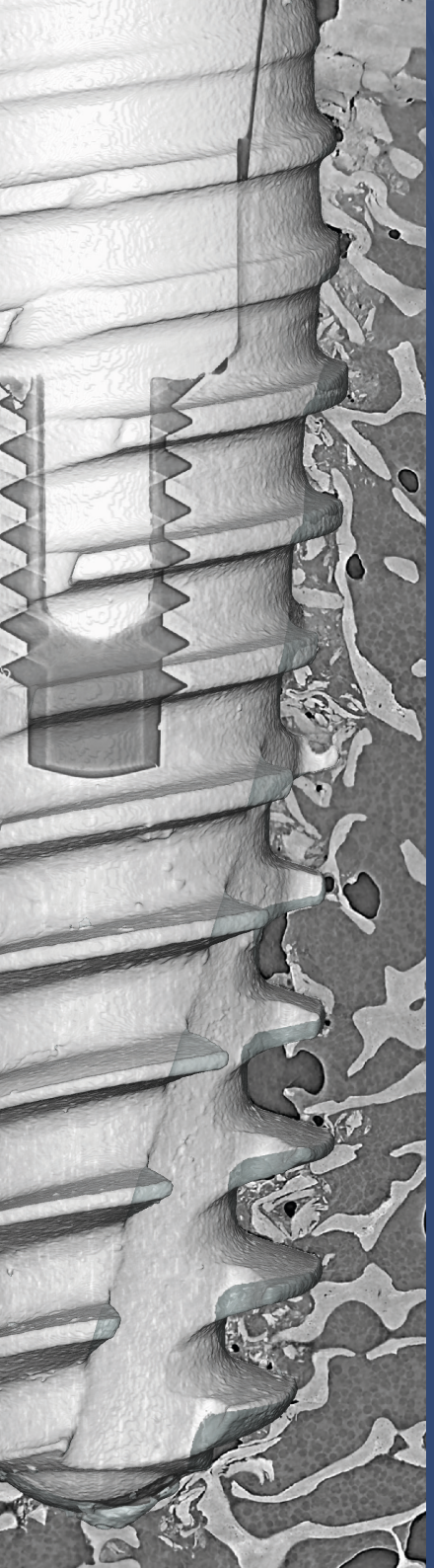
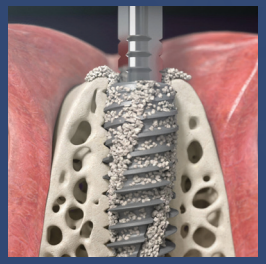


# axiomX3®

Technical and scientific review

## KEY CHAPTERS.





Bone preservation

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## “AXIOM X3® DESIGN ALLOWS THE SAVING OF BONE AND THE REDUCTION OF THE NUMBER OF SURGICAL STEPS, WHILE TARGETING A FIRM PRIMARY STABILITY IN VARIOUS CLINICAL SITUATIONS”

Entering the development of a new dental implant nowadays is a real challenge for a manufacturer. The current clinical results are extremely satisfying, with a broad scope of indications covered by our Axiom® range. The system is firmly relying on evidence-based assets with a strong material, a clean and performing surface treatment and a single conical connection. But still, there was a clear incentive to start Axiom X3® development: the exchanges with our customers. Discussing with practitioners, observing their practice on a daily basis not only reveals their commitment to restore patient smiles with the highest degree of predictability but also their wish to provide efficient treatment workflows. This is where Axiom X3® is coming from. Based on proven features, easing surgeries and preserving living tissues. Relying on scientific foundations on one hand, tailoring the solution to your needs on the other hand, thanks to technical innovation.

We deeply studied the bone-implant interaction at implant insertion, which resulted in the unique design of Axiom X3® threads, now protected by two patents. This design allows the saving of bone and the reduction of the number of surgical steps, while targeting a firm primary stability in various clinical situations. The significance of these improvements was verified by a large survey performed at the European level [1]. Feedback from 63 practitioners from 9 countries on 706 implant placements were compiled, including immediate placement and/or loading in 32% of the cases. A very high satisfaction level of 89% was obtained regarding the implant stability, and a possible reduction in the number of drilling steps by 25% was confirmed compared to Axiom® REG.

**Nicolas COURTOIS.**
Head of Research
& Clinical Affairs

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## INTERNATIONAL PRODUCT LAUNCH SURVEY

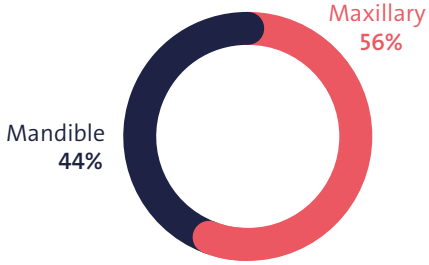
**A LARGE SURVEY WAS PERFORMED AT THE EUROPEAN LEVEL TO MEASURE THE IMPACT OF AXIOM X3® DESIGN IN TERMS OF BONE PRESERVATION, NUMBER OF SURGICAL STEPS AND PRIMARY STABILITY[1].**


## UNIVERSAL BONE ANCHORAGE

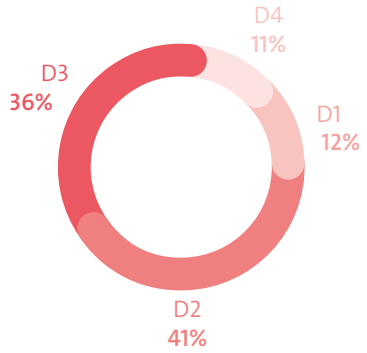
**A VERY HIGH SATISFACTION LEVEL WAS OBTAINED REGARDING THE IMPLANT STABILITY IN VARIOUS CLINICAL SITUATIONS.**

### DISTRIBUTION OF IMPLANTS PLACED

Per position

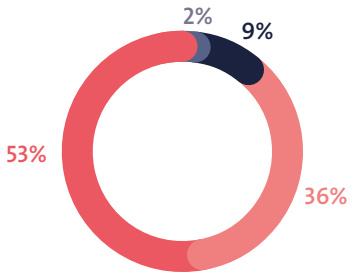



Per density

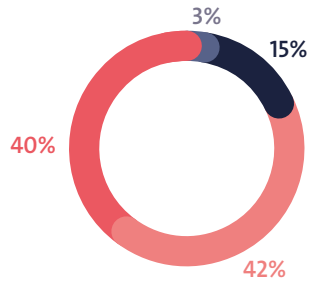



### PERCEIVED PRIMARY STABILITY

All bone densities




Focus on D3/D4





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## A CHALLENGING EQUATION TO SOLVE

Dental implants are used in very different clinical situations, resulting in the need to adapt the preparation protocol and/or to resort to the use of different implant designs. The latter choice forces the user to store a substantial stock for each range, and sometimes even to deal with different prosthetic systems and/or different instruments.

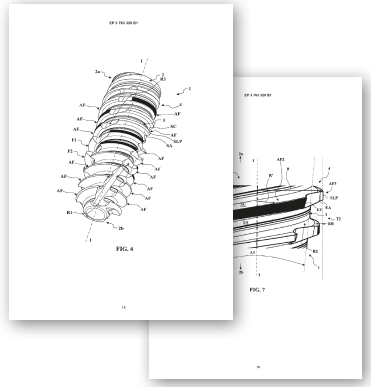
Most often, in hard bone a tap is required to prepare the implant bed. This step is time consuming and a potential source for error when setting the motor speed or direction. The aim of the tap is to create a female thread matching the shape of the implant by removing some bone volume. This implies the removal of a large bone volume exceeding the implant size.

As an alternative to the use of a tap, some manufacturers indicate the use of a final drill whose size is very close to the implant diameter (0.1 or 0.2 mm larger), for the preparation of the upper part of the osteotomy. As for the tap, this is resulting in no or very few bone fragments creation during implant placement.


## UNIQUE PATENTED DESIGN FOR BONE PRESERVATION

**The universality of Axiom X3® is the result of its patented thread design.**

When manufacturing a classical implant, the threading tool makes a helical hollow with a defined pitch. But for Axiom X3®, a second threading cycle is performed with a slightly different pitch. By controlling the difference in pitch between the two threading cycles, it is possible to control the thickness of the thread along the entire implant body (Fig. 1). **This results in a more progressive character of the insertion.**



*Patents #EP3763321B1 - EP376330B1*

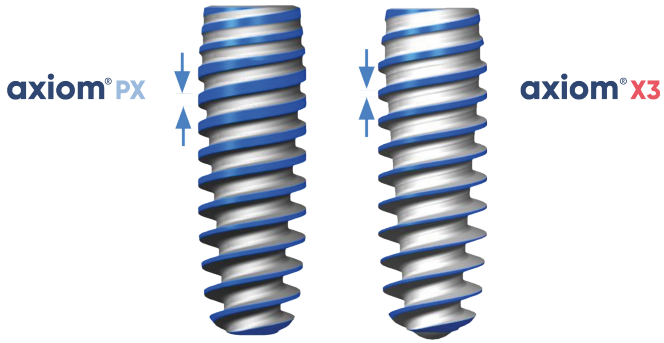



*Figure 1 - Thread comparison between Axiom® PX and Axiom X3®, helical flutes removed*

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In selected area of the external thread of Axiom X3®, represented in yellow in Figure 2, the top of the thread has been lowered by milling. Along the insertion, lowered and non-lowered thread portions are alternatively penetrating the bone.

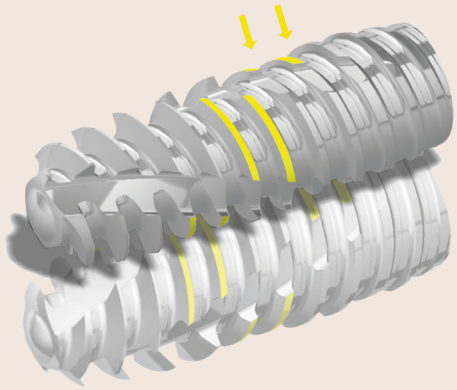

*Figure 2 - Axiom X3®*

*Discover how Axiom X3® behaves in different bone densities.*

**The stress to the bone and the friction is significantly reduced for those lowered zones.**

> **"THIS IS RESULTING, IN COMBINATION WITH THE PREVIOUS FEATURE, IN A BETTER CONTROL OF THE INSERTION TORQUE, ALLOWING INSERTION IN HARD BONE WITHOUT A BONE TAP"**

Table 1 is showing in-vitro measured insertion torque of an Axiom X3® implant, Ø 4.0 mm – length 12.0 mm, in foam blocks, representative of D1-type bone[2] (Sawbones, Pacific Research Laboratory Inc., USA), with a Ø 3.6 mm drilled hole.

*Table 1 - In vitro measured insertion torque*

| | PU BLOCK DENSITY (PCF) | IMPLANT BED DIAMETER (mm) | MAX. TORQUE (N.cm) | MEAN OF MAX. TORQUE (N.cm) |
|---|---|---|---|---|
| AXIOM X3® Ø4.0 - L 12.0 mm | 40 *(representative of D1)* | 3.6 | 34.6 | **37.9** |
| | | | 40.3 | |
| | | | 38.6 | |

As shown in Figure 3, even in hard bone situation, there is a remaining interference volume between the implant and the osteotomy. Therefore, bone fragments are formed during implant insertion and distributed around implant body.

The strains can therefore be distributed along the implant length and not concentrated at the neck (Fig. 4).

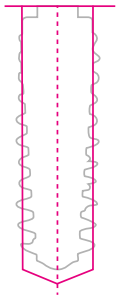

*Figure 3 - External contour of Ø 4.0 – L 12.0 mm Axiom X3® and shape of the Ø 3.6 mm drill*

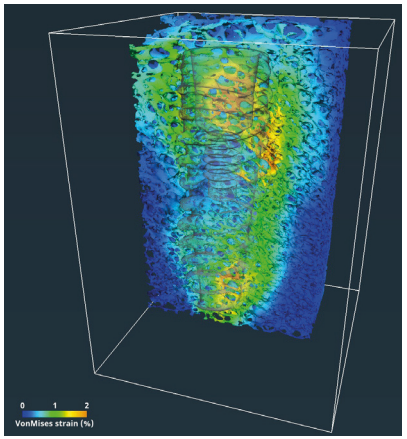


*Figure 4 - High resolution µCT evaluation of bone strains following insertion of a Ø 4.0 – L 12.0 mm Axiom X3®[3]*

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Moreover, during implant insertion, the top of the thread of the lowered zones are guided in the groove created by the previous non-lowered zone, which can facilitate implant placement.

> **AXIOM X3®, WITH ITS THINNER THREADS AND ITS ALTERNANCE OF LOWERED / NON-LOWERED TOP OF THREADS, IS IMPROVING THE SURGEON CONTROL. 56% OF THE USERS HIGHLIGHTED IMPROVED GUIDANCE AS A MAIN FEATURE OF THE IMPLANT**[1]

Anchoring the implant in the correct position in extraction socket is often tricky. The reduced size of Axiom X3® apex allows its insertion in narrow implant beds in soft bone. As an example, in very soft bone Ø 4.0 mm Axiom X3® implant can be inserted in a hole of only Ø 2.0 mm. **More bone is then preserved, and the bone preparation duration is reduced.**

Thanks to the use of High Resolution Tomography (µCT), we were able to measure bone densification, during in vitro experiments performed on domestic pig pelvis, and to characterize bone debris generated during implant placement of Axiom X3® (Fig. 5) and Axiom® REG (Fig. 6)[3].

**Bone debris are generated around Axiom X3® body.**

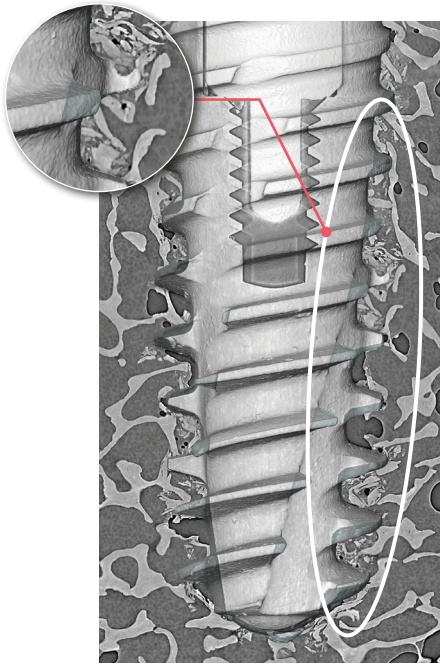

*Figure 5 - Axiom X3® Ø 4.0 – L 12.0 mm in low density pelvic bone of domestic pig*

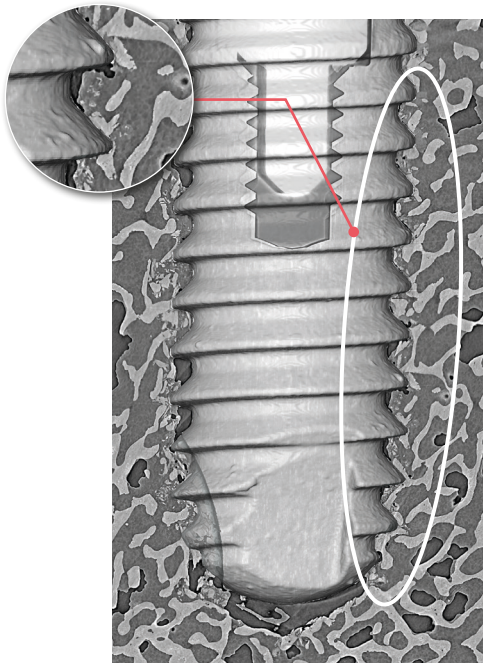

*Figure 6 - Axiom® REG Ø 4.0 – L 12.0 mm in low density pelvic bone of domestic pig*

> **IT HAS BEEN SHOWN THAT THE PRESENCE OF AUTOGENOUS BONE FRAGMENTS CAN BE BENEFICIAL FOR THE REPAIR OF BONE**[7]

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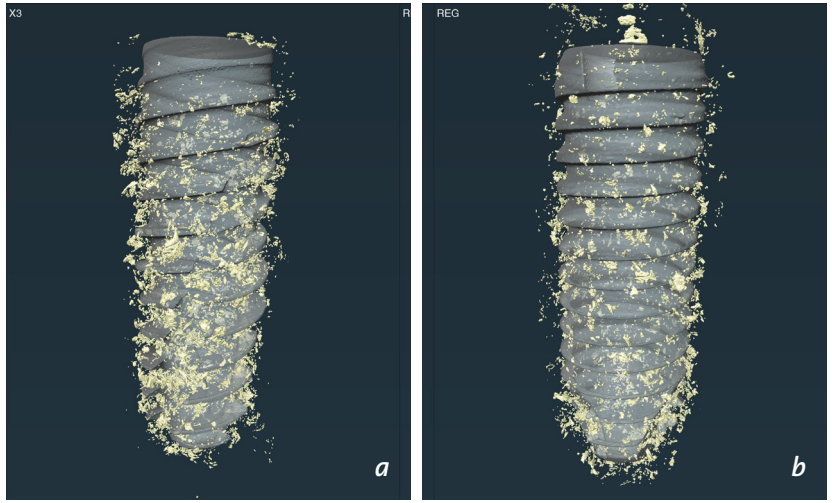
Hervé RICHARD
R&D Engineer

**AXIOM X3® WAS DEVELOPED FOR SURGEONS, WHO WANT TO HAVE AN IMPLANT THAT CAN BE PLACED IN DIFFERENT BONE DENSITIES AND IN MANY CLINICAL SITUATIONS, LOOKING FOR A SIMPLE AND READABLE PROTOCOL THAT DOES NOT REQUIRE THE FASTIDIOUS USE OF A TAP, REDUCE OPERATING TIME, AND IN FAVOR OF BONE PRESERVATION**

**Peri-implant bone densification was reported as an efficient mean to improve primary stability** [4] [5] [6]. **The concept of Axiom X3® with its specific thread design and underpreparation is very straightforward to induce this local compaction in low-density bone, without additional tools nor specific procedures.** This densification was clearly visible after insertion in a low-density bone in Figure 5, where an Axiom X3® implant was surrounded by a shell of higher bone density.

The isolated bone fragments could be identified by image analysis all around the implant. In the same type of bone, whereas debris were rare in a conventional protocol with Axiom® REG type implant there was a positive distribution of them along the Axiom X3® (Fig. 7 and 8)[3].

**It has been shown that the presence of autogenous bone fragments can be beneficial for the repair of bone** [7]. In terms of primary stability, the µCT observations are in good agreement with the reported implant stability in clinical practices, judged "well" or "excellent" in 82% of the cases in low density areas[1].




*Figures 7 & 8 - Isolated bone debris around Axiom X3® (a) and Axiom® REG (b)*

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## CONICAL CONNECTION, THE GOLDEN STANDARD FOR BONE LEVEL IMPLANTS

The connection of a Bone Level implant should ensure the tightness[8] of the implant-abutment interface for crestal bone preservation. A Morse type connection (Fig. 9) allows an even distribution of mechanical constraints in the assembly and reduction of micro-movements at the implant-abutment interface[9]. **These features translate into the absence of bacterial infiltration at the interface level[10] and allow the subcrestal placement of the implant, for easier aesthetic management.**

All Axiom® Bone Level implants have a conical Morse taper type connection of 6° half-angle.

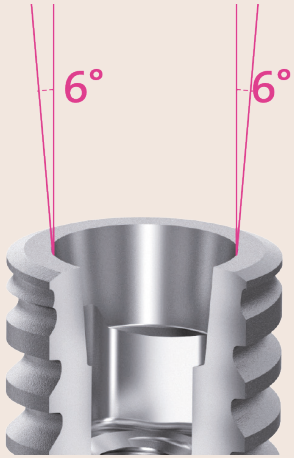


*Figure 9 - Conical Morse taper type connection of 6° half-angle*

## STRONG AND TIGHT CONICAL CONNECTION

### AXIOM® BONE LEVEL SINGLE CONICAL CONNECTION - "ONE SIZE FITS ALL"

**The single conical connection with triangular indexation offers flexibility and facilitates prosthetic management.** The connection diameter is the same for all Axiom® Bone Level Ø 3.4 to 6.4 implants, with X3, REG or PX profiles (Fig. 10).

*Figure 10 - Topview of Axiom® connection*

### ABSENCE OF MICROGAPS

High-resolution X-Ray CT was used to test on an assembly built and loaded in accordance with the geometrical prescriptions of ISO 14801[11]. The assembly was scanned first with no loading then under loading up to 150 N with 30° divergence (Fig. 11).

The tomography slices in the most loaded direction show **the absence of microgaps in the Axiom® BL connection under loading,** within the limit of the micron-size resolution.

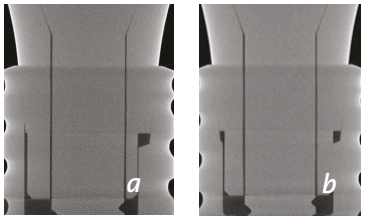


*Figure 11 - Tomography with no loading (a) and 150 N. loading (b)*

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## THE CHOICE OF MECHANICAL PERFORMANCE

Inspired by its historical expertise in machining high strength elements for the spine or aerospace industry, Anthogyr selected the finest material to manufacture Axiom® implants. The implantable grade, extra-low-interstitials titanium alloy was selected to offer the highest degree of safety with the lowest failure probability[12] [13]. Well above the minimum strength requirements set in standards, the ultimate tensile strength of Grade V Titanium* bars used for Axiom® implants manufacturing often exceeds 1200MPa, due to its very fine microstructure (Fig. 12). Fatigue tests of Ø 4.0 mm samples machined in the same conditions, confirmed the large difference in strength between Grade V Titanium* and Ti Grade IV on the long run. (Fig. 13)

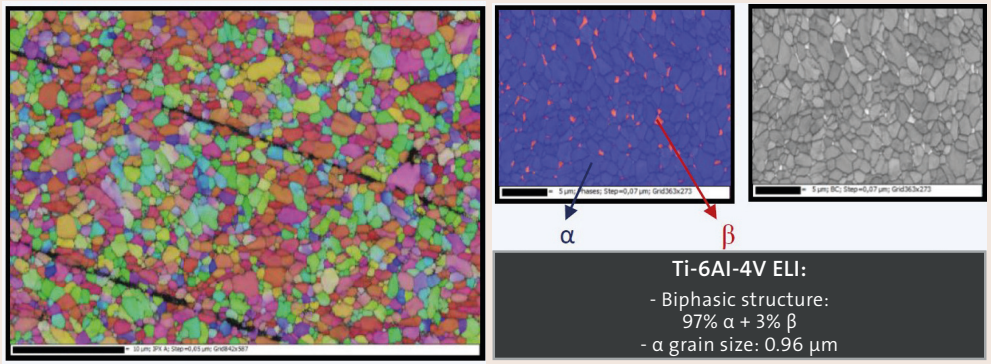


*Figure 12 - Microstructural analysis of Ti6Al4V-ELI in its delivery condition for dental implant machining[14]*

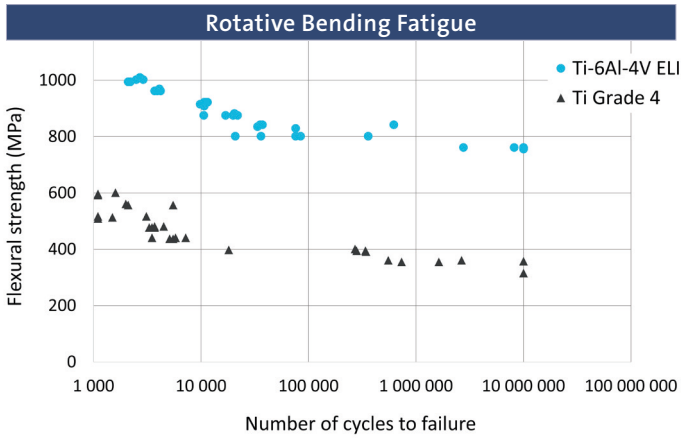


*Figure 13 - Compared fatigue resistance of identical specimen.*

The raw material performance, maintained at a high level during machining and surface treatment steps, confers a very high fatigue resistance to the implants. **Mechanical resistance of narrow diameter implants made of titanium alloys like Grade V Titanium* is reported to be larger than that of Grade IV implants** in a laboratory study comparing various dental implant systems[14]. Another study with identical implant designs but Grade II and Grade V materials get to the same conclusion in terms of fatigue resistance[16].

*Ti6Al4V-ELI

*Ti6Al4V-ELI

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## PROVEN BIOLOGICAL SAFETY

The biological safety of Grade V Titanium* alloys was regularly evaluated in terms of cytotoxicity, genotoxicity[17] and local tissue effects following implantation, also with Anthogyr implants[18] [19].

**Biocompatibility results**

| Biological safety feature | Cytotoxicity | Genotoxicity | Implantation |
|---|---|---|---|
| Reference | [17] | [17] | [18] [19] |
| Main conclusions | No cytotoxity | No genotoxicity | No adverse local tissue effects |

**Over 40 years of continuous use in dentistry and beyond, no adverse effects has been reported that would challenge the use of titanium alloy in contact with bone as an implant material or with the peri-implant mucosa and saliva as an abutment material.**

Several publications, including the 3 cited in references[17] [18] [19], have demonstrated the biocompatibility of Grade V Titanium*, with an absence of cytotoxicity, genotoxicity and adverse effects on surrounding tissues.

*Ti6Al4V-ELI



**This proven safety combined with the mechanical strength** makes Grade V Titanium* **a material of choice for dental implants, enabling the use of smaller implant diameters and promoting less invasive treatments.**

> **IT CAN BE CONCLUDED THAT THIS NEW TI–6AL–4V MATERIAL** (...) **SHOWS GOOD BIOCOMPATIBILITY AND CAN BE CONSIDERED OF CHOICE IN DENTAL IMPLANTOLOGY**[17]

*Ti6Al4V-ELI

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## BCP SURFACE TREATMENT PROVEN CLEANLINESS

Anthogyr surface treatment relies on a highly biocompatible blasting media BCP, Biphasic Calcium Phosphate, that is easily removed from the surface by acid treatment. Regular extensive analyses are performed to guarantee surface purity.

The surface analysis of 65 implant systems by scanning electron microscopy (Fig. 14 - 16) was performed by Dr Dirk Duddeck, Department for oral surgery and implantology, University of Köln, Germany on a large number of dental implants from many implant brands[19].

> **THE RESULTS OF THIS STUDY ON THE AXIOM® PX IMPLANT DEMONSTRATED HIGH ACCURACY OF THE IMPLANT GEOMETRY AND CLEANLINESS AT THE MICRON SCALE, NO ORGANIC NOR INORGANIC CONTAMINANTS WERE FOUND ON THE SURFACE OF THE IMPLANT.**

Figure 14

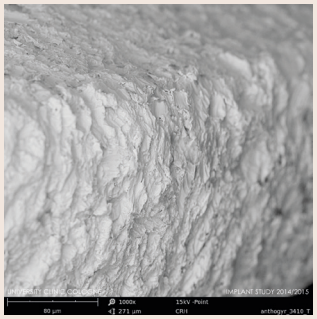

Figure 15

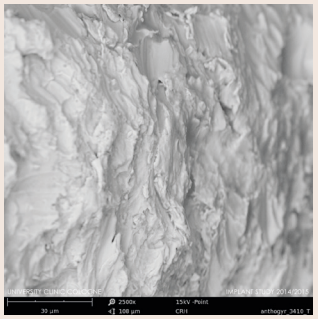

Figure 16

*Figures 14 to 16 - Scanning Electron Microscope views of BCP surface treatment.*

## MODERATELY ROUGH SURFACE TOPOGRAPHY

Anthogyr Axiom® BCP implants were measured according to the guidelines defined by Wennerberg and Albrektsson[21], and the classification proposed by the same authors[22] was applied to qualify the surface. With a Sa value of 1.2µm, the BCP surface can be classified as moderately rough.

**It was reported that moderately rough titanium surfaces like BCP showed stronger bone response than a smoother surface[23].**

A profile based measurement according to metrology standard provides a corresponding Ra value between 1,5 and 2µm (Table 2). 3D surface analyses provide a more complete representation of the actual surface topography as illustrated in Figs 17 and 18.

Table 2 - Average 3D and 2D roughness of BCP implants.

| 3D MEASUREMENT (INTERFEROMETER) ACC TO[2] | 2D MEASUREMENT (PROFILOMETER) ACC. TO ISO4287 |
|---|---|
| Sa, µm | Ra, µm |
| 1.21(±0.12) | 1.5-2 |

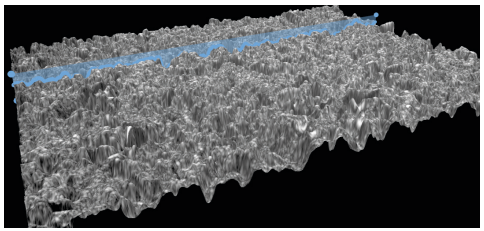

*Figure 17 - Confocal 3D view of the BCP surface.*

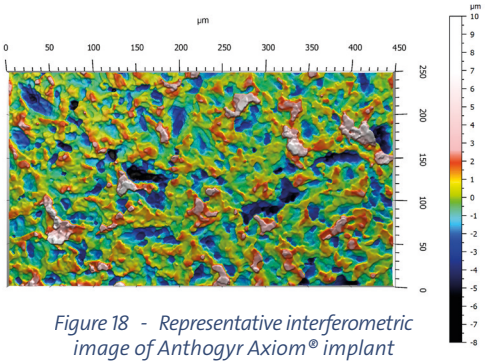


*Figure 18 - Representative interferometric image of Anthogyr Axiom® implant surface.*

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## BCP SURFACE TREATMENT IN VITRO BIOLOGICAL PERFORMANCE

Various in-vitro and preclinical studies established the safety and performance of BCP surface treatments on titanium and titanium alloys[24 - 27] and demonstrated **BCP high biological performance in terms of proliferation activity and ALP expression level of osteoblasts, which is favorable compared to gold-standard SLA-type surfaces**[24].

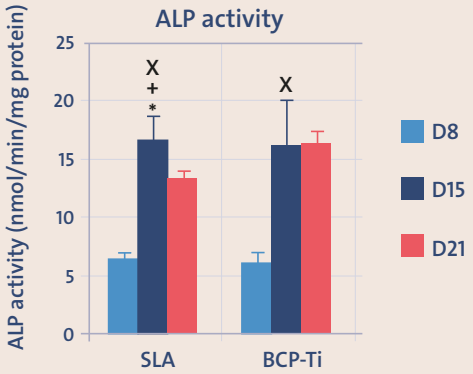


Figure 19

*Figure 18 - Alkaline phosphatase (ALP) activity normalized to protein content of osteoblastic cells cultured on the titanium surfaces for 8, 15 and 21 days. Symbols indicate a statistical difference with $p < 0.05$ between the groups, adapted from[24].*

## IN VIVO BIOLOGICAL PERFORMANCE

BCP treated implants were recently compared with SLA-type surface implants, in an ovine model[28], with identical implant design and final cleaning/sterilization steps.

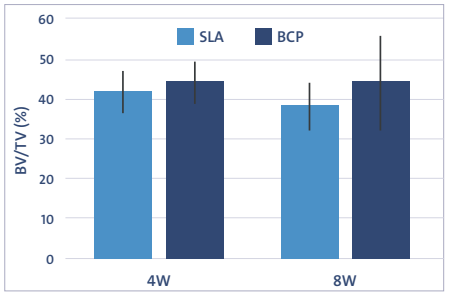


*Figure 20 - Bone volume to Total volume ratio calculated from µ-CT measurements on SLA and BCP surface after 4 and 8 weeks of healing (internal data).*

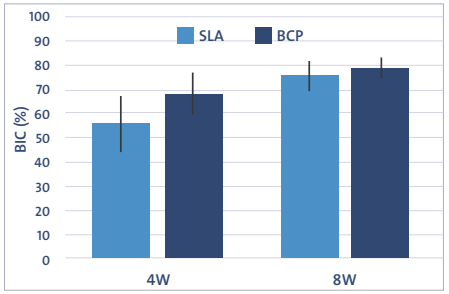


*Figure 21 - Bone-to-Implant contact measured on SLA and BCP surfaces after 4 and 8 weeks of healing (internal data).*

Bone remodeling kinetics were assessed by X-ray microtomography (µ-CT) and histology at 4 and 8 weeks, showing no statistically significant difference between BCP and SLA surfaces.

**Histological analyses indicated a favorable healing scenario for BCP treated implants, from the early time point of 4 weeks, continued until reaching a BIC value of 79% at 8 weeks.**

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## BCP SURFACE TREATMENT IN VIVO BIOLOGICAL PERFORMANCE

More recent implantation studies on Axiom® implants[18] [19] confirmed the osseointegration performance with Bone-to-Implant Contact (BIC) ratio reaching up to 68.4% at 4 weeks, and 92.0% at 13 weeks, obtained in representative animal models (dogs or minipigs) under Good Laboratory Practices. In a study by Chacun et al.[17] Grade V Titanium* implants with an endosseous BCP surface were tested in a split-mouth design (each half-mandible receives either titanium or ceramic implants) in six Beagle dogs in a study aiming to evaluate the pre-clinical performance (local tissue effects and osseointegration properties) in comparison to ceramic implants, often referred as more favorable to biological integration.

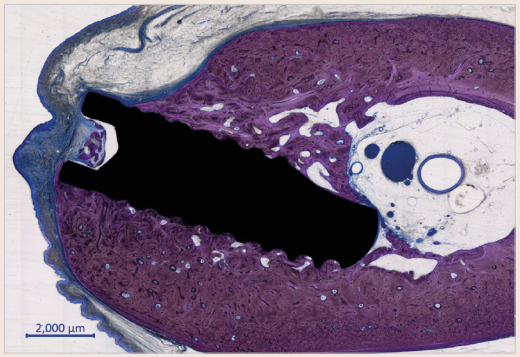


*Figure 22 - Microscopic view of an histologic cut on Axiom® implant.*

*Ti6Al4V-ELI

Local tissue effects and BIC were evaluated at 4 and 13 weeks after implantation through histology.

Implant topographies were evaluated. Axiom® 2.8 implants presenting BCP, a moderately rough surface with a Sa value of 1.2µm, were inserted in the jaw bone and left for submerged healing.

After 4 weeks of healing, the BIC value for BCP reaches 68,4% (+/- 14,7%), and 92% (+/- 8,6%) at 13 weeks. **BIC values obtained for BCP are well above the threshold defined to expect sufficient bone anchorage over titanium implants*.**

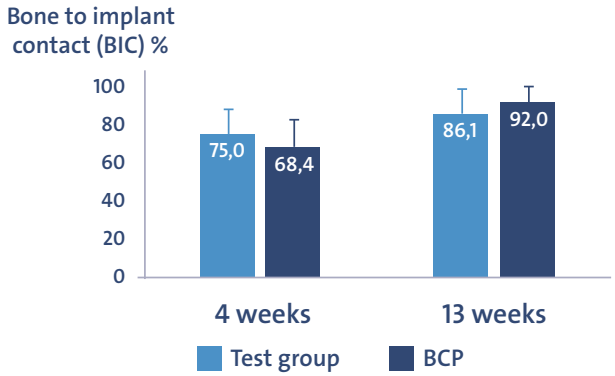


*Figure 23 - Mean (± SD) bone to implant contact at 4 and 13 weeks[17].*

*Considering Albrektsson report [29], who defined at 60% the threshold BIC value required to obtain sufficient bone anchorage over titanium implants.

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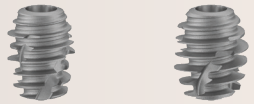
## TOWARDS SHORTER AND IMMEDIATE TREATMENTS

Built on the experience of Axiom® PX in post-extraction sockets[30], Axiom X3® convinced its first users who used it in 32% of the cases for immediate treatments, with a satisfaction rate of 92% regarding its primary stability[1].

But immediacy does not limit to self-tapping implant designs and primary stability. For us it encompasses a wider ecosystem enabling an increased efficiency of surgeries and treatment plans. Axiom X3® integrates in the Axiom® system to render immediacy more universal with reduced protocols (no tap), but also wide diameters for wide post-extraction sockets, and comprehensive prosthetic range for immediate provisionalization or loading.

*Wide diameters for post-extraction sockets*

Ø 5.8 Ø 6.4



-25%

*Straightforward protocols. Number of drilling steps reduced by 25% compared to Axiom® REG*

*Final prosthetic torque 25N. cm. Less risk ofs implant mobilization at prosthesis placement*






**“BUILT FROM THE ORIGINAL AXIOM® RANGE, RELYING ON THE THREE PILLARS OF A MATERIAL, SURFACE AND CONNECTION INTENDED FOR A “ZERO BONE LOSS” SYSTEM, AXIOM X3® SETS THE TONE FOR THE NEXT GENERATION OF IMPLANTS”**

The Axiom® system has constantly been evolving for 15 years, providing our customers with an exhaustive solution to treat their patients with innovative and relevant products and workflows.

Thank to its design that has reached a very high level of maturity, our new Axiom X3® Bone Level implant is addressing a very large scope of clinical needs with minimal invasiveness and a straightforward user experience.
This leaves room for surgeons to refine and adapt protocols to the specific requirements of each clinical situation, either to maximize esthetic results or to apply immediate protocols in response to patient expectations, all within increasingly integrated digital workflows.

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