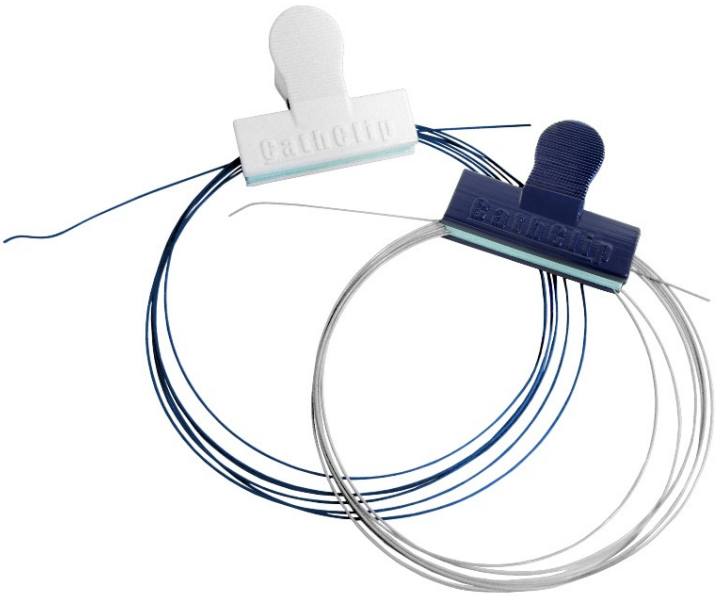
CathClip

guidewire, catheter, and balloon management tool



White Paper –
Timed Simulations Demonstrating CathClip Benefits of Reduced Procedure Time & Improved Clinical Outcomes

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1. Introduction

CathClip – the universal guidewire, catheter, and balloon management tool – was used in simulations to demonstrate the benefits of using CathClip in place of different make-shift techniques needed for management of various guidewires, catheters, and balloons when CathClip is not used.

Without CathClip, make-shift techniques must be used to manage guidewires, catheters, and balloons in between uses during a procedure. Common make-shift techniques are (a) wrapping a guidewire around itself, (b) using Kelly forceps to clip a looped guidewire, (c) returning a guidewire to its original packaging, and (d) storing guidewires, catheters, and balloons in a saline-filled bowl. There are different make-shift techniques because no one make-shift technique can effectively handle all guidewires, catheters, and balloons. Different guidewires, catheters, and balloons must be managed with different make-shift techniques, with the physician or technician choosing which technique to use based on the particular characteristics of the device being managed. What's more, these make-shift techniques are unreliable, taking extra time to use and not always securely holding the device to be managed.

The timed simulations described in this white paper demonstrate that it takes significantly less time to manage guidewires, catheters, and balloons when CathClip is used, as compared to when CathClip is not used.

2. Methodology

A physician experienced and skilled in the management of guidewires, catheters, and balloons was videotaped and timed simulating guidewire, catheter, and balloon management techniques in different scenarios, without CathClip (using only make-shift techniques) and with CathClip.

Every effort was made to simulate real-world conditions, i.e., the physician wore a gown and gloves and the simulations were done on a draped table simulating the sterile back table used in a procedure. Each simulation scenario was completed 10 times. All simulations were videotaped and timed. Videos are available upon request.

For the sake of simplicity, the simulations were performed with guidewires only, with no additional catheters or balloons on the table. Catheters and balloons are also effectively and easily managed by CathClip.

In order to draw logical conclusions between the use of make-shift techniques as compared to the use of CathClip, we distinguish between (i) single guidewire management techniques and (ii) management of multiple guidewires in a saline-filled bowl. Simulations of each are described in detail below.

i. Single Guidewire Management Techniques. The following techniques can logically be compared directly to one another because all techniques can be used to manage one single guidewire at a time: (a) looping the guidewire and then wrapping the back of a guidewire around the looped guidewire (make-shift technique), (b) looping the guidewire and then using Kelly forceps to clip the looped guidewire (make-shift technique), (c) returning the guidewire

to its original packaging (make-shift technique), and (d) looping the guidewire and then using CathClip to secure the looped guidewire.

While CathClip can effectively manage any guidewire, catheter, or balloon, the three make-shift techniques described are not universal in that not one of the three make-shift techniques can effectively manage all guidewires, catheters, and balloons. Only the stiffest, non-hydrophilic guidewires can be managed by wrapping the back of the guidewire around the looped guidewire because less stiff or hydrophilic guidewires are not be able to hold themselves when wrapped and will spring open when placed on the table. Only the most durable guidewires can be managed by using Kelly forceps to clip the looped guidewire because less durable (fragile) guidewires will be kinked when the Kelly forceps are clipped onto the guidewire, thereby damaging the less durable guidewires and rendering them unusable in the procedure. Guidewires that are more flexible or fragile will not be able to be managed by returning them to their original packaging because they are likely to bend or kink when fed back into the packaging, thereby irreversibly damaging them and making them unusable in the procedure.

CathClip, however, is a universal management tool which can manage any single guidewire, catheter, or balloon, no matter its particular characteristics.

For this series of simulations, the same guidewire was used in all simulations: a Cook Medical Lunderquist Extra-Stiff Wire Guide (a "Lunderquist Wire"). This guidewire was chosen for three reasons: (1) the Lunderquist Wire can be managed well with all of these single guidewire management techniques, (2) the Lunderquist Wire is a "best-case" scenario for the make-shift techniques because it potentially can be effectively managed with each make-shift technique, and (3) the Lunderquist Wire is a "worst-case" scenario for CathClip because it is one of the stiffest guidewires, which makes it one of the most challenging guidewires, catheters, or balloons for CathClip to manage since CathClip is universal and can also handle the most fragile guidewires, catheters, and balloons.

The following is a description of scenario set-up and timing for this series of simulations: The Lunderquist Wire was straight across the draped table, simulating the Lunderquist Wire being in the patient, with the back end of the Lunderquist Wire being held by the physician. Any material needed for the management technique, if applicable, was placed on the table in front of the physician (i.e., the Kelly forceps, guidewire packaging, or CathClip). The stopwatch was started, and the physician simulated removal of the Lunderquist Wire from the patient and used the technique being simulated and timed to control the Lunderquist Wire on the table. Control is defined as securely placing the Lunderquist Wire completely on the draped table so that it does not move. The physician paused when the Lunderquist Wire was fully controlled on the draped table. The physician then picked up the controlled Lunderquist Wire and prepared the Lunderquist Wire for its next use on the patient. When the Lunderquist Wire was ready to re-enter the patient, the stopwatch was stopped. Each simulation scenario was completed 10 times, and all simulations were videotaped.

ii. Management of Multiple Guidewires in a Saline-Filled Bowl. A saline-filled bowl is commonly used in procedures to manage multiple guidewires, catheters, and balloons simultaneously. Guidewires, catheters, and balloons can be held in a saline-filled bowl without CathClip. CathClip can also be used to help manage the guidewires, catheters, and balloons while they are being kept moist in the saline-filled bowl by looping a given guidewire, catheter, or balloon, securing the looped device with CathClip, then placing into the saline-filled bowl the looped device with CathClip engaged.

The following guidewires were used in these simulations of management of multiple guidewires in a saline-filled bowl in order to simulate this scenario with a variety of guidewires that are commonly managed with placement in a saline-filled bowl and a mixture of guidewires which is commonly used during procedures: (1) a Boston Scientific .035 Amplatz Super Stiff Guidewire (the "Stiff Wire"), (2) a Cook Medical .035 Roadrunner PC Hydrophilic Wire Guide (the "Hydrophilic Wire"), and (3) a Boston Scientific .018 V-18 ControlWire Guidewire (the "Fragile Wire").

Different guidewires are easier or more difficult to access from within a saline-filled bowl containing multiple guidewires depending on their particular characteristics. In order to demonstrate and quantitate these differences, the following two guidewires were accessed from within the saline-filled bowl, without CathClip and with CathClip (a) the Stiff Wire and (b) the Hydrophilic Wire.

The following is a description of scenario set-up and timing for this series of simulations: The Stiff Wire and Hydrophilic Wire were looped and placed in the saline-filled bowl, and the Fragile Wire was straight across the draped table, simulating the Fragile Wire being in the patient, with the back end of the wire being held by the physician. When the scenario was being simulated using CathClip, CathClips were clipped on the looped Stiff Wire and Hydrophilic Wire in the saline-filled bowl, with an additional CathClip placed on the table in front of the physician. The stopwatch was started, and the physician looped the Fragile Wire and placed it in the saline-filled bowl (using CathClip on the Fragile Wire when the scenario was being simulated using CathClip), taking out of the saline-filled bowl for its next use on the patient, the Stiff Wire or the Hydrophilic Wire, as applicable for the given scenario being simulated. When the Stiff Wire or the Hydrophilic Wire, as applicable for the given scenario being simulated, was ready to re-enter the patient, with the two other guidewires securely controlled within the saline-filled bowl, the stopwatch was stopped. Each simulation scenario was completed 10 times, and all simulations were videotaped.

3. Summary of Timed Simulation Results

CathClip provides a universal way to easily, quickly, and effectively manage any guidewire, catheter, or balloon. Simply clip CathClip on any guidewire, catheter, or balloon and rest assured that it will be gently and securely held, ready for its next use.

Without CathClip, different make-shift techniques must be used to manage the various guidewires, catheters, and balloons used during a given procedure. The timed simulations described in detail below demonstrate the negative aspects of using make-shift techniques: guidewire, catheter, and balloon management takes longer and is more difficult and inconsistent than when using CathClip.

The simulations demonstrate the following benefits of using CathClip:

- Reduced procedure time (lower facility costs),
- Reduced sedation time due to reduced procedure time (improved clinical outcomes), and
- Reduced distraction from guidewire, catheter, and balloon management, so the procedure goes more smoothly and the entire procedure team can focus on patient care (improved clinical outcomes).

4. Detail of Timed Simulation Results

4.1. When CathClip is not used, more time is spent managing guidewires. This leads to longer procedure times (higher costs) and longer patient sedation times (negative clinical impact).

In all scenarios simulated, the average time spent managing guidewires was significantly longer without CathClip than it was with CathClip. The graphs below illustrate this difference.

When the average time spent managing guidewires is longer, procedure time is longer (increasing costs) and patient sedation time is longer (negatively affecting clinical outcomes, especially for clinically urgent cases such as bleeds, aortic dissections, strokes, and myocardial infarctions).

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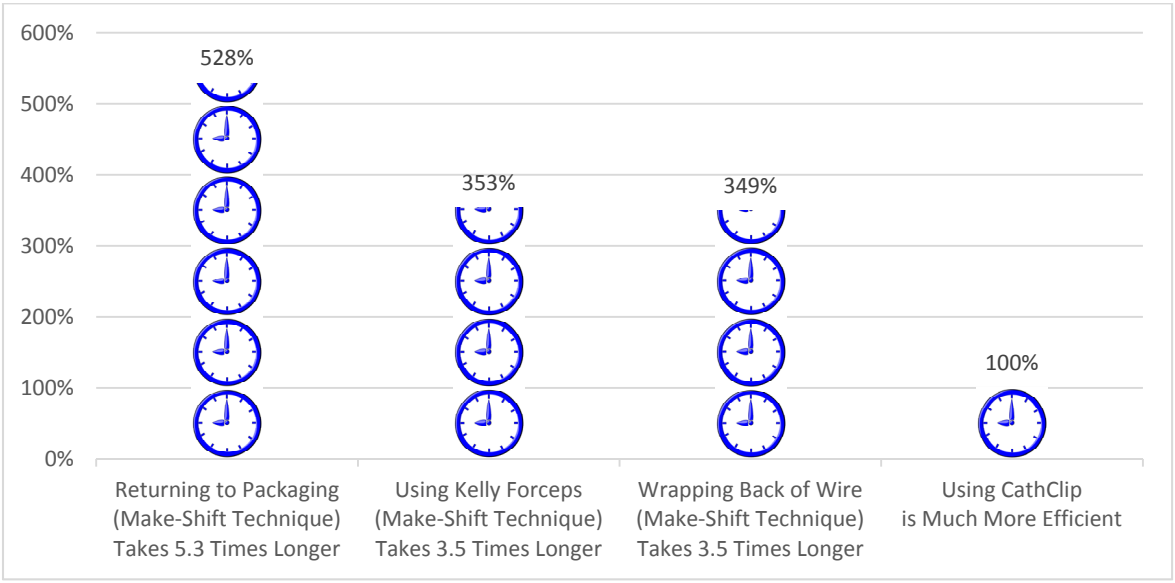
Graph 1. Single guidewire management techniques: comparison of average time spent managing a Lunderquist Wire, without CathClip (make-shift techniques) vs. with CathClip. Managing a Lunderquist Wire takes an average of 3.5 to 5.3 times longer using make-shift techniques than it does using CathClip.



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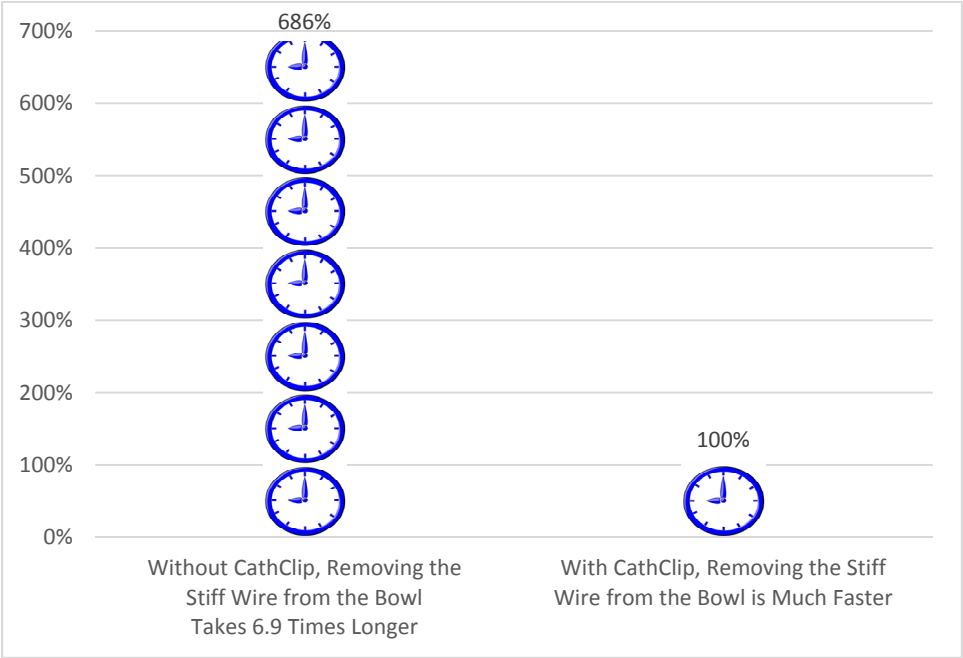
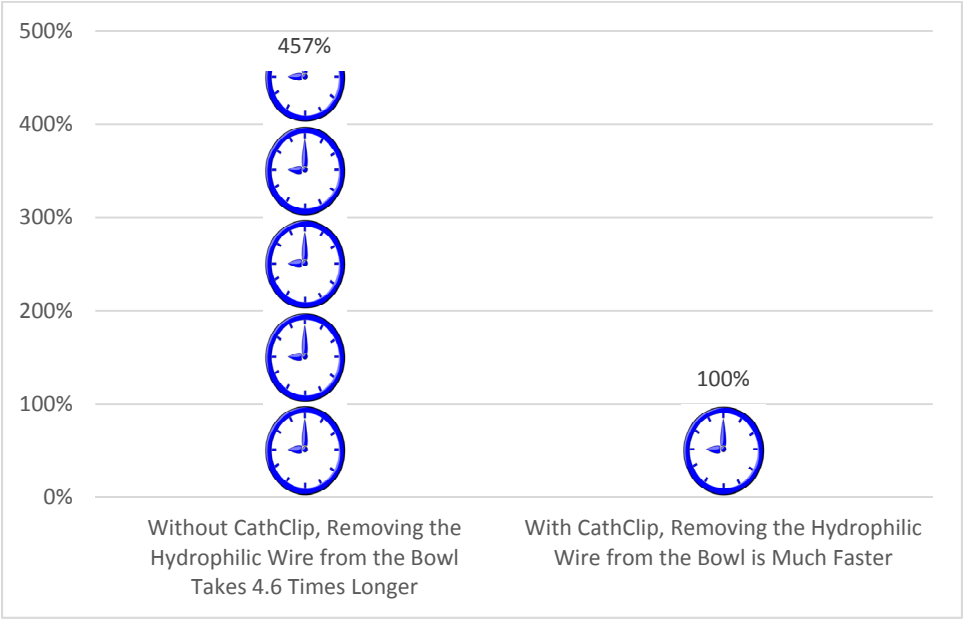
Graph 2. Management of multiple guidewires in a saline-filled bowl: comparison of average time spent accessing a <u>Stiff</u> Wire, without CathClip vs. with CathClip. Accessing a Stiff Wire from a saline-filled bowl with only two other guidewires takes an average 6.9 times longer without using CathClip than it does when CathClip is used.



Graph 3. Management of multiple guidewires in a saline-filled bowl: comparison of average time spent accessing a Hydrophilic Wire, without CathClip vs. with CathClip. Accessing a Hydrophilic Wire from a saline-filled bowl with only two other guidewires takes an average of 4.6 times longer without using CathClip than it does when CathClip is used.

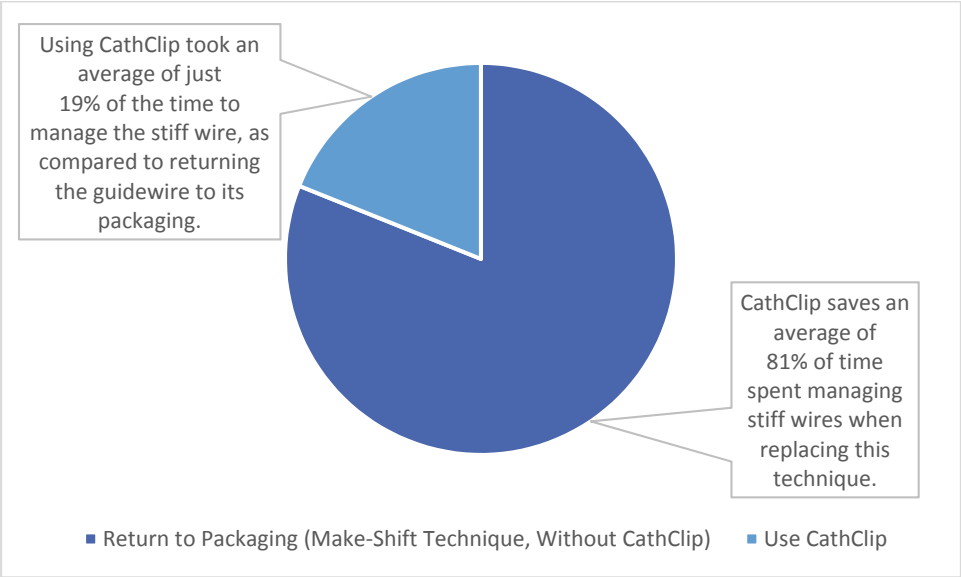


4.2. Using CathClip saves time. This leads to reduced procedure times (cost savings) and reduced patient sedation times (better clinical outcomes).

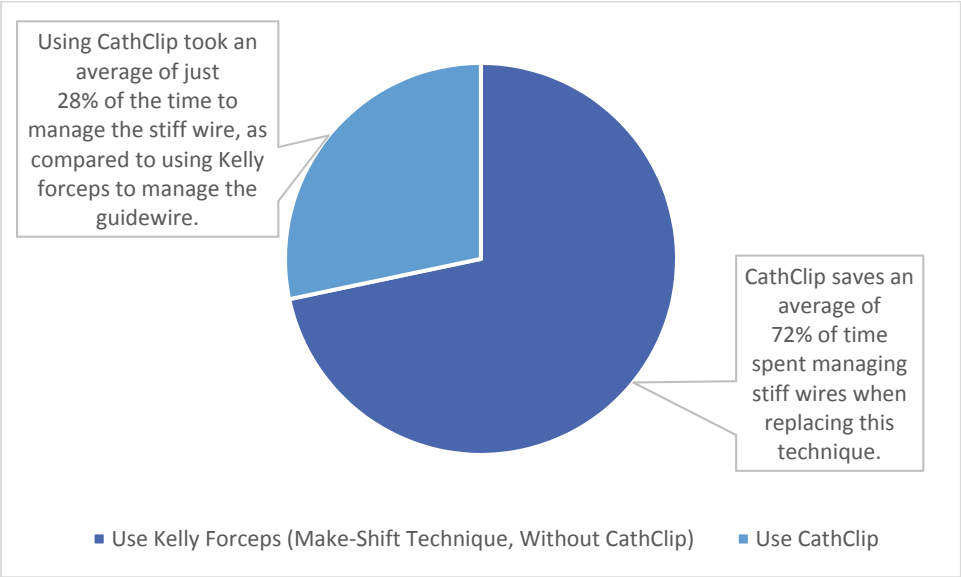
In all scenarios simulated, the average time spent managing guidewires was significantly reduced when CathClip was used. The graphs below illustrate this difference.

When the average time spent managing guidewires is reduced, procedure time is shorter (decreasing costs) and patient sedation time is shorter (leading to better clinical outcomes).

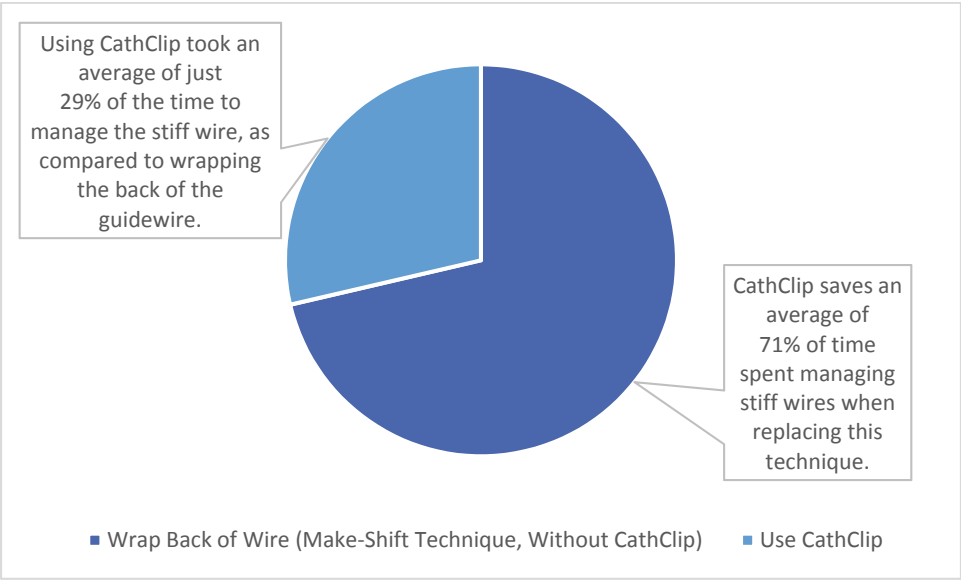
Graph 4. Single guidewire management technique: comparison of average time spent managing a Lunderquist Wire by returning it to its original packaging (make-shift technique) vs. using CathClip. CathClip reduces the amount of time spent managing a Lunderquist Wire, as compared to returning the Lunderquist Wire to its original packaging (make-shift technique), by an average of 81%.



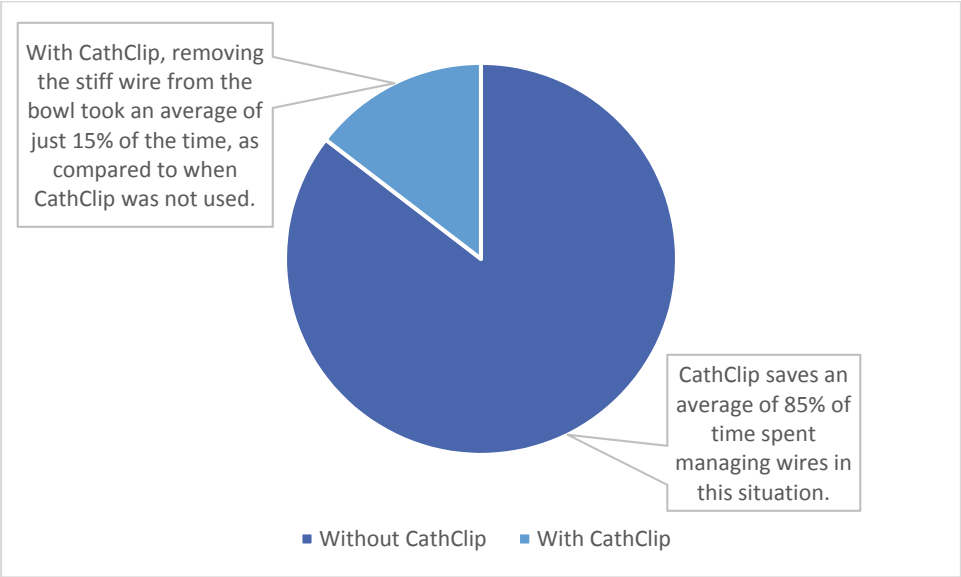
Graph 5. Single guidewire management technique: comparison of average time spent managing a Lunderquist Wire by using Kelly forceps (make-shift technique) vs. using CathClip. CathClip reduces the amount of time spent managing a Lunderquist Wire, as compared to using Kelly forceps (make-shift technique), by an average of 72%.



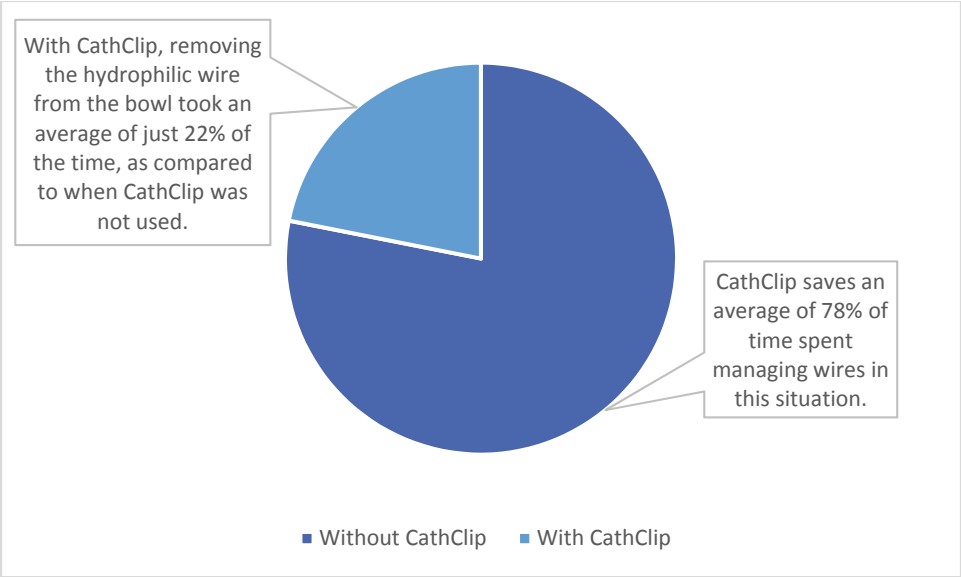
Graph 6. Single guidewire management technique: comparison of average time spent managing a Lunderquist Wire by wrapping the back of wire (make-shift technique) vs. using CathClip. CathClip reduces the amount of time spent managing a Lunderquist Wire, as compared to wrapping the back of the wire (make-shift technique), by an average of 71%.



Graph 7. Management of multiple guidewires in a saline-filled bowl: comparison of average time spent accessing a <u>Stiff</u> Wire, without CathClip vs. with CathClip. Using CathClip reduces the amount of time spent accessing a Stiff Wire from a saline-filled bowl with multiple guidewires by an average of 85%.



Graph 8. Management of multiple guidewires in a saline-filled bowl: comparison of average time spent accessing a <u>Hydrophilic</u> Wire, without CathClip vs. with CathClip. Using CathClip reduces the amount of time spent accessing a Hydrophilic Wire from a saline-filled bowl with multiple guidewires by an average of 78%.



4.3. Using CathClip removes distractions so that the entire team can concentrate on patient care (better clinical outcomes).

In all scenarios simulated, the standard deviations of the average times spent managing guidewires were significantly larger without CathClip than they were with CathClip. The graphs below illustrate this difference, with the standard deviations depicted by error bars.

The larger standard deviations recorded in simulations without CathClip are a mathematical representation of how difficult it is to manage guidewires, catheters, and balloons without CathClip. The time spent managing guidewires without CathClip was not only longer than it was when using CathClip, as described above – the experience was also much more volatile, at times leading to contamination of the devices, depending on how much went wrong trying to wrangle the guidewires in the simulations. This can be quite a distraction in the middle of a procedure, with the patient under sedation or anesthesia.

Inversely, the smaller standard deviations recorded in simulations using CathClip are a mathematical representation of how easy and consistent using CathClip makes the management of guidewires, catheters, and balloons. The time spent managing guidewires with CathClip was not only shorter than it was without CathClip – the experience was also much smoother, also eliminating any damage or contamination.

The standard deviations recorded show that managing guidewires, catheters, and balloons without CathClip is distracting during procedures. However, it is important to note that the simulations do not adequately quantify the distractions of guidewire, catheter, and balloon management during procedures without CathClip because they do not quantify the time and energy that must be taken to determine which technique should be used to manage each guidewire, catheter, and balloon due to the fact that not all make-shift techniques can effectively manage all of them. In the simulations, it was known which technique would be used on the guidewires at hand. This is not true during procedures.

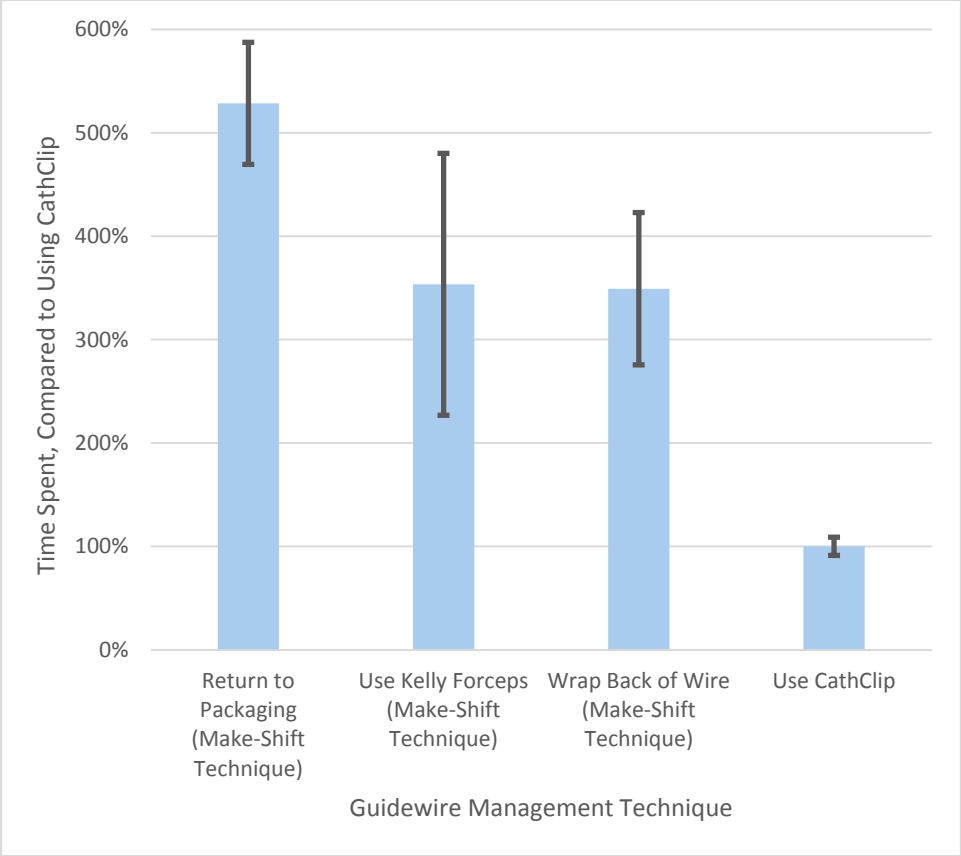
Additionally, for this particular exercise, we focused only on guidewires. There are various make-shift techniques for handing catheters and balloons – in addition to guidewires – including using wet towels and wet gauze, adding additional components of distraction during procedures.

Because it is easy to use and consistently holds any guidewire, catheter, or balloon (it's universal), CathClip removes the distractions associated with guidewire, catheter, and balloon management.

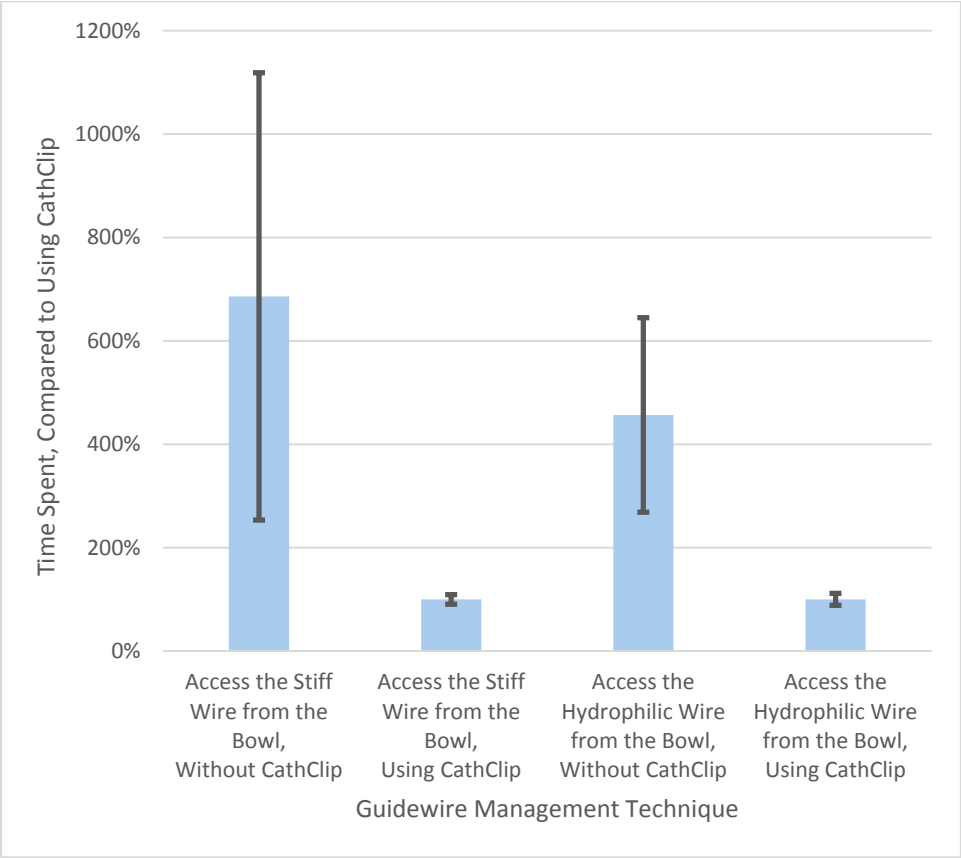
When distractions are removed, the entire team can concentrate on providing the best possible care to the patient (leading to better clinical outcomes).

Further, with CathClip, devices are ready for use when they are needed throughout the procedure: quickly, easily, and without damage. This is especially important in clinically urgent cases such as bleeds, aortic dissections, strokes, and myocardial infarctions.

Graph 9. Single guidewire management techniques: standard deviations illustrate the difficulty and inconsistency of using make-shift techniques vs. the ease, consistency, and reliability of using CathClip. Standard deviations recorded are much larger for the make-shift techniques tested to manage a single Lunderquist Wire (returning the wire to its packaging, using Kelly forceps, and wrapping the back of the wire) than for using CathClip to manage the Lunderquist Wire.



Graph 10. Management of multiple guidewires in a saline-filled bowl: standard deviations illustrate the difficulty and inconsistency of accessing wires without CathClip vs. the ease, consistency, and reliability of using CathClip. Standard deviations recorded are much larger for accessing wires from a saline-filled bowl without using CathClip than for doing so with CathClip.



4.4. Over the course of a typical procedure, using CathClip adds up to significant time savings. This leads to reduced procedure times (cost savings) and reduced patient sedation times (better clinical outcomes).

The timed simulations performed, from which the data presented above was collected, represent individual parts of a typical procedure: exchanges of individual guidewires used on the patient for the next guidewire to be used on the patient. Multiple guidewires, catheters, and balloons are used on the patient over the course of a typical procedure. Keeping these devices sterile and undamaged on the patient or on the sterile draped table adds another layer of complexity when using various make-shift techniques.

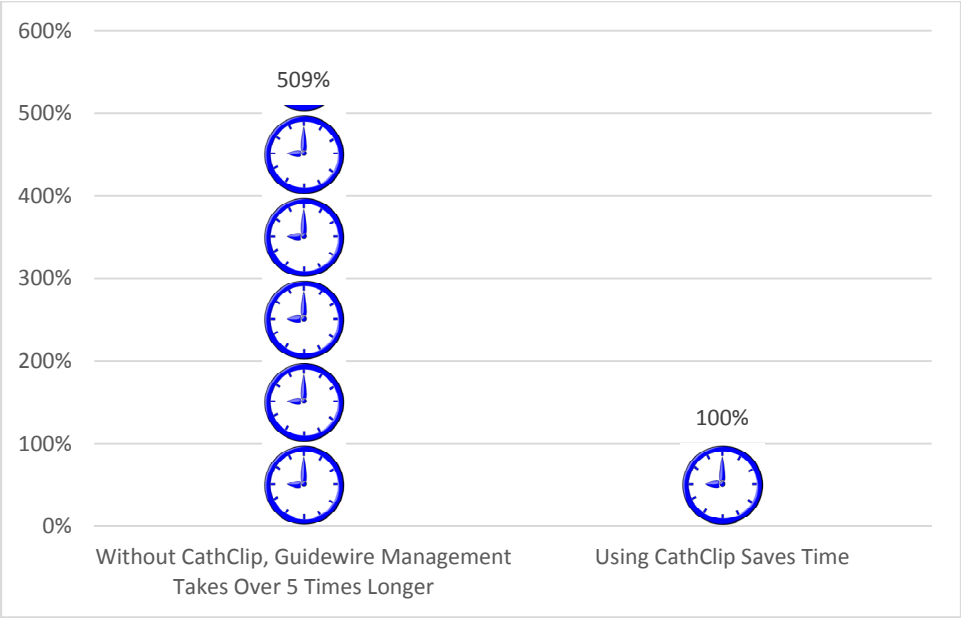
To understand what the timed simulations mean for a real procedure, we must extrapolate from the data gathered. Here, we figure that a "Typical Procedure" uses 4 flexible elongated medical devices (guidewires, catheters, or balloons), with 7 exchanges. The 4 flexible elongated medical devices used are the 4 guidewires used in the simulations: a Lunderquist Wire, a Stiff Wire, a Hydrophilic Wire, and a Fragile Wire. An exchange is defined as a wire being taken out of the patient and controlled on the table, with all other wires also being controlled on the table, and another wire being engaged for use on the patient. Here, we figure that the following 7 exchanges are typical over the course of a complete procedure: (a) 3 exchanges of the Lunderquist Wire, (b) 2 exchanges for use of the Stiff Wire, and (c) 2 exchanges for use of the Hydrophilic Wire.

Over the course of a Typical Procedure, the average time spent managing guidewires was significantly reduced when CathClip was used. The graphs below illustrate this difference.

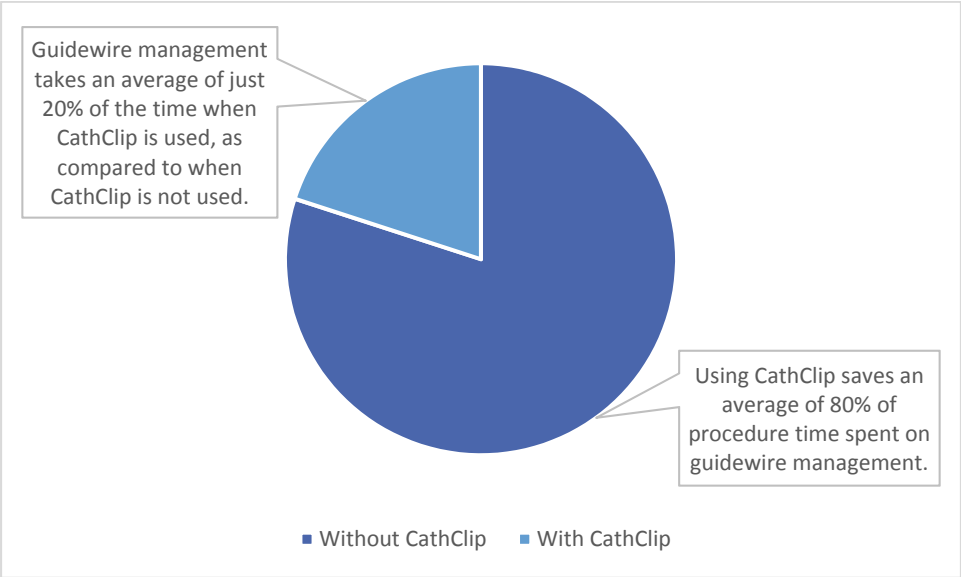
These are conservative numbers, as for in most cases the team would also have to exchange, control, and re-use multiple catheters and balloons, in addition to guidewires, for such a typical Interventional Radiology, Vascular Surgery, Interventional Cardiology, or Interventional Neuroradiology case.

When the average time spent managing flexible elongated medical devices is reduced, procedure time is shorter (decreasing costs) and patient sedation time is shorter (leading to better clinical outcomes).

Graph 11. Guidewire management in a Typical Procedure: comparison of average time spent managing wires, without CathClip vs. with CathClip. Without CathClip, the amount of time spent on guidewire management in a Typical Procedure is 5 times longer than when CathClip is used.



Graph 12. Guidewire management in a Typical Procedure: comparison of average time saved using CathClip vs. when CathClip is not used. CathClip reduces the amount of time spent on guidewire management in a Typical Procedure by an average of 80%, taking just 20% of the time as compared to not using CathClip.



5. Conclusion

The timed simulations described in this white paper demonstrate that managing guidewires, catheters, and balloons using CathClip is faster and more reliable than managing those devices without CathClip. This illustrates that using CathClip lowers facilities costs by reducing procedure time and improves clinical outcomes by reducing sedation time and allowing the procedure team to focus on patient care, rather than device management.