CHAPTER 53

THE EVOLUTION OF A THIRD GENERATION SCREW

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Since Danis pioneered the concept of primary bone healing,[1] surgeons have continuously sought improved methods for the rigid fixation of separated bones in order to promote rapid and predictable healing. Primary bone healing consists of the simultaneous formation and remodeling of bone at the fracture site, thus obviating the intermediate phase of fibrocartilage as seen in local bone callus production.[2,3] The concept of rigid internal fixation, as advocated by the Swiss AO group (Association for the Study of Internal Fixation - ASIF), has remained unchallenged over the last half century as a vital factor to be considered when repairing fractures or osteotomies. Exactly how rigid fixation is accomplished remains an evolving technology.

The screw has remained the device of choice for rigid internal bone fixation. Although there have been several unconventional screws developed (eg. Herbert screw by Zimmer, Accutrak screw by Acumed, Ideal Compression Screw by Newdeal, SPIN snap-off screw by Newdeal, Orthofix Screws), other than the cannulated screw, there have been only limited challenges to bone fixation screw design and placement as were meticulously developed by the Swiss AO/ASIF group. In order to do so, several "principles" — some can be termed "myths" — need to be challenged so as to free designers to explore new ideas for improvement.

CHALLENGES

The first challenge is to the classification of screw threads as cortical or cancellous. The shape or the pitch of the thread is not a dogmatic consideration as long as the thread can be embedded in the hard enough bone — any bone — and produce adequate compressive forces.

A secondary challenge is the requirement for "two threads" to extend beyond the distal cortex to achieve good purchase. Again, as long as the threads can engage into the opposite cortex so the tip is flush with the far surface and gain adequate compression, it is not necessary for any threads to protrude past that surface.

Third, it is not so much a myth that a "cannulated" screw is weaker than a solid screw as whether the bending and torsional strength difference is clinically significant. In other words, there is no doubt that the cannulated screw is weaker than its non-cannulatd counterpart, but clinical experience has shown that the decrease in strength is of no practical significance in bone fixation. Further design modifications, however, can improve the compression produced by existing cannulated screws.

A fourth challenge is to improve the ability of the threads to engage the bone and increase compression or purchase strength. It is not so important to use a "buttress design" to maximize the volume of bone in between threads as in the Synthes screws,[4] as it is to make the threads into a very sharp 'V' cutting edge ("symnetric design") and to maximize their width-to-core ratio (Figure 1).

A sharp thread edge can allow for much better cutting or self-tapping through virtually any type of bone whether it is cancellous, cortical or sclerotic. Instead of using an "electro-polish" technique to chemically deburr the screw and thereby degrade the thread quality, the cannulated screws can be individually machine-polished to increase thread-sharpness. This also allows for self-tapping screws to be made with a cancellous pitch, since the threads can engage so well. The result is minimal bone removal when placing the screw.

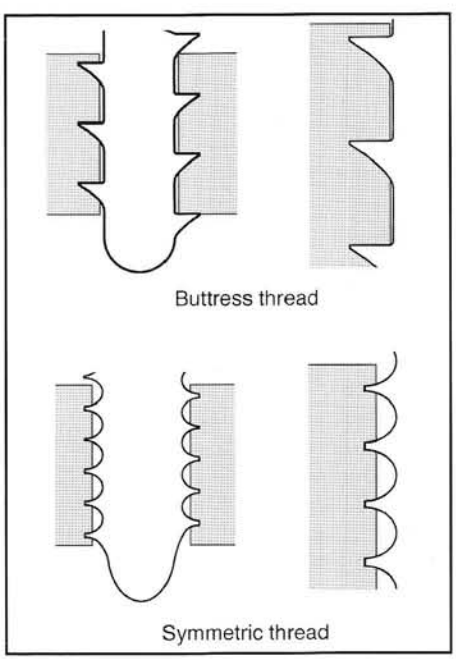

Figure 1. Buttress Thread vs. Symmetric Thread.

Trying to keep the minor (core) diameter as small as possible helps leave a larger surface area across which the thread can transmit compression. This can be challenging for cannulated screws without decreasing the bending strength of the screw. (This is done by limiting the cannulation to ? the shaft diameter.) However, the strength of the metal alloy is so great, that such a loss is not clinically significant.

LAG TECHNIQUE

The lag technique is still recognized and accepted as central to the rigid internal compression of bone for optimal primary healing,[1-4] It consists of creating compression across the contact surfaces of two pieces of bone by drawing the far fragment tightly against the near fragment. The greater the compression, the more secure the environment for primary bone healing. For this to occur, the screw must glide through the hole in the near fragment and firmly engage in the far fragment.

The concepts of tension-compression and reaction forces are important to understand for screw biomechanics. Compression is produced by the reactive tension forces of the head of the screw on one side against the engaged threads on the other (Figure 2). All threads must cross the osteotomy or fracture site to generate compression.

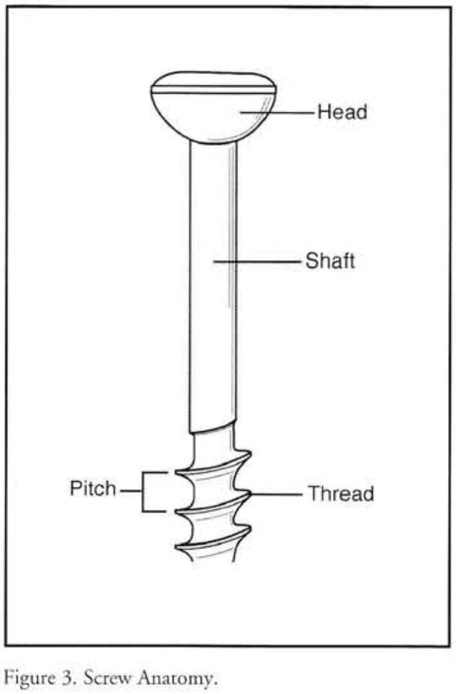

Figure 3. Screw Anatomy.

SCREW ANATOMY

Although, there are numerous terms to describe he various anatomical parts of a screw, it is composed of three segments: head, stem or shaft, and thread. The thread pitch is the distance between successive threads; however, a screw is defined by its thread diameter (Figure 3).

The core or stem is measured by its thread "minor diameter." More important is the thread to minor or core diameter ratio (Figure 4). In cortical screws, there is a small pitch and low thread to minor diameter ratio. In cancellous screws, there is a higher pitch and a high thread to minor diameter ratio.[5]

The thread length is important because the longer the thread length, especially in a partially threaded screw, the more surface area to generate tension-compression. Similarly, the head of the screw must be broad enough in diameter to produce adequate tension-compression, even if it is modified into a low profile.

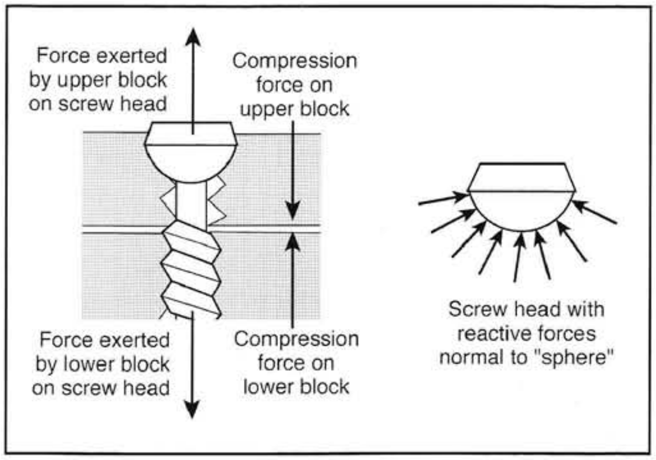

Figure 2. Compression and Reaction Forces in a Lag Screw.

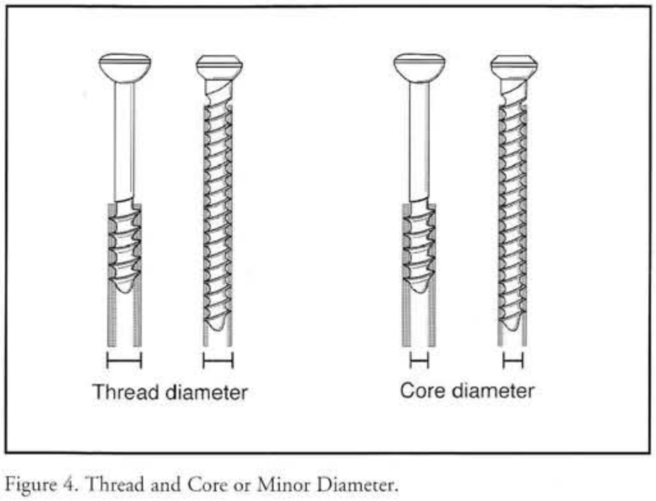

Figure 4. Thread and Core or Minor Diameter.

SCREW COMPOSITION

Various metal alloys are available for screws. The most common is the Swiss-developed 316L type surgical stainless steel which is a chromium nickel molybdenum steel alloy.[6] Although generally compatible with tissues, its one drawback is that an occasional patient will have an allergic reaction to the nickel component. It also interferes with MRI scans. The 316L stainless steel remains a good choice due to compatibility, cost, reliability, consistency and availability.

Titanium (e.g., Ti6A14Veli) has the advantage of no nickel component and there is no MRI interference. However, the increased cost and sporadic supply make it an expensive alternative, in spite of its advantages. Cannulated bone screws are individually machined and are not mass-produced like hardware-store screws.

THIRD GENERATION DESIGN

There are several modifications that would improve the performance of the cannulated screw.

Screw Sizes

Using a cortical thread design, one that has sharper threads with maximum thread surface area for compression, permits the production of 2.0, 2.5 and 3.0 mm. Cannulated screws. These have the advantage of fixating small bones or fragments with very good compression strength. They can also be used in situations where two small screws can provide better, more dissipated compression at the head than one large screw. The result is less risk for stress fracture of the proximal cortex. Screws with a cancellous thread pitch are available in sizes 3.5, 4.0, 4.5 and 6.5 mm (Figure 5).

Material Selection

Except where lack of MRI interference is important or when a patient has a known nickel allergy (e. g., costume jewelry), the preferred screw composition is the 316L stainless steel. Otherwise, titanium screws are available on an "as-needed" basis.

Thread Design

Dramatic improvement in screw purchase strength is obtained by maximizing thread surface area and providing sharp cutting edges. Additional purchase strength can be achieved by increasing the length of the threaded portion of the screw. This is a delicate balance since threads across the fracture or osteotomy site will prevent compression.

Tip Design

Improved self-drilling and self-tapping capability is the result of three cutting tips shaped like parts of a drill bit and superimposed on the thread itself. For effective implanting, all three tips must be engaged simultaneously. This helps cut through bone of almost any density.

Head Shape

First generation and some second-generation screws have a head shaped like a hemisphere to dissipate the transmitted reactive compression forces. Using a relatively shallow head reduces its prominence under the skin and results in less loss of cortical bone during countersinking. Designing a shallow head must be balanced against adequate width to dissipate compression forces and sufficient depth to accommodate the driver shape. The hexagonal driver requires significant depth and this must be further accommodated by cannulation width. Larger diameter requires a larger screw head for sufficient depth to engage the driver. This sometimes requires a delicate compromise (e.g., 2.5 mm screw).

Figure 5. Vilex Screw Sizes.

00mm	Lengths range	Increment	Guide wire	Thread type
2.0	6-21	1	1.6/0.9	cortical
2.5	6-30	2	2.5/1.1	cortical
3.0	6-40	2	2.5/1.1	cortical
3.5	10-50	2	2.5/1.1	mixed
4.0	20-40	2	2.5/1.1	cancellous
4.0	40-60	5	2.5/1.1	cancellous
4.5	20-60	2	3.5/1.1	cancellous
4.5	40-60	5	3.5/1.1	cancellous
6.5	60-120	5	3.5/1.6	cancellous

Cannulation

Because guide wire diameter determines its stiffness, it is important for the cannulation to accommodate as much width as possible. This width helps prevent the pin from bending when it is inserted. If the pin is bent upon placement, the screw cannot be guided along a curved path and as a result the screw may break, the wire may break, or the bone may shatter.

If the cannulation is too wide, it can detrimentally reduce the compression surface area on the threads. (In other words, the thread to core ratio is reduced.) It can further leave the screw weak. The larger the cannulation width causes a reduction in metal area and a reduction in bending resistance.

Using standard guide wire diameter sizes is both practical and cost effective: 0.035 " (0.9 mm), 0.045 " (1.1 mm), 0.062" (1.6 mm).

Driver Mechanism

Selecting the hexagonal design for driver engagement has several advantages. It provides six surfaces with which to produce torsion, while solidly engaging the screw head. Although a triangular shape may transmit forces more efficiently in small screws, using standard-sized hexagonal heads allows interchange with other fixation systems to insert or remove screws in emergency situations. The 2.0 screws use the 1.6 mm hexagonal driver; 2.5, 3.0, 3.5, 4.0 use the 2.5 mm hexagonal driver.

Figure 6. Stength Comparisons.

	Case 1 <u>**Vilex**</u>	**Case 1** <u>**Synthes**</u>	**Case 2** <u>**Vilex**</u>	**Case 2** <u>**Synthes**</u>	**Case 3** <u>**Vilex**</u>	**Case 3** <u>**S&Neph**</u>
Thread OD	3.5	3.5	4.5	4.5	4	4
Length	18	18	20	20	20	20
Thread length	7.6	6	7	7	7	8
Head	5.2	5	6.5	6.5	6	6
Minor Diameter	2.2	2.5	2.6	3.1	2.3	2.7
Pitch	1.2	1.25	1.75	1.75	1.75	1.75
Cannulation	1.1	1.35	1.1	1.75	1.1	1.6
Compression area (mm2)	147	91	170	134	135	125
% Improvement	63%		27%		8%	
Bending Moment Factor	0.94	0.91	0.97	0.9	0.95	0.88
% Improvement	2%		8%		8%	

	Case 4 <u>**Vilex**</u>	**Case 4** <u>**Instratek**</u>	**Case 5** <u>**Vilex**</u>	**Case 5** <u>**Instratek**</u>	**Case 6** <u>**Vilex**</u>	**Case 6** <u>**Osteomed**</u>
Thread OD	3	2.75	3.5	3.5	3	3
Length	22	32	22	22	22	22
Thread length	9.4	9.3	9.4	7	9.4	7.5
Head	4	4.9	5.2	5	4	4
Minor Diameter	2.1	2.3	2.6	2.6	2.1	2.2
Pitch	1	1	1.25	1	1	1.1
Cannulation	1.1	1.75	1.1	1.75	1.1	1.2
Compression area (mm2)	136	66	162	121	123	89
% Improvement	103%		34%		52%	
Bending Moment Factor	0.95	0.66	0.97	0.79	0.95	0.91
% Improvement	43%		22%		4%	

Length-Measuring Technique

The guide wire serves three functions: temporary stabilization of the osteotomy/fracture, guiding the screw through the bone, and for measuring the required screw length. The screw lengths are measured from tip to tip. As a result, once the guide pin is in place, the measurement should be taken before countersinking. This allows the surgeon a certain amount of latitude as to how deep to countersink for the given situation.

Countersinking Approach.

The more angulated the placement of the screw through the bone cortex, the more difficult the cannulation. For hard bone or steep angles, use of the power countersink is advised. Whether hand or power, there is only one countersink to accommodate the shallow screw head for sizes 2.0 through 4.0.

Performance: Pull Strength, Compressive Forces
Figure 6 illustrates some comparison data for various cannulated screws.

Simplicity

Minimal instrumentation to accomplish a four-step procedure illustrates the simplicity of the third-generation cannulated screw. The steps are: 1) drive the guide wire; 2) measure; 3) countersink; 4) implant the screw.

CONCLUSION

By scrupulously analyzing each factor in screw design, the improvement is dramatic and measurable. Some factors cannot be calculated. They include simplicity of design that reduces to only four the number of steps for screw placement, use of a minimum number of instruments and generous screw selection. Instrument interchange with other systems and the use of standard guide wires adds to the efficiency.

Increased cost of the cannulated screw over the solid screw can be justified. The simplicity of the instrumentation, reliable screw purchase, and ease with which a surgeon can complete a procedure substantially reduce the trauma to the patient and cut the time to complete a procedure. Third generation screw systems enable the surgeon to achieve consistent results in the most difficult situations.

REFERENCES

1. Danis R. *Theorie et Practique de l'Osteosyntheses.* Parts, Masson & Cie, 1947. p.9
2. Perren S, Cordey J. *The Concept of interfragmentary strain.* In Uhthoff, K, Stahl E editors, Current concepts of internal fixation of fractures. Berlin: Springer-Verlag;1980. pp. 63-77.
3. Schenk R. *Histology of fracture repair and non-union.* Bern, Switzerland: Buchdruck-Offset; 1978. pp.14-28.
4. Muller M, Allgower M, Willenegger H. *Techniques in internal fixation.* Berlin: Springer-Verlag; 1965. p.3.
5. Muller M, Allgower M, Willenegger H. *Manual of internal fixation.* New York: Springer-Verlag; 1979. pp. 1-289.
6. Willenegger H. Medical and scientific directives. In Sequin F, Texhammer R, editors. *AO/ASIF instrumentation, manual of use and care.* New York: Springer-Verlag; 1981. pp 1-168.