**Need 3:**

A C-shaped aiming device for posterior cervical spinal fixation to increase precision, patient safety and decrease time of surgery

**Problem:**

According to the statistics nearly one-third of the spinal surgical interventions are performed on the cervical vertebrae[1]. Lateral mass fracture, burst fracture and dislocation are amongst top indications of a surgical intervention[2]. The cervical vertebrae are quite different in anatomy with the lumbar vertebrae. The spinal cord, nerve roots and the vasculature are more prone to injury if the fracture screws are not well aligned in the lateral mass[2]. In addition to that, two pedicles of the lumbar screws make almost a horizontal plane with the upper facet of the vertebral mass. The anatomy of the lateral mass in the cervical vertebrae are more complicated because of the angulation of the lateral masses in the sagittal plane. The angulation of the lateral mass decreases from C2 to C7; however most of the fractures are reported to occur in between C3-C6, where the angulation is not negligible.

The sagittal and lateral angulations of the lateral masses mandates a high precision in the screw insertion to the cervical vertebrae. The precision is currently achieved by drilling through the vertebra by multiple X-ray images during the insertion. Moreover, since the angulation is between 25-40 degrees in sagittal plane, usually the skin incision needs to be extended inferiorly to expose the insertion angle of the screw. Figure 1 shows an X-ray view of the cervical spine laid over with the lateral mass angulation and incision projection. The incision could be more extensive in case of obese patients, mainly due to more profound access to the insertion point.

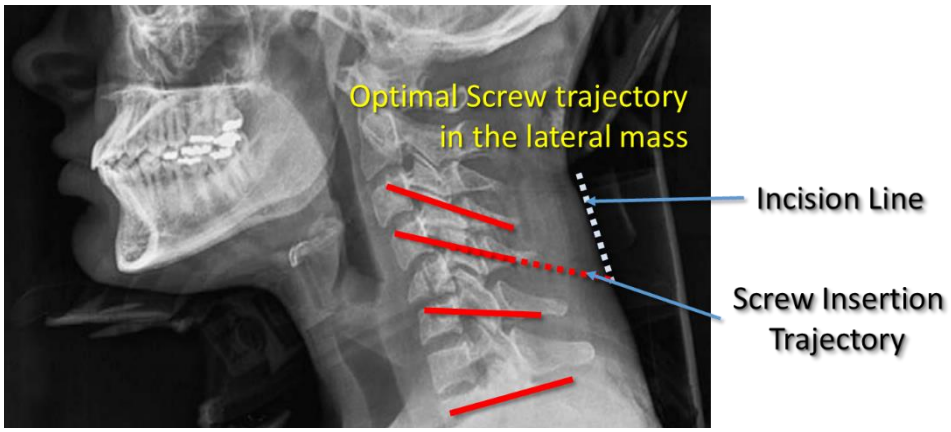


**Figure 1:** The optimal screw trajectory in cervical spine (red lines), and the incision line (white dashed line). Note that the incision should extend inferiorly to ease the direct access of the surgeon to the insertion angle of the screw. (Image from Dhurev et al., 2006 [2], text and lines laid over the original image)

During the surgeries our team observed that a significant time of a cervical spine fixation was spent on finding the proper angle of the screw insertion and extending the incision to place the drill in the correct direction to perform drilling. In addition to that, several X-ray images

were needed to confirm the correct trajectory as the drill was advancing. In the worst case, during a surgery, the patient started coughing which caused the surgeon to withdraw the drilling so the trajectory obtained was lost. The bone drilling took almost 20 minutes in one case.

During the last decade, a less invasive approach is trending in the fracture fixation of extremities. In this approach, thanks to percutaneous techniques and utilization of external aiming devices, the intramedullary nails and some of bone plates are implanted without the conventional vast incisions. The same concept could be used to design a C-shaped aiming device for the cervical spine fixations in posterior approach. Moreover, the device should be capable of restricting the depth of drilling in a surgeon-adjustable limit. Figure 2 shows a similar C-shape less invasive aiming device.


**Figure 2:** A less invasive aiming device for proximal humeral fixation with Philos® plate (DePuy Synthes, Bettlach, Switzerland[3]).

**Market:**

The volume of spinal procedures is expected to be slightly more than 3 million procedures worldwide in 2016[4]. Out of this volume, approximately 800,000 is projected to be performed in the US in 2016[4]. Cervical spinal procedures formed 35% of the total volume and the other 65% is related to thoraco-lumbar procedures[1]. There is a huge discrepancy in the literature comparing the relative percentage of anterior versus posterior approach in cervical fusions [5]. To remain conservative, we assume one-third of the total volume to be performed in posterior approach. The calculation led us to a total number of nearly 650,000 procedures worldwide. Considering each clamp work up to 200 surgeries and targeting 10 percent of marketshare, there is a need of 325 clamps per year. The average selling price for orthopedic aiming device is around 2000-3000 US Dollars with radio-lucent material.

**Need Criteria:**

1. The aiming device should be radio-lucent.
2. The aiming device should be able to restrict the drilling depth.
3. The aiming device should be low-profile, so that doesn't need extra incision extension.
4. The price should be in a competitive range with exteremity aiming devices (2-3 K$)
5. The device should be light-weight, so that doesn't induce extra fatigue.


1. Healthcare cost and utilization project (HCUP). https://www.hcup-us.ahrq.gov/. Updated 2016. Accessed October, 2016.

2. Pateder DB, Carbone JJ. Lateral mass screw fixation for cervical spine trauma: Associated complications and efficacy in maintaining alignment. *The Spine Journal*. 2006;6(1):40-43.

3. *LCP percutaneous aiming system 3.5 for PHILOS for less invasive surgery at the proximal humerus.* Oberdorf Switzerland: Synthes GmbH; 2016.

4. *The orthopedic industry annual report:2009-2010.* 1st ed. OH, USA: Orthoworld Inc.; 2010.

5. Liu T, Xu W, Cheng T, Yang H. Anterior versus posterior surgery for multilevel cervical myelopathy, which one is better? A systematic review. *European Spine Journal*. 2011;20(2):224-235.