

Sterilizasyon Teknolojisinde Yeni Bir Fiziksel Sınır

Patentli (No: TR2019 17785 B) Hidronyum İyonizasyonu ve Uzun Lümen Sterilizasyonunun Fiziksel Kimyasal Modeli Analizi

Hyggen akredite Laboratuvarları Destekli Teknik Rapor

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ÖZET

Minimal invaziv cerrahi ve fleksibl endoskopi sistemlerinin yaygınlaşması, sterilizasyon süreçlerinde geometrik limit problemini ortaya çıkarmıştır. Özellikle:

- \varnothing 1-2 mm çap
- 1-15+ metre uzunluk
- Kompleks iç yüzey yapıları difüzyon temelli düşük sıcaklıklı sterilizasyon yöntemlerinin fiziksel sınırlarını belirlemektedir.

Bu çalışma, $H_2O_2-O_3$ -DBD plazma kombinasyonuna dayalı hidronyum (H_3O^+) ve peroksizon (H_2O_4) oluşumu üzerinden:

- Reaktif üretim kinetiği
- Plazma ortam parametreleri
- Lümen içi taşınım mekanizmaları
- Biyolojik validasyon
- Materyal etkileşimi
- Kalıntı ve toksikoloji başlıklarını bütünlük olarak tanımlar.

Temel yaklaşım:

Sterilizasyon, pasif difüzyon değil; elektrik alan destekli reaktif taşınım ve faz kontrollü kimyasal üretim problemdir.



KEYLER

Peroksizon, DBD Plazma, Reaktif Taşınım, Difüzyon, Kinetik, İyonizasyon, Validasyon, Toksikoloji

1. GİRİŞ VE PROBLEM TANIMI

Fleksibl endoskoplar ve robotik cerrahi enstrümanları:

- Çok katmanlı yapı
- Heterojen yüzey enerjisi
- Uzun ve dar lümen geometri

nedeniyle klasik sterilizasyon modelleri için sınır durum oluşturur.

Difüzyon temelli gaz penetrasyonu:

- Mesafe ile eksponansiyel azalır
- Yüzey etkileşimleri ile enerji kaybeder
- Faz değişimi ile kesintiye uğrar

Bu durum özellikle uzun lümenlerde sterilite sürekliliğini sınırlar.

2. MEVCUT TEKNOLOJİLERİN FİZİKSEL LİMİTLERİ

2.1 Difüzyon Sınırlaması

Lümen boyunca konsantrasyon:

$$C(x) = C_0 e^{-kx}$$

- k: yüzey etkileşim katsayısı
- x: lümen uzunluğu

Sonuç:

- x arttıkça C(x) hızla azalır
- Belirli bir uzunluktan sonra etkisiz hale gelir

2.2 Yoğunlaşma (Condensation)

Gaz fazındaki H₂O₂:

- Duvar çarpışmaları ile enerji kaybeder
- Lokal sıcaklık/parsiyel basınç koşullarında sıvı faza geçer

Sonuç:

- Film oluşumu
- Akış kesilmesi
- İleri penetrasyonun durması

2.3 Gaz Tükenmesi (Depletion)

- Reaktifler lümen boyunca tüketilir
- Son noktalarda aktif tür konsantrasyonu düşer

2.4 Plazma Sistem Limitleri

- Radikaller kısa ömürlü
- Lokal üretim lokal etki
- Lümen boyunca sürdürülemez

2.5 Ozon Sistem Limitleri

- Yüksek oksidatif agresyon
- Kontrol zorluğu
- Materyal hasarı riski

Genel Sonuç

Aynı anda:

- Uzun penetrasyon
- Düşük sıcaklık
- Düşük hasar
- Düşük kalıntı sağlayan sistem bulunmamaktadır.

3. HİBRİT REAKTİF SİSTEM TANIMI

3.1 Sistem Bileşenleri

- H₂O₂: Prekürsör
- O₃: Oksidatif sürücü
- DBD plazma: Enerji kaynağı ve kontrol

3.2 Reaktif Türler

- H₃O⁺: İyonik taşıyıcı
- H₂O₄: Stabil oksidan
- OH: Yüksek reaktif radikal

3.3 Temel Taşınım Mekanizması

Klasik: $J = -D\nabla C$

Hibrit: $J = -D\nabla C + \mu CE$

- D: Difüzyon katsayısı
- μCE : Elektrik alan kaynaklı drift

4. PLAZMA FİZİĞİ

4.1 Operasyon Aralığı

- Basınç: 0.1 – 0.4 Pa
- Voltaj: ~6 kV
- Akım: ~20 mA
- Frekans: 50–100 Hz

4.2 Plazma Parametreleri

- Elektron yoğunluğu: $n_e \approx 10^{13} - 10^{15} \text{ m}^{-3}$
- Elektron sıcaklığı: $T_e \approx 1-3 \text{ eV}$

4.3 Debye Uzunluğu

$$\lambda_D = \sqrt{\frac{\epsilon_0 k T_e}{n_e e^2}}$$

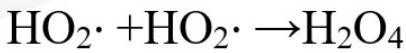
$\approx 10^{-4} - 10^{-3}$ m

Sonuç:

- $\lambda_D <$ lümen çapı
- Plazma hacimsel olarak kararlı
- İyonlar duvara çökmek yerine hacimde kalır

5. REAKSİYON KİNETİĞİ

5.1 Temel Reaksiyonlar



5.2 Diferansiyel Kinetik Model

$$\frac{d[OH]}{dt} = k_1[H_2O_2] + k_2[O_3] - k_3[OH]^2$$

$$\frac{d[H_3O^+]}{dt} = k_4[OH][H_2O] - k_5[recombination]$$

5.3 Faz Yönetimi

- Plasma ON: Radikal üretimi
- Plasma OFF: Stabil tür oluşumu

Bu yapı:

- Reaktif üretim kontrolü
- Radikal baskılama
- Stabil oksidan üretimi sağlar.

6. LÜMEN İÇİ TAŞINIM

6.1 Coulomb İtki

- Aynı yüklü iyonlar birbirini iter
- Merkezde yoğunlaşma oluşur

6.2 Akış Karakteri

- Duvar etkileşimi azalır
- Enerji kaybı düşer
- Jet benzeri akış oluşur

6.3 Sonuç

- Konsantrasyon kaybı minimize edilir
- Uzun mesafe taşınım mümkün hale gelir

7. VALİDASYON

7.1 Test Konfigürasyonu

- Lümen: 2 mm / 15 m
- Yük: full load
- BI: 10⁶ Geobacillus stearothermophilus
- Tek Döngü: 35dk



4.2.3 Positions and results of the microbiological indicators

bionova - biological indicator		
cfu / carrier [lg]	mean value [lg]	
Control 1-2	8,69/8,94	8,82

Wrapping* [yes / no]	sample No.	designation	cfu / carrier [lg]	Enrichment* [3 / 7 days]	lg / carrier	Reduction factor [lg]
upper basket						
yes	91	A	0	-/-	0	≥8,82
yes	99	E	0	-/-	0	≥8,82
yes	93	B	0	-/-	0	≥8,82
yes	95	C	0	-/-	0	≥8,82
yes	101	F	0	-/-	0	≥8,82
yes	97	D	0	-/-	0	≥8,82
middle basket						
yes	103	G	0	-/-	0	≥8,82
yes	105	H	0	-/-	0	≥8,82
yes	104	G	0	-/-	0	≥8,82
lower basket						
yes	94	B	0	-/-	0	≥8,82
yes	100	E	0	-/-	0	≥8,82
yes	92	A	0	-/-	0	≥8,82
yes	98	D	0	-/-	0	≥8,82
yes	102	F	0	-/-	0	≥8,82
yes	96	C	0	-/-	0	≥8,82

legend:

- RF = Reduction factor
- = no turbidity due to microbial growth
+ = turbidity due to microbial growth
n.z. = uncountable

- A = HygCen – white PTFE PCD / PCD 1 mm Ø 850 mm long
B = HygCen – white PTFE PCD / PCD 2 mm Ø 1200 mm long
C = Teknomar – Steel Lumen PCD / PCD 0,7 mm Ø 500 mm long
D = Teknomar – white PTFE PCD / PCD 0,4 mm Ø 900 mm long
E = Teknomar – white PTFE PCD / PCD 2 mm Ø 7500 mm long
F = Teknomar – white PTFE PCD / PCD 2 mm Ø 10000 mm long
G = Teknomar – white PTFE PCD / PCD 2 mm Ø 15000 mm long
H = Teknomar – white PTFE PCD / PCD 2 mm Ø 50000 mm long
I = polyester suture bionova / Geobacillus stearothermophilus. / in double tyvek

7.2 Sonular

- %100 inaktivasyon
- SAL = 10⁻⁶

7.3 İstatistik

- Tekrar sayısı ≥ 3
- Half-cycle doęrulama mevcut

8. MATERİYAL UYUMLULUęU

Test edilen:

- 316L
- PEEK
- Silikon

8.1 Gzlemler

- Mikro-pitting yok
- Pasivasyon korunmuş
- atlak oluřumu yok

8.2 Damage Index

$$DI = \alpha(\text{oxidation}) + \beta(\text{temperature}) + \gamma(\text{radical})$$

düşük DI

9. YÜZEY ANALİZİ (SEM)

- Yüzey topografyası deęişmemiş
- Mikroyapı stabil

10. KİMYASAL KALINTI (FTIR)

- LOD: 0.01 mg/m²
- ölçüm: < LOD

10.1 Dönüşüm Mekanizması

- H₂O₂: H₂O
- O₃: O₂

11. KONTROL ALGORİTMASI

Girdi Parametreleri

- Basınç
- Nem
- Gaz oranı
- Plazma duty

Hedef

Max:

- H₃O⁺
- H₂O₄

Min:

- Radikal
- Kalıntı

Döngü Yapısı

1. H₂O₂ yükleme
2. O₃ enjeksiyon
3. Plasma ON
4. Plasma OFF
5. Geri besleme

12. REKABET ANALİZİ

Parametre	Difüzyon Sistemleri	Hibrit Sistem
Taşınım	Difüzyon	Drift + difüzyon
Lümen	~1 m	15 m
Nem	Problem	Reaktif
Kontrol	Sınırlı	Aktif

13. EKONOMİK ETKİ

- Cihaz ömrü artışı
- Sarf maliyeti azalması
- Bakım ihtiyacı düşüşü

14. REGÜLASYON UYUMU

- MDR 2017/745
- ISO 14937
- ISO 11138
- ISO 10993

15. TOKSİKOLOJİ VE EMİSYON

- Kalıntı: tespit edilemez
- Emisyon: O₂ + H₂O
- Toksikite: non-toxic

16. SONUÇ

Bu çalışma:

- Sterilizasyonun difüzyon modeli ile sınırlı olmadığını
- Elektrik alan destekli reaktif taşınımın kritik olduğunu
- Uzun lümen sterilizasyonunun fiziksel olarak mümkün olduğunu tanımlar.

H₃O⁺ ve H₂O₄ temelli hibrit yaklaşım:

- Kontrollü kimya üretimi
- Düşük hasar
- Düşük kalıntı
- Uzun mesafe penetrasyonu özelliklerini birlikte sağlar.

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KAYNAKÇA

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