Original Article

Assessment of bio-safety of low-cost polyurethane urologic stents used in developing countries

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ABSTRACT

Background: Ureteral stents, despite their ubiquitous use, have not been evaluated for their safety and strength after removal from the patient. While literature is available from the industry with regards to manufacturing and specifications of stents, what happens to a stent after it is inserted into the body, still needs to be explored.

Materials and Methods: We conducted a methodical study of 153 consecutive patients with urological problems who were stented with inexpensive polyurethane stents. Once removed from the patients, the stents were analyzed for breakload, tensile strength, elongation, pH, decomposition temperature, residue as well as diameter change.

Results: There was no significant change in the physical and mechanical properties of the stent after clinical use and the variance was within the acceptable range of biomaterials. There was minimal leaching of material and color change in all stents.

Conclusion: The cheap polyurethane stents were found to be safe for use in patients, for the short time periods of *in situ* stenting. The degradation of physical and chemical properties of the stent was not significant. Thus it can be safely said that the stents currently in widespread use are cost-effective and physically safe for short spans of time.

Key words: Cost-effective stents, polyurethane DJ stents, ureteral stents

INTRODUCTION

Ureteral stents are an integral part of the current urological armamentarium. With the increasing burden of stone formers worldwide, their use has almost become ubiquitous.

These stents are commonly made of polyurethane and silicone, the amount of each being proportionately varied to achieve a fine balance between optimum flexibility and stiffness, for both patient comfort as well as ease of surgical placement.

India, Pakistan, and China make an important part of the stone belt in Asia. Moreover, these nations are also the largest in terms of patient population. As a consequence, the double J stent is one of the most common prosthetic devices to be used in everyday urology practice especially in these countries. Despite ongoing improvement in biomaterial manufacturing and stent specifications, what actually happens to this stent once placed *in situ*, has yet to be systematically assessed.

Another factor to be considered is the expenditure incurred to the patient in procuring these stents. When first introduced into the prosthesis market, these stents were beyond the reach of the average Indian patient. However, with the usage of cheaper biomaterials, the costs have been brought down to approximately US 2$/ stent. In developing nations, affordability forms the most important attribute to be considered prior to any intervention.

Taking into account the importance of expenditure incurred, we attempted to independently test the physical attributes of the most affordable and the most commonly used polyurethane DJ stent, as regards its *in situ* biocompatibility.

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MATERIALS AND METHODS

One hundred and fifty three consecutively stented patients [for various endourological procedures] were selected from three general urology centers in Mumbai, India.

Eight stents had to be retrieved due to persistent stent pain in less than 3 weeks. Sixty eight were renal calculi, 11 stricture ureter, or PUJ obstruction, 69 ureteral stones, 5 with mixed renal and ureteric calculi [142 stone formers and 11 nonstone formers]. Only one stent per patient was used, in case of bilateral ureteral stenting.

The research questionnaire included age, sex, diagnosis, period of *in situ* stay [duration of *in situ* stent implantation], breakload (in Newtons), % elongation, pH, decomposition temperature (°C), residue (mg), UV absorption at 273 nm, diameter (in mm), wt. (in mg), and tensile strength (Newtons/ cm^2).To avoid inhomogenity, all stents used were from the same lot of stents supplied. All physical properties were assessed after stent removal.

pH was determined in 0.9% saline using EUTECH Instruments (model pH 510) to measure pH in mV. Tensile strength and %elongation were determined using INSTRON 4301 with a cross head speed of 50 mm/min. Thermal decomposition profile giving approximate composition was measured using METTLER M3 thermogravimetric analyser. After subjecting the stents to decomposition temperatures, stent residue was calculated. UV/visible absorption spectrum was taken to find out the leachables. For these measurements, Evolution 300 spectrophotometer with a scanning range of 200–1100 nm was employed. Stent diameter was measured using electronic calipers.

Five unused stents were subjected to assessment via the same methods as the used stents, and their mean values were taken as reference standards against which the used stents were assessed.

All stents were placed in sterile containers, post removal from the body, and processed within 48 h of removal.

Statistical analysis of data was done via application of paired *t*-test [parametric] and Wilcoxon analysis [for UV absorption and pH], and *P* values <0.05 at 95% CI were considered as significant.

RESULTS

The mean duration of individual stent placement was 43 days [range: 5-97 days].

Figures 1a and 1b present the results of breakload and tensile strength, respectively, on a total of 153 stents. The values on the *y*-axis represent the density calculated as

Density = Number of patients in the group or bin/(total number of patients × group or bin size [in this case, total number of stents]).

The figures also include the data on the control (new or unused) DJ stent. It can be seen from these two figures that there is no significant change in the breakload and tensile strength values after using the stent, showing only a small distribution around the control stent data. This shows that there is no rapid deterioration *in vivo* of the indigenous polyurethane stent.

Figures 2a and 2b show the correlations among breakload, tensile strength, elongation, and breakload, *in situ* days, tensile strength, respectively. From Figure 2(a), it is seen that higher the tensile strength, higher is the breakload of the stent. Further, there is no appreciable change in the elongation as a function of breakload among different stents removed from patients. From Figure 2(b), it is ascertained that there is no correlation between the breakload or tensile strength and number of *in situ* days of the stent.

Figures 3a and 3b show the density as a function of elongation and pH value, respectively. From Figure 3(a), it is seen that there is no significant change in the elongation data for majority of the stents after their *in vivo* use. A small increase in the pH was noted for most of the stents, as seen in Figure 3b.

Figures 4a and 4b present the density of the used stents with regard to their decomposition temperature and residue, respectively. As seen, the decomposition temperature of most of the stents reduces by about 10–15°C after usage [Figure 4a]. Further, a small amount of residue (amounting to 8–10 mg) deposited in the stents was seen as given in Figure 4b. Figure 4c shows the density of the stents with regard to UV–visible spectro-photometric data. Majority of the stents showed absorption peaks when compared to the unused stent, probably due to a change in the color of the stent. The statistical analysis of data is depicted in Table 1.

Thus, these results prove that there is no significant change in the physical and mechanical properties of the stent after clinical use and the variance was within the acceptable range of biomaterial. The leaching of material was minimal. However, color change was observable in all stents. Biochemical properties (viz. pH and UV absorption) also did not show any significant change after clinical use. There was a small stent to stent variation as shown in the figures.

DISCUSSION

Ureteral stents have been designated as “Right hand men” for the uro-surgeon. Many advances have been made to bring about improvement in this essential tool, since 1978, when Finney developed the first modern-day double-pigtail

Table 1: Statistical analysis of data

Parameter	Reference value (unused stent)	Mean (in used stents)	Difference (95% CI)	*P* value
Breakload (in *units*)	40.2	36.36 ± 7.48	-3.84 (-5.04 to -2.65)	>0.05, Not significant
Tensile strength	35.43	31.92 ± 7.87	-3.51 (-4.77 to -2.26)	>0.05, Not significant
Elongation	170.5	146.23 ± 25.01	-24.27 (-28.37 to -20.17)	>0.05, Not significant
pH	6.3	6.64 ± 0.39	0.34 (0.28 to 0.40)	>0.05, Not significant
Decomposition temperature	328.06	321.52 ± 7.26	-6.54 (-8.21 to -4.87)	>0.05, Not significant
Residue in Mg	6.84	9.66 ± 1.20	2.82 (2.54 to 3.09)	>0.05, Not significant
UV absorption	0	0.62 ± 0.12	0.62 (0.59 to 0.65)	>0.05, Not significant
Diameter (in mm)	1.9	1.95 ± 0.36	0.05 (-0.002 to 0.11)	= 0.60, Not significant

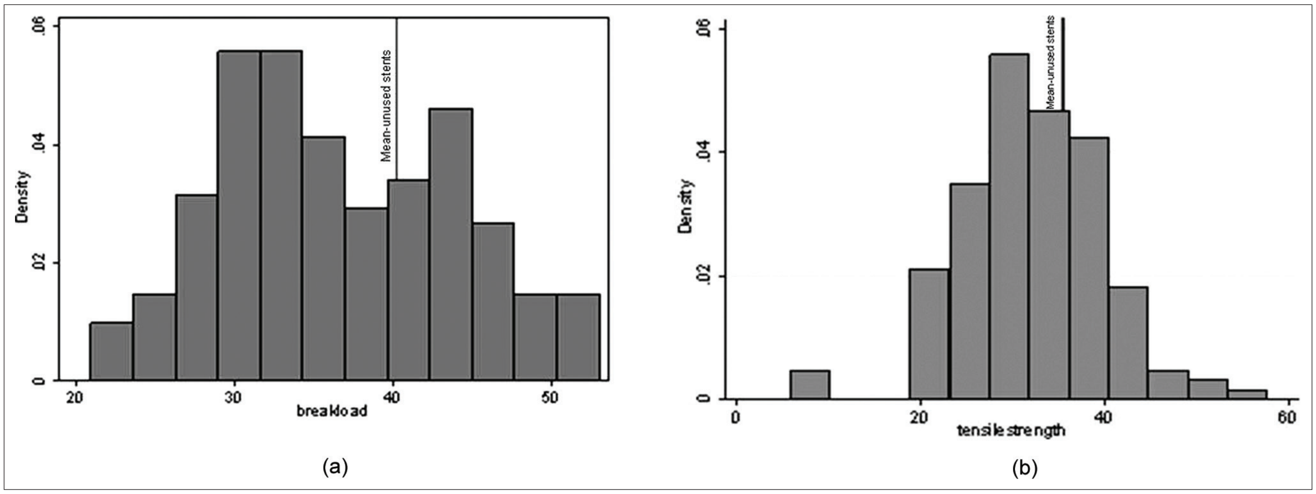


Figure 1: (a) Results of breakload versus stent density. (b) Results of tensile strength versus stent density

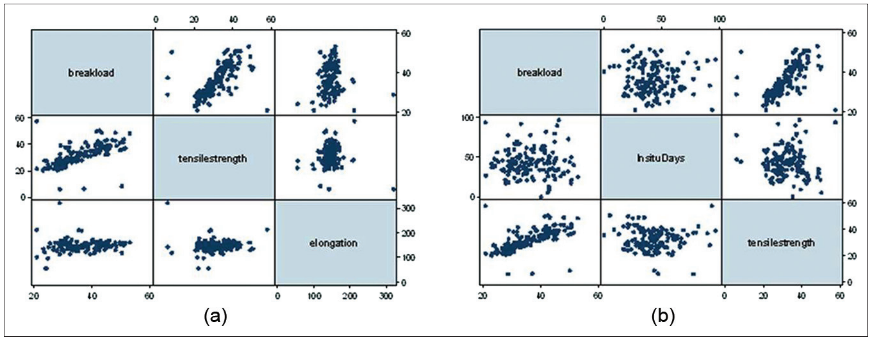
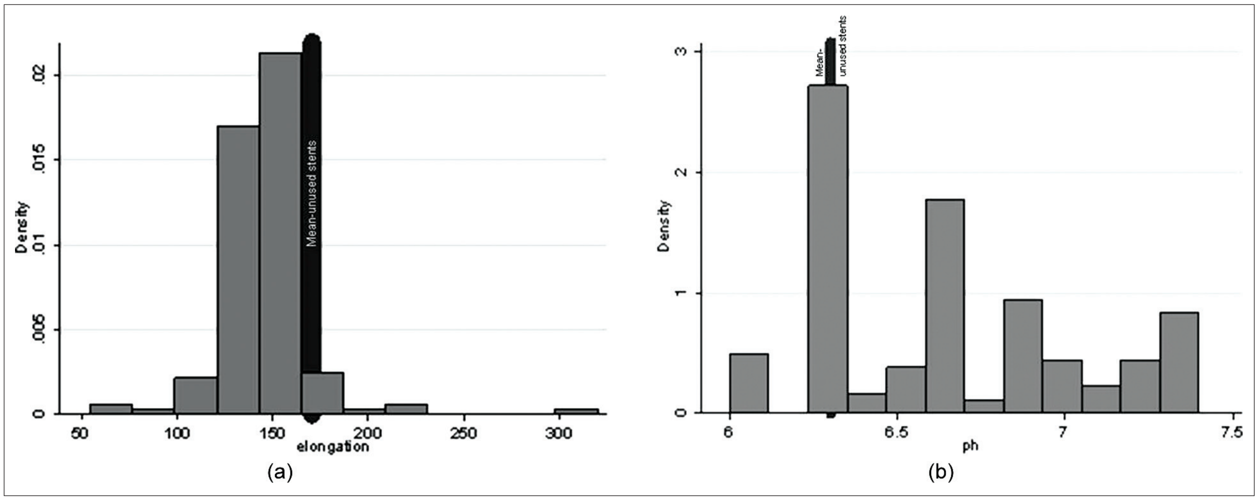


Figure 2: (a) Correlations among breakload, tensile strength, elongation. (b) Correlations among breakload, *in situ* days, tensile strength

stent.[1] However, no consensus has been reached as to what constitutes an ideal stent, till date.[2] Moreover, the expenditure incurred to the patient in procuring a DJ stent forms a major criterion, especially among the developing countries. Taking this into account, we attempted to independently test the physical attributes of the most affordable and the most commonly used polyurethane DJ stent, as regards its *in situ* biocompatibility.

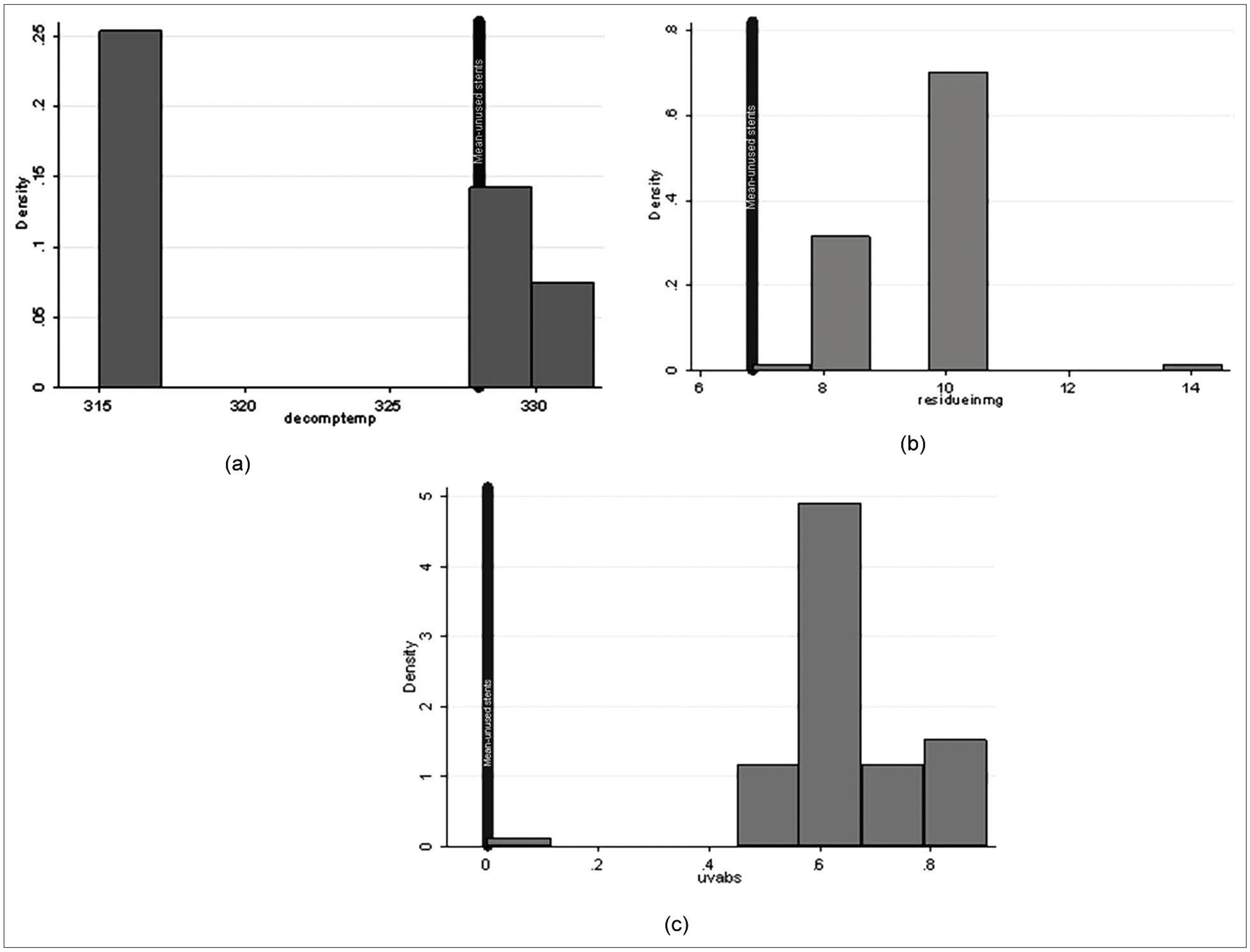
An ideal ureteral stent should be easily inserted and removable,[3] resistant to migration and encrustation, nonrefluxing, radio-opaque, versatile and should have optimal flow properties.[3-7]

However, putting all in perspective, contemporary stents have improved flow characteristics and are relatively more tolerable once inserted. Mardis *et al.* have provided a good insight into comparative evaluation of the materials used for stents in urology.[8]



(a) (b)

Figure 3: (a) Density as a function of elongation. (b) Density as a function of pH



(a) (b) (c)

Figure 4: (a) Density of the used stents with regard to their decomposition temperature. (b) Density of the used stents with regard to their residue. (c) Density of the stents with regard to UV–visible spectro-photometric data

Biodurability [the ability of a stent to resist *in vivo* degradation, when subjected to various factors in the urine and urothelium] and biocompatibility [the degree to which the stent material affects the urothelium and *vice versa*] remain the foremost concerns whilst a stent is placed *in situ*.[9-13]

The tissue response to *in situ* stents also depends on numerous factors such as the extent of inflammatory reaction, implant movement, and degradation[11] as well as leaching [a dominant reaction caused by a progressive chemical urinary assault on the stent plastic and its integrity[12,13]] of the material into the genito-urinary tract.

Biomaterial failure is said to occur following changes in the various mechanical properties of the material.

Breakload, tensile strength, and stent elongation at break are three interdependent, but maximally important parameters for a successful *in vivo* stent stay. A reduced tensile strength and elongation at break, in addition to side drainage holes contribute to an increased propensity of fracture of polyurethane stents.[2] Zisman *et al*.[14] reported a decreased elongation at break of the retrieved polyurethane stents, while Mardis and Kroeger reported the same for silicone stents retrieved from patients, after 20 months *in situ*.[8] From our study, it was seen that there was a directly proportional relationship between the breakload and tensile strength of the polyurethane stents. Further, there was no appreciable change in the elongation as a function of breakload among different stents removed from the patients.

The yellowing of the stent, after removal, is a minor concern. Color change (discoloration) is attributable to drugs. The citrates and oxalates in the urine adsorbed on the stent will be attributed to the barium sulfate in the coating of the stent. Barium sulfate, bismuth subcarbonate and tungsten powder are used as radiopacifiers in the stents, with the economic barium sulfate being used in the low cost polyurethane stents. These chemicals contribute to the residue after being subjected to the decomposition temperature. We found a small residue of 8–10 mg, in our study.

The Beer–Lambert law states that absorbance is directly proportional to the concentration of absorbing species and path length. In accordance with this law, UV–visible spectrophotometric absorption analysis helps in quantitative determination of stent leaching. In our study, most of the stents showed small absorption peaks when compared to the unused stent, mainly due to the color change of the stent. This leaching was found to be statistically insignificant.

Cost effectiveness is another aspect that needs to be borne in mind, especially in developing countries, which are incidentally also bearing the brunt of urinary tract stone disease. A fine balance needs to be obtained between durability, efficacy as well as stent economics.

Continuous research into biomaterials and biocompatibility is mandatory to bring about improvements to this essential urologic tool. Assessments of stent flow dynamics, luminal occlusion via debris and surface encrustation remain facets yet to be explored. In addition, future studies as regards change in the physical stent properties after prolonged *in situ* stay, as well as similar studies on silicone stents will further enable us to widen our perspective, as regards these ubiquitous stents.

CONCLUSIONS

The cheap polyurethane stents were found to be safe for use in patients, for the short time periods of *in situ* stenting. The degradation of physical and chemical properties of the stent was not significant. The long term effects are however, unknown and more research is needed in this area. However, it can be safely said that the stents currently in widespread use are efficient to tide over short spans of implantation time.

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