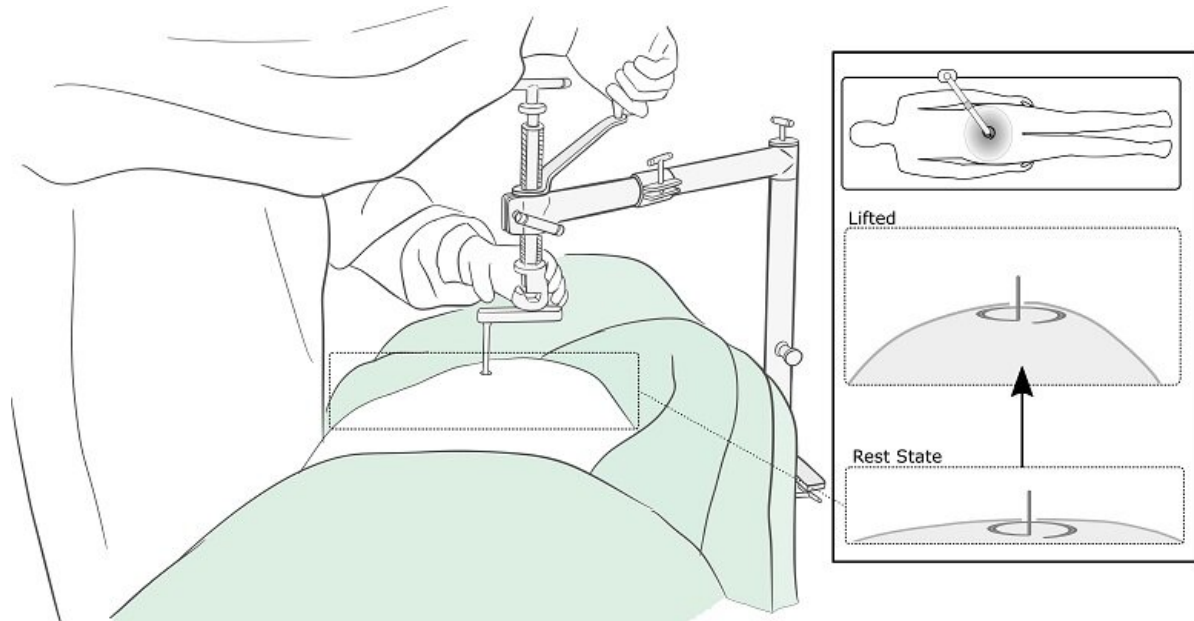


Low-tech—just what the doctor ordered

June 13 2022



A diagram showing how the RAIS retractor is used to lift the abdominal wall during surgery. Credit: University of Leeds/Dr Pete Culmer

Medical equipment that can be manufactured at low cost, is simple to use and can be easily maintained will help extend surgery to the 5 billion people worldwide who currently cannot get access to it, say researchers.

Writing in the *IEEE Journal of Translational Engineering in Health and Medicine*, they argue that surgical technology is often developed for well-resourced healthcare systems—and is of little or no use in poorer settings where hospitals lack sophisticated support infrastructure or appropriately

trained staff.

Without access to [medical equipment](#) they can use, hospitals and clinics in low-to-middle income countries cannot offer surgical treatment to nine out of ten patients.

An international research team led by the University of Leeds is calling for a focus on creating [medical devices](#) specifically for use in low-to-middle income countries. They have pioneered a development approach based on "participatory design", where the users of the technology are closely involved in its design—and where functionality of the device is pared back to key essentials.

To demonstrate their approach, the researchers describe how they designed a simplified surgical tool for performing laparoscopic—or [keyhole surgery](#)—in low resource settings. The result is that laparoscopic [surgery](#) can now be carried out in clinics and hospitals where it was not possible before.

Dr. Pete Culmer, Associate Professor in Healthcare Technologies at Leeds, who supervised the research, said: "Laparoscopic surgery has benefits for patients. People recover more quickly, and the risks of cross infection are lower.

"But in many parts of the world, laparoscopic techniques are not widely used because of the need to use equipment that cannot be easily maintained or relies on complex infrastructure in the operating theater.

"We partnered with clinicians in India to work on developing instruments that would make the process simpler, with the aim of enabling laparoscopic surgery to be available in more locations around the world."

Access to safe surgery

During laparoscopic operations, the surgeon inflates the patient's abdomen with CO₂ gas, to create space to see internal organs and to manipulate instruments. That comes with two challenges. It requires operating theaters to have a reliable CO₂ gas supply. It also requires the patient's [abdominal muscles](#) to be fully relaxed requiring a general anesthetic and an anesthesiologist to give it.

An alternative approach called gasless laparoscopy has been developed. Rather than pumping CO₂ into the abdomen, a mechanical retractor or clamp is used to lift the abdominal wall. With this method, the patient does not need a general anesthetic—instead, a spinal anesthesia is given, and there is no need for a dedicated anesthesiologist to be present.

But this alternative approach has failed to gain popularity, largely because of challenges with using and maintaining the retractors.

Fit for purpose

The researchers, in partnership with surgeons and a medical device manufacturer in India, designed a new retractor, ensuring it was fit for purpose in a low-resourced healthcare setting.

The attached graphic shows how a small ring is manipulated onto the end of the retractor by a surgeon using keyhole techniques. When in place, the device is manually operated to gently lift the abdominal cavity upwards, creating the necessary space for the surgical team to operate.

Known as RAIS (Retractor for Abdominal Insufflation-less Surgery), the innovative retractor went through five design iterations before a prototype was developed and tested.

During a clinical evaluation, it was used in 12 laparoscopic operations: in four cases of appendicitis, two hysterectomies and six cases where the gall bladder was removed.

The [scientific paper](#) reports that there were no adverse events from using the retractor.

Dr. Jesudian Gnanaraj, a surgeon who has pioneered gasless laparoscopic surgery and worked extensively in parts of rural India where surgery has not typically been available, said: "The biggest problem for rural surgeons needing to provide laparoscopic surgery is finding an anaesthesiologist and the equipment to give general anesthesia.

"The RAIS device makes laparoscopic surgery possible, with lower costs and easily available resources like spinal anesthesia.

"Providing [laparoscopic surgery](#) can help rural patients get back to work as soon as possible. This is vital because the longer they take to recover, the higher the chance of them falling below the [poverty line](#)."

Writing in the research paper, the researchers said the device was "...considered convenient to setup in the operating theater, could be readily cleaned and sterilized and transported within and between rural surgical sites".

The simplified design of the retractor meant it was easier for the device manufacturer to get regulatory approval, with the time it takes to go from design to approval being four years in this case. It can sometimes take ten years.

The RAIS device meets the guidelines established by the World Health Organization for the design and development of healthcare technology for low to middle income countries. It says they should follow four key

principles, the 4As—affordability, accessibility, availability and appropriateness.

More information: M. Marriott Webb et al, The RAIS device for global surgery: using a Participatory Design approach to navigate the translational pathway to clinical use, *IEEE Journal of Translational Engineering in Health and Medicine* (2022). [DOI: 10.1109/JTEHM.2022.3177313](https://doi.org/10.1109/JTEHM.2022.3177313)

Provided by University of Leeds

Citation: Low-tech—just what the doctor ordered (2022, June 13) retrieved 26 April 2024 from <https://medicalxpress.com/news/2022-06-low-tech-just-doctor.html>

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