

Use of Artelon® Cosmetic in soft tissue augmentation in dentistry

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Background: Soft tissue augmentation is a widely used procedure in partially and fully edentulous patients to increase soft tissue volume. Polyurethanes have been used for scaffolds in a variety of implantable devices. Artelon® is a degradable polyurethane that has been manufactured as fibers, films, and porous scaffolds to be used for various purposes. In this review, the characteristics of Artelon are described, and its clinical applications in orthopedics, dermatology, cardiovascular medicine, and dentistry are also discussed.

Methods: A Medline (PubMed) search was conducted, and articles published in English were included. Keywords, including “Artelon”, “polyurethanes”, “soft tissue augmentation”, “biocompatibility”, “resorption”, “mechanical stability”, and “complications” were used in different combinations. Titles and abstracts were screened, and full text article analyses were performed.

Results: Most of the studies reported orthopedic, dermal, and myocardial applications. There were only a few reports related to dental and implant applications. Artelon has been successfully used for reinforcement of soft tissues, including the rotator cuff, Achilles, patellar, biceps, and quadriceps tendons in orthopedic surgery, and is used clinically for the treatment of osteoarthritis in the hand, wrist, and foot. One type of Artelon material, Artelon Cosmetic, has been used in the dental field to increase soft tissue volume, and stable results are achieved for up to 6 months. This material is reported to be easily handled when cut to the desired shape, with little additional time needed for manipulation during surgery, eliminates the need for connective tissue autografts, and thereby decreases patient morbidity and postoperative discomfort, with increased likelihood of a positive subjective outcome.

Conclusion: Artelon may be applied in the dental field to increase soft tissue volume. Further studies of various applications in dentistry with long-term results are needed to confirm the safety and efficacy of this material before it can be used on a routine basis in dentistry.

Keywords: Artelon® Cosmetic, dentistry, soft tissue augmentation, polyurethanes

Introduction

Soft tissue augmentation is widely used in partially and fully edentulous patients to increase soft tissue volume, surgically correct localized alveolar defects, augment areas with a lack of or reduced width of keratinized tissue, as preprosthetic site development, and as part of ridge preservation procedures.¹ Dental implants have been widely used, and soft tissue augmentation using dental implantation has been performed using various materials, including autogenous soft tissue.² Localized alveolar ridge deficiencies have been treated with connective tissue grafts and an improvement in residual ridge contour was obtained even though all sites demonstrated shrinkage.³

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It was reported that shrinkage became noticeable within the first 4–6 weeks. However, the treated sites remained stable for up to 3 years, and an improved pontic ridge relationship may be achieved using this approach.³ Comparisons were made between subepithelial connective tissue grafts comprising connective tissue with fatty tissue or free full-thickness gingival grafts, which also include epithelium and connective tissue with fatty tissue in treating a localized alveolar ridge defect, and mean volumetric gain for the connective tissue group was significantly greater than for the free full-thickness gingival graft group.⁴ Additionally, soft tissue stability after connective tissue grafting was evaluated around single-tooth implants.⁵ Even though increased volume was achieved, soft tissue shrinkage of 0.6 mm on average was noticed on the buccal side of the implant crown 1 year after prosthesis insertion.⁵

Palatal incisive vessel-based connective tissue flaps have been performed on partially edentulous patients in the anterior maxilla to increase soft tissue volume.⁶ Using this approach, reduced total treatment time was an added benefit, because a second procedure for soft tissue augmentation was not necessary. Autogenous soft tissue grafts may have disadvantages, such as the necessity of creating additional surgical fields to harvest the graft and the requirement of primary closure, which may reduce ridge height.⁷ Thus, alternative materials have been searched for as substitutes for autogenous soft tissue, such as the acellular dermal matrix graft (Alloderm, Life Cell Corporation, The Woodlands, TX), originally developed for covering full-thickness burns.

Polyurethanes have been used as scaffolds in various implantable devices, and one of the degradable ones, ie, Artelon® (Artimplant AB, Västra Frölunda, Sweden) has been manufactured as fibers, films, and porous scaffolds to be used in various applications.^{8,9} Recently, one type of polyurethane scaffold, Artelon® Cosmetic, has been used in the dental field to increase soft tissue volume.¹⁰ In this review, the characteristics of Artelon are described, and its clinical applications in orthopedics, dermatology, and dentistry are also discussed.

Methods

A Medline (PubMed) search was done and articles published in English were included in the review. Keywords, including “Artelon”, “polyurethanes”, “soft tissue augmentation”, “biocompatibility”, “resorption”, “mechanical stability”, and “complications” were used in different combinations. Titles and abstracts were screened and full-text articles were analyzed for relevant publications. Most of the studies reported were for orthopedic, dermal, and myocardial applications. There were few reports related to dental and implant applications.¹⁰

Results

Artelon

Artelon is one of the degradable polyurethanes, and has been manufactured in various structures, including fibers, films, and porous scaffolds with various chemical and mechanical properties.^{11,12} Scaffolds of the various urethanes are prepared either by packing of fibers or by a solvent casting/particle leaching process.¹² Fibers are formed by extrusion of a 30% w/w polymer solution through a spinneret submerged in a coagulating bath containing hot water. Artelon may be made into different macroscopic structures, such as porous and fibrous forms, and the porous scaffold was reported to be more promising for clinical application.¹¹

Artelon has been used successfully for reinforcement of soft tissues, including the rotator cuff, Achilles, patellar, biceps, and quadriceps tendons in orthopedic surgery,^{8,9,11,13} and is used clinically for treatment of osteoarthritis in the hand, wrist, and foot (Table 1).¹² Moreover, it has also been used for soft tissue augmentation in the oral cavity.¹⁰

Biocompatibility

Materials implanted in soft or hard tissue will produce a cellular response.¹⁴ Activated cells produce cytokines, including interleukin-1, -6, and -10, as well as tumor necrosis factor- α , which are involved in regulating the immune response and wound healing. Many types of cells are involved in this process, including fibroblasts, macrophages, polymorphonuclear cells, and endothelial cells.¹⁵

Table 1 Different types of Artelon® materials

Product	Usage	Indication
Artelon Cosmetic	Augmentation of periodontal and peri-implant soft tissue defects	Volume-restoring
Artelon CMC Spacer	First carpometacarpal joint as an interpositional spacer	Resurfacing
Artelon STT Spacer	Scaphotrapezotrapezoidal joint as an interpositional spacer	Resurfacing
Artelon MTP Spacer	First metatarsophalangeal joint as an interpositional spacer	Resurfacing
Artelon/SportMesh™ tissue reinforcement	Achilles tendon, lateral ankle ligament, rotator cuff, patellar tendon, ulnar collateral ligament, posterior hip capsule, quadriceps tendon, spring ligament	Reinforcement

Biopsy specimens taken after 2 weeks show a large number of cells in the scaffold, most of which seem to be neutrophils and macrophages, confirmed by the use of monoclonal anti-CD68 antibody.¹² Smaller numbers of inflammatory cells are seen after 8 weeks when compared with 2 weeks. The biocompatibility of polyurethane has been compared with that of polystyrene and titanium, and polyurethane induced the lowest capsule formation after both 7 and 21 days.¹⁵

Long-term clinical data, animal data, and biopsy specimens have shown excellent biocompatibility with surrounding tissue without any chronic inflammatory response or multinuclear giant cell formation over a follow-up period of up to 2 years.¹² However, it has been reported that foreign body multinuclear giant cells were seen at histologic evaluation, and it was suggested that slowly degrading polyurethane may present a large unphagocytosable object, and a rough surface topography may favor multinuclear giant cell attachment to the surface.⁸

Artelon is reported to assist the building of new tissue by supporting volume and providing a scaffold for tissue ingrowth.¹⁶ Artelon scaffolds were seeded in vitro with approximately 10^4 cells of cell suspension per scaffold, and the results showed that human fibroblasts not only adhered to the surface but also migrated, proliferated, and produced components of an extracellular matrix.¹⁶ In some reports, Artelon membrane was precoated with laminin $10 \mu\text{g/mL}$ at room temperature and cell suspensions containing 5.0×10^6 cells were applied to the scaffold.¹⁷

Mechanical stability and resorption

In some cases, higher demands are needed regarding mechanical properties because compression and shear forces are constantly applied to the grafts.¹ For artificial tendons, it must be kept in mind that tendons are subjected to cyclic loads during healing and subsequent rehabilitation.

Biodegradable materials, such as chitin and polylactic acid, were tested to determine whether these may be used as scaffold implants in the reconstruction of extra-articular ligaments or tendons.¹⁸ Even though there was good tissue growth among the chitin fibers, the rapid loss of strength and inability to maintain sufficient strength indicated that chitin is unsuitable as an artificial tendon.¹⁹

Artelon grafts showed greater elongation properties (both elastic deformation and plastic deformation) and relatively high suture retention strength.¹⁹ Moreover, the Artelon band has a similar elastomechanical loading profile to that of the human anterior cruciate ligament tested

postmortem, and no relaxation or fatigue was observed after cyclic loading.⁸

In general, the design of scaffolds should enable temporary support of body structures or injured sites through stress transfer from one part to another, and thereafter be degraded over time.²⁰ Ideally, materials should be slowly biodegraded to elicit a minimal host response as well as provide long-term support during the tissue remodeling process.¹² The Artelon graft is reported to be degraded by hydrolysis, and this material may have a degradation time in vitro of more than 4 years.¹¹

Complications

An implant comprised of Artelon material was brought to market several years ago, and has been approved by the US Food and Drug Administration.²¹ The manufacturer claims that Artelon material has excellent biocompatibility, but complications have been reported.^{22–24} Persistent pain was reported after thumb carpometacarpal joint arthroplasty performed using an Artelon implant, and required removal of the Artelon implant and trapeziectomy to achieve subsequent symptomatic relief.²² A foreign body-type reaction associated with Artelon was seen histologically.²² There was one case in which a patient had sustained painful synovitis after implantation of the Artelon spacer in the scaphotrapeziotrapezoidal joint, which resolved clinically on removal of the implant.²⁴ Pathology specimens of soft tissue, synovium, and bone have also demonstrated a vigorous granulomatous foreign body giant cell reaction to the implant material. Patients should be made aware of the potential of the Artelon spacer to cause a foreign body reaction, that may necessitate reoperation for removal of the implant.²⁴ However, of six implants removed because of swelling and pain, five of the patients involved did not receive antibiotics preoperatively according to the protocol.²⁵

Swelling and warmth were noted when the Artelon scaffold was used for regeneration of the dermis, and low-grade inflammation with minor turbid secretion and itching were also noted.¹² It was also seen that the skin covering the scaffolds partly contracted, resulting in protrusion of the scaffold at all study sites.¹² Most of the total tissue volume gained was lost at 3 months in one case when an Artelon graft was used for soft tissue augmentation in dental implant treatment.¹⁰

Orthopedic applications

Artelon is used for treatment of osteoarthritis of the hand, wrist, and foot and to reinforce soft tissues, such as the anterior cruciate ligament of the knee.¹² The Artelon spacer is

designed for surgical treatment of osteoarthritis in the joint, and several spacers are available, such as the CMC spacer for the first carpometacarpal joint, the STT spacer for the scaphotrapeziotrapezoidal joint, and the MTP spacer for the metatarsophalangeal joint.^{23,25} Arthrodesis is associated with loss of mobility and transfer of reaction forces to the neighboring joints. In advanced arthrosis, some type of interposition arthroplasty may be indicated, requiring a period of immobilization of the spacer so that it can adhere.²⁶ In some reports, key and tripod pinch strength increased compared with before surgery in patients with an Artelon spacer and was significantly better compared with that in patients who had undergone ligament reconstruction and tendon interposition.⁹ However, controversy still exists as to whether the Artelon spacer is superior to trapeziectomy with ligament reconstruction and tendon interposition.^{27,28}

Artelon material has also been used in soft tissue reinforcement procedures, such as anterior cruciate ligament reconstruction.¹¹ The anterior cruciate ligament is the primary and most important stabilizer of the knee, and ruptures of this ligament are the most common serious ligament injuries. It was reported that Artelon substitution allowed ingrowth and adaptation of autogenous tissue.⁸ It was emphasized that proper use of preoperative antibiotics and thorough patient selection appear to be important for good results.²⁵

Dermal applications

Human dermal fibroblasts were cultured on discs of Artelon with different macrostructures (fibrous or porous), and they adhered to and migrated into the scaffolds, producing collagen.¹² It was suggested that Artelon may be used as a template for dermal regeneration.¹²

For complete regeneration of full thickness wounds, such as deep burns, both the epidermis and dermis must be replaced to avoid wound healing with scar tissue formation.¹² Much scientific work has focused on the possibility of regenerating the dermal part of the skin as well.²⁹ A potentially more promising way is to allow the body to regenerate the injured dermis *in vivo* by providing optimal prerequisites, such as by implanting a biodegradable scaffold that supports tissue ingrowth. In one study, fibroblasts in a porous Artelon scaffold reached halfway to the center of the scaffold at 1 week, and cells could be seen throughout the entire thickness of the scaffold after 4 weeks of incubation.¹²

Cardiovascular applications

Intramyocardial transplantation of skeletal myoblasts is reported to enhance cardiac function following infarction.³⁰

However, cell therapy via injection is always accompanied by a high death rate for injected cells.³¹ In a rat model, myoblasts were seeded onto an implanted Artelon scaffold.³⁰ This technique allowed transfer of a large number of living myoblasts to the damaged myocardium.³⁰ Furthermore, genetically engineered myoblasts were used to enhance the outcome by constructing a growth factor-producing myoblast-seeded scaffold.³¹ Precoating with laminin may allow more favorable cell attachment.³⁰

Dental applications

Polyurethane has been found to be one of the most successful polymers for soft tissue applications.¹⁴ One type of polyurethane scaffold, Artelon Cosmetic, is reported to be easily handled when cut to the desired shape, with little additional time needed for manipulation during surgery.¹⁰ Porous scaffolds have advantages because interconnections between the pores allow adhesion, proliferation, and migration of cells into the scaffolds.¹⁰ This material may be manufactured with a high degree of reproducibility and minimal risk of contamination.¹² Because there are no cellular elements in the scaffold, immunogenicity is reduced and the risk of disease transmission is very small.¹²

In one dental study, Artelon Cosmetic was applied in the anterior region where soft tissue augmentation was needed.¹⁰ In this study, preoperative and postoperative casts were obtained, and the casts were placed in a three-dimensional scanner for computer measurements, using the preoperative reference model as a baseline.¹⁰ Soft tissue volume was increased up to the final evaluation at 6 months when an Artelon graft was used during implant treatment.¹⁰ By using this product, there is no need to perform a connective tissue autograft, and there is less patient morbidity and postoperative discomfort with a better positive subjective outcome for the patient.¹⁰

Conclusion

Soft tissue augmentation is a widely used procedure in partially and fully edentulous patients to increase soft tissue volume. Polyurethanes have been used as scaffolds in various implantable devices, including degradable ones. Artelon has been manufactured as fibers, films, and porous scaffolds to be used in various applications. Recently, Artelon Cosmetic has been used in the dental field to increase soft tissue volume, and stable results were achieved for up to 6 months. It may be concluded that using Artelon Cosmetic for esthetic purposes can give beneficial results in periodontal plastic surgery or oral surgery procedures. Further studies of its various

applications in dentistry with their long-term outcomes are needed to confirm that this material can be used on a regular basis in dentistry.

Disclosure

The authors report no conflicts of interest in this work.

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