suitcase able to accommodate all the occlusal diagnostic system and an on-off bottom. Each digital screen works with its own battery placed in the suitcase under a metal foil that cover all the electrical connections.

The dental arch in a horseshoe-shaped form was build by a superior and an inferior 3mm height metal foil covered by a hard resin, with the following intra-oral measures: 63mm total width, 62mm total length, 15mm width in anterior occlusal contact area, 19mm width in posterior occlusal contact area, 30mm anterior height and 15mm posterior height. The dental arch dimensions were based on the majority of the dental arches studied during the improvement process.
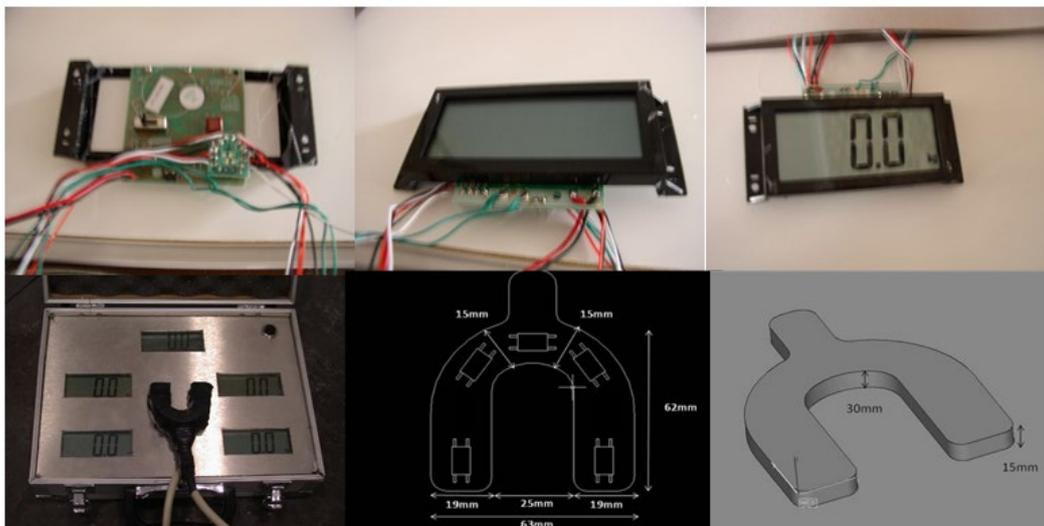
Fig. 2 - Image of the digital screens and sensors distribution

4. COMPATIBILITY

It is very important to ensure compatibility between the pressure or force sensor and the application in which it is used. The following should be considered before a sensor selection is made: (1) material; (2) chemicals; (3) concentration; (4) temperature; (5) exposure time; (6) type of exposure; (7) criteria for failure; and (8) general information such as application environment, protection of the device, and other foreign substances in the area.

BITE TRAINING MACHINE

In order to provide adequate training to the patients and teach how to bite in the same way during the study a bite training machine was developed. The major components of this new machine were: a dynamometer, a force indicator and an occlusal contact area indicator [23].

The occlusal contact area was built in a hard photosensitive resin with a similar strength of the occlusal force diagnostic system, and two springs were placed to allow movement return. The dynamometer was order from Mitutoyo[TM] (Mitutoyo Corporation, USA) and ensure that patient was biting hard enough to see the reading [23].

The occlusal contact area indicator was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized in the dynamometer and the procedure was repeated after 10 minutes until the patient felt comfortable.
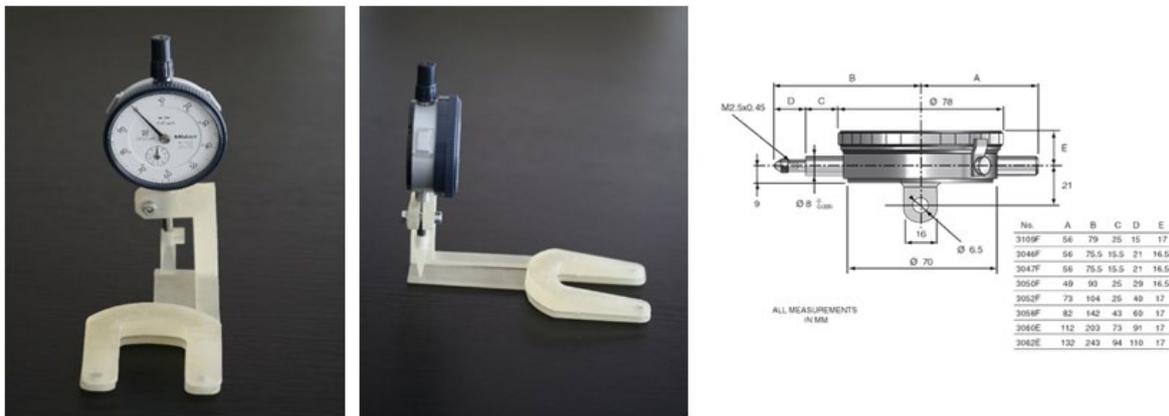
Fig. 3 - Major components of the Bite Training Machine: dynamometer, force indicator and occlusal area. Schematic illustration of the dynamometer

REPEATABILITY TEST

Thirty patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol:

a) Bite Training Machine: The occlusal contact area indicator was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized in the dynamometer and the procedure was repeated after 10 minutes until the patient felt comfortable.

b) Occlusal Force Diagnostic System: The system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and after 1 month (T2).

The five sensors were distributed in the following order, the readings were in kilograms: Sensor A: right maxillary second pre-molar and right maxillary first molar between 1st and 4th quadrants; Sensor B: right maxillary canine and right maxillary first pre-molar between 1st and 4th quadrants; Sensor C: right and left maxillary central incisors and right and left maxillary lateral incisors area; Sensor D: left maxillary second pre-molar and left maxillary first molar between 2nd and 3rd quadrants, and finally Sensor E: left maxillary canine and left maxillary first pre-molar between 2nd and 3rd quadrants.

In the proposed repeatability test, the bite force and occlusal pressure were measured for 30 consecutive patients twice by two different observers (F and C).A combination of different parametric tests has been used to compare the different experimental variables.

EXPERIMENTAL STRATEGY AND STATISTICAL ANALYSIS
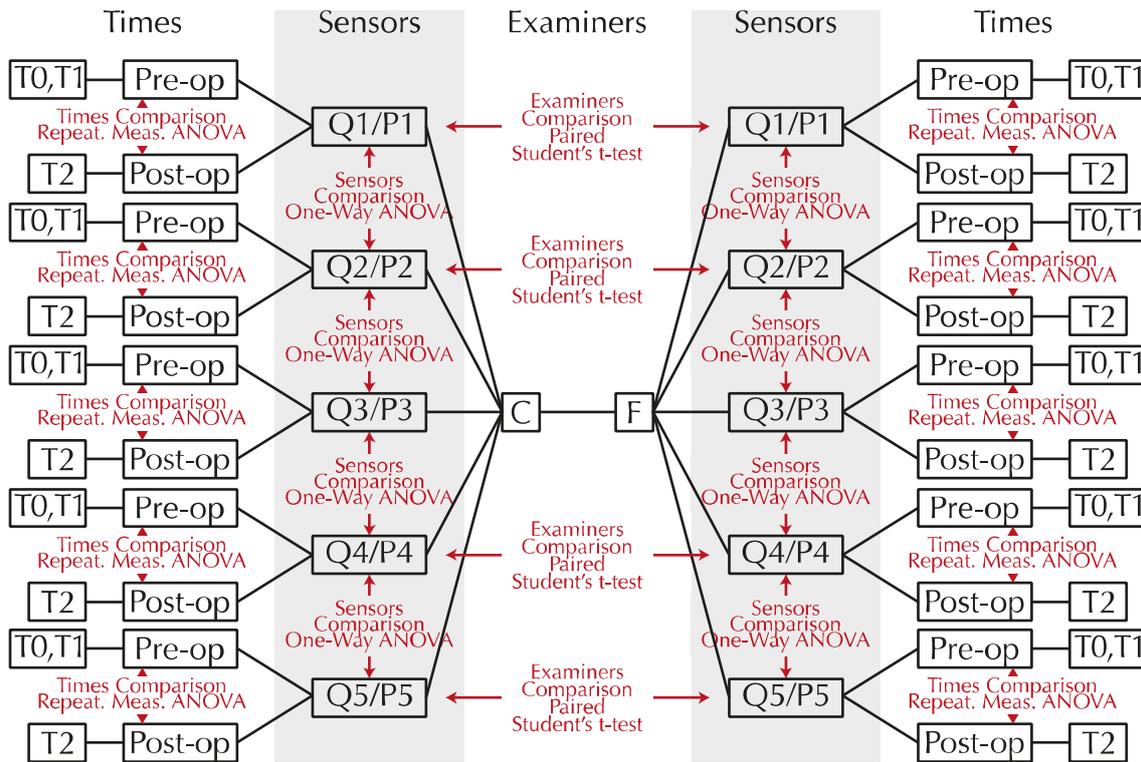
Fig. 4 -Experimental design used for the measurement of occlusal force.The present study is an observational prospective study with quantitative methodology.

IBM® SPSS® version 25, was used to analyze the data obtained. The data were first tested to ensure they conformed to a normal distribution by using Kolmogorov-Smirnov test. The data were then tested to ensure they complied with variance homogeneity by using Levene test.

Descriptive statistics measures included the arithmetic mean ($\bar{x}$) and standard deviation (SD) if the data were normally distributed and the variance was constant. Where the data were not normally distributed nor the variance was constant, the median and the inter-quartile range (IQR) were noted.

Where the requirements for parametric statistical analysis were met, inferential analysis involved the use of paired two-tailed Student's t test (examiners comparison), repeated measures ANOVA (times comparison) and One-Way ANOVA (sensors comparison). In the non-parametrical conditions, the equivalent inferential tests were respectively, Wilcoxon, Friedman and Kruskal-Wallis.

Where statistically significant differences were found by One-Way ANOVA test, the multiple-comparison Post-Hoc Bonferroni or Gabriel test was performed to identify the pairs of categories were the statistically significant differences were located.

The minimum level of significance (α level) accepted throughout the development studies was 0.05 (*), considered to be moderately significant. Levels of 0.01 (**) were considered as significant and 0.001 (***) designated as highly significant. A lack of statistical significance was designated as (ns).

II. RESULTS

Comparison A – Testing the Differences betweenExaminers (F versus C)

Table 1 - Statistical parameters obtained in the Paired Student's t-test for the comparison of examiners F and C when measuring the mean bite pressure (psi) in different experimental conditions.

ExaminersComparison	Mean Diference	Standard DeviationofDifferences	DegreesofFreedom*(df)*	Test statistic from Paired *t-*test	*P-value* fromPaired *t-*test
Examiner F *versus* **Examiner C, P1, Time 0**	0,300	0,823	9	1,152	0,279
Examiner F *versus* **Examiner C, P1, Time 1**	0,100	0,876	9	0,361	0,726
Examiner F *versus* **Examiner C, P1, Time 2**	0,000	1,054	9	0,000	1,000

Examiner F *versus* Examiner C, P2, Time 0	0,200	0,919	9	0,688	0,509
Examiner F *versus* Examiner C, P2, Time 1	0,400	1,647	9	0,768	0,462
Examiner F *versus* Examiner C, P2, Time 2	0,000	0,471	9	0,000	1,000
Examiner F *versus* Examiner C, P3, Time 0	0,000	0,471	9	0,000	1,000
Examiner F *versus* Examiner C, P3, Time 1	0,100	0,316	9	1,000	0,343
Examiner F *versus* Examiner C, P3, Time 2	0,500	0,850	9	1,861	0,096
Examiner F *versus* Examiner C, P4, Time 0	-1,600	4,061	9	-1,246	0,244
Examiner F *versus* Examiner C, P4, Time 1	-0,700	2,263	9	-0,978	0,354
Examiner F *versus* Examiner C, P4, Time 2	2,000	7,055	9	0,896	0,393
Examiner F *versus* Examiner C, P5, Time 0	-0,400	1,075	9	-1,177	0,269
Examiner F *versus* Examiner C, P5, Time 1	-0,800	1,033	9	-2,449	0,037*
Examiner F *versus* Examiner C, P5, Time 2	-0,600	1,506	9	-1,260	0,239

* moderately significant to 0.05 level;
** significant to 0.01 level;
*** highly significant to 0.001 level.

The statistical comparison between examiners F and C regardingthe measurement of mean bite pressure (psi) was performedusing a Paired Student's t-test for the five different FSS sensors(Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at the three differenttime moments (Time 0, Time 1 and Time 2).

There are no significant differences in the mean bite pressure(psi) measured by Examiner F and Examiner C, when themeasurement is made in the same experimental conditions. Almost all experiments reveal p-values above the cutoffvalue of 0,05 (p >0,05), which means that H0 proposition isvalid. Thus,it is concluded that the choice of examiner is not a variablethat affects the mean bite pressure (psi) measured in any of theexperimental conditions tested.

Comparison B – Testing the Differences between Times(T0 vs T1 vs T2)

Table 2 - Statistical parameters obtained in the Repeated Measures ANOVA for the comparison of time moments (Time 0, Time 1 and Time 2) when measuring the mean bite pressure (psi) in different experimental conditions.

Times Comparison	**DegreesofFreedom*(df)***	**Teststatistic*(F)***	**P-value (Sig)**
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P1	2, 18	2,711	0,094
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P1	2, 18	3,372	0,057
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P2	2, 18	0,599	0,560
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P2	2, 18	0,665	0,527
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P3	2, 18	52,762	0,000**
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P3	2, 18	49,924	0,000**
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P4	2, 18	1,042	0,373
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P4	2, 18	0,232	0,796
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P5	2, 18	0,832	0,451
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P5	2, 18	0,808	0,461

The statistical comparison between the three time moments(Time 0, Time 1 and Time 2) regarding the measurement of meanbite pressure (psi) was performed using a Repeated MeasuresANOVA for the five FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 andQ5/P5) and the different examiners F and C.

There are no significant differences in the mean bite pressure(psi) measured at Time 0, Time 1 or Time 2, for the sameExaminer (C or F) and the same Sensor (Q1/P1, Q2/P2, Q3/P3,Q4/P4 or Q5/P5) (p > 0,05). Almost all experimentsreveal p-values above the cut-off value of 0,05 (p > 0,05), whichmeans that H0 proposition is valid. Thus, it is concluded the mean bite pressure (psi) measured atdifferent time frames is consistently the same, showing the highreproducibility of the measurements.

Comparison C – Testing the Differences between Sensors(Q1/P1 vs Q2/P2 vs Q3/P3 vs Q4/P4 vs Q5/P5)

Table 3 - Statistical parameters obtained in the One-Way ANOVA for the comparison of FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions.

SensorsComparison		**Sum ofSquares**	**DegreesofFreedom*(df)***	**MeanSquare**	**Teststatistic*(F)***	**P-value (Sig)**
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner F, Time 0	**Between Groups**	44901,920	4	11225,480	13,854	0,000***
	Within Groups	36462,800	45	810,284		
	Total	81364,720	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5,	**Between Groups**	44727,320	4	11181,830	13,780	0,000***

Examiner F, Time 1	**Within Groups**	36514,700	45	811,438		
	Total	81242,020	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner F, Time 2	**Between Groups**	21315,200	4	5328,800	7,695	0,000***
	Within Groups	31161,300	45	692,473		
	Total	52476,500	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner C, Time 1	**Between Groups**	45045,520	4	11261,380	14,391	0,000***
	Within Groups	35212,900	45	782,509		
	Total	80258,420	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner C, Time 2	**Between Groups**	45192,280	4	11298,070	13,971	0,000***
	Within Groups	36390,600	45	808,680		
	Total	81582,880	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner C, Time 2	**Between Groups**	21982,680	4	5495,670	7,548	0,000***
	Within Groups	32762,200	45	728,049		
	Total	54744,880	49	-		

* moderately significant to 0.05 level;

The statistical comparison between the five FSS sensors (Q1/P1,Q2/P2, Q3/P3, Q4/P4 and Q5/P5) regarding the measurement ofmean bite pressure (psi) was performed using a One-Way ANOVAfor the different examiners F and C at the three different timemoments (Time 0, Time 1 and Time 2).

There are significant differences in the mean bite pressure (psi)measured by the different FSS sensors (Q1/P1, Q2/P2, Q3/P3,Q4/P4 and Q5/P5), when the measurement is made in the sameexperimental conditions. All experimentsreveal p-values below the cut-off value of 0,05 ($p < 0,05$), whichmeans that H0 proposition is invalid. Thus, it is concluded thatthe five FSS sensors detect different mean bite pressures (psi) forthe same Examiner (F or C) at the same time moment (Time 0,Time 1 or Time 2).

Because One-Way ANOVA only gives information about thepresence of differences, not specifying where these differencesare located, a Post-hoc Gabriel test was used to perform pairwisecomparisons between the FSS sensors.

Significant differences ($p < 0,05$) have been identified betweencertain pairs of FSS sensors, allowing the definitionof a three-pressure region model: 1) low-pressureregion located in the anterior part of the dental arch; 2) mediumpressureregion in the intermediate part of the dental arch; and3) high-pressure region located in the posterior part of the dentalarch.

Another interesting observation is that, when two FSS sensorsare located in the same pressure region (i.e., Q1/P1+Q5/P5 andQ2/P2+Q4/P4), no statistical differences are recognisable withinthe pairs of FSS sensors, meaning that the pressures detectedare statistically identical to one another ($p > 0,05$).

On the opposite side, whenever two FSS sensors are located indifferent pressure regions, statistically significant differences ($p <0,05$) have been found between the measured pressures, showing the high sensibility of measurement ofthe experimental device.
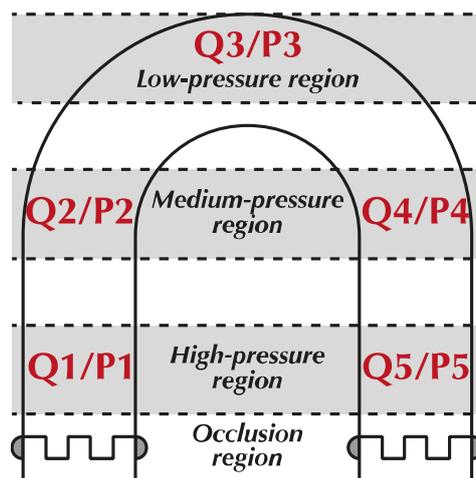
Fig. 5- Three-pressure region model for dental occlusion.

III. CONCLUSIONS

The piezoelectric sensors used in the present study have shownhigh reproducibility of measurement. Neither the variation ofexaminer, nor the variation of time have shown to influence thebite pressure (psi).In contrast, the occlusal force measurement system developedhas shown a high level of sensitivity due to the distribution of thefive FSS sensors in the horseshoe-shaped form.A three-pressure regionmodel fits the experimental data shownin this study, comprising a low-pressure region located in theanterior part of the dental

arch, a medium-pressure region inthe medial part of the dental arch and an high-pressure regionlocated in the posterior part of the dental arch.Due to the recent miniaturization of FSS sensors, the authorsare developing new occlusal force measurement systemscomprising a higher number of piezoelectric sensors, with theobjective of attaining even higher sensitivity of measurementthroughout the different region of the dental arches.

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