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ORIGINAL PAPER

# In vitro simulation of stent fracture mechanisms in ureteric nitinol wire stents

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**Abstract** The ZebraStent® is a new-concept lumen-less teflon-coated nitinol double-J wire-stent, designed to facilitate the passage of residual fragments after extracorporeal shock wave lithotripsy. In clinical practice we observed a small number of stent fractures. Hence, an experimental model was designed to simulate the physical forces that may lead to material fatigue of the stent. Flexion force was simulated by "half circular kidney mimicking structures" (HCKMS) into which the upper part of the stent was placed. All experiments were done for a minimum of 5 million cycles representing a stent indwelling time of 9 months, or until stent fracture, and simulating respiratory kidney movement. It was demonstrated that as the diameter of the HCKMS decreases, thus leading to an increased bending of the stent, the likelihood of stent fracture increased proportionally and occurred earlier. From our results it appears that stent fractures can be avoided by observing a maximum indwelling time of 6–8 weeks (which should suffice for the duration of a average SWL treatment), by choosing the correct (and shortest possible) stent length, and perhaps by manufacturer's modifications decreasing the stent's resistance to flexion. The ZebraStent® concept remains appealing if it is considered as a short-term stent for post-SWL residual fragments.

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## Introduction

Since the introduction of extracorporeal shock wave lithotripsy SWL, obstruction through fragments and/or steinstrasse emerged as a major complication [1]. Ever since, ureteric stenting has been debated as a method to prevent obstruction and to maintain renal drainage [2]. However, ureteric stents have their own inherent problems and the discussion whether to stent or not to stent is still ongoing [3, 4]. Therefore, differing stent designs and materials are being tested continuously [5, 6]. The ultimate aim would be to decrease stent-related complications.

One of the most clinically invasive complications of ureteric stents is stent fracture because it requires in most cases secondary remedial surgery. Ureteric stent fracture is a complication reported mainly for polyurethane and silicone stents [7–9]. The new concept wire-stent (ZebraStent®) was thought to be less prone to fracture due to its composition of a metal nickel-titanium core with soft titanium coils at both ends. When we identified a few cases of stent fracture in clinical practice, we attributed this to the respiratory movement of the kidney in relation to a stent fixed in the relatively less movable ureter. Further stent movement is caused by patient movements such as bending, standing-up and sitting down [10]. This may result in continued flexion of the nickel-titanium shaft of the ZebraStent®, which in turn may lead to material fatigue and stent fracture not unlike those observed in dental appliances [11]. Therefore, we designed a study to investigate mechanical stent failure by in vitro simulation of the stent's movements in the human body, using a model under accelerated test conditions.

## Materials and methods

### The ZebraStent®

The ZebraStent® has a diameter of 0.035 inches (0.89 mm). Its relatively rigid shaft consists of a metal core of nickel titanium, whilst the soft J-ends consist of a titanium coil. The whole stent is coated by Teflon (PTFE) and has a spiraled outer surface over its whole length. For all experiments, stents "ESWL Titan Zebra Stent" (type TS35-24, Neo Medical, Hofolding, Germany) were used.

### The experimental model

An experimental model was designed to reproduce the forces acting on the ZebraStent® in vivo. They result from the movement of the stent within ureter, kidney and bladder, mainly in the form of periodic flexion due to physiological kidney movements with every respiratory cycle. During respiration the lung and the diaphragm move in the cranio-caudal direction, making adjuvant organs (e.g., kidneys, liver, and pancreas) move in the same way. To the contrary, the ureter is relatively fixed below the level of L5 and this causes flexion of the stent inside the body.

Kidney movements under respiration have been measured with the help of magnetic resonance imaging (MRI). For the left kidney, an average movement of $16.9 \pm 6.7$ mm was established, for the right kidney of $16.1 \pm 7.9$ mm [12]. Consequently, we chose for our experiments the upper limit of possible kidney movement, which is 16.9 mm, plus the maximum standard deviation of 6.7 mm, equaling 23.6 mm total linear motion. Stent movement during respiration was simulated with the experimental set-up as shown in Fig. 1. To facilitate the measurement stents were divided into two at the midpoint and each half tested separately. The movement was reproduced by fixing the more rigid stent shaft to an aluminum crank-shaft mechanism. This mechanism produced a 23.6 mm linear motion of the stent with the help of an electric motor (24 Volt DC Servo Motor, Maxon Motor AG, Sahsein/Switzerland). Whereas it would have been more physiological to use a complete stent with its lower curl in a simulated bladder, this turned out technically difficult because the electric motor was not strong enough to move a whole vessel the size of a bladder. On the other hand, in clinic we had always observed fractures in the proximal part of the stent. Therefore, we concentrated on that part of the stent as the possible weak point.

Flexion of the stent in the renal collecting system and upper ureter was simulated by placing the coil of the stent into a box-type half circular kidney mimicking structure (HCKMS) made of transparent thermoplastic polymethyl methacrylate resin (Perspex®) (Fig. 2). HCKMS with

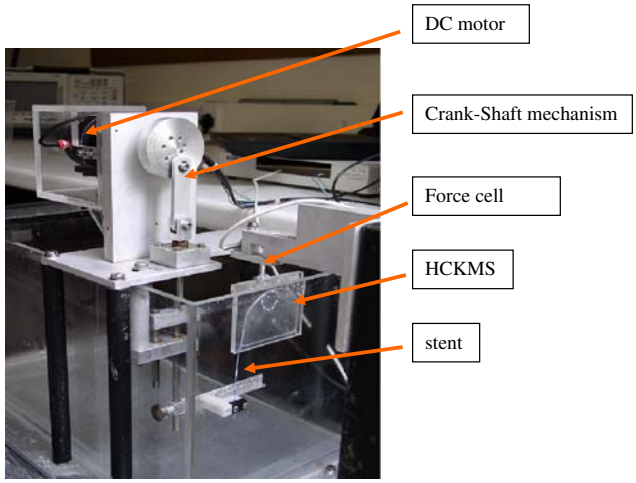


**Fig. 1** The experimental setup. The ZebraStent® can be seen within the hemi-circular kidney mimicking structure (HCKMS)

diameters of 4.5–6.5 cm were representative of different sizes of pelvi-calyceal systems in adult kidneys, as estimated from measurements derived from intravenous urographs (IVU). To be able to conduct the experiments in a reasonable timeframe in an accelerated fashion, simulation was performed at a rate of 990 strokes (flexions) per minute, and individual experiments lasted for ~3.5 days. This corresponds to a stent indwelling time of 9 months, at an average of 12 respiratory cycles per minute, totaling approximately 4.7 million flexions. As mentioned above, the stent displacement of 23.6 mm mimicking respiratory movement was chosen on the basis of physiological considerations. Having chosen this figure, the force necessary to produce this displacement was measured (0.135 N) utilising the static force of known weights. In order to produce the same force acting on the stent in the accelerated testing, the Newtonian law *force = mass x acceleration* was used. This allowed the calculation of the displacement (stroke length) on the rig to give the required acceleration at a stroke rate of 990 strokes per minute. In this manner, the force acting on the stent in the accelerated ex vivo test was matched to that acting upon the stent in vivo. Another stroke rate would require adjustment of the stroke length to produce the same force. Hence fatique, which is directly related to the force acting on the stent is independant of the stroke rate which allowed us to perform this experiment in an accelerated form.

To further simulate physiological conditions, experiments were conducted in a temperature-controlled normal saline bath at 37°C. Immersion in fluid acting as a conductor and a controlled temperature were deemed to be possible influencing factors. To the contrary, since we were using an accelerated model with an average indwelling time of the stent in the bath of 3.5 days, the possible chemical effects of urine on the stent, as well as encrustation, were

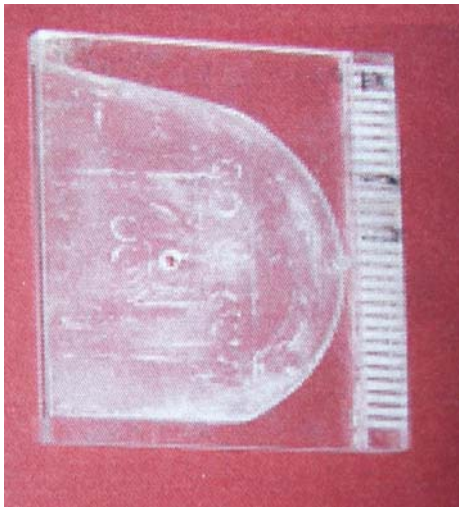

**Fig. 2** Perspex® made hemi-circular kidney mimicking structure (HCKMS)

deemed insignificant in this particular experimental setting and, consequently, we refrained from using artificial or filtered human urine.

The relative force acting on the stent was measured with a force cell attached to the top of the HCKMS. Online conditioned data were displayed and stored to a disk when stent fracture occurred.

A minimum of three experiments for each HCKMS diameter (4.5, 5, 5.5, 6, and 6.5 cm) were performed with either 5 millions cycles or until stent fracture. The fracture point was defined by a distance to the transition point between the soft coil and the metal core of the stent (Fig. 3).

### Statistical analysis

Summary data are presented as means and standard deviations (SD). Due to the small number of experiments per group, non-parametric tests were used to determine the relationship between the diameter of HCKMS and the distance of the fracture point to the transitional point on one hand, and the number of strokes to induce stent fracture on the other hand. Spearman rank order correlations were calculated. The software package Statistica form StatSoft® was used. A $P \leq 0.05$ was considered statistically significant.

**Table 1** Summary of experiments

| HCKMS Ø | No fx/no exp | No flexions | Distance |
|---|---|---|---|
| 4.5 | 5/5 (100) | 88 | 2.7 (0,4) |
| 5.0 | 2/5 (40) | 213 | 2.9 (0,1) |
| 5.5 | 1/3 (33) | 171 | 2.0 (ND) |
| 6.0 | 0/3 (0) | >5,000 | ND |
| 6.5 | 0/3 (0) | >5,000 | ND |

*HCKMS Ø* diameter of half circular kidney mimicking structure HCKMS (in cm), *No fx/no exp* number of fractures per number of experiments (in %), *No flexions* average number of flexions until stent fracture occurred, *Distance* average distance of fracture point from the stent's transition point in cm (SD), *ND* not determined

## Results

Eight out of 19 (42%) stents tested fractured (Table 1).

With larger diameter HCKMS, stents were significantly less likely to break compared to smaller diameter HCKMS. At the smallest diameter of 4.5 cm, all 5 stents tested (100%) fractured.

A significant positive correlation ($R = 0.71$) was observed between HCKMS diameter and the number of strokes needed to induce stent fracture.

All fractures occurred in the metal shaft area of the stents. All fractures occurred at different distances from the transitional point, meaning that no specific "weak" point was identified. A negative but not statistically significant correlation ($R = -0.24$) was observed between HCKMS diameter and distance between fracture point and the stent's transitional point.

Measurements of the relative force acting on the stent revealed a sharp rise in the force value shortly before the stents fractured, with values increasing from <0.1 N to 0.3−0.5 N. For smaller HCKMS diameters, the time interval from this peak force rise until stent fracture was longer than for larger HCKMS diameters.


**Fig. 3** The distance between fracture point and transitional point on the ZebraStent®

No gradual changes of the peak force values were noticed in any of the experiments. Decreasing peak force values as a sign of weakening of the stents were likewise not observed. When peak force values remained stable throughout an experiment, stent fracture did not occur.

## Discussion

Ureteric stents are associated with inherent complications such as bladder irritation, stent encrustation and stent migration. The novel ZebraStent® described in our study may address some of these problems outlined in the literature [13–16]. The novel underlying concept of a lumenless ureter stent is an improvement in drainage of debris and gravel by providing a permanent wire element with a unique surface structure ("mixing blade"). It is also known that indwelling stents relax and straighten the ureter which may further contribute to a smooth passage of fragments. The stent prevents the compacting of gravel in the ureter and consequently decreases the risk for "steinstrasse". Its advantage over conventional stents with lumen is the maximally reduced diameter which results in less ureteral lumen space to be occupied by the stent itself. The ZebraStent® with a diameter of 0.89 mm (2.7 French), as compared to a conventional stent with a diameter of 2 mm (6 French), takes therefore 2.25 times less ureter space in terms of diameter, and >5 times less in terms of cross-sectional area. Thus, it frees a large cross-sectional area of the ureter for stone fragments to pass alongside the stent. Fragments usually do not travel through a stent's lumen anyway. In clinical practice, it happens that fragments do not enter into or pass through the ureter whilst a JJ stent is in situ. They will pass once the stent is removed. The larger cross-sectional ureteric area may be an advantage in those cases.

Due to the lack of lumen, the ZebraStent® cannot of course provide drainage. If this is required, the ZebraStent® is contraindicated, i.e., in strictures, obstruction or infection.

Accordingly, the ZebraStent® has been specifically designed to speed up the clearance of stone fragments after extracorporeal shock wave lithotripsy (SWL). It has been proven to be shock wave resistant [17].

When we introduced this stent in our clinical practice, we were using only stents of a fixed length in all patients. Unfortunately, in three patients fractures occurred in the stiffer metal shaft of the stent necessitating removal surgery.

This led us to design this study and examine stent properties in in vitro accelerated laboratory conditions.

Stent fractures identical to those observed in vivo were successfully reproduced in vitro. Initially, we hypothesized a "weak" point, either at a specific location within the shaft where continued flexion would lead to material fatigue, or at the transition point between the stiffer metal core shaft and the more flexible coils. No such point could be determined.

Accordingly, when we started force measurements we expected a continuous and gradual decrease in force as a sign of material fatigue. To the contrary, the measured force actually increased during a various number of strokes before stent fracture occurred.

These findings contradictory to our expectations may find an explanation in work hardening, which is the strengthening of a material by increasing the material's dislocation density. In metallic crystals, irreversible deformation is usually carried out on a microscopic scale by defects called dislocations,which are created by fluctuations in local stress fields within the material culminating in a lattice rearrangement as the dislocations propagate through the lattice. These dislocations accumulate, interact with one another, and serve as pinning points or obstacles that significantly impede their motion. This leads to an increase in the yield strength of the material and a subsequent decrease in ductility (the mechanical property which describes how much plastic deformation a material can sustain before fracture occurs) [11]. This would however need further experiments to confirm.

With small diameter HCKMS, this force increase occurred earlier, although stent fracture did not necessarily follow immediately. With larger diameter HCKMS, stents were significantly less likely to fracture.

Extrapolated into in vivo conditions, this means that a stent within a 4.5 cm diameter pelvi-calyceal system would last 2 months until it fractures. With an increase in diameter to 5 and 5.5 cm, this estimated indwelling time would increase to 3 and 5 months, respectively.

Considering this, ZebraStent® removal after 2 months can be considered safe which under normal circumstances should suffice for most SWL treatments. This is provided the in vitro data are applicable in vivo. Nevertheless, in our limited experience with 19 patients, no stent fracture occurred before 3 months. To confidently establish a safe indwelling time, clinical studies will be needed.

Given our results and the fact that we used a set stent length in all patients, it is also possible that longer stents in shorter patients constituted another mechanism leading to stent fractures by causing the stent to bend further down the more brittle shaft rather than within the soft coils during respiratory movements.

"Anti-kinking", ureter-straightening properties of metal wire stents may not be as important as the presence of a dynamic "mixing blade" element in the ureter for speeding-up the passage of stone fragments. Since stent fractures always occurred in the stiffer shaft of the stent, perhaps a wire stent more elastic throughout, or with a significantly

shorter shaft could be able to avoid stent fractures. This may retain most of the positive properties of the ZebraStent® whilst making it safer in practice.

Whereas we believe the ZebraStent® is a good and valuable addition to the armamentarium of the endourologist, with currently available stents the shortest adequate stent length should be used (the distance from PUJ to VUJ should correspond to the stent shaft) and a maximum indwelling time of 2 months should not be exceeded.

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