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Mini Review

Self-Retaining Surgical Retractors: Maximum Sustainable Force of Surgical Stays and Stay Hooks in Human Tissue, and the Usual Force Applied to Both During Surgery–An Original Article

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Abstract

Surgical Retractor systems are used by surgeons every day and have been considered as useful tools in hospitals for decades. Modern versions consist of a sterile disposable retractor ring and sterile elastic stays, positioned with cam locks for easier one-handed adjustments. New innovations have recently seen a sliding frame and the addition of surgical light guides attached to the frame. Despite the frequency of use, no formal studies and data exist on tension load capabilities or tension impact on human tissue.

This paper identifies the baseline requirement for retracting tissue during surgery, the common range of tension being used, and the upper maximum of load.

Keywords: Surgical retractors; Self-retaining ring retractors; Cadaveric testing; Force load; Patient safety.

Introduction

The purpose of self-retaining retractors is to reduce the tension on the tissue, reduce clutter around the patient by removing one or more assistants, and allow the surgeon better access to the operative site. Modern retractors allow gentle but efficient adjustable tension of retraction throughout the surgical procedure. However, data on the maximum force that can be safely applied to stays are lacking. The important gap is addressed in the three investigations:

- Stay integrity
- Maximum sustainable pull force

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- Tension normally applied by surgeons when using stays to retract tissue

This is a fundamental work that has never been previously published yet forms a baseline assessment for both product design as well as clinical use in every hospital across the globe. It directly impacts safety during surgery and patient post-operative comfort and recovery.

History of retractors

Surgical retractors probably originated from extremely basic tools used in the Stone Age. Branches or antlers of various shapes were used to dig and extract food from the ground. As the use of tools evolved, a variety of instruments came about to substitute for the use of hooked or grasping fingers in the butchering of meat or dissection of bodies.

The use of metals in toolmaking was of significant importance. A variety of Roman metal instruments of the hook and retractor family have been found by archeologists. These instruments would generally be called hooks if the end was as narrow as the handle of the instrument. If the end was broad, it would be called a retractor. Also arising from this group of tools were other related tools for displacing (elevators and spatulas) and scooping (spoons and curettes).

In the 4th century CE, Indian physician Susruta used surgical tools such as retractors. In a description of the procedure of tonsillectomy from the 7th century CE, Paul of Aegina documents the use of a tongue spatula to keep the tongue out of the way while a form of tonsil hook is used to bring the tonsil forward for excision. In 1000 CE Abu al-Qasim al-Zahrawi, also known as Albucasis or Abulcasis, described a variety of surgical instruments including retractors in his famous text Al-Tasrif [1].

Handheld retractors are dependent on the assistant holding the retractor in terms of force, and tissue impact, which in turn affect the safety and impact on the patient and the surgical outcome. Assistants need to be instructed on how to move, how much to pull, and then to adjust as surgery progresses. It is a health and safety issue from a staff personnel perspective to have someone bend over a wound in a static position, sometimes for hours.

Self-retaining retractors have the benefit of being dependable, not movable without being moved by the surgeon, not needing a break, and never getting tired. Modern manufacturing materials mean they are lightweight, yet strong and reliable, and improved production methods allow for cost-effective sterile single-use retractors with a lower carbon footprint. Newer models have also eliminated screws and other loose small parts, replacing them with easier to use cam locks, which means further improvement in patient care and risk reduction [2].

As innovators investigated and make use of novel opportunities, research on the requirements highlighted the lack of data and documentation for three key questions: How much tension does the retractor need to withstand? When used in one of the main procedures of use, how much load will the surgeon put on the stay hooks? How much force can human tissue take before it breaks?

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Stay Integrity

An examination of stay integrity and maximum sustainable pull force was undertaken.

Materials used

Galaxy II surgical sharp 5mm hooks (n=21), blunt 5mm hooks (n=20), and blunt 12mm hooks (n=21).

Method

The steel hook was attached to a hook at the base of the gauge and the elastic stay tail was pulled and stretched. Each stay was independently tested and pulled to a maximum force of 25 newtons (N). Any changes in product design or stay failures under increasing force were recorded.

It was found that all sharp 5mm stays were pulled to a maximum force of 25N with no visible changes in hook or product design. All blunt 5mm stays withstood a 19N pull force, with 8 coming apart (metal hook detaching from the blue heat wrap) with varying loads above that (Figure 1). No changes in product design were observed for any of the blunt 12mm stays up to the full load of 25N.

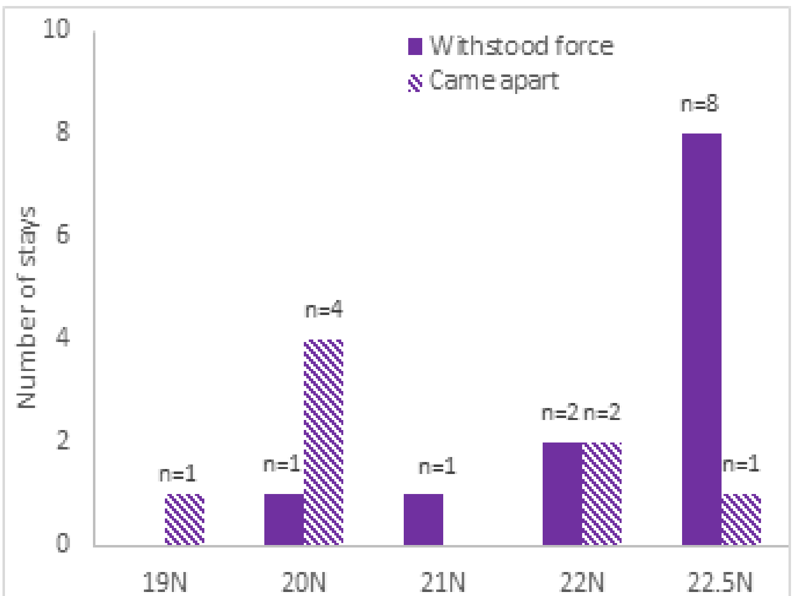

Figure 1: Pull force applied to blunt 5mm stays.

Maximum sustainable pull force

The stay integrity and maximum sustainable pull force were investigated when attached to the human tissue. The investigations were conducted on four fresh, frozen, and non-embalmed human cadaveric whole-body specimens from the Glasgow University [3] donor program [4].

Materials for this investigation

21 Galaxy II surgical sharp 5mm hooks and 21 blunt 5mm hooks were randomly selected.

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Method

The stay hook was attached to the cadaver in 3 locations (vaginal wall, labia, and rectus fascia) and the elastic end attached to the gauge meter. Each stay was pulled to a maximum of 16N.

Using sharp 5mm stay hooks in the vaginal wall, we found that this tissue started to come apart at 3–7N. The blunt 5mm stay hooks were placed in the rectus fascia. This tissue started to come apart at 5–10N. Both sharp and blunt 5mm stay hooks were tested in the outer labia, which started to come apart at 5–15N.

Tension normally applied by surgeons when using stays to retract tissue

Thirteen gynaecological and urological surgical consultants attending a cadaveric dissection and training course in native tissue incontinence repairs in the Glasgow Cadaver Laboratory participated in the investigation.

Surgeons were asked to pull a selection of surgical stay hooks with force representative of the tension they would usually apply when retracting tissue during vaginal procedures.

Materials for this investigation

5mm sharp and 12mm blunt Galaxy II stay hooks.

Method

Stay hooks were attached to a gauge meter and both hook end and tension reading were blinded to the surgeon. It was found that readings of tension applied to stays representative of typical surgical use ranged from 2.5N–7.5N.

Discussion

It is worth noting that the cadaveric tissue donors were probably post-menopausal, which may have affected tissue quality. However, we felt this was adjusted by the tendency of deceased tissue to be slightly tougher than that of surgical patients.

Once tissue started to separate, tension was released to prevent the tissue from ripping. All testings were done with utmost respect to the donors, and no visible injuries were made.

It is difficult for a surgeon to verbally assess how much tension is used on hooks during surgery. It is a question of judgment, based on visual and tactile response from the tissue and the corresponding visual access. During our testing, we found two surprising things:

1) None of the surgeons we asked had ever thought of how much tension would be used and could not answer the question on how much load their instrument could withstand to be considered as safe.
2) When surgeons could see the Newton meter, they pulled much harder than if they were blinded and asked to use their muscle memory.

Further research on this topic will no doubt show a great variance between specialties and different procedures, as well as in different patient groups. As medical device development continues to progress, more data and a better understanding of usage-based requirements for safety and efficacy are

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key factors in product requirement assessment. Instructions for Use (IFU) of many medical instruments are vague for obvious reasons: it would be virtually impossible to outline the scope for what tissue a scalpel can cut into. However, for something like a retractor that holds back tissue, the need for minimum performance data seems prudent, especially since counterfeit low-cost copies now abound which even use stolen images of actual manufacturers in their materials [5].

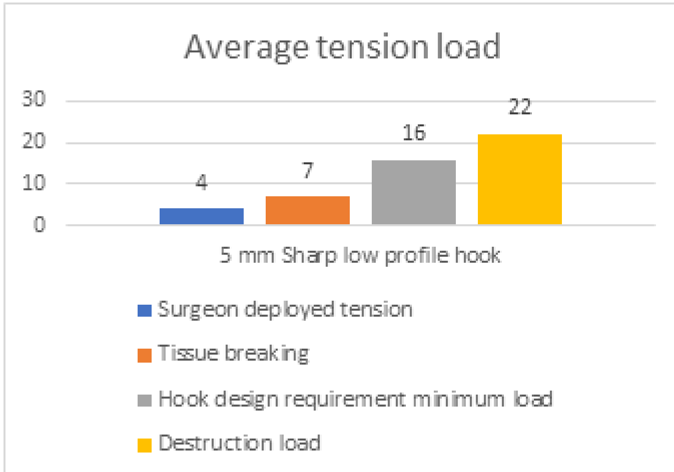

Figure 2: Average Tension Load illustrates the difference between what surgeons use during surgery, compared to when tissue breaks, what minimum requirements are used during design, and at what point hooks finally start to break.

Summary of Findings

The minimum requirement for retracting tissue during surgery is a load ranging from 1N and up, depending on tissue and procedure, and number of hooks used. The common range of tension used in vaginal procedures is between 2.5N–7.5N. The upper maximum load was 10N when applied in vaginal tissue using sharp 5mm low profile hooks. Using sharp 5mm stay hooks in the vaginal wall, we found that this tissue started to come apart at 3–7N. Rectus fascia tissue, when pulled with blunt 5mm low profile hooks, started to come apart at 5–10N. Both sharp and blunt 5mm stay hooks were tested in the outer labia, which started to come apart at 5–15N.

Conclusion

Together, these investigations demonstrate that surgical hook stays can safely sustain a maximum force of up to 3 times the usual tension applied during surgical procedures, without visible changes in hook or product design. Impact on tissue is a balance between higher loads on fewer hooks, or more hooks with lower load (but more puncture sites).

Further investigations and research on other types of tissue, a combination of other hooks and a range of surgical specialties need to be conducted to ensure a safer use of tissue penetrating hooks for optimal patient recovery and minimal damage.

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