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### Abstract

**Purpose**: To measure the pressure generated on simulated maxillary edentulous model using 3 different spacer design and 2 different impression materials.

**Materials and Methods**: Four pressure sensors were embedded on simulated maxillary edentulous model, 1 in the mid-palate area, 1 at the left rugae area and the other 2 in the right and left ridge (maxillary first molar areas). Custom trays of 3 different spacer design i.e. I ,Sanath Shetty and Boucher spacer design were fabricated. The 2 impression materials tested were zinc oxide eugenol and light-body vinyl polysiloxane. A total of 60 impressions were made. For the loading device, a dental surveyor along with a metal indenter that provided a site for placing a 2 kg weight was used. Pressure recorded in the Arduino /genuino Uno software installed in the laptop. The statistical analysis was carried out using ANOVA test, Tukey post hoc analysis and unpaired t test.

**Results**: A significant difference in the pressure produced using different spacer design and impression materials were found (p < 0.001). Zinc oxide eugenol produced a significantly higher pressure than light-body vinyl polysiloxane impression materials.

**Conclusion**: Depending on the condition of patient, different impression materials and the spacer design combination should be used to minimize the effect of pressure produced during impression making.

**Keywords-** simulated maxillary edentulous model; pressure sensors; spacer design; impression material.

#### Introduction

According to hierarchy of dental needs of Dr.Priest, there are basically four levels of patient's need - first comfort then function followed by esthetics & lastly self-esteem. He says that a person cannot rise to the upper level until the lower level is achieved. Once satisfaction with comfort & function is achieved, the patient becomes conscious about esthetics & once all three are acceptable to the patient; the prosthesis definitely helps in increasing his self-esteem.<sup>1</sup>

The objective of the complete denture definitive impression is to accurately record the entire denturebearing area to produce a stable and retentive prosthesis while maintaining patient comfort and esthetics and preserving the remaining tissues.<sup>7</sup> Definitive denture impressions may be made with various materials: impression plaster, zinc oxide eugenol impression paste, polysulfide rubber, irreversible hydrocolloid, polyvinylsiloxane or polyether.<sup>8</sup> The techniques for definitive denture impressions can be classified as mucostatic<sup>9</sup>, maximum displacement<sup>10</sup> or functional<sup>11</sup> and selective pressure<sup>12</sup>. Various impression philosophies have been proposed over vears by various authors. Out of these, the selectivepressure impression technique is highly adored.<sup>6</sup> The philosophy of selective pressure technique is that certain areas of the maxilla and the mandible, by anatomy are better suited to withstand forces of mastication and certain areas cannot withstand such forces and thereby need to be relieved. The oral mucous membrane varies significantly in consistency and thickness in different locations.<sup>18</sup> The submucosa in the region of the median palatal suture is extremely thin, with the result that the mucosal layer almost comes in contact with the periostium of the underlying bone.<sup>19</sup> Excessive trauma to the mucosa beneath the prosthesis can lead to abnormal tissue changes, such as the development of localized hyperkeratosis, epithelial ulceration.<sup>20</sup>Little or no stress should be applied in this region when making definitive impressions.<sup>8</sup> Due to excess pressure, the denture may rock over the centre of the palate during mastication or it can also lead to soreness. Selective pressure technique manipulates the pressure exerted on the different areas of oral mucosa to provide superior results. So the main aim of relief space is to protect the mucosa under the base and to prevent the occurrence of pain, denture instability, denture fracture, nerve and blood vessel compression in addition to providing space in the tray for the impression material. In selective pressure technique, by using custom trays with spacers of different materials and designs, vulnerable tissues are relieved and stresses are distributed selectively to biomechanically sound tissues.

This study measures the variation in the pressure exerted on oral mucosa while making final impression with three different spacer designs using two impression materials.

#### **Materials and Methods**

**Preparation of simulation model-** For preparing simulated model, two layers of modelling wax sheet

(Maarc, India) were heated over the flame and adapted over the area of maxillary edentulous silicon duplicating mould. The thickness at different places were determined and adjusted accordingly to simulate the approximate thickness of actual mucosa over palate with the help of endodontic H file with its rubber stopper. When the thickness was adjusted approximately as desired then according to manufacturer's instruction, Type IV gypsum product (Ultra rock, Kalabhai private Ltd.) was mixed and filled the remaining space of mould. The material was allowed to set for 45 minutes and the cast was retrieved. The thickness of wax at various areas was checked again as the dimension of wax may change due to the exothermic reaction of type IV gypsum product (Ultra rock, Kalabhai private Ltd.). After the proper adjustment of wax, flasking of model was done in the denture flask and the plaster was allowed to set for one hour followed by dewaxing. When the cast and flask was cooled, the four pressure sensors (FlexiForce, India) namely s1, s2, s3 and s4 at different areas of edentulous model (s1 is attached at left rugae area, s2 is attached to part corresponding to left 1<sup>st</sup> molar region, s3 is attached at anterior part of midpalatine raphae, s4 is attached to part corresponding to right 1<sup>st</sup> molar region)were attached with the help of tray adhesive. Then under controlled condition of temperature and humidity, the addition vinyl polysiloxane light /body material was injected over the model and then the simulated model closed tightly and allowed to set. The simulated model was retrieved (fig 1).

#### **Preparation of special trays**

a) 'I' spacer design- The simulated maxillary edentulous model was duplicated using duplicating material and poured in type III gypsum product (Kalstone, Kalabhai private Ltd.). Then after the cast has been retrieved from the mould, 'I' spacer design is adapted on cast using one modelling wax

sheet (Maarc, India) thickness (approximate thickness of 1.5mm) (fig 2.a). Then according to manufacturer's instructions, the cast was duplicated using duplicating material and poured using type IV gypsum product(Ultra rock, Kalabhai private Ltd.). Then modelling wax (Maarc, India) was adapted over the retrieved cast and the flasking was done. The plaster was allowed to set for one hour and then dewaxing of the flask was done. Then the cast and flask were allowed to cool down. Then according to manufacturer's instructions, autopolymerizing acrylic resin (DPI, India) was mixed and adapted over the cast to replace the space of wax to fabricate special tray and flask was closed. The excess material was trimmed and the custom tray was left to polymerize undisturbed for 24 hours. Custom trays were fabricated to end flush with the oral analog land area to ensure positive and consistent seating. Referring to Komiyana et al, 6 escape holes were made with 1mm diameter with round bur no. 6.

- b) Sanath Shetty's spacer design-a thin spacer was adapted over cast except in posterior palatal area. Then 1.5mm thickness of modelling wax sheet (Maarc, India) over the already adapted spacer. The wax from the crest area and from horizontal plates was removed and four tissue stops were made (i.e. 2 in canine region and 2 in first molar region)(fig 2.b). Remaining procedure was same as for 'I' spacer design.
- c) **Boucher spacer design** one sheet of modelling wax sheet (Maarc, India) was adapted over the cast except in the posterior palatal seal area (fig 2.c). Remaining procedure was same as for preparation of 'I' and Sanath Shetty special trays.

#### Preparation of armamentarium for sample testing

For the loading device, a dental surveyor (J.M. Ney Company, Bloomfield, CT, USA) and a model table, along with a metal indenter that provided a site for placing a 2 kg weight was used. For equalization of pressure while compressing the impression materials to the tray, the plane formed by connecting the incisive papilla point with the right and left first molar points was positioned parallel to the floor using spirit level.

The pressure sensors were attached to the arduino board (Arduino Uno R3, Robo Kits, India) compatible with the help of jumper wires to connect with Bread board (generic elementz nickel plated 840 points bread board, India) which is ultimately connected to the laptop (Windows 10, intel i3 core processor) through USB cable. Arduino /genuino Uno software was installed in the laptop (Lenovo Yoga 510, China) which records and display the pressure in Pascal at four different areas of maxillary simulated edentulous model. All these connection helped in converting the analog readings to digital readings. The measured values from the various pressure sensors were recorded after the final set of material (end pressure) which allowed the impression pressure to settle after compression was determined. Data obtained from the pressure sensors (FlexiForce, India) were displayed on the laptop (Lenovo Yoga, China) using an arduino board (Arduino Uno R3, Robo Kits, India) converted to digital and then recorded on laptop (Lenovo Yoga 510; Beijing, China).

In order to place 2 kg weight exactly at the same locations for 60 samples, two lines were marked from buccal notches towards the ridge on right and left buccal notches of special trays.

#### Measuring method

Total 60 impressions (samples) were to be evaluated with three spacer design (i.e. 'I', Sanath Shetty and Boucher ) using ZOE and light body poly vinylsiloxane.

Each tray was measured 10 times using ZOE impression paste (DPI, India)(fig 3.a). Mixing was performed at a temperature of  $23 \pm 1^{\circ}$ C and humidity of  $50\pm5\%$ . The mixing time and operation time for each of the impression materials were set at a total of 60 s and seating of tray begun immediately afterward. ZOE impression paste was carefully loaded onto the special tray and two kg weight was placed on the loaded tray over the simulated model. The pressure readings were noted in all the four pressure sensors after the material was finally set denoted as end pressure in Pascal for each sample of different groups. The measured values from the various pressure sensors were displayed on laptop.

Each tray was measured 10 times using vinyl polysiloxane (Neosilk, India)(fig 3.b). Under controlled condition of temperature of  $23 \pm 1^{\circ}$ C and humidity of  $50\pm5\%$ , vinyl polysiloxane impression material was injected onto the tray and placed on a simulated oral model and 2 kg weight was placed on the loaded tray over the analog. The readings were noted on all the four pressure sensors (FlexiForce, India) after the material was finally set denoted as end pressure in Pascal for each sample of different groups.

**Observations and Results-**In this study, comparative evaluation of pressure generated on simulated edentulous maxillary model at four different areas using pressure sensors i.e. s1, s2, s3 and s4 were recorded (fig 4) while making final impression with special tray of 'I', Sanath Shetty and Boucher spacer designs with zinc oxide eugenol impression paste and light body poly vinylsiloxane impression materials respectively. The statistical analysis was carried out using ANOVA test,

Tukey post hoc analysis and unpaired t test. Results were shown in Table 1-4.

### Discussion

Frank  $(1969)^{26}$ . Iwasaki et al  $(2015)^{54}$ . Chopra et al  $(2016)^{55}$  and Inoue et al  $(2017)^{58}$  used the soft denture liner for simulation of oral edentulous model. Masri et al  $(2002)^{20}$ , Al Ahmed et al  $(2006)^{43}$ used polyvinyl siloxaneas as a pseudomucosa. So in the present study, poly vinylsiloxane is used as pseudomucosa. Frank et al  $(1969)^{26}$ , Masri et al  $(2002)^{20}$ , Al Ahmed et al  $(2006)^{43}$  and Reddy et  $al(2013)^{49}$  have used the pressure transducer for recording the pressure on an edentulous oral model. Rihani  $(1969)^{30}$  used the manometer to record pressure. Komiyana et al (2004)<sup>42</sup>used miniature pressure sensor and rheometer for recording pressure. Iwasaki (2015)<sup>54</sup>, Chopra  $(2016)^{55}$  and Inoue  $(2017)^{58}$  used the small pressure sensor to record the pressure. Fouladi (2016)<sup>56</sup> used mountable pressure sensor for recording the pressure. So pressure sensors (FlexiForce, India) are used in the present study to record the pressure on a simulated oral model.

Masri  $(2002)^{20}$  and A1 Ahmed  $(2006)^{43}$  used a Satec universal testing machine to deliver a constant pressure of 2 kg/cm2, seating over the loaded custom tray onto the oral analog. Fouladi  $(2016)^{56}$  used 0.5kg weight which was glued to the aluminium sheet and in each impression making, it was placed in the same location over the handle. Iwasaki  $(2015)^{54}$  and Inoue  $(2017)^{58}$  used a dental surveyor (J.M. Ney Company, Bloomfield, Connecticut, USA) and a model table, along with a metal indenter that provided a site for placing a 2 kg weight.

In the present study, the pressure generated in 'I' spacer design at left rugae area and at anterior part of midpalatine raphae is 1.43 Pa and at the left and right molar region is 8.44 Pa and 7.90 Pa respectively. Similar studies were conducted by Chopra et al (2016)<sup>55</sup> where the pressure at

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midpalatine raphae as 0.3 MPa and at the right and left molar region as 0.9 MPa with 'I' spacer design. The result showed statistically significant less pressure at midpalatine when compared to the right and left molar region. The present study was in agreement with Chopra et al. Iwasaki et al (2015)<sup>54</sup> measured pressure at midpalatine raphae, at the right and left molar region using light body impression material with no relief as 49.73 kPa, 32.51 kPa and 30.84 kPa respectively; with one part relief tray as 45.79 kPa, 37.69 and 29.24 respectively; with two part relief tray as 37.45 kPa, 47.10 kPa and 30.62 kPa respectively. The results using two part relief tray is in agreement with the present study. But the results found using no relief and one part relief tray is not in agreement with the present study, may be due to the absence of relief and escape holes and less relief area. Komiyana et al  $(2004)^{42}$  measured end pressure at midpalatine raphae and left first molar region with1.4mm partial spacer. With 1mm of escape hole, the pressure was measured as 4.66 kPa and 14.04 kPa, respectively and with 2mm of escape holes, the pressure were at midpalatine raphae was 3.24 kPa and 11.69 kPa respectively. The result is in agreement with the present study. Thus, when a partial spacer used Chopra<sup>55</sup>, Iwasaki<sup>54</sup>, Komiyana<sup>42</sup> showed that with relief, pressure is in midpalatine raphae. With selective pressure technique, there is significant difference of pressure between the midpalatine and the crest of ridge.

With Boucher spacer design, , the pressure generated at left rugae area and at anterior part of midpalatine raphae as 1.43 Pa and at the left and right molar region is 5.92 Pa and 6.10 Pa respectively. Similar studies were conducted by Chopra et al (2016)<sup>55</sup> where the measured pressure at midpalatine raphae as 0.51 MPa and at the right and left molar region as 0.7 MPa and 0.61 with full spacer design. Their result showed significant difference of pressure at midpalatine and the right and left molar

region. Frank  $(1969)^{26}$  found the end pressure at ridge and at palate 4 psi and 3psi respectively in no relief trays; 1.8 psi and 1.8 psi respectively in trays with relief. The difference is significant when spacer is not used and not significant in trays with relief. This study is in agreement with the present study. Fouladi et al $(2016)^{56}$  measured pressure in trays with 1.5 mm thickness with 1mm of relief hole at first molar and midpalatine area as 43.8 g/mm<sup>2</sup> and 23.3g/mm<sup>2</sup>; 36.8g/mm<sup>2</sup> and 19.4 g/mm<sup>2</sup> respectively; with 2mm of relief as 36.8g/mm<sup>2</sup> and 19.4g/mm<sup>2</sup> using light body. The present study is in agreement with Chopra et (2016)<sup>55</sup>, Frank (1969)<sup>26</sup> and Fouladi et (2016).<sup>56</sup> Reddy et al  $(2013)^{49}$  conducted a similar study using full spacer with ZOE impression paste. They showed that pressure at left, right molar region and center of palate is 51.4 microstrain, 55.8 microstrain and 127.8 microstrain respectively; using light body is 54 microstrain, 49.4 microstrain and 130 microstrain. The results are not in agreement with the present study as midpalatine raphae is more. It could be due to absence of relief holes in special trays. Masri (2002)<sup>20</sup>measured pressure using trays with full spacer and escape vent trays, at right crest, palate and left crest as 0.11 MPa, 0.16 MPa and 0.15 MPa respectively. This study is not in agreement with the present study.

Pressure produced using ZOE is more as compared to light body in all spacer design in the present study. Chopra et al (2016)<sup>55</sup> measured pressure at midpalatine raphae is 0.3 MPa and at the right and left molar region is 0.9 MPa in 'I' spacer design. The result showed that ZOE produced more pressure than light body. This study results was in agreement with Chopra et al(2016).<sup>55</sup> Fouladi et al(2016)<sup>56</sup> measured pressure in trays with 1.5 mm thickness with 1mm of relief hole at first molar and midpalatine area as 43.8 g/mm<sup>2</sup> and 23.3g/mm<sup>2</sup> respectively; with 2mm of relief as 36.8g/mm<sup>2</sup> and 19.4g/mm<sup>2</sup> using light body and

50.2g/mm<sup>2</sup>, 29.8g/mm<sup>2</sup> and 42.8g/mm<sup>2</sup> and 22.3g/mm<sup>2</sup> respectively using ZOE paste. Fouladi et al( 2016)<sup>56</sup> is in agreement with the present study. Reddy et al(2013)<sup>49</sup>conducted a similar study using full spacer with ZOE impression paste showed the pressure at left , right molar region and center of palate as 51.4 microstrain, 55.8 microstrain and 127.8 microstrain respectively; using light body as 54 microstrain, 49.4 microstrain and 130 microstrain. This study is not in agreement with the present study as they concluded that equal pressure is produced using ZOE impression paste and light body PVS. Thus light body produced less pressure as compared to ZOE paste.

The pressure measured in Sanath Shetty's spacer design was less as compared to 'I' but more when compared with Boucher spacer design. Till date no studies were conducted to measure pressure using Sanath Shetty's spacer design. This study was an attempt to know whether Sanath Shetty's spacer design could reduce the pressure while making final impression.

# Limitations of the studies are

- 1. Pressure is measured on simulated maxillary edentulous model may not give the exact readings which can be achieved by pressure measured directly in patient's mouth.
- 2. Here we consider only one type of mucosa. In actual oral conditions, if mucosa varies in quality and quantity, the pressure readings will also vary.

#### Future scope of study-

Further studies can be carried out to overcome the limitation of the present study.

- Pressure is measured only on four different areas on maxillary edentulous simulated model. Pressure can be measured even on more areas.
- Only three different types of spacer used. Other spacer design can also be compared.

#### Conclusion

Within the limitation of the study, we concluded the following

- 1. While making final impression on edentulous maxillary arch using ZOE, the pressure exerted at crest region at right and left molar was more as compared to midpalatine raphe and rugae area.
- 2. While making final impression on edentulous maxillary arch using ZOE, the pressure exerted was more in 'I' spacer design than in Sanath Shetty's spacer design and in Boucher spacer design at crest region and equal pressure were recorded in 'I', Sanath Shetty and Boucher spacer design at rugae and anterior part of midpalatine area.
- 3. While making final impression of edentulous maxillary arch using light body, the pressure exerted at crest region at right and left molar was more than in midpalatine raphe and rugae area.
- 4. While making final impression of edentulous maxillary arch using light body, the pressure exerted was more in 'I' spacer design than in Sanath Shetty's spacer design and in Boucher spacer design at crest region and equal pressure were recorded in 'I', Sanath Shetty and Boucher spacer design at rugae and anterior part of midpalatine area.
- 5. While making final impression on edentulous maxillary arch, more pressure was exerted using ZOE paste than light body at crest region than at anterior part of midpalatine raphe and rugae in 'I' spacer design, Sanath Shetty's design and Boucher spacer design.

Referring to the conclusion of the present study, generalised conclusion are as follows -

1. By using different combination of spacer designs and relief holes, the pressure exerted at the ridge

and midpalatine area can be reduced to prevent rate of resorption.

- 2. By using different combination of spacer designs and impression materials, the rate of pressure exerted can be minimised.
- 3. By using varied partial spacers, more pressure can be exerted at the crest area. Hence, in resorbed ridges full spacer design is more preferable.
- Zinc oxide eugenol impression paste exerts more pressure than light body.

Hence, material of choice for final impression should be light body vinyl polysiloxane.

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Page 15

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### **Legend Figure and Tables**



Fig 1: Simulated oral model with sensors s1, s2, s3and s4 attached on it.



Fig 2: a) 'I' spacer design



Fig 2: b) Sanath Shetty's spacer design



Fig 2: c) Boucher spacer design



Fig 3: a)Wash impression with zinc oxide eugenol.



Fig. 3.b) with vinyl polysiloxane impression material.



Fig 4: Recording assembly.

Table 1:Comparison of the pressure generated in terms of {Mean (SD)} on a simulated oral model with I, Sanath Shetty and Boucher spacer designs with ZOE paste and light body wash impression respectively using ANOVA test

Spacer design + impression material	s1	s2	s3	s4
I spacer + ZOE paste	1.43	8.44	1.43	7.9
I spacer + Light body	1.43	6.1	1.43	5.38
Sanath Shetty spacer + ZOE paste	1.43	6.1	1.43	6.82
Sanath Shetty spacer + Light body	2.14	4.66	1.43	4.66
Boucher spacer design + ZOE paste	1.43	5.92	1.43	6.1
Boucher spacer design + Light body	1.43	3.4	1.43	3.58

Table 2: Comparison of the pressure generated in terms of {Mean (SD)} on a simulated oral model with I spacer designs with both the impression materials using unpaired t test at s1,s2,s3,s4 respectively

	I spacer+ ZOE	I spacer+ Light body
s1	1.43	1.43
s2	8.44	6.1
s3	1.43	1.43
s4	7.9	5.38

Table 2a

	Sanath Shetty spacer + ZOE +	Sanath Shetty spacer+ Light body
s1	1.43	2.14
s2	6.1	4.66
s3	1.43	1.43
s4	6.82	4.66

### Table 2b

	Boucher ZOE	spacer+	Boucher spacer+ Light body
s1	1.43		1.43
s2	5.92		3.4
s3	1.43		1.43
s4	6.1		3.58

Table 2c

Table 3: Comparison of the pressure generated in terms of {Mean (SD)} on a simulated oral model with different spacer designs using ZOE impression at s1,s2,s3,s4 respectively using ANOVA test

	I spacer	Sanath Shetty spacer	Boucher spacer
s1	1.43	1.43	1.43
s2	8.44	6.1	5.92
s3	1.43	1.43	1.43
s4	7.9	6.82	6.1

Table 4: Comparison of the pressure generated in terms of {Mean (SD)} on a simulated oral model with different spacer designs using light body wash impression at s1,s2,s3,s4 respectively using ANOVA test

	I spacer	Sanath Shetty spacer	Boucher spacer
s1	1.43	2.14	1.43
s2	6.1	4.66	3.4
s3	1.43	1.43	1.43
s4	5.38	4.66	3.58