

Clinical Anaplastology Guidelines

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Introduction and History

Founded in 1980, the International Anaplastology Association (IAA), formerly the American Anaplastology Association (AAA) defines the professional image and field of anaplastology worldwide by promoting excellence within the field of facial, ocular, and somatic prosthetics to enhance the lives of patients. The IAA provides for continued education, research, and advocacy opportunities among professionals involved in restoring malformed or absent parts of the human body through custom-made prosthetics that normalize appearance and restore function.

The practice of anaplastology has changed significantly during the last several decades. Increased autonomy, clinical team membership, and higher qualifications have developed the operational role and professional sphere of the clinical anaplastologist. Coincident with role development is greater accountability, increasing professional responsibility and the requirement for basic guidelines to ensure patient care and safety.

The Clinical Anaplastology Guidelines (CAG) are evidence-based recommendations for the health and care of patients requiring facial and somatic prosthetics internationally. The IAA is cognizant of both the importance and the challenges of developing sound, credible and relevant guidelines for anaplastologists internationally. Taking this into consideration, these guidelines are suitable for most practitioners and their patients realizing the diversity of specific conditions and needs, and people in unique circumstances and settings.

The guidelines are to give an overview of recommendations on how to perform the task of restoring and/or replacing the form and function of human anatomy with custom-made devices. These guidelines indicate a consensus in the practice of anaplastology based on a uniformity in practice styles.

Who created the CAG? A multidisciplinary group of anaplastology volunteers whose individual knowledge and expertise within their specialties (ocular science, medical illustration, biomaterials, prosthetics/orthotics, etc.) helped to select and prioritize the topic areas.

Who is the intended audience? Anaplastology practitioners, patients, government agencies, medical associations, and insurers.

Is the CAG evidence-based? All efforts have been made to assemble, organize and synthesize the best available evidence.

Can anyone join the CAG committee? Active, associate and emeritus IAA members are encouraged to participate.

How will the CAG committee validate the CAG? Feedback will be sought from relevant stakeholders, including practitioners and supporting organizations during the

development and approval process.

Who will approve the final CAG? The CAG will be submitted first to a small international group of IAA members for comment. During this comment period, all feedback will be submitted to the CAG committee for review. Then it will be submitted to the membership at large for final approval.

How often will the CAG be updated? The CAG will be updated on a regular, scheduled basis to incorporate new evidence.

Definition of Terms

Anaplastology (*Gk. ana-again, anew, upon plastos-something made, formed, molded; logy-the study of*) is a branch of medicine devoted to the reconstruction of absent, disfigured or malformed parts of the face or body with a custom-made life-like prosthesis designed to improve function and normalize appearance. The term *anaplastology* was coined by Walter G. Spohn and is used worldwide.

An **Anaplastologist** is an allied health care professional educated and trained in the design, fabrication and management of prosthetics that include custom-made facial, ocular (eye), and/ or somatic (body) prostheses, surgical templates/guides and other specialized devices based on clinical assessment and, when necessary, a healthcare provider referral and/or a physician's order.

A **Certified Clinical Anaplastologist (CCA)** is a professional whose competence in the practice of clinical anaplastology is credentialed by the Board for Certification in Clinical Anaplastology (BCCA). Such individuals have met minimal, continuing competency and ethical and professional standards set forth by the BCCA to provide safe and effective anaplastology services. Services include clinical assessment for prosthesis suitability, treatment planning, prosthesis design and fabrication based on empirical studies with the patient, prosthesis delivery, and follow-up.

Artistic engineering is the implementation of the principles of art and design to create a custom-made prosthetic device that is a convincing likeness of absent human anatomy.

A **custom-made prosthesis** is a reconstructive device designed and created for an individual patient based on a replica of patient anatomy acquired through direct molding and casting techniques and/or 3-D scanning and printing technologies. A custom-made prosthesis uses the anatomical replica to create a prosthesis that fits the contours of the patient's specific anatomy. A custom-made prosthesis is created in accordance with a physician's order and requires substantial clinical, technical, and artistic judgment in its design, fabrication, and fitting.

Facial prosthetics is the art, science and practice of the design, fabrication, and fitting of custom-made prostheses used to replace a missing, disfigured, or malformed part of the face due to traumatic injury, disease and/or ablative surgery, congenital difference, and other acquired conditions. Facial appearance is central to human identity and normal function; therefore restoration of natural appearance is fundamental to facial prosthetics.

Facial prostheses, also known as epitheses*, or prostheses include auricular, nasal, mid-facial, orbital (including ocular), upper facial, hemi-facial, partial facial, nasal septal and other areas of the head and neck, but exclude intra-oral prostheses. Custom-made facial prostheses restore anatomical structures and support surrounding tissue of the head and neck, increase comfort, and protect exposed internal anatomy such as exposed sinuses, in addition to restoring the appearance of absent or disfigured anatomy.

Functional Simulacra is the term used to describe an acceptable outcome in a prosthetic substitute that is designed and fabricated to precisely fit the individual anatomy where it is placed and to provide functional benefit to the patient who has a congenital defect or an acquired loss of a body part.

Ocular prosthetics is the art, science and practice of the design, fabrication, and fitting of custom-made prostheses used to replace the globe of the eye or cover the existing eye, lost or disfigured as a result of traumatic injury, disease and/or ablative surgery, or congenital malformation. Facial appearance is central to human identity and normal function; therefore restoration of natural appearance is fundamental to ocular prosthetics. Ocular prostheses also provide necessary volume and shape to align the anatomical structures of the orbital socket for increased comfort, lacrimal system function, and protection of interior structures, while also restoring the appearance of missing or distorted anatomical structures. **Eye prostheses** include conformers, scleral shells, and ocular prostheses that fit within the natural socket tissue and eyelids, as well as the custom-made ocular prosthesis component that is incorporated into an orbital, upper facial, or hemi-facial prosthesis.

Patient acceptance is achieved by establishing and meeting realistic expectations set by the patient, the clinical anaplastologist, and the physician, based on restoring absent anatomy with a prosthesis that fits comfortably, has a method of retention that is dependable, normalizes appearance, and fits the patient's lifestyle.

A **prosthesis** is an artificial replacement of an absent or disfigured part of the human body.

Somatic prosthetics is the art, science and practice of design, fabrication, and fitting of custom-made prostheses used to replace a missing, disfigured, or malformed part of the body due to traumatic injury, disease and/or ablative surgery, or congenital malformation with a focus on normalizing appearance. **Somatic prostheses** include fingers, thumbs, partial hands, hands, breasts, tracheostomies, toes, partial feet and other areas of the body, but exclude prosthetic devices for weight-bearing anatomy.

Technical engineering is the implementation of the procedural steps and material manipulation unique to fitting, fabricating and finishing custom-made prosthetic devices.

Visual Simulacra is the term that describes an acceptable appearance in a prosthetic substitute for absent human anatomy that is achieved by the simulation of the normal morphology, pigmentation, and texture of the missing feature of an individual patient so as to provide and restore normal appearance.

* international nomenclature for extraoral facial prostheses

Clinical Anaplastology- Scope of Practice

The Scope of Practice statement describes the role of the clinical anaplastologist as a member of the health care team. This scope of practice is a "living" document that will evolve as the health care industry changes and technology expands.

I. Professional Scope of Practice Statement

Clinical anaplastology is a systematic process that provides patients with prosthetic rehabilitation designed and fabricated to normalize the appearance of parts of the face and body impacted by congenital malformation, traumatic injury, disease, or ablative surgery. The specific processes inherent to the professional practice of clinical anaplastology include, but are not limited to:

- assessment of patient information/needs
 - patient communication and management
 - formulation of prosthetic treatment plan
 - performance of clinical, technical and artistic procedures for prosthetic fabrication
 - development and implementation of quality assurance procedures (examples include patient satisfaction survey, patient complaint resolution, proof of delivery, device record)
 - documentation and practice management

II. Parameters of Profession

- The desired goal of any device or prosthesis provided by an anaplastologist is to assist in restoring optimal function and aesthetics.¹
- Clinical anaplastology is a transdisciplinary health care service drawing upon art, science, medicine, and technology applied to prosthetic rehabilitation.
- Clinical anaplastology encompasses the subspecialty areas of custom-made facial, ocular and somatic prosthetics, as well as other emerging fields.
- The CCA credential from the Board for Certification in Clinical Anaplastology is considered the standard of practice in clinical anaplastology. Credentials from Boards for Certification in Clinical Anaplastology, Dental Technology, Ocularistry, and others are considered the standard of practice in clinical anaplastology. Other allied credentials may include but are not limited to IMPT, IASPE, and BCO.
- Clinical anaplastology excludes intra-oral prosthetics and prosthetic devices that recreate the mobility or functionality of weight bearing limbs, such as limb prosthetics and orthotics.

III. Underlying Values:

- Treatment of patients requiring prostheses is delivered within a caring and supportive private office, clinical, and/or hospital environment.
- Clinical anaplastologists will adhere to the scope of practice and refer clients to the appropriate qualified health care provider when indicated.
- Clinical anaplastologists will provide patients with clear and realistic goals and expectations.
- Clinical anaplastologists will represent their education, training, qualifications and abilities honestly and function within the limitations of their education, skills, and credentials.

III. Clinical Anaplastologist Scope of Practice

- The clinical anaplastologist practices in compliance with legal requirements that regulate the design, fabrication, fitting and maintenance of the prosthetic devices created.
- The clinical anaplastologist designs, fabricates, and fits each prosthetic device based on clinical assessment and a physician's order when necessary.

- The clinical anaplastologist is ethically bound to limit his/her practice to the scope of practice in which he/she has received education and clinical experience, and demonstrated competency.

Clinical Anaplastology Guidelines

The Clinical Anaplastology Guidelines (CAG) are designed to reflect established norms, processes, and practices in clinical anaplastology. The CAG incorporates standards common to many health care specialties, in addition to those specific to clinical anaplastology. The individual subspecialties of clinical anaplastology: facial, ocular, and somatic prosthetics may adopt or refine these recommendations to better reflect the day-to-day practice of each subspecialty. Certification is considered the standard of practice in the health care system. Individuals not yet certified may reference these guidelines to optimize patient care.

Section 1

Patient Assessment

Patient Communication

Formulation of the Prosthetic Treatment Plan

Implementation of the Prosthetic Treatment Plan

Documentation

Patient Assessment

- 1.1 Patient assessment is necessary to determine whether or not anaplastology services will benefit the patient.

The clinical anaplastologist:

- 1.1.1 interviews the patient or patient's representative to gather relevant information (e.g. pertinent medical history, diagnosis, demographic characteristics, family dynamics, previous use of prosthesis, work and vocational activities, patient expectations).
- 1.1.2 examines the patient to determine the extent and condition of the tissue deficit.
- 1.1.3 considers the physical, psychological, and cultural factors affecting the patient.
- 1.1.4 consults with other members of the multidisciplinary team and refers the patient to other colleagues/professionals when appropriate.
- 1.1.5 acquires necessary documentation to begin treatment procedure.

Patient Communication

- 1.2 Effective communication is necessary to develop a positive relationship with the patient and establish realistic expectations.

The clinical anaplastologist:

- 1.2.1 explains his/her professional background and scope of practice.
- 1.2.2 tailors communication to ensure the patient's ability to understand benefits and limitations of prosthetic treatment.

- 1.2.3 explains the prosthetic treatment procedure including estimated time involved in the process.
- 1.2.4 shows photographs of similar patients, when appropriate, and provides models of prostheses to the patient to facilitate discussion and establish realistic expectations.
- 1.2.5 discloses information that assists the patient in making informed treatment decisions.
- 1.2.6 listens actively and responds to patient questions and concerns.
- 1.2.7 refers specific diagnosis, treatment, or prognosis questions to the patient's physician.
- 1.2.8 informs patient of procedures for repairing, adjusting, and/or replacing the prosthesis.
- 1.2.9 provides clear written and oral instructions related to the wear and care of the prosthesis, including potential adverse reactions to use of the prosthesis or related products.
- 1.2.10 Recommends that the patient call the anaplastologist and/or physician if an adverse reaction to use of the prosthesis or related products is observed.

Formulation of the Prosthetic Treatment Plan

- 1.3 Evidence-based practice should be used to formulate an individualized treatment plan that is consistent with the referring physician's order and designed to meet the specific needs of the patient. Evidence, regarding development of a treatment plan draws upon:
 - EXPERIENCE: The practitioner's personal clinical experience based on their observed and measured phenomena. This is deriving knowledge from actual experience rather than from theory or belief.
 - RESEARCH: The practitioner's published research and/or the latest research by other clinical practitioners.
 - PATIENTS: The patient's personal experience, their preferences and culture. Patients believe in what they have seen, heard or undergone which is documented in their medical history.
 - COLLEAGUES/EXPERTS: Collaborating with and utilizing the knowledge base and personal experience of anaplastology colleagues and experts in related fields.
 - THEORY: Theories, ideas and hypotheses that have not yet been confirmed but are based on broad professional experience as well as weighing the advantages and disadvantages of a patient's unique situation.
 - POLICY DIRECTIVES: Policy directives that are published by insurance companies and professional association; laws and regulations published by pertinent governmental regulatory bodies.

The clinical anaplastologist:

- 1.3.1 assesses the patient's physical difference/tissue loss.
- 1.3.2 establishes goals and expected outcomes with feedback from the patient and ordering physician as necessary.
- 1.3.3 independently analyzes information and develops a treatment plan based on the type of prosthesis and the needs of the patient.

- 1.3.4 consults with appropriate health care professionals, when necessary, in order to optimize the treatment plan.
- 1.3.5 presents to the patient the recommended treatment plan and any optional plans, including disclosure of potential risks/benefits/limitations involved.
- 1.3.6 devises a retention strategy that will provide reliable retention and takes the patient's lifestyle into account.
- 1.3.7 applies artistic engineering principles to design the prosthesis.
- 1.3.8 employs technical engineering principles to design and fabricate the prosthesis.

Implementation of the Prosthetic Treatment Plan

- 1.4 Quality patient care is provided through the safe and accurate implementation of a treatment plan.

The clinical anaplastologist:

- 1.4.1 takes into account health, hygiene, and safety issues related to working with patients.
- 1.4.2 refers the patient to physician or appropriate health care professional for issues beyond the scope of the anaplastologist.
- 1.4.3 performs procedures to acquire accurate impressions/models of the patient, seeking assistance of other healthcare providers when necessary.
- 1.4.4 modifies fabrication techniques and materials to fit treatment plan objectives.
- 1.4.5 ensures that manufacturers' guidelines are followed for materials and components used.
- 1.4.6 applies artistic design principles to create a prosthesis that simulates absent anatomical form, color and texture.
- 1.4.7 employs materials and techniques for fabrication that result in an outcome consistent with the treatment plan goals
- 1.4.8 evaluates prosthesis prior to delivery.
- 1.4.9 assesses appearance, fit, comfort, and retention of the prosthesis and makes necessary adjustments with patient at the delivery of the prosthesis.
- 1.4.10 educates the patient and/or patient's representative regarding the care and maintenance of the prosthesis.
- 1.4.11 schedules appropriate follow up appointments with the patient.
- 1.4.12 advises the patient to return to his/her physician for assessment of the prosthesis.

Documentation

- 1.5 Clear and precise documentation is necessary for continuity and accuracy of care.

The clinical anaplastologist:

- 1.5.1 maintains accurate, pertinent, accessible, confidential and secure patient records in accordance with local policy and established procedures
- 1.5.2 charts progress note at each office appointment and telephone follow up.
- 1.5.3 records and documents materials used, lot numbers for materials, and any other components used in the prosthetic device.

- 1.5.4 records and documents the custom-made prosthetic device with photographic images.
- 1.5.5 solicits feedback from the patient, and physician as necessary, to determine the effectiveness of the prosthetic rehabilitation.
- 1.5.6 provides an oral or written summary of the prosthetic treatment plan to the referring physician when applicable or requested.

Section 2

Quality Assurance

Assessment of Equipment, Procedures and Work Environment

Quality Assurance

Quality assurance procedures are designed to enhance the safety of patients, the public, and the clinical anaplastologist. The clinical anaplastologist uses independent judgment and systematic problem solving methods to produce high quality custom-made prosthetic devices. To facilitate quality assurance standards, the clinical anaplastologist develops and implements quality assurance procedures.

The clinical anaplastologist:

- 2.1.1. develops a quality assurance program that is relevant to the individual scope of practice.
- 2.1.2 implements quality assurance procedures.
- 2.1.3 maintains documentation in accordance with established laboratory policies and protocols.
- 2.1.4 regularly updates quality assurance program.

Assessment of Equipment, Procedures and Work Environment

- 2.2 The planning and provision of safe and effective prosthetic service depends on understanding and maintaining equipment and facilities.

The clinical anaplastologist:

- 2.2.1 strives to maintain a safe workplace environment.
- 2.2.2 performs equipment and material quality assurance procedures, as required for acceptable performance level.
- 2.2.3 is aware of regulatory agencies that affect the scope of practice of the anaplastologist and is compliant with their requirements.

Section 3

Quality of Care

Quality of Prosthetic Device

Self-Assessment

Collaboration

Ethics

Quality of Care

3.1 All patients expect and deserve excellent care during prosthetic rehabilitation.

The clinical anaplastologist:

- 3.1.1 collaborates with other health care professionals to optimize prosthetic rehabilitation outcomes.
- 3.1.2 obtains and maintains appropriate professional credentials.
- 3.1.3 adheres to standards, policies and procedures adopted by the profession and regulated by law.
- 3.1.4 applies professional judgment and discretion.
- 3.1.5 stays current with advances in anaplastology through continuing professional education.

Quality of Prosthetic Device

3.2 The desired goal of any camouflage prosthesis is to assist in restoring optimal function and anatomy.

The clinical anaplastologist uses the following criteria to evaluate a prosthetic device:

- 3.2.1 The prosthesis is inconspicuous:
 - 3.2.1.1 The sculptural form creates a natural and balanced appearance.
 - 3.2.1.2 The color and texture simulate a lifelike appearance.
- 3.2.2 The prosthesis is secure and comfortable.
- 3.2.3 The prosthesis is designed and fabricated to minimize health and safety risks to the patient.
- 3.2.4 The prosthesis can be applied and removed with relative ease.
- 3.2.5 The prosthesis is designed for durability.
- 3.2.6 The prosthesis uses appropriate medical or food grade materials.

Self-Assessment

3.3 It is the duty of the clinical anaplastologist to have knowledge of relevant developments and techniques in the best interest of patient care.

The clinical anaplastologist:

- 3.3.1 recognizes personal strengths and talents and uses them to benefit patients, co-workers, and the profession.
- 3.3.2 performs prosthetic procedures only after receiving appropriate academic education and supervised clinical experience.
- 3.3.3 recognizes and takes advantage of educational opportunities, including improvement in technical and artistic problem-solving skills and personal growth.

Collaboration

- 3.4 Quality patient care is provided when all members of the health care team communicate and collaborate efficiently.

The clinical anaplastologist:

- 3.4.1 promotes a positive and collaborative atmosphere with all members of the health care team.
- 3.4.2 effectively communicates with appropriate members of the health care team.

Ethics

- 3.5 All decisions made and actions taken on behalf of the patient adhere to the IAA Code of Ethics upon which the accepted professional standards of conduct are based.

The clinical anaplastologist:

- 3.5.1 adheres to the accepted professional ethical standards as defined by the IAA *Code of Ethics*.
- 3.5.2 is accountable for professional judgments and decisions, as outlined in the *Standards of Fair Practice*.
- 3.5.3 takes the pledge as an IAA member to take responsibility for one's actions.
- 3.5.4 understands and accepts the *Interpretation and Enforcement* of the IAA *Code of Ethics*.

REFERENCES

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