

Guided Precision Surgical Trephines

Precise, Safe and Conservative Bone Harvesting and Osteotomy Technology

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Abstract

The specific aim of this project is to evaluate and substantiate the effectiveness and simplification of the osteotomy creation process using the newly designed and engineered Guided Precision Surgical (GPS) Trephines drills for the purpose of placement of a dental implant while simultaneously collecting substantial volume of autogenous bone that otherwise would have been discarded off during the current osteotomy creation method using sequentially enlarging diameter spade drills.³

Materials and Methods

The current method of creating receptor site for a dental implant results in severe trauma to, destruction and loss of the host bone in the process. Depending on operator experience and bone type, it is very possible to oversize the osteotomy resulting in a non optimum fit of the implant causing non-integration. Occasionally there is need for hard tissue augmentation of the implant and harvesting autogenous bone from a secondary site is not without significant morbidity and risk. This study was designed to compare osteotomy creation and simultaneous bone harvesting using the newly introduced GPS (Guided Precision Surgery, Meisinger) Trephines vs. traditional osteotomy using spade drills. Use of the GPS Trephines 1) significantly simplifies and streamlines the surgical placement of implants, 2) minimizes trauma to the surgical site by using fewer instruments while simultaneously collecting vital autogenous bone in volumes larger than otherwise possible, 3) enables the harvesting of

autogenous bone from the osteotomy site eliminating/decreasing the need for a secondary donor site or the use of alternative bone grafting materials, and 4) autogenous bone, considered to be the “Gold Standard”¹ in bone grafting is invaluable in Guided Bone Regeneration² while further decreasing the costs related to performing implant therapy.

The GPS Trephine system was developed out of the need for a simplified and conservative surgical system for implant dentistry and minimize need for non autogenous sourced hard tissue grafting material.⁴ The eventual benefit would be a faster and safer method to create an ideal osteotomy while simultaneously collecting and harvesting substantial volumes of autogenous bone for grafting purpose.

The system allows the implant surgeon to accomplish the preparation of an osteotomy for the placement of an implant⁵ in only 2 steps, utilizing only 2 surgical drills irrespective of the implant system and size of the implant being used.

The system consists of a 1.3 mm pilot drill (2 pilot drills are included as part of the system package which function as guide and paralleling pins) and 5 Trepine drills of outer diameters starting with 4.0 mm to 6.0 mm in 0.5 mm increments and an autoclavable organizational bur block. The trephine allows for the capture of the bone block⁶ that is 1 mm less in diameter (representing the internal diameter of the trephine) than the osteotomy (outer diameter of the trephine).

The trephines have a parallel walled 1.3 mm central guide pin that protrudes 1 mm past the cutting ends and is flat (non cutting). The unique aspect of this system is that the entire trephine with the central guide pin is fabricated as a one piece using CAD/CAM manufacturing out of a single block of high strength metal. The parallel walls of the guide pin allow the trephine to advance along the shaft left from the pilot drill, preventing misdirection and the extended flat ended pin allows the trephine to advance to the depth defined by the pilot drill and once "bottomed out" the trephine freely rotates around its central axis without risking extension of the osteotomy's depth or width.

This was a primary study using dense plastic model mandibles, from which data obtained would be used to submit for a human trial IRB. 10 plastic mandibles were used to do a quantitative analysis of the amount of plastic salvaged during the osteotomy creation process, using 5 different proprietary implant system drilling protocols as compared to newly introduced GPS Trepine system and drilling protocol for the same diameter implants. Each mandible was designated a control (right) side and an experimental (left) side, and each Implant system were allowed 2 mandibles with a minimum of 4 osteotomy sites per implant

diameter. The drilling was carried out in sequence as per the proprietary implant system protocol⁷ on the control side and on the experimental side according to the GPS protocol.

The 5 implant systems that were compared to GPS Trephines were: Screwline (Camlog, Henry Schein Inc.), Neoss, Osteotite – straight wall (Biomet 3I), Screw-Vent (Zimmer Dental) and Replace Select (Nobel Biocare).⁸

On the control side, 4 osteotomy's for each implant diameter per implant system to a depth of 10 mm were prepared as per the proprietary drilling sequence. On the experimental side, GPS protocol was used to prepare an osteotomy for the identical diameter implant that of the system used on the control side. On the control side, the plastic bone from the flutes of the spade drills was collected per implant site and on the experimental side, the plastic bone collected from within the Trepine or detached from the surrounding plastic mandible after the completion of the osteotomy for the implant was weighted.

After implant planning and identification of the osteotomy sites as per usual manner and defined by standard of care:

Under copious external irrigation and depending on the type of bone⁹, at 750 – 1250 rpm's the pilot drill is first advanced to a depth which measures implant length+1mm, e.g. for an 11 mm long implant, a 11+1=12 mm deep pilot hole will be created. An endodontic rubber stop can be used but not necessary, similar to measurement control for an endodontic file as the pilot drill has laser cut markings at defined depths of 10 mm to 20 mm in increments of 2 mm's to define that length. A verification intraoral radiograph is taken with the pilot drill in place. If multiple side by side implants are being placed then one pilot drill can be left in

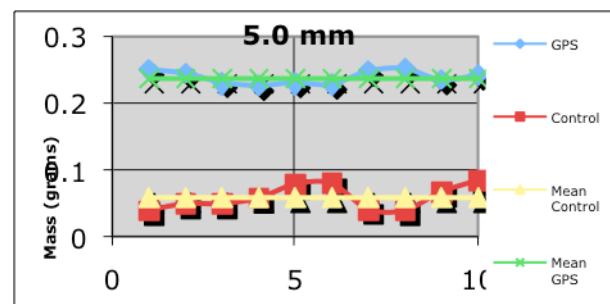
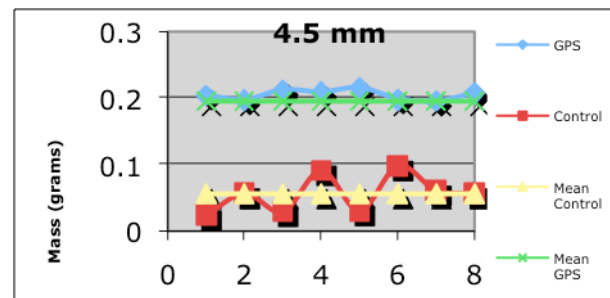
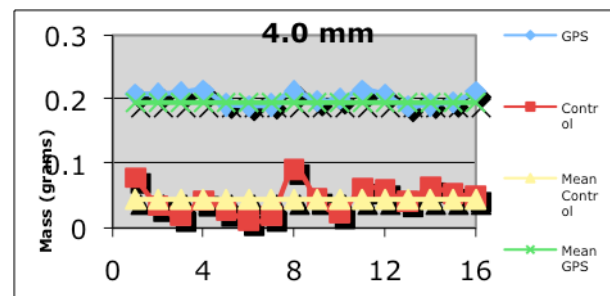
place to be used as a paralleling pin for the adjacent osteotomy.

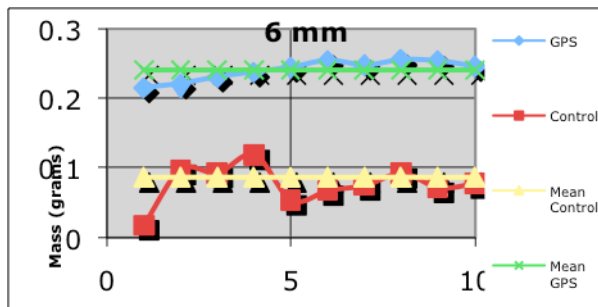
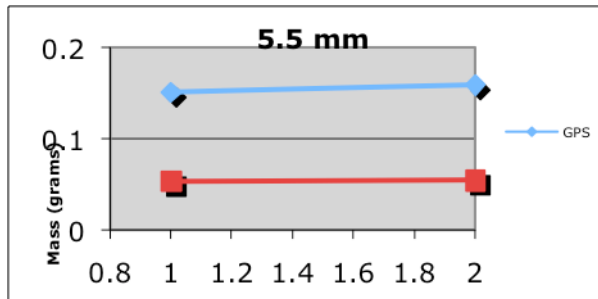
From the assortment of Trepines, one that has an outer diameter equal or no greater than 0.5 mm's narrower than the diameter of the implant planned for the osteotomy is chosen, e.g. for a 4 mm diameter implant, a 3.0/4.0 trephine will be needed (3.0 mm is the internal core diameter of the trephine and will harvest a 3 mm diameter core of autogenous bone, 4.0 mm is the outer diameter of the trephine and leave a 4 mm cylindrical hole as the trephine only has end cutting edges and is not side cutting). For a 4.8 mm diameter implant, a 3.5/4.5 trephine will be needed as the 4.5 outer core of the trephine is $> 4.8 - 0.5 = 4.3$ mm, this will allow a 3.5 mm core of bone to be harvested from the osteotomy site. Under copious external irrigation, the protruding pin of the trephine is introduced into the pilot hole and the cutting edges rested on the alveolar crest firmly. The motor is set in a reverse mode at 500 rpm and activated for a few seconds until a teeth pattern has been created on the ridge. The motor is set back to forward setting and depending on the type of bone¹⁰, under copious external irrigation at 750 – 1250 RPM's the trephine is introduced into the pilot hole and allowed to guide itself down the pilot hole until the trephine doesn't advance any further "bottoms out" and either stalls or spins around it's axis. At this time, the trephine is reversed out of the osteotomy and the bone trapped inside the trephine is slid out using the pointed end of a periosteal elevator. If the core of bone is left inside the osteotomy attached only at the base, the pointed end of the periosteal elevator can be used to free it by luxation and elevated out using a pickup or college forceps'. Upon extraction the core is best stored in either sterile water or sterile normal saline solution. The core can be used as a block graft and retained using bone screws or can be morcellated for use as a particulate graft.¹⁰

The osteotomy is irrigated and visually inspected for integrity and the intended implant is inserted as per the insertion protocol defined by the implant manufacturer. It is always recommended that the few final turns be done manually for tactile feedback as motorized insertion can apply excessive load on the osteotomy walls and may cause the implant to "spin".

The GPS osteotomy creation protocol is the same for a tapered and straight walled implants. For tapered implants, the apical discrepancy between the implant surface and the osteotomy walls will be treated by the body as a 5 walled defect and fill in naturally without any need for grafting.

Results





Discussion

The 4.0 mm GPS's controls were 4.0 and 4.3 mm diameter osteotomy's. 4.5 mm GPS's controls were 4.5, 4.7 and 4.8 mm diameter osteotomy's. The GPS protocol consistently harvested more bone than any of the spade drill systems used for control. The most consistent volume harvested was seen in the larger diameter GPS trephines, this was most likely due to the ease of removal of the core from the larger diameters than the smaller ones. Of all of the control systems used, the most amount of volume was collected from the Camlog system, while the least amount collected was from Nobel Biocare's.

Conclusion

From this study, it can be concluded that the GPS trephine system was not only able to create a perfectly sized osteotomy irrespective of the implant system it was compared with. It was able to harvest bone in volume and weight more

than two times than that with spade implant drills. Even though safety and speed were not part of the parameters being studied, it was observed that the osteotomy's were created faster and with more precision using the GPS protocol.

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