Primary stability vs. viable constraint: A need to redefine

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By Michael R. Norton, UK

Any regular reader of the Journal of Oral & Maxillofacial Implants or indeed of any other publication on dental implants could not fail to have noticed how much attention has been focused on Primary Stability. The concept of primary stability is not new; indeed, as early as the 1970s, there were studies emphasizing the need to establish mechanical stability to ensure un-interrupted healing of the bone.[1] This was most evident in the orthopedic literature as it pertains to hip prostheses.[2]

By the 1990s, numerous reports were being published on immediate loading of dental implants[3-6] and the ground-breaking work by Neil Meredith on the application of Resonance Frequency Analysis (RFA) came to the fore[7-9] with statements that achievement of implant stability was a prerequisite for long-term positive outcomes.

At the same time, Meredith recognized it was possible for clinically firm implants with poor axial stability to still be prone to failure.[8] Of course, Brånemark recognized this in his early work, proposing as he did a period of submerged healing because of his concerns for any destabilization of the bone-to-implant interface during the early healing phase. However, today we all recognize that such protective protocols are frequently unnecessary, with widespread acceptance of not only transmucosal healing but also immediate temporization and/or loading.

So how do we define primary stability? The most simple definition is one of mechanical friction between the implant and bone. Certainly, we can all appreciate that this contrasts with secondary implant stability where secondary stability is achieved by biological integration, i.e., osseointegration. The gradual shift from primary stability to secondary stability is critically poised at around three weeks. This is seen to be the least stable time point where viscoelastic stress relaxation of the bone along with remodeling results in a loss of primary mechanical stability9 but with an as yet poorly established degree of secondary stability or osseointegration.

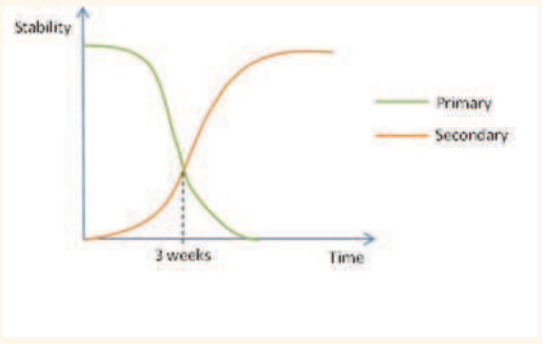

Fig. 1

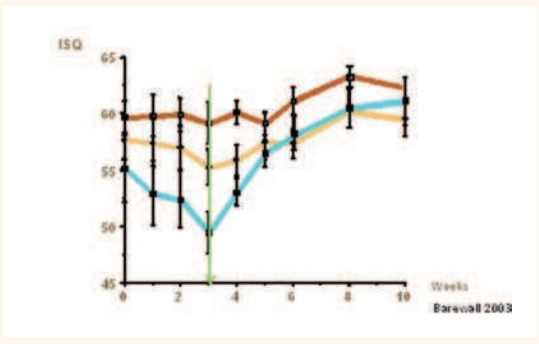

Fig. 2

This is also apparent in RFA curves which, like a heartbeat, always register a certain pattern in healthy bone that reflects this loss of stability at the third or fourth week,10 regardless of bone density.

That said, we still need to define what constitutes primary stability, i.e., that which sets it apart from biological integration. As stated above, mechanical stability is one where a friction occurs between the implant and the surrounding bone giving rise to a resisting torque at time of insertion. This resisting torque is proportional to the effort required to seat the implant or peak insertion torque; they are in essence one and the same and depend largely on the characteristics of the implant, the density of the bone and the differential size of the osteotomy as it pertains to the diameter of the implant. Mathematically, it can be defined as follows:

$$\frac{\text{Resisting Torque}}{2} = \mu * P * H * \pi * D2$$

Where: H * ϖ * D2 = Surface Area of implant in contact with bone where
H = height of the implant cylinder and D = diameter of implant cylinder
P = Critical pressure on the bone
μ = Coefficient of friction

The important factor in this equation is P, the critical pressure on the bone, as high pressure results in unfavorable bone strain, particularly within the cortical compartment. However, the formula indicates that the resisting torque is proportional to the diameter (D) raised to the power of 2. This means that if you double the diameter the resisting torque becomes four times higher. Put another way, if we use the same insertion torque for a 3 mm wide implant and a 6 mm wide implant, then the critical pressure P will be four times lower for the wider implant!

For example, an implant of 3 mm diameter inserted into 1 mm thick cortical bone with a torque of 20 Ncm will transmit the same pressure to the bone as an implant of 6 mm diameter inserted into 2 mm thick cortical bone with a torque of 160 Ncm. (This assumes that 100 percent of the torque originates from the pressure on the cortical bone, and the contribution to torque from bone cutting, etc., is neglected). Yet manufacturers persist in providing a single target value of insertion torque across the range of implant diameters they offer.

It is therefore reasonable to discuss the virtues of insertion torque and ask the pivotal question:
Is insertion torque an appropriate measure by which to quantify optimal primary stability? After all, bone is a living tissue, so any measure of primary stability must also reflect the future viability of the bone.

It is clear that higher insertion torques fulfil the desire to achieve a high degree of mechanical stability as interpreted through manual perception. Indeed, it is usual for manufacturers to provide some guidance on optimal insertion torque with some implant designs being specifically tailored to deliver higher insertion torques, in excess of 75 Ncm. This yields a sense of comfort for the clinician that the implant is initially "stable."

However, such a high torque has not been shown to be propitious to the surrounding bone. Numerous studies have been published that clearly demonstrate the critical pressure these high torques create leads to micro-fracture of the bone[11,12], with a net resorption in the cortical zone[11,12,13] and, indeed, an unfavorable delayed healing process with a reduced bone-to-implant contact.[14] Such a response might well shift the onset for secondary stability and thereby delay or extend the period of potential vulnerability. This is clearly counter to the goal we are trying to achieve with immediate or even early loading protocols, whereby we want to transfer from simple mechanical fixation to full osseointegration in the shortest possible time.

The most fascinating aspect of this debate is the lack of correlation between insertion torque and the Implant Stability Quotient (ISQ) as measured by RFA, which appears to be counterintuitive. How is it possible for an implant that is driven in at 30 Ncm to have the same ISQ as one that required 100 Ncm of torque? Nonetheless, the weight of literature would seem to suggest this to be the case.[15-18]

Because ISQ is measuring axial stiffness, it is must be clear that frictional rotational resistance is a completely different parameter. After all, I don't doubt we have all have experienced the "spinner" (an implant that exhibits little or no rotational stability) that went on to osseointegrate, and there are a number of studies published that report high success rates for immediately loaded implants which were inserted with low insertion torque.[19-22]

By contrast, implants with an ISQ of less than 50 rarely go on to integrate successfully, and ISQ has been described as a good predictor of success.[23, 24] It is this dichotomy that has got me thinking and has led me to write this editorial piece. Could it be that axial stiffness is far more pertinent than rotational friction in ensuring an implant integrates? We already know from the literature that an implant can tolerate a degree of micro-motion, thought to be circa 100-150μm,[25, 26] and this is in essence what ISQ measures.

Studies have also demonstrated that insertion torque correlates closely to the degree of micro-motion.[25] However, it is not the aim to seek complete elimination of micro-motion, a valuable lesson learnt in orthopedics.[27] If it is possible to place an implant with lower insertion torque and still achieve axial stiffness with an ISQ >60, surely this provides us with a more optimal evaluation of primary stability. Our goal must be the rapid onset of secondary stability, with minimal critical pressure to the poorly vascularised cortical bone so unfavorable resorptive responses and delayed healing are avoided. At the same time, we need to employ an objective measure of constraint that reliably ensures the implant can tolerate early or immediate loading. As much was recently proposed by Barewal et al[17].

I have labeled this objective measure Viable Constraint (vC), whose central purpose is to obtain a clinically relevant degree of stability while maintaining a low critical pressure on the vulnerable cortical tissues through which our implants are inserted.

Bone is not wood. It is not inanimate. It would behoove us all to remember this, and avoid the carpenter's approach to implant dentistry.

So I would take this opportunity to ask that we think in terms of Viable Constraint. It will, of course, take controlled prospective studies to determine the optimal conditions for vC, but if I were a gambling man (which I most certainly am!) I would guess for a 4.5 mm implant in bone with a cortex of <1.0 mm thickness that a maximum torque of 20 Ncm and an ISQ of 60 represent the optimal measures we are looking for to ensure safe immediate loading.

In the past, we used to think length was important with implants, whereas today there is increasing focus on short implants. However, I would point out that a strong correlation has been shown to exist between ISQ and implant length[28,29,30] and, as such, for immediate loading, I also believe a longer implant with a higher ISQ, inserted at a lower insertion torque, will yield a more favorable outcome.

Note

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Editorial note: A complete list of references is available from the publisher

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For more than 20 years, Norton has led the way for implant dentistry in the United Kingdom, becoming one of the world's most respected and renowned implant surgeons. His considerable portfolio of research has been ground-breaking, and he has become one of the most sought after lecturers in his field. Since 1989, Norton has dedicated all his clinical and postgraduate time to the practice and study of implant reconstructive dentistry.

He is secretary, board member and fellow of the Academy of Osseointegration (AO) and is past president (1999-2001) and honorary life member of the Association of Dental Implantology (ADI), UK. He is past editor of the AO's Academy News and is currently associate editor of the International Journal of Oral & Maxillofacial Implants (JOMI). He also serves as a referee for a number of other peer-review journals.

“It’s a game-changer”: Prime&Bond universal™ with Active-Guard™ Technology

By Dentsply Sirona

Dentsply Sirona has introduced a new universal adhesive designed to ensure complete coverage and penetration for a reliable bond even if the preparation is overly wet or dry.

We spoke with Dentsply Sirona polymer chemist Dr. Christoph P. Fik to learn about the remarkable properties of this revolutionary dental adhesive and how Prime&Bond universal™ with Active-Guard™ Technology was developed.

Dentsply Sirona: Dr. Fik, can you tell us how a new research and development effort gets started? For example, did the marketing team develop a list of requirements that dentists are looking for in a next-generation adhesive like Prime&Bond universal™?

Dr. Christoph P. Fik: The marketing people do conduct market research and develop a set of requirements based on the voice of customers. As chemists, we also have our own insights into the physical and chemical properties that would improve the product and simplify its use for our dental customers. The clinical team also provides significant input, so it’s a collaboration between all three departments to define the platform requirements for a new product.

We have a series of discussions, document our agreed-upon objectives, and then kick off the actual development effort with a clear set of goals in sight that we believe are both beneficial and achievable.

Talk to us about those goals. What does the ideal dental adhesive need to accomplish?

I see the dentist as a kind of craftsman, and we want to help them achieve a higher level of craftsmanship. Every dentist has preferred techniques to achieve a good restoration for every case, and we’re not necessarily changing that. We want to help enhance craftsmanship with a universal adhesive that dentists can rely on, a product that makes a difference they can see and feel, every day they work with it.

Dentists want a universal adhesive that’s more convenient, easier and faster, while ensuring a reliable bond. It needs to provide robust performance across all the different cases a dentist encounters, including direct and indirect restorations. It needs to be simple and predictable to use in every scenario.

What are the limitations of competing adhesives, and how does Prime&Bond universal™ overcome them?

There are six or seven universal adhesives on the market based on chemistry that’s at least 20 years old. Most of these established adhesives have very high viscosity. Some dentists may regard that as a benefit in certain cases, but more often it’s a significant drawback. Prime&Bond universal™ is the first universal adhesive that offers low viscosity with a surface tension directly adjusted to dental substrates and related materials, making it easier for the adhesive to spread evenly across the substrate and to quickly wet and fully penetrate the dental tubules.

Other universal adhesives show what I would describe as a passive behaviour. They polymerise, but beyond that they don’t exhibit any active properties to help the dentist achieve optimum results. They can resist spreading, they tend to pool, and they don’t mix with water spontaneously – so it can be difficult to achieve complete, even coverage.

By contrast, the “active” in Prime&Bond universal™ with Active-Guard™ Technology refers to the properties you can actually see working when you apply it to the prepared surface. It actively spreads to help ensure complete and uniform coverage across the substrate. It actively mixes with any excess water that may be present, which is important for achieving complete penetration on wet dentin. During air drying, the adhesive solvent and excess water evaporate together to actively create an even, homogenous layer, with low film thickness.

The active properties you’re describing are completely new in the market for universal adhesives. Active-Guard™ Technology is patented. What is it and how does it work?

Active-Guard™ Technology is a resin component. Other universal adhesive systems are based on two parts: they combine a very hydrophilic, low viscosity compound – a so-called reactive diluent – with a very viscous hydrophobic compound, trying to find a balance. With Active-Guard™ Technology, we’ve created a new resin compound that combines hydrophobic and hydrophilic properties in one monomer. So you don’t have to deal with two parts and reactive diluents – you simply find the balance within a single chemical structure.

Could it be described as “amphiphilic.”? Is that what you mean by a balance of hydrophobic and hydrophilic within a single resin molecule?

Yes, but it’s important to distinguish the amphiphilia of Active-Guard™ Technology from the more familiar use of this term to describe surfactants. With those, you have separate hydrophilic and hydrophobic parts in one molecule, and that’s what allows you to disperse oil in water, for example. But with Prime&Bond universal™, the whole molecule in itself balances hydrophobic and hydrophilic properties, without separate hydrophobic and hydrophilic domains of the molecule.

That’s unusual in chemistry, and it allows us to balance several benefits. For example, enamel is hard, dry and quite brittle, while dentin is porous, wet and spongy, and the amphiphilicity of Active-Guard™ Technology allows us to achieve exceptional bond strength with both substrates. We’ve also achieved an optimum balance between the properties needed for direct and indirect restorations, between high and low viscosity, and between the requirements for all etching methods.

What are some of the additional benefits of Prime&Bond universal™?

The adhesive layer is extremely thin compared to other universal adhesives, which can really help avoid fitting problems with indirect restorations. This thinness, combined with a mild pH of about 2.5, also practically eliminates the most common causes of post-operative sensitivity. And it minimizes the risk of pooling, which can otherwise be misinterpreted as a void or decay on a radiograph.

We also thought about simplifying the dentist’s workflow. Prime&Bond universal™ can be stored at room temperature and remains usable for 30 minutes in a closed CliXdish™, so it’s really designed to minimize waste and help streamline procedures, especially when doing multiple restorations in a single visit. And we make sure our products work together, so dentists can have a complete and reliable solution with no risk of product incompatibilities. We designed Prime&Bond universal™ to work optimally with Calibra® Ceram cement. With this combination, there’s no need to apply a separate activator, and the two products have the right pH values to fuse perfectly, providing much greater shear bond strength compared to other adhesives.

In all you have accomplished to develop Prime&Bond universal™, what gives you the most pride? How will this change the practice of dentistry?

Our patented Active-Guard™ Technology platform is completely new. It introduces a new level of robustness along with much simpler, more reliable handling properties for virtually any case, any substrate and any preparation. It’s a future-oriented technology that I’m convinced will lead to more groundbreaking products based on this platform in the future.

I’m very proud of that. It’s a game-changer. DT

For more information on Prime&Bond universal™, please contact your local Dentsply Sirona representative.

Flg. 2: Prime&Bond Universal™