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Prosthesis-prosthesis anastomosis using barbed sutures compared to conventional sutures
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in vitro extracorporeal circulation setup.

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This letter warrants that all authors have seen and approved the manuscript, contributed significantly to the work, and also that the manuscript has not been previously published nor is not being considered for publication elsewhere.

Keywords: Experimental - Cardiac; Minimally invasive surgery; Barbed Sutures

Ethics

No ethical consent required.

The Author(s) declare(s) that there is no conflict of interest
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Visual abstract

Are knotless barbed sutures feasible for prosthesis-prosthesis anastomosis under long term, high-mean pressure?

Knotless barbed sutures are feasible for prosthesis-prosthesis anastomosis compared to conventional sutures in an in-vitro setup using extra corporeal circulation under long term, high-mean, pressures.

Abstract

Background

While barbed sutures have been extensively utilized in other disciplines, they have not been widely adopted in cardiac surgery. The lack of safety and feasibility data has limited its use within the field. To aide in the further understanding of how cardiac surgeons can use barbed sutures, we sought to develop a high-pressure in vitro simulation model. We compared knotless barbed sutures in a highly pressurized anastomosis to conventional sutures.

Methods

Ten specimens in total were utilized in prosthesis anastomosis, using 34mm Gelweave Plexus (Terumo Aortic, Sunrise, FL 33325, USA) and 34mm Hemabridge (Intergard Woven Hemabridge, Getinge, Göteborg, Sweden). Five models of size 3-0 barbed suture anastomoses using non-absorbable, barbed, self-retaining, monofilament polypropylene sutures (Filbloc® 3-0, Assut Europe, Rome, Italy) were compared against five conventional anastomoses using size 4-0 polypropylene monofilament (Ethicon, USA). The systems were connected using a novel-designed extracorporeal circulation system. Pressure was rapidly increased in the specimen to a mean pressure of 300-350mmHg, running then for a minimum of 48 hours to assess anastomosis strength and endurance.
Results

No anastomotic dehiscence or rupture was recorded. Complex, angular anastomosis required extra stitch leakage sutures in both conventional and barbed suture specimens.

Conclusion

Using knotless barbed sutures with an additional self-locking maneuver for prosthesis-prosthesis anastomosis in cardiac surgery is feasible in an in vitro model under long term, high-mean pressure when compared to conventional sutures. In vivo trials should be performed to further validate the in vitro findings.
Introduction

While barbed sutures have been widely utilized in other disciplines, they have not been widely adopted in cardiac surgery\(^1\)\(^-\)\(^3\). Because of the lack in both safety and feasibility data, cardiac surgeons have not extensively used nor published on the use of barbed sutures. This said, a few small series have been published on the topic describing its use\(^4\)\(^-\)\(^6\). Watanabe, et al. described the successful implementation of barbed sutures in 10 cases robotic valvuloplasty versus 24 using conventional interrupted sutures\(^4\). Furthermore, cross-clamp and suturing times were shown to be significantly decreased (\(p < 0.05\)) in those with barbed sutures\(^4\).

Because of the ongoing questions on the use of barbed sutures in cardiac sutures, we sought to create a simulated model to help further the safety profile. An in vitro model was formulated and designed to assess feasibility using knotless barbed sutures in high pressure anastomosis. This model allowed us to compare barbed sutures to conventional sutures. Our study’s primary objective is to discern both mid- and long-term feasibility of using barbed sutures in a high-pressure prosthesis – prosthesis anastomosis when compared to conventional sutures using extracorporeal circulation. Our aim is to show whether or not barbed sutures can withstand high pressure with the intention of translating this project clinically.

Methods

Five paired (\(n=10\)) prosthesis – prosthesis specimens were anastomosed using an ascending aorta prosthesis; they were connected to a novelty-designed setup using extracorporeal circulation (Figure 1a).

Two types of sutures were used for comparison in our study. The first was a 3-0 barbed, nonabsorbable monofilament polypropylene suture (Filbloc, Assut Europe, Rome, Italy). In each experimental set-up, this was compared to a 4-0 conventional, non-absorbable monofilament
polypropylene suture (Prolene, Ethicon, USA). The barbed sutures are cut with a laser cutter from a conventional monofilament polypropylene 3-0 diameter suture, which accounts for the difference in diameter compared to the conventional suture. The tensile strength of a 3-0 monofilament polypropylene barbed suture is therefore comparable to a conventional monofilament polypropylene 4-0. Diameters less than 3-0 are currently not achievable for barbed sutures due to accuracy limitations of the laser cutter.

Three paired setups (n=3x2) using 34-mm Gelweave Plexus (Terumo Aortic, Sunrise, FL, USA) and 34-mm Hemabridge (Intergard Woven Hemabridge, Getinge, Göteborg, Sweden) prosthesis were circumferentially cut and anastomosed using a non-absorbable, self-retaining, monofilament polypropylene, size 3-0 barbed suture (Filbloc, Assut Europe, Rome, Italy) (n = 3), ending in a self-locking maneuver. This was compared against three non-absorbable, conventional, monofilament polypropylene, size 4-0 sutures (Prolene, Ethicon, USA) ending in a knot. (Table 1)

In two other paired setups (n=2x2) an 8-mm round prosthesis using the excess side branch of the 34-mm Gelweave Plexus (Terumo Aortic, Sunrise, FL 33325, USA) was anastomosed in an end-to-side fashion onto a straight ascending aorta prosthesis using 34-mm Gelweave Plexus (Terumo Aortic, Sunrise, FL 33325, USA) and 34-mm Hemabridge (Intergard Woven Hemabridge, Getinge, Göteborg, Sweden) comparing Filbloc and self-locking (n=2) to Prolene (n=2) ending in a knot. (Table 2)

The custom extracorporeal circulation setup was created using a Stockert S5 roller pump, equipped with 3/8-inch silicone tubing (Livanova, London, United Kingdom) (Figure 1b). The prosthesis-prosthesis anastomosis specimens were connected to this setup using uniquely designed connectors of large diameter syringes, scaling up to the prosthesis diameter to avoid bottlenecks and resistance. Prosthesis-prosthesis connections were assessed rather than prosthesis-vessel connections for
standardization purposes with the goal that quality and size of the prosthesis can be more accurately measured.

The substance we injected into the anastomotic vessels was water. Animal blood was not used given the restraints of using a cardiopulmonary bypass machine with non-human blood. Furthermore, using blood or an alternative specimen with varying viscosity would have increased the variations between groups (harder to standardize). Since we could not use whole blood or another alternative, the prosthesis was submerged in 15cm of water (Figure 1c) to better simulate conditions.

Afferent flow to the prothesis was ensured using unobstructed 3/8-inch tubing (Livanova, London, United Kingdom) fixed at the bottom of the basin. Efferent flow from the prosthesis was obstructed using a 3/8-inch perfusion adapter (Cardioplegia Cannulae, Adapters, CA-10040, Livanova, London, United Kingdom). Circulating volume was aspirated by the roller pump through open 3/8-inch tubing (Livanova, London, United Kingdom) submerged at the bottom of the basin in order to prevent aspiration of air (Figure 1).

In each experiment, pressure was rapidly accelerated in the specimens to a mean pressure between 300-350mmHg. Flow rates were held relatively constant between groups. All setups ran at least 48 hours at this high-mean pressure to assess anastomosis strength and endurance. Pressure was measured in the afferent tubing, before entering the specimen using a 3/8-inch x 3/8-inch Luer lock connector (Livanova, London, United Kingdom). Additionally, pressure was measured inside the prosthesis using either the connected side-arm (8-mm) or the anastomosed end-to-side 8-mm prosthesis, respectively. Finally, pressure was measured after the specimen using a 3/8-inch Luer lock connector. Flow per minute through the roller pump was measured in liter per minute.
The sole rupture we encountered was of the poly-vinyl chloride (PVC) tubing inside the roller pump’s runway. After modifying our setup to only use silicon tubing, no more ruptures inside the roller pump’s runway occurred.

Results

Using a paired setup for each of the aforementioned anastomoses, we recorded flow rate and pressure data for each 48-hour run (Dataset Tables 1-11) using the Connect perfusion charting system (LivaNova, London, United Kingdom). In the circumferential cut anastomosis tests, prosthetic dehiscence was not observed for barbed nor conventional sutures. Mean pressures near the anastomosis were similar for both the barbed suture (349 and 336 mmHg) and conventional suture (323 and 336 mmHg) trials. Flow rate with barbed sutures in these trials was 3.09 and 3.16 liters per minute, while flow rate with conventional sutures was 2.94 and 2.57 liters per minute. Complete end-to-end data for the circumferential cut trials is described in Table 2.

Trials for prosthesis with a 45° angular circumferential cut were complicated by stitch leakage for both barbed and conventional sutures. To remedy this defect, three additional stitches were added to reinforce the anastomosis at 42 and 44 hours, respectively. This modification resulted in a notable increase in intra-luminal pressure (233 vs. 301 mmHg) for the barbed suture prosthesis. The same result was not observed for the traditional suture. Additionally, the difference in intra-prosthetic pressure between barbed and conventional suture (233 vs. 306 mmHg, respectively) is notable and likely attributable to a 2.5 cm difference between inflow and side branch measurement location. As a result, the conventional suture’s intra-luminal pressure was made slightly closer to the inflow point. Despite anastomosis leakage in these trials, gross dehiscence was not observed for either stitch type before or after the reinforcement modification. Complete flow rate and pressure measurements for 45° angular circumferential cut trials can be found in Table 3.
The final set of experiments involved suturing a connecting side branch to the main 34mm prosthesis using either a barbed or conventional suture. Pressure readings through the side branch anastomoses with barbed sutures were 338 and 345mmHg, while the same measurements for conventional sutures were 387 and 317mmHg. Dehiscence was not observed in any trial. Complete data for the side branch set-up is shown in Table 4.

**Discussion**

Establishing the safety of barbed sutures under high pressure simulations could enable cardiac surgeons to employ knotless barbed sutures more confidently in minimally invasive procedures. Currently, the use of knotless barbed sutures in cardiovascular surgery is undermined by the existing concern of dehiscence during tissue reapproximation\(^9\). To mediate this concern, we employ a “self-locking” maneuver to counter the knotless nature of the barbed suture. This technique was previously described extensively by the authors\(^8,10,11\). The self-locking maneuver provides strong adhesion of tissue and suture and was shown to provide adequate reapproximation in low-pressure cardiac structures.

Knot-tying in minimally invasive cardiac procedures, even in experienced hands, remains a time-consuming process. Jernigan et al. describe an in vitro model comparing a laparoscopic knot-tying device for minimally invasive cardiac surgery to conventional laparoscopic tools, in which mean knot-tying times were 246 ±116 seconds for conventional knotting\(^12,13\). As such, avoiding this cumbersome process during minimal invasive surgery could help address a time-consuming portion of the procedure. The single most efficient time reducing step in minimal invasive cardiac surgery is eliminating the need for knotting altogether. Additionally, knotless sutures may help reduce surgeon frustration scores with regards to tying minimally invasive knots\(^14\). In the future, this could
potentially result in reduced extracorporeal circulation (ECC) and cross-clamp time, but further research on this topic is recommended.\textsuperscript{9,15}

The aim of this in vitro model was to assess the efficacy of knotless barbed sutures in high pressure anastomosis compared to conventional sutures. In our setup, the most practical way to measure average mean pressure was through the anastomosed side branch as a substitute for actual pressure on the anastomosis, and the pressure results should be considered with this caveat in mind. A similar predicament was encountered in measuring pressure through the Luer lock.

Another improvement to this experimental design could have involved the use of pulsatile flow to better mimic physiological conditions. This characteristic proved impractical due to the longevity of the runtimes in the setup, which would have required extensive supervision. Additionally, a rotary blood pump is not routinely used in our center, and was, as such, not available for our experimentation. Future in vivo studies could utilize this equipment for more realistic physiological conditions.

Because of comparable results between runs of similar specimens and because of practical reasons no additional tests were performed after the initial (n=10) trials. In our center, to correctly register data from Connect, one heart-lung machine needs to be decommissioned from clinical use for the duration of the trial. This leaves us potentially short-stocked on back-up heart-lung machines in case of emergency.

The main objective of this trial was proving longevity and durability of knotless barbed sutures, compared to conventional sutures when used for prosthesis-prosthesis anastomoses. For optimal leakage quantification whole blood as perfusion fluid would have yielded the most physiological results. As leakage at the seams is omnipresent and very hard to avoid in newly joint anastomoses,
equally so in clinical, on-pump, heparinized cases, we opted for tap water as perfusion fluid to optimize comparability and standardization.

Instead of porcine, ovine or bovine tissue, which is less consistent in diameter and quality, we used prosthesis-to-prosthesis tissue, which is consistent in diameter and quality, for the same comparability and standardization optimization. Because of comparable results in this standardized prosthesis-prosthesis setup, comparing barbed sutures to conventional sutures, different tissue could be used for a follow-up trial.

Eventually, following up on the results of these trials, a live animal model where tissue-to-tissue or tissue-to-prosthesis anastomoses are performed, comparing both types of suture would offer the most physiological results.

Ultimately, this specific setup and specimens performed adequately and comparatively under long-term, high-mean pressure. No rupture or dehiscence was observed under these extreme conditions in any trial\(^6\).

**Conclusion**

Compared to conventional sutures in cardiac surgery, the use of knotless barbed sutures with an additional self-locking maneuver for prosthesis-prosthesis anastomosis is feasible in an in vitro model under long-term, high-mean pressure. In vivo trials should be performed to confirm these in vitro findings.
References:


Figure Legend:

Figure 1:
  a. In vitro specimen setup.
  b. Stockert Livanova, S5 roller pump, equipped with 3/8-inch silicone tubing
  c. Submerged specimen

Figure 2:
  a. Schematic setup of straight, circumferential cut, end-to-end anastomosis. End-to-end anastomosis is indicated by the red mark.
  b. Schematic setup of 45° angular, circumferential cut, end-to-end anastomosis
  c. Schematic setup of end-to-end side branch anastomosis

Figure 3:
  a. Continuous recordings of pressures (mmHg) and flow (l/min) in the setup, in an end-to-side side branch anastomosis using barbed sutures.
  b. Continuous recordings of pressures (mmHg) and flow (l/min) in the setup, in an end-to-side side branch anastomosis using conventional sutures.
Table legend:

Table 1:
Paired setups: 3x2 circumferential anastomosis, 2x2 side branch anastomosis

Table 2:
Straight, circular, end-to-end anastomosis paired setup: 2x2

Table 3:
Angled (45°), circular, end-to-end anastomosis, paired setup

Table 4:
End-to-side side branch anastomosis, paired setup: 2x2