Case Study

First-In-Human Use of the allay™ Hydrogel Cap in Sequential Amputations for a High-Risk Patient

Surgeon & Facility
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Specialties
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Case Summary
This case report describes the first-in-human use of the allay™ Hydrogel Cap with Adaptive Hydrogel technology in a female patient with several medical comorbidities and high anesthetic risk. Progressive soft-tissue necrosis following fixation of an ankle fracture necessitated a Below-Knee Amputation (BKA), followed 2.5 months later by an Above-Knee Amputation (AKA). Targeted Muscle Reinnervation (TMR) was deemed unsuitable due to the patient's comorbidities and the risk associated with prolonged general anesthesia, resulting in use of the allay™ Hydrogel Cap, a first-of-its-kind FDA-classified De Novo medical device. While the second procedure was unrelated to the Hydrogel Cap performance, it uniquely allowed evaluation of the potential of allay™ in reducing the risk of neuroma formation and advancing peripheral nerve surgery.

Clinical Problem
Targeted Muscle Reinnervation (TMR) and related techniques remain the most effective surgical solution for prevention and treatment of symptomatic neuromas. However, there are important limitations to these approaches including additional operative time under anesthesia, added morbidity through incisions and dissection, and the technical nature of nerve microsurgery and coaptation, among others. The patient presented in this case report is a high-risk surgical candidate in which TMR was deemed to be unsuitable, prompting the first-in-human use of the allay™ Hydrogel Cap.

Procedure #1: Below-Knee Amputation
A 65 year-old female patient with a history of poorly controlled type 2 diabetes, liver cirrhosis, calciphylaxis, and end-stage kidney disease on dialysis presented with progressive soft tissue necrosis of the leg following fixation of an ankle fracture. Due to the patient's medical history and extent of skin necrosis, she was not a candidate for limb salvage and Below-Knee Amputation (BKA) was recommended. Further, her high anesthetic and surgical risk rendered her a suboptimal candidate for TMR. As a substitute to mitigate the risk of neuroma formation post-amputation, the allay™ Hydrogel Cap was chosen for its ease of use with rapid, in situ deployment. The hydrogel was used to cap the three major peripheral nerves of the lower extremity: the Tibial, Deep Peroneal, and Superficial Peroneal (Figure 1, Table 1). This approach to nerve stabilization required only a few minutes to complete, substantially reducing the duration of anesthesia and operative morbidity compared to when TMR is performed.

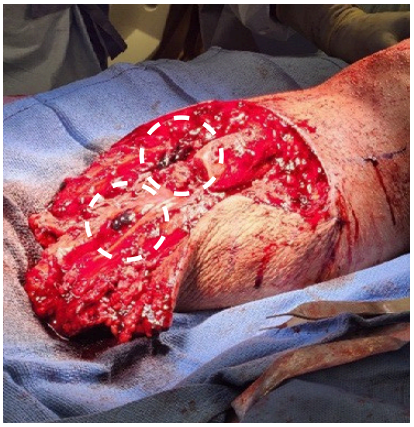

Figure 1: Below-Knee Amputation with allay™ Hydrogel Cap applied to the Tibial, Deep Peroneal, and Superficial Peroneal nerves.

Table 1: Nerves Treated (BKA)

Nerves Treated	Size	allay™ Form Size
Tibial Nerve	6 mm	6 mm
Deep Peroneal Nerve	2.5 mm	3 mm
Superficial Peroneal Nerve	2.5 mm	3 mm

allay™ HYDROGEL CAP

Procedure #2: Above-Knee Amputation (2.5 Months Post-BKA)

Unfortunately, due to the progressive nature of the patient's peripheral ischemia and calciphylaxis, the patient required conversion to an Above-Knee Amputation (AKA) 2.5 months after the initial BKA procedure. During the AKA, the Sciatic nerve was divided into four fascicles and an allay™ Hydrogel Cap was applied to each fascicle, as well as to the Saphenous nerve (Figure 2, Table 2). The surgeon inspected the nerves previously capped during the prior BKA procedure and observed no scar tissue, inflammation, or adhesions present. Each allay™ Hydrogel Cap retained full structural integrity, effectively encapsulating the nerves and demonstrated seamless gliding against local tissues. While the allay™ Hydrogel Cap is designed to fully absorb over an eight-month period (Figure 4), it was observed during the AKA that the hydrogel cap reflected minimal absorption at this stage of operative recovery (Figure 3). These findings suggest promising long-term potential for the allay™ Hydrogel Cap in optimizing recovery and reducing the risk of neuroma formation.

Table 2: Nerves Treated (AKA)

Nerves Treated	Size	allay™ Form Size
Sciatic Nerve (Divided into 4 Fascicles)	12 mm	5 mm (Fascicle 1) 5 mm (Fascicle 2) 2 mm (Fascicle 3) 2 mm (Fascicle 4)
Saphenous Nerve	1.5 mm	3 mm

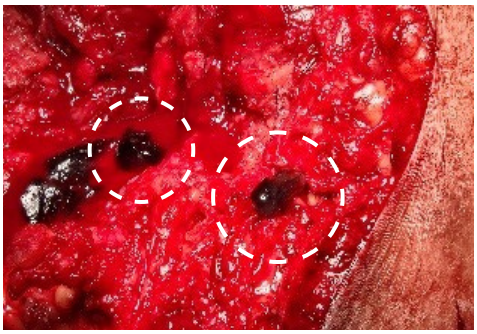

Figure 2: AKA with the allay™ Hydrogel Cap applied to Sciatic nerve fascicles and the Saphenous nerve.

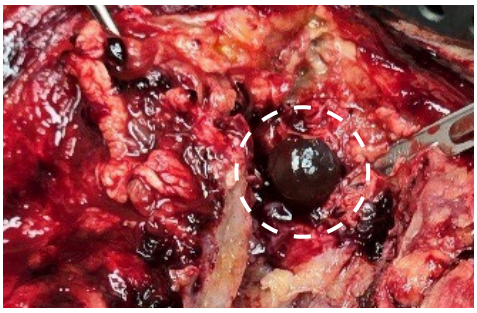

Figure 3: BKA specimen examination at 2.5 months post-BKA showing the allay™ Hydrogel Cap performance, with complete structural integrity and no signs of inflammation, scar tissue, or adhesions.

Conclusion

The allay™ Hydrogel Cap offers a novel solution for high-risk patients unsuitable for TMR. The device prevented symptomatic neuroma formation, preserved nerve integrity without scar tissue or adhesions, and reduced operative time and morbidity, directly addressing the key challenges in peripheral nerve surgery. This unique case underscores the allay™ Hydrogel Cap's potential to reduce the risk of symptomatic neuromas and improve surgical outcomes, making it a valuable alternative or complement to existing techniques.

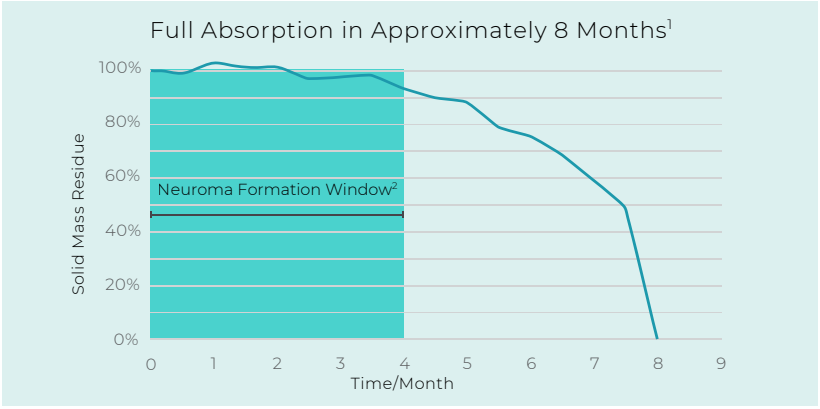

Figure 4: The allay™ Hydrogel Cap remains in place throughout the healing process and is fully absorbed via hydrolysis in approximately 8 months.

"In nerve surgery, we continually seek implant materials that can best support nerve regeneration and replicate the natural environment in which healthy, uninjured nerves are found. ***After having used so many different types of implants, I have never seen anything like this.*** *All implants produce capsules, scar tissue and adhesions, and varying degrees of inflammatory response. In the case of the Hydrogel Cap examined 2.5 months after implantation, I identified no scar tissue, no adhesions, and perfect gliding of the hydrogel in relation to the surrounding tissues which was just remarkable."*

Edward Kobraei, MD

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(887) 885-2841
or email customercare@tulavi.com

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allay™ Hydrogel Cap
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1. Data on File at Tulavi. 2. Oliveira KMC, et al. Time course of traumatic neuroma development. PLoS One. 2018 Jul 16;13(7):e0200548.