Introduction of 3.5mm and 4.5mm cortex screws into the equine distal sesamoid bone with the help of the VetGate Computer Assisted Surgery Systems and comparison of the results with the previously reported ones, acquired with the SurgiGATE 1.0 System – an in vitro study

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Summary: The in vitro experimental study was performed to evaluate the functionality and accuracy of the VetGate Computer Assisted Surgery (CAS) System and compare the results with those achieved with the SurgiGATE System previously reported. On ten cadaveric equine limb pairs free of major phalangeal pathologies (n=20) either a 3.5mm or 4.5mm cortex screw was inserted in lag fashion across a virtual midsagittal fracture of the distal sesamoid bone under real-time supervision by the VetGate CAS-System. Care was taken to avoid penetration of the distal interphalangeal joint and the navicular bursa, as well as avoid damage of the articular cartilage. The placement within the bone was perfect for all 20 screws. The results for the 3.5mm screws were good in all aspects, whereas the screw head of the 4.5mm screws jeopardized the edge of the articular surface of the navicular bone in 8 out of 10 cases. The difference between the screw length determined by the VetGate system during the planning phase and the actually inserted screw length was significantly smaller than with the one experienced with the SurgiGATE 1.0 CAS-System. In conclusion standard 4.5mm screws are not feasible in Thoroughbreds and Warmblood horses of average size, mainly because of the screw head that is too large (8mm), whereas 3.5mm cortex screws serve the purpose very well. The use of the 4.0mm cortex screws is preferred because this screw has the same screw head diameter as the 3.5mm cortex screw and a thicker core diameter, which makes it more resistant towards implant breakage. The latter screw was not tested, but even 4.5mm cortex screws could be inserted without damaging any vital structure. The VetGate CAS-System allows precise screw placement at this difficult location without damaging neighboring structures.

Keywords: Computer-assisted surgery, distal sesamoid bone fracture, osteosynthesis, screw placement, screw head size, passive optic aiming device.

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Introduction

Fractures of the distal sesamoid (navicular) bone are rare causes of lameness in the horse. The forelimbs are more commonly affected (Wintzer and Dämmrich 1967, Reeves et al. 1989). Four different fracture types are distinguished: avulsion fractures of the distal or proximal margin, simple sagittal and parasagittal fractures of the body, multifragment fractures, and fractures along the frontal plane of the bone. Avulsion fractures are often associated with clinical signs of palmar foot syndrome, an osteoarthritic syndrome (Fürst and Lischer 2006). The simple vertical or slightly oblique fracture line running in a parasagittal plane is the most common manifestation of distal sesamoid bone fractures diagnosed (Fürst and Lischer 2006).

Non-surgical therapy involves application of elevated heelshoes and quarter clips to reduce hoof expansion and excessive pressure onto the bone. Initially the patients are kept in a stall. All fractures of the distal sesamoid bone have a poor prognosis for the patient to enter an athletic career or return to it because healing occurs usually by a fibrous union. The failure of bony union is probably caused by continuous instability and micro movement of the fracture fragments (Wintzer and Dämmrich 1967, Wyn-Johnes 1985, Fürst and Lischer 2006). Even after several months of stall rest, slight to moderate lameness persists and a palmar (plantar) digital neurectomy may turn out to be the only option to relieve signs of pain associated with the fracture. Occasionally, adhesions between the deep digital flexor tendon and the fracture region develop. Radiographically the fracture line persists for many years. The typical features of a delayed union including persistent and possibly widened fracture line, new bone formations at the bone edges, etc. are apparent within several months (Wintzer and Dämmrich 1967, Wyn-Johnes 1985, Lillich et al. 1995). Prolonged confinement of the hoof with side clips or a cast inhibits foot expansion during loading and

eventually leads to a contracted foot, which may subsequently give rise to other clinical problems (Wintzer and Dämmrich 1967, Wyn-Johnes 1985).

Insertion of a single cortex screw in lag fashion along the transverse axis results in interfragmentary compression, which may lead to complete fracture healing in some horses. Screw insertion using conventional surgical technique demands extensive radiographic or fluoroscopic monitoring and a specially developed drill guide (Nemeth and Dik 1985, Auer 2006). Computer Assisted Surgery (CAS) has been reported to increase surgical precision (Laine et al. 2000, Bathis et al., 2004, Sikorski and Blythe 2005). However, the system used by Gygax et al. (2006) had several shortcomings that had to be solved (a large number of cables near the surgical field, which jeopardized aseptic technique; no data reference base attached to the drill sleeve, which reduced precision of drilling).

The goals of this study were: 1. to evaluate the practicality of the newly developed VetGate CAS-System for the implantation of 3.5mm and 4.5mm cortex screws along the long axis of in situ cadaveric distal sesamoid bones with a virtual midsagittal distal sesamoid bone fracture; 2. to establish potential discrepancies in orientation between the pre-planned screw hole axis and the actual screw axis after implantation, and 3. to compare the results reported earlier with SurgiGATE 1.0 System with those achieved with the VetGate CAS-System.

Materials and Methods

Cadaveric Limbs

Five equine cadaveric limb pairs ($n=10$) of horses culled for reasons other than musculoskeletal disease, collected at the Equine Hospital of the University of Zurich and the Equine Clinic Niederlenz, were used. The limbs were disarticulated at the carpometacarpal and the tarsometatarsal joint respectively. Because of the difficulties and inconsistencies in creating artificial fractures, a virtual midsagittal fracture was assumed for all samples.

Technical Equipment

The standard instruments for screw insertion in lag fashion were used in this study (DePuy-Synthes GmbH, Solothurn, Switzerland). The isocentric C-arm Arcadis Orbic 3D (Siemens Healthcare, Erlangen, Germany) was used for diagnostic imaging. The VetGate CAS-System used in this study was a custom-made (ARTORG Center for Biomedical Engineering Research, University of Bern, Bern, Switzerland). The system works with a passive, or indirect optic tracking system (Polaris Spectra, Northern Digital Inc., Waterloo, Ontario, Canada). The tracker (Fig. 1A) emits infrared light, which is reflected by retro-reflecting marker balls connected to the bone (Fig. 2) to be treated and selected instruments used for screw insertion and picked up by two cameras (Fig. 1B) of the tracking system. At least three marker balls (BrainLab, Feldkirch, Germany) arranged in a unique configuration relative to each other (angle and distance) are attached to the objects to be navigated, such as hoof (Fig. 2), drill, drill sleeve, drill calibrator and C-arm. The SurgiGATE 1.0 worked with an active optic tracking system, where the instruments were tracked with infrared light emitting diodes. The drill sleeve was not navigated in this system (Andritzky et al. 2005, Gygax et al. 2006, Rossol et al. 2008). This system is not available anymore and the remaining one is not professionally serviced any more. The room position of every marker can be identified relative to the camera. The planning and navigation software is based on the Open Source Framework MARVIN (Rudolph et al. 2008).

Surgical Procedure

The two limbs of each pair were randomly assigned to one of two groups: One to the group where a 4.5mm cortex screw was implanted along the center of the distal sesamoid bone and the other to the group where a 3.5mm cortex screw was inserted.

Fig. 1 The VetGate Tracker/camera system; A: infrared light emitting source; B: camera (there is another one on the other side of the horizontal beam); C: VetGate computer; D: screen.

Fig. 2 Dynamic Reference Base (DRB) attached to the hoof tip showing the light reflecting balls at a specific configuration. The DRB used for the different instruments (drill guide, drill, calibration tool and bone) have different configurations of the reflecting balls for the computer to distinguish among them.

The frozen limbs were solidly fixed with the medial side up in a vice on an exchangeable carbon platform attached to the surgical table. The carbon platform was used as an x-ray penetrable extension of the surgery table. The Dynamic Reference Base (DRB) with its marker-balls was attached with the help of a specially designed clip (ARTORG Center for Biomedical Engineering Research, University of Bern, Bern, Switzerland) to the sagittal tip of the hoof capsule. After two orthogonal fluoroscopic images of the hoof to assure that the anatomic structure of interest was centered well under the C-arm, the 3D imaging was started. The pertinent data of the patient, or in this case the sample number, were entered into the system followed by scanning of the hoof region. The acquired data were shown on the monitor and subsequently transferred to the navigation computer, where the hoof structures could be observed in three orthogonal planes (lateromedial, dorsopalmar/-plantar, and transvers). The contrast of the distal sesamoid bone could be adjusted in a step-less mode between bone-window and soft part-window.

In the planning mode of the navigation computer the ideal screw position (3.5mm) in the bone was chosen on the displayed radiographic pictures in all three planes. The screw diameter was selected, the optimal location for the screw axis was determined and subsequently the screw drawn along this axis. Final corrections in screw orientation and -length based on the drawn screw on the screen were made before the coordinates were identified and saved. Once the screw had been pre-planned and the coordinates saved, the CAS-System was set to the navigation mode. The 3.5mm drill bit was attached to the power drill and its diameter and length verified with the help of the drill calibrator (ARTORG Center for Biomedical Engineering Research, University of Bern, Bern, Switzerland). The entry point and the drill bit direction were identified on the navigation screen and the glide hole for the 3.5mm screw prepared across the hoof wall under constant surveillance and adjustment of the drill bit angles in two orthogonal planes on the computer screen. A hole across the hoof wall (Fig. 3), the collateral cartilage as well as the glide hole up to the virtual fracture line in the sagittal plane of the distal sesamoid bone was prepared. (Fig. 4). The 2.5mm drill bit for the thread hole was attached to the drill, calibrated and after exchanging the drill sleeve on the navigated drill guide the drill guide was inserted across the hoof wall, collateral cartilage and into the glide hole within the distal sesamoid bone. This allowed concentric drilling of the thread hole across the remaining half of the bone (Fig. 5). To facilitate access of the countersink, the hole across the hoof wall was enlarged with the help of a 8mm drill bit down to the bone surface. At that point of the study 3D-imaging – with the DRB still attached to the hoof wall – was repeated to document the location of the screw hole within the bone. The coordinates of the entry- and exit point of the screw axis was identified and recorded for comparison with the previous data collected.

The screw length was determined by subtracting 2–3mm (allowance for countersinking) from the length determined on the computer screen during the preplanning phase. After countersinking the near cortex of the distal sesamoid bone and tapping the thread hole, the screw of predetermined length was inserted and solidly tightened. By study design, the depth gauge was not used to determine the exact length of the prepared hole in the distal sesamoid bone. The same procedure was repeated in the opposite limbs for the 4.5mm cortex screw with the respective instruments.

Fig. 3 Start of the drilling process with a 3.5mm drill. The hoof wall and ossified collateral cartilage is penetrated. The pointed line represents the drilling axis.

Fig. 4 The 3.5 mm glide hole is prepbared to the imaginary fracture line in the sagittal plane of the distal sesamoid bone

Fig. 5 The 2.5 mm thread hole is prepared across the remaining half of the bone

Evaluation

The distal sesamoid bones were removed after opening the distal phalangeal joint and transecting the ligamentous attachments. The bones were boiled for 4 hours to facilitate removal of soft tissue remnants. Once removed the articularand flexor surfaces and the distal and proximal margin of each bone were closely examined for accidental screw penetration. The tolerance for the screw tip at the exit point was set at ± 2 mm. Protruding screw tips were measured with a sliding caliper at their longer end.

Digital photographic images were taken from all bones from all sides. Macroscopic screw placement within the distal sesamoid bone was assessed and subsequently rated as good, moderate or poor. The following criteria evaluating screw pla-

Fig. 6 Dissected distal sesamoid bone: perfect position of the 3.5mm screws

Fig. 7 Dissected distal sesamoid bone: perfect position of the 4.5mm screw but protrusion of the screw head- and damage to the rim of the bone

cement within the distal sesamoid bone and its resulting proximity to the articular cartilage/surface were used: overall screw length, location of the head and trajectory of the long axis of the screw. The postoperatively measured hole length was defined das optimal screw length. The computer data collected during pre-planning and following drilling were evaluated and the coordinates of the screw entry and -exit respectively were determined and subsequently compared.

Statistical Analyses

The statistical analyses were performed by using commercial computer software (STATA). To compare the axis angles, entry and exit point of the 3.5 and 4.5mm screws, the Student t-test was used. To compare the outcome of this study with the one of Gygax et al. (2006) and to compare the outcome of 3.5mm versus 4.5mm screws, the Fisher's exact chi-test was used. For all analyses, a P value < 0.05 was considered significant.

Results

The handling and the implantation of the screws with the Vet-Gate CAS-System is straight-forward. Accidental loosening or removal of the Dynamic Reference Base (DRB) from the hoof must be avoided because this would necessitate starting the entire procedure over from the beginning. During the drilling process the marker balls must not overlap each other.

Inspection of the dissected distal sesamoid bones revealed good positioning of all 3.5mm screws (Fig. 6, Table 1a). For the 4.5mm screws, in 1 case a good, in 1 case a moderate and in 8 cases poor positioning was registered (Tab. 1b). In the poor cases, the screw position within the bone was in all samples good, but the screw head damaged the articular surface because of its width (8mm diameter) (Fig. 7).

Comparing the outcome (Table 1a and b), the 3.5mm screws are significantly better placed within the distal sesamoid bone than the 4.5mm screws ($p < 0.001$). For the 3.5mm screws,

* the correct screw length was not available and a slightly shorter screw was inserted

° the correct screw length was not available and a slightly longer screw was inserted

Legend: + slightly affected by the screw, ++ plainly affected by the screw or screw head, - not affected by the screw; $+$ Difference in precision between group A and B is highly significant (p<0.001); 9*: The screw is located deeper in the bone because the articular surface is damaged.

As a result of the hole length not directly measured after drilling, the screw is too long.

Comments: The numbers in brackets correspond to the desired but not available screw length. "-" refers to the screw being too short.

a mean discrepancy of angulation angle of 1.11˚ (range, 0.12–2.13˚) was calculated. Mean difference in screw entry point was 2.35mm (range, 1.41–3.44mm). The screw exit point had a mean difference of 2.11mm (range, 0.73- 3.43mm). For the 4.5mm screws, a mean discrepancy of angulation angle of 2.09˚ (range, 0.07–4.38˚) was calculated. Mean difference in screw entry point was 2.49mm (range, 1.06–4.13mm). The screw exit point had a mean difference of 2.94mm (range, 1.52–4.27mm). Statistically there was no significant difference between axis angles of the 3.5 mm and 4.5 mm screws ($p = 0.07$), entry- ($p = 0.7299$) nor exit point ($p = 0.0932$). The absolute aberrance from this length to the screws tips protruding and being still located within the bone 1.77 mm (range - 5.8 to 3.6 mm) (Table 2). The results of this study with the 3.5mm screws, compared to the 3.5mm CAS screws of Gygax et al. (2006), are significantly better ($p = 0.023$) (Tab. 3).

Discussion

In this study frozen limbs were used. Treatment of a distal sesamoid bone fracture in a living horse requires that the distal sesamoid bone must be fixed by maintaining the hoof in extension during the surgical procedure (Fürst and Lischer 2012). This places the flexor tendons under tension and fixes the distal sesamoid bone between the deep digital flexor tendon and the distal and middle phalanx. In the study of Gygax (2006) et al. the limbs were thawed but the toe of the hoof dorsally extended with a string attached through holes at the tip of the dorsal hoof wall and fixed through a hole in the frontal plane of the proximal MCIII/MTIII. In the frozen specimens of the present study special attention to fixing the distal sesamoid bone between the deep digital flexor tendon and the distal and middle phalanges was therefore not necessary.

The differences in the axis angle of the 4.5mm screws (2.09˚) and the 3.5mm screws (1.11˚) can only be explained by human error. A greater range could have been tolerated in the smaller screws because the ratio between screw diameter and bone diameter is larger than with the 4.5mm screws, especially in dorsopalmar/dorsoplantar direction. Nevertheless this does not explain the small axis angle difference in the 3.5mm group. The error probability in the calculation of this parameter is high. The axes of the actually implanted screws were drawn in after the screw hole was drilled. It is easily possible that a slight aberrance occurred at the time of axis determination.

The results with the 4.5mm screws are poor. Only one of the 10 specimens had a good screw placement. In one specimen, the articular surface was slightly affected; the screw head minimally deformed the articular cartilage. In the rest of the specimens, the screw head damaged the articular surface. The location of the screw within the bone was correct in all specimens. The screw head with its 8mm diameter is too wide for the distal sesamoid bones. In average size horses the head overlapped the articular rim and damaged the articular surface. The better outcome in 2 of the 10 specimens was probably because of the bone size. In specimen 2 a bone width of 20mm was measured with a sliding caliper at the widest part of the bone (the middle), and in specimen 5 19mm were measured. All other bones were narrower. The average width of all samples was 16.2mm with a range from 14 to 20mm (14–17mm in the other 8 bones). In the 3.5mm screw group, no problems with the screw head size were encountered.

Therefore the standard 4.5mm cortex screws are not feasible in Thoroughbred or Warmblood horses of average size. However, a 4.5mm cortex screw with a smaller head diameter (6mm) may turn out to be the ideal implant for fixation of distal sesamoid bone fractures. Further studies on that aspect are needed. Possible reasons for the significantly better outcome in this study compared to Gygax et al. (2006) were discussed in Schwarz et al. (2017).

The 3.5mm screws are not available in all desired lengths. From 50mm onward the screw size increases in 5mm increments instead of 2mm steps. Hence in 5 cases the desired screw length was not available and a shorter one had to be selected in 3 cases (1, 4, 16) and a longer one in 2 cases (6, 8).

In none of the specimens did the screw tips protrude more than 2mm. It is not possible to determine the exact screw length needed with the help of the slide caliper or postoperative x-rays. This aberration is noticeable in the comparison of actual screw length and postoperative hole length. Furthermore, determination of the actual depth of countersinking is impossible. For the authors the inspection of the bones clinically with the help of diagnostic imaging procedures is the most important factor and considering the results achieved with the 3.5mm treatment of distal sesamoid bone fractures with this implant are more than satisfying.

There is a 4.0mm cortex screw available (DePuy-Synthes Inc. Solothurn, Switzerland) that contains a 6mm head and a 2.9mm core diameter, which is stronger than the standard 3.5mm cortex screw and may turnout to be the ideal screw for this purpose.

The change in insertion technique could (initially drilling the glide hole all the way across the hoof wall and near half of the distal sesamoid bone, followed by enlarging the hoof wall defect after the entire screw hole was prepared) had a significant influence of screw positioning. On a DP view the lateral and medial surfaces of the distal sesamoid bone are at obliquely converging angles. In the study of Gygax et al. (2006) the hoof wall was originally opened with an 8mm drill bit. This facilitated correct selection of the entry point of the glide hole. However because of the oblique surface it was not possible to prevent some displacement of the drill bit at the initiation of drilling. In the present study the hoof wall was initially opened with a 3.5mm drill bit down to the distal phalanx. This provided solid guidance for the drill bit at the entry point of the glide hole, resulting in a more accurate preparation of the screw hole and subsequent screw placement. This coupled with the passive-mode navigation system explains the improved outcome of the VetGate- compared with the Surgi-GATE study of *Gygax* et al. (2005).

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Conflict of interest statement

There is no conflict of interest for the first- and the authors last author. The second and third authors were part of the development team of the VetGATE System.

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Erweiterte Zusammenfassung

Implantation von 3,5mm- und 4,5mm-Zugschrauben in das Strahlbein beim Pferd mit Hilfe des VetGate Computer Assisted Surgery Systems und Vergleich mit vorangegangenen Ergebnisen mit dem SurgiGATE 1.0 System – eine In vitro-Studie

Die experimentelle In vitro-Studie sollte Funktionalität und Präzision des VetGate Computer Assisted Surgery (CAS) Systems während der Implantation von 3,5mm- und 4.5mm-Kortexschrauben durch eine virtuelle, mid-sagittale Fraktur des Strahlbeins beim Pferd untersuchen und die Ergebnisse mit denjenigen einer früheren, ähnlichen Studie vergleichen, die mittels SurgiGATE 1.0 CAS-Systems durchgeführt wurde ver. Zur Verfügung standen zehn Gliedmaßenpaare von Schlachtpferden, die frei von signifikanten Pathologien der Phalangen (n=10) waren. Eine virtuelle sagittale Strahlbeinfraktur wurde entweder mittels einer 3,5mm- oder einer 4,5mm- Kortexschraube unter "real-time" Überwachung mithilfe des VetGate CAS-Systems von der lateralen Seite her fixiert. Es wurde darauf geachtet, dass weder das Hufgelenk, noch die Strahlbein-Bursa mit den Implantaten penetriert respektive der Gelenksknorpel verletzt wurde. Zuerst wird der Huf mittels eines C-Bogens, der während einer Minute um 190° rund um den zu fixierenden Knochen bzw. Huf 100 Röntgenbilder aufnimmt und diese in 3 Schnittebenen widergibt röntgenologisch untersucht. Diese Bilder werden anschließend auf das VetGate übertragen. Auf dem Bildschirm des VetGate Systems können die gewünschten Schraubenlokalisationen genau eingezeichnet werden. Anschließend hilft das Navigationssystem des VetGate Computers dem Chirurgen die Instrumente an die vorgeplante Lokalisation zu dirigieren und den chirurgischen Eingriff mit großer Präzision auszuführen.

Alle Schrauben konnten präzis implantiert werden, ohne eine der oben erwähnten Strukturen zu verletzen. Die Resultate für die 3.5mm-Schrauben war in allen Belangen gut, während der Schraubenkopf der 4,5mm-Schraube in 8 von 10 Fällen Verletzungen der Gelenksrandes der Strahlbeine induzierte. Die Differenz zwischen der geplanten und der aktuellen Schraubenlänge ist mit dem VetGate CAS-System signifikant kleiner als mit derjenigen, die mit dem SurgiGATE 1.0 CAS-System erzielt wurde. Standard 4,5mm Kortexschrauben sind für die Fixation von Strahlbeinfrakturen bei Vollblut- und Warmblutpferden von durchschnittlicher Größe vor allem wegen dem zu breiten Schraubenkopf (8.0mm) nicht geeignet. Hingegen eignen sich 3,5mm-Kortexschrauben (Schraubenkopfdurchmesser 6,0mm) sehr gut. Die Verwendung von 4,0mm-Kortexschrauben ist zu bevorzugen, da diese Implantate bei gleichem Schraubenkopfdurchmesser wie die 3,5mm-Schraube einen dickeren Schraubenkern aufweisen, was zu einer erhöhten Widerstandskraft gegenüber Implantatbrüchen führt. Die 4,0mm-Schrauben wurden in der vorliegenden Studie nicht untersucht, da alle 4,5mm-Kortexschrauben jedoch perfekt implantiert werden konnten, sind die etwas kleineren 4,0mm-Schrauben sicher auch geeignet. Das VetGate CAS-System erlaubt das exakte Einsetzen von Schrauben in heiklen Lokalisationen unter Vermeidung von Verletzungen vitaler, benachbarter Strukturen.

Schlüsselwörter: Computer-assistierte Chirurgie, Strahlbeinfraktur, Osteosynthese, Schraubenplatzierung, Schraubenkopfgröße, Passives optisches Zielgerät