Study Protocol in Restorative Dentistry

Research has often been considered an enigma by most of us - a privilege of the exclusives of the profession. But research simply means 're-search' the existing facts either to solve a problem or improve an existing system - all along the process adding more new facts to the profession. Being an action packed speciality, most of us aspire to be a clinician rather than an academician or a scientist.

However understanding research and its ways is imperative not only to conduct a study but also to assess and evaluate them for the real end use Viz., Clinical usage. Thus research has become a fundamental requirement of a clinician too, in addition to an academician or a research aspirant. On the same token research need not be confined only to the teaching institutes and the research laboratories, but can be conducted in the clinical operatory and the patient's mouth becomes a full fledged laboratory!

Most of the pioneering research has been focussed largely in the field of restorative dentistry since the beginning. It is well known that the first standard for testing of dental materials was developed for silver amalgam. The quantity of work involved and the quality demanded in that work, still make this field a focal point for further exploration. Furthermore continuous influx of generations of materials into this field provides a richer forum for research and also demands a close and careful scrutiny for the new materials' clinical acceptability.

A postgraduate dissertation is intended to educate the student in research methodology. It is also meant to teach them free thinking process to raise the right query at the right time, to observe events which tend to go unnoticed and to do an indepth study of a particular subject. However, these objectives do not preclude the validity and significance of the content of the work. Unfortunately a norm of mediocrity has settled in the making of these projects. Defying the real purposes, they are considered more of just a formality, than fundamental. Therefore curriculum should emphasize more on quality and standard in these projects that, the output of even the simplest and smallest research done with proper scientific foundation end up being beneficial to the profession at large. Being the maiden project of a postgraduate, he/she assuming the responsibility of the first author, the value of a postgraduate dissertation should not disintegrate into a just formality of lifting the skeleton form one coffin to the other.

This article aims to discuss the study protocol and its significance in a research and also highlight the need of the hour of the clinical study in the field of restorative dentistry. The discussion will focus only on the rationale behind each step in the protocol. Therefore further details in this can be referred to in a bio-statistics text. The article further analyses applied research in the material science with respect to the properties of the restorative materials excepting the biological property, which is a voluminious subject on its own.

Study protocol

Research, synonymous with study can be of two types, Viz-fundamental research and applied research. Fundamental research concentrates on the basic concepts of a science and when the

results form this research are studied for a definite, application purpose, it becomes an applied research. Higher percentage of studies in our field are applied research sparing a very few fundamental research on the diseases and the tooth tissue dynamics.

Writing a study protocol is the first and most important aspect of any kind of research. Protocol literally means "a code prescribing to the strict adherence to correct etiquette and precedence". This practically means that every stage of the study has to be well schemed and analyzed before commencement. It also means that it has to be followed meticulously and strictly with little or no change during the study. Even dummy statistical tables have to be prepared beforehand. The proforma, which is submitted to the university, is the same whose importance has weaned off over the years. The ensuing sections will reemphasize the importance of the protocol writing.

Title:

The title of the study should convey the problem, and the method of obtaining the solution to the reader. It should contain maximum information words. Non-specific and non standardized abbreviations should be avoided. The reason to have a comprehensive as well as a descriptive title is to ensure easy cataloguing and search, lest, the article tends to be lost in the sea of information.

Aims (research hypothesis) & Objectives (research question)

These are the fountainheads for the study. There is no real difference between the two. General purpose of the study is aim whereas the objective should clearly define the purpose of the study. In other words it has to state exactly what one intends to do. For example studying the mechanical efficacy of a root canal irrigant is the aim and specifically comparing the monoject irrigating needle with other methods is the objective.

REVIEW OF LITERATURE:

Once a hypothesis is generated or a research question has been raised, it becomes imperative to collect the background information of the subject. Browsing through the literature informs one about the state of art of the problem and the proposed solution. The weakness and the wisdom of the other authors in similar studies can be used effectively. Review of the literature also avoids unintentional duplication of an already conducted research.

Review can be done by preliminary search, systematic computer search or by systematic manual search. When one reference leads to the other, substance keeps building up like a snowball, it is called as preliminary search or snowball search system. Computer search of the electronic databases indeed gives more information in a short time, but only in an abstract form. Therefore total dependence on computer search as is prevalent now is not advisable.

RESEARCH SIGNIFICANCE OR RELEVANCE:

This component though explained in very few words, has got paramount importance in conducting a study. Why the study is done and what beneficial effects are expected by the

solution and how significant is the solution in altering the clinical service to the patient are the vital questions that should be evaluated before commencing the study. A useless research conducted just for the sake of conducting is a tremendous waste of all resources.

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STUDY DESIGN:

Deciding the kind of study will have a great impact in the subsequent steps in study protocol. Study design can be ***Descriptive Studies*** or ***Analytical Studies***. Descriptive study includes ***Case reports*** and ***Surveys***. Analytical study includes ***Observational Study*** and ***Interventional study***. More commonly adopted in restorative dentistry is the analytical research, which is actually a hypothesis testing research. Among observational study and interventional study, the latter is in vogue, which is done through clinical (in vivo) research, laboratory (in vitro) research and animal studies.

But the often ignored observational study is the prime inception of any form of research. Actually most of the discoveries are made from the observational studies. The observational studies can be either ***prospective*** or ***retrospective*** study. Prospective study is also known as ***cohort*** study. Here the causes are studied for the extent of effect by a follow up of the patient. For example, the hypothesis that interfacial stain of composite restorations is more in patients consuming tea. A collection of patients who have already had composite restorations is done and divided into those consuming tea and those not consuming tea. They are followed up over a period of time to see the relationship. Here the composite resin restorations are not the intentional intervention of the operator doing the study.

Retrospective study is also known as "trohoc" (cohort spelled backwards). Here the samples exhibiting the effect and samples not exhibiting the effect are compared backwards in time to determine the causal relationship.

The main advantage of the observational study is that the bias is reduced to minimum. The disadvantage is that the information obtained is only about the association of cause and effect. They can never prove the cause-effect relationship, which can be done only by interventional study. The reason for the non-popularity of observation study lies in the inefficient record keeping system both in institutions and in our private clinics.

Among the interventional studies, the laboratory studies or the in vitro projects are very often undertaken in dissertations because of limited time factor as well as ease of standardization of variables. For the very same reasons, clinical research is kept at bay.

SAMPLE POPULATION:

The next logical step is to choose the subjects on which the study is to be conducted. Sample collection should be based on definitive ***inclusion*** and ***exclusion*** criteria. This standardisation will control the variables present in the samples effectively and provide us sample with uniform charcteristics.

As for as clinical studies are concerned, as many variables as possible should be controlled or accounted for. Some of these variables are age of the patient, nutrition, oral hygiene, salivary pH, quality of restorative material, clinical procedures, size and location of the restoration, manipulation of material prior to insertion and the operator. Patient selection for a clinical study will consist of volunteers ranging in age from 18-45 years. This age group is more suitable because the dentition is fully erupted and is beyond the age of greatest caries activity. Good physical health is also a pre-requisite. The subjects can be students, their spouses or immediate families or staff, faculty members or any citizen of a community who are expected to remain for a least 5 years after treatment. It should be remembered that the results obtained from this group could not be generalized to public at large. Same way, all age groups cannot be generalized with the results from a particular range.

Selection of tooth sample for in vitro study can be standardized more easily. Very often non carious premolars freshly extracted for orthodontic reasons are chosen for various studies. Sometimes the third molars are also used. Though the degree of calcification and maturation of these teeth are almost similar, absence of the disease may sometimes provide results which are contradictory to the clinical situations, where the treatment procedures are actually meant for the diseased tooth. This variation should be borne in mind always and the results have to be corroborated with this lacuna. Classical example is the variation of interfacial bond strength of dentin bonding agents on a healthy dentin and sclerotic dentin, which is actually the real clinical situations.

Now the vital question of how many subjects should be selected from the population we have chosen. In other words studying how many subjects will give a considerable result to be applied for the population at large? This is called sample size. There are two analogies, which caught our

attention. 'Putting a man in the orbit and bringing him back is proof that man can conquer space; checking a single grain of rice is to see whether the whole pot of rice is cooked or not". But unfortunately one sample is not enough to prove a scientific correlation between a cause and effect- the simple reason in our samples being inter individual variation. For example- we want to study the effect of fluoride varnish for hypersensitivity in one patient. When the same study is done in another patient we might not get the same result. If we do the study in 20 patients there is good chance that we may find the same result in most of the cases, if not all. So the logic is , if the samples are too less in number the chance of hitting the fact is less. Therefore an adequate number is required to hit at the truth. If small size can lead to wrong conclusion, same way unnecessarily large sample size will be a waste of resource and time. Especially in a clinical intervention tagged with certain amount of known ill effects it is not justified to expose too many patients. Therefore the determination of the correct sample size is a must and is a difficult task too..

There are few factors that influence the sample size.

a. First one is the expected difference between the group. For example, we are studying the effect of two different surface treatment of dentin for the bond strength of composite in two independent studies. In one study, one surface treatment is increasing the bond strength of the composite by 2 mpa than the control and in the other study the second surface treatment is increasing it by 10 mpa than the control. Since in the first study the difference is less we need more sample to obtain this precise difference. Whereas in the other study where the difference is big, obviously we require less sample to prove it.

b. The other factor is the inter individual variability of the sample. If the data obtained from one sample to the other varies very little, then small size is enough and when the variation of result is more between two samples, then the sample size should be more. Example; the samples in one study provides results in the range of 2,3,4,5,6,3,5 mpa etc., then the sample size can be small. On the other hand if the results obtained are in the range of 10, 20, 4, 9, 13, 7 , 22 mpa etc., then a large sample size may be needed.

c. Alfa error and Beta error: No study is perfect. Any study can give false positive or false negative results. Alfa error or type I error denotes false positive results. The study may conclude that there is difference between groups, when actually there is no difference. This means the result was obtained by chance and not by intervention. This error is decided before starting the study!! Most of the studies in restorative dentistry keep the error to 5%. This is called significance level i.e the level at which you consider your P values significant. Beta error or type II error, on the other hand denotes the false negative results. When there is actual difference exists between the groups, the study may conclude that there is no difference. The chance of happening is more if the sample size is less. Power of the study or Sensitivity of the study is calculated from the the type II error. For example type II error is limited to 5% the power of the study is

100 - 5% (type I error) = 95% (Power of the study).

Most of the study wishes to keep both the Alpha and Beta error to minimum, but it is not possible to reduce both the errors simultaneously. For a given sample size if one is reduced the other is automatically increased. Usually the alfa error is fixed at a tolerable limit (5%) and the Beta error is minimized. After fixing the Alfa error, Beta error can be decreased by increasing the sample size.

d. Loss of Samples: Sample lost during the study can drastically affect the validity of the study, especially when the sample size is small. This must be calculated at the beginning of the study to give allowance while deciding the sample size. The pilot study or similar studies or experience of the guide are the only way to determine the amount of sample that can be lost.

These facts have to be provided by the operator for the statistician to help us with the determination of sample size. This information's have to be looked for in similar previously conducted study. If not available, a pillot study has to be conducted. Discussing the various formulae for estimating the sample size is beyond the scope of this article.

As far as clinical studies are concerned, organizations like FDA and ADA have published the recommended protocol for clinical evaluation of the materials. ADA guidelines currently 40-50 restorations for clinical evaluation at the end of 5 years. The ratio of class II to class I restoration should be at least 2:1. A greater percentage of class 2 ensures that most of the restorative material is unprotected by the natural tooth structure, thus are subjected to more adverse condition. A minimum ratio of molars to premolars should be 1:1. Only the teeth in occlusion have to be considered. The minimum number of restorations should be no less than 2 and no more than 6 per patient.

SAMPLING:

The assignment of the operator, material and the subject should be allocated in a random fashion to minimize the bias. Random sampling can be simple random sampling or systematic random sampling or stratified random sampling. Simple random sampling is most commonly used. Here each unit has an equal chance of being selected. Sampling here is done by the lottery method or by using numbers from a random table. In systematic sampling,the odd numbered sample is placed in the study group and the even numbered sample is placed in the control group. In stratified sampling the sample population is divided into groups of definitive criteria, for example, the population is divided into male and female stratification and then a simple or a systematic sampling is done from this stratification.

CONTROL:

Control subjects need to be obtained for an inteventional study for comparison with the study subjects. The control subject's behaviour is already known to the operator and is included to minimize the variable and bias. It can be a positive control or a negative control. Among the different types of control, concurrent control and paired control should be used whenever feasible. Concurrent control means the control group is observed simultaneously with the treated group. For example: one quardant can be a control and the other quardant can be a study group in

a clinical study or a mesial restoration can be a study material and the distal restoration can be control material.

METHOD OF COLLECTION OF DATA:

In this section the various experimental methodologies with respect to restorative dentistry will be discussed. The laboratory studies as well as clinical studies that are done concerning the properties of restorative materials are highlighted. A comparison between the in vitro and in vivo studies will be drawn to emphasize the validity of clinical studies.

In vitro Vs In vivo study:

The restorative materials reaching the user market traditionally goes through a vigorous evaluation by the standard specification tests set by various organizations , in fact in the laboratories. The in vitro laboratory tests that evaluate the physical, mechanical or chemical properties of a material by various test methods actually serve as primary guide in determining if the material has a potential for clinical use. But unfortunately they are not capable of perdicting their long term clinical performance. Though the relevance of these in vitro results to clinical situation cannot be overruled entirely, a lacuna defintely exists while drawing the inference to clinical performance. Many often, the values obtained by an in vitro do not correlate with the clinical event. This is because, they are conducted under ideal conditions in contrast to a variable dynamic oral environment. Another note worthy point is that the lab test revealing a statistically significant result need not be a clinically significant fact. A classical example quoted by Scandinavian research institute, Ivor Mjor etal is the amalgam marginal leakage. Comparasion of different silver alloy for marginal leakage shows one particular alloy to exhibit statistically more significant leakage. But in clinical situations, the rating does not suggest a replacement of the restoration i.e. considered as clinically acceptable. Thus the final verdict about any material can be given only by using the material in patient service or in a well controlled clinical trial..

Ironically there is a lack of emphasis on clinical trials not only in the masters disseratation topics but also in the material research general. The reasons stated are that they are unpredictable, time consuming, patients are unreliable and the variables that need to be controlled are numerous. The major hiccup of evoulation of material is the rapid profusion of material leading to recession of clinical studies. The evolution is so rapid that the results of the time consuming clinical trials done on product are generally published only when they have been superseded! Though this trend along with these inherent difficulties have discourged clinical studies, their credibility and validity when compared to in vitro studies cannot be overlooked.

Invitro Evaluation of Mechanical Properties -Strength:

This is usually evaluated by 3 point bending test or transverse test, diametral compression – tension test, biaxial flexural strength measured with piston on 3 ball method and recently the shear punch test. They are done in the universal testing machine in various loads. The shear punch test is used particularly to evaluate light cure composite resin, as it examines a specimen size below that of the diameter of the exit window of a normal light curing unit and also at a thickness when depth of cure is not a problem. These tests evaluate the collective complex

stresses, which mildly correlate to the biomechanics of oral environment. However strength of a material is dependent on the crack size present on the surface; so it can vary with the manipulative method of the material. In most of the above mentioned tests the crack or flaw size is not controlled. Hence the results are subjected to statistical scatter

Fracture Toughness:

These tests are generally independent or crack size. By using a 'V' shaped notched specimen beam in a transverse test, the flaw is controlled. Single edge or double edge notched beams can be used. Double cantilever beam (DCB) analysis is also used which includes compact tension, constant moment DCB and the chevron notch short bar test. The recent method is based on the linear elastic fracture mechanism. The fractured surface topography is studied by fracture surface analysis. This is also called fractography or fractology. The quantitative analysis is done from observing the fracture surface of the material by microscopes, Scanning Electron Microscope, Scanning tunneling Microscope and Atomic Force Microscope. Other recent test found in the review of literature is the double torsion test.

Hardness:

Three different concepts are there on which hardness testing is based upon- static indentation tests, dynamic rebound tests and scratch method test. The mostly used tests are the static indentation tests, which include the vicker's hardness test, knoop hardness test and nano indentation test. The micro hardness test uses 0.5 – 4kg of load for indentation whereas nano indentation uses a force in the order of 1 nanonewton.

Abrasion Resistance:

Tribiology is the study related to wear, friction and lubrication. Wear studies in vitro are based on sliding wear and abrasive wear. The abrasive wear test done are 2-body wear test and 3-body wear test. Abrasive slurries are used as the third body to produce abrasion. Another type of test is the erosive wear test, where the stream of abrasive strikes a surface. The sliding wear tests are non-impact sliding wear done by a pin-on-disk friction test and impact-sliding wear test. Three body wear test is done in an ACTA machine and the other equipments used in the wear studies are the masticatory simulator or chewing simulator and the tooth brush apparatus. Another interesting test is the oscillatory wear test where the specimen and the abrasives are placed in a capsule and oscillated.

Invitro Evaluation of Physical, Chemical and Thermal properties Adhesion:

The present studies concentrate on the bond strength of adhesive restorative materials and the dentin bonding agents. The best methods that have evolved over the years were intended to measure either shear bond strength or tensile bond strength. The tests are either uni axial tensile test or the planar interface shear bond test. The latest is the micro tensile test method has been developed to test the bond strength of small areas. The study of stress at the interface of the adhesive and the adherent is another important aspect of adhesion. The methods used here are the finite element analysis, which can calculate the three dimensional stress distribution during

various types of loading. The other method is fractography as explained earlier. The methods of studying the surface structure, sub surface structure and its elements analysis of restorative material, tooth and its interface are by scanning electron microscopy, transmission electron microscopy, confocal microscopy, augur spectroscopy and secondary ion mass spectrometry.

Polymerization Shrinkage:

A very recent study used a gas pycnometer to determine the volume of specimens prior to and after photo polymerization and from which the total volumetric shrinkage was determined. Another method for estimation of volumetric shrinkage is the modified version of ASTM method D792 'specific gravity and density of plastics by displacement'. The linear polymerization shrinkage is assessed by linometer, mercury dialatometer and latest is the use of a He-Ne scanning laser beam. The stress generated by polymerization shrinkage is also focal point for present research. Finite element analysis, photoelastic analysis, deflecting-disk method, Michelson interferometry apparatus are the various tests used to assess the stress generated.

Coefficient of thermal expansion:

This thermal property is evaluated with thermal mechanical analysis and differential scanning calorimetry.

Chemical Stability:

Simple dissolution tests are done to evaluate the solubility and water sorption of various materials.

Microleakage:

These studies are numerous and are all time favorites for a postgraduate dissertation. Traditional methods are dye penetration studies. A silver nitrate staining technique is used to evaluate leakage measured in graticular units (gn) under stereomicroscopy. Other methods include neutron penetration or neutron diffusion analysis and reverse diffusion analysis.

Color Stability:

The latest method of evaluating this property is with a photoelectric tristimulus colorimeter and research grade spectrophotometer. These equipments reportedly correlate well with the visual assessment of the color. From the above list it is apparent that most of the equipment needed are basically engineering equipments whose availability is difficult. One has to dependent on the operator, or educate oneself in bio medical engineering to understand the equipment, to interpret the gross results obtained and correlate to delicate clinical behavior. One has to know the precision and sensitivity of the equipment influence of the sample dimension and preparation on the equipment. Beyond all these constraints, the question " if " is still present – is it clinically relevant? Moreover the clinical behavior of a restorative material is actually influenced by too many properties of the material – not just the single property. A classical example is the wear of the material in the mouth. This is influenced by abrasion resistance, hardness, chemical

solubility, to mention a few. Studying just one property by sophisticated gadgets overcoming obstacles will eventually just provide one piece of huge clinical puzzle leaving the research open and unsolved. Therefore a collective assessment of the comprehensive behavior of a material through a clinical study will be the best solution to certify the long term suitability of the material in patient service.

Clinical Behavior of the Restorative Materials and their Assessment in a Clinical Study:

American dental association has recommended assessing the following behaviors of posterior restorative material in a clinical study.

1. Loss of anatomic form
2. Marginal degradation
3. Color matching ability
4. Interfacial Staining
5. Surface roughness
6. Secondary caries

Evaluating these behaviors requires a definite set of criteria to rate the restoration as clinically suitable or not suitable. This is called rating system. One of the popular rating system is the Ryge criterion, which has been accepted by the Federation Dentaire International (FDA) and the United States Public Health Services (USPHS). This is an ordinal kind of rating which means presence or absence a definite criteria is assessed in a restoration and bipolar decision is taken by asking only two question of 'Yes' of 'No' and depending on the answer, the rating progresses to the next degree of severity of the same criteria. The ultimate decision is to decide whether the restoration is clinically acceptable or not acceptable. If not acceptable, a decision has to be taken whether to replace or to replace later. The ranking that are used in the Ryge criteria in the descending order is Alfa (A), Bravo(B), Charile (C) and Delta(D). The rankings of A, B, C and D differ in their meaning of 'replace or not to replace' with different behavior tested. When assessing two or three behaviors of the restoration together, with Ryge criteria, the restoration assumes the rank of that behavior which has the poor ranking. For example while assessing loss of anatomic form , marginal integrity and color matching of the composite resin restoration, if color matching has obtained a low rank of Charlie, even though loss of anatomic form has obtained a Alfa rating, the restoration is branded as clinically not acceptable – needs replacement. Another system used by the Canadian Dental Association is based on two clinical qualities viz; satisfactory and not acceptable. The satisfactory restorations are subdivided into clinically ideal – Romeo (R), clinically satisfactory – Sierra (S). The not acceptable restorations are divided into restorations requiring replacement later – Tango (T) and those requiring replacement immediately – Victor (V). The clinical evaluation can be done either by direct method or by indirect method. The direct method is done by assessing the restorations in the patient's mouth by a mirror and probe method. The indirect method is done by evaluating the study cases or the photographs, transparencies of the restorations that are replica of the restoration.Just like calibrating and setting an equipment or instrument to obtain a precise result in an invitro study, the evaluators in the clinical study have to be trained with regard to what to assess and how to assess in a restoration. This training aims to obtain at least 85% of inter

evaluator agreement in their observations. Disagreement in the findings between two evaluators less than this level disqualifies the study.

Clinical Assessment of Loss of Anatomic Form:

By Direct Method:

Loss of Anatomic Form is intended for evaluation of the loss of substance as a function of time of service of restorative materials, particularly those that are likely to dissolve or abrade away. This is seen as an under contouring of the restoration or a step defect may be detected with the probe. A metal guide with progressive step is provided to the evaluator to compare the tactile sense of catch with the restoration and the guide to rank it accordingly. The restoration is checked by visual inspection whether the material appeared to be continuous with the normal anatomic form which it was intended to represent or under contoured. If the answer is no, then the rating is Alfa, the code is A. If the answer is yes, the next degree of damage i.e. is the material missing so lost as to expose dentine or base? If the answer is no, then the rating is Bravo and the code is B. If yes, the base/dentin is exposed then the rating is Charlie, the code is C. In this evaluation Alfa and Bravo are clinically acceptable situations and Charlie requires a replacement of the restoration.

By Indirect Method:

The best method of detecting wear rate of posterior composite resin as prescribed by ADA guideline is the indirect method of analyzing the restoration by making quadrant study casts at periodic intervals and subsequently ranking them. The precise detection of the loss of material in a composite resin restoration is difficult in direct method, as the refractive index of the tooth and the restoration are similar and also there is a tendency of the cavosurface margin getting rounded. Therefore the study casts are more widely used in composite resin restorations. The casts can be evaluated by direct observation or by studying under scanning electron microscope for early loss of material.

Clinical Assessment of Marginal Degradation By Direct Method:

Marginal integrity is a characteristic exhibiting loss of restorative material at the margins, which may be attributed to too many properties. The restoration is probed at the margin to feel a catch. However the evaluation does not begin here. If a catch is present on inspection, a crevice is looked for. The ranking starts only now with bipolar decisions. If there is no crevice detected, the rating is Alfa. If the crevice is seen, the next degree of severity is assessed i.e. the exposure of base / dentin. If the answer is no, then the rating is Bravo and if the answer is yes, then the restoration is evaluated for fracture/missing restoration. If it is not so, the rating is Charlie and if the restoration is fractured or missing, then the rating is Delta. It is imperative to note here that the Alfa and Bravo rating certifies the restoration is acceptable and the Charlie and Delta rating denotes a need to replace the restoration.

By Indirect Method:

The best method for assessing marginal integrity in silver amalgam restoration by indirect method is a black and white photograph. The reason stated is the better contrast exhibited in these photograph enables a sharper identification of the defect. The photographs are ranked in 1 – 8 scale. The photographs exhibiting good marginal integrity and poor marginal integrity are divided at large into two groups. Each group is further divided with same criteria till the sub groups are eight in number. These ranking is further subjected to statistical evaluation. Mahler et al in their study have ranked all the photographs between two standard, one with very good marginal integrity and one with worst integrity. Quadrant study casts obtained at regular intervals and analyzed under scanning electron microscopy ,best study the marginal degradation of composite resin.

Clinical Assessment of Color Matching and Interfacial Staining

By Indirect Method:

Color matching is tested for the esthetic restorative material and the restoration is inspected at a distance of 18 inches, which is a conversational distance. A mild mismatch in color or a lack of translucency is assessed and if it is not present, the rating is Alfa. If there is such a mismatch, the next question is if it is beyond the normal range of color. If it is not so, the rating is Bravo and if it is so, the rating is Charlie. Interfacial staining is detected with a mirror in the posterior teeth and without a mirror at 18 inches distance for anterior teeth. On inspection, if marginal stain is not present, the rating is Alfa and if the staining is present, the assessment escalates to the higher degree of staining i.e. if the staining is penetrating towards the pulpal aspect, the rating of Bravo and Charlie is given accordingly.

By Indirect Method:

Though photographs have been used in the indirect assessment of the above behavior, an element of bias and variation is always present which reemphasizes the importance of the double blind study. The fact that photographs can be technique sensitive and dependent on the technicians should be borne in mind.

Clinical Assessment of Surface Roughness

The restoration surface is probed and compared with a glass slab of increasing degree of roughness and ranked accordingly in the direct method. In the indirect method a profilometry method is used to assess the surface irregularity

Clinical Assessment of Secondary Caries

Being a biological failure, the assessment with mirror and probe is strict with only criteria i.e. caries contiguous with the margin of the restoration. If the answer is no, the rating is Alfa and the restoration is acceptable. If the answer is yes, the rating is Bravo and the situation is unacceptable needing immediate repair or replacement of the restoration.The indirect method of using radiograph can be slightly dubious because of the technique sensitivity and also inter evaluator variation. The assessment of plaque deposition over the restoration with plaque

disclosing solution is an indirect correlation of occurrence of secondary caries in the restorations.The simplicity and the logic inherent in the clinical evaluation of the restorative materials is so appealing that adopting more of such studies should be extremely beneficial to this field.The data collected thus from clinical observation and ranking, or from case records, study casts or photographs and from the lab equipment and instruments have to be quantified and generalized to the population at large by statistical evaluations.

Method of Statistical Analysis

The method of the statistical analysis to be undertaken should be discussed with the statistician before commencing the study. The first step in the analysis will be to arrive at one numeric value from all values obtained from each group, for comparison and correlation of datas. This is known as the average or measure of central tendency. Among the various measures of central tendency, mean is the one that is frequently used in restorative dentistry studies. Next step will be to find out the extremes of the values and the scatter of other values around the average. This is known as measure of dispersion. Among the different measures of dispersion, the standard deviation is one that is frequently used. The mean with the standard deviation will give the full profile of any study. To authenticate that the values obtained is not by chance and to extend our results beyond the confines of the sample size to the population it represents, we need to find out the probability distribution of P value. To find out the P value, first we need to carry out certain tests of significance. When all the values are symmetrically distributed around the mean, which when plotted in the form of a graph will appear bell shaped known as normal distribution. For values of normal distribution and for the quantitative study, parametric tests of significance like student's t test, one way analysis of variance etc., are done. When the value does not confine to normal distribution or for qualitative analysis, non – parametric tests like Wilcoxan rank test, Kurskal-wellis analysis etc., are done. The values calculated by these test of significance (t-value, f-value etc.,)when compared with the mathematical table for the same test will give us the p value as 0.2, 0.1, 0.5. 0.01 etc., - When the p value is less than 0.05 the groups are considered to be significantly different. This indicates that the probability of getting a difference purely by chance is less than 5%. Thus the study can state that it is statistically significant.

Statistical Significance Vs Clinical Significance

Statistical significance means that there is a definite difference between the groups studied and that difference is obtained by means of intervention only and not by means of chance. In other words it just means that there is quantitative difference between the groups. In clinical sciences what are needed are the quality and not the quantity! Clinical significance denotes the qualitative difference. Thus only clinical studies can be the final verdict for stating that the study is of clinical significance.

Conclusion

From the above discussion, it is apparent that there is a rapid research activity in the laboratory than clinics. Though less relevant clinically, lab test are more alluring because of quick results. But the availability of sophisticated equipment and finance is the main constraint experienced in our country. However the abundance of clinical material and subjects in our country, provide a

rich forum for clinical studies. This again is impossible unless we take a strong initiative to cultivate the habit of maintaining comprehensive patient records both in the teaching institutes and the private clinics. The record room can become a vast repository of information and the patient's mouth can be become the labs. The only deterrent factor in clinical study is the time involved. Therefore recent laboratory studies are aiming at development of equipments that simulate oral environment and mastication. Progress is also towards development of three dimensional analysis models like finite element analysis. However the basis of any simulated model depends upon available data about fundamental tissues. Until and unless fundamental research improves, which can provide these data, the stimulated models will be yet another methodology with little clinical relevance. As these researches require stronger economy and sophisticated technology, they can be institutional or organizational projects rather than individual projects. The postgraduate dissertation projects can be done as part of the institutional project benefiting both the individual and the institute. The postgraduates can effectively plan a clinical study within the limited time frame, or conduct a clinically relevant laboratory study or combine a clinical and laboratory study for better correlation.The amount of energy, money and the time spent by our postgraduates and fraternity members towards research has not made much contribution towards the improvement of restorative dentistry world wide. They remain merely as exercises in futility. In order to make a mark in the arena of International research, to contribute constructively to the fraternity and to make every effort taken worthy, a willful and prudent change is required in thinking and action.

Suggested Reading

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2. A Practical approach to PG dissertation. R.Raveendran and B.Gitanjali, Jaypee brothers, India.
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