Multi-Center usability study for the percutaneous system VENUSmini®

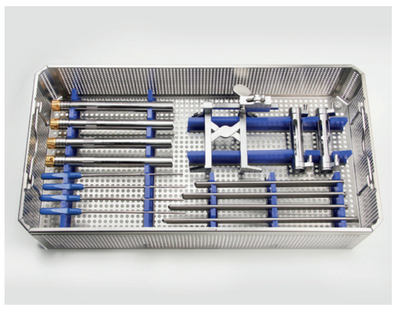
Tobias Colditz[1], Christoph Grimm[2], Jens Richolt[3], Alessandro Rustia[4], Thomas Schachtschabel[5]

HumanTech Medical Devices

[1] Kliniken Delitzsch & Eilenburg; [2] Klinik für Neurochirugie, Günzburg; [3] Chirurgisches Zentrum am Bethanien, Frankfurt am Main; [4] Klinikum Altmühlfranken, Gunzenhausen; [5] OrthoCentrum Saale Bad Neustadt

Introduction

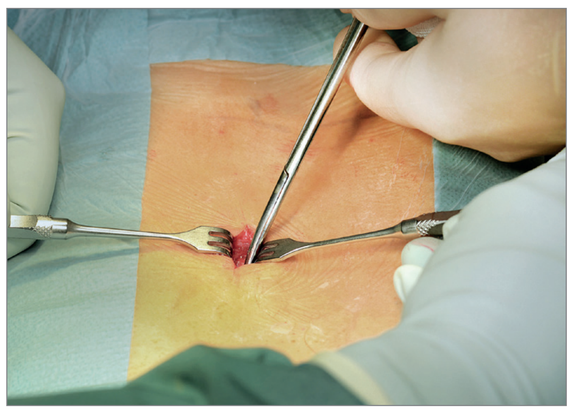
The aim of this work is to verify the high usability and the intraoperative key facts of the percutaneous screw-rod-system VENUSmini®.



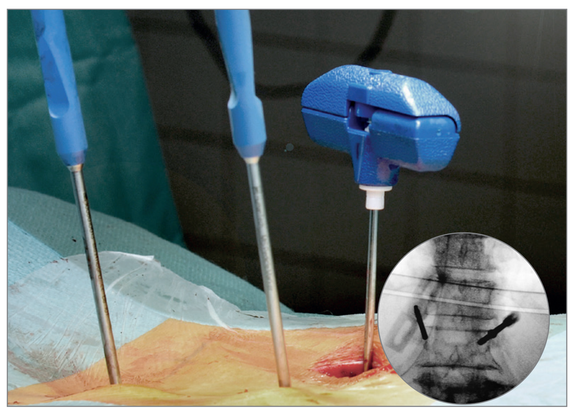
Material and Methods

71 patients (21 Men, 50 Women) with different indications in the spine underwent a dorsal spondylodesis with an internal fixation during the period from January 2017 to November 2018 at 5 different clinics. The average patients‘ age was 69,1 years (range: from 34 till 96 years).The location of the instrumentation ranged from thoracic vertebrae 6 to sacral vertebrae 1. With the help of the VENUSmini® system 346 screws were placed. For the Multi-Center usability study the performed surgeries were clustered into 5 different groups depending on the indication (Spondylolisthesis, Stenose, Fractures without the restoration of the sagital balance, Fractures with the restoration of the sagital balance and Spondylodiscitis). For each group the usability parameters surgery time, surgery time per pedicle screw, blood loss and intraoperative complications due to instruments were evaluated.

Surgical Technique

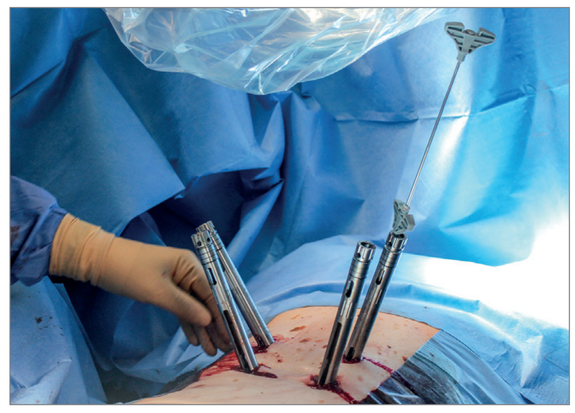


The operation takes place in a prone position of the patient. The skin incision points are determined and an incision with a length of approximately 25mm is made. The access to the pedicle is bluntly prepared.



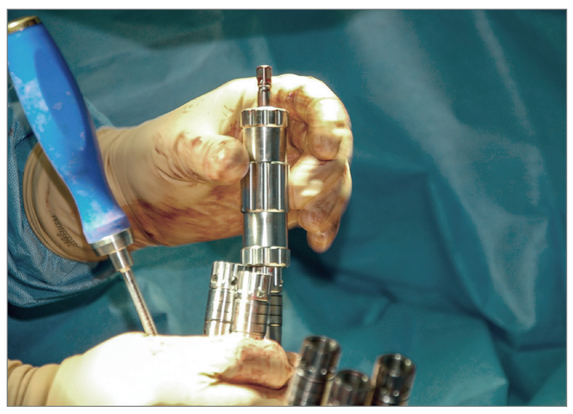
Afterwards the pedicle entry points are distinguished and the preparation of the screw hole can be executed.

After determining the necessary pedicle screw diameter and length, the screw is assembled to the MIS Headholder. Afterwards a screw driver is inserted in the MIS Headholder and the pedicle screw can be implanted. All other pedicle screws are implanted in an identical way.

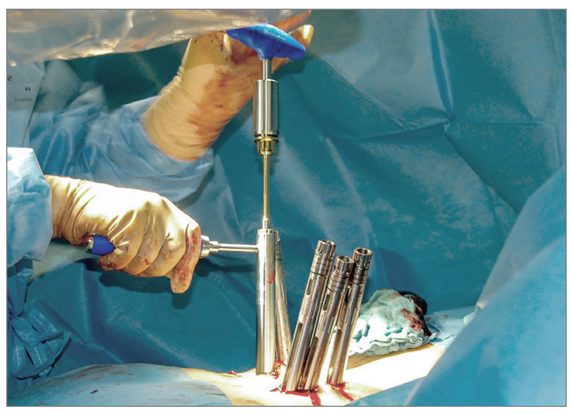


If the screws are in place and the polyaxial screwdriver and guide wires are removed, there is the option to apply cement via the fenestrated screws.

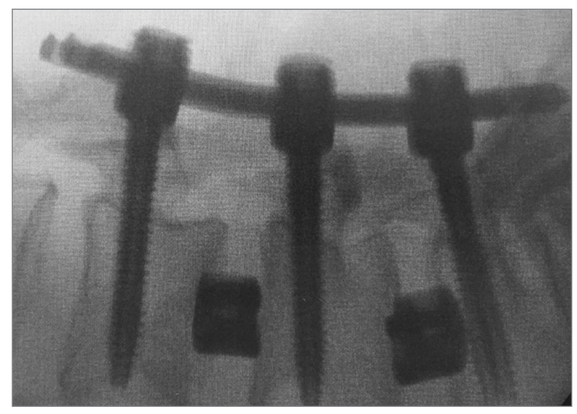
The next step is the implantation of the rod. Therefore the rod is assembled to the MIS Rod Holder and is introduce through the MIS headholders into the screw heads.



If needed now the reduction of a spondylolistheses or the distraction of a foramen stenosis can be done with the help of instruments MIS adapter screw, MIS Pusher Handle and MIS Counter Holder integrated in the system VENUSmini®.



The last step of the surgery concerning the system VENUSmini® is the final fixation of the instrumentation with the Torque Driver and the MIS Counter Holder to reduce the load on the instrumented vertebras.



By suturing the stab incisions the operation is completed. A final X-Ray is done to confirm the correct instrumentation of the spine.

Results

Indications/ Subgroups	Amount of surgeries	Surgery time [min]	Surgery time per pedicle screw [min]	Blood loss [ml]	Complications due to instruments
Spondylolisthesis	22	153 ±37	32 ±8	345 ±138	0
Stenose	29	182 ±61	37 ±37	406 ±188	3
Fractures without restoration of the sagital balance	16*	78 ±33	10 ±2	199 ±189	0
Fractures with restoration of the sagital balance	0	0	0	0	0
Spondylodiscitis	3	40 ± 10	10 ± 2	50 ± 0	0

* Excluding one surgery with a dorsal implantation of a vertebral body replacement

Discussion

This Multi-Center usability study confirms that with the system VENUSmini® surgeons are enabled to treat spondylolisthesises, stenoses, fractures without the restoration of the sagital balance and spondylodiscitis with a minimally invasive, percutaneous approach. The evaluation of the usability parameters surgery time, surgery time per pedicle screw, blood lost and intraoperative complications due to instruments indicate that VENUSmini® is absolutely suitable for carrying out minimally invasive stabilization surgeries of varying indications except the treatment of a fracture including the restoration of the sagital balance and therefore a ligamentotaxis of the anterior longitudinal ligament. The handling and dimension of individual instruments and their suitability for repositioning maneuvers, as well as the incision length, resulted in a low potential of improvement.