SCIENTIFIC DOCUMENT

RMDs cleaning system using Sodium Bicarbonate

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CONTENTS

1. NON ABRASIVITY TEST OF SODIUM BICARBONATE ON METALS – Trento University – Materials Engineering Department

1.1 METHODOLOGY AND TESTED MATERIALS

In the study done by the Trento University and summarized in the table below, several steel and aluminum samples were subjected to BICARjet® cleaning treatment with sodium bicarbonate.
The distance for all treatments was kept constant at 7cm.
The treatments were all carried out keeping the jet perpendicular to the sample.
The granulometry of bicarbonate was kept constant at 400 microns.

STEEL	HARDNESS (Vickers)	PRESSURE (bar)	TIME (seconds)
C45	196 HV	1 3 5	15 15 15
C45 milled	196 HV		
2312	287 HV		
2312 milled	287 HV		
QUENCHED	296 HV	1 2 3	15,30 15,30 15,30
IMPAX	311 HV		
ORVAR	489 HV		
STAVAX	556 HV		

ALUMINUM	HARDNESS (Vickers)	PRESSURE (bar)	TIME (seconds)
AL by molding	130 HV	1 3 5	15,60 15,60 16,60
AL ERGAL 55 polished (1° test)	185 HV	1 3	15,60 15
AL ERGAL 55 polished (2° test)	185 HV	0,5 1 1,5 3	15 15 15 60

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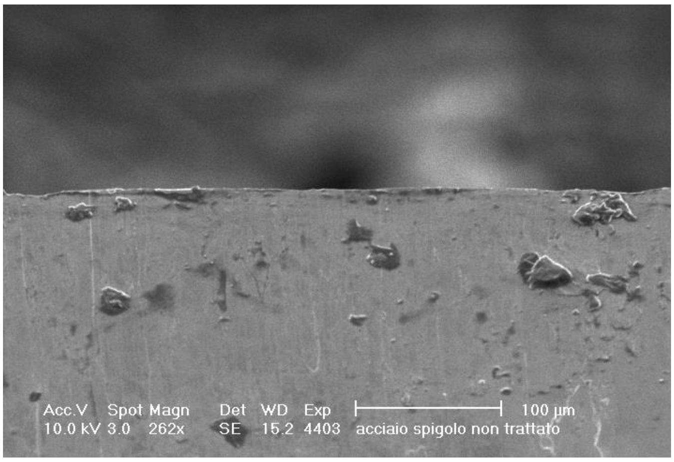
1.2 RESULTS

Have been made measurements of:

- Vickers hardness before and after treatments - Wolpert Durometer
- X-ray diffraction (microstructural analysis) - Rigaku Geigerflex Diffractometer
- profilometry before and after treatments - Hommel Tester T8000-Hommelwerke roughness meters
- GMHB and Tecnor mod. Alphastep200
- scanning electron microscopy (morphological analysis) - Philips XL30 microscope
- atomic force microscopy (morphological analysis) - AFM Burleigh mod. View
- weight loss after treatment - Scales at a sensitivity of 10-6 grams

<table>
<tr><th colspan="2">COMPARISON BETWEEN MORFHOLOGY OF AN AISI 304 STEEL EDGE
In the untreated parts (a) and treated 3 bar for 30 seconds (b)</th></tr>
<tr><td>
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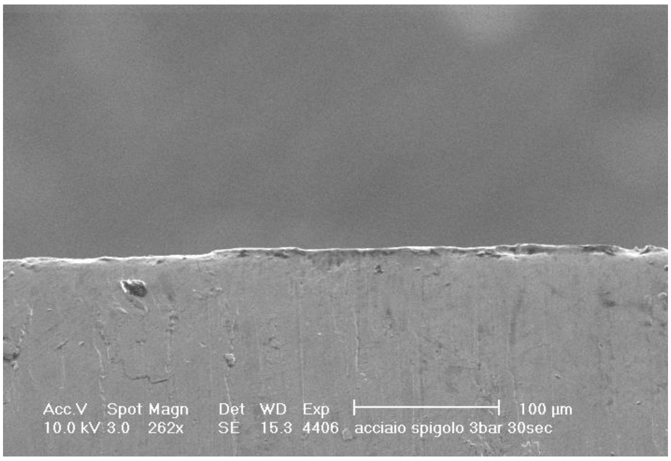
<tr><td>
</td><td>(b)</td></tr>
</table>

The enlargement is 200 times and the bar indicates the distance equivalent to 100 micrometers.

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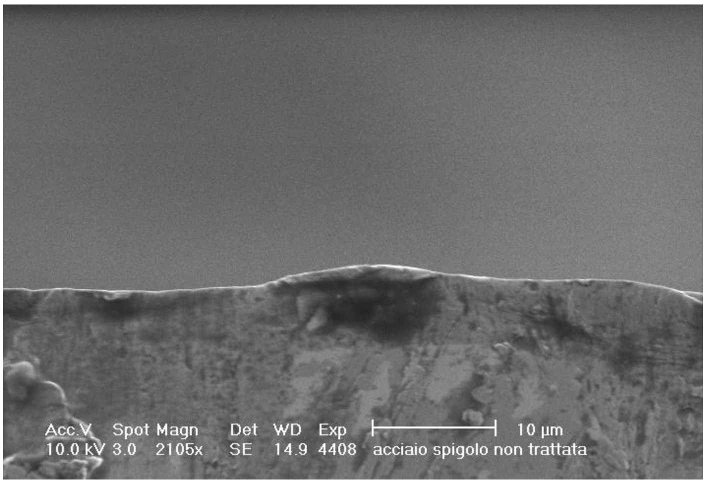
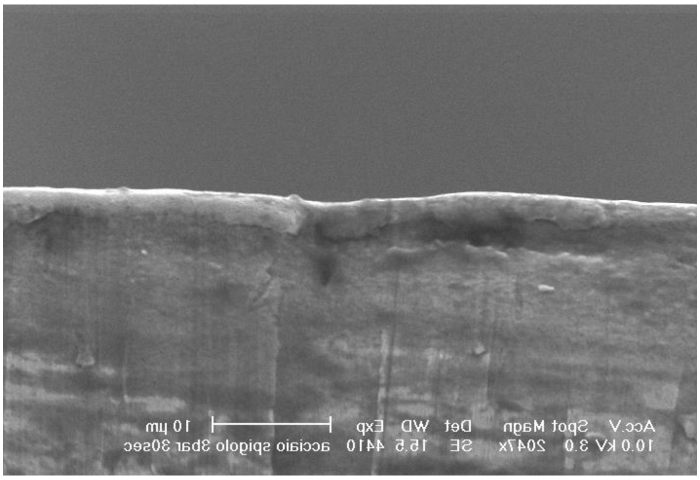
MORFHOLOGIES COMPARED ON AISI 304 STEEL EDGE
In the untreated parts (a); treated parts 3 bar for 30 seconds (b) and at 5 bar (c).



(a)



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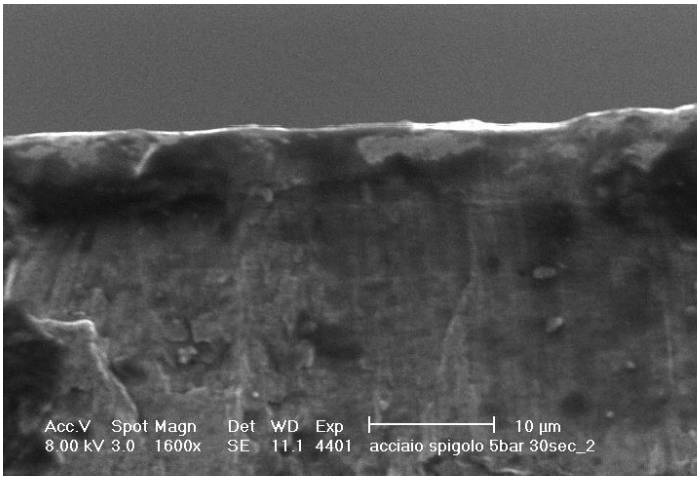

(c)

The enlargement is greater than 1600 times and the bar indicates the distance equivalent to 10 micrometers.

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1.3 CONCLUSIONS

The carried out studies on the selected samples have shown that the sodium bicarbonate treatment affects and modifies metals only for thicknesses of a few micrometers, even at the highest pressures.

On samples with hardness greater than 200-250 Vickers HV up to pressures of 5 bar there are no appreciable roughness variations.

During the cleaning process there is no material removal.
For samples with hardness lower than 200 Vickers the behavior between steel and aluminum samples differs: steels, not very ductile, continue to show no obvious roughness variations whereas aluminum, more ductile, changes at treatment pressures higher than 1 bar.
For pressures of 1 bar or less the behavior of aluminum samples is similar to that of steels, with effects of limited modification of roughness surface which, in specific cases, decreases gloss.

2. TEST OF THE EFFECTIVENESS OF BICARmed® TECHNOLOGY TO THE SODIUM BICARBONATE IN THE REMOVAL OF SURFACE CONTAMINATIONS ON DMR'S - Padova Hospital - Technology Assessment Unit

2.1.1. PHASE 1: OBJECT - Definition of BICARmed® technology parameters

- SAFEKlinic type bicarbonate
- MINIJET® nozzle
- Output pressure 3 BAR
- Distance 5- 10 cm from the instrument
- Duration of baking soda exposure about 30 seconds
- It follows the rinsing

2.1.2. BICARmed® TEST METHODOLOGY

Surgical instrument path:

- Ordinary use.
- Storage of the instrument in sterile test tubes by the staff of the Operative Unit,
- Instrumentation recovery in the ward, application of the identification to the test tube
- Stocked for a time varying between two and fifteen days.
- Subsequently, the instrument was removed from the test tube and underwent the following process:

  a. Photography with Nikon D 300 digital camera.
  b. Scans and photographs with Dino Light digital microscope, enlargement 500 X.
  c. Mechanical cleaning procedure using SAFEKlinic compound
  d. Further scans and photographs with Dino Light digital microscope, enlargement 500 X.
  e. Storage of the treated instrument in a new sterile buffer test tube with application of the piece identifier and the process immediately.

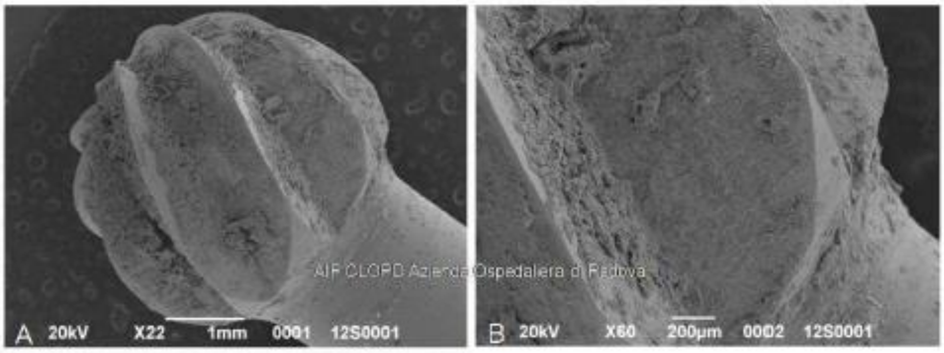
The BICARmed® mechanical cleaning procedure was further investigated through electron microscope (SEM) analyzes conducted within the Complex Anatomy and Pathological Histology Unit of the Padova Hospital and at the Special Pathology Anatomy Laboratories, directed by the Manager Prof. Marialuisa Valente.

The scans were performed first on the contaminated instrument and then on an equal instrument (same model, same operating unit, same intervention, same storage time) treated with BICARmed® technology and SAFEKlinic sodium bicarbonate based product.

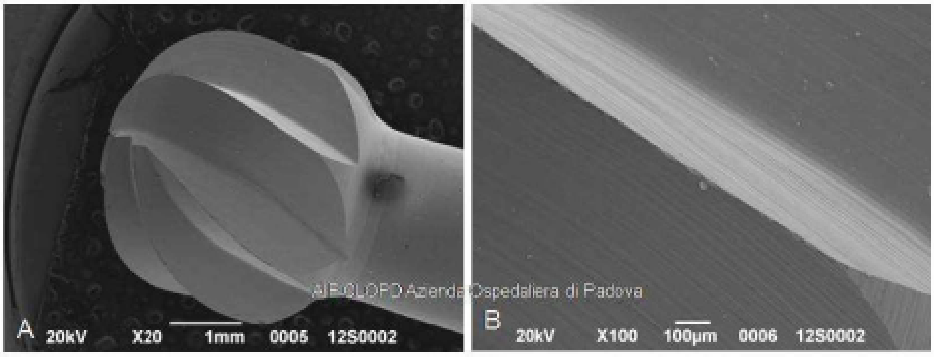
In the detail the instruments analyzed by electron microscope before and after the BICARmed® treatment.

2.1.3. RESULTS

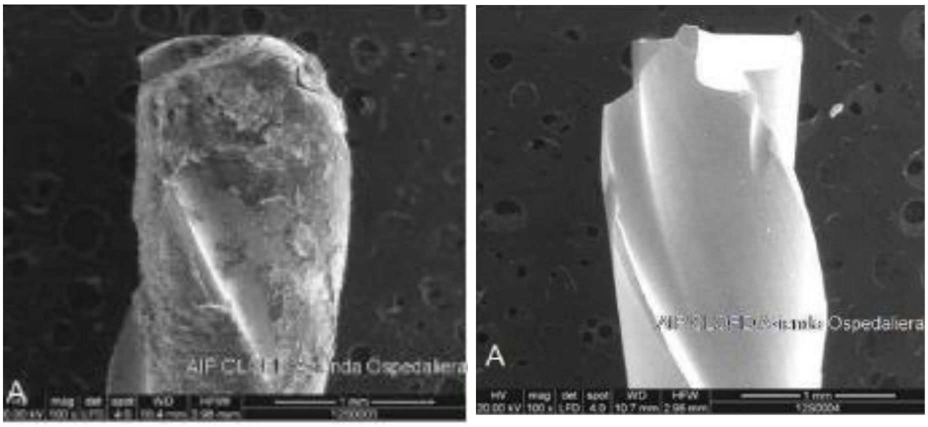
The Rosetta burr under the microscope before cleaning



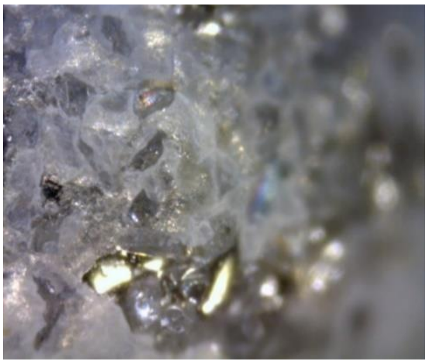
The Rosetta burr under the microscope after cleaning

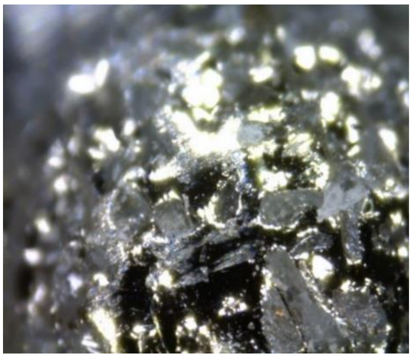


Craniotome before and after cleaning



Digital microscope photo of a 3 mm model diamond cutter before and after BICARmed®





2.1.4. CONCLUSIONS

The images produced under a microscope after the BICARmed® process confirm the effectiveness in removing surface contaminants present before the test.

Furthermore, the proposed technology is not affected neither by the physical characteristics of the instrument nor that by the post-use storage time; in particular, in this test dealt with instruments stored for up to 15 days, time between use in the operating room and the application of the BICARmed® process.

With the test described above, the parameters of use of BICARmed® technology are redefined as follows:

- SAFEKlinic type bicarbonate
- MINIJET® nozzle
- output pressure 3 BAR
- Distance 5- 10 cm from the instrument
- Duration of baking soda exposure 5-10 seconds
- It follows the rinsing

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2.2 PHASE 2: OBJECT - Comparison of the effectiveness between BICAR*med*® technology and traditional pre-wash methods

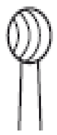
The primary object is to compare the effectiveness between the BICAR*med*® technology and the processes currently used at Padova Hospital.

The secondary object is the evaluation of the efficacy of bicarbonate technology on surgical instruments with adhesion challenges considered critical or severe in terms of geometry and contaminant.

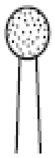
2.2.1 SELECTED SURGICAL INSTRUMENTS

The sample is composed of 29 surgical instruments (cutters for osteotomy polyuse) selected on the basis of the frequency of use in the various Operative Unit of Padova Hospital:

- 10 GE520R **Craniotomes**, of which 1 new to be used as standard reference, 7 taken from the Neurosurgery Operating Unit and used in a craniotomy operation and 2 used on anatomical cadaver with stressing and overheating the burrs.



- 11 GE407R **Rosetta** burrs (4 mm stainless steel), of which 1 new to be used as a standard reference, 8 used in the Neurosurgery Operating Unit during surgery and 2 used on anatomical cadaver with stressing and overheating the burrs.



- 8 GE517R **Diamond** milling burrs (medical grade diamond coated steel), of which 1 new to be used as standard reference, 5 used in the Neurosurgery Operating Unit during a surgery and 2 used on anatomical cadaver with stressing and overheating the burrs.

2.2.2 BICAR*med*® TESTS METHODOLOGY

29 selected samples:

- burrs, one by type, after being used by the Operating Unit with a standard clinical procedure, they were individually stored in a sterile test tube, avoiding any type of external contamination, sent directly to PSIS (Integrated Sterilization Pole In Service) and subjected to routine cleaning of the Padova Hospital, which includes:

  1. Soaking in enzymatic liquid
  2. Manual brushing of the device
  3. Immersion in the ultrasonic washing machine (0.5% dilution for an action time of 5 minutes at a temperature of 30 ° C)
  4. Rinsing

- with collaboration of Maxillo-Facial Surgeon Dr. Luca Guarda and of Head of the autopsy room of the Operating Unit of Pathological Anatomy of the Hospital of Padova, Dr. Massimo Edini, have been used 6 burrs (2 per type) to simulate an operation of craniotomy on anatomical cadaver, subjecting them to a use superior to the ordinary both for extension of the cut that for time of use, increasing the level of adhesion of the protein residue bringing the instrument to a critical temperature as shown by the obtained results from the organic yarn losing obtained.
- The remaining burrs, after being used at the Operating Unit with standard clinical procedure, and the 6 stressed burrs were collected and subjected to cleaning according to the protocol tested in the preliminary phase of the study.

Surgical instrument path:

- Ordinary use in the operating room;
- Storage of the instrumentation in sterile test tubes by the staff of the Operating Unit.
- Recovery of the instrumentation in test tube and identification application.
- The instrumentation was subsequently treated with the BICAR*med*® process after long storage, up to 15 days, and was subjected to the following process:
    - Photography with Nikon D 300 digital camera.
    - Scans and photographs with Dino Light digital microscope, enlargement 500 X.
    - BICAR*med*® cleaning using the SAFEKlinic compound
    - Scans and photographs with Dino Light digital microscope, enlargement 500 X.
    - Storage of the treated instrument in a new sterile buffer test tube with application of the piece identifier and the process immediately.

Parameters :

- SAFEKlinic type bicarbonate
- MINIJET® nozzle
- output pressure 3 BAR
- Distance 5- 10 cm from the instrument
- Duration of baking soda exposure about 30 seconds
- It follows the rinsing

The above samples described have been further investigated by electron microscope (SEM) analysis thanks to the collaboration of the Complex Operating Unit of Anatomy and Pathological Histology of the Padova Hospital of the Special Pathological Anatomy Laboratories directed by the Director Prof. Marialuisa Valente.

Electron microscopy and X-ray microanalysis are really precious tools for the evaluation of protocols for disinfection, cleaning and sterilization of reusable devices.

I The samples were thus fixed in Karnovsky's solution (4% paraformaldehyde + 2.5% glutaraldehyde in 0.1M phosphate buffer, pH 7.2) for 2 hours, dehydrated in a growing series of ethyl alcohol and subsequently in CO2 at triple state by the Critical Point Drying technique. They have been mounted on aluminum supports and have been observed and photographed using a scanning electron microscope (ESEM FEI, Holland); any particles present on the preparations were analyzed with the EDX probe for microanalysis connected to the same electron microscope for the identification of their chemical composition.

Furthermore, it was detected the number of particles eventually found in the samples and the area occupied by them compared to the total area of the sample using a computerized system of morphometric analysis (Image PRO-PLUS, Media Cybernetics, Maryland, USA).

2.2.3 RESULTS

The treatments adopted for the cleaning of the samples (Traditional and BICAR*med*®) have reported different results.

Primary and secondary object:

In the Rosetta burr and in the craniotome the traditional methods have contributed to damage the surface without being able to remove the organic residue; with the BICAR*med*® treatment the surfaces of both "standard" and "stressed" samples appear unaltered and free of any organic residue.

As regards diamond samples, the difference between the two treatments is as follows:

- in the standard diamond sample with the traditional treatment the surface shows leaks of diamond fragments from the matrix and non-organic pollutants constituted by metal particles.
- in the standard diamond sample with the BICAR*med*® treatment the surface is perfect
- In stressed diamond sample were found residues of bone tissue among the diamonds; the reason is related to the special procedure of use and to the architecture of the diamond in its apical part. It should be noted that the cleaning of stressed cutters on a corpse is an extremization to test the effectiveness of the BICAR*med*® process and of the sodium bicarbonate compound SAFEKlinic.

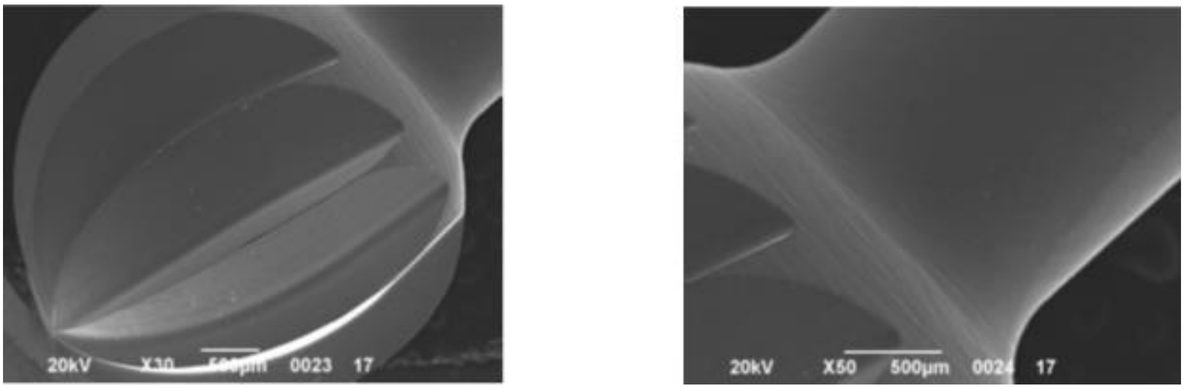


Fig.1 Rosetta Burr

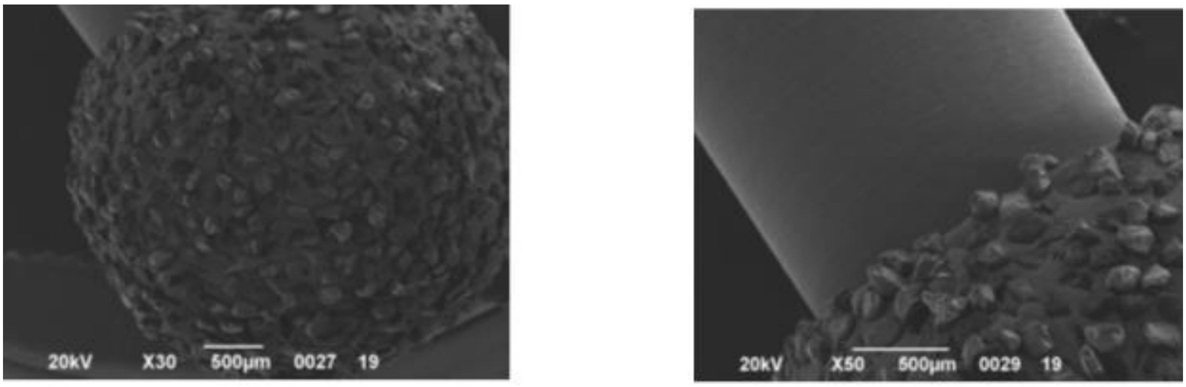


Fig. 2 Diamond Burr

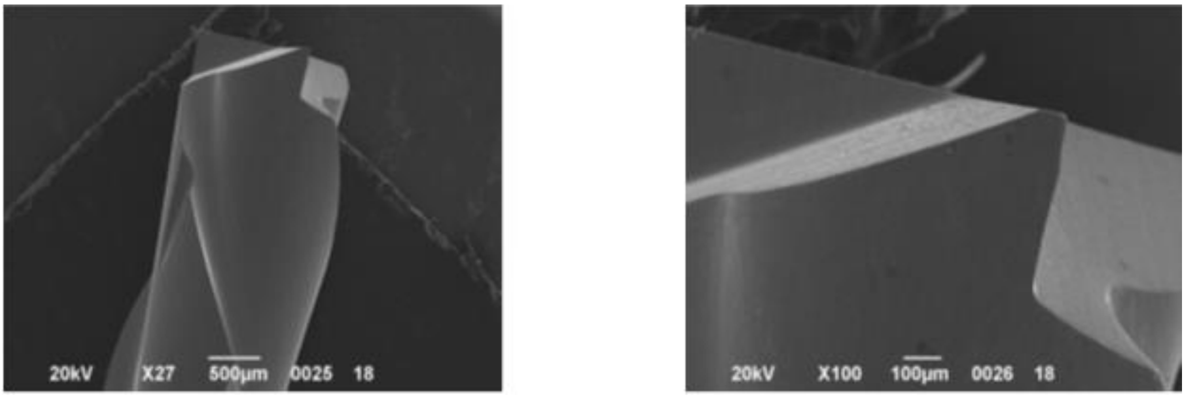
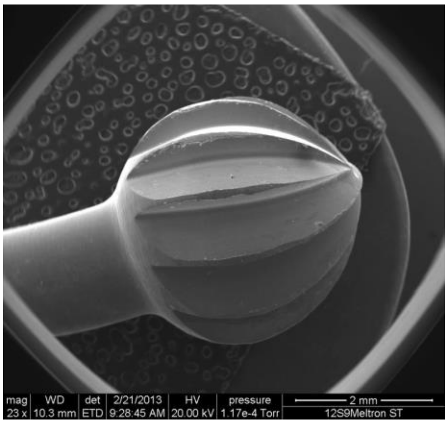
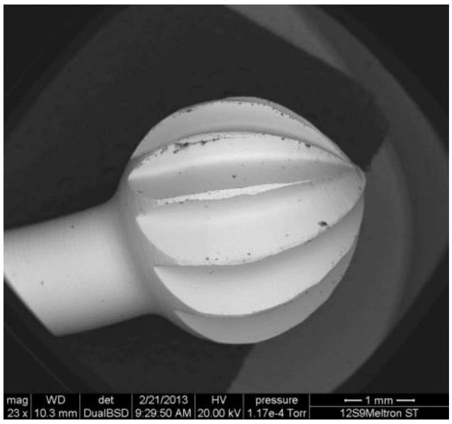


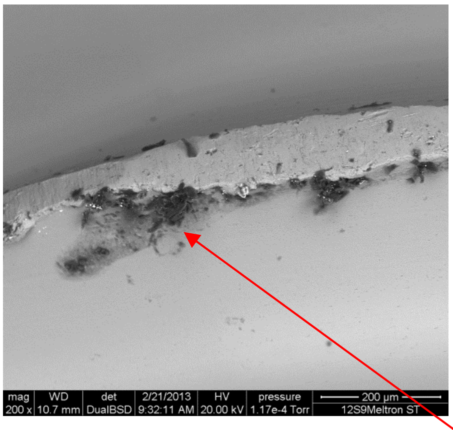
Fig. 3 Craniotome

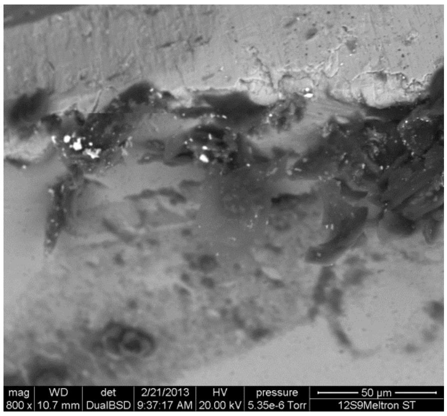
Regarding the treated samples the results were:

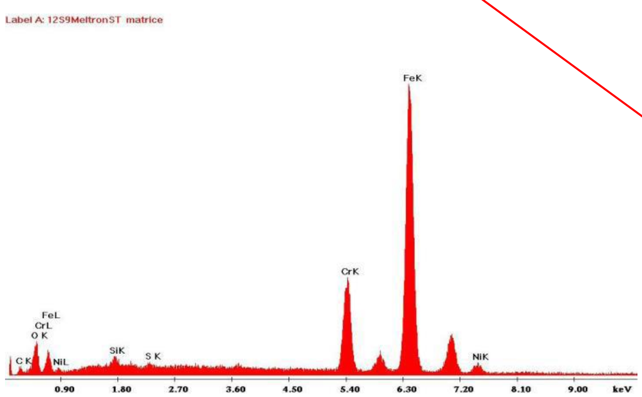
<u>Rosetta Burr with BICARmed® treatment</u> (n. 12-S-0009): the cutter surface , composed of steel, results slightly altered especially along the protrusions where it is possible to identify small particles, whose total area represents 1.14 % of the cutter area; these particles have a varies chemical composition: gold, carbon, chlorine, potassium and sodium plus other trace of elements.





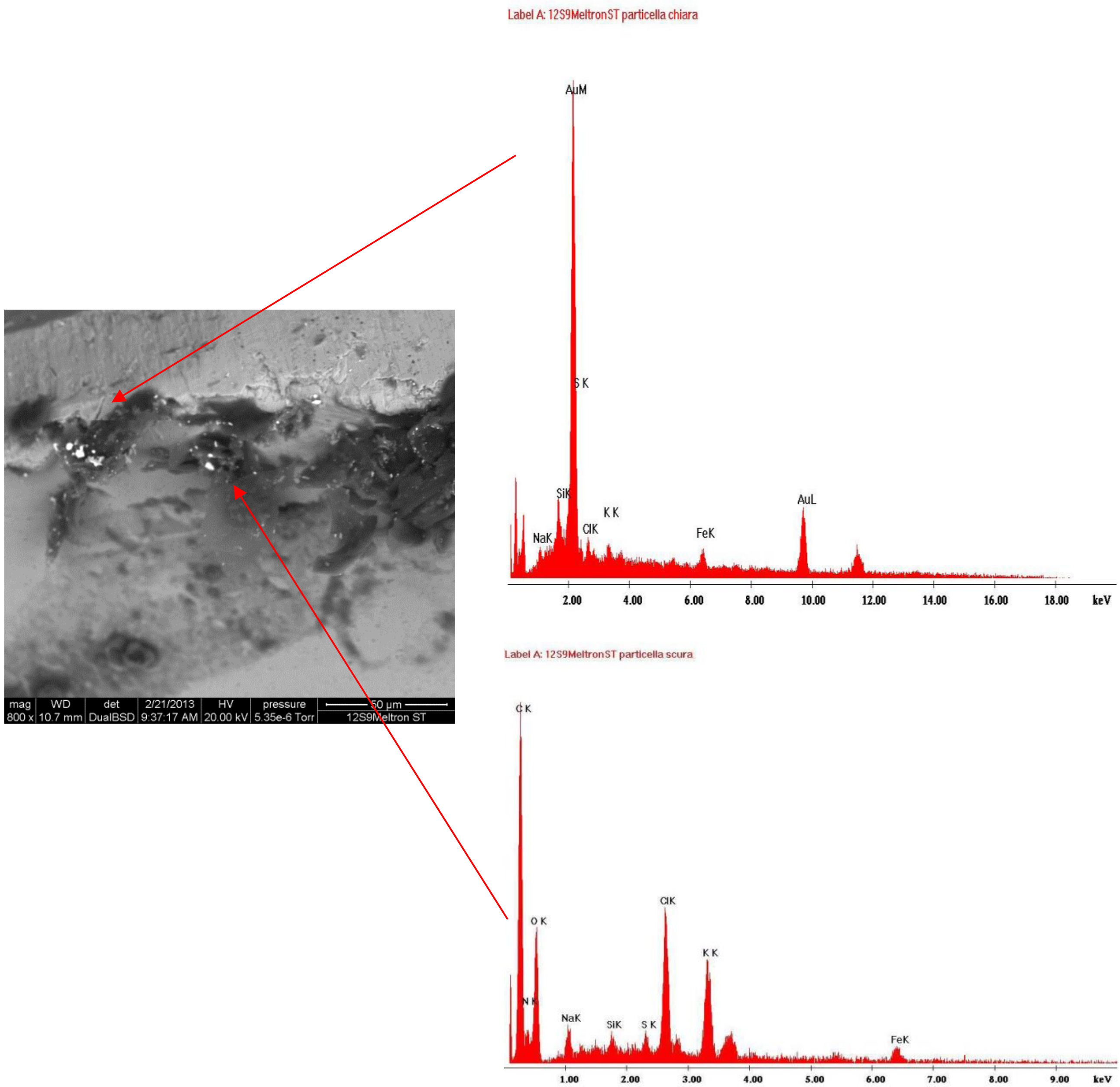






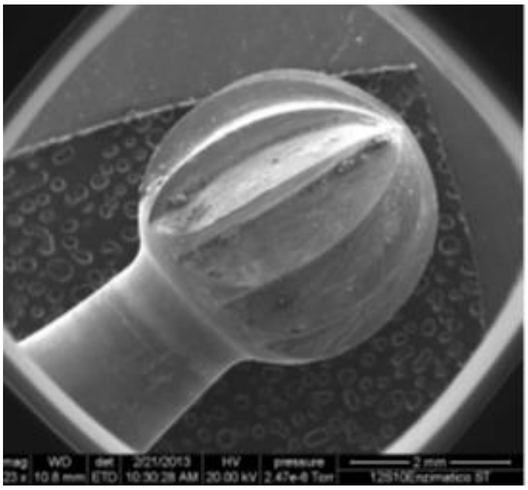
MICROANALYSIS MATRIX:

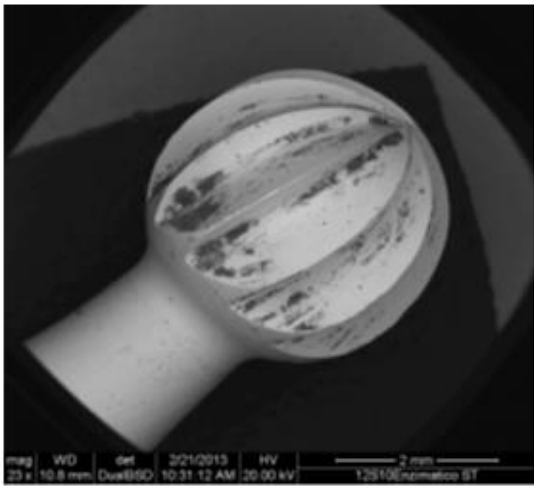
the main elements found are IRON, NICKEL, CHROME identifiable as steel.

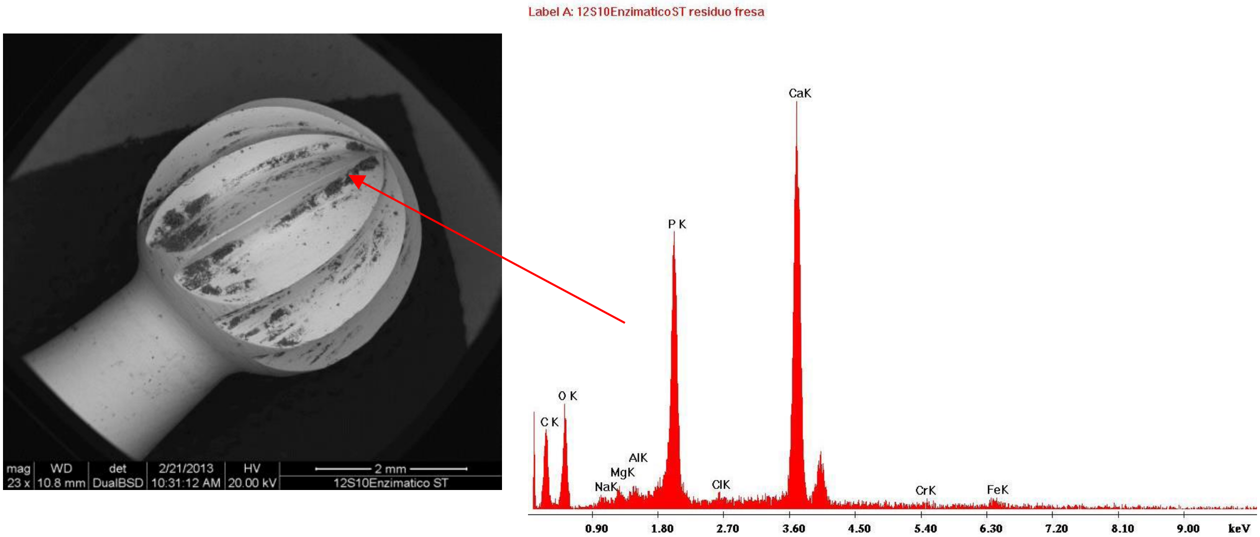


PARTICLES MICROANALYSIS: the main elements found are GOLD and IRON in the clear particle (pollutants of sample preparation, upper spectrum), CARBON, CHLORINE, POTASSIUM and SODIUM in the dark particle (organic compound and saline residue).

Rosetta burr with TRADITIONAL RP26 treatment (n. 12-S-0010): the surface of the cutter is particularly altered; it is possible to identify rather large particles, whose total area represents 9.28% of burr area; these particles have a uniform chemical composition: calcium, phosphorus, oxygen (residual bone tissue) and other elements in traces are arranged mainly along the grooves.

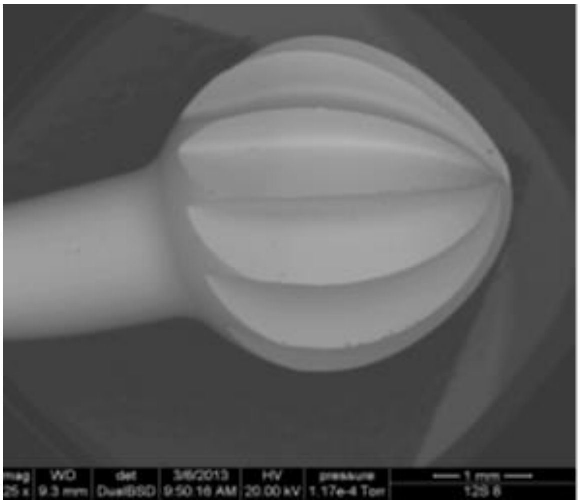


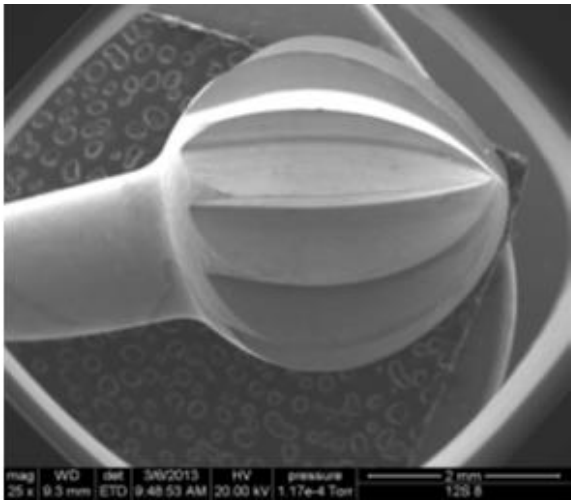




MICROANALYSIS OF DARK PARTICLE: the main elements found are CALCIUM, PHOSPHORUS, OXYGEN (residual bone tissue).

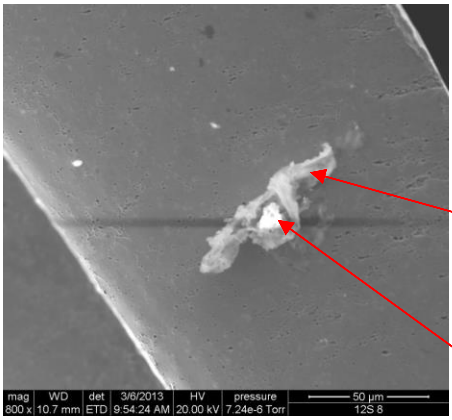
Rosetta burr with BICAR*med*® "stressed" RS5 treatment (n. 12-S-0008):the burr surface results slightly altered especially along the protrusions where it is possible to identify particles of reduced dimensions, whose total area represents 0.21% of the area of the burr; these particles have a varied chemical composition: calcium, oxygen, iron, plus other elements in traces.

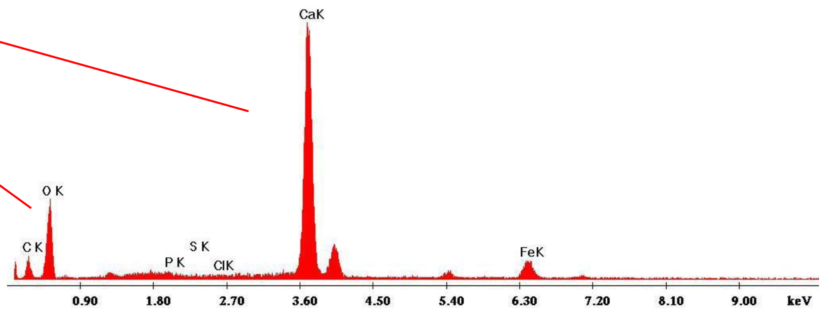




Label A: 12S 8 1

PARTICLES MICROANALYSIS:
the main elements found are CALCIUM, OXYGEN and IRON representing the salt compound containing calcium but not residual of bone tissue





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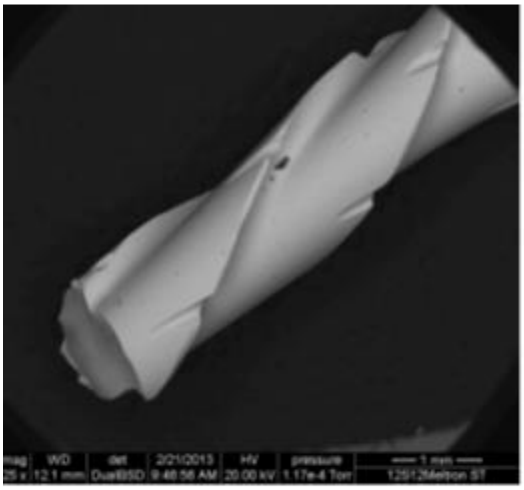
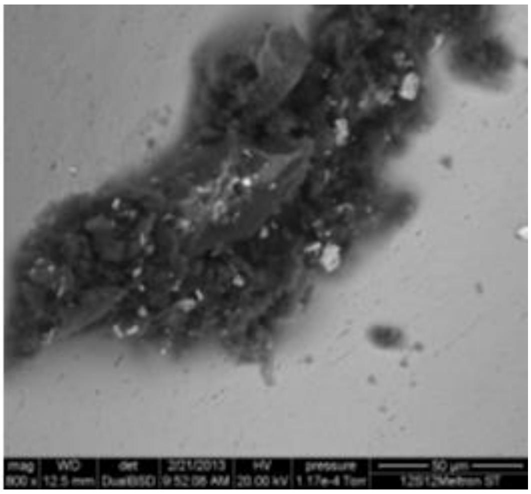
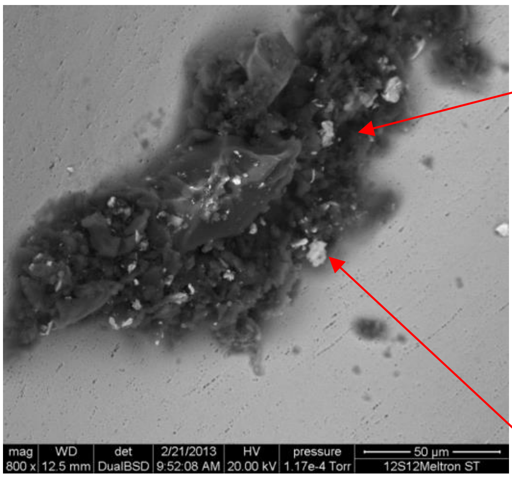
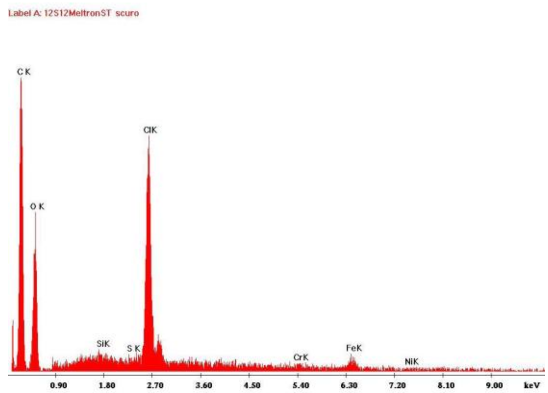
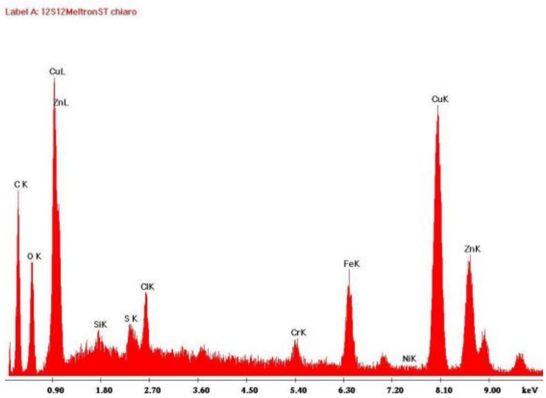
Craniotome with BICAR*med*® C20 treatment (n. 12-S-0012): the surface of the craniotome results slightly altered; it is possible to identify small particles, whose total area represents 0.25% of the area of the craniotome; these particles have a varied chemical composition: chlorine, carbon, oxygen and copper, zinc (brass), iron plus other elements in traces.











DARK PARTICLE MICRO-ANALYSIS (upper spectrum): the main elements found are CHLORINE, CARBON, OXYGEN, constituents of the salt compound.

CLEAR PARTICLE MICROANALYSIS (lower spectrum): the main elements found are COPPER, ZINC, IRON forming a metal alloy (brass) coming from the saline compound delivery system.

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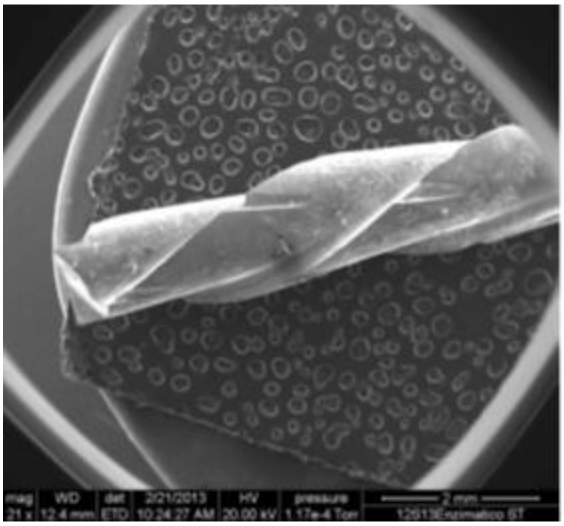
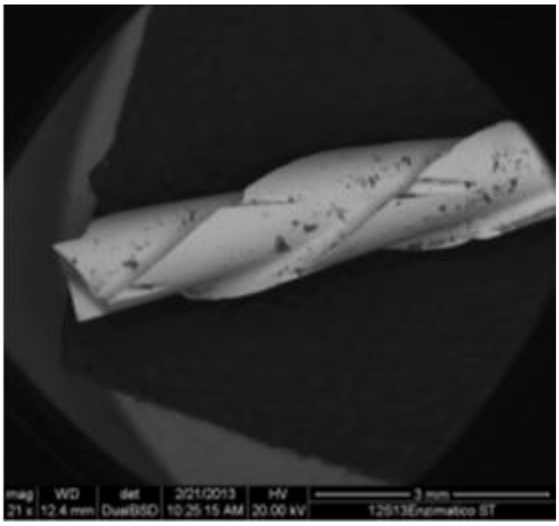
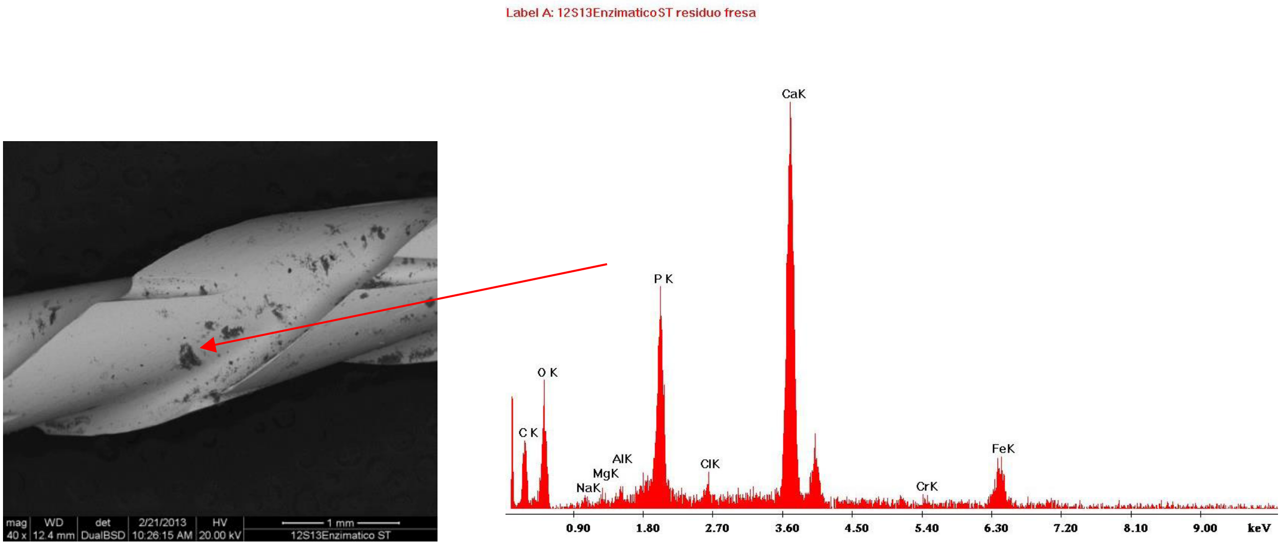
Craniotome with TRADITIONAL CP25 treatment (n. 12-S-0013):the surface of the craniotome results particularly altered, it is possible to identify medium-sized particles, whose total area represents 4.19% of the area of the craniotome; these particles have a uniform chemical composition: calcium, phosphorus, oxygen (residual of bone tissue) and other elements in traces.

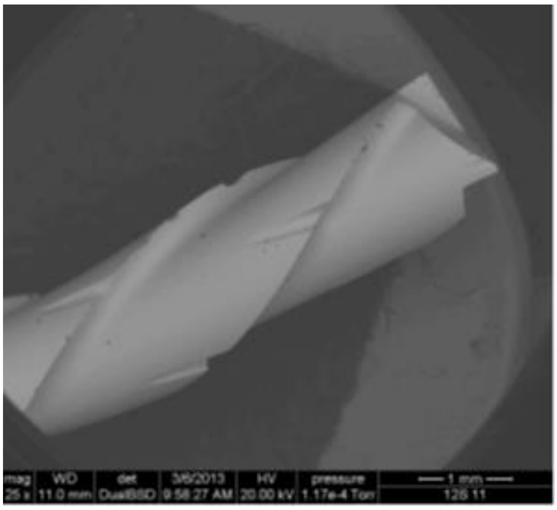


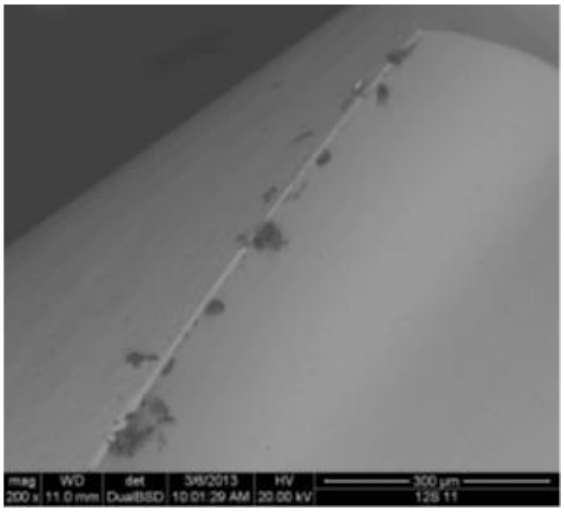


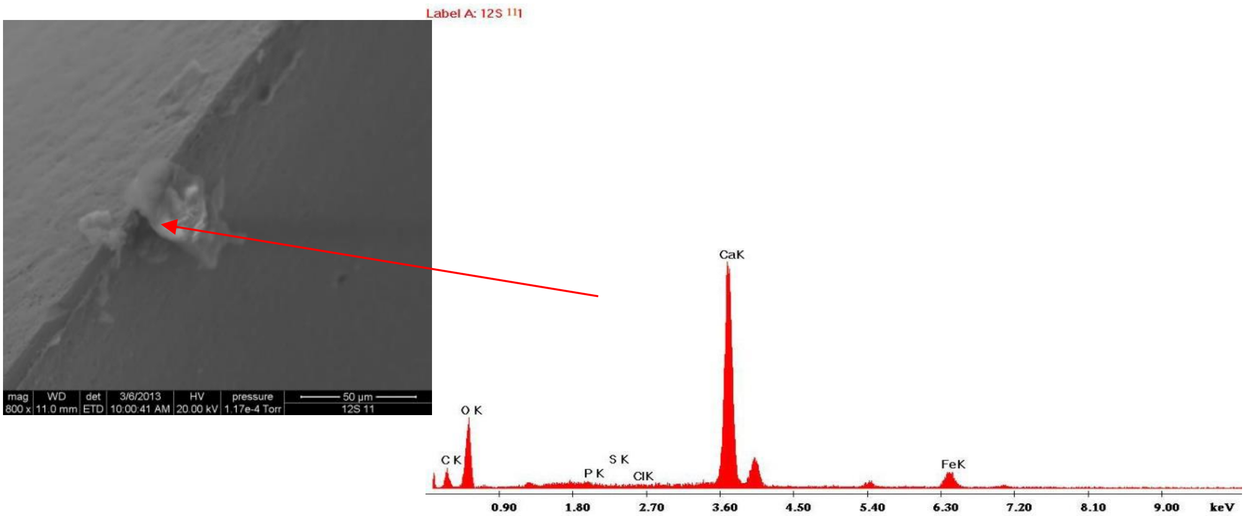


DARK CORPUSCULAR MICROANALYSIS: the main elements found are CALCIUM, PHOSPHORUS and OXYGEN (residual of bone tissue).

Craniotome with BICARmed® treatment "stressed" CS4 (n. 12-S-0011): the surface of the craniotome results slightly altered; furthermore it is possible to identify particles of reduced dimensions, whose total area represents 0.24% of the area of the craniotome; these particles have a varied chemical composition: calcium, oxygen, iron, plus other elements in traces.







CORPUSCULAR MICROANALYSIS: the main elements found are CALCIUM, OXYGEN and IRON attributable to the salt compound containing calcium but not referable to residual of bone tissue.

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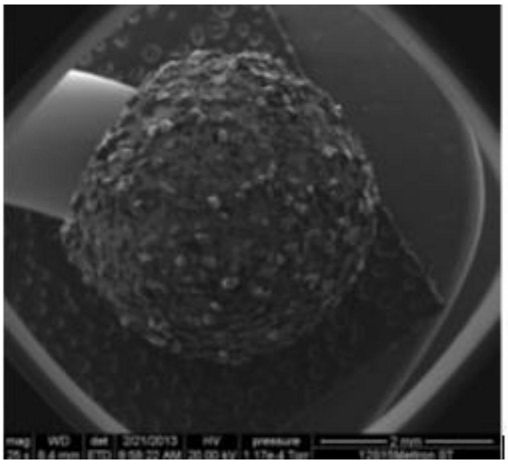
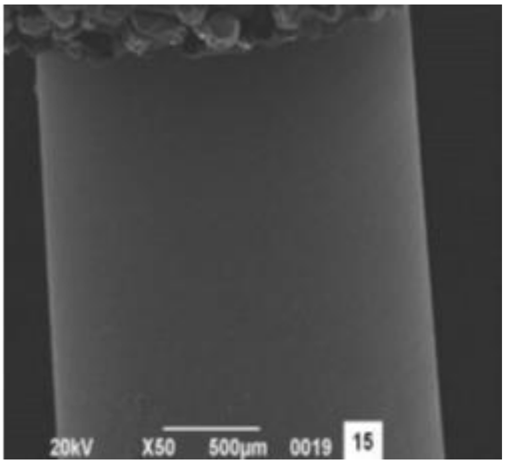
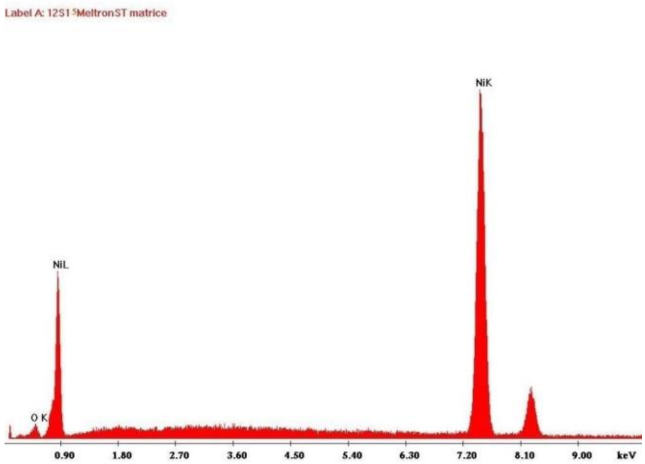
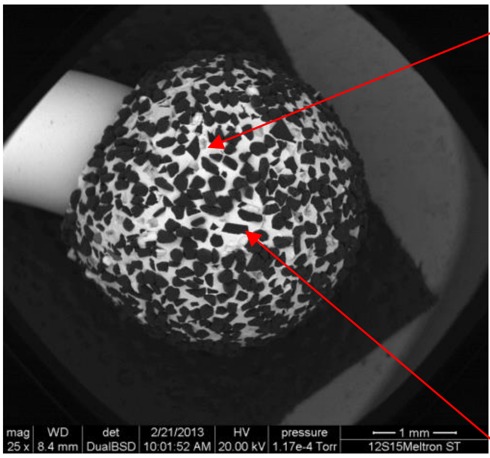
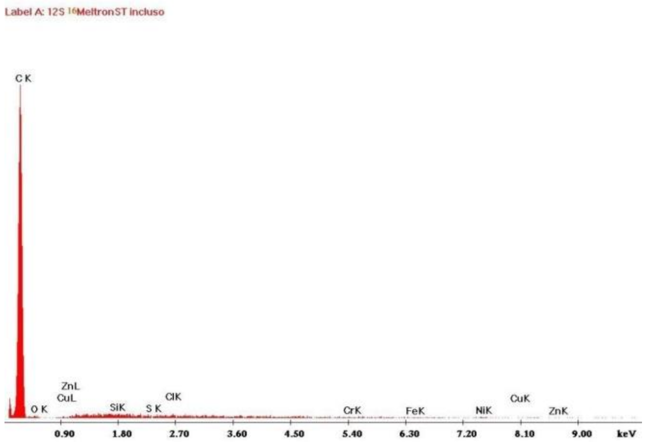
<u>Diamond burr with BICAR*med*® D24 treatment</u> (n. 12-S-0015): the surface of the "head" of the diamond burr, consisting of nickel and carbon (diamond) results intact; isn't there any foreign particles in the surface.











PARTICLES MICROANALYSIS: the main elements found are NICKEL (upper spectrum) and CARBON (lower spectrum).

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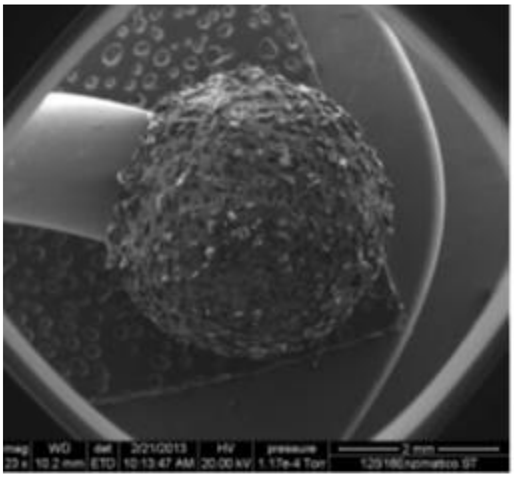
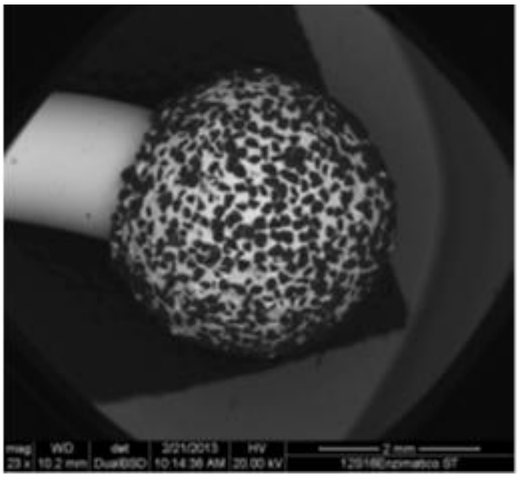
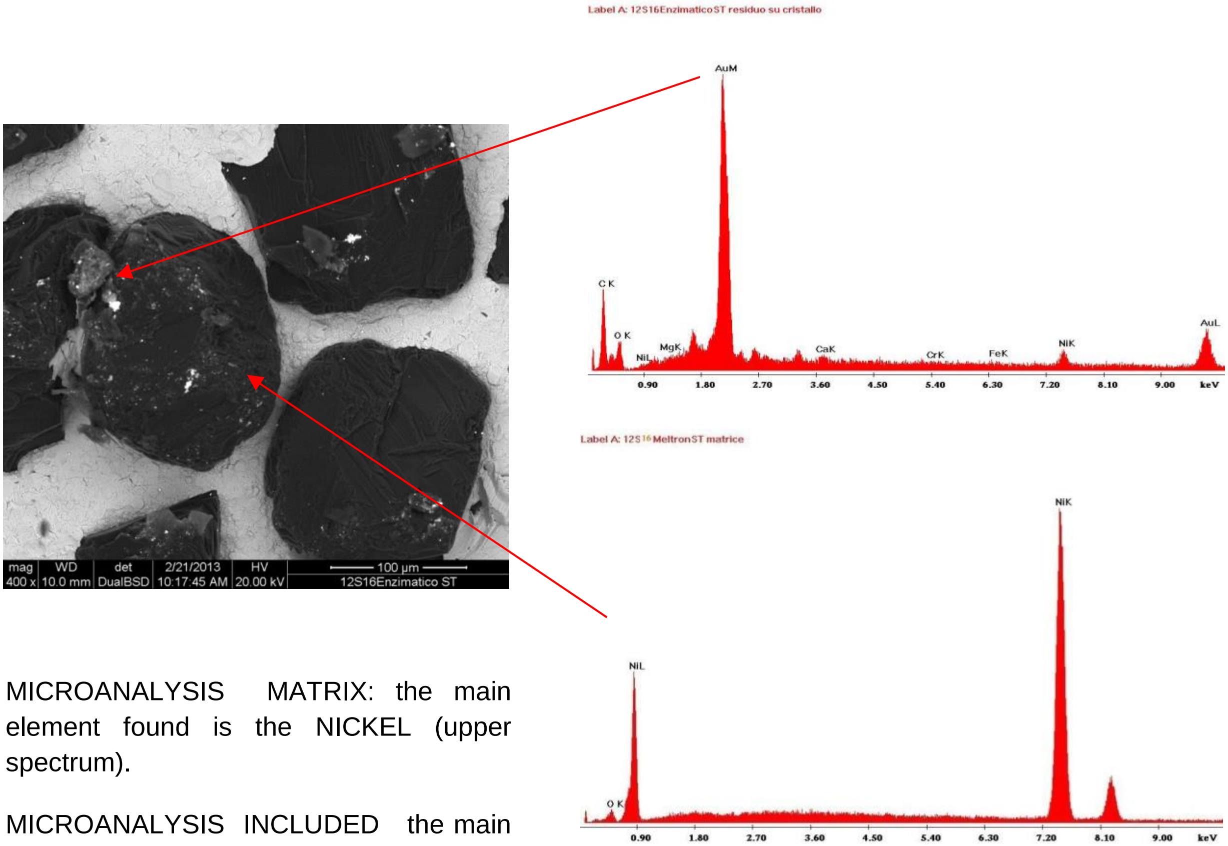
Diamond burr with DP27 TRADITIONAL treatment (n. 12-S-0016): the surface of the diamond burr appears altered with depressions on the matrix due to the absence of diamond fragments; small particles are identified, whose total area represents 0.23% of the overall diamond cutter area; these particles have a varied chemical composition: gold, nickel, iron (steel), oxygen plus other elements in traces.

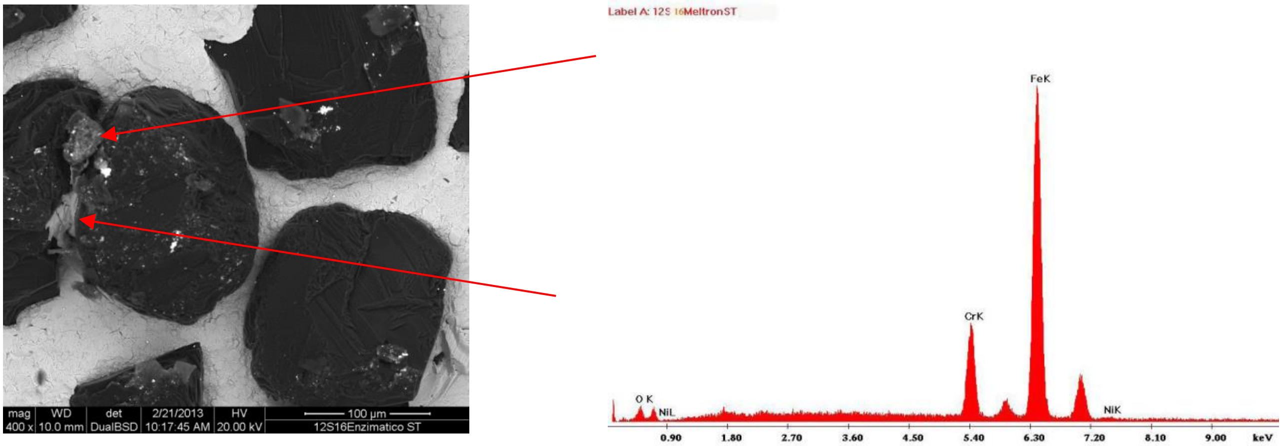




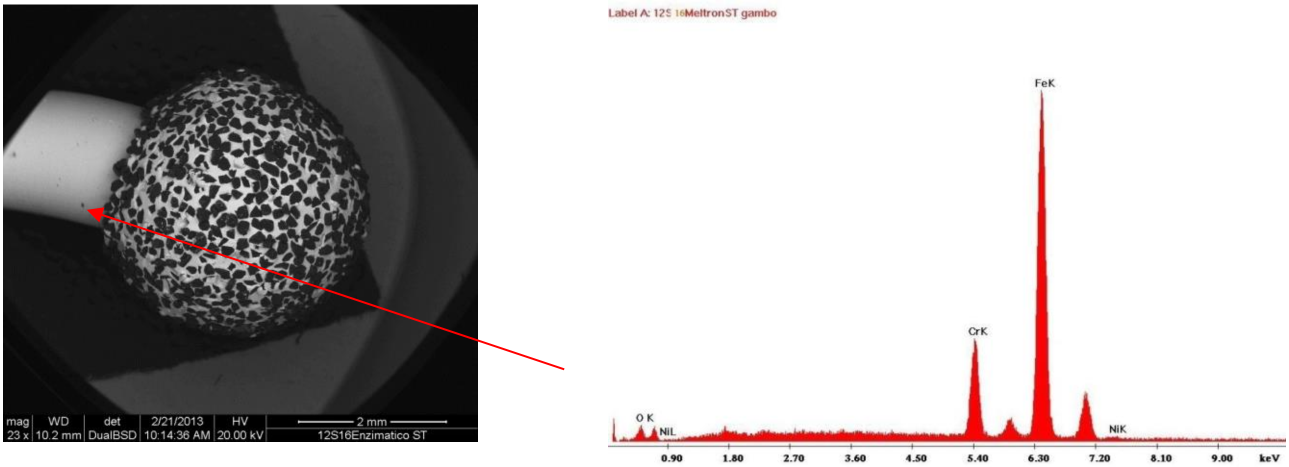


MICROANALYSIS MATRIX: the main element found is the NICKEL (upper spectrum).

MICROANALYSIS INCLUDED the main elements found are GOLD, CARBON, OXYGEN (lower spectrum).



MICROANALYSIS INCLUDED   the main elements found are IRON, CHROME, NICKEL (STEEL).



PARTICLES MICROANALYSIS ON SHAFT: the main elements found are IRON, CHROME, NICKEL (STEEL).

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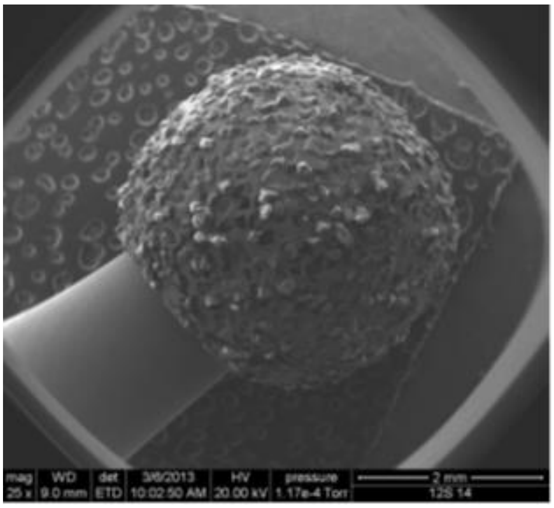
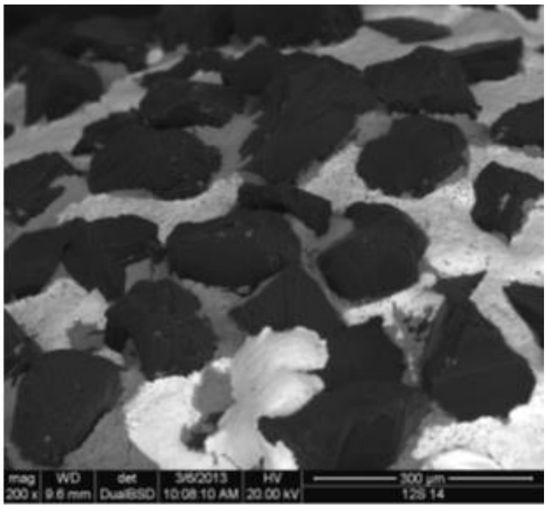
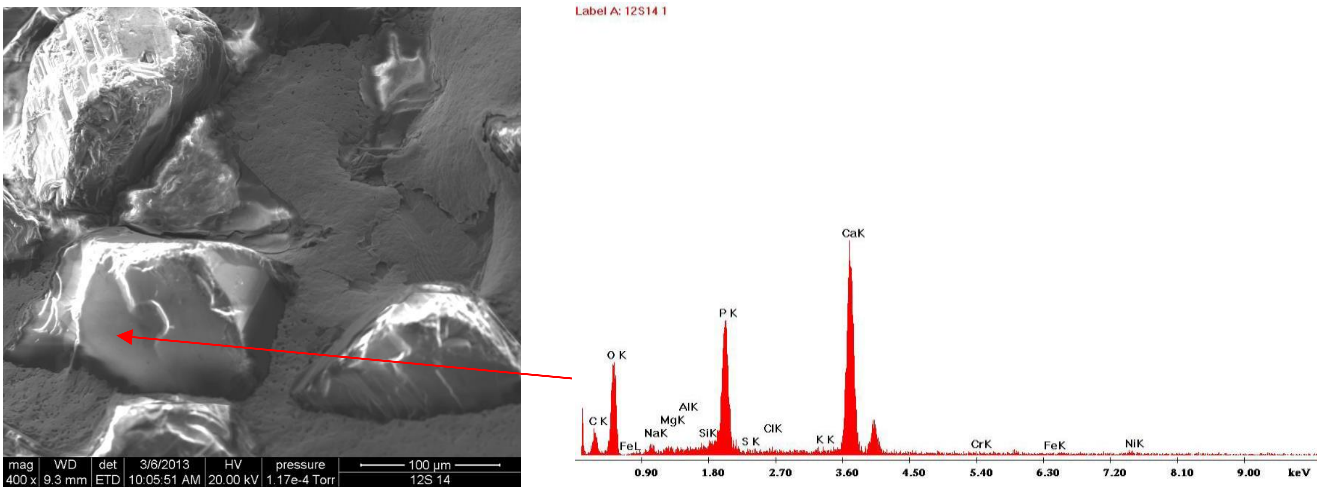
Diamond Burr with BICAR*med*® "stressed" DS6 treatment (n. 12-S-0014): the surface of the diamond Burr does not appear altered; it is possible to identify particles of reduced dimensions, whose total area represents 1.17% of the diamonded area mostly present among the diamond fragments; these particles have a varied chemical composition: calcium, phosphorus, oxygen (residual of bone tissue), potassium, carbon, chlorine, sodium plus other elements in traces.







MICROANALYSIS OF GRAY PARTICLE: the main residues found are CALCIUM, PHOSPHORUS, OXYGEN (representing residual of bone tissue) and POTASSIUM, CHLORINE, CARBON, SODIUM.

2.2.4 CONCLUSIONS

The BICAR*med*® treatment turns out to be more effective than traditional pre-wash treatments, on any type of biological contaminant tested in this phase, blood, bone, cauterized blood, without causing alteration on RMDs.

Therefore, the treatment of the instrumentation in the pre-wash phase with BICAR*med*® technology guarantees an increase in the standard and in the performance of the sterilization process, in fact there is evidence after the BICAR*med*® treatment a high percentage of treated RMDs (over 98%) are free of organic residues and preserved in the original morphological state.

3. VERIFICATION OF BICAR*med*® EFFECTIVENESS TECHNOLOGY ACCORDING STANDARD ANNEX TEST UNI ISO/TS 15883-5 – Vittorio Veneto Hospital

3.1.1. PHASE 1 OBJECT - ANNEX N TESTS – Comparison between BICAR*med*® and washer disinfector

Comparison of the efficacy between BICAR*med*® technology and the treatment in the washer disinfector.

3.1.2. MATERIALS AND TEST METHODS ACCORDING THE STANDARD 15883-5

It was performed the Annex N test of standard 15883-3

Dirty of Annex N: fresh egg yolk 100 ml; defibrinated blood (horse or sheep), 10 ml; dehydrated pork mucus, 2 g.
The standard declares to evaluate on the basis of a visual inspection, but the protein residues have also been measured with the ProReveal machine on 5 of the 57 particular instruments (Poole suction tube, micro-invasive forceps, core and handle, trocar, hemostatic forceps)
Number of soiled instruments according the ANNEX N = 57 pieces, of which:

- 3 suction tubes,
- 2 micro-invasive surgery forceps,
- 2 trocars,
- 3 hemostatic forceps,
- 3 scalpel handles,
- 2 replacement endoscopes,
- 3 vaginal speculums (the minimum number per type indicated by the Annex)

This step is repeated twice, one for the 57 instruments that will be processed in washer disinfector, one for the 57 treated with the BICAR*med*® protocol.

The soiling procedure is done randomly and without differences, by brushing the instruments with the Annex and making the liquid flow inside the hollow instruments such as endoscopes and suction tubes.

- **Washer disinfector:** 2 suction tubes, 2 micro-invasive forceps (2 cores, 2 tubes and 2 handles), 2 trocars, 21 hemostatic forceps, 11 scalpel handles, 2 replacement endoscopes and 13 vaginal speculums.
- **BICAR*med*®**: 4 suction tubes, 3 micro-invasive forceps (3 cores, 3 tubes and 2 handles), 4 trocars, 15 hemostatic forceps, 13 scalpel handles, 2 replacement endoscopes and 11 vaginal speculums.

It were used 3 machineries: BICAR*med*® system,washer disinfector and ProReveal.

3.1.3. RESULTS AND CONCLUSIONS

TEST:	WASHER DISINFECTOR		BICARmed®	
VISUAL PROOF (Table 1-2)	**SOILED** 33/57 **= 57,9%**	**CLEAN** 24/57 **= 42,1%**	**SOILED** 1/57 **= 1,8%**	**CLEAN** 56/57 **= 98,2%**
PROTEIC MEDIUM RESIDUE OF 5 INSTRUMENTS (Table 3-4)	**26,584 µg** with standard deviation of 25,26		**1,48 µg** with standard deviation of 2,2	
HEMOCHECK Level	**SOILED** 1/18 **= 5,5%**	**CLEAN** 17/18 **= 94,4%**	**SOILED** 0/18 = **0%**	**CLEAN** 18/18 **= 100%**

TABLE 1 – visual proof after washer disinfector

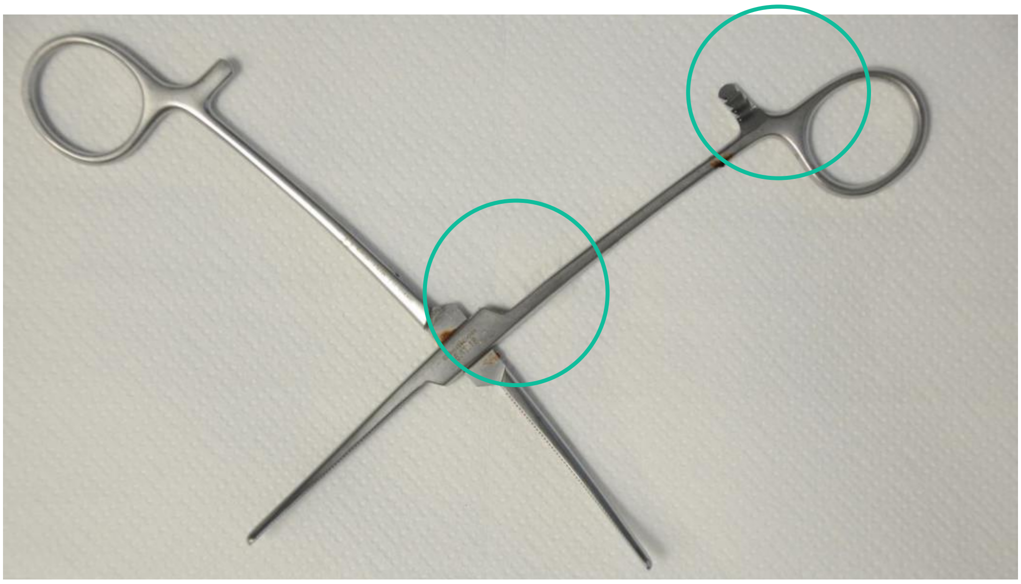


TABLE 1 - visual proof after washer disinfector

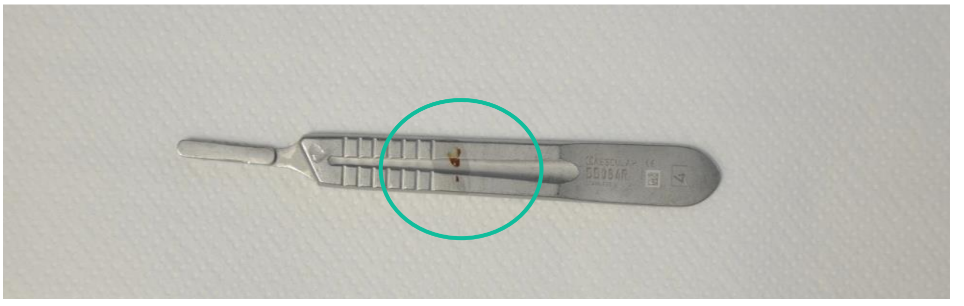


TABLE 2 – visual proof after BICAR*med*® treatment

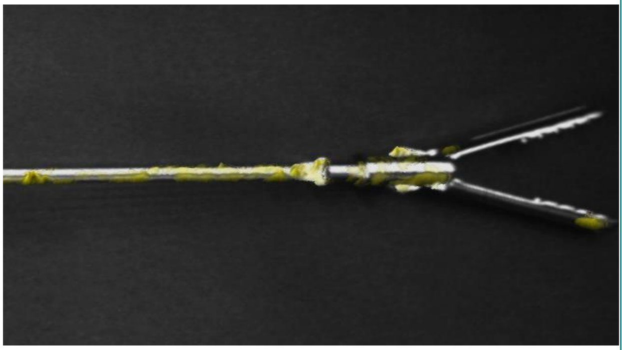
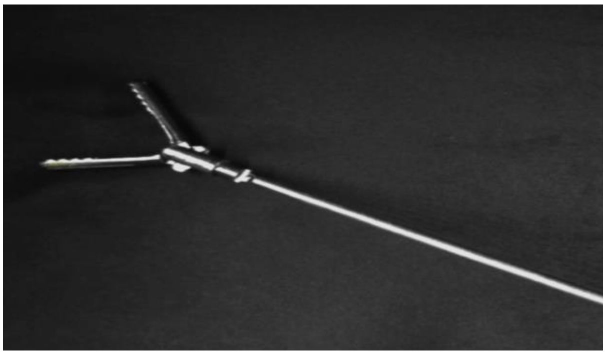
TABLE 3 - protein test of the core pliers clean with washer disinfector and with BICARmed®	
	

TABLE 4 – protein test of handle of pliers clean with washer disinfector and with BICARmed®	
	

EFFECTIVENESS:

From the Annex N tests it is clear that if the instrument is visually clean does not mean clean: most of the instruments that seemed to be cleaned by visual inspection had protein residues.

CONCLUSIONS:

With this test it has been shown that if the instrument is not properly prepared, the instruments washer has a major failure rate.

This treatment should not be considered sufficient, there is a need for a pretreatment in the case of severe dirty (as was Annex N): the higher the quality obtained in the preparation, the greater the success rate of the instrument washes. It has been shown that if the RMD is not adequately prepared, the instruments washer (W.D. - Washing Disinfector) has an important failure rate.

Tale Such treatment cannot therefore be considered sufficient. It should be preceded by manual or ultrasonic cleaning or by BICARmed® machine.

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3.2 PHASE 2 OBJECT - ANNEX N TESTS – Effectiveness of BICAR*med*® technology compared with traditional prewash methods

Effectiveness evaluation of manual and ultrasonic washing compared to the BICAR*med*® machine

3.2.1 MATERIALS E TEST METHODS ACCORDING STANDARD 15883-5

The Annex N test of the 15883-5 standard was performed evaluating the performance effectiveness of cleaning BICAR*med*® machine compared to manual cleaning and ultrasound treatment. The standard states to evaluates on the basis of a visual inspection but have been measured also the protein residues with the ProReveal machine on 5 of the 57 particular instruments (Poole suction tube, micro-invasive forceps, core and handle, trocar, pincer) hemostatic). It were used 3 technologies: BICAR*med*® machine, ultrasonic tub and sinks for manual cleaning.

3.2.2 RESULTS e CONCLUSIONS

TEST	MANUAL		ULTRASOUND		BICARmed®	
VISUAL PROOF **(Tables 5-6-7)**	**SOILED** 5/5 **= 100%**	**CLEAN** 0/5 **= 0%**	**SOILED** 3/5 **= 60%**	**CLEAN** 2/5 **= 40%**	**SOILED** 0/5 **= 0%**	**CLEAN** 5/5 **= 100%**
PROTEIN MEDIUM RESIDUE OF 5 INSTRUMENTS	**13,91 µg** with a standard deviation of 6,26		**5,29 µg** with a standard deviation of 3,84		**6.6 µg** with a standard deviation of 3,34	

TABLE 5: visual proof after manual washing	
	

TABLE 6: visual proof after ultrasound washing	
	

TABLE 7: visual test after BICAR*med*® treatment	
	

EFFICACY:

Excluding manual cleaning due to its obvious limitations, we compared the results of BICAR*med*® and ultrasound: from the point of view of persistent dirt, they are comparable. Our study has therefore analyzed the results from the point of view of complex geometry: BICAR*med*® has been clearly superior, since ultrasound is a directional technology and is not effective inside the cavities.

CONCLUSIONS:

the manual cleaning with brush is very bland and limited and can damage the instrument. The ultrasound cleaning is not effective (it does not completely remove) on the mucus, on the canal, cauterized blood, cement and geometric singularity, undercuts and / or cavities, it is not compatible with optics and non-immersive instruments. While the BICAR*med*® machine is effective even where ultrasound fails. It does not completely remove only some invisible residues.

3.3 BICARmed® TREATMENT EFFECTIVENESS ON COMPLEX GEOMETRIES

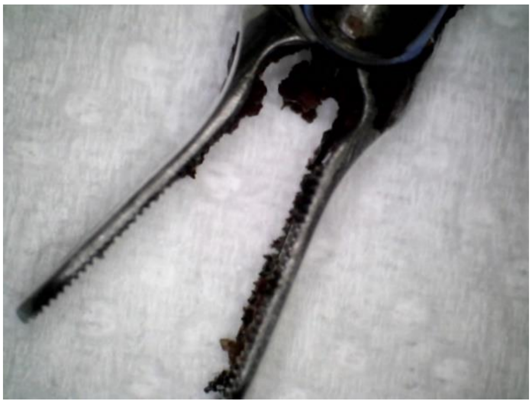
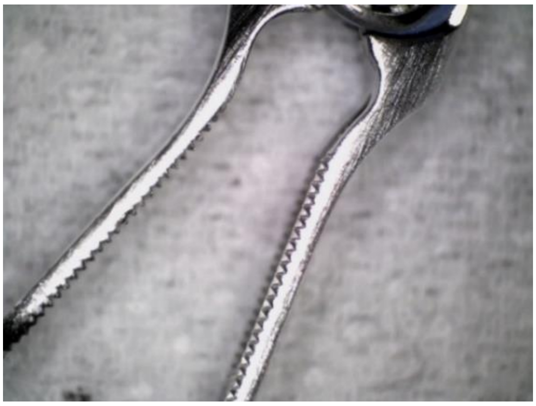
Effectiveness evaluation of BICAR*med*® cleaning on complex geometries.

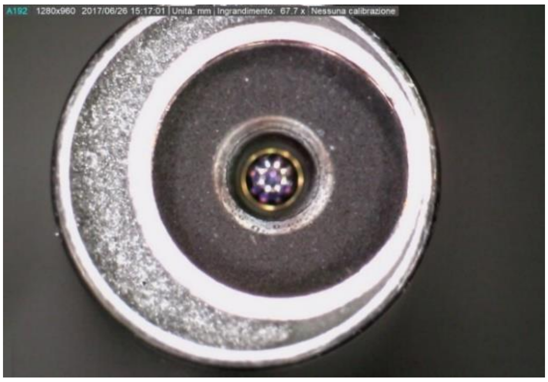
3.3.1 MATERIALS AND METHODS

With the BICAR*med*® machine were treated several instruments characterized by complex geometries as pivot points of laparoscopic forceps, forceps, optics contaminated by cauterized blood residues, oxidation and cement.

3.3.2 RESULTS AND CONCLUSIONS

Detail of a laparoscopic forceps before BICAR*med*® treatment	Detail of the same laparoscopic forceps after BICAR*med*® treatment
	

Detail of a laparoscopic forceps before BICAR*med*® treatment	Detail of the same laparoscopic forceps after BICAR*med*® treatment
	

Detail of an optic before BICAR*med*® treatment	Detail of the same optic after BICAR*med*® treatment
	

Detail of a forceps with cement residues before BICAR*med*® treatment	Detail of the same forceps after the BICAR*med*® treatment
	

CONCLUSIONS:

The treatment of BICAR*med*® was extremely effective on several instruments characterized by complex geometries contaminated by residues of cauterized blood, oxidation and cement. (see the shown pictures).

4 SOURCES

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Dr. M. Castoro (2012). A new technology for higher standards in reprocessing surgical tools and m.d. Second Phase. Evaluation Unit technology assessment – U.V.T.A., Padova Hospital, Italy.

Prof. G. Della Mea (2000). Analysis of the cleaning process of metal surfaces with saturated solutions sodium bicarbonate containing solid sodium bicarbonate dispersions. Materials engineering Department and industrial technologies, Trento University, Italy.

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