

Clinical Finding Form (ClIFF)

Branch

Baseline

ICL29_Dental Crown Loss

Over 60% of all restorative dentistry involves the replacement of restorations. The most common reasons for crown replacement were crown fracture and tooth fracture, followed by esthetics and secondary caries. The UK Adult Dental Health Survey in 1998 identified people aged 45-54 as having the most crowns with nearly half of that age group having at least one crown. (Wilson et al, 2003). Dislodgement of crowns due to vibrations associated with the acceleration forces during launch have been reported by the Russian space program (Hodapp and Jeske, 2020). In the US Space Program, there has been one anecdotal, published report, of a dental crown displacement during the Shuttle era that was successfully treated with the onboard medical supplies (Hodapp and Jeske, 2020). It is recommended that on flights with less than 3 months remaining, if the tooth is asymptomatic after crown loss, that the crown be stored and replaced after landing. This is due to the risk of discomfort secondary to incorrect replacement as well as aspiration, should the crown become dislodged. On exploration missions lasting longer than 3 months, the protocol is to re-cement the crown with temporary cement. (Hodapp and Jeske, 2020)

INCIDENCE DATA INCLUDED IN THE MODEL

The model imports the following incidence information from the MEDPRAT Evidence Library Database: incidence data category, space adaption status, EVA status, incidence data type, incidence and occurrence distribution data and incidence data characteristics. Data category defines the type of data available for incidence calculations (i.e. raw data vs. adjusted data). Space adaptation identifies medical events that where onset occurs in the first 5-7 days of flight and does not reoccur. EVA-related incidence values identify medical events that occur only during an EVA. Incidence values types vary by data category and define the number of medical events per person-year (rates) or medical events per person at-risk (proportion) for each medical condition. Incidence values can be modified by crew characteristics such as gender sex and certain crew medical history characteristics. Modifying characteristics are noted below and incidence values are listed individually for each characteristic. Distributions are assigned to medical events incidence values and occurrences in the model. For each crewmember in a given trial, the incidence and number of occurrences of each medical condition are randomly selected from these probability distributions. Detailed descriptions of the distributions are included in the MEDPRAT Technical Description Document.

INCIDENCE DATA

SPACEFLIGHT LITERATURE

An uncited occurrence of one temporary crown displacement during the Shuttle era, that was appropriately treated using onboard medical supplies, was published in Principles of Clinical Medicine for Space Flight, pg. 863 (Hodapp and Jeske, 2020).

ANALOG LITERATURE

These data were not used to inform the incidence for this ClIFF. Richardson, 2005 reviewed the dental morbidity experienced by U.K. Armed Forces serving in Iraq from deployment on Operation Telic in January 2003 until the end of phase 1 on May 1, 2003. U.K. Armed Forces dental teams treated 1800 emergency patients, including 135 prisoners of war. A total of 1523 of these were regular troops and 101 were reservists or Royal Fleet Auxiliary troops. This gave morbidity rates of 148 cases per 1,000 personnel per year for the Royal Navy/Royal Marines and 160 cases per 1,000 per year for the Army. Lost restorations and fractured teeth were by far the most common problems experienced, followed by pericoronitis, pulpitis, and periapical pathological conditions. Both the rates of morbidity and the types of problems experienced were very similar to those reported by other nations in previous conflicts. Lost/loose/fractured post crowns accounted for 1.7% (n 24) of total dental emergencies. Richardson estimated morbidity rate 148 cases per 1000 person-year Royal Navy and marines; 160 cases per 1000 person-year in the army, which is 0.148 and 0.16 per person-year respectively. Roberts et al, 1999 is a systematic literature review of papers that analyzed after-action reports of dental morbidity from conflict, deployments, and field training exercises in the US military between 1961 and 1998. The incidence of crown loss in this study was 0.00382 per person-year. The active duty military population included in this study is likely similar to the astronaut population in age and overall health, however the military diet and spaceflight diet differ. The incidence of crown-related morbidity from this study was calculated using field training exercise data only because it was the only activity that had crown-related problems as a separate category of dental emergency. Notably, this study spanned the years 1961-1998 and dental advancements are expected to have occurred since the onset of the study that may affect the present-day incidence of dental crown loss.

TERRESTRIAL LITERATURE

These data were not used to inform the incidence for this ClIFF. The incidence of crown loss in terrestrial literature is approximately 2-6 times higher than that of the analog literature. This is likely due to dental screening and access to care in analog populations that more closely approximates the astronaut population, as well as comorbidities and higher ages of participants in the terrestrial literature. The terrestrial literature also focuses on determining superiority or non-inferiority between different types or crown materials, which may skew the incidence values. Goodacre et al, 2003 presents a systematic literature review of papers from the US, Sweden, and Hong Kong that analyzed many complications associated with single crowns, fixed partial dentures, and other restoration methodologies. It presents a dental crown loss incidence of 0.083 per person-year. This is likely an overestimate due to one included study having a disproportionately high incidence with study period of 20 years. Choi et al, 2017 presents a multicenter retrospective cohort study of patients comparing the retention of single crowns and fixed/splinted dental prosthetics. They report an incidence of dental crown loss of 0.0107 per person-year. The patient population was notably older than the astronaut population and suffered from a higher rate of chronic disease (approximately 1/4 had hypertension and/or diabetes mellitus). Schwarz, 2012 presents a prospective observational study of patients who received single implant-supported crowns that were followed for up to 5.8 years for implant survival. This article identified crowns that suffered loss of retention out of 232 single crowns placed. A major limitation of this study was that

it did not describe the population demographics. Menon, 2012 is a retrospective review of PubMed, LSAH data, medical records, and flight surgeon recollection and indicates 1 pre-flight dental crown displacement. Hodapp and Jeske, 2020 describe a published account of a crown displacement in-flight during the shuttle era that was successfully temporarily repaired with onboard medical capabilities.

OVERALL INCIDENCE SUMMARY

INCIDENCE

Mean 0.01639
SD 0.0163

INCIDENCE SUMMARY

The incidence for this CLIFF is based on a published case of 1 dental crown loss in NASA history, in-flight in a shuttle era flier (Hodapp and Jeske, 2020). Person-years is calculated for all NASA fliers through June 6, 2021. Person-years of flight is 120.5613. IR 1.637E-2 (95%CI: 0.08192E-2, 8.075E-2). The distribution is a Bayesian posterior distribution for the incidence rate given the spaceflight data (1 event over 61.07871 person-years of flight) under an uninformative prior is Gamma(shape=1.0111, rate=61.688) with mean 0.01639 and SD 0.0163.

TABLE 1. INCIDENCE MODEL

Incidence Details

Incidence Type

General

Segment

All

Env. Exposure

NA

Sex

Any

Crowns

No

Contacts

Any

Pregnancy

Any

Incidence Distribution

Occurrence Dist

Poisson

Incidence Dist.

Gamma

Mean

0.0163905

SD

0.0163003

Gamma

(Shape): 1.0111

(Rate): 61.688

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Richardson, 2005	Analog	3
Roberts et al, 1999	Analog	2
Goodacre et al, 2003	Terrestrial	1
Choi et al, 2017	Terrestrial	2
Schwarz et al, 2012	Terrestrial	1

Citation	Source	LOC Value
Menon, 2012	Spaceflight	4
Hodapp and Jeske, 2020	Spaceflight	4

Richardson, 2005 is a retrospective review of medical records of UK sailors, marines, and soldiers from the Middle East theater who received dental treatment over a 3 month span. The active duty military population included in this study is likely similar to the astronaut population in age and overall health, however likely had a different diet than the spaceflight diet. Roberts et al, 1999 is a systematic literature review of papers that analyzed after-action reports of dental morbidity from conflict, deployments, and field training exercises in the US military between 1961 and 1998. The active duty military population included in this study is likely similar to the astronaut population in age and overall healthy, however likely had a different diet than the spaceflight diet. The time-frame of this study decreased confidence in its applicability to the current astronaut population as dental implant methods and materials have likely changed since the 1960s. Goodacre et al, 2003 is a systematic literature review of papers from the US, Sweden, and Hong Kong that analyzed many complications associated with single crowns, fixed partial dentures, and other restoration methodologies. It most likely overestimates the total incidence due to one included article with a high incidence and long study duration (20 years). Choi et al, 2017 is a multicenter retrospective cohort study of patients comparing the retention of single crowns and fixed/splinted dental prosthetics. The patient population was older than the astronaut population and suffered from a higher rate of chronic disease (approximately 1/4 had hypertension and/or diabetes mellitus). Schwarz, 2012 is a prospective observational study of patients who received single implant-supported crowns and were followed for up to 5.8 years for implant survival. This article identified crowns that suffered loss of retention out of 232 single crowns placed. A major limitation of this study is that it does not describe the population demographics. Menon, 2012 is a retrospective review of PubMed, LSAH data, medical records, and flight surgeon recollection and indicates 1 pre-flight dental crown displacement. Hodapp and Jeske, 2020 describe a published account of a crown displacement in-flight during the shuttle era that was successfully temporarily repaired with onboard medical capabilities.

CREWMEMBER SELECTION/PREVENTION

DISQUALIFYING CONDITIONS

Refer to Medical Evaluation Documents (MED) Volume A, Medical Standards for ISS Crewmembers, International Space Station Program, Rev 3.4 (2016).

PREFLIGHT PREVENTATIVE MEASURES

Crewmembers undergo dental screening examinations at the time of selection and comprehensive annual dental examinations and cleanings. At 6 months before launch crewmembers additionally undergo a complete dental examination. If treatment is deemed necessary, all such treatment is completed 3 months before launch. All astronauts are expected to maintain optimal physical and oral health and to follow oral hygiene practices (Hodapp and Jeske, 2020).

BEST CASE SCENARIO DEFINITION

Loss of crown requiring no intervention (tooth with prior root canal), or recementing (non-root canaled tooth).

WORSE CASE SCENARIO DEFINITION

Loss of dental crown due to underlying decaying tooth fracture that requires tooth extraction.

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

None

BEST CASE/WORST CASE PROBABILITY COMMENTS

Schwarz, 2012 presents a prospective observational study of patients who received single implant-supported crowns (either ceramic or metal) that were followed for up to 5.8 years for implant survival. This article identified crowns that suffered loss of retention out of 232 single crowns placed. 27 crowns in the study failed during the study period. 17 of these 27 were fixed with semi-permanent cement following loss of retention (62.96%), which matches the best-case scenario criteria for this condition. Therefore, the best-case scenario probability was assigned at 62.96% and the worst-case scenario probability was assigned at 37.04%.

TABLE 3. BEST/WORST CASE PROBABILITY LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Schwarz, 2012	Terrestrial	3

Schwarz, 2012 presents a prospective observational study of patients who received single implant-supported crowns that were followed for up to 5.8 years for implant survival. This article identified crowns that suffered loss of retention out of 232 single crowns placed. 27 crowns in the study failed during the study period. 17 of these 27 were fixed with semi-permanent cement following loss of retention (62.96%).

TABLE 4. CLIFF TREATMENT & OUTCOME TABLE BY CLINICAL PHASE

Case Scenario	Composite Incidence	Condition Probability %	CP1: Diagnosis		CP2: Treatment			CP3: Condition End State				
			TI%	Duration	TI%	Duration		TI%	RTDC	LOCL		
			Preset	Preset	Preset	Min	Max	Preset	Min%	Max%	Min%	Max%
Treated Best Case (TBC)	Mean 0.01639 SD 0.0163	62.96 - 62.96	100	1	0	0	48	0	0	0	0	0
Treated Worst Case (TWC)		37.04 - 37.04	100	1.35	19.0938	1	72	0	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	1	9.11507	0	35040	9.11507	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	1.35	38.1876	1	52560	38.1876	0	0	0	0

TABLE 4 KEY

Composite Incidence: The same composite incidence will be used for both TBC and TWC. For EVA conditions: events per EVA (events/EVA). For space adaptation conditions: events per person (events/person). For non-spaceflight conditions: events per person year (events/py).

Condition Probability: The probability that CLIFF condition progresses to a worst case scenario. Best case scenario: 100%-Worst Case.

Clinical Phase General Comments:

- TI% = Task Impairment %. Task Impairment is the % of tasks that the crewmember is incapable of performing without impairment secondary to the medical condition.
- Durations are defined in hours.
- Removal to Definitive Care (RTDC): The probability the entire crew aborts the mission and returns to earth. This is considered as a condition end state result if any of the following criteria are met: 1) the potential for LOCL, 2) potential for significant permanent task impairment, or 3) potential for intractable pain.
- Loss of Crew Life (LOCL): The probability of death of affected crewmember due to medical condition.

Clinical Phase 1: Initial Assessment and Diagnosis:

- Covers only the initial assessment and diagnosis of the affected crewmember to define his or her medical condition. While the affected crewmember is being assessed, he or she is not able to perform any assigned tasks, thus Task Impairment (TI) during this phase is considered 100%. In the untreated case, there is no diagnosis performed, therefore Task Impairment and Duration will always be " not applicable."

Clinical Phase 2: Stabilization, Treatment, and Convalescence:

- The affected crewmember is receiving any appropriate initial or follow-on treatment for his or her medical condition to allow the crewmember to recover as much as he or she is able to recover in the spaceflight environment. Clinical phase 2 also encompasses relapses or recurrences of the same original medical condition in Clinical Phase 1. The duration of Clinical Phase 2 is expressed as minimum and maximum hours.

Clinical Phase 3: Condition End State:

- Reached once the affected crewmember has recovered from the medical condition as much as he or she is able to recover in the spaceflight environment amongst treated and untreated best and worst case scenarios. This may or may not be recovery from the given medical condition to the full extent possible. If this "recovered" state results in Removal to Definitive Care (RTDC) or Loss of Crew Life (LOCL) this will be noted in the condition end state results.

SCENARIO OVERVIEW COMMENTS

RTDC and LOCL were assumed to be 0% for this CLIFF. No RTDC surrogate was assigned, but dental crown aspiration was considered as a cause of RTDC and found to be negligible. See specific comments for each scenario below.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Based on the best-case scenario definition, the minimal duration of clinical phase 2 is expected to be zero as no intervention would be administered following crown loss. There is a paucity of data on the expected maximum duration to recement a lost crown. It is a very common procedure, but has limited documentation regarding best practice guidelines or procedure duration (Faggion, 2008). The ISS Medical Checklist describes the method to recement a lost crown, but does not estimate the time to complete the procedure (NASA ISS Medical Checklist, 2014). Based on the previous CLIFF duration estimates and the Medical Checklist procedure, astronauts would likely accomplish the recementing within one hour. Patients may experience dental sensitivity or mild pain for up to 48 hours following recementing requiring ibuprofen or acetaminophen for treatment. Therefore the best-case treated scenario duration was set at 0-48 hours. It should be noted that if ground communications are available, the duration would be anticipated to be longer due to interaction with the ground Flight Surgeon and Dentist to assist with treatment planning. RTDC was pre-determined to have a probability of 0% by the ExMC Clinical and Science Team for both the best and worst-case scenarios. However, one of the concerns with re-cementing a crown in spaceflight is aspiration. Susini et al, 2007, in a French study of aspiration events during root canal treatments, experienced a rate of hospitalization from crown aspiration or ingestion of approximately 0.014 hospitalizations/100,000 root canals and no fatalities. All aspiration events required hospitalization for bronchoscopy. Notably root canals are a much more complicated procedure with more tools being used, so this is likely an overestimate of aspiration during crown recementing, but the real concern is aspiration of a dislodged crown after improper placement in-flight. Regardless, applying this rate to an individual event, the incidence of hospitalization due to crown aspiration or ingestion is negligible based on these data, confirming the suspected RTDC probability of 0%. LOCL was also assigned a probability of 0% based on no fatalities secondary to ingestion or aspiration of dental crowns (Susini et al, 2007). Note that Susini et al was located during the RTDC search. No LOCL searches were performed for this condition due to an assumption on the part of the student effort data collection that LOCL would not occur for Dental Crown Loss. This is a significant limitation of this CLIFF.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

The ISS Medical Checklist describes the procedure to perform a simple tooth extraction including an alveolar block. The shortest duration of clinical phase 2 is approximately 1 hour to perform the dental extraction based on an estimation of the time necessary to follow the guidelines as described in the Medical Checklist. Yao, 2017 reported that >90% of all simple extractions in their study were performed in less than one hour. Post-extraction, pain typically peaks approximately 4 hours after the procedure. Al-Khateeb, 2008 reported that 80% of patients experienced pain approximately 4 hours after simple extraction (mean rating 3-4/10) which decreased to 40% reporting pain (mean rating 1-2/10) by post-procedure day 3. Therefore, the duration was assigned as 1-72 hours. It should be noted that if ground communications are available, the duration would be anticipated to be longer due to interaction with the ground Flight Surgeon and Dentist to assist with treatment planning. RTDC was pre-determined by the Clinical & Science Team of ExMC to be 0%. LOCL was assigned a probability of 0% based on no fatalities secondary to ingestion or aspiration of dental crowns during dental root canal procedures in France (Susini et al, 2007). Note that Susini et al was located during the RTDC search. No LOCL searches were performed for this condition due to an assumption on the part of the student effort data collection that LOCL would not occur for Dental Crown Loss. This is a significant limitation of this CLIFF.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

The best-case scenario definition for dental crown loss is either a dental crown loss requiring no intervention (prior root canal) or recementing (no prior root canal). This makes the duration difficult. If circumstances where no intervention is necessary, the lower bound for this duration is 0 hours. The upper bound is informed based on a dental crown loss from a tooth that has not had a root canal. Crowns placed in the absence of a root canal are typically placed to protect a damaged, fractured tooth (but can also be done for cosmetic reasons). If the pulp chamber is breached, then a root canal is indicated. Therefore, this scenario will use WHO classifications "Enamel" and "Uncomplicated Crown Fracture" as surrogates for crown loss in a non-root canaled tooth as surrogates for the duration. Ajayi et al, 2010 performed a cross-sectional study of children with permanent teeth anterior fractures in Nigeria and recorded the World Health Organization classification of the fracture and the length of time from fracture to dental examination. 180 children sustained WHO Classification "Enamel Fractures" and "Uncomplicated Crown Fractures" (Fractures involving enamel and dentin structures only but not the pulp). The maximum duration of time from dental fracture to dental consultation for any of these children was "greater than 6 years", represented by 7% of these children. The majority, however, (70%) had a maximum duration of 4 years, so 4 years (35040 hours) will be assigned as the maximum duration for the untreated best-case scenario based on this article. RTDC was pre-determined by the Clinical & Science Team of ExMC to be 0%. The LOCL probability was assigned as 0%. No LOCL searches were performed for this condition due to an assumption on the part of the student effort data collection that LOCL would not occur for Dental Crown Loss. This is a significant limitation of this CLIFF. It is anticipated that an untreated best-case dental crown loss could progress to pulpitis (ICL#31) or dental abscess (ICL#28) and then the LOCL would be driven by those conditions. However, infection could also occur, which could result in a deep space infection, which are known to be life-threatening. This is an underestimation of LOCL.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

There is a paucity of data regarding untreated dental crown loss. The minimum duration was assigned as 1 hour, accounting for the time to stow

the lost crown, rinse the affected area, and perform dental hygiene and/or dental examination. Since the WC definition is "Loss of dental crown due to underlying decaying tooth fracture that requires tooth extraction," a complicated crown fracture (of the natural tooth, not a prosthetic crown) is a reasonable surrogate to use for duration in the untreated scenario (i.e. if the crown is lost and can't be replaced, the underlying status of the tooth is fractured). Ajayi et al, 2010 performed a cross-sectional study of children with permanent teeth anterior fractures in Nigeria and recorded the World Health Organization classification of the fracture and the length of time from fracture to dental examination. 22 children sustained WHO Classification "Complicated Crown Fractures" (A fracture involving enamel and dentin, and exposing the pulp). The maximum duration of time from dental fracture to dental consultation for any of these children was 6 years. Therefore, a maximum duration of 6 years (52560) will be assigned to the untreated worst-case scenario. RTDC was pre-determined by the Clinical & Science Team of ExMC to be 0%. The LOCL probability was assigned as 0%. No LOCL searches were performed for this condition due to an assumption on the part of the student effort data collection that LOCL would not occur for Dental Crown Loss. This is a significant limitation of this CLIFF. It is anticipated that an untreated worst-case dental crown loss could progress to pulpitis (ICL#31) or dental abscess (ICL#28) and then the LOCL would be driven by those conditions. However, infection could also occur, which could result in a deep space infection, which are known to be life-threatening. This is an underestimation of LOCL.

TABLE 5. CLINICAL PHASE II DURATION LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
NASA ISS Medical Checklist, 2014	Spaceflight	3
Faggion, 2008	Terrestrial	
Hersh et al, 2011	Terrestrial	
Al-Khateeb and Alnahr, 2008	Terrestrial	
Yao et al, 2017	Terrestrial	
Ajayi et al, 2010	Terrestrial	

The durations for treatment of the treated scenarios are based on the ISS Medical Checklist instructions for dental crown recementation or tooth extraction (NASA ISS Medical Checklist, 2014), and literature regarding pain related to dental crown loss. Notably, the ISS Medical Checklist does not explicitly state treatment times, but length of treatment was estimated from the steps in the checklist. Convalescence for clinical phase 2 was informed from literature regarding pain following recementing or extraction for dental crown loss (Hersh et al, 2011; Al-Khateeb and Alnahr, 2008; Yao et al, 2017). There is a paucity of data regarding untreated dental crown loss. The clinical phase 2 duration for the untreated scenarios were informed by Ajayi et al, 2010, a cross-sectional study of Nigerian children with dental fractures in anterior permanent teeth. After a best-case dental crown loss, if untreated, the underlying tooth would have a prior root canal, requiring no treatment, or would likely be fractured or damaged (the reason for crown placement in the absence of a root canal). Thus uncomplicated enamel/crown fractures were used to inform the best-case untreated scenario. The worst-case untreated scenario was likewise informed by dental fractures, but complicated crown fractures (exposing the pulp). Ajayi et al, 2010 presented duration from time of fracture to dental evaluation and these durations were used to inform the untreated scenarios.

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Susini et al, 2007	Terrestrial	3
NASA ISS Medical Checklist, 2014	Spaceflight	

The ExMC CS&T made the pre-determined assumption that RTDC probability for all scenarios of this condition would be 0%. The student effort realized that aspiration of the crown is a clinical concern in spaceflight and found literature regarding crown aspiration during root canal treatments from France (Susini et al, 2017). This article substantiates an RTDC probability of 0% based on crown aspiration/ingestion. No other RTDC surrogates were considered, however, due to the assumption of RTDC probability being 0% made by the ExMC CS&T. This may be an accurate assumption, but it was not further substantiated by a literature search. The ISS Medical Checklist instructions for dental crown recementation or tooth extraction (NASA ISS Medical Checklist, 2014)

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Susini et al, 2007	Terrestrial	0

No LOCL literature searches were performed for any scenario of this condition. It was assumed by the student effort that LOCL would not occur for this condition and no searches were performed as a result. Susini et al, 2017 was used to inform the LOCL for the treated scenarios, but this reference was found in an RTDC search; not an LOCL search. True mortality data was not searched for. This assumption should have been

substantiated with a literature search.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope

Overview

Worst Case Definition: Loss of dental crown due to underlying decaying tooth fracture that requires tooth extraction.

Best Case Definition: Loss of crown requiring no intervention (tooth with prior root canal), or recementing (non-root canaled tooth).

Artificial dental crowns that are lost and the associated medical response to the pain and discomfort associated with the condition. Generally this condition is one of discomfort rather than a medical emergency although, the crown is often associated with reduced infection and pulp exposure. If the loss of the crown can lead to pulp exposure, than infection is likely and may necessitate replacement or antibiotics.

The CRT condition focuses solely on the relief of this discomfort in the best case and the prevention of infection in the worst case.

Diagnostic Scope and Resourcing

In the best-case scenario, diagnosis is based on history and physical examination.

In the worst-case scenario, diagnosis is based on history and physical examination.

Clinical Phase 1 Duration and Rationale

This version of IMPACT presumes physician level knowledge, skill, and ability will be present on the mission. The CRT working group SME consensus duration is as follows:

CP1 BC (Treated or Untreated): 1.0 hours

This is the longest reasonable time to complete this task for an experienced clinician adjusted for being in the spaceflight environment to do the following:

- 1 - Take a proper history of the patient
- 2 - Perform a physical on the patient

CP1 WC (Treated or Untreated): 1.35 hours

This is the longest reasonable time to complete this task for an experienced clinician adjusted for being in the spaceflight environment to do the following:

- 1 - Take a proper history of the patient
- 2 - Perform a physical on the patient with ground support for communication

The highest scope of practice code used in this CRT which includes interpretation of diagnosis, performing diagnostic tests and performing treatment would be a three: this is at a nurse level.

Treatment Scope and Resourcing

In the best-case scenario, treatment is limited to mild pain medications as this was specifically in the definition of the best case for this condition. In terrestrial conditions where medical capabilities are lacking, this is likely a reasonable course of action. The worst case scenario also allocates for temporary replacement of the crown and/or tooth extraction in addition to the mild as well as moderate pain medications and antibiotic prophylaxis.

Most crown loss in terrestrial populations (best or worst case) are resolved with permanent replacement of the crown and mild pain relief without need for temporary fillings or antibiotic prophylaxis.

Communications and Support Needs

In the best-case scenario, diagnosis and course of treatment is uncomplicated and likely within the scope of care of onboard crew members. In the worst-case condition, ground communications will be helpful given the complicated nature of the condition and the scope of care onboard as well as the need to potentially extract a tooth.

IMM CLIFF RECONCILIATION COMMENTS

The best- and worst-case definitions are different in this CLiFF as compared to IMM. This was intentionally changed, with the assistance of the dentist who provides care to astronaut crewmembers. It was felt that the more appropriate definition was a dental crown loss that requires no intervention or recementing (BC) or extraction (WC). Notably, IMM considered dental crown loss to be BOTH loss of the natural crown (the part of the tooth above the gumline) AND a prosthetic crown loss. Natural dental crown loss secondary to fracture (ICL#31) or avulsion (ICL#32) are now their own conditions that did not previously exist in the IMM.

LIMITATIONS SUMMARY

- There is a paucity of data regarding untreated scenarios for dental crown loss. In the event of an untreated crown loss, the state of the underlying tooth is relevant to the duration. It was assumed that in the best-case scenario, non-root canaled teeth would be crowned to protect underlying

fracture/decay. Therefore, uncomplicated crown (natural tooth crown) fracture was used as a surrogate for the best-case scenario. The worst-case scenario states that the underlying tooth is decaying/fractured, so a complicated crown fracture (natural tooth crown) was used as a surrogate for this scenario. The maximum durations were based on a study out of Nigeria that documented the length of time from fracture of permanent anterior teeth in children to dental examination. • The ExMC CS&T made the pre-determined assumption that RTDC probability for all scenarios of this condition would be 0%. The student effort realized that aspiration of the crown is a clinical concern in spaceflight and found literature regarding crown aspiration from France (Susini et al, 2017). This article substantiates an RTDC probability of 0% based on crown aspiration/ingestion. No other RTDC surrogates were considered, however, due to the assumption of RTDC probability being 0% made by the ExMC CS&T. • No LOCL literature searches were performed for any scenario of this condition. It was assumed by the student effort that LOCL would not occur for this condition and no searches were performed as a result. Susini et al, 2017 was used to inform the LOCL for the treated scenarios, but this reference was found in an RTDC search; not an LOCL search. True mortality data was not searched for. This assumption should have been substantiated with a literature search.

TABLE 8. TASK IMPAIRMENT CALCULATION BASED ON AFFECTED HUMAN SYSTEMS TASK CATEGORIES (HSTC)

Clinical Phase 2: Treatment												
	Affected HSTCs											
	Cognitive - Simple	Cognitive - Complex	Communications	Inter-personal Skills	Vision	Hearing	Cardio-pulmonary	Dentition	GI	GU		
Treated Best Case (TBC)												
Untreated Best Case (UTBC)												
Treated Worst Case (TWC)	223	664	113	89				5				
Untreated Worst Case (UTWC)	223	664	113	89				5				
	Affected HSTCs (Continued)								TI Calculation		TI Score	
	Hand (Dom)	Hand (Any)	Upper Extremity	Lower Extremity	Ambul & Standing (g)	Translation & Stabilization (microgravity)	Don/Doff Equipment	Pressure Ops	Total Tasks Impaired By Condition	Total Human System Category Tasks Full Mission	TI Decimal	TI %
Treated Best Case (TBC)									0	3763	0	0
Untreated Best Case (UTBC)	132							211	343	3763	0.0911507	9.11507
Treated Worst Case (TWC)	132							211	1437	3763	0.381876	38.1876
Untreated Worst Case (UTWC)	132							211	1437	3763	0.381876	38.1876
Clinical Phase 3: Condition End State												
	Affected HSTCs											
	Cognitive - Simple	Cognitive - Complex	Communications	Inter-personal Skills	Vision	Hearing	Cardio-pulmonary	Dentition	GI	GU		
Treated Best Case (TBC)												
Untreated Best Case (UTBC)												
Treated Worst Case (TWC)												
Untreated Worst Case (UTWC)	223	664	113	89				5				
	Affected HSTCs (Continued)								TI Calculation		TI Score	

	Hand (Dom)	Hand (Any)	Upper Extremity	Lower Extremity	Ambul & Standing (g)	Translation & Stabilization (microgravity)	Don/Doff Equipment	Pressure Ops	Total Tasks Impaired By Condition	Total Human System Category Tasks Full Mission	T1 Decimal	T1 %
Treated Best Case (TBC)									0	3763	0	0
Untreated Best Case (UTBC)	132							211	343	3763	0.0911507	9.11507
Treated Worst Case (TWC)									0	3763	0	0
Untreated Worst Case (UTWC)	132							211	1437	3763	0.381876	38.1876

TABLE 8 KEY

Human System Task Category (HSTC) Definitions: Cognitive-Simple: Tasks requiring simple cognitive involvement (low levels of attention, following simple checklists, and not requiring extensive decision making) in conjunction with inputs from other systems. Cognitive-Complex: Tasks requiring complex cognitive involvement (requiring constant attention, frequent interpretation of outside stimuli to inform real-time situations) in conjunction with inputs from other systems. Communication: Tasks requiring primarily communication, via hearing and speaking. Interpersonal Skills: Tasks requiring interpersonal, social interaction between crew including complex technical tasks that require extended crew interaction. Vision: Tasks in which visual information is required. Hearing: Tasks in which primarily auditory information is required, excluding communication, e.g. hearing alarms, medical auscultation, OOHAs. Cardiopulmonary: Tasks requiring greater-than-baseline cardiopulmonary effort, e.g. physically strenuous activities. Dentition: Tasks requiring use of teeth for mastication. GI (Gastrointestinal): Tasks requiring use of the alimentary system, e.g. solids/liquids consumption and solids excretion. GU (Genitourinary): Tasks requiring use of the male/female genitourinary systems. Hand (Dominant): Tasks performed using primarily the hand, requiring use of the dominant hand (piloting, medical procedures, dental procedures). Hand (Any): Tasks performed using primarily the hand(s), with no preference for dominance, with equivalent bilateral effectiveness. Upper Extremity: Tasks requiring specific use of the upper extremities, excluding hands. Lower Extremity: Tasks requiring specific use of the lower extremities (excluding ambulation and standing in the presence of gravity), e.g. using exercise equipment. Ambulation and Standing (g): Tasks requiring use of both lower extremities to accomplish ambulation or standing in the presence of gravity. Translation and Stabilization (microgravity): Tasks requiring use of either the upper or lower extremities to accomplish translational movement and stabilization (securing oneself to remain stationary) in the setting of microgravity. Don/Doff Equipment: Tasks requiring the donning of personal equipment (including pressure suit, exercise harness, EVA equipment, etc). Pressure Ops: EVA/contingency tasks performed while pressurized in a suit.

Criteria for Assignment of Conditions to HSTCs (any of the following):

- 1) Is affected crew member physically incapable of performing the human system task category, without impairment, with the condition?
- 2) Would the treatment (e.g. medications) impair the crewmember's ability to perform the human system task category? (Does not apply to UTx)
- 3) Does the condition have a high likelihood of causing a significant aeromedical contraindication with an associated human system task category?
- 4) Would performing tasks in an associated task category worsen the condition? (If so, it is affected).
- 5) Does pain associated with the condition impair any further human system categories?

TASK IMPAIRMENT COMMENTS

CP2: No comment CP3: No comment

EVIDENCE COLLECTION PROCESS

Mesh terms that most closely resembled the best-case and worst-case scenarios, and associated Conditions Included but Not Explicitly Stated (CNES), were utilized to build incidence, duration, RTDC, and LOCL searches by best- and worst-case.

Incidence:

Databases searched for spaceflight and analog incidence data included: PubMed, Google Scholar, NASA Technical Reports Server (NTRS) public search, Defense Technical Information Center (DTIC), and Barratt MR, Baker E, Pool SL. Principles of Clinical Medicine for Space Flight. New York, NY: Springer; 2019. 2nd Edition. Databases searched for terrestrial incidence included: DynaMed, PubMed, and Google Scholar.

Duration, RTDC, LOCL:

Databases searched for duration, RTDC, and LOCL included: Dynamed, Cochrane, PubMed, and Google Scholar. Note, that if duration, RTDC, or LOCL data was found in a DynaMed search, the other search engines were not included. Relevant articles were selected and reviewed. If applicable, the article was included in the CLIFF.

LEVEL OF CONFIDENCE (LOC) SCORING

Articles obtained to update the evidence behind this CLIFF were scored by ExMC editors, based on their applicability to the Exploration Spaceflight environment using the following grading scale:

- 4 – Confident
- 3 – Somewhat confident
- 2 – Neutral
- 1 – Somewhat unconfident
- 0 – Not confident

The following considerations factor into the grading scale above:

- How closely does the paper describe the medical condition as defined by the IMPACT 1.0 Condition List (relevance)?
- How closely does the population included resemble the astronaut population?
- Quality of the paper (number of subjects, methods, etc.)
- How much does the editor trust the source of the evidence?
- How closely does the editor think that the data represents the exploration spaceflight environment?
- Other considerations, at the discretion of the editor, supported in the comments for LOE scoring.

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ACRONYMS

ACRONYM	PHRASE
AAOMS	American Association of Oral and Maxillofacial Surgeons
AMA	American Medical Association
ARCL	All Remaining Conditions List
ARS	Acute Radiation Sickness
BHP	Behavioral Health and Performance
CAC	Coronary Artery Calcium
CHS	Crew Health and Safety
CL	Condition List
ClIFF	Clinical Finding Form

CMO	Crew Medical Officer
COMFORT	Clinical Outcome Metrics for Optimization of Robust Training
CP1	Clinical Phase 1
CP2	Clinical Phase 2
CP3	Clinical Phase 3
CRL	Clinical Resource Level
CRT	Capability Resource Table
CST	Clinical Science Team
DCS	Decompression Syndrome
DRM	Design Reference Mission
ED	Emergency Medicine Doctor
EL	Evidence Library
EMCL	Exploration Medical Condition List
EMT	Emergency Medical Technician
EVA	Extravehicular Activity
EXMC	Exploration Medical Capability
HRP	Human Research Program
ICD	International Classification of Disease
ICL 1.0	IMPACT 1.0 Medical Conditions List
ICU	Intensive Care Unit
IMCL	iMED Condition List
iMED	Integrated Medical Evidence Database
IMM	Integrated Medical Model
IMPACT-MD	Impact Medical Database
IP	Incidence Proportion
IR	Incidence Rate
ISS	International Space Station
IV	Intravenous
JSC	Johnson Space Center
LEO	Low-Earth orbit
LEVA	Lunar Extravehicular Activity
LOCL	Loss of Crew Life
LOM	Loss of Mission
LSAH	Lifetime Surveillance of Astronaut Health
LSO	Lunar Surface Operations
MCL	Master Condition List
MEVA	Medical Extravehicular Activity
NASA	National Aeronautics and Space Administration
N/A	Not Applicable
NP	Nurse Practitioner
OBGYN	Obstetrics and Gynecology
OR	Occurrence Rate
PA	Physician Assistant

PDQ	Pain Disability Questionnaire
PFCL	Proposed Future Conditions List
PPE	Personal Protective Equipment
PTRS	Project Technical Requirements Specification
PRL	Pharmaceutical Resource Level
QTL	Quality Time Lost
RCL	Removed Conditions List
REP	Rochester Epidemiology Study
RTDC	Removal to Definitive Care
SANS	Spaceflight-Associated Neuro-ocular Syndrome
SAS	Space Adaptation Syndrome
SEVA	Spaceflight Extravehicular Activity
SME	Subject Matter Expert
SoP	Standard Operating Procedure
SPE	Solar Particle Event
TBD	To Be Determined
TI	Task Impairment