The SATA, A simple, stiff, and rigid steering mechanism

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The SATA, A Simple, Stiff, and Rigid Steering Mechanism[1]

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1 Background

In meniscectomy, instrument insertion points are routinely placed at the anterior side of the joint level medially and laterally from the patella tendon [1,2]. These insertion points commonly conflict with the location of the defect (e.g., tear) in the menisci, making it difficult to reach the work area especially for defects situated along a large part of the menisci edge (Fig. 1).

In these difficult cases, it is challenging to position a cutter to remove loose parts when using a straight instrument. To solve this problem, precurved instruments have been developed to repair defects in all areas of the menisci. However, there are disadvantages associated with this discrete solution. Since the location and type of defect are not known beforehand, approximately ten different punches must be readily available and undergo traditional standards of cleaning, disassembly, and sterilization even when they are not used. To reduce costs, surgeons must find a balance between instrument reachability and the number of prebent punches available on the OR table. As a consequence of reduced reachability, surgeons must apply excessively high forces on the surrounding tissue around the knee joint (via insertion portals) to accurately position the instrument cutter. This can result in chronic wrist pain to the surgeons and unnecessary portal pain to the patient [3]. Alternatively, producing a steerable mechanism that is small, strong and maintains its position under angles between 0 and 55 deg remains a challenge, especially under strict user demands and functional requirements [4]. For example, the interface must remain simple and intuitive while the bending radius remains small and the hinge mechanism remains stiff and accessible for proper cleaning and sterilization. This paper presents the design of a new rigid linkage steering concept and steerable punch prototype that is easily cleaned and (dis)assembled.

2 Methods

To get the new steerable punch accepted within the standard sterilization process, design requirements were extracted from user-interviews conducted within sterilization departments of the five largest hospitals in the Netherlands. To collect insight for critical features of a new steerable instrument most important for sterilization department employees, we asked questions related to existing instruments and the potential of making changes for improvement. This method provides a list of design requirements for the new steerable punch. A list of standardized questions was also defined to extract the minimal component size and dimensions, hidden surfaces, cannula diameter, length, and dis/assembly effort and time. Early mechanical strength tests are performed consisted of pushing the instrument prototype with its tip on a standard balance for three times till an axial load of 100 N was reached on the display of the balance. The second set of experiments consisted of sideways loading of the tip ($N = 3$) with a free weight of 2 kg hanging on a cable attached to the cutter.

3 Results

The most important feedback from the CSD employees can be summarized as: Every part should be subject to visual inspection, to confirm proper cleaning. Lumens should be easy accessible for brushing and rinsing. Cleaning should be simple and executed in a few steps. Use positioning edges for easier assembling. Let small parts stay attached to each other for easy alignment and prevent them for getting lost. Prevent the use of additional tools for (dis)-assembly. Rough surfaces, ribs, and grooves are difficult to clean. Make surfaces flat and smooth if possible. Prevent tight fitting of moving parts that obstruct flowing water. The CSD instrument inventory at the five hospitals showed us a minimum number of loose parts in a single instrument of 8, a smallest loose component

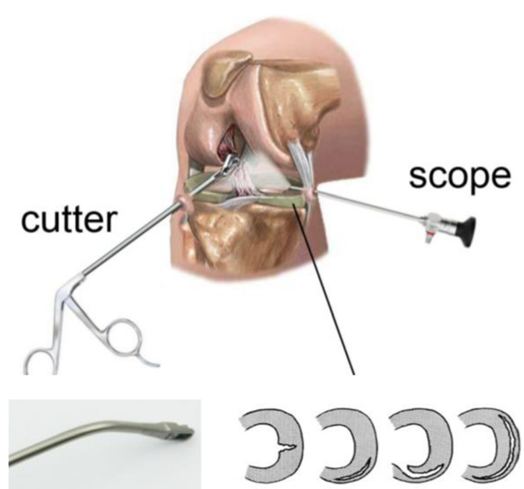

Fig. 1 Posterior view of right knee. (Top) Surgeons use a punch and scope to repair defects in the menisci. (Below right) common lesions of the menisci. (Below left) Side view of an intentionally prebent punch shafts.

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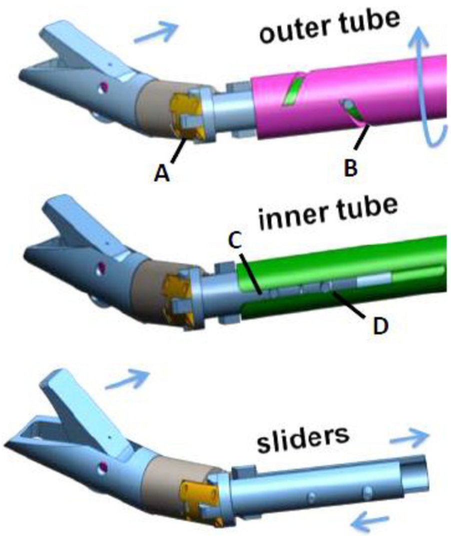

Fig. 2 (Top) rotating the outer tube results in articulation of the hinge (A) at the tip, since the diagonal cut-outs (B) in the outer tube forces the sliders to move in axial direction. (Middle) To prevent axial rotation of the tip the longitudinal cut-outs (C) in the inner tube prevents axial rotation of the sliders. (Below) View on the inner sliders show that there are no cables used for hinge activation. Only the force exerted by the cut-outs on the driving pins (D) actuates the sliders.

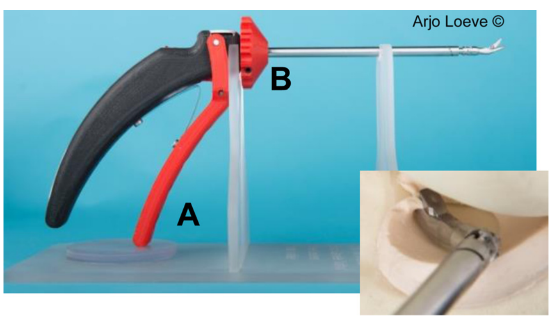

Fig. 3 Picture of the SATA_V1 prototype with tip actuation handle (A) and wheel (B) for sideways tip rotation

size of ø6 × 3 mm a largest hidden surface of 6293 mm^2 and a maximum lumen length of 540 mm and diameter of ø0.4 mm. The longest measured disassembly time was 110 s.

3.1 Shaft Actuated Tip Articulation Design (SATA). A new and simple rigid-body steering mechanism has been developed that contains no actuation cables to prevent problems during (dis)-assembly, cleaning, and sterilization. Figure 2 shows that the steering mechanism is actuated by shaft rotation and designed to allow the instrument tip to articulate 55 deg to each side. With this method the shaft remains strong, hollow and the response of the tool tip due to shaft rotation remains direct even when the distance between hinge and handle is long. By simply choosing the angle of the cut-outs in Fig. 2, the trajectory of the tip can be defined.

3.1.1 Steerable Punch Prototype. A prototype was built that requires only four simple extra parts in the hinge for steering (Fig. 3). The sliders that actuate the three point hinge mechanism are driven forward and backward by the cut-outs of each tube.

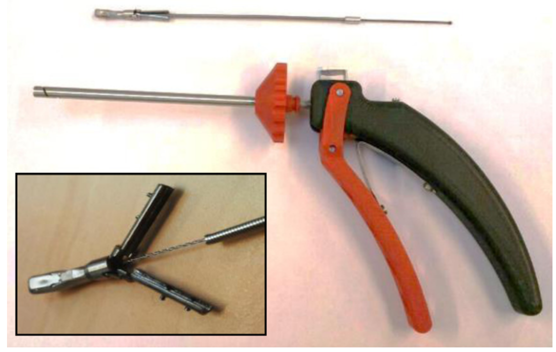

Fig. 4 Steerable punch dismantled into tip assembly, outer tube with wheel and handle. Opening of the hinge results in better access to all openings for cleaning and inspection.

Since the driving pins of the sliders are in continuous contact with the walls of the cut-outs, the tolerance remains minimal (0.05 mm) at all times while the tip positioning error related to wheel the position remains under 1 mm. Three surgeons tested the tip articulation of the steerable punch prototype. Response indicates that rotation of the wheel with one finger was easy and the working-mechanism offers a strong, sturdy feel during articulated cutting. Three sterilization department employees tested the steerable punch prototype and confirmed that the instrument is easy to disassemble into three loose parts that should all be accessible for inspection and rinsing without any hidden surfaces between the lumen.

Figure 4-insert shows that the hinge can be opened after the outer cable that shields the push/pull rod is moved back for cleaning and inspection. With only three loose parts, a smallest loose component size of 15 × 12 × 12 mm, a largest hidden surface of 800 mm^2, a lumen length of 110 mm, and diameter of ø4 mm, the dimensions of the steerable punch remain less critical. After 15 min of explanation and training of three technical students, disassembly of the steerable punch prototype takes on average 20 s (SD 5) and assembly takes 82 s (SD 18). The mechanical tests of the prototype demonstrated that pressing the tip with a force of 100 N for three times on the balance did not damage the prototype. Also, after applying a tangential force at the end of the tip of 20 N for six times, the hinge was not noticeably damaged.

4 Interpretation

A novel steering mechanism was developed that can be used to build a simple reusable punch for meniscectomy. In contrast with available hinges (e.g., EndoWrist, AutoSuture, and EndoGrasp), the SATA mechanism can be disassembled, cleaned, has a smaller bending radius and is noncompliant. Since no cables are used to actuate the SATA mechanism the instrument remains hollow leaving room cables and/or wires required for tip actuation. Further in vivo testing is required to meet all demands of the surgeon.

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