Evaluation of the Surgibit^{TM} Drill

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1 Credentials of Dr. Schmid

Attached to this report is a current edition of Dr. Schmid's curriculum vitae. The following are especially pertinent to the evaluation of the Surgibit^{TM}:

1. Since 1993, Dr. Schmid has been a Professor of Mechanical and Aerospace Engineering at the University of Notre Dame in Notre Dame, Indiana.
2. He received a Bachelor of Science in Mechanical Engineering in 1986, from the Illinois Institute of Technology, Chicago Illinois, and a Master of Science in Mechanical Engineering in 1989, from Northwestern University, and a Doctorate in Mechanical Engineering in1993, from Northwestern University, Evanston, Illinois. He is a Professional Engineer in the State of Illinois.
3. Dr. Schmid is President of Triodyne, Inc., which operates two model shops. The wood shop has 39 different types of drilling machines that represent manual and powered hand drills and braces, and stationary power drills. There are 892 drill bits in sets that include twist drills, brad point drills, augers, ship augers, spade drills, Forstner bits, hole saws and arbors, adjustable drills, barrel making drills, and push drills. These appear in many finishes, drill points, fluting styles, and shanks. The metalworking shop adds more two-drill presses and a large radial drill. The radial press accom modates a class of drill bits with a tapered shank which often terminates in a tongue.
4. He is the author or co-author of sixteen books or book chapters, including the world's most popular manufacturing textbook, *Manufacturing Engineering and Technology*, co-authored by S. Kalpakjian. His manufacturing textbooks have been translated into Mandarin Chinese, Japanese, Italian, Spanish, and Korean, with Macedonian and German translations in progress. Drilling is discussed at length in this textbook as well as a more mathematically intense book, *Manufacturing Processes for Engineering Materials*.
5. He is the author or co-author of over 130 journal or conference papers, the majority of which involve manufacturing. One of his areas of research is in forming and machining mechanics. He has won numerous research awards from the American Society of Mechanical Engineers and the Society of Manufacturing Engineers.

2 Fundamentals of Cutting Mechanics

1. This discussion is an accelerated discussion of cutting mechanics. Further information can be found in Kalpakjian and Schmid [2008, 2010] or Shaw [1984], among many others.
2. The mathematical foundation of modern cutting dates to 1941 when Ernst and Merchant stated their shear plane theory, that is, that cutting involves localized shear in order to produce chips. While a shear plane may be an extreme localization of strain, and a shear zone is possible, the statements in this section are still applicable to all general machining operations, including drilling.
3. A detailed view of an orthogonal cutting operation is shown in Figure 1.

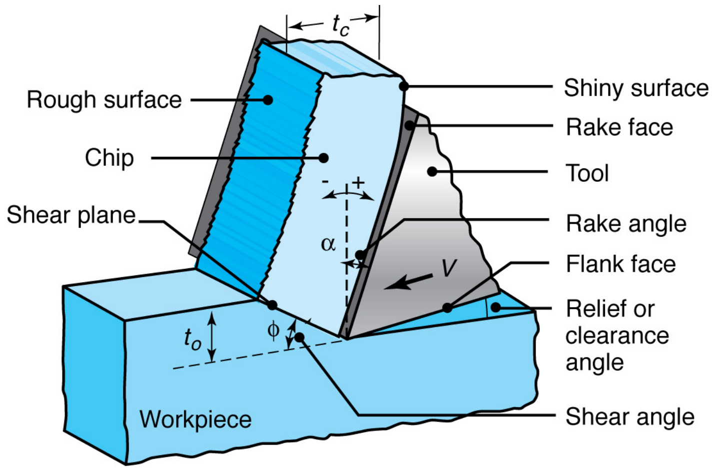

Figure 1: Schematic illustration of orthogonal cutting. *Source:* After Kalpakjian and Schmid [2010].

4. Drilling involves axisymmetric cutting, or wave removal, not orthogonal cutting where the workpiece thickness is constant. However, the mechanics of orthogonal cutting are useful to understand drilling. Figure 1 shows concepts familiar to the artisan, such as shear plane, rake and relief angles, nose radius, cutting edge radius, and chip. All of these geometric features are present in drilling.

5. One of the clear implications of the Ernst and Merchant theory is that machining is a process that involves plastic deformation. This has been demonstrated to be true, as very brittle materials such as glasses and ceramics are also difficult to machine, while materials such as aluminum, typical ductile thermoplastics, and carbon steel have good machinability.

6. One known feature of all materials is that a hydrostatic pressure enhances a material's ability to undergo plastic deformation. Using a small or negative rake angle, or a large cutting edge radius, results in increased hydrostatic pressure in machining. Smaller rake angles are specified for materials such as cast iron than for carbon steel, for example, because the associated increase in material ductility is necessary to cleanly generate chips and undamaged machined surfaces.

7. Cutting edge radius and rake angle have a similar effect for low depths of cut, as can be seen from Fig. 2. For the tool shown, note that the radius has a large effect at low depths of cut which is the case with powered drills held by hand. Note that for low depths of cut (one or two of the dashed lines representing the material surface), the rake angle is negative.

8. Figure 3 is taken from the Solutions Manual to Kalpakjian and Schmid [2008]. As can be seen in this figure, the strain needed to remove a volume of material is higher when the rake angle is low and/or the cutting edge radius is high. A larger strain also denotes a larger energy requirement, so that higher energies and temperatures are associated with low rake angles and high cutting edge radii. A similar set of curves can be generated for cutting edge radius instead of rake angle.

3 Challenges in Cutting Bone

1. Bone is a complicated, composite material, consisting of a cortical shell surrounding a cancellous bone substrate. The cortical bone is dense, with a stiffness of 11-17 GPa [Mow and Huiskes 2005] and ultimate strength of 130-190 MPa. Trabecular bone is more compliant, with a Young's modulus of 3-5 GPa and an ultimate strength of 130-150 MPa [Galante and Rivero 1985]. Bone is a brittle substance of

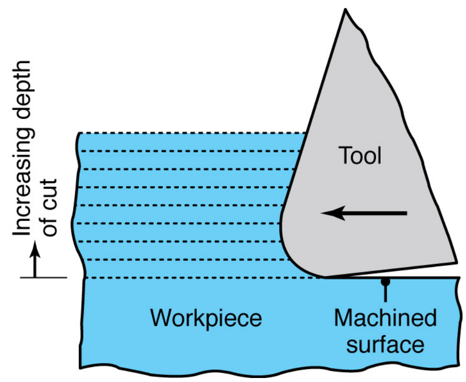

Figure 2: Illustration of the effect of tool radius on rake angle as a function of depth of cut. Note that for a powered drill that is hand held, the depth of cut will be low, so that a large tip radius results in a negative rake angle. *Source:* From Kalpakjian and Schmid [2010].

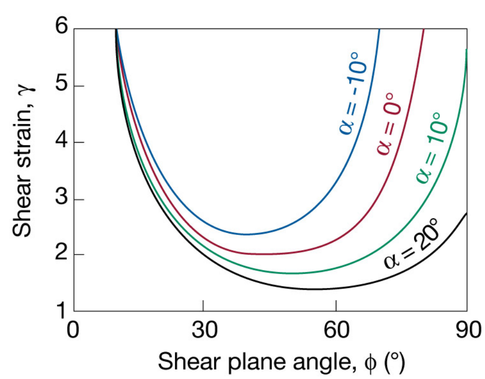

Figure 3: Strain on the shear plane in orthogonal cutting as a function of rake angle, α, and shear plane angle, ϕ.

varying density (depending on age, vitality and gender of the subject). Recognizing that cutting and drilling requires material ductility, chipping and fracture of bone during drilling is a major concern.

2. The brittle nature and high stiffness of bone, especially the cortical shell, can also lead to various drill types locking with the bone, especially as the drilling process begins. When a drill locks, its speed is reduced dramatically and is essentially zero within a very short period of time. At low speeds, motors generally produce high torques; when a drill bit binds or locks on a substrate, the full stall torque of the motor is brought to bear against the drill bit and breakage can result.

3. Bone is very sensitive to heat. Bonfield and Li [1968] showed that temperatures over 50°C are associated with irreversible changes in the structure and physical properties of bone and thus can significantly affect the structural integrity of associated drilled holes. Ardan, et al. [1957] reported cortical necrosis and delayed healing in a canine model after heating above 43.3°C. Natali et al. [1996] measured the temperatures at a distance of 0.5 mm from the cutting edge and found this threshold was routinely exceeded.

4. Huiskes [1980] suggests peak temperatures greater than 70°C results in irreparable damage in bone. Huiskes also defines a thermal damage factor:

$$\Omega = A_1 \int_0^t \frac{-A_2}{\exp\left[T(x,t)\right]} dt$$

where Ω is the thermal damage factor, $T(x,t)$ is the transient temperature distribution, and A_1 and A_2 are constants with $A_1 = 8.013 \times 10^{62}\ \mathrm{s}^{-1}$ and $A_2 = 4.865 \times 10^4\ \mathrm{K}^5$. Huiskes found that irreparable damage occurs whenever $\Omega > 1$, which can occur for short exposure to high temperatures as well as prolonged exposure to moderate elevated temperatures. The Huiskes damage factor does clearly indicate that efficient drilling is needed in order to reduce peak temperatures and simultaneously minimize exposure time.

5. Damaged bone will be resorbed by the body, which in turn loosens implants depending on the bone for fixation. For this reason, it is essential that temperatures during drilling be minimized to avoid thermal necrosis.

6. Additionally, a surgeon is often required to drill at various angles on a highly curved and irregular slippery surface to achieve the surgical objective. This can be difficult as the drill tip will often "walk" or "skive" off the bone and may result in adjacent soft tissue damage, improper placement of the drill hole or a hole that does not meet the intended requirements.

7. With metals, an indentation is produced by striking a sharp punch onto the surface to create an indentation that centers the drill when the hole is started. With bone, such centers cannot be used because the material lacks ductility. Instead, a common approach is to drill out a pilot indentation with the drill oblique to the surface, and then the drill is raised to the desired angle. This may lead to the unnecessary removal of bone stock which can decrease pullout strength, have a negative effect on defect healing or even require a larger guage screw than was otherwise intended or supplied, adding to wastage, pain and suffering and rehabilitation. This process of angling the drill can also result in drill bit breakage as a bending moment occurs with this procedure.

8. Sometimes unicortical fixation suffices, but many bone screws use bicortical fixation so that a hole must be drilled through the cortical layer on both sides of the bone. Standard drill bits will attempt to walk or skive along the far cortex (although admittedly less than the first cortical hole attempt) and will put a significant bending moment strain on the drill bit, often causing it to break. If the drill walks at all, so that the far cortex hole is not in-line with the first hole, a bending moment is produced during drilling. This is often not perceived by the surgeon, so that bending failure of the drill is not an uncommon occurrence. Even if a far cortex hole is secured with such a drill bit it is often improperly aligned and will make effective purchase of a screw difficult.

9. Drill bit breakage is a widespread issue; Price et al [2002] report that drill breakage accounts for the largest proportion of instrument failure in orthopedics; their study of procedures conducted over two years included seven cases where "the broken bit of the surgical instrument was left in the patient. Documentation of this peri-operative complication was deficient, and the patient was often not informed." It is expected that drill breakage will become even more common in the future, since the population of orthopedic implant patients is becoming larger and first users are becoming younger [Biocrossroads 2009].

4 Evaluation of the Surgibit™ Drill

The Surgibit drill has been specially designed to overcome the inadequacies described above and is uniquely positioned as a true bone drilling device. Its key attributes are:

1. The drill utilizes a sharp pyramid point that allows the tip to fix on the targeted entry location and prevents walking of the drill across the bone. Such is the effectiveness of this special pyramidal point that angles of drilling up to 60° can be achieved without risk of significant skiving off the target. This ensures that a true and correct hole is made for the right screw without concern about compromising the integrity of the hole or screw purchase.

2. Misalignment of far cortex holes are virtually eliminated by the sharp point as well, as are bending moments of the drill bit within the cortex. The direct consequences of this are proper implant placement and reduced risk of drill bit breakage.

3. Drill tip breakage is further minimized by the unique pyramidal tip design [Bertello, et al. 2008]. Instead of a chisel or near-chisel cutting surface at small radii like other drills, the Surgibit™ uses a triangle-based pyramid tip at the drill end. This geometry provides greater stability under higher torques and simultaneously reduces the tendency for the drill to break or lock into the material being drilled.

4. Unlike other drills, the cutting edge in the Surgibit™ varies as a function of radius. This is a significant feature of the Surgibit™ which presents higher cutting edge radii nearer to the drill axis. In effect, it applies a larger hydrostatic stress at small radii and thus increases the energy required to remove a given volume of material, also known as specific energy. The effect of a hydrostatic stress on the shear plane will induce greater ductility in the workpiece, in that it inhibits fracture. This is well-known in metal cutting, where a larger rake angle is used for machinable alloys such as aluminum, but smaller and even negative rake angles are prescribed for cast alloys [Kalpakjian and Schmid 2010]. The effect is to produce cleaner cuts without fracture or chipping of the bone.

5. Further, since the cutting geometry is better defined, the forces and energy requirements are lower and more controllable; while the specific energy is higher, cutting takes place in a smaller stressed volume than if repeated fracture is the cutting mechanism. As a result, the unique design of the Surgibit™ brings into effect cutting geometry and workpiece behavior changes which result in more efficient cutting (and associated lower apparent friction), as well as less thermal exposure to the bone.

6. The gradual change in geometry means that less specific energy is needed at larger radii. However, the feed rates are small at the large radii, because of the sharp point and oblique direction of cut. Thus, the result is a clean cut in bone at all radii.

7. The Surgibit™ also has a gradual transition between its drill flute and its concave surface, which enhances debris removal and is another inherent benefit.

5 Conclusions

Based on my experience and training, as well as a review of the Surgibit^{TM} product, I can conclude:

1. The Surgibit^{TM} is a new and improved technology that provides a drill bit that efficiently drills into brittle substrates, such as bone. From a cutting mechanics standpoint, the geometry accomplishes improved drilling by requiring higher specific energy at the the cutting edge close to the tip and providing a lesser amount of energy at larger radii.

2. The triangular based pyramidal tip is better suited to withstand torque without failure than two fluted-drills and thus is less likely to fracture during surgery.

3. The superior stiffness qualities of the Surgibit^{TM} three-fluted configuration provide for greater resistance to bending moments while in use and again lessens risk of drill bit breakage.

4. The Surgibit^{TM} is better suited for accurately initiating drilled holes in bone in the desired location and in the desired orientation than other conventional drills.

5. The geometry is such that chipping and fracture of the cortical bone is less likely, due to the radii and small rake angles used in the Surgibit^{TM}, especially in the vicinity of the tip.

6. The Surgibit^{TM} demonstrates clear improvements and advantages over convential orthopaedic drills.

6 References

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