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(54) NANO-SILVER FOOTWEAR ORTHOTIC WITH INSERT AND METHOD OF MANUFACTURE

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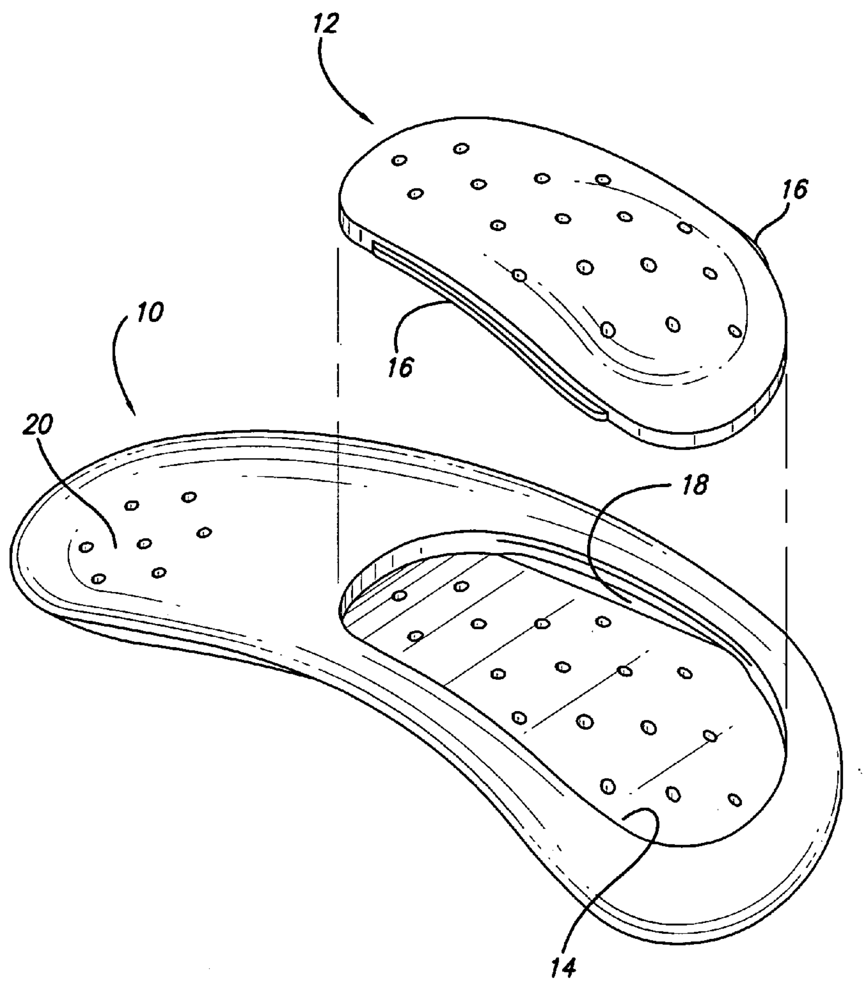
(57) **ABSTRACT**

A nano-silver footwear orthotic includes at least two removable inserts. The footwear orthotic and/or the at least two removable inserts are composed of a nano-silver copolymer being copolymer with silver nano-particles therein. In one aspect, the copolymer is a thermoplastic elastomer. The nano-silver copolymer has anti-microbial effects and ensures bio-compatibility with known undesirable microorganisms. Corresponding manufacturing processes prepare the silver nano-particles with a silver nitrate solution and a sodium borohydride solution and add the silver nano-particles to a master batch and a base material to form the nano-silver copolymer in a mold cavity. The mold cavity may be constructed to form the nano-silver footwear orthotic and/or a removable insert therein. Alternatively, the nano-silver copolymer may be formed within the nano-silver footwear orthotic itself to form a removable insert. Tests showing the content of silver nano-particles in a silver—copolymer mixture and corresponding antimicrobial effect tests show anti-microbial effects against bacteria known to cause foot odor and itchiness.



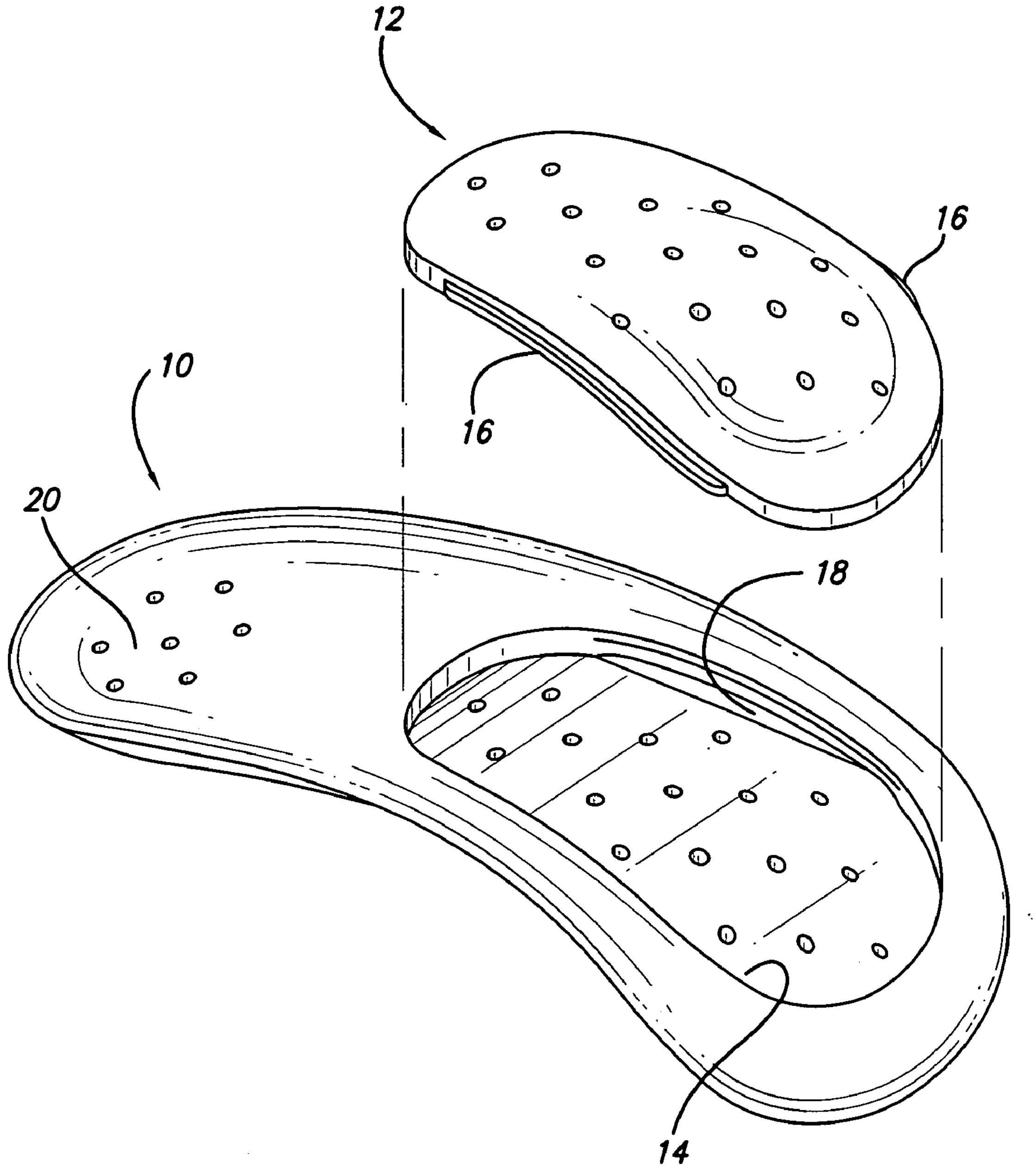


FIG. 1

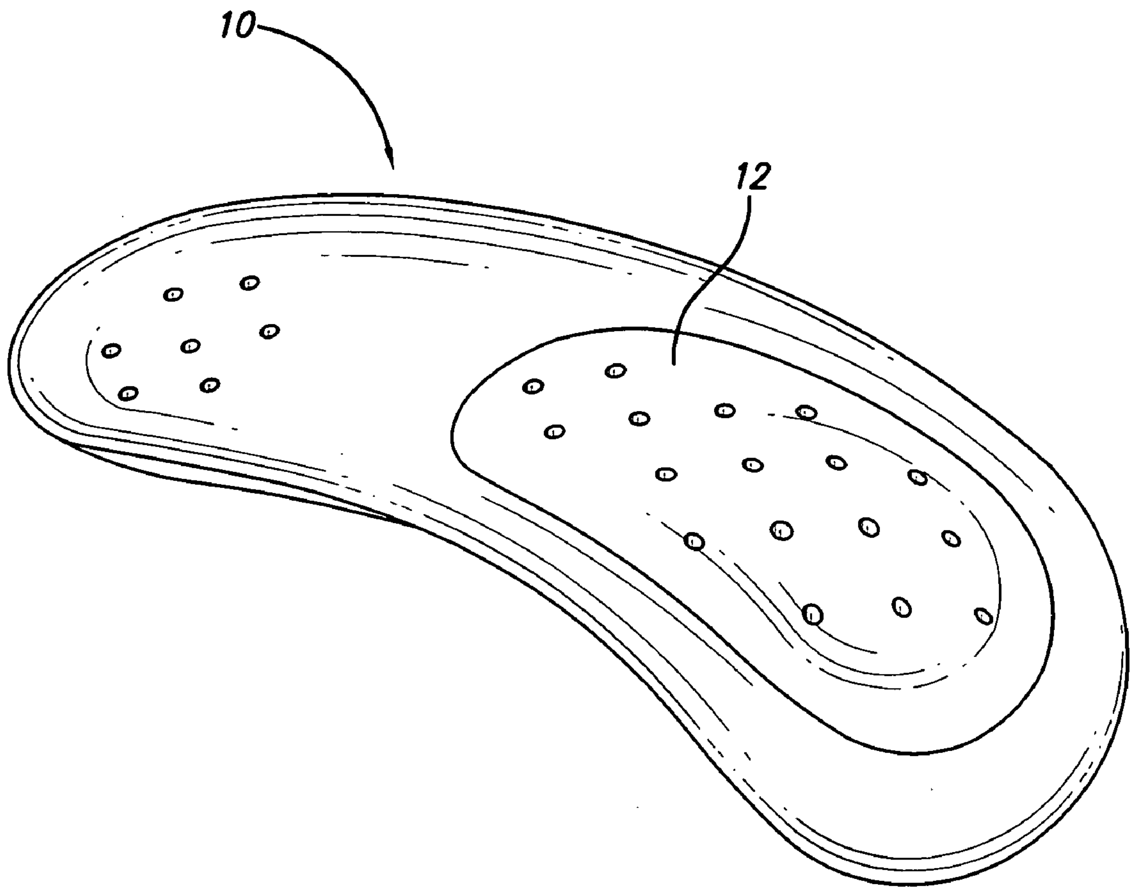


FIG. 2

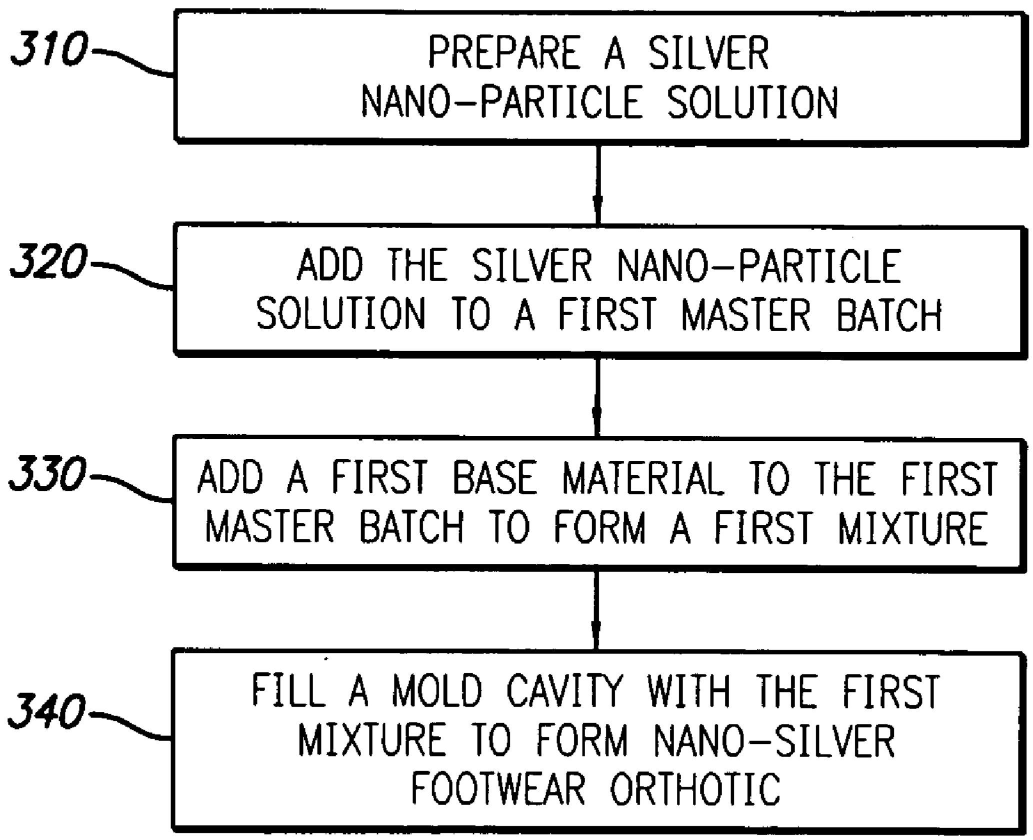

310
PREPARE A SILVER NANO-PARTICLE SOLUTION
320
ADD THE SILVER NANO-PARTICLE SOLUTION TO A FIRST MASTER BATCH
330
ADD A FIRST BASE MATERIAL TO THE FIRST MASTER BATCH TO FORM A FIRST MIXTURE
340
FILL A MOLD CAVITY WITH THE FIRST MIXTURE TO FORM NANO-SILVER FOOTWEAR ORTHOTIC

FIG. 3

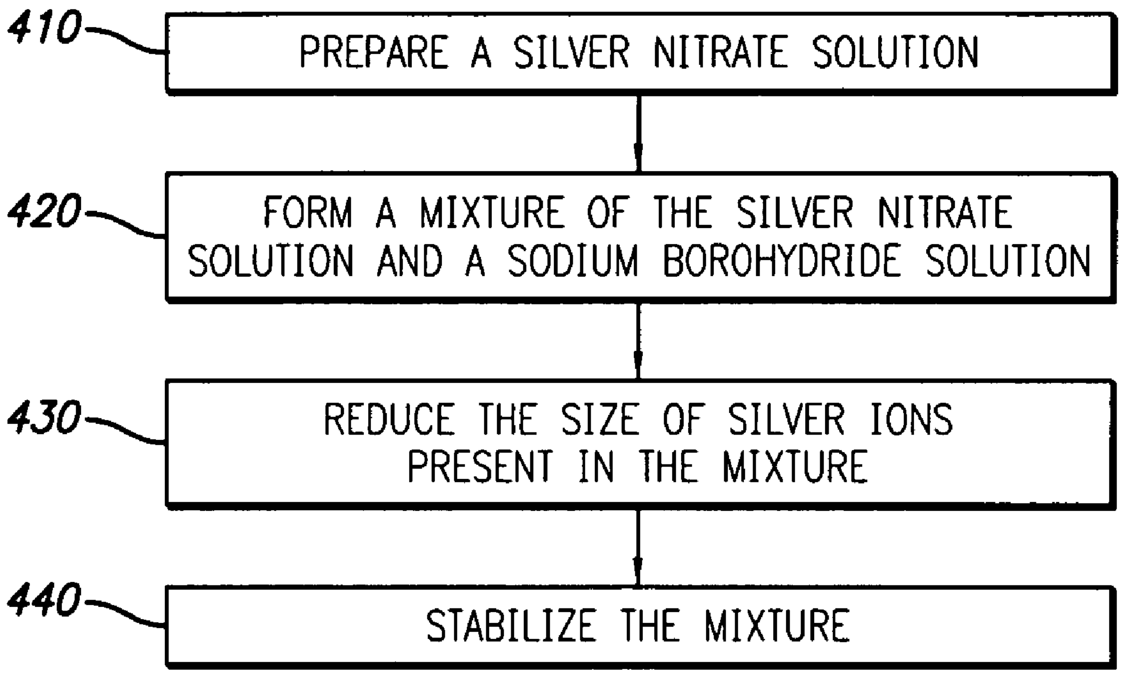

410
PREPARE A SILVER NITRATE SOLUTION
420
FORM A MIXTURE OF THE SILVER NITRATE SOLUTION AND A SODIUM BOROHYDRIDE SOLUTION
430
REDUCE THE SIZE OF SILVER IONS PRESENT IN THE MIXTURE
440
STABILIZE THE MIXTURE

FIG. 4

NO.	SAMPLE ITEM		TEST ITEM	RESULT (mg/kg)
A	PAg−40C; CONTENT: 3.6%; SIZE: 67nm; USAGE RATE: 1.4:100	SBS 85A	SILVER (Ag) CONTENT	85.0
B	PAg−40C; CONTENT: 3.6%; SIZE: 67nm; USAGE RATE: 1.4:100	SEBS 15A		132
C	PAg−40B; CONTENT: 3%; SIZE: 67nm; USAGE RATE: 1.7:100	SBS 85A		214
D	PAg−40B; CONTENT: 3%; SIZE: 67nm; USAGE RATE: 1.7:100	SEBS 15A		115

FIG. 5

FIG. 6

NO.	SAMPLE NAME
1	SBS 85A (FL)
2	SEBS 15A (FL)

TEST METHOD:
JIS Z 2801 : 2000 ANTIMICROBIAL PRODUCTS − TEST FOR ANTIMICROBIAL ACTIVITY AND EFFICACY

TEST ORGANISM: *MICROCOCCUS LUTEUS* AS 1.241

#1 TEST RESULTS:

NAME OF TEST BACTERIA (STRAIN NUMBER)	CONCENTRATION OF BACTERIA (cfu/mL)	THE NUMBER OF BACTERIA RECOVERED FROM			LOG VALUE OF ANTIMICROBIAL ACTIVITY
		/	AT "0H" CONTACT TIME	AT "24H" CONTACT TIME	
MICROCOCCUS LUTEUS AS 1.241	$1.2X10^6$	SAMPLE	/	<10	>5.2
		CONTROL SAMPLE	$1.2X10^5$	$1.6X10^6$	

CONCLUSION:
PASS, THE LOG VALUE OF ANTIMICROBIAL ACTIVITY AGAINST MICROCOCCUS LUTEUS IS >5.2, COMPLIES WITH JIS Z 2801 : 2000 SPECIFICATION FOR ANTIMICROBIAL ACTIVITY AND EFFICACY OF ANTIMICROBIAL PRODUCTS (LOG VALUE OF ANTIMICROBIAL ACTIVITY $\geq$ 2.0)

#2 TEST RESULTS:

NAME OF TEST BACTERIA (STRAIN NUMBER)	CONCENTRATION OF BACTERIA (cfu/mL)	THE NUMBER OF BACTERIA RECOVERED FROM			LOG VALUE OF ANTIMICROBIAL ACTIVITY
		/	AT "0H" CONTACT TIME	AT "24H" CONTACT TIME	
MICROCOCCUS LUTEUS AS 1.241	$1.2X10^6$	SAMPLE	/	40	4.5
		CONTROL SAMPLE	$1.2X10^5$	$1.3X10^6$	

CONCLUSION:
PASS, THE LOG VALUE OF ANTIMICROBIAL ACTIVITY AGAINST MICROCOCCUS LUTEUS IS 4.5, COMPLIES WITH JIS Z 2801 : 2000 SPECIFICATION FOR ANTIMICROBIAL ACTIVITY AND EFFICACY OF ANTIMICROBIAL PRODUCTS (LOG VALUE OF ANTIMICROBIAL ACTIVITY $\geq$ 2.0)

FIG. 7

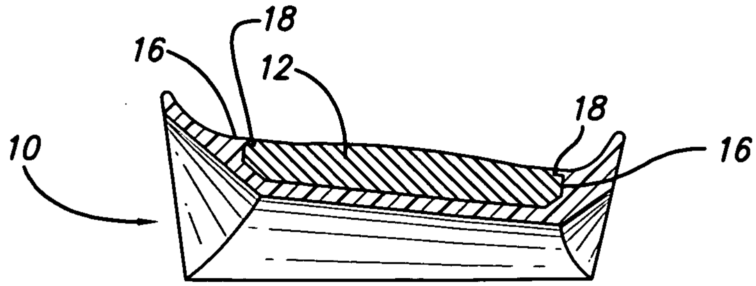


FIG. 8

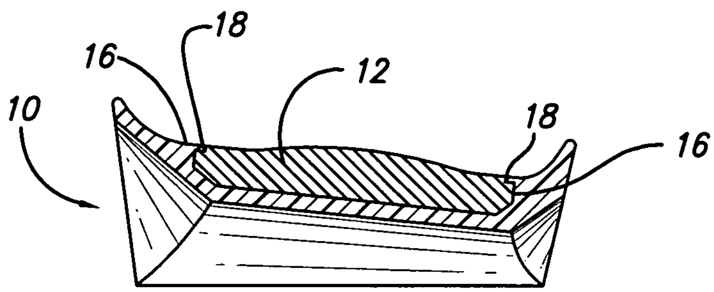


FIG. 9

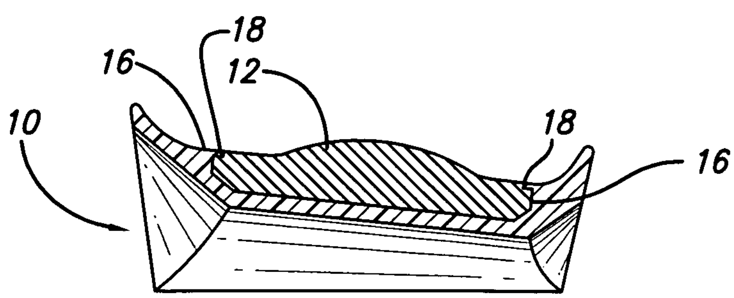


FIG. 10

NANO-SILVER FOOTWEAR ORTHOTIC WITH INSERT AND METHOD OF MANUFACTURE

FIELD

[0001] The field of the present invention is footwear orthotics.

BACKGROUND

[0002] Footwear orthotics have been successfully used to treat persons dealing with foot discomfort and/or pain. Orthotic inserts can augment arch support provided by existing footwear, providing increased support for the medial arch, the metatarsal arch and the plantar arch. Some orthotics now include multipart systems. Reference is made to U.S. Pat. No. 6,990,756, the disclosure of which is incorporated herein by reference.

[0003] People generally wear footwear for hours each day. Over time, footwear can experience growths of bacteria that cause foot odor and itchiness. Bacteria such as *Micrococcus Luteus* and *Corynebacteria* are known causes of foot odor and itchiness. Powders and other measures are available to combat such bacteria. Typically, footwear orthotics, such as the multipart system referenced above, have not been used to treat foot odor or bacteria. It is desirable to provide a foot orthotic that serves the dual purpose of providing support to the user's foot and combating bacteria.

SUMMARY OF THE INVENTION

[0004] The present invention is directed to a nano-silver footwear orthotic with inserts and method of manufacture. Footwear orthotics and inserts therein composed of a mixture of silver nano-particles and base materials have antimicrobial effects, thereby preventing foot odor and itchiness. Corresponding manufacturing processes result in footwear orthotics and inserts therein composed of silver nano-particles of therapeutic ratio to ensure antimicrobial effects. Footwear orthotic systems with inserts composed of nano-silver ensure that bacteria harbored between components may be combated effectively, reaching areas of footwear orthotics that ordinarily cannot be reached with conventional powders and other measures.

[0005] According to one aspect, an anti-microbial footwear orthotic includes an orthotic with an arch section defining an arch opening therein, and multiple inserts of varying profile for insertion into the arch opening one at a time. The orthotic and inserts being elastomer with silver nano-particles therein at therapeutic ratio to be an effective antibacterial agent. The therapeutic ratio being in the range of 2.1% of silver nano-particles to elastomer.

[0006] According to another aspect, there is disclosed a method of manufacturing antimicrobial footwear orthotics by preparing silver nano-particles by reducing the silver from a silver nitrate and sodium borohydride solution. A master batch is then prepared with a thermoplastic elastomer and the silver nano-particles. Footwear orthotics is then molded with master batch, the orthotics having the silver nano-particles at a therapeutic ratio to be an effective antibacterial agent.

[0007] According to another aspect any of the foregoing aspects are contemplated to be employed in combination to greater advantage to create an improved footwear orthotic. Other and further objects and advantages will appear hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. **1** is an exploded assembly prospective view of an exemplary nano-silver footwear orthotic with a removable insert.

[0009] FIG. **2** is a prospective view of an exemplary nano-silver footwear orthotic with a removable insert.

[0010] FIG. **3** is a flowchart illustrating an exemplary process for manufacturing a nano-silver footwear orthotic with a removable insert.

[0011] FIG. **4** is a flowchart illustrating an exemplary process for preparing silver nano-particles.

[0012] FIG. **5** is a test report identifying exemplary nano-silver copolymers and the silver nano-particle content within each of the nano-silver copolymers.

[0013] FIG. **6** is a test report identifying two antimicrobial tests on two different exemplary thermoplastic elastomers containing silver nano-particles.

[0014] FIG. **7** is a test data sheet showing tests in compliance with the Japanese Industrial Standard "JIS Z 2801:2000 Antimicrobial Products—Test for Anti-Microbial Activity and Efficacy."

[0015] FIG. **8** is a cross-sectional view of an exemplary nano-silver footwear orthotic with an exemplary low-profile removable insert installed therein.

[0016] FIG. **9** is a cross-sectional view of an exemplary nano-silver footwear orthotic with an exemplary medium-profile removable insert installed therein.

[0017] FIG. **10** is a cross-sectional view of an exemplary nano-silver footwear orthotic with an exemplary high-profile removable insert installed therein.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0018] The detailed description set forth below in connection with the appended drawings is intended as a description of various aspects of the present disclosure and is not intended to represent the only aspects in which the present disclosure may be practiced. Each aspect described in this disclosure is provided merely as an example or illustration of the present disclosure, and should not necessarily be construed as preferred or advantageous over other aspects. The detailed description includes specific details for the purpose of providing a thorough understanding of the present disclosure. However, it will be apparent to those skilled in the art that the present disclosure may be practiced without these specific details. Acronyms and other descriptive terminology may be used merely for convenience and clarity and are not intended to limit the scope of the disclosure.

[0019] One skilled in the art would understand that the following figures present exemplary aspects of the nano-silver footwear orthotic with insert in this disclosure. Various other aspects of the nano-silver footwear orthotic with insert presented in the figures will be readily apparent to those skilled in the art without departing from the spirit or scope of the present disclosure.

[0020] FIG. **1** is an exploded assembly prospective view of an exemplary nano-silver footwear orthotic with a removable insert. In an aspect, a nano-silver footwear orthotic **10** includes a removable insert **12**. The removable insert **12**

shown in FIG. **1** has been removed from the nano-silver footwear orthotic **10**. The removable insert **12** is made removable to enable a user to customize an orthotic for a specified comfort level and gradually train his or her foot to become accustomed to the maximum arch support provided by an orthotic. The removable insert **12** is press-fitted or friction fitted into a cavity **14** in the nano-silver footwear orthotic **10**. In an aspect, the removable insert **12** has rails **16** positioned on each side to ensure that the removable insert **12** stays in place. The rails **16** engage corresponding guides **18** on each side of the cavity **14** to hold the removable insert **12** in place. The footwear orthotic **10** further comprises a heel section **20**. FIG. **2** is a prospective view of an exemplary nano-silver footwear orthotic with a removable insert. This exemplary nano-silver footwear orthotic has the removable insert **12** installed therein. One of ordinary skill in the art would understand that the manner in which the removable insert **12** is secured to the footwear orthotic may be implemented in one of many ways.

[0021] In one embodiment, the nano-silver footwear orthotic **10** is constructed of a single piece of molded resilient plastic so shaped as to include protrusions and contours for providing proper arch support. The specific shape of the nano-silver footwear orthotic **10** may vary according to the size of the user's feet. One of ordinary skill in the art would understand that the nano-silver footwear orthotic **10** may be implemented with orthotics of various sizes and shapes.

[0022] In an aspect, the nano-silver footwear orthotic **10** is composed of a nano-silver copolymer. In an aspect the nano-silver footwear orthotic **10** is molded. Silver (Ag) ions or salts have known antimicrobial effects. Silver ions and silver-based compounds are highly toxic to microorganisms such as *E. coli, Micrococcus Luteus* and *Corynebacteria.* Silver salts are used to control bacterial growth in a variety of applications including dental work, catheters and burn wounds. However, silver particles can be reduced in size as an efficient and reliable tool for improving their biocompatibility with microorganisms. Reduced to a nano-particle size, silver nano-particles may be mixed with the base material of a footwear orthotic to enhance biocompatibility with known microorganisms that cause foot odor and itchiness.

[0023] In an aspect, the nano-silver copolymer is formed by mixing a copolymer with a percentage of silver nano-particles (e.g., spherical nano-silver powder and/or silver nano-particles) to form nano-silver plastic pellets ready for injection molding. The copolymer and silver nano-particles may also be added to a master batch to ensure proper consistency. The nano-silver plastic pellets may be injection molded to form the nano-silver footwear orthotic **10**. The silver nano-particles have dimensions in the nano-particle range to ensure biocompatibility with several forms of microorganisms known to cause foot odor and itchiness. *Micrococcus Luteus* and *Corynebacteria* are known to cause foot odor and itchiness. The size of the silver nano-particles ensures that more surface area of relatively larger microorganisms is exposed to the anti-microbial effects of silver.

[0024] Mixed with the copolymer, the silver nano-particles destroy or control the growth of microorganisms or bacteria on a person's foot or in the user's footwear. The resulting nano-silver copolymer provides antimicrobial effects against, for example, *Micrococcus Luteus* and *Corynebacteria.* FIGS. **5**, **6** and **7** confirm the antimicrobial effects of the nano-silver copolymer. The nano-silver copolymer also prevents and/or manages a number of other known microorganisms or bacteria growth. The nano-silver footwear orthotic **10** can be composed of a mixture of thermoplastic elastomer and the silver nano-particles.

[0025] FIG. **3** is a flowchart illustrating a process for manufacturing an exemplary nano-silver footwear orthotic with a removable insert. In Block **310**, silver nano-particles are prepared. A method for preparing the silver nano-particles is shown in FIG. **4**. In Block **320**, the silver nano-particles are added to a first master batch. In an aspect, the first master batch is a material compatible to be blended with the silver nano-particles. In Block **330**, a first base material is added to the first master batch to form a first mixture. In an aspect, the first base material is a copolymer. The first base material may also be a copolymer such as a thermoplastic elastomer including poly(styrene-butadiene-styrene) (SBS) or poly(styrene-ethylene-butadiene-styrene) (SEBS). In Block **340**, a mold cavity configured to form a nano-silver footwear orthotic is filled with the first material. Once hardened, the nano-silver footwear orthotic retains the shape defined by the mold cavity. In addition, an insole or heel section of an already-formed orthotic may be filled with the first mixture to form an insert therein. In yet another alternative, the first mixture may be formed into a nano-silver footwear orthotic insert with a separate heel mold cavity and/or a separate insole mold cavity.

[0026] In an embodiment, manufacturing a nano-silver footwear orthotic may also include preparing silver nano-particles, adding the silver nano-particles to a second master batch, adding a second base material to the second master batch to form a second mixture and filling an insert mold cavity with the second mixture. The insert mold cavity must be arranged such that filling the mold cavity with the nano-silver copolymer results in an orthotic form. Alternatively, an insole or heel section of an already-formed orthotic may be filled with the second mixture to form an insert therein. In yet another alternative, the second mixture may be formed into a nano-silver footwear orthotic insert with a separate heel mold cavity and/or a separate insole mold cavity. The second mixture may be softer and/or energy-absorbing. The softer and/or energy absorbing material may be useful for a heel insert and/or an insole insert. The second base material can be a copolymer. The second base material may also be a copolymer such as a thermoplastic elastomer including SEBS or SEBS. The resulting orthotics have the silver nano-particles at a therapeutic ratio to be an effective antibacterial agent. The therapeutic ratio may be in the range of 2.1% of silver nano-particles to elastomer.

[0027] FIG. **4** is a flowchart illustrating an exemplary process for preparing silver nano-particles. In Block **410**, a silver nitrate solution is prepared. In Block **420**, the silver nitrate solution is mixed with a sodium borohydride solution to form a mixture. The silver nitrate solution, the sodium borohydride solution and the mixture of the two solutions have known concentrations sufficient to ensure antimicrobial effects. In Block **430**, the size of the silver ions present in the mixture are reduced. The resulting mixture may be concentrated to a known concentration to form the silver nano-particles. One of ordinary skill in the art would understand that the concentration of silver nano-particles is a characteristic that depends on the required mixture of the nano-silver copolymer. All of these concentrations, as well as the concentration of the nano-silver copolymer, may change depending on the requirements of the resulting content of silver nano-particles in the nano-silver copolymer. In an aspect, reducing the size of the silver ions present in the mixture is achieved by the mixing of the silver nitrate solution and the sodium borohydride solution. In Block **440**, the mixture is stabilized. In an aspect stabilizing the mixture is achieved by continuous stirring of the mixture. Alternatively, a stabilizing agent may be used to stabilize the mixture.

[0028] FIG. **5** is a test report identifying exemplary nano-silver copolymers and the silver nano-particle content within each of the nano-silver copolymers. In Test Result A, the amount of silver (Ag) content in a mixture of silver and SBS thermoplastic elastomer was measured. The specific thermoplastic elastomer tested was SBS 85A, wherein 85A is used to express the hardness of the thermoplastic elastomer. The specific type of silver nano-particles tested was PAg-40C. According to Test Result A, the silver—SBS 85A mixture had a silver nano-particle ratio of about 3.6% by weight.

[0029] In Test Result B, the amount of silver (Ag) content in a mixture of silver and SEBS thermoplastic elastomer was measured. The specific thermoplastic elastomer tested was SEBS 15A, wherein 15A is used to express the hardness of the thermoplastic elastomer. The specific type of silver nano-particles tested was PAg-40C. According to Test Result B, the silver—SEBS 15A mixture had a silver nano-particle ratio of about 3.6% by weight.

[0030] Test Result C, the amount of silver (Ag) content in a mixture of silver and SBS thermoplastic elastomer was measured. The specific thermoplastic elastomer tested was SBS 85A, wherein 85A is used to express the hardness of the thermoplastic elastomer. The specific type of silver nano-particles tested was PAg-40B. According to Test Result C, the silver—SBS 85A mixture had a silver nano-particle ratio of about 3% by weight.

[0031] In Test Result D, the amount of silver (Ag) content in a mixture of silver and SEBS thermoplastic elastomer was measured. The specific thermoplastic elastomer tested was SEBS 15A, wherein 15A is used to express the hardness of the thermoplastic elastomer. The specific type of silver nano-particles tested was PAg-40B. According to Test Result D, the silver—SEBS 15A mixture had a silver nano-particle ratio of about 3% by weight.

[0032] FIG. **6** is a test report identifying two antimicrobial tests on two different exemplary thermoplastic elastomers containing silver nano-particles. In a preferred embodiment of the invention, the therapeutic ration between silver nano-particles and the copolymer is about 0.036 to 0.36 percent by weight. Testing resulted in compliance with the Japanese Industrial Standard "JIS Z 2801:2000 Antimicrobial Products—Test for Anti-Microbial Activity and Efficacy" (JIS Z 2802:2000).

[0033] FIG. **7** is a test data sheet showing tests in compliance with JIS Z 2802:2000. In the first test, a SBS thermoplastic elastomer (SBS 85A) passed the log value of antimicrobial activity test with a score of 5.2 (must be greater than or equal to 2.0 according to JIS Z 2802:2000). The first test started with a concentration of bacteria (cfu/mL) of 1.2×10^6 and after a 24 hour period, resulted in less than 10 bacteria. A control sample started with a concentration of 1.2×10^5 cfu/mL and after a 24 hour period, resulted in a greater concentration, 1.6×10^6.

[0034] In the second test, a SEBS thermoplastic elastomer (SEBS 15A) passed the log value of antimicrobial activity test with a score of 4.5 (must be greater than or equal to 2.0 JIS Z 2802:2000). The second test started with a concentration of bacteria (cfu/mL) of 1.2×10^6 and after a 24 hour period, resulted in 40 bacteria. A control sample started with a concentration of 1.2×10^5 cfu/mL and after a 24 hour period, resulted in a greater concentration, 1.3×10^6.

[0035] The tests of FIG. **7** illustrate the compatibility of the silver nano-particles with the known microbe *Micrococcus Luteus*. The mixture of silver nano-particles with various copolymers ensured antimicrobial effects over a 24 hour period. Accordingly, nano-silver footwear orthotics composed of these materials have antimicrobial effects for microbes such as *Micrococcus Luteus,* known to cause foot odor and itchiness. When inserted into footwear, such orthotics prevent and manage foot odor and itchiness generally associated with footwear.

[0036] FIGS. **8**, **9** and **10** show exemplary nano-silver footwear orthotics **10** with removable inserts **12** having varying degrees of thickness. The varying degrees of thickness may provide corresponding degrees of arch support. FIG. **8** is a cross-sectional view of an exemplary nano-silver footwear orthotic with an exemplary low-profile removable insert installed therein. Accordingly, the low-profile removable insert has the lowest degree of arch support.

[0037] FIG. **9** is a cross-sectional view of an exemplary nano-silver footwear orthotic **10** with an exemplary medium-profile removable insert installed therein. This medium-profile removable insert has a higher profile than that of the low-profile removable insert. In an aspect, the user can benefit from increased arch support in a gradual increment.

[0038] FIG. **10** is a cross-sectional view of an exemplary nano-silver footwear orthotic **10** with an exemplary high-profile removable insert installed therein. The high-profile removable insert has an even higher profile than that shown in FIG. **9**, another gradual increment. The number of orthotics in a set, and the degree to which the profile of each arch increases may vary. In an aspect, the arch of the low-profile removable insert is 25% or lower than the size of the arch of the high-profile removable insert, and the arch of the medium-level profile is 50% lower than the size of the arch of the high-profile removable insert. The removable inserts **12** may be composed of a mixture including the silver nano-particles and a copolymer. In an aspect, the removable inserts **12** are composed of the silver nano-particles and a thermoplastic elastomer. In an aspect, the heel section **20** of the nano-silver footwear orthotic **10** defines an opening where a removable heel insert may be placed. In an aspect, the removable heel inserts are designed to maximize energy absorption. The removable heel inserts may be composed of the nano-silver copolymer or a mixture of silver nano-particles and a thermoplastic elastomer. Both the cavity **14** and the heel section **20** may be defined as a customizable support section, including at least one opening therein.

[0039] The previous description of the disclosed embodiments is provided to enable any person skilled in the art to make or use the present invention. Various modifications to these embodiments will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other embodiments without departing from the spirit or scope of the invention.

What is claimed is:

1. An anti-microbial footwear orthotic comprising

an orthotic including a customizable support section defining at least one opening therein;

multiple inserts of varying profile for insertion into the at least one opening one at a time;

at least one of the orthotic and the multiple inserts being copolymer with silver nano-particles therein at a therapeutic ratio to be an effective antibacterial agent.

2. The anti-microbial footwear orthotic of claim **1**, the therapeutic ratio being about 0.036 to 0.36 percent of the silver nano-particles to the copolymer by weight.

3. The anti-microbial footwear orthotic of claim **1**, the copolymer being a thermoplastic elastomer.

4. A method of manufacturing an anti-microbial footwear orthotic comprising

preparing silver nano-particles by reducing the silver from a silver nitrate and sodium borohydride solution;

preparing a master batch of the prepared silver nano-particles with a copolymer;

molding a footwear orthotic from the master batch, the molded footwear orthotic including copolymer with the prepared silver nano-particles therein at a therapeutic ratio to be an effective antibacterial agent.

5. The method of claim **4**, the therapeutic ratio to be an effective antibacterial agent being about 0.036 to 0.36 percent of the silver nano-particles to the thermoplastic elastomer by weight.

* * * * *