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Technical note

A new bone-cutting approach for minimally invasive surgery

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ABSTRACT

Aims: Resection of bone is performed in over 75% of all orthopaedic procedures and the electrically powered oscillating saw is commonly used to cut bone. Drawbacks are relatively large incisions and tissue damage due to overshooting often occur. Therefore, the goal of this study is to develop an improved bone-cutting system that has minimally invasive characteristics.

Methods: A new reusable sawing system was designed that can be used in Minimally Invasive Surgery (MIS) consisting of a steerable wire passer and a tissue saving wire saw guide. The system was tested during surgery on a human cadaveric tibia and calcaneus.

Results: A MIS steerable compliant Nitinol needle was built and successfully used in a cadaveric surgery to position the cutting wire around a tibia and calcaneus. A wire saw operating system was built that was successfully used to cut the tibia and calcaneus.

Conclusion: A MIS bone-cutting system was successfully designed, manufactured and used in a cadaver study showing that safe minimally invasive bone-cutting is feasible for two bone types with minimal damage to the surrounding tissue. Design optimization is needed to stabilize the compliant Nitinol needle during wire saw positioning and to allow cutting of bones with smaller diameters.

1. Introduction

1.1. Bone-cutting in surgery

Resection of bone is performed in many reconstructive orthopeadic procedures. During resection, the electrically powered oscillating saw is the most important tool to create bleeding surface planes in bone. However, most of the saws in use are heavy and their manual handling requires considerable training as there is a serious risk of overshooting and consequently damaging surrounding soft tissue [1]. To protect the surrounding tissue, the surgeon's assistant uses clamps around the bone. Unfortunately, these clamps require a larger incision and mainly protect the adjacent tissue of the bone, while the opposite tissue relative to the incisional entry point remains unprotected. Osteotomies are performed in the upper limbs, pelvis and spine, but mainly on the lower limbs [1,2]. Although osteotomy is used for several specific indications and different types of bone cuts, this study focusses on procedures that require fully cutting of the bone.

1.2. Minimally invasive sawing

The clinical need was posed to develop a compact, affordable and efficient reusable sawing device that prevents tissue damage. Although there are many potential methods to cut material (Supplemental material 1), the wire saw was chosen to cut bone in this study. Different from an oscillating saw that requires a force directed towards the bone and tissues from above to cut, a wire saw is placed around the bone and then directed away from the adjacent tissue through the bone. This means that there is no possibility of jumping or overshooting of the cutting blade into the surrounding tissue during the procedure. To further decrease the tissue damage, the goal of this project was to develop an osteotomy solution that allows the wire saw system to be operated as a minimally invasive surgical (MIS) tool.

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2. Methods

2.1. Essential requirements

The following requirements for a reusable MIS bone-cutting system need to be met in order to address known clinical functioning prerequisites. Although human bones come in many different diameters [3], the authors choose to make an adjustable system that can be used on the larger bones diameters with a minimum of 25 mm and maximum of 40 mm. The system must be modular for easy cleaning and fast replacement of damaged components. To be able to keep the healing time and the risk of infection as low as possible, it is important to ensure minimal tissue damage and a short procedure time. To minimize the healing time, the incisions should be as small as possible to allow entry of the wire-saw. It is important to keep the temperature below 45° to prevent osteonecrosis [4]. To reposition the bone parts after sectioning a straight and clean cut is desired. For safety reasons, it should not be possible to come in contact with the moving parts. Assembly and disassembly of the instrument by trained central sterile services department (CSSD) personnel should not take more than 2 min each [5]. Dimensions and mass of the wire saw should not exceed that of the oscillating saw (e.g. max length 200 mm and mass 500 g) to ensure the new solution is manageable during surgery. To be able to keep the procedural costs low and to make the solution viable also for use in low and middle income countries, it should be possible to use the wire saw system without the use of additional devices that are not already commonly used in the orthopaedic OR.

2.2. System design

To create a new MIS bone wire cutting method, two challenges need to be overcome. First, the wire saw needs to be brought in place around the bone structure without enclosure of critical soft tissue such as vessels or nerves. Secondary, when the saw is placed, it needs to be operated through small incisions without cutting the surrounding muscles and skin layers during operation. Therefore, we developed two separate devices:

1 MIS Cable passer needle to bring the wire saw in place,
2 MIS Wire saw and support system to guide the wire during operation.

To keep the costs low and the device versatile we have used our “bare-minimum design” methodology that has a strong focus on modular design for efficient cleaning and function expansion of standard components [5,6]. In combination with a stepwise development and evaluation plan that involves all key users who come into contact with the innovation, this method should facilitate sustainable use of surgical instruments.

2.2.1. MIS cable passer needle

Currently used cable passers are solid instruments that contain a curved tube at the distal end or are clamp-shaped. The curved hook is inserted along the side of the bone through a large incision before it is rotated around the bone (Fig. 1-1). The clamp (Fig. 1-2) can be used in a MIS fashion but still has a risk of capturing soft tissue surrounding the bone leading to serious complications (Fig. 1-3, 4) [7,8]. As soon as the needle is installed a wire saw can be passed through the needle’s cannula and the needle can be removed leaving the bare wire saw in place.

In line with the bare minimum design method, an active steering function was added to the distal tube in order to guide the wire in place without the need of a large incision. Although there are many different methods to steer the tip of an instrument [9], almost all of them require additional components [5,10]. However, by changing the needle from stainless steel to more elastic Nitinol, it becomes possible to combine the required stiffness for insertion with flexibility for curving (Fig. 2-1). To reduce the actuation force for curving towards a normal operating force, cut-outs are made along one side of the needle (Fig. 2-2).Final element analysis in Solid Works (SW 2017, Solid Works Corporation, US) was used for simulation and optimization of the needle curvature and material stresses. Towards the distal tip of the needle, the remaining wall length reduces progressively forcing the needle to start curving at the tip (Fig. 2-4A, B, C). This feature forces the tip to remain in close contact with the bone during insertion and curling around the bone surface. The needle design is kept modular to facilitate cleaning and to be able to change the needle diameter and radius in case of smaller bones (Fig. 2-3). Although stress limits were not reached during final element simulations, in-vitro tests are performed in which the needle is fully actuated for 100 times. Visual cracks due to material fatigue did not occur after microscope examination with 100X magnification.

2.2.2. MIS wire saw and support system

To cut bones with different diameters up to 40 mm, an modular adjustable wire saw support system (Fig. 3-1) is developed with 5 successive positions. All handle parts are made from red and grey PVC (Fig. 3-1, 5). The three metal parts (Fig. 3-2, 3) of the frame are printed from 316 L stainless steel. A standard surgical wire saw (e.g. Gigli saw) is used in the system that is first modified by adding bushes with an outer diameter of 2.5 mm and length of 8 mm that are brazed on the distal ends of the wire. With this modification the wire can be guided through the cable passer and wire guiding device before attached to the hook in handles (Fig. 3-6). To minimize friction between the moving wire saw and support frame, a rotating pulley in each frame guide the wire through the frame. A pulley diameter of 20 mm is chosen to prevent weakening of the wire saw due to plastic deformation while keeping the design practical and not unnecessarily bulky. Rims on each side of the pulleys keep the wire saw in the middle of the surface during actuation and prevent contact between wire saw and frame (Fig. 3-2). As the wire saw and pulley are made from stainless steel 316 L wear can occur. Therefore tests were conducted on a setup that mimic wheel-saw contact during use to identify potential wear patterns that can cause damage to the system. For 1 min, the researcher applied as much force as possible on the saw ends during sawing. Afterwards the wheel surface was inspected under a microscope (VHX-900 system) and the data was analysed in Matlab (MATLAB Release 2017b, The MathWorks, Inc., Natick, MA).

2.3. Experimental cadaver study

To verify the functional requirements that provide insight in design criteria, such as duration of the procedure, surrounding tissue damage and quality of cut, a performance experiment was performed with the new wire saw system in a cadaver experiment performed by an experienced orthopaedic surgeon. To show that the system can be used on completely different bone types of different size, a tibia and a calcaneus of a defrosted fresh frozen human cadaver were cut. For cadaver studies our institutional ethical review board does not require an approval request according to the Medical Research Involving Human Subjects Act. The Tibia and Calcaneus sectioning are executed as realistic as possible and the different surgical steps as illustrated in Fig. 4 are measured with a stopwatch in minutes. To investigate the surrounding tissue damage after the experiment the surgical site was carefully opened by hand with a scalpel and visually inspected. To determine the quality of the cuts, dental casting clay is used to transmit the bone surface for an accurate roughness measurement [11]. From this sur-

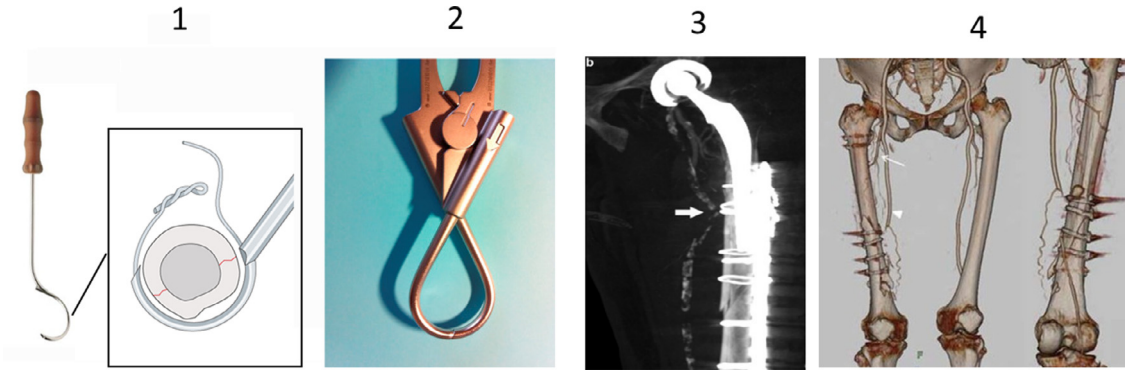


Fig. 1. Cerclage placement. 1, cable passer hook. 2, Minimally invasive cerclage clamp still has a risk of capturing soft tissue surrounding the bone leading to serious complications. 3 and 4, examples from the literature in which the cerclage wire completely obstructed the femoral artery, leading to ischemia of the leg [7,8].

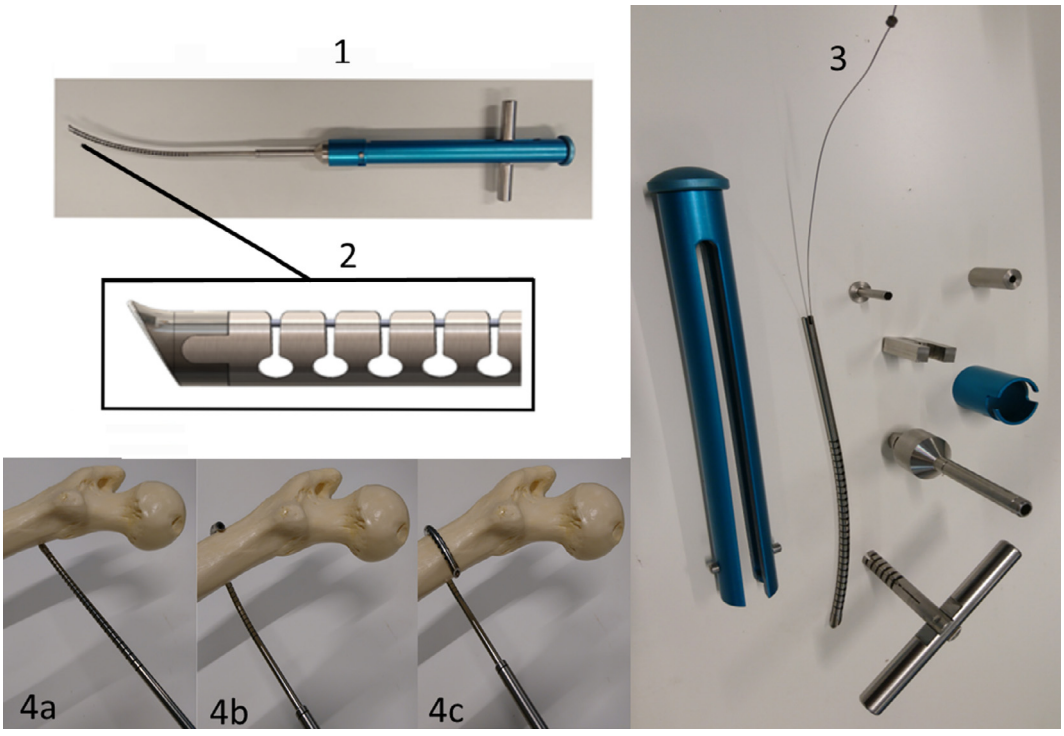


Fig. 2. The cable passer needle. 1, the cable passer needle 2, oval cut-outs in the needle facilitate deflection if the inner wire is pulled. 3, modular design allows cleaning and (re)placement of needles and other components. 4, basic principal of needle placement around the bone demonstrated.

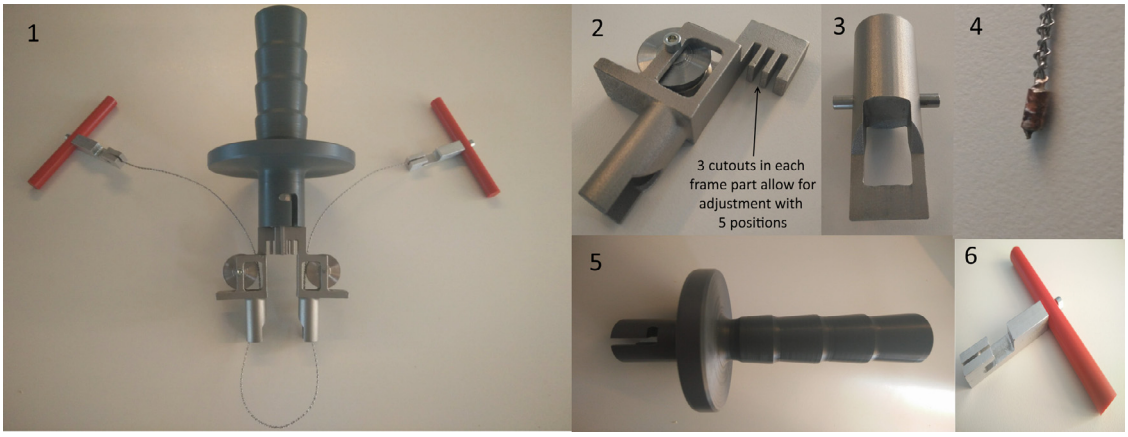
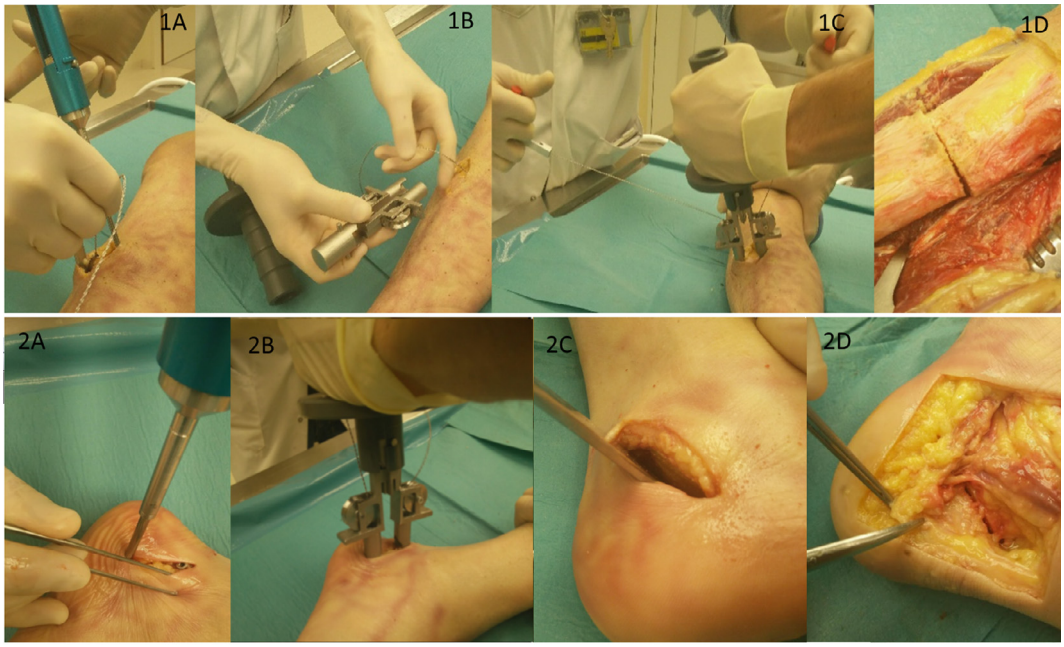
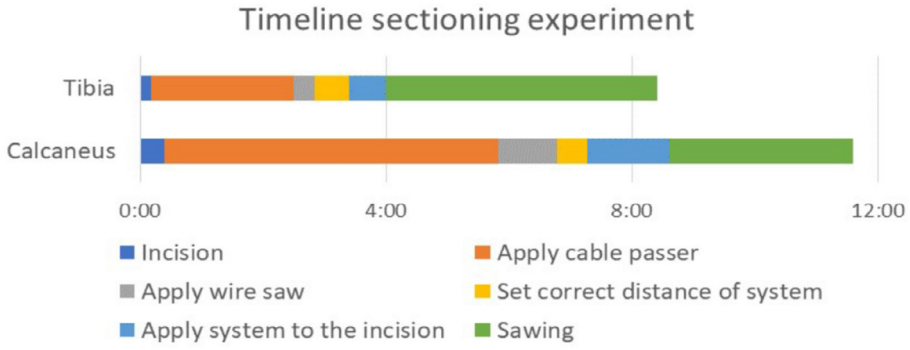


Fig. 3. MIS Wire saw and Support system. 1, system components assembled and ready for use (bone not included). 2, Single side of wire guiding and support.3, locking system that links two wire guiding parts together and allows for adjustable space between openings for different bones. 4, hard welded end stop on wire saw allows passage through the cable passer needle. 5, handle with bayonet that locks all parts together. 6, handle that hooks into the end stop of the cable for sawing.





	Incision [min]	Apply cable passer [min]	Apply wire saw [min]	Set correct distance of system [min]	Apply system to the incision [min]	Sawing [min]	Total [min]
Tibia	00:10	02:19	00:21	00:34	00:35	04:25	08:24
Calcaneus	00:23	05:26	00:58	00:29	01:20	03:00	11:36

Fig. 4. Top, The steps during the two cadaver experiment. 1A, Compliant passer needle used to drive the wire saw around cadaveric tibia bone. 1B&1C, Size adjusted wire saw device is installed and cutting is started. 1D, Analysis after procedure shows a nice and clean cut of the tibia. 2A Passer needle is guided around the heel bone. 2B, Installed wire saw device guides the wire saw during sawing. 2C and 2D, analysis of the cut shows minimum damage to the skin or surrounding tissue layers. No damage to the medial neurovascular bundle was observed. Bottom, Timeline of sectioning experiments conducted on the Tibia and Calcaneus.

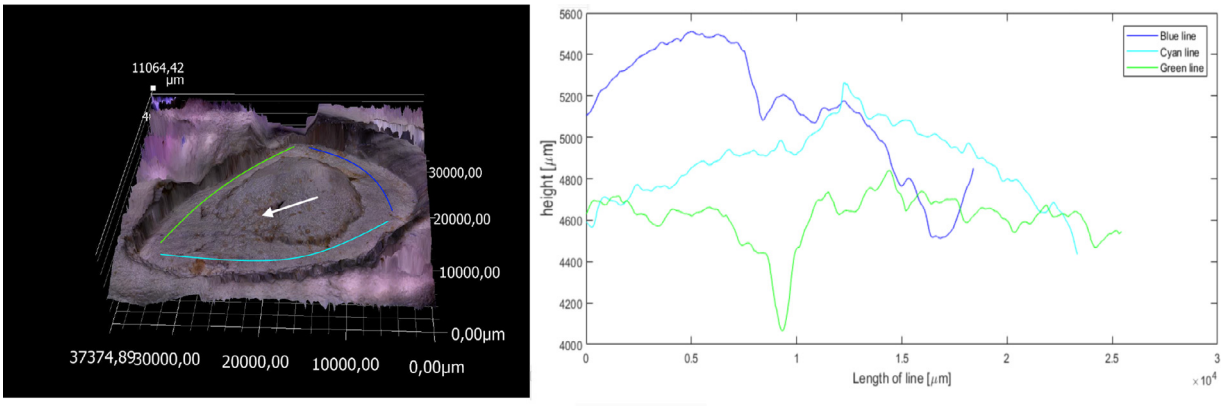


Fig. 5. Analysis of the dental clay indentation of the cut tibia. Left, picture of the indentation as analysed in Matlab R2017b. The 3 lines indicate the locations were depth was measured. Right, representation of the depth measured along the 3 lines. The white arrow indicates the sawing direction.

face, the flatness tolerance will be used as indication of the flatness of the cut.

2.4. Experimental assembly and disassembly pilot

At the end of the experiment the devices were processed at the CSSD and inspected for pre-cleaning potential and possible sterilisation methods. The assembly and de-assembly time for each device was measured with three unexperienced participants that each repeated the test for three times. Before each trial started, the disassembly and re-assembly was demonstrated once and the subject was only allowed to ask questions during the first trial.

3. Results

A MIS cable passer system, two wire saws and a support system were successfully developed and tested on a human lower leg. When fully actuated, the curve of the needle of the cable passer describes a diameter is 36 mm being small enough to guide the wire saw around a small calcaneus bone and a larger tibia bone. The needle bending tests indicated that the needle can be fully actuated for 100 times without showing any visual cracks. The wheel-contact experiment conducted with parts of the wire saw support system showed little surface dents in consistent patterns of about 100 µm in length. No cracks or structural damage was found during inspection.

3.1. Experimental cadaver study

During the initial phase of the surgical procedure, it was observed that the surgeon had to re-insert the needle for a maximum of 3 times before a pathway around the bone was created and the cable could be inserted from the distal to proximal side of the needle. In one occasion it was noticed that it is possible to deflect the needle backwards. After the cable passer was installed, the surgeon was able to remove the needle in seconds before installation of the wire saw device. Before placement of the wire saw device, the surgeon had to set the correct distance between cannulas. Thereafter, the loose ends of the wire saw were guided through the cannulas of the wire saw device and attached to two handle bars. No additional instructions or support was needed during this phase of the procedure. Finally, the assistant was asked to hold the wire saw device in place and the surgeons started to cut the bone. At the end of the sawing phase, the surgeon experienced loss of sufficient wire tension when cutting the opposing part to the bone relative to the exposure site. Fig. 4 shows the sectioning timeline of the two different bones and the different surgical steps from placement of the cable passer needle till sectioned bone in chronological order. The surgeon experienced some difficulties during cutting the final proximal section of the tibia bone when the saw got stuck in the saw cut but was able to conduct both sawing experiments with a single wire saw.

The bone indent, made on the proximal side of the tibia was analysed using the Keyence VHX-900 system. Tilt correction has been applied for easier evaluation of the data. Fig. 5 shows the resulting profile and measurement data. Only the outer ring of the indentation of Fig. 5 is included in the measurements as this represents the indentation of the cortex, whereas the inner surface represents the marrow, which is soft and therefore is found not to be a good indication of the flatness of the sample. The lines have therefore been drawn in the outer ring. The flatness tolerance zone is defined as the maximum height minus the minimum height of the lines and found to be 1.44 mm.

3.2. Experimental assembly and disassembly pilot

Three participants were asked to assembly and disassembly the instruments for three times (Supplemental Table 1). Both devices were disassembled within 5 s. The average disassemble time for the cable passer was 4 s (SD 3) and for the wire saw system 7 s (SD 3). Assembly took on average 32 s (SD 20) s for the cable passer and 7 s (SD 4) for the sire saw system. The prototype system was evaluated by the CSSD expert and all components were found to be easy cleanable and visually inspection was possible. The following suggestions were made by the CSSD expert: The Instructions For Use (IFU) should explicitly state that the wire guiding pulleys should be removed from the holder every time it is cleaned and sterilized to ensure a build-up of residue and microorganisms in the system. The design should be adapted to facilitate easy removal of the pulleys. In the final design, all grips should be made from the plastic “PEEK” [12]. PEEK can be processed in the autoclave and is fairly resistant against cleaning chemicals. Finally, it was advised to make the handles of the wire saw part of the disposable package as otherwise there is a risk that smaller parts are lost in the cleaning process.

4. Discussion

A fully functional, detachable, cable passer needle was created that can shape around a tibia and calcaneus. This needle allows for placement of a 2 mm wire saw (or cerclage) around the bone without damaging or inclusion of vessels and nerves. Secondary, a MIS wire saw device was developed and tested successfully on a tibia and calcaneus. Both device can also be assembled and disassembled for cleaning and sterilization within an acceptable time frame and requires low-tech cleaning methods and meet the functional requirements.

4.1. Experimental cadaver study

The handle interface on the steerable needle passer proved to be intuitive enough for the surgeon to start using the tip steering actuation within seconds. The wire saw device required some collaboration between assistant and surgeon as the assistant needed to be instructed on how to place and secure the device above the incision and how to control the position and force on the handle during sawing. During surgery it was noticed that in one case reinsertion up to three times was needed because the needle deflected sideways after hitting an obstruction on its path around the bone. Therefore, clinical experience and training is advised to apply the correct counter movements and needle actuation force for efficient placement. When the needle curves backwards due to misalignment between axial line of the needle passer and the incisional entry point, the Nitinol material can tear due to over stressing. To prevent that the needle breaks, the design could be modified with an over tube that only allows the Nitinol needle to curve when it is in contact with the bone. During the sawing phase of the experiments it was found that if the wire is not applied tightly against the bone surrounding skin and tissue, it can enter the space between mechanism and bone and get damaged. Adding a rim around the distal end of the two cannulas of the wire saw device should keep the tissue layers away from the saw and help keeping contact between bone and cannulas. When sawing is almost completed there is a risk that the saw comes into contact with the proximal tissues directly under the skin. Therefore, instead of two smaller incisions for each of the cannulas it is advised to create a single incision around both of the cannulas that keeps the tissue layers away from the proximal side of the bone. Finally, it was found that if the cannulas are not completely positioned on the proximal side of the bone but more in contact with

the side of the bone, the lack of upwards force makes cutting of the upper proximal section of the cortex more difficult. Therefore, it is advised to keep the space between both cannulas of the wire saw device to maximal 50% of the diameter of the bone. Despite some difficulties experienced during cutting of the final proximal section of the bone, the surgeon was able to conduct both sawing experiments with a single saw. This demonstrated that the wire saw did not damage in the wire guiding device due to plastic deformation or fatigue.

The indentation tests performed with dental clay indicated a maximum surface height fluctuation in the zero zone of 1.4 mm. The highest variation of height was found along the distal area of the bone that had the thickest cortex (dark blue line Fig. 5). Most likely this area gives the most resistance against the saw that influence the pathway the saw follows during sawing. Nevertheless, a maximum of 1.4 mm was found to be acceptable reification of bone during the constructive phase of an osteotomy.

4.2. Experimental assembly and disassembly pilot

The average assembly and disassembly time of 39 s and 11 s are shorter than the required 2 min. Since 2 min was the largest observed (dis)assembly time during an inventory conducted at 5 large Dutch hospitals [5,6], a conventional sterilization department with skilled personnel should be able to process this kind of modular instruments. Both assembly tests show the largest data variation in the first attempt and when components of the needle needs to be placed in a specific order. Due to the open structure of both instruments, all the moving parts can be followed visually until the parts are fully connected and secured by the bayonet lock resulting in an acceptable task time during the experiment.

4.3. Clinical relevance

Minimally Invasive Surgery has clear advantages but also disadvantages [13]. Among the advantages are a smaller incision leading to less wound complications, lower infection rates and better cosmetics. Unfortunately, the downside is that limited visibility may lead to undetected damage and thus inferior results. The use of a low speed burr to perform a calcaneal osteotomy is becoming more common practice [14] as the published results are equally good to open procedures. However, similar to the oscillating saw, it does have the possibility to damage surrounding structures. A wire saw does not expose the patient to this risk. Although the needle that is described in this paper is developed to pass a wire saw, it could also be used to place cerclage wires for bone fixation (Fig. 2). Therefore, it may offers a safer method of positioning the wire around the bone without the need for multiple incisions and with reduced risk on trapping of important blood vessels. The combination of instrument and technique described in this study is clinically highly relevant because it offers the advantages of minimally invasive surgery while avoiding the risk of soft tissue damage and potentially provides a better method to place a cerclage wire.

4.4. Limitations

In this exploratory study an alternative MIS approach for open bone-cutting was demonstrated on two different locations on the human body. Further analyses with a representative group size and comparison with other cutting methods is needed to demonstrate the full potential of our new design and protocol. In this experiment only one needle size was designed and used on the smaller and larger bone. This resulted in a larger incision and more space between needle shaft and bone surface than needed during the experiment on the smaller bone. Optimization is needed to create multiple needles for specific bone diameters.

4.5. Future work

To show the advantage of this modular reusable wire application and bone-cutting technology over conventional static needle passers and open cutting methods, future steps should include an elaborate technical and clinical evaluation of both systems as mentioned in the limitations. Special focus is needed on corrosion, wear and deformation aspects due to contact between pulley and wire saw during operation to determine if wire saws can be reused.

5. Conclusion

A minimally invasive bone-cutting system was successfully designed, manufactured and used in a cadaver study showing that minimally invasive bone-cutting is feasible with minimal damage to the surrounding tissue and good cutting surfaces. Further design modifications are needed to stabilize the compliant Nitinol needle during wire saw positioning and to allow cutting of smaller bones.

Declaration of Competing Interest

None.

Acknowledgment

J Minnaard, RP Kleipool, W Baars, J Dankelman, SAS Stufkens and T Horeman have no conflicts of interest or financial ties to disclose.

Informal consent

For cadaver studies our institutional ethical review board does not require an approval request according to the Medical Research Involving Human Subjects Act.

Ethical approval

Work on human beings that is submitted to *Medical Engineering & Physics* should comply with the principles laid down in the Declaration of Helsinki; Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. You should include information as to whether the work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work.

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Not Applicable.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.medengphy.2020.11.011.

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