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ARCHIMEDES

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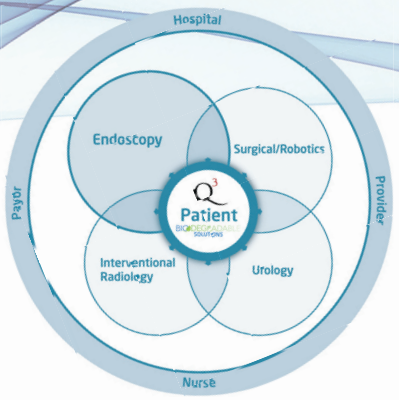


Clinical Evolution of ARCHIMEDES

BIODEGRADABLE SOLUTIONS

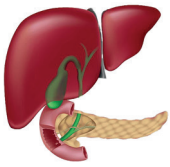
Biodegradable stents are safe and efficacious for biliary and pancreatic duct drainage.[1]

Novel bio-degradable stent in patients with biliary or pancreatic obstruction: a pilot study to assess clinical efficacy and safety.
Lakhtakia, S., Yaacob, N., Jarmin, R., Mohamed, Z., JasminRoslan, E., Othman, H., & NageshwarReddy, D. (2018).

FAST degrading stent	**12 days**
MEDIUM degrading stent	**20 days**
SLOW degrading stent	**11 weeks**

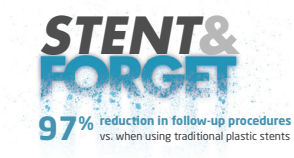
Biodegradation of the new biliary and pancreatic stents is reliable and in line with expected time.[2]

New biliary and pancreatic biodegradable stent placement: a single-center, prospective, pilot study (with video).
Anderloni, A., Fugazza, A., Maroni, L., Ormando, V., Maselli, R., Carrara, S., & Repici, A. (2020).



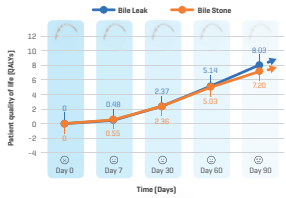
The major advantages of biodegradable stents is the avoidance of a second ERCP to retrieve the stent, the cost-benefit and less strain on the health care systems, aswell as the psychological reassurance for patients. time.[3]

A new biodegradable stent in bilio-pancreatic diseases: a prospective multi-center feasibility study.
Enrique Pérez-Cuadrado Robles, Sundeep Lakhtakia, Hairol Othman, Harsh Vardhan Tewethia, Nur Yaacob, Razman Jarmin, Zahiah Mohamed, Elsa Jasmin Roslan, Guillaume Perrod, Hédi Benosman, Christophe Cellier, Gabriel Rahmi, Nageshwar Reddy.



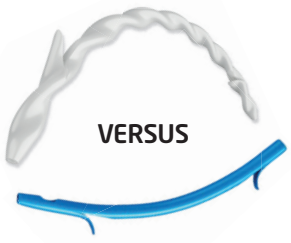
Follow up procedures were eliminated in 97% of cases.[4]

Biodegradable biliopancreatic stents could help conserve health care resources during the COVID-19 pandemic: An observational multicentre study.
Maieron, A., Erhart, L., Pramhofer, P., Schöfl, R., Spaun, G., Steiner, E., & Ziachehabi, A. (2023).



Biliary Biodegradable Stenting showed a 17 fold increase in quality adjusted life years.[5]

Utility of bio-degradable bile duct stents following pre-operative stone clearance and management of post-surgical bile leaks: Prospective, multicentre, observational cohort study (The Archimedes-BD study).
Suresh Vasan Venkatachalapathy, Martin W James, Deepak Joshi, Gavin Johnson, & Guruprasad P Aithal.
PUBLICATION SUBMITTED



Biodegradable stents are non-inferior to standard plastic stents and show a significant reduction in bilirubin levels.[6,7]

Plastic stents have complications rates as high as 30% where Biodegradable stents have less than 4%.[8,9]

Comparing Plastic vs Biodegradable Pancreatic Stents for the Prevention of Post Endoscopic Retrograde Cholangiopancreatography Pancreatitis: Preliminary Results of A Single-center Randomized Controlled Trial.
Carlos Robles-Medranda MD/FASGE/AGAF, Domenica Cunto MD, Maria Egas-Izquierdo MD, & Juan Alcivar-Vasquez MD.
ABSTRACT ACCEPTED AT DDW 24 AND ESGE 24 - PUBLICATION PENDING

Use of the Archimedes biodegradable stent at ERCP.
Siva Dwarampudi, Usama Al Farsi, John Devlin, Ashley Barnabas, Phil Harrison, David Reffitt, & Deepak Joshi.
ABSTRACT ACCEPTED AT DDW 24 AND ESGE 24 - PUBLICATION PENDING

Indomethacin alone was INFERIOR to the combination of Indomethacin plus prophylactic pancreatic stent.[10]

Indomethacin is not FDA approved for the prevention of Post-ERCP Pancreatitis.[11]

Indomethacin with or without prophylactic pancreatic stent placement to prevent pancreatitis after ERCP: a randomised non-inferiority trial.
Elmunzer, B.J., Foster, L. D., Serrano, J., Coté, G. A., Edmundowicz, S. A., Wani, S., & Waters, A. M. (2024).

The Skyrocketing Cost of Rectal Indomethacin.
B. Joseph Elmunzer, MD,MSc, Inmaculada Hernandez, PharmD,PhD, and Walid F. Gellad, MD,MPH.

Biodegradable Stenting showed an economic cost benefit saving ranging from £10- £3500+ per patient to healthcare systems.[5,12]

The cost implication of a care pathway using biodegradable pancreatic stents versus conventional plastic stents in the prevention of post-ERCP pancreatitis.
George Webster.
ABSTRACT ACCEPTED AT DDW 24 AND ESGE 24- PUBLICATION PENDING

EMAIL: info@q3medical.com
WEBSITE: www.q3medical.com

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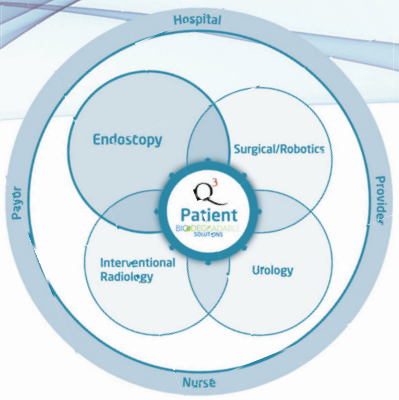

Clinical Evolution of ARCHIMEDES

BIODEGRADABLE SOLUTIONS

References:

1. Lakhtakia, S., Yaacob, N., Jarmin, R., Mohamed, Z., JasminRoslan, E., Othman, H., & NageshwarReddy, D. (2018). 339 Novel bio-degradable stent in patients with biliary or pancreatic obstruction: a pilot study to assess clinical efficacy and safety. Gastrointestinal Endoscopy, 87(6), AB71-AB72.
2. Anderloni, A., Fugazza, A., Maroni, L., Ormando, V., Maselli, R., Carrara, S., ... & Repici, A. (2020). New biliary and pancreatic biodegradable stent placement: a single-center, prospective, pilot study (with video). Gastrointestinal Endoscopy, 92(2), 405-411.
3. Robles, E. P. C., Lakhtakia, S., Othman, H., Tewethia, H. V., Yaacob, N., Jarmin, R., ... & Gabriel, R. (2022). A new biodegradable stent in bilio-pancreatic diseases: a prospective multi-center feasibility study. Revista espanola de enfermedades digestivas: organo oficial de la Sociedad Espanola de Patologia Digestiva, 114(9), 529-533.
4. Maieron, A., Erhart, L., Pramhofer, P., Schöfl, R., Spaun, G., Steiner, E., ... & Ziachehabi, A. (2023). Biodegradable biliopancreatic stents could help conserve health care resources during the COVID-19 pandemic: An observational multicenter study. Digestive and Liver Disease, 55(3), 310-315.
5. Suresh Vasan Venkatachalapathy, Martin W James, Deepak Joshi, Gavin Johnson, Simon Philpotts, Manu Nayar, Matthew Huggett, Danny Cheriyan, Christopher Clarke, Damilola Olajide, Aloysious D Aravinthan, Guruprasad P Aithal. Utility of bio-degradable bile duct stents following pre-operative stone clearance and management of post-surgical bile leaks: Prospective, multicentre, observational cohort study (The Archimedes-BD study).
6. Carlos Robles-Medranda MD/FASGE/AGAF1, Domenica Cunto MD1, Maria Egas-Izquierdo MD1, ... & Juan Alcivar-Vasquez MD1. Comparing Plastic vs Biodegradable Pancreatic Stents for the Prevention of Post Endoscopic Retrograde Cholangiopancreatography Pancreatitis: Preliminary Results of A Single-center Randomized Controlled Trial.
7. Siva Dwarampudi, Usama Al Farsi, John Devlin, Ashley Barnabas, Phil Harrison, David Reffitt, Deepak Joshi. Use of the Archimedes biodegradable stent at ERCP.
8. Pfau, P. R., Pleskow, D. K., Banerjee, S., Barth, B. A., Bhat, Y. M., Desilets, D. J., ... & Rodriguez, S. A. (2013). Pancreatic and biliary stents. Gastrointestinal endoscopy, 77(3), 319-327.
9. Q3 Medical Clinical Data on file.
10. Elmunzer, B. J., Foster, L. D., Serrano, J., Coté, G. A., Edmundowicz, S. A., Wani, S., ... & Waters, A. M. (2024). Indomethacin with or without prophylactic pancreatic stent placement to prevent pancreatitis after ERCP: a randomised non-inferiority trial. The Lancet.
11. Elmunzer, B. J., Hernandez, I., & Gellad, W. F. (2020). The skyrocketing cost of rectal indomethacin. JAMA internal medicine, 180 (5), 631-632.
12. George Webster. The cost implication of a care pathway using biodegradable pancreatic stents versus conventional plastic stents in the prevention of post-ERCP pancreatitis.

Limitation Statement:

The information compiled in the Clinical Evolution of the data related to the biodegradable technology has some possible limitations, as it was not an exhaustive search but one that details key early investigator-led studies, that confirmed findings represented by the company and its CE approval related to the attributes of the stent. The findings of the studies, individually or collectively, may need additional evaluation in the form of more rigorous analysis and further future studies around economics, as well as multi-centre randomized studies to further evaluate the biodegradable technology against the limitations of the current standard of care for plastic and metal implants that require a 2nd surgery for removal.

Items to include: We suggest that you divide your limitations section into three steps: (1) identify the study limitations; (2) explain how they impact your study in detail; and (3) propose a direction for future studies and present alternatives.

This document will look to add more clinical data and information, as biodegradable products are further studied and utilized. Whilst there are limitations to the information, we look to build more randomized clinical data to further show increased patient care, healthcare cost savings, sustainability benefits as well as hospital resources and waiting list improvements.

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