

Noninvasive Pacing

An Evidence-Based Approach to Clinical Claims

Some suppliers of external pacing devices continue to claim their devices have superior performance. It is important to evaluate these claims in light of the highest standards of clinical evidence:

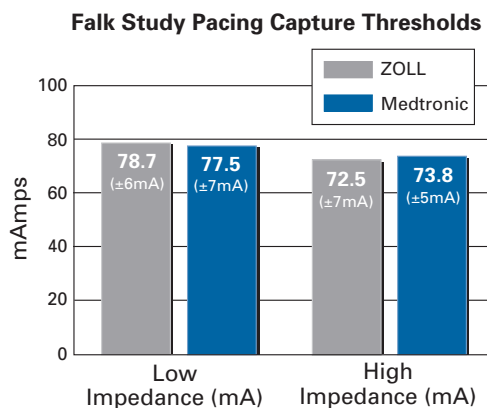
- Independent studies with prospective, randomized design
- Studies that match patients in each comparison arm by demographics and medical condition

It is also important to avoid cross-study comparisons involving disparate study designs and endpoints.

THE DEFINITIVE STUDY ON PACING EFFICACY

Medtronic devices use a pacing impulse duration of 20ms while ZOLL uses a pacing impulse duration of 40ms. A study by Falk et. al.¹ demonstrates there is no statistically significant difference between Medtronic and ZOLL pacing technologies in terms of capture thresholds, capture rates or pain. Falk concludes “there is no benefit in increasing the pacing impulse duration, at least >20 ms.”

This is the definitive clinical comparison of these pacing technologies—providing the highest level of clinical evidence available. It’s a head to head, randomized comparison with matched patient arms.



PATIENT COMFORT

Competing claims have also been made about differences in patient comfort associated with various pacing technologies. While addressing patient comfort, Falk states, “Both devices caused an equal amount of discomfort . . . suggesting that the difference in pacing impulse characteristics is of no clinical significance.”¹

Anecdotal evidence about potential differences in patient comfort was supplied in a 1988 court case by a former president of ZOLL. In that case, he testified under oath that he personally had been paced with a Medtronic device and a ZOLL device, that he could not “distinguish between the two machines,” and that “they were indistinguishable as to comfort.”²

THE MEDTRONIC POSITION

Medtronic remains committed to operating under the highest standards of evidence when educating and informing our customers. We believe clinical claims should be thoughtfully made in order to avoid overinterpretation. At this time there are no well-designed clinical studies that support any company’s claims of superior pacing technology.

1. Falk RH, Battinelli NJ, 1993. External cardiac pacing using low impedance electrodes suitable for defibrillation: a comparative blinded study. *J Am Coll Cardiol.*; 8: 1354–1358.

2. (W.D. WA 1988) ZMI Corporation v. Physio-Control Corporation, 1998. U.S. Dist. LEXIS 17280.

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