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New Geometry Improves Handling of Self-Drilling IMF-Screw

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Introduction

Intermaxillary fixation (IMF) has established itself as the supplementary method for the treatment of fractures and/or correct occlusion adjustment in the jaw area. Developed specifically for such applications, many companies offer IMF screws of different types.

MEDARTIS has introduced its self-drilling IMF-screw in 2005 and has had both excellent clinician's feedback as well as good clinical outcome. Crucial for good in-vivo performance are ease of handling and soft tissue preservation. For the surgeon this primarily means screw-in behavior as defined by the following properties:

- Axial force necessary for the screw's initial grip in the bone; the lower the gripping force, the easier the screw can be controlled.
- Torque needs to drive the screw in: a lower torque means easier screw insertion.
- Work required to drive the screw to a defined depth: reduced work results in less fatigue for the surgeon.

Ideally, all of these should be minimized. While gripping force is dependent on the tip design, torque (and hence work) can be influenced by changing the screw's cutting edge or by changing the screw's diameter. However, a reduced diameter significantly reduces the screw's overall strength and is therefore not an option.

MEDARTIS has addressed these challenges with the development of its new IMF-screws featuring the patented SpeedTip.

Method and Materials

Testing was carried out on a Zwick universal testing machine with two axes for independent control of force (z-axis) and torque (rotation) at the Zwick testing facility in Ulm, Germany.

All experiments were carried out using custom made laminated Sawbones material as bone substitute: an outer 3 mm-layer of high-density Sawbones (50 pcf) was used to simulate cortical bone, while 10 mm of average density material (20 pcf) was used to approximate human cancellous bone. The following screws (Ø = 2.0 mm, length= 14 mm) were compared:

- 'Standard': MEDARTIS self-drilling IMF-screw M-5144.14
- 'SpeedTip': MEDARTIS self-drilling IMF-screw M-5148.14
- 'Competitor': Self-drilling IMF-screw of a leading competitor

Gripping force was determined by starting at an initial load of 1 N, rotation was applied at a rotational speed of 80°/s. Successful 'grip' was established when insertion was >0.5 mm. If grip was not achieved after four full rotations, load was increased.

Torque measurements were carried out with an axial load of 5 N and a rotational speed of 80°/s. Screws were inserted at least 11 mm.

Results

Figure 1 shows the different screw's gripping force. The MEDARTIS screws with their sharp tips outperform the competitor by a ratio of more than 3 to 1.

Figure 2 shows the screw insertion torque and illustrates two of SpeedTip's advantages: 'normal' tip and thread designs will lead to constant or even increased driving torque for longer screws. With SpeedTip, driving torque remains constant and low once the hard cortical bone has been cleared. SpeedTip not only leads to low insertion torque, but also gives the user excellent feedback as to to the tip's actual position in the bone.

Figure 3 shows cumulated screw insertion work required for the different screws. It demonstrates again that SpeedTip offers a significant advantage over conventional screw designs especially for longer screws. Figure 4 shows cumulated insertion work for a depth of 8 mm and 11 mm corresponding to the MEDARTIS standard lengths for IMF-screws.

Conclusion

Compared to a leading competitor's and to the MEDARTIS Standard IMF-screw, the new MEDARTIS SpeedTip leads to significantly reduced gripping force and insertion work. This means both better control and less fatigue for the surgeon. Due to its patented design, torque does not increase linearly with screw insertion depth. Hence, tactile feedback regarding bone quality is guaranteed even for long screws.

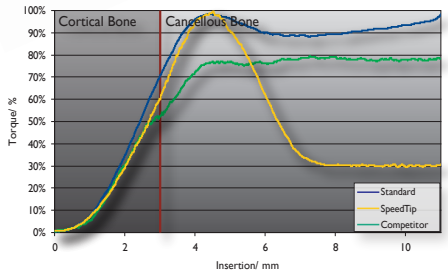

Figure 2: *Screw Insertion Torque*

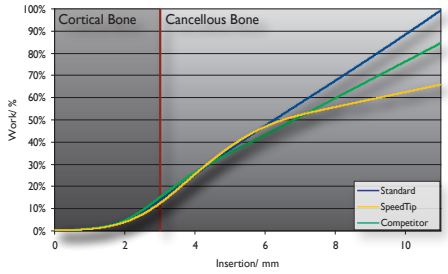

Figure 3: *Cumulated Screw Insertion Work*

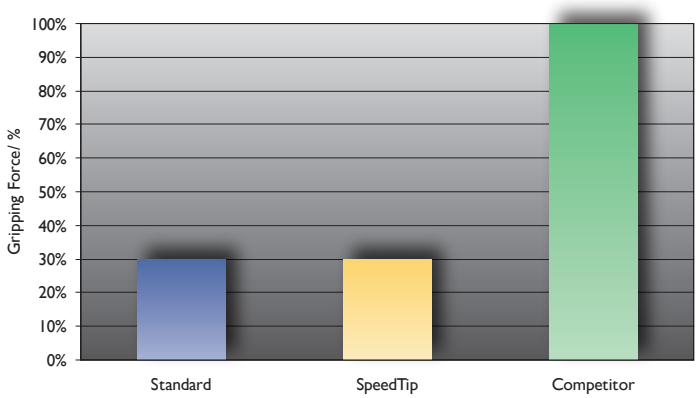

Figure 1: *Screw gripping force*

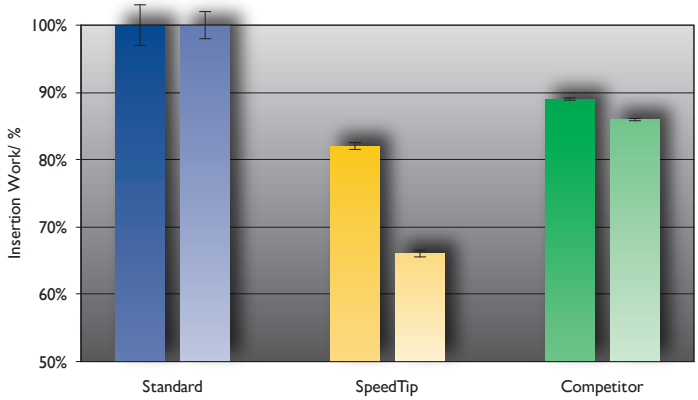

Figure 4: *Cumulated screw insertion work at 8mm (dark) and 11mm (light)*