Design and Preliminary Evaluation of a Stiff Steerable Cutter for Arthroscopic Procedures

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This article describes a novel and simple shaft actuated tip articulation (SATA) mechanism that allows arthroscopic instruments to articulate while remaining stiff. Since the SATA mechanism requires only independent rotation of two tubes for hinge articulation, cables, gears, or other internal components that are normally found in steerable endoscopic instruments become obsolete. The SATA mechanism was integrated in a new steerable cutter prototype and tested. Early user, mechanical strength and cadaver experiments were performed that indicate that this first prototype withstands an axial and sideways force of 100 N and 20 N, that trained users can (dis)assemble the instrument in less than 1.5 min and that a surgeon is able to reach all important locations on the menisci. [DOI: 10.1115/1.4030506]

Introduction

Different from most endoscopic procedures, the tissues (e.g., ligaments and menisci) that are manipulated during arthroscopic surgery are much tougher. These tissues need to resist high forces that act on the joints during daily functioning of the musculoskeletal system. Additionally, the space in the joint cavity for positioning of the arthroscope and instruments is tight. The most frequently performed arthroscopy in the knee is a meniscectomy, which usually consists of cutting a stable rim in a ruptured meniscus to prevent further tearing [1]. The access portals are routinely placed at the anterior side of the joint level medially and laterally from the patella tendon [2,3] (Fig. 1). The combination of these limited access points, the complex curvature of the condyles and the location of the lesions in the meniscus cause difficulties in treatment of the meniscus.

To improve the reachability, prebend cutters are available to facilitate the cutting of the lesions in all parts of the meniscus (Fig. 1). However, this solution poses the major drawback of surgical workflow interruption due to exchanges of different prebend cutters to reach the entire lesion [4–6]. This relative large set of prebend cutters needs to be present during the operation and need to be cleaned, disassembled, and sterilized even when they are not used.

If prebend cutters are not used, surgeons try to reach the target location with a straight cutter by applying high forces on the surrounding tissue of the portals. This can cause chronic wrist pain to the surgeons [7,8] and unnecessary portal pain to the patient [9]. In our previous work, we presented a concept that would solve these limitations, which is a sideways steerable cutter [5,6]. However, the concept that existed out of a compliant rolling element and compliant steering beams was not sufficiently stiff and appeared difficult to clean. In this paper, we present the design of a completely new solution. It finds its core in a stiff and steerable mechanism that uses rotation of the instrument shaft to steer the tip of an endoscopic instrument toward its target. The functionality of this mechanism is demonstrated in a full prototype of a steerable cutter including the shaft, instrument tip, and handle.

Materials and Methods

Technical and User Requirements From Literature. In earlier work of the authors, the mechanical and user requirements of a steerable cutter were determined and are summarized in the second column of Tables 1 and 2 [4–6]. However, two changes were made to the available requirements. First, since a hinge design can also be noncompliant, the "maximum tangential tip force for deflection" is now interpreted as the "maximal tangential tip force before breaking of the cutter." Second, the force that acts on the push/pull rod during cutting depends on the type and tolerances of the hinge mechanism, the material and sharpness of the cutter. Therefore, this value cannot be extracted from literature. Instead, we measured the force on the handle of a new standard cutter (Duckbill cutter, Smith and nephew, Boston). The force on the handle ring was measured during cutting of specially prepared artificial menisci as used for the PASSPORT simulator [10], and gave values of 9 N, 9.5 N, 10 N, and 9 N. Since the lever ratio of this cutter is 85/12 the average pulling force on the cable during a cut is 70 N.

Cleaning Requirements From Central Sterilization Department (CSD) Study. In the literature, guidelines for cleaning and sterilization of reusable endoscopic instruments can be found [11,12]. However, it is unclear how these are applied in the CSDs. To improve acceptance of the new steerable cutter, requirements for cleaning and sterilization were defined based on observations and interviews with five CSD employees ($N = 5$) of the five largest Dutch academic medical centers.

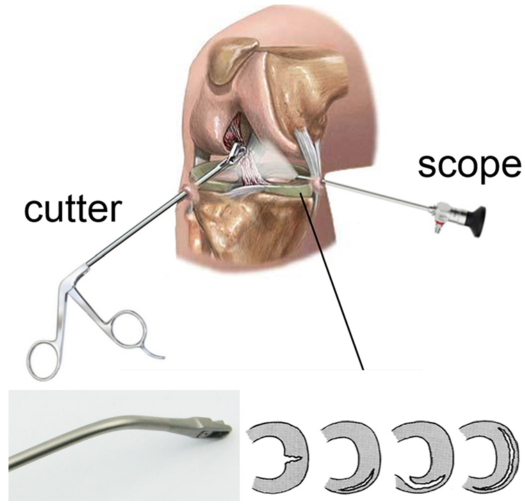

Fig. 1 Anterior view of right knee. (Top) Surgeons use a cutter and arthroscope to cut meniscus lesions. (Below R) Common lesions of the menisci. (Below L) Side view of a prebend cutter.

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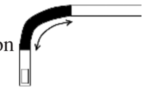
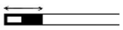
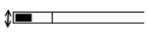
Table 1 Mechanical requirements. Second column shows the requirement from the literature, third column shows the value from the steerable cutter prototype.

Requirement	Literature	Prototype
Pulling force in cable acting on tip	≤70 N	100 N
Tube and tip diameter	≤5 mm	5 mm
Bending portion 	≤30 mm	8 mm
Tip length 	≤15 mm	20 mm
Tip width or diameter 	≤5 mm	5 mm
Jaw length 	≤15 mm	15 mm
Jaw width 	≤3.5 mm	3.5 mm
Shaft length 	≤105 mm	110 mm
Flexing angle of tip 	−55 to 55 deg	50 deg
Upward orientation tip 	17 deg	17 deg
Sideways force at tip before damage 	≤10 N	20 N
Deflection due to transverse force at 20 N (Beta) 	≤13 deg	From aside, 5 deg from top, 4 deg
External axial force at tip before damage 	≤5 N	100 N

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 straightforward and executed in minimal steps. Positioning edges should be used to facilitate assembling. The number of small parts should be minimal to prevent them from getting lost. Additional tools for (dis)assembly should be prevented. Surface should be flat and smooth for ease of cleaning. Moving parts should have space to allow flowing water between them. Besides these general findings, more detailed geometric requirements for the new steerable cutter were derived using a standardized checklist for the five CSD departments. The results showed that instruments contained up to eight loose small parts, the size of a loose component was as small as ø6 × 3 mm that instruments have hidden surfaces up to 6293 mm^2 and lumen lengths are up 540 mm with lumen diameters being ø0.4 mm and up. Also, we found that the longest measured disassembly time was 110 s.

Design—A Novel Steering Mechanism. Based on the complete list of requirements, we developed a new SATA concept [13]. Since it is desirable to keep the instrument stiff to withstand the high cutting forces, it was chosen to avoid compliant components in the hinge mechanism. Furthermore, actuation of steering by cables was avoided to maintain a fixed position of the tip under high tangential load and to prevent problems during (dis)assembly. Our "bare minimum" approach focused on providing the hollow tube that acts as shaft an additional function as follows. By using two tubes for the shaft which can rotate in respect to each other, rotation of the outer tube at the handle side can be translated into axial translation of two sliders at the other end of the tube while no inner space is lost (Fig. 2). With this mechanism, the tube provides resistance against loading while remaining hollow. Also, the response of the tip on actuator movement remains direct even when the distance between the hinge and the handle is large. The angle of the cut-outs in the outer tube can be chosen to define a specific trajectory of the tip related to the wheel rotation (Fig. 2).

Design Integration—Complete Prototype Steerable Cutter. A complete prototype of the steerable cutter was fabricated based on the SATA mechanism (Fig. 3). The design requires a wheel fixed

Table 2 User requirements. Second column shows requirement from the literature, third column shows the value from the steerable cutter prototype tests.

Requirement	Literature	Prototype
Control options	≤2	2
Intuitive design	Handle intuitive and self-explaining	4 s (SD 1.2 s) to acquire total control
Actuator control	Tip position should correlate with handle position	Sam control as in car steering
Control instrument	Single hand	Single hand
Operation handle	Thumb or index finger	Both possible
Size grip	Fit nicely in one hand	Agreed by all surgeons
Actuation force and surface of finger on button for tip steering	≤0.4 N/mm^2	0.1 N/mm^2
Actuation force and surface grip	≤0.3 N/mm^2	0.13 N/mm^2

on the outer tube (Fig. 4(*c*)) to transform the finger actuated wheel rotation toward axial movement of the sliders of the hinge. All metal parts were custom build from stainless steel (340) except for the instrument tubes and hinge pins. The tubes were made from a donor arthroscopic shaver (Dyonics 5.5 mm shaver, Smith and Nephew) while the hinge pins were cut from the shaft of 0.5 mm drill bits. The handle shape is designed such that the surgeon can hold the instrument upside down to enter the knee cavity when desired. Therefore, the handle back follows the natural curve of the hand palm. The plastic parts were printed with a 3D printer (Makerbot replicator 2 ×, MakerBot® Industries, LLC).

Since the driving pins (Figs. 2(*B*) and 2(*D*)) are enclosed by the walls of the cut-outs at all times, the tolerance is maximal 0.1 mm while the tip accuracy after positioning remains high (0.5 mm measured at tip) giving it a strong feel. The instrument can be dismantled into three simple parts that are all accessible for inspection and rinsing leaving no hidden surfaces between lumen (Fig. 4).

Disassembly is achieved by rotating the pin stop holder away from the 1 mm pull rod and by removing the clip on the handle site that keeps the steering wheel in place (Fig. 4(*a*)). Subsequently, the outer tube with pull rod can be pulled outward (Figs. 4(*b*) and 4(*c*)) and removed from the inner tube and handle (Fig. 4(*d*)). Assembly of the steerable cutter is done vice versa.

Mechanical Strength—Breakage of Pins. The three pins that are located in the hinges between the sliders and cutter are defined as the most critical components that probably will break first.

To prevent instrument breaks in the joint, strength calculations are performed on the weakest hinge components when the tip is tangentially loaded (Fig. 5). Using the loading requirements, the highest force on the cross-sectional area of pin-*b* is calculated considering the equilibrium of the moments with respect to hinge pin-*a* by

$$\sum M = \mathrm{Fr}_{vb} \cdot L_2 + P \cdot L_1 = 0$$
$$\mathrm{Fr}_{vb} = \frac{21\mathrm{mm}}{4\mathrm{mm}} P = 5.25P \tag{1}$$

The reaction force acting in horizontal direction in pin-*b* (Fr_{hb}) is half of the applied load (P) since the load is carried by two hinges

$$\sum F_x = P - \mathrm{Fr}_{ha} - \mathrm{Fr}_{hb} = 0$$
$$\mathrm{Fr}_{hb} = \frac{P}{2} = 0.5\,P \tag{2}$$

As the reaction forces in horizontal and vertical direction are known, the absolute reaction force (Fr) on the hinge can be found by means of Pythagorean theory

$$\mathrm{Fr} = \sqrt{\mathrm{Fr}_{\mathrm{hb}}^2 + \mathrm{Fr}_{vb}^2}$$
$$\mathrm{Fr} = \sqrt{(5.25P)^2 + (0.5P)^2} = 5.27P \tag{3}$$

Figure 5 right shows that (Fr*)* should be divided by two to find the force acting on one cross-sectional area of the hinge ($F1$). To prevent breakage, the absolute force $F1$ should be smaller than the maximum allowable shear force (V) as calculated according the Von Misses theory. Since the 17-4 PH stainless steel hinge pin has a radius of 0.25 mm *(r)* and known yield tensile strength (σ_Y) and therefore yield shear strength ($\tau_{\max}$), the shear force is calculated as

$$V = \frac{3}{4}\pi r^2 \tau_{\max} = \frac{3}{4}\pi r^2 \frac{\sigma_{\mathrm{Y}}}{\sqrt{3}}$$
$$V = 0.75 \cdot \pi \cdot (0.25\,\mathrm{mm})^2 \cdot 577\,\frac{\mathrm{N}}{\mathrm{mm}^2} = 85\,\mathrm{N} \tag{4}$$

This indicates that choosing a hinge pin diameter of 0.5 mm makes the hinge strong enough to withstand a tangential force (P) of 10 N

$$F1 < V \rightarrow \frac{5.27P}{2} < 85\,\mathrm{N} \rightarrow \mathrm{P} < 32.3\mathrm{N} \tag{5}$$

Testing the New Design. Based on the previous stiffness and strength experiments of Nai et al. [5], two tip loading experiments were conducted for the steerable cutter prototype. In a third series of experiments the instrument was tested for intuitiveness. In a last experiment, the instrument was used in a cadaver to find any flaws in the design.

The first experiments 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 balance read from display. The

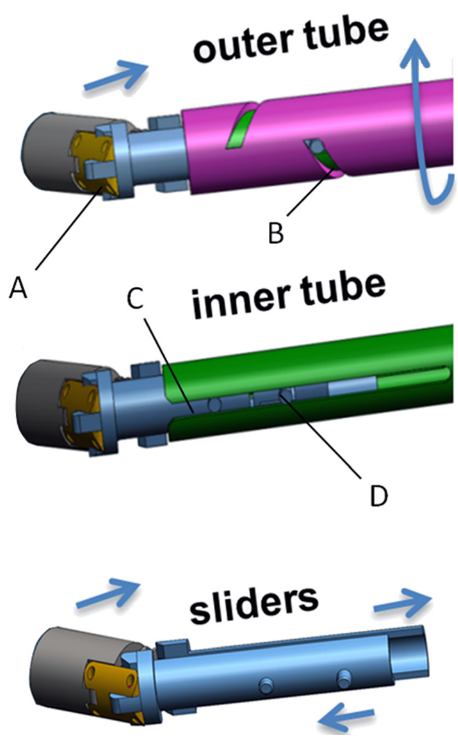


Fig. 2 (Top) Rotating the outer tube results in articulation of the hinge (*A*) at the tip, since the diagonal cut-outs (*B*) in the outer tube forces the sliders to move in axial direction. (Middle) To prevent axial rotation of the tip the longitudinal cut-outs (*C*) in the inner tube prevent axial 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.

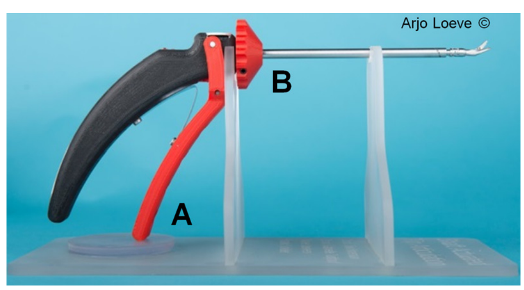


Fig. 3 Picture of the SATA_V1 prototype with tip actuation handle (*A*) and wheel mounted to outer tube (*B*) for sideways tip rotation

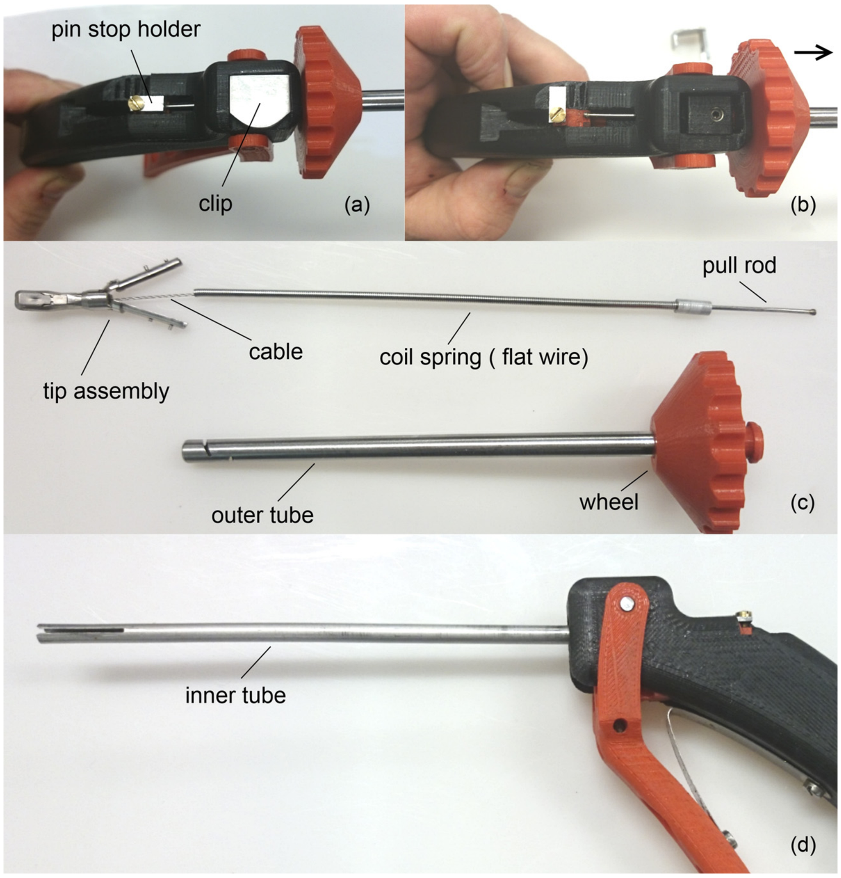


Fig. 4 Steerable cutter dismantled by removing the clip and rotation of the pin stop holder (*a*) and (*b*)). Subsequently, the steerable cutter can be disassembled into a tip assembly and an outer tube with wheel (*c*) and handle (*d*). Opening of the hinge provides better access to all openings for cleaning and inspection ((*c*) top).

second set of experiments consisted of sideways loading of the tip with a free weight of 2 kg. This weight was attached to a small steel cable at the end of the cutter opening while the horizontally fixed instrument tube is supported by a plastic frame that supports the handle and tube (Fig. 6). Figure 6 shows that during the first test series ($N=3$) the tip was articulated 50 deg before loading. For the second test series ($N=3$), the instrument with aligned tip was taken out of the plastic frame rotated around its shaft for 90 deg and placed back before loading.

The design intuitiveness was tested by performing an ergonomics test with eight surgeons. The instrument was given without explanation to the surgeon. The time it took the surgeon to control

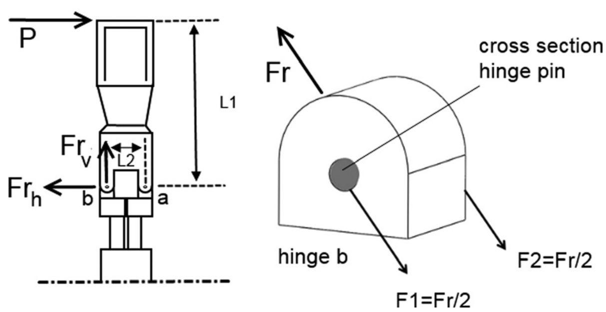


Fig. 5 Left: Schematic overview of the steerable cutter tip taken from above showing the reaction forces on hinge pin *a* under loading *P*. Right: Detailed impression of hinge part *a* or *b* showing that each hinge pin has two cross-sectional areas that both need to resist half of the reaction force.

the instrument completely was measured. In addition, the surgeons were asked to give their impression about the actuating capability.

In a third series of experiments, three biomechanical engineering students were explained how the instrument should be assembled and disassembled. During 15 min, they were allowed to practice and questions were answered. Subsequently, they had to disassemble and assemble the instrument three times in a row. The time was recorded till the instrument was completely disassembled and till it was assembled again.

In the last experiment, the steerable cutter was used in a cadaver knee by an experienced surgeon (i.e., >200 meniscectomies). The surgeon was asked to enter the knee through the anteromedial portal and to steer the instrument tip to all locations of the medial meniscus and subsequently position the tip in the lateral compartment and point at all locations of the lateral meniscus. Finally, the surgeon was asked if tip control is still possible during surgery.

Results

All dimensional requirements are fulfilled when comparing the steerable cutter components with the critical dimensions as identified in the CSD study.

The mechanical tests of the prototype demonstrated that it meets the mechanical requirements from the literature (Table 1). Pressing the tip with a force of 100 N for three times did not damage the prototype; neither did the tangential load of 20 N.

The results of the early user evaluation show that it took the eight surgeons an average of 4 s (SD1.2) to fully understand the control of the instrument (Table 2). They all mentioned that the

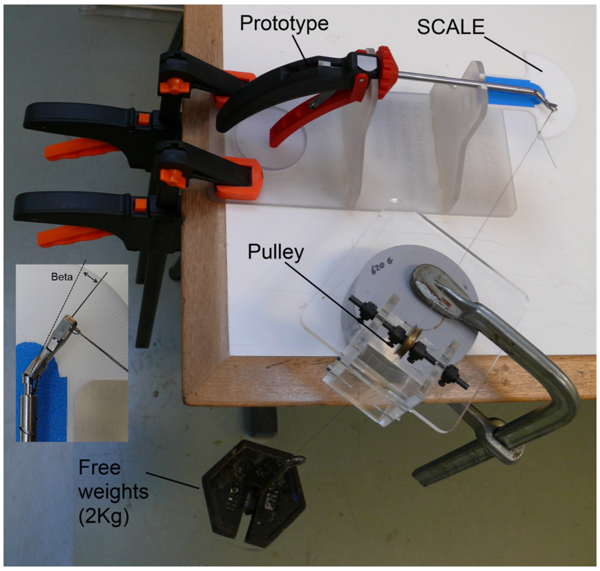


Fig. 6 Setup used to measure the deformation angle Beta under a tangential sideways tip load of 2 kg for sideways and upward tip load (latter condition is not shown in the picture). The inlay picture shows that a custom made angular scale was used to read out the angular deformation Beta.

handle grip was acceptable for knee surgery and that it is possible to use it with both the right and the left hand. Three of the eight surgeons mentioned that it must be possible to manually open the cutter tip by hand if it got stuck. All surgeons agreed that the steerable cutter as presented can become a valuable tool for orthopedic surgery.

The students participating in the (dis)assemble test took on average 82 s (SD18) to fully assemble the steerable cutter and 20 s (SD 5) to disassemble it again.

The cadaver knee experiment performed by the orthopedic surgeon was successful and shows that it is possible to navigate the tip toward the tibia plateau through both portals and to reach all potential lesion locations on the menisci (Fig. 7). The surgeon confirmed that a steerable shaft increases the reachability compared with a rigid cutter in real surgery.

Fig. 7 Steerable cutter prototype used inside the knee by a surgeon. The photographs show that the menisci can be reached and that the prototype allows control in various grip configurations.

Discussion

A complete new SATA mechanism was designed [13] and integrated in a full prototype including a tip and a handle. Evaluation of the mechanism shows that the new steerable cutter meets all important mechanical and user requirements that were derived from literature as well as the extracted requirements from the five CSDs. Although the evaluation was preliminary, it suggests that a future generation of steerable endoscopic instruments equipped with the SATA mechanism could enable additional functionality without cause difficulties in cleaning and sterilization. The limitation of this work lies in the preliminary evaluation with few repetitions and few participants. Additional mechanical tests should be conducted to test whether the instrument does not fatigue. However this remains difficult as no data are available on the number of cycles and loads typically experienced by these types of instruments.

Comparing the SATA concept with the state of the art in steering mechanisms as reviewed by Jelínek et al. [14], it can be concluded that no similar concept exist. Also Jelínek et al. show that although new rotation and translation transmission were thoroughly explored, the actuation remains conventional (i.e., cables, push rods, and gears). Especially the combination of SATA's sliders connected to the three point hinge ensures that the instrument remains strong and predominantly hollow, which makes the proposed SATA concept interesting for a broad field of endoscopic instruments.

Conclusion

A new steering concept (SATA) was developed for endoscopic instruments. The potential of the SATA concept was demonstrated by a prototype of a new steerable arthroscopic cutter in which SATA was integrated. The results show that the simple steering mechanism is sufficiently strong to withstand the forces acting on the tip during orthopedic surgery, that it is intuitive and can be taken apart for cleaning. Further fatigue followed by in vivo testing is needed to quantify the strength and benefit of steerable cutters in terms of time and cost.

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