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## Challenges in the development of a new obturation device: A questionnaire survey

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### ABSTRACT

*Dental anatomy plays a crucial role in human body as it helps in survival. The after-treatment protocol in the root canal treatment (RCT) for improper functioning of the anatomy is major challenge for dentists. RCT deals with repairing and saving the tooth that is badly decayed or becomes infected. The RCT, if analyzed mechanically; various factors govern efficacy of the treatment out of which incomplete filling and sealing of 3D root canal space with suitable biomaterial against bacterial growth is major parameter. Today, thanks to modern technologies satisfactory results are obtained, but the cost of treatment is substantially increased which is unaffordable. Thus, a survey was carried by visiting doctors practicing for more than 25 years in conservative dentistry to recent students admitted to dental surgery in various colleges to understand tools/aids used during RCT with hypothesis of developing low cost obturation device for augmenting the dental device feasibility. The success rate of obturation device is high over hand pluggers; but the cost parameter limits the usage of same. The survey also conveys that complete sealing is also not possible with hand pluggers as well as existing available aids, and thus there is a need to develop a low cost obturation device using dual energy (low operating frequency and heat) source for increasing efficacy of treatment. To test feasibility of the collected data, it's being analyzed through p-test ( $p > 0.05$ ) for selected parameters and correlation was found to be statistically significant.*

**Keywords**—Root Canal Treatment, Obturation Device, Dual Energy Source

### I. INTRODUCTION

Endodontology is a branch of science which deals with the Knowledge of what is inside the tooth and which deals with complete chemo-mechanical cleansing of the root canal system is essential to achieving success. A root canal is a dental procedure that involves the extraction of pulp (root nerves & blood cells) from a tooth, cleaning and shaping the canal cavity and then inserting fillers to prevent bacteria from re-entering apical end of root canal. In medical terms the activity of cleaning and shaping the canal cavity is said to be 'Biomedical Preparation' & 3D filling and sealing canal to achieve intact seal is called as 'Obturation'. Basically RCT is a treatment used to repair and save the tooth which is badly decayed or becomes infected. The basic functions are mainly; (a) To prevent nutritional elements from accessing the pulpal space along any entrance to the root canal, including apical foramina, accessory canals and the oral access cavity and (b) To eliminate space for further growth of microorganisms that may have survived the biomechanical preparation.




In today's era the design process for medical devices is highly regulated to ensure the safety of patients and healthcare workers and thanks to modern technologies satisfactory results can be obtained in obturation. According to literature, if the root canal is not completely cleaned and sealed, inflammation and infection may continue [1]. It is also identified that cleaning and shaping is of paramount importance in successful endodontic treatment. This is validated by the fact that nearly 60% of failures in endodontics can be attributed to incomplete obturation of the root canal. Hence, a 3D obturation is critical for endodontic success [2]. Over the decades, devices developed across the world are not assuring 100% obturation and inline research is going on under the regulatory board such as Medical Device Directives (MDD) for Europe, Federal Drug Administration for USA and in India, BIS which certifies & regulates low technology devices though concept of regulations governing investigations involving biomedical devices is relatively new in India [3-11]. In order to fulfill this requirement to certain extent, various biomedical industries have their major focus on developing such devices. The theoretical design of such device that comply with set requirements can be carried out as per the available medical device design standards. In India, rural population suffering from dental related problems have to spend much of their money on current crude dental practices with old devices which is unaffordable. RCT, if analyzed mechanically with the technology and aids used by regular practitioners; the success index of the root canal treatment largely depends on several






mechanical factors such as Kinematic Viscosity of Filling Material, Compaction Force, Specific Heat and Pliability of Filling Material, Geometry Parameter, Canal Curvature Coefficient, Adhesive Bond Strength between Filling material and Dentin [3]. Thus to find out intricacies of the devices and to identify the need of the doctors to reduce cost of treatment, a questionnaire survey was carried out with hypothesis of developing low cost obturation device which will certainly enhance and augment the dental device feasibility, and go a step further to reduce the economic burden for common people for dental expenses. The success of the current study will be beneficial to dental surgeons, dental experts, and in turns the common patients in terms of cost. Also, in elderly patients the future complications related to root canal therapy can be avoided with the use of a state of art dental handheld device. Most of the infections arise in the dental root cavity and further lead to various other diseases in the body, in order to reduce the possibility of such infections, the latest obturation devices will definitely serve better for human health.





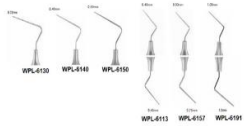


## 2. SURVEY ON EXISTING DEVICES

The technology is continuously upgrading in biomedical devices over the decades; particularly in obturation devices, modern technologies as Operative Microscope, ultrasonic tips, M-Wire Files, devices to activate irrigation and tridimensional obturation reaches to the maximum success index [41]. To understand tools/aids used in obturation a survey was carried out on available biomedical devices (overall 20) based on the (a) Manufacturing company (b) Name of device (c) Filling method employed and (d)Technique used.

**Table I:** Survey of Obturation Devices available internationally [42]

Sr. No.	Manufacturing Company	Device	Filling Method	Technique/Type
1	Sybron Endo (www.sybronendo.com)	'Elements Obturation System' 	Continuous Wave of Condensation	(System B) Motor driven extruder handpiece
2	Sybron Endo	'System B' 	Continuous Wave of Condensation	(System B Heat Source) Temperature controlled electric heat plugger(Buchanan)
3	Sybron Endo (Dr.HerbSchilder)	'Touch 'N Heat 5004' 	Warm Gutta Percha method	Internally heated autoclavable tips
4	Obtura Corp. <b>OBTURA SPARTAN Endodontics</b> (http://www.obtura.com/system-b/) (Quality Endodontics Distributors Ltd.) (www.qedendo.co.uk)	'Obtura' 	Thermoplastic Obturation	Injectable Gutta-percha System(with digital temperature display & memory)
5	GT Obturators (Dr. Ben Johnson) www.dentsply.com	Thermafil (DENTSPLY) Tulsa	Carrier based obturation (Type of centered obturation)	New generation of System B Pluggers (Recent innovation)
6	Morita B & L, Korea. (TRACOM Services Pvt. Ltd. New Delhi) (www.tracom.in www.bnlbio.com)	'Super Endo alpha -II' 	Vertical Condensation	Lasts more than week in 1 charge. (4 hrs. continuous use) 16 patients.Battery:12 V, 850 mA. Thermal Tester: £ 70 Plugger: £ 60
7	Nisha Enterprises, Bhayandar (W), Thane-01.	Gutta Percha Cutter	Condense GP, cut it using heated blade.Removexcess GP.	(3 tips + circuit) imported from US. Rechargeable battery lasts 6 hrs. to 15 days.(Charging time 4 to 5 hrs.), treating 80 to 100 patients.

8	<p>Gutta Cut (VDW GmbH, Endodontic Synergy) Germany. (<a href="http://www.vdw-dental.com">www.vdw-dental.com</a>) Selmark Ltd. Lucknow, UP India.</p>	<p>‘Gutta Cut’ </p>	<p>Hot cutting of GP points. (with autoclavable tips/inserts)</p>	<p>Induction charging unit + 4 tips. Warm GP tip lasts 2 to 3 yrs. 45 gm. Rechargeable Ni-Cd battery 1.2v, charger 220-240 v, 50-60 Hz, 2.5 w. Charging base 145 gm. Upto 80 cuts per battery charge.</p>
9	<p>DENTAMERICA (Chromadent Dental Equipments, Kandivali (W), Mumbai-67.) (<a href="http://www.dentamerica.com">www.dentamerica.com</a>) (<a href="http://www.chromadent.com">www.chromadent.com</a>)</p>	<p>Gutta Percha Cutter</p>	<p>Condense GP, cut it using heated blade. Remove excess GP.</p>	<p>Tips VS, S, R, VR, and 1.2 V, Ni MH rechargeable battery</p>
10	<p>DISCUS DENTAL USA (M &amp;M Dental Associates, Lower Parel, Mumbai-13.) (<a href="http://www.discusdental.com">www.discusdental.com</a>) (<a href="http://www.mmental.com">www.mmental.com</a>)</p>	<p>‘Hot Tip’ GP Cutter </p>	<p>Pen type hot tip cutter (tip costs @ Rs.2000/- to 3000/- ) Warm vertical compaction</p>	<p>Rechargeable battery lasts for 6 to 8 hrs, (3.7 V, 1620 mA, Li-ion battery ), Size 45, .04 Taper Plugger, Charging Base and Power Cord, Adapter: 120V, 1620MAH</p>
11	<p>DENT CORP Research &amp; Development, NY, USA. (<a href="http://www.dentcorp.com/files/EasyCut">www.dentcorp.com/files/EasyCut</a>)</p>	<p> ‘EasyCut’</p>	<p>Light weight, Cordless electronic device</p>	<p>4 interchangeable heads, &amp; Rechargeable battery option.</p>
12	<p>META Dent Corp. NY USA. Biomed (Patent No. 0668424) <a href="http://www.meta-biomed.com">www.meta-biomed.com</a> <a href="http://www.metadentalco.com">www.metadentalco.com</a></p>	<p>‘E &amp; Q Master’ </p>	<p>Master Pen- Pen type hot tip cutter. (Cordless GP Obturator)</p>	<p>Rechargeable battery: Li-ion ICR18650-26 SAMSUNG SDI, 3.8V, 2400 mA. Charging time is 3 hrs. Pen: Heating time is 1 sec, Pen charger I/P 100-240V, O/P DC 9V, 1.8 A.</p>
13	<p>META Dent Corp. NY USA. Biomed <a href="http://www.meta-biomed.com">www.meta-biomed.com</a> <a href="http://www.metadentalco.com">www.metadentalco.com</a> (Patent No. 0531015 US 6948933 US 7008222)</p>	<p>‘E &amp; Q Plus’ </p>	<p>Pen type hot tip cutter. Vertical Compaction of warm GP.</p>	<p>Battery: Ni-MH, dc 3.6 v, 8.8 A/H, dia.18.4, 63 gm, 6EA, 0-45°C. charging time continuous 3 hrs per charging capacity. Pen: Temperature Sensor K-type, Heating time is 1 sec, Temp 100-300 °C.</p>
14	<p>CALAMUS Tulsa Dental (By Dr. Clifford J. Ruddle) <a href="http://www.tulsadental.com">www.tulsadental.com</a></p>	<p>Dual 3D Obturation System </p>	<p>3 electric heat pluggers, cartridge, Nut, heat shield, bending tool.</p>	<p>Thermal Response tip (sold separately) (tip costs at \$ 270 )</p>

15	CALAMUS Tulsa Dental (By Dr. Clifford J. Ruddle) www.tulsadental.com	CALAMUS Pack 	Vertical Condensation delivery system	(Information not available)
16	ACEONEDENT Korea Industrial Company www.aceonedent.com	 'G/P Trimmer'	4 types of interchangeable tips	Rechargeable battery
17	Endo Ingenuity Hu-Friedy Mfg. Co. Inc Chicago, IL USA www.endoingenuity.com (Romania www.redinternational.ro)	'DownPack' (Cordless obturation device) 	Temp range 50- 350°C at tip, Autoclavable to improve asepsis.(14 tip designs) Warm Obturation Technique.	Rechargeable battery (Ni-MH) pack with charger. Lasts for 1 day. Delivers heat and vibrations to condense GP, patented vibration. (Charger- \$279, Battery pack- \$129, tips set- \$110- \$140)
18	FAROMED GmbH Medizintechnik Berlin (Germany) www.faromed.de	 Gutta Percha Cutter	(Information not available)	(Information not available)
19	OBTURA www.obtura.com	'OBTURA' Heated GP System	(Information not available)	(Information not available)
20	MEDESY, Italy. www.medesy.it	---	(Information not available)	(Information not available)
21	Hand Plugger		(Information not available)	WALDENT
22			(Information not available)	GDC ROOT CANAL PLUGGER
23			(Information not available)	BUCHANAN HEAT PLUGGER

### III. QUESTIONNAIRE SURVEY AND OUTCOMES

Data collection; a pioneer in research basically works on process of gathering and measuring the information on targeted variables which then helps to answer relevant questions and evaluate possible outcomes. In the present study, data collection is being done through questionnaire survey in consultation with experts in the field of dentistry and understanding needs. The survey was conducted assuming **h<sub>0</sub>**: Existing tools/aids are sufficient and **h<sub>1</sub>**: Need to develop a new device. The questionnaire survey was consisting of finite number of questions in printed form and carried out by visiting doctors practicing from more than 25 years in conservative dentistry to recent students admitted to dental surgery and the response was recorded individually. Total 100 responses were recorded out of which 70 responses were recorded from Pune Municipal Corporation and surrounding areas, 14 responses from outside pune city and 8 responses out of Maharashtra and 8 overseas responses collected through online forms. The preceding section summarizes the outcomes of the survey in line with the typical obturation method preferred by doctors, success rate of RCT

in single seating also the tools/aids used for obturation and requirements to be addressed prescribed by experts in the field of dentistry. The in person discussion with the doctors while conducting survey; clearly states that there are lot of scope to develop new obturation tool/aid which will assists RCT in regard (a) provision of aid for filling of lateral canal (b) technique/ aid for determination of exact filling material volume (c) analyze the effect of rotary instrument on dentin (interface between teeth and bone) (d) automation of tools/techniques and aids used in dentistry. The survey declares 38% of the response is collected for 80-90% success rate of RCT in single visit shown in Fig no. 1. The survey also clears that the spread of success rate clearly varying between 70-90%, while very few respondent states that the success rate is more than 90%. The success rate is goes hand in hand with on skilled personnel and easy usage of modern technology. Variation in one of the parameter certainly affects the success rate. The only parameter which is in our hand is to ease the functional usage of tool/aid/technique used for RCT by improving existing design or by developing the new tool/aid. Limitation of success rate in single visit was found to be statistically significant and in-line with assumed hypothesis as  $p > 0.05$  (i.e. 0.36).

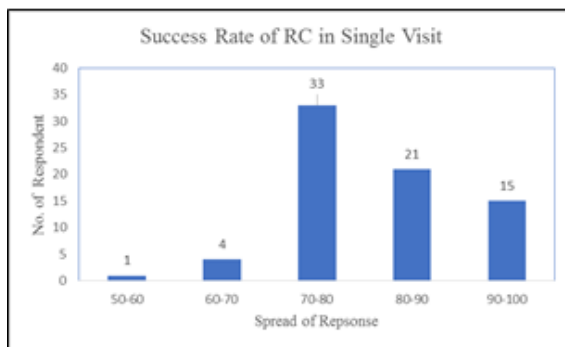


Fig No. 1. Success rate spread in Single Visit

The other aspect of the survey was clearly about the technique used for RCT. In General, there are various techniques which are available for RCT such as Cold Lateral Compaction, Warm Compaction, Continuous Wave Compaction Technique, Thermo-Plasticized GP Technique, Chemically Plasticized Technique, and Thermo-Mechanical Compaction. The respondent clearly indicates that out of these two techniques Cold Lateral Compaction and Warm Compaction are equally preferred over one another as shown in Fig. No.2 due to better sealing capacity over the length, and avoid the chances of overfilling. But limitation of these techniques cannot be overlooked as cold lateral compaction may not fill the canal irregularities efficiently as it doesn't produce homogeneous mass and presence of voids may be observed [15,17]. Also in Warm compaction as biomaterial is in soften stage, exact force required can't be determined and risk of root fracture results of undue force [15,17].

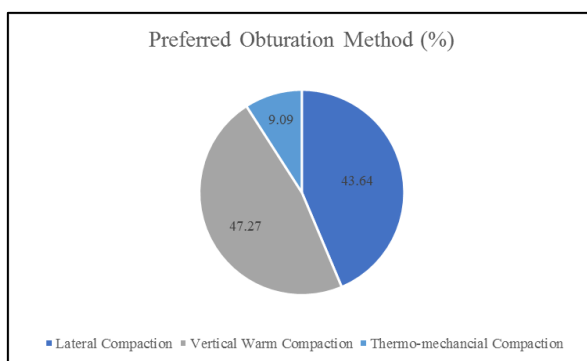


Fig No. 2. Preferred Obturation Method

The major aspect is addressed after knowing the limitations of the methods being used is efficacy of sealing over the entire length of canal. Basically dental canal is nothing but a curved conical channel having overall length of approximately 15mm which is divided in three sections namely upper, middle and apical as shown in fig no. 3. Thus, with both the method the being analyzed simultaneously the efficacy of sealing in was found to comparatively on lower side in middle portion of the anatomy. Expert also suggest that this can be overcome if the device is embedded with particular element which will generate excitation of lower frequency to achieve complete sealing.

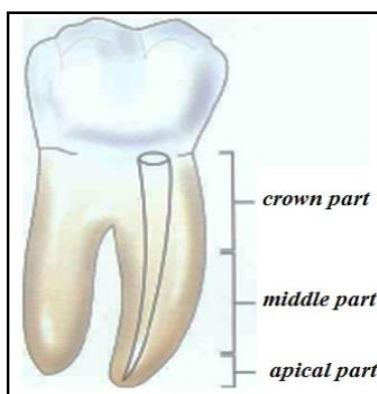


Fig No. 3. Anatomy of Root Canal

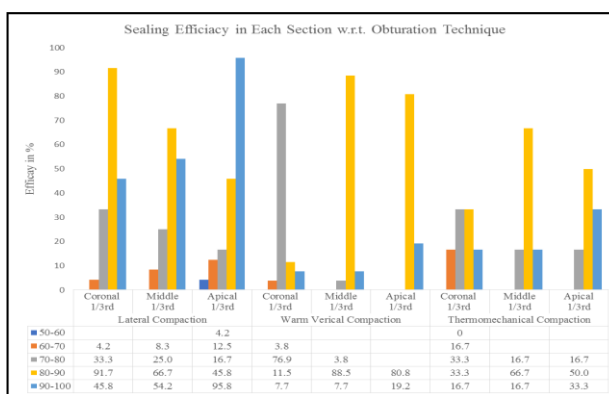


Fig No. 4. Sealing Efficacy in Each Zone

The fig. no.4 clearly indicates that the spread of the sealing efficacy in middle part of anatomy is 70 to 80% irrespective of technique where as in lower part where the dimension of the cavity becomes very narrow, the spread reaches to maximum value i.e. 90 to 100% for Lateral Compaction and for other techniques it varies from 80-90%. The drawback of increasing apical sealing efficacy [2, 28-31] identified by the researchers is now completely overcome by the usage of modern tool and techniques. If geometry of the canal analyzed mathematically the connectivity between middle part and lower part need be plotted correctly in order to reduce undue force causing root fracture [32]. The recent study [43] also states the need prescribed by experts that, automation used in the Obturation process to extract experimentally the loading pattern which strengthen the hypothesis. The significant correlation was found during the statistical analysis performed for sealing efficacy in each part analyzed individually as well as together; and p-value was coming out to be 0.69 and 0.79 respectively.

The concluding part of the survey was related to the devices which are being used during RCT; the choice was given between hand pluggers and obturation pen irrespective of the make. And response clearly states that the regular practitioners are preferring hand pluggers over obturation pen shown in fig no.6. The experts highlighted that the usage of obturation pen increases the cost of the treatment and success rate of RCT with hand plugger though less as compared to obturation pen is proven over the years. Thus existing devices stated in earlier section irrespective of the make need to be examine correctly to ensure success rate with its usage. The statistical analysis was performed separately for usage of hand pluggers and obturator pen; for both significant statistical correlation was found. On one side, success with hand pluggers (the p-value to be 0.07) which conveys that there is significant scope for improvement in available tool and aid; whereas the respondent for usage of obturation pen was very limited but the statistical correlation was found to be significant (with p value as 0.367).

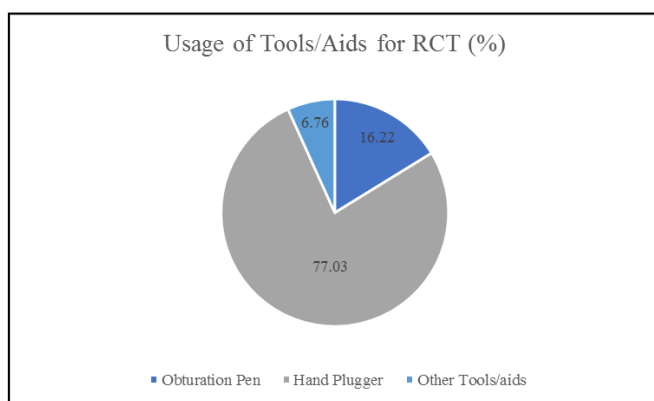


Fig No.5. Usage of the Device

Over the variety of hand pluggers, mostly Buchanan Heat Pluggers are widely used due to its shape that closely matches the final root canal preparation [23] and are designed to fill by heating, plugging, softening and compacting biomaterial during a continuous wave of condensation [7].

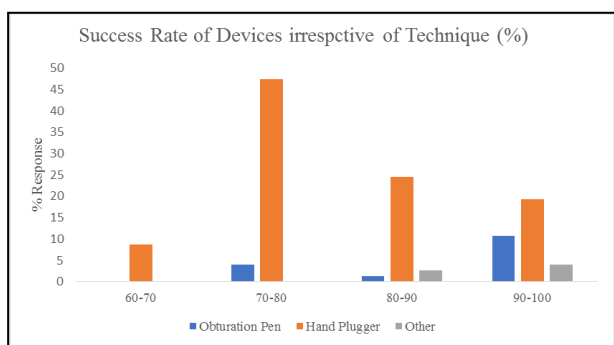


Fig No. 6. Success rate w.r.t. device irrespective of technique

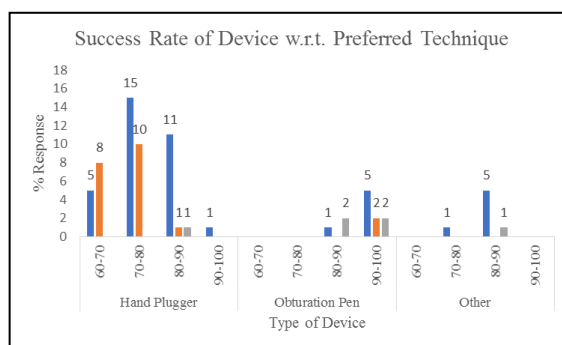


Fig No.7. Success rate w.r.t. device and preferred techniques

As discussed, dentists using Obturation Pens have a greater success rate than the dentists using Hand Pluggers, but most of the dentists uses hand pluggers as they are affordable and they are hesitant to change. But even though the dentist using Obturation pen is less, its efficiency is more than Hand Plugger as shown in fig. 7.

#### IV. DISCUSSION

The questionnaire survey clearly indicates the significance of assumed hypothesis through;

1. The only parameter which is in our hand is to ease the functional usage of tool/aid/technique used for RCT by improving existing design or by developing the new tool/aid.
2. Limitation of commonly used techniques cannot be overlooked as cold lateral compaction may not fill the canal irregularities efficiently as it doesn't produce homogeneous mass and presence of voids may be observed. Also in Warm compaction as biomaterial is in soften stage, exact force required can't be determined and risk of root fracture results of undue force.
3. Most commonly used methods for RCT i.e. lateral compaction and vertical warm compaction; if analyzed simultaneously the efficacy of sealing in was found to comparatively on lower side in middle portion of the anatomy. Expert also suggest that this can be overcome if the device is embedded with particular element which will generate excitation of lower frequency to achieve complete sealing.

- Existing devices stated in earlier section irrespective of the make need to be examine correctly to ensure success rate with its usage.

## V. CONCLUSION

The survey clearly justifies the hypothesis by collecting response through every parameter. The common problem addressed by consulting the experts in the field of conservative dentistry and individual interaction with the respondent are calcification within the canal especially in the middle and coronal 1/3<sup>rd</sup>, locating accessory canal and preparing curved canal, and exact filling volume determination and many more. Determination of exact loading pattern to overcome fractures observed due to excess force has been untouched and can't be overlooked. Enhancing efficacy of sealing in middle part of canal is to be addressed by modification of the tools/aids used for the same which will enhance the success rate of RCT. The statistical results gives an important indication that obturation pen and related new designs is required to be developed to enhance the success rates as for major parameters of the survey p-value was more than 0.05 which completely goes hand in hand with the hypothesis.

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