# Design of an Endonasal Graft Placement Tool for Repair of Skull Base Defects

**Richard J. Hendrick**

**Ray A. Lathrop**

**John S. Schneider**

**Robert J. Webster, III**

Department of Mechanical Engineering,
Vanderbilt University

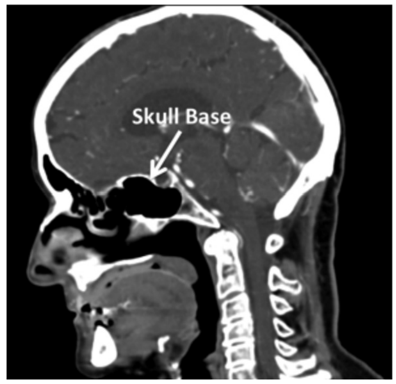


**Fig. 1 Sagittal head MRI revealing the skull base anatomy and relative positioning of the nasal passage and skull base**

## 1 Background

Endonasal skull base surgery (see Fig. 1) has proven to be a safe, effective, and significantly less invasive surgical approach when compared to open, highly invasive techniques [1]. Nevertheless, one initial difficulty with this minimally invasive approach has been postoperative leakage of cerebrospinal fluid (CSF) [2]. While the incidence of postoperative CSF leaks are low ($<1\%$), the potential consequences are severe and include meningitis, brain abscess, neurologic deficits, brain hemorrhage, and death [1].

Depending on the nature of the surgery, violation of the skull base may be inevitable and is not uncommon during skull base surgery, regardless of the surgical approach. Several techniques for defect repair exist, but all are predicated on graft placement at the defect site (with the exception of the pedicled flap approach). It has been noted that, with current surgical tools, endonasal manipulation and placement of these grafts is difficult [2].

Endonasal graft placement is difficult for a variety of reasons. First, tool manipulability is severely limited by the narrow nasal passage; the surgeon's first challenge is maintaining control of the small graft (potentially as small as one mm) as the tool traverses from the nasal passage to the skull base defect. Further complicating the task of positioning this graft is the high variability in graft types (mucosa, bone, cartilage, or fascia [1]). Each of these grafts has varying rigidity, size, and thickness. Regardless of the graft's properties, the graft needs to be oriented in such a way that it optimally mates with the skull base defect to ensure full coverage or adequate fill, depending on the technique. The tools that are currently in use are either blunt instruments (with no gripping mechanism) that can be used to push the graft into place (with various curvatures) or graspers (forceps or grippers). Each of these tools has limitations; blunt instruments make holding the graft challenging as it traverses the nasal passages, and graspers make the simultaneous orienting of the graft and force application difficult. It is critical to note that these tools are not designed for endonasal graft placement. They are being used because, currently, there is no better solution.

Ideally, the surgeon would like to be able to hold the graft while it is oriented and placed, and then continuously apply force perpendicular to the skull base and release the graft. In this paper, we describe the design of a tool that incorporates these intuitive concepts and is compatible with any graft type.

## 2 Methods

Our first goal was to give the surgeon the ability to hold and let go of the graft as they wish while simultaneously applying pressure to the skull base. This was particularly challenging because of the graft variations. The simplest version of holding and letting go is a gripper mechanism that can be actuated to open and close like a human hand. However, simultaneous pressure on the skull base is difficult with this setup. When the surgeon opens the gripper jaws, they often lose control of the graft and drop it into the surgical space, adding several minutes of costly surgical time to retrieve the graft and reattempt the placement.

These difficulties inspired the idea of a "finger" that could extend and retract out of the tool when actuated by the surgeon. We realized that graft loading could be accomplished outside of the patient, and our tool only needed to be able to release the graft. This led to the development of a design consisting of a shelved tube with a Nitinol (NiTi) gripping wire. In this design, a small diameter tube is cut at the end to create a "shelf" for the graft as depicted in Fig. 2.

As the graft is manually wedged onto this shelf (outside of the patient), the NiTi wire bends away from the shelf, and the graft is held in place by the opposing forces of the tube and the bent superelastic NiTi wire. The force on the graft created by the elastic deformation of the NiTi wire increases as the graft is slid between the wire and the shelf, towards the base of the shelf. Just as a beam in bending requires more energy to deflect closer to its base, the NiTi wire requires more energy to deflect closer to the base of the shelf. This fact allows the surgeon to select grip force as desired during initial loading of the graft, by manually adjusting the position of the graft relative to the shelf base, and to accommodate grafts of varying thickness and rigidity.

We envision this tool operating in three configurations: load, hold, and release. In the loading configuration, the wire is fully extended and is easily manually deflected by the surgeon's hand to insert the graft. In the holding configuration, the wire retracts a short distance (to get the wire out of the way — this step does not change gripping force), and the tool is inserted through the nose. Lastly, after the graft is positioned as desired at the skull base, the graft is released by full wire retraction, and simultaneously pushed in place with the shelf until the surgeon is confident the graft is adequately set.

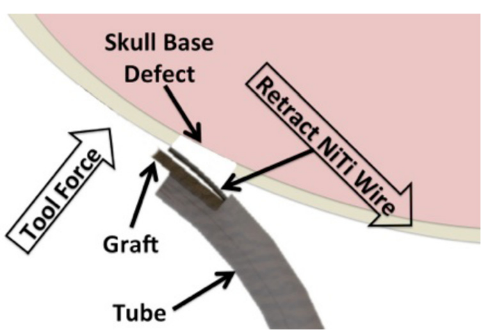


**Fig. 2 Shelved tube with NiTi wire gripping design**

Manuscript received March 15, 2013; final manuscript received April 24, 2013; published online June 12, 2013. Assoc. Editor: Michael G. Olsen.

  

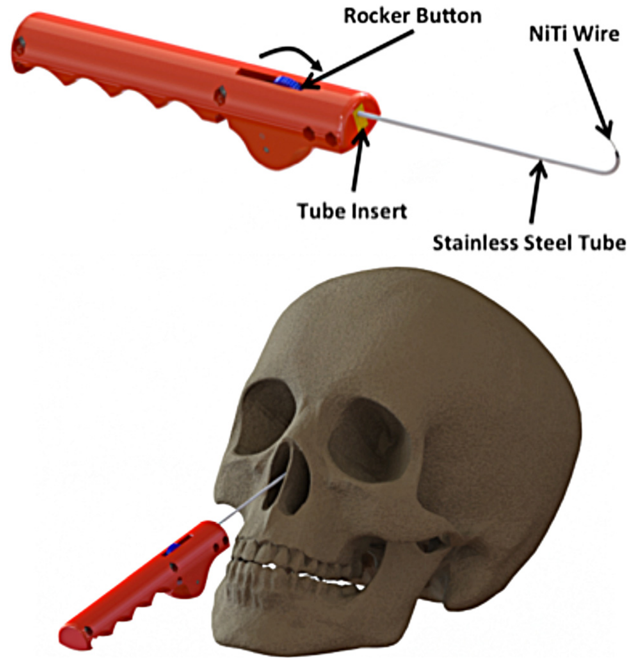


Fig. 3 Device in the loading position (top) and depiction of endonasal graft placement with the new design (bottom)

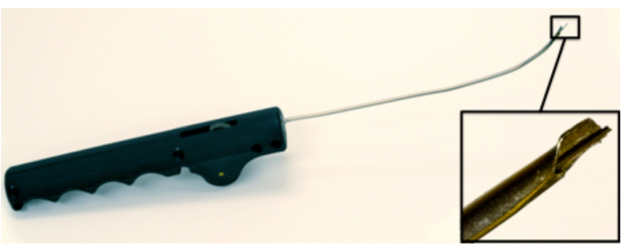

Fig. 4 Prototype of endonasal graft placement tool

It is important that the tool be operated completely with one hand, leaving the surgeon's other hand free for other surgical tasks. Thus, we designed a finger-actuated rocker button for NiTi wire retraction. The NiTi wire is attached to this rocker button (See Fig. 3). The handle can be grasped in either a power grasp, in which the surgeon's thumb actuates the rocker, or in a pen grasp (Fig. 5) with the index finger operating the rocker.

## 3 Results

Finally, we built a prototype of the above design. The handle was split along the midline for easy assembly and was 3D printed. The rocker and the insert that secures the tube were laser cut from acrylic. The outer tube was manually curved stainless steel hypodermic tube 2.15 mm in diameter, and the rocker was pinned with a brass pin. The shelf at the end of the tube was cut with a dremel tool and filed for smoothness. Our proof of concept prototype is depicted in Fig. 4.

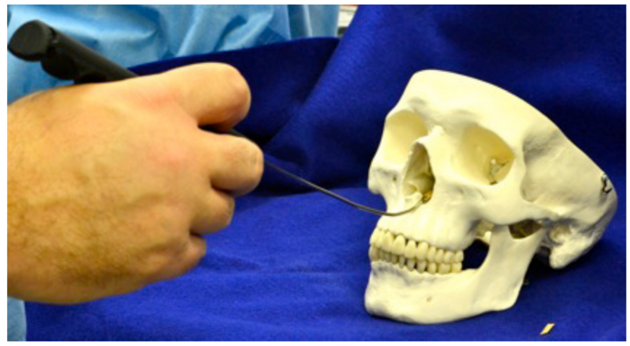

Fig. 5 Qualitative experimental validation of endonasal graft placement tool

To verify the functionality and ease of use of our design, we conducted benchtop testing to obtain qualitative feedback from an experienced skull base surgeon. We set up a skull model and the surgeon inserted the instrument while holding a small simulated graft made of cardboard with the approximate thickness and size of a clinical graft (see Fig. 5).

We asked the surgeon to evaluate the manipulability and ability to control graft placement compared to current surgical tools. The surgeon felt that the primary advantages of this device were complete control of the graft and the ability to place the graft and continue to apply force. He noted that these advantages would lead to increased surgeon confidence in the quality of skull base defect reconstruction and a significant decrease in operating time (up to 30 minutes per case).

## 4 Interpretation

We have presented a novel surgical tool design utilizing a shelved tube with a Nitinol wire gripping mechanism. This tool has been designed specifically for skull base graft placement and fills a gap for surgeons who currently struggle placing grafts using tools that are not well-suited for the task. Because this design allows for simultaneous gripping, orienting, and force application, we believe that this tool will increase surgeon confidence in skull base defect reconstruction quality, while decreasing operating time.

In future work, we plan to replace the materials in the handle with autoclavable materials. It is unclear whether a future commercial version of the tool would be disposable or reusable, but either approach is straightforward technically, so the choice will likely be dictated by business considerations. We also intend to evaluate the next iteration of our design in cadaver studies that directly compare the performance of our design against the tools that are currently used.

## References

[1] Kim, E., and Russell P., 2010, "Prevention and Management of Skull Base Injury," Otolaryngol. Clin. N. Am., **43**, pp. 809–816.
[2] Zanation, A., Thorp, B., Parmar, P., and Harvey, R., 2011, "Reconstructive Options for Endoscopic Skull Base Surgery," Otolaryngol. Clin. N. Am., **44**, pp. 1201–1222.