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Durodent™
Capsules
Strong Teeth

Freshadent™
Lozenges
Fresh Breath

Hydrodent™
Softgels
Dry Mouth Relief

32625 West Seven Mile Road, Livonia, Michigan 48152 T) 800-866-6887 P) 248-474-3068 F) 248-474-0733

Durodent ™

Summary:
Microcrystalline hydroxyapatite (MCHA) is a calcium compound that contains minerals in their natural ratio. MCHA makes up the natural crystalline matrix of the teeth and bones and maintains their integrity.

Treatment:
Two (2) capsules daily of Durodent's comprehensive bone support.

Active Ingredients:
Protein
Vitamins C , D-3, K-2, B-1
Calcium
Phosphorus
Magnesium
Zinc
Copper
Manganese
MCHA
Glucosamine Potassium Sulfate Complex
Horsetail

Published Studies and Clinicals:
See attachments.

A Comparative Efficacy and Safety Study of Durodent:
MCHA contains calcium and phosphorus as well as magnesium and other essential trace minerals. Vitamin C, D and K are also present, which aid in the synthesis and maintenance of tooth and bone tissue.

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Durodent™

Tooth - Jaw - Bone Health Formula*

120 Capsules
Dietary Supplement

Microcrystalline Hydroxyapatite (MCHA) is a natural compound that makes up the crystalline matrix of bone and teeth, and is the substance that gives them their rigidity. MCHA is a source of highly absorbable Calcium and Phosphorus, which are the major mineral components of bone. This product is a comprehensive bone support product providing 4 g (4,000 mg) of MCHA. It also contains Magnesium and other important minerals, as well as Vitamins C, D and K to aid in the synthesis and maintenance of bone tissue.*

Our Microcrystalline Hydroxyapatite (MCHA) is derived exclusively from Australian cattle.

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Do Not Eat Freshness Packet. Keep in Bottle.

Store in a cool, dry place. Please Recycle.

Recommended by Dental Healthcare Professionals

Suggested Usage:
Take 3 daily or as directed by your dental care professional.

Manufactured for

DentiCorp

32625 W. Seven Mile Rd.
Livonia MI 48152
www.denticorp.net

Professional
Dental Care Formulas

0 13964 15626 3

Supplement Facts

Serving Size 3 Capsules Servings Per Container 40

Amount Per Serving		% Daily Value
Calories	5	
Protein (from MCHA and Amino Acid Chelates)	1 g	2%*
Vitamin C (from Magnesium Ascorbate)	100 mg	167%
Vitamin D-3 (as Cholecalciferol)	500 IU	125%
Vitamin K-2 (as Menaquinone)	50 mcg	63%
Vitamin B-1 (from Thiamine HCl)	2.5 mg	167%
Calcium (from MCHA)	500 mg	50%
Phosphorus (from MCHA)	215 mg	22%
Magnesium (from Magnesium Oxide and Ascorbate)	300 mg	75%
Zinc (from Zinc Amino Acid Chelate)	5 mg	33%
Copper (from Copper Amino Acid Chelate)	0.5 mg	25%
Manganese (from Manganese Amino Acid Chelate)	1.5 mg	75%
MCHA (Microcrystalline Hydroxyapatite)	2.0 g (2,000 mg)	†
Glucosamine Potassium Sulfate Complex	150 mg	†
Horsetail (Equisetum arvense) (Aerial Parts)	50 mg	†
Boron (from Amino Acid Chelate)	350 mcg	†

*Percent Daily Values are based on a 2,000 calorie diet. † Daily Value not established.

Other ingredients: Gelatin (capsule), Cellulose, Stearic Acid (vegetable source), Magnesium Stearate (vegetable source) and Silica.

Contains shellfish (crab, shrimp, lobster, crayfish) derivative. Contains no sugar, salt, yeast, wheat, gluten, soy , milk, egg or preservatives.

Calcium MCHA

Microcrystalline Hydroxyapatite Calcium (MCHA) Research

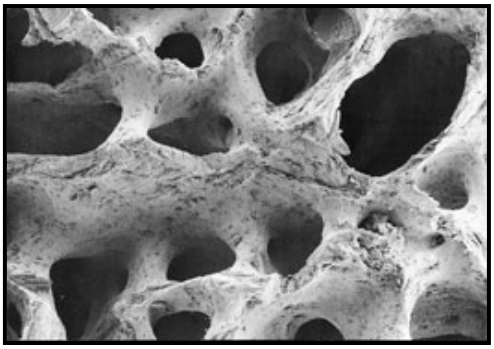
Post menopausal women and those at risk from osteoporosis.

Research on whole bone MCHA dates back as far as the 1960's, with the most recent work published in November 2008. Published scientific literature on whole bone MCHA demonstrates its effectiveness at **slowing or halting loss of bone mineral density** in post menopausal women, **improving symptoms of bone pain** in those with osteoporosis and **slowing or halting the progression of osteoporosis.**

Research also demonstrates its effectiveness as a complementary therapy to drug treatments such as raloxifene and estradiol. Two studies have shown that the efficacy of these drug therapies combined with daily MCHA supplementation was better than either of the two treatments alone.
It is important to note that this research does not apply to bone meal products, where the naturally occurring bone proteins have been destroyed by excessive heat treatment, or synthetic hydroxyapatites, where no protein is present. MCH-Cal™ from Waitaki Biosciences contains 25% naturally occurring bone proteins.

Specifically, whole bone MCHA, with the naturally occuring bone proteins present, taken as a daily nutritional supplement has shown the following positive effects:

- **Reduced loss of bone mineral density** in postmenopausal women when taken in conjunction with Raloxifene *(Pelayo et al, 2008).*
- **Increased vertebral bone mass** in post menopausal women when used in conjunction with hormone replacement therapy (estradiol) to a greater extent then either treatment alone *(Castelo Branco et al, 1999).*
- **Increased bone mineral density** in postmenopausal women with either below normal bone mineral density or inadequate dietary calcium intake *(Fernandez-Parejo et al, 2007).*



- **Prevented bone loss** in a group of post menopausal women who had refused hormone replacement therapy *(Castelo Branco, 1999)*
- **Dramatically reduced skeletal (back) pain** in a group of patients developing osteoporosis *(Pines et al, 1984).*
- **Slowed the progression of osteoporosis** in patients receiving long term corticosteroid treatment *(Pines et al, 1984)*
- **Restored lost bone mineral density** in a group of women on corticosteroid therapy for primary billiary cirrhosis *(Epstein et al, 1982).*
- **Improved bone healing** in rabbits with experimentally induced bone defects *(Annefeld et al, 1986).*

Comparison to other forms of calcium supplementation

Whole bone MCHA has been compared to both calcium carbonate and calcium gluconate in clinical trials.

Four trials have compared MCHA to calcium carbonate, and in all four of these studies MCHA has shown superior performance at improving loss of bone mineral density in post menopausal women *(Pelayo et al 2008, Castelo Branco 1999, Ruegsegger et al 1995, Annefeld et al 1985).* There have been two published trials comparing MCHA to calcium gluconate. One of these studies demonstrated that whole bone MCHA was better than the equivalent amount of calcium gluconate at promoting the absorbtion of radio labeled calcium in elderly osteoporotic patients *(Windsor et al, 1973).* In the second study, whole bone MCHA was able to restore lost bone mineral in a group of corticosteroid treated patients. Patients treated with calcium gluconate had their bone loss halted, but not restored *(Epstein et al, 1982).*

Calcium Supplements Reduced Fracture Risk in Clinical Trial

Abstracted by Marcia J. Egles, MD, June 24, 2008 from "Effect of calcium supplementation on fracture risk: a double-blind randomized controlled trial" by Heike A Bischoff-Ferrari, Judy R Rees, Maria V Grau, Elizabeth Barry, Jiang Gui and John A Baron in The American Journal of Clinical Nutrition, Vol. 87, No. 6, 1945-1951, June 2008.

Medical literature includes conflicting data and opinions concerning the role of calcium supplements, with or without vitamin D, and bone health and the prevention of osteoporosis[1]. In a recent clinical trial, a clear benefit in reducing bone fracture risk was found for a group of healthy Americans treated with 1200 mg per day of calcium supplements for four years. The trial is a follow-up study of the Calcium Polyp Prevention Study[2] which began in 1988 in six U.S. locations, ranging from Minnesota to sunny southern California.

The Calcium Polyp Prevention Study involved 1,118 men and women, aged 27 to 79, (average age 61), who recently had a benign polyp* removed by colonoscopy. They were randomly assigned to swallow either a placebo tablet or 3 grams of calcium carbonate (1200 mg elemental calcium) daily over four years. No vitamin D was supplemented and no additional supplements with calcium were allowed. The calcium dietary intake of the placebo group averaged 865 milligrams per day and that of the calcium group was 889 milligrams per day. The average vitamin D levels in the blood of both groups were slightly low (but nearly normal). Over 83% of the participants reported taking at least 80% of the tablets for the four years.

The original trial reported a moderate reduction in bowel polyps on repeat colonoscopy in the calcium group, compared to the placebo group. The participants were informed of the results of the study, but not which group they were in. Whereas only 2% of the subjects had used calcium supplements prior to the trial, 26% reported taking them for at least half of the follow-up years.

The new study looked at the frequency of bone fractures in the two groups, both during the four-year calcium treatment trial, and until the end of the study in 2003. Nine hundred and thirty participants, 72% male, were recruited for the extended study. Bone fracture events were reported through telephone interviews. The reported fractures were classified and confirmed by medical record review performed by two independent physicians. The bone fractures were classified as with either “minimal” or “significant’ trauma. Trauma was defined as minimal if the fracture occurred after falling from standing height or lower while sitting, standing or walking. Examples of significant trauma would include sports injuries, car crashes, or falling down stairs.

During the original four-year treatment phase, there were no minimal trauma fractures at all in the calcium treatment group. Nine such fractures occurred in the placebo group. After the end of calcium treatment, minimal trauma fractures were reported at statistically similar rates of frequency between the two groups. The rates of significant trauma fractures were found to be similar between both groups in the treatment and in the follow-up phase of the study.

This clinical trial is important because it shows a beneficial reduction in bone fractures occurring with low-level impacts among generally healthy adults who took 1200 milligrams daily calcium supplements. Adding in the baseline dietary intake, the calcium intake of the Americans treated in this trial was around 2100 milligrams per day.

The United States National Institute of Health and other experts recommend that, in general, adults should consume 1,200 milligrams of calcium each day. They also endorse that up to 2,000 - 2,500 milligrams a day of calcium from dietary sources and supplements appears to be safe.

REFERENCE:

[1] Bischoff-Ferrari HA, Dawson-Hughes B, Baron JA, et al. Calcium intake and hip fracture risk in men and women: a meta-analysis of prospective cohort studies and randomized controlled trials. *Am J Clin Nutr* 2007;86:1579–80

[2] Baron JA, Beach M, Mandel JS, et al. Calcium supplements for the prevention of colorectal adenomas. Calcium Polyp Prevention Study Group. *N Engl J Med* 1999;340(2):101–7

[3] Calcium Recommendations: http://www.nlm.nih.gov/medlineplus/ency/article/002412.htm

** A colon polyp, also known as an adenoma, is a fleshy growth that can occur on the inside lining of the intestine. They are generally harmless, but sometimes can develop into cancers. See http://www.mayoclinic.com/health/colon-polyps/DS00511*

MCHA (Microcrystalline Hydroxyapatite)

J Invest Surg. 1998 Jan-Feb;11(1):29-48.

A mechanical and histomorphometric analysis of bone bonding by hydroxyapatite-coated strain gages.

Wilson DL, Szivek JA, Anderson PL,
Miera VL, Battraw GA.

Department of Surgery, Arizona Health
Sciences Center, Tucson, USA.

Abstract

Identification of the strains controlling bone remodeling is important for determining ways to prevent bone loss due to load deprivation, or implant placement. Long-term monitoring of strains can potentially provide the best information. Glues are resorbed within 2-3 weeks.

Two formulations of microcrystalline hydroxyapatite (HA) were used to attach strain gages to rat femora to assess their long-term in vivo strain measurement capability. Seven male rats received HA-coated gages, and 2 animals underwent a sham procedure. The gages were prepared using a published technique and placed on the antero-lateral aspect of the left femora. After 6-7 weeks, the animals were euthanized and both femora explanted. Gages were attached to the right femora with cyanoacrylate. All femora were tested in cantilever bending, then embedded, sectioned, and stained with mineralized bone stain. The undecalcified sections were examined using transmitted and ultraviolet light microscopy.

Mechanical testing showed one HA formulation provided 70-100% bonding. Histology showed intimate contact between the gage and bone surface. Histomorphometry indicated increased bone activity under the gage compared to the remaining bone, the controls, and the shams. The results indicate that microcrystalline HAs bond to bone quickly and can allow long term in vivo measurements.

Publication Types, MeSH Terms, Substances

Publication Types:

- Research Support, Non-U.S. Gov't
- Research Support, U.S. Gov't, P.H.S.

Copper

Complementary Naturopathic Medicine for Periodontitis

This study has been completed.

First Received: February 2, 2001 Last Updated: August 17, 2006

Sponsor:	National Center for Complementary and Alternative Medicine (NCCAM)
Information provided by:	National Center for Complementary and Alternative Medicine (NCCAM)
ClinicalTrials.gov Identifier:	NCT00010634

Purpose

This study aims to assess selected naturopathic medicines for adult periodontitis and to identify variables that influence successful outcomes when traditional and alternative approaches to preventing and treating periodontal diseases are combined. Collaboration between Kaiser Permanente, Oregon Health Science University and the National College of Naturopathic Medicine provides an unsurpassed environment for such investigations. Periodontitis is a major cause of tooth loss and negatively impacts systemic health. The limitations of traditional periodontal treatment have compelled scientists and clinicians to investigate new remedies, and naturopathic medicine holds several promising interventions.

Because they are used to improve elements of host resistance that are known to be important in periodontal health and disease, three naturopathic medicines are potential adjuncts in preventing and treating periodontitis. Connective tissue components are enzymatically degraded in periodontitis. In naturopathy, Connective Tissue Nutrient Formula (CTNF) (vitamins A, C and D, glucosamine sulfate, oligoproanthocyanindins, copper, zinc, manganese, boron, silicon, magnesium, and calcium) is prescribed specifically to enhance the integrity of key connective tissue elements and improve their resistance to degradation.

Periodontitis begins when permeability of the oral sulcular epithelium permits pathogenic bacterial components to invade deeper periodontal connective tissues. In naturopathy, glutamine is prescribed to reduce oral-intestinal epithelial membrane permeability. Chronic activation of the hypothalamic-pituitary-adrenal (HPA) axis during the stress response, is a risk factor for periodontitis.

Adaptogenic herbs (AH) (Panax ginseng, Withania somnifera and Eleutherococcus senticosus) are prescribed by naturopathic physicians to reverse the impact of bacterial and psychosocial stressors. Because glutamine, CTNF and AH target pathophysiologic mechanisms known to underline periodontitis, they are compelling candidates in clinical and mechanistic investigations of complementary medicine approaches to the management of periodontitis.

.Kaiser Permanente adult periodontitis patients will serve as subjects and receive standard periodontal treatment. Three of the four randomly assigned groups will also receive supplements of glutamine, CTNF, or AH.

We will determine the effects of these supplements on clinical outcomes (attachment loss, pocket depths, indicators of inflammation, plaque composition, need for periodontal surgery, acute periodontal problems, tooth loss). In addition to completing the battery of self-report measures (stress, coping, quality of life), study subjects will provide samples of blood, saliva, gingival cervicular fluid and bacterial dental plaque.

These samples will be examined as part of the Laboratory Core to identify biologic and genetic characteristics that correlate with successful outcomes. Storage of portions of the samples will allow future examination of additional variables as part of the Developmental Projects carried out as the Craniofacial Complementary & Alternative Center is established and Phase III trials are undertaken.

Condition	Intervention	Phase
Periodontitis	Drug: Connective Tissue Nutrient Formula Drug: Adaptogenic herbs Drug: glutamine	Phase II

Study Type: Interventional

Study Design: Allocation: Randomized
Primary Purpose: Treatment

Official Title: Complementary Naturopathic Medicine for Periodontitis

Further study details as provided by National Center for Complementary and Alternative Medicine (NCCAM):

Study Start Date: September 1999

Estimated Study Completion Date: July 2004

Detailed Description:

See Brief Summary

Eligibility

Ages Eligible for Study: 35 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No
Criteria
Inclusion Criteria:

- Adult periodontitis

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00010634

Locations

United States, Oregon

The Oregon Health Sciences University (OHSU)
Portland, Oregon, United States

Sponsors and Collaborators

National Center for Complementary and Alternative Medicine (NCCAM)

Investigators

Principal Investigator:	Theresa Madden	Center for Health Research, Kaiser Foundation Hospitals

More Information

ClinicalTrials.gov Identifier:	NCT00010634
Obsolete Identifiers:	NCT00009347
Other Study ID Numbers:	P50 AT000076-01P3, P50 AT000076-01
Study First Received:	February 2, 2001
Last Updated:	August 17, 2006
Health Authority:	United States: Federal Government

Additional relevant MeSH terms:
Periodontitis
Periodontal Diseases
Mouth Diseases
Stomatognathic Diseases

ClinicalTrials.gov processed this record on February 28, 2011

Glucosamine sulfate: Effective osteoarthritis treatment

Natural Medicine Journal

Article Summary

Osteoarthritis, the most common form of arthritis, results primarily from a progressive degeneration of cartilage glycosaminoglycans (GAGs). Standard drug therapy suppresses pain and inflammation, but actually promotes progression of the disease process by inhibiting GAG synthesis and cartilage repair. In contrast, glucosamine sulfate offers an effective treatment for osteoarthritis by providing the rate-limiting step in GAG synthesis. Glucosamine serves as the fundamental building block for GAGs. Numerous double-blind studies have shown glucosamine sulfate to produce better results than standard drug therapy. The pharmacology and clinical features of glucosamine sulfate are reviewed.

Osteoarthritis, also known as degenerative joint disease, is the most common form of arthritis. It may be the most prevalent disease in America. Surveys have indicated that over 40 million Americans have osteoarthritis. It is seen primarily, but not exclusively, in the elderly.

The Weight-bearing joints, like the knees and hips, and joints of the hands are the joints most often affected with osteoarthritis. In affected joints, there is much cartilage destruction followed by hardening and the formation of large bone spurs in the joint margins. Pain, deformity, and limitation of motion in the joint results.

The onset of osteoarthritis can be very subtle, morning joint stiffness is often the first symptom. As the disease progresses, there is pain on motion of the involved joint that is made worse by prolonged activity and relieved by rest.

What Causes Osteoarthritis?

The cumulative effects of decades of use leads to degenerative changes in joints. This damage is compounded by a decreased ability to repair joint structures. Specifically, with aging, there is a decreased ability to restore and manufacture normal joint structures like cartilage. Much of this reduced function may reflect nutritional status.

A broad-range of nutrients have been shown to be critical to healthy joints. A deficiency of any of these nutrients can result in impaired cartilage structure or function.

Arthritis Medications

Clinical and experimental research indicates that current drugs being used in osteoarthritis may be producing short-term benefit, but actually accelerating the progression of the joint destruction.

The first drug generally used in the treatment of osteoarthritis is aspirin. It is often quite effective in relieving both the pain and inflammation. It is also fairly inexpensive. However, since the therapeutic dose required is relatively high (2 to 4 grams per day), toxicity often occurs. Tinnitus (ringing in the ears) and gastric irritation are early manifestations of toxicity.

Other nonsteroidal anti-inflammatory drugs (NSAIDs) are often used, especially when aspirin is ineffective or intolerable. The following are representative of this class of drugs; ibuprofen (Motrin), fenoprofen (Nalfon), indomethacin (Indocin), naproxen (Naprosyn), tolmetin (Tolectin), and sulindac (Clinoril). These drugs are also associated with side effects including gastrointestinal upset, headaches,

dizziness, and are therefore recommended for only short periods of time.

One side effect of aspirin and other NSAIDs that is often not mentioned is their inhibition of cartilage repair and acceleration of cartilage destruction.[1-3] Because osteoarthritis is caused by a degeneration of cartilage, it appears that while NSAIDs are fairly effective in suppressing the symptoms, they possibly worsen the condition by inhibiting cartilage formation and accelerating cartilage destruction. This has been upheld in clinical studies which have shown that NSAIDs use is associated with acceleration of osteoarthritis and increased joint destruction.[4-6] Simply stated, aspirin and other NSAIDs appear to suppress the symptoms but accelerate the progression of osteoarthritis. Their use should be avoided.

Natural alternative to arthritis medications

If current arthritis medications should be avoided, what is an arthritis sufferer to do? A naturally occurring substance found in high concentrations in joint structures appears to be nature's best remedy for osteoarthritis. This compound is glucosamine sulfate.

This simple molecule is composed of glucose, an amine (nitrogen and two molecules of hydrogen), and sulfur. The manufacture of glucosamine is the rate-limiting step in GAG synthesis. Glucosamine is formed from the glycolytic intermediate fructose-6-phosphate via amination with glutamine acting as the donor, yielding glucosamine-6-phosphate which is then acetylated and/or converted to galactosamine for incorporation into the growing GAG.

The main physiological function of glucosamine on joints is to stimulate the manufacture of cartilage components as well as promote the incorporation of sulfur into cartilage. In other words, glucosamine is not only responsible for stimulating the manufacture of substances necessary for proper joint function, it also is responsible for stimulating joint repair.

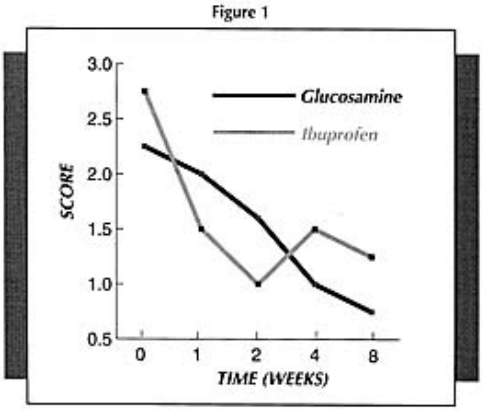
It appears that as some people age, they lose the ability to manufacture sufficient levels of glucosamine. The result is that cartilage loses its ability to act as a shock absorber. The inability to manufacture glucosamine has been suggested to be the major factor leading to osteoarthritis. This link lead researchers in Europe to ask an important question, "What would happen if individuals with osteoarthritis took glucosamine?" The results have been astonishing.

Clinical Trials

Numerous double-blind studies have shown glucosamine sulfate to produce much better results compared to NSAIDs and placebos in relieving the pain and inflammation associated with osteoarthritis. This is despite the fact that glucosamine sulfate exhibits very little direct anti-inflammatory effect and no direct analgesic or pain relieving effects.[7-13]

While NSAIDs offer purely symptomatic relief and may actually promote the disease process, glucosamine sulfate appears to address the cause of osteoarthritis. By getting at the root of the problem, glucosamine sulfate not only improves the symptoms including pain, it also helps the body repair damaged joints. This effect is outstanding, especially when glucosamine's safety and lack of side effects is considered.

Figure 1



It must be pointed out that the beneficial results with glucosamine are more obvious the longer it is used. Because glucosamine sulfate is not an anti-inflammatory or pain relieving drug per se, it takes a while longer to produce results. But once it starts working, it will produce much better results compared to NSAIDs.

For example, in one study (Figure 1) which compared glucosamine sulfate to ibuprofen (the active ingredient of Motrin, Advil, and Nuprin), pain scores decreased faster in the first 2 weeks in the ibuprofen group; however, by week 4, the group receiving the glucosamine sulfate was doing significantly better than the ibuprofen group.11 Physicians rating the overall response as good or fair rated 44% of the glucosamine sulfate-treated patients as good compared to only 15% of the ibuprofen group.

Results from a large, open trial

In addition to showing benefit in double-blind studies, oral glucosamine sulfate was shown to offer significant benefit in an open trial involving 252 doctors and 1,506 patients in Portugal.[14] This large study provides valuable clinical information on the appropriate use of glucosamine sulfate.

The patients in this study received 500 mg of glucosamine sulfate three times daily over a mean period of 50+/-14 days. The results were analyzed and showed that the symptoms of pain at rest, on standing, and on exercise and limited active and passive movements improved steadily throughout the treatment period.

Objective therapeutic efficacy was rated by doctors as "good" in 59% of patients, and "sufficient" in a further 36%. Therefore, a total of 95% of patients achieved benefit from glucosamine sulfate. The results with glucosamine sulfate were rated by both doctors and patients as being significantly better than those obtained with previous treatment including NSAIDs, vitamin therapy, and cartilage extracts.

Only injectable glucosamine sulfate was comparable to the oral glucosamine, but even that was less effective. Glucosamine sulfate produced good benefit in a significant portion of patients who had not responded to any other medical treatment.

Complete tolerability of oral glucosamine was reported by a significantly larger proportion of patients than with any other treatment. Possible adverse reactions occurred in only 12.1% of patients. All of these possible side effects were light to moderate gastrointestinal symptoms including epigastric pain or tenderness, heartburn, diarrhea, nausea, and dyspepsia.

Obesity is associated with a significant shift from good to fair. This finding may indicate that higher dosages may be required for obese individuals or that oral glucosamine is not enough to counteract the stress of obesity on the joints.

Patients with peptic ulcers and individuals taking diuretics were also associated with a shift from good to sufficient in efficacy, as well as tolerance. Individuals with current peptic ulcers should try and take glucosamine sulfate with foods. Individuals taking diuretics may need to increase the dosage to compensate for the reduced effectiveness.

The improvement with glucosamine lasted for a period of 6 to 12 weeks after the end of treatment. This result indicates that a repeated course of administration are necessary. Given the safety and excellent tolerability of glucosamine, it is suitable for long-term use, even if continuous.

Glucosamine sulfate vs. cartilage extracts

Cartilage extracts, including purified chondroitin sulfate, sea cucumber, green-lipped mussel, and shark cartilage, are popular nutritional supplements which may also help osteoarthritis by improving cartilage function. However, these compounds differ in their degree of purity and effectiveness in osteoarthritis compared to glucosamine sulfate.

Shark cartilage, sea cucumber, and green-lipped mussel contain a mixture of GAGs. One of the key

GAGs is chondroitin sulfate. Chondroitin sulfate is composed of repeating units of glucosamine with attached sugar molecules.

The difference between glucosamine sulfate, cartilage extracts, and chondroitin sulfate products is similar to the difference between crude ore (shark cartilage or chondroitin sulfate) and pure gold (glucosamine). While there is gold in crude ore, if you are trying to make jewelry, it is better to use the pure gold. If you are trying to restore cartilage and joint structures, it is best to use glucosamine sulfate rather than chondroitin sulfate or shark cartilage.

The key reason is the improved absorption and utilization of glucosamine sulfate. Cartilage extracts, shark cartilage, green-lipped mussel, sea cucumber, and chondroitin sulfate products are composed of large molecules that are extremely difficult to absorb. The absorption rate for chondroitin sulfate, the smallest molecule in these products, is estimated to be between zero and 8%.[15] In contrast, detailed pharmacokinetic studies in animals and humans have shown up to 98% of orally administered glucosamine sulfate is absorbed.[16,17]

These pharmacokinetic studies have shown that after glucosamine sulfate is absorbed, it is preferentially taken up by cartilage and other joint structures, where it then simulates the manufacture of chondroitin sulfate and other mucopolysaccharides. One of its key effects is to also stimulate the incorporation of sulfur into cartilage.

While the effectiveness of oral glucosamine sulfate has much documentation, the effectiveness of oral cartilage extracts, chondroitin sulfate, green-lipped mussel, sea cucumber, and shark cartilage in osteoarthritis is a subject of much debate. The positive clinical studies with glycosaminoglycan preparations have utilized injectable forms.[18-20] The use of pharmaceutical grade cartilage preparations and chondroitin sulfate injections, according to established protocols has well-documented benefit, but the benefits are less than that attributed to glucosamine sulfate.

When all is considered, it is quite easy to see why glucosamine sulfate is preferred to cartilage extracts in the treatment of osteoarthritis.

Glucosamine sulfate vs. NAG

Currently companies marketing N-acetyl-glucosamine, commonly referred to as "NAG," are misleading many physicians into believing that NAG is better absorbed, more stable, and is better utilized than glucosamine sulfate. These contentions are without support in the scientific literature. In fact, the literature contains just the opposite. Glucosamine sulfate is clearly the preferred form.

As mentioned above, detailed human studies on the absorption, distribution, and elimination of orally administered glucosamine sulfate have shown an absorption rate of as high as 98% and that once absorbed it is then distributed primarily to joint tissues where it is incorporated into the connective tissue matrix of cartilage, ligaments, and tendons, In addition, there are the impressive clinical studies on thousands of patients. In contrast, there has never been a double-blind study using NAG for any application. Nor have there ever been any detailed absorption studies on NAG in humans.

Further evidence of the superiority of glucosamine sulfate to NAG is offered by studies in laboratory animals. Over the years, numerous researchers have researchers have repeatedly demonstrated that glucosamine is superior to NAG in terms of absorption and utilization by at least a factor of 2:1.[18-29] These researchers have concluded that glucosamine is a more efficient precursor of macromolecular hexosamine [glycosaminoglycans] than N-acetyl-glucosamine does not penetrate the cell membranes and, as a result, is not available for incorporation into glycoproteins and mucopolysaccharides.[20]

Comparative analysis:	Glucosamine sulfate	NAG	Glucosamine HCL
Active intestinal transport	YES	NO	YES
Detailed absorption studies	YES	NO	NO
Detailed clinical studies	YES	NO	NO
Contains sulfur molecule	YES	NO	NO
Long history of use	YES	NO	NO
Over 20 double-blind studies	YES	NO	NO

The absorption of NAG is quickly digested by intestinal bacteria; 2) NAG is a known binder of dietary lectins in the gut with the resultant lectin-NAG complex being excreted in the feces; and 3) a large percentage of NAG is broken down by intestinal cells.

NAG differs from glucosamine sulfate in that instead of a sulfur molecule, NAG has a portion of an acetic acid molecule attached to it. Glucosamine sulfate and NAG ware entirely different molecules and appear to be handled by the body differently. The body preferentially utilizes glucosamine sulfate compared to NAG. This preference is exhibited by the fact that the absorption of glucosamine sulfate is an active process.[29] In other words, there are mechanisms in the body which are designed specifically for the absorption and utilization of glucosamine sulfate. No such mechanisms exist for NAG.

It is highly unlikely that NAG possesses the same kind of anti-arthritic and anti-reactive properties that glucosamine sulfate has been shown to possess.[30-31] In addition to the question of absorption, several studies have shown that the articular tissue is not able to utilize NAG as well as it does glucosamine.[18-19]

The marketing information on NAG will often use the term slow acetylators to describe a very small group of individuals with Crohn's disease and ulcerative colitis who are unable to convert glucosamine to NAG as fast as individuals without these diseases. Glucosamine and NAG are necessary in the manufacture of mucin, the glycoprotein lining of the intestinal tract.

Distributors of NAG hold up only one study as evidence that NAG is better. The study demonstrated that when intestinal cells from patients with Crohn's disease or ulcerative colitis were bathed in a solution containing a ratio of radioactive NAG:glucosamine of 10:1, the cells incorporated more NAG than the cells from individuals without these diseases.[30] These results are expected due to the higher concentrations of NAG in the media artificially promoting passive diffusion to a greater extent than the active accumulation of glucosamine. How distributors of NAG can then use this information to claim that NAG is better than glucosamine sulfate is puzzling since the significance of this test tube study is unclear and other studies have demonstrated an increased utilization of glucosamine in these patients.[33]

The problem of acetylation of glucosamine is not a factor for most people as it is not a rate-limiting step in the manufacture of glycosaminoglycans, instead it is the manufacture of glucosamine. Another form of glucosamine presently being marketed is glucosamine hydrochloride (HCI). As with NAG, the research simply does not support the use of glucosamine HCI.

It appears the sulfur component of glucosamine sulfate may be critical to the beneficial effects noted.

Sulfur is an essential nutrient for joint tissue where it functions in the stabilization of the connective tissue matrix of cartilage, tendons, and ligaments. As far back as the 1930's, researchers demonstrated that individuals with arthritis are commonly deficient in this essential nutrient.[34] Restoring sulfur levels brought about significant benefit to these patients.[35] Therefore, it appears the sulfur portion of glucosamine sulfate is extremely important and is another reason why glucosamine sulfate is the preferred form of glucosamine.

Dosage Information

The standard dose for glucosamine sulfate is 500 mg three times per day. Obese individuals may need higher dosages based on their body weight (20 mg/kg body weight/day).

Glucosamine sulfate is extremely well-tolerated. In addition, there are no contra-indications or adverse interactions with drugs. Individuals taking diuretics may need to take higher dosages. Glucosamine sulfate may cause some gastrointestinal upset (nausea, heartburn, etc.) in rare instances. If this occurs, have the patient try taking it with meals.

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Horsetail

COMMON NAMES

- Bottlebrush
- Horsetail
- Mare's Tail
- Scouring Rush
- Shave Grass

Horsetail is a well known herb; it is a perennial herb growing in moist loamy or sandy soil found in much of the North American continent, as well as in similar climates in Europe and Asia. The morphology of the horsetail herb is very strange and the plant has a creeping, or string like rootstock which gives it its name. The roots at the nodes are turned into numerous hollow stems of two kinds.

Horsetail begins growth in two stages, initial growth of the plant is through a fertile and flesh colored stem, this stem can grow to a height of four to seven inches and comes out a cone like spike - this spike contains spores of the plant. The initial stem does not last long and withers away. The second stem is a green and sterile structure reaching a length of eighteen inches in height and crowned by whorls of small branches - this is the final shape that the plant will take for its life span.

Horsetail plants have an ancient lineage, for example, related plants belonging to the era of the dinosaurs could reach very incredible heights of forty feet or more, the ancient horsetails probably resembled skinny lodge pole pines - though they lacked the green boughs of pines. Horsetails have been used in a variety of roles in Europe, for example, during the Middle Ages, horsetail clumps were normally used as scouring pads to facilitate the cleaning of iron cookware and hard pewter dishes - the plant has a high silicon content and is very effective in this role.

The silicon content of the horsetail is the highest in the entire plant empire, and no other herb comes even near to the silica levels found in the plant. Silica is an important trace element for the body; it helps in binding protein molecules together in tissues such as the blood vessels and other connective tissues in the human body. Collagen, an important constituent of the tissues is largely made from silicon. The role of the collagen in the body is to act as the "body glue", enabling the skin and muscular tissues to stick together as an integrated whole. The growth and stability of the skeletal system in the body is also promoted by the mineral silicon - the mineral is required in trace amounts in the diet.

The properties of the horsetail have been measured in a few European clinical studies - where it was determined that broken and fractured bones tend to heal quicker if horsetail supplements were taken by the patients. When horsetail is added to the diet of patients, it also led to a reduction in the incidence of osteoporosis - thus, there is direct health benefits associated with the use of the horsetail.

Some herbalist and folk healers suggest that athletes suffering from problems such as sprains and dislocated joints, and pulled hamstrings or torn ligament injuries could benefit from supplements of the horsetail herb in the diet. Dosages of the horsetail is usually three tablets or capsules taken a day and continuously, till such times as total healing from the physical injury is achieved.

The herb also has other uses, and the horsetail herb can be seen as one of those rare and exceptional cosmetic agents - that work to beautify from the inside rather than just altering external appearances. The texture, strength and tone of hard tissues such as the hair, the nails and the skin is also greatly improved by horsetail, at the same time the herb is very good at greatly strengthening the bones and the teeth of people. A positive hidden "youth factor" present in the horsetail is also alluded by some individuals.

Problems such as minor edema can be treated by drinking an herbal tea made from the horsetail. If half a cup of this tea is consumed every forty five minutes during the day, it can effectively put a stop to bleeding problems resulting in blood specks in the urine and the stool of the person. Topical injuries of a minor nature can also be treated using the horsetail, a minor cut or bruise can be treated using some herbal horsetail powder from a capsule or a crushed tablet. Urinary problems of all types can also be treated using the horsetail herb, which is a reliable diuretic.

To prepare horsetail herbal tea, put two tablespoons of the herb and steep it for half an hour in one pint of boiling water. Dosage for this herbal tea can be three cups of the herb taken on a daily basis or three tablespoons taken once every one to half an hour during treatment.

Supporters of the horsetail herb suggest the great value of the horsetail in the role of a diuretic as well as an astringent - they point out the capability of the herb and its potential in the treatment of all kinds of kidney and bladder conditions. These herbal promoters of the horsetail also stress the effectives of the herb in disorders ranging from kidney stones to cystic ulceration - they suggest its great effectiveness as a rapid acting remedy for the disorder called dropsy.

The beneficial effects of the horsetail also lie in its ability in treating tuberculosis - particularly when the disease has progressed and is accompanied by behaviors such as the spitting of blood by the patient. Horsetail remedies when externally used are said to promote rapid healing of cuts and bruises as well as being able to stop the bleeding of wounds.

The horsetail on chemical analysis is also found to contain approximately five percent of a saponin, called equisetonin, and several types of flavone glycosides such as isoquercitrin, the compound galuteolin, and equisetrin aside from the silica fraction. Horsetail also contains minute traces of nicotine at 0.00004 percent of total volume. The diuretic action of the horsetail is probably due to a combined effect of the flavone glycosides and the saponins. This diuretic action has been demonstrated experimentally in the laboratory, though it is a rather mild effect. The belief that the silica and silicic acid derivatives found in the horsetail medication actively promote healing in bleeding tubercular lesions found in the lung is not supported by any experimental studies and thus, this hypothesis is incorrect.

Care should be taken with the use of some species of horsetail herb, as several species belonging to the genera Equisetum have been known to induce poisoning in livestock - especially with regard to horses. This poisoning action has been experimentally verified in horses, the disease is called equisetosis, where a thiaminase or thiamine destroying enzyme

in the herb had been implicated in the toxic activity in the body of horses. The consumption of large doses of thiamine and the complete elimination of the horsetail containing hay from the diet of poisoned horses is the only treatment for cases of equisetosis.

For example, in Canada, the department of Health and Welfare Canada requires the manufacturers of the horsetail feeds to prove that the E. arvense they sell is free of thiaminase enzymes. A toxic alkaloid compound known as palustrine is found in a related European horsetail species called Equisetum palustre L. The necessity of examining all of the commercial supplies of E. arvense species sold in the German market for any possible adulteration with the other Equisetum species, like the E. palustre is a policy of German Pharmacopoeia in Europe. There is very little scientific support for the traditional healing virtues attributed to the horsetail, and strong pleading from herbalist does not change this fact. At most, the horsetail is a weak diuretic herb and has few other uses.

PARTS USED
AERIAL PARTS.
USES

Traditionally used to stop bleeding in wounds, the horsetail herb is said to be an excellent clotting inducer. The herbal horsetail remedies have been used to staunch all kinds of wounds; it has been used to stops excessive nosebleeds, and also in bringing about a reduction in the coughing up of blood during different diseases. The urinogential system of the human body is also positively affected by the astringent effect of the horsetail herb; this property is especially valuable in those cases of bleeding occurring within the urinary tract of a person - including disease such as cystitis and urethritis in patients. The internal tissue damage in connective tissue is also repaired and corrected by the horsetail herbal remedies, which speeds up the rate of tissue repair, thereby promoting the strength and elasticity in the newly formed tissues. Symptoms caused by rheumatic and arthritic problems are also treated utilizing horsetail based remedies, the horsetail is also used in the treatment of various chest ailments like emphysema, it is used for the treatment of chronic swelling affecting the legs, and also in the treatment of various other conditions affecting people. Slow healing sprains and fractures can also be topically treated using a decoction of the horsetail herb added to bathwater.

The horsetail herb has a long lineage and is a descendant of prehistoric plants; these ancient relatives of the herb were tall as trees. The horsetail is also known to be the richest plant source for the mineral silica aside from other useful and beneficial minerals. This makes the plant a very valuable herbal remedy for the treatment and healing of tissues as well as a useful and effective herbal nutritious tonic. The horsetail herb strongly affects the functioning of the urinary system in people, and endows a mild diuretic as well as soothing effect on the affected urinary tissues. It is also capable of healing all manners of irritation and infection affecting the urinary tract in general. Children affected by frequent urges to urinate, by bed wetting behaviors and incontinence for a long time can be treated using the horsetail as the astringent properties of the herb make it a very useful remedy to check such problems.

Inflammation in various tissues of the body is frequently treated using the horsetail based remedies and the herb is also used in the treatment of problems like the benign and harmless enlargement of the prostate gland in patients. The herbal remedies made from the horsetail are also useful as general tonics for boosting the performance of the kidneys and the urinary system in people. The reproductive system is also beneficially affected by the horsetail herbal remedies; the herb is very effective at reducing hemorrhage and heavy

bleeding in patients affected by such disorders. The horsetail is also effective in treating such disorders which affect the functioning of the digestive tract, it is capable of healing inflammation and ulcers in the stomach, and similar problems affecting the respiratory tract - traditionally the horsetail was the remedy used for treating TB and coughing of blood streaked sputum. Lusterless hair and brittle nails can also be treated using the herbal horsetail remedy, and the herb is also useful for treating debility and anemia in patients. Horsetail has a lot of silica, which actively aids in the rapid absorption of calcium from the food, and this action of the herb so helps guard the body against the danger of osteoporosis and muscular cramps, and for this reason horsetail can greatly help in the prevention of atherosclerosis in patients. Irritated skin and skin conditions like eczema can be topically treated using a herbal horsetail lotion, this can also be used to heal all manners of cuts and wounds, it can be applied to alleviate sores and ulcers, and it can also be applied to areas of skin affected by chilblains and related problems.

Horsetail based mouthwash and gargle can also be used for the treatment of problems such as mouth ulcers, it can be used to stanch bleeding gums and in the treatment of sore throats and other oral problems.

Other Medical Uses
Homeopathy, Osteoarthritis, Urinary incontinence.

HABITAT AND CULTIVATION

The horsetail prefers damp soils for maximum growth and is a very common plant, it is native to much of Europe, to North Africa and can also be seen in parts of northern Asia and the whole of the new world. Harvesting of the horsetail and especially the sterile stems occurs during the summer months and these are carefully dried in preparation for storage, during this process all the discolored parts are thrown away.

CONSTITUENTS

The silicic acid and the other chemical silicates make up about fifteen percent to total chemical constituent of horsetail, aside from the other compounds such as flavonoids, the phenolic acids, and the alkaloids – e.g. nicotine, and sterols which are also present in variable amounts. The high silica content of the horsetail is responsible for most of the therapeutic effectiveness ascribed to the horsetail herb. This silica is largely soluble and is absorbed well in the body. Connective tissue regeneration is one of the main functions supported by the silica.

USUAL DOSAGE

Herbal horsetail tea at doses of one to four grams daily is ideal as a supplemental measure. An alternative is to use an herbal horsetail based tincture at a dose of two to six ml daily.

SIDE EFFECTS AND CAUTIONS

When given at the recommended adult doses, the horsetail is normally seen as being very safe and useful for treating men and non-pregnant women. The use of the correct species of horsetail should be the chief concern of the person using the herbal remedy. Horsetail species such as the Equisetum palustre contain some toxic alkaloids and are traditionally identified as livestock poison - these should never be used as supplements. All supplement manufacturers in Canada, have to follow the Canadian Health Protection Branch

requirement that products are certified as not containing the enzyme thiaminase, which is found in crude horsetail of the Equisetum variety - this enzyme destroys B vitamin thiamin in the body and can cause serious problems. For medicinal use, all raw horsetail has to undergo processing, and the alcohol and temperature regulated processes, as well as the alkalinity neutralizes the potentially harmful enzyme in the herb. During processing, all herbal horsetail tinctures, the various fluid extracts, and the other preparations of the herb are also subjected to 100°C temperatures and this processing is preferred for medicinal use of the herb.

APPLICATIONS

Aerial parts:

DECOCTION – An herbal decoction made from the horsetail herb is used for the treatment of excessive menstruation in women. The same decoction is also used in the treatment of various skin conditions like acne and eczema in patients. This herbal decoction can be prepared by simmering some horsetail herb a minimum of three hours to extract the main chemical constituents and straining the liquid. Herbal healers often prescribe this decoction for the treatment of problems such as stomach ulcers; they also prescribe this for the treatment of urinary tract inflammations, and for treating various prostate and lung conditions affecting various patients.

POULTICE – The horsetail can also be made into an herbal poultice. Use the horsetail powder and form a paste for application on leg ulcers, topical wounds, as well as sores and chilblains of all kinds.

MOUTHWASH/GARGLE – The horsetail herbal decoction can also be diluted down with water and used for the effective treatment of mouth as well as gum infections and other throat inflammations in patients.

JUICE – An herbal horsetail juice made from liquidized horsetail stems are ideal. A dose of 5 -10 ml of this juice, taken thrice daily, can be good for treatment of urinary disorders in patients. The same juice can be used for the treatment of nosebleeds in people, dip a cotton wool swab in some of this juice and stuff it into a nostril for pain relief. The same herbal horsetail juice is also suggested for the treatment of long term lung damage in patients.

CAPSULES – Aside from the juices and the decoctions, another effective way to use horsetail is in the form of powdered horsetail capsules. The same disorders can be treated using these capsules - with the exception of bleeding in the nose.

HORSETAIL POWDER

Heat the previously dried horsetail in a cast-iron frying pan at fairly high heat. Stir vigorously with a thick, wooden spoon (boxwood, olive) until a fine powder is obtained. Preserve in a glass jar.

This powder is very useful for stopping bleeding and skin suppurations. Diluted in a little water and taken internally, it soothes heartburn and even digestive hemorrhaging. Combined with flower pollen, it combats tumors.

Magnesium: For Bone Health

Sandra Denton, M.D.

Often my patients are shocked to learn that they have Osteoporosis because they have been taking a “ton” of calcium supplements for years. Contrary to popular belief, populations consuming the greatest amount of milk also have the highest Osteoporosis rate. One study found that calcium supplementation to postmenopausal women (2000mg/day for 2 years) did not significantly reduce bone loss! How can that be?

Most of us know someone in our family who has suffered the devastation that accompanies Osteoporosis. And it seems to be getting worse, not better. Worldwide, the lifetime risk for a woman is 30-40%, according to the International Osteoporosis Foundation. In the next 50 years, the number of fractures for both men (yes, men get Osteoporosis too) and women will more than double. So what is the answer? Prevention.

Not all calcium supplements are the same.

First of all, the form that the calcium is in does make a difference. Of all the forms of calcium available on the market today, my personal favorite is a plant-based concentrate from seaweed. Calcium from seaweed sources are popular in Asian and European markets where consumers already know the health benefits of seaweed, which contains a variety of other minerals as well. One recent study, done by the University of Minnesota, proved the bioavailability of calcium from seaweed to be superior.

Another study gathered evidence over a 13-year period and showed the enhanced bone mineral density effects of calcium from seaweed on hip and particularly lumbar region. There is even evidence suggesting that it can relieve pain and improve mobility in osteoarthritic joints.

Secondly, bone is more than a collection of calcium crystals. Bone is an active, living tissue that is constantly remodeling itself through building up (formation) and tearing down (resorbing) activity. Like any other living tissue, bone has diverse nutritional needs. Ignoring those needs could have a negative impact on the strength and integrity of bone tissue. The American diet is extremely deficient in all of these nutrients that are so vital to bone health.

Magnesium is often forgotten in Osteoporosis research. Calcium alone cannot be utilized and deposited into bone without magnesium. Alkaline phosphatase, an enzyme involved in new calcium crystals, is activated by magnesium. Conversion of vitamin D into its biologically active form requires magnesium. The ratio of calcium to magnesium is also important, and many feel that 3:2 and 1:1 is ideal.

Vitamin D3 increases calcium absorption and inhibits bone resorption. Isoflavones from soybean concentrate also inhibit bone resorption and stimulate bone formation. Vitamin D and isoflavones together appear better at preventing bone loss than either agent alone.

Vitamin D with calcium has been shown to reduce fractures even when bone density may remain unchanged (NEJM, 1997; 337).

Boron plays an important role in bone health by reducing urinary calcium excretion by as much as 44% and seems to be important in vitamin D metabolism. Zinc is essential for normal bone formation and enhances the biochemical actions of vitamin D. Low levels of zinc have been found in those who have accelerated bone loss of the mandible (jaw bone).

Deficiencies of Copper lead to reduced bone mineral content and reduced bone strength. Studies show that copper supplementation may inhibit bone resorption and also strengthen connective tissue. Manganese is required for bone mineralization and for synthesis of connective tissue in cartilage and bone. Manganese stimulates the production in bones of a group of protein-like molecules, which provide a structure upon which calcification can take place.

The importance of folic acid, vitamin B6, and vitamin B12 seems to come from their ability to block the conversion of methionine to homocysteine (a potentially toxic substance) in the body. Individuals with high homocysteine levels in the blood develop Osteoporosis at an early age and have a higher risk of developing Alzheimers and heart disease.

In my opinion, one should take a balanced calcium/magnesium blend at bedtime because the calming aspects of the minerals may result in a better night's sleep. In addition, there is less competition for absorption from other nutritional supplements.

Who should take it? Anyone interested in being pro-active in preventing and, yes, even reversing Osteoporosis. I believe even teenagers can benefit by ensuring strong bones for their very active lifestyles and avoiding problems later on in life. I would also expect a speedier healing time for fractures and other injuries as well as improved pH balance in the body.

Summary
Maintaining healthy bones in people with kidney disease can be a challenge. Even without kidney disease, we are more prone to weak bones as we age. The best treatments to date appear to be keeping your vitamin D level, blood calcium and phosphorus in the normal range, and keep your PTH under control with various prescription medications when required. Regular exercise can help keep your muscles stronger and actually stimulate your bones to stay healthy.

Manganese

Complementary Naturopathic Medicine for Periodontitis

This study has been completed.]

First Received: February 2, 2001 Last Updated: August 17, 2006

Sponsor:	National Center for Complementary and Alternative Medicine (NCCAM)
Information provided by:	National Center for Complementary and Alternative Medicine (NCCAM)
ClinicalTrials.gov Identifier:	NCT00010634

Purpose

This study aims to assess selected naturopathic medicines for adult periodontitis and to identify variables that influence successful outcomes when traditional and alternative approaches to preventing and treating periodontal diseases are combined. Collaboration between Kaiser Permanente, Oregon Health Science University and the National College of Naturopathic Medicine provides an unsurpassed environment for such investigations. Periodontitis is a major cause of **tooth** loss and negatively impacts systemic health. The limitations of traditional periodontal treatment have compelled scientists and clinicians to investigate new remedies, and naturopathic medicine holds several promising interventions.

Because they are used to improve elements of host resistance that are known to be important in periodontal health and disease, three naturopathic medicines are potential adjuncts in preventing and treating periodontitis.

Connective tissue components are enzymatically degraded in periodontitis. In naturopathy, Connective Tissue Nutrient Formula (CTNF) (vitamins A, C and D, glucosamine sulfate, oligoproanthocyanindins, copper, zinc, manganese, boron, silicon, magnesium, and calcium) is prescribed specifically to enhance the integrity of key connective tissue elements and improve their resistance to degradation.

Periodontitis begins when permeability of the oral sulcular epithelium permits pathogenic bacterial components to invade deeper periodontal connective tissues. In naturopathy, glutamine is prescribed to reduce oral-intestinal epithelial membrane permeability. Chronic activation of the hypothalamic-pituitary-adrenal (HPA) axis during the stress response, is a risk factor for periodontitis. Adaptogenic herbs (AH) (Panax ginseng, Withania somnifera and Eleutherococcus senticosus) are prescribed by naturopathic physicians to reverse the impact of bacterial and psychosocial stressors.

Because glutamine, CTNF and AH target pathophysiologic mechanisms known to underline periodontitis, they are compelling candidates in clinical and mechanistic investigations of complementary medicine approaches to the management of periodontitis.

Kaiser Permanente adult periodontitis patients will serve as subjects and receive standard periodontal treatment. Three of the four randomly assigned groups will also receive supplements of glutamine, CTNF, or AH. We will determine the effects of these supplements on clinical outcomes (attachment loss, pocket depths, indicators of inflammation, plaque composition, need for periodontal surgery, acute periodontal problems, **tooth** loss). In addition to completing the battery of self-report measures (stress, coping, quality of life), study subjects will provide samples of blood, saliva, gingival cervicular fluid and bacterial dental plaque.

These samples will be examined as part of the Laboratory Core to identify biologic and genetic characteristics that correlate with successful outcomes. Storage of portions of the samples will allow future examination of additional variables as part of the Developmental Projects carried out as the Craniofacial Complementary & Alternative Center is established and Phase III trials are undertaken.

Condition	Intervention	Phase
Periodontitis	Drug: Connective Tissue Nutrient Formula Drug: Adaptogenic herbs Drug: glutamine	Phase II

Study Type: Interventional

Study Design: Allocation: Randomized
Primary Purpose: Treatment

Official Title: Complementary Naturopathic Medicine for Periodontitis

Further study details as provided by National Center for Complementary and Alternative Medicine (NCCAM):

Study Start Date: September 1999

Estimated Study Completion Date: July 2004

Detailed Description:

See Brief Summary

Eligibility

Ages Eligible for Study: 35 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

- Adult periodontitis

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00010634

Locations

United States, Oregon

The Oregon Health Sciences University (OHSU)
Portland, Oregon, United States

Sponsors and Collaborators
National Center for Complementary and Alternative Medicine (NCCAM)
Investigators

Principal Investigator:	Theresa Madden	Center for Health Research, Kaiser Foundation Hospitals

More Information

No publications provided

ClinicalTrials.gov Identifier:	NCT00010634
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Phosphorus

Healthy Bones: Maintaining Strength and Preventing Fractures

By Daniel W. Coyne, MD

As we age, the risk of broken bones and fractures increases dramatically. Regardless of age, people on dialysis or who have received a kidney transplant have a higher chance for fractures. Several factors affect your likelihood of avoiding fractures: the density of bones, structurally strong bones, strong muscles and your balance.

The health of bones is complex. Healthy bones need to be dense, which can be measured by a test called a DEXA scan. The DEXA scan assesses bone mineral density (BMD). The density of bones is made up of calcium and phosphorus deposited as crystals onto a protein matrix. But density alone is not enough to avoid fractures. Fluoride has been tied to increase bone strength. It dramatically increased bone density, but led to brittle weaker bones.

The best dense bones have natural calcium and phosphorus deposited into a protein matrix, or scaffold. For this to occur, you need a hormone called PTH (parathyroid hormone) to be neither too low nor too high in your blood. You also need adequate vitamin D, and its active product calcitriol or a similar active form of vitamin D. With chronic kidney disease (CKD), the PTH can get too high, partly due to low vitamin D and calcitriol levels. High phosphorus in your blood can also make the PTH too high.

While good architecture and strong bones are important for avoiding fractures, a third component may be less obvious – the strength of your muscles and good balance. Regular exercise can build and maintain muscle strength and help reduce your chance of falls and fractures. The stress and strain of exercise actually stimulates bones to get stronger.

If you have a tendency to fall due to an injury, weakness or other malady, use of a cane or walker can lower your chances of a serious fall. A physical therapist can recommend simple exercises to improve strength, and decide if you need a cane or walker.

Phosphorus and Calcium

Phosphorus is an element crucial to building healthy bones. We get phosphorus in many foods we eat, though some foods have very high phosphorus content. Our kidneys keep the phosphorus in a normal range by dumping extra phosphorus in the urine. When kidneys are damaged, the phosphorus can get too high in the blood, which makes the PTH too high, and can weaken your bones. You can help keep your phosphorus normal by following a diet low in phosphorus, and taking binders with meals. Binders literally bind some of the phosphorus in your meals so you absorb less. They should be taken with your meals.

There are several types of binders. The least expensive are calcium carbonate. Also relatively inexpensive is calcium acetate, a prescription medication. Both of these binders also provide some calcium. For many people with kidney disease, the calcium is fine. For others, it may increase the calcium in your blood too high. If your blood calcium gets too high, your doctor may need to decrease or stop calcium binders. Non-calcium binders are mainly sevelamer and lanthanum carbonate. These prescription medications are more expensive. They work the same way as the other binders, but don't give you calcium. This may be better for patients, but much more work needs to be done to prove if this is true. The most important thing for your health is not the type of binder you take, but controlling your blood phosphorus by adjusting your diet, taking your binders and getting regular blood tests. By keeping

phosphorus in the normal range, you can help keep PTH normal and your bones stronger.

Vitamin D
Vitamin D is made when ultraviolet light strikes the skin. For many reasons – like wearing clothes! – at least half of all people have low vitamin D levels. Inexpensive vitamin D supplements bought over the counter or prescription supplements can be taken as pills to keep your vitamin D stores normal. There appear to be many benefits and no clear harm from taking small doses of vitamin D, such as vitamin D3 (cholecalciferol) 1000 or 2000 IU per day, or vitamin D2 (ergocalciferol) 50,000 IU capsules once or twice per month.

This may not only help your bones, but also improve your muscle strength and balance. Studies in the frail elderly have shown treatment with vitamin D increases strength and balance, and can decrease the risk of falls. Low vitamin D levels have also been associated with the risk of developing certain cancers, developing hypertension and having poorer heart function. We don't know if the low vitamin D levels caused these other problems, but having a normal vitamin D level appears safe.

If you have kidney disease, ask your doctor to check your vitamin D levels and recommend a supplement if they are low. He or she can recommend a safe dose for you if you have low vitamin D levels.

Calcitriol, the Active Vitamin D
Your kidneys should make calcitriol from vitamin D, but due to damage, they make less and less. Calcitriol, also called active vitamin D, helps keep your PTH from getting too high and helps you absorb calcium and phosphorus. Your doctor can give you small doses of calcitriol to help push down PTH. Too much calcitriol can cause problems, such as too much calcium or phosphorus in your blood. To avoid this, your doctor will need to monitor your blood tests regularly. He or she can also use a drug similar to calcitriol which is less likely to cause problems with high calcium and phosphorus, such as paricalcitol or doxercalciferol. These drugs seem to suppress PTH better than calcitriol and cause less of these side effects.

Controlling PTH
Your doctor may prescribe calcitriol, paricalcitol or doxercalciferol to lower your PTH toward normal. These drugs may even make you live longer. Studies suggest people with kidney disease who get one of these drugs live longer than similar patients not given these medications. Further study is needed, but if your doctor determines you should get these medications, make sure to take them regularly and have routine blood work testing. In patients on dialysis, cinacalcet is sometimes given to lower the PTH. This pill should be taken every day, and works in a different fashion than the active vitamin D medications. Side effects of cinacalcet include nausea and vomiting, and low blood calcium. It is not unusual to use cinacalcet with calcitriol or one of the other active forms of vitamin D.

Summary
Maintaining healthy bones in people with kidney disease can be a challenge. Even without kidney disease, we are more prone to weak bones as we age. The best treatments to date appear to be keeping your vitamin D level, blood calcium and phosphorus in the normal range, and keep your PTH under control with various prescription medications when required. Regular exercise can help keep your muscles stronger and actually stimulate your bones to stay healthy.

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This article originally appeared in the May 2008 issue of *Kidney Beginnings: The Magazine*.

B-Complex

B-Complex Vitamins Are Essential to Oral Health

One of the vitamins that are essential for oral health is vitamin B, or more specifically, the B-complex vitamins. The B-complex vitamins are actually a group of eight vitamins, which include thiamine (B1), riboflavin (B2), niacin (B3), pyridoxine (B6), folic acid (B9), cyanocobalamin (B12), pantothenic acid and biotin.

Aside from helping to maintain oral comfort and health, the B-complex vitamins are essential for the breakdown of carbohydrates into glucose (this provides energy for the body), the breakdown of fats and proteins (which aids the normal functioning of the nervous system), muscle tone in the stomach and intestinal tract, as well as maintaining the skin, hair, eyes and liver.

A little known consequence of certain vitamin deficiencies is a number of conditions that can affect the mouth.

We have all been told that vitamins are good for us, but I would like to take a minute to go over what vitamins are and how they work. The word vitamin is derived from a combination of words -- vital amine -- and was conceived by Polish chemist Casimir Funk in 1912. Funk isolated vitamin B1, or thiamine, from rice. This was determined to be one of the vitamins that prevented beriberi, a disease marked by inflammatory or degenerative changes of the nerves, digestive system and heart. Vitamins are organic (carbon containing) molecules that mainly function as catalysts for reactions within the body.

A catalyst is a substance that allows a chemical reaction to occur using less energy and less time than it would take under normal conditions. If these catalysts are missing, as in a vitamin deficiency, normal body functions can break down and render a person susceptible to disease. The body requires vitamins in tiny amounts -- hundredths of a gram in many cases. We get vitamins from three primary sources: foods, beverages and our own bodies. Vitamin K and some of the B vitamins are produced by bacteria within our intestines, and vitamin D is formed with the help of ultraviolet radiation, or sunshine, on the skin.

A deficiency of any of the B-complex vitamins -- except pantothenic acid and biotin -- can cause a wide variety of oral problems. These problems include irritation and painful cracking of the lips, as well as inflammation of the tongue, and irritation inside the cheeks and other areas of the mouth.

The B-complex vitamins are found in many foods, including whole-grain cereals, bread, red meat, egg yolks, green leafy vegetables, legumes, peas, soybeans, sweet corn, brown rice, berries, yeast, the germ and husks of grains, nuts, cheese and other food sources. Deficiencies of the B-complex vitamins are rare in healthy individuals, but are often found in alcoholics, the malnourished, the poor, the elderly and those who are unable to absorb food due to certain diseases, such as topical sprue or gluten enteropathy.

As we age, we can also become susceptible to B12 deficiency due to an increasingly difficult time metabolizing the vitamin. Consequently, many doctors recommend that people over 60 have their vitamin B12 levels checked to see if a B12 shot is needed.

Although the vast majority of dental problems are related to untreated infections of the teeth and gums, this is not always the case. In situations where oral discomfort cannot be explained by a dental infection, your dentist and family doctor should explore a deficiency in one or several of the B-complex vitamins.

Ascorbic Acid

Ascorbic Acid Treatment in CMT1A Trial (AATIC)
This study has been completed.

First Received: January 3, 2006 Last Updated: July 2, 2008

Sponsor:	Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA)
Information provided by:	Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA)
ClinicalTrials.gov Identifier:	NCT00271635

Purpose

Charcot-Marie- Tooth type IA (CMT1A) is the most prevalent hereditary peripheral neuropathy. Demyelination of peripheral nerves is the hallmark of CMT1A. Ascorbic acid has been shown to have a favorable influence on myelination in in vitro studies and in a mouse model for CMT1A. We will study the efficacy and safety of ascorbic acid treatment in young patients with CMT1A.

Condition	Intervention	Phase
Charcot-Marie-Tooth Disease Hereditary Motor and Sensory Neuropathies	Drug: Placebo Drug: ascorbic acid	Phase II

Study Type: Interventional

Study Design: Allocation: Randomized
Control: Placebo Control
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Phase 2 Study of Ascorbic Acid Treatment in Charcot-Marie-Tooth Type 1A

Further study details as provided by Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA):

Primary Outcome Measures:

- Change in motor nerve conduction velocity of the median nerve after 1 year
  [Time Frame: 1 year] [Designated as safety issue: No]

Secondary Outcome Measures:

- Change in minimal F response latency of the median nerve after 1 year [Time Frame: 1 year] [Designated as safety issue: No]
- Changes in compound muscle action potential amplitude and area after 1 year [Time Frame: 1 year] [Designated as safety issue: No]
- Change in motor unit number estimation of the abductor pollicis brevis muscle after 1 year [Time Frame: 1 year] [Designated as safety issue: No]
- Changes in handgrip strength, strength of armflexors, foot dorsiflexors, knee extensors and hip flexors after 1 year [Time Frame: 1 year] [Designated as safety issue: No]
- Change in overall disability sum score after 1 year [Time Frame: 1 year] [Designated as safety issue: No]
- Change in AMC Linear Disability Scale score after 1 year [Time Frame: 1 year] [Designated as safety issue: No]
- Evaluation of serum ascorbic acid concentrations during 1 year [Time Frame: 1 year] [Designated as safety issue: No]
- Evaluation of side effects during 1 year [Time Frame: 1 year] [Designated as safety issue: No]

Enrollment: 13
Study Start Date: January 2006
Study Completion Date: July 2007
Primary Completion Date: July 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
1: Experimental Ascorbid Acid Intervention: Drug: ascorbic acid	Drug: ascorbic acid Ascorbic acid 1000 mg (4 capsules of 250 mg) b.i.d. during 1 year Other Names: • Ascorbic Acid • Vitamin
2: Placebo Comparator Placebo Intervention: Drug: Placebo	Drug: Placebo Placebo 4 capsules b.i.d. during 1 year Other Name: Placebo

Detailed Description:

Charcot-Marie-Tooth type 1A (CMT1A), or hereditary motor and sensory neuropathy type Ia (HMSN Ia), is an autosomal dominant disease, most often caused by a 1.5 Mb duplication of chromosome 17, giving rise to three copies of the peripheral myelin protein 22 gene (PMP22). Mutations in this gene rarely cause CMT1A. It is a primarily demyelinating neuropathy, as has been shown in nerve conduction studies and in histopathological investigations. The conduction velocities of peripheral nerves are already slowed at the age of five years. Longitudinal data show that these conduction velocities do not change during life, indicating that the degree of demyelination is rather constant during life.

CMT1A is characterized clinically by distal muscle weakness and wasting, legs more than arms, impaired distal sensation, and reduced or absent reflexes. Moreover, foot and hand deformities are often encountered. In childhood, disease progression has been shown. In adults, there are indications for disease progression, but properly conducted longitudinal studies are awaited. Cross-sectional studies show that disease severity in adults is variable: a group of CMT1A patients is asymptomatic (5-10%), whereas other patients are wheelchair dependent (5-10%), still most have the classical CMT phenotype. Therapy is symptomatic and aims at maintaining functional possibilities and learning compensation mechanisms. There is no medication available that stabilizes or improves the clinical signs and symptoms.

Ascorbic acid is needed in in vitro studies for proper myelination of axons (in cultures containing serum). Recently, in a mouse model for CMT1A it has been shown that ascorbic acid improves the CMT1A phenotype. Mice (2-4 months old) treated with ascorbic acid once a week during three months showed an increase in the percentage of myelinating nerve fibers and showed better results in locomotor tests.

In this phase 2 study we will study the efficacy and safety of ascorbic acid in young patients with CMT1A. We will investigate whether ascorbic acid induces remyelination by measuring the nerve conduction of a peripheral nerve during a one year study period. CMT1A patients aged 12 years or older may cooperate sufficiently in nerve conduction studies. We include young patients, as clinical signs and symptoms especially develop relatively early in life. These signs and symptoms are due to axonal dysfunction, secondary to the demyelination. This is why we will investigate additionally whether there is an effect of ascorbic acid treatment on axonal function, strength and disabilities.

Eligibility

Ages Eligible for Study:	12 Years to 25 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria
Inclusion Criteria:

- DNA-proven CMT1A patients
- Age 12-25 years
- CMT 1A patients with symptomatology defined as muscle weakness in at least foot dorsiflexion

Exclusion Criteria:

Due to possible influence on severity of the neuropathy:

- Known other disease that may cause a neuropathy, that may decrease mobility, or that may lead to severe disability or death in a short time
- Medication that may cause a neuropathy
- Chronic alcohol abuse

Due to study medication (ascorbic acid):

- Regular use of vitamin C
- Clinical or echographic signs of nephrolithiasis
- Reduced glomerular filtration rate

- Iron overload
- No regular dental control at the dentist
- Pregnancy or active pregnancy wish for women

Due to study design and primary outcome:

- Not signing the informed consent
- Psychiatric co-morbidity which may influence compliance
- Not being comfortable during nerve conduction studies of the median nerve
- A too small CMAP amplitude of the abductor pollicis brevis muscle for a proper determination of the nerve conduction velocity of the median nerve

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00271635

Locations

Netherlands

Department of Neurology Academic Medical Center University of Amsterdam
Amsterdam, P.O.Box 22660, Netherlands, 1100 DD

Sponsors and Collaborators

Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA)

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M. de Visser, MD, PhD	Department of Neurology, Academic Medical Center, University of Amsterdam
I. N van Schaik, MD, PhD	Department of Neurology, Academic Medical Center, University of Amsterdam

More Information

Publications:

- Passage E, Norreel JC, Noack-Fraissignes P, Sanguedolce V, Pizant J, Thirion X, Robaglia-Schlupp A, Pellissier JF, Fontes M. Ascorbic acid treatment corrects the phenotype of a mouse model of Charcot-Marie-Tooth disease. Nat Med. 2004 Apr;10(4):396-401. Epub 2004 Mar 21.
- Verhamme C, van Schaik IN, Koelman JH, de Haan RJ, Vermeulen M, de Visser M. Clinical disease severity and axonal dysfunction in hereditary motor and sensory neuropathy Ia. J Neurol. 2004 Dec;251(12):1491-7.

Additional publications automatically indexed to this study by National Clinical Trials Identifier (NCT ID):

- Verhamme C, de Haan RJ, Vermeulen M, Baas F, de Visser M, van Schaik IN. Oral high dose ascorbic acid treatment for one year in young CMT1A patients: a randomised, double-blind, placebo-controlled phase II trial. BMC Med. 2009 Nov 12;7:70.

Responsible Party: Academic Medical Center, university of Amsterdam (C.

	Verhamme, MD)
ClinicalTrials.gov Identifier:	NCT00271635
Other Study ID Numbers:	04/320
Study First Received:	January 3, 2006
Last Updated:	July 2, 2008
Health Authority:	Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)

Keywords provided by Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA):
Charcot-Marie-Tooth Disease
Hereditary Motor and Sensory Neuropathies
Ascorbic Acid
Vitamin C

Additional relevant MeSH terms:

Charcot-Marie-Tooth Disease	Neuromuscular Diseases
Tooth Diseases	Congenital Abnormalities
Ascorbic Acid	Genetic Diseases, Inborn
Vitamins	Stomatognathic Diseases
Nerve Compression Syndromes	Antioxidants
Hereditary Motor and Sensory Neuropathies	Molecular Mechanisms of Pharmacological Action
Nervous System Malformations	Pharmacologic Actions
Nervous System Diseases	Protective Agents
Heredodegenerative Disorders, Nervous System	Physiological Effects of Drugs
Neurodegenerative Diseases	Micronutrients
Polyneuropathies	Growth Substances
Peripheral Nervous System Diseases	

ClinicalTrials.gov processed this record on February 28, 2011

Vitamin D3, Vitamin K2, And Warfarin Regulate Bone Metabolism In Human Paranasal Sinus Bones.

This study has been completed.

Rhinology. 2007 Sep;45(3):208-13.

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Department of Otorhinolaryngology, Head and Neck Surgery, Division of Clinical Medical Science, Programs for Applied Biomedicine, Graduate School of Biomedical Sciences, Hiroshima University, Hiroshima

Abstract

Several recent studies have indicated that the para nasal sinus bones undergo pathophysiological changes in patients with chronic sinusitis. We examined the mineralization activity of osteoblasts and the production of osteocalcin and cytokines in cultured human osteoblasts derived from ethmoidal bones treated with vitamin D3, vitamin K2, and warfarin to investigate the metabolic effects of these treatments on para nasal sinus bones.

In the bones treated with vitamin D3 plus vitamin K2, osteocalcin production and the ratio of the mineralization of osteoblasts were increased. Warfarin inhibited the promotive effects of vitamin K2 in the presence of vitamin D3. With regard to TGF-beta production, there was quite a difference in response depending on the isoforms.

In conclusion, we have demonstrated that these vitamins and warfarin may be useful in improving bone metabolism in paranasal sinus bones, and may additionally improve the pathogenesis of chronic sinusitis.

Effects Of Vitamin K2 Administration On Calcium Balance And Bone Mass In Young Rats Fed Normal Or Low Calcium Diet.

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OBJECTIVE: The purpose of this study was to examine the effects of vitamin K2 administration on calcium balance and bone mass in young rats fed a normal or low calcium diet.

METHODS: Forty female Sprague-Dawley rats, 6 weeks of age, were randomized by stratified weight method into four groups with 10 rats in each group: 0.5% (normal) calcium diet, 0.1% (low) calcium diet, 0.5% calcium diet + vitamin K2 (menatetrenone, 30 mg/100 g chow diet), and 0.1% calcium diet + vitamin K2. After 10 weeks of feeding, serum calcium and calciotropic hormone levels were measured, and intestinal calcium absorption and renal calcium reabsorption were evaluated. Bone histomorphometric analyses were performed on cortical bone of the tibial shaft and cancellous bone of the proximal tibia.

RESULTS: Feeding a low calcium diet induced hypocalcemia, increased serum parathyroid hormone (PTH) and 1,25-dihydroxyvitamin D [1,25(OH)2D] levels with decreased serum 25-hydrovyvitamin D [25(OH)D] level, stimulated intestinal calcium absorption and renal calcium reabsorption, and reduced cortical bone mass as a result of decreased periosteal bone gain and enlarged marrow cavity, but did not significantly influence cancellous bone mass. Vitamin K2 administration in rats fed a low calcium diet stimulated renal calcium reabsorption, retarded the abnormal elevation of serum PTH level, increased cancellous bone mass, and retarded cortical bone loss, while vitamin K2 administration in rats fed a normal calcium diet stimulated intestinal calcium absorption by increasing serum 1,25(OH)2D level, and increased cortical bone mass.

CONCLUSION:
This study clearly shows the differential response of calcium balance and bone mass to vitamin K2 administration in rats fed a normal or low calcium diet.

Zinc

The positive effects of zinc on skeletal strength in growing rats.

Ovesen J, Møller-Madsen B,
Thomsen JS, Danscher G,
Mosekilde L

Department of Neurobiology, Institute of Anatomy, University of Arhus, Arhus, Denmark.

Abstract

The aim of the present study was to assess the skeletal effects of alimentary zinc depletion and supplementation in an animal model of intact, growing rats.

The study was planned as a dose-response study. Thirty-six male Wistar rats, 4 weeks old, were divided into three groups of 12 rats each. The rats had free access to a semisynthetic diet with different amounts of zinc added. Group 1 was given a zinc-free diet containing 2 mg zinc/kg, group 2 was given a normal-zinc diet containing 47 mg zinc/kg; and group 3 was given a zinc-supplemented diet containing 60 mg zinc/kg.

All animals were killed 4 weeks after initiation of the experiment and the right femora were removed. The biomechanical effects were measured at the following skeletal sites: femoral diaphysis; femoral neck; and distal femoral metaphysis.

In addition, static histomorphometry was performed at the middiaphyseal region. Biomechanical testing revealed a significant zinc-induced increase in bone strength at all sites investigated. It also showed that zinc influenced bone strength in a dose-dependent manner except at the distal metaphysis, where there was no significant difference between the group fed normal-zinc diet and the group fed a hyper-zinc diet. Zinc also improved the rates of growth in the rats.

The body weights and length of femora increased dose-dependently. Static histomorphometry showed that zinc exerted its main effect on the periosteal envelope, thereby increasing bone area, tissue area, and axial moment of inertia.

We conclude that alimentary zinc supplementation in growing rats induces an increase of bone strength in both the femoral neck and the femoral diaphysis. These results further support the view that zinc has a positive effect on bone metabolism which mimics that of growth hormone (GH) or insulin-like growth factor 1 (IGF-1).

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Prevention Of Streptococcal Pharyngitis By Anti-Streptococcus Pyogenes Bacteriocin-Like Inhibitory Substances (BLIS) Produced By Streptococcus Salivarius.

Tagg JR.

Department of Microbiology, University of Otago, P.O. Box 56, Dunedin, New Zealand.

Abstract

BACKGROUND & OBJECTIVES: Streptococcus salivarius is a numerically prominent member of the human oral microbiota that produces a variety of bacteriocin-like inhibitory substances (BLIS) having in vitro inhibitory activity against S. pyogenes.

Our previous studies of S. salivarius isolates from children using a deferred antagonism BLIS production (P)-typing scheme showed that the 9 per cent of children having large populations of P-type 677 S. salivarius experienced fewer S. pyogenes acquisitions than either the 11 per cent of children having predominant P-type 226 populations or the 60 per cent of children with largely non-inhibitory (P-type 000) S. salivarius.

Amongst the other BLIS P-types detected were a number of strongly-inhibitory (P-type 777) S. salivarius. In the present study the inhibitory agents produced by prototype strains of P-types 226, 677 and 777 S. salivarius are compared.

METHODS: The prototype BLIS-producing S. salivarius strains SN, 20P3, and K12 were isolated from tongue swabbings. BLIS P-typing was done using standard procedures. The BLIS molecules were purified and characterized.

RESULTS: S. salivarius SN (P-type 226) produces a heat-labile muramidase. S. salivarius 20P3 (P-type 677) produces the 2315 Da lantibiotic salivaricin A and S. salivarius K12 (P-type 777) produces two lantibiotics; salivaricin A2 (2368 Da) and salivaricin B (2733 Da).

INTERPRETATION & CONCLUSION: The P-type 777 S. salivarius strain produced salivaricin A2 and salivaricin B. The combined production of two anti-S. pyogenes BLIS activities by this strain indicates that it could be adopted as a colonizing strain in bacterial interference trials.

Collection of Dental Plaque and Saliva for Studies of Bacterial Colonization of Teeth

This study has been completed.

First Received: July 12, 2006 Last Updated: September 5, 2009

Sponsor:	National Institute of Dental and Craniofacial Research (NIDCR)
Information provided by:	National Institutes of Health Clinical Center (CC)
ClinicalTrials.gov Identifier:	NCT00098267

Purpose

This study will explore how bacteria colonize human teeth and how this process changes over the lifetime of individuals. It will include an investigation of transmission of bacteria that initiate colonization between adults and from adults to infants.

Selected NIH scientists and members of their immediate families, including infants, are eligible for this study. Participants provide a small sample of saliva and a sample of bacteria collected by rubbing a cotton swab over the surfaces of the lower four incisors. Adults collect and submit their own specimens; a dentist collects specimens from children.

Condition
Healthy

Study Type: Observational

Official Title: Collection of Dental Plaque and Saliva for Studies of Oral Microbial Colonization

Further study details as provided by National Institutes of Health Clinical Center (CC):

Estimated Enrollment:	30
Study Start Date:	December 2004
Study Completion Date:	August 2009
Primary Completion Date:	August 2009 (Final data collection date for primary outcome measure)

Detailed Description:

Interactions between different bacteria play an important role in biofilm development during primary colonization of the human tooth surface. Well studied examples of such interactions include the receptor polysaccharide (RPS)-mediated interactions between viridans group streptococci and other oral bacteria including type 2 fimbriated Actinomyces naeslundii.

Previous studies have resulted in the identification of different structural, antigenic and molecular types of RPS on the streptococci that initiate colonization of the tooth surface. This information provides the basis for the current protocol, which addresses a number of important questions involving the nature of the commensal relationship that exists between biofilm-forming bacteria and the host. For example: (1) How many types of RPS are produced by the resident flora of an individual at any one time? (2) Does the resident population of RPS-producing clones change over the lifetime of the host? (3) Do individuals produce secretory antibodies against bacterial RPS, and if so, does this drive a change in the antigenic type of RPS produced? (3) When and how do infants acquire RPS-producing bacteria, before or after tooth eruption? To address these questions, we wish to collect and analyze samples of early dental plaque from the members of individual families. The collection of such samples will be accomplished by gently rubbing exposed tooth surfaces with a sterile cotton swab.

Adult volunteers will also be asked to provide small samples of saliva, which will be assayed for the presence of specific anti-RPS antibodies. The sampling procedures proposed in this protocol do not present any significant risk to either adult or infant volunteers. The information gained from these studies, although not directly beneficial to these individuals, is expected to provide important insights into the commensal relationship that exists between biofilm-forming bacteria and the host. This in turn will contribute to an improved understanding of variables associated with the maintenance of oral health and the initiation of disease.

Eligibility

Ages Eligible for Study:	3 Months and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria

- INCLUSION AND EXCLUSION CRITERIA

This is a pilot study with no inclusion or exclusion criteria other than availability. Participants will include Dr. Yoshida, his wife and their infant son and members of Dr. Cisar's family including his wife and adult children. Other NIH scientists and their infant children will also be included. All participants will be asked to sign the appropriate consent / assent forms.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00098267

Locations

United States, Maryland

National Institutes of Health Clinical Center, 9000 Rockville Pike
Bethesda, Maryland, United States, 20892

Sponsors and Collaborators

National Institute of Dental and Craniofacial Research (NIDCR)

More Information

Publications:

Cisar JO, Sandberg AL, Abeygunawardana C, Reddy GP, Bush CA. Lectin recognition of host-like saccharide motifs in streptococcal cell wall polysaccharides. Glycobiology. 1995 Oct;5(7):655-62.

Takahashi Y, Sandberg AL, Ruhl S, Muller J, Cisar JO. A specific cell surface antigen of Streptococcus gordonii is associated with bacterial hemagglutination and adhesion to alpha2-3-linked sialic acid-containing receptors. Infect Immun. 1997 Dec;65(12):5042-51.

Takahashi Y, Ruhl S, Yoon JW, Sandberg AL, Cisar JO. Adhesion of viridans group streptococci to sialic acid-, galactose- and N-acetylgalactosamine-containing receptors. Oral Microbiol Immunol. 2002 Aug;17(4):257-62.

ClinicalTrials.gov Identifier:	NCT00098267
Other Study ID Numbers:	050051, 05-D-0051
Study First Received:	July 12, 2006
Last Updated:	September 5, 2009
Health Authority:	United States: Federal Government

Keywords provided by National Institutes of Health Clinical Center (CC):
- Bacteria
- Biofilm Formation
- Secretory Antibodies
- Teeth
- Health and Disease

Additional relevant MeSH terms:
- Dental Plaque
- Dental Deposits
- Tooth Diseases
- Stomatognathic Diseases

ClinicalTrials.gov processed this record on March 03, 2011

Probiotic Lactobacilli

Use of Probiotic Lactobacilli for the Treatment of Lactational Mastitis

This study has been completed.

First Received: July 14, 2008 Last Updated: May 22, 2009

Sponsor:	Universidad Complutense de Madrid
Information provided by:	Universidad Complutense de Madrid
ClinicalTrials.gov Identifier:	NCT00716183

Purpose

A total of 300 women with lactational infectious mastitis will daily ingest 9 log10 cfu of Lactobacillus salivarius HN6, Lactobacillus reuteri CR20 or Lactobacillus fermentum LC40 for 4 weeks. The three lactobacilli strains were originally isolated from milk of healthy women. On days 0 and 28, milk samples will be collected, and staphylococci/streptococci and lactobacilli will be counted and identified. Evolution of clinical signs will be recorded by midwifes on days 0, 7, 14 and 28.

Condition	Intervention	Phase
Mastitis	Biological: Lactobacillus salivarius HN6 Biological: Lactobacillus reuteri CR20 Biological: Lactobacillus fermentum LC40 Drug: Beta-lactam antibiotic	Phase II Phase III

Study Type: Interventional

Study Design: Allocation: Non-Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Phase 2/3 Evaluation of Three Lactobacilli Strains Isolated From Human Milk for the Treatment of Infectious Mastitis During the Lactation Period

Resource links provided by NLM:

MedlinePlusrelated topics: Antibiotics Breast Feeding

Drug Information available for: Cloxacillin Amoxicillin Amoxicillin sodium Clavulanic acid Amoxicillin trihydrate

U.S. FDA Resources

Further study details as provided by Universidad Complutense de Madrid:

Primary Outcome Measures:

- Staphylococcal and/or streptococcal count in milk [Time Frame: 0 and 28 days] [Designated as safety issue: No]

Secondary Outcome Measures:

- Assessment of local and systemic symptoms associated to mastitis [Time Frame: days 0, 7, 14 and 28] [Designated as safety issue: No]

Enrollment:	300
Study Start Date:	July 2008
Study Completion Date:	May 2009
Primary Completion Date:	July 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Probiotic 1: Experimental Women receiving Lactobacillus salivarius HN6 Intervention: Biological: Lactobacillus salivarius HN6	Biological: Lactobacillus salivarius HN6 9 log colony-forming units, capsules, daily, four weeks
Probiotic 2: Experimental Women receiving Lactobacillus reuteri CR20 Intervention: Biological: Lactobacillus reuteri CR20	Biological: Lactobacillus reuteri CR20 9 log colony-forming units, capsules, daily, four weeks
Probiotic 3: Experimental Women receiving Lactobacillus fermentum LC40 Intervention: Biological: Lactobacillus fermentum LC40	Biological: Lactobacillus fermentum LC40 9 log colony-forming units, capsules, daily, four weeks
beta-lactam: Active Comparator	Drug: Beta-lactam antibiotic

The evolution of the women ascribed to the other three arms will be compared with that of 100 women suffering lactational mastitis that will follow a conventional antibiotic treatment as prescribed by the pediatrician/gynecologist Intervention: Drug: Beta-lactam antibiotic	Use of amoxicillin, cloxacillin or amoxicillin/clavulanic acid(500-750 mg), orally, every 8-12 h, for 2-3 weeks (as prescribed by the physician responsible for the clinical diagnosis of lactational mastitis) Other Name: Amoxicillin (generic), Cloxacillin (generic), Amoxicillin/clavulanic acid (generic), Clamoxyl, Orbenin, Augmentine

Eligibility

Ages Eligible for Study: 19 Years to 38 Years
Genders Eligible for Study: Female
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Clinical diagnosis of mastitis
- Staphylococcal and/or streptococcal count higher than 3000 colony-forming units per ml of milk
- Milk leukocyte count higher 6 log10/mL
- Must be able to provide a milk sample without the aid of a milk pump

Exclusion Criteria:

- Mammary abscesses
- Any kind of parallel disease

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00716183

Locations

Spain

Dpt. Nutricion, Bromatologia y Tecnologia de los Alimentos
Madrid, Spain, 28040

Sponsors and Collaborators

Universidad Complutense de Madrid

More Information

Publications:

Jiménez E, Fernández L, Maldonado A, Martín R, Olivares M, Xaus J, Rodríguez JM. Oral administration of lactobacilli strains isolated from breast milk as an alternative for the treatment of infectious mastitis during lactation. Appl Environ Microbiol. 2008 Jun 6; [Epub ahead of print]

Martín R, Olivares M, Marín ML, Fernández L, Xaus J, Rodríguez JM. Probiotic potential of 3 Lactobacilli strains isolated from breast milk. J Hum Lact. 2005 Feb;21(1):8-17; quiz 18-21, 41.

Martín R, Langa S, Reviriego C, Jimínez E, Marín ML, Xaus J, Fernández L, Rodríguez JM. Human milk is a source of lactic acid bacteria for the infant gut. J Pediatr. 2003 Dec;143(6):754-8.

Martín R, Heilig GH, Zoetendal EG, Smidt H, Rodríguez JM. Diversity of the Lactobacillus group in breast milk and vagina of healthy women and potential role in the colonization of the infant gut. J Appl Microbiol. 2007 Dec;103(6):2638-44.

Delgado S, Arroyo R, Martín R, Rodríguez JM. PCR-DGGE assessment of the bacterial diversity of breast milk in women with lactational infectious mastitis. BMC Infect Dis. 2008 Apr 18;8:51.

Martín R, Jiménez E, Olivares M, Marín ML, Fernández L, Xaus J, Rodríguez JM. Lactobacillus salivarius CECT 5713, a potential probiotic strain isolated from infant feces and breast milk of a mother-child pair. Int J Food Microbiol. 2006 Oct 15;112(1):35-43. Epub 2006 Jul 14.

Olivares M, Díaz-Ropero MP, Martín R, Rodríguez JM, Xaus J. Antimicrobial potential of four Lactobacillus strains isolated from breast milk. J Appl Microbiol. 2006 Jul;101(1):72-9.

Additional publications automatically indexed to this study by National Clinical Trials Identifier (NCT ID):

Arroyo R, Martín V, Maldonado A, Jiménez E, Fernández L, Rodríguez JM. Treatment of Infectious Mastitis during Lactation: Antibiotics versus Oral Administration of Lactobacilli Isolated from Breast Milk. Clin Infect Dis. 2010 May 10; [Epub ahead of print]

Responsible Party:	Universidad Complutense de Madrid (Juan M. Rodríguez)
ClinicalTrials.gov Identifier:	NCT00716183
Other Study ID Numbers:	Promast08
Study First Received:	July 14, 2008
Last Updated:	May 22, 2009
Health Authority:	Spain: Comité Ético de Investigación Clínica

ClinicalTrials.gov processed this record on March 03, 2011

Safety Assessment Of The Oral Cavity Probiotic Streptococcus Salivarius K12.

Burton JP, Wescombe PA, Moore CJ, Chilcott CN, Tagg JR.

BLIS Technologies, Centre for Innovation, University of Otago, P.O. Box 56, Dunedin, New Zealand. jeremy.burton@blis.co.nz

Abstract

Streptococcus salivarius is a prominent member of the oral microbiota and has excellent potential for use as a probiotic targeting the oral cavity. In this report we document safety data relating to S. salivarius K12, including assessment of its antibiogram, metabolic profiles, and virulence determinants, and we examine the microbial composition of saliva following the dosing of subjects with K12.

Streptococcus Salivarius Probiotics

The Rationale And Potential For The Reduction Of Oral Malodour Using Streptococcus Salivarius Probiotics.

Oral Dis. 2005;11 Suppl 1:29-31.

Burton JP, Chilcott CN, Tagg JR.

BLIS Technologies, Center for Innovation University of Otago, Dunedin, New Zealand.

Abstract

The primary treatment for oral malodour is the reduction of bacterial populations, especially those present on the tongue, by use of a variety of antimicrobial agents or mechanical devices. However, shortly after treatment the problematic bacteria quickly repopulate the tongue and the malodour returns. In our studies, we have used a broadly-active antimicrobial (chlorhexidine) to effect temporary depletion of the oral microbiota and then have attempted to repopulate the tongue surface with Streptococcus salivarius K12, a benign commensal probiotic.

The objective of this is to prevent re-establishment of non-desirable bacterial populations and thus help limit the re-occurrence of oral malodour over a prolonged period. In this paper, we discuss why contemporary probiotics are inadequate for treatment of oral malodour and examine the rationale for selection of particular bacterial species for future use in the treatment of this condition.

In our preliminary trials of the use of a chlorhexidine rinse followed by strain K12 lozenges, the majority (8/13) of subjects with confirmed halitosis maintained reduced breath levels of volatile sulphur compounds for at least 2 weeks. We conclude that probiotic bacterial strains originally sourced from the indigenous oral microbiotas of healthy humans may have potential application as adjuncts for the prevention and treatment of halitosis.

HYDRODENT™

Summary:
Hydrodent provides a balanced blend of two (2) essential polyunsaturated fatty acids necessary for many body functions.

Treatment:
Two (2) softgels daily for beneficial roles in eliminating dry mouth.

Active Ingredients:
Flax Seed Oil
Evening Primrose Oil
Canola Oil
Black Currant Oil
Pumpkin Seed Oil

Published Studies and Clinicals:
See attachments

A Comparative Efficacy and Safety Study of Hydrodent:
By using Hydrodent you will increase the moisture in your mouth, initiate digestion which will help protect your teeth from decay.

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with Essential Fatty Acids

100 Softgels

Dietary Supplement

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This product provides a balanced blend of two essential polyunsaturated fatty acids (and their derivatives) necessary for many body functions: Omega-3 oil from Flax Seed and Canola, and Omega-6 oil (GLA) from Primrose and Black Currant. Oleic Acid, an Omega-9 oil from Canola and Flax Seed, is a monounsaturated fat not considered "essential" but does play beneficial roles in human health.

Each serving may also provide the following naturally occurring amounts of polyunsaturated fats and monounsaturated fats:

Omega-3 oils: Alpha Linolenic Acid (ALA) .....900 mg

Omega-6 oils: Linoleic Acid and Gamma Linolenic Acid (GLA) .....530 mg

Omega-9 oils: Oleic Acid .....350 mg

Other oils: Short chain fatty acids, saturated fats, phospholipids, etc. ..220 mg

*This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Contains no sugar, salt, starch, yeast, wheat, gluten, corn, soy, milk, egg, shellfish or preservatives.

Recommended by Dental Healthcare Professionals

Suggested Usage: Take 2 daily or as directed by your dental care professional.

Manufactured for

DentiCorp

32625 W.Seven Mile Rd.

Livonia MI 48152

www.denticorp.net

Professional Dental Care Formulas

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Supplement Facts

Serving Size 2 Softgels Servings Per Container 50

Per Serving	Amount	% Daily Value
Calories	20	
Calories from Fat	20	
Total Fat	2 g	3%*
Saturated Fat	< 0.5 g	2%*
Trans Fat	0 g	†
Polyunsaturated Fat	1.5 g	†
Monounsaturated Fat	< 0.5 g	†
Cholesterol	0 mg	0%
Flax Seed Oil (cold pressed, organic) (Linum usitatissimum) (seed)	1400 mg	†
Evening Primrose Oil (cold pressed) (Oenothera biennis) (seed)	300 mg	†
Canola Oil (cold pressed)	260 mg	†
Black Currant Oil (Ribes nigrum) (seed)	20 mg	†
Pumpkin Seed Oil (Cucurbita pepo) (seed)	20 mg	†

* Percent Daily Values are based on a 2,000 calorie diet. † Daily Value not established.

Other ingredients: Softgel Capsule (gelatin, glycerin, water , carob).

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Store in a cool, dry place. Please Recycle.

Black Currant

Comparative Study Of Diets Enriched With Evening Primrose, Black Currant, Borage Or Fungal Oils On Blood Pressure And Pressor Responses In Spontaneously Hypertensive Rats.

Prostaglandins Leukot Essent Fatty Acids. 1993 Oct;49(4):809-14.

Engler MM.

Department of Physiological Nursing, University of California, San Francisco 94143-0610.

Abstract

The effects of oils enriched with gamma-linolenic acid (GLA) on blood pressure and pressor responses were examined in spontaneously hypertensive rats (SHR). Rats were fed purified diets containing evening primrose (EPO), black currant (BCO), borage (BOR) or fungal (FGO) oils for 7 weeks.

Significant reductions in blood pressure were obtained in SHR rats maintained on diets enriched with GLA oils. The antihypertensive effect was not associated with enhanced pressor responsiveness to norepinephrine or angiotensin II.

Moreover, no differences were found in blood pressure responses to the calcium channel blocker, verapamil. The results suggest that GLA-enriched oils inhibit the development of hypertension in the SHR rat. The blood pressure lowering effect is not mediated by altered pressor responses to vasoconstrictor hormones or intracellular calcium mechanisms.

Canola Oil

Dietary Modeling Shows That The Substitution Of Canola Oil For Fats Commonly Used In The United States Would Increase Compliance With Dietary Recommendations For Fatty Acids.

J Am Diet Assoc. 2007 Oct;107(10):1726-34.

Johnson GH, Keast DR, Kris-Etherton PM.

Department of Food Science and Human Nutrition, The University of Illinois, Urbana-Champaign, USA. guy@nutritionsolutions.net

Comment in:

- J Am Diet Assoc. 2007 Oct;107(10):1701.
- J Am Diet Assoc. 2007 Oct;107(10):1723-5.

Abstract

OBJECTIVE: To examine the effect of substituting canola oil for selected vegetable oils and canola oil-based margarine for other spreads on energy, fatty acid, and cholesterol intakes among US adults.

DESIGN: Twenty-four-hour food recall data from the 1999-2002 National Health and Nutrition Examination Survey (NHANES) were used to calculate the effect of substituting canola oil for dietary corn, cottonseed, safflower, soybean, and vegetable oils described as "not further specified" and of canola oil-based margarine for other spreads at 25%, 50%, and 100% replacement levels.

SUBJECTS: Adult participants aged>or=20 years (n=8,983) of the 1999-2002 NHANES.

STATISTICAL ANALYSIS: Sample-weighted mean daily intake values and the percentage of subjects meeting dietary recommendations were estimated at the various replacement levels. Standard errors of the means and percentages were estimated by the linearization method of SUDAAN.

RESULTS: Significant ($P<0.05$) changes compared to estimated actual intakes included: saturated fatty acid intake decreased by 4.7% and 9.4% with 50% and 100% substitution, respectively. Complete substitution increased monounsaturated fatty acid and alpha-linolenic acid intakes by 27.6% and 73.0%, respectively, and decreased n-6 polyunsaturated fatty acid and linoleic acid intakes by 32.4% and 44.9%, respectively. The ratio of n-6 to n-3 fatty acids decreased from 9.8:1 to 3.1:1 with 100% replacement. Energy, total fat, and cholesterol intakes did not change.

CONCLUSIONS: Substitution of canola oil and canola oil-based margarine for most other vegetable oils and spreads increases compliance with dietary recommendations for saturated fatty acid, monounsaturated fatty acid, and alpha-linolenic acid, but not for linoleic acid, among US adults.

Evening Primrose Oil

The Clinical Advantages Of Cold-Pressed Non-Raffinated Evening Primrose Oil Over Refined Preparations.

Med Hypotheses. 2004;62(1):116-8.

Puri BK.

Department of Imaging Sciences, MRI Unit, MRC Clinical Sciences Centre, Faculty of Medicine, Imperial College School of Medicine, Hammersmith Hospital Campus, Du Cane Road, London W12 0HS, UK. basant.puri@csc.mrc.ac.uk

Abstract

The non-triglyceride fraction of unrefined evening primrose oil has recently been shown to contain 3-O-trans-caffeoyl derivatives of betulinic, morolic, and oleanolic acid. These lipophilic pentacyclic triterpenes have free radical scavenging, cyclooxygenase and neutrophil elastase inhibitory activities, and are therefore likely to be of benefit to human health.

However, biochemical assays have suggested that these lipophilic antioxidants only occur in trace amounts, if at all, in commercial samples of evening primrose oil. A newly available commercially available cold-pressed, non-raffinated evening primrose oil preparation was found to contain a pentacyclic triterpene ester.

Given the potential benefits of the triterpene esters, it is suggested that such a cold-pressed, non-raffinated commercially available evening primrose oil product is likely to have greater health benefits than conventional evening primrose oil preparations

Development And Validation Of A Flax (Linum Usitatissimum L.) Gene Expression Oligo Microarray.

Fenart S, Ndong YP, Duarte J, Rivière N, Wilmer J, van Wuytswinkel O, Lucau A, Cariou E, Neutelings G, Gutierrez L, Chabbert B, Guillot X, Tavernier R, Hawkins S, Thomasset B. Université Lille Nord de France, Lille 1 UMR INRA 1281, SADV, F- 59650 Villeneuve d'Ascq cedex, France.

Abstract

BACKGROUND: Flax (Linum usitatissimum L.) has been cultivated for around 9,000 years and is therefore one of the oldest cultivated species. Today, flax is still grown for its oil (oil-flax or linseed cultivars) and its cellulose-rich fibres (fibre-flax cultivars) used for high-value linen garments and composite materials. Despite the wide industrial use of flax-derived products, and our actual understanding of the regulation of both wood fibre production and oil biosynthesis more information must be acquired in both domains.

Recent advances in genomics are now providing opportunities to improve our fundamental knowledge of these complex processes. In this paper we report the development and validation of a high-density oligo microarray platform dedicated to gene expression analyses in flax.

RESULTS: Nine different RNA samples obtained from flax inner- and outer-stems, seeds, leaves and roots were used to generate a collection of 1,066,481 ESTs by massive parallel pyrosequencing. Sequences were assembled into 59,626 unigenes and 48,021 sequences were selected for oligo design and high-density microarray (Nimblegen 385K) fabrication with eight, non-overlapping 25-mers oligos per unigene. 18 independent experiments were used to evaluate the hybridization quality, precision, specificity and accuracy and all results confirmed the high technical quality of our microarray platform. Cross-validation of microarray data was carried out using quantitative qRT-PCR.

Nine target genes were selected on the basis of microarray results and reflected the whole range of fold change (both up-regulated and down-regulated genes in different samples). A statistically significant positive correlation was obtained comparing expression levels for each target gene across all biological replicates both in qRT-PCR and microarray results. Further experiments illustrated the capacity of our arrays to detect differential gene expression in a variety of flax tissues as well as between two contrasted flax varieties.

CONCLUSION: All results suggest that our high-density flax oligo-microarray platform can be used as a very sensitive tool for analyzing gene expression in a large variety of tissues as well as in different cultivars. Moreover, this highly reliable platform can also be used for the quantification of mRNA transcriptional profiling in different flax tissues.

Pumpkin Seed Oil

Characteristics And Composition Of Watermelon, Pumpkin, And Paprika Seed Oils And Flours.

J Agric Food Chem. 2001 Mar;49(3):1253-9.

El-Adawy TA, Taha KM.

Food Science and Technology Department and Agricultural Biochemistry Department, Faculty of Agriculture, Menofiya University, 32516 Shibin El-Kom, Egypt.

El_Adawy@hotmail.com

Abstract

The nutritional quality and functional properties of paprika seed flour and seed kernel flours of pumpkin and watermelon were studied, as were the characteristics and structure of their seed oils. Paprika seed and seed kernels of pumpkin and watermelon were rich in oil and protein.

All flour samples contained considerable amounts of P, K, Mg, Mn, and Ca. Paprika seed flour was superior to watermelon and pumpkin seed kernel flours in content of lysine and total essential amino acids. Oil samples had high amounts of unsaturated fatty acids with linoleic and oleic acids as the major acids. All oil samples fractionated into seven classes including triglycerides as a major lipid class.

Data obtained for the oils' characteristics compare well with those of other edible oils. Antinutritional compounds such as stachyose, raffinose, verbascose, trypsin inhibitor, phytic acid, and tannins were detected in all flours. Pumpkin seed kernel flour had higher values of chemical score, essential amino acid index, and in vitro protein digestibility than the other flours examined.

The first limiting amino acid was lysine for both watermelon and pumpkin seed kernel flours, but it was leucine in paprika seed flour. Protein solubility index, water and fat

absorption capacities, emulsification properties, and foam stability were excellent in watermelon and pumpkin seed kernel flours and fairly good in paprika seed flour.

Flour samples could be potentially added to food systems such as bakery products and ground meat formulations not only as a nutrient supplement but also as a functional agent in these formulations.

Study of Oral Bacteria in Patients With Dry Mouth

This study has been completed.

First Received: November 5, 2002 Last Updated: March 3, 2008

Sponsor:	National Institute of Dental and Craniofacial Research (NIDCR)
Information provided by:	National Institutes of Health Clinical Center (CC)
ClinicalTrials.gov Identifier:	NCT00048685

Purpose

This study will examine the types of bacteria present in the dental plaque of patients with persistent dry mouth. Saliva is essential for digestion and swallowing and for maintaining the normal mineralization of teeth. People who suffer from dry mouth usually have a significant increase in tooth decay (caries). This study will determine if this increase is due solely to reduced salivary flow or also to an increase in certain types of bacteria in the mouth.

Patients participating in the following NIDCR protocols may be eligible for this study: Evaluation and Treatment of Salivary Dysfunction (84-D-0056), Natural History of Salivary Gland Dysfunction and Sjogren's Syndrome Research Project (99-D-0070), and Salivary Evaluation in Normal Volunteers (94-D-0018).

Participants will have three appointments at the NIH dental clinic as follows:

Visit 1

Dental examination and instruction on keeping a detailed diary of food intake.

Visit 2 (1 week after visit 1)

Attachment of a bacteria collection device (described below) to the side of a tooth.

Visit 3 (48 hours after visit 2)

Removal of the collection device, tooth cleaning and polishing, and submission of food diary.

The bacteria collection device is a 4mm x 2mm x 2mm square of sterilized tooth obtained from slicing an extracted healthy tooth donated by another patient. The donated teeth are either extracted impacted third molars (wisdom teeth) or teeth extracted for teeth straightening (orthodontics). The device is heat-sterilized before being bonded to the participant's tooth. The dental cement used for bonding can be removed after 48 hours with no damage to the surface of the participant's tooth.

Condition
Xerostomia Autoimmune Diseases

Study Type: Observational

Official Title: Incidence and Frequency of Cariogenic Microflora in atients with Clinical Xerostomia and Autoimmune Disease

Further study details as provided by National Institutes of Health Clinical Center (CC):

Estimated Enrollment: 44

Study Start Date: November)02

Estimated Study Completion Date: August 2004

Detailed Description

Although significant improvements have been made in the dental health status of the US population, dental caries remains a significant problem. The most recent Surgeon General's Report (2000) noted that 20% of the US population bears 60% of the caries burden. Caries incidence is even higher in children of minorities, the chronically ill, the physically handicapped, the elderly and the institutionalized.

Dental Caries is a multi-factorial disease in which the fermentation of dietary carbohydrate by oral bacteria results in acid dissolution of tooth structure. Important risk factors include the frequency of dietary carbohydrate intake, intra-oral plaque levels, the levels of cariogenic oral bacteria, salivary insufficiency and past fluoride exposure.

A medical condition shown to be associated with increased caries risk and caries incidence is Sjogren's syndrome (Kolavic et al 1997, Pedersen et al 1999, Almstahl et al 1999). Sjogren's syndrome (SS) predominantly affects women and is an auto-immune disorder characterized by an epitheliitis or exocrinopathy. Both primary and secondary forms are described. Secondary SS sees the condition co-exist with other auto-immune disease such as rheumatoid arthritis (See reviews by Fox and Maruyama 1997, Fox et al 1999, Pflugfelder 1998)

A recent study by Sreebny and Zhu (Adv. Dent Res 1996), demonstrated that individuals with a diagnosis of SS are nearly 40% more likely to harbor high levels of the species Lactobacillus in

plaque and saliva than healthy individuals. LB has been shown in to be a major etiological agent in dental caries progression.

The principal hypothesis of this study is that SS patients are at a higher risk of caries development not just because of reduced salivary flow (xerostomia) but also changes in the output of organic and inorganic microbial regulatory components in saliva secondary to their auto-immune disease. These alterations favor a selective increase in the proportion of cariogenic microflora in plaque located on their teeth. Specifically, mutans streptococci (MS) and Lactobacillus (LB) species are increased in frequency and number in SS patients compared with xerostomic patients with no detectable auto-immune disease.

The proposed study will investigate microbial counts of MS and LB in the plaque of patients with a clinical diagnosis of markedly reduced salivary flow (pooled unstimulated flow &eq; 0.1 ml/min). All clinical procedures will take place at NIH. Some samples and all data, without any patient identifiers, will be analyzed outside.

Plaque samples will be collected from sites identified to be at high-risk for caries initiation and development. It is generally accepted that discernment of microbial etiology is blunted by using salivary or pooled plaque monitoring of MS and LB as a surrogate for samples of plaque in areas of high caries risk. This is supported by current knowledge of the biology of MS/LB and expected locations of carious lesions.

Saliva samples will not be collected due to difficulties in obtaining sufficient fluid as a result of the concurrent xerostomia.

The proposed study will examine the relationship between MS/LB and reduced salivary flow in two patient groups:

1. A patient group with reduced salivary flow AND a diagnosis of primary or secondary SS (as per the Revised International Criteria for diagnosis of SS) OR auto-immune disease of non-SS etiology.
2. A non-disease control group, who do not meet the criteria for SS, with reduced salivary flow AND who have suffered subjective symptoms of xerostomia or xerophthalmia for a period longer than 6 months OR who are taking medication with xerogenic effect.

Plaque micro-organisms will be harvested from a "collection device" bonded to the surface of a posterior tooth shown to be at high risk for caries development. Plaque collected in this way has been shown to closely simulate the complex ecology of a mature cariogenic plaque. The harvested organisms will then be plated on non-selective media for enumeration of total microbial load and on selective media for enumeration of specific cariogenic bacteria.

More comprehensive knowledge of the effect of SS on microbial flora in different predeliction sites for oral diseases would be of great value for effective treatment planning in SS and for the evaluation of the effect of oral treatments and of preventive measures implemented in individuals with SS.

Eligibility

Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Selection of subjects for the study will be restricted to the pool of NIDCR patients already participating in protocol 84-D-0056, Evaluation and Treatment of Salivary Dysfunction.

INCLUSION CRITERIA

A. Salivary Flow = 0.1ml/min pooled unstimulated; and

B. A diagnosis of SS (primary or secondary)

C. A diagnosis of non-SS auto-immune disease

D. The use of a medication with known xerostomic effect

E. Subjective xerostomia or xerophthalmia

F. The presence of permanent teeth.

EXCLUSION CRITERIA

A. Child and Adolescent:

Children and Adolescents will not be included in the study due to the presence of deciduous teeth which are less suitable for bonding and which show an altered enamel morphology and pattern of plaque accumulation

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00048685

Locations

United States, Maryland

National Institute of Dental And Craniofacial Research (NIDCR)
Bethesda, Maryland, United States, 20892

Sponsors and Collaborators

National Institute of Dental and Craniofacial Research (NIDCR)

More Information

Publications:

Almstahl A, Kroneld U, Tarkowski A, Wikstrom M. Oral microbial flora in Sjogren's syndrome. J Rheumatol. 1999 Jan;26(1):110-4.

Babaahmady KG, Challacombe SJ, Marsh PD, Newman HN. Ecological study of Streptococcus mutans, Streptococcus sobrinus and Lactobacillus spp. at sub-sites from approximal dental plaque from children. Caries Res. 1998;32(1):51-8.

Boutsi EA, Paikos S, Dafni UG, Moutsopoulos HM, Skopouli FN. Dental and periodontal status of Sjogren's syndrome. J Clin Periodontol. 2000 Apr;27(4):231-5.

Other Study ID Numbers:	030026, 03-D-0026
Study First Received:	November 5, 2002
Last Updated:	March 3, 2008
Health Authority:	United States: Federal Government

Keywords provided by National Institutes of Health Clinical Center (CC):

Caries	Autoimmune
Bacteria	Dry Mouth
Saliva	Salivary Gland Dysfunction
Teeth	Sjogren's Syndrome

Additional relevant MeSH terms:

Autoimmune Diseases	Salivary Gland Diseases
Xerostomia	Mouth Diseases
Immune System Diseases	Stomatognathic Diseases

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GMP Certification

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Assessment of Manufacturing Processes

- Manufacturing processes are clearly defined and controlled. Processes involved in manufacturing the product require consistency to meet the quality standards set. All processes controlled and monitored regularly help the company determine flaws that hamper manufacturing. It helps analysts find solutions and correct them immediately.

Clear Instructions and Procedures

- Company instructions and procedures are clear and unambiguous. All information provided by management must be simple and easy to understand. They must be clear, concise and precise for proper execution. Employees and quality specialists must understand all manufacturing procedures they are involved in. Knowledge of these things will help them perform tasks and duties completely and at par with standards set.

Skilled Operators

- Operators of manufacturing equipment perform and document procedures. Employees assigned to perform operational tasks must write down and record their observations clearly and completely. This information is useful in assessing productivity, quality and efficiency. Recorded data helps operators analyze and evaluate the processes of manufacturing regularly. This is necessary for process and quality improvement.

Review and Address Complaints about Products Produced

- Company management examines complaints about the products in the market and recalls defective batches through an effective method. The company is liable for any inconsistencies or deficiencies in the products manufactured and released in the market. The organization must recall defective or dangerous products from the market immediately. Ensuring the safety of the consumers' health and well-being is must be paramount to the company.

GMP Certification Requirements by the World Health Organization (WHO)

- A product certificate (COPP or TRS 823, 863) is a document certifying a specific product received an authorization for distribution in the consumer market and has passed quality standards set by the country where a company plans to distribute it. It ensures that the product or service meets standards and specific purposes for its production. WHO issues a COPP when the product in question is under consideration for a product license that will authorize its importation and sale. Administrative action is required for renewal, extension, variation or review of such a license. Other documents needed are statement of licensing status (TRS 823, 863), and batch certificate (TRS 823, 863) for WHO GMP certification.

GMP Certification

News Flash – August 2010: The Natural Products Association (formerly NNFA) has recertified our manufactures facility as an "A-rated" GMP facility. This follows another rigorous inspection by an independent auditor for the Natural Products Association.

This 250,000 sq. ft. state-of-the-art manufacturing facility is complete with Quality Assurance and Quality Control systems and processes have been GMP certified and “A-rated” by NPA/NNFA since 2000. Today, NPA GMP Certification includes all requirements for the new FDA dietary supplement cGMPs, and more.

GMP certification covers standard operating procedures, employee training, product specifications, expiration dating, vendor certifications and much more. Standard operating procedures include sampling and testing incoming materials according to our specifications, inspecting manufacturing processes, and testing finished products to specifications. Tests include organoleptic evaluation (human senses such as sight, taste, smell), physical testing of tablets and capsules, chemical identity of ingredients, potency and contamination testing by the company’s in-house state-of-the-art analytical testing lab, as well as microbiological testing by our in-house rapid analysis microbiological lab.

Our GMP certification by the NPA is a cornerstone of our commitment to quality. As industry leaders in analytical and microbiological testing, we have the technical and professional personnel, lab facilities, standards and procedures to ensure the highest quality products. Our quality commitment also includes continuous improvement programs to get even better.

Our Quality Philosophy

It is sometimes difficult to believe that we have been providing natural health products for more than 40 years. Looking back at the history of our company we have made many commitments to offer our customers exceptional value. During this time, we have experienced tremendous growth and expansion. We have progressed from a family-run health food store to a leader in the nutritional supplement industry. We have fought for the rights of consumers to use dietary supplements. And through it all, we have never lost sight of our mission to provide value in products and services that empower people to lead healthier lives.

But these are different times that we live in, and our industry is constantly being challenged. False media reports have consistently downplayed the value of dietary supplements, challenging their efficacy and safety.

We will continue to be committed to manufacturing quality products. This includes the utilization of current, cutting-edge science in the formulation of our products, strict scrutiny when choosing raw materials, advanced testing and validated methods development, and the employment of skilled, highly trained individuals who are passionate about fulfilling our mission.

As a company, we are one of the most visible quality advocates in the natural products industry. In addition to assisting in the development of the Natural Products Association’s Standards Committee, we have initiated, promoted, and supported initiatives to validate the safety and benefit of nutritional supplements. We have a full-time truth advocate who responds to misleading science and media reports, as well as one of the most dedicated teams of Quality Control and Quality Assurance professionals in the industry. In short, you don’t have to look too far to see that we are committed to what we do. This is a commitment that grows daily, as we continue to understand the changing needs of those we serve.

We are also committed to social and environmental responsibility. We want to make our products affordable, but at the same time available to those who can’t afford them. Our partnership with charitable organizations, such as the Vitamin Angel Alliance, is a reflection of our commitment to make our products available to those who have the least amount of resources and the greatest need. We have also been recognized as a leader in environmental responsibility, as we continue to explore new ways to preserve our natural resources for future generations.

In today’s business world of corporate takeovers and industry consolidation, we remain a family owned company that will continue to strive to honor our commitments for generations to come!

Our Quality Assurance

Over the past few years, we have made tremendous strides in the quality of our products, and we are proud to tell you how we have done this using leading methods and procedures. With the industry constantly evolving, we too have evolved in order to offer products that exceed the expectations of those of you who recommend, use, and sell them.

In short, our products work. Our products are formulated for safety and we strive to be As Natural as Possible™. Our products are manufactured according to Good Manufacturing Practices and tested to exceed the stringent specifications set forth by the FDA. These pages on quality, in essence, are our way of opening the doors to you. We want to share our practices with you, so that you can understand what we are doing to improve product quality—not only for our products, but for the greater good of the entire Natural Products Industry.

From start to finish, our quality processes are robust. Our staff of experienced scientists and technicians fully understands the concept of natural product quality. More importantly, our skilled professionals are well versed in applying in-depth technical understanding to meet your needs. Throughout these web-pages, you will see some of our employees in their actual day-to-day roles. We believe that this will provide you with a clearer understanding of what we do, how we do it, and why it is so important.

We test. We check. We verify. We are vigilant. We integrate leading-edge science and research to understand and identify the characteristics of our ingredients. We also closely scrutinize our ingredients for potential contamination, adulteration, or dilution. We work closely with our suppliers and have learned from over 40 years of experience how to select and test these ingredients prior to manufacturing. This scrutiny yields products that we are confident taking ourselves and recommending to our own loved ones. Ultimately, we go to these lengths to earn and keep your trust. In the event that a mistake is made, we work to correct it by initiating procedures that prevent it from happening again.

In order to bring you products that are both affordable and of the highest quality, we refuse to cut corners. Instead, we rely on our other strengths—strong buying power, reduced overhead expenses, managed distribution costs, and efficient manufacturing. Year after year we have significantly increased our investment in quality above and beyond our industry colleagues. These collective measures result in contemporary formulas that meet today's needs; products that are developed with safety in mind and are As Natural As Possible™.

Many of you have written to us to tell us about the good job we are doing, and some of your letters are posted on our web-site to read and review. On behalf of our entire family, I hope that our products will bring you and your customers continued health and wellness.

Safety is Our Top Priority

Your concern for safety is our concern for safety. We take countless steps to ensure we select safe ingredients and we follow those ingredients through the manufacturing process to finished packaging, testing each step of the way for contaminants and imperfections. Ensuring safety requires robust and rigorous systems and processes. Our state of the art facility and equipment and our dedicated professional staff work hard to ensure product safety for everyone.

These are some examples of the many systems and processes we have put in place to ensure product safety.

- We examine the toxicological and safety data for our ingredients when formulating our products. Our scientists work to ensure that products are formulated at safe ingredient levels.
- We work with trusted, high quality raw material suppliers. We determine their commitment to safety and audit all of them to ensure that they too have systems and processes for safety and quality.
- We test all our products and ingredients for adulterants and contaminants. This includes testing for heavy metals, microbiological contamination, cross contamination and for specific allergens and gluten. We test our water and air to insure there is no outside contamination coming in and we test to make sure our equipment is clean and sanitized.
- Our manufacturing processes follow dietary supplement cGMPs and we are certified by the National Products Association. We use HACCP (Hazard Analysis Contamination Control Point) systems to identify potential hazards and to put in place barriers to prevent them from occurring. These hazards include metals, glass, pests and microbial contamination.

- Our manufacturing control systems are automated. Our electronic MRP (Manufacturing Resource Planning) system is designed to ensure that the correct materials are used in production with measures such as bar codes to double check accuracy. We have many other checks and balances in manufacturing including separate QC inspection processes.

- Our QC inspectors accept or reject raw materials, in-process materials, and finished products, based on meeting specifications. Our QC inspectors work independently from our manufacturing personnel so as to eliminate any conflict of interest.

- Our products are packaged in containers designed to protect their integrity. We strive to ensure the safety and freshness of all our products through their shelf life.

- We make sure that all necessary cautions and warnings are placed on product labels, and that any allergens are clearly identified. We have a rigorous label approval process designed to best comply with all relevant laws and regulations and we exceed federal requirements for allergen labeling by also including corn and gluten. As an added layer of caution, we are a peanut-free processing facility.

We firmly believe that exceptional finished products start with the best quality raw materials. To ensure product quality from start to finish, we work with the industry's most trusted and reputable raw material suppliers, many of whom are GMP and/or Organic Certified. All vendors are thoroughly screened in accordance with our strict Quality Assurance standards, and each is required to submit a detailed certificate of analysis on every lot that is shipped. Our Quality technicians perform mandatory inspections on all incoming batches of raw materials. Additionally, audits are conducted to ensure that our key raw material suppliers are in compliance with our demanding quality standards.

If an incoming batch of raw material does not meet our quality standards, we have no reservations when it comes to rejecting and returning it. Chondroitin is just one of many examples. In one recent year, we pre-tested 45 batches for potency, identity and potential contamination. Of the 45 batches that we tested throughout the year, only 4 were accepted after meeting our strict quality standards. The other 41 batches were rejected and returned to their suppliers.

The relationships that we have forged over the years are rooted in a collective desire to provide today's health-seeking consumers with superior health products. With assistance and input from nearly a dozen different departments, we work closely with our raw material providers to ensure product quality from the very start. Strong attention to detail and consistent scrutiny in choosing our raw materials are visible throughout each phase of the manufacturing process. This constant scrutiny is of immeasurable worth when it comes to ensuring that the our products on your shelves have been carefully tended to; from the moment they arrive at our facility to the time they are shipped to our customers.

Professional Staff

We have the best professional staff to ensure the highest quality products available. Our team of highly qualified scientists and technicians has many years of combined experience in the natural products industry, and in other relevant industries. We have many professional disciplines, including chemists, biochemists, nutritionists, food technologists, and product formulators.

Our team of scientists includes many with advanced degrees, including eight Ph.D.'s and one M.D. We also work with respected industry consultants. All of our lab chemists are degreed and many of our experienced product formulation and quality control staff have professional qualifications which set them apart from their industry colleagues. Some of our scientists and nutritionists have published analytical methods, and other natural product science, in scientific and technical journals. Our scientists and nutritionists have given presentations on their work at scientific and technical conferences.

DentiCorp™

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