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Welcome to the 2018 issue of *Invibio Insider*. We invite you to discover how innovation isn't just what we do, it is who we are. Explore how we apply our expertise and original thinking supported by research and clinical evidence to every phase of the product lifecycle. This issue presents specific case studies, material trends and advancements, perspectives from healthcare professionals, and insights into patient outcomes.

Key Factors for Long-Term Success with JUVORA™ High-Performance Implant-Supported Prosthetics

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*A summary of a presentation delivered by Bernd Siewert, DDS, at an Industrial Symposium at a tri-lateral meeting of EAO 26th Annual Scientific Meeting, SEPES 47th Annual Congress, and 5th SEPA European Symposium, October 5-7, 2017, Madrid***

In industry, one of the many reasons that PEEK is used is because it is highly resistant to nearly all types of chemical attack. Also, the mechanical properties are hard and stiff, but at the same time elastic. It is strong and has good frictional properties. This combination of properties is rare, but very exceptional; PEEK is hardly subject to fatigue. It is also very resistant to hydrolysis. These dental-relevant properties naturally make PEEK of interest to the field of dentistry, but a crucial advantage is that PEEK is also biocompatible and an alternative to titanium for implants.

At Clínica Somosaguas, we discovered this remarkable thermoplastic in 2008, and we went ahead and designed the world's first dental framework constructed from PEEK (Figure 1). It was a full-arch implant-supported framework, with screw retention. We made it using old-fashioned dental techniques, and this proved to be a very difficult and time-consuming process. Nevertheless, it remained a central feature of our clinical practice.



*Figure 1:
World's first full-arch
implant-supported
PEEK framework**

PEEK Implant-Supported Prosthetics

Between 2008 and 2011, at Clínica Somosaguas, we implemented our first generation using an analog workflow, where the framework was constructed by the injection molding of melted PEEK. In total, we made 9 of these injection-molded frameworks for full-arch prostheses. The results we obtained with these full-arch implant-supported bridges indicated that the bone around the implants was stable, as also were the PEEK frameworks. There was no chipping of the aesthetic PMMA veneers placed over the PEEK framework. However, deterioration of the bottom surface of the framework required improved polishing of the PEEK surface. In some cases, there was also wear in the occlusion.

So that is how our procedure evolved, and it has probably been a similar experience for the MALO CLINIC. We learn from our errors; then we had to follow a learning curve.

But after three years we were finally, very satisfied with the outcome, and we decided to continue using the PEEK material.

During this time, we were still in the era of frame manufacture by analog injection molding, and this was the case until about 2013 when we moved to a fully digital workflow. At Clínica Somosaguas, the first PEEK dental disc was milled on a Wieland machine in 2011, because by then the first JUVORA™ Dental Discs (Invibio Biomaterial Solutions™) had become available. The use of a full CAD/CAM design flow began shortly before 2013.

Once we were using a digital workflow for our second-generation prosthetics we could easily repeat the process, if required, as all the information was stored digitally.

By 2017, we had amassed the results of 9 years use and experienced the pros and cons. Among the pros, was that the bone around the implants was stable. The PEEK frameworks were also stable. There was no loosening of the screws; there were no fractures of the direct-to-implant PEEK abutments, and there was no chipping or wear of the composite veneering.

On the con side, in some cases, there was occlusal wear when PMMA veneers were used. There was also some chipping of the PMMA veneers on the machined framework.

Long-Term Clinical Evaluation

At the end of December 2016, we presented, "A Long-Term Clinical Evaluation of PEEK Full-Arch Implant-Supported Prostheses, a Retrospective Review." This review looked at the results obtained from 21 patients with full-arch implant-supported screw-retained bridges on a PEEK framework. Among the 21 was a subgroup of 9 patients who appeared to be heavy bruxers.

Between them, these 21 patients had received a total of 96 implants. The average time period under observation was 56 months (4 years, 8 months), with the maximum time period 8 years, 9 months, and the minimum 1 year, 2 months.

Our findings showed that the implant survival rate was 99%, with a prosthesis survival rate of 100%. Average bone loss was 0.2mm mesial and 0.3mm distal. Occurrence of peri-implantitis was 1%. Patient satisfaction, according to an OHIP survey, was 9.4 (Table 1).

Long-Term Clinical Evaluation of PEEK Full-Arch Implant Supported Prostheses

A retrospective review (end December 2016)

Patients	Number of Implants	Observation Time
21 with full-arch implant supported screw retained bridges with PEEK framework	96	Average: 56 months (4 years and 8 months)
9 (subgroup) showing signs of heavy bruxers		Maximum: 8 years and 9 months Minimum: 1 year and 2 months

Results	
Implant Survival Rate	99%
Prosthesis Survival Rate	100%
Average Bone Loss	Mesial 0.2 mm Distal 0.3 mm
Peri-Implantitis	1%
Patient Satisfaction (OHIP Survey)	9.4%

Table 1

These perhaps surprising clinical outcomes can be explained by the material properties of PEEK. PEEK has a low modulus of elasticity, making it inherently flexible and allowing for a 'passive fit' – meaning that if there are some minor errors in the fit, the PEEK compensates for them. Its flexibility also facilitates shock absorption of the occlusal forces. In addition, PEEK has a density of 1.320g/cm³ and a very low rate of water absorption of 0.1%, and these properties enable bridges that are light in weight, but large in volume. The bridges also possess PEEK's high flexural strength, with extremely low fatigue, and, like the polymer, are not subject to fracture.

For the medical field generally, PEEK of a high purity displays excellent biocompatibility, with all the advantages of being metal-free. There is no corrosion, and healthy soft tissue is maintained. There is no bad odor after a bridge has been in the oral cavity for an extended period of time.

The Next Generation

In 2017, we began to implement a third generation of PEEK frameworks for full-arch implant-supported bridges. These were manufactured from a JUVORA Dental Disc and the frameworks were combined with a full set of single zirconia crowns milled for the teeth. We used a fully digital production process and were able to retain the important features of flexibility and shock absorption. Everything was done to ensure that patients were comfortable and function was restored. Through the use of zirconia on top of the PEEK, we also found that this process could easily fulfill the aesthetic demands that patients required (Figure 2).



Figure 2: Before (left). After (right).*

With this latest generation of prosthetics, we can say that all the positive aspects of PEEK prosthetics have been combined with the benefits of other dental materials and the manufacturing time has been reduced by using a fully digital workflow to make the parts. ▲

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Dr. Bernd Siewert has been Director of his private practice at Clinica Somosaguas, Madrid, Spain for the past 20 years, specializing in implantology. Since 2007, he has also been an instructor at the International Training Centre of Dental Implantology (IFZI) in Nuremberg, Germany. Dr. Siewert attended the Christian Albrechts University, Kiel Germany and worked in Hamburg while completing his doctorate. In 2015, Dr Siewert founded PEEK-O-BELLO, a metal-free dental lab for dental restorations.



* During 2012 to 2017, Bernd Siewert, DDS, Dr. med. dent., provided ad hoc consultancy services to Invbio Ltd.
 * The case studies and conclusions presented have been provided by a practicing dental specialist. His view and experiences are his own and do not necessarily reflect those of others. "Invbio" disclaims any liabilities or loss in connection with the information herein.
 ** EAO: European Association for Osseointegration
 SEPES: Spanish Society of Stomatological Prosthesis
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A Lab Perspective on PEEK: Problems and Solutions

AUTHOR: António Silva CDT, MALO CLINIC, Lisbon, Portugal*

*António Silva, CDT, MALO CLINIC, spoke at an industry symposium sponsored by Invibio Biomaterial Solutions™ at the EAO 26th Annual Scientific Meeting, SEPES 47th Annual Congress and 5th SEPA European Symposium, October 5-7, 2017, Madrid.** The following is a summary of his presentation, which incorporates a practical guide to the use of PEEK in dental prosthetics.*

The objective of this study was to test the JUVORA™ PEEK prosthetic structures, when used under the MALO CLINIC protocol. This subjected them to different kinds of loading conditions and combinations. The process allowed us to define a PEEK protocol for the MALO CLINIC and provide guidelines that would apply in all cases where PEEK is used.

Key factors that we considered included the:

- PEEK finish
- Bonding of PEEK with the acrylic that creates the aesthetics
- Types of bonding that can be achieved

The processing and finishing of the PEEK structure are very important because it is a ductile material. For example, you must consider the thickness of the design and threads, which can weaken the structure, especially when implemented vertically.

Bonding of the PEEK with the aesthetic acrylic was the major consideration for us. This was where it was a struggle to optimize the results. Regardless of the bonding that you are going to use, you must roughen the surface of the PEEK beforehand to increase the mechanical retention. This is done by sandblasting with silica or aluminum oxide at a 3-bar pressure at an angle of 45°, at a distance of 10 mm.

We did a lot of development to determine the best acrylic and process to generate the aesthetics around the PEEK framework (made with the JUVORA CAD/CAM Dental Disc from Invibio Biomaterial Solutions). In the beginning, when preparing the acrylic, we first tried using an injection molding acrylic system, called the Palamat Elite, at 55° for 20 minutes. However, this took too long, and the results were the same as to those obtained with just pouring acrylic.

So we then started using a system called an articulator, and the resulting acrylic was of much better quality than before. Previously, using the injection system, the acrylic was too hard and viscous - but with the articulator system we used a better flowing acrylic and the results were optimized for us. The process involves cutting the sprues, placement in the articulator, checking the occlusion (teeth contact), and installing the protective caps. For finishing the prosthesis, the procedure is exactly the same as for the regular acrylic, and the PEEK is finished in exactly the same way.

Bonding with Metal

We also developed a protocol for bonding metals to the PEEK framework, for example, cementing in connectors or abutments or sleeve inserts. We use these metal sleeves to prevent hard, angular metal implant screws from coming into direct contact with and eating into the softer PEEK.

We examined the use of different metal bond solutions. This required sandblasting with silica at 3-bar pressure at 45°. Applying a particular metal bond solution (called Metal Bond I), and then waiting 30 seconds. This step is very important, as it ensures the acid in the metal bond solution fully reacts with the surface structures. With this kind of bond there are considerations, such as allowing for reductions in the tensile strength of the bond. The process with a different metal bond solution (called Metal Bond II), is richer in methyl methacrylate and behaves differently. Again the surfaces are roughened and conditioned by sandblasting with aluminum oxide at 3-bar pressure at 45°, then jet-cleaning, using air that is free of any oil contaminants. You then apply a thin layer of Metal Bond II and wait 2 to 4 minutes, then light cure for 90 seconds. This kind of bonding, however, has an opposite result from that of Metal Bond I. In this case, the tensile bond strength is greater than that of the shear bond. In practice, this means that you have to consider how the design will be stressed in the mouth of a particular patient and then choose the best system for them. It is important to not only select the right systems but also follow the manufacturer's recommendations.

Complications Inevitably Arise

As in any study, where you are starting out with a new product, we had complications. The first complication we encountered involved the holes for the screws. Depending upon the particular dental implant system, the design of the connector screw head can vary. Because PEEK is a polymer, if an angulated, conical screw head design is used, the screw can cut through from one side to the other. So we needed to invent a solution in order to use PEEK with these particular implant systems; in this case, we used a titanium sleeve as an interface between the PEEK and the connector abutment. This meant we had to change the design of the structure slightly to allow for added thickness, as the titanium sleeves increased the width of the screw insertions.

The thickness of the overlying acrylic (typically used for the gum soft tissue aesthetics) is a very important factor, because if you have only a small amount of acrylic, the PEEK, which is a little resilient, absorbs some of the forces. Eventually, this will result in small cracks; the veneer adhesion will then fail, and the acrylic will fall out.

The thickness of the PEEK framework is also a consideration, especially in those cantilever zones at the back of the mouth. These are especially created using our MALO CLINIC surgical protocol, which is used in the All-On-Four™ (Nobel Biocare) procedure. This is where the frame extends back beyond the last directly supporting implant. Every patient is different and has their own challenges. For example, unbalanced occlusion (contact between teeth) creates problems, as does an excessively deep bite. The framework must resist all of these forces.

Summary of Complications and Solutions

Complications	Solutions
Interface PEEK Abutment	Use of titanium sleeve
Cantilevers	Reinforce with “PEEK islands”
Thickness of the acrylic	Reinforce with fine finish line, if no space
Thickness of the PEEK	Increase the thickness of PEEK in the cantilever
Unbalanced Occlusion	Use connector for greater tensile-bond strength
Excessive deep bite	Maintain bite zone in PEEK far from the occlusion

Table 1: Summary of the solutions that were developed to overcome the complications encountered during the development of a protocol for using PEEK prosthetics in the MALO CLINIC protocol.

Summary

Fortunately, there are solutions (Table 1). The first solution, the titanium sleeves, will eliminate a lot of the problems as we continue to develop the technique. With the cantilevers, we started to reinforce the zones around the titanium sleeves and form PEEK islands with extremely fine finish lines to securely seal against infiltration by bacteria-containing saliva (Figure 1 and 2). ▲

Option of Choice



Figure 1: Solutions developed to overcome the complications encountered during the development of a protocol for using PEEK prosthetics in the MALO CLINIC protocol. Use of metal sleeves at the screw interface (top and bottom left), Increased thickness to reinforce particular areas (top right), Use of PEEK islands to act as stress breakers for the overlying acrylic (bottom right).



Figure 2: Final PEEK prosthetics, upper and lower full arch, in-situ.

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* Since 2017, António Silva, CDT has provided ad hoc consultancy services to Juvora Ltd.

* The case studies and conclusions presented have been provided by a practicing dental technician. His view and experiences are his own and do not necessarily reflect those of others. “Invibio” disclaims any liabilities or loss in connection with the information herein.

** EAO: European Association for Osseointegration
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* Images provided courtesy of António Silva, CDT.

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The Potential Contribution of PEEK Infrastructure to the Maintenance of Excellent Long-Term Results

AUTHOR: Miguel de Araújo Nobre, RDH, MSc Epi, Director, MALO CLINIC Research and Development Department, Lisbon, Portugal*

*MALO CLINIC Director, Miguel de Araújo Nobre, RDH, MSc Epi, spoke at a tri-lateral meeting of the EAO 26th Annual Scientific Meeting, SEPES 47th Annual Congress and 5th SEPA European Symposium, October 5-7, 2017, Madrid***

When the definitive prosthesis is installed, everyone – the surgeon, the lab technician, the prosthodontist, the patient – is happy. Nevertheless, there remains a vital need for maintenance. With a procedure such as the All-on-4™, it is not possible to have excellent results without long-term maintenance. By maintenance, we mean modern maintenance, in the sense of an epidemiological approach that allows us to profile the patient, foresee problems, and provide better treatment – in short, to start solving problems by preventing them.

For the patient at least, there is a whole lifetime ahead, and this is why it is important to assemble a strong team, one capable of establishing a protocol that can monitor the patient long-term – and, even more importantly, can hold the patient accountable for what is going to happen to him or her over the long term.

This is in a situation where peri-implant pathology is the main menace to excellent long-term results. In our opinion, *peri-implant pathology* is preferable to the term *peri-implantitis*, since *peri-implantitis* implies a disease process similar to that of periodontitis. Precisely defined, *peri-implant pathology* is a group of multifactorial situations that negatively affect the implant. Both biological and biomechanical factors can intervene, with biofilm-mediated infection not considered significantly instrumental.

Study of Bone Loss – Refining the Model

On the basis of this definition of peri-implant pathology, we undertook a study of bone loss. In terms of methodology, bone loss requires a multifactorial model to explain its occurrence. However, all the factors are not yet understood, and that limitation must be taken into account when completing the model.

Adopting this approach, 22,009 patients were studied over three years for the prevalence of the three main chronic oral conditions. The results indicated that the prevalence of peri-implant pathology was 13.9% (Figure 1).



Figure 1: Patients studied over 3 years demonstrated a peri-implant pathology prevalence of 13.9%.

So now that we have the term, the definition and the prevalence, how can we apply them? Our objective is to obtain excellent results over the long term, so the need is to measure the risk, manage the risk and communicate the risk. Failure in one of these will result in an exponential increase in the probability of overall failure.

Implementing a Multifactorial Strategy

Our strategy was to begin by comparing more than 30 variables. Of these 30-something variables, 19 were inferentially significant. This is a causation-component model that says you have different manifestations of the disease based on a set of risk factors that are interacting with each other. Different risk factors might have the same outcome because implants are not exactly the same as teeth. With this in mind, we assembled our model.

*Measure the risk,
Manage the risk,
Communicate the risk*

Using these variables, we were able to build 25 models. Applied in clinical practice, analysis of the results allowed us to calculate an odds ratio of whether a patient with a particular factor will or will not manifest the disease.

For example, in those cases where the prosthesis is a *passive fit*, the PEEK compensates for any minor errors in the fit. But when the prosthesis is not a passive fit, the patient will be five-times more likely to develop periodontology.

Study of a Possible Correlation Between Plaque and Bleeding

Another study that attempted to isolate a variable and define an odds-ratio looked for a possible relationship between plaque and bleeding. Here, 15 subjects suspended oral-hygiene habits for three weeks. Each was scored from 0-3 for plaque and bleeding, where 0 meant zero correlation between plaque and bleeding; 1 indicated some evidence of correlation, and 3, a large amount of correlation.

What was observed, over the following weeks, was something of a linear-positive relationship between plaque and bleeding. Then at six months, while there was still a significant correlation, it was not that strong. And then at 12 months, there was no significant correlation. (Figure 2).

Correlation between mPLI (plaque) and mBI (bleeding)

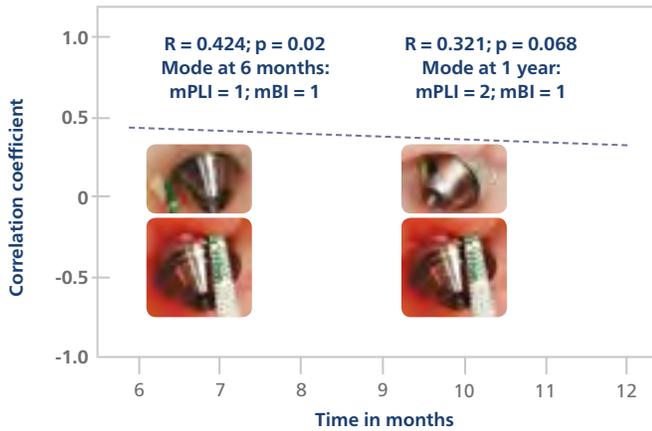


Figure 2

In terms of marginal bone loss, the median value was 0.34 mm, which can be considered an excellent result for an All-on-4 procedure.

How Does a PEEK Prosthetic Impact Risk?

But what, precisely, in terms of risk score, will be the impact of using a PEEK infrastructure (made with the JUVORA™ CAD/CAM Dental Disc from Invisio Biomaterial Solutions™)? It will not have any impact on a history of periodontitis, nor the proximity to other teeth or implants, at least not in this particular study because it is a full-arch

reconstruction. It won't teach patients to improve their brushing and cleaning – and bleeding, as previously noted, was present. And it won't help patients quit smoking!

Basically, the use of a PEEK infrastructure increases the probability of a passive fit since it is CAD/CAM manufactured. A passive fit translates to six-to-eight points of prevention – a significant number of points.

In summary, the absence of a correlation between plaque and bleeding, with low marginal bone resorption, plus a low incidence of biomechanical complications and a complete absence of biological complications, translates as a good prognosis for the long term.

Summary - One Recall Schedule at a Time

We began with the observation that installation of the definitive prosthesis makes everyone happy. But the maintenance of excellent clinical results, over the long term, is very dependent on the patient and the compliance between patients and clinicians.



Figure 3: Installation of the definitive prosthesis makes everyone happy – There's a lifetime to go!

We don't need to plan according to a 10-year overview. Instead, both clinicians and patients should live their lives one recall schedule at a time. Together, the clinician and the patient plan for the next visit. This is the MALO CLINIC's approach to the better maintenance of excellent clinical results over the long term (Figure 3). We plan in steps. ▲

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Clinical Experience with PEEK Infrastructure: Short-Term Results of an Ongoing Prospective Study using the JUVORA™ Dental Disc

AUTHOR: Carlos Moura Guedes, DDS, MALO CLINIC, Lisbon, Portugal*

*Carlos Moura Guedes, DDS, spoke at a tri-lateral meeting of EAO 26th Annual Scientific Meeting, SEPES 47th Annual Congress and 5th SEPA European Symposium, October 5 - 7, 2017, Madrid.** This is a summary of Dr Guedes' presentation.*

For the last 20 years, our main objective at the MALO CLINIC has been to achieve a simple and cost-effective procedure for providing fixed teeth to edentulous patients. We would like those fixed teeth to be in place immediately, at the time of the surgery – and with high success rates, both for the implants and also for the prosthodontic rehabilitation.

We have attained these objectives with two different protocols. The first was the All-on-4™ protocol; it is a surgical protocol that allows us to use implants to achieve the correct support for our bridges. The second is the MALO CLINIC bridge, which has been developed specifically for the All-on-4 surgical protocol and allows the patient to have fixed teeth that are both highly functional and highly aesthetic (Figure 1).



Figure 1: All-on-4 procedure with MALO CLINIC bridge.*

Cases can be Problematic

Of course, not all cases are straightforward. We have situations where, for example, patients are heavy bruxers, with parafunctional habits. We have fractures of the material, including fractures of the ceramic, and breakages of the teeth. In the worst-case scenario, we can even have fractures of the titanium framework.

In one particular case, the challenge was to replace the titanium infrastructure (which was very rigid) with a PEEK infrastructure (made with the JUVORA CAD/CAM Dental Disc from Invibio Biomaterial Solutions™). Then we could see if, given the resilience of the PEEK material, we could absorb some of the loads that were causing damage both to the crowns and to the veneer material.

First, we did a pilot study with only four patients, with five prostheses. One of the mechanical complications we then saw in these five prostheses was the deformation of the PEEK material when we torqued the prosthetic screw. We had to find a solution to this before we could start our study. The solution we devised was to include titanium

sleeves, placed occlusally where the prosthetic screw is tightened. Doing this, we were not applying pressure to the PEEK material, but instead to the titanium sleeve. We incorporated these titanium sleeves with every bridge, from this point on.

Following the Healing Phase

After the healing phase we waited between four to six months, according to the type of bone the patient presents, and we then start making our definitive impressions. When using CAD/CAM techniques, we always try to use models that are as precise as possible, so we use a ferrulized technique for the impression copings, to try to have the most precise model possible. This is the starting point for every case, the final models. Using the immediately positioned provisionals, we then cross-reference the final master casts with the models of the provisionals. We try to provide as much referencing as possible, so that the technicians can start to build the new and final bridges. We can remove these models in order to make the silicone indexes, or now that we have the digital process, we can scan the provisionals and have the design made entirely by CAD. We can also use a more manual and traditional approach and design the PEEK infrastructure using the silicone indexes.

The Prospective Study

For the prospective study, which is ongoing, we had 37 patients, which meant 49 prostheses, because some of the cases were bimaxillary. We studied two essential outcomes. The primary one was prosthetic survival – determining whether all the prostheses had survived, or if some need to be replaced. The secondary outcomes were also extremely important, and here we checked implant survival, while also looking for technical, mechanical and biological complications.

We had one prosthesis that had to be replaced due to a fissure that occurred in the cylinder area. It was No. 35, on the left side. This meant that we had a 98% survival rate for the prostheses. Regarding the secondary checks, we had some technical complications, as we had anticipated, because when we change the materials and also the techniques, there's a learning curve. The more evident technical complications were veneer-adhesion issues. We found this type of issue in six patients, with seven prostheses affected. This indicated debonding of the acrylic teeth from the pink infrastructure.

We made three changes to obtain better results. The first, and the most important, was to change the bonding primer. When we did that, we immediately stopped having this type of problem. Another measure was to increase the mechanical retention of the PEEK material, to increase the adhesion. We also increased the thickness of the PEEK, in order to reduce the flexibility of the material and to make it more compatible with the acrylic teeth

Mechanical and Biological Complications

In terms of mechanical complications, we also had fractures of the acrylic teeth without exposure of the infrastructure. This exact complication occurred in a patient that had a fissure in the PEEK infrastructure. Here, the solution was to improve the design, to increase the thickness of the PEEK and give it more resistance. The other problem we saw, and sometimes this also happens with the titanium frameworks, was the loosening and fracturing of the prosthetic screws. That occurred in two patients and in three prostheses. Here we controlled the occlusion. We changed the screws; we re-tightened them, and this particular problem never recurred within the observation period. In some areas, especially in those areas where we have the cantilevers, we needed to increase the thickness of the PEEK to gain more resistance in a particular area.

The other factor we wished to test was the use of different veneer materials in combination with PEEK. We changed the veneering material from acrylic to ceramic, and this resulted in a completely different design of the PEEK framework, compared to those where we wrap around with acrylic.

We had excellent biological results. The bone loss was 0.5 to 1.13 mm, and for the tilted implants, 0.43 to 1.14 mm (Table 1). These are very good values, indicating that the bone is responding really well to the PEEK polymer.

Biological Complication	Axial Implants	Tilted Implants
Marginal Bone Loss	0.51 - 1.13mm	0.43 - 1.14mm

Table 1

These one-year results mean that we at the MALO CLINIC are very happy with the performance of PEEK. Regarding patient satisfaction, the response has also been extremely positive. Patients tell us they feel very comfortable. ▲

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has been an invited guest speaker at international conferences on topics such as Oral Rehabilitation, Fixed Prosthodontics, Interdisciplinary Treatments and Aesthetics.

* Since 2016, Carlos Moura Guedes, DDS, has provided ad hoc consultancy services to JUVORA Ltd.

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