



Novel ankle cast designs with non-toxic material

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Foot and ankle immobilization is usually based on circular support, either using casts or boot-like orthoses. Basic requirements for immobilization of the ankle region include reliable support and possibility of full weight bearing during healing. Woodcast® is a novel, freely 3D moldable cast material based on non-toxic components. The material is strong but light weight and can be used as a split or a cast. Our hypothesis was to test in a proof-of-concept type study, whether a new open cast design, leaving the calf area free can be clinically used in ankle immobilization. Thirty patients with an acute ankle fracture or a recently performed ankle arthrodesis were recruited. Two different types of cast designs were used, one semi-rigid cast and one rigid cast. All fractures and arthrodesis healed well, with no major postoperative complications. Patient satisfaction was high in both groups and slightly higher in the semi-rigid group. This study shows that the ankle area can be immobilized using a novel type of a very light weight Woodcast® material. By combining soft and hard wood composite materials, an optimal open cast design leaving the calf area free can be performed, allowing full weight bearing and reliable immobilizing of the ankle.

Key words: Ankle, fracture, immobilization, cast, orthosis, wood, orthopaedic equipment, orthopaedic fixation devices

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Immobilisation in fracture treatment has a long history. Fractures have been treated millennia with natural materials such as wood sticks, but it was only until 1852 that Plaster-of-Paris (POP) was first used in fracture treatment. Inorganic calcium based component had been traditionally used in building walls, but it required additional binding material to be used in limb immobilization. Cotton offered this possibility, and it was utilized almost simultaneously by two army doctors, Dutch Antonius Mathysen and Russian Nikolay Pirogov.

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It took a long time to get the first commercially available POP on the market (Cellona, Germany 1932). Typically, POP offered sufficient rigidity with relatively thick and heavy layers, allowing at least partial weight bearing. But it was also brittle and did not tolerate water. As a first improvement to POP, fiberglass was introduced to fracture treatment in the 1950s. It is lightweight, rigid or semi-rigid, and tolerates both water and continuous mechanical loading during walking. It is partially moldable with a strong net like support structure as a limiting factor [1-3]. Modern orthopedic plaster casts are commonly based on synthetic plastic that contains up to 25% methylene diphenyl diisocyanate (MDI). Severe issues have been raised in occupational health sector related to use of isocyanates used in modern paints, moldable glues and orthopaedic casting materials like fiberglass and polyurethane [4].

Ankle fractures can be treated in a conservative way when certain criteria are fulfilled. Some centers prefer cast immobilization also after plate fixation, others rely more on ORIF stability and accept functional orthosis or free mobilization. If cast is to be used, it is however of one basic design regardless of material used. The leg and calf area are covered with a circular cast having different additional layers for sufficient stability [5-9]. Different kind of pre-shaped orthosis have come to the market, initially for functional treatment of ankle sprains, and in some studies also for treatment of ankle fractures [10-14].

In 2010, an innovative wood-composite material was introduced for fracture treatment by Onbone Oy, Helsinki, Finland. The Woodcast® material is an ecologically friendly, biodegradable, wood-plastic composite material, with absolutely free three-dimensional (3D) molding properties. Because of its extreme strength and exceptional molding properties, we hypothesized that it could be possible to treat common ankle fractures and postoperative immobilization in ankle arthrodesis with a novel, open cast design. The goal for the cast was to leave the calf area free, and to allow cast removal and reinserting without tools. Absolute requirements were that the new cast design has to be stiff enough to allow full weight bearing.

This proof-of-concept type multicenter trial was conducted in accordance with the ethics principle originating in the latest version of the Declaration of Helsinki, applicable regulatory requirements, including the standards of the International Organization, and Finnish law and regulations. The study protocol was approved by the Ethics Committee of the Helsinki University Central Hospital (HUCH) and informed consent was obtained of the patients. The study was registered at www.clinicaltrials.gov.

Major hypothesis were that novel light weight cast designs could be successful in treatment of ankle fractures and as postoperative supporting device after ankle arthrodesis.

Methods

Casting materials

Woodcast® is a composite of thermoplastic polymer and a woody material approved for clinical use in limb immobilization (European approval in 2010). The material is hard in room and body temperature, but becomes moldable when heated up to +62 °C. During cooling, it retains moldable down to 45 °C offering extended working time. When ready, casting hardening can be enhanced with external cooling. The material is non-toxic, does not release irritant aerosols, and can be handled without protective gloves. It is strongly self-adhesive and slightly adhesive toward padding and bandage materials, but does not attach to skin. It can be composted after use. The Woodcast® materials can be reheated repeatedly without affecting their mechanical properties, and they can be stretched and bent freely in 3D.

Patients

Thirty patients were enrolled in the study. The inclusion criteria were: Finnish or Swedish speaking patient, age between 0-90 years, a non-complicated ankle fracture or a performed elective foot arthrodesis normally requiring cast immobilization. The exclusion criteria were compromised co-operation for any reason, a complicated fracture, other simultaneous or earlier fractures, nerve, vessel or tendon injuries on the index extremity, malignancy and other severe diseases.

Postoperatively the patients were treated with other casting materials for two weeks. After two weeks the postoperative cast was changed either to a Woodcast® semi-rigid ankle cast model (Group 1) or a rigid model (Group 2). The cast technicians were educated for both models and the choice of design depended on the hospital they were working in.



Figure 1 A removable semi-rigid orthosis.

The semi-rigid model was made of 80 cm long Woodcast® 2 mm Soft, 40 cm long Woodcast® 4 mm and of a 15 cm piece of Woodcast® 2mm. The Woodcast® 4 mm offers mechanical stability and the Soft product is used to achieve flexibility. The cast material was applied on the anterior part of the extremity leaving the posterior side of the extremity free and then allowed to cool. The cast was then removed and finalized with soft tape around the edges (Figure 1). Padding and Velcro tape were used. During the immobilization period the patients were allowed to remove the cast temporarily.

The rigid cast was made of two 80 cm long Woodcast® 2mm pieces with paddings protecting the skin. A U-shaped casting material was applied from the lateral side, around the heel area and extending to medial side. The other 80 cm piece was cut oblique in two parts and applied anteriorly to stabilize the TC-joint and protect the plantar area during walking (Figure 2).



Figure 2 A non-removable rigid cast.

Results

All patients completed the study. Thirteen (13/30) patients with ankle fractures were treated with the semi-rigid orthosis (Group 1). In 17/30 cases the rigid cast was used (Group 2) including 10 ankle arthrodesis patients and 7 trauma cases. In Group 1 the average age was 47.5 (the youngest patient being 24, and oldest 66 years old) and in group 2 the average age was 50.1 (the youngest patient being 24, and oldest 76 years old). Applying time was not depended on cast type rather skills of the technician. There were no major difference in immobilization time between Groups 1 and 2 (Table 1).

The orthopedic technicians reported that no primary complications occurred in Group 1, although in one case orthosis soft material broke from the metatarsus area during the last week of immobilization, but didn't cause complications for the patient. Twelve (12/13) of the patients in Group 1 reported that they removed the orthosis themselves during the immobilization at least once.

Primary complications were reported by technicians in Group 2. Molding the cast was not easy in one case and in six of the cases there were issues applying the

	Group 1	Group 2
	Removable semi-rigid orthosis (n=13)	Non-removable rigid cast (n=17)
Age in years (mean ± SD)	47.5 ± 12.3	50.1 ± 14.5
Applying time in minutes (mean ± SD)	25.5 ± 12.8	15.2 ± 7.5
Immobilization time in weeks (mean ± SD)	4.2 ± 0.90	3.9 ± 0.78
Trauma/elective n	13/0	7/10
Successful immobilization n	13/13	16/17
Complications n	0/13	12/17

Table 1 Results of removable semi-rigid orthosis versus non-removable rigid cast.

cast in correct position because of the multilayer composition. In two of the cases preheating the casting material didn't occur fast enough.

Patient satisfaction was high in both groups yet superficial skin complications were seen in Group 2. Superficial maceration reported in 6/17 cases, focal compression in the cast 3/17 and 3/17 both simultaneously (Table 1). One rigid cast was changed to the semi-rigid orthosis because of the increased level of moisture in the cast with good results. There were no skin complications in Group 1. There were no post-operative infections in either of the reported groups.

Discussion

Cast designs used in this study concentrate especially in immobilization of ankle joint and subtalar joint lines. Shortening the distal dimension in the cast gives more freedom to the toes, to the Lisfranc area, and finally to midtarsal Chopart joint line. This more targeted immobilization is possible with the specific material properties, but whether this has an effect on functional recovery remains to be seen in future studies. In acute ankle sprains (grades II & III), functional brace seems to give better outcome than total immobilization of the lower extremity [12,14]. It can be at least assumed that this kind of new material offers possibilities to design functional braces in the near future.

The anteromedial margin of tibia is the area where soft tissue layers are thinnest. This offers a good contact area for bone immobilization, but requires good fitting of cast material. Cast designs used in this

study utilize this area as an anchor site for ankle immobilization. Although no direct force measures were included in this study, our emphasis is that this is far more stable than padded circular cast around the whole calf area with soft tissues on the posterior area. No patient had discomfort on this anteromedial area, even with the use of hard material only. The hard version of Woodcast®, 4 mm and 2 mm are extremely stiff and durable materials. Hard material can be used as an internal support in elastic constructions, but if it is used as the only material attention must be paid on breathability and edges of cast design. Based on our experience in this relative small patient population, skin maceration and compression discomfort can occur in closed cast design. In Group 1, no patients with combined soft and hard material had cast related discomfort. This emphasizes the role of careful cast design, and use of appropriate padding.

The immobilization or the cast itself can cause several complications. Pressure sores are common complications if improper techniques are used. The risk receiving pressure sores increases in patients who suffer from peripheral nerve or vessel disorders. Compartment syndrome may develop due to a too tight cast [15]. Immobilization may also lead to problems such as joint stiffness, muscle atrophy, cartilage degradation, ligament weakening and osteoporosis [9]. Deep venous thrombosis (DVT) is perhaps the most common complication in lower extremity immobilization, with an incidence of 1.1% to 20% in various type of lower limb injuries treated with a circular cast [16]. In this study, no DVT occurred although no prophylactic agents were used. The number of patients in this proof-of-concept

study is too low to draw any solid conclusions on this, but it can be assumed that this type of novel cast design leaving the calf muscle area free could even decrease the risk of DVT. If a DVT is suspected, a circular cast has to be removed, but this open design allows ultrasound diagnostics directly with cast on.

Achilles tendon ruptures are prone to wound complications [18]. Although these ruptures were not in the scope of this study, it is evident that this kind of easily removable cast will fit well in treatment of these injuries. One advantage would be to monitor and treat wound complications even with the cast on. It also gives a direct access to healing tendon, either to monitor tendon healing with ultrasound, or possibly to stimulate tendon healing with external pulsating equipment.

Conclusions

This study challenges the long-time circular cast design in ankle immobilization. It seems that even a semi-rigid open wood composite cast is safe and strong enough to stabilize common ankle fractures, and to successfully protect postoperative period after ankle arthrodesis. Taken together current data is very promising for an open type cast technology, further and larger studies are highly warranted.

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