APSC496

Reference Report

**Praxim Surgical Robot**

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**1.0 Introduction**

The aim of this project is to build upon previous designs implementing the dynamic physical constraint mechanism for haptic interfaces in aiding orthopaedic surgery. As such, a developed understanding of the existing device designs are necessary to both fully evaluate the benefits of potential improvements and to compare results to quantify the projects achievements. This report will examine existing products, the previous prototype and concepts important to the function of this project.

**2.0 Existing Products**

Research was done on existing bone-shaping devices and their corresponding orthopaedic surgical procedures in order to formulate a list of common failures of the devices and complications of the procedures. In general, reports on existing bone-shaping robots lack any enumeration of failures of the device performing its specified bone-shaping task correctly. Rather, the failures found which were related to the actual devices mostly spoke about problems in device-bone mounting and excessive load or stress in the area of the mount connections. On the other hand, numerous different reports and articles were found about complications of surgeries done with existing bone shaping devices. These problems range from poor fusion of fractured bone after surgery (non-union) to significant misalignment of critical bone joints and failure of implants due to improper placement. These failures are important to find and understand, since they are directly related to the performance of the bone shaping devices, especially the device accuracy. The following is a list of failures that was generated from the research:

* Bone damage due to improper surgical procedure or excessive forces causing mechanical failure in the device or the bone structure [1]
* Loosening of device components (any or all) due to improper device placement or fastening or due to forces exceeding the tolerance threshold of the device post-operation (implants) [2][3]
* Mechanical failure of the device as a result of excessive force during implantation or during normal patient activity (implants) [3][4]
* Mechanical failure of the device as a result of improper mounting to the base bone during operation (bone-shaping surgery) [5]
* Allergic reaction to any of the device components or elements which the body is exposed to during the implantation procedure [1]
* After implantation, excessive pressure from the implant on back tissues which can result in tissue damage [1][3]
* Infection related to surgery from improper sterilization of equipment or the surgical environment or improper sterile practices of the surgical staff [1][3][6]
* Loss of neurological function or impairment of neurological function due to insults or obstructions to the nervous system (during surgery and after completion) [1]
* Cardiovascular damage, including hemorrhage from improper healing during or post-operation as well as damage to bone vasculature [1]
* Mechanical failure of the device such as loosening of its connection(s) with the bones. [6]
* Early failure of implant due to asymmetric loading, which is a direct cause of inaccurate bone-shaping and/or referencing [3][4]
* Poor knee mechanics and/or loosening of the components due to improper implant alignment with respect to bones and soft tissues (direct cause of inaccurate surface shaping) [3][4]

## 3.0 Previous Prototype

The current prototype has been qualitatively reviewed by the current design team to identify potential areas of improvement. As is, the device consists of two linkages and a motor setup as described above, where the current position of the end effecter is determined by two relative encoders and one linear encoder along the linear rail.

shows the previous prototype adapted for 2D drawing exercises. Here the motor and gear box position a pin that impedes the motion of linkage (2). The two encoders track the position of the linkages and the controller (not pictured) will reposition the pin to meet linkage (2) when it reaches the desired hard surface.

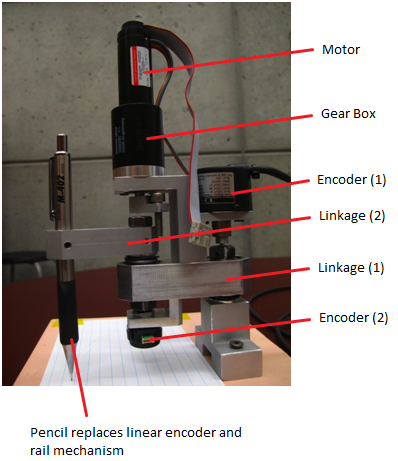


Figure 1 – photograph of the previous prototype illustrating two linkage mechanism taken from *Three-Dimensional Haptic Emulation of Hard Surfaces with Applications to Orthopaedic Surgery*

The observations made here are an initial assessment made by individuals (the project team) with no prior experience with the device or surgical procedures. The results provided in Three-Dimensional Haptic Emulation of Hard Surfaces with Applications to Orthopaedic Surgerysuggest that no additional improvements need to be made to the performance of the device with respect to hard surface generation [11]. shows a line that has been created using the previous prototype. Vertical lines are either side of a sinusoidal bump and indicate the desired surgical area and the diagram shows that the device accurately traces out the desired shape within these limits. The surface is firm when subject to collisions, but curves does not remain linear at the edges and actively forces the user away from the surgical area – a phenomenon known as lateral deflection.

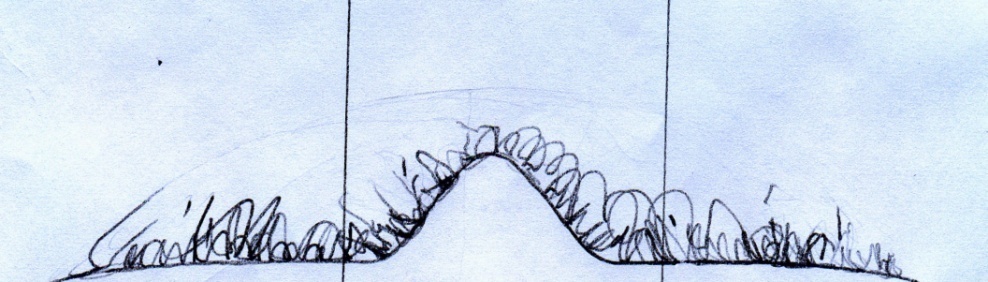


Figure 2 - Recreation of line with sinusoidal bump subject to repeated collision all along surface. Taken from *Three-Dimensional Haptic Emulation of Hard Surfaces with Applications to Orthopaedic Surgery*

As inexperienced users our analysis focused on the user experience and the user interface. We made the following observations.

### Surface Instability:

In our review the project team noted instability at the far edges of the surface – likely due to lateral deflection described previously – and at any sharp corners. This instability resulted in the device constantly making minor adjustments and significantly reduced the user’s sense of control.

### Freedom Away from Virtual Surface:

Hungr describes this quality as a freedom perceived by the user and the current design has significant ‘virtual weight’ i.e. the user must support the weight of the device throughout operation [12]. This significantly inhibits motion and makes control the end effecter position away from the surface difficult to the extent of making the device unusable.

### Control System:

The previous control system has two main issues; the use of relative encoders requires calibration of the device and the 3D surfaces are currently modelled using functions describing the surfaces. Limiting the amount and complexity of calibration required will significantly improve the user experience, especially for novice users. The second issue limits the number and type of surfaces that can be implemented. In order for the device to be used effectively in a surgical environment, the virtual surface must be able to be adapted to the unique features of a specific knee or implant. This issues provides a great problem as the current modelling technique has been implemented to ensure that the device updates frequently enough to accurately locate the position of the end effecter which can lead to hysteresis.

**4.0 Main Functions of the Robot**

## In order to effectively improve upon the previous design, a clearer understanding of the robot's main functions was required. This section investigates the following functions: hard surface emulation, haptic interface and sterilization.

4.1 Hard Surface Emulation

In Haptic Emulation of Hard Surfaces with Application to Orthopedic Surgery Nikolai Hungr suggests that the ideal features of a haptic interface would be [12]:

* A realistic surface collision, to simulate an impenetrable surface when met with force
* A realistic surface rigidity, to ensure precise creation of the desired surface
* Unimpeded surface departure, to give user complete control of motion
* Smooth and precise surface tracing, to aid the generation of defined and reproducible surface
* Unimpeded motion away from surface, to ensure that there is no unnecessary force required to operate the device

The dynamic physical constraint mechanism achieves these objectives using a two linkage system that changes the position of a physical constraint - accounting for the current position of the linkages and the 3D surface desired - to impede the motion of the linkages, thereby creating a 3D hard surface.

4.2 Haptic Interface

There are three issues regarding ergonomics with surgical robots – interface to the robot, interface to the patient and interface to the user. Many of the existing robots incorporate a touch-screen to allow user input and give visual feedback. The apparent drawbacks with using a touch-screen display are increased complexity and design time. Surgical robots with industrial robotic arms like the Acrobot have to be fixed to the ground due to their large size and require the operating area of the patient to be immobilized by attaching it to an apparatus to the operating table. Any misalignment detected during the procedure will require the surgeon to recalibrate the robot. The Praxiteles, for example, solves this problem by reducing the size of the robot and attaching it directly to the femur. This uses less valuable real estate in the operating room and eliminates the need to immobilize the leg, but imposes additional challenges due to constraints on size and weight. Other surgical robots do not have issues with the weight of the robot resisting the user’s actions as the robots are suspended from an arm. With respect to this project in particular, there is no available literature on this issue since there are none similar products in existence. However, the non-surgical haptic device from Haption employs a system to compensate for gravity. This could reduce the strain on the user and prevent any unwanted movement due to gravity.

4.3 Sterilization

In order for a robot to be used in an operating room, it is required to be sterilized before every use. Some common methods for sterilizing surgical robots include: autoclave, ethylene oxide gas (EOG), ultraviolet sterilization and a presterilized drape. The most widely used method is the autoclave; however, many surgical robots cannot be sterilized with the autoclave because of its negative effect on many motors and delicate sensors [13]. EOG, as used for the NeuBot [14], and ultraviolet are less damaging to motors and sensors, but these methods are not as common and not available in every hospital. Many surgical robots have the end effectors sterilized using an autoclave while the rest of the robot is draped in presterilized bags.

**5.0 Conclusion**

Now that we have gained a clearer understanding of this project we must now reassess and modify our original requirements and evaluation criteria to better reflect our understanding of the challenges we face.

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**Appendix A - Abstracts of Related Articles**

**Orthopedic surgical device for simultaneous bone removal on both sides of a fixation pin**

A slotted bone rasp for reciprocal planing of opposed bone surfaces joined by a fixation pin so that the bone surfaces are made congruous and parallel to each other preparatory to bone fusion irrespective of pin orientation includes a shank with a pair of legs defining a slot for accommodating the pin and the legs having a flat side and an opposed abrasive side for remodeling the bone surfaces. Each leg includes an inner opposed convex surface whereupon the slot is narrowest at its midline so that the rasp is laterally pivotal transverse to the pin axis providing oblique angulations of the plane of bone removal relative to the pin axis; and the rasp also being rotatable to at least 90 degrees arc of rotation about the pin for 360 degree coverage of the bone surface creating two parallel bone surfaces in maximal end-to-end contact for successful bone fusion.

**MBARS: Mini Bone Attached Robotic System for Joint Arthroplasty**

A mini bone attached robotic system (MBARS) was developed for shaping of the bone cavity in joint arthroplasty. While the system is designed for a general use in joint replacement procedures, the initial implementation was for patellofemoral arthroplasty (PFA) procedure. The current application is image-based, with the plans to develop an image-free approach in which all data collection and planning is performed intra-operatively in the robot coordinate system, eliminating the need for external tracking in the operating room. Experiments conducted using the first MBARS prototype supported the feasibility of the approach. The applied methodology could be extended to other orthopaedic procedures to improve the accuracy and operational time. Moreover, it enables use of the next generation, more anatomically shaped implants and related minimally invasive surgical procedures.

**Robot-aided system for surgery**

**United States Patent 5154717**

A system and method for positioning a tool relative to a patient's bone to facilitate the performance of a surgical bone alteration task. The system comprises a bone immobilization device for supporting the bone in a fixed position with respect to a reference structure, and a robot that includes a base fixed in position with respect to the reference structure. The robot also includes a mounting member, and a manipulator connected between the base and the mounting member and permitting relative movement there between. The tool to be positioned by the system is mounted to the mounting member. The mounting member is caused to move relative to the reference structure in response to movement commands, so that the tool can be moved to a desired task position to facilitate performance of the task. The system preferably also includes a template attachable to the mounting member, a feature of the template representing a portion of a task. Preferably, the template is secured to the mounting member, and the template is then manually manipulated such that the template feature is properly oriented with respect to the patient's bone. The template position is then recorded as a reference position that may thereafter be combined with a geometric database defining the task to determine the position of the tool. Particular embodiments for a bone immobilizer, a template and a saw guide are also described, together with a stabilizing device for the robot and a safety device for the robot base.

**Endoprosthetic bone joint devices**

**United States Patent 4106130**

An endoprosthetic bone joint device of ball-and-socket form has a socket component with a compound concave surface therein including a cup bounded by an annular trough, the co-operating ball normally seating in the cup but being alternatively seatable in the trough when dislocation would otherwise occur.

**Prosthesis-to-bone interface system**

**United States Patent 4064567**

A woven basket is placed over the stem of a prosthesis and receives bone cement therewithin and through its intersticies. The resulting prosthesis-to-bone interface greatly improves the distribution of forces transferred to the bone.

**Assessing the condition of a joint and assessing cartilage loss**

**United States Patent 7,184,814**

Methods are disclosed for assessing the condition of a cartilage in a joint and assessing cartilage loss, particularly in a human knee. The methods include converting an image such as an MRI to a three dimensional map of the cartilage. The cartilage map can be correlated to a movement pattern of the joint to assess the affect of movement on cartilage wear. Changes in the thickness of cartilage over time can be determined so that therapies can be provided. The amount of cartilage tissue that has been lost, for example as a result of arthritis, can be estimated.

**System and method for performing image directed robotic orthopaedic procedures without a fiducial reference system**

**United States Patent 6,033,415**

A method for transforming a bone image data set representing at least a partial image of a long bone to a robotic coordinate system, comprising: generating the bone image data set from a bone image; registering a bone digitizer arm to the robotic coordinate system; generating a digitized bone data set by taking bone surface position measurements with the digitizer arm; and transforming the bone image data set into the robotic coordinate system by performing a best-fit calculation between coordinates of the bone image data set and corresponding coordinates of the digitized bone data set.

**Imageless Robotized Device and Method for Surgical Tool Guidance**

**US Application 20070156157**

An imageless robotized device for guiding surgical tools to improve the performance of surgical tasks is provided. The method of using the robotized device may include the steps of: collecting anatomical landmarks with a robot arm; combining landmarks data with geometric planning parameters to generate a position data; and automatically positioning a guiding tool mounted to the robot arm. Particular embodiments for a limb fixation device are also described.

**Computer-assisted hip resurfacing surgery using the Acrobot Navigation System**

Proc. IMechE Vol. 221 Part H: J. Engineering in Medicine

The authors have previously reported on the laboratory development of the

Acrobot Navigation System for accurate computer-assisted hip resurfacing surgery. This paper describes the findings of using the system in the clinical setting and including the improvements that have been made to expedite the procedure. The aim of the present system is to allow accurate planning of the procedure and precise placement of the prosthesis in accordance with the plan, with a zero intraoperative time penalty in comparison to the standard non-navigated technique.

At present the navigation system is undergoing final clinical evaluation prior to a clinical study designed to demonstrate the accuracy of outcome compared with the conventional technique. While full results are not yet available, this paper describes the techniques that will be used to evaluate accuracy by comparing pre-operative computed tomography (CT)-based plans with post-operative CT scans. Example qualitative clinical results are included based on visual comparison of the plan with post-operative X-rays.

**BRIGIT, a Robotized Tool Guide for Orthopedic Surgery**

Proceedings of the 2005 IEEE

International Conference on Robotics and Automation

The BRIGIT project (Bone Resection Instrument Guidance by Intelligent Telemanipulator) aims at developing a surgical robot for orthopedic surgery. This robot should be used as a positioner of a guide providing a mechanical support during bone sawing or drilling. The planned position of the guide is obtained after a registration procedure consisting in collecting anatomical landmarks on the surface of the patient's bone. This can be done in a cooperative mode, by grabbing the tool tip, through an appropriate force control, or in a teleoperated mode via a master device. In order to facilitate the installation of the robot in the operating theatre and to improve its performance, a procedure based on interval analysis has been developed to optimize the robot placement with respect to the patient, the surgical staff, and the obstacles of the environment.

**Haptic Emulation of Hard Surfaces with Applications to Orthopaedic Surgery**

A generally accepted goal in orthopaedic surgery today is to maximize conservation of tissue and reduce tissue damage. Bone-conserving implants have bone-mating surfaces that reproduce the natural curvature of bone structures, requiring less bone removal. No small, reliable, inexpensive and universal bone sculpting technique currently exists, however, that can both create and accurately align such complex surfaces. The goal of this thesis was to develop a haptic hard surface emulation mechanism that could be applied to curvilinear bone sculpting using a surgical robot. A novel dynamic physical constraint concept was developed that is able to emulate realistic hard constraints, smooth surface following, and realistic surface rigidity, while allowing complete freedom of motion away from the constraints. The concept was verified through the construction of a two-link manipulator prototype. Tests were run on nine users that involved each user tracing out five different virtual surfaces on a drawing surface using the prototype. The primary purposes of prototype testing were to obtain subjective data on how effectively the dynamic physical constraint concept simulates simple surfaces, to assess how it reacts to typical user interactions and to identify any unexpected behaviour. Users were 100% satisfied with the prototype’s ability to emulate realistic and stiff hard surfaces and with its ease of manipulation. The amount of incursion into each of the virtual surfaces by all the users was measured to assess the precision of the system with the goal of deciding whether this new haptic concept should be further developed specifically for precision applications such as surgery. For curvilinear surfaces, 90% of the cumulative distribution of the measured data was less than 2mm, while for linear surfaces it was less than 6mm. Four behavioural effects were noticed: lateral deflection, reverse ‘stickiness’, hysteresis and instability in certain areas. These effects were studied in detail to determine how to either eliminate them or to minimize them through system design optimization. A computer simulation was also used to model the behaviour of the prototype and to gain further understanding of these effects. These analyses showed that the concept can be successfully used in curvilinear bone sculpting.

**Medical Robotics in Computer-Integrated Surgery**

This paper provides a broad overview of medical robot systems used in surgery. After introducing basic concepts of computer-integrated surgery, surgical CAD/CAM, and surgical assistants, it discusses some of the major design issues particular to medical robots. It then illustrates these issues and the broader

themes introduced earlier with examples of current surgical CAD/CAM and surgical assistant systems. Finally, it provides a brief synopsis of current research challenges and closes with a few thoughts on the research/industry/clinician teamwork that is essential for progress in the field.

**Micromanipulator system (NeuRobot): Clinical Application in Neurosurgery**

The NeuRobot, telecontrolled micromanipulator system, having a rigid neuroendoscope and three robot arms, has been developed for less invasive and telecontrolled neurosurgery. It has a capability of ophisticated surgical procedures through a small window of 10-mm width. In this paper, bipolar coagulator system, sterilization, and experience of clinical application are reported. The NeuRobot

will become a promising neurosurgical tool for less invasive neurosurgery.

**Risk analysis and safety assessment in surgical robotics: A case study on a biopsy robot**

One of the most important issues in medical robotics is safety and integration into the clinical workflow. If a robot is not safe and its use is complicated by difficult handling and complex user interfaces physicians would not use a robotic system during clinical patient trials, whatever the other advantages are. However, there are only few publications on this topic, in particular on risk management in developing a robotic prototype (for clinical trials). In this paper risk management and the safety of using robot-assisted surgery equipment are discussed and demonstrated exemplarily in the process of developing a prototype biopsy robot.

**Appendix B - User / Device Interactions**

# User/Device Interaction

The following lists potential user device interactions and general guidelines and considerations for each. Interactions have been split up into those that relate closely to the actual surgery and the surgical procedure – time and user critical – and those that can be completed in less time critical environments.

### During and in preparation for surgery

1. Mounting and installation
   1. User must attach and orient the device with respect to the patients knee in a operating room
   2. User should fit securely to the knee and have means to restrain the device and the knee with respect to the user
   3. May be time sensitive
2. Model Input
   1. The user must input a model specific to the surgery – based on patients kneed and the type of implant used – into the device
   2. User should be confident that the shape has been implemented accuretley before proceeding with the surgery – a method to verify what the outcome is likely to be
3. User connection
   1. User must have means to control the device using their arm
4. Tool connection
   1. User must have ability to connect various surgical tools to the device that could potentially improve the quality of the surgery – milling tool, scalpel, saw
5. Device Motion
   1. User must be able to move device to create and position the device for the required cuts
   2. User should have the necessary range of movement to make all desired cuts
   3. User should not be required to add excessive force to create motion and should have complete control of device away from the hard surface
6. Operation
   1. Use must have means to activate/deactivate device both for normal operations and in case of emergency or error

### Other Interactions

1. Sterilzation
   1. Device must be sterilized before surgeries
2. Maintenance
   1. Maintenance should be able to be implemented regularly – between surgeries - with minimal technical knowledge of the device
   2. All device specific calibration should take place outside of the operating room. This refers to orienting the device with respect to itself rather than with respect to the desired hard surface and patients knee.