*Pressure Necrosis And Osseointegration: An Editorial White Paper**

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Introduction

The purpose of this paper is to discuss the risks and benefits of high insertion torque and its perceived correlation to the phenomenon called *osseous pressure necrosis*. Current evidence has not shown that properly applied high insertion torque leads to pressure necrosis when using the BIOMET ***3i*** Tapered Implant System.

Background

As implant dentistry continues to evolve, there is increasing interest in providing patients with immediate functional and aesthetic replacement for a missing tooth or teeth. In an effort to achieve this outcome, clinicians are faced with several unique biomechanical challenges. Traditional dental implant protocols require the clinician to place an implant and allow it to osseointegrate (biologically stabilize) before it is exposed to the forces of occlusion and parafunction.[1-3]

Newer protocols involve reduced healing periods, the use of shorter length implants, inserting implants into poorer quality bone, and placing a restoration on an implant immediately. Some clinicians are inserting implants within an extraction socket or sockets coupled with immediate restoration.[4-7]

These newer protocols expose the implant to potential mechanical stresses prior to biologic integration and the stresses may place the implant at risk for micromovement early within the healing process. It is well documented that excessive micromovement is detrimental to osseointegration and may well be the most common cause of implant failure, especially when following an immediate placement and immediate restoration protocol.[8-11]

In an effort to avoid this common complication, researchers have suggested controlling micromovement by splinting several implants together and/or ensuring that the implant has high primary stability.[12-16]

A common technique for evaluating primary stability is to monitor insertion torque on the drill unit. It is generally accepted that implants placed with higher torque have better survival rates than those seated with torque in the 20Ncm range.[17]

Several of the authors have tested numerous drill units and have evaluated torque accuracy. Due to potential variability in drill unit torque accuracy, the authors recommend use of a calibrated hand wrench if one desires to accurately determine insertion and final seating torque.

Insertion torque may be defined as the amount of torque required to advance the implant into the prepared osteotomy. *Final seating torque* may be defined as the torque measurement recorded when the implant reaches its final apico-occlusal position.

While there have been several attempts to evaluate primary stability, one available method involved quantifying insertion torque. Historically, clinicians have used an additional method of measuring implant stability by using an Osstell Mentor Device (Osstell AB, Göteborg, Sweden) to obtain an Implant Stability Quotient (ISQ) value.

The literature includes studies that describe standards for both insertion torque[18, 19] (cutting torque) and ISQ values,[20-22] which may correlate to higher primary stability. These values have been correlated with a lower potential risk of excessive micromovement and subsequent implant failure.

Minimal insertion torque values have been suggested to be at approximately 35Ncm. While some researchers suggest an ISQ value of at least 60,[23, 24] others have also suggested that implants with an ISQ over 70 may be indicated for an immediate-load protocol.[25]

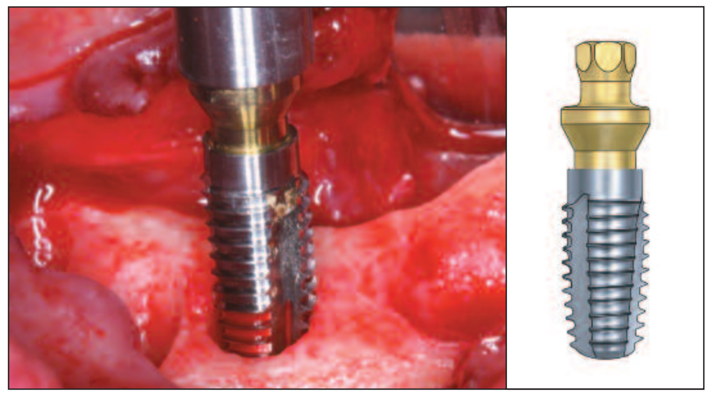
Historically, some researchers have relied on ISQ values as a significant part of the data presented in their research. However, the authors as well as some current researchers feel that the lack of clearly defined reference values makes the clinical use of the Osstell Device *alone* unreliable.[26] Therefore, relying upon ISQ readings in lieu of clinical interpretation of implant insertional torque, is not recommended. Nonetheless, use of this device remains a *suitable adjunct* for confirming the extent of implant primary stability.

Modified drilling guidelines and new implant macrogeometric designs have evolved. The driver of these new designs and protocols has been a desire to improve primary stability and to reduce the risk of excessive micromovement during the early healing process, which involves the transition from primary stability to osseointegration. It is commonly accepted that the osseointegration process takes several weeks to months.[27, 28]

While the optimal values for insertion torque and ISQ values remain unknown, there is a general consensus that achieving higher Initial Bone-to-Implant Contact (IBIC) throughout the length of the osteotomy may correlate with achieving higher ISQ values and higher insertion torque values.[29-31]

While there are no known papers evaluating and comparing insertion torque to final seating torque and relating the numbers to implant survival (particularly in early and immediate load situations), there is a general consensus among the authors of this paper, that low insertion torque with a higher final seating torque is less desirable and may provide a false sense of security when compared to a higher insertion torque coupled with a high final seating torque. The latter appears to provide the more desirable finding of top-to-bottom stability.

Turkyilmaz et al demonstrated that undersizing an osteotomy appears to improve primary stability and implant survival, implying that top-to-bottom initial stability is a desirable outcome.[32]



A Dense Bone Tap is used to thread the osteotomy prior to implant placement.

In the authors' opinion, it is crucial that the reader understand the purpose of high insertion torque. High torque, per se, is not the objective, but rather high insertion torque is an indicator of three-dimensional primary stability. The implant surgeon must think not only in terms of mechanical force, but of the fact that the force reflects an intimate three-dimensional contact between the walls of the osteotomy and the surface of the implant. High insertion torque must not be confused with high final seating torque, which may not imply three-dimensional top-to-bottom contact providing optimal primary stability throughout the length of the implant. Trisi et al reported when implants were placed with more than 100Ncm of torque, the implants were always below the risk threshold for micromovement, which may lead to implant failure.[33] In a clinical study, Ottoni et al showed that increasing peak insertion torque may significantly improve the survival rates of immediately loaded implants.[34]

As stated, high insertion torque and high ISQ values may be considered "go ahead" indicators by some clinicians when following newer biomechanically challenging protocols. While preliminary reports of clinicians and researchers following these new guidelines appear to be producing positive outcomes, others are concerned that higher insertion torque may be responsible for a phenomenon called *osseous pressure necrosis*.[35-37]

The term *osseous pressure necrosis*, although used frequently, has never been clearly defined in the dental literature. The authors define *osseous pressure necrosis* as excessive compression (pressure) of bone created during implant insertion. Compression of bone beyond its physiologic limits may result in ischemia leading to osseous necrosis. This phenomenon is generally viewed as being limited to cortical bone.[35, 36]

Some feel this process may lead to early bone loss and implant failure. The purpose of this document is to support new clinical recommendations and enhanced implant designs along with their use in accelerated treatment protocols, while reducing concerns about pressure necrosis.

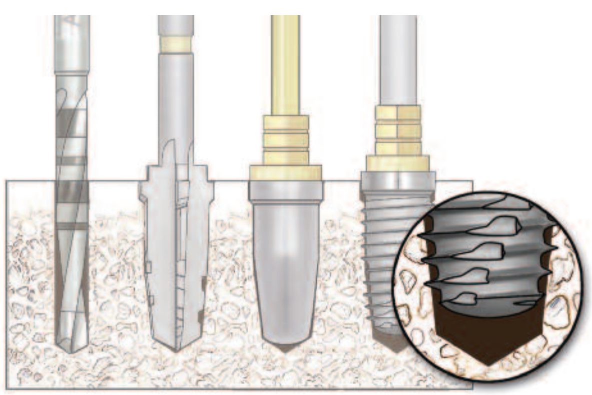


Illustration depicts a tapered implant (far right) that is incompletely seated within the prepared osteotomy. When this occurs, the result will be reduced IBIC and potentially decreased initial primary stability. Complete seating frequently requires the use of a hand ratchet.

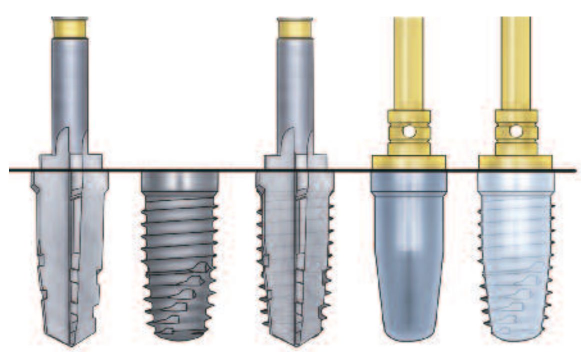
Pressure Necrosis and Osseointegration

If pressure necrosis exists, the most likely causes are from one of three potential sources: the macrogeometry of the implant, the macrogeometry of the osteotomy site and the bone quality. It is generally accepted that the phenomenon would only be present in cortical bone.[35-37]

Although the placement guidelines for the BIOMET ***3i*** Tapered Implant involve high insertion torque, bone taps are a part of osteotomy preparation guidelines when placing implants into cortical bone. This tapping process reduces implant insertion torque in cortical bone.

The authors feel that the major risk of high insertion torque may be deformation of the implant's macrogeometric features (i.e. stripping of the internal hex or driver tip) or an inability to fully seat the implant into dense bone. Further, it is the opinion of the authors that it is more for this reason rather than concerns over pressure necrosis that dense bone guidelines are required for placement of this properly macrogeometrically designed implant.

The BIOMET ***3i*** Enhanced Tapered Implant's depth and diameter specific drills replicate the minor diameter of the



In order to maximize IBIC, a tapered implant should be completely seated within the prepared osteotomy. Use of the corresponding drill and direction indicator prior to implant placement may confirm the proper apical-occlusal positioning of the implant. The corresponding drill and direction indicator are equal to the minor diameter of the specific implant.

implant. Additionally, the design of these drills includes a built-in countersink, which accommodates the collar dimension of tapered implants. Therefore, compression of the implant against the walls of the osteotomy is unlikely with this macrogeometric relationship. Under these conditions, insertion torque may be caused by the threads simply cutting their way into the adjacent host bone (cutting torque resistance).[38]

Each implant system must be evaluated to make sure its unique macrogeometric relationships and dense bone protocols do not produce excessive compressive stresses on the associated osseous structures or place the implant at risk for macrogeometric failure.

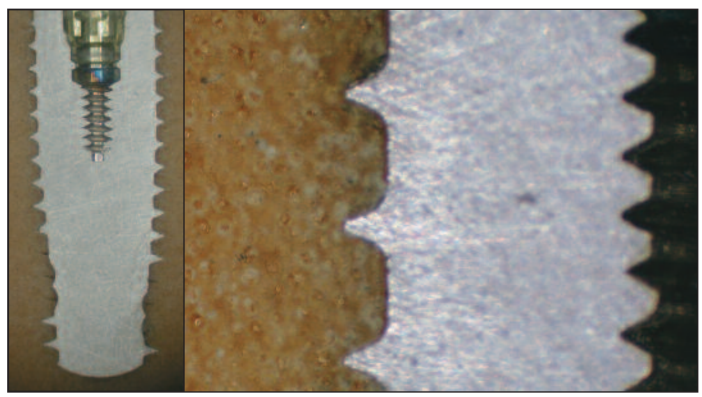
The lead author has followed and compared initial insertion torque on numerous BIOMET ***3i*** Tapered Implants placed at higher torques with an average of 90Ncm. ISQ values were recorded initially and on several implants at 4, 8 and 12 weeks. ISQ values remained stable throughout the test period within 5%. Additionally, no unusual radiographic or crestal bone changes were noted.

Image depicts an Osstell SmartPeg placed into the internal interface of the implant in order to record an ISQ value with the Osstell Mentor Device.

Khayat et al presented results with Zimmer Tapered Implants inserted with torques up to 176Ncm. The implants were followed for one year and no signs of pressure necrosis, crestal bone change or untoward healing were noted when compared with the control group.[39]

In a study conducted by the lead author, BIOMET ***3i*** Tapered Implants were immediately placed and provisionally restored in sites that were periodontally and endodontically compromised. Seventy-seven implants placed with insertion torque of 90 or greater, were followed for 3 to 24 months. Seventy-six of the implants survived with no adverse bone or soft tissue outcomes.

"Therefore, compression of the implant against the walls of the osteotomy is unlikely with this macrogeometric relationship. Under these conditions, insertion torque may be caused by the threads simply cutting their way into the adjacent host bone (cutting torque resistance).[38]"



Sawbone cut-away of an INT515 Tapered Implant demonstrating the intimate implant-to-osteotomy fit and high IBIC.

Finally, current histologic research performed by Trisi evaluating the effect of high insertion torque (up to 150Ncm with a mean torque of 110Ncm) on osseointegration, failed to demonstrate any adverse outcomes. As a matter of fact, this 1-to-45 day study demonstrated benefits including accelerated rates of osseous remodeling without any adverse effects on implant stability as a result of placing implants at what is traditionally considered high insertion torque.[40]

"Current histologic research performed by Trisi evaluating the effect of high insertion torque on osseointegration, failed to demonstrate any adverse outcomes."

Conclusion

In conclusion, while *osseous pressure necrosis* may potentially adversely impact osseointegration, it is the experience of the authors that implant failure due to high insertion torque has not been noted. Furthermore, there is no clinical or histologic evidence to support the hypothesis that high insertion torque applied to an appropriately designed implant system leads to osseous pressure necrosis and possible subsequent implant failure. To the contrary, with the placement of BIOMET ***3i*** Tapered Implants at high insertion torque, osseous pressure necrosis has not been noted by the authors. Rather, the authors concluded that high torque may positively impact traditional implant protocols, as well as, immediate placement and immediate restoration protocols.

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*While these surgeon experiences are true, the results are not necessarily typical, indicative or representative of all procedures in which the BIOMET ***3i*** Implant and related components are used. The BIOMET ***3i*** Tapered Implant and related components have been used successfully in patients. However as with any implant device, there are surgical and post-operative factors, which ultimately may result in unpredictable variable outcomes. These factors include, but are not limited to, the patient's pre and post-operative health conditions, bone quality, number of surgical procedures and adherence to instructions regarding the procedural guidelines. Due to these variables, it is not possible to predict or warrant specific results, patient or clinician satisfaction.

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