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# MONASH HEALTHCARE INNOVATION SUMMER SCHOLARSHIPS

## Project Nephros



**Monash Partners**  
Academic Health Science Centre



**MONASH  
YOUNG  
MEDTECH  
INNOVATORS**

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# Executive Summary

Percutaneous Nephrolithotomy (PCNL) is the procedure of choice for large and complex kidney stones. A significant issue is that the procedure has a steep learning curve and depends on surgeon expertise to determine the angle and trajectory of puncture from the initial patient imaging and free hand the puncture; this puncture is guided by relatively low resolution x-ray imaging. Due to this up to 1 in 10 patients will experience perioperative bleeding as well as risk of adjacent organ injury. In addition, limited visualisation of the puncture mean that often surgeons will need multiple punctures to reach the stone, thereby increasing risk of bleeding and complications.

The outcomes we want to achieve:

- Reduced blood loss and blood transfusion
- Reduced risk of adjacent organ injury
- Reduced fragments of kidney stone that are retained
- Retained kidney function and decreased risk of organ failure
- Increased surgical confidence

**Our mission is to develop a tool to reduce the rate of complications caused by inaccurate puncturing during PCNL kidney stone removal surgery.**

## Acceptance Criteria

1. The solution will reduce the need for multiple punctures, hence reduce bleeding, blood transfusion and damage to internal organs.
2. The solution will be easily incorporated into the existing healthcare system i.e surgeon and operating team training, private vs public uptake.
3. The solutions will allow surgeons to navigate real-time visuals of the kidney.
4. The solution will reduce operator dependency.

When screening for solutions, there was also an emphasis on utilising a high resolution scan and/or reconstructed model which, as discussed in gaps analysis, is already being done in some hospital settings. The solution also needed to improve surgical planning of the optimal route of puncture.

# Gaps analysis

As the most commonly used technique, fluoroscopy provides real-time intra-operative visualisation. It, however, provides poor-visibility of internal structures (shown in figure 1) and involves visualising a three dimensional anatomy on a two dimensional screen [1].

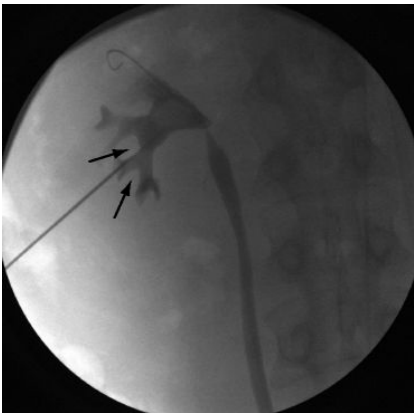


Figure 1: Real-time fluoroscopic imaging of the kidney as can be seen by the surgical team during PCNL surgery

A proper access is the gateway to success and is the crucial step that has the steepest learning curve [1]. The puncture technique may vary between surgeons.

| Existing Solutions/Techniques                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Gaps in Solutions                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Three-dimensional reconstruction by segmenting volumetric CT data</b></p> <p><i>Monash Urology has developed a technique using 3D visualisation to optimise the trajectory for puncture. CT KUB data is segmented to reconstruct the renal collecting system, stone location and volume, renal parenchyma, lung bases, overlying thoracic ribs and vertebrae. This allows the shortest route of puncture to be planned, guiding the access point and access angle from the skin. [2]</i></p> | <p>While Monash Urology and other group in literature [3] have used 3D reconstructions to cognitively plan PCNL, automation of this process is yet to occur. Without automation, it is unlikely that surgeons in practice will learn new software and spend 30-45 minutes (in addition to the current preoperative procedure) modeling the patient’s abdomen.</p> |
| <p><b>Ultrasound guided puncture</b></p> <p><i>Ultrasound guided renal access is an alternative to fluoroscopic visualisation that is currently employed in few PCNL cases. It is low-cost and no radiation alternative to real-time fluoroscopic visualisation</i></p>                                                                                                                                                                                                                            | <p>Some data demonstrates that there is no significant difference between ultrasonographic and fluoroscopic guided access PCNL [4]. It poses the same issue of two dimensional view of anatomy and does not decrease the learning curve or reduce dependency on surgeon expertise.</p>                                                                            |
| <p><b>Changing puncture technique</b></p> <p><i>The way in which the surgeon determines the angle and trajectory of the puncture can be changed. The surgery set up can be modified to accommodate this</i></p>                                                                                                                                                                                                                                                                                    | <p>Studies comparing the “Bull’s eye” technique with the “triangulation” technique [5] produced no significant difference between complication rate (20% vs 15%)</p>                                                                                                                                                                                              |

# Systems Map

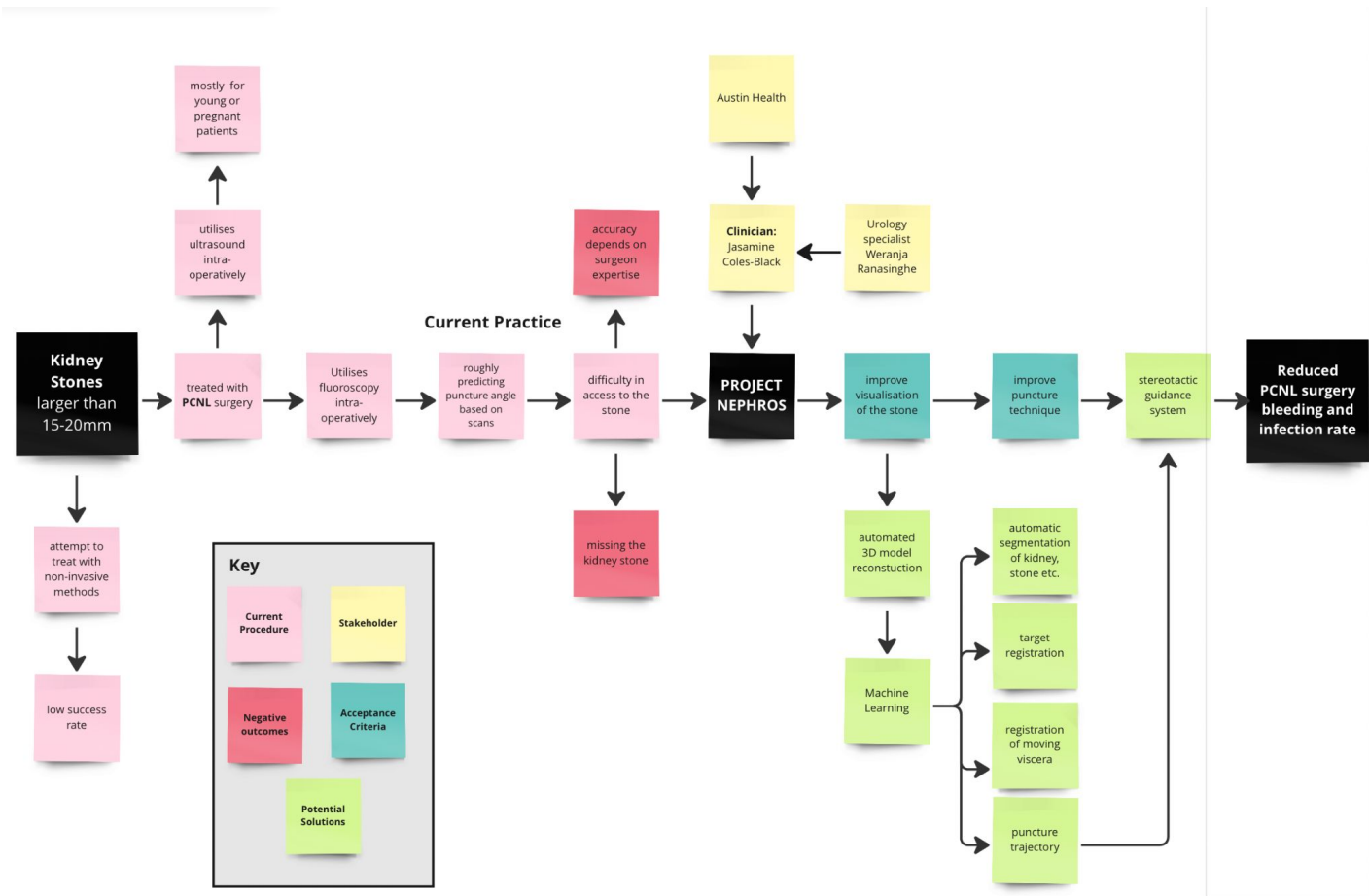


Figure 2: This is a systems map summarizing the current procedure and where the key issues arise. Due to difficulty in stone access and poor visualisation of puncture trajectory, the rate of complications for the procedure depends on the expertise of the surgeon conducting it. Project Nephros attempts make the surgery easier for surgeons to conduct and gain proper access to the stone; i.e. reduce the number of punctures it takes thereby reducing bleeding and complications.

# Stakeholder Map

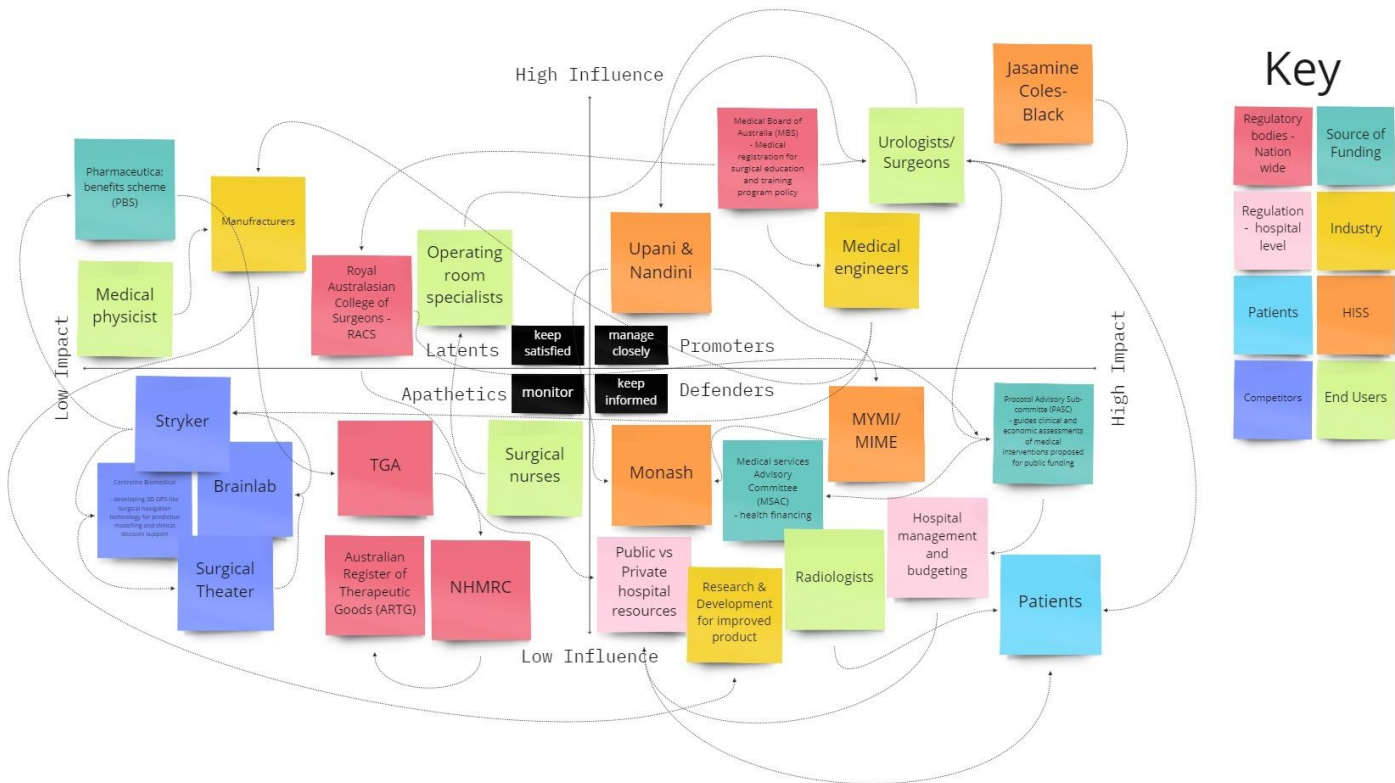


Figure 3: Stakeholder Map

Depicts the range of stakeholders and the position they hold in terms of the direct influence they have on the project, and the impact the project will have on them.

Stakeholders have been categorised into: regulatory bodies (nation wide and at the hospital level), possible sources of funding, industry, competitors and HISS/MYMI related.

The project's clinician champion Jas is largely responsible for the navigation of the development of the solution. She has first hand experience of the difficulties and gaps within kidney stone surgery and PCNL and therefore will advise many of the steps taken towards the solution. Other clinicians, hospital staff, academics and engineers will also pull the trajectory of the project in the early stages. Regulatory bodies such as the TGA will move to become higher in influence as the project progresses. The competitors that can be found in the map only develop similar guidance systems or modeling techniques, however none that can be easily used for our purposes of PCNL surgery. How far the project can progress will depend on the expertise we manage to gather, both from a medial and technical/engineering standpoint as well as infunding to prototype.

# Outcomes of Qualitative and Quantitative Research

## Background

Percutaneous nephrolithotomy (PCNL) is the procedure of choice for patients with kidney stones larger than ~20mm [6], complex kidney anatomy or have stones that have not responded to non-invasive treatment methods. The aim of the procedure is to fragment stones in the kidney telescopically using a ~1-cm “keyhole” skin incision in the patient's back [7]. The kidney is punctured with a needle, under ultrasound or X-ray (specifically fluoroscopy) guidance; and stretch up a ‘track’ into the kidney through which a telescope can be passed [8]. The stone is broken up using a laser fibre, a lithoclast (small pneumatic drill) or ultrasonic suction probe [8].

PCNL is performed under general anesthesia with the patient lying face down on their abdomen. Choosing the correct imaging modality for kidney stones involves many factors including the clinical setting, patient anatomy/build, cost, and tolerance of ionising radiation. Multiple visualisation techniques are available but live-tracking of the puncture during the surgery is limited to fluoroscopy and in some cases ultrasound, usually if fluoroscopy is deemed inappropriate for the patient.

Preoperative imaging is required before instrumentation. In most cases, non-contrast computed tomography (CT scan) can be performed as the cross-sectional imaging allows evaluation of the stone burden and renal anatomy, nearby organs and body habitus in relation to the kidney [9]. CT scans are used to plan the surgery including puncture angle and trajectory.

## Clinical Gaps and Needs

“Despite being one of the main endoscopic procedures for managing stones, PCNL remains a difficult procedure with a long period of learning” [10]. The surgery requires surgeon experience to determine the angle and trajectory of puncture from the initial CT scans. The puncture technique itself relies heavily on surgeon expertise therefore complications and number of punctures required to access the stone varies from surgeon to surgeon.

Poor stone visualisation prior to and during the PCNL cause inaccurate puncturing which increases the chance of damaging adjacent organs and structures. Furthermore, if the puncture trajectory is unable to gain proper access to the stone, then additional punctures would be required which will increase patient bleeding and risk of needing a blood transfusion. It should be noted that in some cases multiple punctures will be required to retrieve the entire stone or multiple stones.

# Outcomes of Qualitative and Quantitative Research

## Health Outcomes and Risks

### **Perioperative bleeding rates of up to 10%**

Morbid technique, due to difficulty in access to the stone  
Risk of blood transfusion 2-12% [7]

### **Failure to remove stone of up to 10-20% [7]**

Due to difficulty in access, visualisation, size and hardness of stone

It is difficult to quantify the exact complication rates as it is quite variant with surgeon expertise. A 2022 study that looked into haemorrhagic complications in percutaneous nephrolithotomy concluded that “as hemorrhagic complication in PCNL is associated with considerable morbidity and mortality, prudent intraoperative decision and postoperative care are necessary for its timely prevention, detection, and management” [11].

The stone clearance, success rate, of the PCNL procedure is 80-90% following an initial surgery and 90-100% following a “second-look” procedure [7]. Therefore in a small portion of cases the procedure may need to be repeated or open surgery may need to be conducted to retrieve the stone. Cases as such may arise due to: the nature of the stone itself, whether it is too hard to laser or crush; due to the stone being in a difficult position to access within the kidney without doing significant damage to surroundings; or poor visualisation of the stone and surroundings resulting in missing the stone too many times.

There is also risk of adjacent organ injury of the spleen, lungs, bowel and unavoidable damage to the kidneys. When looking a potential solutions, it is important to minimise these risks and damage to the kidneys.

Overall, complication rates for PCNL reportedly range from 20-83% [12] and the true complications rates are difficult to determine and compare.

# Solution Concept Discussion

## Current Procedure + Auto-segmented 3D reconstruction

Monash Urology and other groups in literature have explored the possibility of utilising three dimensional reconstruction of the kidney to plan surgeries such as PCNL [2][3]. Currently, with manual reconstruction, a model similar to the image in the top right of figure 4 can be produced to allow surgeons to better visualise the location of the stone. The CT scan in figure 4, top left, is what is currently used by the surgeon to guess the puncture trajectory to the stone.

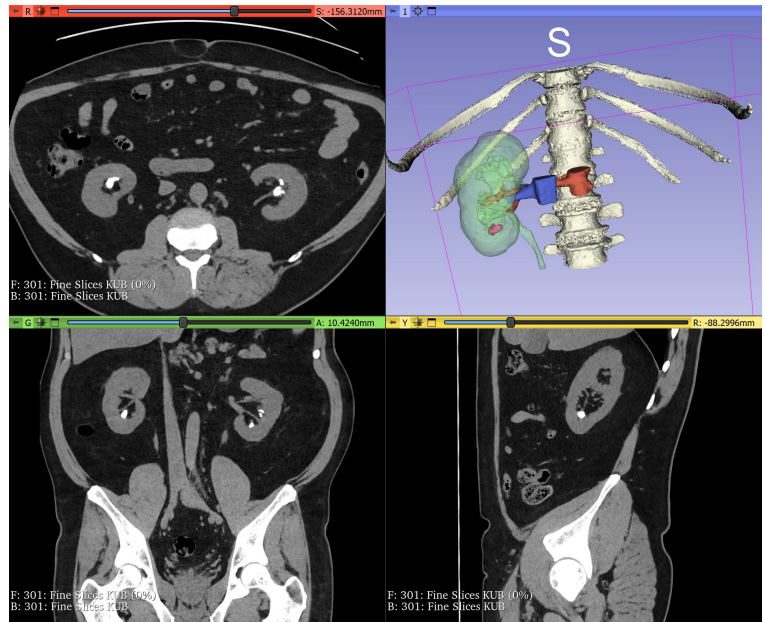


Figure 4: prototype of 3D reconstructive technology using 3D-Slicer software depicting the various segments of the kidney derived from CT scans

It is much easier to imagine a trajectory on the top right. If medical image could be automatically segmented and reconstructed to increase operative efficiency and reduce error.

## Stereotactic Guidance System + Auto-segmented 3D reconstruction

Stereotactic guidance in surgery is currently used within the nero and sinus fields to assist with procedures such as biopsies. It is a technique which utilises a three-dimensional coordinate system combined with an imaging technique, such as CT or MRI, to precisely locate targets. It will assist alignment of the puncture from the exterior and the surgeon will have to validate the position before inserting the needle. If this system were to be developed alongside the automated 3D reconstruction technique it will reduce much of the operator dependency that this procedure currently has as the puncture trajectory can be validated using the model.

A study with 400 patients conducted traditional PCNL surgery in half the patients and conducted “stereotaxic localisation puncture and dilation procedures” (where the distance and horizontal angle of the puncture pathway between the puncture point and the target site were calculated accurately) in the other 200 under X-ray guidance [13]. It concluded that the cases requiring blood transfusion were 9 and 5 respectively and success rates for each puncture were 42.9% and 88% respectively and that the stereotaxic localisation system was statistically better.

# Final Concept

Our solution is to improve puncture technique by developing a stereotactic guidance system, essentially a way of precisely directing the tip of a needle using three-dimensional coordinates based on medical imaging. Development of an automatic 3D visualisation technique to be used in combination with this system would be ideal.

## Stereotactic guidance system

Implementation of the stereotactic guidance system will result in slight changes to the surgical workflow, however, is not expected to cause significant disruptions. Extra steps of placing fiducials on the skin surrounding puncture area, needle calibration and patient to image registration can be easily incorporated into the current workflow as shown below.

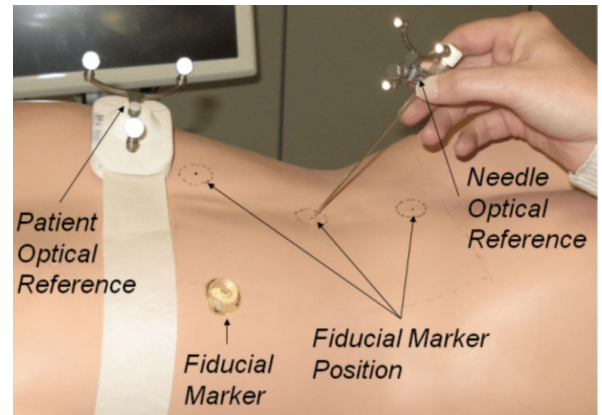


Figure 5: Fiducial Markers on a patient's back

## Proposed Workflow

1. **Imaging Patient Preparation:** fiducial markers are placed on patient skin surrounding the approximated puncture area.
2. **Preoperative imaging:** a preoperative CT scan with the fiducial markers is taken. The precise location of the markers can be drawn onto the skin and the fiducials are removed.
3. **Surgical Planning:** planning is usually done prior to procedure using CT scans. *New 3D reconstructed model could be used here to plan the procedure.*
4. **Patient Preparation:** Patient is placed in the final position and optical reference is attached.
5. **Needle Calibration:** Calibrate based on placed fiducials and fixed bony landmarks
6. **Patient to Image Registration:** establish correspondence between the surgical scenario and planning
7. **Needle Guidance:** needle is inserted using the real-time feedback provided by the navigation system. *New 3D model would be implemented here for live-tracking.*
8. **Position Validation:** needle position is checked. The current method uses fluoroscopy to guide the needle, however, since it is not needed anywhere else in the new workflow we could validate needle position via endoscopy to check correct calyx is punctured. This avoids the hassle of wearing lead protection [14]
9. **Stone Removal:** stone is removed as normal with a laser device or crushed.

The system will be classified as a Class IIa medical device and will need registration with the Australian Register of Therapeutic Goods (ARTG).

To develop the automated 3D reconstruction will involve concepts of segmentation, machine learning and target registration. Initially it will be used as a still 3D model and later developed into a live-tracking system to use during surgery.

# Business Model

Stereotactic surgical systems will be brought by device reps on the day of surgery to start with, until the service is established at which points the surgical system can be rented or purchased when there is sufficient volume of cases. 24/7 device representatives will be available on call for troubleshooting as expected in the medical device industry.

The business model will be a combination of the **sale of consumables/disposables and capital equipment that comes with service and maintenance contracts**. Our solution is an updated workflow for PCNL surgery which will utilise an additional intraoperative visualisation technique and stereotactic needle guidance system. Generation of revenue will be via sale of proprietary single use sterile drapes, puncture needles, dilators, wires, stereotactic cage etc as well as through service fees. Each consumable used can be priced similar to competitors or made compatible with large established competitors to sell out e.g. cook nephrostomy pneumatic dilation is \$2000.

It should be considered that the device will be Class IIa and will need ARTG registration. Funds will also be required to run clinical trials, train surgical staff and operating room specialists. Components of the system developed can be built to be compatible with existing products for PCNL puncture for e.g. the Webb dilator.

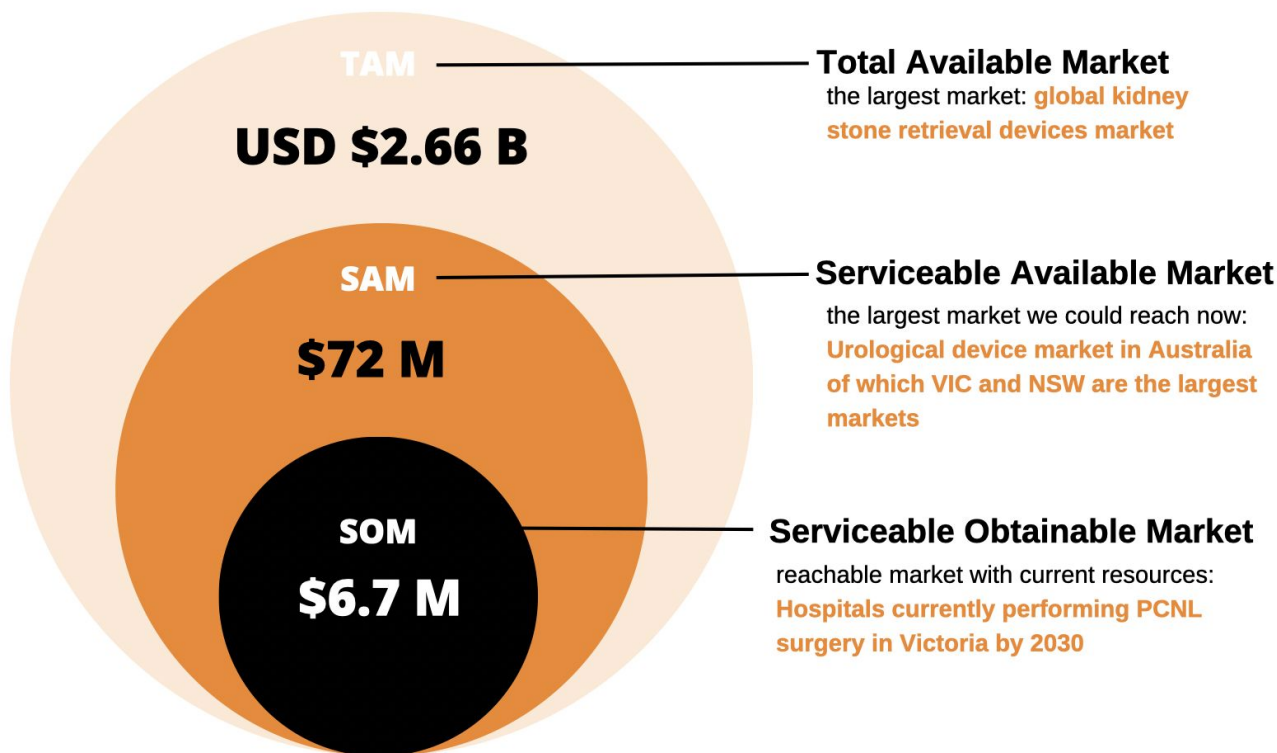
The device will fall under the existing medicare code 36543 for Nephrolithotomy. Additionally, the technology can be used in other procedures that involve targeting of the kidney including 36604, 36607, 36649, 36650. Once established, the technology can also be used for enhanced visualisation and guidance for live tracking of puncture of any solid organ, such as for biopsy or brachytherapy in addition to the kidney.

## Proposed KPIs

Stereotactic guidance systems exist currently in hospitals within neuro and sinus to improve the accuracy and stability of puncture therefore our solution can be expected to fit within the KPIs. Improving the accuracy of puncture will reduce the number of punctures needed to gain proper access to the stone, the rate of bleeding and the likelihood of other complications. This will contribute to a reduced hospital stay, less follow-ups and fewer prescribed resources to the patient saving the hospital money overall.

The solution fits within the MIME/Monash Partners KPIs regarding perioperative procedures. It will work towards making a major surgery more safe. Broad key performance indicators include improved patient satisfaction, improved patient safety and reduced patient mortality and complication rates.

# Market Analysis



The total addressable market (TAM) for our solution will fall within the global kidney stone retrieval devices market at USD \$2.66 billion in 2021 and is expected to expand at a compound annual growth rate of 3.7% from 2022-2030, during our device's development [15].

In 2020, the Australian urological devices market was valued at nearly \$72 million, with 167,000 yearly urological procedures performed every year. This market is expected to increase at a compounded annual growth rate of 3% to reach nearly \$89 million in 2026 [16].

The serviceable obtainable market can be taken as the hospitals currently performing PCNL surgery in Victoria. The figure has been calculated using the MBS code 36543 [17] and the Medicare Item Reports [18] (for Nephrolithotomy or pyelolithotomy). Where:

1. Vic is the largest market in Aus
2.  $6,549 \times \$1,023.75 = \$6,704,538.75$  in Vic annually
3.  $19,576 \times \$1,023.75 = \$20,040,930.00$  in Aus annually

The device would fall into the market specifically for PCNL or stone retrieval surgery within the urological devices market.

Our solution would have no competitors within the market as there are no commercially available stereotactic systems for stone surgery. It has potential for expansion by decreasing the learning curve for PCNL surgery and therefore the number of surgeons who can perform the procedure.

# The Team

## Clinical Champion



**Jas Coles-Black, MD PhD BBMed  
PGradDipAnat**

PhD 3D Visualisation and 3D  
Printing in Surgery  
Editorial Board, Artificial Intelligence  
Surgery  
Faculty, Biofabrication for Surgeons  
RACS Course  
International Regulatory Body Policy  
Citations  
RACS ASERNIPS Health  
Technology Assessment Scholarship  
2020  
Winner Best Affordable New  
Technology in Urology, SIU 2021

## Student Leads



**Upani Mapala-Gamage**

3rd Year Bachelors of Engineering  
(Honours), Biomedical | Medical  
Devices Stream



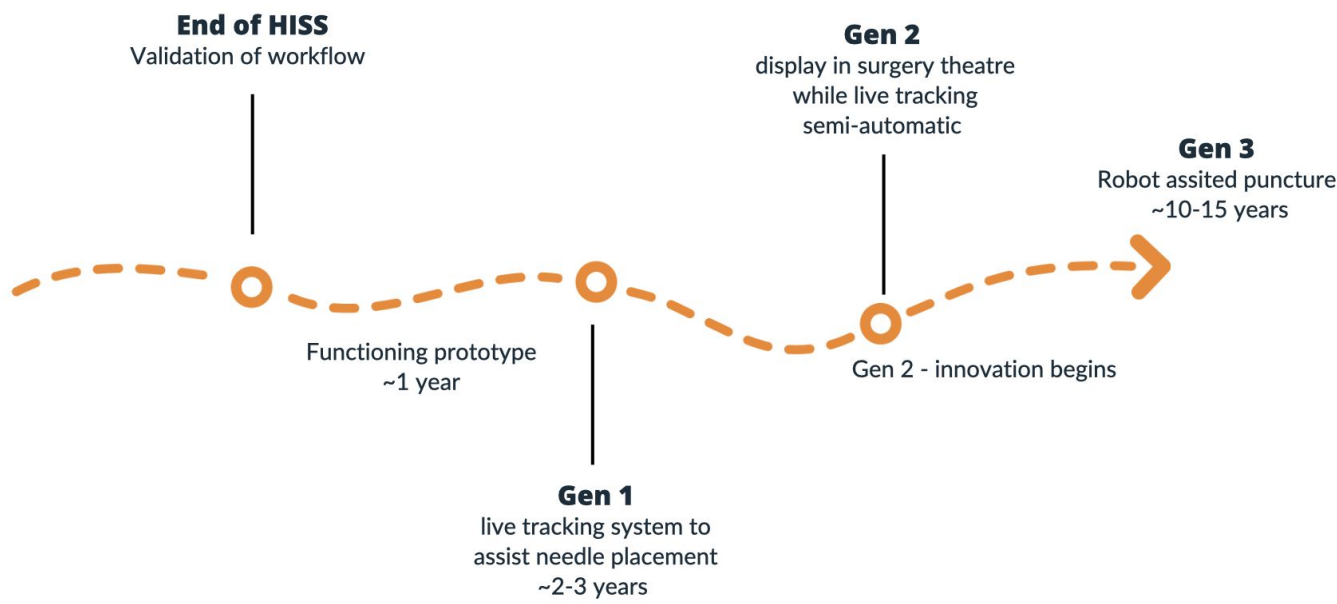
**Nandini Pandya**

Final Year Bachelors of  
Science, Biochemistry and  
Pharmacology

## Our Ask

The team is looking to **expand with computer science or engineering** experience specifically with **machine learning, segmentation and mechatronics**.

# Timeline



## End of HISS

By the end of HISS, the goal is to validate the proposed workflow with clinicians who are familiar with PCNL techniques, academics and engineers. Some considerations to make: is the 3D model going to make significant enough of a difference to outcomes? What will the automation process look like? How are stereotactic systems run? Does an engineer set it up and monitor it during the surgery?

Once these clarifications are made, it will be easier to plan out the development of our product and the number of generations that may come into fruition. The plan is to start with the minimum requirement for a stereotactic system, similar to those used in other forms of surgery and to implement changes once the basic system has gone to market, with the eventual goal of robot-assisted puncture.

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