CathClip

guidewire, catheter, and balloon management tool

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Re: **CathClip New Product Justification / Value Analysis**

I. Product Introduction: CathClip improves profitability and safety.

Without CathClip, guidewires, catheters, balloons, and other similar flexible elongated devices (many of which are extremely expensive, costing hundreds and even thousands of dollars each) are held between uses during procedures with makeshift techniques, such as by placing them in buckets of saline and wrapping them in gauze and cotton towels. This leads to costly waste and safety issues.

When using makeshift techniques rather than CathClip, guidewires, catheters, balloons, and other similar flexible elongated devices can become damaged, such as by dropping on the floor or getting kinked, requiring new, duplicate devices to be used. These duplicate devices are extra costs that CathClip eliminates. CathClip is the only universal solution to handling flexible elongated medical devices (such as guidewires, catheters, and balloons) between uses during procedures. Simply make a standard loop, clip on CathClip, and the device will be ready for its next use.

CathClip will securely and gently hold any such device, from a Super Stiff Amplatz (and even Lunderquist) to a gentle microwire or microcatheter. Its hydrophilic gripping pads make it safe for hydrophilic coatings as well, and it will even securely hold a Stiff Glidewire. CathClip's foam is a dimensionally stable polyurethane and therefore does not release lint as gauze and cotton towels do.

Physicians, nurses, and techs love CathClip because it makes their lives easier by solving a real problem: guidewire, catheter, and balloon management. Facilities benefit from CathClip's use because it cuts costs, even paying for itself, while improving safety and outcomes.

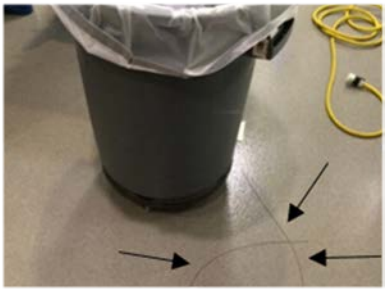
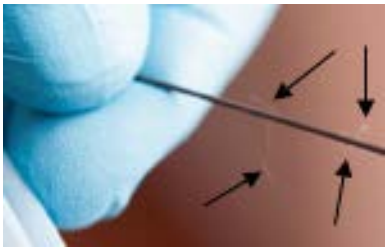
Using CathClip increases productivity and profitability by taking care of guidewires, catheters, and balloons so that duplicate devices are not needed, paying for itself in materials cost savings alone. CathClip provides additional cost savings in reduced procedure times.

In addition to improving productivity and profitability, CathClip improves patient safety and outcomes, as devices are kept in the sterile field (decreasing infection risk), procedure times are decreased (meaning less radiation and improved outcomes due to less sedation), and the team can focus on patient care rather than device management (devices are ready for use when needed and procedures go more smoothly), all while eliminating embolization/stroke risk from lint introduced when devices are wiped and held by cotton fiber materials such as gauze and cotton towels (CathClip is lint-free).

CathClip also improves worker safety by decreasing radiation exposure by avoiding damage to guidewires, catheters, and balloons, and minimizing contamination of the procedure room and team by effectively managing those devices.

For an introduction to CathClip and its benefits, please see Attachment A, *CathClip Sales Flyer*.

Using CathClip solves the problems caused by mismanagement of devices, improving procedure profitability, productivity, and safety, including as described in the table below.

Description of Improvement	**Improvement Category**
Reduces materials costs by (a) **over $51 per case when used in all cases** and (b) **over $231 per case when used in complex cases only** by protecting guidewires, catheters, and balloons from irreparable damage which necessitates their otherwise unnecessary replacement (**net positive for facility**). 	Profitability
Minimizes the effects of backorders by protecting the devices in use, thereby reducing the use of otherwise unnecessary duplicate devices.	Profitability & Productivity
Reduces procedure time by decreasing the time spent on device management by an average of 80% and eliminating the time wasted on retrieving and preparing duplicate devices for use, all while the patient is sedated.	Profitability, Productivity, & Safety (Patient) / Outcomes
Eliminates embolization (stroke) risk from lint released when using items with cotton fibers, such as gauze and cotton towels, to hold and wipe devices. **CathClip is lint-free.** 	Safety (Patient) / Outcomes
Reduces infection risk, as mismanaged guidewires, catheters, and balloons that touch outside the sterile field are often cleaned with chlorohexidine and reused on the patient since the exchange for a new device during critical times of the procedure may negatively affect patient outcome.	Safety (Patient) / Outcomes
Reduces radiation exposure, as damage to a device is often noticed only when not functioning properly inside of a patient, after everyone has been exposed to unnecessary radiation.	Safety (Patent & Worker) / Outcomes
Reduces sedation time by managing devices effectively.	Safety (Patient) / Outcomes
Procedures go more smoothly as the team can focus on patient care rather than device management and devices are ready for use when needed, quickly, easily, and without damage.	Safety (Patient) / Outcomes
Minimizes contamination by managing devices properly, particularly while removing them from bowls of saline, so that blood and contaminated fluids do not splatter the procedure room and team, thereby keeping the room cleaner and the team safer.	Safety (Worker)

II. Ordering Information

CathClip is available in 2 ways for clinical use: (1) as a stand-alone sterile product and (2) in custom procedure packs. CathClip is universal, and there is no functional difference between different colored CathClips. The different colors are simply to aid in organization.

Sterile CathClips (Stand-Alone Sterile Product)
Catalog # CathClip-201
1 Package of CathClip-201 = 2 CathClips (1 Blue and 1 White)
Standard Unit of Measure: Box
Packages Per Box: 20
Shipping not included.

Sterile CathClips in Custom Procedure Packs
CathClip is also available for inclusion in procedure packs. CathClips can be added to packs in any number, in colors blue and white (no functional difference between the colors). Catalog numbers vary by procedure pack provider; below are our catalog numbers.
Blue: Catalog # CathClip-001-BLUE
White: Catalog # CathClip-001-WHITE

Contact for orders:

Phone:	650-683-0448
Fax:	650-434-3807
Email:	orders@cathclip.com

Purchase orders may be submitted via fax or email.

III. Clinical Rationale and Cost Justification

Analysis shows that CathClip pays for itself and that facilities actually come out ahead in cost savings, plus CathClip has additional benefits to safety (patient and worker) and clinical outcomes.

CathClip provides the following benefits, positively impacting quality of care: reduces costs, improves safety, and improves outcomes. This is all with one single tool that can provide these benefits in any procedure using flexible elongated devices, such as guidewires, catheters, and balloons (multiple specialties using one simple tool, providing operational benefits). Please reference the attached white papers and articles cited herein for more details on the information throughout this new product justification / value analysis.

CathClip's cost savings benefits are easiest to see in two ways which can be measured: (a) duplicate devices are eliminated and (b) procedure times are decreased. These benefits are described in more detail below and in the attached white papers, Attachment B, *White Paper – Cath Lab Materials Usage at a Major Academic Hospital as Cost Effectiveness Analysis Illustrating CathClip Benefits of Cost Savings (Materials and Time), Improved Clinical Outcomes, & Improved Safety*; Attachment C, *White Paper – Cath Lab Materials Usage at a Major Academic Hospital as Cost Effectiveness Analysis Illustrating CathClip Benefits of Cost Savings (Materials and Time), Improved Clinical Outcomes, & Improved Safety When Used In Complex Cases Only*; and Attachment D, *White Paper – Timed Simulations Demonstrating CathClip Benefits of Reduced Procedure Time & Improved Clinical Outcomes*.

In addition to its cost savings benefits, CathClip improves safety. With CathClip, the procedure team can focus on patient care rather than device management. Safety improves as devices are kept in the sterile field (reducing

infection risk and therefore reducing readmission rate) and as devices are managed without lint (reducing embolization/stroke risk).

Reducing the costs of wasted materials and unnecessarily long procedure times, while improving safety, increases value in health care. If value is defined by health outcomes achieved per dollar spent, value increases when cost is reduced while the best outcomes are achieved. CathClip reduces waste in materials and time, therefore reducing cost, and improves safety and outcomes by eliminating embolization/stroke risk from lint, decreasing infection risk by keeping devices in the sterile field, decreasing procedure/sedation time, and helping interventionalists focus on the procedure at hand rather than focusing on the management of flexible elongated medical devices, thereby helping to achieve the best outcomes. Reducing cost while achieving best outcomes increases value.[1]

A. CathClip eliminates duplicate devices, paying for itself in materials cost savings alone and providing additional benefits to profitability, safety (patient and worker), and clinical outcomes.

Without CathClip, flexible elongated devices, such as guidewires, catheters, and balloons (many of which are extremely expensive, costing hundreds and even thousands of dollars), can become damaged, such as by dropping on the floor or getting kinked, requiring new, duplicate devices to be used. Duplicate devices are extra costs that would not be incurred if flexible elongated devices were properly cared for. These duplicate devices are extra costs which CathClip eliminates by effectively managing these flexible elongated devices.

In a study of duplicate devices used in Interventional Radiology at a major academic hospital, the cost of duplicates in all cases worked out to an average of over $51 per case. This figure includes the cost of duplicates during the time period studied in all cases, including everything from the most complex to the simplest. Attachment B.

The same data revealed that more duplicate devices were often needed in more complex cases as compared to simpler cases, with the cost of duplicates higher in complex cases than in simpler cases. The cost of duplicates in complex cases only worked out to an average of over $231 per case. While complex cases made up only 21% of all cases, complex cases accounted for 94% of replacement device materials costs. Attachment C.

CathClip takes care of guidewires, catheters, and balloons during procedures so that duplicate devices are not needed, eliminating this cost of over $51 per case for all cases and over $231 per case for complex cases. In this way, CathClip pays for itself, and in fact, facilities come out ahead in cost savings. CathClip is like an insurance policy for the most expensive devices used.

While this study shows that CathClip pays for itself and that facilities actually come out ahead in cost savings (CathClip is a net positive), the cost of duplicate devices is likely to be even greater in more complex cases and in specialties other than Interventional Radiology, such as Interventional Cardiology and Vascular Surgery, where more expensive flexible elongated devices are used, such as drug-eluting balloons and stents.

In addition to adding to materials costs, duplicate devices lengthen procedure times and sedation times and distract patient care teams. When duplicate devices are needed during procedures, they must be retrieved from the stock room and prepared for use, all while the patient is on the table and under sedation, further adding to the length of the procedure.

Duplicate devices are also a safety issue (patient and worker) because flexible elongated device damage for which a replacement device would become necessary (for example, a kinked wire or catheter) is often noticed only when not functioning properly inside of the patient, after everyone in the room (the patient and the procedure team) has been exposed to unnecessary radiation.

[1] See Porter ME. *What Is Value in Health Care?* N Engl J Med 2010; 363:2477-81. DOI: 10.1056/NEJMp1011024.

The total cost of a replacement device, therefore, includes the following costs:

- Increased materials costs (increased cost for the facility),
- Increased procedure time (increased cost for the facility),
- Increased sedation time due to increased procedure time (negative clinical outcomes),
- Distraction of procedure team from patient care (negative clinical outcomes), and
- Increased radiation exposure (patient and worker safety issue).

CathClip eliminates these costs. For more details on the findings on duplicate devices described throughout this section, please see Attachment B and Attachment C.

B. CathClip decreases procedure times, thereby improving profitability further and providing additional benefits to patient safety and clinical outcomes.

On top of the materials cost savings and related benefits due to avoiding duplicate devices described above, CathClip provides additional cost savings in reduced procedure times, reducing the time spent on flexible elongated device management by 80% in a typical procedure. Guidewire management takes an average of over 5 times longer and is much less reliable without CathClip. In addition to making it quicker, CathClip makes device management much more reliable and consistent, as illustrated by the standard deviations in the figures in Attachment D.

Procedure time correlates directly with cost variation and is the largest contributor to overall procedure cost. With procedure suite costs conservatively estimated at $600 per hour, a recent study found that the time a patient is in a procedure suite is the largest contributor to the overall cost of a procedure. The study concludes, "These findings suggest that utilization of equipment, which allows for expedient procedure resolution, regardless of cost, may be paradoxically more cost effective overall for select routine procedures."[2]

Reduced procedure times mean that more procedures can be performed in one day and employees will not have to be paid to stay late. Reduced procedure times also lead to improved outcomes and reduced drug usage due to less sedation.

C. CathClip improves patient safety and clinical outcomes as it is lint-free, thereby eliminating embolization/stroke risk from lint, and aids in organization, thereby reducing infection risk and allowing the team to focus on patient care rather than device management.

In addition to improving profitability as described above, using CathClip improves safety in a number of ways:

- Embolization/stroke risk from lint is eliminated when CathClip is used in place of items such as gauze and cotton towels, as CathClip is lint-free,
- Devices are kept in the sterile field, thereby decreasing infection risk,
- Radiation exposure is reduced with decreased damage to devices,
- Procedure times are decreased with effective device management and decreased damage to devices, and
- The team can focus on patient care rather than device management, with devices ready to be used when needed during every procedure.

Introduction into the patient's body of a variety of foreign materials, including lint, can occur during interventions, and complications can occur as a result of embolization of such foreign materials. Products containing cotton fibers, such as gauze and cotton towels, contain cellulose, which is not digested by macrophages and therefore

[2] R.A. Charalel, R.S. Winokur, J. Jo, A.S. Amorosso, B.B. Pua; Radiology, NewYork-Presbyterian-Weill Cornell Medical Center, New York, NY; Weill Cornell Medical College, New York, NY. *Major contributors to operating cost variation for common interventional radiology procedures.* Abstract presented at: SIR 2015 Annual Scientific Meeting; 2015 Feb 28 - Mar 5; Atlanta, GA.

can result in a cascade of inflammatory and thrombotic reactions, causing foreign body embolization. Potential complications from lint include inflammation/granuloma formation, arterial thrombosis leading to myocardial infarction and stroke, adhesions, stent restenosis, infection, and embolized organ necrosis. "Unintentional foreign body emboli remain common in modern angiographic practice and are probably underappreciated clinically. Particulate embolization, which is usually a cotton fiber, is present in as many as 25% of resected arteriovenous malformations."[3]

For more details on the risks associated with lint, please see the following articles:

Silberman J, Cravioto H, Feigin I. *Foreign Body Emboli Following Cerebral Angiography.* Archives of Neurology (1960). Vol. 3, 119-126.

Heath D and Mackinnon J. *Case reports: Cotton-Wool Granuloma of Pulmonary Artery.* British Heart Journal (1962). Vol. 24, Issue 4, 518-520.

Dimmick JE, Bove KE, McAdams AJ, Benzing III G. *Fiber Embolization – A Hazard of Cardiac Surgery and Catheterization.* Medical Intelligence (1975). Vol. 292, No. 13, 685-687.

Whelan DM, van Beusekom HMM, van der Giessen WJ. *Foreign Body Contamination During Stent Implantation.* Catheterization and Cardiovascular Diagnosis (1997). Vol. 40, 328-332.

Van Langenhove G1, Diamantopoulos L, Regar E, Foley DP, Tuin J, Carlier SG, Serruys PW. *Distal embolization: A threat to the coronary artery?* Circulation (2000). Sep 26; 102(13): E95.

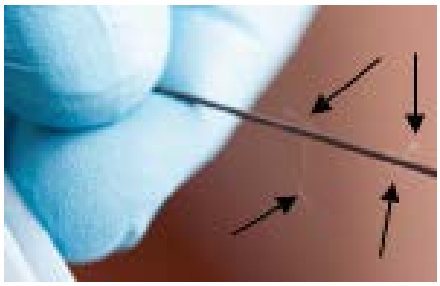
Glasgow D and Sommers J. *Lint Shedding Cannot Be Overlooked.* The Clinical Services Journal (2003). 28-30.

Fischi M and Narins CR. *Coronary Embolization of a Gauze Fragment: A Cautionary Case Report.* Catheterization and Cardiovascular Interventions (2005). Vol. 66, 570-572.

Shannon P, Billbao JM, Marotta T, Terbrugge K. *Inadvertent Foreign Body Embolization in Diagnostic and Therapeutic Cerebral Angiography.* American Journal of Neuroradiology (2006). Vol. 27, 278-282.

Ramot Y, Amir G, Willenz EP, Nyska A. *Foreign Body Granulomas within Intramyocardial Arteries in a Transcoronary Safety Assessment in Pigs.* Toxicologic Pathology (2008). Vol. 36, 385-387.

Holding and wiping flexible elongated devices, such as guidewires, catheters, and balloons, with materials which release lint, such as gauze and cotton towels, can cause lint to adhere to these devices and then be introduced to the patient's body when the devices are used. The aforementioned complications can result, even when using low-lint towels, which also release lint. This risk is eliminated with CathClip, as CathClip's foam is a lint-free, dimensionally stable polyurethane and therefore does not release lint.



Lint on Guidewire

On top of its significant safety benefit of being lint-free, CathClip further improves patient safety by being more reliable than makeshift techniques, thereby aiding in organization. This provides the following benefits:

[3] Shannon P, Billbao JM, Marotta T, Terbrugge K. *Inadvertent Foreign Body Embolization in Diagnostic and Therapeutic Cerebral Angiography.* American Journal of Neuroradiology (2006). Vol. 27, 278-282.

- Reduced infection risk. Mismanaged devices which touch outside of the sterile field are often cleaned with chlorohexidine or Betadine and reused. With CathClip, flexible elongated devices are effectively managed within the sterile field.
- Reduced radiation exposure. During a procedure, device damage, such as a kinked guidewire, is often noticed only when the device is not functioning properly inside of a patient, after everyone in the room (both the patient and the care team) has been exposed to unnecessary radiation. CathClip reduces radiation exposure by effectively managing flexible elongated devices, thereby protecting them from damage.
- Reduced procedure times. Flexible elongated devices are managed properly with CathClip, thereby decreasing procedure times. This, in turn, reduces patient sedation times, helping to improve clinical outcomes.
- Procedures go more smoothly. With CathClip, the patient care team can focus on patient care, rather than device management. Throughout procedures, devices are ready for use: quickly, easily, and without damage.

IV. Service Areas

Any specialty that uses flexible elongated medical devices (such as guidewires, catheters, and balloons) can use CathClip to save time and materials costs, thereby increasing productivity and profitability, and to improve safety (patient and worker) and clinical outcomes. This includes the following specialties:

- Cardiothoracic Surgery,
- Gastroenterology,
- Interventional Cardiology,
- Interventional Nephrology,
- Interventional Neuroradiology,
- Interventional Pulmonology,
- Interventional Radiology,
- Urology, and
- Vascular Surgery.

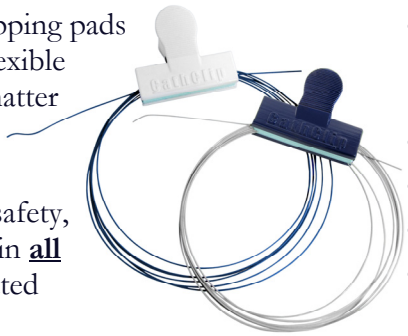
Attachment A

CathClip

guidewire, catheter, and balloon management tool

The UNIVERSAL Solution to Managing Guidewires, Catheters, and Balloons

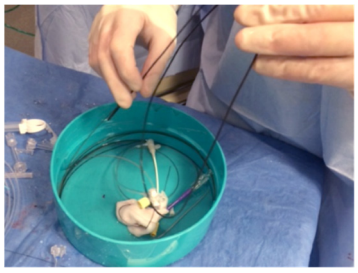
- Lint-free, hydrophilic foam gripping pads securely and gently hold **any** flexible elongated medical device, no matter its particular characteristics.
- To maximize improved clinical outcomes, patient and worker safety, and cost savings, use CathClip in **all** procedures with flexible elongated devices (multiple specialties).

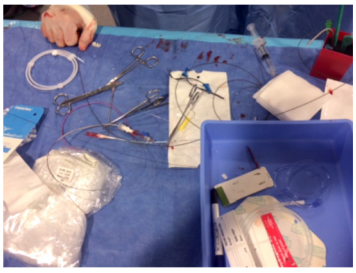


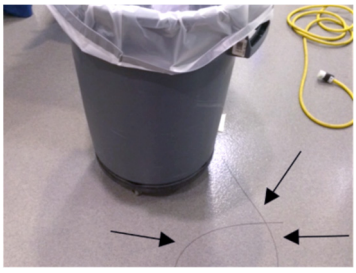
- Integrates seamlessly with current techniques (easy to use, with virtually no education needed).
- No extra procedure prep time.
- Small sized, single-use disposable.
- Different colors aid in organization.
- Available as stand-alone sterile product and in procedure packs.

CathClip Pays for Itself by Reducing Procedure Time and Materials Costs

Without CathClip, makeshift techniques are used to manage flexible elongated devices between uses. These techniques are time-consuming and unreliable, resulting in wasted time and damaged materials.





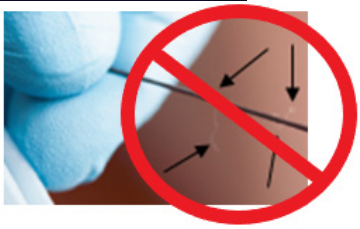


The images to the left were taken during actual procedures to show the current standard of care.

CathClip replaces makeshift techniques with a simple, universal clip that holds all flexible elongated devices.

- Reduces procedure time (80% reduction in time spent on device management; more reliable).
- Reduces materials costs (pays for itself by avoiding duplicate devices, measured at over $51 per case).

CathClip Improves Patient and Worker Safety and Clinical Outcomes



- Eliminates embolization/stroke risk from lint. Using cotton materials, such as gauze and towels, to hold and wipe devices increases the risk of intra-procedure complications. CathClip's foam is lint-free.
- Reduces infection risk. Mismanaged devices which touch outside the sterile field are often cleaned with chlorohexidine and reused. With CathClip, devices are effectively managed within the sterile field.
- Reduces radiation exposure. Device damage (for example, a kinked wire) is often noticed only when not functioning properly inside of a patient, after everyone (patient and care team) has been exposed to unnecessary radiation. CathClip reduces radiation exposure by protecting devices from damage.
- Procedures go more smoothly. With CathClip, the team can focus on patient care, rather than device management. Throughout a procedure, devices are ready for use: quickly, easily, and without damage.

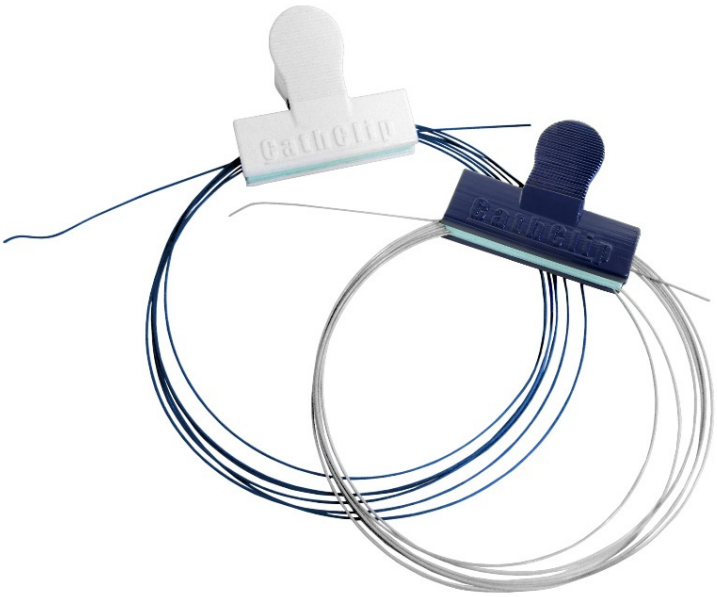
CathClip positively impacts quality of care.
Its use reduces costs, improves safety, and improves outcomes.

For more information or to place an order, please visit CathClip.com.

Attachment B

CathClip

guidewire, catheter, and balloon management tool



White Paper –

Cath Lab Materials Usage at a Major Academic Hospital as Cost Effectiveness Analysis Illustrating CathClip Benefits of Cost Savings (Materials and Time), Improved Clinical Outcomes, & Improved Safety

September 2017

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CathClip

guidewire, catheter, and balloon management tool

For more information
or to place an order,
please call (650) 683-0448
or visit www.cathclip.com.

1. Introduction

CathClip – the universal guidewire, catheter, and balloon management tool – saves costs (materials and time), improves clinical outcomes, and improves patient and worker safety by reducing the incidence of replacement guidewires, catheters, and balloons that must be used in procedures when guidewires, catheters, and balloons are damaged or contaminated due to mismanagement of those devices during a procedure.

Guidewires, catheters, and balloons are typically reused throughout entire procedures, with no need for replacement devices. However, if a device is damaged or contaminated (falls outside of the sterile field) during a procedure such that it can no longer function as needed, a replacement device must be used. The replacement device represents an additional cost which otherwise would not have been incurred.

2. Methodology

Data in the form of lists of the materials used in each Interventional Radiology case at a major academic hospital was collected for a period of two months (November and December 2014). Patient information was deidentified. The lists were sorted and replacement materials, including duplicates in each case, were noted. Pricing information was collected for all replacement materials from each replacement material's manufacturer.

For each procedure, there is a standard set of materials that is usually used. Therefore, the materials lists tell a story of what went on in each particular case. By examining the materials lists, it can be determined what type of procedure was being performed and conclusions can be drawn from the materials listed.

Because guidewires, catheters, and balloons are re-used during procedures, certain devices should not be repeated in a list, nor should there be any devices similar to those devices. Where such a device is repeated, or where there is a device listed that is similar to such a device, it can be deducted that the repeated or similar device was a replacement device that had to be used because the first such device used was damaged or contaminated.

3. Summary of Data on Cath Lab Materials Usage

The data examined revealed that replacement devices were used in a substantial proportion of procedures, amounting to significant added costs.

CathClip protects guidewires, catheters, and balloons from damage by gently and securely holding any such device. This leads to a decrease in the number of replacement devices used, resulting in the following benefits when the total cost of replacement devices is considered:

- Decreased materials costs (lower facility costs),
- Decreased procedure time (lower facility costs),
- Decreased sedation time due to decreased procedure time (improved clinical outcomes),
- Procedure team can focus on patient care (improved clinical outcomes), and
- Decreased levels of unnecessary radiation (improved patient and worker safety).

4. Detail of Data on Cath Lab Materials Usage

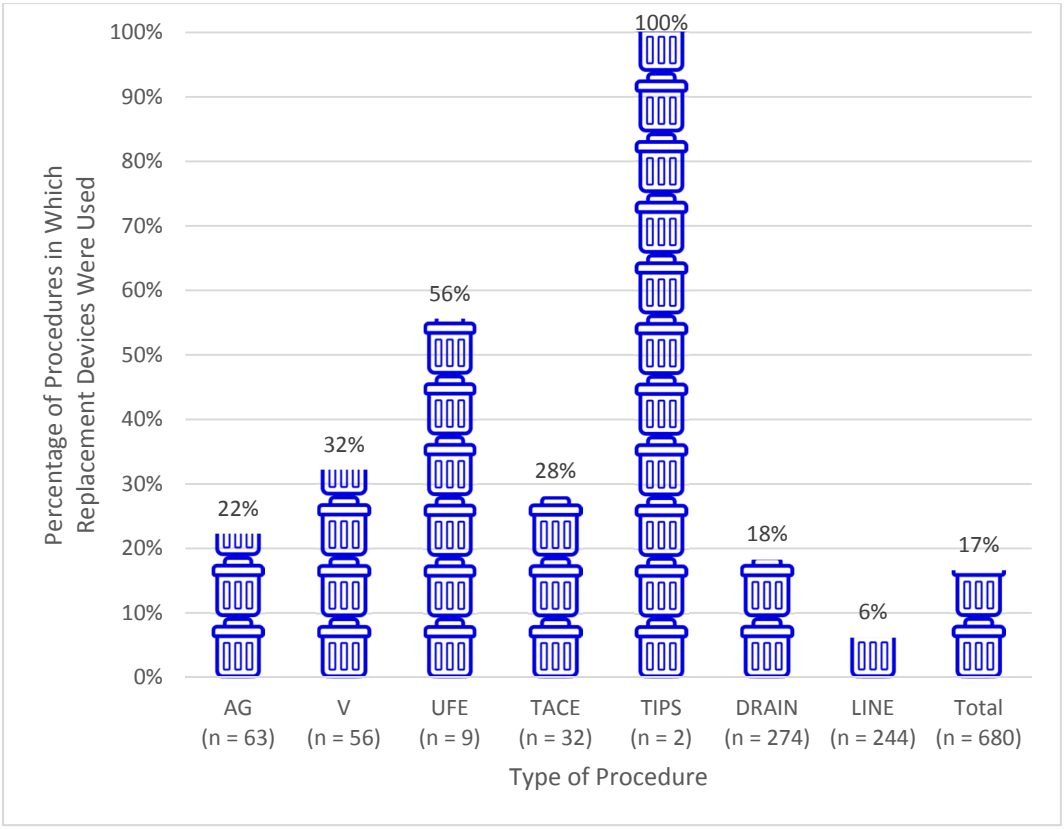
4.1. Replacement devices were used in a substantial proportion of of procedures.

All 680 cases over the 2-month period observed were grouped into procedure type as follows:

Procedure Type Label	Label Description
AG	Arterial Angiogram and Interventions
V	Venous Interventions, including Arteriovenous Fistula, Arteriovenous Graft, Dialysis Catheter Placement, IVC Filter Placement or Removals, Venous Recanalizations, Pulmonary Embolism Thrombolysis, Transjugular Liver Biopsies, and Gonadal Vein Embolizations
UFE	Uterine Fibroid Embolizations
TACE	Transarterial Chemoembolizations
TIPS	Transjugular Intrahepatic Portosystemic Shunts
DRAIN	Nephrostomy, Biliary, and Abscess Drain Interventions
LINE	Mediport, Hickman, and Dialysis Catheter Interventions

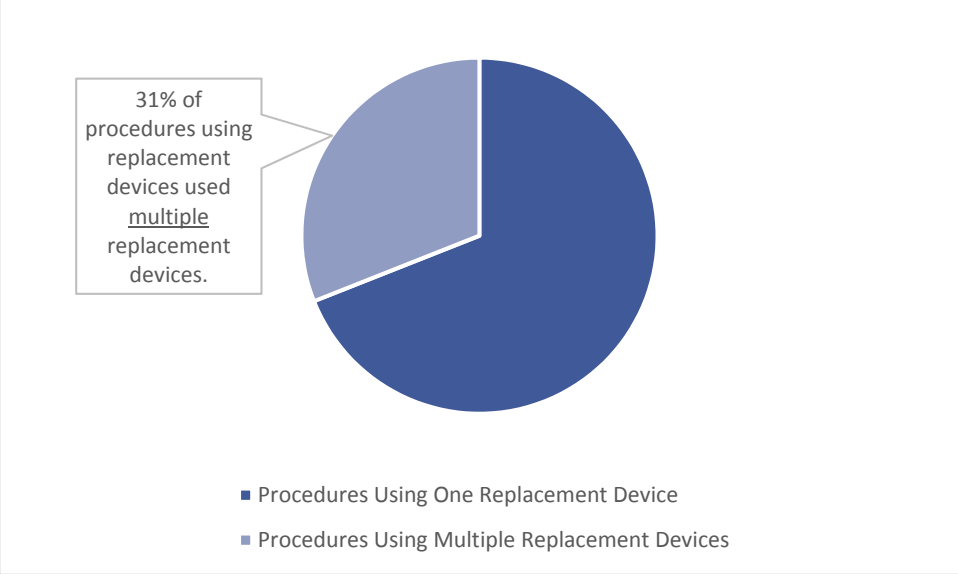
The graph below illustrates the proportion of procedures in which replacement devices were used.

Graph 1. Percentage of procedures in which replacement guidewires, catheters, or balloons were used.



In 31% of those procedures in which replacement devices were used, more than one (multiple) replacement devices were used. This illustrates how the cost of replacement devices can add up quickly. This may reflect that not only complex cases, such as TIPS, but also routine cases, such as UFE, may lead to multiple replacement devices when using make-shift guidewire, catheter, and balloon management techniques, rather than CathClip, thereby increasing costs and procedure duration.

Graph 2. Percentage of procedures in which multiple replacement guidewires, catheters, or balloons were used.

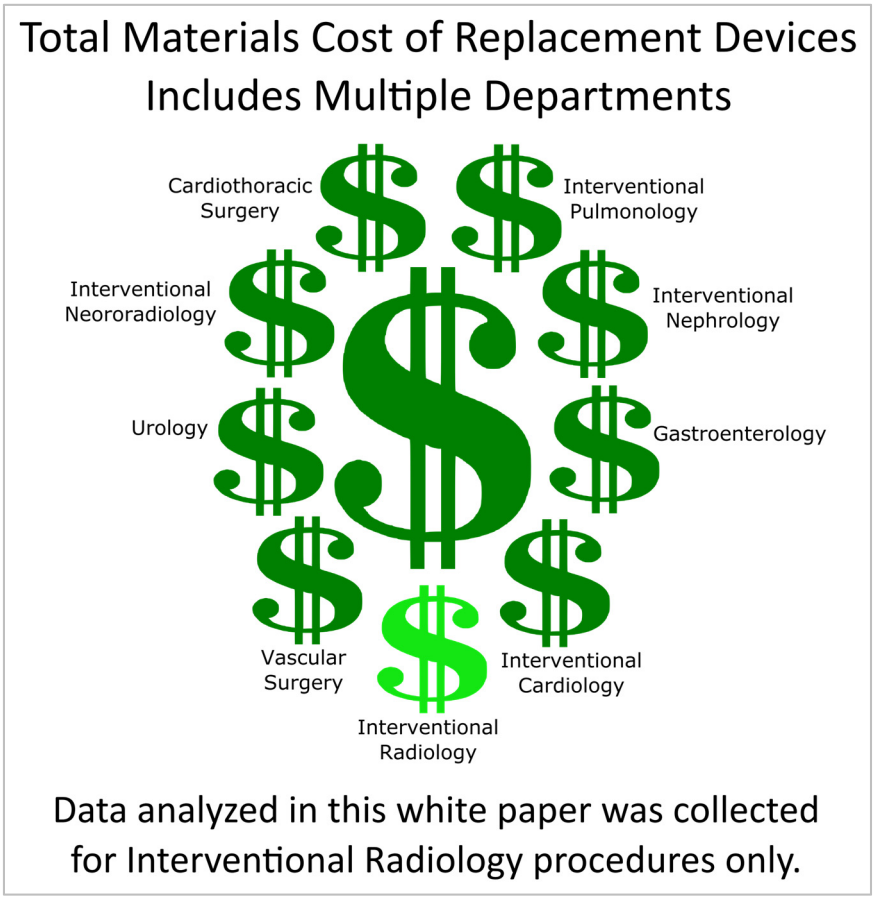


4.2. The materials cost of replacement devices is significant.

The cost of replacement devices observed was significant, although the data analyzed was only for Interventional Radiology procedures, within a single institution. Overall, 170 replacement guidewires, catheters, and balloons were used over the course of the 2-month period observed. These extra replacement devices ranged in price from $28.05 to $2,600.00. The replacement devices used over the course of the 2-month period observed totaled over $32,000. Over the course of a year, the projected extra cost of replacement devices is over $196,000.

It is important to note that these replacement devices were recorded in procedures only in Interventional Radiology, within a single institution. CathClip is appropriate for use in 9 specialties: Cardiothoracic Surgery, Gastroenterology, Interventional Cardiology, Interventional Nephrology, Interventional Neuroradiology, Interventional Pulmonology, Interventional Radiology, Urology, and Vascular Surgery.

If all 9 specialties are equally busy and if the rate of replacement devices holds across all specialties, the projected extra cost of replacement devices observed throughout the entire institution over the course of the year is over $1.75 million.



4.3. The total cost of replacement devices includes the time and effort it takes to retrieve and prepare replacement devices for for use (increased costs and negative clinical outcomes).

Each replacement device used also represents an increase in procedure time and a source of distraction during the procedure, in addition to an increase in materials costs.

When a replacement device must be used, time must be taken during the procedure to prepare that new device for use. Of note, many replacement devices are not close at hand within the procedure room – they must be retrieved from the storage area outside of the procedure room by a member of the procedure team. Additionally, the replacement device must be removed from its packaging and prepped for use.

The total cost of a replacement device, therefore, includes the following costs:

- Increased materials costs (increased cost for the facility),
- Increased procedure time (increased cost for the facility),
- Increased sedation time due to increased procedure time (negative clinical outcomes), and
- Distraction of procedure team from patient care (negative clinical outcomes).

4.4. Replacement devices are evidence of likely unnecessary radiation (patient and worker safety issue).

Flexible elongated device damage for which a replacement device would become necessary (e.g., kinked wire or catheter) is often noticed only when not functioning properly inside of the patient, after everyone in the cath lab (the patient and the procedure team) has been exposed to unnecessary radiation. With a retrospective study such as this one, it is difficult to assess when this may have happened. However, it is likely that a good number of the 170 replacement devices used over the course of the 2-month period observed replaced devices that the operator noted as damaged while inside the patient during the case, resulting in unnecessary radiation to the patient and the team.

4.5. CathClip decreases the incidence of replacement devices, thereby saving costs (materials and time), improving clinical outcomes, and improving safety.

CathClip decreases the incidence of replacement devices because CathClip effectively protects guidewires, catheters, and balloons by holding them gently and securely, eliminating the inefficiencies and the substantial distraction in the cath lab caused by the use of make-shift techniques to handle those devices. By decreasing the incidence of replacement devices, using CathClip decreases materials costs, decreases procedure time, improves clinical outcomes, and improves patient and worker safety.

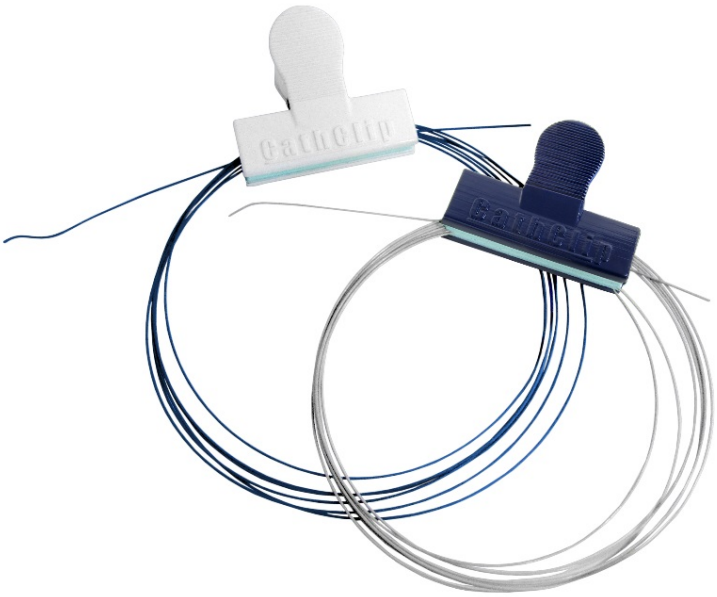
5. Conclusion

This study of materials usage in Interventional Radiology cases at a major academic hospital illustrates that the use of replacement devices is common and costly. If devices are managed properly, replacement devices are not necessary. CathClip helps properly manage guidewires, catheters, and balloons by holding them gently and securely, thereby protecting these devices from damage. Using CathClip decreases the number of replacement devices needed, resulting in lower facility costs (materials and time), improved clinical outcomes, and improved patient and worker safety, when the total cost of replacement devices is considered.

Attachment C

CathClip

guidewire, catheter, and balloon management tool



White Paper –
Cath Lab Materials Usage at a Major Academic Hospital as Cost Effectiveness Analysis Illustrating CathClip Benefits of Cost Savings (Materials and Time), Improved Clinical Outcomes, & Improved Safety When Used In Complex Cases Only

January 2021

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guidewire, catheter, and balloon management tool

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1. Introduction

CathClip – the universal guidewire, catheter, and balloon management tool – saves costs (materials and time), improves clinical outcomes, and improves patient and worker safety by reducing the incidence of replacement guidewires, catheters, and balloons that must be used in procedures when guidewires, catheters, and balloons are damaged or contaminated due to mismanagement of those devices during a procedure.

Guidewires, catheters, and balloons are typically reused throughout entire procedures, with no need for replacement devices. However, if a device is damaged or contaminated (falls outside of the sterile field) during a procedure such that it can no longer function as needed, a replacement device must be used. The replacement device represents an additional cost which otherwise would not have been incurred.

2. Methodology

Data in the form of lists of the materials used in each Interventional Radiology case at a major academic hospital was collected for a period of two months (November and December 2014). Patient information was deidentified. The lists were sorted and replacement materials, including duplicates in each case, were noted. Pricing information was collected for all replacement materials from each replacement material's manufacturer.

For each procedure, there is a standard set of materials that is usually used. Therefore, the materials lists tell a story of what went on in each particular case. By examining the materials lists, it can be determined what type of procedure was being performed and conclusions can be drawn from the materials listed. This includes whether a case was complex or not.

Because guidewires, catheters, and balloons are re-used during procedures, certain devices should not be repeated in a list, nor should there be any devices similar to those devices. Where such a device is repeated, or where there is a device listed that is similar to such a device, it can be deducted that the repeated or similar device was a replacement device that had to be used because the first such device used was damaged or contaminated.

3. Summary of Data on Cath Lab Materials Usage

The data examined revealed that replacement devices were used in a substantial proportion of procedures, amounting to significant added costs. See *White Paper – Cath Lab Materials Usage at a Major Academic Hospital as Cost Effectiveness Analysis Illustrating CathClip Benefits of Cost Savings (Materials and Time), Improved Clinical Outcomes, & Improved Safety*, September 2017 (the "2017 Cost Savings White Paper").

This data was further examined in complex cases as a subset of all cases, revealing that replacement devices were used in a greater proportion of complex cases only as compared to all cases together, amounting to more significant added costs in complex cases only as compared to all cases together.

CathClip protects guidewires, catheters, and balloons from damage by gently and securely holding any such device. This leads to a decrease in the number of replacement devices used, resulting in the following benefits when the total cost of replacement devices is considered:

- Decreased materials costs (lower facility costs),
- Decreased procedure time (lower facility costs),
- Decreased sedation time due to decreased procedure time (improved clinical outcomes),
- Procedure team can focus on patient care (improved clinical outcomes), and
- Decreased levels of unnecessary radiation (improved patient and worker safety).

4. Detail of Data on Cath Lab Materials Usage

4.1. Replacement devices were used in a substantial proportion of procedures.

All 680 cases over the 2-month period observed were grouped into procedure type as follows:

Procedure Type Label	Label Description
AG	Arterial Angiogram and Interventions
V	Venous Interventions, including Arteriovenous Fistula, Arteriovenous Graft, Dialysis Catheter Placement, IVC Filter Placement or Removals, Venous Recanalizations, Pulmonary Embolism Thrombolysis, Transjugular Liver Biopsies, and Gonadal Vein Embolizations
UFE	Uterine Fibroid Embolizations
TACE	Transarterial Chemoembolizations
TIPS	Transjugular Intrahepatic Portosystemic Shunts
DRAIN	Nephrostomy, Biliary, and Abscess Drain Interventions
LINE	Mediport, Hickman, and Dialysis Catheter Interventions

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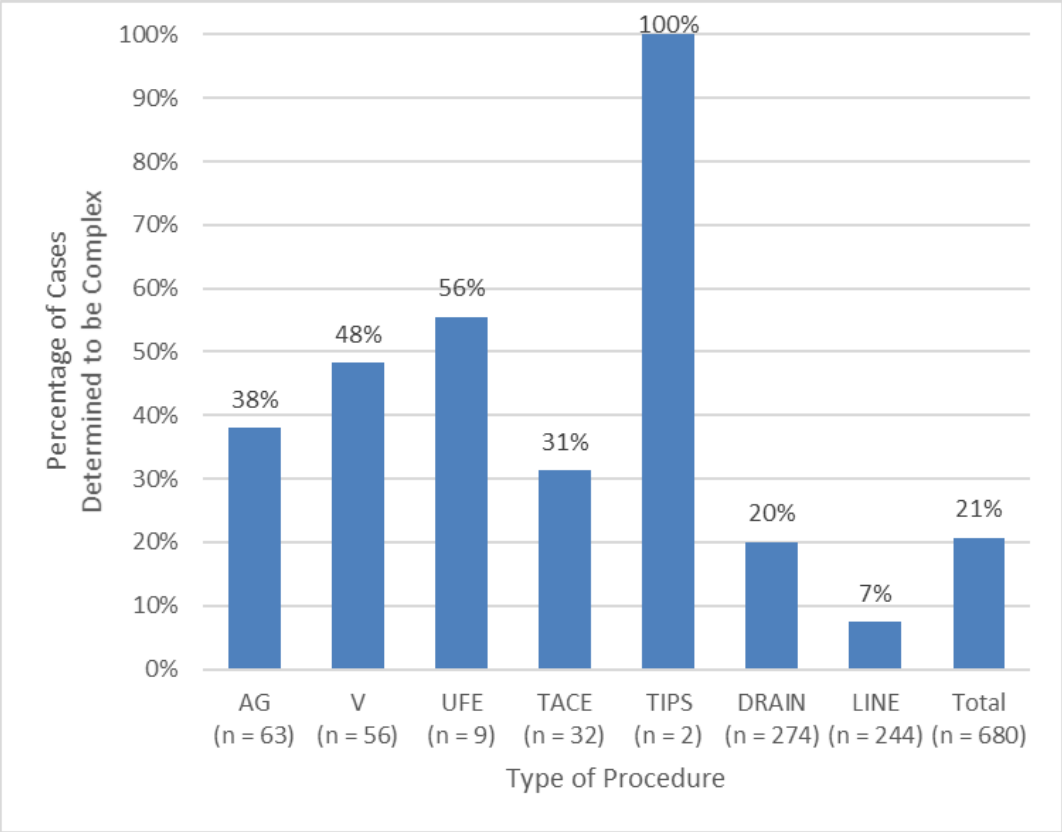
All 680 cases were further classified as complex or routine. Out of 680 cases over the 2-month period observed, 141 cases were determined to be complex cases.

The graph below illustrates the proportion of cases in each procedure type category which were determined to be complex.

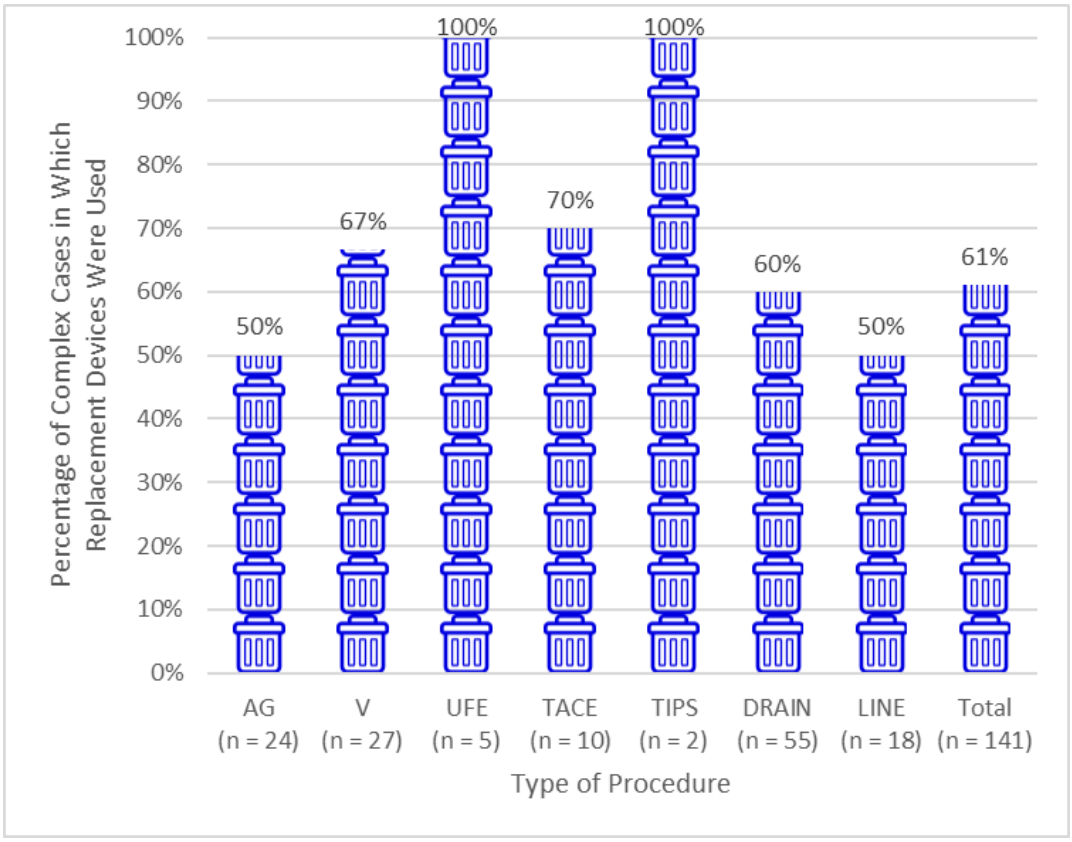
Graph 1. Percentage of cases which were determined to be complex.



The proportion of complex cases in which replacement devices were used was greater than the proportion of all cases in which replacement devices were used (61% of complex cases versus 17% of all cases). Cf. 2017 Cost Savings White Paper.

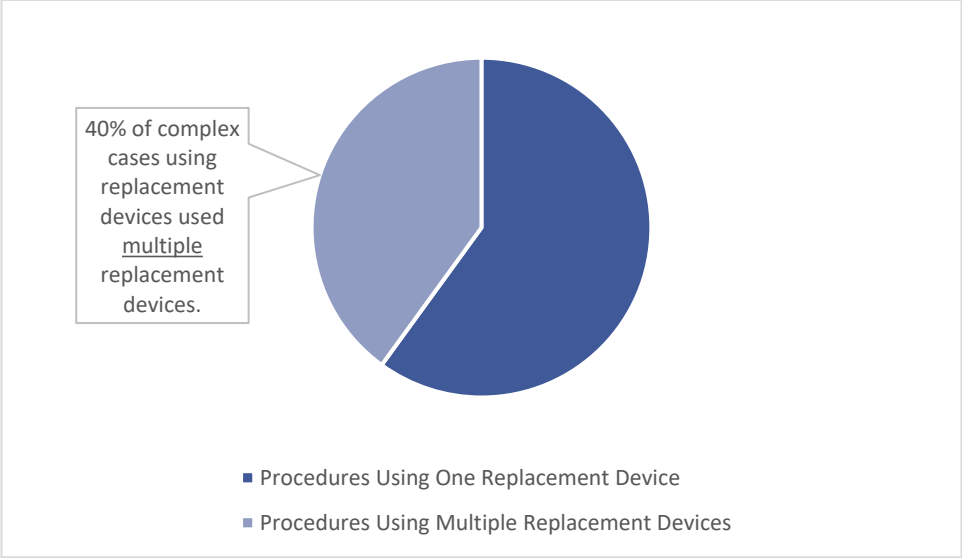
The graph below illustrates the proportion of complex cases in each procedure type group in which replacement devices were used.

Graph 2. Percentage of complex cases in which replacement guidewires, catheters, or balloons were used.



In 40% of complex cases in which replacement devices were used, more than one (multiple) replacement devices were used (versus 31% of all cases in which replacement devices were used). Cf. 2017 Cost Savings White Paper. This illustrates how the cost of replacement devices can add up even more quickly in complex cases, as compared to all cases. However, the cost of replacement devices also adds up quickly in all cases. This may reflect that not only complex cases, but also routine cases, may lead to multiple replacement devices when using make-shift guidewire, catheter, and balloon management techniques, rather than CathClip, thereby increasing costs and procedure duration.

Graph 3. Percentage of complex cases in which multiple replacement guidewires, catheters, or balloons were used.



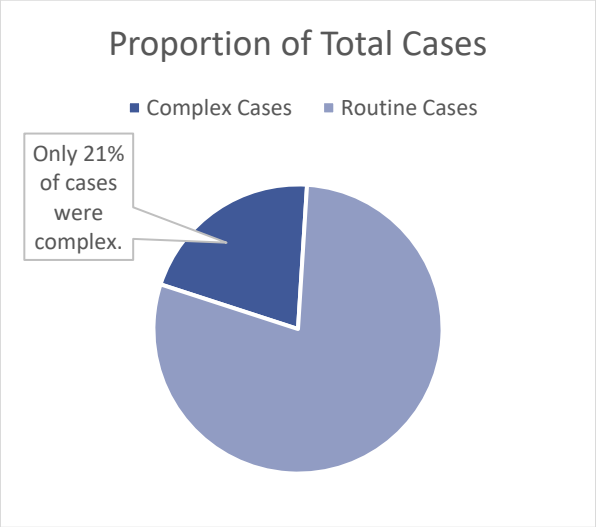
4.2. The materials cost of replacement devices is significant.

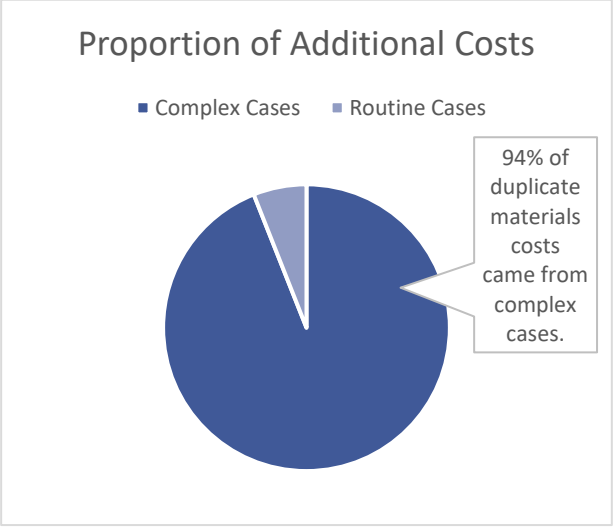
The cost of replacement devices observed was significant, although the data analyzed was only for Interventional Radiology procedures, within a single institution. Overall, 170 replacement guidewires, catheters, and balloons were used over the course of the 2-month period observed. These extra replacement devices ranged in price from $28.05 to $2,600.00. The replacement devices used over the course of the 2-month period observed totaled over $32,000. Over the course of a year, the projected extra cost of replacement devices is over $196,000. The extra cost per case, in the cost of replacement devices alone, is over $51. There are additional costs in increased procedure time as well.

In complex cases alone, 141 replacement guidewires, catheters, and balloons were used over the course of the 2-month period observed. These extra replacement devices ranged in price from $28.05 to $2,600.00. The replacement devices in complex cases alone used over the course of the 2-month period observed totaled over $30,000. Over the course of a year, the projected extra cost of replacement devices is over $180,000 in complex cases only. The extra cost per complex case, in the cost of replacement devices alone, is over $231. There are additional costs in increased procedure time as well.

While complex cases made up only 21% of all cases, complex cases accounted for 94% of replacement device materials costs.

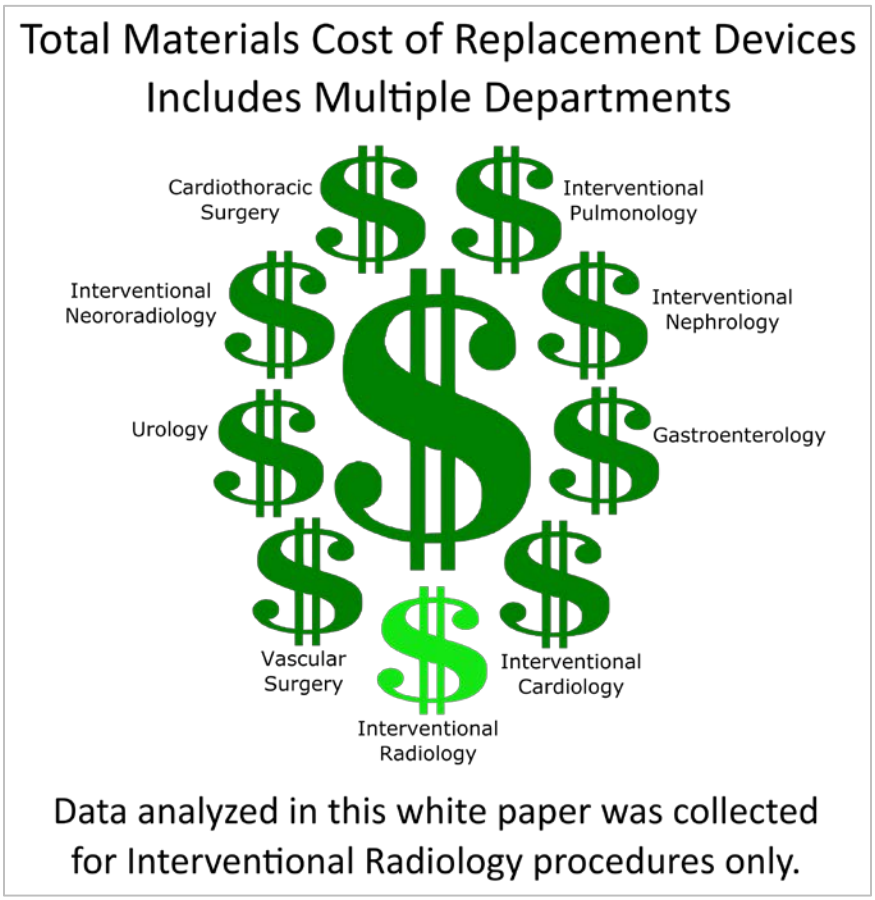
Graphs 4 and 5. Complex case proportion of total cases and proportion of total additional costs due to replacement guidewires, catheters, or balloons used.





It is important to note that these replacement devices were recorded in procedures only in Interventional Radiology, within a single institution. CathClip is appropriate for use in 9 specialties: Cardiothoracic Surgery, Gastroenterology, Interventional Cardiology, Interventional Nephrology, Interventional Neuroradiology, Interventional Pulmonology, Interventional Radiology, Urology, and Vascular Surgery.

If all 9 specialties are equally busy, with equal rates of complex cases, and if the rate of replacement devices holds across all specialties, the projected extra cost of replacement devices observed throughout the entire institution over the course of the year is over $1.75 million, $1.645 million of which is extra costs from complex cases alone.



4.3. The total cost of replacement devices includes the time and effort it takes to retrieve and prepare replacement devices for use (increased costs and negative clinical outcomes).

Each replacement device used also represents an increase in procedure time and a source of distraction during the procedure, in addition to an increase in materials costs.

When a replacement device must be used, time must be taken during the procedure to prepare that new device for use. Of note, many replacement devices are not close at hand within the procedure room – they must be retrieved from the storage area outside of the procedure room by a member of the procedure team. Additionally, the replacement device must be removed from its packaging and prepped for use.

The total cost of a replacement device, therefore, includes the following costs:

- Increased materials costs (increased cost for the facility),
- Increased procedure time (increased cost for the facility),
- Increased sedation time due to increased procedure time (negative clinical outcomes), and
- Distraction of procedure team from patient care (negative clinical outcomes).

4.4. Replacement devices are evidence of likely unnecessary radiation (patient and worker safety issue).

Flexible elongated device damage for which a replacement device would become necessary (e.g., kinked wire or catheter) is often noticed only when not functioning properly inside of the patient, after everyone in the cath lab or hybrid OR (the patient and the procedure team) has been exposed to unnecessary radiation. With a retrospective study such as this one, it is difficult to assess when this may have happened. However, it is likely that a good number of the 170 replacement devices used over the course of the 2-month period observed (141 replacement devices in complex cases) replaced devices that the operator noted as damaged while inside the patient during the case, resulting in unnecessary radiation to the patient and the team.

4.5. CathClip decreases the incidence of replacement devices, thereby saving costs (materials and time), improving clinical outcomes, and improving safety.

CathClip decreases the incidence of replacement devices because CathClip effectively protects guidewires, catheters, and balloons by holding them gently and securely, eliminating the inefficiencies and the substantial distraction in the cath lab or hybrid OR caused by the use of make-shift techniques to handle those devices. By decreasing the incidence of replacement devices, using CathClip decreases materials costs, decreases procedure time, improves clinical outcomes, and improves patient and worker safety.

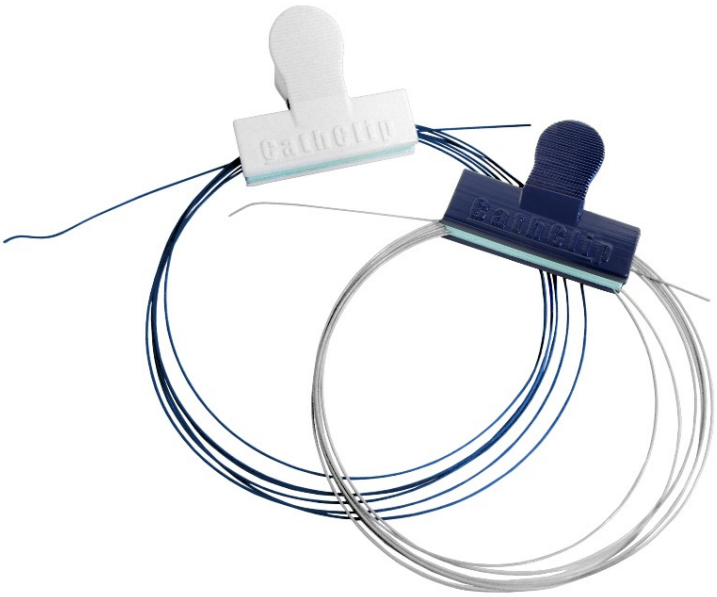
5. Conclusion

This study of materials usage in Interventional Radiology cases at a major academic hospital illustrates that the use of replacement devices is common and costly, especially in complex cases. If devices are managed properly, replacement devices are not necessary. CathClip helps properly manage guidewires, catheters, and balloons by holding them gently and securely, thereby protecting these devices from damage. Using CathClip decreases the number of replacement devices needed, resulting in lower facility costs (materials and time), improved clinical outcomes, and improved patient and worker safety, when the total cost of replacement devices is considered.

Attachment D

CathClip

guidewire, catheter, and balloon management tool



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

September 2017

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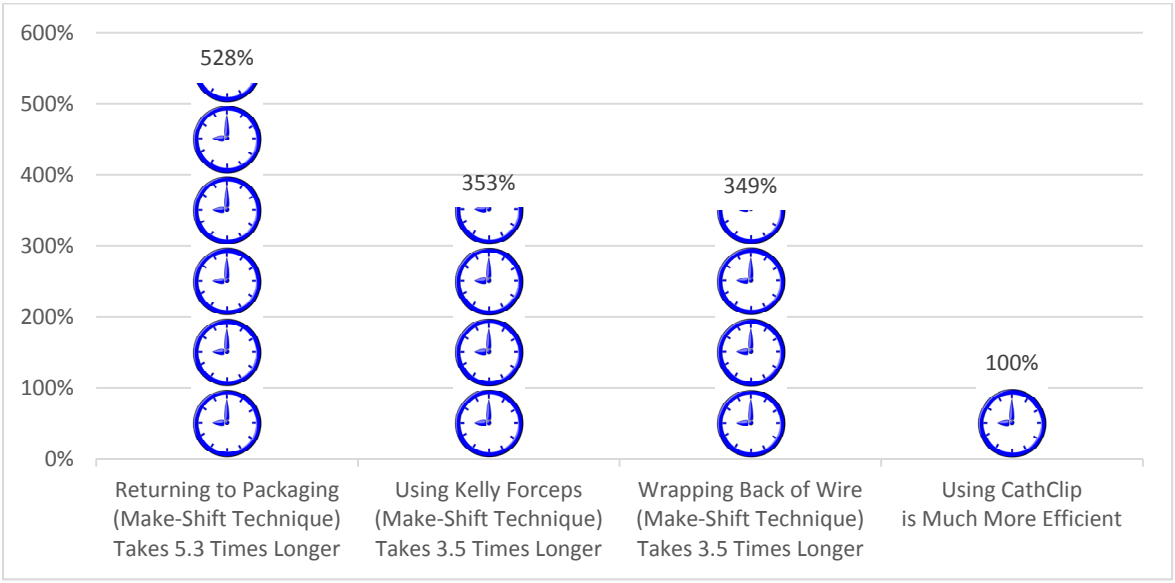
Graph 1. Single guidewire management techniques: comparison of average time spent managing a Lunderquist Wire, without CathClip (make-shift techniques) vs. with CathClip. Managing a Lunderquist Wire takes an average of 3.5 to 5.3 times longer using make-shift techniques than it does using CathClip.



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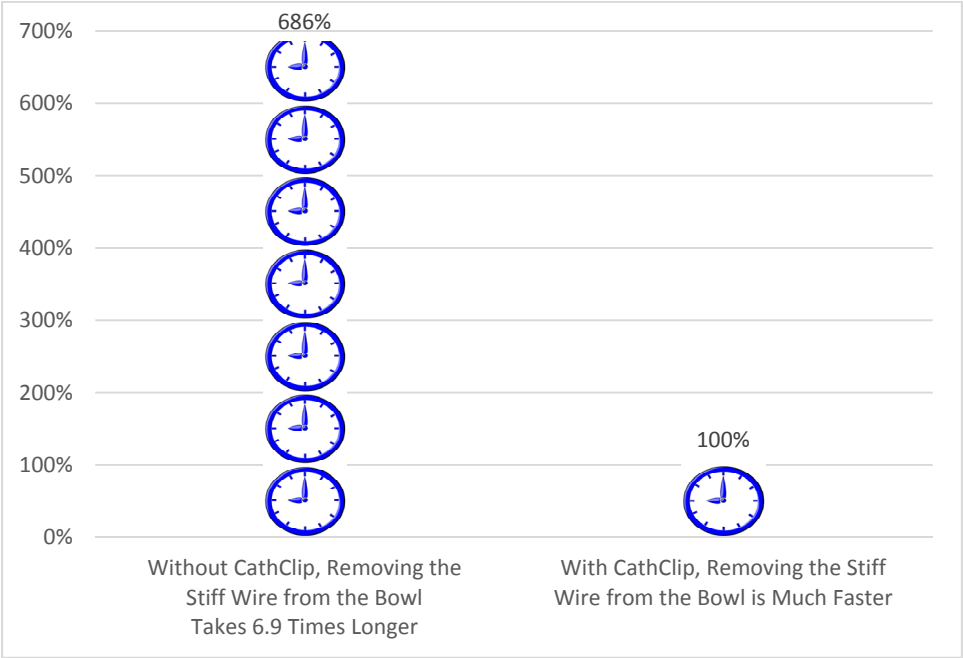
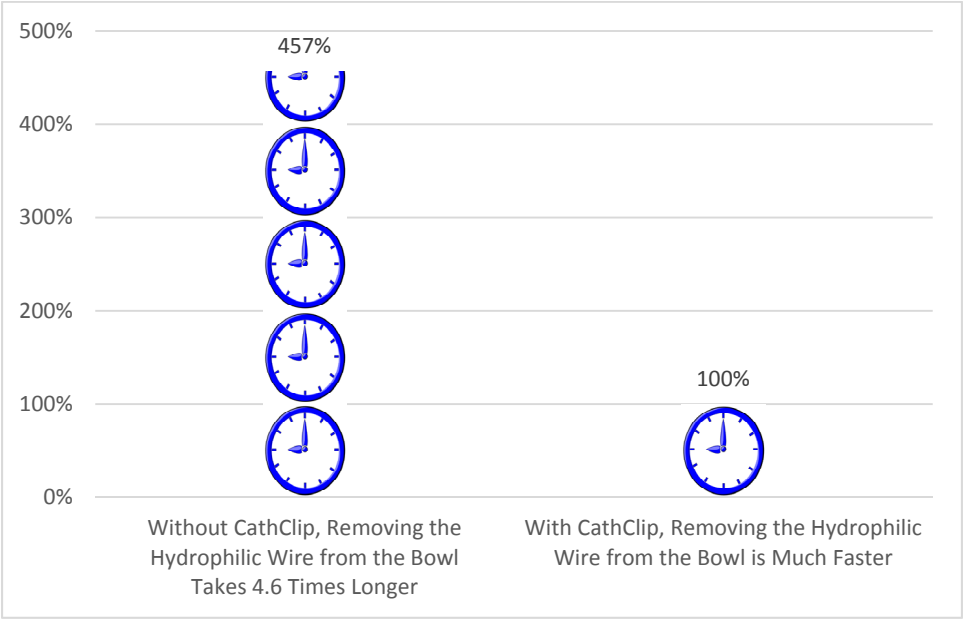
Graph 2. Management of multiple guidewires in a saline-filled bowl: comparison of average time spent accessing a <u>Stiff</u> Wire, without CathClip vs. with CathClip. Accessing a Stiff Wire from a saline-filled bowl with only two other guidewires takes an average 6.9 times longer without using CathClip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

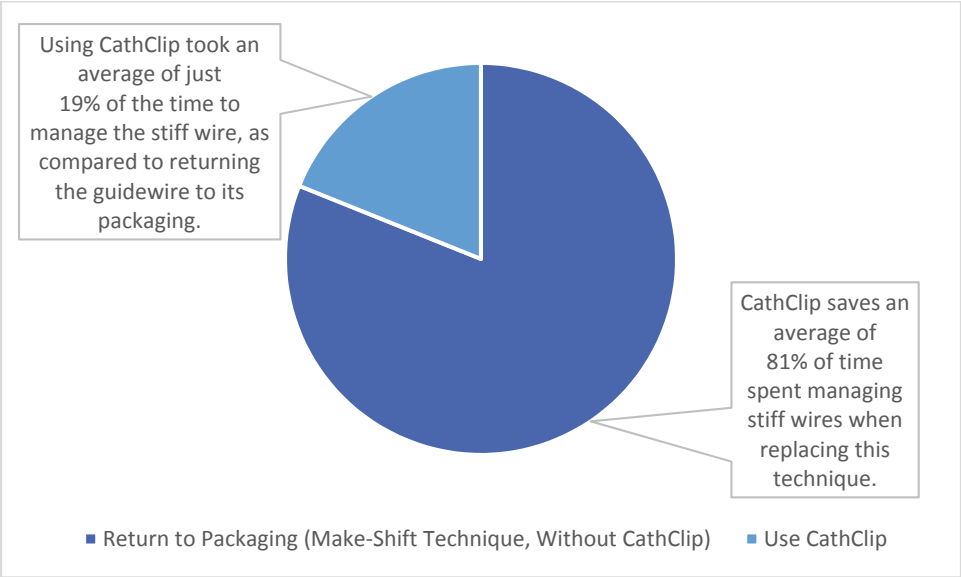


4.2. Using CathClip saves time. This leads to reduced procedure times (cost savings) and reduced patient sedation times (better clinical outcomes).

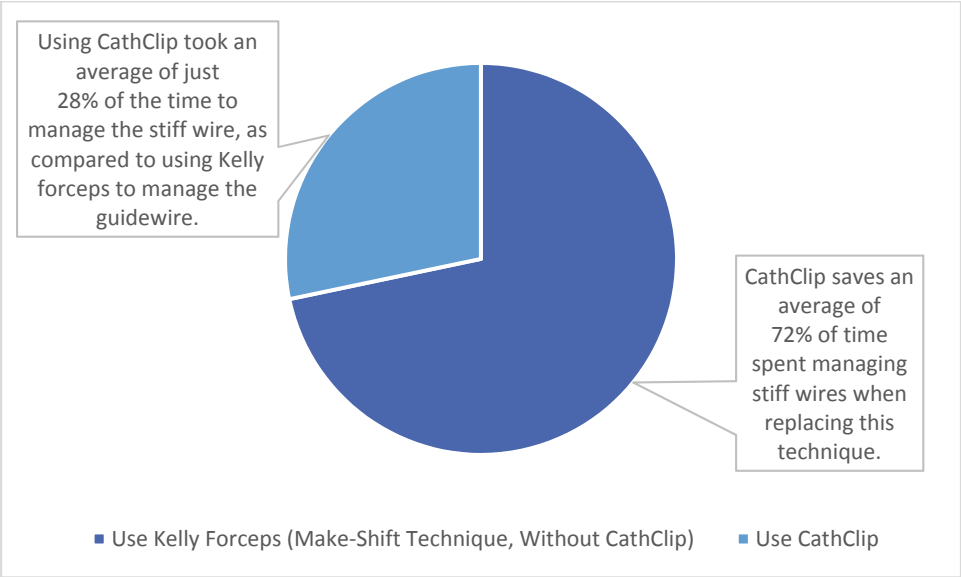
In all scenarios simulated, the average time spent managing guidewires was significantly reduced when CathClip was used. The graphs below illustrate this difference.

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).

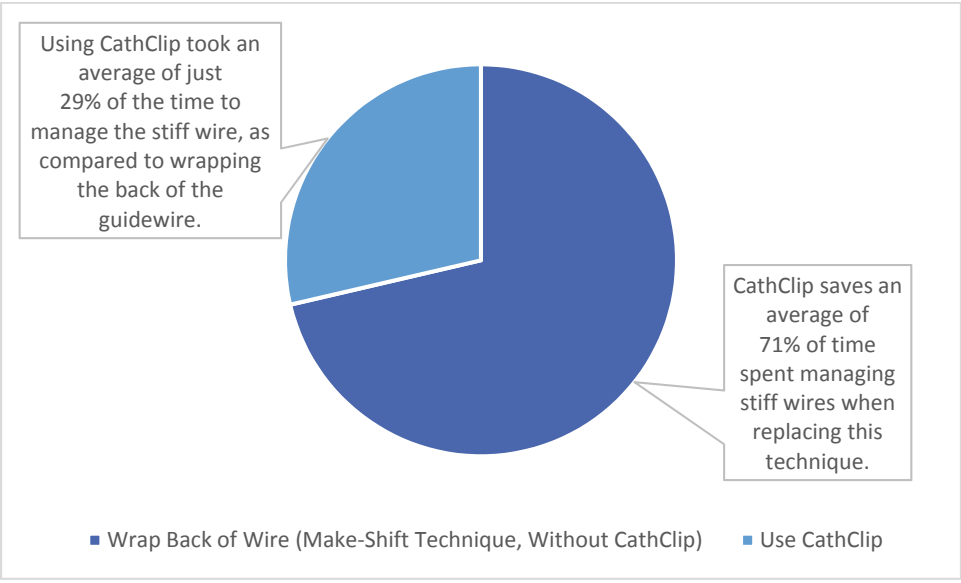
Graph 4. Single guidewire management technique: comparison of average time spent managing a Lunderquist Wire by returning it to its original packaging (make-shift technique) vs. using CathClip. CathClip reduces the amount of time spent managing a Lunderquist Wire, as compared to returning the Lunderquist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



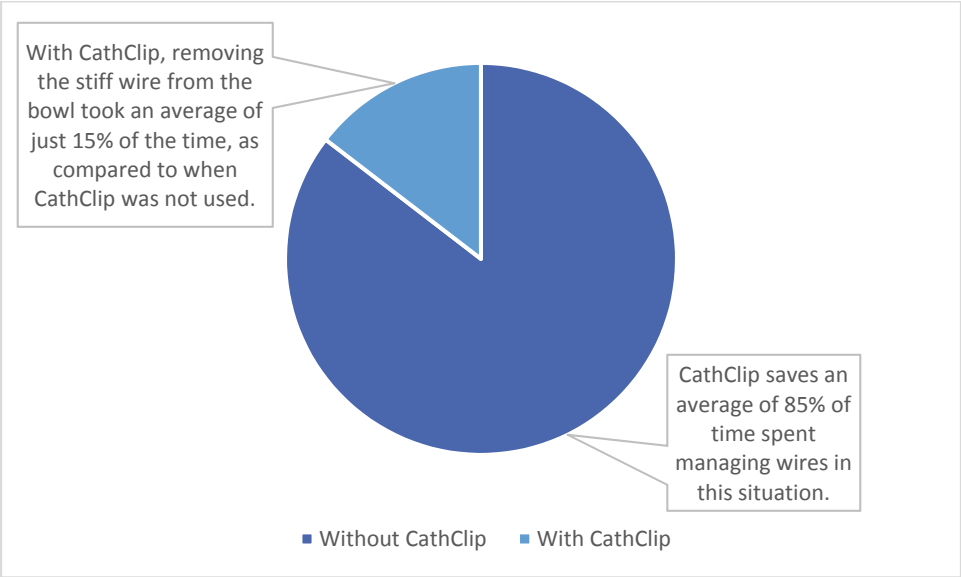
Graph 5. Single guidewire management technique: comparison of average time spent managing a Lunderquist Wire by using Kelly forceps (make-shift technique) vs. using CathClip. CathClip reduces the amount of time spent managing a Lunderquist Wire, as compared to using Kelly forceps (make-shift technique),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



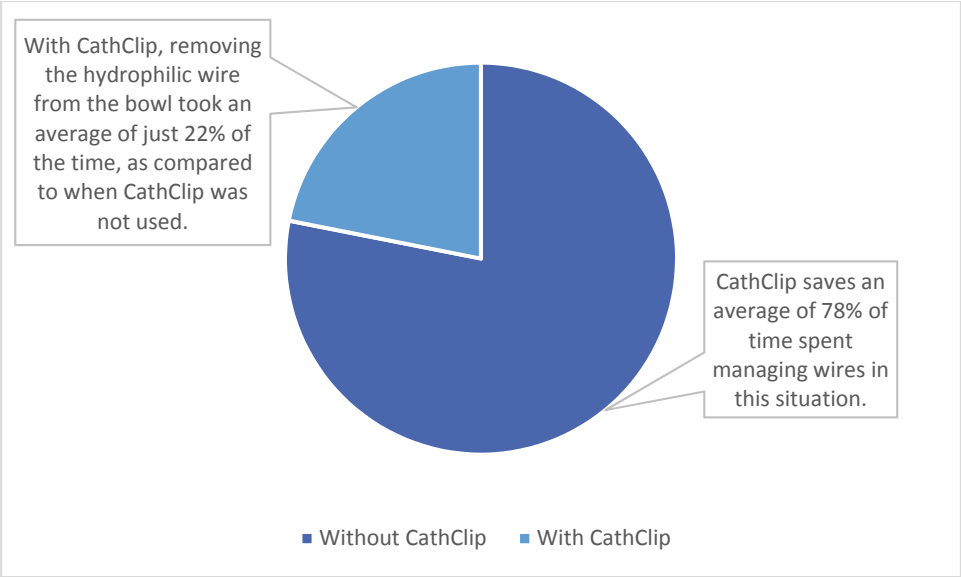
Graph 6. Single guidewire management technique: comparison of average time spent managing a Lunderquist Wire by wrapping the back of wire (make-shift technique) vs. using CathClip. CathClip reduces the amount of time spent managing a Lunderquist Wire, as compared to wrapping the back of the wire (make-shift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

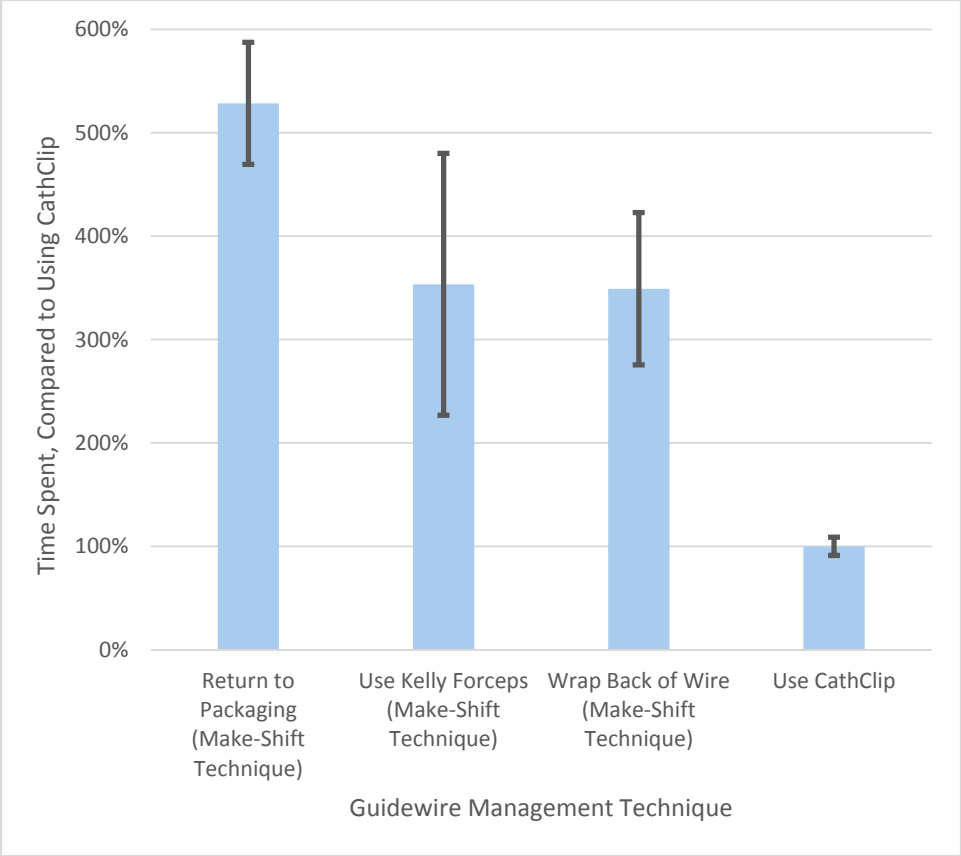
Additionally, for this particular exercise, we focused only on guidewires. There are various make-shift techniques for handing catheters and balloons – in addition to guidewires – including using wet towels and wet gauze, adding additional components of distraction during procedures.

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.

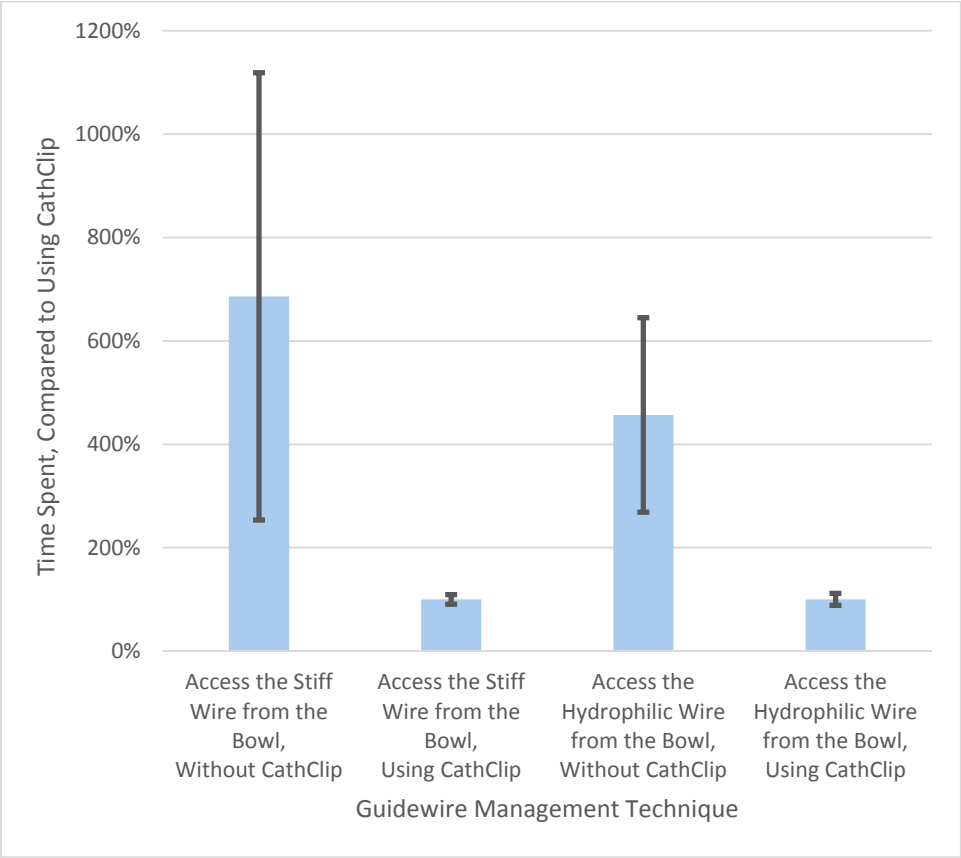
When distractions are removed, the entire team can concentrate on providing the best possible care to the patient (leading to better clinical outcomes).

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.

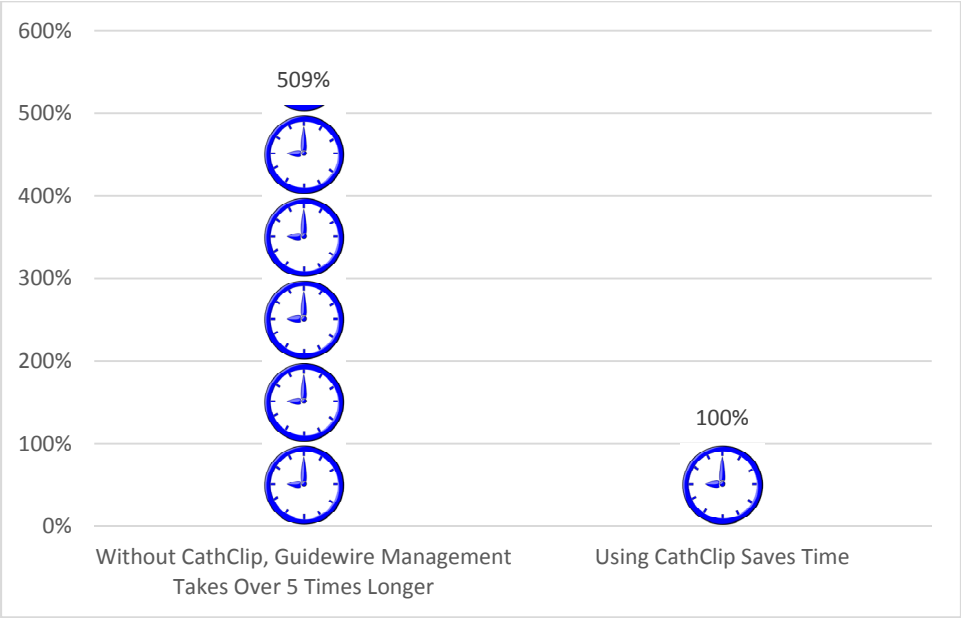
To understand what the timed simulations mean for a real procedure, we must extrapolate from the data gathered. Here, we figure that a "Typical Procedure" uses 4 flexible elongated medical devices (guidewires, catheters, or balloons), with 7 exchanges. The 4 flexible elongated medical devices used are 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.

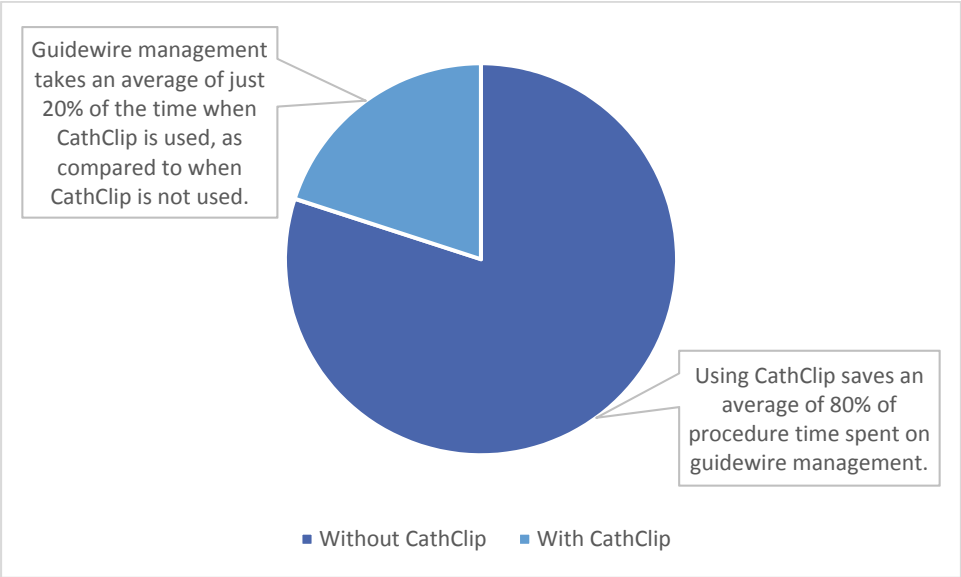
These are conservative numbers, as for in most cases the team would also have to exchange, control, and re-use multiple catheters and balloons, in addition to guidewires, for such a typical Interventional Radiology, Vascular Surgery, Interventional Cardiology, or Interventional Neuroradiology case.

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.