Rehabilitation programs after the implantation of transfemoral osseointegrated fixations for bone-anchored prostheses: A protocol for a scoping review

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Abstract
This scoping review aims to answer two research questions (1) What is the clinical indicators' intra-variability for both screw-type (Q1) and press-fit fixations (Q2)? (2)What is the clinical indicators' inter-variability between screw-type and press-fit fixations (Q3)? The objectives of this scoping review are therefore, to characterize the rehabilitation programs performed by individuals with transfemoral amputation following the implantation of an osseointegrated fixation for bone-anchored prostheses; to describe partial weight bearing exercises in each rehabilitation program for screw-type and press-fit fixations; and to compare key rehabilitation parameters for each of these exercises within each program for screw-type and press-fit fixations (intra-variability) as between programs for screw-type and press-fit fixations (inter-variability). This scoping review will consider studies involving individuals with transfemoral amputation fitted with a bone-anchored prosthesis using either screw-type or press-fit osseointegrated fixation. This scoping review will examine the concepts of intra-variability and inter-variability in clinical indicators of the rehabilitation programs for screw-type and press-fit fixations fitted to bone-anchored prosthesis of individuals with transfemoral amputation. This scoping review will consider studies providing broad and specific clinical elements underlying the rehabilitation program aiming at promoting bone remodeling around osseointegrated fixation. Also, this scoping review will consider studies relying on measurements conducted in different settings. This scoping review will consider a broad range of study designs in order to capture the concepts outlined above. The search strategy will aim to find both unpublished and published studies.

Keywords
Direct skeletal attachment; Osseointegrated fixation; Prosthesis; Rehabilitation program; Transfemoral amputation

Review question

The primary objective of this scoping review is to characterize rehabilitation programs performed by individuals with transfemoral amputation following the implantation of screw-type or press-fit osseointegrated fixations for bone-anchored prostheses.

The secondary objective of this review is to describe partial weight bearing exercises including static and dynamic exercises as well as use of walking aids in each rehabilitation program for screw-type and press-fit fixations.

The third objective of this review will be to compare key rehabilitation parameters for each of these partial weight bearing exercises (e.g., type of training prosthesis, loading time and progression, monitoring of loading, loading direction, instructions given to patients, the use of loading regulators) within each program for screw-type and press-fit fixations (intra-variability) as between programs for screw-type and press-fit fixations (inter-variability).

The specific review questions are:

- **Review Question 1:** What are the intra-variabilities within rehabilitation programs corresponding to the differences in rehabilitation parameters within programs for each screw-type (Q1) and press-fit (Q2) fixations?
- **Review Question 2:** What are the inter-variabilities between rehabilitation programs corresponding to the differences in rehabilitation parameters between programs for screw-type and press-fit fixations (Q3)?

Background

Prosthetic attachment: Shortcomings of current methods

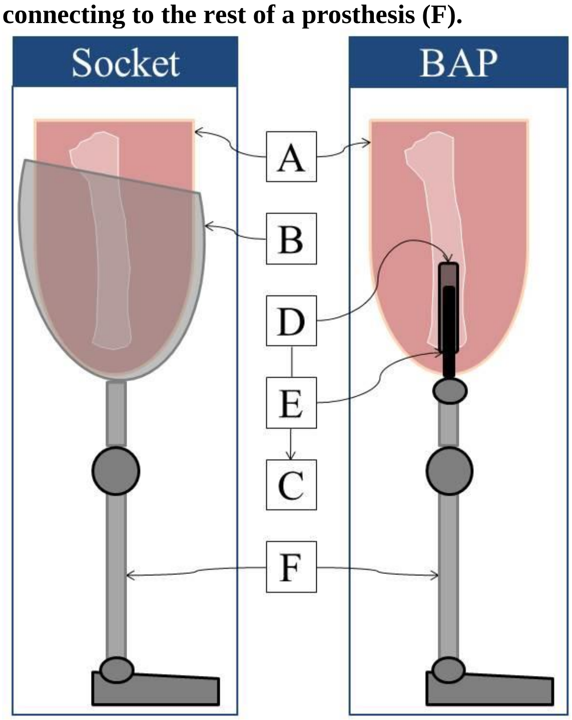
Typically, individuals with transfemoral amputation could be fitted with a socket suspended to the residual limb enabling attachment of prosthesis. This method of attachment often causes discomfort leading to a significant decrease in quality of life. The most frequent issues are related to the skin-socket interface (e.g., blisters, allergies), lack of trust in prosthesis due to insecure suspension (e.g., variation of residuum volume, excessive sweating), challenging attachment and detachment of the prosthesis as well as compromised sitting comfort.[1-7] Furthermore, individuals with particularly short residuum experience further challenges to achieve suspension that could limit mobility of the hip joint and use of their prosthesis, bounding them to a wheelchair.

Bone-anchored prosthesis: a solution

Problems with socket-suspended prostheses led to the development of, so-called, osseointegrated fixations for bone-anchored prosthesis.[8-26] This method of prosthetic attachment is now commonly accepted as a viable alternative to socket-suspended prostheses, particularly for young, active and nonvascular individuals with limb loss. Commercial osseointegrated fixations currently available include a medullar part directly connected to the femur, and a percutaneous part enabling external attachment of the prosthesis. Typically, both parts are surgically inserted following a two-step procedure.

Fixations with a medullar part relying on the screw-type design were initially developed. These cylindrical with threaded outlier fixations, inherited from dental implants, are screwed in the residual femur. They are the most common and acknowledged intervention (e.g., FDA approval for OPRA system).[18-21, 27-31] However, fixations with a medullar part relying on press-fit design have emerged over the last decade and they are increasingly used.[11-15, 32, 33] These fixations cylindrical with rough surface comparable to hip joint implants are hammered into the residual femur. Furthermore, several other devices are currently at various stages of development, particularly in Europe and the United States.[14, 16, 17, 22-25, 34-49]

Figure 1. Schematic representation of the residuum (A) of an individual with transfemoral amputation using conventional method of prosthetic attachment relying on socket (B) in contact with the skin (Left side) or bone-anchored prosthesis (BAP) relying on osseointegrated fixation (C) including a medullar part inserted into the femur (D) and percutaneous part (E) protruding the residuum (Right side) each connecting to the rest of a prosthesis (F).



Clinical outcomes: benefits overcoming harms

Level of evidence about clinical outcomes of bone-anchored prostheses varies between designs. Several cohort studies have focused on one or more particular clinical benefits (e.g., quality of life, prosthetic use, body image, hip range of motion, sitting comfort, ease of donning and doffing, osseoperception, walking ability).[15, 18, 21, 27, 28, 31, 32, 50-57] Other studies focused on specific harms (e.g., implant stability, rate of infection, effects of a fall).[15, 18, 30, 58-62] Altogether, the literature demonstrated that this method of attachment allows amputees to sustain extended daily activities.[53-55, 63-66] Overall, bone-anchored prostheses enhance markedly quality of life while presenting acceptable risks.

Previous reviews: research gap

To date, only a handfull of systematic reviews synthesizing descriptive information and/or quantitative data about bone-anchored prostheses are currently available.

Brånemark et al published a seminal article presenting historical developments of orthopedic osseointegration starting with the dental and facial implants, hearing aids and, finally, clinical applications for upper and lower prosthetic limb attachments.[19] Pitkin gave an overview of the design features of the different osseointegrated fixations previously implanted in humans or animal studies.[8] Kumar et al conducted a brief review study giving a general view about the osseoperception capability of osseointegrated fixations.[50, 67, 68] Isaacson and Jeyapalina presented a review introducing the basic biological principles for attaining osseointegration and discusses the major factors for assuring successful cementless fixations.[69] More recently, Van Eck et al performed the first attempt to systematically review clinical outcomes of bone-anchored prostheses and confirmed that this method of attachment can result in a good quality of life and patient reported outcomes.[57]

Need for a systematic comparative analysis of rehabilitation programs

By definition, the success of bone-anchored prostheses relates to surgical procedures and subsequent rehabilitation programs.[70-72] Typically, rehabilitation programs involve progressive mechanical loading aiming at promoting bone remodeling around the medullar part of the fixation.[73, 74]

These programs are guided by the principle that a timely application of a suitable stress stimulates bone remodeling and gradually prepares the bone-implant unit to tolerate the mechanical loading likely to occur during activities of daily living. [53-55, 60, 61, 63, 64, 73, 75-77]

Consequently, early overloading might place the bone-implant interface at risk while underloading might slow down osseointegration and delay unrestricted use of the prosthesis.

This balance is achieved by combining static and dynamic load bearing exercises as well as the use of walking aids that could be evidenced by several key rehabilitation parameters such as type of training prosthesis, loading time and progression, monitoring of loading, loading direction, instructions given to patients and the use of loading regulators.[64, 73-75, 78]

These generic guidelines are followed after implantation of all current commercial fixations. However, each type of medullar part requires a specific surgical procedure and subsequent rehabilitation program. Clinicians are, indeed, stating significant variations in programs for different types of fixations, particularly in terms of overall duration ranging from six weeks to six months and loading progression, ranging from quasi-immediate to careful and slow loading for press-fit and screw-type fixations, respectively.[27, 79-82]

A thorough exploration of these claims is essential to better comprehend potential differences in favorable (e.g., patient satisfactions, short term medical cost) and undesirable (e.g., infection, occurrence of periprosthetic factures, short and long term fixation stability, on-going medical costs) clinical outcomes between treatments. Ultimately, this understanding will have flow-on effects for patients in particular (e.g., choice for treatment, risk and benefits analyses) and, eventually, other decision makers (e.g., reimbursement policies, cost-effectiveness analyses).

Scoping review to explore rehabilitation programs

Surprisingly, typical systematic reviews and, eventually, a meta-analyses looking at the effect of rehabilitations programs on clinical outcomes (e.g., benefits, harms) are yet to be presented. This might be due to the lack of systematic differentiation of rehabilitation programs currently presented in the literature.

Consequently, there is a need for a comprehensive comparison of rehabilitation parameters of programs for both screw-type and press-fit fixations.Indeed, a scoping review characterizing rehabilitation programs with a systematic description of partial weight bearing exercises and comparison of key rehabilitation parameters for each of these exercises would be an initial step. Ultimately, such study could provide a shortlist of relevant rehabilitation parameters that should be considered as co-variables in future systematic reviews and meta-analyses.

Methods

Inclusion criteria

Participants

This scoping review will consider studies involving individuals with transfemoral amputation fitted with a bone-anchored prosthesis using either screw-type or press-fit osseointegrated fixation.

Concepts

This scoping review will examine the concepts of:

- Intra-variability within rehabilitation programs corresponding to the differences in rehabilitation parameters within programs for each screw-type and press-fit fixations,
- Inter-variability between rehabilitation programs corresponding to the differences in rehabilitation parameters between programs for screw-type and press-fit fixations.

Context

This scoping review will consider studies describing at least one parameter of a rehabilitation program aiming at promoting bone remodeling around screw-type and press-fit osseointegrated fixations such type of training prosthesis, loading time and progression, monitoring of loading, loading direction, instructions given to patients and the use of loading regulators. Also, this scoping review will consider studies relying on measurements conducted in care facilities (e.g., in or out-patient in rehabilitation centers), experimental settings (e.g., motion analysis laboratories) as well as participants' own environment (e.g., home).

Study types

This scoping review will consider a broad range of study designs in order to capture the concepts outlined above. Such designs will include:

- descriptive observational study designs including case series, individual case reports and descriptive cross-sectional studies,
- analytical observational studies including prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies,
- published articles but also book chapters, text and opinion papers as well abstracts provided for publication in conference proceedings.

We will also include narrative studies focusing on qualitative data including, but not limited to, designs such as phenomenology, grounded theory (e.g., bone remodeling), action research and basic qualitative description.

Search strategy

The search will be conducted by two reviewers. The search strategy will aim to find both unpublished and published studies in peer and non-peer reviewed sources. An initial limited search of Medline/Pubmed has been undertaken to identify articles on this topic, followed by analysis of the text words contained in the titles and abstracts, and of the index terms used to describe these articles.[8, 19, 57, 68, 69] This informed the development of a search strategy including identified keywords and index terms which will be tailored for each information source. Furthermore, individual search strategy will be done for each database following using specific descriptors. A full search strategy is detailed in Appendix 1. The reference list of all included studies will be screened for additional studies.

The databases to be searched include:

- Medline/PubMed
- CINAHL
- Web of Science
- Google Scholar
- EMBASE
- SCOPUS
- LILACS
- ProQuest Dissertations and Theses Global

Studies published in English, German, Dutch and French will be included giving the strong involvements of teams located in Lübeck (Germany) and Nijmegen (The Netherlands).

Only studies published since 1990 will be included corresponding to the year of first implantation of osseointegrated fixation to an individual with a lower limb amputation.[19] The upper date limits will be the date when the search will be conducted.

Data extraction

The data extracted will broadly include information about concept, context, and study methods of significance to the scoping review question and specific objectives of each reference (e.g, intra-variability and inter-variability of rehabilitation parameters).

As organized in the data extraction tool presented in Appendix II, the raw data extracted will describe the treatment (e.g., population, fixation, surgery) and, more importantly, the rehabilitation parameters specific to partial and full weight bearing exercises in each program. A strong emphasis will be put on extracting information about the type of training prosthesis, loading time, loading progression, monitoring of loading, loading direction, instructions given to patients and regulators during static load bearing exercises, as well as the type and duration of dynamic load bearing exercises alone and with walking aids.

Here, a dataset will correspond to the column of data in the data extraction tool including a series of information about a particular rehabilitation program provided within a single publication. It is more likely that a given publication will focus on limited aspects of a program creating incomplete dataset.[11-15, 18, 32, 33, 47, 49] Nonetheless, a publication detailing more than one program might generate several datasets.[27]

Two independent reviewers will complete the data extraction tool. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. Authors of papers might be contacted to request missing or additional data where required. The draft data extraction tool will be modified and revised as necessary during the process of extracting data from each study included. Modifications will be detailed in the full scoping review report.

Data mapping

All datasets collected using the data extraction tool will be collated into a single database enabling the recording, analysis and reporting of all critical information related to the review questions. First, the compiled information will be extracted and/or calculated from the raw data and will include, but not be limited to, the following rehabilitation parameters,

- Duration of each phase of the rehabilitation program (e.g., Static and dynamic load bearing exercises, use of walking aids)
- Use of regulators to establish load progression
- Load progression (e.g., loading increment over period of time)
- Monitoring of the load bearing exercises

Then, the compiled data will be grouped in relation to the type of fixation (i.e., screw-type, press-fit). Finally, the compiled data will be presented in diagrammatic or tabular form in a manner that aligns to the objective/s and scope of this scoping review. For instance, the tables and charts will report on intra-variability and inter-variability of rehabilitation parameters for both and between fixations, respectively. A narrative summary will accompany the tabulated and/or charted results and will describe how the results relate to the reviews objective and question/s.

To know more

Conflicts of interest

The authors have no conflict of interest to declare.

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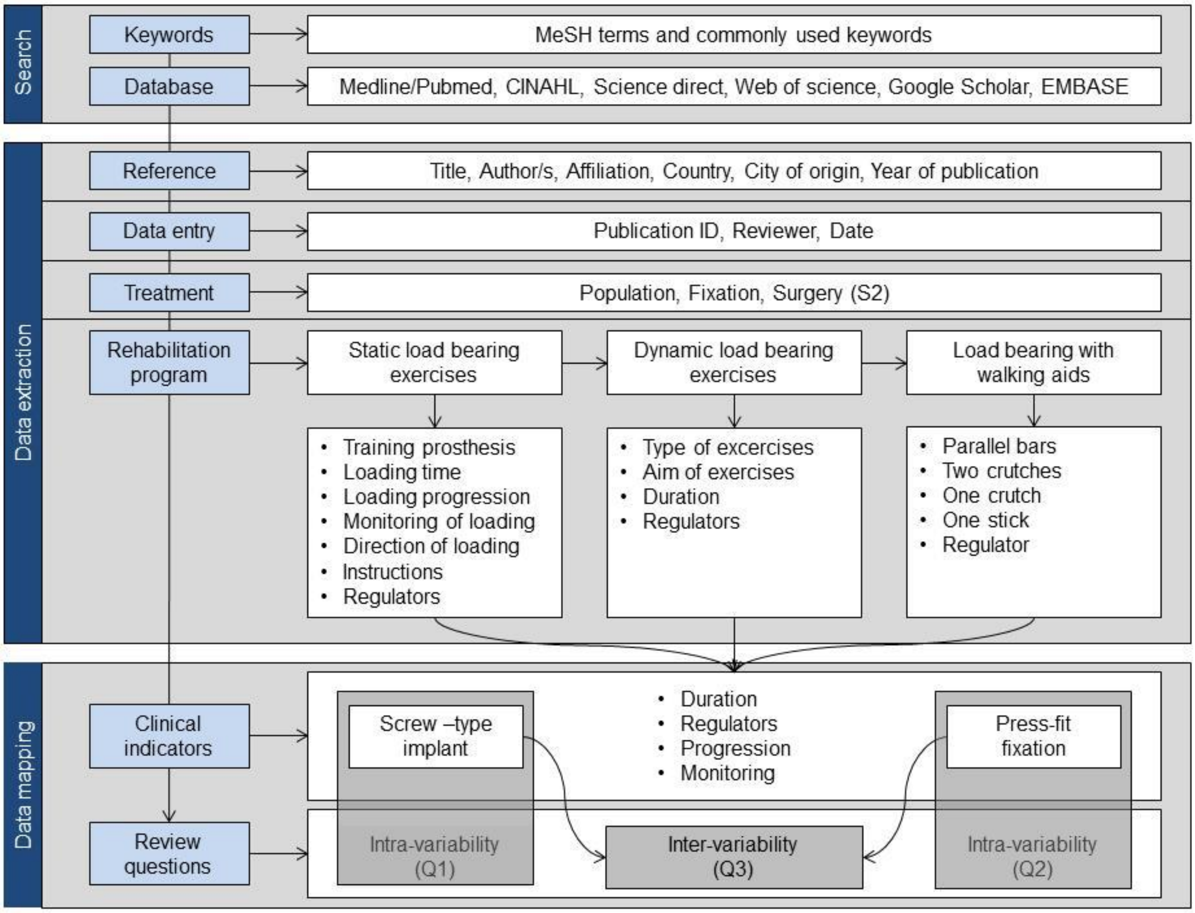
Figure 2. Overview of the search, data extraction, data mapping and review questions of the scoping review. S2: Second or final stage of surgery marking the beginning of rehabilitation program.



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Appendix I: Search Strategy

First, the search strategy to find relevant publications will rely on selection of databases to be searched including, Medline/Pubmed, CINAHL, Web of science, Google Scholar, EMBASE, SCOPUS, LILACS and ProQuest Dissertations and Theses Global.

Then, each database will be searched individually using relevant search syntaxes and combining key MeSH and other database-specific subject terms together with commonly used keywords provided in Table 1. Using these keywords will be paramount giving the proliferation of general terms referring to bone-anchored prosthesis and individual acronyms for each fixation.

Table 1. Key MeSH terms and commonly used keywords for key aspects of the treatment and rehabilitation program

MeSH terms	Commonly used keywords
Treatment - Population	
• Adolescent • Adult+ • Amputees • Humans	• Above-the-knee prosthesis • Individuals with transfemoral amputation • Limb prostheses • Prosthetic limb • Prosthetics • TFA • Transfemoral amputees • Transfemoral prosthesis • Unilateral amputation
Treatment - Fixation	
• Amputation • Amputation stumps • Osseointegration • Bone and bones • Lower extremity • Orthopedics • Prostheses and implants+ • Prosthesis failure • Reconstructive surgical procedures+ • Titanium	• BAP: Bone-anchorage/anchored prosthesis • Direct bone attachment • DSA: Direct skeletal attachment • EEFP: Endo-exo femoral prosthesis • Endo-exo prosthesis • ILP: Integral leg prosthesis • Implant supported prosthesis • Intramedullary attachment • Intraosseus fixation/implant/device • ITAP: Intraosseous transcutaneous amputation prosthesis • OGAAP: Osseointegration Group of Australia Accelerated Protocol • OIP: Osseointegrated (femoral) prosthesis • OPL : Osseointegrated prosthesis leg • OPRA: Osseointegrated Prosthesis for the Rehabilitation of Amputees • Osseointegrated percutaneous implant • Percutaneous fixation/implant/device • POP: Percutaneous osseointegrated prostheses • Press-fit • Prosthetic pylon • SBIP: Skin and Bone Integrated Pylon • Screw-type • Skeletal attachment • Skin-implant bone interface • Transcutaneous
Rehabilitation program	
• Canes • Crutches • Gait • Monitoring, ambulatory • Rehabilitation+ • Weight-bearing	• Dynamic load bearing exercises • Gait training • Load bearing • Monitoring device • Parallel bars • Partial weight bearing • Prosthetic gait • Prosthetic rehabilitation • Rehabilitation of amputees • Static load bearing exercises • Training prosthesis • Walking aids • Walking sticks

Appendix II: Draft study details, characteristics, and results extraction instrument/s
Data extraction instrument/s

Reference data extraction form

Full reference selected	Completion rate

Reference data and dataset			
Section	**Variables**	**Unit**	**Information**
1	**Data entry**		
1.1	Publication ID	(#)	
1.2	Reviewer	(txt)	
1.3	Date	(dd/mm/yyyy)	
2	**Reference**		
2.1	Title	(txt)	
2.2	Author/s	(txt)	
2.3	Affiliation	(txt)	
2.4	Country	(txt)	
2.5	City of origin	(txt)	
2.6	Year of publication	(txt)	
2.7	EndNote Nb	(txt)	
2.8	Dataset ID	(#)	
3	**Comments**		
3.1	Comment 01 - Aims of study	(txt)	
3.2	Comment 02 - Methodology/design	(txt)	
3.3	Comment 03 - Concept/intervention	(txt)	
3.4	Comment 04 - Key findings	(txt)	
4	**Treatment**		
4.1	Population		
4.1.1	Level of amputation	(txt)	
4.1.2	Causes of amputation	(txt)	
4.2	Fixation		
4.2.1	Type	(txt)	
4.2.2	Name	(txt)	
4.2.3	Brand	(txt)	
4.2.4	Dimensions	(cm)	

4.3	Surgery		
4.3.1	Number of surgical procedures	(#)	
5	**Rehabilitation program**		
5.1	Static load bearing exercises		
5.1.1	Training prosthesis		
5.1.1.1	Shape of distal end	(txt)	
5.1.1.2	Length	(txt)	
5.1.2	Loading time		
5.1.2.1	Nb of cessions	(#/d)	
5.1.2.2	Duration	(min/cession)	
5.1.2.3	Total duration	(min/d)	
5.1.3	Loading progression		
5.1.3.1	Elapse S1-S2	(wks)	
5.1.3.2	Start post S2	(wks)	
5.1.3.3	Starting load	(kg)	
5.1.3.4	Magnitude	(kg/wk)	
5.1.3.5	Application	(dd)	
5.1.3.6	End	(wks)	
5.1.4	Monitoring of loading		
5.1.4.1	Device	(txt)	
5.1.4.2	Apparatus	(txt)	
5.1.4.3	Height adjustment	(txt)	
5.1.4.4	Hand position	(txt)	
5.1.5	Direction of loading		
5.1.5.1	Axial	(Y/N/U)	
5.1.5.2	Rotation	(Y/N/U)	
5.1.6	Instructions to participants		
5.1.6.1	List	(txt)	
5.1.7	Regulators		
5.1.7.1	Pain	(Y/N/U)	
5.1.7.2	Monitoring	(txt)	
5.1.7.3	Threshold	(#)	
5.2	Dynamic load bearing exercises		
5.2.1	Type of exercises	(txt)	
5.2.2	Aim of exercises	(txt)	
5.2.3	Duration		
5.2.3.1	Start post S2	(wks)	
5.2.3.2	End	(wks)	
5.2.4	Regulators	(txt)	

5.3	Load bearing with walking aids		
5.3.0	Start - Time since last surgery	(wks)	
5.3.0	End - Time since last surgery	(wks)	
5.3.1	Parallel bars		
5.3.1.1	Use	(Y/N/U)	
5.3.1.2	Time after last surgery	(wks)	
5.3.2	Two crutches		
5.3.2.1	Use	(Y/N/U)	
5.3.2.2	Time after last surgery	(wks)	
5.3.3	One crutch		
5.3.3.1	Use	(Y/N/U)	
5.3.3.2	Time after last surgery	(wks)	
5.3.4	On stick		
5.3.4.1	Use	(Y/N/U)	
5.3.4.2	Time after last surgery	(wks)	
5.3.5	Regulator		
5.3.5.1	End based on X-Ray	(Y/N/U)	
6	**Appraisal**		
6.1	Source	(txt)	
6.2	Type	(txt)	
6.3	Outcome		
6.3.1	Reviewer 1	(txt)	
6.3.2	Reviewer 2	(txt)	
6.3.3	Reviewers	(txt)	