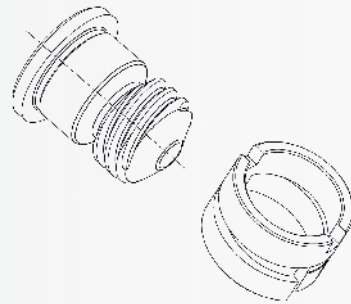
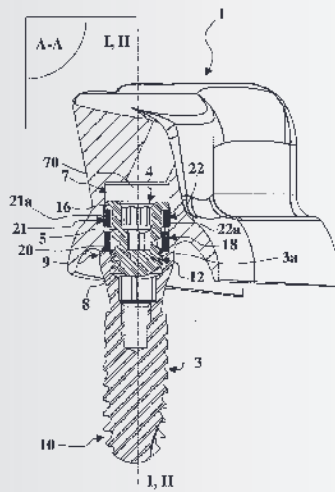
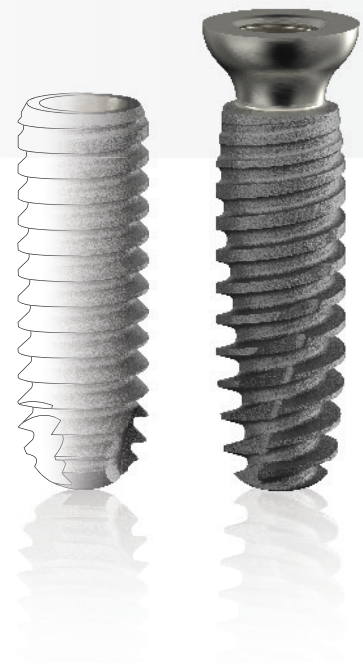


axiom[®]

MULTI LEVEL[®]



Axiom[®] Multi Level[®]
validation report



Developing products in line with clinical needs

Anthogyr, a French manufacturer, is constantly seeking to develop innovative, affordable and relevant solutions to promote access to implantology.

Thanks to the joint efforts of the R&D and Marketing Divisions and the collaboration of a group of practitioners and prosthetists, today Anthogyr is offering a new solution: **Axiom® Multi Level®**.

An innovative therapeutic solution, **Axiom® Multi Level®** has been the subject of an important technical validation detailed in this report and of an extensive clinical validation presented in La Revue Clinique **Axiom® Multi Level®**.

The Axiom® Multi Level® Philosophy

In perfect harmony and continuity with all Anthogyr products developed to date, the **Axiom® Multi Level®** line expands possibilities by offering total compatibility between the Bone Level and Tissue Level philosophies.

Axiom® Multi Level® is an implant concept that offers a **smart implant, surgical and prosthetic range and total compatibility between Axiom® BL, Bone Level and Axiom® TL, Tissue Level with inLink® abutment**.

Axiom® Multi Level® offers Axiom® BL endosseous implants or Axiom® TL transmucosal implants, according to the aesthetic or biological impact. Each type of implant is therefore available with an **REG or PX profile** to suit different bone conditions.

SMART RANGE
Total integration in
the Axiom® universe

NEW IMPLANT

Axiom® TL, Tissue Level

Axiom® BL, Bone Level

PEACE
OF MIND
of a full
CAD-CAM
prosthesis
Simeda®

inLink® abutment

INNOVATION
New inLink®
connection

axiom®
MULTI LEVEL®

Implant's outstanding resistance

The dynamic loads supported by dental implants vary according to clinical and technical parameters. The basic technical criteria are: the choice of material, geometry and size of implant, implant connection and prosthetic structure. These criteria have been thoroughly researched for Axiom® BL, Bone Level et Axiom® TL, Tissue Level to bring you implants that offer **the safety required for the patient and limit their invasiveness by using small diameter implants** (as recommended in the user manuals).

CHOICE OF MATERIAL

The first characteristic influencing the dynamic performance of the implant is the material, which must be at the same time **perfectly biocompatible and as strong as possible**.

In this view of excellence, Axiom® BL, Bone Level and Axiom® TL, Tissue Level implants are manufactured with **Grade 5 titanium** that complies with the requirements and international guidelines on implantable medical devices* with the following advantages:

- Dynamic strength higher than Grade 4 titanium and of other titanium alloys (Table 1)¹
- Recognised biocompatibility in oral and orthopaedic surgery. Additionally, it has been scientifically demonstrated that Grade 5 titanium has no cytotoxic or genotoxic effects².

*ISO 5832-2 and ISO 5832-3 “Implants for surgery – Metallic materials” Parts 2 and 3.

	Grade IV Minimum requirements ISO5832-2	Grade IV dynamic tests (Liens study 2015 ¹)	Grade V-ELI Minimum requirements Norme ISO5832-3	Grade V-ELI Anthogyr (Liens study 2015 ¹)
Tensile strength (MPa)	483	805	795	1087
Fracture toughness (MPa)	550	970	860	1251
Compressive strength (MPa)	-	340	-	760

Table 1 - dynamic performance of various grades of titanium used in implantology

DYNAMIC FATIGUE TEST

ISO 14801: 2007 defines a series of tests to measure the dynamic strength of the “implant / abutment / fixing screw” assembly. Before accessing the market, all implant systems must have been tested according to this standard (**Fig. 1**).

Two types of tests are conducted to ensure adequate strength with habitual masticatory forces:

- A **“static” test**: the assembly is loaded until it collapses. The maximum load born defines the **ultimate theoretical dynamic strength** of the assembly. This result should be compared with the maximum stress born by a single tooth occasionally.
- A **“fatigue” test**: the assembly is loaded in cycles at a frequency of 15 Hz. A number of assemblies are tested with different loads. For each test, the number of cycles before deformation or fracture occurs is measured and indicated on a graph (No. of cycles – on a logarithmic scale / F being the maximum load born). This allows the tracing of the S-N curve, called the Wöhler curve. The asymptotic limit of this curve, at over 5 million cycles, defines the **theoretical dynamic fatigue strength** of the assembly. This result should be compared with the masticatory forces applied on a single tooth regularly over time.

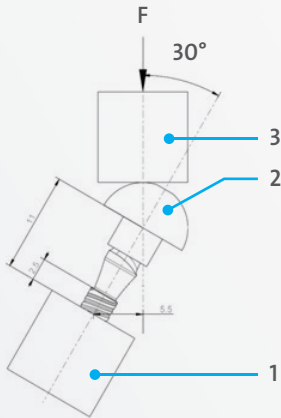
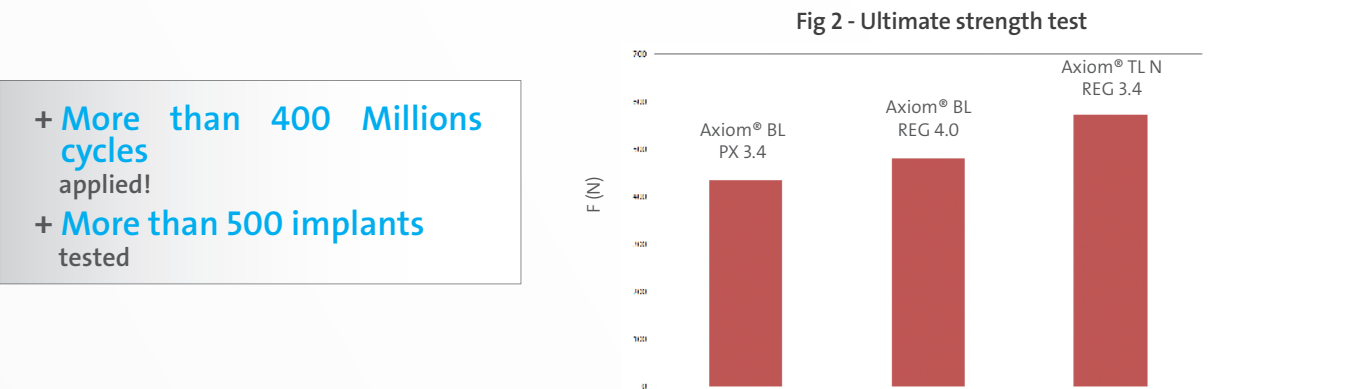


Fig. 1: Configuration of fatigue testing to ISO 14801: (1) Standard resin block. (2) Implant /abutment / fixing screw in simulated -3 mm bone loss (3) Loading block on assembly at 30° (F) Load applied to the assembly.

ULTIMATE DYNAMIC STRENGTH

- The ultimate strength of assemblies of equal diameter implants with a REG profile or a PX profile are comparable.
- Axiom® BL Ø 3.4 implants bear occasional loads higher than masticatory peak loads recorded on a single tooth, i.e. 390 N* (**Fig. 2**).
- It is even higher on Axiom® TL, Tissue Level implants on platform 4.0 (N) or 4.8 (R) than that of Axiom® BL, Bone Level implants with the same diameter (**Fig. 2**).

* Ferrario, V. F., Sforza, C., Serrao, G., Dellavia, C. and Tartaglia, G. M. (2004), Single tooth bite forces in healthy young adults. Journal of Oral Rehabilitation, 31: 18-22.

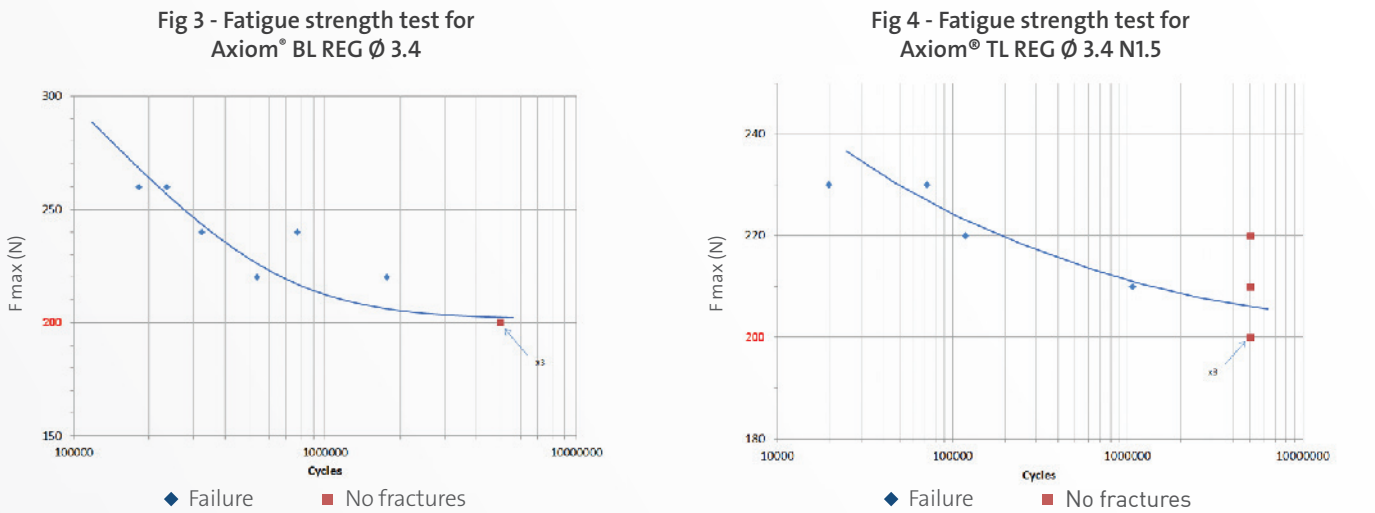


DYNAMIC FATIGUE STRENGTH

The **fatigue strength of assemblies on implants Axiom® BL, Bone Level Ø 3.4 and Axiom® TL, Tissue Level Ø 3.4 is higher than 200 N**, an objective value usually recognised by the manufacturers (**Fig. 3 and 4**).

The fatigue strength of implants Axiom® BL, Bone Level and Axiom® TL, Tissue Level is appropriate for the manufacturing of implant restorations for most sectors (with a minimum diameter of 3.4 mm).

It should be noted that during all these tests the implants maintained their integrity.



In summary:

	Single restorations*	Multiple restorations*
Axiom® BL, Bone Level Ø 3.4 to 5.2 mm	All single restorations Anterior to posterior sectors Ø 3.4 mm implants not recommended in the molar sector	All multiple restorations Anterior to posterior sectors
Axiom® TL, Tissue Level Ø 3.4 to 5.2 mm platform 4.0 (N) and 4.8 (R)	All single restorations Anterior to posterior sectors	

* For more details, please refer to the instructions for use available on ifu.anthogyr.com.

¹ Liens A., et al, Multi-scale microstructural and mechanical characterization of titanium and titanium alloys used in dentistry (2015), poster presented at the 24th EAO's Annual Scientific Congress, Stockholm, Sweden.
² Velasco-Ortega, E., Jos, A., Cameán, A. M., Pato-Mourelo, J., & Segura-Egea, J. J. (2010). In vitro evaluation of cytotoxicity and genotoxicity of a commercial titanium alloy for dental implantology. Mutation Research/Genetic Toxicology and Environmental Mutagenesis, 702(1), 17-23.

inLink®: an innovative connection for multiple screw-retained restorations

inLink® is a new connection for **multiple screw-retained prostheses with an integrated lock system**, consisting of a fixation lock and a retaining ring (Fig. 5). The ring is on the bottom surface of the prosthesis within a specifically machined retainer (Fig. 6). The prostheses are tightened to a 25 N.cm torque with a ball wrench. The inLink® connection is available on Axiom® TL, Tissue Level implants on platform 4.0 (N) and 4.8 (R) (Fig. 6) and on Axiom® BL, Bone Level implants with an inLink® (Fig. 7) 4.0 and 4.8 diameter abutment.

AN INNOVATIVE CONCEPT

inLink® offers several advantages in terms of ergonomics and prosthetic solutions:

- Significant recovery of implant axe divergences with no need for intermediate abutments.
- Access channels angulated to 25° with compact screw channels.
- Lock integrated in the prosthesis, with no intraoral screw handling and removable extraorally if needed.

A TESTED CONCEPT

Prior to clinical monitoring, numerous dynamic tests were conducted to offer a technical solution at least as strong as multiple screw-retained restorations on Multi-Unit Axiom® BL, Bone Level abutments. The latter being the technical solution most frequently adopted.

Dynamic strength tests

Assemblies with inLink® connection screw-retained on Axiom® TL, Tissue Level implants have been the subject of ultimate strength tests and fatigue resistance according to ISO 14801 testing configuration: 2007 (See page 4 of this document). **The results obtained have shown that the strength of a screw-retained assembly using inLink® is at least as strong as that of an assembly screw-retained on a Multi- Unit and Axiom® BL, Bone Level.**

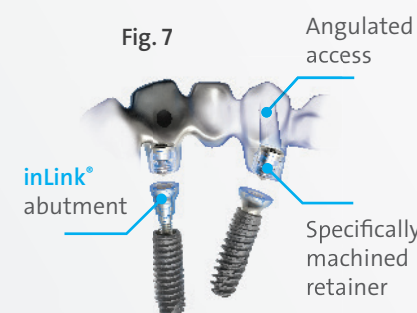
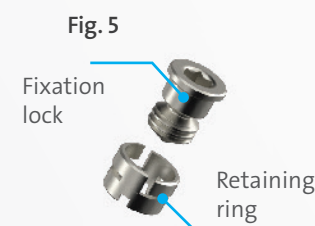
Additionally, inLink® ensures the integrity of the Axiom® BL and Axiom® TL implants in conditions of significant bite overload. In fact, the fixation lock has been designed with a fracture groove that works as a "fuse" (area shown in orange Fig. 8): this is the first element in the implant / prosthesis assembly that will break in case of overload.

Screw loosening test

No screw loosening has been observed during the dynamic strength tests mentioned above. However, these tests do not reproduce multidirectional masticatory forces. Also, R&D has devised a specific screw loosening test to simulate this type of condition, by applying loading cycles with 180° prosthesis rotation. These tests have shown **that no screw loosening has occurred in the the inLink® connection than on the Multi-Unit Axiom® BL connection.**

Tightening performance

The inLink® locks (Ø 2.8 mm) are tightened to **25 N.cm**, whilst the MU140 prosthesis screws (Ø 1.4 mm) are to 15 N.cm (Fig. 9).



CAD-CAM Simeda® Prosthesis and inLink® connexion

THE EXPERTISE OF CUSTOMISED PROSTHESIS

A CAD-CAM manufactured prosthesis has many advantages: customised profiles, homogeneous material, strong upper structure with an appropriate design, choice of materials, including zirconia and a complete range of types of restorations...

Simeda® customised prostheses offer these advantages and a quality of machining that matches the expertise of the whole manufacturing process. This expertise is important particularly to ensure **the passivity of screw-retained upper structures** and thus limit the risk of intraoral prosthetic maintenance, i.e. the risk of implant loss.

The precision of screw-retained upper structures is ensured by Simeda® and its cutting-edge technology at each step of the digital process:

- Digitalisation of implant platforms requires high-precision laboratory scanner and scan-adapters.
- Machining expertise with 5-axis machining centres (Fig. 10).
- Quality control with 3D probe (Fig. 11).

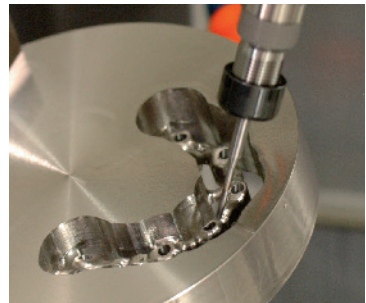


Fig. 10 - 5-axis machining

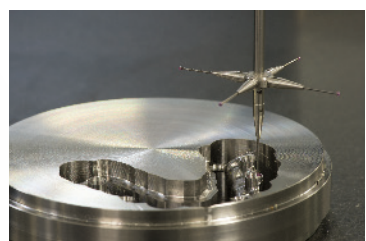


Fig. 11
3D probe testing

SPECIFIC MACHINING OF THE inLink® CONNECTION

The precision of the inLink® connection requires a **perfectly mastered manufacturing process**:

- The design and machining of **Angulated Accesses** (Fig. 12).
- The optimal machining of the groove that houses the retaining lock ring on the bottom surface of the prosthesis (Fig. 12).
- The machining of platforms and volumes, including in case of strong implant divergences.

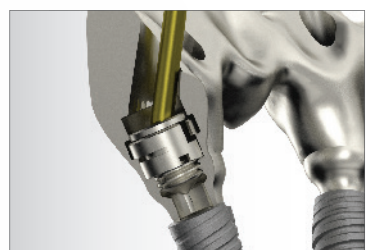


Fig. 12

PROPRIETARY ZIRCONIA EXPERTISE

Anthogyr is the expert on all aspects of zirconia, both at the R&D Innovation Unit and on the Simeda® site, where its proprietary zirconia **Sina Z®** and **Sina T** are manufactured (Fig. 13).

- Isostatically pressed high quality zirconia powder.
- Optimal management of material removal.
- Microstructure control and dimensional control.

This expertise is a guarantee of strength, aesthetic results and durability suitable for different restorations.

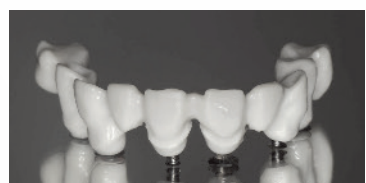


Fig. 13 - Sina Z® zirconia implant bridge

Physical properties:

Anthogyr Zirconia	Sina Z® / T
Fracture toughness (Mpa)	> 800
Thermal expansion coefficient (µm/mK)	10
Elasticity modulus (GPa)	210

Conical Morse taper type connections suitable for endosseous Axiom® BL, Bone Level implants

The connection of an endosseous implant should ensure the tightness* of the implant-abutment interface for crestal bone preservation. A Morse taper type connection (Fig.14) allows even distribution of mechanical constraints in the implant-abutment assembly and absence of micro-movements in the implant-abutment interface**. These dynamic characteristics translate into the absence of bacterial infiltration and allow the endosseous placement of the implant, with subcrestal apical-coronal placement for easier aesthetic management.

The Axiom® BL implants have a conical Morse taper type connection according to clinical indications. They are 2 types, according to the implant diameter:

- ½ 6° angle screw-retained cone for all Axiom® BL Ø 3.4 to 5.2 implants
- ½ 1.5° angle compressed cone for Axiom® BL Ø 2.8 implants

* Schmitt CM, Nogueira-Filho G, Tenenbaum HC, Lai JY, Brito C, Döring H, Nonhoff J. (2014), Performance of conical abutment (Morse Taper) connection implants: A systematic review. J Biomed Mater Res Part A 2014;102A:552–574. Assenza B, Tripodi D, Scarano A, Perrotti V, Piattelli A, Iezzi G, D'Ercole S. (2012), Bacterial leakage in implants with different implant-abutment connections: an in vitro study. J Periodontol., 83(4):491-7.

** Zipprich, H., Weigl, P, Lange, B., & Lauer, HC. (2007). Micromovements at the implant-abutment interface: Measurement, causes, and consequences (in German). Implantologie, 1, 31-46.

AXIOM® BL, BONE LEVEL: CONICAL CONNECTION, STRONG AND TIGHT

Axiom® BL single conical connection

This conical connection measuring ½ 6° angle and with tri-lobe indexing is common to all Axiom® BL Ø 3.4 to 5.2 implants, with REG or PX profiles (Fig.15), which offers flexibility and facilitates prosthetic management.

This connection has undergone dynamic tests to measure its strength (see pages 4 and 5) and ensure the absence of microgaps.

Absence of microgaps

Testing was conducted with tomography on an assembly built in accordance with the guidelines of ISO 14801: 2007. The sample under load was scanned with high resolution X-ray tomography***. The assembly was scanned first with no loading then under loading up to 150 N (Fig.16).

The microgap test was conducted in collaboration with INSA Lyon.

The tomography scans show the absence of microgaps in the Axiom® BL connection, including under loading.

*** Adrien, J. et al (2016), Comparative in-situ loading analysis of narrow diameter implants by high resolution X-Ray tomography, Poster presented at the 25th EAO's Annual Scientific Congress, Paris, France.



Fig. 14 - Conical Morse taper type connection



Fig. 15

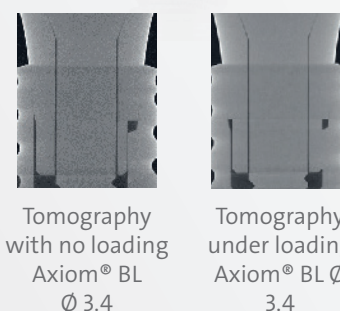


Fig. 16

Axiom® BL Ø 2.8: the incisor choice!

CONICAL INTERNAL COMPRESSED CONNECTION

This connection with conical Morse taper of ½ 1.5° angle is specific to Axiom® BL Ø 2.8 implants.

The abutment and implant connection is made with calibrated compression. 5 compressions with Safelock® are required for an effective connection.

This conical compressive connection is a patented technology developed by Anthogyr's R&D Division.

Prior to clinical validation, this specific implant was subjected to a number of different tests:

- Dynamic strength
- Connection tightness
- Technical validation of calibrated abutment compression.

DYNAMIC STRENGTH

The dynamic strength tests conducted on Axiom® BL Ø 2.8 show an ultimate strength of 290 N and a fatigue strength of up to 128 N.

These levels of strength are suitable for single restorations in the incisor with narrow mesiodistal space: mandibular incisors and maxillary lateral incisors.

ABSENCE OF MICROGAPS

Testing was conducted with tomography, as for the Axiom® BL conical connection (see page 8). The tomography scans show the absence of microgaps in the Axiom® BL 2.8 connection, including under loading (Fig.18).

CALIBRATED AND SECURED COMPRESSION THANKS TO SAFE LOCK®

The effectiveness of compression was validated with an abutment removal test. The test shows that a force of 295 N is required, i.e. a value higher than the force required to remove a crown* (Fig.19). This result guarantees that the abutment will be retained for the duration of the prosthesis.

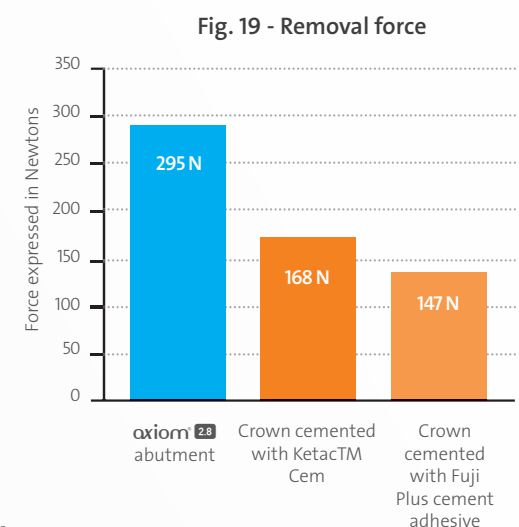
* Cement Selection for Cement-Retained Crown Technique with Dental Implants. James L. Sheets, Charles Wilcox & Terry Wilwerding - Journal of Prosthodontics - Feb. 2008.



Fig. 17



Fig. 18
Tomography under loading Axiom® BL Ø 2.8



Powerful bone attachment

OSTEOCONDUCTING MATERIAL AND SURFACE TREATMENT

The performance of Grade 5 titanium osseointegration has been demonstrated demonstrated in one in vivo study conducted by Saulacic, Buser et al³ in 2012 . No significant difference in the soft and hard tissue surface colonisation was observed in the three materials tested: Grade 4, Grade 5 and Roxolid® at 4 and 8 weeks.

Clinically, De Leonadis et al⁴, have shown a 98% clinical success rate at 5 years on 100 implants. The body of Axiom® TL and Axiom® BL implants shows a BCP surface clean and effective for osseointegration. Subcrestal endosseous placement is recommended for the BCP treated implant surface (Fig.20).

BCP (BIPHASIC CALCIUM PHOSPHATE) surface coating is obtained by subtractive sandblasting with a special manufacturing process certified by GMED (notified body, from the design to the manufacturing of its specific medical devices).

It provides effective osseointegration and secondary implant stability:

- Biocompatibility preserved with no peri-implant contamination.
- Rough texture, promoting osseointegration.
- Excellent osseointegration observed: 97.6% success rate after clinical follow-up at 1 year (Own data).

Additionally, the neck of Axiom® TL implants presents a smooth machined surface for optimal contact with soft tissues.

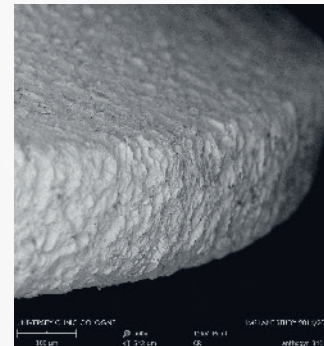


Fig. 20 - Microscopic observation (x500) of implant surface with Anthogyr BCP coating

³ Saulacic, N., Bosshardt, D. D., Bornstein, M. M., Berner, S., Buser, D (2012). Bone apposition to a titanium-zirconium alloy implant, as compared to two other titanium-containing implants. Eur Cell Mater, 23(1), 273-286.

⁴ Dario De Leonadis, D. D. S., Garg, A. K., & Pecora, G. E. (2000). Osseointegration of rough acid-etched titanium implants: 5-year follow-up of 100 minimatic implants. Int J Oral Maxillofac. Implants, 14(3), 384-391

REG OR PX PROFILE FOR A PRIMARY ATTACHMENT APPROPRIATE TO THE BONE CONDITION

The endosseous segment of the Axiom® TL and Axiom® BL implants has been designed to stimulate growth of the peri-implant bone:

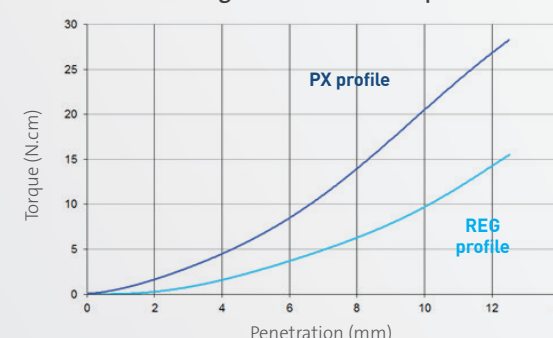
- Optimal use of the effective blade surface.
- Low concentration of pressure on edge of blades.
- Transformation of occlusive loads into compression force, which promotes bone stimulation.

The different profiles of the REG or PX implant body (Fig.21) result in a level of primary stability appropriate for the bone condition:

- **REG profile: progressive compression in all types of bone:** cylindrical-conical shape with self-guiding insertion, asymmetrical progressive self-tapping blade.
- **PX profile: effective bone condensation in immediate post-extraction implants or low density bone:** conical shape for optimal attachment, double symmetrical self-tapping blade for fast guided insertion.



Fig. 22 - Progression of tightening torque during insertion of the implant



A tightening torque test* (Fig.22) was conducted in the lab on synthetic material simulating low density bone. The PX profile showed its ability to achieve an effective torque in low density materials.

*Test conducted in polyurethane plates with a 0.24g/cm³ density, resembling the behaviour of D3 density bone. (Internal test report No. T13037)

Clinical validation of Axiom® BL, Bone Level

- 168 implants with Axiom® BL, REG and PX profiles, were monitored for 1 year within a clinical validation programme.

- 3 implants showed a bone loss of at least 2 mm (Fig. 23).

- The success rate at 1 year is 97.6 %.

- With its limits, this clinical monitoring shows that the implants of the Axiom® BL range contribute to bone level preservation.

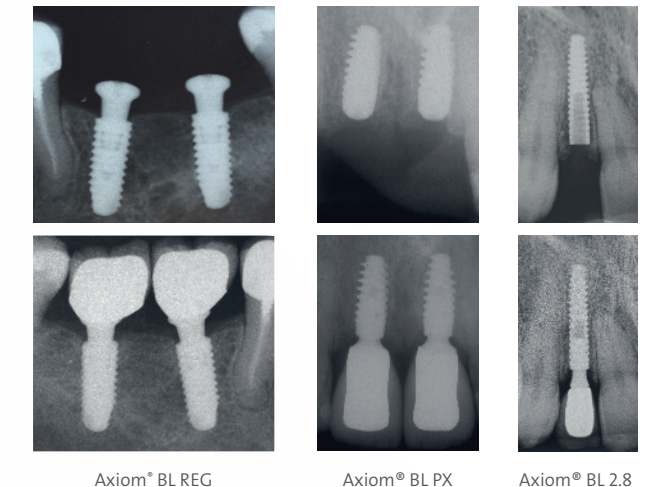


Fig. 23 - 3 follow-up X-rays showing bone level preservation.

Clinical validation of Axiom® TL, Tissue Level

Axiom® TL (Tissue Level) implants and the inLink® connection were tested:

connection were tested:

- 26 practitioners and 19 prosthetic laboratories participated in the clinical follow-up

- 116 patients with an indication for multiple screw-retained prosthesis were included, 50% of whom with complete prostheses,

- 546 implants were placed according to current practice.

- The development of peri-implant bone level was measured in: 122 implants at 8 months post-loading. With an average bone loss of -0.2 mm, and a 99% survival rate, the success level matches the values reported in the scientific literature.

The ergonomics of the inLink® connection was validated by the practitioners when loading the temporary and permanent prostheses.

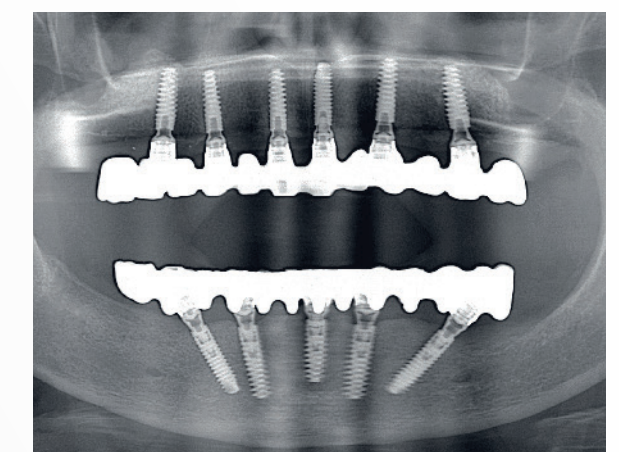


Fig. 24 - Bimaxillary restoration on Axiom® TL



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