



**PHILIPS**

**Azurion**

Image guided therapy



## 30% reduction in table repositioning during interventional procedures with Philips FlexArm geometry – an independently verified study

Philips with FlexArm geometry enhances image guided procedures through reduced table repositioning, better upper extremity access and improving ergonomics and staff experience.

Hospitals and health systems are constantly faced with challenges referred to as the Quadruple Aim, namely the need to: achieve better clinical outcomes, improve patient experience, improve staff experience and strive for a lower cost of care.

Working towards all these goals at once becomes increasingly important given the

constant cost pressure faced by global healthcare systems, an ever-growing incidence of chronic diseases, the aging population and increasing competition between healthcare facilities.

**The key results of the MCVI study are shown below. Read on to find out how these results were achieved.**

### What

Study conducted in 2017/2018 at Miami Cardiac & Vascular Institute (MCVI), involving a total of 200 interventional cardiology, interventional radiology and vascular surgery procedures.

### Challenge

To perform complex procedures including upper extremity vessel access with fewer required table repositioning, better workflows and improved staff ergonomics.

### Key results

The new FlexArm geometry enabled the medical team to:

- Reduce table repositioning by 30%
- Work in an ergonomically optimal position for most of the time for 96% of the procedures performed
- Experience less pain and/or fatigue for all body areas
- Reduce risk of losing needle access, catheter- or wire location and the risk of pulling wires/ tubes/lines connected to the patient
- Achieve 97.8% satisfaction with ease of imaging off-center anatomy while performing upper extremity access procedures (i.e. via the radial-, brachial- or ulnar artery)



The strong growth of image guided therapies worldwide and their importance to healthcare in recent years is a logical consequence of the developments described in the previous paragraph, as image guided procedures offer satisfactory treatment outcomes in conjunction with comparably low patient trauma.

Miami Cardiac & Vascular Institute (MCVI), a long-standing partner of Philips, is at the forefront of revolutionizing image guided therapies for cardiac and vascular diseases with cutting-edge technologies that can improve the quality of care provided. Azurion with FlexArm is Philips' next step on its Azurion innovation journey. In early 2016, a prototype of the FlexArm geometry was installed at MCVI to address a range of challenges faced during image guided therapy procedures including the need to improve staff experience.

Clinical studies were performed while the product was developed to make sure that benefits or limitations were understood and documented. Despite a recent stronger focus on staff experience and in light of increasing competition between healthcare facilities, many operators still report occupational injuries caused by suboptimal ergonomic working conditions in interventional suites. The table repositioning required for patient positioning and imaging, as well as a lack of system positioning flexibility, are suspected to contribute to these challenges.

FlexArm geometry offers a new approach to image guided therapy, providing increased imaging flexibility for diverse procedures through its ceiling-suspended C-arm geometry, among other features. The lateral movement range of 236 cm with the FlexArm geometry used by MCVI, combined with the regular longitudinal movement, allows all imaging positions to be reached without impeding optimal team positioning and without needing to reposition the patient table. The commercial version of Azurion with FlexArm is also equipped with image beam rotation with 270 degrees rotation freedom of the C-arm realizing the full potential of the FlexArm geometry and further addressing the workflow-related issues faced by physicians when performing image guided procedures.

Following twelve months of clinical use, MCVI conducted a clinical study to evaluate the value of the FlexArm geometry on a variety of factors, including table repositioning, staff ergonomics and perceived workflow. The results of the study were verified by North American Science Associates (NAMSA), an independent third-party expert on study design and analytics. The results of the study revealed a significant, favorable difference in the reported experience of physicians at MCVI using the FlexArm. FlexArm was believed to improve workflow by reducing efforts associated with positioning patients and equipment, and facilitating the use of upper extremity access. The capabilities of the FlexArm geometry were also associated with lower physical discomfort experienced by operators.

# Innovation driven by passion

## A powerful partnership

Established in 1987 by renowned interventional radiologist Barry T Katzen, MD, the Miami Cardiac & Vascular Institute is the largest and most comprehensive cardiovascular facility in the region.

Recognizing the importance of Vascular Imaging, in 2005 Dr. Constantino S Pena was introduced as MD for Vascular Imaging at MCVI. The Miami Cardiac & Vascular Institute was one of the first centers in the United States to treat the heart and blood vessels as one entity. This unique approach, coupled with cutting-edge techniques and technologies, advanced research and an international focus, has led to the Institute becoming a leader in cardiovascular care.

Philips and MCVI have partnered for more than 30 years to develop innovations in image guided therapy, 3D abdominal imaging, advanced endovascular treatment and more, working together to improve outcomes and increase efficiency. Over the last ten years, Philips and MCVI have joined forces to create a geometry that brings a significantly higher level of imaging and positioning flexibility to the interventional suite, simultaneously improving workflow for physicians and staff performing image guided therapy procedures, both now and in the future. Interactions and discussions with multiple members of the entire interventional team at MCVI were conducted with the development team of FlexArm contributing to its overall benefits and ease of use.

## Better staff experience

Philips recognizes the importance of improving the ergonomics and experience of staff as they perform complex interventional procedures, and its role in improving both clinical outcomes and the patient experience. The FlexArm system was designed with this in mind. Prior to first clinical use a separate simulation study was conducted with interventional radiologists, interventional cardiologists and vascular surgeons in a simulated environment to evaluate the capacity of the FlexArm geometry when performing diverse procedures through exceptional imaging flexibility and positioning freedom, with excellent results<sup>1</sup>.



## MCVI clinical study design

Utilizing information obtained from the simulation study, MCVI conducted a clinical study aimed to assess the potential benefits of FlexArm geometry and the impact of: minimizing table repositioning on perceived workflow and staff comfort; flexible system positioning on physician ergonomics; and lateral system movements on upper extremity access procedures.

Detailed data was collected for each of these assessments, combining objective measurements such as system log files and dose reports with subjective evaluations. This took the form of a survey which was completed after each of the 200 procedures by physicians and staff (mainly primary physicians, and sometimes fellows or secondary operators if present for majority of procedure).

Each of the three benefit assessments were carried out twice, for both interventional radiology, interventional cardiology and vascular surgery procedures, to capture the full range of insights. User groups included cardiologists, radiologists and vascular surgeons. The study design compared the results of 100 procedures performed in a room equipped with a FlexArm system (from here on

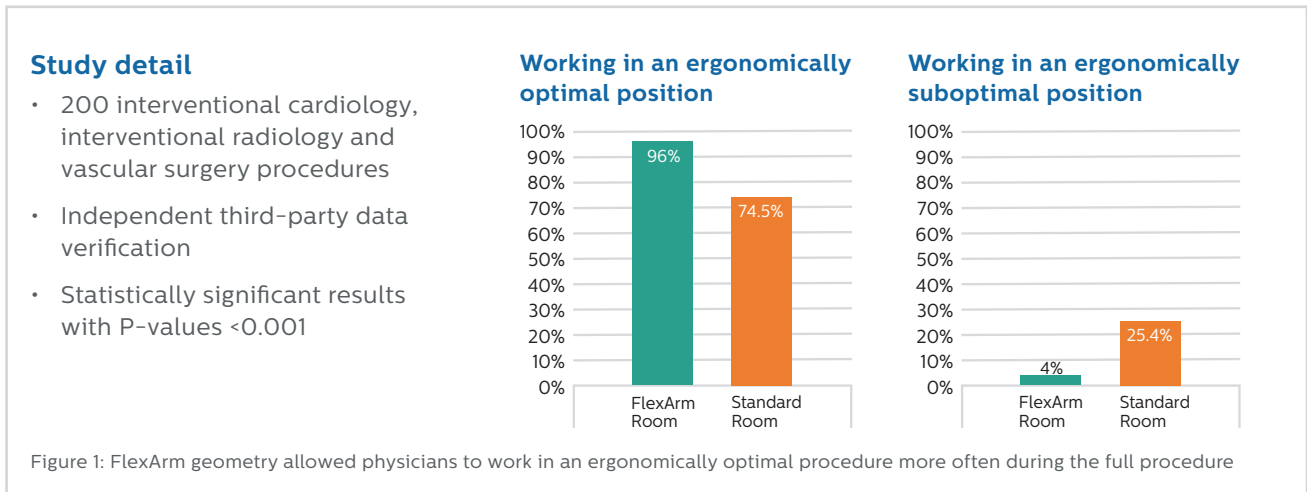
referred to as “the FlexArm room”) to a control group of 100 procedures performed in a similar, adjacent room equipped with a standard ceiling-mounted Philips Allura R8.2.17 system (from here on referred to as “the standard room”). Where available, system logging data from both labs were used to analyze table- and gantry repositioning for comparison.

## Independent third-party verification

To verify the study results, statistical analysis of the electronic case report form data (eCRF) and survey data was performed by North American Science Associates (NAMSA), a Medical Research Organization (MRO). The investigators concluded that compared to the standard room, physicians in the FlexArm room reported a significant

improvement in factors associated with operator ergonomics (detailed below), significant improvement in factors associated with upper extremity access procedures (detailed below), and significantly reduced need to reposition the table during the procedure.

## Improved staff experience and enhanced patient care throughout the patient journey



## Results

### Better operator experience

Poor usability, design and ergonomics can have a negative effect on medical procedures and patient safety<sup>2</sup>. Those who work in interventional suites and experience these suboptimal ergonomic working conditions – in combination with the additional burden of wearing lead and other protective equipment – can suffer from a range of occupational injuries including

degenerative spine disease and lower extremity joint disease<sup>3,4,5</sup>. FlexArm offers features to address these issues, enabling a better operator experience and allowing physicians to maintain their focus on the procedure.

After every procedure, physician surveys were conducted to evaluate their physical discomfort. Those working in the FlexArm room reported



working in an ergonomically optimal position in 96% of procedures compared to 74.5% of procedures in the standard room (see *Figure 1*). Expanding this, physicians reported working in ergonomically suboptimal positions in 4% of cases, compared to a significantly higher 25.4% of cases in the non-FlexArm room.

When asked to specify the degree of physical discomfort experienced during each individual procedure for body areas, specifically the head and neck, shoulders and upper back, and the middle/lower back, physicians reported significantly less discomfort in all areas when working in the FlexArm room (see *Figure 2*).

**A number of features of the FlexArm system** contributed to this improvement in ergonomics and operator experience. The lateral movement range and off-center imaging enabled by the FlexArm

geometry, combined with the system’s regular longitudinal movement, allowed greater positioning flexibility without impeding optimal team positioning or the need to reposition the patient table.

This increased flexibility is further facilitated by the Axsys controller which allows physicians to intuitively control the 8-axis flexible arm, providing predictable and precise system movements that promote less disturbance and greater staff concentration.

The ceiling-mounted gantry also allows the system to be moved into a standby position or parking position away from the table when a minimally-invasive procedure has to convert to open surgery, giving the clinical team more space around the patient.

**Question: Please indicate the degree of physical discomfort experienced during procedure**

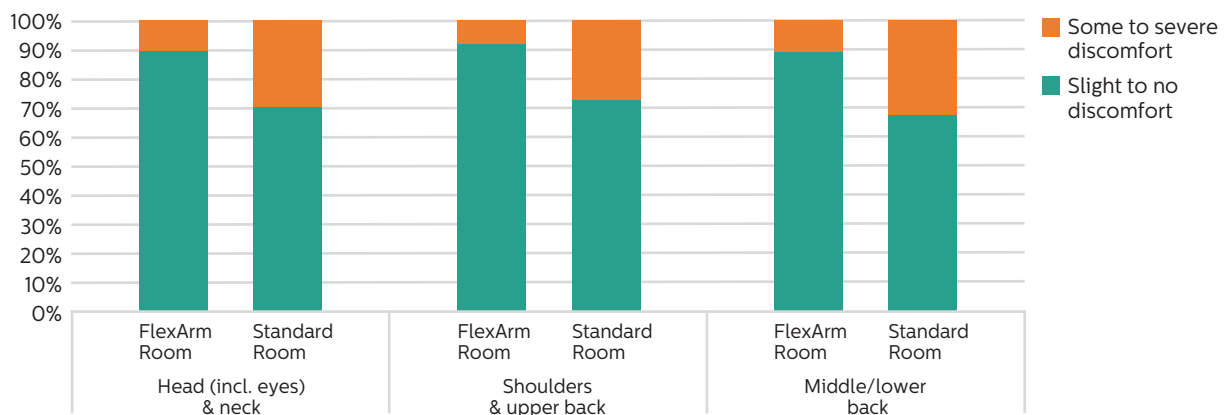


Figure 2: Physicians experienced less discomfort across a range of body areas when using FlexArm geometry

### Enhanced patient care due to reduced table repositioning

The FlexArm geometry was designed to address several pressing issues faced by physicians in the interventional suite. A prior exploratory assessment conducted at MCVI demonstrated that the table had to be repositioned an unexpectedly high number of times per case, ranging up to 200 occurrences per case. This repositioning can displace devices (e.g. catheters, needles), wires and tubes connected to the patient and disrupt the equipment and instrument set up. This can have implications for procedure consistency and quality of care. In the FlexArm room, measurements taken showed a 30% overall reduction of table repositioning. 9% of the physicians even reported that they never had to reposition the table during the procedure, compared to 0% in the standard room (see *Figure 3*). Also, fewer physicians in the FlexArm room reported that they had to reposition the table ‘very often’ (12%) compared to physicians in the standard room (30%). Overall, the system analysis showed a statistically significant reduction of table movements with the FlexArm geometry compared to the standard room.

The FlexArm system provides medical teams with the capability to handle cases requiring full body access with either 2D or 3D imaging from three sides of the table, without pivoting or panning it. All 3D navigation tools can be used from various points around the table to support optimal staff/equipment positioning and patient access. This can improve catheter control and intubation, and facilitates consistent workflow by enabling teams to optimize and standardize their clinical set-up.

Further, physicians in the FlexArm room experienced a significant improvement in workflow compared to those in the standard room, reporting among other benefits a reduced need to reposition interface devices or reposition ceiling mounted X-ray shielding, decreased risk of losing needle access, catheter or wire location, and a reduction in the occurrence of non-ergonomic work positions that can lead to bad posture, burden on the hands, arms and other areas, and fatigue.

### Improved workflow for upper extremity access procedures

The need to facilitate imaging during upper extremity access procedures was also a key issue addressed through the design of the FlexArm geometry. Minimally-invasive procedures are increasingly being performed by using upper extremity access rather than by using the femoral artery. This change in approach has significant benefits including reduced patient discomfort, reduction in potentially life-threatening complications and faster patient discharge<sup>6,7,8</sup>. Imaging is key in upper extremity procedures as anomalies in the anatomy are relatively common, occurring in 13.8% of patients<sup>9</sup>. However, such imaging can take considerable time due to conventional X-ray systems not being designed to visualize fully or partially extended arms.

In the study, 97.8% of physicians performing upper extremity access cases were satisfied with the ease of imaging off-center anatomy while using the FlexArm system. *Figure 4* shows comparative image positions in the FlexArm and standard rooms with each dot representing a single irradiation event.

How often did you feel the need to reposition the table?

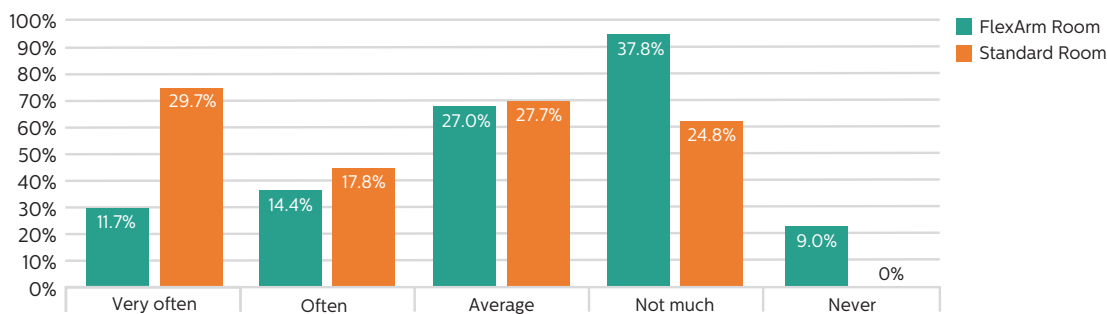
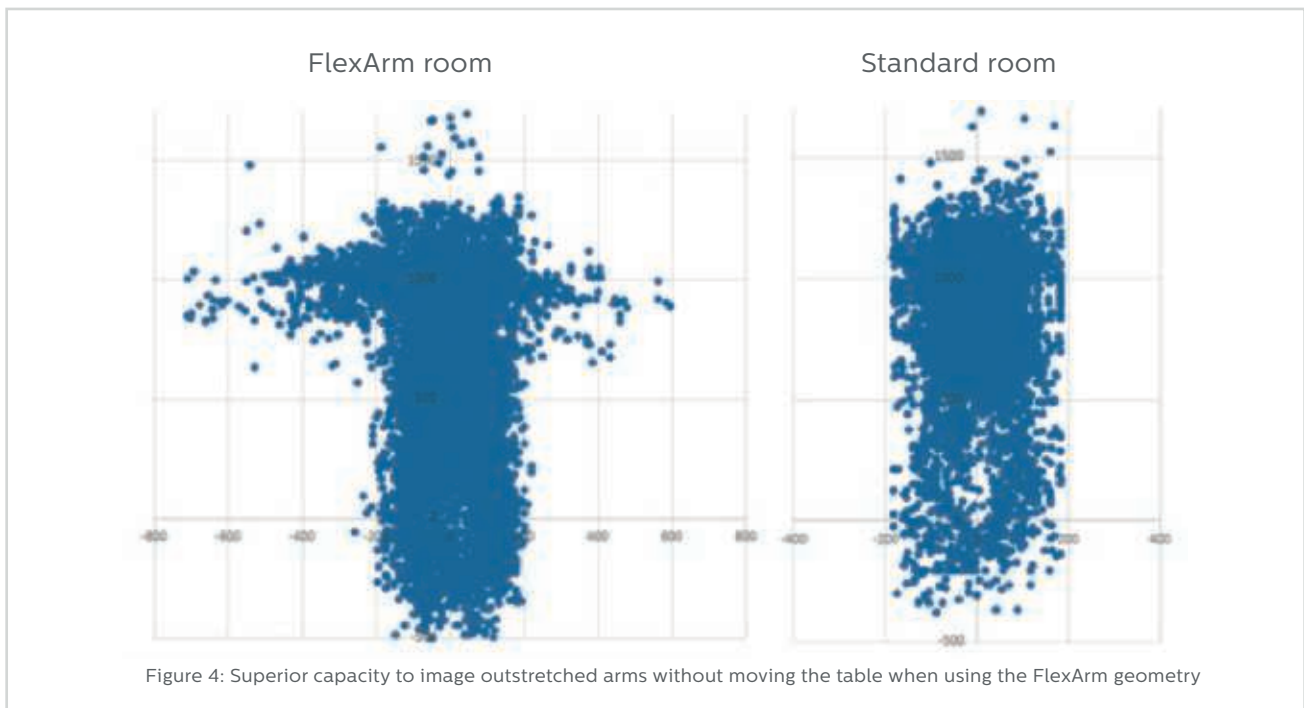


Figure 3: Physicians reported needing to reposition the table less often when using FlexArm geometry



The graph for the FlexArm room mirrors the silhouette of a human figure with arms extended out. The graph for the standard room shows that imaging outside the table borders was not possible using this system.

In the FlexArm room, 89.5% of physicians reported that a low or very low effort was needed to position the patient’s arm in the X-ray field of view, a significant difference compared to just 55.1% in the standard room. Further still, 65.6% of physicians in the FlexArm room reported that very low effort was needed to subsequently transition from arm to body imaging where applicable, compared to just 16% in the standard room.

The FlexArm’s range of motion allows wide lateral movements and off-center imaging to visualize both outstretched arms when performing upper extremity access procedures. This can all be achieved without impeding optimal team positioning. This was reflected by 73.3% of physicians reporting that they were ‘extremely satisfied’ or ‘very satisfied’ with the ease of imaging off-center anatomy during the procedures performed in the FlexArm room compared to 31.7% of physicians in the standard room.

During the duration of the study, the FlexArm room rapidly became the preferred room of

choice amongst the physicians in the institute for upper extremity access procedures.

#### Lower cost of care

While delivering these benefits, it was also vital that the FlexArm geometry creates a highly cost-effective environment by improving workflow and allowing procedures to be performed in a more efficient manner.

Work-related injuries are common in radiologists and interventional cardiologists due to the bending of the back and twisting of the neck inherent in their work<sup>10,11</sup>. In a study of 424 interventional cardiologists in the USA, over 33% reported neck and back issues that had caused them to miss work<sup>11</sup>. The FlexArm geometry improves staff ergonomics; during the study, physicians reported significantly less pain and/or fatigue for all body areas while working with the FlexArm.

The FlexArm geometry also offers better imaging flexibility during upper extremity access procedures. Such types of access has several economic advantages compared with femoral access: an estimated \$282 can be saved per radial access (a type of upper extremity access) procedure for coronary angiography and intervention; furthermore, no hospital overnight stay is needed (22% cost saving)<sup>12,13</sup>.



## Conclusion: FlexArm and the Quadruple Aim

Taken as a whole, the study results showed that the FlexArm geometry contributed to all four components of the quadruple aim:

- **Patient experience:** Repositioning the table multiple times may contribute to the patient's anxiety while the patient is still under sedation during procedure. The reduced need to reposition the table during procedures associated with the FlexArm geometry is reducing the risk of dislodging devices, wires and tubes connected to the patient and disrupt the equipment and instrument set up and the resulting impact on patient experience. The increased imaging coverage facilitated by the FlexArm geometry is also associated with an improved patient experience<sup>14</sup> and workflow. Flexibility of the FlexArm geometry supports better and faster patient flow.
- **Clinical outcomes:** The FlexArm geometry enabled easy imaging of off-center anatomy during upper extremity access procedures, with minimal effort required from staff. This facilitates the use of imaging to guide upper extremity access procedures, a type of access associated with less vascular complications and less major bleeding<sup>12</sup>.
- **Staff experience:** Physicians and all staff members in the FlexArm room were able to work in an ergonomically optimal position four times more often, reducing discomfort during procedures through the system's intuitive controls and user interface, and the advanced FlexArm geometry.
- **Lower costs:** The improved ergonomics resulting from the FlexArm geometry further reduce long term costs associated with staff absences due to workplace related injuries, and increase same-day discharge reducing the need to keep patients overnight as a result from ease of upper extremity access procedures.

Azurion with FlexArm was designed as a result of the partnership with leading institutions such as MCVI to identify unmet needs and to create a successful and innovative imaging solution capable of addressing issues through the flexibility and ease-of-use necessary to future-proof interventional suites, equipping them to handle the growing number of interventional procedures worldwide and deliver optimal patient care for years to come.

To learn more about FlexArm geometry and its benefits visit [www.philips.com/FlexArm](http://www.philips.com/FlexArm)





Barry T. Katzen, MD, Founder and Executive Medical Director, Miami Cardiac & Vascular Institute Baptist Hospital, Miami, USA

“FlexArm enables us to dramatically optimize procedures around the patient: we can get the optimal view of what’s going on inside the patient without encumbering all of the clinicians that are working around the table. The result is an innovation that’s not only clinically important but also very simple and intuitive to use – a critical factor in the heat of a complex procedure.”



Brian Schiro, MD, Interventional Radiologist, Miami Cardiac & Vascular Institute Baptist Hospital, Miami, USA

“I think patient experience has improved because there is less table repositioning so we’re disturbing the patients less during the procedure as most of our patients are sedated during the procedure, so they are asleep and if we’re moving things around a lot, that wakes them up.”



Constantino S. Peña, MD, Medical Director for Vascular Imaging, Miami Cardiac & Vascular Institute Baptist Hospital, Miami, USA

“The flexibility made possible with the FlexArm geometry, combined with the system’s intuitive controls, place us in a strong position to adapt to any range of procedures and clinical developments the future may hold.”



Aurea Mazuelos, Vascular Interventional Technologist, Miami Cardiac & Vascular Institute Baptist Hospital, Miami, USA

“Before, our doctors working on the other (nurse) side of the table, would be squeezed between the C-arm and the monitor, this would cause contamination problems, as they are sterile and the C-arm and monitor are not. With the system in 45 degrees, they have a lot more space to work. This is great.”

# Appendix

## Why is statistical significance important?

Statistical significance refers to whether any differences observed between groups being studied are reliable or whether they are simply due to chance. Mathematical formulae are used to examine differences in outcomes between the groups and result in a “p-value” to describe the probability of observing a difference purely by chance in two groups. Mathematical probabilities like p-values range from 0 (not by chance) to 1 (chance).

A p-value of 0.05 means there is a very good chance – 95% – that the difference in outcomes was not due to chance. If it is unlikely enough that the difference in outcomes occurred by chance alone, the difference is pronounced “statistically significant.”

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**Disclaimer:**

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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