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JJ Tolerance and Encrustations : Biomaterial is  
the only important parameter!

*not*  
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[Because Silicone is superior to Polyurethane]

*not*  
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# Disclosure

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Unrelated to the topics of this debate

- I am an inventor on patents licensed to HistoSonics.
- I hold stock in HistoSonics.

Further information:

*<http://www.engin.umich.edu/admin/adaa/disclosure>*

*<http://histosonics.com/>*

*David Bloom, MD Chairman of Urology UM*



# ED visits after URS

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## Data from Michigan Urological Surgery Improvement Collaborative (MUSIC)

- Reducing Operative Complications from Kidney Stones (ROCKS) initiative
  - 9.7% of URS had an ED visit
  - 72% of URS had stent placed
    - 5.4% presented to ED with pain, hematuria, urinary symptoms.



# Stent pain and discomfort

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- Mechanism poorly understood
- Theories
  - Irritation of bladder mucosa
  - Smooth muscle spasm
  - Inflammation
  - Reflux of urine into kidney

# Direct Comparison

- Pryor ( J Urol 1991)

TABLE 1. *Relative hardness of catheters*

Catheter	Composition	Durometer* (Shore A scale)
Cook polyurethane	Polyurethane elastomer	98†
Surgitek Silitek Uropass	Polyester elastomer	91.4
Cook C-Flex	C-Flex	90
Van-Tec Soft	C-Flex	65

\* Durometer is a measure of hardness with higher numbers representing harder materials.

- No difference in terms of frequency, nocturia, hematuria, flank pain, suprapubic pain, and dysuria



# Stent Biomaterials

Table 9.1 Biomaterials: Advantages and Disadvantages.




Material	Commercial Products	Advantages	Disadvantages
Silicone	Silitek	Greatest biocompatibility	Decreased drainage efficacy
		Decreased struvite and CaP stones	Increased CaCarb and CaOx stones
Modified Polyurethane	Tecoflex	High resistance to extrinsic compression	Higher bacterial adhesion
		Softens quickly - ease of insertion	Severe COM and UA stone encrustation
	Percuflex	Soft and smooth, enhanced physical properties	Very compressible
	Sof-Flex	Low frictional coefficient	Increased CaCarb and CaOx stones
	Inlay/Optima	66–79% less encrustation than competitors	
	C-Flex	Highly resistant to external force	Higher bacterial adhesion
Metal Alloys	Resonance	Very highly resistant to external compression	Encrustation difficult to detect
Biodegradable materials	TUDS	Almost all eliminated at 15 days	Small number breakage and retained fragments
	Uriprene	No reported retained fragments	4 weeks to completely dissolve

Todd AM and Knudsen BE, Ureteral stent materials: past, present, and future, in Ureteric Stenting, Kulkarni R ed. 2017

# Silicone stents

## SILICONE STENTS

Exceptionally **soft**, biocompatible, and **nonirritating**. Ideal for long-term, indwell use with resistance to encrustation. Choose from three different high-quality silicone stents. All configurations are radiopaque for clear fluoroscopic visualization and capable of up to 365 days of indwelling.

Double-J Ureteral Stent	Single J Urinary Diversion	UroGuide
		
OLYMPUS VALUE PROPOSITION		
<ul style="list-style-type: none"> <li>▪ The first modern ureteral stent</li> <li>▪ One step cystoscopic and surgical insertion</li> <li>▪ Resists encrustation</li> <li>▪ Promotes anastomotic healing</li> <li>▪ Post-cystectomy stenting</li> <li>▪ Closed tip to assist in placement post kidney transplant</li> </ul>	<ul style="list-style-type: none"> <li>▪ Patient comfort and encrustation resistant</li> <li>▪ Promotes anastomotic healing</li> <li>▪ Post-cystectomy stenting</li> <li>▪ 90cm length allows for kidney drainage through an external stomach</li> </ul>	<ul style="list-style-type: none"> <li>▪ Patient comfort and encrustation resistant</li> <li>▪ Tapered-tip to aid in placement and reduce trauma</li> </ul>

# Silicone stents

Make patient comfort a priority.



The Filiform Double Pigtail Ureteral Stent Set (Black Silicone) is used for temporary internal drainage from the ureteropelvic junction to the bladder. Made from soft, black silicone, the stent is designed for patient comfort and can remain indwelling for up to 12 months. Set includes stent, wire guide, and stent positioner.



[www.cookmedical.com](http://www.cookmedical.com)





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Does hardness (durometer) correlate with increased symptoms (USSQ)?



# Urinary Stent Symptom Questionnaire (USSQ)

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- Developed by Joshi et al 2003
- Validated instrument to quantify symptoms associated with ureteric stents
- Domains:
  - Urinary symptoms
  - Body pain
  - General health
  - Work performance
  - Sexual matters
  - Additional problems



# Comparative Trials

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- Lee (J Endo 2005) [*USSQ study*]
  - Bard Inlay polyurethane
  - Cook Endo sof AQ
  - Microvasive Contour Percuflex
  - Applied Medical Vertex
  - Surgitek Classic double pigtail
- No sig difference in pain, general sx's, narcotic use.
- Inlay stent – less-severe urinary sx's on day 3

# Comparative Trials

- Joshi (J Urol 2005) [USSQ study]
  - Percuflex plus (firm)
  - Contour Percuflex (soft)

TABLE 3. Comparison of the USSQ domain scores and p values for 2 groups

	Mean $\pm$ SD		
	Wk 1	Wk 4	After Stent
Urinary symptom index:			
Group 1 (firm)	30.2 $\pm$ 7.1	30.5 $\pm$ 7.4	16.3 $\pm$ 3.6
Group 2 (soft)	30.6 $\pm$ 6.9	31 $\pm$ 7.5	17.3 $\pm$ 4.4
p Value	0.79	0.77	0.2
Body pain index:			
Group 1 (firm)	22.8 $\pm$ 13	23.1 $\pm$ 13	2.7 $\pm$ 5.6
Group 2 (soft)	23.5 $\pm$ 12.6	24.4 $\pm$ 12.5	3 $\pm$ 7.2
p Value	0.79	0.63	0.80
General health index:			
Group 1 (firm)	14.7 $\pm$ 5.1	15.3 $\pm$ 5.5	8.3 $\pm$ 2.3
Group 2 (soft)	14.1 $\pm$ 5.8	14.4 $\pm$ 5.7	8.7 $\pm$ 4.1
p Value	0.58	0.43	0.54
Work performance:			
Group 1 (firm)	7.7 $\pm$ 3	8.3 $\pm$ 3	4 $\pm$ 2.4
Group 2 (soft)	7.6 $\pm$ 3.2	7.8 $\pm$ 3.8	3.6 $\pm$ 1.8
p Value	0.94	0.70	0.66

– No difference in any domains

# Comparative Trials

- Davenport (J Urol 2011) [*USSQ study*]
  - Polaris
  - Inlay

*USSQ domain scores in each group with stent in situ and after stent removal*

Health Domain	Max Score	Inlay		Polaris		p Value
		No. Affected	Median Score (IQR)	No. Affected	Median Score (IQR)	
Urinary symptom:	55					
Stent in situ		43	32 (24–38)	52	32 (25–38)	0.7
Stent removed		42	19 (15–20)	51	18 (14–21)	0.79
Bodily pain:	70					
Stent in situ		40	26 (16–34)	50	28 (21–38)	0.28
Stent removed		16	15 (8–18)	23	16 (12–26)	0.05
General health:	28					
Stent in situ		45	14 (8–21)	53	16 (11–21)	0.14
Stent removed		42	9 (7–11)	53	10 (7–13)	0.44
Work performance:	15					
Stent in situ		29	7 (4–9)	28	7 (5–10)	0.6
Stent removed		25	5 (3–6)	25	5 (3–7)	0.32
Sexual performance:	10					
Stent in situ		13	4 (3–6)	11	3 (3–4)	0.06
Stent removed		26	3 (2–4)	23	3 (2–3)	0.32

– No significant differences on any domain

# Summary

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1. Mechanism of stent pain is unclear
2. Marketing is directed at getting you to believe that “soft” (silicone) equates to less pain/discomfort
3. Only direct comparison of polyurethane to silicone (Pryor 1991) showed no difference in sx's
4. When looking at the three studies that used USSQ to compare variety of different stents - essentially no substantial differences were seen.



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Thank you!



# Imajin vs. Percuflex

- Prospective RCT Imajin (Coloplast Porgès) vs Percuflex Plus (Boston Scientific) after flexible URS
- N=95 (45 vs 50)
- D20 USSQ Body pain score
  - Imajin: 17
  - Percuflex: 27
- Conclusion: Silicone Imajin® hydrocoated stent is better tolerated at 3-week indwell time.



## BUT

- No data presented on other USSQ domains
- Gender imbalance between groups
- No publication or further presentation of data since 2016 ??



- Quality of Life in Patients With Double Loop Ureteral Stent (JJ Silicone Hydrogel Study)

Study Type :Interventional (Clinical Trial)

Estimated Enrollment :140 participants

Allocation:Randomized

Intervention Model:Parallel Assignment

Masking:Single (Participant)

Primary Purpose:Treatment

Official Title:Effect of a Silicone Hydrocoated Double Loop Ureteral Stent on Symptoms and Quality of Life in Patients Undergoing F-URS for Kidney Stone; a Comparative Randomized Multicenter Clinical Study.

Study Start Date :September 2013

Estimated Primary Completion Date :December 2016

Estimated Study Completion Date :December 2016

- <https://clinicaltrials.gov/ct2/show/study/NCT02489656>



# Stent pain and discomfort

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## Stent length

- No association with flank pain
- Association with urinary frequency and urgency

Ho CH et al J Endo 2008

Al-Kandari AM et al J Endo 2007

- Trend increased sx's with longer stent length

Calvert RC et al BJU Int 2013 [USSQ]

- No assoc. between intravesical stent position and sx's.

Abt Det et al Korean J Urol [USSQ]



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# Stent pain and discomfort

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## Stent Diameter

- No difference in stent symptoms based on stent diameter

Erturk E et al J Endo 2003

Damiano R et al Eur Urol 2005 [USSQ]



# Comparative Trials

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- Lingeman (2009)
  - Short loop tail, Long loop tail, Polaris, Percuflex plus
  - No significant differences; slight advantage of short loop tail stents