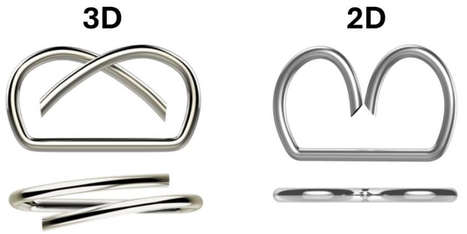
Improving Surgical Outcomes: A Novel 3D Staple Design for Endoscopic Staplers

Obieda M Atiyani, MD[1] ; Kevin Fiebig, MS[2] ; Sina Safayi, DVM, PhD[2] ; Jeffrey W Clymer, PhD[2] ; Crystal D Ricketts, PhD[2]

University of Cincinnati Medical Center[1]; Johnson and Johnson MedTech[2]



Introduction:

Enhancing the integrity of surgical staple lines is crucial, with staple geometry playing a key role. Studies indicate that 3D staples offer consistent compression and fewer leak pathways, leading to better hemostasis compared to traditional 2D "B-form" staples.[1] 3D staples have primarily been used in open staplers and later incorporated into circular staplers. In light of these advancements, A new design incorporates two rows of 3D staples alongside one row of 2D staples in endoscopic staplers, allowing for improved hemostasis and reduced leaks while fitting within a 12-mm trocar.

Objective:

To evaluate the effectiveness of the novel 3D staple design compared to traditional 2D staples.

Methods:

- **Tissue Model**: The rate of staple line malformation was compared between the 3D and 2D staplers in IFU tissue range and overstressed thick porcine tissue model using a predefined categorical scale.
- **Leak Evaluation**: Staple line leaks were evaluated by measuring the pressure required to generate a leak in fluid-filled ex vivo porcine ileum that had been sealed with 3D or 2D staples. Comparisons were made for both mean leak pressure and rate of leaks below a predetermined pressure criterion.
- **Intervention Assessment**: Hemostasis was compared in sealing of in vivo porcine gastroepiploic vessels. The level of bleeding was assessed on the widely used Siegel 5-point hemostasis scale. [2] Both average hemostasis scores (i.e. scores greater than 3) and percentage of interventions were reported.

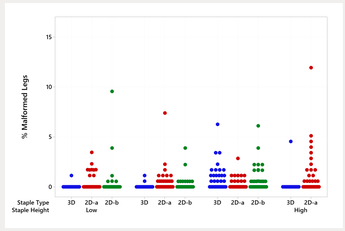
Table 4. Hemostasis Ratings[1]

Likert Rating	Description
1	No bleeding at the tissue site after initial blotting of staple line
2	Blood oozing at tissue site; stops prior to 15 seconds; no intervention needed
3	Blood oozing, still progressive after 15 seconds; no intervention needed at time of rating; would re-assess before closing
4	Blood oozing at tissue site, mild intervention (cautery); intervention is needed but *not an immediate* need
5	Significant bleeding requiring intervention such as extensive coagulation or ligation with suture or clips. Examples: Pulsatile bleeding; Bleeding that has to be addressed prior to the rating period

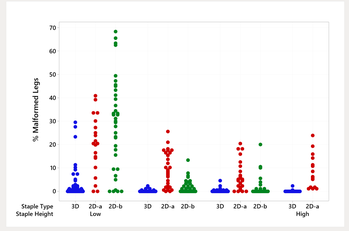
Results:

1. Staple Line Malformation in IFU tissue range vs overstressed tissue model:

- In the IFU tissue range, the use of 3D compared to 2D-a resulted in a 66.8% reduction in malformed staples across the tissue range. Additionally, there was a 64.1% decrease in staple malformations when comparing 3D to 2D-b.
- In the overstressed tissue model, the use of 3D staple compared to 2D-a and 2D-b resulted in similar reduction of 88.6%



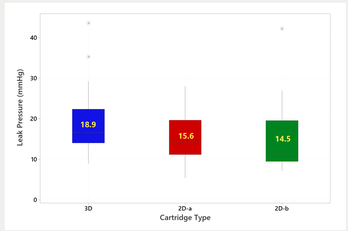
IFU tissue range



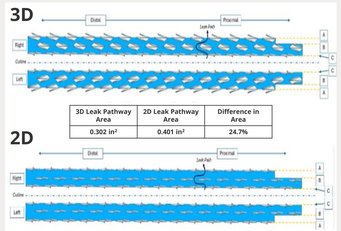
Overstressed tissue model

2. Leak Evaluation:

- When compared to the traditional 2D staples, the novel stapler showed a reduction in its leak pathway area by 24.7%.
- On evaluation of staple leak performance, 3D vs 2D-a resulted in an average staple leak pressure increase of 3.33mmHG (21.4%). In addition, the use of 3D vs 2D-b resulted in an average staple line pressure increase of 4.40mmHG (30.3%)



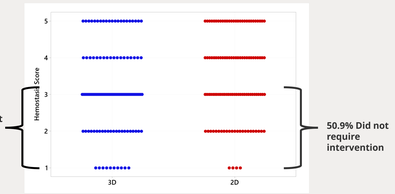
Boxplot of Minimum Staple Leak Pressure (mmHG) for all Cartridge Groups



The blue color indicates the surface area of the cartridge, with 3D representation on the top and 2D representation on the bottom.

3. Intervention Assessment

- In a preclinical study using the hemostasis scale to compare traditional 2D staples with a novel stapler, it was observed that the percentage of cases requiring no intervention was 65.8% with the novel stapler, compared to 50.9% with the traditional 2D staples.



Individual value plot of hemostasis scores for 2D and 3D staple systems in porcine gastroepiploic bundle using the Siegel hemostasis scale specifically designed to capture minor differences and sensitive data relevant to bleeding in the preclinical laboratory setting.

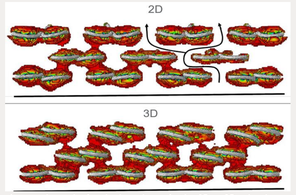


Image above depicts leak pathway in the 2D vs 3D reloads

J&J MedTech

Discussion

- 3D design reduces malformed staples in ex-vivo thick tissue models.
- There is a risk of complications from inconsistent staple lines.
- Increased leak pressures imply higher resistance to leakage.
- Lower mean hemostasis scores indicate less bleeding & fewer required interventions in-vivo.
- Fits into a 12-mm trocar, enhancing utility in minimally invasive surgeries.

Conclusions

- Novel hybrid stapler design: significant advancement for endoscopic applications.
- Lower occurrence of malformed staples.
- Improved hemostasis compared to 2D staplers.
- Promising for enhancing surgical outcomes in minimally invasive procedures

Future direction

These encouraging results pave the way for further clinical evaluation to establish the potential benefits of this design in enhancing patient safety and efficacy during minimally invasive surgical procedures.

References

1. Rojatkar P, Nalagatla AK, Ricketts CD, Clymer JW, Yosh E. The Science of Stapling: Staple Form. Surgical Technology International. 2024 Mar 19;44:sti44-1773.

2. Siegel JM, Cummings JF, Clymer JW. Reproducible, repeatable and clinically-relevant hemostasis scoring. J Adv Med Pharm Sci 2014;1:30-9.