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Clearing the Air

Off-shore dental laboratories and the question dentists should ask their laboratories

Off-shore dental labs might be one of the most debated topics in the U.S. dental profession today. It's awash with various allegations that sting the sensibility of most Americans. Visit the message boards of Dentaltown.com and you can find countless posts about off-shore labs – pro and con. That being said, Modern Dental Laboratory USA (MDL USA) remains proud to inform dentists that its restorations are all made in Shenzhen, China, and President and CEO Patrick Tessier wants to set the record straight about his lab. *Dentaltown Magazine* recently spoke with Tessier to learn more about his lab.

Patrick, can you tell us a little about yourself, your history in dentistry and your involvement in the company?

Tessier: I'm not a dental technician or a dentist, but I have spent most of my career in manufacturing management, having earned a bachelor of science in mechanical engineering and a master of business administration in operations management and finance. I entered the dental business in 2000 when I was introduced to the dental lab business through a national lab company that was looking for a western regional vice president. When I took this job I fell in love with the business. I was later introduced to a laboratory based in Shenzhen, China, called Modern Dental Laboratory (MDL Shenzhen). The fellow who introduced me to MDL Shenzhen told me, "The everyday quality of this laboratory is better than your best technician on his best day." Curious, I traveled to Hong Kong. Managing Director Godfrey Ngai and I traveled about an hour to his facility in Shenzhen. I was in the lab for a very short time when I realized that this lab was very different than the dental labs I had visited in the past. This company is very organized and disciplined, but at the same time relaxed and friendly.

*Patrick Tessier
president and CEO, MDL USA*

How did MDL Shenzhen stand out from what you'd seen in the past?

Tessier: The biggest difference I noticed right away was its organization, cleanliness and manufacturing processes. During the tour, Godfrey explained how the business was based on the process, not the person. He shared that this was the fundamental philosophy he used to build the company from 40 technicians to the 900 they had in 2003. From his decades of experience teaching at the University of Hong Kong Faculty of Dentistry, Godfrey designed and wrote a technical school curriculum for new employees. The MDL Shenzhen School, complete with beginning and advanced classes, is the fundamental backbone to the organization. It is at this school that the patient-centric culture is instilled and adherence to very specific manufacturing processes is taught. He then humbly shared the certifications they had achieved at that time: ISO 9001:1996 and European Standard EN 46002. He explained that certification under the rigid ISO and EN was relatively easy because of the school. The manufacturing processes were all documented, taught and followed as part of the educational process – which is what's needed for certification – and therefore becoming certified was a natural, final step. Because of my education and experience in manufacturing, I understood the complexity and discipline required by the ISO standards and although he made it sound easy, it is actually quite an accomplishment to obtain such certification.

So business that is sent to MDL USA is then sent to MDL Shenzhen?

Tessier: Yes, and the process is much the same as any other lab: The dentist puts the case in a box, adds it to the other cases for the day, places them in a recyclable plastic bag, puts a shipping sticker on the outside of the bag, and calls our lab for a pickup. We provide a return date calendar and about two weeks later, the completed cases are delivered. We have a 99.96 percent on-time delivery record with more than 100,000 cases over five years. We track the entire lifecycle of each case through our sophisticated computer network, and provide all the shipping materials, for free. We also store electronic copies of all case documentation for almost instant retrieval, including the lot numbers of the materials used. One of the big benefits about our business model is that our manufacturing facility in Shenzhen focuses on producing a very consistent, high-quality product, and MDL USA focuses on serving our customers.

What is the largest challenge you face in having the manufacturing facility so far from the end user? In other words, you have a dentist in the United States who is sending a crown out, if there is an issue, how do you manage that?

Tessier: We create very close working relationships between our dentists and their MDL USA regional service center so that questions or concerns can be instantly resolved. After our merger into MDL USA in 2009, we now have three service centers for our clients: Seattle, Los Angeles, and Chicago. All interactions with our dental offices are handled by our small service centers, staffed with five to 20 employees. For example, in Seattle, Julian Infante and Heikas Martirosian are our technical consultants. Heikas is our technical director and is a double certified dental technician (CDT). He is a sustaining member of the American Academy of Cosmetic Dentistry and has personally built more than 15,000 crowns in his career. Julian is also a CDT and a member of the International Congress of Oral Implantologists (ICOI), holding a certificate in implantology. You might also work on a case with Julie McBarron, our case management manager, who also holds a certificate in implantology from the ICOI; or Mary Wilson, our client relations manager who has more than 20 years of experience in customer service. Our dentists interact with a top flight service team who can answer any question and solve any problem. Combining this “customer-centric” approach with our manufacturing capabilities, we believe our dentists enjoy a unique combination of quality and service that is unmatched in the dental laboratory industry. In addition to our staff, we also work behind the scenes to provide better service to our dentists by improving operations at MDL USA. For example, we've become a bonded warehouse for customs and the Food and Drug Administration (FDA) because this saves our dentists one day in logistics.



*Heikas Martirosian, CDT,
technical director, MDL USA*



MDL USA Seattle service center staff.

How common is the business model of dealer labs forwarding work to other places in the U.S. dental market?

Tessier: Like many other industries today, trade within the dental industry is quite common between the United States and other countries. Many of the dental industry's materials and equipment come from Germany, Switzerland, Austria and Liechtenstein. KaVo, Ivoclar Vivadent, 3M ESPE, Kerr, Sirona, Wieland, Straumann are a few of the names you might recognize that export products to the United States. Dentists purchase these products everyday from dealers like Patterson Dental or Burkhart. Laboratories do the same thing. And since the 1970s, laboratories have been importing restorations – manufactured using many of these European materials – from the Philippines and Mexico. In the last five years, imported restorations from China, Thailand and Indonesia have increased in popularity, which are also manufactured using these European materials. MDL USA's restorations from MDL Shenzhen are the same – international in nature and not unusual in dentistry.

In early 2008 there was a serious lead scare that many thought came from a lab in China. Your company is very transparent about where its restorations come from, what the process is, but others are not. How can a dentist sort that out? Is there a resource they can use to understand this?

Tessier: That story saturated the media and people paid attention since crowns are common. The focus and blame was placed squarely on China because initial reports stated that the crown was manufactured in China. Around the same time, reports were flooding the media about toys made in China containing lead paint. This progression of lead scares created an air of fear that was easily sold to the general public. It was a powerful force at the time. Politicians from Florida to Oregon introduced legislation that would force dentists to dis-

close the country of origin per restoration – continuing to propagate this obtuse notion, when in fact country of origin is a very poor predictor of product safety and quality. In fact, the *Journal of Dental Technology* published a study that finds dental porcelains contain such little lead that eating bread, fruits and soups provides thousands of times more lead.

To answer your question: Yes, there is a way for dentists to get help in evaluating the competency of dental laboratories and their ability to produce safe, consistent and high-quality restorations, and that is through certification. Third-party and non-biased exams, which result in professional certifications, are the most trusted common denominator to make these evaluations – just as a dentist earns a diploma from an accredited dental school and then passes a dental board exam to earn a state license. Dental laboratories can obtain both individual certifications and organizational certifications. However, while dentists are regulated by state governments, U.S. dental laboratories have almost no government regulation. In its place, a voluntary national organization called the National Association of Dental Laboratories, the sister organization the National Board for Certification (NBC), has been providing this valuable service since 1955. The NBC examines and certifies both dental technicians and dental laboratories. In addition, the ISO has been creating international industry standards for more than 100 years. Rather than being concerned about country of origin, dentists should instead verify that their dental laboratory has achieved accredited certification and adheres to manufacturing standards that produce safe, consistent and high-quality restorations. Ask your lab for their certifications.

Should dentists really be concerned with whether or not their lab is certified?

Tessier: Yes. We feel so passionate about this that beginning this year, we are working with others in the dental industry to improve dental health care by raising awareness about the importance of using certified dental laboratories. We believe this issue is paramount because currently, only an alarmingly low three percent of dental laboratories in the United States have been certified at the basic level offered. Also, according to a survey conducted by *Lab Management Today* (April 2003), more than two thirds of dentists state that inconsistent quality and technical problems are the top reasons they leave their laboratories. Additionally, as we've discussed, there have been recent fears over dangerous materials making their way into patient's teeth. As a health-care provider, you have the right and responsibility to administer health care effi-



Lab training class at MDL Shenzhen.



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ciently to the best of your ability. As your laboratory, it is our responsibility to help you achieve this goal. If a laboratory has proven their competency by subjecting itself to an evaluation and obtaining certification, then you have some confidence that it has the ability to provide you with restorations that meet industry standards and are consistent, safe and perform to your expectations.

Can you explain more about the manufacturing process in dental laboratories and why certification is a relevant concern?

Tessier: This gets to the heart of the matter. The main task of a dental laboratory is to manufacture a custom prosthesis from complex materials. This sounds simple, but if one of the hundreds of variables is off, the product fails. For example, when a technician creates a fixed restoration by firing porcelain – if he or she doesn't have the right vacuum, or the equipment isn't calibrated to standard, or he or she adds too much liquid, and so on – it fails. Manufacturing restorations is complicated and it's difficult to get consistent results. If a lab is handling hundreds or thousands of cases, you can see why a lack of standards can create inconsistencies and problems. Certification ensures that a laboratory has the standards in place to manufacture consistent restorations. As I mentioned earlier, at MDL Shenzhen written procedures are created for these very specific manufacturing processes, taught to each technician, and adherence to these processes is verified. This discipline has allowed MDL Shenzhen to obtain the highest level of certification in the dental laboratory industry, and is one of the only labs to do so in the world. Its ISO 13485:2003 certificate is the international standard in quality management for medical device manufacturing, and is the most rigid global standard in manufacturing, exceeding even those of the FDA. Obtaining this level of certification is important to us because our goal is to eliminate variability in our processes so that our dentists always get consistent output.



Lab technicians at MDL Shenzhen.

MDL Shenzhen is certainly proud of its ISO 13485:2003 certification. Give me a brief description of what that process is about and maybe some examples of what a company needs to do to obtain a certification like this.

Tessier: Let me start by laying out what types of certifications are available to dental laboratories. As I mentioned earlier, dental laboratories can obtain certification for individuals and its organization. For individual competency, the NBC offers the CDT, which is available in five specialties: Ceramics, crown and bridge, orthodontics, complete dentures, and partial dentures. For organizational competency, the NBC offers the Certified Dental Laboratory (CDL) and now also recognizes the Dental Appliance Manufacturers Audit Scheme (DAMAS). In addition to the NBC national certifications, there are also the ISO certifications available to dental laboratories, which include ISO 9001:2008 and ISO 13485:2003. The level of difficulty in achieving these organizational certificates varies and is as follows (easy to most difficult): CDL, DAMAS, ISO 9001:2008 and ISO 13485:2003. The requirements for each certification are based on ability to demonstrate compliance to standards by documentation, adherence to written processes, internal and external quality management, and material traceability record keeping. This is a detailed and disciplined process, it is hard work, but it helps sharpen an organization into an efficient quality driven machine, which is exactly the type of partner dentists want to produce their prescribed restorations.

Because of the costs and administrative issues, certainly for a small lab, ISO certification would be impractical. Do you think the lack of that certification puts a greater burden on them to prove themselves?

Tessier: The CDL from the NBC is the best start for a small lab and is a manageable process that is not cost prohibitive. I also know that the folks at the NBC will bend over backwards to assist any lab in obtaining its CDL, as its mission is also to improve and develop our industry.

What would you say to dentists who are searching for new labs or might be looking to explore new options?

Tessier: Very simple, ask for certification. Please feel free to reach out to me anytime if you have questions, want to discuss further or would like to get involved. I can be reached at patrick@modern-dentalUSA.com or 800-860-5006. ■



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ISO 9001:2008 #1210029444TMS

ISO 13485:2003 #Q2N090659559002

Service Center Third Party Certifications

Chicago FDA # 3003358121, CDL # in process

Los Angeles FDA # 3006988076, CDL # in process

Seattle FDA # 3004016005, CDL # 123276-00