Design, Development and Characterization of Jaw Biting Force Measuring Device for Assessment of the Masticatory System

Aarush Gupta[1], Sandeep K Prajapati[1], Suril V. Shah[1], and Ankita Chugh[2]

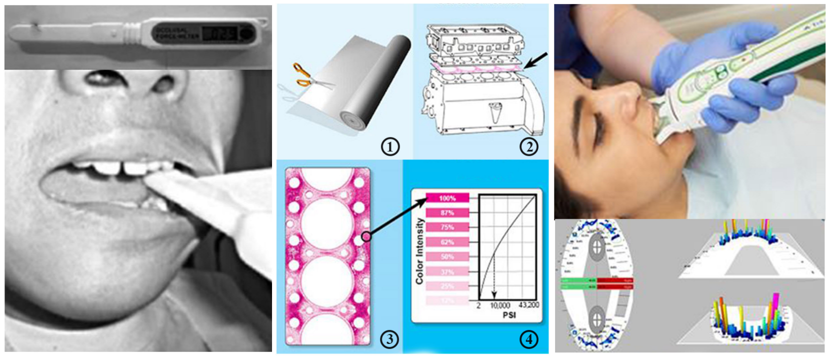
[1] Indian Institute of Technology (IIT) Jodhpur, India,
[2] All India Institute of Medical Sciences (AIIMS), Jodhpur, India

Abstract. The paper presents the design, prototyping, and calibration of a Jaw biting force measurement device considering cost, ergonomics, accuracy, ease of manufacturing, and simplicity as design parameters. At first, commercially available devices are bench-marked. According to the results of background research, the selection matrix is created depending on the various parameters. Finally, the Selection of the optimum sensor and structural design is carried out. The use of Flexi Force sensor is proposed for force measurement. Flexi Force sensor has better force sensing properties, linearity, hysteresis, drift, and temperature sensitivity than any other thin-film force sensors. The preliminary and final designs based on the primitive thermometer design were made and 3D printed. The characterization of the device is done by calibration using UTM. The final embedded hardware was developed using a Flexi force sensor and LCD Display incorporated with i2c communication. The final design was tested for safety purposes as it is to be used by medical practitioners. Human trials are carried out to demonstrate the efficacy of the final design.

Keywords: Design, Characterization, Jaw Biting Force, Mandibular fractures

1 Introduction

Fractures of the mandibular bone alone account for a large proportion, approximately 70% of all facial injuries [1] which affect mastication, the process of chewing and crushing or squeezing. Clinical Dentists rely on clinical Judgments to determine Prosthetic design, size & shape for Mandibular Fractures. However, this intuitive judgement can further be supported by quantitative & qualitative analysis using the Jaw Biting force device, which can provide a valuable parameter to determine the efficacy of Masticatory System, post-fracture. The clinical trials at AIIMS Jodhpur certify that the Biting force increases significantly with the healing of the fracture. Moreover, an inverse relationship was found between the values of Jaw bite force and the number of fractures in the mandibular bone. Thus the device can supplement the treatment of Mandibular disorders



(a) (b) (c)

Fig. 1. (a) GM 10 [5] (b) Prescale Occluzer FPD707 System [6] (c) Tekscan TScan [7]

by monitoring the healing process, apart from deducing the state of the mandible fracture.

Several traditional Bite force devices have been used to administer the Mandibular fractures. Previously devices were mechanically built. First such device being built by Borelli in 1681, called Gnathodynomometer [3]. It used to attach different weights to the chord passing over the molar teeth of the mandible. Nowadays, sensitive electronic devices are available. Like the one developed in Sweden, Dentoforce 2 [4] which uses a strain gauge sensor between the two forks pressed between the molars. Although it has proven to be accurate, the fear of breaking cusps & edges of teeth, thereby affecting dental fillings have emerged as some of the major concerns. Moreover, the use of thick metal plates or bite fork causes Jaw separation which not only causes discomfort to the patient but reduces bite force. To counter the flaws, some devices used Piezoelectric sensors, which uses a 2mm thin sheet of quartz crystal, thereby reducing the jaw separation but they have reported incorrect readings.

Another device, widely used for the commercial purpose is GM 10, Japan shown in Fig. (1.a), which uses a thin tube (5.4mm diameter) connected to a hydraulic pressure gauge sensor, to determine bite force [8]. It provides the comfort of a soft biting element, but since air is compressible, its property changes with temperature which has an adverse effect on the sensor performance & long-term reliability of sensor data. Another device which address the issue of hard biting element is Prescale system developed in Japan. It uses a pressure sensitive film with numerous micro-capsules which collapse on application of pressure. According to the amount of pressure, different color densities are formed, which are visible when the pressure film is analysed in Occluzer FPD707 [9], as shown in Fig. (1.b). Though the readings are accurate & reliable but the procedure involved is tedious and cumbersome, as the pressure film after the application of pressure has to be put in light resistant container immediately to prevent any contamination. The device developed by Tekscan Company to assist occlusal analysis as shown above in Fig. (1.c). It uses a mylar laminated pressure-sensitive ink grid (0.1mm), which is in the shape of a dental arch [10]. It provides a real-time, relative occlusal force. However, the device provides inaccurate readings but is still a potent clinical tool to access stress points on application of occlusal force.

Development of such devices are essentially important in a country like India because otherwise such devices cost high, to a large section of vulnerable population. Moreover, the healthcare demands have changed dramatically in the last decade which has further pushed for the development of indigenous medical device industry. Post-liberalisation, many sectors have gone structural changes, with India becoming self-reliant in drugs but still, 75% of the medical devices are imported in India [11] which limits the accessibility of proper treatment to a large section of the population due to high cost and meagre resources. The main objective behind Designing, Prototyping & Calibrating a Jaw Biting Force device consistent with the requirements of Indian scenario, was to supplement the efforts of developing indigenous Medical Device Industry. .

The rest of the paper is organized as follows: The process of Mechanical Design is enumerated in Section II & electric Circuit Design is presented in Section III. The Sensitivity Adjustment & Calibration of the device is presented in Section IV, while the Clinical Tests & results of the proposed device are presented in Section V. Finally, conclusion is given in Section VI.

2 Mechanical Design

In this section the methodology to arrive at the mechanical design of the device has been enumerated. We observed various medical apparatus and tried to come up with a novel design which not only caters to the needs of the patient but also suits the Indian scenario in its precarious state.

2.1 Design Parameters

After having exhaustive discussion with Doctors at AIIMS Jodhpur we came up with a list of observations. The foremost goal was to keep the the Jaw separation minimal while using device since the patient is already going through the pain due to the Mandible fracture. Doctors claimed that while using ECG Machines, they have to handle heavy chords hence it was decided that the power requirements of the device should be born by a mechanism within the device, preventing the use of heavy chords which makes it difficult for application of device in certain situations where power supply is not available nearby. The design & procedure to operate should be simple enough to be understood by medical practitioners and the device should have longevity that is, it could be used for longer periods without replacing the elements of the device.

These recommendations were followed by a thorough discussion regarding the probable list of parameters to be kept in mind, which not only took the Doctor's suggestions into account but also enlisted the issues faced by the indigenous

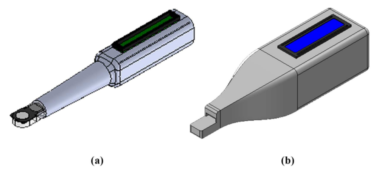


Fig. 2. Preliminary Design

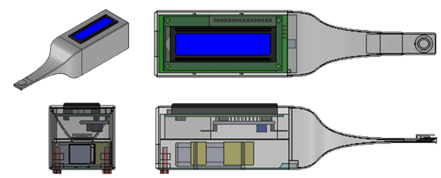


Fig. 3. Final Design

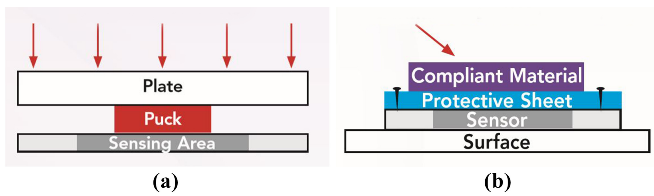


Fig. 4. Puck Deign (a) Distributed Load (b) Protective layer preventing Shear force

Medical Device Industry of India. Finally, Accuracy, Cost Effectiveness, Simplicity & Modularity, Ergonomics, Long-term reliability and Ease of Manufacturing were selected as the key parameters.

2.2 Design Evolution

The preliminary idea was to design a device similar to electronic thermometer, the most widely used medical device hence the most suitable device to study the ergonomics in Human-machine-interaction. Efforts were to enable small mouth opening and good modularity. Keeping that in mind the first design was developed, Fig. (2.a). The layout was further iterated such that it accommodated the power supply & electrical circuit within the device itself. Easy screwing and locking mechanism, was also added for simplicity. Extensive use of Fillets was preferred for ease of manufacturing. Fig. (2.b)

The device underwent clinical trials and doctors suggested further insights regarding probable issues with the design. The device had to be used to measure the Jaw biting force not only for the anterior teeth group but for the posterior teeth group as well. Moving forward with the stipulated recommendations, the final design was formulated with an elongated sensor portion with significant reduction in the width and height to prevent any discomfort to patient, Fig. (3). The puck was integrated into the model itself to restrict its movement, thereby ensuring ease of utility while application of device.

2.3 Puck Design

It is recommended that 100% of the force should be concentrated within the sensing area and the maximum of 70-80% of the sensing area should be loaded [12].The best way is to use a concentrator or Puck as shown in Fig. (4.a) which not only protects the sensor from cusp of teeth but also ensures uniform distribution of load. The material needs to be complaint and rigid to give accurate results. With application of force on the sensor, a shear force also develop. For example, when rubber is compressed, the edges tend to expand, or deform. The sliding of the deforming rubber across the sensor face can impart shear. This deformation can be quantified through Poissons Ratio, Eq. (1).

$$\nu = \frac{\epsilon_{lateral}}{\epsilon_{axial}} \tag{1}$$

A protective layer, a teflon sheet has been used between the complaint material & sensing area as shown in Fig. (4.b) to prevent any shear force due to deformation or otherwise.

3 Electrical Design

In this section the modus operandi to arrive at the electrical circuit has been elucidated. The procedure involves the selection of an appropriate sensor and later designing a reliable circuit.The selection of a suitable sensor is at the core of the problem statement. After carrying out the literature survey, it was perceived that piezo-resistive sensors will be best suited for the application of device. It's a transducer which converts variations in mechanical stress into an electrical output using a piezo-resistive material, which changes resistance to the flow of current when it is compressed or strained. According to Sensor Characteristics, as the pressure on the sensor film increases, the resistance of the sensor decreases. Moreover, when there is no pressure on sensor area, the sensor acts like an infinite resistor (open circuit)

Commercially available Flexi Force A201 Piezo-resistive Sensor was found to be the most suitable sensor because it has better drift, force sensing properties, hysteresis, linearity and temperature sensitivity compared to other thin-film force sensors.

Sensor is manufactured from two layers of polyester based substrate. Each layer is applied with Silver like conducting material and a thin layer of pressure sensitive ink [13]. In a Circuit, the sensor acts like a variable resistor registering high resistance (greater than 5MΩ) when unloaded, while the resistance decreases when force is increases on the sensor area. It is an ultra-thin sensor with flexible printed circuit. It has a 3-pin male connector, the outer two pins of the connector are active while the middle pin is inactive. It has an active sensing area of 285.022mm^2 [12]. It can stand up to most of the environmental conditions due to its impeccable performance characteristics, [14].

3.1 Circuit Design

The twin objective of Circuit Design was to achieve linearity in output characteristic & adjust Sensitivity to obtain circuit characteristics to measure maximum force which in our case is 1000N, over the full scale of dynamic range.

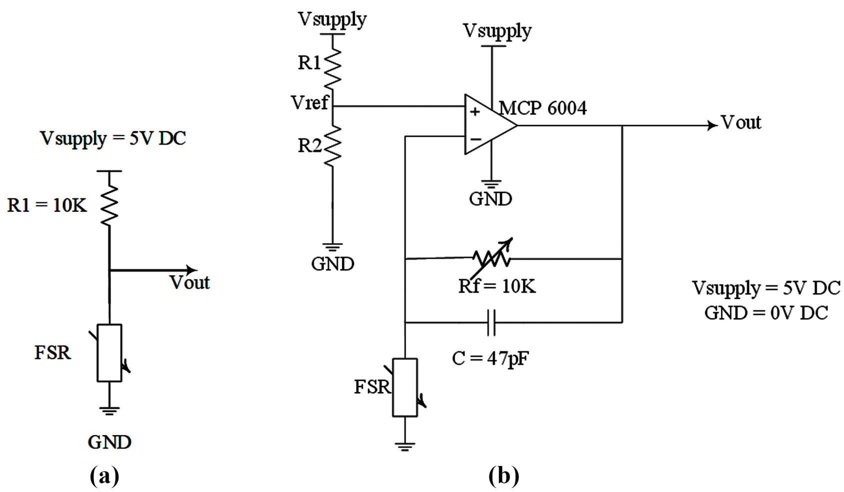


Fig. 5. Circuit Design (a) Voltage Divider (b)Non-inverting Op-Amp

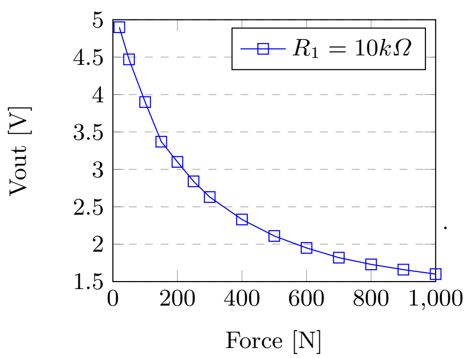


Fig. 6. Output Characteristic of Sensor using Voltage Divider

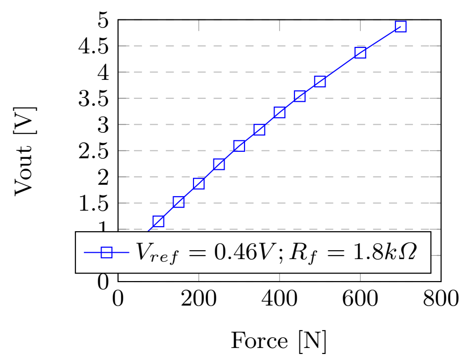


Fig. 7. Output Characteristic of Sensor using Non-Inverting Op-Amp Circuit

We started with a primitive circuit Fig. (5.a), a Voltage Divider to evaluate the sensor characteristics. We received a non-linear curve as shown in Fig. (6). We stored the values of output characteristics in an array and used it for calculating the value between the two data set points using the equation of line passing through the two points, Eq. (2). Although voltage divider circuit is simple & inexpensive but the issue of non-linearity causes problem in further calibration.

$$y - y_1 = \frac{y_2 - y_1}{x_2 - x_1}(x - x_1) \tag{2}$$

We then formulated a circuit design using Op-Amps in order to linearize the Voltage output characteristic. The non-inverting op-amp circuit we devised is

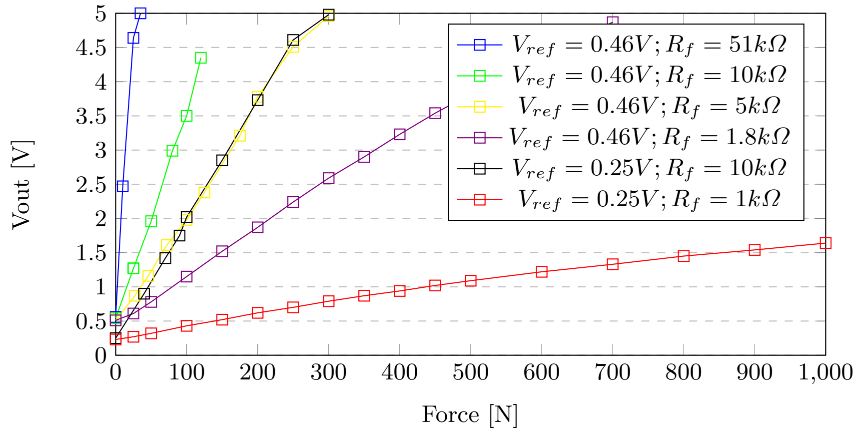


Fig. 8. Sensitivity Characteristics

shown in Fig. (5.b). Though, it is a complex circuit design compared to voltage divider but it provided linearity in voltage output with respect to the force applied throughout the dynamic range of the circuit as shown in the Voltage Characteristic, Fig. (7).

4 Sensor Sensitivity Adjustment & Calibration

The objective behind devising a stringent Sensitivity mechanism was multitudinal. The prima facie purpose was the adjustment of the maximum force rating for the circuit according to the applied force of the application which in our case is 1000N. In a Non- inverting circuit, by changing the feedback resistance (R_f) & drive voltage (V_{ref}), the sensitivity can be adjusted to the desired output. As formulated in Fig. (8), we derived output characteristics at different values of R_f & V_{ref}. When the feedback resistance is decreased, a higher load can be measured. And when the feedback resistance is increased, a lower value of load can be measured. Also, lower drive voltage (V_{ref}) corresponds higher sensitivity and higher drive voltage corresponds lower value of load sensitivity. We hereby found that the suitable values of R_f & V_{ref} are 2-3kΩ & 0.25V respectively for the optimum application of our device. Apart from this, the selection of a suitable duty cycle was equally important since a lower duty cycle potentially increases battery and sensor life. Hence, we used 50% Duty Cycle for the application of device.

Calibration is set of operations done under specific conditions to establish a relation between sensor's electrical output and actual Engineering Unit (in Our case force in Newton). To calibrate we recorded the sensor output resistance to the known forces applied on UTM machine withing the testing range of equipment. Because of the inherent part-to-part variation in Flexi Force sensors, independent/ individual sensor calibration is crucial for achieving accurate

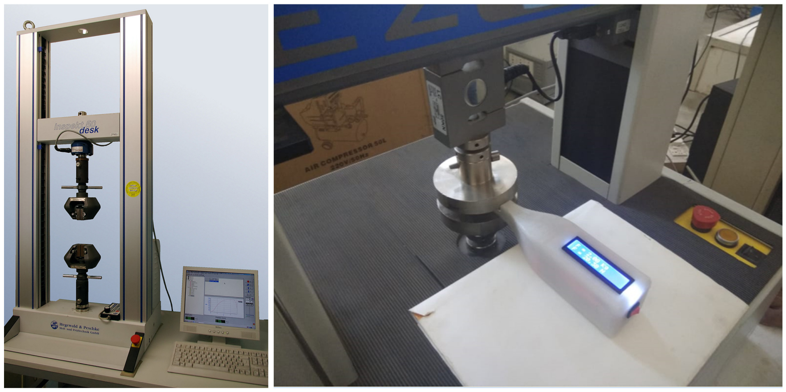


Fig. 9. Calibration Setup on UTM Machine

results. We carried the calibration of our device on a UTM 500 machine setup as shown in Fig. (9). The Following Calibration methodology was followed -

1. Apply a known load to sensors loading area.
2. While Calibrating avoid near saturation loading. In case the sensor saturates at load below Experimental requirements, adjust "Sensitivity" to achieve required load range.
3. In order to achieve accurate readings, distribute the load evenly across sensing area. You may even use a puck to prevent changes in Load distribution over sensing Area.
4. Need to calibrate sensor at a temperature at which it is to be used in operations, especially in case of High-Temp Sensors which have wide operating temperature range. If temperature changes dramatically during operation then calibrate sensor according to all possible temperature ranges.

After running the device at room temperature upon force application of 100N to 1000N at regular intervals of 100N each, carrying a full cycle of loading and unloading of sensor, we carefully analysed the sensor performance according to the calibration methodology and deemed the sensor calibrated on satisfactory results.

5 Clinical Trials

The Jaw Biting force device was used to carry out a study at AIIMS Jodhpur on Mandible Fracture healing process. In the study, the Bite force device was initially used for recording standard bite force measurements of 20 healthy individuals. The mean Anterior Bite force (ABF) was recorded as 140 N and mean Posterior Bite force (PBF) was recorded as 350 N. We have used these bite forces as the normal mean bite force for further comparison.

Table 1. Baseline characteristics of Control and Treatment groups [15]

Variables		*Group 1 (Control)*	*Group 2 (Tab Reunion)*	*Group 3 (Inj.Teriparatide)*
Age (Mean ± SD)		26.8 ± 8.8	26.6 ± 9.2	25.8 ± 3.6
Gender	Male	8	7	8
	female	0	1	0
No. of Fractures	Single	5	6	5
	Multiple	3	2	3
Anterior bite force		2.43 ± 6.89	2.32 ± 6.58	5.27 ± 10.03
Posterior bite force		0	19.98 ± 30.31	5.3 ± 9.92

A randomised control trial was planned to monitor & compare maxillofacial fracture healing process on application of Treatment 1 (Tablet Reunion given to Group 2) and Treatment 2 (Injection Teriparatide administered on Group3) compared to control Group (Group 1). Bit force measurements for both Anterior and Posterior points were taken to monitor the healing process. [15]

5.1 Methodology

For clinical Trials, All the eligible patients with mandible fracture, visiting AIIMS Jodhpur from July 2019 on wards, till May 2020 were analysed. A written informed consent underlining the possible risks, benefits & procedural alternatives was agreed upon by the patients. Moreover, Procedural approval was taken from Institutional Ethics Committee (AIIMS/IEC/2018/769). Following Procedure was followed [15] -

1. **Size -** As per the availability, Patient count was kept at 8 per treatment group
2. **Eligibility Criteria -** A normal healthy Patient or a patient with only mild systemic disease; Patient of 18-60 years age group with maxillofacial fracture; Patients with malignanttumours, pagets disease, hypercalcemia, myofascial pain dysfunction syndrome, prior exposure to radiation treatment, less than 50% of teeth, significant polytrauma and pregnant or lactating female patients were excluded from the study;
3. **Allocation -** Random computerized allocation of patients into 3 groups was done with an allocation ratio of 1:1:1, by an individual A.
4. **External Intervention -** Group 1 - No specific fracture healing drugs were given after ORIF; Group 2 - one Reunion tablet twice a day was given; Group 3 - 20g Injection of Teriparatide subcutaneously once a day with modified insulin penwas was administered for continuously 4 weeks after ORIF.
5. **Measurements -** Bit force measurements for both Anterior and Posterior points were taken in all patients pre-operatively and post-operatively at regular intervals (at 1^{st} week, 2^{nd} week, 4^{th} week, 6^{th} week, 8^{th} week, and 12^{th} week) to monitor the healing process.

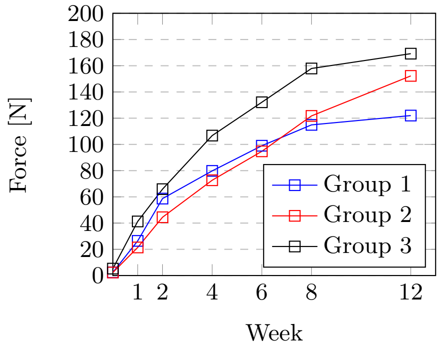


Fig. 10. Mean change in ABF [15]

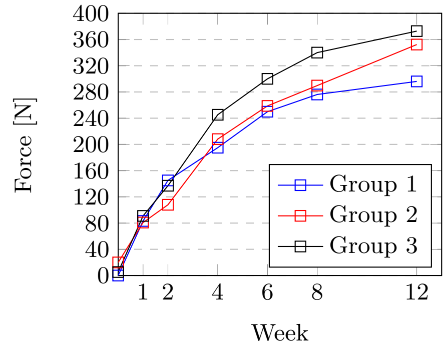


Fig. 11. Mean change in PBF [15]

5.2 Observation & Conclusion

The jaw biting force measurements for both Anterior & Posterior points were consolidated as shown in Fig. (10) & Fig. (11) respectively. Following observations were made while observing the Jaw Biting force data [15] -

1. The Jaw biting force values steadily increased on measurement over the course of healing from 1^{st} to 12^{th} week, in all the three groups.
2. In Group 1, only one patient achieved mean ABF(140N) in 6^{th} Week and two patients achieved in 8^{th} Week i.e. 37.55% of patients in group 1 achieved normal mean ABF before 12 weeks. While, 75% of patients in Group 2 achieved the same within 12 weeks. However, highest recovery was seen in case of Group 3 with 87.5% patients achieving normal mean ABF by 12^{th} week.
3. Group 1 patients showed poor recovery since no patient could achieve normal mean PBF by 12 weeks. Compared to Group 1, Group 3 performed better with 62.5% of patients achieving normal mean PBF by 12^{th} week. However, Group 2's performance was the best with 75% patients achieving normal mean PBF by 12^{th} week.

From the data observed, It is clear that Jaw biting force is a crucial parameter not only for monitoring the healing process but for comparing various medical procedures and deducing the suitable one for literature purposes and in future practical purposes. Our device on application gave reliable data, while keeping into account the ergonomic comforts of patients in distress.

6 Conclusion

In this work, a jaw biting force device was designed and manufactured to suit the Indian Medical Industry requirements. The device not only provides accurate results but give utmost importance to the safety of the patient. At a time when similar devices around the world cost lakhs of rupees [16], our device costs just two to three thousand, thereby reducing the cost significantly so that the device could be used by a large section of vulnerable population. Future steps consist of devising an auto-calibration accessory which could help doctors to calibrate the device themselves, after using the sensor for a certain period of time. This would enable universal applicability & long-term reliability.

References

1. K. Yildirgan, Mandibular fractures admitted to the emergency department: Data analysis from a swiss level one trauma centre, Emergency Medicine International, vol. 2016, p. 7, (2016).
2. C. J. Haggerty, Atlas of Operative Oral and Maxillofacial Surgery. USA: John Wiley and Sons Inc, (2015).
3. D. Koc, Bite force and influential factors on bite force measurements: a literature review, European Journal of Dentistry, (2010).
4. M. G. Tzakis, A study of some masticatory functions in 90-year old subjects, Gerodontology, (1994).
5. Z. M. A. Jammali, Clinical Evaluation of Maximum Bite Force in Patient with Heat Cure acrylic and Flexible Partial Dentures. PhD thesis, University of Babylon, (2017).
6. Sensor Products inc., Four steps for using fujifilm prescale to monitor gasket contact. https://www.sensorprod.com/glossary/pressureindicating-film/pressure-indicating-film.php,(2018)
7. Tekscan, Inc., T-scan novus. https://www.tekscan.com/products-solutions/systems/t-scan-novus, (2018).
8. S. Varga, Maximum voluntary molar bite force in subjects with normal occlusion, European Journal of Orthodontics, (2011).
9. K. Ikebe, Comparison of gohai and ohip-14 measures in relation to objective values of oral function in elderly japanese, Community Dentistry and Oral Epidemiology, (2012).
10. W. L. Maness, Pressure and contact sensor system for measuring dental occlusion, US Patent 4,734,034,(1988).
11. A. Dang, Economics of medical devices in india, International Society for Pharmacoeconomics and Outcomes Research, vol. 18, pp. 1417, (2019).
12. Tekscan, Inc., Flexiforce sensor manual., https://www.tekscan.com/products-solutions/force-sensors/a301,(2018).
13. Tekscan, Inc., How does a force sensing resistor (fsr) work.,https://www.tekscan.com/blog/flexiforce/how-does-force-sensing-resistor-fsrwork,(2018).
14. Tekscan, Inc., Tekscan flexiforce sensor manual.,https://robu.in/wp-content/uploads/2019/06/FlexiForce-A201-Sensor.pdf, (2018).
15. Gigi, Ankita Chugh, Kirti Chaudhry, Amanjot Kaur, Pravin Kumar, Shubham Gaur, Shailendra Kumar, and Surjit Singh, "Comparison of Teriparatide and Combination of Cissus Quadrangularis and Dalbergia Sissoo on Bone Healing Against the Control Group in Maxillofacial Fractures: A Randomized Open-label Control Trial." Craniomaxillofacial Trauma and Reconstruction (2022): 19433875211067007.
16. Tekscan, Inc., Dr Ben A Sutter, T-scan novus. [Online; accessed: https://www.tekscan.com/products-solutions/systems/t-scan-novus, 2018].