Challenges in Measuring Outcomes Following Digital Replantation

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Abstract

Keywords

- ▶ digital replantation
- ▶ outcome of replantation
- ▶ research design
- ▶ health-related quality of life instruments
- ▶ cost effectiveness

In the early period of replantation surgery, the emphasis was on digit survival. Subsequently, with better microsurgical techniques and instrumentation, the focus has shifted to function and in recent years to consideration of cost-effectiveness. Despite over 40 years of effort in refining digital replantation surgery, a rigorous evaluation of the outcomes of digital replantation has not been performed. This is because of the many confounding variables that influence outcome comparisons. These variables include the mechanism of injury (guillotine, crush, avulsion), the injury itself (total, near total, subtotal, partial amputation), and the surgical procedure (replantation, revascularization). In addition, the traditional outcome measures (two-point discrimination, range of motion, grip strength, or the ability to return to work) are reported inconsistently and vary widely among publications. All these factors make meaningful comparison of outcomes difficult. The recent emphasis on outcome research and cost-effectiveness necessitates a rethinking in the way we report outcomes of digital replantation. In this article, the authors summarize the challenges in assessing outcomes of digital replantation and explain the need to measure outcomes using rigorous clinical research designs that incorporate cost-effectiveness studies in the research protocol.

A right-handed 20-year-old construction worker sustained a crush amputation of his right middle finger at work. He has no other associated injuries and is in good health. He was seen at the hospital 1 hour after his injury and underwent a successful replantation procedure. He eventually developed a stiff insensate digit, which prevented him from returning to work. One year later and following two secondary procedures, much therapy, and use of significant health care resources, he still had not returned to work. Eventually, he underwent a ray amputation of the digit. Although the replantation was successful, it worsened the patient's existing function.

The common tendency to equate digit survival with success is erroneous. Success must be measured in terms of the contribution of the replanted digit to subsequent overall performance of the patient.¹ Mortality in digital replantation is rarely an issue, so the end result of the interventions should

be functional gain.² In the presented case, success is attained at the cost of the patient's functional outcome.

In today's consumer-driven medical environment, patients and payers demand reliable data that can help them make informed medical decisions that lead to cost-effective medical practices. The literature regarding digital replantation surgery is full of personal case series and anecdotal experience, which is no longer an acceptable platform for making medical decisions. Patients want more information not only about surgical outcomes and functional recovery, but also about the delivery of care, psychological and social well-being, and the aesthetic appearance.³ Outcomes research provides patients with this information. In this article, we will summarize the challenges in assessing outcomes of digital replantation and suggest measures to improve the reporting of outcomes.

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The Injury

An injury can either be a total amputation, which means total separation of the injured parts or a subtotal amputation that implies some residual connection of the amputated parts. A total amputation injury is always devascularized, whereas a subtotal amputation may have varying degrees of circulatory compromise (arterial, venous, or both). In addition, the degree of injury to the other tissue components (bone, extensor tendon, flexor tendon, nerve, and skin) can differ widely from one subtotal amputation to another. The survival and functional outcomes of subtotal amputations can therefore vary widely, depending on the degree of circulatory compromise and injury to other tissues. A lot of studies combine both total and subtotal amputations in their series, which makes it impossible to extract comparable outcomes.⁴⁻⁷ Biemer suggested classifying subtotal amputations into five subtypes based on the structures that remained intact (► **Table 1**).⁸ Although this approach is rational, it allows for more than 30 different combinations of injuries that add much more complexity in the functional assessments. An amputation can occur following a clean cut, a crushing, an avulsion, or any combination of these injury patterns. It is accepted that the immediate as well as late functional outcomes depends to a great extent on the mechanism of injury; however, there is no accepted classification or definition of what constitutes a specific injury. Although a clean-cut amputation or a pure avulsion-type injury is easily identified, there can be wide variability among different grades of crush injury. Some authors have attempted to categorize crush injury into mild, moderate, and severe crush; however this distinction is subjective.⁹ Other authors report actual mechanisms of injury like power saw, press machine, chain sprocket, etc.^{10,11} This makes comparing outcomes from different articles difficult.

The Operation

At the VIIth Symposium of the International Society of Reconstructive Microsurgery at Vienna in May 1979, replantation was defined as the procedure used for total amputation (no remaining connection with the body) and revascularization as a condition in which most of the functional structures are separated, but in which there is evidence of residual circulation that can only be improved by a vessel anastomosis.⁸ Kleinert et al defines replantation as restoration of a completely amputated part and revascularization as restoration of circulation to an

Table 1 Biemer's classification of subtotal amputations⁸ (according to the structures that remain intact)

Type	Structure intact
I	Bone connection
II	Extensor tendon connection
III	Flexor tendon connection
IV	Nerve connection
V	Skin or soft tissue connection

incompletely severed part that has lost circulation.¹² Although the definition of replantation is clear, the definition of revascularization is open to misinterpretation. Does restoration of circulation refer to restoration of only the arterial inflow, only the venous outflow, or both? The need for venous repair changes the outcome significantly. Some surgeons consider a near totally amputated digit that is held together only by nonvascular shreds of tissue (tendon, nerve, etc.) as a replantation because the surgical procedure needs both arterial and venous repair, and is almost akin to a replantation.¹³ However, depending on the structure (nerve, tendon, skin-bridge, etc.) that was holding the amputated part, the outcomes can vary significantly. A lot of studies report outcomes for replantation and revascularization together, making it difficult to extract outcome data separately.^{14,15}

The Outcome

The traditional outcome measures (sensation, range of motion, and grip/ pinch strength) vary widely among publications. For example, some authors report two-point discrimination (2-PD) for sensation,^{4,11} whereas others use monofilament testing. Ideally, both parameters should be measured, as they measure different aspects of sensation.^{5,13,16} The 2-PD measures sensory density, whereas monofilament testing measures sensory threshold. Similarly when describing range of motion (ROM), some use the specific ROM at a particular joint,¹⁷ whereas others use total active motion (TAM),¹⁸ which is the sum of the active arc of flexion at the interphalangeal and the metacarpophalangeal joints minus any extension deficit at these joints. To make comparison even more difficult, some report sensation, TAM, or ROM as a percentage of the opposite normal side.¹⁴ Yamano graded late results of fingertip amputations into good (no deformity, and no problems in daily living), fair (mild deformity, atrophy, sensory disturbance, and patient being able to use the fingers well), and poor (atrophy, sensory disturbance, and patient not being able to use the fingers well).¹⁹ The scoring system introduced by Susumu Tamai is useful in evaluating function after hand and digital replantation (► **Table 2**). It gives a numerical score (0-20) for motion, sensation, activities of daily living, subjective symptoms, patient satisfaction, and return to work (0-10).²⁰ However, there is no objective grading of complications like cold intolerance, paresthesia, nail deformities, and pulp atrophy. Chen's criteria for evaluation of late results of replantation¹ (► **Table 3**) are more suitable for upper limb replants proximal to the wrist rather than digital replants.

Improving Reporting of Outcomes of Digital Replantation

Standardize Injury Nomenclature

It is important to separate total amputations from subtotal amputations. This will automatically separate replantations from revascularizations and allow comparing outcomes from different centers. We also feel that the term "revascularization" should be reserved for subtotal amputations in which both arterial and venous repairs are required. If only an arterial repair is sufficient, it would be better to use the term "critical arterial repair" instead of revascularization. Rarely, only venous repair

Table 2 Tamai Functional Scoring System²⁰

Range of motion (0-40)			
Thumb (20)	Opposition: Possible (10); Difficult (5); Impossible (0)		
	Total ROM: >50% of normal (10); < 50% of normal (5); Stiff thumb (0)		
Fingers (20)	Total ROM: >151° (20); 111°-150° (15); 71°-110° (10); <70° (5); Stiff finger (0)		
Activities of daily living (0-20)			
Easy (1); Difficult (0.5); Impossible (0)			
Pushing	Power grasp	Washing face	Hammering
Tapping	Picking up a coin	Knotting	Using screw driver
Hanging or drawing	Picking up a needle	Buttoning	Using clothes pin
Grasping soft material	Wringing towel	Writing	Fumbling in pocket
Grasping hard material	Dipping up water	Scissoring	Showing scissor, paper, stone
Sensation (0-20) (British Medical Research Council Grading)			
S0 (0)	S2 (8)	S3+ (16)	
S1 (4)	S3 (12)	S4 (20)	
Subjective symptoms (0-20)			
Pain (rest or motion pain); cold intolerance; numbness, paresthesia, tightness, etc.			
Severe (-3); Moderate (-2); Mild (-1)			
Cosmesis (0-20)			
Atrophy, scar, color change, deformities (angulation, rotation, mallet, swan neck, buttonhole, etc.)			
Severe (-3); Moderate (-2); Mild (-1)			
Patient satisfaction (0-20)			
Highly satisfied (20); Fairly satisfied (15); Satisfied (10); Poorly satisfied (5); Not satisfied (0)			
Job status (0-10)			
Same job (0); Changed (-5); Cannot work (-10)			

may be required in subtotal amputations. In these selected situations, the correct term would be “critical venous repair.” We have summarized the different injury types and the respective surgical procedures in ►**Fig. 1**. We agree with Yamano's classification of the different mechanisms of injury¹⁹ and have modified it slightly (►**Table 4**). Such classification is easy to understand and eliminates the subjectivity involved in classification of crush amputations.

Objective Measures of Hand Function

Objective measures of hand function provide precise, quantifiable outcomes data. The commonly reported outcome measures in hand surgery include measurements for impairment of movement, sensibility, and power.^{3,21} The minimum parameters that are needed for objective assessment of hand function following replantation have been summarized in ►**Table 5**. To

obtain reliable and valid data, these measurements must be performed with calibrated instruments under strict protocols. One should wait for at least one year before measuring these parameters. This will ensure that recovery of sensation and motion, especially following any secondary surgery has reached a plateau and further improvement is unlikely. Some authors report the outcome of a digital replant as a partial success.²²⁻²⁵ Although this may be true in the early period, one has to report it as a success or a failure later on. These partial successes may have a higher incidence of complications like pulp atrophy and nail deformity, which should be reported. The ROM of a replanted digit is best measured by measuring total active motion. This takes into consideration any joints that were fused as a part of the replantation surgery, the ROM of the remaining joints, and flexor as well as extensor functions. When reporting complications, it is best to report it as being

Table 3 Chen's criteria for the evaluation of late results of replantation¹ based on analysis of four variables: (1) Ability to work, (2) range of joint motion, (3) recovery of sensibility, (4) muscular power

Grade	Function			
	Return to work	Range of Motion	Sensory Recovery	Motor Recovery
I	Resume original job	>60% of normal	Normal/ near normal	Grade 4/5
II	Resume suitable work	>40% of normal	Near normal	Grade 3/4
III	Activities of daily life	>30% of normal	Partial recovery	Grade 3
IV	Almost no function of survived limb

Fig. 1 Standardization of nomenclature.

present or absent. The terms “mild cold intolerance,” “slight pulp atrophy,” or “minimal nail deformity” are very subjective and add no value to the literature. It is also important to report outcomes for all patients or at least a majority of the patients. The usual practice is to report survival outcomes for all the patients and late follow-up outcomes for only a small percentage of the patients. The small numbers make statistical analysis of outcomes data unreliable.

Patient-Reported Measures of Hand Function

Patient-reported outcome measures such as patient satisfaction and health-related quality of life (HRQL) are being used increasingly to monitor patients over time, help select patients for surgery, determine the effects of surgical treatments, and assist in making policy decisions. They offer patients a means of evaluating and comparing options based on the perspectives of previous patients. The elements of patient satisfaction research include two measurable components: (1) patient satisfaction with the decision-making

process for surgery, and (2) patient satisfaction with the surgical outcome.³ Patients can appraise differently their satisfaction with the treatment outcome and the process by which they arrive at a treatment approach. The traditional components of HRQL include three main dimensions of health—physical, mental, and social well-being.²¹ HRQL measures have been used sparingly because surgeons are not accustomed to measuring outcomes in terms of HRQL.² In a review article, Guyatt et al teaches how to appraise articles appearing in the surgical literature where the outcome was measured with HRQL measures.²⁶

There are three broad types of HRQL questionnaires (general health, region specific, and disease specific). General health questionnaires have too broad a scope to be useful in hand surgery and are often used in combination with more region- or disease-specific instruments. They provide an assessment of general health and allow comparison of results across interventions. A disease-specific scale detects the minimum important difference in items specific to a disease

Table 4 Classification of different mechanisms of digital amputation

Mechanism	Description
Clean cut	It is caused by a narrow-edged sharp instrument. The wound edges are clean and minimal debridement is required.
Blunt cut	It is caused by a narrow-edged blunt instrument. The wound edges are jagged and show crushing, which extends to a very limited distance proximal and/or distal to the amputation. Moderate debridement is required.
Crush	It is caused by heavy blunt trauma. The wound edges are irregular and there is significant tissue injury that extends proximal and/or distal to the amputation. Extensive debridement is required.
Avulsion	It is caused by traction and the tissue is torn rather than cut. The separation of tissues (vessels, nerve, tendon, bone, skin) occurs at different levels and the overall tissue injury is diffuse. There is extensive and multilevel injury to the vessels, which usually requires resection and vein grafting. A degloving injury is a special type of avulsion amputation usually caused by a tight ring (ring avulsion amputation) that gets caught during motion. The skeletal and tendinous apparatus is preserved, whereas the surrounding soft tissue envelope is pulled off. Peripheral bony parts of varying lengths may be ripped off together with the tissue covering.
Combined	It is caused by a combination of crush, avulsion, or other mechanisms of injury. For example explosions, dog bites, etc.

Table 5 Recommended parameters for assessment of outcomes following digital replantation (all to be assessed at least one year after surgery)

Parameter	Outcomes
Survival	Failure/ Success
Arc of Motion	Total active motion (in degrees)
Sensation <ul style="list-style-type: none"> • 2-PD • SWF 	Mean of radial and ulnar 2-PD (in mm.) Measure at mid pulp
Grip strength	Level 2 Jamar (in kg). Report as a ratio (affected side / normal side)
Return to work	Same job/ different job/ no job
Complications <ul style="list-style-type: none"> • Pulp atrophy • Nail deformity • Cold intolerance 	Present/ absent Present/ absent Present/ absent

Abbreviations: 2-PD, two-point discrimination; SWF, Semmes Weinstein Monofilament Testing.

or condition. Some examples of general, region-specific, and disease-specific questionnaires that are relevant to hand surgery are summarized in ►Table 6.^{27–41} The Michigan Hand Outcomes Questionnaire and Disabilities of the Arm and Shoulder (DASH) Questionnaire have been found to be equally valid and reliable in assessment of patient reported outcomes after trauma.³ These questionnaires should ideally be administered at baseline and at various times after the intervention. It is better to choose time points that represent early, intermediate, and late benefits.² The outcome of a digital replant may require a follow-up of at least 1 year or longer.

Table 6 Health-related quality of life scales that can be used in digital replantation surgery³

General health questionnaires
Short Form-36 (SF-36) ²⁷
Nottingham Health Profile (NHP) ²⁸
Patient Satisfaction Questionnaires ²⁹
Sickness Impact Profile (SIP) ³⁰
Quality of Well Being (QWB) Scale ³¹
EuroQoL-5D ³²
Region-specific questionnaires
Michigan Hand Outcomes Questionnaire (MHQ) ³³
Disabilities of the Arm, Shoulder, and Hand (DASH) ³⁴
Upper Extremity Function Scale (UEFS) ³⁵
American Shoulder and Elbow Surgeon's Questionnaire ³⁶
Shoulder Pain and Disability Index ³⁷
Patient Evaluation Measure (PEM) ³⁸
Patient Related Wrist Evaluation (PRWE) ³⁹
Disease-specific questionnaires
Australian/Canadian Osteoarthritis Hand Index ⁴⁰
Carpal Tunnel Questionnaire (CTQ) ⁴¹

Economic Analysis

An economic analysis evaluates the health outcomes and resource costs of health interventions. Its central function is to show the relative value of alternative interventions for improving health.⁴² It is important to clearly define whether the study is being made from the financial perspective of the patient, provider, society, or health care system and to assess all types of costs, including direct, indirect, and intangible costs.⁴³ Economic consideration is an especially relevant outcome of hand surgery due to the frequency of workers' compensation claims. The financial costs of a traumatic digital amputation directly affect the individual, the local health care system, the employer, and society at large from lost work productivity.^{44,45} Emergency departments are having difficulty finding hand surgeons to cover digital replantations because of declining reimbursement, an increase in uninsured patients, and adversarial medicolegal environments.⁴⁶

There are four different types of economic evaluation: cost-minimization analysis, cost-effectiveness analysis, cost utility analysis, and cost-benefit analysis.⁴⁷ The definitions, metrics reported, advantages, and disadvantages of these four types of studies are listed in ►Table 7.^{47–50} Cost-effective analyses are playing a more substantial role in health care policy as payers are demanding information on how much benefit is derived from each health care dollar spent. Cost utility analyses, which are a form of cost-effectiveness analyses, allow the comparison of different health outcomes by evaluating them all in terms of a single unit. This single unit is called a quality adjusted life-year (QALY). The health units range from a 0 (death) to a 1 (perfect health). Interventions that result in a higher QALY per given dollar should be highly valued when allocating scarce health care resources.³ Health utilities are individual's preferences for specific health states or treatments. Several methods have been used to collect data on utilities, such as the standard gamble approach, the time trade-off approach, rating scales, and the willingness-to-pay approach. These health utilities are used as preference weights within the QALY model.⁵¹ Measurements of utilities help account for the indirect costs of a medical intervention, which range from loss of earnings, time to travel to the hospital, and "nonmarket" items, such as loss of lifestyle and leisure.⁵²

High-Quality Research Design

The hierarchy of the different research designs is shown in ►Fig. 2.² Although it is recommended that research be performed using study designs at the top of the hierarchy of evidence, most articles dealing with digital replantations consist of either case reports or case series and are at the lower end of the hierarchy of evidence. A randomized controlled trial design is not possible in digital replantation surgery because it would be unethical and unfeasible to randomize patients to replantation or revision amputation, as doing so would deny the patients the choice of a reconstructive procedure. The best study designs for studying outcomes in digital replantation could either be a prospective cohort study (level II), a systematic review of prospective cohort studies (level II), a retrospective observational study

Table 7 Types of economic analysis studies^{47–50}

Type	Characteristics	Parameter	Advantages	Disadvantages
Cost-minimization	Used when two or more interventions of equal effectiveness are being compared, but their costs are different	Cost	Easier to conduct than full cost-effectiveness analysis	Interventions must have equal effectiveness
Cost-effectiveness	Health outcomes are not valued but are reported in physical units such as life-years gained or cases successfully treated	Cost/ non-quality-adjusted outcome	May be quicker and easier to conduct than cost-utility analysis	Difficult to compare studies with varying outcomes; give little credit to interventions that primarily improve quality of life; fail to account for adverse effects
Cost utility	A type of cost-effectiveness study that typically measures health improvement in QALYs	Cost/ QALY	Useful when comparing alternative treatments that produce outcomes of different types; useful when increased survival is bought at the expense of reduced quality of life	May bias in favor of those individuals with potentially more years to live in a good health state
Cost benefit	Attaches a monetary value to the consequences (costs and effectiveness) of an intervention by asking health care consumers what they would be willing to pay for health services that achieve certain outcomes	Cost	Allows comparison of medical and nonmedical interventions (nonmedical interventions typically use cost-benefit); provides a more definitive endpoint than cost effectiveness	May show bias toward interventions for the rich (if they are more willing to pay than the poor); places a dollar value on human life

Abbreviations: QALY, quality adjusted life-year.

(level III), or a systematic review of retrospective observational studies (level III). There are no prospective cohort studies or high-quality systematic reviews of digital replantation in the literature. There are several retrospective obser-

vational studies; however, comparison of outcomes is difficult because of differences in the data reporting. The major limitation of observational studies is that the observed outcome may be caused by biases in the treatment allocation. Surgeons' recommendations and patients' decisions about submitting themselves to a particular intervention are often influenced by prognostic factors such as age, comorbid conditions, or injury characteristics.⁵³ When conducting an observational study, one should attempt to (1) prevent selection bias by ensuring that the comparison groups in an observational study are as similar as possible, except for the factors under study; (2) define the time horizon for measuring the outcome; and (3) account for all patients at the end of the study.²

It is good to follow the PICOT (Population/ Intervention/ Comparison/ Outcome/ Time Frame) format when trying to find outcomes from the literature.² It consists of the four essential steps outlined in ► **Table 8**. The following example illustrates this approach. While performing a distal digital replantation in a patient in whom a suitable vein could not be found in the amputated part, the resident assisting you asks which technique of venous drainage—no venous anastomosis, leeching, or pulp/nail bed bleeding—is superior. To answer this question, we could perform a literature search using PubMed. We use the PICOT approach to organize this question efficiently (► **Table 9**). We enter the keywords distal replantation and venous drainage from PICOT and set the limits to the past 10 years, humans, and English. The search yields six potentially relevant articles. We review these six articles, and one of the articles titled, "Fingertip Replantations: Importance of Venous Anastomosis and the Clinical Results"⁵⁴ seems to be addressing our question.

Fig. 2 Hierarchy of evidence of outcomes based on research design.

Table 8 Steps in finding the outcomes in the microsurgery literature²

Step	Description
Step 1	Ask a foreground question (i.e., a question that asks for specific knowledge about managing patients with a particular problem)
Step 2	The foreground question has five components (PICOT) <ol style="list-style-type: none"> 1. The Population studied 2. The novel Intervention 3. The Comparative intervention 4. The Outcome 5. Time frame for the outcome
Step 3	Search the literature by using filtered sources, and if the evidence is not found there, search for unfiltered sources
Step 4	Appraise the retrieved articles by asking three questions: <ol style="list-style-type: none"> 1. Is the study valid? 2. What are the results? 3. Can I apply them to my specific patient?

Table 9 Example of a foreground PICOT question²

Foreground question	In a patient undergoing distal digital replantation with no suitable veins, which alternative method of venous drainage (no venous anastomosis, pulp/ nail bed bleeding, leech) is superior?
Population	Patients who undergo distal digital replantation
Intervention	No venous repair; pulp/ nail bed bleeding; leech
Comparison	Venous repair
Outcome	Survival
Time frame	1 month

Surgery,⁵⁵ there are very few outcome studies concerning digital replantation. Most studies of digital replantation only have a level IV or Level V impact and more clinical trials are required to elevate the quality of the evidence. Future outcomes studies must also consider cost within studies so that the outcomes of digital replantation are considered in conjunction with economic burden on individuals and society.

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Conclusion

Clinical decision making in digital replantation surgery is influenced by many factors (► **Fig. 3**). Outcomes derived from best evidence are one of them.² Although Hand Surgery has embraced the outcomes movement and almost 2,236 outcomes related papers were published in the *Journal of Hand*

Fig. 3 Factors influencing clinical decision making in digital replantation.

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