XGATE DENTAL

ANALYSIS AND PRESENTATION OF XGATE P&P DENTAL IMPLANT'S SURFACE QUALITY AS COMPARED TO SLA AND RBM SURFACES

OCT 2021

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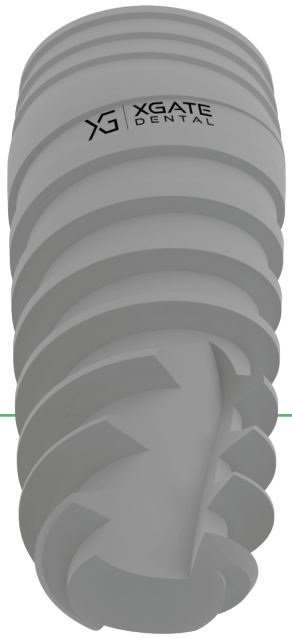
X11 THE SAFEST IMPLANT ON EARTH.

Pure & Porous Careful production process. Well-prepared and professional implants.



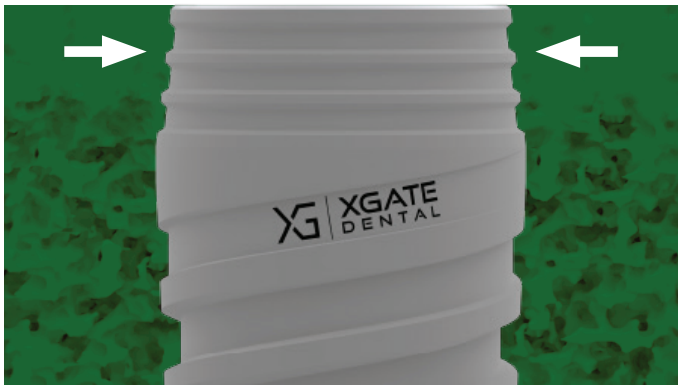
The true measure of success is the final result, which in our case, is natural-looking prosthetics.

To achieve this, we've designed the X11 implants in a narrowing fashion, from top to bottom, and included an inbuilt platform switch.

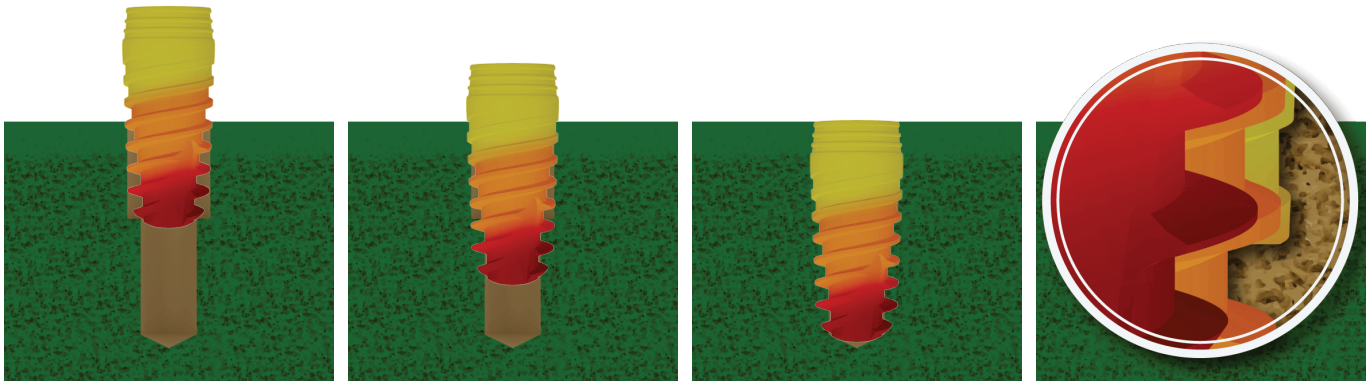
Design

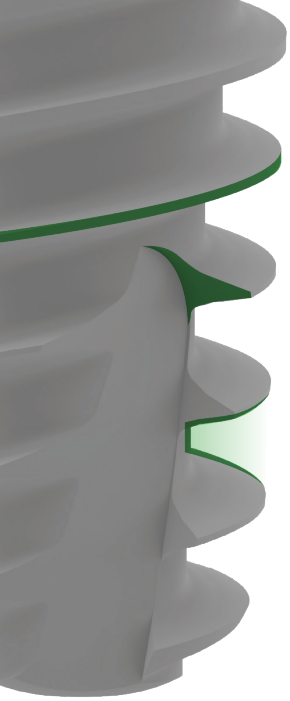
Back-tapered coronal design (alternatives)

- Narrowing cylinder design
- Conical design, cone-shaped
- Funnel-shaped.



XGate Dental cone-like implant compresses the bone in a gradual fashion, while the special drilling blades at the bottom enable smooth and minimal osteotomy incisions. These features allow achieving high primary stability in difficult situations when there is a soft bone or an existing sockets from previous extractions. XGate Dental implants allow for immediate implant placement and enable functionality soon after the procedure.





Advantages Of The “Tiger Claw” Geometric Form

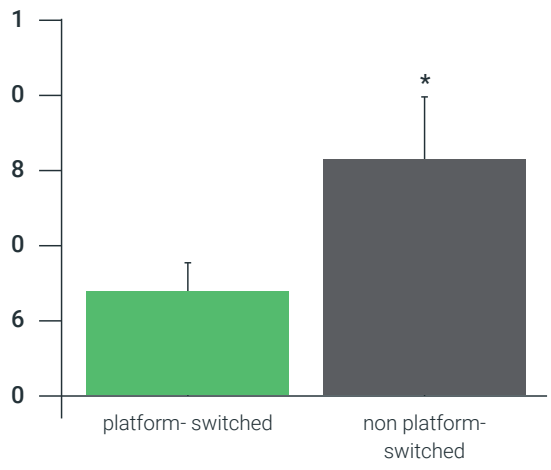
- Narrowing cylinder design
- Great initial and continual implant stability
- Easy insertion and optimal cutting efficiency (due to the sharp thread shape)
- Increased surface area (due to the round-faced design)
- Excellent Primary stability
- Extraordinary bone-to-implant contact
- High resistance to compressive forces
- Minimized shear force during implantation
- Supports angiogenesis & sustains blood supply

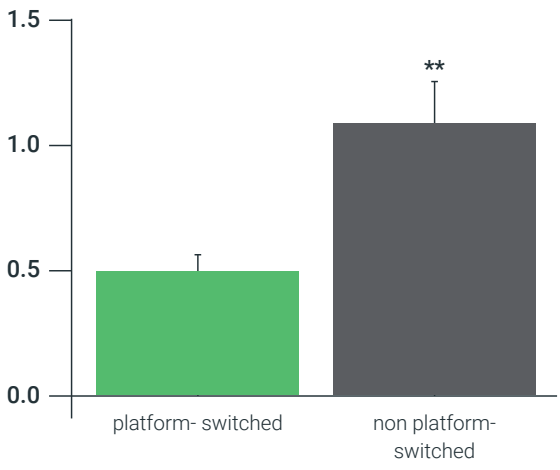
Platform Switching

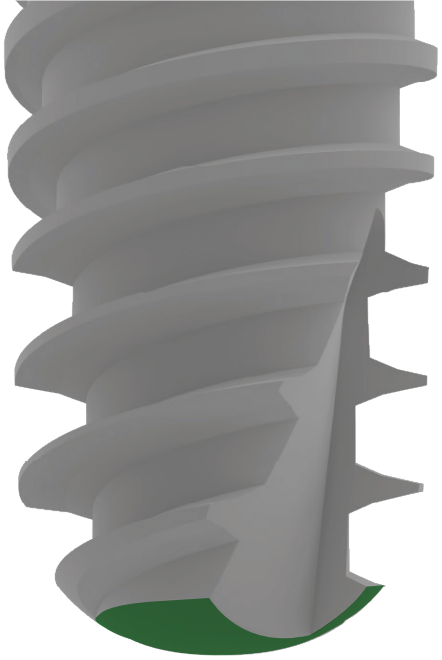
XGate’s built-in platform switching system within the implant keeps it away from bone, thereby minimizing bone resorption. Furthermore, it enables the excellent growth of the soft tissue.

The present study confirms that the platform-switching concept can minimize marginal bone loss over a one year period, in agreement with the previous trial and recent meta-analysis. Specifically, average marginal bone loss around non-platform-switched implants (0.78 mm mesially and 0.90 mm distally) was more than twice the average marginal bone loss around platform-switched implants (0.30 mm mesially and 0.38 mm distally).

Significantly less bone loss was seen around platform-switched implants (left) at the time of insertion of the definitive prosthesis and (right) after one year of function. Data is presented as means ± standard errors of the mean; statistical analyses were performed using two-tailed t tests for unpaired comparisons. *P < .05, **P <.01.

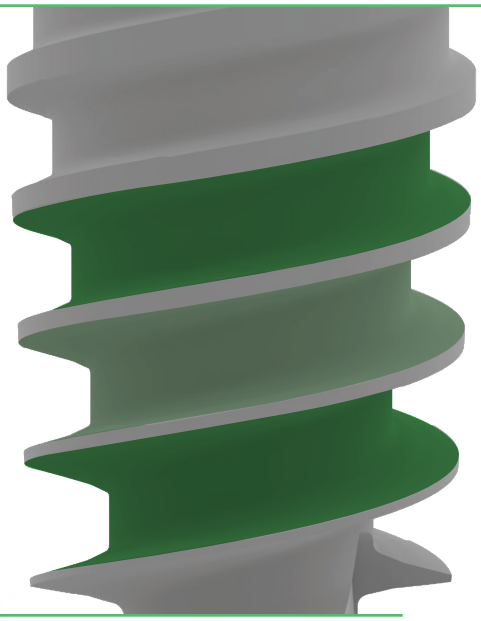






Two Spiral Channel & a domed apex (head/top)

XGate's implant is composed of a domed apex that provides high tolerance, and two cutting blades at the bottom that provide self-screwing properties. This enables a simpler, quicker, and, more importantly, safer procedure.

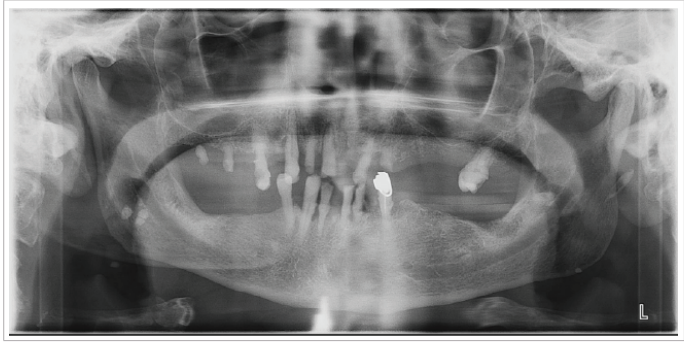
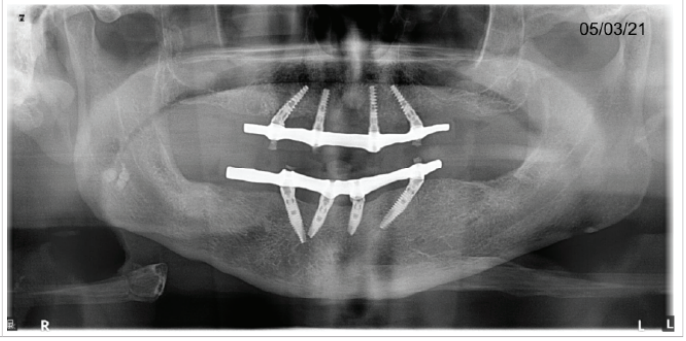


Dual thread

XGate's dual thread design doubles the implant's insertion rate (2.0mm), facilitating a simpler and faster implant placement. Additionally, the self-screwing and low bone compression properties improve primary stability.

Case Study

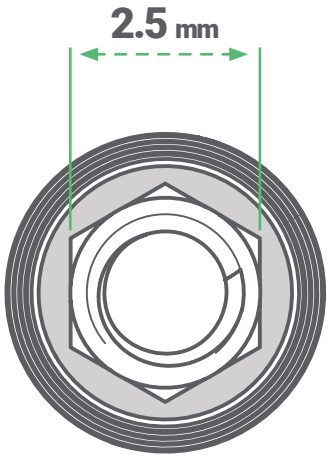
Here you can see X-rays of before and after the implantation procedure, using XGate's implants. You can clearly see that there was a successful osseointegration due to cleanliness of the surface and the advanced design.

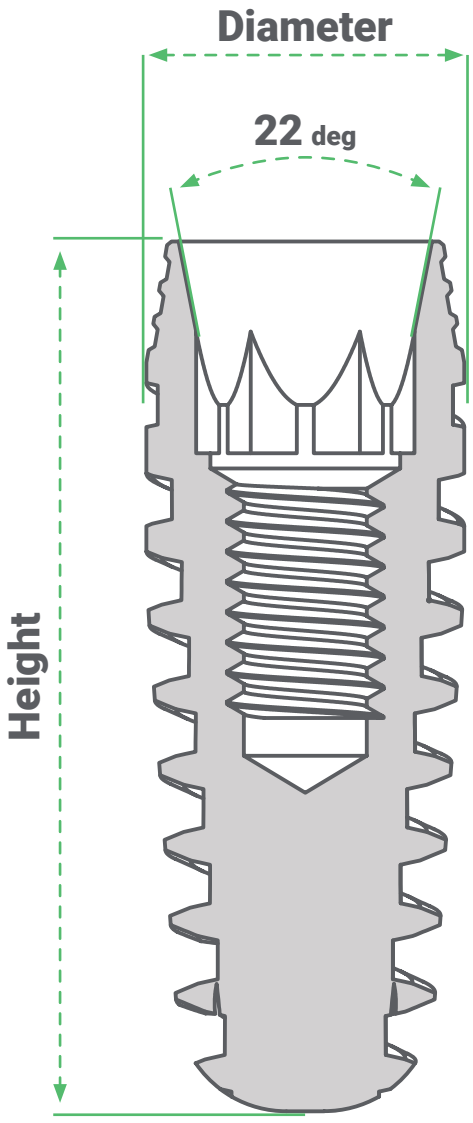
Before	After
	

Regular Platform

Conus Angle: 22° • Hex: 2.5 mm

Diameter	Height	S/N
3.75 mm	8mm	UCI-3708
	10mm	UCI-3710
	11.5mm	UCI-3711
	13mm	UCI-3713
	16mm	UCI-3716
4.2 mm	8mm	UCI-4208
	10mm	UCI-4210
	11.5mm	UCI-4211
	13mm	UCI-4213
	16mm	UCI-4216
5.0 mm	8mm	UCI-5008
	10mm	UCI-5010
	11.5mm	UCI-5011
	13mm	UCI-5013
	16mm	UCI-5016

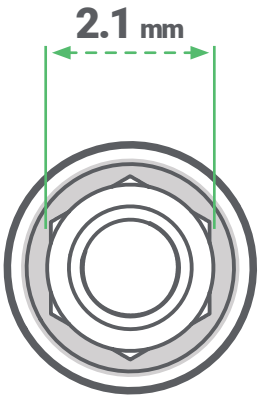


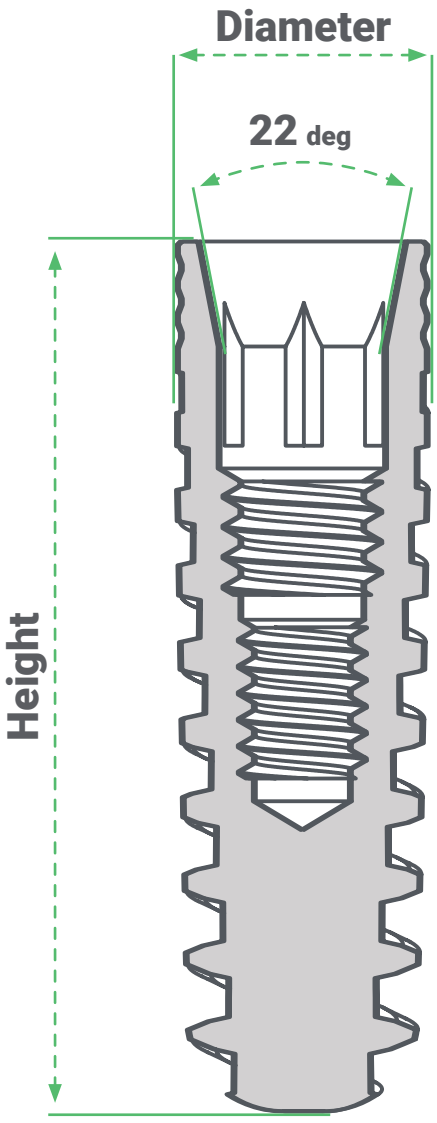


Mini Platform

Conus Angle: 22° • Hex: 2.1 mm

Diameter	Height	S/N
3.3 mm	8mm	UCI-3308
	10mm	UCI-3310
	11.5mm	UCI-3311
	13mm	UCI-3313
	16mm	UCI-3316



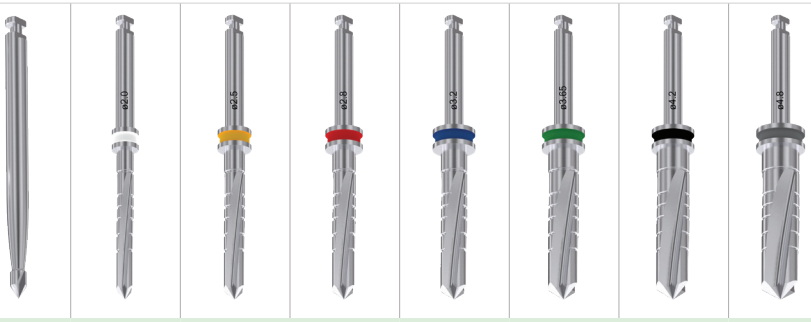


Recommended drilling protocol for X11 implants

Ø Implant	Soft bone Type IV	Medium bone Type II-III	Dense bone Type I
3.3 mm	2.0mm/(1)	2.0mm/(1)	2.0mm/(1)
	2.5mm/(1/2)	2.5mm/(1/2)	2.5mm/(1/2)
	2.8mm/(1/4)	2.8mm/(1/4)	2.8mm/(1/4)
			3.2mm/(1/4)
3.75 mm	2mm/(1)	2mm/(1)	2mm/(1)
	2.5mm/(1/2)	2.5mm/(1/2)	2.5mm/(1/2)
	2.8mm/(1/4)	2.8mm/(1/4)	3.2mm/(1/4)
			(3.65mm/(1/4))
4.2 mm	2mm/(1)	2mm/(1)	2mm/(1)
	2.5mm/(1)	2.5mm/(1)	2.5mm/(1)
	2.8mm/(2/3)	2.8mm/(2/3)	2.8mm/(2/3)
	3.2mm/(1/2)	3.65mm/(1/2)	3.65mm/(1/2)
			4.2mm/(1/4)
5.0 mm	2mm/(1)	2mm/(1)	2mm/(1)
	2.5mm/(1)	2.5mm/(1)	2.5mm/(1)
	2.8mm/(2/3)	2.8mm/(2/3)	2.8mm/(2/3)
	3.65mm/(1/2)	3.65mm/(1/2)	3.65mm/(1/2)
		4.2mm/(1/4)	4.6mm/(1/4)

Maximum insertion torque is 50Ncm

Number in the brackets (-) denotes for the drilling depth relative to implant length



Regular	ø 3.75	Soft bone Type IV	✎	1	½	¼			
		Medium bone Type II-III	✎	1	½	¼			
		Dense bone Type I	✎	1	½		¼	¼	
	ø 4.2	Soft bone Type IV	✎	1	1	⅔	½		
		Medium bone Type II-III	✎	1	1	⅔		½	
		Dense bone Type I	✎	1	1	⅔		½	¼
	ø 5.0	Soft bone Type IV	✎	1	1	⅔		½	
		Medium bone Type II-III	✎	1	1	⅔		½	¼
		Dense bone Type I	✎	1	1	⅔		½	¼
Mini	ø 3.3	Soft bone Type IV	✎	1	½	¼			
		Medium bone Type II-III	✎	1	½	¼			
		Dense bone Type I	✎	1	½	¼	¼		

MUA D-TYPE

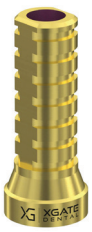
Ratchet screw driver for abutments
USDR1210 NA

1.25 mm

Screw for MUA sleeve, D-type
UMSD-0002 NA

Castable sleeve for MUA
USCD-0001 18

Temporary sleeve for MUA, D-type
USTD-0001 NA



CAD/CAM Long sleeve for MUA, D-type
USTD-0004 18

CAD/CAM short sleeve for MUA, D-type
USTD-0003 18

Straight multi unit abutment, D-type
USMD-OR3701 11

Angled multi unit abutment, D-type
UAMD-OSR1702 11

Straight multi unit abutment, D-type
USMD-OSM3701 11

Angled multi unit abutment, D-type
UAMD-OSM1702 11

X11 Pure&Porous Implant
UCI-XXXX NA

X11 Pure&Porous Implant
UCI-33XX NA

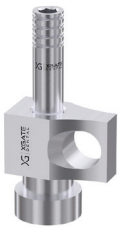
REGULAR PLATFORM

MINI PLATFORM

Healing cap for MUA, D-type
UMHD-0004 18

Transfer for MUA Closed Tray, D-type
UMTD-0003 NA

Transfer for MUA Open Tray, Short, D
UMTD-0002 NA



Transfer for MUA Open Tray, D-type
UMTD-0001 18

Scan body – MUA level, D-type
USBD-0001 10

Straight multi unit abutment, D-type
USMD-OR3701 11

Angled multi unit abutment, D-type
UAMD-OSR1702 11

Straight multi unit abutment, D-type
USMD-OSM3701 11

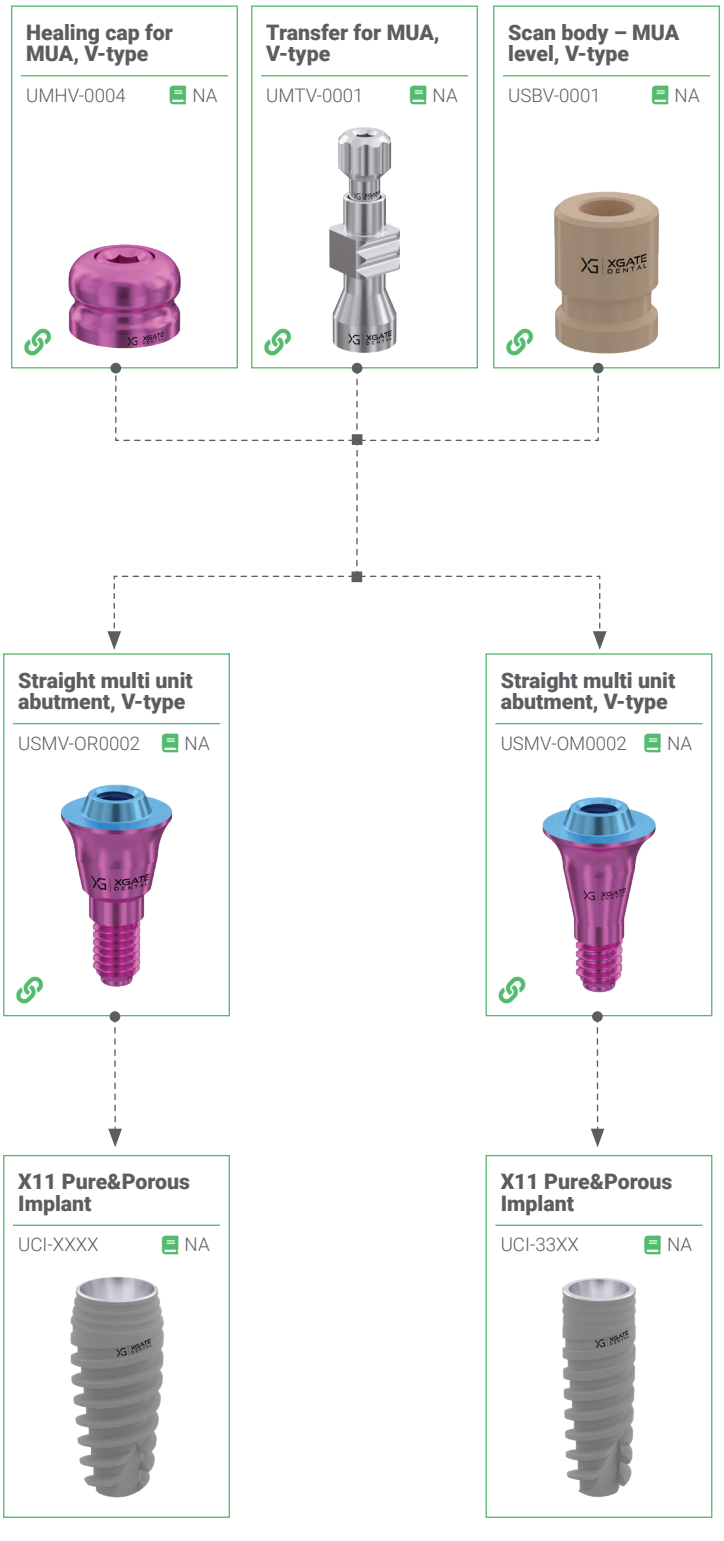
Angled multi unit abutment, D-type
UAMD-OSM1702 11

X11 Pure&Porous Implant
UCI-XXXX NA

X11 Pure&Porous Implant
UCI-33XX NA

REGULAR PLATFORM

MINI PLATFORM



REGULAR PLATFORM

MINI PLATFORM

Ratchet screw driver for abutments
USDR1210 NA

1.25 mm

Screw for MUA sleeve, V-type
UMSV-0002 999

Sleeve for MUA, V-type
UTBV-0015 NA

Sleeve for MUA, V-type
UTBV-0003 NA

Sleeve for MUA, V-type
UTBV-0004 NA

Sleeve for MUA, V-type
UTBV-0006 NA

Temporary sleeve for MUA, V-type
USTV-0001 999

Castable sleeve for MUA, V-type
USCV-0001 999

Straight multi unit abutment, V-type
USMV-OR0002 NA

Straight multi unit abutment, V-type
USMV-OM0002 NA

X11 Pure&Porous Implant
UCI-XXXX NA

X11 Pure&Porous Implant
UCI-33XX NA

REGULAR PLATFORM

MINI PLATFORM

Ratchet screw driver for abutments

USDR1210 NA

1.25 mm 1.25 mm

Screw for abutment

UOSR-0001 58

Screw for Scan Abutment

UMSD-OSR0007 NA

1.25 mm 1.25 mm

Transfer open tray

UOTO-R0001 50

Healing Cap

UOHR-5005 54

Straight abutment

UOTR-45703 58

Ti Base UNO

UTBR-OSR0402 NA

Plastic castable abutment

UOCR-0001 NA

Scan body Implant Level

USBI-OR0009 NA

1.25 mm

Cover Screw

CSOSR-0001 NA

X11 Pure&Porous Implant

UCI-XXXX NA

REGULAR PLATFORM

Ratchet screw driver for abutments
USDR1210 NA

1.25 mm 1.25 mm

Screw for abutment
OSM-0001 59

Screw for Scan Abutment
UMSD-OSM0007 NA

1.25 mm 1.25 mm

Transfer open tray
UOTO-M0001 50

Healing Cap
UOHM-4505 54

Straight abutment
UOTM-45703 59

Ti Base UNO
UTBR-OSM0404 NA

Plastic castable abutment
UOCM-0001 62

Scan body Implant Level
USBI-OM0009 NA

1.25 mm

Cover Screw
CSOSM-0002 NA

X11 Pure&Porous Implant
UCI-33XX NA

MINI
PLATFORM

01. BACKGROUND

Surface formation process implemented.

XGate dental implants are among the new and advanced implants on the market, using unique Pure & Porous (P&P) surface treatment and advanced geometry in order to maximize the osseointegration success chances as well as making the procedure less complex.

It is generally recognized by the world dental community, that surface quality is one of the most important factors affecting osteo-integration of dental implants: the surface microstructure must be well developed, and the surface cleanliness must be high, with minimum surface contaminants.

Two dental implants surface treatment processes are mostly usable in the world industry:
• SLA process, consisting of Alumina blasting for the surface roughening, and Double Acid Etching for Alumina removal,
• RBM process, consisting of Hydroxyapatite (HA) blasting for the surface roughening, and soft acid dissolution of HA remained on the surface.

XGate Dental Implants are manufactured by the unique
• Pure & Porous (P&P) Process, which combines advantages of SLA and RBM and is free from their drawbacks. It consists of Hydroxyapatite (HA) blasting, soft acid dissolution of remaining HA, and surface beneficiation.

Following is quality & technological comparison of these three Processes:

Advantages

• Both SLA and Pure & Porous provide the unique effect of a highly porous two-level microstructure of the surface, which is a very valuable characteristic welcomed in modern dental implant practice.
• Both RBM and Pure & Porous use biocompatible, readily soluble and easily removable Hydroxyapatite (HA) as abrasive medium, instead of bio-incompatible insoluble Alumina, requiring aggressive double acid etching for its removal.

Drawbacks

• SLA uses non-biocompatible Alumina for blasting and aggressive Double Acid Etching to remove remains of Alumina, which potentially may cause serious surface damages; additionally, remains of Alumina on the surface are statistically inevitable in this process; Pure & Porous is free of these drawbacks, since it doesn't use Alumina as blasting media.
• RBM does not allow to achieve a highly porous two-level surface microstructure, while Pure & Porous is featured by the ability to provide such surface microstructure.

Comprehensive Surface Treatment (CST) approach.

The Pure & Porous (P&P) process of XGate Dental Implants manufacturing is carried out using principles of our Comprehensive Surface Treatment (CST) approach:
• Compliance with fundamentals and laws of chemical technology.
• Operating of newest equipment.
• Thorough Quality Control at all stages of the process, including on-line control of academic instruments.
• Professionally skilled supervising and operating staff.
The high surface quality performances of XGate dental implants as compared to global quality are the result of the Pure & Porous process guided by the CST approach.

Academic Instruments and analysed Implants.

For evaluation and elaboration of dental implants surface quality, academic instruments allowing micron-size resolution to distinguish surface quality performances are usually operated. Examination of the P&P surface quality and its comparison to SLA and RBM is realized and presented on the following pages using these instruments.

Scanning Electron Microscope – SEM - for evaluation and controlling surface microstructure of implants.

Laser Profilometry (LP) and Atomic Force Microscope (AFM) – for qualitative evaluation of surface roughness.

Energy Dispersive Spectroscopy – EDS – for point chemical composition of the surface.
X-ray Photoelectron Spectroscopy – XPS – for full chemical analysis of the surface, thickness of oxide layers, and chemical composition in depth.

SEM, EDS, XPS and LP analysis for Xgate P&P implants (Ti-grade-5 made) were performed at the Nano Science Institute, Ben-Gurion University of the Negev, for samples of implants, shortly after their manufacturing at the production line. Total of seven samples of implants was randomly taken from the Xgate production line during June-October 2020. These samples, identified and cited further by the Lot#, are presented in the current examination. A few implants of other manufacturers were tested there as well, and the results are presented for comparative purpose only, with no identification.

SEM, XPS and LP results for SLA and RBM implants are cited in the comprehensive Review "POSEIDO Journal Periodontology, Oral Surgery, Esthetic & Implant Dentistry, Volume 2, Issue 3, September 2014". Nine cases of SLA implants made of Ti-grade-5 are evaluated at pp. 37- 55 of the Review, and they are cited below as "Poseido-1", and six cases of RBM implants made of Ti-grade-5 are evaluated at pp. 57-74, and they are cited below as "Poseido-2".

02. XGATE PROVIDES A SURFACE MICROSTRUCTURE OF DENTAL IMPLANTS ON THE HIGHEST LEVEL OF SLA MANUFACTURERS

SEM enables qualitative evaluation of the implants surface microstructure through presenting electron microphotographs of the surface at various magnifications. We chose a magnification of 5,000 in the Secondary Electrons mode (SEM SE), allowing volume perception of the tested surface. Comparison of the SEM microphotographs for P&P, SLA and RBM implants are presented in Charts 1 and 2.

Surface microstructure for both SLA and P&P samples reveals a well-organized two- levelled surface topography: valleys 10-30 microns wide and long, covered inside with craters 1-3 microns diameter. Such surface microstructure is considered worldwide as the most appropriate for bone cells proliferation onto implant surfaces, i.e., optimal for osseointegration.

The surface of the RBM implants reveals a chaotic topography presenting no regular pattern of microstructure.

Chart-1. Comparison of the P&P implants' surface microstructure with the microstructure of SLA and RBM implants (by original SEM micro-photographs)

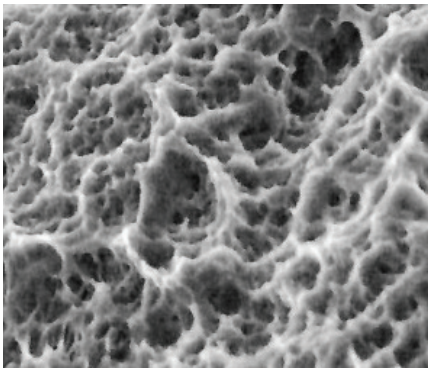
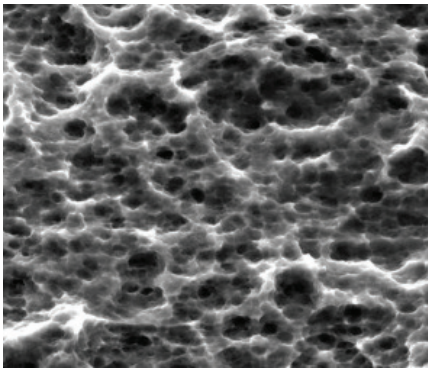
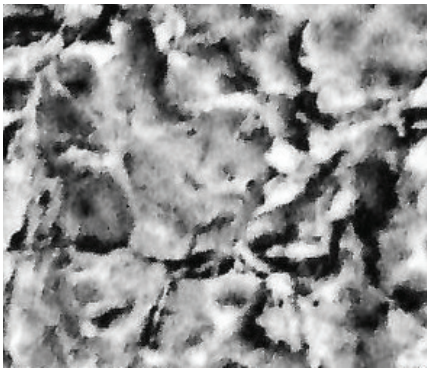
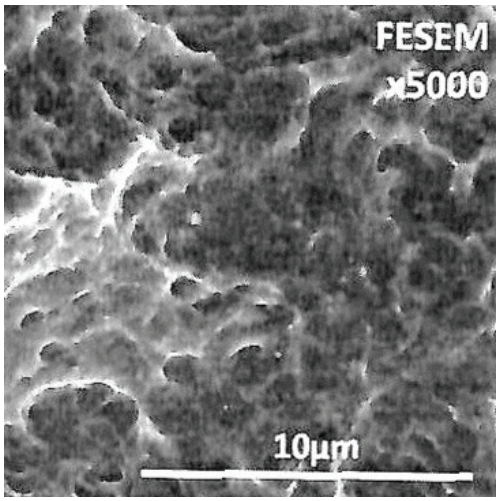
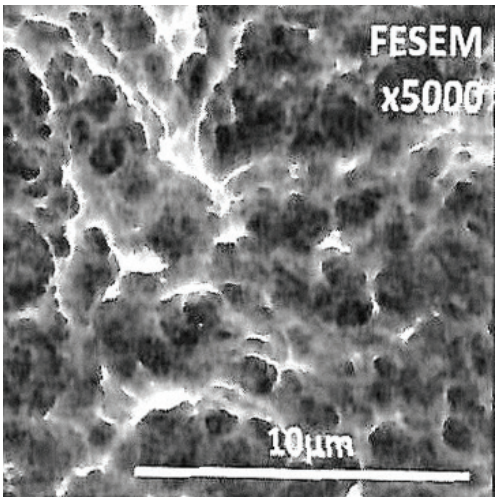
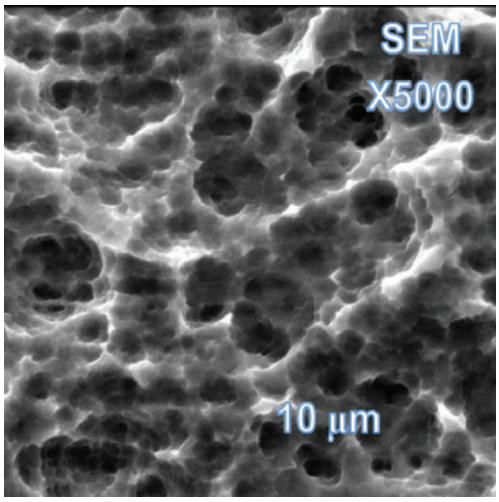
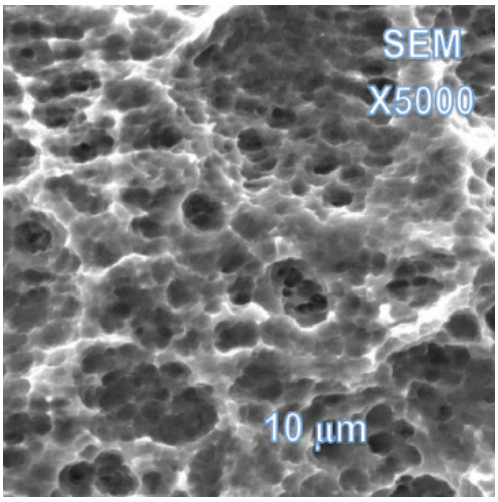
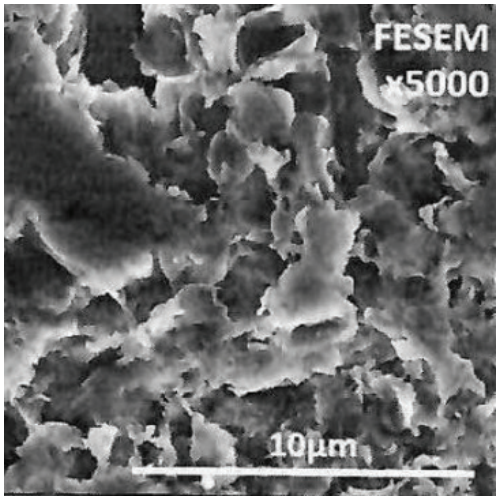
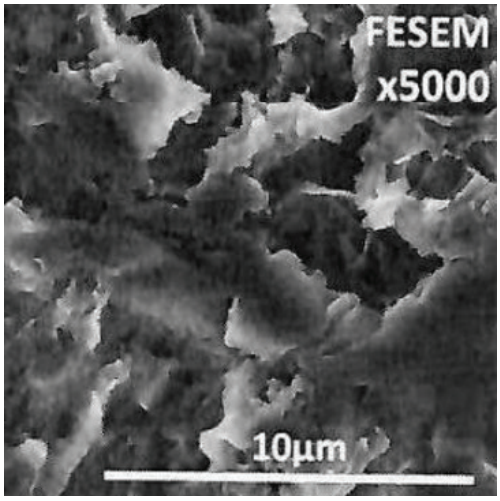
SLA surface one of worldwide leaders	**P&P surface** E01-0011 August 2020	**RBM surface** a well-known manufacturer
		

Chart-2. Comparison of the P&P implants' surface microstructure (by original SEM micro-photographs) with the microstructure of SLA and RBM implants (by the Poseido Review's microphotographs)

SLA SAMPLES		
	Poseido-1. Sample 10	Poseido-1. Sample 11
P&P SAMPLES		
	E01-0010 August 2020	E01-0034 October 2020
RBM SAMPLES		
	Poseido-2. Sample 1	Poseido-2. Sample 7

03. XGATE PROVIDES COMPLETELY ALUMINA-FREE SURFACE, AS INTENDED BY THE RBM PROCESS

Alumina blasting of SLA requires a heavy acid etching to clean the surface from alumina. Technological windows of cleaning and over-etching are very close, so the surface contamination by non-biocompatible Alumina is statistically inevitable. The basic concept of the RBM process is to prevent this hazard by replacing the Alumina with Hydroxyapatite.

Chart 3 below presents comparative results of Alumina content on the P&P, SLA and RBM implants' surface. Since the tested implants are Ti-grade-5 made, the alloy originated Al naturally occurs on the surface, while content of Al surface contamination, originated from Alumina blasting, was calculated as difference between total Al content and its alloy-born quantity.

The results show that the manufacturer's operating well-grounded SLA technology, enabling high Ti surface content, is capable of eliminating Alumina surface contaminants, but less controlled SLA lines, reaching poor Ti surface content can't avoid Alumina residuals on the surface.

For RBM cases, manufacturers of any level ensure Alumina-free surface.

P&P samples reveal a completely Alumina-free surface, as intended by the RBM process.

Chart-3. Comparative results of Aluminum content on the P&P, SLA and RBM implants' surface (in ascending order), by XPS tests.

Source of info	Sample identification (sample's # from Poseido, or Lot # of Xgate)	Surface process	Ti content, at. %	Total Al content, at. %	Al content as Alumina hazard, at. %
Poseido-1	Figure 12	SLA	20.9	1.5	0
Poseido-1	Figure 10	SLA	20.3	2.6	0
Poseido-1	Figure 9	SLA	19.2	2.2	0
Poseido-1	Figure 11	SLA	16.3	2.0	0
Poseido-2	Figure 1	SLA	15.4	1.5	0
Poseido-1	Figure 2	SLA	10.3	9.9	8
Poseido-1	Figure 15	SLA	8.4	9.3	7
Poseido-1	Figure 17	SLA	8.2	13.8	12
Poseido-1	Figure 13	SLA	4.7	3.2	2
Poseido-2	Figure 7	RBM	17.3	1.8	0
Poseido 2	Figure 2	RBM	16.3	1.9	0
Poseido-2	Figure 8	RBM	15.8	1.6	0
Poseido-2	Figure 11	RBM	15.0	1.3	0
Poseido-2	Figure 12	RBM	13.0	1.5	0
Poseido-2	Figure 3	RBM	2.0	0.5	0
XGate Dental	E01-0013 September 2020	P & P	17.8	3.1	0
XGate Dental	E01-0002 June 2020	P & P	17.7	2.8	0
XGate Dental	E01-0011 August 2020	P & P	17.4	4.0	0
XGate Dental	E01-0012 September 2020	P & P	17.3	3.0	0
XGate Dental	Lot E010010 August 2020	P & P	17.2	3.0	0
XGate Dental	E010001 June 2020	P & P	17.0	2.2	0
XGate Dental	E01-0034 October 2020	P & P	16.3	2.1	0

04. XGATE P&P DENTAL IMPLANTS DEMONSTRATE HIGH SURFACE CLEANLINESS AS COMPARED TO WORLDWIDE QUALITY STANDARDS

The surface cleanliness of dental implants depends more rather on the general level and culture of production than on the surface treatment process chosen. Surface cleanliness may be qualitatively evaluated by SEM microphotographs, and quantitatively analysed by EDS (point surface analyses) and by XPS (overall surface analyses) techniques.

All three test systems demonstrate high surface cleanliness of Xgate dental implants as compared to worldwide quality level, as a result of high general level and culture of production of Xgate processing and its adherent CST approach.

Surface cleanliness by SEM-EDS

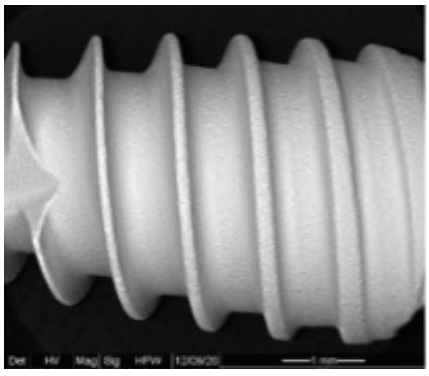
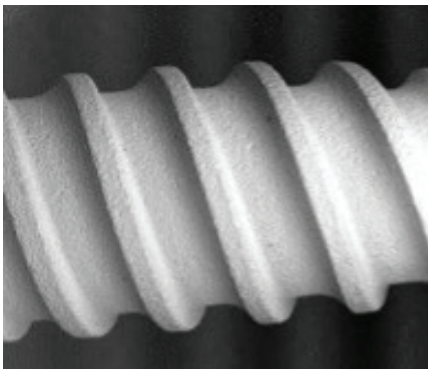
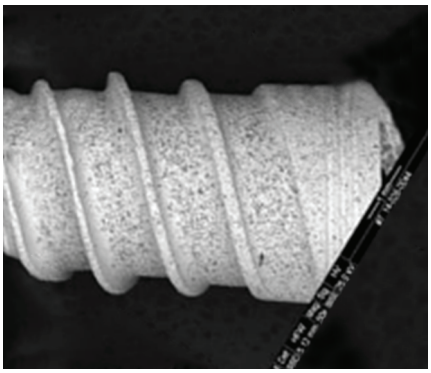
results 4.1.1. SEM results

SEM microphotographs in Back Scattering mode (SEM BC) allow black highlighting of any non-metallic surface inclusions. This method is a good instrument for initial qualitative evaluation of surface cleanliness: the more black points, the more contaminated surface.

Chart 4, SEM BC microphotographs at magnification 50 presents dental implants of: XGate Dental (image 1), one of worldwide leaders in the field (image 2) and a well-known manufacturer (image 3).

XGate implants demonstrate surface cleanliness equal to the worldwide leader in the field

Chart-4. SEM BC microphotographs at magnification 50

SEM image 1 XGate Lot E010036 Nov 2020	**SEM image 2** one of worldwide leaders	**SEM image 3** a well-known manufacturer
		

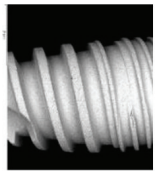
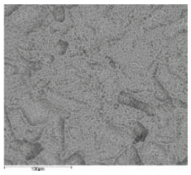
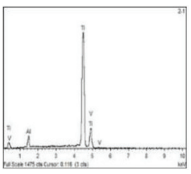
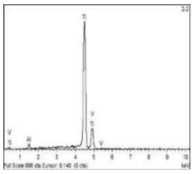
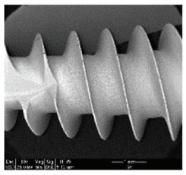
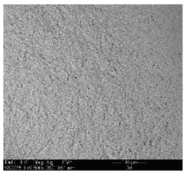
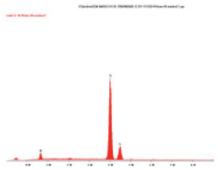
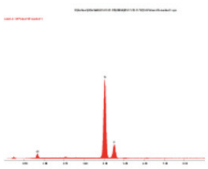
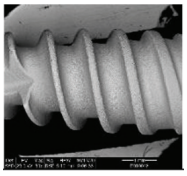
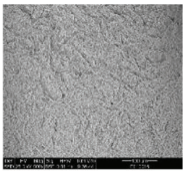
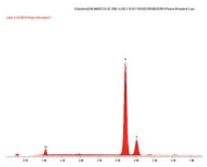
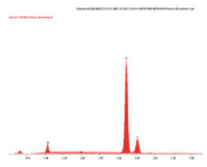
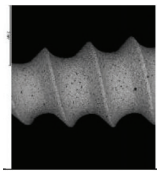
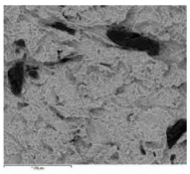
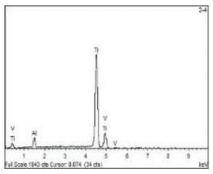
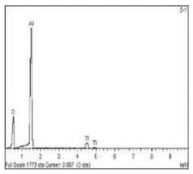
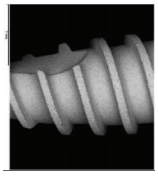
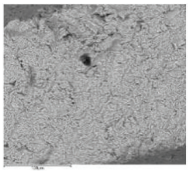
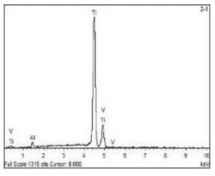
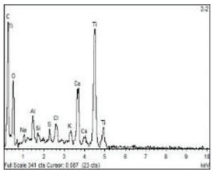
4.1.2. EDS results

EDS (usually embedded in SEM) is another method for surface cleanliness evaluation. Electron beam reaching a surface leads to secondary emission of energy quantum, specific for every element on energy axes, with amplitude related to its content. With this method a chemical composition of any point on the surface may be analyzed.

Chart-5 presents SEM microphotographs of P&P, SLA and RBM implants' surface and appropriate EDS spectrum for two random points of every sample; the explanations are written in the Table's cells.

XGate implants demonstrate surface cleanness equal to the worldwide leaders in the field.

Chart-5. EDS spectra for dental implants with different surface cleanliness

SEM microphotograph Magnification 50	SEM microphotograph Magnification 500 or 1000	EDS spectrum 1	EDS spectrum 2	Surface quality value
One of the worldwide leaders in the field of SLA Process				Perfect surface cleanness
				
No visible contaminations	No visible contaminations	Only peaks of Ti alloy components (Ti, Al, V) are detected at the first random point	Only peaks of Ti alloy components (Ti, Al, V) are detected at the second random point	
XGate Lot E010034 November 2020 Pure & Porous Process				Perfect surface cleanness
				
No visible contaminations	No visible contaminations	Only peaks of Ti alloy components (Ti, Al, V) are detected at the first random point	Only peaks of Ti alloy components (Ti, Al, V) are detected at the second random point	
XGate Lot E010018 September 2020 Pure & Porous Process				Perfect surface cleanness
				
No visible contaminations	No visible contaminations	Only peaks of Ti alloy components (Ti, Al, V) are detected at the first random point	Only peaks of Ti alloy components (Ti, Al, V) are detected at the second random point	
Well-known manufacturer SLA Process				Conta minate d by remain s of Alumina
				
Visible contaminations	Visible contaminations	Only peaks of Ti alloy components (Ti, Al, V) are detected at the random point of the clean area	Peaks of Alumina components (Al, O) are detected at the random point of the contaminated area	
Well-known manufacturer RBM Process				Conta minate d by organic and other matters
				
Slightly visible contaminations	Visible contaminations	Only peaks of Ti alloy components (Ti, Al, V) are detected at the random point of the clean area	Peaks of Carbon (C) and other elements (Cl, S and more) are detected at the random point of the contaminated area	

Surface cleanliness by XPS results

XPS enables quantity evaluation of surface quality through presenting surface chemical composition of the tested sample.

Titanium content

The most essential feature of the dental implants' surface is Titanium content, its value within 15-20% is acceptable worldwide as optimal. In Chart 6 below, comparative results of Titanium content in the P&P, SLA and RBM surfaces are presented.

The results demonstrate a stable solid place of the P&P process in terms of optimal Titanium content in the implants surface within 16-18%, while SLA and RBM processes may lead to Titanium content as low as 2-8%.

Chart-6. Comparative results of Titanium content on the P&P, SLA and RBM implants' surface (in descending order)

Source of info	Sample identification (sample's # from Poseido, or Lot # of Xgate)	Surface process	Titanium content, at. %
Poseido-1	Sample 12 from the Review	SLA	20.9
Poseido-1	Sample 10 from the Review	SLA	20.3
Poseido-1	Sample 9 from the Review	SLA	19.2
XGate Dental	Lot E01-0013 September 2020	P & P	17.8
XGate Dental	Lot E01-0002 June 2020	P & P	17.7
XGate Dental	Lot E01-0011 August 2020	P & P	17.4
XGate Dental	Lot E01-0012 September 2020	P & P	17.3
Poseido-2	Sample 7 from the Review	RBM	17.3
XGate Dental	Lot E010010 August 2020	P & P	17.2
XGate Dental	Lot E010001 June 2020	P & P	17.0
XGate Dental	Lot E01-0034 October 2020	P & P	16.3
Poseido-1	Sample 11 from the Review	SLA	16.3
Poseido 2	Sample 2 from the Review	RBM	16.3
Poseido-2	Sample 8 from the Review	RBM	15.8
Poseido-2	Sample 1 from the Review	SLA	15.4
Poseido-2	Sample11 from the Review	RBM	15.0
Poseido-2	Sample 12 from the Review	RBM	13.0
Poseido-1	Sample 2 from the Review	SLA	10.3
Poseido-1	Sample 15 from the Review	SLA	8.4
Poseido-1	Sample 17 from the Review	SLA	8.2
Poseido-1	Sample 13 from the Review	SLA	4.7
Poseido-2	Sample 3 from the Review	RBM	2.0

Contaminants content

Another essential feature of dental implants' surface is the content of contaminants.
To calculate elements as contaminants, we adhered to the following considerations:

- Titanium alloy components (Ti, Al and V for Titanium grade 5), Oxygen of surface metal oxides, and Carbon and Nitrogen adsorbed from the atmosphere as CO2 and N2, are natural parts of the dental implants surface. Ca and P are often not considered contaminants as well, due to belonging of these elements to the bone tissue.
- Any other elements are related to contaminants.
- Alumina-born Al as contaminant is calculated separately (see Chart-3 above).

In Chart 7 below, comparative results of contaminan content for P&P, SLA and RBM surfaces are presented.

The contaminan content for the Pure & Porous surface shows good cleanness of not more than 0.9% contaminants, while SLA and RBM may lead to 3-5%.

Chart-7. Comparative results of contaminants' content on the P&P, SLA and RBM implants' surface (in ascending order)

Source of info	Sample identification (sample's # from Poseido, or Lot # of Xgate)	Surface process	Titanium content, at. %
Poseido-1	Sample 10 from the Review	SLA	0.0
Poseido-1	Sample 9 from the Review	SLA	0.0
XGate Dental	E01-0013 September 2020	P & P	0.0
Poseido-2	Sample 11 from the Review	RBM	0.0
Poseido 2	Sample 2 from the Review	RBM	0.2
XGate Dental	E01-0011 August 2020	P & P	0.3
XGate Dental	Lot E010010 August 2020	P & P	0.4
XGate Dental	E01-0034 October 2020	P & P	0.4
Poseido-2	Sample 12 from the Review	RBM	0.4
Poseido-1	Sample 12 from the Review	SLA	0.6
XGate Dental	E01-0002 June 2020	P & P	0.6
XGate Dental	E01-0012 September 2020	P & P	0.6
Poseido-1	Sample 11 from the Review	SLA	0.7
XGate Dental	E010001 June 2020	P & P	0.9
Poseido-2	Sample 8 from the Review	RBM	1.5
Poseido-2	Sample 7 from the Review	RBM	2.0
Poseido-1	Sample 17 from the Review	SLA	3.1
Poseido-1	Sample 2 from the Review	SLA	3.2
Poseido-2	Sample 3 from the Review	RBM	3.2
Poseido-2	Sample 1 from the Review	SLA	3.9
Poseido-1	Sample 13 from the Review	SLA	3.9
Poseido-1	Sample 15 from the Review	SLA	5.3

05. XGATE P&P IMPLANTS DEMONSTRATE HIGH SURFACE ROUGHNESS AS COMPARED TO SLA AND RBM IMPLANTS

Roughness of dental implants' surface is one of their most important characteristics: higher surface roughness leads to better conditions for successful osteo-integration process.

The main and commonly adopted surface parameters is Roughness Average Ra, calculated as average value of profile curve ordinates: the more Ra value is represented, the more developed roughness. The profile curves are built by profilometers; for structure as fine as dental implants surface Optical and Laser Profilometers are used.

In Chart 8 comparative results of P&P, SLA and RBM surface roughness measurement are presented.
Xgate P&P implants demonstrate high surface roughness as compared to SLA and RBM implants.

Chart-8. Roughness of implants' surface by Ra value for P&P, SLA and RBM processes

Source of info	Implat's identification	Process type	Ra, µm
XGate Dental	sample 2 (previous years)	P&P	2.3
XGate Dental	sample 1 (previous years)	P&P	2.1
Poseido-1	Figure 2	SLA	1.6
Poseido-2	Figure 2	RBM	1.3
Poseido-2	Figure 11	RBM	1.2
Poseido-2	Figure 12	RBM	1.2
Poseido-1	Figure 12	SLA	1.2
Poseido-1	Figure 17	SLA	1.2
Poseido-1	Figure 9	SLA	1.2
Poseido-1	Figure 10	SLA	1.1
Poseido-2	Figure 8	RBM	1.1
Poseido-2	Figure 3	RBM	1.0
Poseido-2	Figure 7	RBM	1.0
Poseido-1	Figure 11	SLA	0.9
Poseido 2	Figure 1	RBM	0.8
Poseido-1	Figure 15	SLA	0.8
Poseido-1	Figure 13	SLA	0.6

06. SURFACE QUALITY STATISTIC EVALUATION AND STABILITY OF XGate DENTAL IMPLANTS AS COMPARED TO WORLDWIDE STANDARDS

Statistical evaluation of implants collection represented in the Review illustrates poor consistency of dental implants' surface quality in today's dental implants industry.

Both SLA and RBM manufacturing populations provide implants containing surface Titanium (see Chart-9) though at not so bad 13% level, but with deviations from unacceptable 2% up to outstanding 20%. The same improper situation is revealed for contaminants content (see Chart 10).

Comparison of the average best and average worst cases for SLA (Chart-9) shows 11% Titanium content difference between them (from 19.2% the best to 7.9% the worst), resulted from stressed chemical situation in the process of surface formation, which may be good only if managed by manufacturers having a high technological level.

Equal comparison of RBM cases shows less stressed situation, because the chemical treatment is softer: though the best average producer reaches lower (but good) surface of Titanium content of 16.1, the worst average doesn't fall below 11.5.

For the P&P for Xgate implants, the average Ti surface content stands on a very good 17.2% level with small deviation of only 0.5%, and the best and the worst cases differ a little, keeping 17% level. The situation is the result of the soft chemical treatment like in RBM case and strict adhering to the rules of CST approach to the manufacturing process.

Chart-9. Statistical evaluation of Ti surface content for SLA, RBM and P&P collections of implants (numbers are in atomic %)

The process	All collection		4 best		4 worest	
	average	st devia	average	st devia	average	st devia
SLA	13.7	6.0	19.2	2.0	7.9	2.3
RBM	13.2	5.7	16.1	1.0	11.5	6.4
P&P	17.2	0.5	17.6	0.2	17.0	0.5

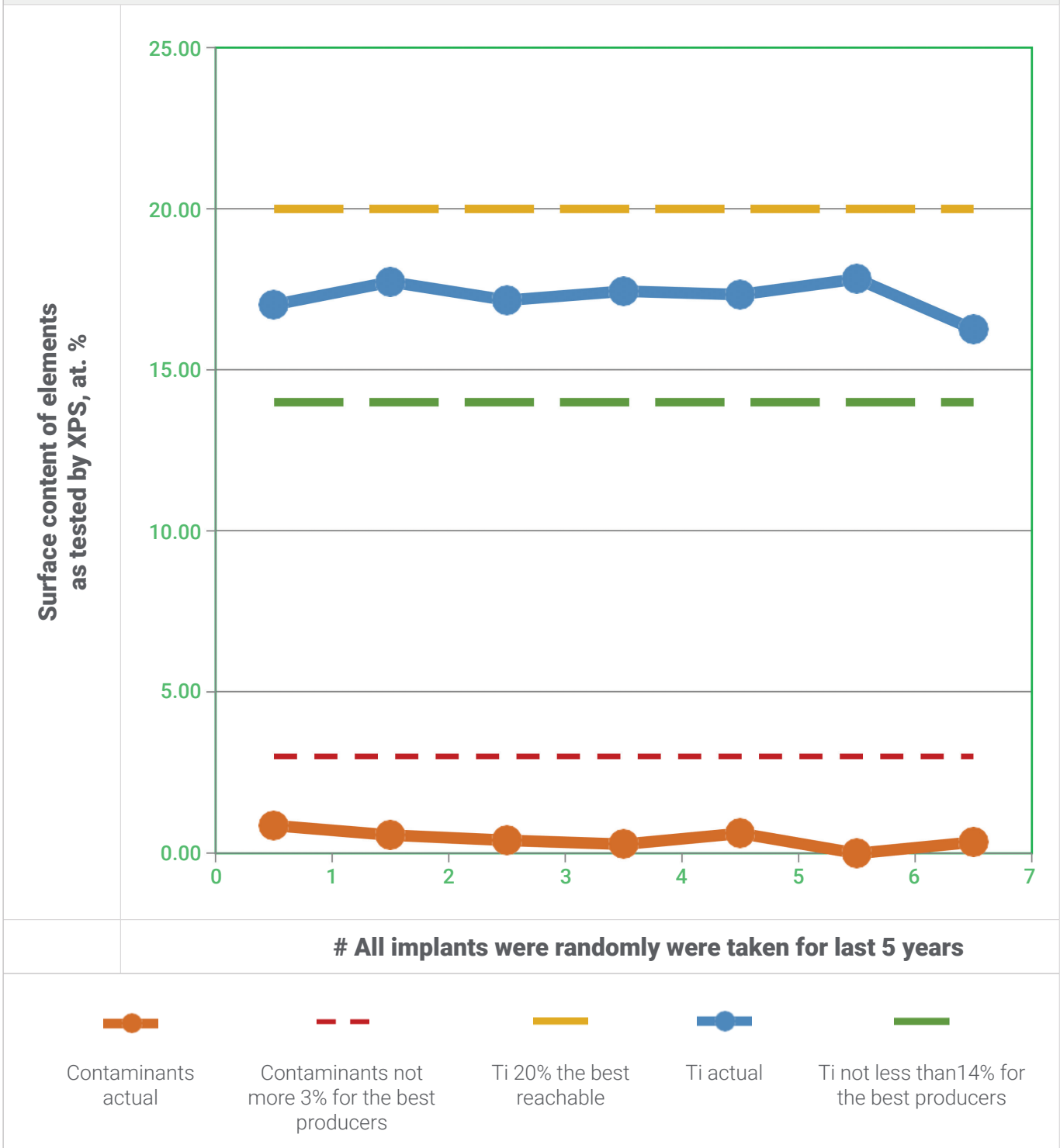
Chart-10. Statistical evaluation of contaminants' surface content for SLA, RBM and P&P collections of implants (numbers are in atomic %)

The process	All collection		4 best		4 worest	
	average	st devia	average	st devia	average	st devia
SLA	2.3	2.0	0.3	0.4	3.9	1.0
RBM	1.2	1.2	0.5	0.7	1.8	1.2
P&P	0.5	0.3	0.3	0.2	0.6	0.2

The most significant result of P&P-CST technology of dental implants surface formation is stability of surface chemical composition of the implants within acceptable range of surface components concentrations, on the manufacturing time axes – see Chart 11.

We can't compare this quality achievement with other manufacturers, since we didn't find such information published.

Chart 11. Stability of surface quality of the dental implants Xgate during production period from June to October 2020




XGATE
DENTAL