



Smart Dentin Grinder™

Tissue Engineering Bone Grafting Process

FREQUENTLY ASKED QUESTIONS

Version 1.0 – May 5th, 2015

Overview:

The following guide addresses frequently asked questions by dentists in regards to the Smart Dentin Grinder and the associated protocol. If your question has not been addressed, please contact your sales rep or contact us directly at info@kometabio.com.

1. Can dentin be used as a graft?

Short answer: Absolutely. Dentin is very similar to bone as for its chemical and biological composition. Furthermore, due to its strength it acts as the ultimate scaffold.

Long answer: Dentin is 50% Hydroxyapatite (HA) and 50% Fibrous collagen type 1. This is very similar to the bone makeup. It is denser than bone, contains growth factors, but more importantly, Dentin is easily fused with bone in a natural process called ‘ankylosis’. In this process, Dentin and bone undergo fusion and remodeling. This has been shown in many studies that go back over 40 years. Dentin contains all the natural growth factors that not only promote osseointegrative properties (scaffolds) but also promotes generation of bone (new bone regeneration) - induction.

2. Is Dentin graft better than allograft?

Short answer: Yes. It is better than allograft due to its autologous nature, same proteins, and no immunogenic response. Dentin is denser than Allograft, which makes the site ready to implant at half the time in comparison to allograft. Most importantly it promotes new bone regeneration at the site.

Long answer: Dentin is better than allograft for the following reasons: A) it is a harder substance and therefore acts as a better scaffold. B) it resorbs slower than allografts and therefore much more aligned with bone remodeling profiles. C) since the Dentin, in our procedure, is also autologous, this provides added benefits vs. an external material that is introduced such as allografts. The fact it is autologous makes it recognizable by the body, and specifically by progenitor cells at the site of implantation. D) Since it is an autograft, it eliminates the risk of disease transmission that exists with allografts. E) Dentin also seems to maintain crest of alveolar bone to its original volume at the site and in the long run does not lose height due to its density.



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3. Why would I spend 15 minutes making Dentin graft when I can immediately use allograft?

Short answer: It's a shame to discard perfectly reusable patient's tissue and use artificial bone or cadaver bone when instead the tooth itself can be used in order to provide superior care.

Long answer: Aren't you willing to spend a little bit more time, but show the patient that you practice according to the highest care standards? Furthermore, most of the processing time (approximately 12 minutes) is assistant time and not your own. During that time you can care for other patients while the graft patient is waiting. More importantly, those 15 minutes will save you lots of time down the road. The reason being the fact that Dentin graft generates bone faster at the site. Therefore, it might even cut down on an extra check-up visit and will allow you to move forward with the dental plan much faster.

4. Sterility of the graft – how do I sterilize the graft?

Short answer: Our cleanser is very effective in eliminating bacteria and any organic matter. Coupled with the fact that the Dentin graft is autologous, the risk of infection is almost zero and certainly lower than other pre-packaged grafts.

Long answer: Many of the allografts and Xenografts on the market are not sterile since the sterilization process ruins the organic collagen aspect of the graft that many manufacturers want to keep intact. However, when you take bone from another human or animal and TRANSPLANT in a patient, the question of sterilization becomes very important due to concerns about disease transmission and inflammatory effects. This is not the case for AUTOLOGOUS graft such as the Dentin Graft. This is because the graft comes from the patient and isn't TRANSPLANTED from someone else. As a result there is no exposure to potential disease transmission nor inflammatory effects. This is one of the key benefits of using an autologous graft. The patient's body knows how to deal with the array of bacteria that already exists in his/her mouth or body. However, our protocol takes an extra measure and applies a very effective cleansing process which strips out all bacteria, fungi, virus and other contaminants that might exist in the graft. Our studies have shown that our cleanser produces results of less than 10 CFU's. Which is an order of magnitude lower bacterial count than bottled water. The nice thing about our cleanser is that it does not deteriorate the natural organic content of the graft which is the collagen Type 1 that contains the growth factors and bone growth inducing elements. Still, if you are still adamant about sterilizing the graft, you can certainly place it in an Autoclave using the glass Dappen Dish that is provided as part of the kit.

5. Can I use an autoclave to sterilize the graft?

Short answer: Yes, but we certainly don't recommend it, because anyhow the surgical site in the mouth isn't sterile. Our grinding chambers do come sterile and therefore external bacteria will not come in contact with the material.



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6. Graft resorption – how fast does the Dentin Graft resorb and replaced by bone?

Dentin does not resorb but rather it is fused (ankylosed) by bone. Together the fused bone-dentin matrix will remodel according to function. This bone-dentin matrix is identified by cells at the site as bone, unlike other grafts! All non-autologous grafts do not fuse and will resorb independently of bone. This creates a problem since they need to both resorb as well as generate bone:

- Fast resorption of graft (measured in weeks) will disappear faster than the bone is able to regenerate and therefore the graft will be displaced by granular tissue, or at best, low density woven bone (bad for most indications). It will also not sustain scaffold for a required duration.
- Medium resorption of graft (measured in months) will allow bone to regenerate to a certain extent. Some woven bone and some lamellar bone. In most cases will eventually result in cancellous bone (might be good for some indications, but bad for others).
- Slow resorption of graft (measured in years) will allow bone to regenerate and will act as a long sustaining scaffold. It will generate lamellar bone depending on the type of bone graft. The intent is to generate cortical bone. However, the slow resorption grafts today tend to be synthetic grafts which, unlike bone grafts that get naturally resorbed, these synthetic grafts last forever. The problem with slow resorption materials, such as synthetic grafts, is that they typically have low integration with the bone and therefore are mostly static fillers – which is no good.

7. Will the Dentin graft stay forever or will it eventually get completely resorbed?

Short answer: Autologous Dentin is the same as patient’s own bone and therefore it can be remodeled but if not it may serve the site forever, serving the aesthetics.

8. What is the cleanser?

Short answer: The cleanser is a Sodium Hydroxide solution mixed in 20% ethanol.

Long answer: We have done a lot of work to optimize the cleanser for effectiveness, safety and speed. We recommend leaving the Dentin graft in the cleanser for 7-10 minutes for optimal effect. Our pharmacological reports of the Dentin graft post cleanser show bacterial count of less than 5 CFUs. After using the cleanser, you must drain excess liquid and apply the PBS (Saline) solution in order to bring the Dentin graft back to normal pH.

9. Can the graft be stored? For how long?

Short answer: The Dentin mineralized graft prepared by the Smart Dentin Grinder can be stored at room temperature indefinitely.

Long answer: In case you have Dentin graft left after placement, or if you decide to grind the tooth and keep the graft for later use, you can certainly do so by first drying the graft prior to



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storing it in the Dappen Dish that's provided as part of the kit. To dry the graft, simply place it in your autoclave on a dry cycle, or use a hot plate. Once Dentin graft is dry, place the cap over the Dappen dish, and mark it up with the date and name of the patient. Once opened for re-use, you will need to repeat the cleansing steps (cleanser and PBS) in order to assure that any possible bacteria is removed. Alternatively - autoclave.

10. Do I grind the entire tooth? Crown, root, pulp, enamel and all?

Short answer: Yes. You will grind the entire tooth after removing any amalgam or composite during the mechanical cleaning stage.

Long answer: The enamel which is HA acts as a filler to the Dentin graft and will resorb over time without any issues. The pulp will dissolve during the cleansing step. The cleansing step will also dissolve any gingiva that might still be attached to the tooth, decay, soft tissue and organic matter.

11. Why can't I use endodontically treated teeth?

Short answer: Since it's hard to tell what type of endo fillers and sealers have been used on the endo tooth, therefore we can't guarantee that these materials do not contain toxic elements that will not be discarded by the cleanser. Therefore we prefer to indicate that endo treated teeth should not be used.

Long answer: If the dentist chooses to remove the sealer and GP from the endo treated tooth, then they can certainly use whatever remains from the tooth. Some dentists cut the crown of the tooth from the rest of its anatomy and only use that.

12. Can I use the Dentin Graft with PRF, blood, membranes and other grafts?

Short answer: Absolutely. We have documented some great cases using the above. Furthermore, we recommend that you use the Dentin graft the same way that you use any other graft. We are not asking the dentist to change anything in the way they use bone grafts.

13. Is this FDA approved?

Short answer: Yes. The product is classified as a Type 1 medical device and it is 510K exempt under FDA ruling. Manufacturing is conducted in medical grade (GMP) facilities and all consumable components undergo rigorous sterilization and inspection prior to shipping.

14. What is the particulate size?

Short answer: 250-1200 microns.

Long answer: The Smart Dentin Grinder has two separate drawers that capture the Dentin granules. The top drawer will capture particle size of 250-1200 microns that are ideal for bone grafting. The lower drawer will capture particle size of under 250 microns that can be used in conjunction with the top drawer particles in case more graft volume is required.



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15. How much graft can I get from a single tooth?

Short answer: You will get three times the volume of the tooth.

Long answer: For example, an incisor will usually generate 0.8 – 1.2 cc of Dentin graft, a pre-molar will typically generate 2 – 2.5 cc of graft and a molar would generate 3-3.5 cc of graft.

16. How much research do you have to support this concept?

Short answer: Our research spans over the last 5 years and includes both scientific studies as well as clinical studies.

Long answer: The work on Dentin as a graft can be traced as far back as 35 years ago. Research has been done by various research teams from around the world. The consensus in regards to autologous graft and ankylosis is widely reported and accepted as a gold standard.

17. Who are the KOL's that are using it?

Short answer: The list of KOL's that are using the Smart Dentin Grinder and excited about the results is growing daily. We are also actively working with a number of North American Universities and Dental Schools on a variety of studies using our protocol. Please ask your rep for specific names of KOL's that are currently using the Smart Dentin Grinder.

18. Where can I find cases, studies and additional information?

Short answer: Please go to the manufacturer website: www.kometabio.com. There you will be able to find scientific articles, research papers, published articles, clinical cases and presentations. You can also go to www.youtube.com and search the term 'Kometabio'. It will bring up demonstrations of the product as well as recorded presentations and lectures.

19. Is there an instructional document, video,...?

Short answer: We supply an instruction manual with every shipment of the Smart Dentin Grinder. You can also go to www.youtube.com and search the term 'Kometabio'. It will bring up demonstrations of the product and user guide videos.

20. What if the tooth has amalgam, composites or deep decay?

Short answer: All these elements need to be stripped off the tooth by mechanically cleaning the tooth with a tungsten bur prior to placing the tooth in the grinder. The dentist should try and get as much of it off the extracted tooth as possible. As for decay or organic elements, there's no need to eliminate it entirely. If there remain traces of decay and such – these will all be dissolved by the cleanser.

21. To what extent do I need to mechanically clean the tooth?

Short answer: Please refer to the previous question. It is important to thoroughly dry the tooth before placing it in the chamber.



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22. Can I use the disposable chamber for more than one tooth?

Short answer: Yes. As long as the teeth come from the same patient during the same visit. You can't use the same chamber to grind teeth of different people. Doing so will render the graft non-autologous. Please keep in mind that the grinding chamber can't be re-used nor sterilized. The chamber should be discarded after use for a specific patient.

23. How long do I need to wait after placing the graft before I can place implants or load implants?

Short answer: Do not change your best practices at first, but your experience will show you that with the Dentin graft you will be getting strong bone formation in a shorter time.

Long answer: Our studies have shown that the Dentin grafted site will be ready for implants and reconstruction at about half the time it would normally take with other grafts. This is contributed to the autologous nature of the graft, its strength/density, and its ability to attract progenitor cells through the Ankylosis process. Full Ankylosis (fusion) is fully established at about half the time that otherwise would be required. In other words we don't wait for remodeling and new bone formation-we wait for ankylosis which is very strong dentin-bone fusion. The remodeling will start in parallel and resorption will take about 5-6 years. Once fused, you should be ready to continue the reconstruction.