

SOLIDFLEX™ - THE FOURTH GENERATION IN ENDOSCOPY

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WORLD NOVELTY

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Summary.- OBJECTIVES: To design and develop the fourth generation in endoscopy after the rigid, semi-rigid and flexible instruments. This next generation technology has been named SolidFlex™, and it was designed by a surgeon based on many years of research with the objective to provide easier and faster solutions for physicians when performing endoscopic procedures.

METHODS: This new endoscope called SolidFlex™ has been brought to light with the latest technology to provide surgeons of every age the capabilities to carry out any possible endoscopic procedure. SolidFlex™ is state-of-the-art in both design and construction, giving the

instrument a much better balance with only one third of the weight of the usual flexible endoscope. The Instrument is ergonomic, intuitive (instinctive perception) and coherent, meaning that the handle control moves the instrument's active flexible section towards predictable, pre-selected areas, driving the procedure fluidly throughout. It provides the stability of a rigid and semi-rigid instrument with the exploration capabilities of the flexible endoscope in order to achieve the best means of rendering a patient 100% stone free.

RESULTS: The SolidFlex™ ureteroscope prototype has retrieved urinary stones in 9 patients and 11 renal units. These procedures were divided in two groups: Group I, pre-stented after double "J" withdrawal for a previous renal colic episode. Group II, during the acute renal colic episode. Ureteral dilatation was carried out only in Group II and after dilatation in both groups, insertion up to the renal pelvis or the area where the obstruction was present, took only a matter of 15 seconds at the most. All procedures could be completed in each group and stones in the renal papilla from 200 nm, to 4 mm in any given papilla were removed either by laser energy, retrieved with a basket or both. Patients did not experience any pain or major discomfort after the procedure, and no analgesic medication was required, nor requested by any of the patients.

CONCLUSIONS: The new SolidFlex™ technology has been tested in surgery and proven to solve most of the difficulties faced by surgeons when performing endoscopic surgery. The surgeon can perform surgery comfortably seated, so that he/she can easily introduce and maneuver the instrument, and introduce operating tools without help or coordination from anyone else during critical moments such as stone extraction. A urologist made the SolidFlex™ research and development for the benefit of physicians and patients, and it does solve many of the issues and limitations that surgeons face today with the rigid, semi-rigid and flexible endoscope technology.

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Resumen.- OBJETIVO: El diseñar y desarrollar la cuarta generación en endoscopia posterior a las enseñanzas rígida, semirrígida y flexible. Esta nueva tecnología se le ha llamado SolidFlex™ y ha sido diseñada por un cirujano, basado en mucho años de investigación con el objetivo de proveer soluciones más fáciles y rápidas para los médicos cuando realicen los procedimientos endoscópicos.

MÉTODOS: Este nuevo endoscopio llamado SolidFlex™ ha salido a la luz con tecnología de punta para proveer a cirujanos de todas las edades la capacidad de llevar a cabo cualquier procedimiento endoscópico imaginable. SolidFlex™ es lo más innovador en ambos, diseño y construcción, que da al instrumento un mejor balance con solamente un tercio del peso del endoscopio flexible habitual. El instrumento es ergonómico, intuitivo (Percepción Instintiva) y coherente, lo que significa que un rotor en el mango de sujeción mueve la sección activa flexible del instrumento de manera predecible hacia áreas pre-seleccionadas, navegando a lo largo del procedimiento con suavidad y soltura. Provee la estabilidad del instrumento rígido y semirrígido con las capacidades exploratorias del endoscopio flexible a modo de poder alcanzar los mejores medios para dejar al paciente 100% libre de litiasis.

RESULTADOS: El prototipo del ureteroscopio SolidFlex™ ha extraído litiasis urinarias en 9 pacientes y 11 unidades renales. Estos procedimientos se han dividido en dos grupos. Grupo I, pre-cateterizados posterior a retiro de catéter doble "J", colocado inicialmente por un episodio de cólico renal. El grupo II, durante el episodio de cólico renal agudo. Se realizó dilatación ureteral solamente en el grupo II y la introducción hasta la pelvis renal o el área en donde se encontraba la obstrucción tomó como máximo 15 segundos. Todos los procedimientos pudieron ser completados en cada grupo y las litiasis recuperadas en las papilas renales van desde las 200 micras hasta los 4 mm en cualquier papila renal que se encontraran y fueron removidas con energía láser, con canastilla o ambas. Los pacientes no experimentaron ningún dolor o incomodidad posterior al procedimiento y no requirieron o solicitaron ningún analgésico.

CONCLUSIONES: La nueva tecnología SolidFlex™ ha sido probada en cirugía y ha demostrado solucionar la mayoría de las dificultades enfrentadas por los cirujanos cuando realizan la cirugía endoscópica. El cirujano puede hacer la cirugía sentado de manera confortable, así él o ella pueden introducir y maniobrar el instrumento e introducir herramientas operatorias sin ayuda externa y sin la necesidad de coordinarse con alguien más durante momentos críticos tales como la extracción de

una litiasis. La investigación y desarrollo SolidFlex™, ha sido llevada a cabo por un urólogo para el beneficio de todos los médicos y pacientes y de manera fehaciente soluciona la mayoría de las cuestiones y limitaciones que el cirujano de hoy desafía con la tecnología rígida, semirrígida y flexible.

Palabras clave: Endourología. Ureteroscopia. Nueva Tecnología. Enfermedad Litiásica. Litiasis.

INTRODUCTION

The Fourth Generation of endoscopy named SolidFlex™ (Patent Pending - Figure 1) has been designed and developed to permit a simplified and thorough flexible inspection of the whole urinary system while providing the stability of the rigid or semi-rigid instrument. Flexible endoscopy is the preferred method for exploration of the soft and capricious curvatures of the urinary system for diagnosis and treatment. Nevertheless the latter is difficult to perform due to the fragility of today's flexible instruments, in addition to the uncomfortable standing position for the surgeon; who usually wears a heavy lead apron during the one to two hour endoscopic procedures and may be performing several surgeries per day. All in conjunction affect surgeon's performance.

Generally, the less traumatic or minimally invasive the instruments or procedures, the more physically demanding they become for the surgeon with very steep learning curves. The SolidFlex™ fourth generation of endoscopy has been designed to incorporate novel features that create an ergonomic, intuitive (instinctive perception) and coherent, exploratory instrument for the obscured portions of the human cavities that diminish and eases them.

OBJECTIVES

- To create the fourth generation of endoscopy after the rigid, semi-rigid and flexible teachings for the benefit of patients, physicians and healthcare costs.
- To design a new instrument to reduce the flexible endoscopy learning curve.
- To permit surgeon's of every age to perform the commended task in every patient.
- To develop an ergonomic, intuitive (instinctive perception), coherent and lightweight endoscope with better balance.

- That the concept can be applied to every endoscope employed today in every part of the human body.
- To provide the surgeon with new armamentarium that has few parts at full operation, increasing functionality and ease of use in office based and operating room procedures.
- To simplify the procedure assuring a greater percentage of success.
- To develop an instrument that can have the stability of the rigid or semi-rigid endoscope with the exploratory diagnostic and treatment capabilities of the flexible (Figure 1).
- To avoid the need to change optics or instruments during the same procedure, whereby, only two instruments are required in order to perform most endoscopic procedures.
- To allow surgeons to be comfortably seated during the complete procedure (Figure 2).
- To design an instrument that can easily be introduced and maneuvered inside the urinary system by the surgeon only, without the need to coordinate with another person during difficult maneuvers that require more than two hands i.e. during a basket stone retrieval with the traditional flexible endoscope (Figure 3).
- To obtain an anatomic-compatible endoscope to the body cavities (Figure 4).

MATERIAL AND METHODS

This new endoscope technology is a revolutionary concept that has been brought to light to provide surgeons of every age the capabilities to carry out any endoscopic procedure. SolidFlex™ is state-of-the-art in both design and construction, which gives the instrument a much better balance and only one third of the weight of the usual flexible endoscope. It is the result of a completely new design from the handle to the face tip.

- The Handle is the successful outcome of the blending interaction of a human hand with an instrument to be harmonically unified. Robotic interaction has also been considered during development for coupling with SolidFlex™. It has a rotor in the upper surface to predictable direct the distal segment of the shaft (Figure 1).
- The Shaft has three or more different elastic segments that include a rigid and semi-rigid segment, a

passive flexible interface and an active flexible section (AFS) that all may or may not enter inside the body cavity.

- The SolidFlex™ coordinated movement between the rotor and the AFS at the resting position is toward the right and left (Figure 1), instead of the usual up and down movement in today's traditional flexible endoscopes.

These SolidFlex characteristics translate into:

- **Ergonomic:** meaning that anthropometrics and biomechanics of the surgeons human body with the interaction of the instruments engineering have been greatly taken into account to improve perception, reasoning and motor response for instant or even precognition reaction during procedures.
- **Intuitive** (Instinctive Perception): this has been obtained by the communication of the rotor with the AFS section of SolidFlex™. It translates in that the handle control moves the instrument's AFS towards predictable, pre-selected areas, driving the procedure fluidly throughout.
- **Coherent:** meaning logical for a rational and consistent response.
- SolidFlex™ is the only instrument that provides the stability of a rigid or semi-rigid instrument with the resources of the flexible exploration.

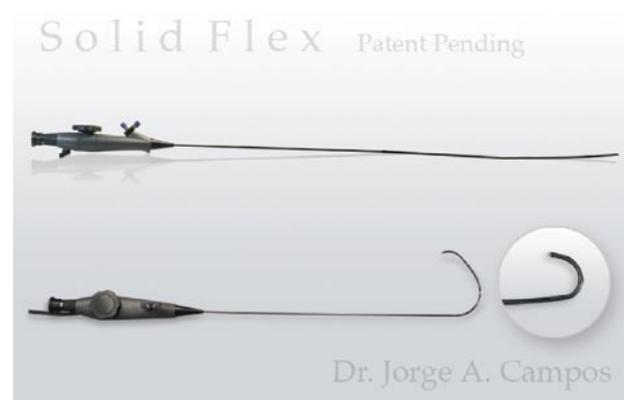


FIGURE 1. The SolidFlex™ teaching is exhibited in full. The interrelation between the ergonomic handle and the unique shaft is deployed. At its resting position the active flexible section (AFS) is activated through the rotor towards right or left.

RESULTS

The SolidFlex™ prototype has been successfully tested in 9 patients and 11 renal units in the urinary system (Table I).

The SolidFlex™ Prototype was initially utilized in 7 renal units of pre-stented patients that were explored after double “J” removal due to a prior acute renal colic and a catheter was left in place. All patients had renal calcifications in the URO-CT in the renal units subject to exploration after double “J” withdrawal.

In 4 renal units, SolidFlex™ was used during the acute episode of renal colic and in all of them soft coaxial ureteral dilatation was carried out. The time to introduction up to into the renal pelvis for the first

group was 5 seconds as an average and 10 to 15 seconds for the second group without counting the ureteral dilatation procedure.

The procedures were completed in all cases (as shown in the accompanying video), this being defined in the first group that any calcification that protruded from a renal papillae from approximately 200 microns to 4 mm in size were retrieved either by laser energy, a basket or both, at any level the urinary system, even the most difficult papilla to reach in the lower pole of the kidney. These can be easily reached with one hand at the handle and very soft movements (Figures 2, 3, 4).

In the second group it means that the urinary obstruction and the stone retrieval could be solved during the same procedure. The time to complete

TABLE I.

SolidFlex™	Ureteral dilatation	Time to Introduction	Completed Procedures
# of Patients 9			
# of Renal Units 11			
Group I: 7 renal units explored after double “J” catheter withdrawal.	Ureteral dilatation was not required.	Through a guide wire up to the renal pelvis: 5 seconds as an average	100% **
Group II: 4 units explored during an acute renal colic.	Ureteral dilatation carried out in all of them. *	10-15 seconds without counting the ureteral dilatation.	100% ***

* Soft ureteral dilatation was carried out with coaxial dilators in all cases since the SolidFlex™ prototype is unique.
 ** 100% means that the procedure could be carried out and remnant upper urinary caliceal and papillary stones retrieved.
 *** 100% means that the urinary obstruction and the stone retrieval could be solved during the same procedure.

Time to complete the procedure	Anesthesia	Stone Migration
15-20 minutes with laser, basket use or both.	General	None
15-20 minutes without counting the ureteral dilatation. With laser, basket use or both.	General	3 cases. No other instrument was required.

the procedure was about the same in both groups without counting the ureteral dilatation for the second group. The usual anesthesia already employed has been utilized. In three cases of group II migration into the upper urinary system occurred and SolidFlex™ was the only instrument required by only advancing it to find the urinary stone into the upper urinary system without need to switch from the semi-rigid to the flexible endoscope as is the common and at present necessary practice.

DISCUSSION

SolidFlex™ allows the surgeon to overcome several of the difficulties typically faced during surgeries like the difficulties during insertion of a flexible endoscope, the difficulties of maneuverability once inside the ureter, and the confusion that exist when the upper urinary system is under exploration by having to rotate 45 degrees or more the handle of the traditional flexible endoscope in order to orient the AFS towards right or left which is the true position of a patient's urinary system under exploration. Also, to activate the operating instruments during critical moments like stone extraction and others, requires coordination with another person.

The latter is originated because the surgeon is required to operate with both hands to sustain the traditional flexible endoscope in position; one hand for the handle and the other to maintain the comple-

tely flexible shaft in position. In addition, there sometimes exists the requirement to replace a semi-rigid for a flexible endoscope during a procedure, which is traumatic to the patient and time consuming for the surgeon; and not all departments of Urology in the world have both semi-rigid and flexible endoscopes.

Another situation that precludes success is the uncomfortable posture that has to be assumed by the surgeon during endoscopic surgery, standing up on one foot in order to be able to action the pedals of the laser, table or fluoroscope with the other during the procedure, also wearing a heavy lead apron, that in conjunction produces fatigue and desperation that decreases surgeon's performance.

SolidFlex™ is introduced effortlessly into the urinary system, with one hand maneuvering the ergonomic handle. The shaft provides stability by the rigid and semi-rigid portion to properly maneuver once inside the cavities of the human body and easily introduce the flexible segments. These unique features permit the surgeon to be comfortably seated (Figure 2) while performing flexible exploration of the intrarenal urinary system. In addition, by having the rotor to activate the AFS towards right or left which is the true position of the urinary system while under exploration, produces an intuitive (Instinctive Perception) endoscope that eliminates confusion during the exploration of the renal papillae that are located not only in the three Cartesian planes, but also below the level of the renal pelvis; this is the lower pole of



FIGURE 2. The extremely comfortable seated position that is attained during surgery engenders serenity throughout the procedure. Inset reveals two microscopic stones in a lower pole papilla that were not detected by the URO-TAC or any other imaging modalities.



FIGURE 3. The stability for exploration provided by SolidFlex™ gives the surgeon complete control and one hand is sufficient to introduce and maneuver the instrument and the other is free to simultaneously utilize operating tools and self coordinate every effort during critical activity. Such as during the stone extraction shown in the inset.

the kidney. This translates into a coherent relationship between the ergonomic handle and the shaft. The stability for exploration provided by the rigid and/or semi-rigid segment gives the surgeon complete control and one hand is sufficient to introduce and maneuver the instrument, leaving free the other to introduce and accurately drive the operating tools by the surgeon's hands only during the whole procedure (Figure 3). The different shaft segments softly accommodate inside the lower and upper urinary system due to anatomic compatibility (Figure 4). It also avoids the need of replacing the semi-rigid to a flexible ureteroscope during the same surgical event because SolidFlex™ has both capabilities.

The SolidFlex™ endoscope technology is state-of-the-art in design and engineering, and the ureteroscope prototype instrument is a novel concept that weighs half the average of any given endoscope with a much better balance. The SolidFlex™ prototype preliminary results are impeccably promising.

The benefits for this revolutionary technology extend to:

Patient

- The introduction of the instrument is fast, effortless and non-traumatic.



FIGURE 4. The shaft segments softly accommodates inside the lower and upper urinary system. SolidFlex™ avoids the need of replacing the semi-rigid to a flexible ureteroscope during the same surgical event because it has both capabilities.

- Very little or No analgesia is required after the procedure.
- A faster exploration of the upper urinary system occurs because the surgeon never gets lost or confused inside the upper urinary system. It easily accommodates into the Urinary System (Figure 4).
- Eliminates traumatic instrument change from the semi-rigid to a flexible one.
- Greater chance to achieve a 100% stone free rate, and lower recurrence rate.
- Reduces operating and anesthesia times due to ease-of-use and rapidness.
- It has been readily and successfully tested in the both, Female and the Male.

Physician

- SolidFlex™ becomes part of the surgeon's hands.
- The surgeon can be concentrated in the procedure itself instead of thinking of instrument introduction, behavior and maneuvering.
- SolidFlex™ allows the surgeon to maneuver with utmost precision the instrument with one hand into predetermined areas and simultaneously control the stone basket or laser fiber with the other hand (Figure 3).
- This technology permits the surgeon to be comfortably seated during the complete procedure (Figure 2).

Instrument

- Is the Fourth generation of endoscopy.
- The shaft has three or more different elastic properties, including rigid or semi-rigid, passive flexible inside or not all them into the body cavities.
- It saves time by accomplishing the mission of both rigid and semi-rigid and flexible endoscopes without the need of changing instruments during the same procedure.
- Its construction slides straightforward through the capricious curvatures of the urinary system.
- The shaft teaching permits easy exploration of every corner of the urinary system including the lower pole of the kidney.

- The handle is ergonomic and intuitive (instinctive perception), because the active flexible segment is directed through a rotor in the handle that moves towards right or left in the instrument's resting position, producing a coherent instrument.
- The SolidFlex™ Cystoscope and Ureteroscope reduce the number of parts in the Urologic Armamentarium (Figure 1).
- The instrument is easily introduced into the urinary system, and it requires very little effort and movements during the procedure.
- The surgeon only requires one hand to efficiently introduce and maneuver the instrument, while the other hand can introduce and utilize operating tools and be able to self coordinate (Figure 3).

CONCLUSIONS

- SolidFlex™ has been utilized as a first line endoscope.
- It does make flexible endoscopy easier and faster to perform from the first time.
- The SolidFlex™ endoscope technology is less traumatic for patients.
- It's very comfortable and friendly for surgeons to use from the first time.
- This new teaching does facilitate flexible exploration thanks to its ergonomic, intuitive design and coherent behavior.

- These features do make flexible exploration and treatments more efficient.
- This novel concept can be applied to a cystoscope, ureteroscope, nephroscope, robotics and many other medical areas.
- It also can be compatible with robotic and Natural Orifice Transluminal Endoscopic Surgery (NOTES).
- SolidFlex™ allows surgeons to potentially achieve 100% stone free rate, which in turn reduces patient probability of recurrence.
- This teaching will permit the surgeon to perform smoothly, which translates into fast, efficient and successful procedures.
- Surgeons of every age will be able to effectively perform every desired endoscopic procedure with exact precision.
- Substantially decreases healthcare costs by reducing time and cost per procedure, and more importantly by improving patient recovery.
- The SolidFlex™ solution was created by a Urologist to achieve an effective and simplified flexible endoscope technology that can thoroughly explore the complete urinary system for the benefit of physicians and patients.

AUTHOR'S NOTIFICATION

At present there are 25 SolidFlex™ Prototypes for sale.

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