Medtronic

Statistical Analysis Plan

Clinical Investigation Plan Title	Xpede Clinical study
Clinical Investigation Plan Version	version 3, 17 Sep 2018
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1. Version History

Version	Summary of Changes	Author(s)/Title
1.0	• First Release	Ester Tartaglione

2. List of Abbreviations and Definitions of Terms

Abbreviation	Definition
AE	Adverse Event
BKP	KyphoPlasty Baloon
CEC	Clinical Events Committee
FAS	Full Analysis Set
ICH	International Conference on Harmonization
ITT	Intention To Treat
NRS	Numeric Rating Scale
ODI	Oswestry Disability Index
OVCFs	Osteoporotic Vertebral Compression Fractures
PPS	Per Protocol Set
PMM	PolyMethylMetacrylate
SF36	36-Item Short Form Health Survey
VP	VertebroPlasty

3. Introduction

Osteoporotic vertebral compression fractures (OVCFs) have gradually evolved into a serious health care problem globally. In order to reduce the morbidity of OVCF patients and improve their life quality, two minimally invasive surgery procedures, vertebroplasty (VP) and balloon kyphoplasty (BKP), have been developed. Both VP and BKP require the injection of bone cement into the vertebrae of patients to stabilize fractured vertebra. As such, bone cement as the filling material plays an essential role in the effectiveness of these treatments. The study will randomize subjects into two arms the Xpede and the Mendec as comparative products. The Mendec Bone Cement has been launched on China Market and has very similar composition material with the Kyphon®Xpede and they are both polymethylmetacrylate (PMM). ™Bone Cement.

Due to these reasons the design of this study is a non-inferiority based on the margin δ as the maximum acceptable extent of clinical non-inferiority of Kyphon®Xpede™Bone Cement.

This SAP is based on Protocol Version 3, 17 Sep 2018 titled, "Xpede study". The SAP has been prepared in agreement with Medtronic internal procedures and using the CONSORT Statement[1] and International Conference on Harmonization (ICH) guidelines E3, E6 and E9 as guidelines.

4. Study Objectives

4.1. Primary Objective and Endpoint

The primary objective of this study is composed by two primary endpoints aimed to demonstrate that Kyphon®Xpede™Bone Cement is effective by showing that:

- the mean change of Numeric Rating Sore (NRS) score from baseline at 6 months post operation in the subjects treated with Kyphon®Xpede™Bone Cement is non-inferior to that in the subjects treated with Mendec Spine Bone Cement;
- the mean change of Index Vertebral Body Angles from baseline at 6 months in the subjects treated with Kyphon®Xpede™Bone Cement is non-inferior to that in the subjects treated with Mendec Spine Bone Cement.

4.2. Secondary Objectives and Endpoints

The secondary endpoints include:

- Change of NRS score from baseline at 1 day and 3-month visit
- Change of ODI from baseline at 1 day, 3-month visit and 6-month visit
- Change of SF-36 from baseline at 1 day, 3-month visit and 6-month visit
- Change of Vertebral body height restoration at 1 day and 3-month visit and 6-month visit
- Change of Vertebral body Angles from baseline at 1 day, 3-month visit and 6-month visit
- Adverse events through 6-month visit. In particular, the following events will be reported:
  - Bone Cement Implantation Syndrome;
  - Bone Cement leakage;
  - Vertebral body compression fracture;
  - Adjacent vertebral body fracture;

5. Investigation Plan

The Xpede Study is a prospective, 1: 1 randomized, single blinded, multi-center human clinical trial designed to confirm the safety and efficacy profile of the Kyphon®Xpede™Bone Cement for regulatory approval in China. This study will enroll up to 180 subjects in order to demonstrate that the Kyphon®Xpede™ Bone Cement is non-inferior to the Mendec Bone Cement by more than a small pre-specified amount in terms of the primary endpoint. This amount is defined as the noninferiority margin (see section 13 from Protocol for details). Subjects will be randomly assigned with a 1:1 ratio to the Kyphon®Xpede™ Bone Cement arm or to the Mendec Bone Cement arm and then followed for a duration of 6 months in all sites. All study sites will be in China. Total duration of the study is anticipated to be approximately 12 months (6 months of enrollments and 6 months follow-up after study procedure).
Patients will be randomized 1:1 to either Xpede™ Bone Cement or Mendec bone cement. The sequence of treatments will be randomly permuted in blocks of 2 or 4 patients per block. The

blocked randomization will be centralized and schedules will be created by the study statistician using statistical software. To minimize the selection bias, the randomization procedure for this study will use the site (3 sites), the number of vertebral to be treated (1,2 or 3) and the type of procedure (2 procedure: VP and BKP) as stratification factors, so that there will be a separate permuted block randomization list for each stratum (18). This guarantees treatment balance within strata.

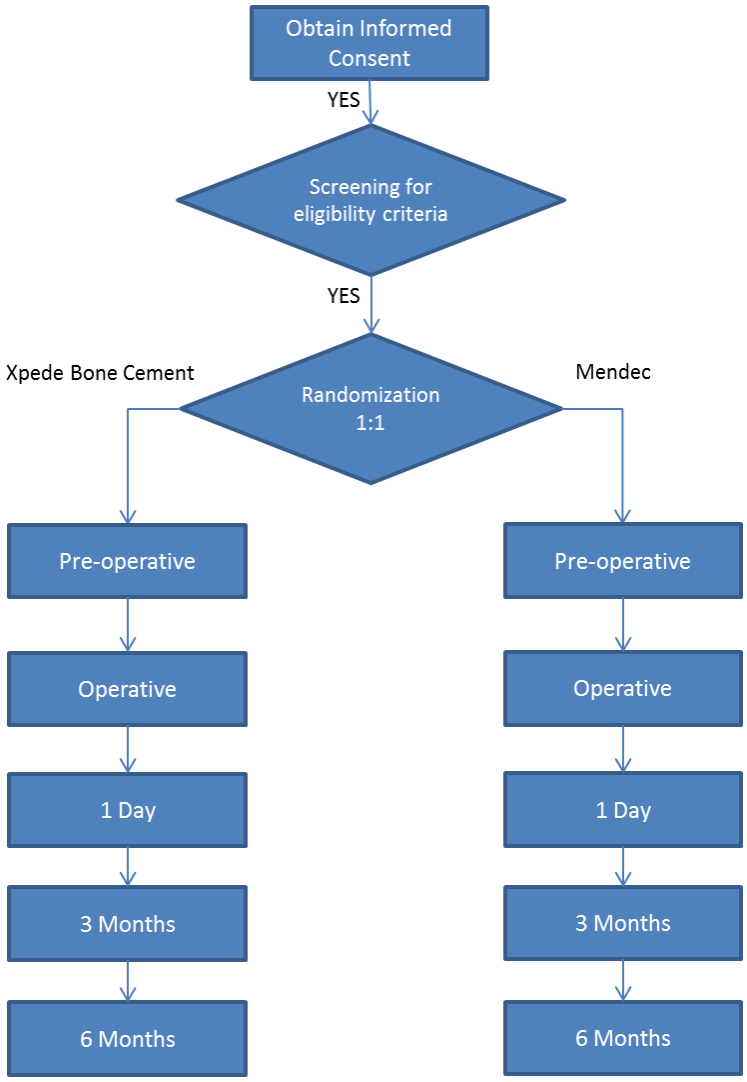


Figure 1: Study Flowchart

6. Determination of Sample Size

Since the primary endpoint is composed of two efficacy endpoints, the sample was determined by the primary objective that requires the larger sample size. For the determination of the sample size

for both endpoints the required power was 0.80, type I error 0.025. The sample size calculations were performed using SAS software (SAS Institute Inc., Cary, NC, USA). If we use 3 * 3 * 2 strata the final sample size should be divisible by 18. More detail in section 13.1.2 of the protocol.

6.1. Primary Endpoint on NRS

The following assumptions were used for the determination of the sample size for NRS non-inferiority hypothesis:

- The NRS score which ranges from 0 to 10 is assumed to be approximately normally distributed.
- The NRS score is to be assessed at 24 weeks (6 months) after the procedure.
- The NRS at 24 weeks (6 months) is expected to be 3.5 in the MENDEC Spine treatment, and 3.5 or more in the Xpede. A difference in NRS score of 1.5 or less is considered clinically unimportant for this comparison. It is considered the maximum acceptable increase in NRS score compared to the MENDEC Spine arm.
- The standard deviation of the NRS score is expected to be approximately 3.27 for each treatment. Common standard deviation will be assumed for both arms.
- The sample size should be sufficient to produce an 80% chance (power) of a significant result at a one-sided 0.025 significance level.

The non-inferiority hypothesis on the NRS requires 152 subjects and including 15% of potential loss-to-follow-up, the total sample size for the study will be 179 randomized subjects by 1:1 randomization schedule. Since there are strata, the sample size should be 180 to be divisible of 18 strata, i.e. 90 patients per arm. If we use 3 * 3 * 2 strata, the sample size should be 180 to be divisible of 18. Considering an average of 1.35 level per patient (FREE trial 72% with 1 level, 21% with 2 levels, 7% with 3 levels[2]), we should have around 243 levels treated in 180 patients.

6.2. Primary Endpoint on Vertebral Body Angles

The following assumptions were used for the determination of the sample size for VBA non-inferiority hypothesis:

- The Angulation is assumed to be approximately normally distributed.
- The Angulation is to be assessed at 24 weeks (6 months) after the procedure.
- The Angulation at 24 weeks (6 months) is expected to be 1.2 in the MENDEC Spine treatment, and 1.2 or more in the XPEDE. A difference in Angulation of 2.5 or less is considered clinically unimportant for this comparison (half standard deviation rule). It is considered the maximum acceptable increase in Angulation compared to the MENDEC Spine arm. Standard deviation of 5.0 at 1 month from CAFÉ study was conservatively used to derive the non-inferiority margin of 2.5.
- The standard deviation of the Angulation is expected to be approximately 5.6 for both arms. Standard deviation of 5.6 at 12 months from CAFÉ study[3] was conservatively used as the standard deviation for both arms.
- The sample size should be sufficient to produce an 80% chance (power) of a significant result at a one-sided 0.025 significance level.

The non-inferiority hypothesis on the Vertebral Body Augmentation assuming 20% of potential loss-to-follow-up, the total sample size for the study will be 148 randomized subjects by 1:1 randomization schedule. Since there are strata, the sample size should be 162 to be divisible of 18 strata, i.e. 81 patients per arm.

Since final sample size was determined to be 180 patients, i.e. 90 patients per arm.

7. Statistical Methods

7.1. Study Subjects

7.1.1. Disposition of Subjects

Disposition of subjects will be reported following the CONSORT flow Diagram[1]. Number of individuals at each stage of study (number of total assessed for eligibility, number enrolled, number analyzed and number with 1 Day post-operative follow-up, 3 months post-operative follow-up and 6 months post-operative follow-up) will be reported by randomization group. Reason for not participation at each stage will be reported where known.

Table 1.2 - Eligibility by Inclusion/Exclusion Criteria - All assessed for eligibility Subjects

Table 1.1 - Summary of Disposition - All Subjects

Figure 1.1.2 - Subject Enrollment Accrual by Site Overtime

Figure 1.1.1 - Flow diagram of Patient Disposition

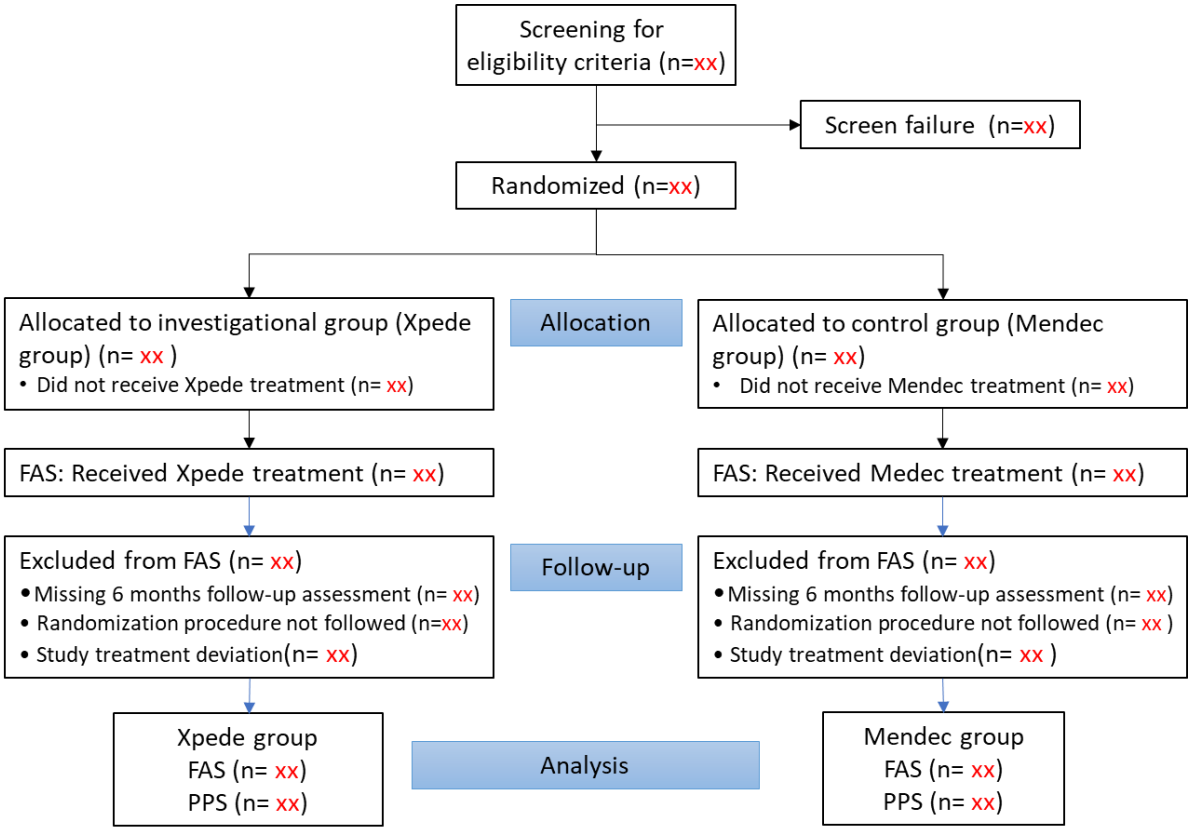


Figure 1.1.1 - Flow diagram of Patient Disposition

7.1.2. Clinical Investigation Plan (CIP) Deviations

All deviations will be collected in the case report form, with the type of the deviation and the reason for the deviation. All Deviations will be reviewed and classified by the clinical study team. Protocol deviation will be defined as major protocol deviation if the deviation impacts the primary objective, for example:

- Missing 6 months follow-up assessment (see table in section 9. 1 for CIP).
- Randomization procedure not followed
- Study treatment not done
- Study treatment deviation

The following tables will describe study deviations:

Table 3.3.1 - Summary of Protocol Deviation by Category

Table 3.3.2 - Summary of Protocol Deviation by Associated Visit

Listing 1 – Protocol deviations

7.1.3. Analysis Sets

The analysis will be performed according the Intention To Treat (ITT) principle and a Per Protocol Set will be used as deemed appropriate. The following subject sets will be used for the analysis respectively:

The ITT analysis will use the Full Analysis Set (FAS), which includes all patients enrolled in the study, signed the Informed Consent, were randomized and received the study treatment.

- The Per Protocol Set (PPS) includes all patients enrolled in the study that meet the inclusion/exclusion criteria with no major protocol deviation (see section 7.1.2) that could impact the clinic outcomes and have 6 months follow-up visits completed. The PPS will be used as secondary analysis.

  For those patients who drop out of the study, the analyses will include all data up to the point of their last data collection.

The table below shows which population should be used for each of the planned analysis.

Population set	Baseline assessment	Primary Endpoint	Secondary Endpoints	Safety
ITT	√	√	√	√*
PP	√	√		

*in case of patients enrolled but not randomized, a listing of all the adverse events occurred will be presented.

7.2. General Methodology

For FAS and PPS descriptive statistics will be used to summarize patient demographics and baseline characteristics. This will include mean, standard deviation, median and interquartile range, minimum and maximum for continuous variables, and counts and percentages for categorical variables. It is anticipated that SAS 9.4 (SAS Institute Inc., Cary, NC, USA) will be used to perform all statistical analyses. Analysis of endpoints based on comparisons between groups on continuous measurements will be performed by Student's t-test or non-parametric test (Mann–Whitney U test) for normal and non-normal distributions, respectively. Normality will be assessed by means of Shapiro-Wilks test and the p-value will be reported. Categorical variable parameter comparisons will be performed using a Chi-square test, or a Mantel-Haenszel test for trend for ordinal variables

with 3 or more categories. The randomization will ensure the two cohorts will be not different but they will be compared in terms of baseline characteristics to check possible confounding covariate. MMRM models will be used to analyze the primary endpoint, taking into account for multiple measures recorded per patient.

7.3. Center Pooling

The study is a multicenter trial and a multicenter impact on primary outcome will be investigated. A description on primary outcome by sites and a graphical representation of the proportions of safety events for each center will be provided.

7.4. Handling of Missing, Unused, and Spurious Data and Dropouts

Outliers and influential observations will be identified via graphical plots and according to study team decision the analysis could be repeated excluding potential outliers.

If the proportion of missing data is less than 10% of data, data will not need a multiple imputation. It is considered that the missing data mechanisms and the missing data patterns have greater impact on research results than does the proportion of missing data when lower than 10% on this sample. In case of missing data greater than 10% and a missing pattern at random, the imputation of missing data will be performed using the most appropriate method depending on the pattern of missing in the data and the type of the imputed variable. The outcome variable will not be imputed. After the imputation of the missing values the models will be rerun.

7.5. Adjustments for Multiple Comparisons

No adjustments for multiple comparisons or multiple look at data will be performed.

7.6. Demographic and Other Baseline Characteristics

Descriptive statistics by group will be used to summarize demographic and baseline characteristic variables for both FAS and PPS. This will include mean, standard deviation, median and interquartile range (IQR), minimum, and maximum for continuous variables, and counts and percentages for categorical variables. Demographic and Baseline variables will be collected through: Medical history, Demographic information, Physical Exam, MRI scan, Study Procedure, AP/Lateral X-ray, Concomitant specific medication, NRS, ODI SF36 questionnaire.

7.7. Treatment Characteristics

Duration of Study Exposure will be measured in days starting from the point of enrollment (informed consent completed and inclusion/exclusion criteria confirmed per the screening evaluation) through and including the time of study exit: Duration of study exposure (days) = (Study Exit date – date of enrollment). Extent of study exposure will be presented in a summary table and supporting data listing.

7.8. Interim Analyses

Interim analyses are not planned for this study.

7.9. Evaluation of Objectives

In this section a detailed information about each objective is included together with calculations and derivations of outcome parameters, analysis methods, datasets analyzed (FAS or PPS).

7.9.1. Primary Endpoint

The primary endpoint is composed by two co-primary endpoints and it is considered reached if both the two co-primary endpoints are met.

7.9.1.1. Primary Endpoint on NRS

The primary endpoint on NRS is the mean change of NRS score from baseline at 6 months post operation in subjects treated with Kyphon®Xpede™Bone Cement compared with subjects treated with Mendec Spine Bone Cement. It will be claimed that XPEDE is not inferior to MENDEC with respect to NRS score if the upper bound of the two-sided 95% confidence interval of the difference (Mean NRS in the XPEDE arm at 6 months - Mean NRS in the MENDEC arm at 6 months) < 1.5 (see an example in section 10.2).
Both change from baseline to 6 months (primary analysis) and absolute value at 6 months (sensitivity analysis) will be reported and analyzed.

7.9.1.2. Primary Endpoint on Vertebral Body Angles

The primary endpoint on Vertebral Body Angles (VBA) is the mean change of Index Vertebral Body Angles from baseline at 6 months in the subjects treated with Kyphon®Xpede™Bone Cement compared with subjects treated with Mendec Spine Bone Cement. It will be claimed that XPEDE is not inferior to MENDEC with respect to Vertebral Body Angles if the upper bound of the two-sided 95% confidence interval of the difference (Mean Vertebral Body Angles in the XPEDE arm at 6 months - Mean Vertebral Body Angles in the MENDEC arm at 6 months) < 2.5.
X-ray images will be reviewed by independent radiological reviewers who will be blinded to the subjects' treatment groups for each analysis. Adjudications provided both by the site and by the independent reviewers will be analyzed separately. Final conclusion will be made according to independent reviewer adjudication.
The analysis will be performed by means of Generalized Estimating Equation (or mixed models for repeated measures) using patient as the subject. The model will have the Index Vertebral Body Angles as dependent variables and baseline value, number of levels treated (as the multiple data points), type of procedure and arm as explanatory variables. All assumptions for regression models will be assessed by viewing plots of the residual values.
As sensitivity analysis, comparison will be also performed by t-test on:

1. the average value of VBA for the 3 separate treated levels;
2. the value of VBA for all the 3 pooled treated levels.

7.9.2. Secondary Endpoints

The secondary endpoints include:

- Change of NRS score from baseline at 1 day and 3-month visit
- Change of ODI (see section 10.3 for details) from baseline at 1 day, 3-month visit and 6-month visit
- Change of SF-36 (see section 10.3 for details) from baseline at 1 day, 3-month visit and 6-month visit
- Change of Vertebral body height restoration (see section 10.3 for calculation) at 1 day and 3-month visit and 6-month visit
- Change of Vertebral body angle from baseline at 1 day, 3-month visit and 6-month visit

The analysis will use multiple data points per patient (1 day, 3 months, 6 months). Assuming not completely independence among measures within same patient the analysis will be performed by means of Generalized Estimating Equation (or mixed models for repeated measures) using patient as the subject ID. The model will have the NRS, ODI, SF-36 (PCS, MCS), height restoration and angle as dependent variables (for each model) and baseline value, arm as explanatory variables. All assumptions for regression models will be assessed by viewing plots of the residual values. Potential confounders could be included in the model to adjust estimates.

7.10. Safety Evaluation

All adverse events are collected throughout the duration of this study, starting from the time of signing the Informe Consent through study closure. Adverse Events will be recorded and reported according to local regulatory requirements. The current version of MedDRA coding will be used.

The following summary tables and supporting data listings:

Table 3.1.2 – Adverse Events by System Organ Class and Preferred Term – FAS

Table 3.1.3 – Adverse Events by System Organ Class, Preferred Term and Relationship to Bone Cement – FAS

Listing 2- Adverse Event – FAS

Listing 3- Adverse Event leading to death – FAS

7.11. Health Outcomes Analyses

No health economic outcomes have been planned for this study.

7.12. Visit windows

The visit windows for this study were defined in the table below. The days should be counted from the day of the study procedure.

For endpoints which can be collected remotely and are filled by patient (e.g., NBS, SF-36, ODI questionnaires), follow-up visit should be performed as closely to the target day as possible (± 2 weeks are allowed for the last two follow up visits).

For the endpoints which require assessment on site and X-ray/MRI assessment (e.g., vertebral body angle and vertebral body height), the follow-up visits can be completed at any time during the visit window.

Visit name	Target day	Endpoints/assessments which can be done remotely	Endpoints/assessments which require on-site visit
Baseline and randomization	≤ Day 0		
Study Procedure	Day 0		
1 Day post-operative	Day 1	Day 1 – Day 7	Day 1 – Day 7
3 months postoperative	Day 90	Day 8 – Day 135	Day 8 – Day 135
6 months postoperative	Day 180	Day 136 – Day -365	Day 136 – Day 365

Note: In case of missing assessments within the visit windows, clinical judgment could lead to acceptance/rejection of some measurements out of windows.

7.13. Changes to Planned Analysis

The analysis described in the CIP could differ from that presented in this SAP due to data availability. Any deviation from the original statistical plan will be described and justified in the final report, as appropriate.

8. Validation Requirements

All collected data will be reviewed for completeness, correctness and consistency. In case of issues, queries will be sent to the investigator to complete, correct or comment the data. To ensure the quality of the results provided for the study in the form of tables, listings and figures, and the derived datasets the following processes are used:

- Statistical programming and analysis will be done by qualified programmer(s) and statistician(s) following applicable procedures and best practices.
- The derived datasets will be validated by a second programmer or statistician.
- The tables will be validated by a second programmer or statistician.
- Statistical results will be reviewed and confirmed by a second statistician.

The entire set of tables, listings, and figures (TLF) will be 100% checked for accuracy, completeness, and consistency prior to inclusion in the final clinical study report. Double programming will be implemented for both Datasets and TLFs.

9. References

1. http://www.consort-statement.org/
2. Jan Van Meirhaeghe, Leonard Bastian, Steven Boonen, Jonas Ranstam, John B. Tillman, Douglas Wardlaw, on behalf of the FREE investigators. A Randomized Trial of Balloon Kyphoplasty and Nonsurgical Management for Treating Acute Vertebral Compression Fractures. SPINE Volume 38, Number 12, pp 971–983. ©2013, Lippincott Williams & Wilkins
3. James Berenson, Robert Pflugmacher, Peter Jarzem, Jeffrey Zonder, Kenneth Schechtman, John B Tillman, Leonard Bastian, Talat Ashraf, Frank Vrionis, for the Cancer Patient Fracture Evaluation (CAFE) Investigators. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. Lancet Oncol 2011; 12: 225–35.

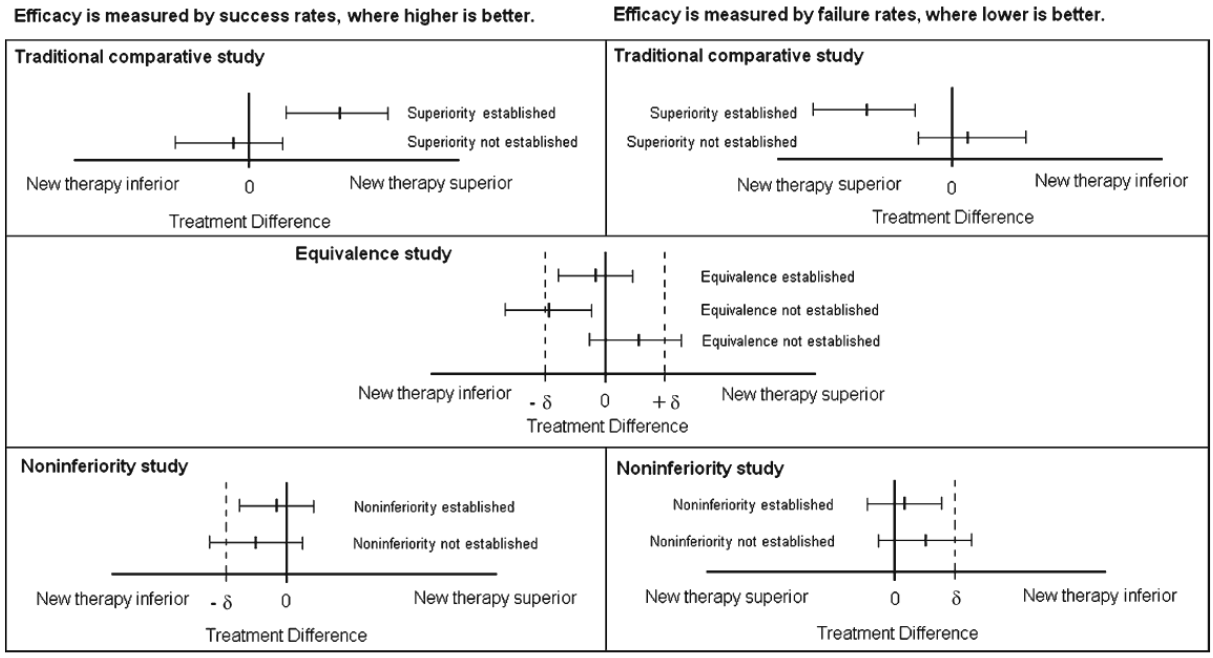
10. Statistical Appendices

10.1. Mock TLFs

Please refer to a separate TLF mock-up.

10.2. Graphical explanation for primary endpoint

The primary endpoint will be presented as the low box on the right of the example figure below:



10.3. Secondary Endpoint calculation

10.3.1. Vertebral Body Height Restoration

The vertebral body height restoration will be expressed as Absolute Height Restored (AHR) for anterior, mid and posterior defined as:

AHRa: $Ha_{\text{post-treatment}} - Ha_{\text{at treatment}}$: where the anterior (Ha) vertebral body height is measured in millimeters (mm)

AHRm: $Hm_{\text{post-treatment}} - Hm_{\text{at treatment}}$: where the mid (Hm) vertebral body height is measured in millimeters (mm)

AHRp: $Hp_{\text{post-treatment}} - Hp_{\text{at treatment}}$: where the posterior (Hp) vertebral body height is measured in millimeters (mm)

Note that *change from baseline treatment to post-treatment* will be calculated as the difference between post-treatment in treated level and the baseline treatment in nearest superior, adjacent, non-fractured level.

10.3.2. SF36

The SF-36 has eight scaled scores; the scores are weighted sums of the questions in each section. Scores range from 0 – 100, Lower scores = more disability, higher scores = less disability.

It is composed by the following sections:

- Vitality
- Physical functioning
- Bodily pain
- General health perceptions
- Physical role functioning
- Emotional role functioning
- Social role functioning
- Mental health

The following link gives guidance:
https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form/scoring.html

10.3.3. ODI

The Oswestry Disability Index (ODI) is one of the condition-specific questionnaires recommended for use with patients with back pain. It is composed by 10 section as follow:

Section 1: Pain Intensity
- I have no pain at the moment. [0 points]
- The pain is very mild at the moment. [1 point]
- The pain is moderate at the moment. [2 points]
- The pain is fairly severe at the moment. [3 points]
- The pain is very severe at the moment. [4 points]
- The pain is the worst imaginable at the moment. [5 points]

Section 2: Personal Care
- I can look after myself normally without causing extra pain. [0 points]
- I can look after myself normally but it is very painful. [1 point]
- It is painful to look after myself and I am slow and careful. [2 points]
- I need some help but manage most of my personal care. [3 points]
- I need help every day in most aspects of self care. [4 points]
- I do not get dressed, wash with difficulty and stay in bed. [5 points]

Section 3: Lifting
- I can lift heavy weights without extra pain. [0 points]
- I can lift heavy weights but it gives extra pain. [1 point]
- Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table. [2 points]
- Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned. [3 points]
- I can lift only very light weights. [4 points]
- I cannot lift or carry anything at all. [5 points]

Section 4: Walking
- Pain does not prevent me walking any distance. [0 points]
- Pain prevents me walking more than one mile. [1 point]
- Pain prevents me walking more than a quarter of a mile. [2 points]

- Pain prevents me walking more than 100 yards. [3 points]
- I can only walk using a stick or crutches. [4 points]
- I am in bed most of the time and have to crawl to the toilet. [5 points]

Section 5: Sitting

- I can sit in any chair as long as I like. [0 points]
- I can sit in my favourite chair as long as I like. [1 point]
- Pain prevents me from sitting for more than 1 hour. [2 points]
- Pain prevents me from sitting for more than half an hour. [3 points]
- Pain prevents me from sitting for more than 10 minutes. [4 points]
- Pain prevents me from sitting at all. [5 points]

Section 6: Standing

- I can stand as long as I want without extra pain. [0 points]
- I can stand as long as I want but it gives me extra pain. [1 point]
- Pain prevents me from standing for more than 1 hour. [2 points]
- Pain prevents me from standing for more than half an hour. [3 points]
- Pain prevents me from standing for more than 10 minutes. [4 points]
- Pain prevents me from standing at all. [5 points]

Section 7: Sleeping

- My sleep is never disturbed by pain. [0 points]
- My sleep is occasionally disturbed by pain. [1 point]
- Because of pain I have less than 6 hours sleep. [2 points]
- Because of pain I have less than 4 hours sleep. [3 points]
- Because of pain I have less than 2 hours sleep. [4 points]
- Pain prevents me from sleeping at all. [5 points]

Section 8: Sex Life (if applicable)

- My sex life is normal and causes no extra pain. [0 points]
- My sex life is normal but causes some extra pain. [1 point]
- My sex life is nearly normal but is very painful. [2 points]
- My sex life is severely restricted by pain. [3 points]
- My sex life is nearly absent because of pain. [4 points]
- Pain prevents any sex life at all. [5 points]

Section 9: Social Life

- My social life is normal and causes me no extra pain. [0 points]
- My social life is normal but increases the degree of pain. [1 point]
- Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc. [2 points]
- Pain has restricted my social life and I do not go out as often. [3 points]
- Pain has restricted social life to my home. [4 points]
- I have no social life because of pain. [5 points]

Section 10: Traveling

- I can travel anywhere without pain. [0 points]
- I can travel anywhere but it gives extra pain. [1 point]
- Pain is bad but I manage journeys over two hours. [2 points]
- Pain restricts me to journeys of less than one hour. [3 points]

- Pain restricts me to short necessary journeys under 30 minutes. [4 points]
- Pain prevents me from travelling except to receive treatment. [5 points]

Total score calculation:
Now, simply add up your points for each section and plug it in to the following formula in order to calculate your level of disability: point total / 5 X Number of question checked X 100 = % disability (aka: 'point total' divided by 50 multiply by 100 = percent disability).

Possible interpretation of the total score:

- 0% to 20% (minimal disability): Patients can cope with most activities of daily living. No treatment may be indicated except for suggestions on lifting, posture, physical fitness and diet. Patients with sedentary occupations (ex. secretaries) may experience more problems than others.
- 21%-40% (moderate disability): Patients may experience more pain and problems with sitting, lifting and standing. Travel and social life are more difficult. Patients may be off work. Personal care, sleeping and sexual activity may not be grossly affected. Conservative treatment may be sufficient.
- 41%-60% (severe disability): Pain is a primary problem for these patients, but they may also be experiencing significant problems in travel, personal care, social life, sexual activity and sleep. A detailed evaluation is appropriate.
- 61%-80% (crippled): Back pain has an impact on all aspects of daily living and work. Active treatment is required.
- 81%-100%: These patients may be bed bound or exaggerating their symptoms. Careful evaluation is recommended.