

# Safety and Accuracy Considerations in Developing a Small Sterilizable Robot for Orthopaedic Surgery

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**Abstract** – The objective of this work was to design a compact, accurate, safe, and ease-to-use surgical robot for total knee arthroplasty. The goal of the bone-mounted robot, named *Praxiteles*, is to precisely position a surgical bone-cutting guide in the appropriate planes surrounding the knee, so that the surgeon can perform the cuts manually using the guide. The robot architecture is comprised of 2 motorized degrees of freedom (DOF) whose axes of rotation are arranged in parallel, and are precisely aligned to the implant cutting planes with a 2 DOF serial adjustment mechanism. An initial prototype was first developed and tested on saw bones and cadavers, and construction of a new, refined version is now well underway. A backdrivable system, with high-stiffness, high-precision static positioning capabilities and safe low-force dynamic movement is achieved using a quick-release, spring-loaded mechanical braking system integrated in a gear transmission unit at the level of the motor outputs. This paper discusses the technical challenges encountered during the development, design, and construction of the system.

**Index Terms** – Medical robotics, Robot-aided orthopaedic surgery, surgical safety, robotic bone milling, miniature robots.

## I. INTRODUCTION

Robotized surgical instrumentation has great potential to increase the precision and capabilities of the surgeon, to improve outcomes and recovery times for the patient, and to reduce the large number of mechanical instruments required in the operating room [1]-[4]. Even though conventional total knee arthroplasty (TKA) is in general a very successful operation, TKA is an attractive application for robotic assistance for a number of reasons. Firstly, knee mal-alignments of as little as 3° in the frontal plane have been correlated to early failures, so a high degree of implant placement accuracy is key for good clinical results [5]. Secondly, conventional TKA instrumentation systems that rely on mechanical jigs to aid bone resurfacing have been known to produce variable and suboptimal results with respect to implant alignment and fit of the femoral component [6]. Saw-guides, for example, that reference the anterior, posterior, and chamfer cuts from the distal cut may produce an outer femoral surface which is incongruent with the inner surface of the implant [7][8]. Furthermore, manual instrumentation systems usually

require that a number of guides be available in the operating room (OR) to cover the entire range of implant sizes (typically one template for each of the five to seven sizes), which can take up valuable space around the operating table and increase sterilization costs.

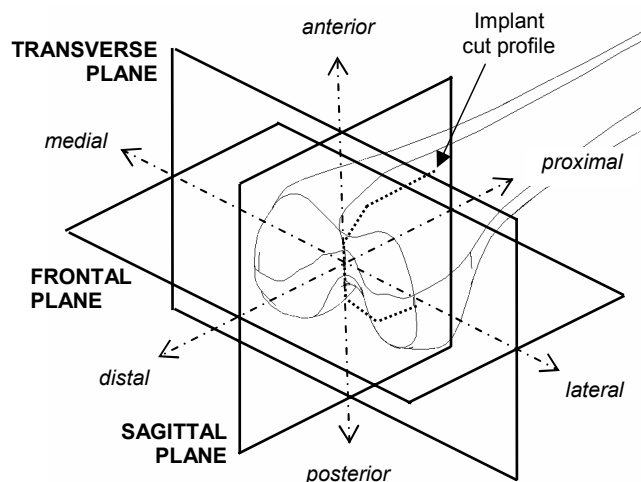


Fig. 1 Anatomical co-ordinate system of the knee. The implant cut profile (---) is projected onto the sagittal plane, illustrating the five planar cuts of a typical TKA femoral implant.

### A. State of the Art in Robotic Knee Assistants

1) *Large Sized Robots*: Much of the research in robotic knee surgery over the past decade has focused on relatively 'large' or 'floor-mounted' robots [1]-[4],[9],[10]. These systems can either position cutting-guides for the surgeon, or they can carry out bone-milling autonomously. They have been classified as being either semi-active or active, respectively [3][16]. Almost all systems, however, use more or less industrial robotic arms that have been modified for use in surgery, by, for example, incorporating a force sensor in the end-effector and redundant encoders in the joints.

The passive system described in [1], for instance, uses a large industrial six-axis PUMA 560 robot. The surgeon communicates with the arm during the operation via pushbuttons on a handheld control box which directs the robot through a series of predefined steps. Other motion

\* This work was supported in part by the ANRT France (Convention CIFRE n° 770/2002), NSERC Canada, and PRAXIM medivision.

control modes include performing large “passive” movements of the robot by the surgeon (i.e. force following) to bring the robot into the vicinity of the desired position, and small precise adjusting movements made autonomously by the robot. In [9], a smaller, six-axis PUMA 260 robot (16kg) is employed to position saw or drill guides around the knee, and the surgeon uses a computer touchscreen to slowly advance the robot from one position to the next. The authors selected a smaller, lower payload arm to minimize the space occupied in the OR and to maximize safety in the event of a controller malfunction. Although the low payload arm was initially thought to be adequately stiff because the robot was immobile while the surgeon carried out the cutting/drilling, stiffness tests revealed that a force of 18N on the saw-guide produced an unacceptable displacement of 2.5mm, which required the addition of stiffening links.

One current drawback to these types of robot assistants is that the tibia (shin) and femur (thigh) bones have to be immobilized to the operating table as rigidly as possible, typically by connecting a number of bone clamps to the OR table. Ref. [1], for example, describes a 6DOF fixturing arm equipped with heavy duty locking joints. The fully active ‘ROBODOC’ system (Integrated Surgical Systems, Davis, California) uses a milling tool rigidly attached to a 3DOF wrist on a large RRP (SCARA) arm, and has a mechanical sensor to monitor if any bone motion has occurred with respect to the robot base during cutting. If a certain amplitude of motion is detected during the autonomous milling stage, cutting is automatically stopped and the surgeon must re-register the patient and robot coordinate systems. This system also employs an emergency stop button and an instrumented end-effector which monitors the forces during milling and stops the process automatically if forces exceed a certain threshold value [12].

The ACROBOT system (The Acrobot Company Limited, London, UK), which was one of the first specially built large robots for TKA, uses a ‘hands-on’ approach where the surgeon controls the position of the milling tool using a handle instrumented with a force sensor [4]. The robot architecture is comprised of a unique backdrivable roll-pitch-yaw mechanism mounted on a ‘gross positioning’ arm which brings the ACROBOT head into the vicinity of the knee [10]. This active constraint robot allows the surgeon to move the milling tool under servoassistance within a preprogrammed region as determined from the pre-operative CT scan images [2]. Although this system may still be of considerable size and cost, the active constraint control scheme gives the surgeon enhanced control during the milling process while preventing the milling tool from entering forbidden regions of the patient.

2) *Mini Bone-Mounted Robots*: More recently, miniature robotic guide positioning devices have become available for TKA [13][14]. The Galileo (PI Precision Implants, Germany) system uses a hybrid navigated-robotic device which is fixed to the anterior-distal portion of the femoral shaft [13]. This system also allows the surgeon to navigate the guide orientation in the frontal and

transverse planes with a 2DOF mechanical adjustment mechanism. A motorised linear DOF in the proximal/distal direction then positions a distal cutting-guide to the correct cutting depth so that the surgeon can make the distal cut. A second linear DOF then slides a conventional 4-in-1 saw guide in the anterior-posterior direction so that one cutting block with four angled slots can be used for the entire size range of one specific implant geometry. This system can precisely control the cutting-guide position in the proximal-distal and anterior-posterior directions, though some drawbacks include no control of sagittal plane alignment and reduced visibility during cutting due to the conventional cutting block. A relatively high degree of bone exposure is also necessary to mount the robot base/motors on the distal shaft clear of the distal cut.

## II. PRAXITELES ROBOT CONCEPT

Within a collaborative framework between the TIMC - GMCAO (UJF) and Neuromotor Control (UBC) laboratories, and PRAXIM medivision, we are developing a new ‘universal’ bone-mounted mini-robotic guide positioner for bone sawing and milling in TKA. The device is universal in the sense that it can be used to position a single saw or mill guide at any cutting plane orientation and depth in the sagittal plane so that the distal femoral bone surface can be prepared for any implant geometry that is comprised of planar cuts.

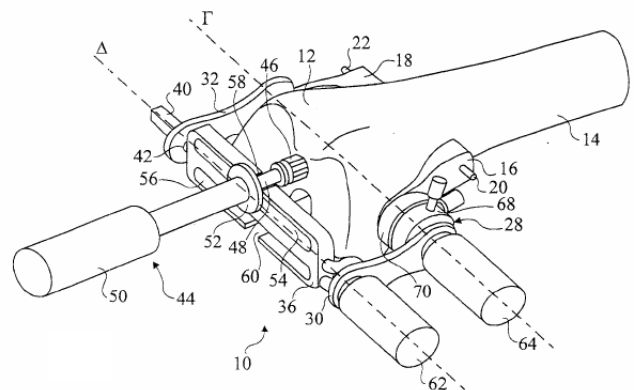


Fig. 2 Initial concept for the *Praxiteles* surgical robot.

### A. Description of Robot Architecture and Components

The modular device consists of three primary components (Fig. 2):

- 1) a fixation and adjustment system that secures the robot to the bone and incorporates a 2DOF adjustment mechanism (68,70) which permits the surgeon to manually align the robot axis ( $\Gamma$ ) to the implant profile in the frontal and transverse (or axial) planes;
- 2) a cutting tool interface that guides a saw-blade or milling tool (36).
- 3) a 2DOF actuation unit which (62,64) has two motorised rotational axes ( $\Gamma$ ,  $\Delta$ ) arranged in parallel and moves the cutting guide interface relative to the bone fixation/adjustment system.

The modular design permits attachment of the guide interfaces for the various supported cutting techniques. We

chose a robot architecture that has two motorised rotational DOFs aligned perpendicularly to the profile of the implant cuts (i.e. in line with all 5 cutting planes) so that we could precisely control the following variables:

- 1) global implant alignment in the sagittal plane,
- 2) global anteroposterior (AP) implant positioning,
- 3) global proximal-distal (PD) implant positioning,
- 4) implant geometry (shape), and
- 5) implant scaling (size)

This leaves the surgeon with two variables to adjust manually during surgery: 1) global frontal plane and 2) global transverse plane implant alignment, both of which are controlled using the 2DOF manual adjustment mechanism under computer navigation.

### III. DESIGN SPECIFICATIONS

#### A. Accuracy Requirements

To attain an overall frontal plane leg alignment within the critical  $3^\circ$  window >95% of the time [5], we would need to achieve a final cut reproducibility better than  $\sim 1^\circ$  standard deviation (SD) both on the distal femur and on the proximal tibia (our tibial cutting guide is not presented in this paper). Additionally, to consistently attain a precise fit of the femoral component, we would need similar accuracy in the sagittal plane for all five femoral cuts. The accuracy in determining the mechanical axis of the femur (i.e. the line joining the hip and knee centers) using computer assisted techniques is relatively high, introducing only  $\sim 0.3^\circ$  of variability in the frontal and sagittal planes [16]. The variability of the manual sawing process for an experienced surgeon using a slotted guide has been estimated to be on the order of  $0.3^\circ$  in the frontal plane and  $0.7^\circ$  SD in the sagittal plane [8]. Summing the variances leaves us with a narrow frontal plane error margin of  $\sim 0.4^\circ$  SD, and virtually no room for error in sagittal plane positioning.

#### B. Load bearing Requirements

The first step in specifying an adequate motor size and transmission ratio was to estimate the loads applied to the cutting guide during surgery. Unfortunately, we could not find any published studies that have measured the forces applied to a surgical cutting guide during manual sawing. Moctezuma *et al* [17] measured the forces and the moment in the plane of an unguided saw-blade while cutting bovine cortical bone blocks with a conventional oscillating saw. The saw was rigidly connected to and constantly advanced by a CNC industrial milling machine. Maximum forces and torques were on the order of 10N and 5Nm, respectively. Due to the inhomogeneous nature of the epiphyseal bone at the knee, as well as the interaction between the vibrating saw-blade and the interior walls of the guiding slot, however, we suspect that maximum forces encountered in manual surgery can be significantly higher. Indeed, conventional saw-blades have been known to jam in the slot and ‘kick-back’ in the surgeons hands during cutting [7]. We therefore estimated our target for load bearing capability as 100N applied perpendicular to the guide plane and 2Nm applied about the mediolateral axis.

#### C. Sterilization Conditions

Sterilization is defined as the process of killing all microorganisms including bacteria, fungi, viruses, and spores with the use of either chemical or physical agents. The typical procedure employed by many hospitals to prepare instruments for invasive surgery is to first clean them by washing, scrubbing, and/or soaking them in a toxic bath of diluted glutaraldehyde solution for  $\sim 10$ -30 minutes. It is mandatory that the instruments then undergo steam sterilization in an autoclave under the following conditions: temperature  $135^\circ\text{C}$ , water vapour pressure 2.1 bar, relative humidity 100%, duration of cycle >20 minutes. We therefore require a completely waterproof design in which components could be easily disassembled for cleaning/washing. We also needed to encapsulate the electrical system and connectors, to employ only chemically stable materials such as stainless steel, titanium, PEEK, and to use biocompatible lubricants for the mechanical actuation system.

#### D. Safety Systems

Several contrasting articles have been published on the safety issues related to medical robotics in orthopaedic surgery [20][21]. In general, we feel that systems which allow the surgeon to carry out the actual bone cutting are more easily accepted by clinicians than automated cutting systems in which the robot is in control of the cutting path. Although incorporating a system of position or velocity constraint could potentially enhance the cutting process, we felt that this would make our bone-mounted robot too large and cumbersome. We therefore decided to implement a fully passive cutting system in which the surgeon is in full control of the cutting process, as in conventional surgery.

We then considered several possible scenarios in which the robot could potentially cause harm to the patient or surgeon, including power/motor failure, control malfunctions, etc. For each of the following potentially hazardous scenarios, we specify a corresponding preferred result:

- 1) disruption of the robot power supply during cutting: the guide should maintain its current position
- 2) motor failure or seizing during surgery: motors should be easily replaceable at any stage of the procedure
- 3) controlling malfunctions:
  - a. the motors should be physically incapable of moving the guide, unless authorised by the surgeon
  - b. the system should be backdrivable to allow the surgeon to manually position the cutting guide in a safe zone.

### IV. VERSION I – INITIAL PROTOTYPE CONSTRUCTION

Before considering any of the above specifications in detail, we manufactured an initial non-sterilizable prototype of nominal dimensions to investigate the general feasibility of using the device in a ‘simulated’ OR setting (Fig. 3 left). In this initial system we rigidly connected the medial and lateral fixation bases (16, 18) with an arch



Fig. 3 (left) Initial prototype hardware shown positioning a saw-guide during the cadaver trials. (right) Experimental setup for measuring the accuracy and stiffness of the initial prototype.

shaped frame that traverses the anterior aspect of the femur. This helped to better distribute the loads on either side of the bone and keep the  $\Gamma$  axis straight. We incorporated the orthogonal adjustment mechanism (68, 70) on the inner side of the frame in-between one of the fixation bases (16) and the arch. On the opposite side, we put a clamping mechanism that advanced the opposing fixation base (18) into the bone so that we could clamp the frame onto different size femurs. Screw holes were added on either side of the frame so that the arch could be rigidly fixed after the  $\Gamma$  axis was adjusted. Once the arch is fixed, the 2DOF motor unit and saw-guide is attached and the zero position of each motor axis is calibrated with respect to the bone in a single step using an optical marker (rigid body) placed in the cutting-guide slot.

The following sections discuss the accuracy we achieved with this initial design configuration, and what refinements were deemed necessary as a result of the accuracy measurements and initial cadaver trials.

#### A. Manual adjustment and navigation system accuracy

Frontal and axial plane alignment is set manually under computer navigation by adjusting the pose of axis  $\Gamma$  with adjustment screws (68,70), respectively. The adjustment screws we selected had a thread pitch of 0.5mm per rotation. Assuming the smallest femur that we are likely to encounter would have a transepicondylar width of  $\sim 50$ mm [18], this would give us an angular adjustment resolution of  $\sim 0.5^\circ$  per screw rotation in the worst case. We found that, in general, a user equipped with a tool could rotate each screw such that the final resolution was better than  $0.1^\circ$ . In addition, the clamping force applied through the frame helped to eliminate any backlash in the adjustment mechanism. The final axis orientation was often offset, however, when additional fixation screws were inserted to secure the arch to the bone. The extent of this offset generally depended on how much care and time the user spent during screwing, though this was typically on the order of  $1^\circ$ – $3^\circ$ .

The precision with which a Polaris optical camera (Northern Digital, Waterloo, Canada) can localize a rigid body with three retro-reflective spherical markers spaced  $\sim 50$ mm apart has been reported to be 0.46mm and  $0.713^\circ$  SD (95% confidence interval) at the time of camera characterization [17]. The measurement frequency is on the order of 60Hz. This level of noise made it nearly impossible for a user to manually adjust the axis

orientation in real time to sub-degree precision using only the raw data. To reduce noise and keep latency unnoticeable, we implemented a simple moving average filter that selectively discards any measurement within the current window that is greater than 2 times the current SD. We found empirically that updating the display at the capture frequency with the average of the last 10 acceptable measurements provided a stable readout within  $\sim 0.1^\circ$  with virtually no detectable delay.

#### B. Motor positioning accuracy and load capabilities

Guide positioning in the sagittal plane (cut orientation and depth) is actuated with the two parallel motors. Positioning reproducibility is thus a function of the angular measurement system resolution, the gear reduction factor and the system backlash, among other factors. We could not find any sterilizable encoders on the market, so we selected a brushless DC-servomotor motor that had an integrated sensor for position feedback, and lifespan rating of 100 autoclave cycles minimum. We measured the motor sensor repeatability in reporting a static position to be  $0.24 \pm 2.0^\circ$  and  $-1.2 \pm 4.1^\circ$  (mean  $\pm$  SD,  $n = 25$ ), for the first and second motor, respectively. We therefore needed a transmission ratio on the order of 100 to keep our positioning precision well below  $0.1^\circ$  at each shaft output.

In constructing our initial prototype we used a 37 watt motor with an 86:1 planetary gearhead for both axes. The overall dimensions and weight of each component set were  $\sim \varnothing 20 \times 80$ mm and 100g, respectively. The gearhead is specified to have a backlash of  $\bullet 1^\circ$  at no load, and a torque capacity of 0.5Nm for continuous operation and 0.7Nm for intermittent operation. To reduce the backlash and increase the torque capacity, we added an additional 8:1 reduction stage between the gearhead outputs and each final output shaft of the 2DOF unit using precision machined straight spur gears. This resulted in a total reduction ratio of 688:1 and a theoretical maximum torque capacity of  $\sim 5$ Nm for each axis, assuming the spur teeth could sustain the load. We turned the final output shafts from stainless steel 304L blanks, leaving a wide flange at the output side for the spurs. To increase the number of engaging teeth and to reduce the maximum tooth stress on each spur, we machined the output shaft teeth so that they meshed with the teeth on the far side of the gearhead output spur (i.e. akin to a planetary system). We slightly over-drilled the motor mounting holes so that the gearhead outputs could be abutted against the final output spur teeth during assembly. The centre distance between each gearhead and the flanged output shaft was  $\sim 26$ mm, so we limited the sweep angle of the first and second output shaft to  $100^\circ$  and  $80^\circ$  respectively, and put the flanges on the outside of the motor housing to keep the unit relatively compact (the exposed flanges of the output shafts can be seen in Fig. 3). This provided a kinematic workspace just large enough to allow us to perform all five femoral cuts using a side milling or sawing approach.

We measured the backlash, stiffness and positioning reproducibility at the saw-guide of our initial prototype by rigidly clamping a 0.01mm resolution dial-gauge to the fixation frame (Fig. 3 right). The individual backlash

TABLE I

BACKLASH, STIFFNESS, AND POSITIONING REPRODUCIBILITY MEASUREMENTS FOR THE INITIAL PROTOTYPE

Parameter	Value
Backlash	
1 <sup>st</sup> Axis only	0.24°
2 <sup>nd</sup> Axis only	0.14°
Guide Output	0.4°
Guide Output	0.25mm
Stiffness	
1080g load, 50mm <sup>a</sup>	0.04mm
1080g load, 100mm <sup>a</sup>	0.13mm
Positioning Reproducibility ( $n = 7$ )	
Guide Output (SD)	0.04mm
Guide Output (Range)	0.12mm

<sup>a</sup>Load application and measurement point along saw-guide, referenced from the output shaft of the motor unit.

measured for the first and second axis was 0.24° and 0.14°, respectively. This resulted in a final angular and linear backlash of ~0.4° and 0.25mm at the tip of the saw-guide (Table I). The stiffness of the guide was measured by hanging a weight at various points along the guide and measuring the deflection at the point of the applied load. A mass of 1080g suspended from the saw-guide at distances of 50 and 100mm from the 2DOF unit resulted in corresponding deflections of 0.04 and 0.13 mm. The robot positioning repeatability was determined by rotating both motors by a random value, returning them to their initial positions, and then noting the dial-gauge value. The variability in positioning was 0.04 mm SD, with an error range of 0.12mm. Backlash did not significantly influence the static positioning repeatability results since gravity proved a biasing force which consistently kept the guide at one side of the backlash window.

From our preliminary feasibility experiments with sawing on cadavers, we found that the usability, visibility and stability of the guide during cutting were in general very satisfactory [15]. However, there were clearly a number of refinements that had to be undertaken before the robot could be used in real surgery. These included:

- 1) improving the safety of the positioning protocol
- 2) improving the final accuracy and ease-of-use of the fixation arch/adjustment mechanism system
- 3) incorporating space for tissues surrounding the bone
- 4) improving the guide positioning such that the leading saw-guide edge can be abutted against the bone surface
- 5) reducing the overall size and weight of the motor unit.
- 6) realising a waterproof, sterilizable, easy-to-clean design.

## V. VERSION II – MECHANICAL DESIGN REFINEMENTS

### A. Improving the positioning accuracy, clinical ease-of-use, and surgical exposure requirements of the clamp/arch

There were two important design refinements that had to be carried out on our initial prototype frame: we needed to (1) design a stiff, precise, and lockable adjustment system that regulates the  $\Gamma$  axes orientation after the system is rigidly fixed to the bone, and (2) move all elements that were adjacent to the medial and lateral

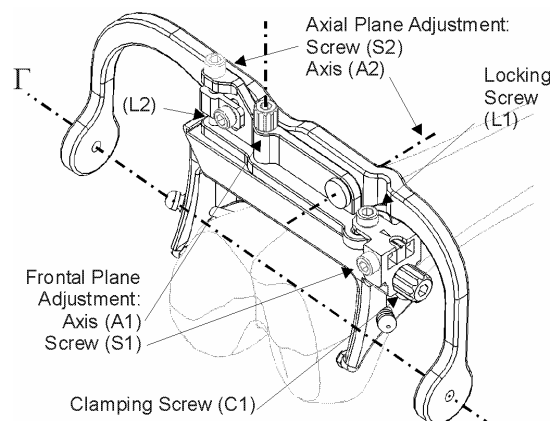


Fig. 4 Refined design of the bone fixation clamp and adjustments. Space is provided on either side of the femur for surrounding tissues.

aspects of the femur so that there is ample space for the patellar mechanism and soft tissues surrounding the knee. After several conceptual design iterations, we settled on a serial adjustment mechanism which has two axes of rotation arranged perpendicular to each other, spaced apart by ~4cm (Fig. 4). In this system, the bone clamp and arch are completely separable. This allows the clamp to be navigated and screwed or pinned onto the bone first. Then the pre-assembled arch/motor-unit/cutting-guide system can be secured onto the clamp in one simple step. To improve the ergonomics of the clamp, we incorporated a large sliding joint that slides in and out freely during navigation. Once the clamp is positioned on the bone, the small pins at the bases can be advanced into the bone by turning the clamping screw (C1). The arch mechanism is then attached to the clamp and the final orientation of the  $\Gamma$  axis can be controlled using the optical localising camera. The frontal and axial DOF can be locked using the locking screws L1 and L2. The locking screws compress each moving piece up against its corresponding base. Large surfaces at the part interfaces ensure secure locking.

### B. Improving the accuracy and safety of the motor unit

Although the system backlash did not significantly influence the position reproducibility tests on our prototype, we suspect that play will become more problematic during actual cutting with an oscillating saw. The oscillating action of the saw-blade inside the guiding slot could cause the entire guide to vibrate within the 0.4° backlash range while making the cut. To stay within our specified precision goal of <0.1° in the sagittal plane, it was necessary to investigate more precise gear solutions for our second prototype.

Harmonic drives are a compact alternative commonly used for high precision/ratio/torque applications. Backlash is extremely low and torque capacity is high because of the large tooth engagement area as compared to planetary spur gears of comparable size. We selected a small (Ø30×22mm) component set that had a high reduction ratio (100:1) and torque capacity (4.8 and 9 Nm maximum for repeated and momentary peak torque, respectively). Based on a torsional stiffness calculation, this gear should

yield a deflection of  $\sim 0.1^\circ$  for an applied torque of 2 Nm, equivalent to our nominal load bearing limit.

To improve the safety of the automated positioning protocol, we needed a configuration that satisfied all of our safety design specifications. In our initial prototype design, the torque of the motor held the guide in position during cutting. However, this did not meet any of our specified safety requirements in the cases of power or motor failures and controlling malfunctions. We therefore chose to incorporate a manual spring-loaded brake in between the harmonic drive inputs and the motor output. In this system the surgeon must hold a button down in order to release the brake and free both gear inputs to rotate. This ensures that (1) the cutting guide maintains its position regardless of the state of the motors, and (2) the motors cannot move the guide unexpectedly if the button is not depressed.

Since the brake mechanism bears the loads applied to the guide during the cutting phase, the motors need only provide enough power to position the cutting guide. We could therefore afford to use the motors directly without the planetary gearheads. This should supply enough torque to lift the cutting guide with the surgeon's hand on the brake button, but not enough to pose a significant threat to the patient or surgeon. Moreover, the surgeon should be able to overpower the motor and backdrive the system in the case of a controller malfunction.

Finally, we needed to devise a system that permitted easy replacement of the motors during surgery. Since the motors are rated only for 100 autoclave cycles, we assumed that a hospital would be likely to use them until the very end of their functional lifespan. To avoid having to frequently service the 2DOF drive unit just to replace the motors, we opted for a completely modular system in which the motors are encapsulated in a separate housing so that they could be easily detached from the gear unit and disposed of after failure. It was important to use small diameter seals at the motor outputs and gear inputs to minimize the friction forces resisting the motor.

Fig. 5. depicts our second prototype. We decreased the distance between the two motor axes to reduce the overall size and weight, and we incorporated a sliding saw-guide insert so that the surgeon can bring the tip of the saw-guide into direct contact with the bone surface [22]. We are currently in the process of constructing this new version, and we are anticipating performing laboratory and clinical validations within the coming months.

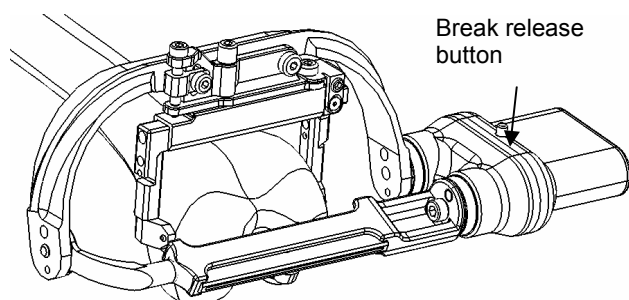


Fig. 5. Second prototype version of the *Praxiteles* surgical robot.

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