SUPPLEMENTARY MATERIALS

Investigating Titanium Fastener Technology – Results from the Multi-centre Prospective CRIMP Study

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CONSORT Checklist

Investigating Safety and Efficacy of Titanium Fastener Technology – Results from the Multi-centre Prospective CRIMP Study

1. Title & Abstract

X Randomized trial identified in title
→ not randomized, therefore not in title

X Structured abstract provided

2. Introduction

X Scientific background and rationale described

X Clear study objectives or hypotheses stated

3. Methods – Study Design

X Study design described (prospective, single-arm)

X Changes to methods after trial commencement documented→ none.

3. Methods – Participants

X Inclusion and exclusion criteria defined

X Recruitment settings and locations described

3. Methods – Interventions

X Interventions described in sufficient detail for replication

3. Methods – Outcomes

XPrimary and secondary outcomes clearly defined

X Any changes to outcomes after trial start documented → none

3. Methods – Randomization

☐ Sequence generation method described

☐ Allocation concealment mechanism explained

☐ Implementation of randomization described

Note: no randomization performed.

3. Methods – Blinding

☐ Who was blinded (participants, personnel, outcome assessors)

☐ Blinding procedure described

Note: No blinding performed.

3. Methods – Statistical methods

X Statistical methods fully described

X Handling of missing data explained

X Sample size / power calculation reported

4. Results – Participants

X Numbers randomized, treated, and analyzed reported

X Losses and exclusions with reasons described

4. Results – Recruitment

X Recruitment and follow-up periods stated

4. Results – Baseline data

X Baseline characteristics of groups provided

4. Results – Outcomes

X Results for each outcome reported per group

☐ Effect sizes and confidence intervals provided

Note: single-arm design precludes this.

4. Results – Harms

X Adverse events reported

5. Discussion

X Interpretation of results provided

X Study limitations discussed

X Generalizability addressed

X Comparison with existing literature included

6. Other information

X Trial registration number provided

X Protocol access stated

X Funding sources disclosed

X Conflicts of interest declared