**Requirements and Evaluation Criteria:**

Problem Statement:

“Refining specific hardware & software components of an existing 3D Haptic Interface, based on client feedback, to produce a prototype that will be ready for cadaver testing”

The inputs of the interface are as follows:

* A power source, required for the operation of all electrical components
* The computer-generated data of the 3D surface to be shaped
* User-applied forces, which move linkages and the cutting tool

The outputs of the interface are as follows:

* The feedback that the device provides to the user (in the form of a virtual surface constraint)

This project will have a set of requirements that come from either the previous iteration of the project and its prototype, from client feedback regarding current issues with the existing prototype, or completely new concepts/requirements developed by the current design team. The following are the design requirements for the 3D Haptic Interface Device:

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| --- | --- | --- | --- | --- |
| **#** | **Design Module** | **Requirement Type** | **Design Requirement** | **Rationale** |
| 1 | System | Functional | Device provides a hard constraint when the user pushes the tool beyond the operational boundary (minimum resistance of 10kN/m) | This is the product concept |
| 2 | System | Functional | The tool, when mounted on the device, is able to make both curved and planar cuts in 3-dimensions | This is the product concept |
| 3 | System | Functional | System constantly monitors position of device and cutting tool | This allows the device to properly respond to user movements |
| 4 | System | Functional | Device’s hard surface constraint must be physically imposed within 0.5mm of the desired model surface | This provides accurate and aligned surgical results |
| 5 | System | Functional | Device must facilitate the drawing of 3D shapes unique to each surgery generated by the user. | Facilitates performing unique surgeries for a wide variety of different implant shapes and sizes |
| 6 | System | Interface | Device must be able to be solidly mounted on bone/knee during surgery, completely secured with minimal movement (+/- 0.5mm) | Required for ensured safety of system, minimizing tissue damage, allows surgeons to be confident in positioning |
| 7 | System | Interface | Device must be capable of being sterilized (steam at 134°C) without deteriorating materials and/or components | Allows surgeon/surgical staff to maintain the sterile area while the device is in use, and allows for multiple uses |
| 8 | System | Interface | Any un-sterilizable components must be completely and sealed and contained in a sterilizable encasement | Allows surgeon/surgical staff to maintain the sterile area while the device is in use, and allows for multiple uses |
| 9 | System | Ergonomics | Device must be small/compact enough to both fit into a standard hospital-sized autoclave and be mounted to the operating location without impeding the user’s access. | Allows for easy sterilization, and is less cumbersome for surgeons to work with |
| 10 | System | Ergonomics | Device must be light-weight, weighing less than 10 lbs in total | Minimizes external forces applied to surgical area |
| 11 | System | Ergonomics | Device must have a resistance to user-directed movement less than a virtual weight of 1 kg | Ensure that movement is not difficult to achieve and easily follows the surgeon’s directions. |

**2.3 Evaluation Criteria**

The impact of the requirements mentioned above on the user depends on immediate needs or priorities versus preferences. The main priority for the user lies in the sheer functionality of the device – in its immediate performance. In simple terms, the device must be accurate, smooth, and easy to operate. Satisfaction curves for “functional” evaluation criteria are thus expected to be sharp, as the user will never be satisfied with less performance for the device. This trend will be less profound in interface requirements, since users are generally willing to sacrifice small additional functions without much dissatisfaction. The following descriptions present the reasons why the requirements stated earlier are considered priorities. Also, satisfaction curves for major requirement criteria are provided.

**Tool Position Instability:**

A user expects that vibrations and roughness which commonly occur at sharp corners in the desired surface to be reduced. Practically, these areas in the surface are critical to the success of the entire surgery altogether. Thus, in order to satisfy the user (surgeon and ultimately, the patient), a strict limit of 1 mm was chosen for the radius of inaccuracy in areas of high instability. Similarly, maximum satisfaction occurs when there is no instability present (radium = 0), and radii above 2 mm will be deemed as unsatisfactory.

**Surface Shape Acquisition Method:**

This desired surface to be shaped is the main input into the device, thus, making this method of input easier on the user has a very high impact on the user’s satisfaction. Currently, there are only three basic shapes possible for the user to choose from. In order to sufficiently satisfy the user, shapes must not be imposed on them; rather, they should be able to generate the shapes they would like to implement. An interface with the ability to process the desired shapes of a user, provided they are in mathematical equations, will sufficiently satisfy the majority of surgeons on the market. For utmost satisfaction, this interface can be upgraded to immediately be able to process any 3-D computer file of the shape, for example, from a CT scan or a CAD program.

**Total Device Weight:**

The overall weight of the device is crucial to reduce, for a variety of reasons. Most importantly, a heavy device might not be mountable on the femur during the surgery due to its excessive weight. Even when mounted, any misalignment or movement by a heavier device continually creates larger forces and stresses on the existing bone, an occurrence which can lead to complications in tissue healing. Finally, a lighter device is easier for clinical staff to carry, transport, clean, and sterilize. Thus, weight is considered to be a high-impact requirement on user satisfaction.

**Resistance to Motion (*virtual* weight):**

It is important to reduce the total weight of the device, but it is equally important to minimize the “virtual weight” the user experiences when operating the device. Surgeons want a device which operates smoothly and follows the natural movements of their hands with the least resistance. This is a high-value priority for the new design, as it directly impacts the main function of the device. In order to quantify *virtual* weight, we used our knowledge of *actual* weights which normal human hands can operate under with ease and low resistance motion. To sufficiently satisfy the user, this *virtual* weight should fall between 1 and 2 pounds, with anything under 1 pound being maximally satisfactory, and anything above 2 pounds being unsatisfactory.