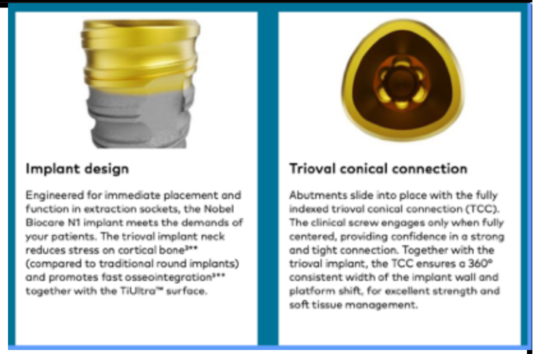
Analysis of the Shortcomings of NobelBiocare's N1 System



NobelBiocare claims its N1 implant is designed with a Trioval neck to "reduce stress on cortical bone [compared to traditional round implants]." It makes the same claim regarding the back-tapered neck of its NobelActive implant. These claims and the N1 surgical protocol are based on a unsubstantiated premise that crestal bone will resorb if subjected to high (40Ncm+) implant insertion torque. There are no studies showing a correlation between insertion torque and crestal bone loss. Compression of the cortical bone is irrelevant when placing implants in the soft bone of the maxilla or extraction sockets of immediate insertion. For these applications, the Trioval and back-tapered necks are counter-productive to optimizing initial stability. Furthermore research shows that a lack of the contact between the implant and the crest of the ridge contributes to bone recession. For situations where there is dense cortical bone that is preventing full seating of the implant, crestal bone drills are available to enlarge the opening to the same diameter as the implant, while still maintaining a seal at the crest.

N1 Implant includes an OsseoShaper drill — a 1-time use OsseoShaper2 drill adds $109

OsseoShaper™

The OsseoShaper instrument preserves vital bone due to less trauma with low speed and no irrigation[1*]. It creates a specific osteotomy for the co-packed Nobel Biocare N1 Implant. The torque measured during shaping guides the surgical procedure.

NobelBiocare recommends 50 rpm for preparation of the final sizing of an osteotomy with its side-cutting OsseoShaper drill. Conventional drill speeds for end-cutting spade drills is 800-1200 rpm. Progressively enlarging the osteotomy with a series of spade drills takes little if any additional time while allowing the dentist to progressive enlarge the socket depending on the density of bone (Niznick 2000 Article). The end-cutting feature of a spade drill also controls the trajectory of the drill and avoids oversizing the socket, which can happen with side-cutting drills. Nobel's noise/vibration comparison video is misleading - don't go directly to the final size of a spade drill.

1. **Nobel claims the N1 is "designed for immediate placement". This claim is for "immediate placement," not immediate loading. For an implant and its surgical protocol to be designed for immediate load, it must predictably achieve 35-40Ncm of implant insertion torque.**

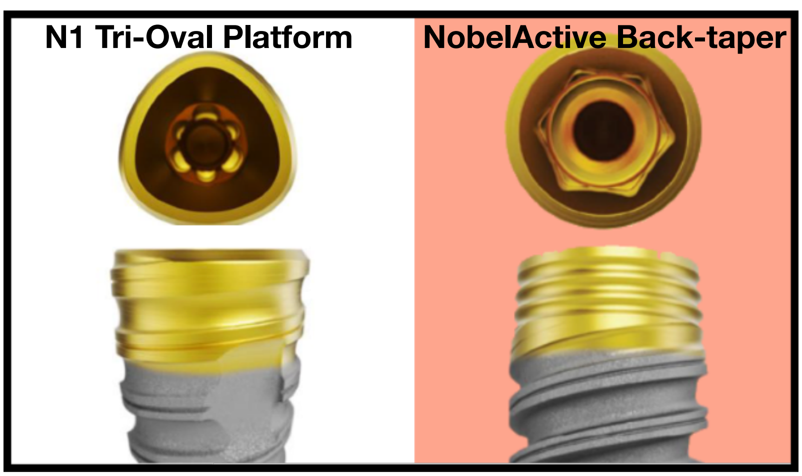
> More than an implant, N1 is a comprehensive system of dedicated instruments, prosthetic components, and surgical protocols. New features of the system include an implant designed for immediate placement and predictable insertion torques, a trioval conical connection for the abutment to slide into place, and an emergence profile designed for soft tissue maintenance.

2. **NobelBiocare claims the N1's surgical protocol yields "predictable insertion torque" but in-fact, it yields predictable drilling torque as Nobel recommends not exceeding 40Ncm during the drilling procedure. The correlation between drilling torque and implant insertion torque is dubious. Rather than following a series of sequentially larger diameter drills to establish the appropriate socket diameter, depending on the density of the bone, the Osseoshaper drill provided with each implant may oversize the socket in soft bone, compromising stability. It often undersizes the socket in dense bone, requiring use of a second larger diameter 1-time use drill called OsseoShaper2, which costs $109. Because the OsseoShaper is side cutting it can oversize the socket, further reducing initial implant insertion torque.**

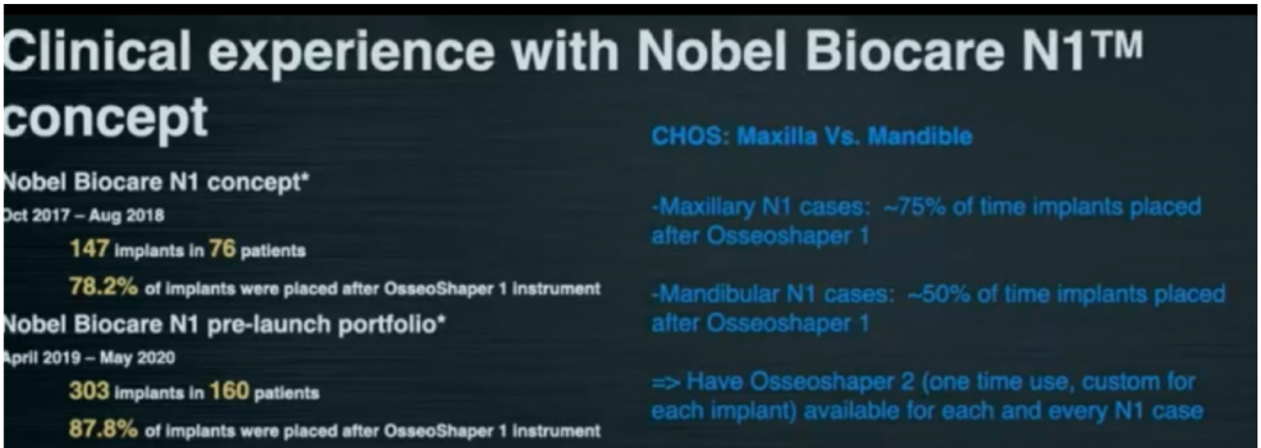
3. **Nobel's claim that the N1 has a "Trioval conical connection" is misleading. A conical connection consists of mating cones that gain stability by tightening the abutment's cone into the conical shaped internal shaft of the implant, the angle of the abutment's bevel being slightly flatter to assure initial contact at the opening to the internal shaft. The abutment's Trioval surface cannot rotate within the implant's Trioval internal shaft so it cannot create a frictional stability — it is held in place by a screw.**

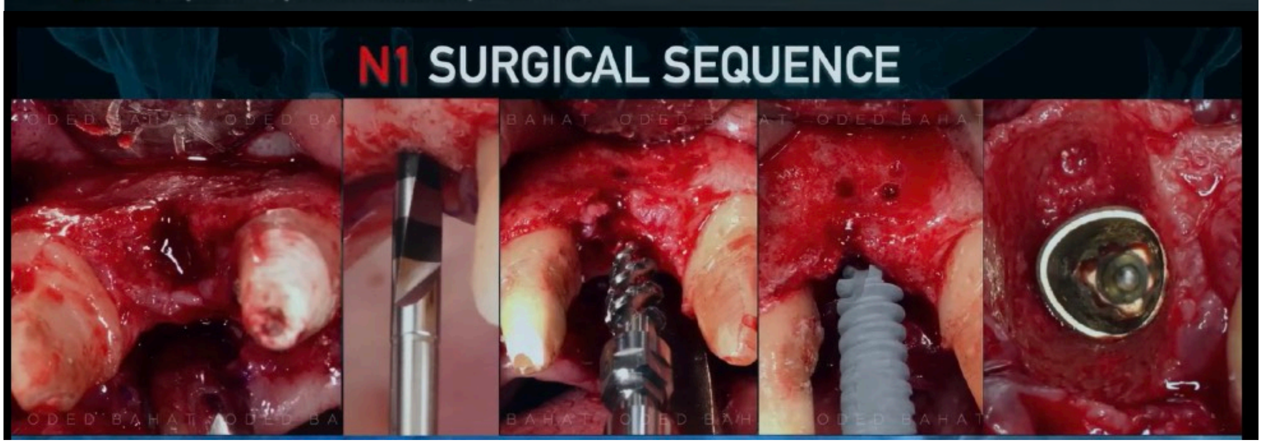
4. **Nobel claims N1's "Trioval connection [creates] …an emergence profile designed for soft tissue maintenance," Posterior teeth are rectangular not triangular.**

A fatal flaw in the design of the N1 Trioval connection is that it can not accept a 1-piece healing collar or abutment.



Early reports on the clinical experience with the N1 implant indicated that 25% of the cases in the maxilla and 50% of the cases in the mandible required use of the OsseoShaper2 drill which is not provided with the implant and is a single use drill. This adds an additional $109 to the cost of the N1 implant. Nobel requires that a dentist take a course before buying N1.





Subcrestal Positioning of Implants with a Convergent Hyperbolic Collar Profile Int J Oral Maxillofac Implants 2022;37:1160-1168. "The placement of implants with a hyperbolic convergent profile collar in the subcrestal position resulted in higher buccal bone resorption and more soft tissue recession."

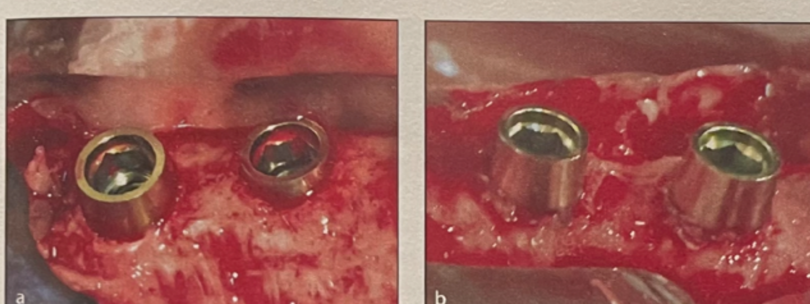


Fig 1 Clinical images at placement. The test implants were placed subcrestally either 0.8 mm (*a*; test-1) or 1.8 mm (test-2), while the respective control implants were placed flush to the buccal bone crest (*b*; control-1 and control-2).

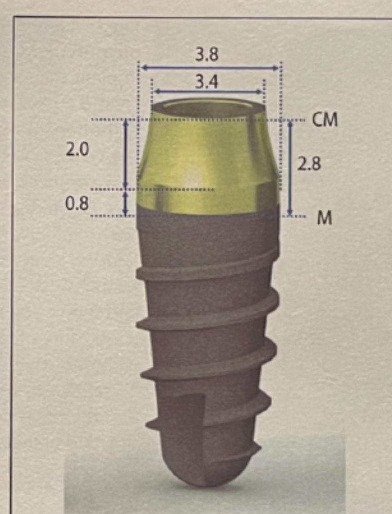
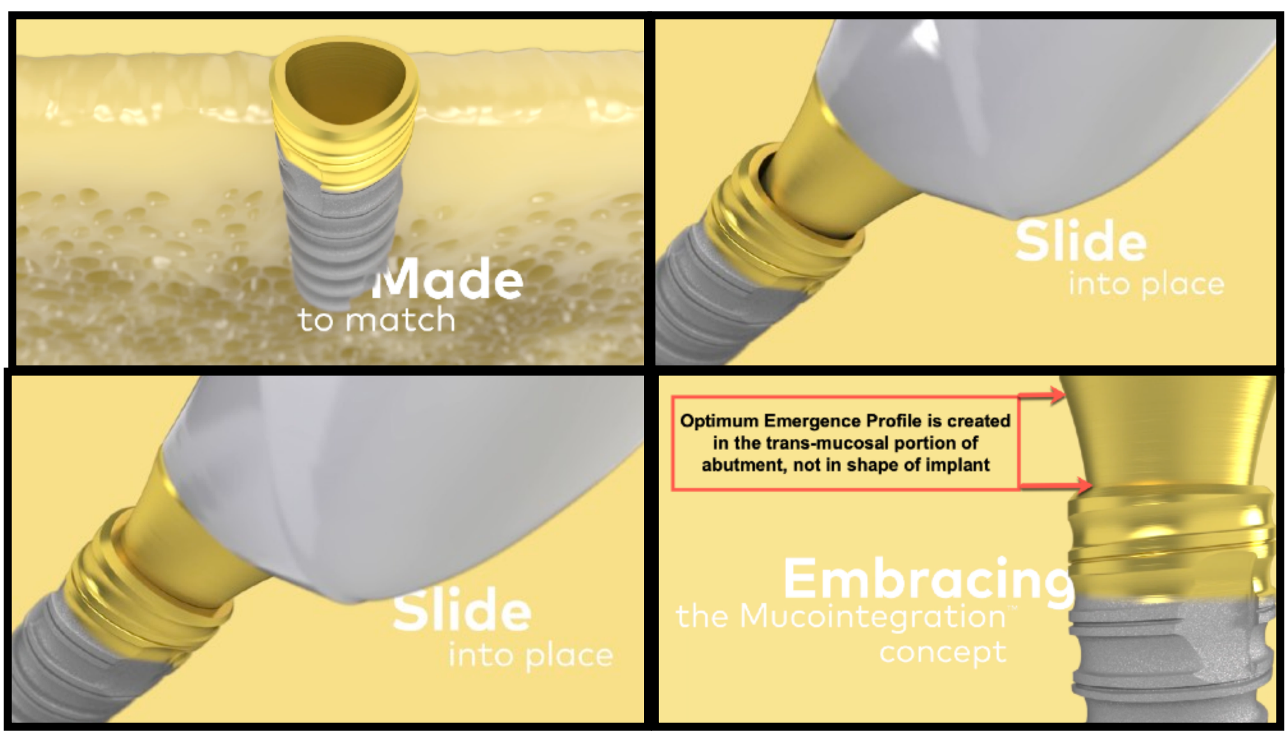


Fig 2 *(Right)* The implant used (PRAMA, Sweden & Martina; Fig 2) had a tapered one-piece conformation with a moderately rough surface. The transmucosal collar was 2.8 mm high, composed of a straight cylindrical section 0.8 mm high at the apical region, and hyperbolic convergent geometry, 2.0 mm high, coronally. CM = collar margin; M = coronal margin of the rough surface.

NobelBiocare includes a final sizing, tapered drill i with each N1 implant. This defeats the well established concept of using a series of progressively wider diameters to enlarge the osteotomy without overheating while evaluating the density of the bone. Following use of a locator or pilot drill, the N1 surgical protocol calls for using a single "OsseoShaper" drilll turning at 25rpm to create the osteotomy. This is a slower process than using an intermediate and a final sizing drills turning at 1200 rpm in dense bone. In soft bone, creating an undersized socket will allow a tapered screw implant to expand and compress the bone for increased initial stability. G. Niznick. Achieving Osseointegration in Soft Bone Oral Health, Aug. 2000

NobelBiocare further claims that the "Trioval conical connection" on the N1 implant with its matching Trioval shaped abutment neck provides *"optimized emergence profiles."*

Only the anterior teeth are somewhat triangular in shape. The bicuspids could be considered more rectangular and the molars more square. Therefore the N1 implant's design rational has a very limited application. Furthermore, emergence profile is, as its name indicates, the profile of the abutment as it emerges from the implant connection. The ideal emergence profile for anterior as well as posterior teeth can be achieved with custom cad-milled abutments that take into consideration the angle of emergence, the diameter of the implant as well as the B-L and M-D widths of the final crown to be attached to the abutment. There is no 1 size fits all, remanufactured oval shape, that matches the emergence profile of teeth. The desired emergence profile will be dictated by the tooth number being replace, the M-D space of the missing tooth and the diameter of the implant that was selected based on available bone width.



NobelBiocare claims that its new N1 implant is *"Engineered for immediate placement and function in extraction sockets."* In immediate extraction sockets, the Trioval shape of the N1 implant just contributes to a wider gap between the implant and the bone compared to a round implant, and will require more bone graft material to fill the void.

NobelBiocare's rational behind the N1 design is that its "*Trioval implant neck reduces stress on cortical bone (compared to traditional round implants) and promotes fast osseointegration*****

Journal of *Clinical Medicine* MDPI

Article

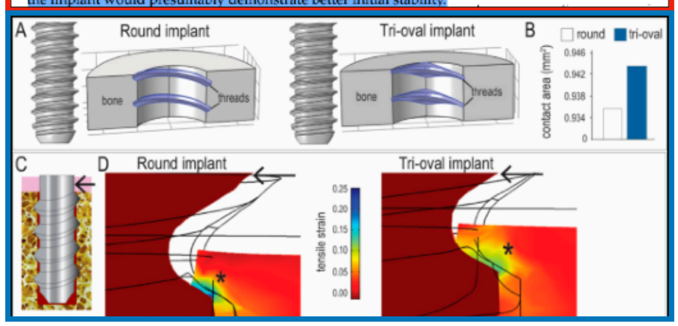
Mechanical and Biological Advantages of a Tri-Oval Implant Design

Xing Yin [1,2], Jingtao Li [1,2], Waldemar Hoffmann [2], Angelines Gasser [3], John B. Brunski [2] and Jill A. Helms [2,*]

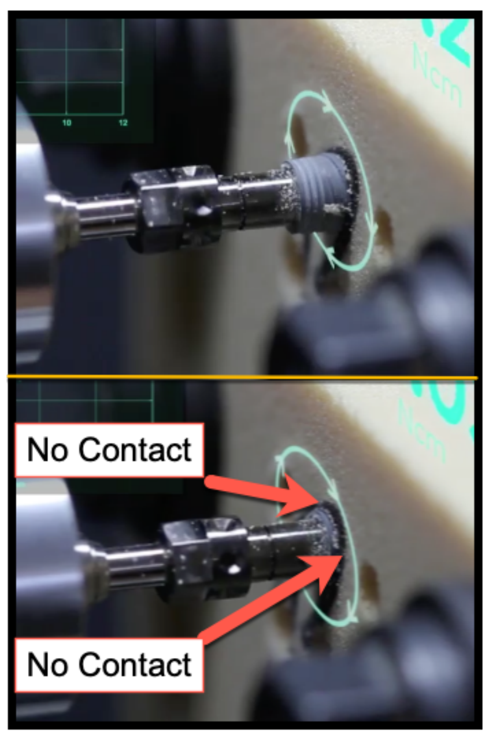
*****This study, referenced by NobelBiocare to support its claim of "faster osseointegration" with the N1 implant does not withstand scrutiny.**

4.1. The Maxima of a Tri-Oval Implant aid in Mechanical Stability

Compared to round implants, the tri-oval implants exhibited better primary stability, which was achieved without using a higher IT (Figure 1). The larger stability was achieved because the maxima of the tri-oval implant penetrated a greater distance into bone than did the threads of the round implant (Figure 2). Based on our data, one might legitimately ask if the novel tri-oval implant design would be negated simply by undersizing the osteotomy for the round implant. In this thought experiment, the threads of the round implant would penetrate deeper into bone and as a result the implant would presumably demonstrate better initial stability.



It consists of insertion torque tests in wood and histology in mice. The data demonstrated the same insertion torque for both the round and Trioval implants, while lateral lateral stability of the Trioval implant was slightly greater. The slight increase on bone contact after healing in the mouse model was interpreted as "faster osseointegration" and was attributed by the authors to the increased lateral stability.
The study acknowledged that this increased initial stability was due to the threads of the Trioval implant penetrating deeper into bone, as shown in this picture from the article. The major diameter of the threads is a factor that could easily been controlled in manufacturing the test implants, so all the study proved was that increasing the depth of penetration of threads into bone increases stability and that could effect osseointegration i.e the study did not prove the efficacy of a Trioval implant design. .

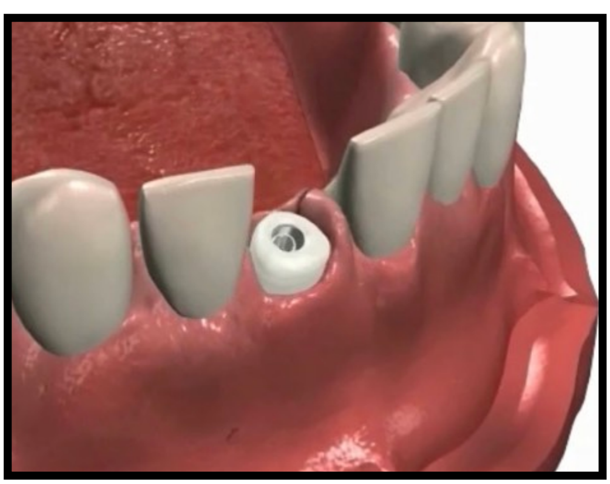


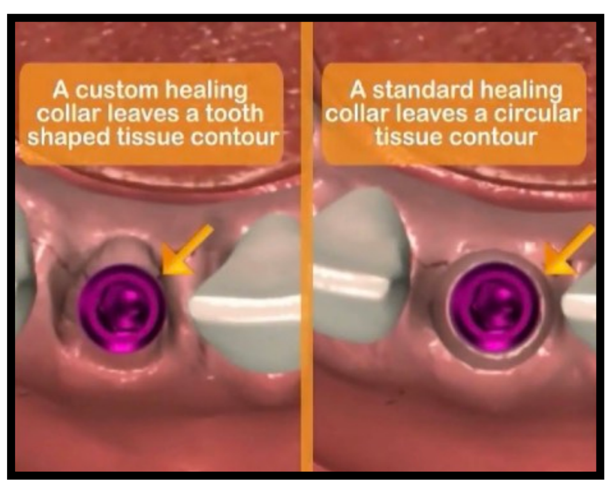
The authors further acknowledge that higher initial stability can be achieved by inserting a round tapered implant into an undersized socket. This successful technique was developed for soft bone insertions to increase stability and densify the bone. This study further claims that the Trioval shape reducing stress at the neck of the implant compared to a round implant. This can also be achieved by back-tapered the implant neck (NobelActive) as shown here but back-tapering the neck reduces initial stability.

Gerald Niznick DMD, MSD • You
Dental Implant Pioneer

A "harmonized emergence profile" is one that replicates the dimensions and flare of the neck of the tooth being replaced. The neck of the Trioval N1 implant is sub-crestal and therefore plays little if any role in creating a natural emergence profile. The neck of the abutment is also oval shaped as it emerges from the implant's oval internal conical connection. Its cross-sectional dimensions bear little if any relationship to the B-L and M-D dimensions of most natural teeth.

The way to "harmonize emergence profile" is to first make a customized healing collar that supports the tissue in an immediate extraction socket or forms the tissue from a surgical opening. Shown below (left) is a shortened titanium carrier from a Legacy2 implant modified by adding acrylic to create the desired emergence profile. This can be replicated in a soft tissue model (right), followed by fabrication of a cad milled abutment with its trans-mucosal section matching the emergence profile and dimensions of the customized healing collar.





Achilles Heel of NobelBiocare's New N1 Implant System

Gerald Niznick DMD, MSD • You
Dental Implant Pioneer

I finally realized the Achilles Heel of the N1 System. THE TriOval connection cannot accept 1-piece healing collars, 1-piece multi-unit abutments or 1-piece Locator abutments. Nobel's rational for the N1 system's Trioval implants and abutments is that they will improve emergence profile for optimal esthetics. One certainly does not need to be concerned about esthetic emergence profiles under an over-denture or under a fixed-detachable full arch prosthesis. This implant's non-circular internal connection precludes its use for restoring any edentulous jaw where 1-piece screw-in abutments or 1-piece over-denture abutments are indicated to simplify these restorative procedures. In esthetic areas the only healing collar available for the N1 implant is the 2-piece On-1 extender that converts the implant's conical connection to a flat, butt-joint connection.

Prosthetics NO 1-PIECE HCs OR ABUTMENTS

Dedicated prosthetics with optimized emergence profiles, surfaces, and triovaI shapes showcase the wisdom of the Mucointegration™ era for soft tissue maintenance and esthetics. The Xeal™ surface is featured on the Multi-unit Abutments and the Nobel Biocare N1 Base**, a two-piece abutment placed at the time of surgery and left in the situ to preserve the connective tissue structure throughout the restorative workflow. All Nobel Biocare N1 TCC abutments achieve a strong and tight connection with a torque of only 20 Ncm, allowing for slim restorative components.

N1 TriOval Connection

NobelActive Round Connection

Nobel Biocare
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🔉🔉🔉 Listen!
Is the sound of drilling distressing for your patients?

Our biomechanics lab compares the noise of a conventional drill vs the OsseoShaper™ instrument: part of the #NobelBiocareN1 system site preparation protocol.

Operating at a low speed and without irrigation, it minimizes noise and vibration and is considerate of patient comfort.

#nobelbiocare #dentalimplants #implantdentistry #OsseoShaperYB #biomechanics dentalimplants #implantdentistry #OsseoShaper #biomechanics

Nobel's mantra at the end of this video is "WE FOLLOW NO ONE". This is not accurate when you consider that I invented the internal hex connection with a lead-in bevel in 1986 (Screw-Vent - patent issued 1990) and NobelBiocare launched the NobelActive in 2008, waiting 17 years for my conical connection patent expired. Now Nobel's claim of "innovation" is to run a drill at 50rpm to reduce the noise compared to running at 1200rmp. It claims that the N1 Shaper drill is the monumental design innovation that allows bone cutting at slow speeds, going right to the final sizing of the osteotomy. Of course, one could run the spade drill at 50 rpm if noise were the most important factor in reducing patient stress. Real patient (and doctor) stress occurs when the implant fails to osseointegrate and we know for a fact that in soft bone, insertion of a tapered implant into an undersized socket generates higher initial stability by compressing the bone. This is important to achieve consistent osseointegration and absolutely critical for immediate loading. As shown in the comparison picture the spade drill is only end-cutting compared to the side-cutting Shaper dill. It is obvious which drill is more likely to result in an oversized socket in freehand preparation.

New low-speed site preparation protocol significantly reduces noise

3053

Jérôme Zemp[1], Stefan Velikov[1], Sergej Weißbrot[1], Florian Fuchs[1]

[1]Nobel Biocare AG, 8302 Kloten, Switzerland

Introduction

In dental implantology, site preparation often involves the use of several high-speed drills in a stepwise protocol. The noise emitted by conventional drills depends on the design and speed of the instruments[1]. Unfortunately, this noise is considered a primary trigger for patient distress.[2,3,4] Recently, a new site preparation instrument (OsseoShaper™, Nobel Biocare AB, Gothenburg, Sweden) was developed to work efficiently at low speeds (<50 rpm) offering the potential to reduce the emitted noise during surgery compared to conventional drills.

Figure 1. Renderings of the OsseoShaper (OS) and conventional drill (CD) used in this comparative study.

Objective

In the present study we set out to quantify and characterize the sound emitted during osteotomy preparation with a recently developed implant site preparation instrument (OS) and conventional drill (CD) as shown in Figure 1.

Materials and Methods

Forty sites were prepared in bone surrogate (Sawbones®, Pacific Research Laboratories) fitted with a piezoelectric pick-up (Schaller Oyster S/P). Implant sites were prepared either 1 cm (OS, n = 10; CD, n = 10) or 3 cm (OS, n = 10; CD, n = 10) from the sensor (Figure 2). All OS and CD sites were prepared at 50 rpm or 1200 rpm, respectively. The moving root mean square (mRMS) amplitude with an averaging window size of 500 ms and the time-resolved frequency spectra were analyzed in the audible spectrum (up to 20 kHz) using MATLAB (The MathWorks Inc.). The two drill protocols were then compared using the maximum of the mRMS during drill insertion. The mRMS averages out single peaks in the audio signal and better represents the human perception of the noise loudness than the raw audio signal. This is due to the fact that high single peaks in the audio signal might not be perceived as "loud" if they are of very short duration.

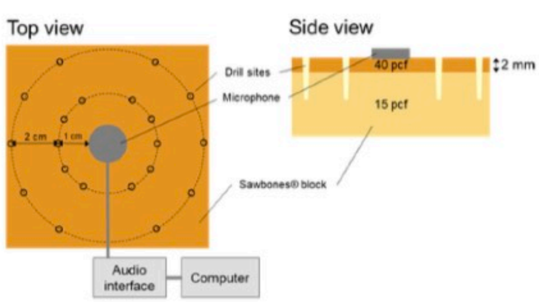

Figure 2. Schematic representation of the test setup.

Results

The louder perceived noise during testing of the CD as compared to the OS manifest themselves in large spikes in the audio signal of the CD and a higher mRMS amplitude (Figure 3).

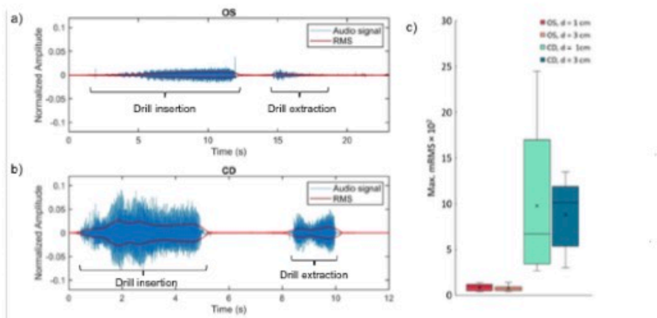

Figure 3. Noise produced during implant site preparation. Representative normalized (blue) and root-mean-square (red) amplitude measurements for the a) OS and b) CD site preparation protocols. c) Box plot of the maximum mRMS at 1 cm and 3 cm distance from the senor for each condition evaluated (n=10 each).

The maximum mRMS was analysed statistically using a 2-sample t-test comparing the OS to the CD for both d = 1 cm and d = 3 cm. For the CD test group with d = 1 cm, two samples showed an untypically high maximum mRMS value, which might be a result of local density differences in the bone surrogate material. Both values are considered outliers and excluded from the statistical analysis. Although this might underestimate the noise generated by the CD, it is deemed appropriate to avoid bias towards a better performance of the OS. In both cases, the maximum mRMS is significantly lower for the OS ($p<0.05$).

The characteristics of the OS audio signal can be compared to a monotonous human whistle, while the CD resembles the typical sounds of drilling. This can shown by analyzing the frequency spectrum of the audio signals (Figure 4). The sound emitted during OS preparation was characterized by a single-pitch note with a fundamental frequency of 1.3 kHz and harmonics at higher frequencies originating from the drill unit motor. Site preparation with the CD had a less defined spectrum, with wide peaks at 2 kHz and 3 kHz and greater background noise.

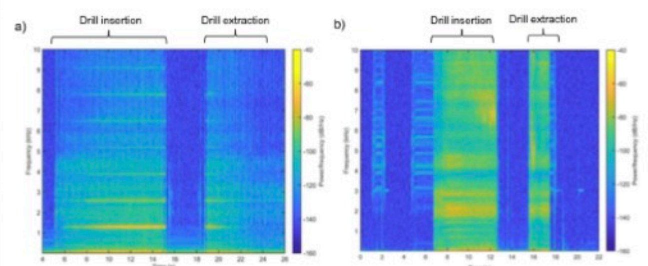

Figure 4. Power/frequency for the a) OS and b) CD in the audible spectrum of the human ear (100 Hz to 20 kHz).

Conclusions

Reducing noise and vibration can be an effective measure for anxiety prevention and to improve the quality of the work atmosphere in dental clinics. This study showed that the slow and controlled site preparation of the OS produces significantly reduced noise compared to CD. In fact, the anxiety-inducing noise characteristic of CD is nearly eliminated with the OS protocol. Therefore, patient comfort may be improved with the OS over conventional protocols.

References

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IADR GENERAL SESSION

Funding for this study was provided by Nobel Biocare™

40 YEARS OF INNOVATION
37 PATENTS - 4 SPECIFIC TO GEN5

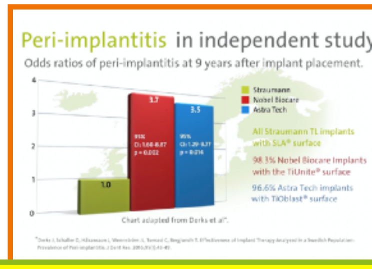
USE THIS QR CODE TO VIEW THIS DOCUMENT ONLINE AND HAVE ACCESS TO THE LINKS INSIDE

RESEARCH SUPPORTS REDUCTION OF PERI-IMPLANTITIS BY USING A HYBRID DESIGN SURFACE WITH THE IMPLANT-ABUTMENT JUNCTION SUPRA-CRESTAL

Applies to Straumann's TLX implant and Paragon's GEN5 implant BUT not the BLX

Dr. Niznick Article: AO News Vol.33 No. 2, 2022:

"Dr. Buser cites a Swedish 10-year study comparing three implants: Astra, NobelBiocare and Straumann's Tissue Level implant, claiming the latter exhibited significantly less peri-implantitis. Assuming part of the smooth neck of the Straumann TL implant was inserted in bone, this would give it a hybrid bone interface. It also adds the variable that the implant-abutment connection would be supra-crestal… [which] is at least as important a factor in minimizing peri-implantitis as a hybrid surface."



Dr. Michael Dard, Prof. NYU Interview:

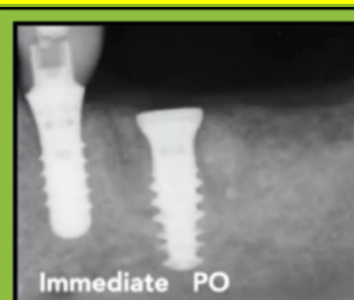
1. **Explains peri-implantitis** and
2. **Discusses results of the Derks et al study**

Video Lecture and interview of Dr. Daniel Buser, explaining importance of Hybrid Surface and how he partially submerges smooth neck of "Tissue Level" Implants

Dr. Daniel Buser explains insertion of Straumann's "Tissue Level" implant with 1.8mm of its 2.8mm smooth neck sub-crestal, leaving 1mm and the implant-abutment junction, supra-crestal.

Buser Quote on Straumann's Website:
"The Future of Implant Dentistry is with neck designs combining a smooth surface in the trans-mucosal area with a micro-rough surface inside the bone. As the Derks study showed, moving the micro-gap away from the bone and having a smooth surface in the peri-implant sulcus reduces the risk of peri-implant complications." Derks 9 Year Comparative Study

PARAGON'S GEN5 IMPLANT HAS A 2.5mm ANODIZED, SMOOTH NECK, CONFIGERED TO BE 1mm SUPRA-CRESTAL



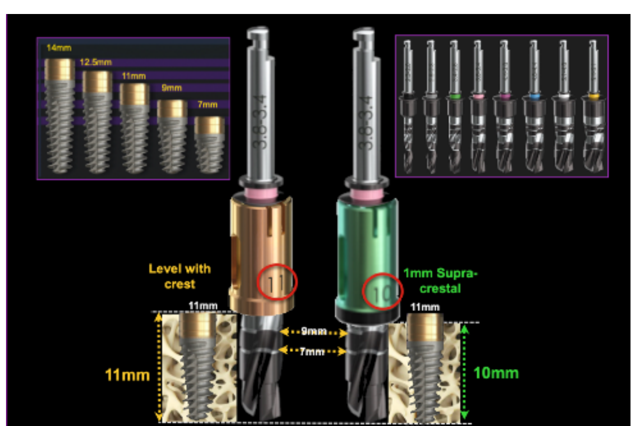
Influence of Implant Placement Depth and Soft tissue Thickness on Crestal bone Stability Around Implant with and Without Platform Switching

This case control study measured early crestal bone changes around sub-crestal placed platform-switched implants surrounded by thin soft tissue and compared them with regular, matching-platform implants placed in a supra-crestal position and surrounded by thick soft tissue. After 1 year, mean bone loss was 0.28 mm (SD:0.36 mm; range: 0.1-1.63 mm) in the control group and -0.6 mm (SD:0.55 mm; range: 0.05-1.8 mm) in the test group. Platform-switched implants placed in a subcrestal position in vertically thin soft tissues showed statistically significantly more bone loss than non-platform-switched implants placed supra-crestal with vertically thick tissues.

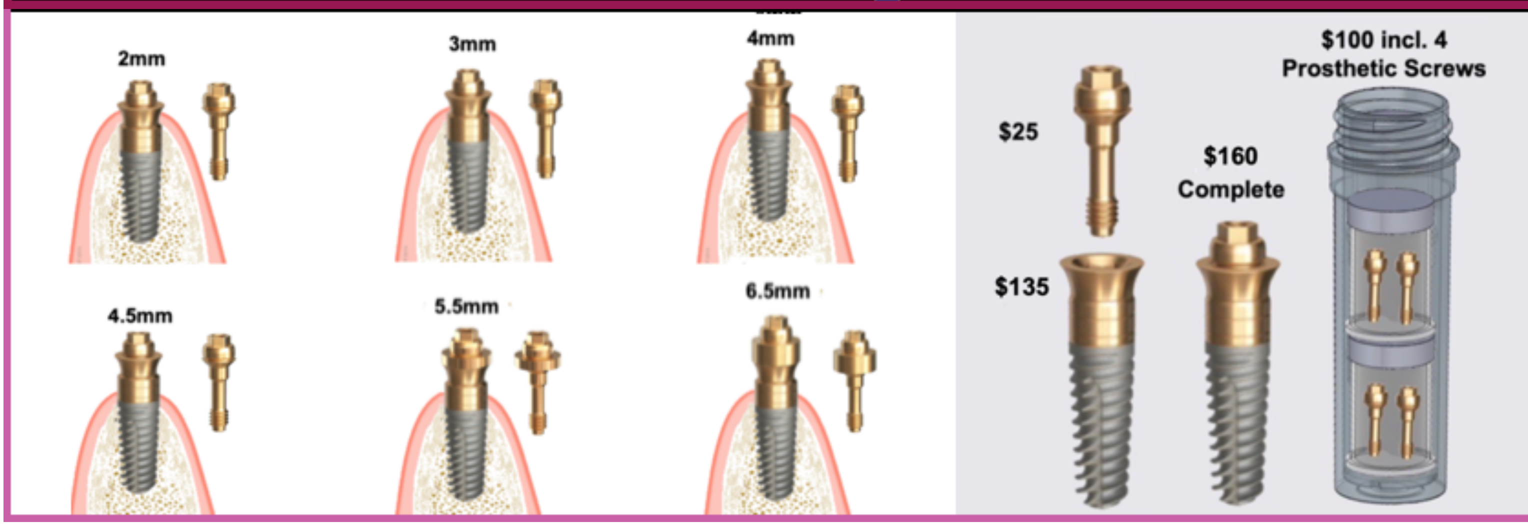
Fig 2 (a) Control group patients had implants placed in a supercrestal position, and (b) test group patients had implants placed in a sub-crestal position.

Paragon's GEN5™ , GEN5+ and NizPlant™ implants have the same implant body with a 2.5 mm machined, anodized neck. Depth gauge lines at 1 mm, 2 mm and 2.5 mm from the top (Pat. Pend.), along with 2 depths of drill stops, facilitate placement level with or 1mm above the crest of the ridge. The insertion depth control, in conjunction with the ability to varying the height of the prosthetic screw, minimizes the need and cost of maintaining an inventory of abutment heights. The GEN5+ offers the additional flexibility of a 2 mm friction-fit collar that can serve as the trans-mucosal collar of an abutment or be removed for abutment connection directly to the top of the implant for unprecedented vertical flexibility.

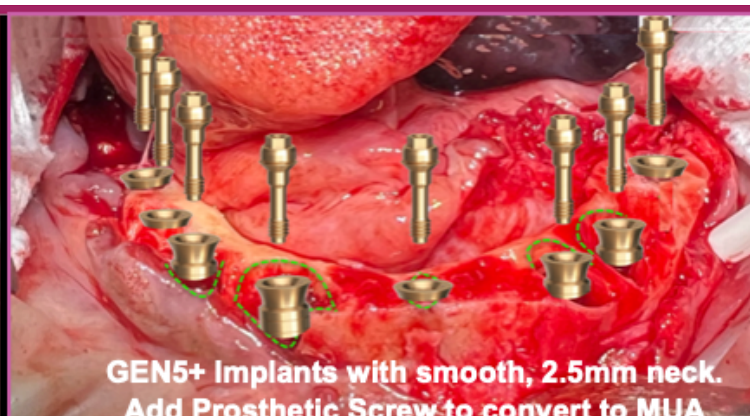
Each Paragon implant is 1 mm longer than the standard lengths of the respective Screw-Vent and Legacy implants. Paragon's surgical system includes two options of drill stops. One is for placement 1mm supra-crestal, which moves the implant-abutment junction away from the bone and and creates a 1mm supra-crestal zone of titanium for undisturbed soft tissue attachment when prosthetic components are attached and removed from the implant. The other drill stop positions the implant level with the highest point on the the ridge, usually on the lingual, leaving the smooth neck exposed if there is bone recession on the labial/buccal. The diameters of the drill stops and the freedom of rotation of the drills within the drill stops allow there use through surgical guide without the need for keys.



GEN5+ is a GEN5 with a Friction-Fit 2mm Extender that serves as a Healing Collar, a MUA with the addition of a Prosthetic Screw of different heights and a Platform for a Variety of Abutment Options



Simulated case (right) shows 8 GEN5+ implants replacing exposed implants (left). Little or no bone grafting needed because only smooth surfaces exposed. Attaching a Prosthetic Screw converts platform to standard MUA.



NIZPLANT 1-PIECE IMPLANT WITH DUAL FUNCTION PLATFORM FUNCTION AS OVERDENTURE AND MULTI-UNIT ABUTMENT

NizPlant 1-Piece Locator Compatible Implant with Internal Threads

ABSTRACT:
A screw-type endosseous dental implant includes, near the top on the implant's external surface, a ridge projecting laterally, and an internally-threaded shaft with a lead-in, beveled opening, an internal wrench-engaging surface located below said lead-in, beveled opening, and, below said internal wrench-engaging surface and above said internal threads, an internal under-cut/groove forming a chamber configured to receive a snap attachment for retention of an over-denture.

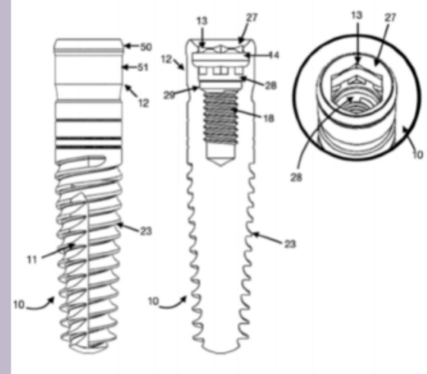
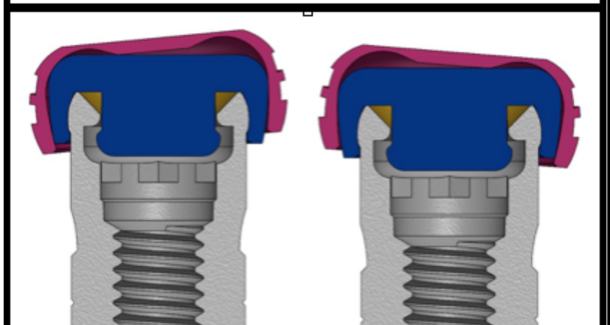


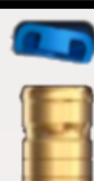
Fig. 1 Fig. 2 Fig. 3

NizLoc Attachments Engage both outside and inside of the NizPlant implant. The male projection can be removed to reduce the degree of retention.



Zest LODI 2-Piece Implant with Over-denture Attachment

@$220, Includes Cap Attachment Components



NizPlant 1-Piece Implant with Dual Function Platform

@ $150, Includes Cap Attachment Components