How Dental Implant Quality and Performance Improve Patient Treatment

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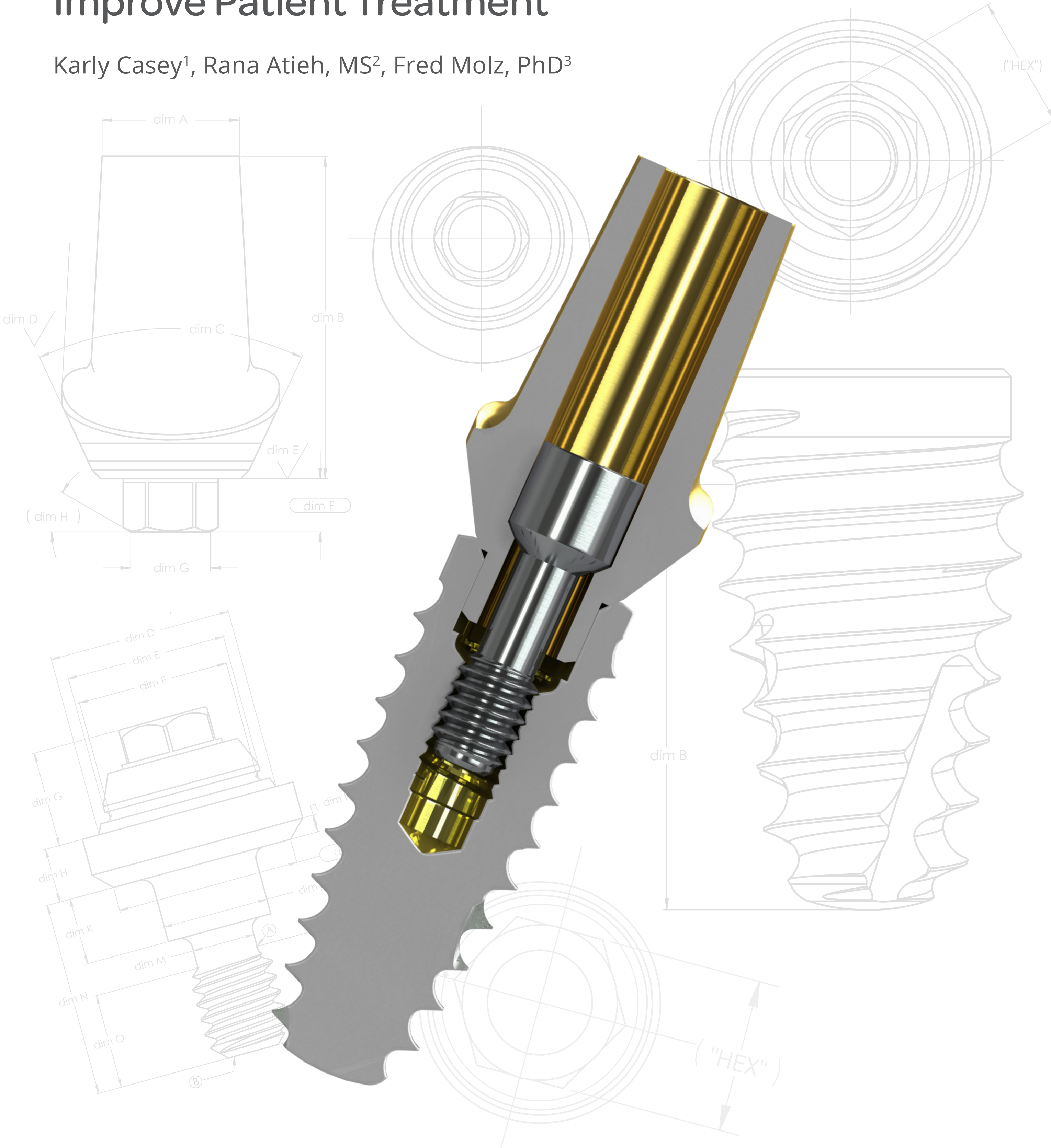

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Executive Summary

The quality and performance of dental implants are key features to the clinician's and patient's experiences. Mechanical strength, manufacturing quality and surface treatment are all factors that influence a dental implant's quality and performance. Understanding the science behind different implant designs and technologies on the market today is crucial for clinicians to make an informed choice of what system to use to treat their patients. This engineering evaluation serves as a review and comparison between two dental implant systems: BioHorizons® and Neodent®, assessing key components to implant system design, including the connection, through a series of tests and evaluations.

Introduction

Dental implant systems have various design aspects relevant to the overall quality and clinical performance. When comparing implants to one another, important design features like the prosthetic connection, implant thread, surface and overall manufacturing quality can influence the mechanical strength and performance of the system. Considering patient expectations for dental implant therapy, survival rate is a key parameter. In this evaluation, BioHorizons and Neodent implant systems are compared based on these design features.

The BioHorizons implant portfolio includes a conical, hexed connection available in 3.0, 3.5, 4.5 and 5.7 mm prosthetic platform sizes with implant diameters ranging from Ø3.0 mm to Ø8.0 mm. BioHorizons implants are indicated for all bone densities (I-IV). Prosthetic platform sizes increase with implant diameter, and platform-switching options are available. The implants include a tapered body with a reverse buttress thread design as well as a resorbable blast textured (RBT) surface with a Laser-Lok® collar. The implants utilize cutting flutes, or a self-tapping feature, at the apex of the implant to assist with implant placement. BioHorizons implants, abutments and abutment screws are manufactured using surgical-grade titanium alloy, Ti-6Al-4V ELI (ASTM F136).

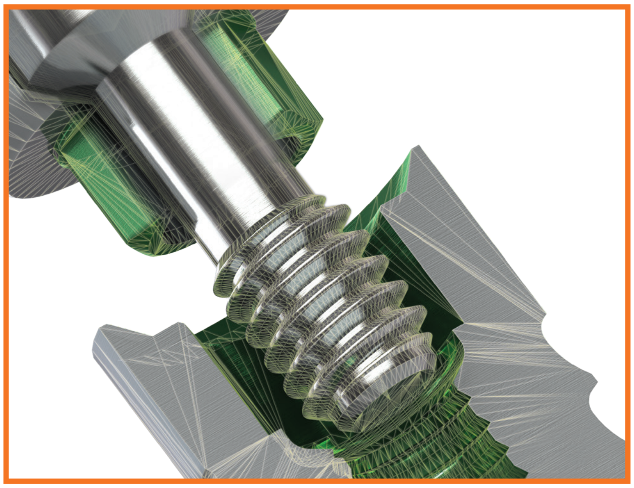


Figure 1. BioHorizons connection

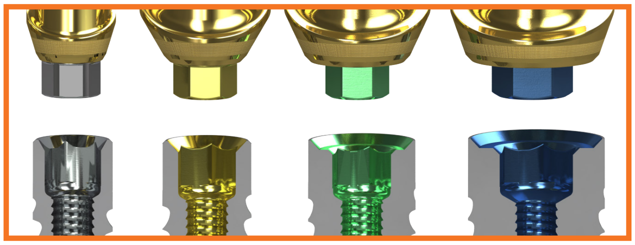


Figure 2. BioHorizons prosthetic connections

The Neodent Grand Morse™ (GM) implant portfolio includes a deep conical connection in a single prosthetic platform size, 3.0 mm, across all implant diameters ranging from Ø3.5 mm to Ø7.0 mm. Neodent Helix™ GM Ø3.5 mm to Ø5.0 mm implants are indicated for all bone densities (I-IV), while Ø6.0 mm and Ø7.0 mm implants are only indicated for bone densities III and IV.

The Neodent Helix GM implants include a tapered body with a trapezoidal (buttress) thread as well as a sandblasted and acid-etched surface (Neoporos). The implants utilize cutting flutes, or a self-tapping feature, at the apex of the implant with a v-shaped thread to assist with implant placement. Neodent implants are manufactured from commercially pure grade 4 titanium (CP4) and Neodent abutments and abutment screws are manufactured from titanium alloy, Ti-6Al-4V.

Figure 3. Neodent connection

Figure 4. Neodent prosthetic connection

Assessing key design features of the two implant systems provides insight on their performance. This evaluation addresses various strengths and weaknesses of each feature, and how they translate to successful dental implant therapy. It is important for clinicians and dental professionals to understand these features and their limitations when deciding how to treat their patients.

Morse Taper and Prosthetic Connection in Implant Dentistry

Dental implant companies often promote their implant-abutment seal as a morse taper connection. While many designs feature a conical seal (as opposed to flat-on-flat seal with parallel internal or external hex), the question remains whether a true morse taper can be achieved in implant dentistry.

Reviewing international standards on morse tapers, specifically ones related to the dimensions of a morse taper connection, the scale is not relevant to implant dentistry. ISO 296:1991, Machine tools — Self-holding tapers for tool shanks, specifies dimensions of self-holding tapers for tool shanks according to their use, and provides the following measurements for morse tapers in milimeters[6].

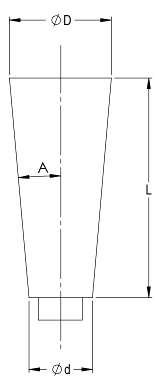


Figure 5. Internal morse taper socket schematic

Morse Taper No.	ØD (mm)	Ød (mm)	L (mm)	A (Degrees)
0	9.045	6.7	49	1.4908
1	12.065	9.7	52	1.4287
2	17.780	14.9	62	1.4307
3	23.825	20.2	78	1.4377
4	31.267	26.5	98	1.4876
5	44.399	38.2	125	1.5073
6	63.348	54.8	177	1.4933

Table 1. Internal morse taper socket conditions defined by ISO 296:1991

In order to achieve the friction fit and accurate centering between the mated components of a morse taper connection, the defined dimensions must be maintained. Notice how the smallest possible length of a standardized internal morse taper is 49 mm, well above the length of the taper found in implant connections. The largest standardized angle of a morse taper is 3.0146°, well below the average taper of a dental implant connection. Without maintaining proper dimensions, the advantages of a morse taper come into question. Morse tapers, as defined by technical standards, cannot and do not exist in implant dentistry.

Conical connections are often defined by their depths (grand, deep etc.) to emphasize stronger and more robust seals. However, to create a perfect friction-fit between the implant and abutment, the tapered angles of the components must perfectly match. Taking into account manufacturing processes and engineering tolerances, the perfect friction-fit is often unachievable on physical components. This is compensated and corrected by a connection design favoring a single point of contact at the most coronal end. The abutment conical mating surfaces are designed with a larger included angle compared to the implant to ensure this conical seal. Thus, when comparing a conical connection to a deep conical connection, it is important to acknowledge that the implant-abutment true seal is often at the coronal end, regardless of the depth.

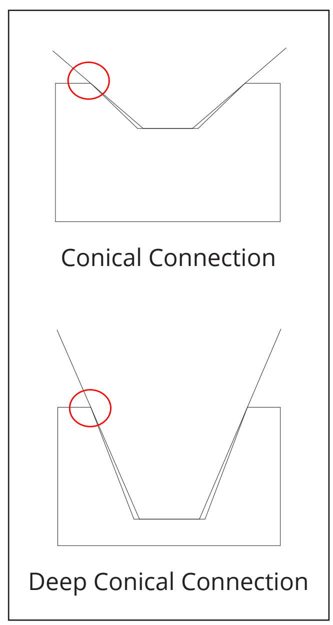


Figure 6. Visual representation of the implant-abutment junction between a conical and deep conical connection

Increasing the diameter of the prosthetic connection, specifically for large diameter implants, is a pivotal design feature that increases the mechanical strength of the system. Large diameter implants are often placed in the posterior region of the mouth to account for higher occlusal forces and are restored with a crown that has a wide emergence profile. To compare simple models of different sized prosthetic connections, a Finite Element Analysis (FEA) between the same diameter implant (Ø5.0 mm), but two different prosthetic connection sizes (Ø3.0 mm and Ø4.5 mm) was performed.

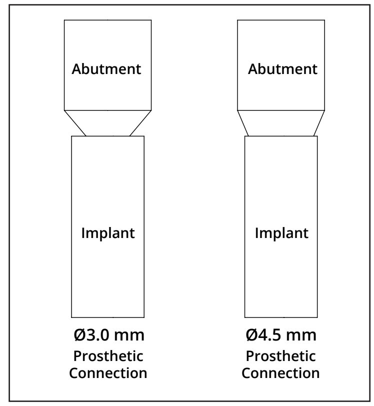


Figure 7. Side by side comparison between models used for FEA

In this FEA, only the prosthetic connection diameter changes dimensionally. The implant diameter, abutment height, connection height and emergence height are the same between the two models. An identical single point load of 50 lbf (222.41N) is applied to the top of the abutment in each scenario to represent a lateral occlusal force (represented by the red arrow). The implant is fixed in the system to represent osseointegration (green arrows). When presented with this force, the abutment with the larger prosthetic connection experiences less stress at the implant-abutment connection compared to the smaller prosthetic connection. The max stress at the implant abutment connection is almost double for the smaller prosthetic connection (4.367×10^8 N/cm^2) compared to the larger prosthetic connection (2.632×10^8 N/cm^2). This ability to withstand higher stresses defines higher mechanical strength. This representative analysis demonstrates the increased mechanical strength at the prosthetic connection when a larger diameter is used.

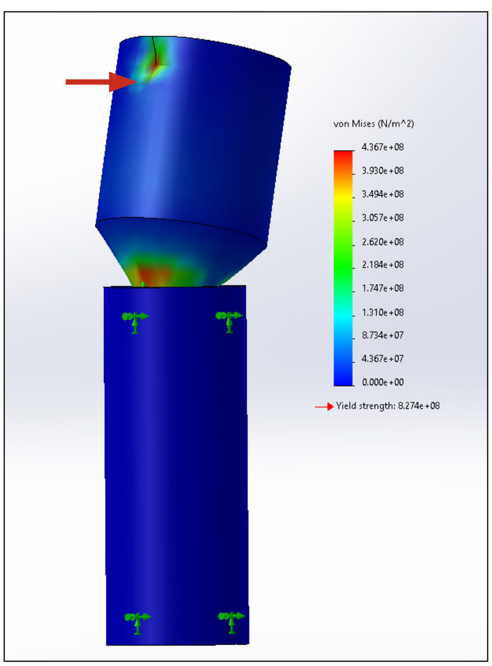


Figure 8. Ø3.0 mm prosthetic connection Finite Element Analysis stress results

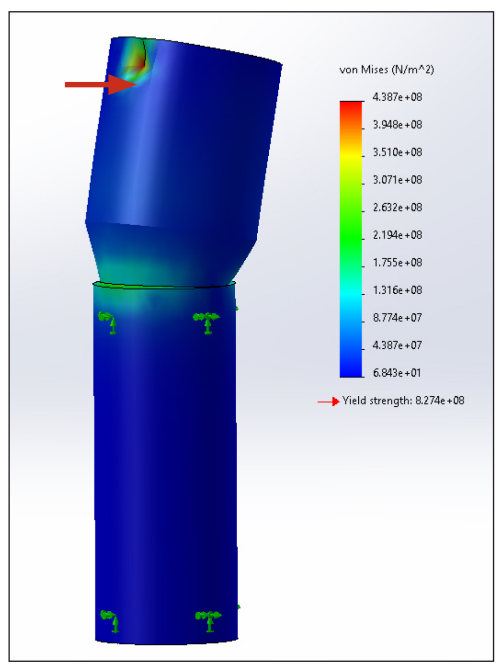


Figure 9. Ø4.5 mm prosthetic connection Finite Element Analysis stress results

Mechanical Strength

Mechanical strength of a dental implant system provides information relevant to the system's indications for use, specifically where the implant can be placed intraorally for successful function throughout the lifetime of the device. Mechanical failure in the system, whether it appears at the implant or abutment level, compromises the whole system and quality of life for a patient. The following mechanical testing performed on BioHorizons and Neodent systems highlights the advantage of increasing the diameter of prosthetic connection, specifically for large diameter implants, over the simplicity of the one-sized prosthetic connection.

International state-of-the-art standards are developed by specialized technical committees and globally recognized by dental implant manufacturers. BS EN ISO 14801:2016 – Dentistry – Implants. Dynamic loading test for endosseous dental implants - specifies a procedure for static and dynamic testing of different designs and sizes of endosseous dental systems, including implant and prosthetic components[7]. Using the procedures defined by ISO 14801:2016, both Neodent and BioHorizons implant systems were tested for direct comparison of mechanical strength.

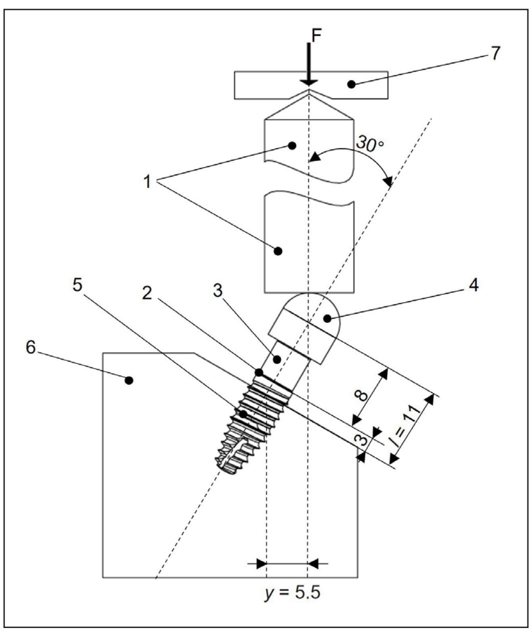
The endosseous dental implants selected were as close as possible in diameter and indication for use to ensure valid comparison and reduce variability as much as possible. The corresponding abutments were connected and the abutment screws were torqued appropriately per the manufacturer's recommendations.

	BioHorizons		Neodent Implant System	
	Part Number	**Description**	**Part Number**	**Description**
Implant	BTA5212	Tapered Pro Implant Laser-Lok, RBT 5.2 x 12mm	109.955	GM Helix Implant, Titanium, 5.0 x 11.5 mm
Abutment	PGNEA	Internal 4.5mm Narrow Emergence Abutment	114.573	GM Exact Click Universal Abutment, Titanium, 3.3 x 6 x 1.5 mm

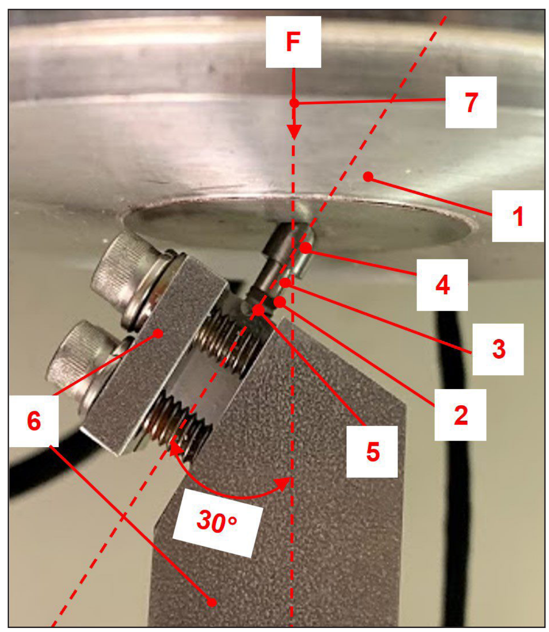
Table 2. BioHorizons and Neodent components selected for testing per ISO 14801:2016

Figure 10. Representative BioHorizons test system, with and without hemispherical loading member

Figure 11. Representative Neodent test system, with and without hemispherical loading member



(a)



(b)

1 – Loading device
2 – Nominal bone level, fixed to simulate 3.0 mm ± 0.5 mm of bone resorption
3 – Implant abutment
4 – Hemispherical loading member
5 – Implant body
6 – Specimen holder
7 – Force application

Figure 12. Test schematic per ISO 14801:2016 (a) and representative test setup (b). All dimensions shown are in millimeters (mm).

Mechanical Strength (continued)

Results indicate higher mechanical strength for the BioHorizons endosseous dental implant system. The average loads to failure for the BioHorizons and Neodent systems were 196.67 lbf (874.83 N) and 152.80 lbf (679.69 N), respectively. When comparing all sample values for load to failure through an unpaired t test, these results are statistically significant ($p<0.0001$). More important than static strength, fatigue strength provides an indication to the durability and longevity of the implant system during clinical use. The fatigue limit for the BioHorizons system was 78.67 lbf (349.94 N, 40% of the average load to failure), while the fatigue limit for the Neodent system was 45.22 lbf (201.15 N, 30% of the average load to failure). From the failed systems, both failure modes provide a measure in which only the abutment can be replaced. When comparing fatigue limits between both systems, the BioHorizons system is 74% stronger. Additional BioHorizons testing data per ISO 14801:2016 on Ø4.6 mm implants (part number TSL4606) also showed a higher fatigue limit of 57.10 lbf (254 N, 26% stronger than the Neodent fatigue limit), proving that even with a smaller diameter implant, the BioHorizons implant system with a wide diameter prosthetic connection is mechanically stronger.

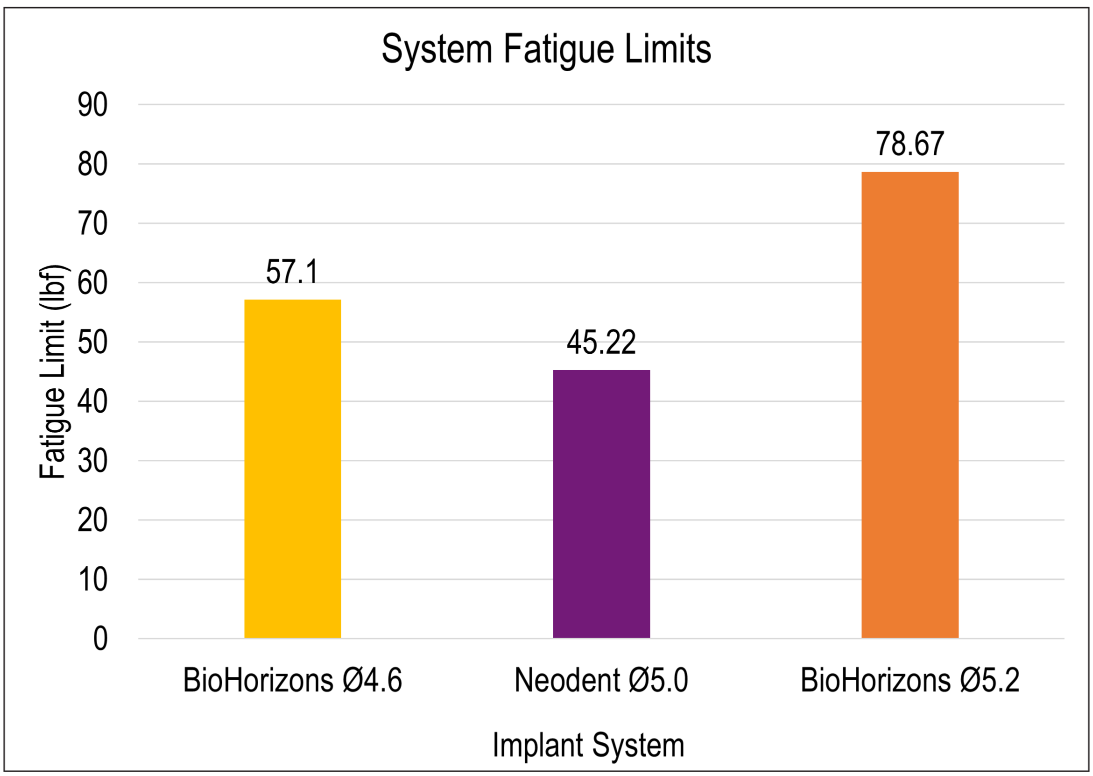


Figure 13. Comparison between BioHorizons and Neodent system fatigue limits

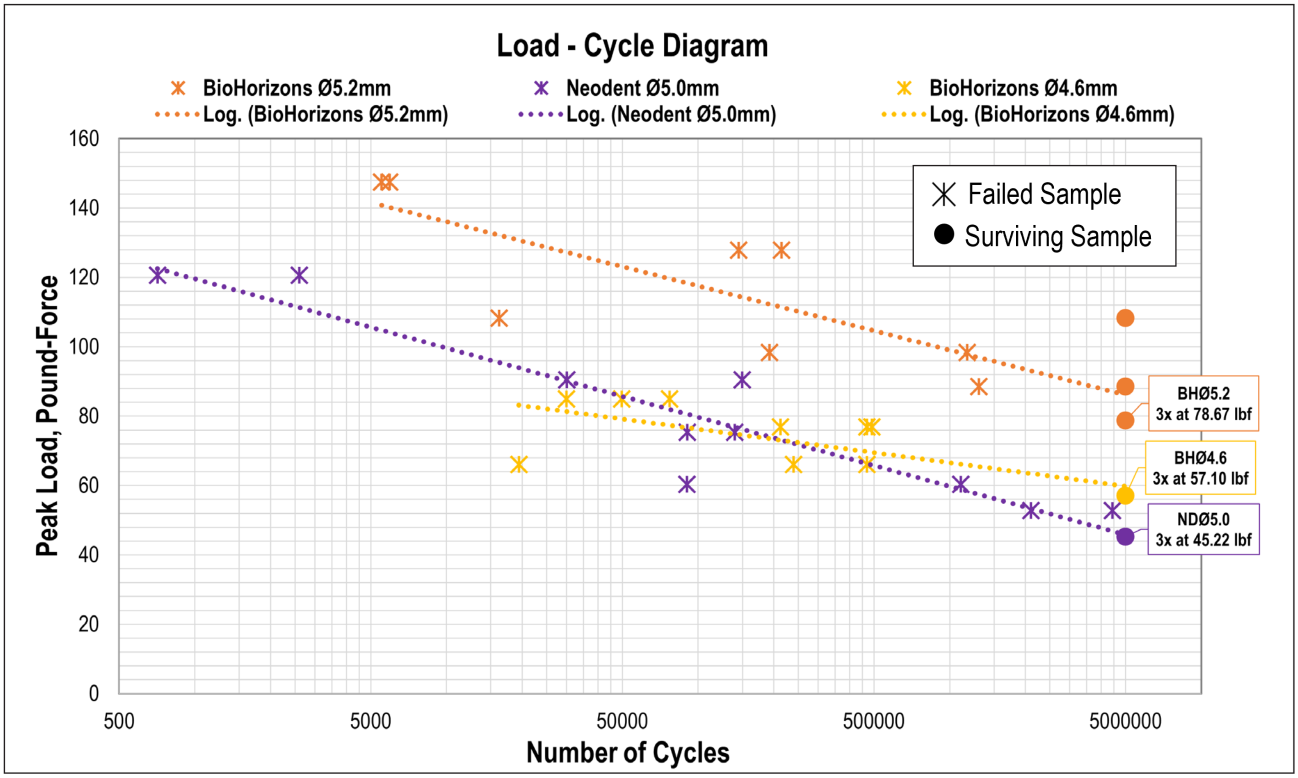


Figure 14. Load-Cycle Diagram of BioHorizons and Neodent implant systems

Higher mechanical strength translates to higher clinical safety and performance for the BioHorizons system, and a decreased chance of failure throughout the lifetime of the device. The Neodent system has higher chance of failure, which will subsequently require extended chair time and follow up appointments for prosthesis rework. The results put in question the convenience of the one size prosthetic connection. Surely, this convenience does not outweigh the significant loss of strength and reduced lifetime of the restoration when considering patient satisfaction.

Manufacturing Quality

The quality of component manufacturing can play a role in dental implant success and survival. Using a stereo microscope, Neodent and BioHorizons implants and abutments were inspected for different types of manufacturing defects including burrs (material accumulation) and surface abrasions. All samples were inspected out of their respective packaging by quality engineers. Manufacturing defects provide insight on the overall manufacturing quality of the components. Evidence of these defects has the potential to increase complications related to the survival and success of the implant (fractures, infection etc.) Both BioHorizons (Tapered Pro) and Neodent (Helix GM) production-level implants were inspected for these manufacturing defects.

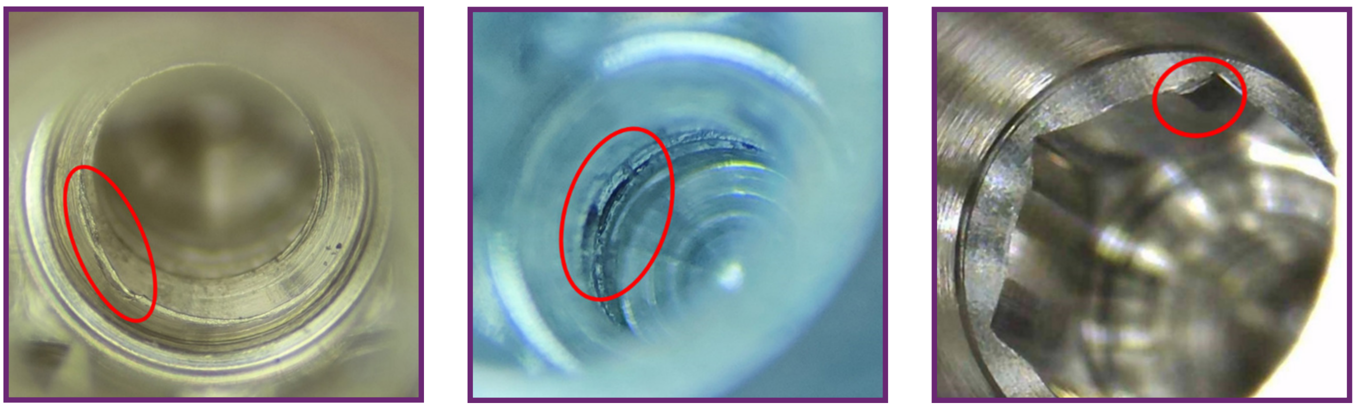


Figure 15. Burrs identified on the internal threads of the Neodent implant samples

Figure 16. Burr identified at the entrance of the hexed connection of a Neodent implant sample

For Neodent Helix GM implants (part numbers 109.945, 109.983 and 109.950) burrs were identified in the implants on and around the internal threads as well as at the entrance of the hexed connection. These burrs may cause obstruction or galling during mating with the abutment.

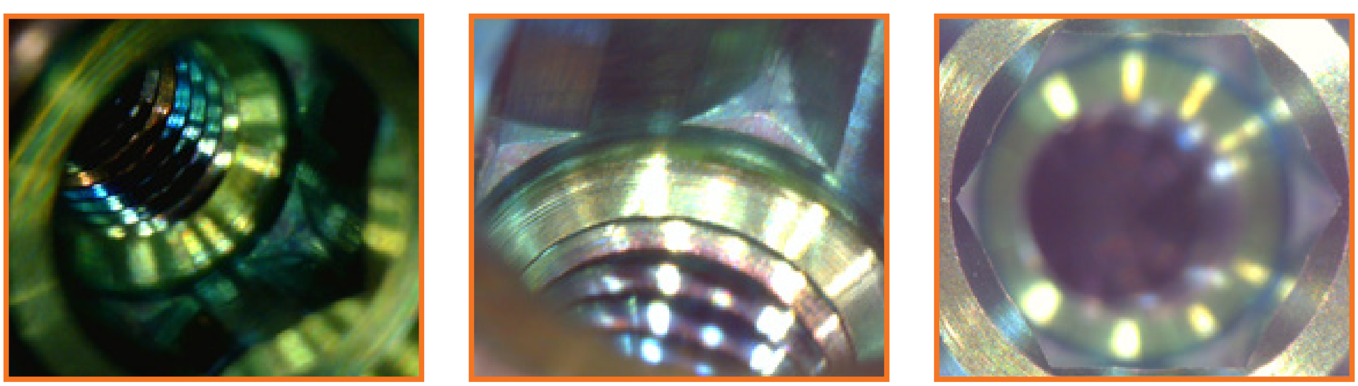


Figure 17. No evidence of manufacturing defects in the internal threads or around the hexed connection of the BioHorizons implant samples

For BioHorizons Tapered Pro implants (part numbers BTA5210 and BTA5212), there was no evidence of manufacturing defects in the internal threads or around the hex connection.

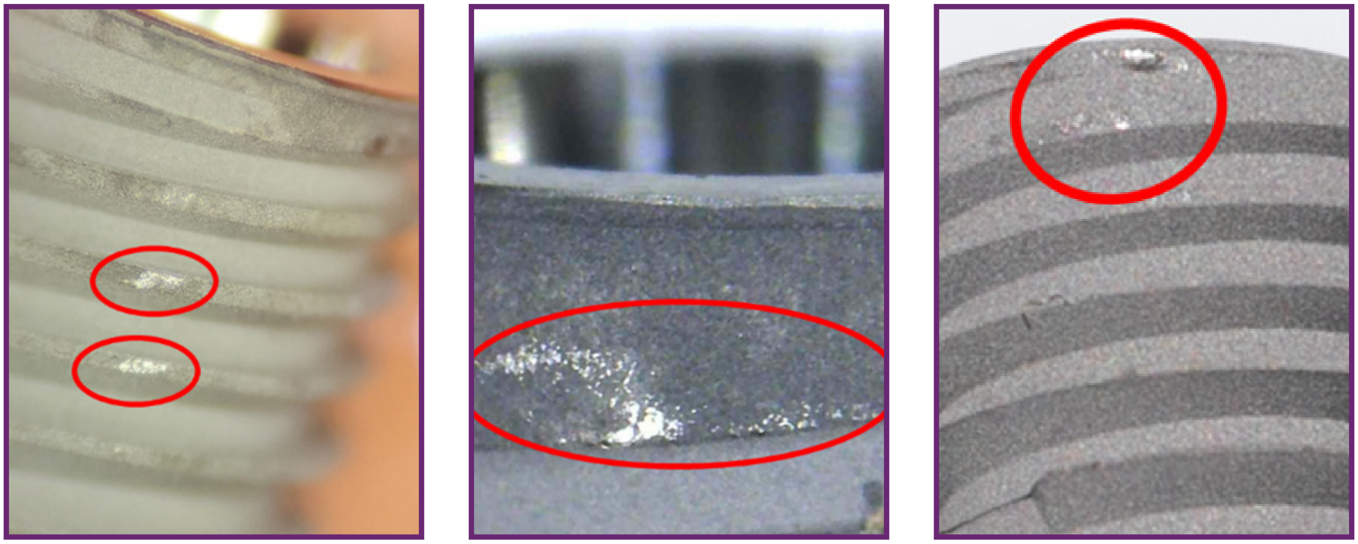


Figure 18. Surface abrasions on the Neodent implant samples

Surface abrasions were noticed with unaided vision on the surface of the Neodent implants (part numbers 109.945, 109.983 and 109.950), most likely from the metal clips used in Neodent implant packaging. Since the clips do not securely hold the implant in place, rather in the upright position, it is possible that movement during packing and handling caused these metal clips to scratch or abrade the implant surface.

Figure 19. No evidence of surface abrasions on the BioHorizons implant samples. There is a notable change in coloring between the implant collar and the implant body due to the Laser-Lok application around the collar.

No surface defects were observed on the BioHorizons implant samples (part numbers BTA5210 and TRXP5809). There is a notable change in coloring between the implant collar and the implant body due to the Laser-Lok application around the collar.

Material and Surface Evaluation

The material composition of a dental implant is another key factor of clinical safety and biocompatibility. As shown through energy-dispersive X-ray spectroscopy (EDS), BioHorizons implants are manufactured from titanium alloy and Neodent implants from commercially pure titanium. Both materials have been shown to osseointegrate effectively[8], however, Ti-6Al-4V ELI has higher ultimate and yield strengths compared to Grade 4 CP Titanium[9,10]. No chemical impurities or foreign materials were noted on the surfaces of the two systems.

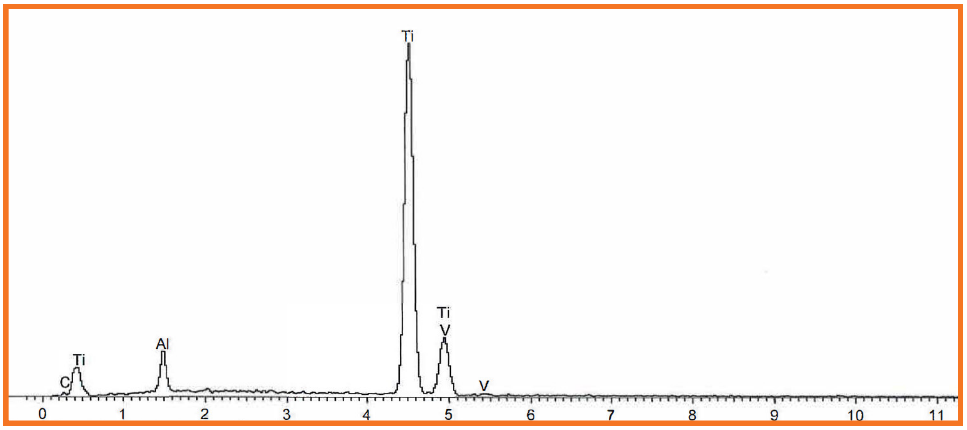


Figure 20. EDS plot for the BioHorizons (Ti-6Al-4V ELI) implant

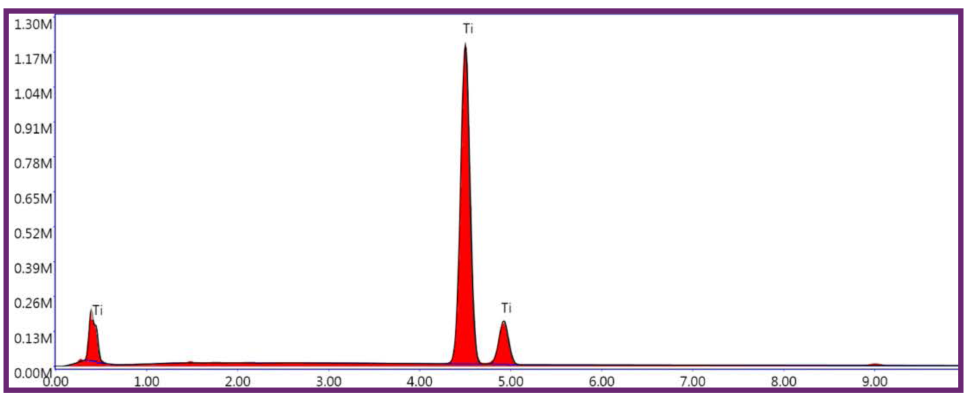


Figure 21. EDS plots for Neodent (CP4 Ti) implant

	Ti-6Al-4V ELI[9]	Grade 4 CP Titanium[10]
Ultimate Strength (MPa)	860	550
Yield Strength (MPa)	790	480-552

Table 3. Ti-6Al-4V ELI has higher ultimate and yield strengths compared to Grade 4 CP Titanium

In addition to the implant's base material, the surface texture is known to affect osseointegration. Both BioHorizons and Neodent implant systems achieve a favorable level of surface roughness through grit blasting and/or acid etching. BioHorizons implants further have the advantage of Laser-Lok microchannels around the implant collar. The implant-abutment junction is the most critical section of the system, subjected to the highest level of stress concentration. Any micromovements at the IAJ may result in bacterial infiltration and tissue inflammation. While a solid mechanical connection at the IAJ is vital, Laser-Lok provides the added advantage of the biological seal. A number of peer-reviewed publications on Laser-Lok demonstrated the surface's ability to create a connective tissue attachment, to prevent epithelial downgrowth and thus, to reduce instances of peri-implantitis and peri-implant mucositis[11-14].

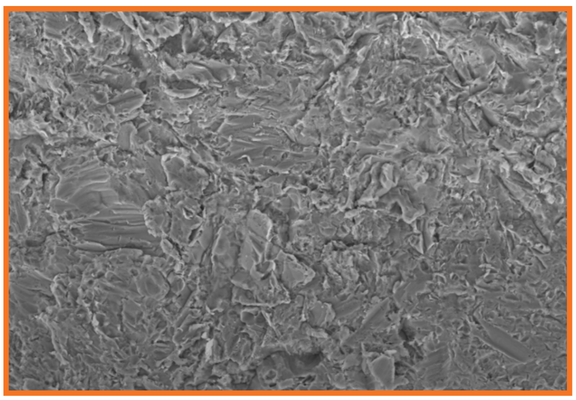


Figure 22. SEM image of BioHorizons RBT implant surface

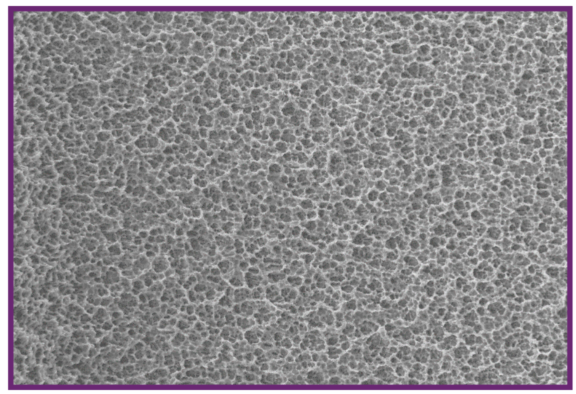


Figure 23. SEM image of Neodent Neoporos implant surface

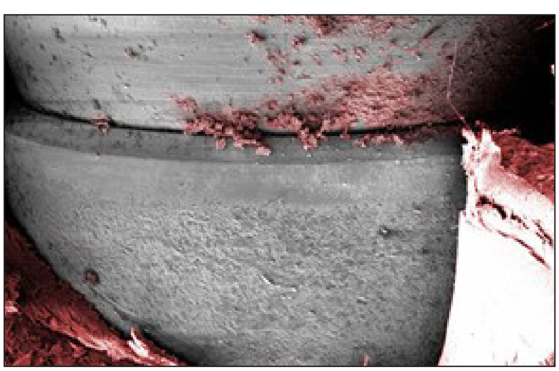


Figure 24. Lack of cellular attachment to a traditional roughened surface

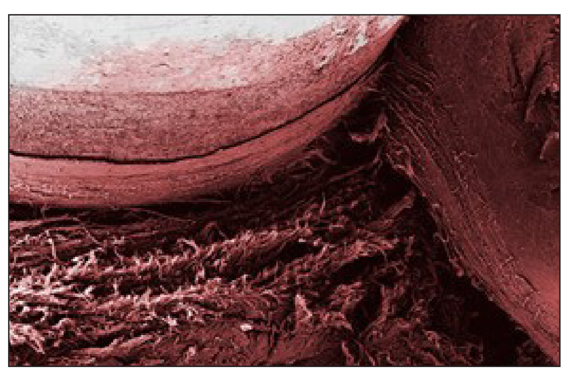


Figure 25. Connective tissue attachment to a Laser-Lok surface

Conclusion

Mechanical strength of the connection, manufacturing quality, implant material and surface treatment all play key roles in a system's overall safety and performance. This evaluation compared BioHorizons and Neodent dental implant systems:

- A standardized comparison of mechanical strength between the two dental implant systems demonstrated higher fatigue limit (78.67 lbf, 336.60 N) for the BioHorizons system compared to the Neodent system (45.22 lbf, 201.15 N), providing a higher factor of safety. These results demonstrated that an increased prosthetic platform diameter strengthens the implant system, and therefore, decreases the potential incidence of abutment and prosthetic failures. While a new prosthesis may be fabricated to restore the implant again, both clinicians and patients are at a disadvantage. Drawbacks include: (1) patient inconvenience and discomfort, (2) added restorative chair time for patient and clinician, (3) added cost for new healing abutment, final abutment and crown, (4) added turn around time for final prosthesis delivery.

- Defects including small burrs and surface abrasions were noted on components manufactured by Neodent. Those defects may have clinical implications including but not limited to jeopardizing appropriate connection between components.

- The material composition of BioHorizons implants (Ti-6Al-4V ELI) provides higher ultimate and yield strengths compared to commercially pure titanium. This, along with favorable surface roughness and the addition of Laser-Lok microchannels, all work in synergy to improve osseointegration and patient outcome.

Evaluating and rating key design features between dental implant systems on the market help clinicians and implantology specialists decide on the best treatment option. Compared to Neodent's, BioHorizons' implant systems were proven to have better manufacturing quality, mechanical performance and material / surface composition.

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