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Elements of dental instrument design

_case report

The use of a new bioceramic material

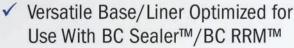
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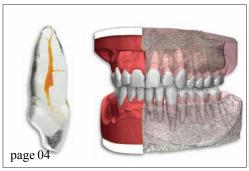
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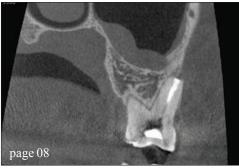
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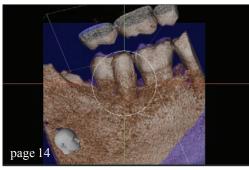
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Seiler's new 3-D surgical microscope. For more information, see pages 12-13.







Elements of dental instrument design

Author_L. Stephen Buchanan, DDS, FICD, FACD, Dipl. ABE

_Dentists are inveterate inventors because every procedure we do is a prototype. All human teeth in a state of disease are alike but different, and in honoring those diversities we invent all day long, every day in practice. Add to this the fact that dentists are very mechanical people. We do micro-procedures all day long, and we are regularly frustrated by the limitations of the tools and materials we use. Because of this irritation, it occurs to pretty much every dentist

during our careers that some of these tools and materials could be better. This is how it begins.

The epiphany, the Big Idea, is the second-best experience in inventor-land. More than most people realize, big idea epiphanies are perhaps the most fun a dental nerd can have with all their clothes on, especially if it is never followed up with a patent application. On the other hand, the best experience in inventor-land is seeing a new product you invented make it to success in the marketplace, but this is very rare, and it often involves a personal financial experience I call "the valley of death" — the inevitable delay in return after all the development money has been spent.

What is involved in applying for a patent? The first part is cheap — it's called a provisional patent — and it requires as little as a pencil-drawn illustration

of the novel and inventive idea. In the U.S. the provisional application costs less than \$1,000 for the legal work and application fees. After that you have a year to write and submit your final patent application with claims. The legal expense for this is \$5,000 plus the USPTO application cost.

The biggest hit comes when the inventor must declare, at the one-year mark, any foreign countries that are to be included in the application. This is the part that can suck \$100,000 out of your pocket within two to four years, and the deadline to this fateful decision often comes before the full potential of the patent application is known, as licensing negotiations can be on hold for months and years before a company prototypes, licenses or dumps the product.

There is an inventor joke that goes, "What is the most predictable way to become a millionaire from patenting inventions?" The answer is, "Start with \$5 million, and sooner or later you will be a millionaire." So, what goes into a successful new product and how do we avoid a crash and burn?

Peter Drucker states in his essay "The Discipline of Innovation" that: "There are of course innovations that spring from a flash of genius. Most innovations, however, especially the successful ones, result from a conscious, purposeful search for new innovation opportunities, which are found in only a few situations [my emphasis]. Four such areas of opportunity exist within a company or industry: unexpected occurrences, incongruities, process needs, and industry and market changes.

"Three additional sources of opportunity exist outside a company in its social and intellectual environment: demographic changes, changes in perception, and new knowledge." I highly recommend reading the entire essay in Harvard Business Review's compilation "On Innovation," published in 2013.1

The question to ask oneself before jumping in is, "Have I found one of these areas of opportunity with a product/service/tool that will make dentists' lives better?" If the extent of the answer instead is, "I want

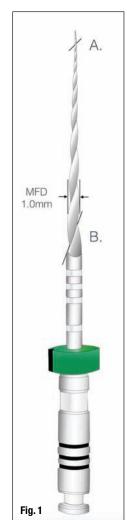


Fig. 1_Traverse Rotary File by
Kerr Endodontics. The design and
fabrication of these instruments
empower them to negotiate
canals to their terminal points.
(Photos/Provided by
Dr. L. Stephen Buchanan)

to be an inventor," that's cool as long as you know what you don't know, and you do your homework before spending cash and heart muscle on a vision quest. Falling in love with your invention can deafen you to your friends' sage advice, then break your heart and empty your bank account like dating a ridiculously good-looking person without character.

If you want to get your mind right about this, cue up Kristen Wiig's "Red Flag" skit for "Saturday Night Live" on YouTube and then keep an eye out for red flags that surface during development. Watch the opera "Carmen" to understand how you can be in love with someone or something that doesn't love you at all. Or, just do it like I have: spend hundreds of thousands of dollars on "brilliant" patents for products that will never get built or licensed.

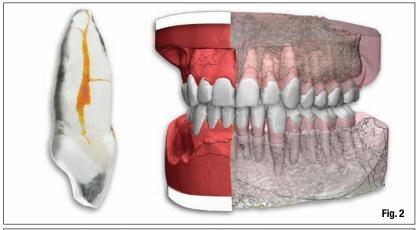
_The value of prototyping

Dan Fischer, founder of Ultradent, advised: "It's one thing to draw and create something in dimensions as large as a napkin or a piece of paper. It's another thing to create them at the sizes that may be needed to enter inside of a canal or inside of a cavity preparation."²

My experience has been that I can seldom intellectualize, during early stages of an invention, what the final product will look like and exactly how it will behave. Stated another way, I can only get half way there before a prototype must be fabricated and put into action to know any more about it. I've had 22 U.S. and foreign patents granted and usually have several in process, and I can say without embarrassment that very few of my ideas ended up the way I thought of them working upon conception.

Successful innovation requires careful deconstruction of the failures of every round of prototyping, redesigning the next round to answer the identified problem(s) and fabricating another prototype — rinse and repeat until it works the way you hoped. The design process for Kerr Endodontics' newly introduced Traverse Rotary Negotiation Files required 23 prototype iterations before the instruments worked to my specifications (Fig. 1).

Once in a great while, the challenge is to accurately deconstruct an unexpected success. This is undoubtedly a quality problem, but these can be as mystifying as the unexpected failures. It took me two and a half years of using a System-B Heat Source with The Continuous Wave of Obturation Technique before I understood how a method that took 2.5 seconds to perform could be superior to warm gutta-percha techniques taking 10-15 minutes to complete. Weirdly, the CW electric heat pluggers I designed worked the first time they were used. More typically, GT Files took several years of trials to get right.





_Understanding the market

In the same article, Fisher encourages potential inventors to study and realize what the dental market really is going to be like for the proposed product. He cautions that: "Early inventors can start doing multiplication, without ever subtracting or dividing. We're usually multiplying, and we're multiplying how many units we feel are going to be bought by how many dentists who are going to use them. How many times a day can be multiplied by how many patients in a year. We can come up with tens of millions of dollars of projected successes.

"If we're not careful, the numbers become so tantalizing in our brains that it's difficult for us to accept a small start that may be required first. It's that human nature thing that can run away with us if we're not careful."

Perhaps most important, the tool solves a genuine problem that dentists currently encounter, and that the benefit of the solution (the new tool) is greater than the cost of the solution. Taking it a step further, Peter Drucker, in his book "Innovation and Entrepreneurship," states that to be successful any new product, tool or technique must deliver a 10X advantage to make it worthwhile for new users to go through the expense and difficulty of changing their current mode of work.³ The best tool on earth won't sell if it costs too much to buy and has too long of a learning curve to competence for neophyte users.

Finally, inventors must understand that both markets and technology are dynamic realities, a factor that must be seriously considered. The right innovation developed before its time is not going to happen

Fig. 2_TrueTooth and TrueJaw 3-D-printed procedural training replicas created by my company, DELabs.

Fig. 3_Endo-Bender™ plier. Note the smooth ergonomic contours where the clinician's thumb and palm connect with it, and the end view showing the concave upper clamp jaw and the convex lower bending anvil jaw that together can immediately emboss a smooth curve onto the very last flutes of a negotiating file to enable it to bypass coronal or apical impediments. The lower jaw graduates from a 0.5 mm bending radius to fully flat for straightening previously bent instruments or pluggers.



Fig. 4_DELabs new hand instruments, The Legacy Collection, with unique handle and identification features. Note the oversize SS finger grips to optimize manual control, separated by a narrow waist that enables smooth instrument flips, and identification rings in ISO colors next to each working end. Note the rings on each finger grip, designed to provide enhanced grip for gloved fingertips; these grooves have a concentric pattern to enable their cleansing of sticky dental materials.

Fig. 5a_DELabs The Legacy
Collection DG-16 and DG-16-Bent
Ends Endodontic Explorers. The
custom secondary bends in the
working ends of the DG-16 Bent
Ends Endodontic Explorer enable
earlier identification of molar orifices
in calcified pulp chambers and when
cutting minimally invasive access
cavities.

Fig. 5b_DELabs The Legacy
Collection Double-Ended Mirror with
16- and 20-mm-sized Zirc Crystal
HD Mirror Heads. These mirrors
reflect at least 30 percent more light
and are more scratch-resistant than
traditional rhodium-plated mirror
surfaces. The 16 mm mirror size
is great for views into lower molar
access cavities when sitting in the
12 o'clock position.

until its time arrives. Bill Gross, a serial entrepreneur from the age of 12, explains in his TED talk, "The biggest single reason startups succeed," that timing trumps all other variables. My experience indicates that he is dead-on in his assessment. Inventors must ask themselves if the market is ready for their idea, and whether all the technologies necessary for the success of their product already exist. Sometimes a great idea needs to be put on the back shelf until the timing is right.

For example, when I met Chuck Hull, the inventor of stereolithography (3-D printing), I asked him if we could use 3-D printing to print an actual scale tooth replica from reconstructed CT scans. He replied, "Yes, but it will be 20 years or so before costs go down and the resolution of 3-D printing is small enough."

His prediction was realized 22 years later after the original patents expired, the costs of the machines went down, and the resolution improved so a printed root or canal curvature was smooth rather than staircased, and my products TrueTooth® and TrueJaw® were born (Fig. 2).

_Designing the anatomic interface between doctor and tooth

Tools designed by dentists for dentists are the most efficient tools to use. In my experience, Intuit, the Quickbooks accounting software company, takes that a step further in requiring creative employees to "Design for Delight" in order to acquire users who are active promoters of the product. Designing for delight means creating a quality experience for users as the No. 1 priority, rather than designing for minimal cost of manufacturing — which is OK if one accepts the fact that the result will be less elegant in practice.

It's not much more work and expense to design

facility and elegance into tools. For example, during the development stage of my first dental invention, the EndoBender™ plier, two separate tool makers edited my design to be cheaper to make (but less fun to use), I fired them, bought a block of carving wax, cut out and finished the upper and lower members to myspecifications, had them cast in stainless steel and welded together — so worth the extra effort (Fig.3).

Another example is the new DELabs™ dental instrument and procedural kit line, The Legacy Collection™. Given the go-ahead by DenMat's Hartzell Instruments, my mission was to design a unique new dental instrument handle for traditional as well as custom working ends from my own instrument sets (Fig.4). The signature handle has large-diameter finger grips to improve clinical comfort and manual control.

The surface is made by lathe-cut rings that increase in pitch just under fingertip positions, yet are able to be easily and completely cleaned of blood, sealer, etc., by rotating the handle back and forth under an alcohol gauze (unlike other common texturing surfaces on instrument handles, such as cross-hatch knurling and complex grind patterns, which are difficult to fully clean). The stainless-steel finger grips are separated by a narrow waist that aids baton-twirling to quickly switch between working ends.

At either end of each Buchanan Continuous Wave™ Plugger and Buchanan Minimally Invasive Endo™ Plugger are ISO color rings to indicate plugger tip sizes.

The Legacy Collection instruments and products come individually or in procedural sets, including a set for each conventional endodontic procedural step, such as: diagnosis, isolation, access, negotiation, shaping and cleaning, obturation and assistants. The sets have curated instruments with traditional working ends like the DG-16 Endodontic Explorer, as well as custom ends like the DG-16 Bent Ends Endodontic Explorer, which features a second bend to enable early identification of molar orifices in calcified pulp chambers and when cutting minimally invasive access cavities. Certain procedural sets include a double-ended mirror handle with 16 and 20 mm Zirc Crystal HD Mirrors (Figs. 5a, b).

_Getting your baby to market

In most ways, the lowest-risk path to new product development is to license the patent(s) to a company that will complete its development, manufacture and sell it. However, dealing with a corporate structure can be nearly impossible because so many individuals, cells and divisions have to sign off on it, and that is assuming they want to do it in the first place. Sometimes, the engineering department will stiff arm marketing with an NIH (not invented here) argument, and it's blocked.

My first file design — the Safety Hedstrom File (later to become the "Safe-Sider" by EDS) — took so many years to be prototyped by the corporation I licensed to make it, that the market for it passed before its introduction as rotary files made their debut. Conversely, the licensee of my GT System patent — Ben Johnson's privately owned Tulsa Dental Products — rapidly finished development of my GT Hand File just in time for it to be swept up into the rotary revolution, and GT Rotary Files became Tulsa Dental's flagship product for the following five years and still sells remarkably well.

In this case, hedging my bet made the difference between success and failure, and since then I have had most of my licensing successes in tool design with privately owned companies. The problem with this strategy is that the majority of those small, nimble companies that develop successful new products get bought by larger corporations, and then you have to work with them.

The reason corporations buy smaller companies is because of the much greater leeway these privately held companies have to spend development money and wait several years before seeing the return on their investment. The strength of corporations is their ability to wring every last penny of market value from existing intellectual property, but eventually they often suck more of the previously created IP equity out of their acquisition than they create and a long slow downward trend is seen unless further acquisitions can be put in place to obfuscate this reality.

The biggest entrepreneurial successes in endodontics — Tulsa Dental and Edge Endo, for example — were only achieved because the endodontist inventors, Dr. Ben Johnson and Dr. Charles Goodis, respectively, did it themselves by starting companies. Sonendo, a startup out of a med-tech incubator with no previous dental experience, developed a multi-sonic root canal cleaning technology, building a company around it and in the process changing the specialty of endodontics. Starting your own company has the highest potential reward, however it also has the highest risk profile — typical of most scalable revenue streams.⁶

_Don't call my baby ugly: Some final pieces of advice

Be really fickle about whatever material, tool or technique you are currently using. I *love* tools for the power they provide to accomplish previously unattainable missions, like Continuous Wave™ Electric Heat Pluggers reducing the time to three-dimensionally fill root canals from minutes to seconds. However, the day I find a better, faster or simpler way to fill root canals, CW Pluggers will be dead to me. Ideally, you obsolete your own inventions before somebody else does.

Listen to everybody's opinion, but make up your own mind in the final assessment. Most users have ideas about how existing products could be incrementally improved, but they lack the vision to ask for an entirely new product category — i.e., nobody ever asked Apple for an iPod, iPhone, iPad or iWatch. You can't get to the finish line without persistence, but persistence by itself will never get you there either. Those who persist but can pivot on a dime when faced with new data will get there first.

With that said, there is nothing like the thrill of successfully seeing an invention through all the impediments that stand in its way. Never forget that with the right lever and fulcrum, you can move the world.

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about the author

roots

L. Stephen Buchanan, DDS, FICD, FACD, Dipl. ABE, has lectured and taught handson endodontic continuing education courses for 30 years, both in his DE*Labs* Academy in Santa Barbara, Calif., as well as in dental schools and meetings around the world. He currently serves as an assistant clinical professor at the



University of Southern California School of Dentistry and University of California at Los Angeles School of Dentistry. Buchanan is nationally and internationally known as an expert in the research and development of new technology, instruments and techniques in endodontics, designing many of these products, including 3-D-printed teeth and jaw replicas, TrueTooth® and TrueJaw®, and The Legacy Collection™ dental instruments and procedural sets, for his company DE*Labs*. He is the owner of more than 22 U.S. and international patents, and his tools are used by endodontic specialists and general dentists worldwide. Buchanan also maintains a private practice limited to micro endodontics and implant surgery in Santa Barbara, Calif., and is a diplomate of the American Board of Endodontists and a fellow of the International and American College of Dentists.

The use of a new bioceramic material in endodontic microsurgery

Author_Dr. Leandro Pereira

_Despite the high percentage of success in the treatment of periapical disease by conventional endodontics, failures may occur. Such unfavorable results may be reversed by standard retreatment, tooth extraction or microsurgery. With above 90 percent rate of positive outcomes, endodontic microsurgery is a therapeutic alternative to be considered for the functional and esthetic preservation of teeth with recurrent periapical disease.

Introduction

Endodontic treatment has a high success rate. However, failure occurs. Conventional retreatment is commonly selected to deal with persistent apical periodontitis and presents an 83 percent success rate. 2

Nonetheless, with the growing use of microscopy associated with ultrasound and MTA, endodontic microsurgery evolved significantly and became an adequate alternative to conventional retreatment.^{3,4} The evolution of the technique improved the outcomes from less than 60 percent⁵⁻⁸ to a level of 90 percent success rate.^{6,7,9-12} Such less-than-60-percent success rate of the "macro" surgical technique (no microscope, no ultrasound) does not define it as a viable option to attack the complexity of apical periodontitis.

Fig. 1_Radiographic view of first emergency consultation. (Photos/Provided by Dr. Leandro Pereira)

Fig. 2_Tomography, distobuccal root of tooth 26.

Fig. 3_Tomography, periapical lesion of tooth 27.

Fig. 4_Pre-op radiography.

_Description of case

A female, age 64, ASA I (physical status: healthy), blood pressure 125/85 mm Hg, heart rate 61, oxygen saturation 98 percent, temperature 36.5oC, weight 69 kg, presented herself at the clinic complaining about pain and swelling around teeth 26 and 27 (upper left first and second molars) on Nov. 28, 2017.

During examination, a buccal acute abscess was

observed between these teeth, at the apical region. The patient reacted with light pain to tests of apical palpation and vertical percussion. Response to horizontal percussion was negative. Thermal and electrical pulp test results were negative for both teeth.

Radiographically, two porcelain-fused-to-gold crowns and two intrarradicular posts (probably glass fiber) presented correct adaptation. Endodontic treatment of both teeth were deficient, and periapical pathology could be observed (Fig. 1). Pre-op tomography revealed a buccal cortical bone rupture at the distobuccal root of tooth 26 and periapical disease in teeth 26 and 27 (Figs. 2, 3).

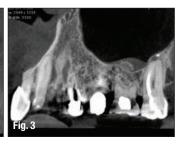
Following careful analysis of all clinical and imaging data, the diagnosis was chronic apical periodontitis on teeth 26 and 27 probably because of unsatisfactory root canal treatment. As an emergency procedure, the abscess was drained.

Two alternatives were considered to solve the case. The first involved removal of the crowns and posts with the purpose of providing access for standard root canal retreatment. Consequently, after root canal intervention, posts and crowns would have to be rebuilt. The second would be the microsurgical approach, aiming at root canal retrofilling of both teeth. One major benefit of the latter is that posts and crowns would not be removed. After detailed explanation of all advantages and compromises of the two options, endodontic microsurgery was selected. Because of personal reasons, the patient did not return until April 8, 2018 (Fig. 4), and surgery was scheduled for June 4, 2018.

Pre-op medication was 4 mg of oral dexamethasone for preemptive analgesics, ¹³ one hour before the procedure. Local anesthesia was 3.6 ml of 4 percent Articaine/1:100,000 epinephrin: palatal infiltration









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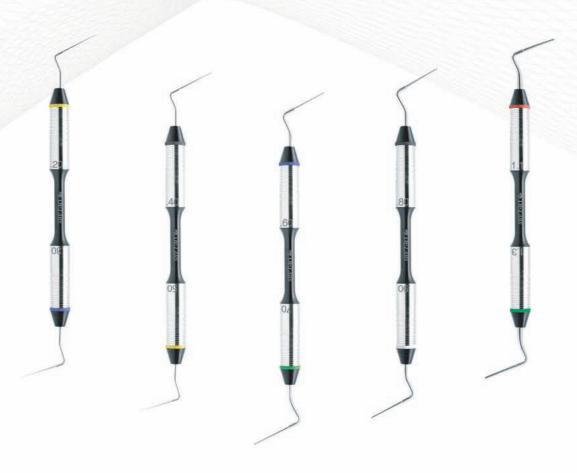
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