

ZEST DENTAL SOLUTIONS WHITE PAPER: Prosthetic Materials & Guidelines for Use

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Abstract & Summary:

Restoring patients with full-arch fixed restorations requires careful planning and execution of clinical procedures followed by a detailed understanding of the appropriate prosthetic material employed. LOCATOR FIXED is a paradigm shift in full-arch implantology because it utilizes a snap-in housing and insert to securely attach the prosthesis to LOCATOR Abutments. Because there is no screw-channel in combination with the unique design of LOCATOR FIXED, clinicians and technicians can employ techniques to minimize surgical invasiveness, minimize complexity of clinical and technical procedures, simplifying long-term maintenance, and minimizing the number of clinical visits while performing the procedure.

To ensure best practices for LOCATOR FIXED prosthetics, this whitepaper aims to describe material properties for the restorative choices employed for LOCATOR FIXED. Additionally, measurable testing parameters evaluating prosthetic materials, design of the prosthesis, cantilever lengths, and luting protocols to attach Housings to the prosthesis will be discussed.

Summary of Clinical Recommendations:

- Prosthetic options for LOCATOR FIXED include high-strength or esthetic zirconia; denture teeth and PMMA on a metal frame (traditional analog prosthesis); monolithic PMMA with a metal frame (milled); monolithic PMMA without a metal frame (milled); monolithic resin photopolymer materials (3D printed); nanoceramic hybrid resin photopolymer materials (3D printed); and nanoceramic/PMMA hybrid (milled)
- There is no "ideal material" for LOCATOR FIXED, the best material is one that balances out strength, esthetics, and function and the decision to choose one material over another should be made with a careful decision-making procedure for each patient
- Zirconia-based restorations are considered the strongest, followed by PMMA with a metal substructure, followed by monolithic resin base restorations
- Restoring patients with prosthetics that have reinforcement substructure is recommended for definitive prosthetics and those patients with higher bite strength
- Patients who exhibit signs of bruxism should have additional prosthetic reinforcement such as increasing prosthesis thickness or addition of a reinforcement substructure
- Luting FIXED Housings using resin-cement (CEMEZ) or composite-resin (LOCATOR CHAIRSIDE/APM) is recommended for optimal bonding to prosthetics with metal bases
- LOCATOR CHAIRSIDE APM can be reliability used to lute LOCATOR FIXED prosthetics that are fabricated from resin-based materials such as PMMA or photopolymers
- Chairside processing techniques are recommended for LOCATOR FIXED prosthetics
- At least 4 implants required per arch; in some situations, more than 4 implants per arch may be preferred for prosthetic strength and long-term maintenance
- Implants should be distributed evenly across the arch; ideal implant position for LOCATOR FIXED is two implants in posterior/molar region on each side of the arch and two to four implants in the anterior/interformal region of the arch
- Recommendations for cantilever based upon A/P spread are maximum values and do not mean the prosthesis cantilever should be set to those values as a "baseline"
- LOCATOR abutments should be as parallel as possible prosthetics with divergent abutments may be more difficult to seat and have a higher chance of dislodgement of the prosthesis
- LOCATOR FIXED requires at least 9-11mm of vertical restorative space; more than 9-11mm is recommended in all resin prosthetics and patients with higher bite force
- A minimum of 3mm of prosthetic thickness should surround the LOCATOR FIXED Housings in all dimensions; resin-based prosthetics require additional thickness for strength
- A substructure is recommended for interim and/or definitive prosthetics when restorative space or thickness is minimal

Introduction

Dental clinicians and technicians are often faced with challenging decisions treating patients that are edentulous or present with a failing dentition who request treatment. Patients are often faced with decisions related to the type of prosthetic option: fixed or removable. Patients who seek fixed restorations typically seek a more "permanent" feeling to their restoration, something that is non-removable by the patient and only by the clinician.

Rehabilitation of the dentition with fixed restorations with dental implants is a procedure that is well-adopted and shown to be successful long-term.¹⁻² Patients who receive fixed rehabilitations report high levels of satisfaction with esthetics, speech, long-term maintenance, hygiene, and function.³⁻⁴ While complication rates with fixed full-arch restorations are lower than that of removable restorations, complications for fixed full-arch restorations remains a clinical challenge.5-6

Complications can be segmented into two categories: surgical or prosthetic complications. Surgical complications for fixed rehabilitation include: infection, lack of osseointegration, early failure, late failure, placement/iatrogenic errors, bleeding, lack of hemostasis, and anatomical concerns.7 Commonly reported prosthetic complications include: loss of retention, loosening of prosthetic/abutment screws, excessive occlusal surface wear, fracture and/or chipping of prosthesis, implant fracture, abutment fracture, screw-access material lost, tooth wear, prosthesis remake, substructure fracture, and abutment screw fracture.⁸⁻⁹ Surgical complications are typically encountered earlier throughout treatment and are often less visible to the patient, prosthetic complications tend to occur over time and are often discovered by the patient.

While all technical complications are important to minimize, the more acute complications such as prosthetic fracture or loss of retention may be of the most interest to clinicians who utilize LOCATOR FIXED to rehabilitate patients. Clinicians and technicians who fabricate restorations rely upon guidance on prosthetic design and choice of materials used for fixed full-arch restorations.

Prosthetic material options may vary based upon indication and business model of the practice or practices. In some scenarios, optimum flexibility and lower cost prosthetic materials may be advantageous to permit a recurring revenue cycle of prosthetic replacement. Further, in those same business models, exact digital reproduction outweighs the factor of extreme prosthetic strength. In other practice models, the clinician may weigh the lower strength of some prosthetics versus more convenience and lower costs when needing to be remade.

In this whitepaper, we aim to evaluate prosthetic factors related to LOCATOR FIXED. We will review prosthetic options available for LOCATOR FIXED, their composition and biocompatibility, and manufacturing methods. Further, we will perform a technical analysis of cantilever design, material strength, and bonding strength of various luting materials to attach housings to the prosthesis. Importantly, we will discuss how the technical analysis has implications for clinicians and technicians for prosthetic material choices for LOCATOR FIXED prosthetics. Lastly, we aim to outline clinically relevant recommendations based upon the testing parameters established in this whitepaper.

LOCATOR FIXED[®]

A new fixed full-arch system was introduced by Zest Dental Solutions - LOCATOR FIXED®. By using the same abutment as used in a removable overdenture, LOCATOR FIXED allows the clinician to easily and quickly convert from a removable overdenture into a full-arch fixed prosthesis simply by changing housings and inserts.10 LOCATOR FIXED utilizes

a unique housing and insert pair that combines a super-strong and rigid snap-in style retentive mechanism together with a uniquely designed titanium housing that results in a prosthesis that is firmly attached to implants.

Since the prosthesis is fabricated without screw channels that can weaken a prosthesis, patients can be restored with less restorative space requirements compared to traditional screw-retained

bridges. Additionally, because of the less restorative space required, less invasive surgical techniques may be utilized, simplifying surgical placement for even challenging patient cases.

Hygiene is also enhanced as the snap-in-and-out mechanism allows for fixed function; however, rather than screw-retained bridges that take 20 to 30 minutes of clinician time to remove, removal of the LOCATOR FIXED prosthesis is performed quickly by clinician and/or a dental auxiliary using a specialized removal tool. Clinical procedures of LOCATOR FIXED are fundamentally the same as that of overdentures including from the same impression techniques as overdentures to the same procedures to attach (pick-up) housings to the prosthesis.

Because clinicians can use similar clinical workflows as that of removable overdentures, LOCATOR FIXED helps dramatically enhance simplicity of performing full-arch fixed procedures compared to that of conventional screw-retained restorations. The combination of the simplicity and efficiency allows the clinician to keep the total cost of the procedure substantially lower than

that of screw-retained restorations. The prosthesis is fixed for the patient and is removable only by the clinician or technician using specialized tools provided by Zest Dental Solutions.

The LOCATOR FIXED prosthesis affords flexibility, affordability, and simplicity to clinicians that is unique in implant dentistry. It is important to understand, however, ensuring the appropriate prosthesis material and technique is chosen for each patient to ensure long-term success.

LOCATOR FIXED® Patient Comfort

Comfortable:

- ← Less time intensive chairside procedures = shorter patient visits and greater patient comfort
- \checkmark No cylinders to prep or screw access channels to fill with gutta percha or composite

Easier In-Office Maintenance for Patient:

← Maintenance and FIXED Insert replacements done extra-orally

Prosthetic Materials Options and Seeking the "Ideal" Material

Prosthetic choice typically depends upon clinician preferences, number of implants, location of implants, interocclusal space, restorative space, prosthesis height limitations, clinical technique, opposing dentition, parafunction, weight, and esthetics.

Materials commonly used in full-arch fixed restorations include traditionally fabricated denture teeth and poly(methyl) methacrylate (PMMA); digitally fabricated monolithic PMMA (reductively manufactured / milled); digitally fabricated photo-polymer methacrylate materials (additively manufactured / 3D printed); nano-ceramic/PMMA hybrid (milled), titanium, and zirconia.

(3D Printed)

(3D Printed)

Milled Monolithic PMMA Teeth & Base with Layered Pink Composite

The quest for an "ideal dental material" remains elusive and defining what properties construe ideal properties remains a challenge. For full-arch fixed restorations, an ideal material would need to be biocompatible, easy to fabricate and deliver, not dislodge during function, resist cracking and/or fracture, and affordable to produce. Some consider that a single restorative material serving all purposes including for all patients wearing full-arch restorations does not exist.¹¹

The choice of materials and design of the prosthesis should be made by clinicians and technicians collectively, balancing out clinical and technical factors that are unique for that patient. Key to guiding the clinicians is understanding what factors go into this choice and how they impact the functionality of the fixed full-arch rehabilitation.

Material Composition & Biocompatibility

Recognizing the proper use of dental materials for restoration of a full-arch prosthesis requires an understanding of the composition of the materials. The use of biocompatible dental materials is a critical component of rehabilitation of patients. A dental material is considered biocompatible when it can exist within the oral cavity in harmony without causing adverse reactions.¹¹

Alloys are used routinely in full-arch fixed prosthetics both as a reinforcement framework and an

abutment interface. Cobalt chrome and titanium are two commonly used alloys; both exhibit excellent biomechanical and biocompatibility properties.12 Cobalt chrome has long been used in clinical practice for removable partial denture frameworks and dental implant substructures. Dental implants and prosthetics utilize 4 variations of commercially pure titanium from cp grade I to cp grade IV and two variations of titanium alloy, grade 5 and grade 6.13 Reports of irritation, sensitization, or allergic

response with cobalt chrome, titanium, or titanium alloys are rare and the materials has been used successfully in dental implantology for many years.¹⁴⁻¹⁵

Polymers such as poly(methyl) methacrylate (PMMA) have a long track record of use in clinical dentistry. PMMA materials have historically been optimal for use with denture prosthetics because of its ease of processing, natural colorization, sufficient mechanical properties, affordability, and low toxicity.¹⁶

PMMA can be produced utilizing analog methods such as combining heat-curing with compression molds and those that involve a chemical process such as a liquid pour or microwave curing technique. While these traditionally produced materials have been shown to be stable over time, the procedure to fabricate often leeches compounds in the fabrication process in the form

of free monomers and methacrylate that dissipates within the first 24 hours after initial cure. Some materials utilize fillers such as nanocomposites, glass, fiber, and ceramics as a stabilizer and reinforcing method for PMMA. Water and biofilm tend to seep into the PMMA material, potentially altering physical properties over time.¹⁶ While these factors are important to consider, PMMA based prosthetics are widely considered biocompatible with physical properties that are clinically acceptable for full-arch restorations for patients.

Digital production methods can greatly enhance production and ease of fabrication. Additive manufacturing processes, such as employed with 3D printing, or reductive manufacturing processes, such as employed with milling permit the use to employ computer aided design and

manufacturing (CAD/CAM) techniques to fabricate the restoration. PMMA polymer discs formed under high pressure may decrease water sorption and increase physical properties.¹⁷ Additively produced polymer restorations are similar to traditional PMMA, however, they utilize a photopolymer to initiate the polymerization process and produces a prosthesis that still has free acrylates on the surface. After the printing procedure, the materials require rinsing in a series of alcohol baths and photocuring under heat and UV light to enhance biocompatibility and

physical properties. Additively produced prosthetics tend to have physical properties that are similar to traditionally fabricated PMMA prosthetics, whereas reductively produced prosthetics have physical properties that exceed that of traditionally fabricated restorations.¹⁸

Ceramics, notably zirconia-based, remain a popular restorative choice for restoration of fullarches cases. Zirconia oxide has high resistance to corrosion, moderate weight, high strength, low plaque absorption, and esthetics. Zirconia oxide physical properties can be enhanced by the additives such as yttria, alumina, and magnesium. Zirconia based restorations in the fully-sintered state are considered highly biocompatible.¹⁹ Zirconia based restorations are produced by a

CAD/CAM procedure that involves machining of the zirconia in a chalky "green-state" that is easier to machine. After milling, the zirconia restoration is sintered in a furnace until it reaches a high temperature (approx. 1500 \degree C) for a prolonged period (approx. 7-14 hours). While the final restoration has high strength properties, the process to fabricate zirconia is more labor intensive, more expensive, and typically more difficult to produce than PMMA or alloy-based restorations.

Physical Properties of Materials

The best material for fixed full-arch prosthetics should be strong enough to resist deformation, fracture, and displacement in function. Understanding the physical properties of the restorative material is an important factor of knowing which material to choose for LOCATOR FIXED cases.

Material testing is well-established in the dental literature.²⁰ Materials are tested with a variety of tests including fracture toughness, tensile strength, compressive strength, fatigue, shear, flexural modulus, and flexural strength. Most dental prosthetic materials fit within a defined range of measurable physical properties. We will aim to evaluate several physical properties and evaluate the impact upon a LOCATOR FIXED case.

Strength values have been reported in the literature for various materials that are used in

LOCATOR FIXED prosthetics. Zirconia is reported as typically having the highest flexural strength of all prosthetics, followed by titanium, fiber-composite materials, lastly PMMA-based and 3D printed resins.*

While analog produced restorations continue to be a sizable portion of the LOCATOR FIXED prosthetics produced, digitally produced restorations are growing in popularity as laboratories and clinicians embrace digital technology. Digitally produced resin restorations, on average, have higher strength than analog prosthetics.17 CAD/CAM prosthetics, notably milled PMMA, utilize a denser resin material that is industrially produced under highpressure and controlled environments that produce higher strength prosthetics.

Fracture toughness is a critical property, denoting a material's capacity to thwart crack growth, which might initiate from small surface or internal defects. Acrylic resins used in denture materials often incorporate impact resistance modifiers like elastomers, creating core-shell-

bead polymers. These polymers feature a rubbery core encased within a hardened PMMA shell. Upon interaction with methyl methacrylate (MMA) liquid, the matrix swells encapsulating the core thereby diminishing crack propagation through stress peak mitigation and force redistribution. This enhancement significantly reduces the likelihood of denture base failure or fracture.²¹

To evaluate material fracture toughness, a classic 3-point fracture test have shown to be the better testing method when compared to alternative methods like pendulum testing.²² Fracture toughness is usually expressed in the term Kmax which is the maximum stress intensity factor experienced by a material before fracture occurs. This value is an important parameter in fatigue crack growth studies, where it helps in understanding the highest stress intensity that a material can withstand during cyclic loading without leading to immediate crack growth or failure. The difference between Kmax and the threshold stress intensity factor KTh (below which crack growth does not occur) is crucial for predicting the lifetime of materials under cyclic loading conditions.

Work of fracture (WF) is the total energy absorbed by a material per unit area of crack surface created during fracture.²³ WF encompasses not only the initiation of crack growth but also its propagation until final failure; this energy includes both elastic and plastic deformation energies. The work of fracture provides a comprehensive measure of a material's toughness and its ability to withstand mechanical loading without catastrophic failure.²⁴ Imagine you have a chocolate bar with a small crack in it. WF is best thought of the analog that the effort needed to break the chocolate bar starting from that crack while including all the energy you put into bending and snapping the bar until it breaks apart. The effort/energy includes both stretching (elastic deformation) and permanent bending or distortion (plastic deformation) of the material around the crack until it finally breaks. Ultimately, work of fracture is about how much energy a material can soak up before it splits into pieces.

WF further focuses on the energy absorption capacity of a material during fracture, while Kmax focuses on the maximum stress intensity at the crack tip that a material can withstand before crack propagation occurs. Now, think of the chocolate bar again, but this time focus on the moment right before it starts to break. "Kmax" is like measuring how much pressure you're applying with your fingers right at the edges of the crack, just before the chocolate snaps. It's a way to quantify the maximum "stress" or force concentration at the tip of the crack right before the material gives way and the crack grows. The higher the fracture strength, the stronger the force you're applying at that critical moment before the break occurs.

Evaluating Prosthetic Strength for LOCATOR FIXED

While material properties for various materials have been established, the relationship of the choice of material for the LOCATOR FIXED prosthesis affects long-term success. Importantly, a prosthesis can function ideally in a controlled environment, however, when placed in challenging environments such as the oral cavity, additional challenges present.

Human bite strength has been measured and is estimated to be for 330N for females and 487N for males with a maximum biting force of 597N for females and 847N for males.²⁵⁻²⁸ Parafunctional forces increase the biting force dramatically; patients exhibiting bruxism have been reported to have double the amount of bite force as those who do not.²⁹ As cantilever length is increased, compressive loads of 2 or 3 times the value of the occlusal load may occur on the most distal implant in the arch and patients with increased number of occlusal contacting teeth proportionately increase the strength of biting force.30-31

To properly evaluate the material properties for use in clinical practice, an evaluation of the strength of the materials is required. Estimating occlusal forces and functional needs shall be evaluated to determine forces required to displace/fracture a LOCATOR FIXED prosthesis.

Methodology

Prosthetic material groups were identified based upon feedback to represent a relevant picture of the prosthetic materials and techniques utilized for LOCATOR FIXED prosthetics. Samples of each of the groups were produced at dental laboratories with standardized production and

technical procedures utilized in their laboratories. Groups C and P were produced using analog methods. Groups PMD, PMI, OnXT2, SRHI, SRAX, DCA, AVA, and L were produced using digital methods.

A master cast was designed with 4 LOCATOR abutments in positions replicating dental arch positions corresponding to teeth #20, 22, 27, 29. An anatomically-correct prosthesis was designed and fabricated based upon prosthodontics principles and design parameters.32

The master cast and prosthesis were digitized using an optical desktop scanner. A digital prosthesis was designed to match the master prosthesis design using dental software (exocad, exocad GMBH) and files were exported and sent to the corresponding laboratories for production of the samples. A total of 5 samples of each test group were produced.

Housings were attached using a luting process to the prosthetics using a dual-cure resin-composite (LOCATOR CHAIRSIDE Attachment Processing Material, Zest Dental Solutions) and a standardized jig to ensure housings were placed evenly in the prepared recesses.

A MTS Electrodynamic Test Systems (Eden Prairie, Minnesota) was used to apply a simulated bite force load to each specimen in the identical position on each sample in the first molar position using a three-point bending mode at a crosshead speed of 0.50mm/min. Values were measured and recorded in newtons (N).

Results & Clinical Implications

The results of the simulated biting force reveal a mean 1333N for Group C, 1080N for Group AVA, 905N for ONXT2, 532N for Group P, 522N for Group PM, 634N for Group PMI, 605N for Group SRHI, 452N for Group DCA, 514N for Group SRAX, and 542N for Group L.

When separating each group into separate categories as a factor of prosthetic design – 1206N for resin prosthetics with a reinforcement substructure (teal), 905N for the nanoceramic hybrid

resin prosthetics (dark teal), 578N for resinbased prosthetics produced using a milling procedure (neon blue darker), 532N for resinbased prosthetics without a reinforcement substructure (neon blue lighter), and 528N for both high-impact and the standard photopolymer resin prosthetics.*

Analyzing the reported values in conjunction with reported human bite strength, all the prosthetics tested would fall within the average female and male biting force values. Maximum female and male biting forces, however, exceed the fracture force determined for groups P, PMD, DCA, SRAX, and L.

In this evaluation, all prosthetics tested reported simulated chewing forces that would withstand average biting forces applied to the prosthesis. When a higher level of simulated biting force is applied, however, prosthetics with substructures have sufficient physical properties to resist fracture. Interestingly, the SprintRay OnX Tough 2 photopolymer without a substructure reported resistance to high fracture loads. While the bite forces reported in this paper represent average across multiple references, the clinical implication of this finding is clinically relevant.

Clinical Recommendations:

- Monolithic resin prosthetics are adequate for restorations where the patient will be wearing the prosthesis for shorter periods of time or those patients with lower bite strength
- Utilization of a reinforcement substructure is recommended for definitive prosthetics / long-term function and those with higher bite strength
- Monolithic nanoceramic photopolymer prosthetics are suitable for short and potentially longer-term LOCATOR FIXED prostheses
- Patients who exhibit signs of bruxism should have additional prosthetic reinforcement

Evaluating Housing-Luting Material Bond

Zest Dental Solutions recommends attaching the LOCATOR FIXED Housing to the prosthesis using a luting material. The luting material attaches to the Housing and prosthesis using one of two methods, 1) mechanical undercuts or 2) a chemical bonding mechanism. The ideal material used for this purpose should be easy to dispense and use, have low shrinkage, no odor, and have a total working time that is between 2-5 min.

A clinician or technician can employ one of two possible methods for attaching LOCATOR FIXED Housings to the prosthesis. The first technique is performed in the laboratory, attaching the housings to the prosthesis on a stone cast/model. The second technique is performed clinically, attaching the housing to the prosthesis intraorally. The goal of this procedure is to firmly attach the denture attachment housing to the prosthesis to ensure that during insertion, removal, and laboratory procedures, the housing remains embedded in the prosthesis without dislodging. Further, the housing should remain within the prosthesis during masticatory function, minimizing patient reported looseness and/or technical complications over time.

Since auto-polymerizing acrylic resins (aka "cold-cure PMMA") use the same generalized chemistry as denture acrylics in the laboratory, the two materials will share covalent bonds and become chemically bonded.³³ The material is inexpensive, easy to use, and is predictable. While this classic approach has been long advocated for by many, some express concern with utilizing auto polymerizing resins in the mouth including shrinkage, smell, burning sensation, and potential allergic reactions. Auto polymerizing acrylic resin has been shown to have volumetric shrinking between 6-15%.³⁴ Shrinkage of the luting material can increase the chances of the prosthesis engaging deeper undercuts around the LOCATOR abutment or implant surfaces, potentially even locking in the prosthesis so the clinician or technician has difficulty removing the prosthesis.

Alternatives to PMMA include resin-cements and composite-resin materials. These materials have numerous advantages over PMMA including easier handling, dual-cure with light curing option for faster procedures, odorless, minimal burning or taste alteration, low curing temperature, and low shrinkage. The shrinkage of composite-resin materials has been shown to be substantially

less than that of acrylic resins; limiting the risk of locking in undercuts during attachment processing procedures.³⁵ Evaluations of luting agents historically have shown that luting housings using traditional PMMA has higher bonding strength compared to resin-cements and composite-resin materials.³⁶⁻³⁷ Clinicians are requesting additional guidance on luting strategies for LOCATOR FIXED housings to the prosthesis; an evaluation of luting strength of FIXED housings to simulated prostheses is warranted.

Methodology

Prosthetic material groups were grouped into two major categories: metal and resin. Each of the major categories is separated into subcategories, representing the luting material chosen including auto-polymerizing acrylic resin (PMMA), resin-cement (CEMEZ), and composite-resin (LOCATOR CHAIRSIDE APM).

A master digital computer aided design (CAD) file was created with a base and test apparatus. The base is designed with a mechanism to attach to an Instron testing machine on the inferior

portion of the base. On the superior side, a well is prepared in the shape of the geometry representing a LOCATOR Scan Body, simulating the intaglio of a LOCATOR FIXED prosthesis. The test apparatus is designed as a rod mechanism that permits attaching to an Instron testing machine on one end. On the opposite, the geometry of the LOCATOR FIXED housing is prepared. The test apparatus is machined out of a single rod of titanium alloy. The base is fabricated out of the designated test group material. 5 bases and 5 test apparatuses respectively were fabricated to permit 5 pull tests per subgroup (N=5).

The test apparatus was attached using a luting process to the prosthetics

using the designated luting material in the subgroup following manufacturer's recommendations outlined in the instructions for use (IFU). For PMMA groups, the base was air dried and 2mL of powder and 2mL of liquid was mixed for 30 seconds, then poured into the base. A small amount of mixed resin was applied to the test apparatus and seated into the base. For the CEM EZ groups, the base was air abraded using 27µm Aluminum Oxide (Danville Materials / Zest Dental Solutions), air dried, Z-Bond (Danville Materials / Zest Dental Solutions) was applied to the base and evaporated using a gentle air stream. A tip was applied to the CEM EZ and resin-cement injected into the base recess and a small amount placed around the test apparatus, then seated. For the Chairside APM groups, the base was air dried, a tip placed onto the syringe, and injected into the base recess, a small amount applied to the test apparatus, and seated. A standardized jig to ensure each test apparatus was attached in the prepared recesses the same for each subgroup.

A MTS Electrodynamic Test Systems (Eden Prairie, Minnesota) was used to apply a pull force to the test apparatus. The base was firmly attached to the inferior portion of the machine. A separation force of each specimen using a pull test was performed at a crosshead speed of 0.50mm/min. Values were measured and recorded in newtons (N).

Results & Clinical Implications

The results of the 5 simulated debonding forces per group were averaged and reported as a single value in the table below. The strongest bond strength results are achieved with titanium

bases in combination with resincement with the lowest results found with PMMA.*

Separating each group into separate base material categories the overall highest resistance to

debonding forces occurs when using the metal base material in combination with resin-cement/CEMEZ luting material. Housing bond strength using compositeresin/LOCATOR CHAIRSIDE APM was lower than that of the resin-cement, however, only but a small amount. Likely the reason for this is due to the surface treatment (air abrasion and primer/Z-Bond) used during luting procedures. The use of PMMA material had a substantially lower bonding strength to the metal base than the other materials used for luting. This was interesting as historically PMMA has long been

advocated for luting housings, however, at this time, the results show the forces to debond are below the threshold of average chewing forces and could increase the risk of debonding during prosthesis removal.*

Resin base material represented an overall lower resistance to debonding forces of LOCATOR FIXED Housings. The PMMA luting material represented the highest bond strength and the resin-

cement had the lowest bond strength. Resincomposite/Chairside APM bond strength was found to be like that of the PMMA with the lowest bond strength found in the resin-cement/CEM EZ subgroups. Interestingly, the results are somewhat the opposite results found within the metal base groups where the PMMA had the lowest and the resincement the highest bond strength. A possible reason for this finding is that the chemistry of the PMMA luting material is more like that of the resin base than that of the metal base enhancing bond of those materials to the resin base.

When evaluating the forces required to debond the housings and comparing them to the forces required to fracture in a purely vertical dimension such as prosthetic removal, housings will remain bonded in test groups in the metal or resin even when forces approach the fracture strength of the materials for all groups except PMMA. The bond of resin-cement to resin base material groups is lower than the use of other luting agents.

The laboratory approach for processing housings for overdenture restorations is typically advocated for use with bar restorations, reline procedures, non-resilient attachment systems,

multiple implants in an arch, and patients with challenging edentulous ridges.³⁷ Some clinicians do prefer the ease and simplicity of this approach and request the dental laboratory to process FIXED Housings. Further, some feel that the control of the luting process in the laboratory, especially with Zirconia-based restorations, will lead to

less moisture contamination and a greater ability to restore case with increase divergence of implants. While there are advantages to using laboratory processing techniques, the approach is technique sensitive and requires careful technique to ensure errors are minimized.

Clinical processing techniques of housings, also known as "chairside processing or "pick-up technique," has gained traction in the clinical setting. The chairside technique is typically advocated in scenarios where clinical predictability and enhanced accuracy of housing to implant

positions are required. 37 The prosthetic flexibility of chairside processing permits the clinician to restore any restoration including resin, metal, and fiber-based restorations. Additionally, with straight-forward cases, such as those with 4-6 implants that are parallel, many clinicians feel that the chairside approach is the preferred technique.*

While both laboratory and chairside techniques are employed by clinicians and technicians, several advantages to each technique. The image below is a summary of each.

Laboratory processing techniques have numerous advantages including a shorter delivery appointment as the housings are already processed to the prosthesis, thus not requiring clinical techniques to attach the housings. Additionally, the technique is very simple for clinicians and results in a streamlined clinical-laboratory protocol. The laboratory technique requires an accurate dental cast or stone model to ensure an accurate fitting restoration. Ensuring the accuracy of the model is performed with a verification jig at the implant or abutment-level.

Chairside techniques, however, remain popular with clinicians because of clinical predictability and accuracy of housing to implant abutment fit. Luting procedures at the delivery appointment result in a very precise adaptation of the housing to the abutment which enhances the stability of the LOCATOR FIXED prosthesis. Accurate fit of the LOCATOR FIXED Housing has been shown to be important for the delivery and long-term performance of LOCATOR FIXED.*

Clinical Recommendations:

- Luting FIXED Housings using resin-cement (CEMEZ) or composite-resin (LOCATOR CHAIRSIDE/APM) is recommended for optimal bonding to prosthetics with metal bases
- The use of auto-polymerizing PMMA is not recommended for luting LOCATOR FIXED Housings to prosthetics with metal substructure
- LOCATOR CHAIRSIDE APM can be reliability used to lute LOCATOR FIXED prosthetics that are fabricated from resin-based materials such as PMMA or photopolymers
- The use of resin-cements should be avoided when restoring cases with resin bases
- Chairside processing techniques are recommended for LOCATOR FIXED prosthetics
- When employing laboratory processing techniques, careful technique is required including ensuring an accurate impression and stone dental model are used during production of the prosthesis
- Verification of the accuracy of the model should be employed by using a verification jig or template at the implant or abutment level

Abutment Number, Distribution, Location & Cantilever Length

Most patients with complete set of natural teeth have approximately 14 teeth per arch: four incisors, two canines, four premolars, and four molars. When patients seek rehabilitation with dental implants, many have the goal of having a complete set of teeth for function and esthetics with their new prosthesis.

LOCATOR FIXED requires a minimum of 4 implants per arch and some clinicians prefer to restore arches with 5 or 6+ implants per arch. In evaluating completed cases, the average number of implants per arch for LOCATOR FIXED cases is approximately 5 implants per arch.* While

evidence does show that 4 implants per arch leads to successful treatment of patients with LOCATOR FIXED cases, when anatomical features permit placement of additional implants, many clinicians do prefer to place more than 4 implants per arch.^{*}

Anatomical limitations often preclude the ability to place implants in the posterior regions of the maxillary or mandibular jaws. When anatomical features restrict implant placement only in the anterior region of the arch, typically a prosthesis cantilever may be present to provide a patient a full complement of teeth. In some scenarios, a shorter dental arch may result. When anatomical features permit placement of implants posteriorly, a complete arch of teeth is more predictable as minimal cantilever is required.

Evaluating a prosthesis cantilever is performed by measuring the prosthesis or the model itself using a ruler with mm markings. A measurement is made from the occlusal orientation of the

prosthesis, from the center of the most anterior LOCATOR abutment to the center of the most posterior LOCATOR abutment. The measurement provides the Anterior-Posterior (A/P) spread between the implants. The ruler is used to measure the distance from the center of the most posterior abutment until 0.5x or 1.0x the measured spread.

In scenarios where implants are placed

smm AP Spread 17mm AP Spread o.5x AP - Blue Line (2.5mm) o.5x AP - Blue Line (8.5mm) 1.0x AP - White Line (5mm) 1.0x AP - White Line (17mm) asymmetrically, evaluating the prosthesis cantilever should be evaluated per side of the arch. In

The implications of A/P spread become even

more evident when evaluating asymmetrical dental arches. For example, comparing a proposed cantilever for four implants placed in the interforminal region of the edentulous mandible to of a scenario when two implants can be placed in the regions of the first or second molar and the other two implants in the interforminal region. The example in the latter example illustrates that spacing LOCATOR Ideal

abutments as widely apart leads to the clinician and technician enhancing the ability to provide the patient for a greater number of posterior teeth compared to the former example.

In the example shown below, the cantilever on the patient's right side is measured from the most anterior implant to the posterior positioned implant, providing the ability to extend a cantilever

substantially longer than that of the left side. On the left side, the measured cantilever is 5mm from anterior to posterior abutments and the maximum prosthetic cantilever maximum was exceeded in this example. Excessive cantilevers beyond 1.0x A/P spread will increase the risk of dislodgement of the LOCATOR FIXED prosthesis during function.* While anatomical features may restrict implant placement throughout the arch, symmetrical implant placement

1.0x AP = White Line

Cantilever on right side
exceeding 1.0x AP spread 0.5x AP = Blue Line 1.0x AP = White Line

is ideal. Asymmetrical placement of implants and abutments increases prosthetic complications, stresses on individual implants, and increased chances for long-term complications on full-arch prosthetics.38

The use of cantilevers may increase the risk of fracture of the prosthesis. If a cantilever is required, as shown earlier in the analysis of prosthetic strength, the use of a reinforcement substructure is highly recommended. Cantilevers should be avoided for any prosthetics that use monolithic resin structures such as traditional PMMA, digitally produced PMMA, or photopolymers since their reported strength is substantially lower than that of the reinforced prosthetics. This is especially true of bruxing patients where occlusal forces may exceed the reported forces required to fracture the prosthesis.

Many dental patients do not present with "ideal bone" and have varied anatomical configurations unique to individual patients. The use of cone-beam computed tomography (CBCT) and surgical guides is recommended to enhance implant positioning, placement of dental implants in parallel positioning, and in posterior areas that due to proximity to critical structures may be more challenging to treat with freehand surgical technique.

Clinical Recommendations:

- At least 4 implants required per arch; in some situations, more than 4 implants per arch may be preferred for prosthetic strength and long-term maintenance
- Implants should be distributed evenly across the arch; ideal implant position for LOCATOR FIXED is two implants in posterior/molar region on each side of the arch and two to four implants in the anterior/interformal region of the arch
- Consider implant placement in posterior dental arches to eliminate prosthetic cantilevers
- Consider using digital technologies such as CBCT and surgical guides to place implants posteriorly to minimize cantilevers
- Minimal to no cantilever recommended for LOCATOR FIXED when using prosthetics without substructure, such as PMMA or photopolymer restorations
- Prosthesis cantilevers should be no more than 1X A/P spread
- Patients that are bruxers/clenchers: no more than 0.5X A/P spread
- Recommendations for cantilever based upon A/P spread are *maximum* values and do not mean the prosthesis cantilever should be set to those values as a "baseline"

Abutment Angulation

Abutment angulation has a relationship with the flexural, fatigue, and compressive strength of a prosthesis. LOCATOR abutments have been shown to provide the ability to correct for angulation up to 40 degrees of total divergence for LOCATOR.*

Existing evidence shows that as abutment angulation increases, abutment and insert wear increases.39 Angulation of abutments also may affect fracture rates of the prosthesis and/or the abutment itself. While retention of some prosthetics increases with slight angulation divergence, technical complications increase beyond 10 degrees of abutment angulation.⁴⁰⁻⁴¹

Anatomical features such as insufficient bone volume, limited mouth opening, and critical anatomy such as maxillary sinus cavities, undercuts, or nerve positions preclude the ideal placement of dental implants. Accommodating these challenges may result in implant placement and subsequently LOCATOR abutment placement that diverge from parallelism.

Narrow ridge width

Ideal implant position

Narrow ridge width Non-Ideal implant position

Ideal ridge width

Ideal implant position

LOCATOR FIXED permits angulation correction of up to 20° between implants or up to 40° degrees of total angulation across the arch. Properly assessing these measurements requires understanding of how to measure angulation of abutments. The simplest way to measure angulation is to engage a manual driver into the healing abutment or dental implant platform between two implants and then use the Zest Angle Measurement Guide. The center of the guide "0 mark" should be lined up with the implant that is straighter of the two. The driver engaged on the more angled implant will line up to one of the lines indicated on the ruler, this measured angle is the angle difference between the two implants. Once that measurement is obtained, repeat with the other implants. Add the numbers together and that provides the total angulation of the arch and needs to be below 40° .

In traditional screw-retained "AllonX" designs, implants are placed in the anterior in an

axial/parallel to occlusal plane and additional implants are placed anterior to the mental foramen or maxillary sinus. The anterior implants receive a straight abutment, and posterior implants receive an angled abutment. Angulation of the posterior implant is typically 25-30 $^{\circ}$ and to facilitate the prosthesis seating, the angle is corrected using a multi-unit abutment. To restore LOCATOR FIXED cases when using this approach, a LOCATOR Multi-Unit Abutment can be placed on top of the multi-unit abutment.

The LOCATOR Multi-Unit uses a two-piece component made up of a sleeve that fits over the outside of the multi-unit abutment and is held in place by the LOCATOR abutment that threads into the multiunit screw-channel.

The LOCATOR Multi-Unit abutment requires an additional 3mm of additional vertical restorative

space to accommodate the multiunit abutment hardware. Clinicians and technicians should consider choosing the lowest height multiunit abutment possible and placing implants slightly deeper if anticipating using LOCATOR Multi-Unit for LOCATOR FIXED.

Cases can include a combination of straight implants and LOCATOR abutments and combine using LOCATOR Multi-Unit Abutments. In the example image shown on the right, the maxillary FIXED case is restored with all straight abutments and implants. The mandibular arch is restored with two straight implants in the anterior and two multi-unit abutments in the posterior. The angulation of the multi-unit abutment should closely match the angulation of the implant. In the anterior maxilla, the angulation of the implant is typically 15-17° and the angulation of the implant in the posterior aspect of the arch this is typically 30°. The multi-unit abutment itself corrects this angulation difference and after placement, the LOCATOR multi-unit abutment is placed on top of the multi-unit abutment.

Restoring cases beyond 20 $^{\circ}$ per implant and/or beyond 40 $^{\circ}$ of total divergence across the arch will increase the risk of dislodgement of the prosthesis.' Key methods to avoid excessive angulation include use of diagnostic imaging such as CBCT, intraoral scanning, or dental study models to properly analyze the restorative plan in relationship to the surgical plan prior to implant placement. Additionally, intraoperative use of surgical templates greatly enhances the ability of the clinician to place implants parallel to each other and in calculated pre-planned angulation to avoid critical anatomical features.

Clinical Recommendations:

- Abutments should be as parallel to each other as possible
- Angulation between individual abutments should not exceed 20°
- Total angulation of all abutments across the arch should not exceed 40°
- Prosthetics with divergent abutments may be more difficult to seat
- Prosthetics with divergent abutments may have a higher chance of dislodgement of the prosthesis than cases with non-divergent abutments
- **LOCATOR Multi-Unit Abutments can be utilized to correct 15-30** $^{\circ}$ **of angulation**

Prosthetic/Restorative Space Requirements

A properly designed dental restoration should have sufficient thickness, space around the LOCATOR FIXED housing, and bulk of the prosthesis to resist fracture. To guide laboratories and clinicians, we must differentiate the differences between prosthesis height and restorative space.

Prosthesis height is measured from the edentulous ridge to the most superior portion of the prosthesis, most often the incisal edge or occlusal surface of the restoration.⁴² This measurement is typically utilized in the laboratory on the dental model when restoring cases. In cases where the incisal edge is positioned facially or lingually/palatal, the measurement is made from the ridge to the portion of the lingual/palatal prosthesis positioned above the implant platform.

Restorative space is typically measured vertically from the top of the implant platform to the most superior portion of the prosthesis, most often the incisal edge or occlusal surface of the restoration.43 This measurement is typically utilized when planning implants and/or during surgical procedures. In cases where the incisal edge is positioned facially or lingually/palatal, the measurement is made from the implant platform to the portion of the lingual/palatal prosthesis positioned above the implant platform. The restorative space is typically calculated by adding the prosthesis height to the measured tissue depth from the implant platform to the edentulous ridge. If the tissue depth is unknown, an estimate of 2mm tissue depth for mandibular cases and 3mm tissue depth for maxillary cases are appropriate averages for use in calculating restorative space.^{*}

Ensuring sufficient thickness of the prosthesis circumferentially around the LOCATOR FIXED Housing is important to consider. Based upon the technical analysis performed in this evaluation, the following are recommendations for LOCATOR FIXED prostheses.^{*}

To measure prosthesis height and/or thickness, the clinician has the choice to use an analog or a digital method.

The analog method to measure the prosthesis height is performed using a ruler (left) or Boley gauge to measure the distance from the inferior to the superior portion of the prosthesis. Line up the zero mark of the ruler to the inferior border of the prosthesis, then measure the distance to the incisal edge. Add a measurement of the tissue thickness from implant platform to the edentulous ridge to this value to properly calculate the restorative space value. If a flange is present, measure the length of the flange from the recess wall and subtract that length from the total length. To measure the thickness surrounding the LOCATOR FIXED Housing, a crown caliper (right) or Boley gauge can be utilized, placing one end on the inside of the recess and placing the other end on the cameo/outside surface of the prosthesis.

[x] Prosthesis Height + [x] Tissue Depth = Vertical Restorative Space Example Shown: 13mm Prosthesis Height + 2mm Tissue Depth = 15mm Vertical Restorative Space

Recommended 3-5mm Prosthesis Thickness Around Housing Example Shown: Caliper Gauge Measurement is 3.3mm

The digital method to measure the prosthesis thickness involves using measuring features of the dental computer aided design (CAD) software to perform a cross-sectional slice and measure. There are two methods employed. Method one is employed during the initial design steps using the prototype or "waxup overlay" on top of the scan with the LOCATOR FIXED Housings or Scan Bodies (left). The measurement is made from the LOCATOR Housing/Scan Body to the prosthesis surfaces of the overlaid waxup prosthesis in defined areas. In the second method, the same crosssection technique is employed, however, a measurement is made from the surface of the final digitally designed prosthesis to the interior of the recess cavity of the prosthesis (right).

Example Shown: Waxup Overlay Prosthesis Height: Measure from Edentulous Ridge to Incisal Edge / Prosthesis Surface Prosthesis Thickness: Measure from Top of Housing/Scan Body to Prosthesis Surface

Example Shown: Final Prosthesis Design

Prosthesis Height: Measure from Intaglio of Prosthesis to Incisal Edge / Prosthesis Surface Prosthesis Thickness: Measure from Prosthesis Surface to Interior of Recess Cavity

Clinical Recommendations:

- At least 9-11mm of vertical restorative space from the platform of the dental implant to the incisal edge or the cameo/superior surface of the restoration is recommended; more than 11mm is clinically acceptable for LOCATOR FIXED
- 3mm of thickness is recommended surrounding the LOCATOR FIXED Housing in all dimensions for zirconia or AvaMax prostheses
- 4mm of thickness is recommended surrounding the LOCATOR FIXED Housing in all dimensions for conventionally fabricated denture teeth and PMMA restorations with a substructure, monolithic nanoceramic resin prostheses, and resin/composite prostheses with a fiber composite frame
- 5mm of thickness is recommended surrounding the LOCATOR FIXED Housing in all dimensions for monolithic PMMA and photopolymer resin prostheses
- Monolithic resin prostheses require additional restorative space / prosthesis height and prosthesis material thickness to minimize fracture
- A substructure is recommended for interim and/or definitive prosthetics when prosthesis space or thickness is minimal

Summary & Conclusions

Choosing the appropriate prosthetic material for restoring a LOCATOR FIXED restoration is imperative to the long-term success of the restoration. The use of prosthetic material must be balanced based upon patient factors such as anticipated bite forces, bone availability for implant placement, potential implant positions, number of teeth to restore, and esthetic requirements. Additionally, luting material and surface treatment of the prosthesis base should be evaluated on a per patient basis to ensure successful treatment. The data shown in this whitepaper is designed to assist clinicians make those decisions in a more scientific and clinically-relevant approach.

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